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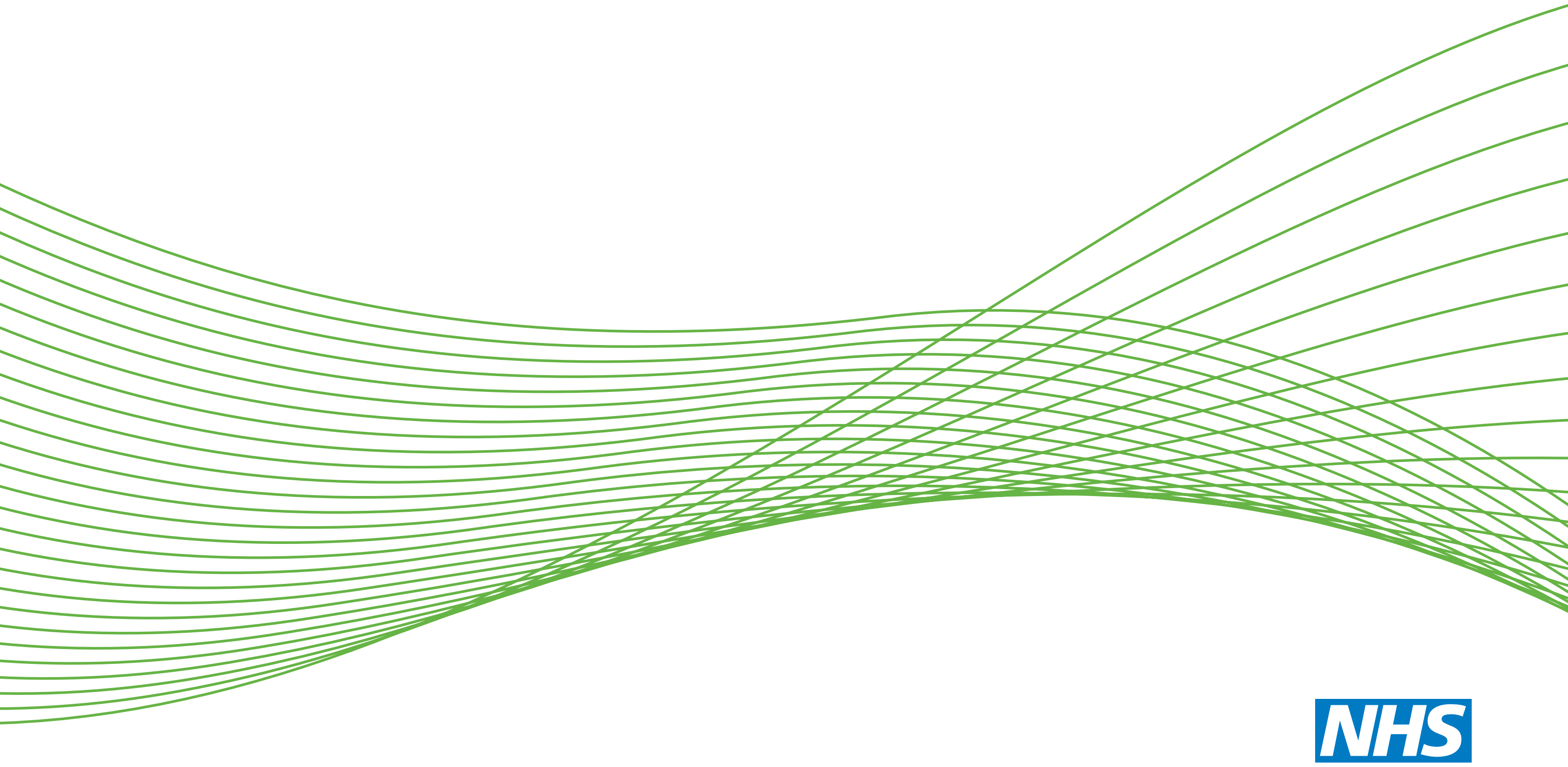

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Abstract

Developing and evaluating a child-centred intervention for diabetes medicine management using mixed methods and a multicentre randomised controlled trial

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Aim: To develop and evaluate an individually tailored age-appropriate diabetes diary and information pack for children and young people aged 6–18 years with type 1 diabetes to support decision-making and self-care with a specific focus on insulin management and blood glucose monitoring, compared with available resources in routine clinical practice.

Design: Four-stage study following the Medical Research Council framework for designing and evaluating complex interventions. Stage 1: context – brief review of reviews and mixed-method systematic review; updating of database of children's diabetes information; children's diabetes information quality assessment and diabetes guideline analysis; and critical discourse analysis. Stage 2: intervention development – working with expert clinical advisory group; contextual qualitative interviews and focus groups with children and young people to ascertain their information preferences and self-care practices; ongoing consultation with children; development of intervention programme theory. Stage 3: randomised controlled trial (RCT) to evaluate the diabetes diaries and information packs in routine practice. Stage 4: process evaluation.

Findings: The RCT achieved 100% recruitment, was adequately powered and showed that the Evidence into Practice Information Counts (EPIC) packs and diabetes diaries were no more effective than receiving diabetes information in an ad hoc way. The cost per unit of producing the EPIC packs and diabetes diaries was low. Compared with treatment as usual information, the EPIC packs fulfilled all NHS policy imperatives that children and young people should receive high-quality, accurate and age-appropriate information about their condition, self-management and wider lifestyle and well-being issues. Diabetes guidelines recommend the use of a daily diabetes diary and EPIC diaries fill a gap in current provision. Irrespective of allocation, children and young people had a range of recorded glycated haemoglobin (HbA_{1c}) levels, which showed that as a group their diabetes self-management would generally need to improve to achieve the HbA_{1c} levels recommended in National Institute for Health and Care Excellence guidance. The process evaluation showed that promotion of the EPIC packs and diaries by diabetes professionals at randomisation did not happen as intended; the dominant 'normalisation' theory underpinning children's diabetes information may be counterproductive; risk and long-term complications did not feature highly in children's diabetes information; and children and young people engaged in risky behaviour and appeared not to care, and most did not use a diabetes diary or did not use the information to titrate their insulin as intended.

Limitations: Recruitment of 'hard to reach' children and young people living away from their families was not successful. The findings are therefore more relevant to diabetes management within a family context.

Conclusions: The findings indicate a need to rethink context and the hierarchical relationships between children, young people, parents and diabetes professionals with regard to 'partnership and participation' in diabetes decision-making, self-care and self-management. Additional research, implementation strategies and service redesign are needed to translate available information into optimal self-management knowledge and subsequent optimal diabetes self-management action, including to better understand the disconnection between children's diabetes texts and context; develop age-appropriate Apps/e-records for recording blood glucose measurements and insulin management; develop interventions to reduce risk-taking behaviour by children and young people in relation to their diabetes management; reconsider what could work to optimise children's self-management of diabetes; understand how best to reorganise current diabetes services for children to optimise child-centred delivery of children's diabetes information.

Study registration: Current Controlled Trials ISRCTN17551624.

Funding: The National Institute for Health Research Health Services and Delivery Research programme.

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Glossary

Diabetes UK Diabetes charity in the United Kingdom.

Dose Adjustment for Normal Eating programme Adult diabetes patient education programme.

EPIC diary A diabetes blood glucose monitoring diary designed as part of the EPIC project intervention (part of the EPIC randomised controlled trial along with the EPIC packs).

EPIC pack Individually tailored and age-appropriate information folder (the main intervention aspect of the EPIC randomised controlled trial).

European Quality of Life-5 Dimensions Outcome questionnaire used in economic evaluation as a utility measure.

Evidence into Practice Information Counts (EPIC) National Institute for Health Research Health Services and Delivery Research-funded randomised controlled trial of a children's individually tailored and age-appropriate information intervention.

Glycated haemoglobin Measure of glycaemic control. The amount of glycated haemoglobin in blood is related to the concentration of blood glucose over an approximately 2- to 3-month period. This can be measured by taking a blood sample and analysing the red blood cells.

Google Internet search engine.

Juvenile Diabetes Research Foundation A diabetes charity.

Postprandial After eating a meal.

Predictive analytics software Another name for SPSS statistical analysis software.

Preprandial Before eating a meal.

Promoting Action on Research Implementation in Health Services framework A framework for guiding the implementation of evidence-based practice.

SurveyMonkey® SurveyMonkey is a private American company that enables users to create their own Web-based surveys.

Wikipedia A free online encyclopaedia built collaboratively using wiki software.

List of abbreviations

ADNAT	Adolescent Diabetes Needs Assessment Tool
ANCOVA	analysis of covariance
CASCADE	Child and Adolescent Structured Competencies Approach to Diabetes Education
CDA	critical discourse analysis
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
CRC Cymru	Clinical Research Collaboration Cymru (now the National Institute for Social Care and Health Research Clinical Research Centre)
CRF	clinical report form
CSII	continuous subcutaneous insulin infusion
CSRI	Client Service Receipt Inventory
DAFNE	Dose Adjustment for Normal Eating
DAWN	Diabetes, Attitudes, Wishes and Needs
DECIDE	Delivering Early Care In Diabetes Evaluation
DEPICTED	Development and Evaluation of a Psychosocial Intervention for Children and Teenagers Experiencing Diabetes
DH	Department of Health
DMEC	data monitoring and ethics committee
DMMP	Diabetes Medical Management Plan
DRN	Diabetes Research Network
EPIC	Evidence into Practice Information Counts
EPPI-Centre	Evidence for Policy and Practice Information and Co-ordinating Centre
EQ-5D	European Quality of Life-5 Dimensions
FCS	fully conditional specification
GP	general practitioner
HbA_{1c}	glycated haemoglobin
HCP	health-care professional
ICP	individualised care plan
IHP	Individualized Health Care Plan
IMP	Information Matters Project
ISPAD	International Society for Paediatric and Adolescent Diabetes
ITT	intention to treat
JDRF	Juvenile Diabetes Research Foundation
LSOA	lower layer super output area
MCRN	Medicines for Children Research Network
MDI	multiple daily injection
MI	multiple imputation
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NSF	National Service Framework
NWORTH	North Wales Organisation for Randomised Trials in Health and Social Care
PARiHS	Promoting Action on Research Implementation in Health Services
PASW	Predictive Analytics SoftWare
PDSN	paediatric diabetes specialist nurse
PedsQL	Paediatric Quality of Life Inventory
PI	principal investigator
QALY	quality-adjusted life-year

RCT	randomised controlled trial	T1D	type 1 diabetes
SD	standard deviation	T2D	type 2 diabetes
SPICE (stream 1: intervention studies)	Setting, Population, Intervention, Comparison and Evaluation	TAU	treatment as usual
SPICE (stream 2: non-intervention studies)	Setting, Perspective/People, Phenomenon of interest, Context and Evaluation	VAS	visual analogue scale

Scientific summary

Background

The Evidence into Practice Information Counts (EPIC) project was conducted alongside the parallel children's Information Matters Project (IMP) (NIHR 08/1745/145), which researched the practice of and requirements for age-appropriate health information for children and young people. In type 1 diabetes (T1D), clinical guidelines indicate that high-quality, child-centred information underpins the achievement of optimal insulin management and glycaemic control with the aim of minimising acute readmissions and reducing the risk of complications in later life. Comprehensive, accessible and timely information about both risks and benefits and decision support are imperative if children and young people are to be active partners in decision-making about diabetes management and self-care choices.

The IMP was designed to explore these issues more broadly in common childhood long-term conditions, including diabetes. A lack of child-centred research has hampered the development of effective interventions to optimise long-term self-management and minimise the risk of complications.

The EPIC project was conceived to address the lack of appropriate children's diabetes information and a diabetes diary in routine NHS care and to generate evidence of what works concerning delivery and use of diabetes information and diaries as a way of enabling children and young people to engage in optimal self-care with a focus on insulin management. The overarching aim of the multiple strands of work was to develop and evaluate an individually tailored, age-appropriate diabetes diary and information pack for children and young people aged 6–18 years with T1D to support decision-making and self-care with a specific focus on insulin management and electronic blood glucose monitoring, compared with available resources in routine clinical practice.

Type 1 diabetes is one of the most common chronic conditions in childhood, with a current estimated prevalence of one per 700–1000 children in the UK, giving a total population of 25,000 under-25s with T1D. The incidence in children under 5 years doubled between 1985 and 1995 and in children under 15 years there is an overall increase of around 4% each year. Children with T1D need individual insulin regimes, monitoring of their blood glucose levels four to six times a day and close attention to a healthy diet and exercise.

This report describes primary and secondary research undertaken to develop a range of child-centred diabetes information resources and describes the outcome of a pragmatic randomised controlled trial (RCT) to evaluate the effectiveness and cost-effectiveness of the EPIC diabetes information packs, including a diabetes diary, in routine practice.

Objectives

1. To review gold standard diabetes clinical guidelines, currently available diabetes information, including findings from the linked qualitative IMP project, to identify best practice, and types/formats of information most likely to assist age-appropriate decision-making and choices concerning blood glucose monitoring and insulin management.
2. To develop an age-appropriate diabetes information intervention (child-centred diabetes diary and information pack) for children and young people to support the appropriate use of blood glucose monitoring to optimise management of and concordance with their insulin regime.

3. To explore the utility of the child-centred diabetes diary and information pack (in this context utility refers to ease of use and fitness for purpose) within different contexts in which children and young people manage their routine diabetes care (home, school, community), with and without support from parents or health-care professionals (HCPs), and in alternative settings.
4. To explore how children and young people with and without their parents, teachers, nurses or doctors use (or not) the diabetes diary and information pack to support decision-making, in particular how children and parents 'self-prescribe' the correct (or incorrect) dose of insulin.
5. To identify similarities and differences between the diabetes diary and information pack developed for adolescents and those available within adult diabetes services.
6. To evaluate the diabetes diary and information pack within the context of routine diabetes care in relation to patient outcomes (diabetes-specific health-related quality of life, generic health-related quality of life, medicine and treatment concordance, acceptability, ease of use and glycaemic control).
7. To identify gaps in knowledge to inform a future research agenda.

Theoretical frameworks

In developing and evaluating a children's diabetes information pack and diabetes diary we drew on the same three theoretical frameworks as in the IMP: a biopsychosocial and anthropological model of childhood and illness management; the Promoting Action on Research Implementation in Health Services framework; and the Medical Research Council (MRC) framework for developing and evaluating complex interventions.

At the conclusion of the IMP we developed two theoretical models and a proposition to describe the critical success factors for partnership and participation between children, parents and health professionals and services, and successful implementation of children's health information in routine clinical practice. These two theoretical models and the proposition are used in the trial process evaluation to help interpret the findings and specifically to explain why the EPIC pack and diary did not have the desired effect on children's diabetes outcomes.

Methods

To meet our objectives, which are aligned with the phases of the MRC framework for RCTs of complex interventions, a four-stage study was designed.

Stage 1: context

We conducted multiple strands of investigation to focus our understanding on the context of children's diabetes care, including:

- a review of reviews and mixed-method systematic review of the barriers to and enablers of optimal diabetes self-care by children and young people in educational settings
- further searching for currently available children's diabetes information to add to the database constructed for the IMP
- an extension and update of the IMP comparative analysis to establish whether key health messages in children's diabetes information matched with diabetes clinical guidelines
- extension and refocusing the critical discourse analysis on diabetes to investigate content and meaning of selected currently available children's diabetes resources.

Stage 2: intervention development – diabetes diaries and information packs

In addition to incorporating evidence from the IMP and conducting stage 1 of this study, we carried out further strands of investigation and consultation including:

- convening an expert clinical advisory group to advise on intervention development and clinical risk management
- undertaking qualitative interviews and focus groups with children and young people to ascertain their information preferences and self-care practices with an emphasis on children who had spent time away from their families
- obtaining children's and young people's perspectives on various iterations of the age-appropriate diabetes diary and information pack (web consultation and stall at diabetes charity family days).

Children's diabetes information resources produced for the trial

In an iterative approach, integrating findings from the linked IMP and building throughout stages 1 and 2, we produced the following range of resources that can be individually tailored for pragmatic evaluation in routine clinical practice (stage 3):

- three diabetes diaries for children and young people using insulin injections (6–10 years, 11–15 years and 16–18 years)
- one diabetes diary (6–18 years) for children and young people using insulin pumps
- child-friendly sheets for recording carbohydrate intake
- three age-appropriate information packs containing published diabetes information bound in an age-appropriate folder (6–10 years, 11–15 years and 16–18 years)
- stickers (6–10 years) and stickers and marker pens (11–15 years) for children to personalise their folder.

We then applied to the National Institute for Health Research (NIHR) for permission to brand the diaries with the official NIHR logo, which was granted. Finally, selected clinical experts were asked to formally sign off the EPIC packs and diaries as being suitable for use in the NHS.

A detailed intervention programme theory was developed. Critical discourse analysis of current children's diabetes information revealed a dominant discourse of 'normalisation' of medicine management and medicines as a social enabler, conveyed in a sometimes authoritarian way to children and young people through diabetes texts. A logic model was developed to show the implementation of the EPIC diabetes resources within routine diabetes care and existing diabetes clinical guidelines and care pathways.

Stage 3: randomised controlled trial to evaluate the diabetes diaries and information packs in routine practice

We designed and carried out a pragmatic RCT to assess the effectiveness and cost-effectiveness of the diabetes diaries and age-appropriate information packs in routine practice.

Stage 4: process evaluation

As the trial did not detect an intervention effect, we used the process evaluation to help explain the outcome. For the process evaluation we collected the following strands of evidence:

- interviews with HCPs in each site to document current routine practice and local clinical care pathways for children with T1D
- a baseline survey to determine the ethnic profile of trial participants
- baseline postcode analysis to determine the index of deprivation of trial participants
- qualitative interviews with children and parents to ascertain their experiences and perspectives
- a questionnaire completed by HCPs at the conclusion of the trial to ascertain their perspectives.

Findings

Randomised controlled trial and economic analysis

The RCT achieved 100% recruitment, was adequately powered and showed that the EPIC packs and diabetes diaries were no more effective than receiving diabetes information in an ad hoc way. The costs per unit of producing the child-centred and age-appropriate EPIC packs and diabetes diaries were low.

Compared with treatment as usual information, which may not, the EPIC packs fulfilled all NHS policy imperatives that children and young people should receive high-quality, accurate and age-appropriate information about their condition, self-management and wider lifestyle and well-being issues. As children's diabetes practice recommends that children should use a diabetes diary as part of their diabetes care pathway and daily self-management, EPIC diaries fill a gap in current provision.

Process evaluation

Irrespective of allocation, children and young people in the EPIC RCT had a range of recorded glycated haemoglobin (HbA_{1c}) levels, which showed that as a group their diabetes self-management would generally need to improve to achieve the HbA_{1c} levels recommended in National Institute for Health and Care Excellence guidance. This concurs with the recent report on children's outcomes that highlighted the need for children in England to have better control over their diabetes and lower HbA_{1c} levels.

Inappropriate dominant theory underpinning children's diabetes information

The discourse of 'normalisation' of medicine management and medicines as social enablers as key messages conveyed in a sometimes authoritarian way to children and young people through diabetes texts appears to be counterproductive with some children and young people. Findings point to an extra textual context of the relationship between children, parents and diabetes professionals as one possible reason why there seems to be a lack of 'compliance' to what children and young people, and sometimes parents, are being told and what diabetes professionals 'expect' of them. It is this tension in the relationship between these parties that may partly explain why some children, young people and parents become less interested in 'optimal diabetes self-care and management' as they grow older. It may be that children and young people just get fed up with the regimen and having life seemingly defined by diabetes and 3-monthly clinic visits, despite discourses which claim that life can be 'normal', but only if they do as they are told by adults.

Children's ignorance of risky behaviour and long-term complications of diabetes

Very few children's diabetes information resources that we located – especially for younger children – said anything about serious risks and long-term complications of poorly managed diabetes. In contrast, diabetes information produced for adults was explicit about the risks of long-term complications and the need to optimally self-manage to mitigate these risks.

Many children and young people interviewed were taking risks with their diabetes-related health but did not convey any significant degree of concern about the potential consequences; indeed, many teenagers appeared uninterested. Some parents wanted to protect their children from receiving information about risks and complications whereas others wanted to expose their children to the actual reality of serious life-threatening complications such as renal failure.

Non-use or inappropriate use of a diabetes diary

The diabetes diary is considered an essential tool for children and young people to record and observe trends and titrate their insulin dose. Irrespective of allocation, children – especially older children – mostly did not use a diabetes diary to record their blood glucose levels and insulin management. Many children and young people did not see the need to have this important information to titrate their insulin and appeared to think that they were recording this information for the benefit of diabetes professionals.

Promotion of the EPIC packs and diaries at randomisation not happening as intended

Although diabetes professionals were intended to actively promote and explain the pack and its optimal use by children at home, in reality the EPIC packs were mostly given to children by research nurses and not referred to in routine clinical encounters again. Minimal individualisation of packs occurred.

Service delivery and organisational issues

The current model of diabetes service delivery does not easily accommodate time for ongoing active facilitation or promoting children's diabetes information as part of routine ongoing care.

Conclusions and recommendations

Other recently completed trials of interventions to promote children's diabetes self-management conducted in the NHS have found no difference in outcomes. Optimising children's diabetes care and self-management remains an unresolved challenge. The key unresolved question is what would work to improve children's diabetes self-management.

Our findings clearly indicate a need to rethink context and the hierarchical relationships between children, young people, parents and diabetes professionals with regard to 'partnership and participation' in diabetes decision-making, self-care and self-management.

Additional research, implementation strategies and service redesign are needed to enable children, young people, parents and diabetes professionals to translate the available information into optimal self-management knowledge and subsequent optimal diabetes self-management action, including to:

- better understand the disconnection between children's diabetes text and context
- develop age-appropriate Apps and e-records as an option for recording blood glucose measurements and insulin management
- develop interventions to reduce risk-taking behaviour by children and young people in relation to their diabetes management
- reconsider what could work to optimise children's self-management of diabetes
- understand how best to reorganise currently available children's diabetes services to optimise child-centred delivery of children's diabetes information and services.

Study registration

This study is registered as Current Controlled Trials ISRCTN17551624.

Funding

The National Institute for Health Research Health Services and Delivery Research programme.

Chapter 1 Introduction

Background

The Evidence into Practice Information Counts (EPIC) project was commissioned in 2007 by the National Institute for Health Research (NIHR) Health Services and Delivery Research programme (England). The EPIC project was conducted alongside the parallel children's Information Matters Project (IMP) (NIHR 08/1745/145),[1] which researched the practice of and requirements for age-appropriate health information for children and young people.

At the time of commissioning there was a lack of high-quality, child-centred and effective health information to support the development of self-care practices and expertise in children with acute and long-term conditions. In type 1 diabetes (T1D) clinical guidelines indicate that high-quality, child-centred information underpins the achievement of optimal insulin management and glycaemic control with the aim of minimising acute readmissions and reducing the risk of complications in later life. This report describes primary and secondary research undertaken to develop a range of child-centred diabetes information resources and reports the outcome of a pragmatic randomised controlled trial (RCT) to evaluate the effectiveness and cost-effectiveness of the EPIC diabetes information packs, including a diabetes diary, in routine practice. As the trial found no difference in outcomes between the EPIC children's diabetes information packs and usual practice, we have used the process evaluation to explore and explain why an intervention effect was not detected.

In this chapter we consider first the general policy context and then key policies in relation to children's diabetes information and self-management. The remainder of the chapter deals with the theoretical frameworks that have helped us to make sense of the empirical work and presents an overview of the research methodology underpinning the conduct of the study.

General policy context

People of all ages require high-quality information promoting health, self-care and medicines management to help facilitate their engagement in participative models of health care and assist them in making choices.[2–6] In the UK the NHS Constitution makes clear that patients require information to engage fully and knowledgably in decision-making and be aware of the risks and benefits of treatment options. Policy-makers also identify a need for health and social services providers to increase the capacity, confidence and efficacy of individuals for self-care and to build social capital in the community.[4,7–12] The requirement for prevention, early intervention and support for individuals for self-care and promoting well-being for the wider population is a fundamental policy aspiration.[4,7–12] However, there is uncertainty about the positioning of children and young people and their families within these models and policies and about what practical plans and processes exist for successful implementation.

Children's age-appropriate and child-centred health information is likely to be critical to developing self-care and well-being as children's autonomy increases with age.[13] Information needs and informed choice are central to the children's National Service Framework[14] (including a standard on medicines management[15] and *The Children's Plan*,[13] which make specific reference to the requirement to provide high-quality, age-appropriate and child-centred information in varying formats). There is, however, little reliable evidence concerning the effectiveness of different types of provision of health information for children and young people. There is even less evidence about types and formats of information that could empower children and young people to make decisions, when appropriate, about aspects of their care.[9] The parallel IMP[1] sought to explore these latter issues.

Progress has been made on a UK strategy for service delivery and organisation of medicines for children and young people to facilitate not only a measurable increase in appropriately labelled and formulated medicines and conduct of trials but also the provision of information for prescribers, carers and children.[11] One outcome is the setting up of the Medicines for Children Research Network (MCRN),[16] which supported the EPIC project and the linked foundation study, the IMP,[1] funded by the NIHR.

The standard patient information that is available is often of poor quality and may not be easily accessible or understandable for children, young people and their families.[1] The need for child-centred, age-appropriate information on medicines specifically and self-care management in general is highlighted when viewed against the broader NHS public health policy context. Children's health policy is centred on the notion of 'family-centred' care, with family members providing a large proportion of care and with children taking on more responsibility for their health care as they gain autonomy. The children's National Service Framework model of children's acute and chronic disease management focuses on educating children and young people in age-appropriate ways to deliver aspects of their own health care and specifically identifies parents as experts.[14] The shift in focus to care at home and in community settings requires complex arrangements for medicines and treatments and greater support for parents, children and young people who are administering increasingly complex medicines in increasingly complex ways (e.g. insulin pumps) and who are recommended to adapt their lifestyles to optimise health. Information on self-administration and medicines management is required to support delivery of children's health care in various community settings (e.g. home and school).[14]

Kennedy[17] clarifies the importance of communication of information to support decision-making and informed choice and incorporating children's perspectives on issues surrounding their health and the delivery of services for children in his review of children's NHS services in England, published in September 2010. It extends the White Paper's[18] very few references to the role of patients, and specifically children, signalling that patients will be involved in making decisions about their own health care. Kennedy[17] also writes of the need to find ways of working in partnership to communicate information to children and families about services and treatment options. It is proposed that services and consultations with professionals need to be managed differently and that staff will need training to achieve a truly child-centred and holistic approach. There is, however, a noticeable shift in emphasis from the importance placed on types and formats of information per se to a sharper focus on context, and in particular the communication and facilitation of information for children and young people. Kennedy's vision of 'the right child receiving the right information at the right time' is mirrored in 'the information revolution' policy published by the Department of Health (DH) in 2010.[18]

Comprehensive, accessible and timely information about both risks and benefits and decision support are imperative if children and young people are to be active partners in decision-making about diabetes management and self-care choices. In the IMP,[1] paediatric diabetes specialist nurses (PDSNs) were identified as the main providers of information to children and their families. The NHS is developing a number of information portals and, in the IMP,[1] specialist NHS children's hospital websites were found to contain high-quality information; however, NHS Choices, digital television and NHS Direct (now NHS 111) were not specifically designed with children in mind. The Patient Advocacy and Liaison Service was set up as the previous Labour administration's response to supporting patients' information needs throughout their journey through care. However, as reported in the IMP,[1] Heaton and Sloper's[19] evaluation found that the service for children was limited by the quality, scope and availability of child-orientated information and resources. *Choosing Health*[20] also advocated practical solutions such as copying letters for patients and, when appropriate, tape recording consultations, but little is known about what children themselves would find helpful in terms of their information needs.

There is little information available for young people and their families around transition between child and adult service provision, with many young people seemingly unprepared to manage their own care and live independently.[21] Findings from an overlapping NIHR study looking at the transition of young people with T1D to adult services have now been reported[22] and provide a greater understanding of the complex nature of transitioning as a young person with diabetes to adult services. Kennedy[17] notes with reference to earlier policy[23] how 'transition' in reality often amounts to no more than 'transfer'. For many young people transition is experienced as a disruptive discontinuity in their care as they move suddenly from child services.

Kennedy's report[17] stresses the need to take 'culture' into account. Care should be seen 'in the round' and information should be well co-ordinated. He recommends dedicated people to manage the communication of information to children, young people and their families, recognising the need to understand the family perspective. The models of communication and facilitation of information in routine practice are equally as important as the quality of the information. There is, however, little evidence on the best ways to facilitate and integrate children's health information in routine care in ways that are effective and meaningful to children and their families.

Children's diabetes medicines management and self-care

Type 1 diabetes is one of the most common chronic conditions in childhood, with a current estimated prevalence of one per 700–1000 children in the UK, giving a total population of 25,000 under-25s with T1D.[24] The incidence in children under 5 years doubled between 1985 and 1995 and in children under 15 years there is an overall increase of around 4% each year.[24] Management of diabetes is aimed at maintaining blood glucose levels within the normal range. A recent response to the Kennedy report reiterated that glycaemic control of children with T1D in England was unacceptably higher than in other European countries.[25] Lewis and Lenehan[25] concluded that better diabetes services and optimisation of children's self-management were required to minimise long-term comorbidity and poor outcomes.

Children with T1D need individual insulin regimes, monitoring of their blood glucose levels four to six times a day and close attention to a healthy diet and exercise.[26,27] Parents, young people and, when appropriate, children are taught to measure blood glucose and adjust the insulin dosage in response to blood glucose readings, diet and exercise. Children are usually supplied with an electronic blood glucose meter but they may purchase one without a medical prescription. There is little evidence to indicate that children and young people and their families are using blood glucose monitoring effectively to identify patterns and trends in blood glucose readings and calculate their insulin dose accordingly.

Children and young people need to be involved with their families/carers and professionals in decision-making about their self-care and diabetes management, including understanding the risks and benefits and specific instructions to ensure optimum effect.[14] Research has been aimed at identifying important aspects of structured education programmes, for example comparing their effectiveness,[5] developing innovative curricula[3] and exploring acceptability to adolescents and their parents, and eliciting ideas on how they would set about designing education sessions.[28] Work has also been carried out on psycho-educational interventions.[29] There is, however, insufficient evidence on the effectiveness of information underpinning diabetes education and medicines management for children and young people.[2,7,8] Tailored, child-centred information could equip children and young people with the knowledge to become experts in diabetes care.[26,30,31]

The National Institute for Health and Care Excellence (NICE)[26] and Skills for Health[32] provide childhood diabetes competencies and signpost the need for children's diabetes information. The NICE diabetes guidelines[26] outline that 'information provided should be accurate and consistent and it should support informed decision making' and be 'appropriate for the child's or young person's age, maturity, culture, wishes and existing knowledge within the family' (p. 8). The Skills for Health competencies stipulate that children and their families should receive an age-appropriate, individually tailored, intensive structured education programme and high-quality, child-centred information to support the achievement of clinical management goals, including optimal glycaemic control, minimisation of acute readmissions and risk reduction of long-term complications.

However, at the outset of the project there was insufficient evidence concerning the types and formats of information that could inspire children with diabetes to manage their medicines and encourage concordance with diabetes self-management plans.[9] The IMP[1] was designed to explore these issues more broadly with common childhood long-term conditions, including diabetes. Moreover, a lack of child-centred research has hampered the development of effective interventions to optimise long-term self-management and minimise risk of complications.[7–9]

Central to optimal diabetes self-management is the real-time recording of blood glucose levels and titration of insulin doses in a diabetes diary.[26,33] This allows children and parents to view trends and optimise their individual diabetes self-management to achieve glycaemic control within the optimal range stated in national and international clinical guidelines on children's diabetes. Children and young people are encouraged to start recording their own readings in their diaries as soon as they are capable of doing so. There is also envisaged to be a key transition towards self-care for each individual child, when recording his or her blood glucose readings and insulin doses in the diary becomes his or her own responsibility. Despite the critical importance of the diabetes diary in optimal self-management, a key finding from the IMP[1] was that the NHS had not produced a national age-appropriate children's diabetes diary for use in routine NHS care. Children and young people were being offered adult diaries produced by pharmaceutical companies and some had obtained children's diaries from diabetes charities. The lack of a quality-assured and age-appropriate children's diabetes diary for routine use in the NHS became a central concern that we sought to address through the EPIC project.

Health literacy

Children's diabetes information and self-completion of diabetes diaries are likely to be key to developing the notion of self-care as children's autonomy increases with age. As McPherson[34] notes (citing Schmidt *et al.*[35]), childhood long-term conditions such as diabetes can impact on psychosocial well-being in adulthood if appropriate coping strategies are not adopted. Although knowledge may not predict adherence either in childhood or in a young person, failure to involve children with long-term conditions with their health care not only can result in suboptimal management in childhood but also has serious ramifications for health later in life (p. 18).[34]

The ability to use diabetes information and diabetes diaries to support decision-making and self-care is undoubtedly linked to health literacy. In this context health literacy means the degree to which children and young people have both the motivation and the capacity to obtain, process and understand basic diabetes self-management information and make optimal use of diabetes services and PDSN support to make appropriate decisions about their insulin management and lifestyle adjustments. Medication literacy encompasses the skills needed to access, understand and act on medicines information. In the IMP[1] our interest in medication literacy was the availability, effective communication and facilitation of information to support the decisions of children, young people and their families made at home and in their everyday lives. In contrast, the EPIC project goes a step further by providing children and young people with an individually tailored, quality-assured and age-appropriate diabetes self-management pack and diabetes diary through which we explored how and when they acted (or not) on medicines and diabetes self-management information.

Focus and aims of the EPIC project

The EPIC project was conceived to address the lack of appropriate children's diabetes information and a diabetes diary in routine NHS care and to generate evidence of what works concerning delivery and use of diabetes information and diaries as a way of enabling children and young people to engage in optimal self-care (see *Appendix 1* for the study protocols).

Aim

The overarching aim of the multiple strands of work was to develop and evaluate an individually tailored, age-appropriate diabetes diary and information pack for children and young people aged 6–18 years with T1D to support decision-making and self-care with a specific focus on insulin management and electronic blood glucose monitoring, compared with available resources in routine clinical practice.

Objectives

The EPIC study objectives were as follows:

1. to review gold standard diabetes clinical guidelines, currently available diabetes information, including findings from the linked qualitative IMP study, to identify best practice, and types/formats of information most likely to assist age-appropriate decision-making and choices concerning blood glucose monitoring and insulin management
2. to develop an age-appropriate diabetes information intervention (child-centred diabetes diary and information pack) for children and young people to support the appropriate use of blood glucose monitoring to optimise management of and concordance with their insulin regime
3. to explore the utility of the child-centred diabetes diary and information pack (in this context utility refers to ease of use and fitness for purpose) within different contexts in which children and young people manage their routine diabetes care (home, school, community), with and without support from parents or health-care professionals (HCPs), and in alternative settings
4. to explore how children and young people with and without their parents, teachers, nurses and doctors use (or not) the diabetes diary and information pack to support decision-making, in particular how children and parents 'self-prescribe' the correct (or incorrect) dose of insulin
5. to identify similarities and differences between the diabetes diary and information pack developed for adolescents and those available within adult diabetes services
6. to evaluate the diabetes diary and information pack within the context of routine diabetes care in relation to patient outcomes (diabetes-specific health-related quality of life, generic health-related quality of life, medicine and treatment concordance, acceptability, ease of use and glycaemic control)
7. to identify gaps in knowledge to inform a future research agenda.

In the following sections we outline the complex legal framework that is applied to children's health care, which was at the forefront of our minds when developing age-appropriate diabetes information packs and diabetes diaries for children and young people aged 6–18 years. Having explained the legal framework, attention is then turned to describing the theoretical frameworks and proposition underpinning the development and evaluation of the children's diabetes information packs and diabetes diaries.

The legal framework

As previously outlined, clinical guidelines and care pathways set out the optimal daily self-management approaches and optimal biomarker ranges, such as for glycated haemoglobin (HbA_{1c}), that children and young people are encouraged to achieve. From a professional perspective, children and young people have limited choices about deviating from advice for optimal diabetes self-care and management. In recent years, however, there are more treatment options available in some centres, such as administering insulin using an insulin pump rather than by injections. There is also increasing recognition of the need to balance the rights of a child with the rights of parents and to gauge the appropriateness of whatever balance is achieved. Achieving this balance can be especially challenging when the potential catastrophic consequences of children's suboptimal diabetes self-care (e.g. blindness, kidney failure, lower limb amputation) may not manifest until years later.

In routine NHS practice children and young people with diabetes are commonly asked to make decisions on a number of issues ranging from decisions about types of medication and insulin regimes and whether to have a blood test through to decisions concerning complex interventions such as whether to swap to an insulin pump. Young people with diabetes are also no different from other young people in that some will decide to have a tattoo, engage in underage sexual activity, drink alcohol and experiment with illegal drugs, all of which may impact on their optimal diabetes self-management.

The legal framework referring to children and information, health care, choice and informed consent is complex. For the purposes of giving consent to care plans and treatment children are treated differently in law according to their age, which is why the provision of high-quality, age-appropriate information is important to present the benefits and risks to a child audience. In a legal framework age-appropriate information that provides clear guidance about treatment, options for treatment and benefits and risks of different options is conceived as essential to backing up verbal information shared by diabetes professionals. The legal framework, however, is not helpful when children and young people and their families are uninterested about optimal diabetes self-care and glycaemic control and, although competent to use information and make decisions and engage in optimal self-care practices, they opt not to.

Health-care professionals currently follow the general principle that children and young people should be involved as much as possible in decisions about their care, even when they are not able to make decisions on their own.[36] The legal position concerning ability to consent differs depending on whether the young person is aged over or under 16 years.

Children aged < 16 years

Children aged < 16 years are not deemed to be automatically legally competent to give consent. The courts have determined that such children can be legally competent if they have sufficient understanding and maturity to enable them to understand fully what is proposed. This concept – now known as Gillick competency – initially arose in the case of Gillick *v.* West Norfolk and Wisbech Health Authority in 1985.[37] The term 'Fraser guidelines' is also used in this respect (Lord Fraser was the judge who ruled on the case). Decision-making regarding consent will depend on the relationship of the HCP with the child and the family and also the kind of consent being sought. Even if a child cannot give consent in law he or she will need appropriate information to give his or her assent. Children may be competent to take some decisions even if they are not competent to make others. For example, even young children may be competent to make some health-care decisions such as their preferred choice concerning whether to take the liquid or the tablet form of a medicine, whereas young children would not be expected to understand or weigh up information concerning the need for an operation. If a child is aged < 16 years and deemed not legally competent, consent will need to be obtained from someone with parental responsibility, unless it is an emergency.

In the context of the IMP and EPIC study, which focus on long-term conditions, competency is something that can be developed over time by presenting children with information appropriate to their age and level of education and understanding. The emphasis in DH guidance[38] is that families of children in this age group should be involved in decisions about their care unless there is a very good reason for not doing so. If, however, a competent child aged < 16 years is insistent that his or her family should not be involved, the child's right to confidentiality must be respected, unless such an approach would put the child at serious risk of harm.

Young people aged 16 and 17 years

Once children reach the age of 16 years they are presumed in law to be competent unless there is evidence to the contrary. Importantly, children aged 16 or 17 years cannot refuse treatment if it has been agreed by a person with parental responsibility or the court and it is in their best interests. Therefore, they do not have the same status as adults aged ≥ 18 years. Nonetheless, in a diabetes context, young people in this age group frequently do not follow advice or maintain optimal glycaemic control, but this is considered lack of concordance, adherence or compliance rather than outright refusal to treatment.

The Mental Capacity Act 2005[39] applies to people aged 16 years and over. The DH[38] recommends that it is nonetheless good practice to encourage young people of this age to involve their families in decisions about their care, unless it would not be in their interests to do so. Evidence suggests, however, that parents often find it difficult to keep track of what their teenage children are doing in a diabetes self-care context.

Adults aged > 18 years

Once a person has reached the age of 18 years no-one can give consent on his or her behalf. If he or she is not competent HCPs can provide treatment and care providing that this is in his or her best interests, which may be determined by the court.[38]

Assessing competence

Even if a young person is aged > 16 years this does not, as with adults aged ≥ 18 years, necessarily mean that the person is competent. A competent person is able to:

- understand and retain information pertinent to the decision about their care, that is, the nature, purpose and possible consequences of the proposed investigations or treatment, as well as the consequences of not having treatment
- use this information to consider whether or not he or she should consent to the intervention offered and to communicate his or her wishes.

The DH guidance[38] advises HCPs that they should not assume that children with learning difficulties are unable to make competent decisions, which can be aided by presenting them with information in an appropriate way. If, however, any child aged < 18 years is deemed not competent a person with parental responsibility would need to give consent. Similar provision is made in Scotland by the Age of Legal Capacity (Scotland) Act 1991.[40]

Parental responsibility

Parental responsibility includes the right of parents to consent to treatment on behalf of a child or young person aged < 18 years when he or she is unable to provide valid consent, provided the treatment is in the best interests of the child.

Devolving parental responsibility

Provision in law is made for parents who are not with their children 24 hours a day. There are times when parents can devolve the responsibility for consent to care and treatment to others, for example grandparents, child minders and school teachers, for certain situations such as emergency care, management of minor illness and support with ongoing treatment of long-term conditions such as diabetes.

The DH guidance[38] outlines that parental devolved consent does not need to be in writing if consent is devolved to close family members. It is, however, best practice for professionals such as school teachers and employed carers to develop a shared care plan with parents that outlines an agreed approach in specific circumstances (such as administering medicines in a school setting to a child experiencing an acute hypoglycaemic attack).

In the EPIC study we were particularly interested in finding out children's experiences of managing their diabetes away from their families and in situations such as at school where parental responsibility is devolved and they are required to self-care with minimal or no adult supervision.

Having outlined the legal framework, attention is now turned to the theoretical frameworks.

Theoretical frameworks

In developing and evaluating a children's diabetes information pack and diabetes diary we drew on the same three theoretical frameworks as in the IMP:[1] a biopsychosocial and anthropological model of childhood and illness management, the Promoting Action on Research Implementation in Health Services (PARiHS) framework[41] and the Medical Research Council (MRC) framework[42,43] for developing and evaluating complex interventions. The theoretical frameworks are described in the following sections.

At the conclusion of the IMP we developed two theoretical models and a proposition to describe the critical success factors for partnership and participation between children, parents and health professionals and services, and successful implementation of children's health information in routine clinical practice (p. 207).[1] These two theoretical models and proposition are used in the trial process evaluation to help interpret findings and specifically to explain why the EPIC pack and diary did not have the desired effect on children's diabetes outcomes.

Biopsychosocial and anthropological model of childhood and illness management

As with the IMP,[1] from conception we were influenced by the imperative, drawn from social anthropology, to elucidate and critically analyse context and content, diversity of viewpoint and ideas driving motivation and actions.[44,45]

We recognised that policies need to be placed within the context of children's lives and the illnesses they experience, and acknowledged that our research should take the anthropological context into account. Inspired by Jordan's[46] account of birth in four cultures, we also recognised that, although biomedically conditions may be considered universally the same (e.g. childhood diabetes), how conditions are experienced and managed may be strikingly different for different children and their families and different groups. Nevertheless, despite differences in orientation and interpretation, certain ideas about how care is managed are shared. Levine,[47] an anthropologist writing in 1986, writes that the shared organisation of ideas includes the intellectual, moral and aesthetic standards prevalent in a community, and the meanings of communicative actions (pp. 66–77). It is, he suggests, important to take account of general rules, concepts or assumptions that generate the particulars readily accessible to the researcher.

The social anthropological perspective acknowledges that individual children's experiences of having diabetes are unique. They have to manage diabetes within the context of their everyday lives, which includes being part of a family within society, attending school and participation in out-of-school activities. Families need to take responsibility for diabetes management, with support from specialised diabetes teams. When younger children are diagnosed parents assume responsibility for their child's diabetes, but there is a gradual shift in responsibility from parent to child as children and young people become more knowledgeable about diabetes and develop the necessary cognitive skills to make decisions about, for example, insulin titration according to blood glucose levels.

Children also have different experiences as they grow and develop and, although there are periods of equilibrium, they need to constantly consider and manage their diabetes as they encounter changes in their lives. In adolescence puberty is known to increase insulin requirements and has a negative effect on glycaemic control. In addition, teenagers are more likely to ignore diabetes management because of, for example, increased independence from parents, increased risk-taking behaviours and a desire for peer conformity.

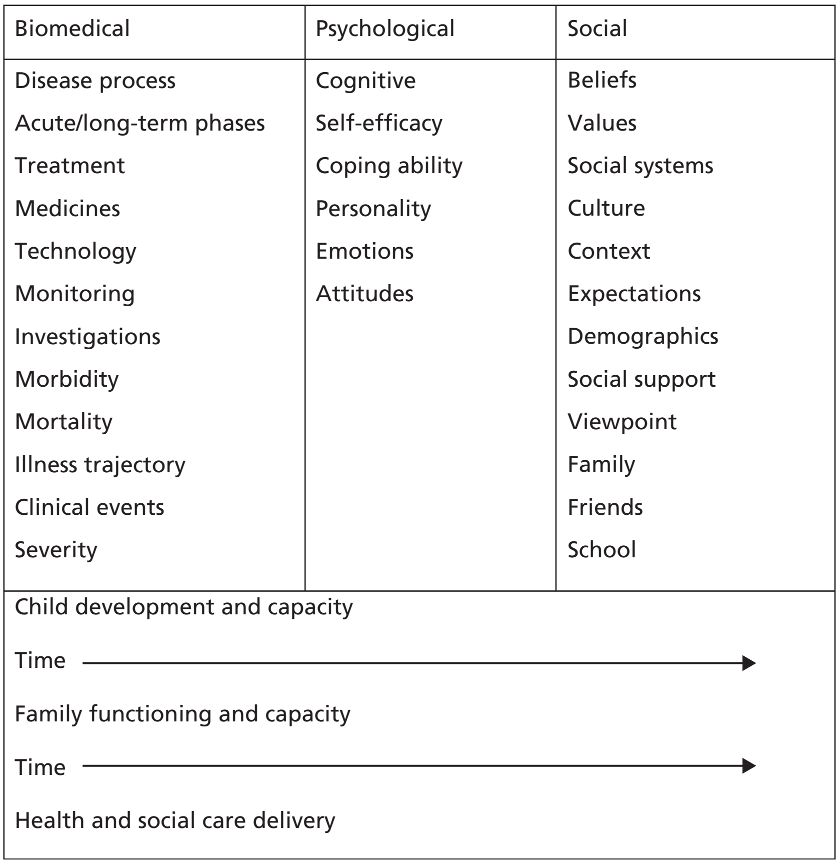
This approach to conceptualising the child, and in particular their long-term diabetes management, primarily within the family and society, is fundamentally different from the acute medical model whereby children enter the health-care system for diagnoses and treatment under the direction of a lead doctor and a team of HCPs who direct and initiate care (e.g. Kennedy[17]).

The context of children's and young people's lives in relation to their health, medicines management and self-care is an important consideration involving the interplay between their medical condition, how they orientate themselves to their condition, their values and expectations, as well as the settings in which they find themselves. In *Figure 1* we have summarised the key concepts that we have taken into consideration when collecting and analysing data to support this approach.

The Promoting Action on Research Implementation in Health Services framework

In addition to using the MRC framework for designing and evaluating complex interventions, the PARiHS framework will be used as the framework for the translation of evidence into practice evaluation.[41,48] The framework has been theoretically and empirically developed to represent the interplay and interdependence of the many factors influencing the implementation of evidence into practice. This is explained by a function of the relation between evidence, context and facilitation.[41,49,50] The hypothesis offered is that for implementation of evidence to be successful there needs to be clarity about the nature of the evidence being used, the quality of context and the type of facilitation needed to ensure a successful process. The framework has been used by others to inform the design and evaluation of evidence into practice initiatives.[51–53] The PARiHS framework is particularly relevant to this study because:

1. The study aims to introduce new diabetes diaries and assembled diabetes information packs (evidence) into children's self-care regimes and health-care practice to improve blood glucose monitoring and insulin management. Understanding the factors that influence its implementation and use will be important in determining the acceptability and feasibility of the information pack (facilitation) – this framework will provide a conceptual guide for mapping these issues.
2. Understanding how the information pack is used in different contexts where children and young people manage their diabetes will be key in the evaluation of its utility and contribution. Applying the



Biomedical	Psychological	Social
Disease process	Cognitive	Beliefs
Acute/long-term phases	Self-efficacy	Values
Treatment	Coping ability	Social systems
Medicines	Personality	Culture
Technology	Emotions	Context
Monitoring	Attitudes	Expectations
Investigations		Demographics
Morbidity		Social support
Mortality		Viewpoint
Illness trajectory		Family
Clinical events		Friends
Severity		School

Child development and capacity

Time →

Family functioning and capacity

Time →

Health and social care delivery

FIGURE 1 Biopsychosocial model for families and children with acute and long-term conditions.

framework will allow a focus on the key contextual variables mediating the implementation and use of the information pack.
3. It facilitates the gathering of individual (e.g. child/practitioner/carer) experiences as well as appreciating the fit with the broader context of care delivery.

Medical Research Council framework for developing and evaluating complex interventions

Children's health information is part of a complex intervention, or a number of different complex interventions, that contribute to care pathways and clinical management plans in different settings for different tracer conditions. Our approach to exploring the use of children's health information in routine practice settings follows the theoretical phase of the MRC framework[42] to understand better child, family, HCP and organisational behaviours concerning the use (or not) of children's health information, and informal evidence regarding organisational, child and family, and professional constraints or beliefs that may promote or inhibit behavioural change. This initial phase of the MRC framework to assess theory and evidence was considered to be most useful when identifying preliminary ideas about the types, formats and facilitation of health information most likely to help children and young people manage their illnesses in different settings in age-appropriate ways.

The 2008 updated MRC guidance[43] provides further clarity on the complexity of interventions and how to consider the relative roles of active ingredients, interacting components and the relative contribution of children's health information when used within a larger complex system of children's service delivery, and beyond that when used by families and in different community contexts such as home and schools. We have used the updated framework to consider different dimensions of complexity, such as the number and difficulty of behaviours, and age-appropriate behaviours, required by those delivering and receiving children's health information in various settings, and the degree of flexibility or age-appropriate tailoring of children's health information to specific children and contexts. We were also interested in developing our understanding of how children's health information was used by children, parents and HCPs in different settings in order to establish its practical effectiveness and where strong and weak links occurred that could potentially impact on outcomes and quality of family and child-centred care.

An integrated model of complex interventions, implementing and using evidence in practice and understanding the family and societal context

Figure 2 shows how we have integrated the three frameworks into a single model to guide the systematic review, interpretation of the critical discourse analysis (CDA), intervention development, delivery of the trial and analysis of the process evaluation.

Theoretical models of partnership and participation and the critical success factors for successful translation of children's health information into routine practice

As in the parallel IMP,[1] the EPIC project is anchored to the idea that partnership between the public and the UK NHS has the potential to build a healthier society.[10] Information on medicines management is regarded as critical to effective partnership.[11,12] If 'partnership' is to be promoted then it is important to recognise that children and young people are capable of being partners in the approach to their treatment. A detailed description of how the theoretical models were developed is reported in the IMP.[1] The theoretical model shown in *Table 1* represents high and low levels of partnership and participation in NHS service delivery and organisational contexts.

Translation, implementation and use of children's health information

The theoretical model of the critical success factors for translation and use of children's health information in routine NHS care (*Table 2*) uses the conceptual domains of the PARiHS framework to show high and low levels of 'partnership and participation' in care and decision-making between children, families and HCPs, and successful implementation of children's health information in routine clinical practice. Process evaluation findings will be mapped against the theoretical models to identify where barriers to successful implementation and use of the EPIC packs have occurred.

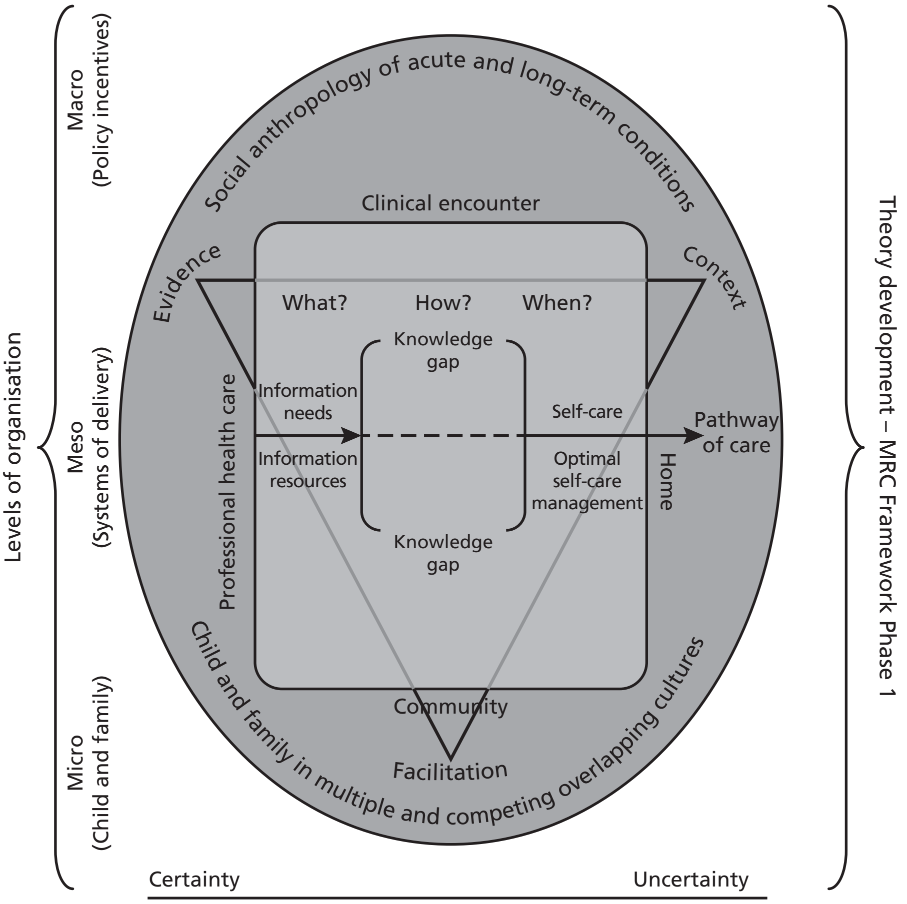


FIGURE 2 Single theoretical model: IMP conceptual model.

TABLE 1 Explanatory model of ‘partnership and participation’ between children, families and HCPs in NHS contexts

Partnership and participation: core concepts	Levels of partnership and participation	
	Low	High
Culture	HCP – biomedical and diagnostic/treatment focus centred around monitoring treatment concordance	HCP – child-centred, listening and responding to cues from child, discussing options, presenting treatment plans and information with strategies to enable high-quality self-care of condition
	Parent – family culture does not facilitate independence	Parent – family culture encourages independence and involvement in decision-making
Choice	HCP – limited or no choice provided	HCP – all possible options presented enabling child to choose, facilitating a sense of self-control and ownership
	Parent – inhibits choice provided	Parent – encourages child to make choice as appropriate
Negotiation	HCP – prescriptive/dogmatic approach	HCP – treatment plans and information presented in an age-appropriate risk/benefit scenario
	Parent – over-rides any opportunity for child by negotiating on his or her behalf	Parent – encourages child to take part in negotiations and is willing to negotiate and compromise as well as advocate on his or her behalf
Engagement	HCP – ignoring child; parent as proxy or top-and-tail approach (acknowledging child at the beginning and the end of the consultation/clinical encounter with condition-unrelated questions)	HCP – direct communication with child throughout the consultation/clinical encounter; uses age-appropriate language to facilitate understanding; involvement as much as possible in condition-relevant decisions
	Parent – dominates consultation/clinical encounter or has not expectations of involving child	Parent – addresses child and refers to him or her directly in communication with the HCP and encourages him or her to answer or ask questions
Setting/environment	HCP – e.g. adult environment for consultation/clinical encounter	HCP – child-friendly: colours, posters (large print, simple language), range of age-appropriate toys and interactive condition-appropriate props and other information formats in a range of age-appropriate age bands; age-appropriate seating/furniture, etc.
Child-centred, e.g. use of age-appropriate language	HCP – complex terms used, information text not appropriate to age	HCP – language used appropriately for age, complex terminology translated and explained using language appropriate for individual child
Decision-making	HCP – child not involved in making any decisions related to his or her care and treatment of condition	HCP – involved in decisions required, allowing time to consider and discuss options, inviting questions, anticipating concerns if unexpressed
Resources: interactive props	HCP – none used verbal information	HCP – drawing of diagrams or use of objects (real or model) to illustrate treatment or care process

TABLE 1 Explanatory model of 'partnership and participation' between children, families and HCPs in NHS contexts (*continued*)

Partnership and participation: core concepts	Levels of partnership and participation	
	Low	High
Information	HCP – none or just verbal information with no supportive written information	HCP – information provided in a number of reinforcing age-appropriate formats, provided in a timely fashion in the condition trajectory
Care pathways	HCP – rigid adherence to care pathway approach as the focus of the consultation/clinical encounter	HCP – flexible use of care pathways allowing consultation to be led by needs of the child and accompanying parent/carer
Empowerment	HCP – child prevented or actively disempowered from entering discussions regarding his or her care and treatment	HCP – child actively encouraged to take part in discussions and decisions involving his or her care and treatment
Autonomy	HCP – ignoring individual capacity (within child development parameters) of child to think for self and determine own needs and negotiate appropriate options	HCP – recognition of age and capacity of individual child (child developmental stages) to understand and engage in consultation/clinical encounter
Capacity: mental	Child – is intellectually unable to make choices and decisions on his or her own behalf, e.g. severe autism	Child – is able to comprehend information given to him or her (in an age-appropriate manner) irrespective of disability and communication difficulties
	HCP – does not attempt to establish the level of comprehension possible by the child	HCP – is able to establish the mental capacity of a child and adjust as appropriate the level of information and engagement that is reasonably possible
Communication (language, comprehension)	HCP – does not attempt to find an appropriate approach/level of communication with a child (for reasons such as age, e.g. too young, or disability)	HCP – ensures that he or she communicates directly with any child irrespective of age or disability and has the skills to address the child appropriate to his or her level of comprehension
Emotional/psychological	HCP – is not sensitive to or able to pick up cues from the child or parent regarding their emotional or psychological needs	HCP – appreciates, acknowledges and addresses the emotional and psychological needs of the child and parent; this also includes the capacity to anticipate what these needs may be in light of experience with the condition
Parenting	Parent – style of parenting lacks the capacity to involve the child in making choices or involve the child in his or her own care; may be related to the parent's own sense of responsibility or may be that the parent is overwhelmed and unable to cope with the child's condition	Parent – style of parenting is able to facilitate the child in being actively involved with his or her care; parent is able to determine when to intervene and when to encourage independence

TABLE 2 Explanatory model of the critical success factors for translation, implementation and use of children's health information in clinical practice by HCPs

PARiHS framework concepts/domains	Critical success factors for translation, implementation and use of children's health information in routine practice	
	Low	High
Context – service, quality assurance, evaluation, beliefs and values, culture and leadership	Low partnership and participation between service, HCP and children and parents Service is adult-orientated, rigid and inflexible, children are processed through the clinical encounter with limited time, choice or opportunities for decision-making Inconsistent staff and high turnover leading to lack of continuity of care Resources: limited or no supply of children's health information resources for HCP use Children and/or parents do not value the service and frequently do not attend or cancel HCPs and organisation not receptive to change, poor leadership	High partnership and participation between service, HCP and children and parents Service is welcoming and accommodating and allows sufficient time to engage with children and parents to discuss choices and facilitate decision-making Consistency of core HCPs who know child and can see the big picture and understand the complexity of the child's diagnosis, care pathway and social context Resources: a supply of various types and formats of high-quality children's information resources is available for HCP use Children and/or parents value the service and attend as intended HCPs and organisation actively engage with service users to evolve and improve services Appropriate skill mix and staff experienced and skilled in working with children, including play therapists. Strong team ethos with clear leadership High percentage of nurse-led care delivered in non-clinical environment, whereby nurses spend additional time focusing on information, knowledge exchange and checking understanding
Evidence – clinical guidelines, care pathways and children's health information, child and family evidence and experiences	Evidence-based clinical guidelines and care pathways not available or not valued and not used HCPs place low value on children's health information resources and rely on telling children and parents what to do and on children and parents remembering instructions. HCPs are unaware of what is available and do not seek out children's information resources Children's information resources: there is little or no available high-quality condition-specific children's health information for use, available children's health information does not match clinical guidelines, information is not quality assured or there is a supply of high-quality children's health information but HCPs are unaware of it or do not use it Children's and parent's experiences not counted as evidence or valued	Evidence-based clinical guidelines and care pathways, which are valued and integrated into care processes HCPs place high value on children's health information and children's participatory model of service delivery Children and parents place high value on children's health information. HCPs have high awareness of the availability and quality of children's health information and actively seek out new high-quality information and resources Children's information resources: there is a range of different types and formats of high-quality age-appropriate children's health information; there are robust quality assurance processes to monitor the quality of children's health information Children's and parent's experiences actively sought and highly valued

TABLE 2 Explanatory model of the critical success factors for translation, implementation and use of children's health information in clinical practice by HCPs (*continued*)

PARiHS framework concepts/domains	Critical success factors for translation, implementation and use of children's health information in routine practice	
	Low	High
Facilitation – holistic enabling support, guidance and purposeful knowledge exchange	Low level of episodic contact and low level of partnership and participation between child, parent, HCPs and service HPCs are not skilled or experienced at communicating with or caring for children and/or parent and/or child not receptive or engaged HCPs perceive giving information as a task or someone else's responsibility and may 'give' or 'signpost' information for use outside the clinical encounter. No follow-up to see if information needs met. Children's health information regarded as a 'one-off' and an 'add-on' to care (e.g. leaflet rack in waiting room or responsibility of PALS). Onus is on children and parents to seek out and locate what information they need HCPs focus on issues of interest to themselves (e.g. compliance). Child and parent remain largely dependent on HCP	High level of sustained partnership and participation between child, parent, HCPs and service HCPs perceive knowledge exchange with children and parents as an active holistic process and actively explore wider biological consequences and social context of living with the condition HCPs highly trained and skilled at communicating with children in age-appropriate ways High levels of nurse-led care in non-clinical contexts whose role it is to enable children to self-care and bridge the gap between hospital and home HCPs receptive and actively integrate and facilitate individually tailored children's health information at regular and key points within routine clinical encounters. HCPs liaise closely with PALS to ensure consistent approach HCPs actively enable and exchange high levels of information and feedback with parent and child to allow development of self-care and expertise. Parent and child receptive and engaged Service model facilitates active follow-up, feedback and evaluation, and re-evaluation to ascertain progress and ongoing outcomes

PALS, Patient Advice and Liaison Service.

The EPIC project proposition

More broadly, the theoretical models developed at the conclusion of the IMP[1] helped us consider a theoretical proposition to explore further in the EPIC project. We proposed that for optimal translation of children's health information and participation in care:

> *High quality, age-appropriate and accessible children's health information, valued by health care professionals, children and parents, and shared using child-centered, facilitative and partnership approaches to care and service delivery, will be more highly used and a more effective component of complex interventions to optimize children's long-term condition management.*
>
> *p. 207*[1]

Design and methodology

To meet our objectives, which are aligned with the phases of the MRC framework for designing and evaluating complex interventions, a four-stage study was designed. The four stages are detailed in the following sections.

Stage 1: context

We conducted multiple strands of investigation to focus our understanding on the context of children's diabetes care, including:

- a review of reviews and mixed-method systematic review of the barriers to and enablers of optimal diabetes self-care by children and young people in educational settings (see *Chapter 3*)
- further searching for currently available children's diabetes information to add to the database constructed for the IMP
- an extension and update of the IMP comparative analysis to establish whether key health messages in children's diabetes information matched with diabetes clinical guidelines (see *Chapter 2*)
- an extension of the CDA refocusing on diabetes to investigate the content and meaning of selected currently available children's diabetes resources (see *Chapter 2*).

Stage 2: intervention development – diabetes diaries and information packs

In addition to incorporating evidence from the IMP[1] and stage 1 of this study, we conducted further strands of investigation and consultation, including:

- convening an expert clinical advisory group to advise on intervention development and clinical risk management
- undertaking qualitative interviews and focus groups with children and young people to ascertain their information preferences and self-care practices with an emphasis on children who had spent time away from their families
- obtaining children's and young people's perspectives on various iterations of the age-appropriate diabetes diaries and information packs (web consultation and stall at diabetes charity family days).

Children's diabetes information resources produced for the trial

In an iterative approach, integrating findings from the linked IMP and building throughout stages 1 and 2, we produced the following range of resources that could be individually tailored for pragmatic evaluation in routine clinical practice (stage 3):

- three diabetes diaries for children and young people using insulin injections (6–10 years, 11–15 years and 16–18 years)
- one diabetes diary (6–18 years) for children and young people using insulin pumps
- child-friendly sheets for recording carbohydrate intake
- three age-appropriate information packs containing published diabetes information bound in an age-appropriate folder (6–10 years, 11–15 years and 16–18 years)
- stickers (6–10 years) and stickers and marker pens (11–15 years) for children to personalise their folder.

We then applied to the NIHR for permission to brand the diaries with the official NIHR logo, which was granted, and finally selected clinical experts were asked to formally sign off the EPIC packs and diaries as being suitable for use in the NHS.

Intervention development is reported in *Chapter 4*.

Stage 3: randomised controlled trial to evaluate the diabetes diaries and information packs in routine practice

We designed and carried out a pragmatic RCT to assess the clinical effectiveness and cost-effectiveness of the diabetes diaries and information packs in routine practice (see *Chapters 5* and *6*).

Stage 4: process evaluation

As the trial did not detect an intervention effect, we have used the process evaluation to help explain the outcome. For the process evaluation we collected the following stands of evidence:

- interviews with HCPs in each site to document current routine practice and local clinical care pathways for children with T1D
- a baseline survey to determine the ethnic profile of trial participants
- baseline postcode analysis to determine the index of deprivation of trial participants
- qualitative interviews with children and parents to ascertain their experiences and perspectives
- a questionnaire completed by HCPs at the conclusion of the trial to ascertain their perspectives.

The process evaluation is reported in *Chapter 7*.

Chapter conclusion

This opening chapter has introduced and discussed key policies and key ideas driving the study. The theoretical frameworks that we integrated to make sense of empirical work are described and the research methodology is summarised for each of the main study stages. The different stages are described in detail in *Chapters 2–7*. *Chapter 7* also presents the implications of the study for health care and recommendations for further research.

Chapter 2 Comparison of diabetes clinical guidelines with children's diabetes information, and critical discourse analysis of selected children's diabetes information

Introduction

In this chapter we report several streams of contextual work to underpin the development of the EPIC intervention and programme theory. Much of this work aligned with streams of work undertaken for the IMP, extended here to focus on T1D.

We first report findings from scoping of currently available children's diabetes information to establish a database of the potential range, types and formats of diabetes information available to children, young people and their families with T1D. Next, we report the extent to which key messages in current children's diabetes clinical guidance in relation to blood glucose monitoring, insulin management and record keeping are translated into contemporaneous children's diabetes information resources.

We then move on to a CDA of the ways in which such children's diabetes texts represent information in certain 'age-appropriate' ways, as well as the extent to which they are inclusive or not of children and young people with disabilities and of different ethnicities and sex, as well as young people who are living away from their families. We identify and analyse the assumptions made by diabetes information sources about their relationships with their readership, assumptions that, in turn, shape the messages of diabetes information materials. The ways in which diabetes information needs change within the context of the family and throughout the child's 'journey' towards diabetes self-care are explored.

Finally, selected findings to inform EPIC intervention and programme theory development are summarised.

Scoping of currently available children's diabetes information

This section of the report describes the searches for currently available diabetes health information for children and young people with T1D aged 6–18 years and their families, specifically in relation to insulin management and blood glucose monitoring.

Searching for children's diabetes information

The scoping exercise to identify children's diabetes information conducted for the IMP[1] identified 69 paper-based resources, 40 web pages and eight multimedia resources up until August 2008 (p. 57). This work was extended commencing in August 2008 and continued intensively for approximately 6 months. Examples of current diabetes information for children and young people were sought from charities, pharmaceutical companies, health and medical institutions and some international sources that could be accessed in the UK through the internet, for example sources in Canada, the USA and Australia. Since the initial period of intensive searching, update searches have been conducted on a monthly basis throughout the life of the project. However, as we cannot claim to have a comprehensive record of all such information sources, our aim has been to provide a snapshot of information that is currently available around the UK. The methods followed the same approach as in the related scoping exercise in the IMP.[1]

In addition, we also contacted selected NHS organisations providing children's diabetes care, including children's diabetes services that were being considered as sites for the EPIC RCT, those known to have already produced children's resources and a well-known children's hospital in the UK. An audit trail of organisations and individuals contacted throughout our search can be found in *Appendix 2* (see *Audit of all organisations and individuals contacted for diabetes information resourcing*). The websites of all NHS organisations, pharmaceutical companies and charities were first searched and then contacted by e-mail or telephone to request copies of their most up-to-date information.

Children's diabetes information resources found

In total, 142 children's diabetes information resources (leaflets, booklets, bespoke locally produced information, teaching aids, DVDs, CD-ROMs) were found and a database was established (see *Appendix 2*, *Diabetes information database*). Details of all of these resources including source, format, age range for which the information was written (as determined by two EPIC researchers) and date of publication were recorded on this database. Of these, 120 were currently available and made reference within the text to blood glucose monitoring and insulin management. A separate list of books ($n = 10$) (see *Appendix 2*, *Resources: books*) and a separate list of interactive websites ($n = 36$) (see *Appendix 2*, *Resources: websites*) were also produced.

Addressing diversity

The 110 paper-based children's diabetes information resources (referred to henceforth as leaflets) were explored for issues of diversity (sex and ethnicity). It was found that there is a lack of availability of leaflets for children and young people whose first language is not English as all of the diabetes leaflets were written in English. However, in some centres in Wales, translations of selected leaflets were available in the Welsh language.

Images in the leaflets were also explored for issues of sex and ethnicity. Photographs, cartoons, clip art and pencil drawings were critically analysed. The results of this analysis of the visual representation of diversity are provided in *Table 3*. If a leaflet contained images of both males and females (but not necessarily in balance) it was recorded as representing a gender balance. If a leaflet contained images of children and young people from different ethnic backgrounds it was recorded as representing ethnicity. Overall, we found ethnicity to be well represented in leaflets for children and young people with T1D, with the images representing a wide mix of cultures and races. The gender representation of children was usually balanced; that said, boys and girls tend to be portrayed as having interests conventionally or stereotypically attributed to their respective genders. In several leaflets, however, there were more images of boys than girls. This over-representation of boys is similar to that seen in mainstream children's media.[54,55] When animals and inanimate objects were used as the main characters/providers of information, these were almost exclusively male (Lenny the lion, Hu-Mee the frog, Frankie the frog, Desmond the dragon).

Ethnic and gender differences, although clearly present (e.g. different ethnicity is represented, especially in drawn illustrations; boys and girls are portrayed as having interests conventionally attributed to their respective genders), are not *linguistically* addressed in the texts. In other words, these texts construct boys and girls and minority ethnic and white children as essentially the same. As such, they do not take into consideration how T1D might be differentially experienced by boys and girls, or by those children and young people living within non-Westernised, non-white cultures within the UK. Normative maleness and whiteness shape the mode of address employed, which may have certain consequences for children, young people and their families in terms of the management of their condition. In other words, what is not taken into account, if normative maleness and whiteness largely shape these texts, is how diabetes is experienced differently by different genders, ethnicities, social class backgrounds, etc. Thus, for example, the healthy diet suggested might assume a standard white British diet and not take into account children from different ethnic backgrounds in which to eat healthily means eating different foods from those suggested by the text. Or it might mean that the reader judges his or her diet as somehow lacking or 'unhealthy' because it does not resemble what is presented, typically, in these texts.

TABLE 3 Addressing diversity: sex and ethnicity in children's diabetes health information resources

Title	Visual representations of		Images
	Gender balance	Ethnicity	
Tadpole Times (two editions)	Yes	Yes	Photographs in school yard and at home, cartoon frog (male) and tadpoles
On the Level (two editions)	Yes	Yes	Magazine format, photographs used within every article
Link Up	Yes	Yes	Magazine format, photographs used within every article
Just for You	Yes	Yes	Magazine format, photographs used within every article
Go 4 It	Yes	Yes	Magazine format, photographs used within every article
Tots to Teens	Yes	Yes	Magazine format, photographs used within every article
Children with Diabetes in School	Yes	Yes	Magazine format, photographs used within every article
When your Child Has Diabetes – What Care to Expect	Yes	Yes	Magazine format, photographs or clip art used within every article
Teenage Diabetes. What Friends Need to Know	Yes	Yes	Drawings of children's faces with speech bubbles
A Child in your Care Has Type 1 Diabetes	No	No	Photograph of mother and daughter, pink leaflet
Your Child Has Diabetes	Yes	Yes	Photograph of mother and son, red leaflet
Diabetes Doesn't Rule	Yes	Yes	Photograph on front cover
Type 1 Diabetes: a New Diagnosis	Yes	Yes	Photograph of girl checking her blood sugar, smiley face of boy
T1(pilot magazine)	Yes	Yes	Magazine format, photographs used within every article
Countdown for Kids	Yes	Yes	Magazine format, photographs used within every article
Streetwise collection: *Sex and beyond with Diabetes*	Yes	No	Cartoon boy, photograph of girl at condom machine
Streetwise collection: *Travelling with Diabetes*	Yes	Yes	Cartoon boy, photograph of boy with mum at airport, photograph of boy and girl in café on beach
Streetwise collection: *Hypos with Diabetes*	No	No	Cartoon boy, photograph of girl looking poorly
Streetwise collection: *Exercise with Diabetes*	Yes	No	Cartoon boy, photograph of boys playing football
Streetwise collection: *Drinking Safely with Diabetes*	No	Yes	Cartoon boy, photograph of two boys having a drink
Streetwise collection: *Sick Day Rules with Diabetes*	No	No	Cartoon boy, photograph of boy pouring a fruit drink
Streetwise collection: *Body Piercing and Tattoos with Diabetes*	Yes	No	Cartoon boy, photograph of girl's face with tattoo, photograph of stomach with piercing (? girl), photograph of boy with ear piercing

continued

TABLE 3 Addressing diversity: sex and ethnicity in children's diabetes health information resources (*continued*)

Title	Visual representations of		Images
	Gender balance	Ethnicity	
Streetwise collection: *Top Tips for School with Diabetes*	Yes	Yes	Cartoon boy, photograph in classroom
Streetwise collection: *High Blood Glucose with Diabetes*	Yes	No	Cartoon boy, photograph of dad with girl doing finger prick
Streetwise collection: *Home Blood Glucose Testing with Diabetes*	Yes	Yes	Photograph of dad with girl
Streetwise collection: *Feet with Diabetes*	No	No	Photograph of boy with mum at airport
Streetwise collection: *Emotional Wellbeing with Diabetes*	Yes	No	Cartoon boy, photographs of girl looking poorly, dad with girl doing finger prick, boy with football, girl looking stressed, happy boy with mum
Hanging with Hu-Mee	No	No	Cartoon frog (male)
Log Book	No	No	Cartoon frog (male)
A Parent/Carer Guide; Bringing up a Child with Diabetes	Yes	Yes	Lots of images, photographs of mums and dads
Humapen Luxura HD (part of Hu-Mee range)	No	No	Cartoon frog (male)
Desmond Motor Gets Diabetes	No	No	Cartoon car (male)
Joe's Rough Guide to Diabetes	No	No	Road signs, etc.
What Is a Hypo	Yes	No	Mum with dog in field, child and granny, two nurses, lady drinking
Diabetes Made Simple	Yes	Yes	Cartoon children (group of five)
Help with Hypos	No	No	Man running
Children; Helping your Child with Diabetes	No	No	General information
Ultrabox, with One Touch Meter	Yes	No	Cartoons
From Glucose to Ganja	No	No	Drugs
Managing your Diabetes	Yes	Yes	Cartoon children (group)
Know the Score	No	No	Cartoon boy on a skateboard, drugs
Get the Low Down on Hypos	No	No	Cartoon character
Making the Jump to Insulin Pumps	Yes	Yes	Cartoon character – boy on bike
What Do You Know about HbA_{1c}	Yes	Yes	Cartoon character – woman juggling
Giving your Fingertips a Rest from Testing	Yes	Yes	Cartoon character – a happy black lady showing finger tips
Taking the Sting Out of Testing	Yes	Yes	Cartoon character – finger pricker
Time to Test	Yes	Yes	Cartoon character – man being chased by a clock
Managing your Diabetes	Yes	Yes	Lots of images
Getting Started with Diabetes	Yes	Yes	Lots of images
Self Injection Certificate and Injection Site Guide	No	No	Certificate with cartoon dog

TABLE 3 Addressing diversity: sex and ethnicity in children's diabetes health information resources (*continued*)

	Visual representations of		
Title	Gender balance	Ethnicity	Images
10 Questions about Lipodystrophy	No	No	Plain text
What You Need to Know about Lipodystrophy	Yes	Yes	Just photographs of skin
Facts You Should Know about Needle Reuse	No	No	Plain text, no images
Getting Away	No	No	Photograph of sunglasses
Sick Day Rules	No	No	Woman blowing nose
Living with Diabetes: A Guide for Teenagers	Yes	No	Photograph of headphones on front cover, photograph of boy and girl inside
The Diabetes Team	No	No	Plain text, no images
The Yearly 'MOT' Clinic	No	No	Plain text, no images
Holiday Plans	No	No	Plain text, no images
Sick Day Rules – Information for Teenagers	No	No	Plain text, no images
Sick Day Rules – Information for Parents	No	No	Plain text, no images
Diabetes and your Periods	No	No	Female issue
Type 1 Diabetes in the Under 5s	Yes	Yes	Photographs of children playing with toys, girl looking happy, boy in swimming pool, mum and baby
Diabetes – Eating Well and Keeping Active	Yes	Yes	Photographs of active people running and cycling and a girl skiing
Diabetes and Sport	Yes	Yes	More pictures of boys than girls
Sick Day Rules	No	No	Plain text, no images
Diabetes in Five Minutes – A Survival Guide to Going Home	No	No	Plain text, no images
Diabetes and Me (under review)	Yes	Yes	Cartoon characters
MOT Clinic	No	No	Plain text, no images
Foot Care	No	No	Plain text, no images
From Home to Hospital. A Guide for Families of Children with Newly Diagnosed Insulin Dependent Diabetes	Yes	Yes	Lots of images – clip art and children's own drawings
Hypoglycaemia	Yes	Yes	Tiny photographs, more of a logo in top right-hand corner
Animas 2020. The Insulin Pump Made for Just One Kid. Yours – includes the leaflet *Hello. We're Animas*	Yes	Yes	Photographs of children of all ages and pumps
Take a New Path	Yes	Yes	Father and son, boy playing football; mother and daughter cooking and doing make-up. For adults as well. Six specific pages for children and parents

continued

TABLE 3 Addressing diversity: sex and ethnicity in children's diabetes health information resources (*continued*)

Title	Visual representations of		Images
	Gender balance	Ethnicity	
The Insulin Pump that Grows with the Knowledge – Step by Step	No	No	Father and son photographs
Growing up	Yes	Yes	More photographs of boys
Living with Diabetes	Yes	Yes	Lots of photographs and images
Caring for Children with Diabetes	Yes	Yes	Lots of photographs of children and lots of other images
Making Connections	Yes	Yes	Lots of faces throughout the booklet
Dealing with 'Sick Days' When on 2 or More Injections a Day	Yes	Yes	Plain text with clip art images
Changing Insulin Doses Based on Blood Glucose Tests	Yes	Yes	Plain text with clip art images
Hypoglycaemia: Information for Children and Young People Taking Insulin	Yes	Yes	Plain text with clip art images
Moving on	No	No	Plain text with clip art images
Diabetes Type 1	Yes	Yes	Magazine format, photographs used within every article
Childhood Diabetes – A Guide	Yes	Yes	Clip arts images, more images of boys
Travel and Holiday Information	No	No	Plain text, no images
Changing to a Basal–Bolus Insulin Regime	No	No	Plain text, no images
Altering your Insulin	No	No	Plain text, no images
Learning Disabilities Booklet	Yes	Yes	More photographs of boys
Diabetes Clinic Brochure	Yes	No	Logo in left-hand corner – boy and girl
The Basal Bolus Insulin Regimen for Newly Diagnosed Diabetes	Yes	Yes	Logo in left-hand corner – boy and girl; clip art of food item
Dealing with 'Sick Days' When on 4 or More Injections a Day	Yes	Yes	Plain text with clip art images
What is your HbA$_{1c}$	Yes	Yes	Logo in left-hand corner – boy and girl
The Problem with Families	Yes	Yes	Logo in left-hand corner – boy and girl
Blood Ketone Testing	Yes	Yes	Logo in left-hand corner – boy and girl
Sick Day Rules for Children with Diabetes	Yes	Yes	Logo in left-hand corner – boy and girl
Alcohol	Yes	Yes	Logo in left-hand corner – boy and girl
Diabetes Complications Explained	Yes	Yes	Logo in left-hand corner – boy and girl
Puberty	Yes	Yes	Logo in left-hand corner – boy and girl
Golden Rules for Teenagers	No	No	One clip art – computer with thermometer
Golden Rules for Children	No	No	One clip art – computer with thermometer
Type 1 Diabetes – Information for Families	Yes	Yes	Lots of photographs and clip art throughout
Driving with Diabetes	No	No	Plain text, no images

TABLE 3 Addressing diversity: sex and ethnicity in children's diabetes health information resources (*continued*)

Title	Visual representations of Gender balance	Ethnicity	Images
Patient Instructions for Giving Insulin Injections	No	No	Plain text, no images
Multiple Daily Injection Therapy	No	No	Plain text, no images
Salisbury Child & Adolescent Diabetes Clinic Information Folder	Yes	Yes	Lots of photographs and clip art throughout
What is Type 1 Diabetes	No	No	Plain text
Growing up with Diabetes	No	No	Pencil drawing of mum, child and teddy
Information for Children with Diabetes and their Families	No	No	Plain text, no images
Lenny Explains Diabetes	No	No	Cartoon of boy and lion

Although this work enabled a greater understanding of how gender was represented in texts, when developing the EPIC diary and packs we were not able to specifically address gender differences linguistically. We had insufficient resources to produce additional gender-specific, age-appropriate diaries and we selected currently available children's health information for inclusion in the pack.

Diabetes clinical guidelines and analysis of children's diabetes information quality

Clinical guidance is likely to be effective only when accurate translation into child and parent information has been achieved and children, parents and diabetes HCPs value the information and use it as intended to inform their decision-making and self-care. Children's diabetes clinical guidelines specify optimal self-management of diabetes and provide target HbA_{1c} ranges for children and young people to achieve. It was considered important to establish the consistency and accuracy of clinical information presented in diabetes information resources for children and families as a marker of quality. Within the IMP,[1] a small-scale study was undertaken to explore the quality of selected children's diabetes information to establish whether information on blood glucose monitoring and insulin management in children's diabetes information matched with best practice in nationally recommended diabetes clinical guidelines. We found that children's diabetes resources were less detailed and sometimes vague about this key aspect of diabetes self-management. We extended this work in the EPIC study to inform the choice of children's diabetes information resources for inclusion in the EPIC packs and to better understand how to write key health messages for children in the EPIC diaries.

Aim

The aim was to establish whether a sample of children's diabetes health information resources on self-management of blood glucose monitoring and insulin management was consistent with clinical standards and best practice in selected diabetes clinical guidelines.

Methods

The methodology used was the same as in the IMP[1] and is reported in the following sections.

Identification and selection of diabetes clinical guidelines

Policies and clinical guidance that made reference to the clinical management of children and young people with T1D in the UK and Ireland were identified, with the search completed in 2011. A total of 97 policies and clinical guidelines were identified in the search (see *Appendix 2*, *Policies, clinical guidelines and care pathways*). In collaboration with the children's diabetes team at the University Hospital of Wales, Cardiff, the three clinical guidelines that were considered the current gold standard, or most widely used in current routine practice, and which included information on self-monitoring of blood glucose and insulin management were selected.[26,33,56–58] These guidelines are listed in *Box 1*.

As part of the IMP,[1] content referring to the self-monitoring and range of blood glucose levels and insulin management was extracted. This work was extended to include content referring to record keeping (i.e. how and where children and young people should record their blood glucose measurements and titration of their insulin dose. Evidence was extracted into a table for comparison (*Table 4*).

Identification and selection of children's diabetes information for quality analysis and critical discourse analysis

The search strategy for locating children's diabetes information is detailed in the IMP report (p. 56).[1] The IMP scoping exercise had identified 56 individual items of diabetes information for children and young people with T1D aged between 6 and 18 years and 13 for their families and friends (69 in total). Books and websites were not included in this sample. We adopted a purposive and pragmatic approach to selecting examples of children's diabetes information for quality analysis of the content and subsequent CDA based on available time and resources to conduct the analysis. The process of selection is shown in *Figure 3*. Children's diabetes information resources were excluded for a variety of reasons. The final sample included only those resources that focused on blood glucose monitoring and insulin management. Selection of resources was prioritised according to whether contextual information about the resource, determined as part of the IMP, was available (see *Appendix 2*, *Discourse analysis: contextual information*), NHS staff reported that the resource was commonly used in the NHS (see *Appendix 2*, *Information used within NHS trusts for children and young people with diabetes*), the resource was described as 'popular' in IMP fieldwork, the resources had been subject to CDA in the IMP and the final selection represented pharmaceutical companies, charities and health and medical institutions. In total, 19 children's diabetes resources focusing on blood glucose monitoring and insulin management were analysed, as shown in *Box 2*.

Data extraction

Content referring to self-monitoring, record keeping and range of blood glucose levels in guidelines and children's diabetes information was extracted into tables for comparison (*Tables 5–7*). With the exception

BOX 1 Children's diabetes clinical guidelines

1. National Institute for Health and Care Excellence. *Type 1 diabetes: diagnosis and management of type 1 diabetes in children and young people*. Clinical Guideline 15. London: NICE; 2004.
2. *ISPAD Clinical Practice Consensus Guidelines 2006–2007.*
    - Hanas H, Donaghue K, Klingensmith G, Swift P. ISPAD clinical practice consensus guidelines 2006–2007. *Paediatr Diabetes* 2006;**7**:341–2 (*ISPAD Clinical Practice Consensus Guidelines* were subsequently updated and published in 2009[59]).
    - *ISPAD Clinical Practice Consensus Guidelines 2009 Compendium*. Rewers M, Pihoker C, Donaghue K, Hanas R, Swift P, Klingensmith GJ. Assessment and monitoring of glycemic control in children and adolescents with diabetes. *Pediatr Diabetes* 2009;**10**(Suppl. 12):71–81.
    - *ISPAD Clinical Practice Consensus Guidelines 2009 Compendium*. Bangstad H-J, Danne T, Deeb LC, Jarosz-Chobot P, Urakami T, Hanas R. Insulin treatment in children and adolescents with diabetes. *Pediatr Diabetes* 2009;**10**(Suppl. 12):82–99.
3. Diabetes UK. *Care recommendations: self-monitoring of blood glucose*. London: Diabetes UK; 2006.

ISPAD, International Society for Paediatric and Adolescent Diabetes.

TABLE 4 Comparison of guidance on self-monitoring of blood glucose, record keeping and insulin management

Clinical guidance	Targets	Monitoring of blood glucose levels	Insulin management	Record keeping
NICE 2004[26]	Short term: blood glucose levels: preprandial 4–8 mmol, postprandial < 10 mmol Long term: HbA_{1c} < 7.5%, checked two to four times per year	Frequent monitoring as part of a continuing package of care, generally between four and five times per day Children and young people with T1D and their families should be informed that aiming to achieve low levels of HbA_{1c} can lead to increased risks of hypoglycaemia and that high levels of HbA_{1c} can lead to increased risks of long-term microvascular complications	Insulin regimens are individualised for each patient. Children using MDI regimens should be encouraged to adjust their insulin dose if appropriate after each preprandial, bedtime and occasional night-time blood glucose measurement Children using twice-daily injection regimens should be encouraged to adjust their insulin dose according to the general trend in preprandial, bedtime and occasional night-time blood glucose measurements	Children and young people with T1D should be encouraged to use a diary in conjunction with a blood glucose monitor because recording food intake and events such as intercurrent illness can help to reduce the frequency of hypoglycaemic episodes
ISPAD 2009[33,56]	Short term: blood glucose levels: preprandial 5–8 mmol, postprandial 5–10 mmol, bedtime 6.7–10 mmol, nocturnal 4.5–9 mmol Long term: HbA_{1c} < 7.5%	The frequency and regularity of self-monitoring of blood glucose levels should be individualised depending on availability of equipment, type of insulin regimen and the ability of the child to identify hypoglycaemia Successful application of intensified diabetes management with multiple injection therapy or insulin infusion therapy requires frequent self-monitoring of blood glucose levels (four to six times a day) and regular, frequent review of the results to identify patterns requiring adjustment to the diabetes treatment plan It should be recognised that, without accurate monitoring, the risks of acute crises and long-term vascular and other damaging complications are greatly increased leading to high levels of health-care costs and personal disability	The choice of insulin regimen will depend on many factors including age, duration of diabetes, lifestyle (dietary patterns, exercise schedules, school, work commitments, etc.), targets of metabolic control and particularly individual patient/family preferences The basal–bolus concept (i.e. a pump or intermediate-acting/long-acting insulin/basal analogue once or twice daily and rapid-acting or regular boluses with meals and snacks) has the best possibility of imitating the physiological insulin profile At least two injections of insulin per day (mixing short-/rapid-acting and basal insulin) are advisable in most children	Record keeping of glycaemic control: It is common practice for a monitoring diary, logbook or some type of electronic memory device to be used to record patterns of glycaemic control and adjustments to treatment. The record book is useful at the time of consultation and should include the time and date of blood glucose levels; insulin dosage; notes of special events affecting glycaemic control (e.g. illness, parties, exercise, menses); hypoglycaemic episodes; description of severity; potential alterations in the usual routine to help explain the cause for the event; and episodes of ketonuria/ketonaemia Monitoring records should not be used as a judgement but as a vehicle for discussing the causes of variability and strategies for improving glycaemic

continued

TABLE 4 Comparison of guidance on self-monitoring of blood glucose, record keeping and insulin management (*continued*)

Clinical guidance	Targets	Monitoring of blood glucose levels	Insulin management	Record keeping
			Most regimens include a proportion of short- or rapid-acting insulin and intermediate-acting insulin, long-acting or basal analogue, but some children may during the partial remission phase maintain satisfactory metabolic control on intermediate- or long-acting insulins alone (i.e. an HbA_{1c} close to the normal range)	control. Frequent home review of records to identify patterns in glycaemic levels and subsequent adjustment in diabetes management are required for successful intensified diabetes management. In some instances, especially among teenagers, maintaining written monitoring records is difficult. If the family has access to a computer and can upload the blood glucose monitoring data for review, this may substitute for a manual record, although details of management may be lost with this method
ISPAD 2006[57]	Short term: blood glucose levels: preprandial 4–8 mmol, postprandial 10 mmol Long term: HbA_{1c} < 7.5%	Post fast, during the night, before each meal, before and after exercise, in response to the action profiles of insulin, during intercurrent illness, post hypoglycaemic episode Increased frequency with multiple injection or pump therapy The aim of blood glucose monitoring is to help prevent both the acute complication of hypoglycaemia and the chronic complications of microvascular and macrovascular diseases	No insulin regime can be optimised without frequent assessment of blood glucose monitoring On twice-daily insulin regimens dosage adjustments are usually based on recognition of blood glucose levels over the day or for a number of days On basal–bolus regimens, flexible or dynamic adjustments of insulin are made before meals and in response to frequent blood glucose monitoring	See above
Diabetes UK 2006[58]	Short term: blood glucose levels: preprandial 4–6 mmol, postprandial (2 hours after food) 10 mmol Long term: HbA_{1c} < 6.5% (< 7.5% if at risk of severe hypoglycaemia)	Conventional therapy two times per day, varying the time of testing. The majority of children and young people will need to test two to four times per day but this will vary according to the intensity of insulin therapy, i.e. pump therapy, MDIs	Not covered	Not covered

ISPAD, International Society for Paediatric and Adolescent Diabetes; MDI, multiple daily injection.

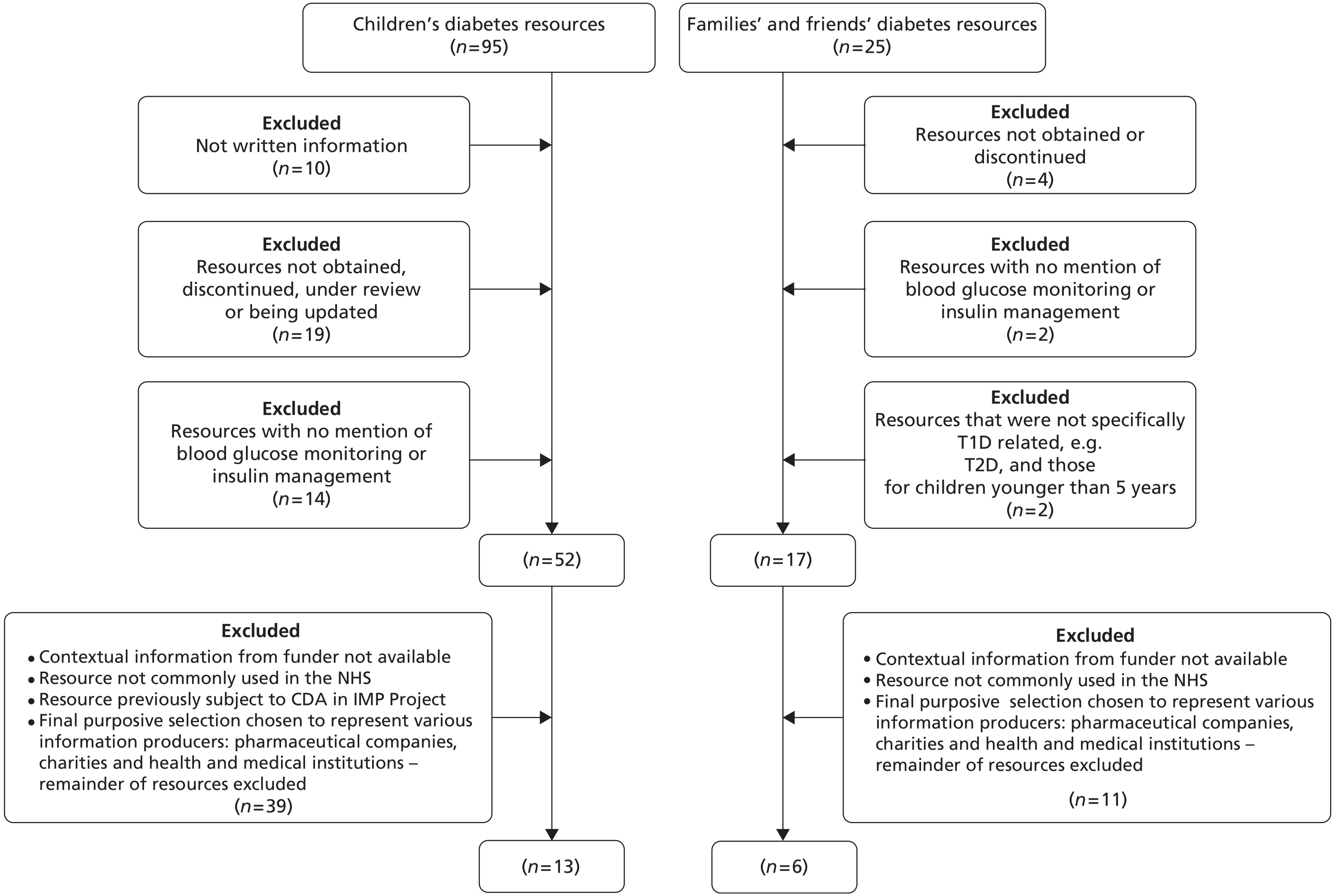


FIGURE 3 Flow diagram of selection of children's diabetes resources for quality analysis and CDA. T2D, type 2 diabetes.

BOX 2 Children's diabetes information used in quality analysis and CDA

6–10 years

Just for You – Diabetes UK, 2004/5.
Diabetes Made Simple – Novo Nordisk, 2005.[a]
Hangin' with Hu-mee – Eli Lilly, 2007.
Tadpole Times – Diabetes UK, 2010.[a]
T1 – Juvenile Diabetes Research Foundation, 2010.[a]

11–15 years

T1 – Juvenile Diabetes Research Foundation, 2010.[a]
Managing your Diabetes – Roche Diagnostics, 2005.
On the Level – Diabetes UK, 2010.
Growing up with Diabetes – BD Medical – Diabetes Care, 2009.
Home Blood Glucose Testing with Diabetes, *Streetwise* collection – Eli Lilly, 2008.[a]
High Blood Glucose with Diabetes, *Streetwise* collection – Eli Lilly, 2008.[a]

16–18 years

Home Blood Glucose Testing with Diabetes, *Streetwise* collection – Eli Lilly, 2008.[a]
High Blood Glucose with Diabetes, *Streetwise* collection – Eli Lilly, 2008.[a]
Living with Diabetes – Abbott Diabetes Care, 2008.[a]
Joe's Rough Guide to Diabetes – Sanofi Aventis, 2009.
Living with Diabetes – BD Medical – Diabetes Care, 2009.[a]

Parents/families

From Hospital to Home – Waltham Forest Primary Care Trust, 2006.
Tots to Teens – Diabetes UK, 2007/8.
A Parent/Carer Guide. Bringing up a Child with Diabetes – Eli Lilly, 2007.[a]
Caring for a Child with Diabetes – BD Medical – Diabetes Care, 2009.[a]
Type 1 Diabetes – Information for Families – Royal United Hospital Bath NHS Trust and Wiltshire Primary Care Trust, 2009.[a]
Salisbury Child & Adolescent Diabetes Clinic Information Folder – Salisbury NHS Foundation Trust, 2004.[a]

Adults[b]

Managing your Diabetes, an Introduction – Roche Diagnostics, ND.
Testing, Testing. The Balanced Guide to Blood Glucose Testing – Diabetes UK, 2011–12.
Complications – Eli Lilly, 2010.

ND, not dated.

Abbott Diabetes Care – glucose meter company; BD Medical – Diabetes Care – medical technology company; Diabetes UK – charity; Eli Lilly – pharmaceutical company; Juvenile Diabetes Research Foundation – charity; Novo Nordisk – pharmaceutical company; Roche Diagnostics – medical technology company; Sanofi Aventis – pharmaceutical company.

[a] Children's diabetes information used in CDA.

[b] Adult information used only in CDA.

TABLE 5 What children's diabetes resources say about record keeping

Information resources	Discussion of record keeping
Information resources: 6–10 years age range	
Just for You Newly diagnosed magazine, Diabetes UK	'It is important to write down the results of your blood test every time you do one. Then you should take your book with you when you visit the clinic'
Diabetes Made Simple Newly diagnosed booklet, Novo Nordisk	No reference to record keeping
Hangin' with Hu-mee Newly diagnosed booklet, Eli Lilly	'Every time I do a blood test, I write it down in my Log Book. I note the time, date, and number I got when I tested. I also write down how I felt and how much insulin I took. I sometimes include how much I ate or what my activities were' 'I can tell you for sure that it's a great idea to keep good records. Doctors, diabetes nurses and other people on your diabetes team will think you're a superstar for doing it. They use that information to check how your diabetes is doing'
Tadpole Times Quarterly magazine, Diabetes UK	No reference to record keeping
Information resources: 11–15 years age range	
T1 Pilot magazine, Juvenile Diabetes Research Foundation	No reference to record keeping
Managing your Diabetes Newly diagnosed booklet, Roche Diagnostics	'It is important to write your readings in a special diary to help you spot patterns and know if changes to your treatment are needed'
On the Level Quarterly magazine, Diabetes UK	No reference to record keeping
Growing up with Diabetes Newly diagnosed booklet, BD Medical – Diabetes Care	'Record the reading from your meter and enter it into your diary'
Information resources: 16–18 years age range	
Home Blood Glucose Testing with Diabetes Streetwise collection, Eli Lilly	No reference to record keeping
High Blood Glucose with Diabetes Streetwise collection, Eli Lilly	No reference to record keeping
Living with Diabetes Abbott Diabetes Care	'Write your results in your monitoring diary'
Joe's Rough Guide to Diabetes Sanofi Aventis	'It might also be worth writing down the results in a diary. It's a bit tedious but after you've learnt how everything affects you (insulin, activity, climate etc.) you wouldn't have to use it anymore'
Living with Diabetes Newly diagnosed booklet, BD Medical – Diabetes Care	'Record the reading from your meter and enter it into your diary'

continued

TABLE 5 What children's diabetes resources say about record keeping (*continued*)

Information resources	Discussion of record keeping
Information resources for parents/families	
From Hospital to Home Newly diagnosed guide, Waltham Forest Primary Care Trust	'Record result in your diary'
Tots to Teens Newly diagnosed guide, Diabetes UK	'It doesn't matter which method you use; what is important is that you have a record of your child's blood glucose levels that both you and your paediatric diabetes team can use'
A Parent/Carer Guide. Bringing up a Child with Diabetes Eli Lilly	'Record keeping is essential to managing your child's diabetes. This helps you understand if your child's treatment plan is keeping blood glucose levels well controlled'
Caring for a Child with Diabetes BD Medical – Diabetes Care	'Record the reading from the meter and enter it to your child's diary'
Type 1 Diabetes – Information for Families Newly diagnosed guide, Royal United Hospital Bath NHS Trust and Wiltshire Primary Care Trust	'We suggest you and your child record the blood tests in a blood glucose diary that we can give you, or you can use one of your own'
Salisbury Child & Adolescent Diabetes Clinic information folder Newly diagnosed guide, Salisbury NHS Foundation Trust	No reference to record keeping

TABLE 6 What children's diabetes resources say about insulin management

Information resources	Discussion of insulin regimes
Information resources: 6–10 years age range	
Just for You Newly diagnosed magazine, Diabetes UK	Doing an injection; mentions insulin and changes to insulin performed in clinic
Diabetes Made Simple Newly diagnosed booklet, Novo Nordisk	'important that you have all the injections that the doctor and nurse have said you should do'
Hangin' with Hu-mee Newly diagnosed booklet, Eli Lilly	What is insulin, why the body needs insulin
Tadpole Times Quarterly magazine, Diabetes UK	Cartoon stories in which character Emma explores issues around insulin 'Emma still has to inject her insulin as she would normally even if she hasn't eaten, being poorly can make her blood glucose levels go high'
Information resources: 11–15 years age range	
T1 Pilot magazine, Juvenile Diabetes Research Foundation	Insulin pump article
Managing your Diabetes Newly diagnosed booklet, Roche Diagnostics	'The Diabetes specialist team decide how much and which type of insulin you will need at first'
On the Level Quarterly magazine, Diabetes UK	Response to question on problem page: 'It is also worth discussing your treatment options – a different approach may work better for you. Some people have just two injections a day, others have four a day (an injection at each mealtime and one 24 hour injection). An insulin pump is also an option, which some people find really helps to keep their blood glucose levels stable'
Growing up with Diabetes Newly diagnosed booklet, BD Medical – Diabetes Care	Injections using a pen, injection technique, types of insulin, rotating sites, using fresh needles

TABLE 6 What children's diabetes resources say about insulin management (*continued*)

Information resources	Discussion of insulin regimes
Information resources: 16–18 years age range	
Home Blood Glucose Testing with Diabetes Streetwise collection, Eli Lilly	Insulin adjustment suggested: 'do you need a "lower" amount of insulin?'
High Blood Glucose with Diabetes Streetwise collection, Eli Lilly	Common reasons for high blood glucose: not enough insulin, or missed a dose
Living with Diabetes Abbott Diabetes Care	Discussed extensively, including dose adjustments, effect of exercise, illness and alcohol
Joe's Rough Guide to Diabetes Sanofi Aventis	Discussed extensively, including dose adjustments, effect of exercise, illness and alcohol
Living with Diabetes Newly diagnosed booklet, BD Medical – Diabetes Care	Injections using a pen, injection technique, types of insulin, rotating sites, using fresh needles
Information resources for parents/families	
From Hospital to Home Newly diagnosed guide, Waltham Forest Primary Care Trust	All about insulin, where to inject insulin, how to give insulin, storage of insulin, rotating injection sites, problems with injection sites, different types of regimens mentioned
Tots to Teens Newly diagnosed guide, Diabetes UK	Coping with injections, injection sites, insulin absorption, how to inject, supporting your child to inject, injecting a baby, types of insulin, storing insulin, insulin regimes, insulin pump therapy
A Parent/Carer Guide. Bringing up a Child with Diabetes Eli Lilly	What is insulin, all about insulin types, storage and handling of insulin, insulin regimes
Caring for a Child with Diabetes BD Medical – Diabetes Care	Injections using a pen, injection technique, types of insulin, rotating sites, using fresh needles 'By understanding your child and their lifestyle, their doctor will choose the best insulin regime for them'
Type 1 Diabetes – Information for Families Newly diagnosed guide, Royal United Hospital Bath NHS Trust and Wiltshire Primary Care Trust	What is insulin, storage of insulin, how to give injections, where to give injections with a syringe and a pen 'The amount of insulin your child needs will change as he/she grows. They may need more if they are ill or have an infection and less insulin if they are exercising'
Salisbury Child & Adolescent Diabetes Clinic information folder Newly diagnosed guide, Salisbury NHS Foundation Trust	What is insulin, different types of regimens, changing insulin types

TABLE 7 What children's diabetes resources say about self-monitoring blood glucose

Information resources	Self-monitoring blood glucose discussed	Blood glucose target range covered	Frequency of testing covered
Information resources: 6–10 years age range			
Just for You Newly diagnosed magazine, Diabetes UK	Yes	Yes – short term: 'between 4–7 is great' No – long term	No
Diabetes Made Simple Newly diagnosed booklet, Novo Nordisk	Yes	No	'Regular testing of your blood sugar is very important'
Hangin' with Hu-mee Newly diagnosed booklet, Eli Lilly	Yes	No	'Check your blood glucose regularly'
Tadpole Times Quarterly magazine, Diabetes UK	Yes	No	Cartoon stories in which character Emma explores issues around blood glucose monitoring in different situations
Information resources: 11–15 years age range			
T1 Pilot magazine, Juvenile Diabetes Research Foundation	No	No	Variety of articles in which issues around blood glucose monitoring in different situations are discussed
Managing your Diabetes Newly diagnosed booklet, Roche Diagnostics	Yes	Yes – short term: 'between 4–7 mmol/l' No – long term	Two to four times per day; 'feeling unwell . . . check your blood glucose level more frequently'
On the Level Quarterly magazine, Diabetes UK	No	No	Variety of articles in which issues around blood glucose monitoring in different situations are discussed
Growing up with Diabetes Newly diagnosed booklet, BD Medical – Diabetes Care	Yes	Yes – short term: 'Yours should be kept between 4–8 mmol/l before lunch and dinner and under 10 mmol/l two hrs after'	'You need to monitor your blood sugar regularly using a meter'
Information resources: 16–18 years age range			
Home Blood Glucose Testing with Diabetes Streetwise collection, Eli Lilly	Yes	No	'Try testing at different times of the day', 'try testing when your routine changes'
High Blood Glucose with Diabetes Streetwise collection, Eli Lilly	Yes	Yes: 'Well controlled HbA_{1c} level of under 7%'	No
Living with Diabetes Abbott Diabetes Care	Yes	Yes – refers to Diabetes UK targets for short-term and long-term glucose levels: 'these are general guidelines – your nurse . . . can give you targets that will work for you' Complications mentioned	'Spend a couple of weeks finding out exactly what is happening to your blood glucose levels test before and 2 hours after a meal'

TABLE 7 What children's diabetes resources say about self-monitoring blood glucose (*continued*)

Information resources	Self-monitoring blood glucose discussed	Blood glucose target range covered	Frequency of testing covered
Joe's Rough Guide to Diabetes Sanofi Aventis	Yes	Yes – short term: 'in general glucose levels should be 4–7 mmol/l before meals and 2 hrs after . . . go no higher than 11 mmol/l' Yes – long term: 'will take your glycosylated haemoglobin level' Complications mentioned	'if you are measuring a lot four or more times a day'
Living with Diabetes Newly diagnosed booklet, BD Medical – Diabetes Care	Yes	Yes – short term: 'The glucose in your blood needs to be kept within healthy limits – typically between 4–7 mmol/l before lunch and dinner and under 9 mmol/l two hrs after' No – long term	'Monitor your blood glucose regularly to know what action to take' 'To know when and what help you need, you must monitor your blood glucose level regularly throughout the day'
Information resources: parents/families			
From Hospital to Home Newly diagnosed guide, Waltham Forest Primary Care Trust	Yes	No	'2 to 3 times a day', 'lunchtime test is difficult . . . eliminated for the majority'
Tots to Teens Newly diagnosed guide, Diabetes UK	Yes	Yes – short term: 'The general target ranges are 4–8 mmol/l before a meal and under 10 mmol/l by two hrs afterwards' Yes – long term: 'The recommended level for children is generally > 58 mmol/mol (7.5%)' Complications mentioned	'It is often recommended to test at the following times Before a main meal Before bed If your child feels unwell Before and after physical activity If your child feels hypo'
A Parent/Carer Guide. Bringing up a Child with Diabetes Eli Lilly	Yes	Yes – short term: 'Guidelines for children and young people with T1D aim for pre-prandial (pre-meal) blood glucose 4–8 mmol/l and 2 hrs post prandial blood glucose less than 10 mmol/l' Yes – long term: 'Good control of HbA_{1c} will reduce the risk of your child developing long term complications of diabetes. Guidelines aim for HbA_{1c} less than 7.5%, without frequent disabling hypoglycaemia' Complications mentioned	'The majority of people with T1D should consider monitoring their blood glucose levels between 2–4 times daily depending on their treatment'

continued

TABLE 7 What children's diabetes resources say about self-monitoring blood glucose (*continued*)

Information resources	Self-monitoring blood glucose discussed	Blood glucose target range covered	Frequency of testing covered
Caring for a Child with Diabetes BD Medical – Diabetes Care	Yes	Yes – short term: 'Your child's blood glucose level needs to be kept within healthy limits – typically between 4–8 mmol/l before lunch and dinner and under 10 mmol/l two hrs after' No – long term	'Tests are usually needed several times a day'
Type 1 Diabetes – Information for Families Newly diagnosed guide, Royal United Hospital Bath NHS Trust and Wiltshire Primary Care Trust	Yes	Yes – short term: 'Between 4–8 mmol means that the glucose in your blood is just right' Yes – long term Complications mentioned	'Blood tests are carried out initially approximately 4 times/day. Blood tests should be carried out more frequently when your child is unwell and the team will advise you about this'
Salisbury Child & Adolescent Diabetes Clinic information folder Newly diagnosed guide, Salisbury NHS Foundation Trust	Yes	Yes – short term: 'We try to achieve blood glucose levels between 4–8 mmol/l' Refers to NICE guidelines that blood glucose levels should be < 8 mmol/l before a meal and < 10 mmol/l/ 2 hours after a meal (postprandial). Instructions on how to manage levels if they go above 10 mmol/l Yes – long term Complications mentioned. Refers to NICE guidelines for HbA_{1c} of < 7.5%	Yes. Specific instructions for sick-day rules to check blood glucose at breakfast, lunch, tea, bed and night-time

of the quarterly magazine publications *On the Level* and *Tadpole Times* from Diabetes UK and *T1* from Juvenile Diabetes Research Foundation (JDRF), the publication dates were pre 2009 and pre the new International Society for Paediatric and Adolescent Diabetes (ISPAD) guidance (also dated 2009);[33] therefore, the extent to which translation of key health messages from the 2006 ISPAD clinical guidelines into children's health information had been achieved was determined.

Key findings from the comparison of children's diabetes guidelines and children's diabetes information resources

Key findings from the comparison of children's diabetes guidelines and children's diabetes information resources were as follows:

- Children's diabetes clinical guidelines were broadly consistent, with a small degree of variation regarding recommended blood glucose levels and varying levels of detail (see *Table 4*).
- Children's diabetes information resources were far less specific than clinical guidelines about self-monitoring of blood glucose, and presentation of key information and messages were sometimes vague and open to interpretation (see *Table 7*).
- At the time of the analysis conducted for the IMP[1] (2008), children's diabetes information was not always consistent with clinical guidelines for self-monitoring of blood glucose and did not appear to be consistently based on gold standard evidence-based guidelines. However, on extending this analysis to a wider selection of resources published since the gold standard clinical guidance was published in 2004[26] (see *Table 7*), a greater degree of consistency was found.

- Insulin management varies for different children and young people dependent on factors such as lifestyle (e.g. exercise, diet), cognitive ability, culture, age, weight, school issues, adherence/concordance with treatment, child and parent choice and consultant's preference. Approaches to insulin administration include multiple daily injection (MDI); insulin injections once, twice or three times a day; and continuous subcutaneous insulin infusion (CSII). Insulin injections may be administered by pen or syringe. Given these varied approaches and multiple factors that influence decision-making, it is not surprising that insulin management is mentioned only in vague terms in all children's diabetes information (see *Table 6*).
- Most children's diabetes resources make reference to record keeping. Children and young people are encouraged to record their blood glucose readings in their diary and this is strongly emphasised in the information targeted at parents (see *Table 5*).
- The risk of long-term complications is not mentioned in diabetes information for younger children aged 6–10 years and only brief mention is made in the 11–15 years' resources.
- There is a need to update the content of children's diabetes health information to reflect the updated gold standard clinical guidance published in 2004.[26]
- NICE[60] provides a lay version of its clinical guidelines but this is written in the third person and is not specifically written for children and young people living with the condition. However, in the further information section it does state that 'If you need further information about any aspects of type 1 diabetes or the care that you or your child is receiving, please ask a member of the diabetes care team.'
- Children's diabetes health information did not usually carry a quality badge indicating that it was suitable for use in the NHS and it was unclear what (if any) quality assurance processes had been followed.

Summary of clinical guidelines and transfer of guidelines to children's diabetes information resources

We found that the key health messages in children's diabetes information resources generally fit with current UK clinical guidance.[26,57] The most recently produced information appears to be the most accurate; however, older, less accurate resources are still in circulation. Most of the resources available from the pharmaceutical companies and diabetes charities (Diabetes UK and JDRF) included details about self-monitoring of blood glucose levels, diabetes record keeping and insulin administration (although not all resources emphasised each of the separate aspects of diabetes self-care). Despite many of the resources being of reasonable quality in terms of publishing and the standard of written and graphical information, not many of the resources were badged as information provided by the 'NHS'. There is a need for children's diabetes information to be regularly reviewed when updated NICE clinical guidance is published.

Evidence to inform intervention development

The following important findings from this work have implications for EPIC intervention development:

- the diabetes diary is conceived as an important element of diabetes self-management
- children and young people should be developing self-management skills from an early age to titrate their insulin by daily recording of their blood glucose levels in their diary
- children's diabetes information varies in quality and some resources better align with children's diabetes clinical guidelines than others
- some deficiencies in children's diabetes information are the consequence of commercial pressures and conflicts of interest from their sources
- some children's diabetes information is obsolete and should be removed from circulation
- lack of NHS quality approval of diabetes resources needs to be addressed.

In the next section, a CDA of children's diabetes information resources will be presented.

Critical discourse analysis of selected currently available children's diabetes information resources

In this section we focus on a CDA of paper-based children's diabetes information resources. The objectives were to:

- build on the CDA of children's health information resources from the IMP,[1] to inform the current work and extend the scope to focus in-depth on childhood diabetes
- explore the management of childhood diabetes and focus on blood glucose monitoring and insulin management as a key exemplar of medicine management, self-care and concordance
- look specifically for similarities and differences in the discourses and philosophies underpinning children's, young people's and adult care pathways and management plans to see how and in what ways medicine management and self-care discourses/philosophies change at key stages across throughout childhood.

An introduction to critical discourse analysis

A *discourse* is a 'way of knowing' or 'way of talking about' some aspect of reality.[61] Two main discourses have been identified in contemporary health information: 'patient education' and 'patient empowerment'.[62] We can identify the presence of both of these in contemporary health information for children; however, in line with our study aims and objectives, our focus was a CDA of empowerment in relation to managing medicines, as reflected, or not, in the texts sampled from our database of predominantly paper-based health information for children, young people and their parents.

Critical discourse analysis is concerned with the textual relationship between, on the one hand, meaning making and, on the other hand, social structure and change. In other words, what critical discourse analysts are trying to make clear is how the hierarchical power relations of particular societies shape what is, and can be, said and how it is said. Examining textual features of diabetes texts produced for children and young people thus allows us to lay bare the power relations underlying the messages found in texts. For example, by analysing such diabetes texts we are able to better understand how certain ways of talking about the condition are used and their potential consequences for the child or young person with diabetes (and those around him or her). From this we might ask how do such texts construct the relationships between the child or young person with diabetes, HCPs and parents? To what extent do such texts reproduce existing power relations between these actors? If HCPs and parents are constructed as those who have the greatest power and authority to make decisions about health-care management, is that an issue or a problem? If so, how might future diabetes texts challenge these power relations in ways that help to encourage and empower children and young people to take greater control over their own care? As such, CDA offers a powerful tool for illuminating such power relations and in so doing provides insights that may be used to rethink those relations through the range and types of information provided for children and young people with diabetes. Of course, CDA never simply examines texts in isolation from the contexts of their production, and therefore it is always important to analyse them in relation to the wider processes in which children and young people with diabetes are enmeshed – with HCPs (including doctors, nurses, pharmaceutical companies and diabetes charities), parents or carers, siblings and extended family, and teachers and peers.

Silverman[63] presents the case that we should not think of texts as if they were correct or incorrect written representations of reality, but rather as accounts that help to construct the reality, and Grime and Ong take this further, stating that 'the language of the patient information leaflet is not simply an intermediary which enables an understanding of the "truth" about health and disease but actually helps construct particular understandings of health and disease' (p. 2).[64]

Institutional discourse appears to be especially in need of critique and as particularly amenable to a CDA approach. What is meant by 'institutional discourse' is the ways of knowing and talking about diabetes as it is defined by the health-care profession through its policies, practices and processes in relation to children and young people with the condition. The strictly bounded and hierarchical structure of institutional organisations, and the largely textual nature of their internal mediation/communication, suggests that the production and maintenance of power relations may be to some extent 'recovered' by means of engagement with these texts. In the context of this study, we were interested to pose questions about the institutionalised social relationship between health-care practitioner and child or young person. Following Fairclough (p. 226),[65] the kinds of questions that we wanted to explore through CDA were:

- How are children discursively positioned with regard to decision-making?
- What are the constraints on their choices?
- How are these represented?

Critical discourse analysis tools and mechanisms

Mechanisms at work in the data identified as relevant to the CDA of health information resources for children, young people and their families include intertextuality and recontextualisation. Intertextuality is concerned with describing and explaining how specific meanings are made in and across specific texts and how such texts are formally linked to each other. Intertextuality may be realised by several modes of communication– for example language or visual layout.

Recontextualisation is a useful way of understanding intertextuality as the recontextualisation of social practices. There are two social practices at issue in the analysis of health information texts aimed at children, young people and their families: (1) the practice of promoting health practices and (2) the practices surrounding the management of an illness, such as the administration of medicines, and the decision-making process. We attend to both in our analysis. With the concept of recontextualisation, we assume that text producers must use information existent in an adult context (broadly speaking) and reformulate it with a child reader in mind. They must try and understand that information in the context of childhood and construct texts accordingly.

We define a social practice as having the following characteristics: activities, participants, performance indicators, times, tools and materials, dress and grooming, and eligibility conditions.[61] In the process of recontextualisation the characteristics of social practices are subject to a variety of 'transformations'. *Box 3* provides the mechanisms of transformation that are suggested as analytical tools, that is, as ways of understanding how health information is recontextualised for children readers.

Our study of children's diabetes information produced for children, young people and their families aims to consider how power and choice are represented, primarily in relation to medicines management (blood glucose monitoring and insulin management). A key focus for us is the *legitimation* of certain discourses and social practices.

BOX 3 Mechanisms of transformations

Deletion is concerned with the aspects of a social practice that are included or omitted in its representation.

Substitution is a transformation in which elements of a social practice are substituted for by other elements in representations of that social practice (p. 288).[61]

Rearrangement is concerned with how the elements of a social practice are represented in terms of the order in which 'they actually occur' (p. 97).[66]

Addition is concerned with describing the addition of certain elements, such as 'reactions, purposes and legitimations' (p. 98).[66]

Summary of the critical discourses analysis from the Information Matters Project

The CDA in the IMP[1] was conducted to better understand the types and formats of health information resources using text and pictures that could empower the decision-making and choices about care of children, young people and their families. It was observed that health messages conveyed in information for children use fantasy, and in some cases medicines and/or doctors were represented as having magic powers. Children were discursively positioned with friends or knowledgeable adults and then families. As well as gaining insight into discursive mechanisms to promote empowerment, we found evidence of processes at work to create choice where choice may not seem to exist. For example, in the diabetes texts medicines are presented as necessary to the management of the condition – and in this sense there is no choice. But at the same time the illusion of choice is made available to the child in a consumer context. For example, the child with diabetes may appear to be able to choose an insulin pen from those available, some of which also allow a choice of colour. The pen may be referred to as a 'special pen'. In reality, the insulin appropriate to the child's treatment regimen and, in younger children, the ability to dial up insulin in half units are often determined by diabetes HCPs and will limit the child's choice of available pens. The findings also demonstrated the importance of involving children and young people in the production of health information to establish whether key messages conveyed are received and interpreted as intended (see p. 67 of the IMP report[1] for further details).

Empowerment discourse

Critical discourse analysis of six children's information texts identified three types of empowerment (medical, patient and identity). These are discussed further in relation to children's diabetes information in *Finding 1: what does 'empowerment' mean in contemporary child-centred health texts?*.

Furthermore, the meaning(s) of empowerment – even in the medicine-oriented texts – extends beyond empowerment concerned primarily with empowering the person/child as a patient to the various other areas of his or her life affected by a given condition. In the IMP report[1] a typological description of the discourses of 'empowerment' that have emerged during the analyses of contemporary child-centred health texts is described (p. 78).

The role of the critical discourse analysis in informing EPIC intervention development

The intention was to use relevant findings from the CDA to inform the EPIC intervention development. The key issue for intervention development was to gain a better understanding of discourses used in children's diabetes information in order to develop a programme theory. The understanding that children and young people will get about their T1D from the written component of the EPIC information pack will depend on the facts included and on the discourse employed. In addition, the shared understanding of empowerment will depend not only on how the child or young person understands the information that he or she receives but also on the 'voice' used to convey this information. It is with these important intervention development issues in mind that we undertook the CDA.

Research questions for the critical discourse analysis

The research questions posed for the purposes of the CDA element of the EPIC study related specifically to the discursive positioning of children, young people and their families within the children's diabetes health information texts and to the idea of 'empowerment', which, in turn, related to our stated aim of identifying types and formats of information that could empower the decision-making and choices about care of children, young people and their families. The research questions posed are:

1. What does 'empowerment' mean in contemporary child-centred diabetes texts?
2. What textual means are deployed to appeal to the child reader?
3. How are children and/or their families discursively 'positioned', especially with regard to decision-making and medicines and how this changes throughout childhood?

The first step was to finalise the sample of children's diabetes information resources to be drawn on and the processes to be put in place to undertake the CDA.

Sample of children's diabetes health information for the critical discourse analysis

The process of selecting a subset of diabetes information for the CDA is described in *Identification and selection of children's diabetes information for quality analysis and critical discourse analysis*. The final selection of children's diabetes leaflets (agreed by the CDA working group) can be found in *Box 2* (see box notes). Not all of the resources identified the target age range for which they were intended. The research team therefore classified the resources into three age categories (6–10 years, 11–15 years and 16–18 years) based on the age group of the images on the cover and within the texts. A small sample of generic 'adult' information from the same text producers (charities and pharmaceutical companies) was obtained to address the research objectives for the CDA.

Processes involved in critical discourse analysis

The data for CDA are the words and images that are used in children's diabetes health information. Each piece of information was examined to further explore the issues identified in the CDA within the IMP and to identify any new areas in order to answer the research questions. Quotations and examples from the texts and images were used to further illustrate the analysis when appropriate.

Finding 1: what does 'empowerment' mean in contemporary child-centred health texts?

Medical empowerment

In child-centred health texts across all ages the child is empowered to manage the condition on a daily basis through the use of medicines and/or other treatments. The medicine is represented as a *social enabler* – as a 'fix' for the constraints on social life (e.g. participation in play activities) that are potentially a part of the 'baggage' of diabetes.

In the magazine-style texts, the children and young people (target age range 11–18 years) themselves and celebrities with T1D share their stories of life with diabetes. The children and young people talk about their condition as something that recedes into the background as it is managed by their medicines (*Box 4*).

BOX 4 Examples of medical empowerment

> *I treat my diabetes as something that is just there . . . I control it, it doesn't control me.*
>
> On the Level, *autumn 2010, 'Meet Helen', pp. 14–15, Diabetes UK*
>
> *At first, I took insulin shots, but it was just too hard on the road to give myself shots. I switched to a pump, which has been great . . . I've decided not to let type 1 diabetes slow me down.*
>
> T1, *issue three, celebrity feature of Nick Jonas (from the Jonas Brothers band), p. 6, JDRF*

Patient empowerment

Patient empowerment discourse acknowledges that patients could have problems in understanding and remembering medical information and therefore paper-based resources can be a way to empower children and young people as opposed to being used to correct them.[67]

Empowerment here is concerned with the 'promotion' of the child to the status of adult, in terms of the access that an adult may have to knowledge and the expertise of the medical profession. The texts seek to empower the younger child (aged 6–10 years) as he or she learns to manage his or her diabetes, with diabetes advice and care being reinforced by parents, typically mothers, and the health-care team (*Box 5*).

The young girl (aged 6–10 years) in this scenario has limited authority. It is assumed that, although she would know something about her condition, she would not have established expertise, so she has to rely on a parent. This parent is usually the mother, with the father rarely present in most of the diabetes information resources.

Also implicit in the discourse of patient empowerment is the notion of the power of children to have information about their condition presented in an accessible register, in other words in 'child-friendly' language. In a general sense, the traditional social structure of child patient and medical professional is somewhat diminished, thus elevating the child's social status.

Identity empowerment

Three types of identity empowerment were found in the IMP, with texts variously discursively constructing the child who has diabetes as (1) 'normal' – so like other children; (2) 'special' – different from other children in a positive sense; and (3) 'same but different' – like other children but with different needs from those who do not have diabetes.

Child with diabetes as 'normal'

This particular discourse of empowerment constructs the notion that the child and young person living with T1D may live a 'normal' life, in other words the life of a non-'sufferer' (*Box 6*). This discourse can be established through the images contained within the texts. This can be through the use of real people or

BOX 5 Example of patient empowerment

> *Emma tells her mum about her exciting day, but that she has been feeling very tired. Emma's mum thinks back over the last week, and remembers that Emma has been more tired than usual. Emma's mum thinks she could be going low in her sleep so tells Emma that she will wake her up in the middle of the night to check. The next week, Emma goes to see her healthcare team.*
>
> Tadpole Times, *cartoon character Emma after a school trip to the zoo, Diabetes UK*

BOX 6 Examples of child with diabetes as 'normal'

> *Diabetes doesn't stop you doing stuff. You'll still be doing pretty much everything you like.*
>
> Growing up with Diabetes, *BD Medical – Diabetes Care, Spring 2000, pp. 6–7*
>
> *With diabetes properly managed your child can lead a perfectly normal life.*
>
> Caring for Children with Diabetes, *BD Medical – Diabetes Care*

cartoon images. For older children and young people (11–18 years), the photographs are of young people at clubs, partying, listening to music and skateboarding (*Living with Diabetes*, BD Medical – Diabetes Care). In a text for younger children (6–10 years) and their parents by the same company, the use of photographs of happy healthy children being active and sporty gives the impression that children with diabetes can do anything they want, just like any other child.

An example of a text aimed at younger children (6–10 years), which uses cartoon images, is *Tadpole Times*, the quarterly magazine produced by the charity Diabetes UK (*Figure 4*). Cartoon tadpoles are portrayed as enjoying different everyday 'normal' activities and having fun, for example cooking, gardening, playing, practising for the school Christmas play and make-believe (pretending to be astronauts or pirates).

However, in the effort to include a child who is living with diabetes in the larger group of 'normal' children, a very circumscribed notion of 'normality' is constructed. In other words, a narrow and, realistically, unachievable notion of what constitutes 'normality' is discursively constructed by many of the texts examined. That is, because diabetic children have diabetes, they can never be exactly the same as, and thus 'normal' like, others who do not have the condition. Although the social and physical benefits of controlling the effects of a condition in children are undeniable, the representations of normality may be too strongly emphasised as a positive and something that children and young people with diabetes ought to try to achieve as, inevitably, in discursive and real-life terms they will always be left out of any construction or experience of 'normality.'

Child with diabetes as 'special'

In one text (*On the Level*, Diabetes UK) the focus is very much on the achievements of children and young people (11–18 years) who just happen to have diabetes. Individual stories explore the challenges and problems that these people face whilst accomplishing these achievements, often portraying a heroic narrative. It is assumed that, if one works hard enough, one can also accomplish such things (see the mountain climbing example in *Figure 5*).

It is hoped that these images would be a source of inspiration; the message that is given is that even this is possible. There is no mention of inhibitors or barriers that might prevent them from doing such things, for example cost. There may actually be a risk of *excluding* those children living with diabetes who are not inclined to participate socially in the 'ideal' way.

It was found that in an effort to present children and young people with diabetes as 'normal' there is sometimes a degree of overcompensation in their activities and accomplishments. In these instances the

FIGURE 4 Front covers of *Tadpole Times* (images reproduced with the kind permission of Diabetes UK).

FIGURE 5 *On the Level*, autumn 2010. Young person trekking in the Himalayas (image reproduced with the kind permission of Diabetes UK).

bar for personal physical achievement is set very high, such as in the *On the Level* magazines from Diabetes UK (*Box 7*).

In this sense, then, 'special' is discursively constructed in the texts in very specific ways, that is, children and adults with diabetes are textually positioned as participating in very challenging activities that demand high levels of physical endurance that would be extremely demanding for anyone. In discursive terms such exceptional children, young people and adults are constructed as role models for what can be achieved, and in so doing this often neglects to acknowledge that it is a rare individual, with or without diabetes, who can undertake such activities. This form of identity empowerment may, in some cases, disempower child readers who may have limited physical abilities not usually associated with diabetes.

Child with diabetes as 'same but different'

Within each issue of *Tadpole Times* magazine (Diabetes UK magazine for children aged 6–10 years) there is a section called 'Cartoon time' (see link to intertextuality in *Critical discourse analysis tools and mechanisms*) that follows the life of a girl called Emma and how she manages her diabetes in a variety of everyday situations, for example during a school trip, going to the dentist, at the Christmas disco, at sports day. In these situations the child is portrayed as being the 'same but different' as there are extra things that she needs to do to effectively look after her diabetes. The cartoon character Emma is displayed as having some knowledge and looking after her diabetes, for example knowing when to check her blood glucose levels and how to correct them (*Box 8*)

BOX 7 Examples of activities and accomplishments from *On the Level* magazine

Winter 2008 – boy cycling from coast to coast across the UK.

Winter 2008 – girl backpacking – Brilliant Backpacking! 'Diabetes didn't stop me!'

Autumn 2008 – boy doing the Snowdon horseshoe walk.

Spring 2008 – boy climbing the Alps.

Summer 2009 – boy playing rugby.

Summer 2010 – wakeboarding – girl aged 14 years.

BOX 8 Examples of child with diabetes as 'same but different'

Before sports day:

> *Emma does a quick blood test to check it's ok to exercise.*
>
> *It's a bit lower than usual, so Emma has an apple to bring her levels back up.*
>
> *Later on at home, Emma has an extra snack before bedtime because she's been so active during the day.*

Tadpole Times, *summer 2010, pp. s5–8, Diabetes UK*

In the spring 2010 edition of *On the Level* from Diabetes UK there is an article about a 17-year-old boy (Joe) with T1D who went to the Glastonbury music festival:

> *It was good to know we were all the same, returning home with wrecked tents and rucksacks of dirty washing. In my case, there was also two sorts of spare insulin, spare insulin pens, a box of needles, a blood sugar monitor, test strips, multiclix lancets, glucose tablets and a sharps bin . . . the same but a bit different.*

On the Level, *spring 2010, 'Festival Fever', pp. 6–8, Diabetes UK*

Finding 2: what textual means are deployed to appeal to the child reader?

Self-care philosophies/discourses through childhood

Developmental psychologists such as Piaget[68] and his proponents hold the view that children develop according to systematic cognitive stages and, as such, they cannot acquire certain skills before they are cognitively ready. Children are described as being able or not able to do certain psychological and physiological tasks at certain ages. This idea that intellectual development is rigidly linked to age and biological stage is seen by sociologists such as James and Prout[69] and Jenks[70] as too simplistic. Such critics of Piaget suggest that social and cultural experiences have a greater influence on child development. Most information booklets for children and young people are based around age boundaries. Age is often used as a marker of differences in cognitive abilities, although there is tremendous variation in how and when children develop.[71] Despite individual differences between children, it is also true, and perhaps an obvious point, that children gain an increasing amount of knowledge and experience as they grow older. The management of T1D requires the frequent monitoring of blood glucose levels, carrying out daily insulin treatment, controlling carbohydrate intake and adjusting insulin dosages to match diet and activity patterns. For the youngest children (6–10 years) these tasks require support and assistance from family members[72] until they are able to manage them on their own.

The challenge for diabetes self-care is finding a balance between diabetes care requirements and a child's level of knowledge, experience and maturity.[73] What we see for all age groups across the texts that we analysed is that empowerment (medical, patient and identity in *Finding 1: what does 'empowerment' mean in contemporary child-centered health texts?*) is largely structured within predefined age boundaries that broadly draw on developmental psychology theories. As such, these texts tend to delimit possibilities of control and choice for the child reader, assuming certain levels of intellectual and practical competence that may or may not be appropriate to an individual child.

Use of colour

As in children's books, a range of often very bright colours feature prominently (*Table 8*), particularly in texts for younger children (6–10 years), to connote fun, excitement and engagement with a text and its narrative. The use of colour in children's diabetes texts across all of the age ranges constructs discursive cohesion between the different resources that are deployed.

TABLE 8 Analysis of colour and branding in children's diabetes information resources

Resource	Company brand	Images of participants	Written text
Diabetes Made Simple, Novo Nordisk	The very 'pure' blue of the Novo Nordisk logo	The blue clothes of the NovoCrew boys	The blue text of the title *Diabetes Made Simple*
Tadpole Times, Diabetes UK	The pink and purple of the Diabetes UK logo		
On the Level, Diabetes UK	The pink and purple of the Diabetes UK logo		
Tots to Teens, Diabetes UK	The pink and purple of the Diabetes UK logo		The pink or purple text of the subheadings
Growing up with Diabetes, BD Medical – Diabetes Care	The 'bright' blue and 'bright' orange of the BD Medical logo	The snorkel of the young boy	The orange text of the title *Growing up with Diabetes*
Living with Diabetes, BD Medical – Diabetes Care	The 'bright' blue and 'bright' orange of the BD Medical logo	The surf board of the young person	The orange text of the title *Living with Diabetes*
Caring for Those with Diabetes, BD Medical – Diabetes Care	The 'bright' blue and 'bright' orange of the BD Medical logo		The orange text of the title *Caring for Those with Diabetes*
Living with Diabetes: a Guide for Teenagers, Abbot Diabetes Care	The orange and black of the Abbot Diabetes Care logo		All text orange on a white background or white on an orange background

In the Novo Nordisk *Diabetes Made Simple* brochure, the colour blue is used in the logo (branding) and also for the clothes of the 'Novo Crew' boys (blue is also a stereotypical colour for a boy in the UK) and the text (matching with the blue colour in the logo). The colour blue then becomes associated with both the Novo Nordisk company and the messages that the booklet is providing to the reader.

Use of language

Clereham *et al.*[74] suggest that language can be used to construct a role relationship between patients and diabetes HCPs and that text may be written in an 'assertive, directive, conciliatory and/or collaborative way' (p. 337). Within patient discourse the language can be less personal (indirect), as seen in the use of terms such as 'people', 'children', 'nurses' or 'doctors', or more personal (direct), as in 'you', 'your child'. Within this patient discourse there is often a discursive shift as the mode of address changes from an indirect approach, with the aim of getting a message across whilst not engaging the individual directly, to needing to connect with the individual to get him or her to manage his or her medicine correctly (*Box 9*).

BOX 9 Examples of use of language

From:

> *the majority of people with Type 1 diabetes should consider monitoring their blood glucose levels*

to:

> *you'll want to test more often.*

A Parent/Carer Guide. Bringing up a Child with Diabetes, *Eli Lilly*

Within a number of texts the discourses that relate to insulin and blood glucose monitoring often shift between providing the medical information (medical discourse) that is required in a formal manner and more informal patient discourse as the activity is connecting back to the child and young person (*Box 10*).

The technicality of medical vocabulary used in the text refers to the degree of complexity of the medical terminology. Making assumptions about the level of understanding of the intended readers will influence the author's choice of vocabulary. The texts for parents of children newly diagnosed with T1D assume no previous knowledge, with all of the specific medical terms related to diabetes explained to the reader.

Characters as types

In younger children's texts (6–10 years), linguistic and visual resources are deployed to clearly delineate characters *as types*, especially when grouped into 'gangs'. In the groups represented in texts for young children there are never less than five members. These members represent discrete sexes, body types, subcultures, races, even degrees of confidence. The characters are apparently all of the same approximate age. Linguistically, each character's name is short, informal and easy for children to remember, for example the 'Novo Crew' are called Abbie, Sal, Maxx, Will and Jaz.

This delineation serves to *individuate* the child, who may be encouraged to self-identify with one or more of the characters, appropriately fitting with the notion that each child is different, having different condition-related needs.

In older children's and young people's texts (11–18 years), such as the *Streetwise* series (Eli Lilly), fictional characters are absent; it may be that the authors of these texts assume that fact rather than fiction best orients readers to the information. Instead, anonymous children and adults are depicted and the content of such images is of general relevance to the subject matter.

Use of images

Images are used to *expand* meaningfully on written language. The authors of the texts produced 'in house' attempt to engage the reader through the use of clip art images whereas those produced by the diabetes charities and pharmaceutical companies have the resources to use full colour photographs (*Box 11*).

Branding and legitimisation

Within certain texts the representation of information can be shaped by commercial interests. Pharmaceutical companies, as well as presenting useful information, use the opportunity to promote their products, which are prominently situated throughout the texts. There are often disproportionate amounts of information displayed about their products and proportionately less information about other issues (*Box 12*).

BOX 10 Examples of use of language

> *The glucose in your blood needs to be kept within healthy limits.*
>
> *Your blood levels can fluctuate throughout the day – don't worry it's pretty normal . . . you must monitor your blood glucose level regularly throughout the day.*
>
> Living with Diabetes, *BD Medical – Diabetes Care*

BOX 11 Examples of use of images

A photograph of a cereal bar to highlight:

> *Sometimes when I test my glucose levels they aren't what I expect . . . that's OK, I just use my insulin or a cereal bar to move my level back to where it should be.*
>
> Living with Diabetes. A Guide for Teenagers, *Abbot Diabetes Care*

A photograph of a teenage girl eating a bar of chocolate positioned in proximity to the text 'Common reasons for high blood glucose', followed by such reasons.

High Blood Glucose with Diabetes, Streetwise *collection, Eli Lilly (Figure 6)*

BOX 12 Examples of branding and legitimisation

Caring for Children with Diabetes/Living with Diabetes/Growing up with Diabetes, BD Medical – Diabetes Care

BD Medical manufacture insulin pen needles and lancets for finger prickers and the six middle pages in all of the booklets are the most prominent for linking with the company logo and brand identification.

A Parent/Carer Guide. Bringing up a Child with Diabetes, Eli Lilly

Eli Lilly manufactures insulin and within the booklet there are four full pages of text covering different aspects of insulin management (What is insulin? All about insulin types, Storage and handling of insulin). This section is the most technical within the booklet.

Living with Diabetes. A Guide for Teenagers, Abbot Diabetes Care

Abbot Diabetes Care is a manufacturer of blood glucose monitors and it is noticeable that there is not a section in the booklet on insulin injections or pumps.

Common reasons for high blood glucose:

If you can control your blood glucose, you will

FIGURE 6 *High Blood Glucose with Diabetes* (image reproduced with the kind permission of the Royal College of Nursing and Eli Lilly).

The representation of educational information by charitable bodies (Diabetes UK, JDRF) is also influenced by the wider charitable purposes of raising actual awareness of the charity and its supportive and fund-raising activities. The fund-raising activities that the young people have been involved in, or could get involved in, are presented throughout the magazines as real-life stories or through the letters pages. There is usually a link to their children's support holidays and weekends and the promotion of such activities grants legitimacy to the organisation, giving reasons for its continued existence.

These features of both pharmaceutical companies and charitable bodies make a discursive link between the child- and young person-friendly narrative and the company, drawing by association positive connotations for the company. They present themselves as being the child's or young person's friend, and thus this relationship builds into the brand's identity.

Typography

Throughout the booklets the use of capital letters, bold font, larger font size and change of colour are all strategies used to emphasise certain points within the text (*Box 13*).

Within *Growing up with Diabetes*, information for children is presented using larger text, with plenty of white space, whereas on the opposite page the size of the text is smaller. The authors are therefore assuming that an adult is going to read through the text. There is also a discursive assumption that the parent will be in a more powerful position vis-à-vis the child who has diabetes and that the child will want to know a bit but will leave the difficult stuff to the parent.

The authors of *Type 1 Diabetes – Information for Families* (Royal United Hospital Bath NHS Trust and Wiltshire Primary Care Trust) and the Salisbury Child & Adolescent Diabetes Clinic information folder (Salisbury NHS Foundation Trust), produced 'in house', change the colour of the font to red when they want to draw the reader's attention to information that they consider is really important, red signalling the need to stop and to pay special attention to what is being said.

Intertextuality

Intertextuality refers to the use of certain textual features from other, already-known texts. It is assumed that readers are familiar with those other texts and it thus creates a sense of connection, familiarity and knowingness in the audience. So, for example, we see texts drawing on narratives of adventure from children's fiction in which the children are drawn into the world of the protagonist. The use of language on the initial pages of texts for the younger child (6–10 years) forms part of this narrative (*Box 14*).

Intertextuality is also evident in information for older children (11–15 years) and young people (16–18 years), with the texts drawing from youth culture texts and their language and interests (e.g. activities such as skateboarding or surfing). The titles of a number of texts also link in with youth culture. For example, the title of one series of booklets is called *Streetwise* (Eli Lilly), the dictionary definition of which is 'having the shrewd resourcefulness needed to survive in an urban environment', thereby implying that young people with T1D can have the resources that they need to live with T1D.

BOX 13 Example of typography

The emphasis on the word MUST in capital letters when talking about injecting insulin as portrayed within *Growing up with Diabetes* (BD Medical – Diabetes Care):

> *Injecting insulin helps you manage diabetes.*
>
> *It doesn't cure it You MUST take insulin you'll be very ill if you don't.*

BOX 14 Examples of intertextuality

> *a first time guide for really cool adventurous kids, diabetes stuff . . .*
>
> *Ready for a little adventure? Then let's get going.*
>
> Growing up with Diabetes, *BD Medical – Diabetes Care*

There is also a link with social and cultural experiences that would appeal to young people, hence displaying intertextuality. In particular, the term 'street' is in juxtaposition with youth culture, rap music, hip hop music and gang culture. There is a discursive tension as well as connection between 'street' knowledge and 'medical' knowledge, between individual knowledge and expertise of one's condition and 'expert' knowledge and expertise.

Finding 3: how are children and/or their families discursively 'positioned', especially with regard to decision-making and medicines?

Appealing to children by representing medicines in a familiar context

In the diabetes texts there are a number of discursive strategies at work in the representations of practices with regard to insulin management and blood glucose monitoring to younger child readers (6–10 years). The first is recontextualisation, in which text producers use information presented in adult texts (broadly speaking) and reformulate it with a child reader in mind. These representations can be further understood in terms of substitutions, additions and deletions, with examples shown in *Box 15*.

In the texts for younger children (6–10 years) the authors make assumptions about the children's level of understanding and certain medical words are substituted with words that children would be familiar with to increase their level of understanding. In such instances the authors go further and add other words, describing the pen as 'special' or 'whizzy', which specifies a function (to inject) that is unusual in the context of writing tools. In that sense the adjective 'whizzy' describes an aspect of the pen's function, differentiating it from other pens or the child's concept of 'pen'.

The pen is represented as a functional near-equivalent to the 'magical agent' in folktales. In his study of 100 Russian folk tales, Vladimir Propp found that there was a regular set of characters (hero, helper, magical agent) and actions (p. 124).[61] The represented 'special' pen or 'whizzy' pen references the *stage* in

BOX 15 Representations of recontextualisation

Substitutions and additions: blood glucose monitoring:

- substitutions: 'sugar' for 'glucose' (*Growing up with Diabetes*, BD Medical – Diabetes Care)
- substitutions and additions: 'special paper' for 'test strip' (*Growing up with Diabetes*, BD Medical – Diabetes Care)
- additions: 'special diary' for 'diary' (*Growing up with Diabetes*, BD Medical – Diabetes Care).

Additions: insulin management:

- additions – 'special pen' for 'pen' (*Diabetes Made Simple*, Novo Nordisk, and *Tadpole Times*, Diabetes UK)
- additions – 'whizzy pen' for 'pen' (*Growing up with Diabetes*, BD Medical – Diabetes Care).

the folk tale genre at which the magical agent appears, and therefore suggests that provision of the 'special' or 'whizzy' pen is a similar stage in the 'story' of children's diabetes management, that is, use of the 'pen' is the only way to overcome diabetes (especially as an obstacle to socialisation). What are the effects of such recontextualisation? Most obviously, both the equipment itself and the practice of injecting are contextualised in a manner assumed to be *familiar* to children.

Deletions

A review of a range of patient information leaflets across a range of conditions found that leaflets tend to give an optimistic view of treatment, emphasising the benefits while downplaying the adverse effects, and to hide medical uncertainty.[67] We did not pick up on the importance of this until after we had analysed the process evaluation interviews with young people and their parents.

The Diabetes Control and Complications Trial (DCCT) demonstrated that lowering the blood glucose concentration slows or prevents the development of complications (e.g. nephropathy, neuropathy and retinopathy).[75] However, there was no reference to this in texts of diabetes information for younger children (6–10 years and 11–15 years). This information was included very simply though in texts for young people (16–18 years) and for parents, for example:

> *Good control of HbA_{1c} will reduce the risk of your child developing long term complications of diabetes.*
>
> A Parent/Carer Guide. Bringing up a Child with Diabetes, *Eli Lilly*

> *Keeping to these targets could significantly reduce your risk of developing diabetic complications*
>
> Living with Diabetes. A Guide for Teenagers, *Abbot Diabetes Care*

In one previous research study by Lochrie *et al.*,[76] diabetes HCPs reported giving more information to parents, older children and children with diabetes of longer duration than to younger or newly diagnosed children. This may be because diabetes HCPs believe that parents should decide when to impart these facts to their children, to avoid children's anxiety and distress, and that young people need to be aware of the risk of complications as they become more self-caring and autonomous in diabetes management. Variability in the practices and attitudes of diabetes HCPs with regard to how much information about diabetes complications should be given to parents and older children has also previously been reported[76] and is seen within the following texts:

> *If the blood glucose levels are outside the range over many years, it may affect your child's health, growth and development.*
>
> Type 1 Diabetes – Information for Families, *Royal United Hospital Bath NHS Trust and Wiltshire Primary Care Trust*

> *The higher the HbA_{1c} the more damage to the body. The damage can affect all blood vessels, especially the eyes, kidneys, heart and leg.*
>
> *Salisbury Child & Adolescent Diabetes Clinic information folder*

The journey towards diabetes self-care

The goal of diabetes education is that children, young people and their parents are empowered so that they can gain the skills and knowledge to be able to live with T1D on a daily basis.[77,78] Parental involvement is crucial and should gradually change from a participatory role to a supportive role.[79,80]

Responsibility

When a young child (6–10 years) is first diagnosed with T1D a large amount of support and assistance for daily management (blood glucose monitoring, insulin adjustments, treatment, etc.) is needed from family members,[72] the amount of support needed varying with the individual child. The texts for parents of newly diagnosed children with T1D assume that the child is very young when diagnosed and not capable of managing their own diabetes. The responsibility is constructed as 'naturally' being with the parent (primarily mothers) for testing blood glucose, record keeping and maintaining good control to prevent long-term complications. Instructions are given so that the parent conducts the activity for the child (*Box 16*).

Obviously, very young children who are cognitively and linguistically not able to understand anything about their condition and not physically capable of self-injecting must have adult assistance. However, fairly young children are often able to quickly learn what they need to do to manage their condition. That being the case, what are the ideological assumptions made about the relationships of power between the child and the adult when it is assumed that adults will be in charge? According to sociologist Phillip Scraton,[81] adults tend to exercise their power over children in the following ways:

> *children's experiences are reconstructed by adults who easily portray power as responsibility, control as care, and regulation as protection. Typically adults direct and children obey with age and status (parents, guardians, professionals) ensuring legitimacy.*
>
> *p. 163*

In other words, adults have created childhood as a life stage, one ruled and controlled by adults. In a sense, then, what we see, in discursive terms, is the exercise of one type of adult control (medical) over another (parental) 'in the interests of the child'. Thus, adult power itself is, in this instance, hierarchically

BOX 16 Examples of responsibility

You'll want to test more often.

A Parent/Carer Guide. Bringing up a Child with Diabetes, *Eli Lilly*

To know when and what help your child needs, you must monitor their blood glucose level regularly throughout the day.

Caring for Children with Diabetes, *BD Medical – Diabetes Care*

Record keeping is essential to managing your child's diabetes. This helps you understand if your child's treatment plan is keeping blood glucose levels well controlled.

A Parent/Carer Guide. Bringing up a Child with Diabetes, *Eli Lilly*

Record the reading from the meter and enter it to your child's diary.

Living with Diabetes, *BD Medical – Diabetes Care*

It doesn't matter which method you use; what is important is that you have a record of your child's blood glucose levels that both you and your paediatric diabetes team can use.

Tots to Teens, *Diabetes UK*

Good control of HbA_{1c} *will reduce the risk of your child developing long term complications of diabetes.*

A Parent/Carer Guide. Bringing up a Child with Diabetes, *Eli Lilly*

Getting the balance right means that the blood glucose levels are not too low and not too high and that your child feels well. If the blood glucose levels are outside the range over many years, it may affect your child's health, growth and development

Type 1 Diabetes – Information for Families, *Royal United Hospital Bath NHS Trust and Wiltshire Primary Care Trust* constructed, privileging one form of adult knowledge and expertise over another (medical vs. familial) through the texts, and both are privileged over child empowerment. It follows, then, that 'empowerment' is perhaps a more complex notion than is often assumed, as there is a need to take into account such hierarchical social relations.

Autonomy

Across the texts written specifically for children and young people there are different assumptions about who is in control. In the younger texts (6–10 years) there is a link from the child to the parent. In the texts for older children (11–15 years) greater autonomy is assumed, whereas younger texts (6–10 years) assume some autonomy but direct the younger child to other people:

> *Together, we'll find out how, and when, you need to inject insulin.*
>
> *Your doctor, nurse and your family will all help you out.*
>
> *Soon doing your injections will just be routine.*
>
> Growing up with Diabetes, *BD Medical – Diabetes Care*

The assumption is that the older child is more willing to learn. Information concerning what they need to do is presented in a factual manner: 'Something you can do and you can control' (*Living with Diabetes*, BD Medical – Diabetes Care).

In the texts for young people (16–18 years) parents have a lower profile than in the texts for younger children. There is more sense of the control being the young person's responsibility. The growing expertise of the child/parent in knowing his or her own/his or her child's diabetes is acknowledged:

> *You and your parents/carers are the best people to learn how to look out for you.*
>
> Growing up with Diabetes, *BD Medical – Diabetes Care*

> *You're the best person to learn how to care for yourself.*
>
> Living with Diabetes, *BD Medical – Diabetes Care*

> *You just need to take steps to keep your diabetes under control.*
>
> Living with Diabetes, *BD Medical – Diabetes Care*

Moving forward

In some leaflets the discourse assumes that parents are slowly enabling their child to take responsibility for their own care and undertake their own insulin injections (*Box 17*).

'You are not alone'

Diabetes HCPs can play an important role in this journey as a child or young person takes on more responsibility and moves towards self-care. Kelo *et al.*[73] suggests that nurses should 'adopt an empowering manner of education; recognize and assess a child's readiness to learn diabetes care and be responsible for it' (p. 2106). This is reflected throughout the texts as diabetes HCPs are portrayed as having an important role in this journey, particularly at the beginning (in the first few pages of the texts). Straight away, parents know that support is available to help them manage their child's condition. Working together is presented as including the doctor, nurse and family, for example:

> *We're in this together.*
>
> *Along with advice from your child's doctor or diabetes nurse, this booklet will help you.*
>
> Caring for Children with Diabetes, *BD Medical – Diabetes Care*

BOX 17 Examples of moving forward

> *There is no right age for your child to take responsibility for their injections. Some children prefer to do it themselves straight away; others may want to get used to having injections before doing it themselves. They need to make the decision in their own time. When they are ready, you can gently help them to take on the responsibility.*
>
> Tots to Teens, *Diabetes UK*

> *Giving or helping your child to give, an insulin injection will become a normal part of your daily routine. The first few injections may be difficult, but you will get used to them.*
>
> Type 1 Diabetes – Information for Families, *Royal United Hospital NHS Trust and Wiltshire Primary Care Trust*

> *Once they reach a certain age, children can usually inject themselves without difficulty.*
>
> *Their doctor or nurse will tell you if your child can inject themselves, if so, they'll be taught the correct procedure with you. Otherwise you will be doing the injections for them.*
>
> Caring for Children with Diabetes, *BD Medical – Diabetes Care*

Some texts describe this process as a journey that can be both challenging and gratifying:

> *You've already begun the process of managing your child's diabetes. While it may seem like an overwhelming amount to learn right now, in time you'll find it all becomes second nature. Watching your child grow and take on more responsibility for their own care will be challenging, but can be gratifying.*
>
> A Parent/Carer Guide. Bringing up a Child with Diabetes, *Eli Lilly*

At this point, diabetes HCPs are discursively positioned as the experts and others with the condition as a secondary source. Throughout the texts there is continual reinforcement of the information that is presented by directing the reader to the child's doctor or nurse (*Box 18*)

Transitions into adulthood

As well as to educate them about their condition and to empower them to self-manage, the role of information for children and young people with diabetes and their parents is to provide information to enable them to weigh up the risks and benefits of treatment. This information is reiterated by diabetes

BOX 18 Examples of reinforcement of information giving by diabetes HCPs

> *Their doctor or nurse will explain to you.*
>
> *Their nurse will discuss and review.*
>
> *Follow the advice of your child's doctor or nurse.*
>
> *Your child's nurse will talk you through.*
>
> *Your child's doctor or nurse will explain.*
>
> *Your child's nurse will show you both.*
>
> Caring for Children with Diabetes, *BD Medical – Diabetes Care*

HCPs at appropriate points along the 'journey' towards self-care using a variety of formats. We have already determined that information on the long-term consequences of diabetes is missing from many paper-based children's diabetes resources, and when it is present it is often 'downplayed'. However, when a young person makes the transition to adult care NICE current guidance[26] suggests that:

> *Young people with type 1 diabetes who are preparing for transition to adult services should be informed that some aspects of diabetes care will change at transition. The main changes relate to targets for short-term glycaemic control and screening for complications.*
>
> *p. 33*

This is reflected in adult diabetes health information in which much more information on long-term complications is provided (*Box 19*). The adult philosophy of diabetes self-care is geared more towards the 'expert patient'. Adults are seen in clinic less often and are mostly seen on their own and not with their families. As young people with T1D make the transition into adulthood the assumption is that they should now be able to be fully responsible for their diabetes self-care. However, it has been suggested that just because a young person has the capacity to act independently it does not mean that they may actually choose to do so.[82] It has been shown that young people retain close relationships with their parents in today's society,[83] with some studies suggesting that the need for parental support can actually increase in young adulthood.[84] A number of research studies specific to T1D have shown continued parental involvement to be important,[85,86] with the day-to-day responsibility for medication management being shared.[87] The point at which young people assume greater responsibility for their medication has been reported to most commonly occur in response to specific occasions or circumstances, such as moving to senior school or staying overnight with friends.[87]

Family-orientated paradigms

Within the texts we see a number of family-orientated paradigms at play that enhance our understanding of the relationships between the family of a child or young person with T1D and the diabetes HCPs who are involved in his or her care. The models being considered are the professionally centred, family-allied, family-focused and family-centred models proposed by Dunst *et al.*[88,89]

Professionally centred models

In the professionally centred model, professionals see themselves as experts on most matters concerning the child or young person with T1D and give little or no value to the views and opinions of the child or young person with T1D and their family. The balance of power is with the diabetes HCPs and texts are authoritative with the voice of the authority telling the reader the 'right thing'.[90]

In one particular text aimed at the child or young person with T1D and their family this expert model of help giving is very prominent (Salisbury Child & Adolescent Diabetes Clinic information folder). Within the text, when children are mentioned, it is in the third person. The discourse alternates between being more direct and less about medical control and being about what the reader actually needs to know. A paternalistic tone is maintained throughout the discourse. Families are seen as needing professional assistance and advice to acquire the skills necessary to manage their child's T1D. The institution and the diabetes HCPs involved in this document are saying that this is what you need to know and this is the manner in which you need to know it. The direction of power and control is with the diabetes HCPs as opposed to the person with the condition being enabled to manage his or her condition. The institution is the authority and the information being provided is presented as reliable medical knowledge. The institution has the power; in a sense it is saying that we know, you do not, but you can know more, within certain limits (*Box 20*).

Decisions about treatment choices in this model are made by diabetes HCPs, and children and young people and family members are informed only about what diabetes HCPs deem best and appropriate. In some instances a hierarchy of expertise is displayed, with certain members of the diabetes team having

BOX 19 Presentation of long-term complications in adult diabetes information

Complications, Eli Lily, 2010

> *The aim of treatment for diabetes is to keep blood glucose levels as near to normal as possible to prevent immediate and long-term problems (also known as complications).*
>
> *Stroke: the risk of stroke is increased.*
>
> *Heart disease: this is more common, though it is also linked to other factors and complications.*
>
> *Diabetic foot: foot problems can happen when diabetes affects the circulation and nerves to the feet – in the worst cases, amputation may be necessary. The risk is reduced with careful daily foot care.*
>
> *Eye damage: the retina, which is the layer at the back of the eye, can be damaged. This can lead to blindness. Make sure you have an eye examination or eye photograph once every year.*
>
> *Kidney problems: these happen if the blood vessels that supply the kidneys become damaged.*
>
> *Erection problems: these can affect some men with diabetes. Treatment can usually help.*

Testing, Testing. The Balance Guide to Blood Glucose Testing, Diabetes UK, 2011–12

> *Research has proved that good control of blood glucose levels and blood pressure greatly reduces the risk of developing the complications of diabetes.*
>
> *Evidence shows that good blood glucose control can reduce your risk of developing diabetic complications, such as neuropathy (nerve damage), retinopathy (eye disease), nephropathy (kidney disease) and cardiovascular disease (heart attack or stroke) . . . Regularly testing and responding to the results (your healthcare team will help you to know how to act on the results) helps you to keep good control and protect against these complications.*

What Do You Know about HbA$_{1c}$, Roche Diagnostics, 2004

> *People who manage their HbA$_{1c}$ low can delay or prevent some of the long-term health problems that diabetes can cause in the future.*
>
> *Foot problems e.g. ulcers*
>
> *Heart and circulation problems*
>
> *Eye problems*
>
> *Kidney problems*
>
> *Nerve damage*
>
> *Infection*
>
> *Impotence*

BOX 20 An institutional authority: example 1

In the section on blood glucose monitoring in the information folder from the Salisbury Child & Adolescent Diabetes Clinic, instead of referring to the child and/or the parent as needing to control blood glucose levels, the text reads 'We try to achieve blood glucose levels between 4 and 8 mmol/l'.

This could be read as the diabetes team and the family working together to achieve this, or that this is the goal of the unit that everyone needs to achieve. If this is not achieved in the long term then the potential long-term complications are referred to, shifting the responsibility back to the family.

certain types of knowledge. In these instances the child is being discursively positioned as a patient – as a receiver of medicine (*Box 21*).

Family-allied models

In the family-allied model, families are seen as 'agents of professionals' – they are expected to implement the decisions and courses of action that professionals prescribe.[88,89] Families are seen as minimally capable of independently effecting changes in their lives.

In some texts, what is meant by support is not team working but a power relationship being played out between the diabetes HCPs and the family. The diabetes HCPs are portrayed as the experts who have the information that the family need (*Box 22*).

This can be seen as the diabetes team making the decisions and telling family what it needs to do to achieve this. The diabetes HCPs are the team and the family is not seen as being a part of this but as working with the HCPs to achieve the team's goals.

BOX 21 An institutional authority: example 2

> *Your doctor will tell you what insulin is right for your child.*
>
> A Parent/Carer Guide. Bringing up a Child with Diabetes, *Eli Lilly*

BOX 22 Examples of diabetes HCPs as experts

> *Your diabetes team will work with you and your child to select the best blood glucose target range.*
>
> A Parent/Carer Guide. Bringing up a Child with Diabetes, *Eli Lilly*
>
> *You and the paediatric diabetes team will also have worked out which insulin is best for your child and when to inject.*
>
> Tots to Teens, *Diabetes UK*

Family-focused models

The focus of this model is families and professionals working together collaboratively.[88,89] Families are seen as capable of making choices that diabetes HCPs see as important for optimal glycaemic control. Diabetes HCPs provide advice and encouragement to families on the basis of their choices and decisions.

One text demonstrates this role of the paediatric diabetes team as working with the families in a collegiate/collaborative manner (*Box 23*). No one person within the diabetes team is portrayed as having the ultimate authority. The team includes a group of people who have knowledge and expertise and who want to share it with the families. It is about teamwork and a circuitous egalitarian approach. The language is constructed in a way that is all about enabling, encouraging, promoting and supporting the family of a child with diabetes.

It is a discourse of facilitation and seeks to empower families to manage their child's diabetes. It is not about the institution, but about the individual with T1D. In this leaflet the aim of the paediatric diabetes team to help you care for your child is presented along with a logo underneath that contains the word 'teamwork' written across a picture of three children holding hands. In this sense the child is invited to become part of the team and the role of the institution is downplayed. The team are still in a more powerful position as holders of medical knowledge and they want to share this with the child with diabetes to make the child's life easier. They are saying that we are open and available.

Family-centred models

Families are seen as fully capable of making informed choices and acting on their choices. Professionals view themselves as agents/partners of families and provide support in ways that seek to maximise the self-care behaviour of the child or young person. The balance of power in family–professional relationships shifts toward the family.[88,89] This paradigm is often represented on the last pages, or in some cases the back page, of the texts. It demonstrates that, as families become more confident in managing the condition, their need for information decreases. The expertise is now being positioned with parents/carers of children and young people with T1D (*Box 24*).

BOX 23 Examples of team working

> *We are all in this together.*
>
> *A lot we know but you also know your child.*
>
> *We realise that we expect you to learn a lot about diabetes quite quickly, but there will always be a member of the team to answer your questions and please don't be afraid to ask again and again.*
>
> Type 1 Diabetes – Information for Families, *Royal United Hospital NHS Trust and Wiltshire Primary Care Trust*

BOX 24 Examples of family as experts

> *Remember! You're not alone. One of the best ways of finding out more about diabetes is to talk to other parents/carers of children who have it. Your child's nurse will be able to help you get in touch with other parents/carers if you want to, especially if you don't know anyone with diabetes yourself.*
>
> Caring for Children with Diabetes, *BD Medical – Diabetes Care*
>
> *It is important to remember that you are not alone. You've got family, friends, and an entire team of healthcare providers supporting you.*
>
> A Parent/Carer Guide. Bringing up a Child with Diabetes, *Eli Lilly*

Implications of the critical discourse analysis for EPIC intervention development

As highlighted in *Chapter 1*, children's diabetes information is conceived as one component of a complex or series of complex interventions to enable children and young people to learn about their condition and make informed choices and decisions about their self-care and management. The implications of the CDA findings for EPIC intervention development are discussed in the following sections.

Selecting appropriate existing high-quality diabetes information

The CDA provided a clear steer that the type and format of text and images are important in terms of establishing and supporting children and young people's empowerment to self-manage their T1D:

- Diabetes texts have been constructed with the aim of empowering and motivating children and young people to manage their diabetes on a daily basis as they take the 'journey' of living with T1D through childhood and into adulthood.
- Understanding the 'empowerments' inherent in children's diabetes information, and how 'empowerment' is variously defined and represented, are essential to developing a robust intervention programme theory.
- Achievement of empowerment depends on how well the child or young person understands the information that he or she receives through the presentation of facts and advice. As such, the selection of appropriate medically informed discourses used to convey these facts is paramount.[91]
- If children and young people are to engage and subsequently be empowered and motivated to manage their T1D then their ability to understand the materials given to them will also depend to a large extent on the visual presentation of these texts.
- Age-appropriate as well as visually and verbally appealing resources are an important consideration for intervention development because they draw children and young people to them, thereby encouraging their use in the development of T1D self-management.
- Use of colour, language and typography appear key because these are features of a text that interpolate or call to the reader to engage with age-appropriate diabetes leaflets, books and other texts. Bright, primary colours are often associated with children's story books and connote excitement, fun and something of interest to young children. Language that is easily understood by specific age groups of children also facilitates interest and engagement. Likewise, typography is important as large, varied fonts are more easily engaged with by young readers, whereas older children typically seek text that connects to their interests and exposure to other texts which may use stylised fonts, for example.
- Combining texts and pictures enhances understanding, particularly for young children. Visual representations support understanding of written text with younger age groups. With older children this combination draws the reader in through a connection with representations of young people of a similar age, encouraging them to read the written text.
- Images on the front covers of the diabetes texts for children were not necessarily related to diabetes but drew on texts already familiar to children and young people ('intertextuality'), as they connect the children and young people to familiar images appropriate to their age group – cartoons for younger children (6–10 years) and photographic images for young people (16–18 years), with a combination of both for older children (11–15 years).
- It is important to understand the importance of reconstitutions and substitutions and additions/deletions as they are sometimes used to make, for example, insulin injections seem less frightening and more familiar (the use of the term 'special' or 'whizzy' before the word 'pen', for example).
- Use of the authoritarian voice mirrors the approach to management of diabetes professionals. Across the texts that we examined this mode of address is typically associated with more traditional forms of top-down communication from medical professionals who are discursively positioned as diabetes 'experts' in relation to their 'patients'. Knowledge flows from those who have 'expertise' to those who do not but who have T1D. Such discourses are very different from those in which expertise is more diffused across medical practitioners (including doctors and diabetes nurses), children with T1D and their families.

- Finally, quality assurance of children's diabetes information is essential and branding and legitimisation for use in the NHS is important. We found that various drug companies discursively linked their products to organisations such as the NHS, as well as to diabetes charities such as Diabetes UK, to help establish their brands as having been endorsed by such organisations. By association, then, their brands garnered esteem and legitimacy.

Evidence to inform development of the EPIC intervention programme theory

- Identity empowerment of diabetes as 'normal', whether a cartoon image of an animal or a person, a pencil drawing or a photograph, is used to connect to the intended audience. These images are in the forefront of the majority of texts, which strongly portray identify empowerment.
- Children and young people with T1D are represented as wanting to be seen as 'normal'. Not wanting to be different from their peers was also a finding highlighted across all of the interviews conducted for the EPIC study (see *Chapters 4* and *7*); this point is backed up by other empirical research[92–96] and is a major factor that influences self-care abilities at school as reported in the systematic review (see *Chapter 3*).
- Insulin is represented throughout the texts as a social enabler – 'normalcy' is presented as being achievable if a strict diabetes self-management regimen is adhered to. Empowerment to be normal is the dominant discourse in children's diabetes information.
- Real-life stories are shared of children and young people in everyday situations, and in some instances empowerment is represented via the form of the child with T1D as 'special', which is sometimes accompanied by a degree of overcompensation through the representation of extraordinary activities and accomplishments of some children and young people with diabetes (mountain climbing, extreme sports, etc.).
- Some resources reflect that empowerment is also about being the 'same but different' as there are extra responsibilities that go hand in hand with diabetes self-management. As such, normalcy is discursively delimited, albeit not ultimately undermined, by such responsibilities.
- The importance of children's age and developmentally 'appropriate' journey towards adult diabetes care: child working with parent with responsibility shifting to the child as he or she feels able to be more autonomous – assumptions of control, moving forward, you are not alone, transitions into adulthood.
- Family-orientated paradigms locate children and young people primarily within the family (particularly preteen children); it is in the social context of the family that age-appropriate diabetes management is seen to be best undertaken.
- The need for active promotion and facilitation of children's diabetes resources by diabetes professionals in routine care.
- Diabetes risks and diabetes-related complications are presented differently in children's and adult diabetes information resources. In children's information resources risks do not feature prominently whereas in adult information they are highly prominent. It seems reasonable to presume that outlining risks, especially for young children with diabetes, is not regarded as desirable in terms of the type of information that they need to have to manage their condition. The absence or marginalisation of risk discourses is founded on prevailing Western conceptions of the child and his or her vulnerability and thus need for protection from difficult facts, situations and knowledge. How this might impact on children's and young people's conceptions of their condition and empowerment to self-manage is worthy of further exploration in future research.

The next chapter reports the systematic review.

Chapter 3 Systematic review to determine the barriers to and facilitators of optimal diabetes self-care and management within educational settings for children and young people with type 1 diabetes

Introduction

In this chapter we report a mixed-method systematic review that focused on self-care and management of diabetes within educational settings. The review builds on the diabetes stream of the scoping review of the empirical literature conducted and reported as part of the IMP.[1]

An important element of the original funder brief was to, when possible, include children and young people who had experience of living away from their families. As reported in *Chapter 4* on the intervention development, we were unable to achieve this ideal. A pragmatic decision was therefore made in collaboration with our funder project manager to focus the review on diabetes self-care and management within educational settings as an example of a context in which children have to manage their diabetes away from their families.

We first briefly report a review of reviews, which confirmed that there is a gap in the evidence and provided a clear rationale for focusing on educational settings. The review methods, processes and findings are then reported and the chapter closes by drawing out evidence to inform the development of the EPIC intervention.

Brief review of reviews

We searched Scopus and MEDLINE for existing systematic reviews conducted over the last 10 years on the broad topic of children with T1D. The preliminary keywords that were searched are displayed in *Box 25*. This exercise identified 26 reviews.[3,7,73,97–119] The aim and focus of the reviews were contrasted in a summary table (see *Appendix 3*, *Summary table of reviews of children and young people with type 1 diabetes*). Published reviews covered a wide range of topics but there was little evidence on optimal diabetes self-management in educational establishments. Two recent reviews[98,99] found that the majority of research into managing diabetes in school investigated a broad range of issues including school attendance, peer relations, classroom behaviour and psychosocial status, cognitive functioning and classroom attention, levels of school achievement, teachers' awareness of diabetes, on-campus nurses as resources and the educational/legal rights of students. The quality of the studies and the research methodology were not assessed and both of the reviews were narrative in nature. The review by Tolbert[98] used a very limited keyword search.

Given that managing self-care away from home and parents was a key issue that we had not been able to address in fieldwork, we set out to conduct a systematic review focusing on self-care and management of T1D in children and young people within educational settings.

BOX 25 Preliminary keywords

Diabetes mellitus type 1

Diabetes.
Diabetic.
DM and type 1/I/one.
Childhood diabetes.

Children/young people

Child/children.
Preschool.
Adolescent.
Student.
Young people.
Young person.
Paediatric.
Pediatric.

Educational establishments

School.
Nurseries.
Institute.
College.
Polytechnic.
University.
Higher/further/tertiary education.

School as a context for self-care and management of diabetes

Children and young people with T1D who are enrolled at educational establishments spend a long time away from their families on a daily basis. It is important that systems are in place so that children and young people feel comfortable in these settings to confidently manage their diabetes. To optimise the child's diabetes management, school personnel must be knowledgeable about diabetes self-care issues and provide an environment that promotes optimal diabetes management. As a principle of equality, the pupil with diabetes should be able to participate fully in all school activities while performing blood glucose testing, eating appropriately and administering insulin as needed.

In the following sections we highlight key aspects of best practice from the UK and Europe and the USA as a general practice framework to contextualise and analyse findings. There was insufficient time and resources to describe additional country contexts, and most of the evidence mapped onto best practice indicators originates from the UK, Europe or the USA. There was also considerable overlap from the limited number of best practice guidelines obtained and so we have assumed that there are likely to be some core similarities in a global developed country context.

Policy and best practice context in the UK and Europe

In the UK the DH[120] recommends that all children should be supported to manage their diabetes according to their individual health-care plan and that school and early years settings should be encouraged to offer effective levels of support so that parents do not have to attend school to administer medication. In the UK the use of individual health-care plans in educational settings is recommended to ensure that school staff are sufficiently informed about a pupil's medical needs and, in relation to T1D, they should describe all parties' responsibilities regarding diabetes supplies and provisions.[121] Common elements that current guidelines and policy documents[27,33,56,120–125] recommend for the management of children and young people with T1D in school are shown in *Box 26*.

BOX 26 Best practice guidelines on the management of children and young people with T1D in UK and US schools

UK guidelines

1. Individualised health plan.
2. Support for blood glucose monitoring and guidance on the interpretation of blood glucose results and any subsequent action.
3. Provision of hand-washing facilities and a clean environment.
4. Support of administration of insulin including treatment changes and a suitable location to carry it out.
5. Appropriate storage of insulin and blood glucose testing kit; administration of insulin training, with written parental agreement; and risk of needle stick injury, including the correct procedures to follow and safe storage of sharps bins.
6. Training of school staff about the recognition and management of hypoglycaemia.
7. Treatment of hypoglycaemia and illness management.
8. Awareness by school staff of the signs of hyperglycaemia.
9. The provision of emergency supply boxes.
10. Participation in physical activity programmes, including potential off-site activities, such as playing sport at other schools.
11. Staff in charge of physical education or other physical activity sessions should be aware of the need for children and young people with T1D to have glucose tablets or a sugary drink to hand.
12. Participation in extracurricular and social activities.
13. Food and dietary management – availability of snacks and suitable lunchtime arrangements that may include the facilitation of carbohydrate counting.
14. Training and signposting for school staff, including frequency of training for staff, guidance and useful contacts and local diabetes management guidelines.

US guidelines

1. Individualised health plan.
2. Where and when blood glucose monitoring and treatment will take place.
3. Identity of trained diabetes personnel – the staff members who are trained to perform diabetes care tasks such as monitoring blood glucose, administering insulin and glucagon and treating hypoglycaemia and hyperglycaemia.
4. Location of the student's diabetes management supplies.
5. Need for free access to the restroom and water.
6. Nutritional needs, including provisions for meals and snacks.
7. Full participation in all school-sponsored activities and field trips, with coverage provided by trained diabetes personnel.
8. Alternative times and arrangements for academic exams if the student is experiencing hypoglycaemia or hyperglycaemia.
9. Permission for absences without penalty for health-care appointments and prolonged illness.
10. Maintenance of confidentiality and the student's right to privacy.

In the UK there is no legal duty requiring school staff to administer insulin to children and young people with T1D. However, in an emergency situation or under certain circumstances school staff might be expected to administer insulin or take other appropriate action. This is seen as a voluntary role, but school staff who are responsible for children and young people with T1D on a daily basis have a responsibility to ensure that children and young people remain safe and healthy while on school premises.[126]

A DH working group examined the current challenges surrounding children and young people with diabetes, producing the report *Making Every Young Person with Diabetes Matter*.[120] The need for effective, integrated and accessible services for children and young people and their families was set out in this document.

Policy and best practice context in the USA

In the US, federal law requires schools to have a trained nurse available to manage children with T1D, and the most recent guidelines for diabetes management state that at least one adult should be available for all diabetes management needs if a school nurse is unavailable.[127]

In the US a number of key publications set out the components of diabetes care at school.[128,129] The American Diabetes Association[128] has produced a position statement to 'provide recommendations for the management of children with diabetes in the school and day care setting' (p. S76) and the National Diabetes Education Program publication *Helping the Student with Diabetes Succeed. A Guide for School Personnel*[129] is designed 'to educate school personnel about effective diabetes management and to share a set of practices that enable schools to ensure a safe learning environment for pupils with diabetes' (p. 1).

The recommendations within these documents are not necessarily required by the federal laws enforced by the US Department of Education for each student with diabetes. State and local requirements in the USA vary from state to state and from school district to school district. But it is recommended that they be used in conjunction with federal as well as state and local laws.

In the USA a Diabetes Medical Management Plan (DMMP) outlines how each student's diabetes will be managed. The DMMP should be used as the basis for the development of an Individualized Health Care Plan (IHP) and Emergency Care Plans for Hypoglycemia and Hyperglycemia within a school setting. Common elements that the plans are likely to address are shown in *Box 26*.

Review aim

The review aims were to determine the barriers to and facilitators of providing optimal care and management for children and young people with T1D within educational settings.

Objectives

1. To undertake a review of the effectiveness of interventions that are conducted within an educational setting that seek to improve the care and management of children and young people with T1D (stream 1).
2. To explore the experiences of children and young people with T1D and those involved with their care and management in an educational setting (stream 2).
3. To conduct an overarching synthesis of the first and second objectives to determine the extent to which interventions address the barriers identified by children, parents and teachers and build on the facilitators for providing optimal care and management of children and young people with T1D in educational settings (stream 3).

Review design

The design was informed by methods developed by the Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre).[130,131] This 'mixed-methods' triangulation approach combines data from effectiveness studies (trial data) with data from studies that obtain the views of participants (includes both surveys and qualitative studies). The synthesis from both streams is then combined using a matrix to juxtapose the findings and uses both a priori codes and themes emerging from the syntheses to group and summarise the findings.

Figure 7 provides the framework for combining different study types following the EPPI-Centre approach.[130,131]

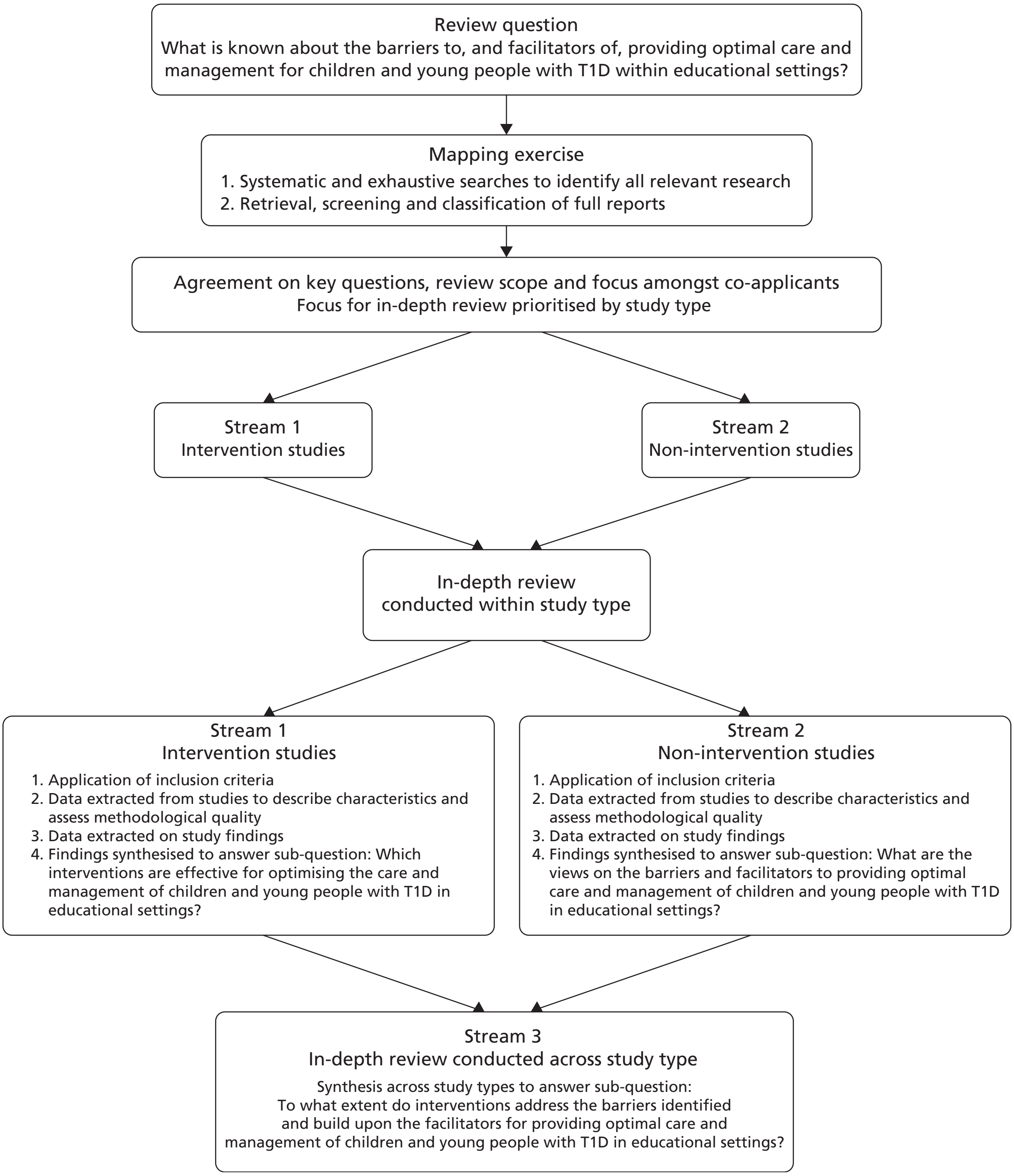


FIGURE 7 Mixed-methods review design.

Review methods

Inclusion criteria

A modified version of the SPICE framework[132] was used to inform the systematic review. For stream 1 this was Setting, Population, Intervention, Comparison and Evaluation (*Table 9*) and for stream 2 this was Setting, Perspective/People, Issues of interest, Context and Evaluation (*Table 10*).

For stream 1 (intervention studies) any RCTs were considered. In the absence of RCTs other research designs, such as non-RCTs, clinical trials, cohort studies, experimental and non-experimental studies, observational studies, descriptive studies and before-and-after studies, were considered for inclusion.

For stream 2 (non-intervention studies) all studies reporting the views of participants (includes both surveys and qualitative studies) were considered.

Types of participants

Studies were included if they focused on children and young people with T1D within an educational setting and included those aged 3–18 years in preschool or formal education and those aged 18–25 years in post-compulsory education. A search was conducted to determine the age range of young people with diabetes who were participants within studies conducted in post-compulsory educational settings to inform the inclusion criteria of this review. The minimum age for these studies was 18 years and the maximum age reported was 24 years.[133–138] In addition, studies including or focusing on parents, school personnel and school health professionals that related to this age group were included.

Exclusion criteria

Studies were excluded if there were no before-and-after measures (stream 1); they did not directly obtain the views of children and young people, parents, peers or professionals (stream 2); the children and young people were aged < 3 years or > 30 years (streams 1 and 2) or they were not in the English language (streams 1 and 2).

TABLE 9 SPICE framework for stream 1 (intervention studies)

Setting	Population	Intervention	Comparison	Evaluation
Educational setting in any country	Children/young people with T1D 3–18 years of age preschool or formal education; 18–30 years of age in higher education	All interventions to promote optimal management of diabetes in school settings Secondary issues to include programme theory and service delivery	Any comparison of interest including intervention compared with usual care	Any of interest, e.g. blood glucose monitoring, HbA_{1c}, hypoglycaemia, dietary behaviour, insulin management, quality of life

TABLE 10 SPICE framework for stream 2 (non-intervention studies)

Setting	Perspective/people	Issues of interest	Context	Evaluation
Educational setting in any country	Children/young people with T1D 3–18 years of age preschool or formal education; 18–30 years of age in higher education	All research studies that explore experiences/ perspectives Barriers and facilitators	Compare children with parents/ professionals	Any of interest, e.g. blood glucose monitoring, hypoglycaemia, dietary behaviour, insulin management

Study selection

An initial scoping search was conducted in MEDLINE and Scopus using keywords drawn from the natural language of the topic. The preliminary keywords that were searched are displayed in *Box 25*.

The databases searched for relevant studies over the last 15 years (1996–2011) were:

- Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- MEDLINE
- Scopus
- British Nursing Index
- The Cochrane Library
- EMBASE
- PsycINFO
- Web of Science.

The final search strategy is summarised within the modified SPICE table (see *Appendix 3*, *Search terms presented within the SPICE framework*).

The search terms included medical subject heading and 'free-text' terms in combination and was adapted according to the particular database (for a sample of the searches see *Appendix 3*).

All studies identified were assessed for relevance to the review based on the information provided in the title and, when available, the abstract. For studies that appeared to meet the inclusion criteria, or in cases in which a definite decision could not be made based on the title and/or abstract alone, the full paper was obtained for detailed assessment by two researchers against the inclusion criteria. A screening tool to aid this process was used (see *Appendix 3*, *EPIC screening tool*). Any disagreement was resolved by referring back to the protocol and, when necessary, by consultation with a third independent reviewer.

In addition, reference lists of retrieved papers and published reviews were searched for potentially relevant papers. References were managed using EndNote version X1 (Thomson Reuters, CA, USA). Restrictions were not applied in terms of research design or methods, as a single search was used for both stages of the review. Unpublished data were not sought from authors.

A flow chart showing the number of studies/papers at each stage of the selection process is provided in *Figure 8*. In total, 71 papers (describing 66 studies) were included in the review.

Quality assessment

The decision was made to include all studies unless they were fatally flawed and a discussion with regard to quality assessment would be reported for each stream.

For stream 1 (intervention studies), randomised intervention studies were assessed on the following quality elements:[139]

- adequacy of randomisation
- concealment of allocation
- blinding of outcome assessors/data analysts
- use of power calculations
- comparability of groups at baseline
- level of detail provided about the intervention
- intention-to-treat (ITT) analysis
- use of validated outcome measures
- length of follow-up
- identification of confounding factors.

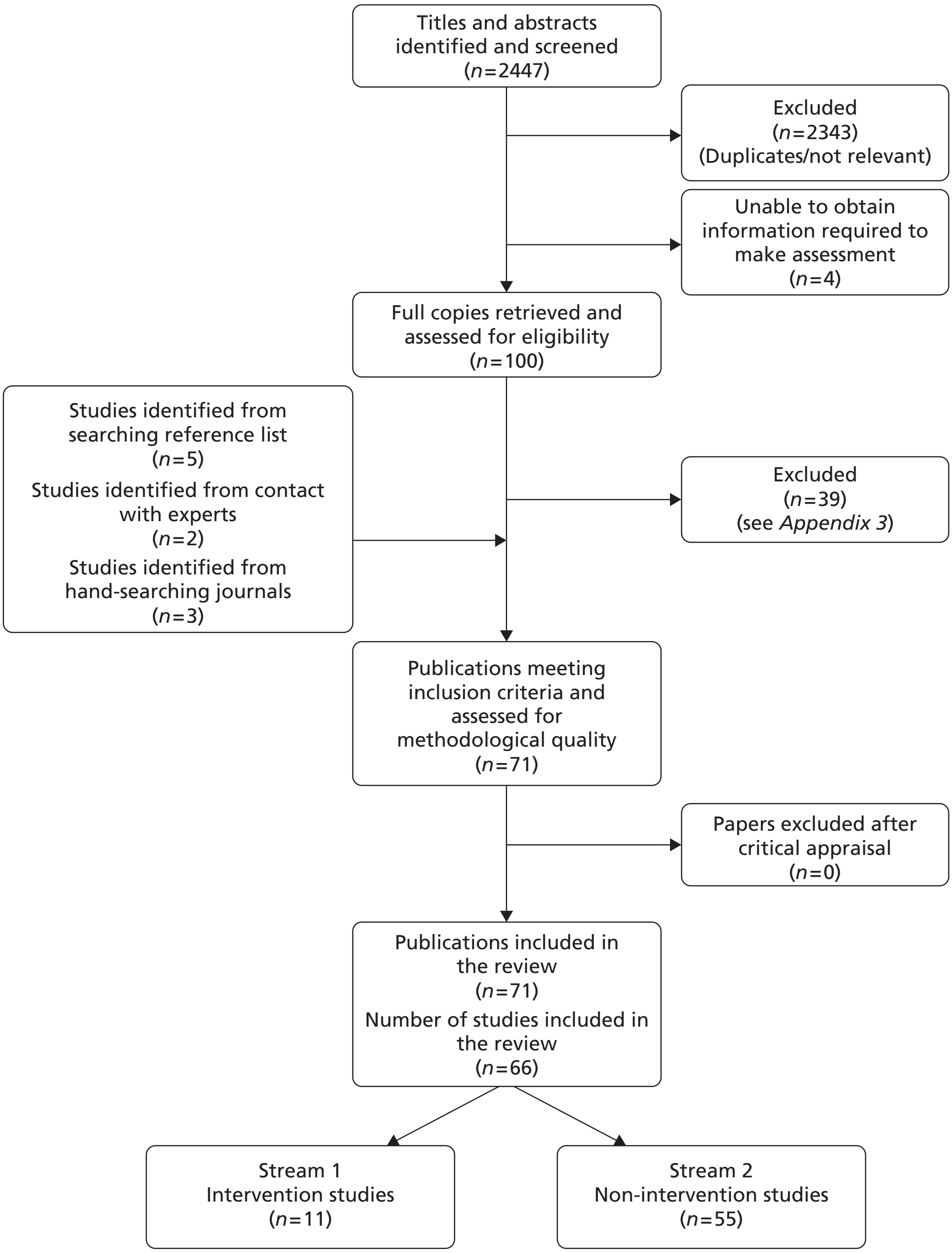


FIGURE 8 Flow chart of the study selection process.

Key aspects of quality for non-randomised intervention studies in stream 1 were based on the work of Deek *et al.*[140] and are summarised below (see p. 39 of the Centre for Reviews and Dissemination, University of York, guidance on undertaking reviews in health care[141]):

- how the treatment groups were created (how allocation occurred and whether the study was designed to generate groups that are comparable on key prognostic factors, e.g. by 'matching' participants in each group)
- the comparability of intervention and comparison groups at the analysis stage, for example whether prognostic factors were identified and whether case mix adjustment was used to account for any between-group differences

- blinding of participants and investigators
- the level of confidence that the participants received the intervention to which they were assigned and experienced the reported outcome as a result of that intervention and the adequacy of the follow-up
- the appropriateness of the analysis.

For studies in stream 2 (non-intervention studies) that used a survey design we used the checklist designed by Rees *et al.*[142] and for qualitative studies we used the appropriate checklists available from the Critical Appraisal Skills Programme.[143] These were then incorporated with the following quality criteria that were adapted from Kirk *et al.*[139] to provide a summary of quality assessment:

- clear statement of the aims of the study
- adequate description of the context for the study
- clear specification of the research design and its appropriateness for the research aims
- clear reporting of details of the sample and method of recruitment/sampling
- clear description of data collection
- clear description of the data analysis
- attempts made to establish rigour of the data analysis
- discussion of ethical issues/approval details
- inclusion of sufficient original data to support interpretations and conclusions.

Data extraction

For stream 1 data were extracted directly into electronic tables and followed the format recommended by the Centre for Reviews and Dissemination[141] as outlined in *Box 27*.

For both streams one researcher extracted the data and a second researcher independently checked the data extraction forms for accuracy and completeness.[141] Any disagreements were noted and resolved by consensus among the researchers. A record of corrections was kept.

Data synthesis

To answer the study objectives three types of syntheses were performed. First, for stream 1 (intervention studies) meta-analysis was inappropriate for the review because of the heterogeneous nature of the studies in relation to populations, interventions and outcomes. Instead, the results from the studies are summarised and reported in a narrative summary within and across studies. Second, the process for stream 2 was a narrative analysis and synthesis using Ritchie and Spencer's[144] thematic framework analysis approach of non-intervention studies. An index ladder of codes aligned with issues of interest from the review questions and objectives was developed, refined and adapted for the different streams. Third, a final overarching synthesis of intervention and non-intervention studies was conducted. For this final synthesis a matrix was constructed that mapped the barriers and facilitators identified by children and young people, parents, school personnel and school health professionals alongside descriptions of the interventions and outcomes included in stream 1.

Results: intervention studies – stream 1

The purpose of stream 1 was to undertake a review of the effectiveness of interventions conducted within an educational setting that sought to improve the diabetes care and management of children and young people with T1D. The key features of the 11 included studies[145–155] are summarised in *Table 11*.

BOX 27 Details of the data extraction

Identification features of the study:

- author
- citation
- country of origin.

Study characteristics:

- aims/objectives of the study
- study design
- study inclusion and exclusion criteria
- recruitment process (e.g. details of randomisation, blinding)
- unit of allocation (e.g. participant, school).

Participants characteristics (at the beginning of the study):

- age
- sex
- ethnicity
- socioeconomic status
- disease characteristics
- education setting characteristics
- number of participants in each characteristic category for intervention and control group(s).

Intervention and setting:

- setting in which the intervention is delivered
- description of the intervention and control groups
- how the intervention was developed and theoretical basis (when relevant).

Outcome data:

- unit of assessment/analysis
- statistical techniques used
- measurement tool or method used.

Results:

- results of study analysis, e.g. dichotomous: odds ratios, risk ratios and confidence intervals, *p*-values; continuous: mean differences, confidence intervals.

TABLE 11 Study characteristics of the intervention studies (stream 1)

Study, country, design and aims	Participants and providers	Intervention
Izquierdo *et al.* 2009,[146] USA RCT, two arms To test the feasibility and effectiveness of telemedicine to improve care of children with T1D in schools	25 schools randomised 41 pupils: I = 23, C – UC = 18 School nurse, PDSN	A school telemedicine system (with a centrally managed internet-based portal to facilitate communication between the school and the diabetes centre) in addition to usual care Usual care was visits to the diabetes centre every 3 months and communication with the school nurse and parents as needed by telephone The intervention involved the ability to exchange graphical and tabular blood glucose measurement information with the PDSN; prescheduled regular monthly meetings (10–20 minutes) between the school nurse and pupil, with or without a parent; the availability of an 18-module educational curriculum for school nurses and other school personnel
Engelke *et al.* 2008,[148] USA Before-and-after study To implement and evaluate a school-based case management programme for children with chronic illnesses	36 pupils School nurse	School-based case management programme Development of an IHP and emergency action plan with specific goal setting as appropriate for each pupil Individual goals and intervention set for each child Training was provided to all school nurses, which reviewed the principles of case management and procedures for enrolment
Nguyen *et al.* 2008,[145] USA RCT, two arms To determine if school nurse supervision of blood glucose monitoring and insulin dose adjustment would lead to improvements in HbA_{1c} levels in paediatric patients with poorly controlled T1D	36 pupils: I = 18, C = 18 School nurse, parents	Supervision of insulin administration as a strategy to improve glycaemic control Insulin glargine injections and periodic appropriate insulin dose adjustment Blood glucose check and insulin injections at lunch under the direct supervision of (a) the school nurse during school days and (b) parents or their adult designees at the weekends and during school holidays The control group were instructed to continue with their usual diabetes care and insulin regime
Faro *et al.* 2005,[150] USA Before-and-after study	27 pupils PNP	PNP-directed school-based intervention Monthly visits lasting 20–30 minutes

continued

TABLE 11 Study characteristics of the intervention studies (stream 1) (*continued*)

Study, country, design and aims	Participants and providers	Intervention
To conduct periodic diabetes care visits in school with the goal of promoting optimal management of diabetes for high-risk youth		Activities included a review of school blood glucose readings and developmentally appropriate teaching focused on increasing the students' understanding of diabetes management and improving diabetes-related problem-solving skills and coping. As part of the intervention pupils and school nurses were provided with school menus that included carbohydrate servings for all food items listed so that they could easily ensure that students' individualised meal plans were followed in school
Wdowik *et al.* 2000,[155] USA Controlled trial To develop and evaluate *Control on Campus* for college students with T1D	31 students: I = 21, C = 10 RD/CDE	*Control on Campus* is a 92-page comprehensive guide that provides up-to-date information on diabetes management; it was delivered over three sessions lasting for 2 hours over three consecutive weeks Attendance at one individual session with the group facilitator
Husband *et al.* 2001,[147] Canada RCT, two arms To determine whether a CD-ROM teaching tool increases teachers' diabetes knowledge and confidence	44 elementary teachers: I = 22, C = 22 Diabetes researchers	A CD-ROM teaching tool entitled *Type 1 Diabetes in Children: A Passport to Knowledge* Available commercially for parents of children with T1D with information presented in a question-and-answer format using full-motion video, cartoon sequences, audio and text Included is a section for teachers that contains basic information on diabetes pathophysiology and treatment of T1D Asked to view 'The student with diabetes' section on the CD-ROM over a 2-week period
Siminerio and Koerbel 2000,[149] USA Before-and-after study To assess diabetes knowledge and needs of school personnel and to determine the effectiveness of the '5 Cs of Diabetes' programme	156 school personnel Diabetes educators	The '5 Cs of Diabetes' programme highlighted new information in the areas of cause, classification, complications (acute and chronic), care and cure The programme was presented in a lecture format that lasted for 60–90 minutes It was delivered by two CDEs from the Children's Hospital of Pittsburgh
Cunningham and Wodrich 2006,[152] USA Analogue experiment (allocated)	90 regular and SE elementary teachers (four schools) Researchers	Teachers were provided with varying levels of information about T1D with each participant receiving only one T1D information level, creating a between-subjects design

TABLE 11 Study characteristics of the intervention studies (stream 1) (*continued*)

Study, country, design and aims	Participants and providers	Intervention
To examine the effect of providing teachers with varying levels of information about T1D		Level one (no disease information) provided teachers with one page of information on general education unrelated to T1D. The content of this page focused on current issues in education, including the challenges of providing all children with equal access to education and educating atypical students. T1D was not mentioned in this literature Level two (basic disease information) provided a one-page description of T1D and its psychological implications Level three (basic disease information, classroom implications) provided a one-page description of T1D and its psychological implications and examples of well-targeted classroom accommodations for children with T1D
Wodrich 2005,[151] USA Analogue experiment (random assignment) To investigate the effects of disclosing information about T1D and the implications for classroom learning and behaviour	122 CE and PS teachers from one university Researchers	Each participant learned facts from two sources about one hypothetical elementary student who had T1D The first information source was a cumulative folder that summarised information about the student's family (e.g. family size and parents' vocations), health (differed across the three health information levels) (see Cunningham and Wodrich[152]), educational background, educational records (e.g. attendance records, report card grades) and educational environment (e.g. class size, curriculum material used) The second source of information was a video of a teacher and a school psychologist discussing the student Teachers were randomly assigned to one of three levels of health information (no knowledge, diagnosis only, diagnosis and facts) and provided with a list of sources to which the problematic classroom performance may be attributed
Bullock *et al.* 2002,[153] USA Cohort study To determine whether attendance at specific continuing education programmes increased the competence of school nurses who enrolled on and completed the programmes	537 school nurses: I = 120, C = 417 Researchers from MDHSS/MUSSON	Intervention: those attending the continuing education programme on diabetes management. No further details provided Control: those not attending the continuing education programme on diabetes management

continued

TABLE 11 Study characteristics of the intervention studies (stream 1) (*continued*)

Study, country, design and aims	Participants and providers	Intervention
Bachman and Hsueh 2008,[154] USA Programme evaluation To develop and evaluate an online continuing education programme to educate school nurses in how to manage care for children with diabetes in schools using current practice principles outlined in *Helping the Student with Diabetes Succeed: A Guide for School Personnel*[129]	15 school nurses	Online continuing education programme that consisted of three lessons. Lesson 1 was an overview of diabetes in children and an update on diabetes management in the school setting. Lesson 2 covered managing students with insulin pumps. Lesson 3 discussed the role of the school nurse in managing children with diabetes Course participants used the revised *Helping the Student with Diabetes Succeed: A Guide for School Personnel*, which includes (a) first steps in developing a diabetes programme in the school; (b) an overview of diabetes; (c) nutrition guidelines for diabetes; (d) exercise and exercise safety tips in diabetes; (e) insulin, insulin therapy, insulin pumps and troubleshooting insulin pumps; (f) monitoring blood glucose levels; (g) emergency action plans and sample tools needed to implement emergency action plans; (h) health management (eye, oral, foot, immunisations); (i) references with links to local and national resources; (j) a survey to elicit feedback about the manual; and (k) forms and handouts that can be adapted easily by the school nurse, printed out and distributed as appropriate

C, control; CDE, certified diabetes educator; CE, continuing education; I, intervention; MDHSS, Missouri Department of Health and Senior Services; MUSSON, University of Missouri-Columbia Sinclair School of Nursing; PNP, paediatric nurse practitioner; PS, preservice; RD, registered dietician; SE, special education; UC, usual care.

Design

Only three[145–147] of the 11 studies were RCTs, one[155] was a controlled trial, three[148–150] were before-and-after studies, two[151,152] were analogue experiments, one[153] was a cohort study and one[154] was a programme evaluation. Sample sizes were small and ranged from 20–156 participants with the exception of the cohort study[153] in which the number of nurses attending the continuing education program was 417. Follow-up periods ranged from 3 months to 1 year. Studies were all published after the year 2000.

Settings

The majority of the studies ($n = 10$) were conducted in the USA, with one study conducted in Canada.[147]

Participants

Four studies involved children and young people, which included children from kindergarten to sixth grade[150] and kindergarten to eighth grade,[146] those aged 5–19 years[148] and those aged 10–17 years.[145] Of these, one study[148] focused on children with T1D who were struggling academically or who were having difficulty managing their illness at school and was part of a wider study on chronic illness, and another focused on those with poorly controlled T1D with a $HbA_{1c} \geq 9\%$.[145] Only one study[155] focused on students within a higher education setting; the intervention was delivered to three cohorts of students aged 18–27 years recruited from a university health centre. Three of the studies[145,150,155] reported sex. The study by Faro *et al.*[150] was the only study to report ethnicity; this study included an ethnically diverse sample (55% African American, 25% Hispanic, 18% white and 1% other). A further six studies involved school personnel and the samples included both school nurses and school teachers,[149] elementary school teachers,[147] regular and special education elementary teachers,[152] continuing education and preservice teachers[151] and school nurses.[153,154]

Interventions and outcomes assessed

Those conducted with children and young people with type 1 diabetes (*n* = 5)

Interventions involved school-based care and/or diabetes-related education provided by the school nurse and PDSN through a telemedicine system between the school and the diabetes centre,[146] an individual case management programme provided by the school nurse,[148] monthly visits with a paediatric nurse practitioner,[150] multiple education sessions, supervised blood glucose monitoring, insulin glargine injections and periodic appropriate insulin dose adjustment by the school nurse,[145] and one individual session with a dietician or a certified diabetes educator.[155]

The studies assessed a wide range of outcomes in evaluating the effectiveness of the interventions and all but one[155] identified a clear primary outcome. The primary outcomes included HbA_{1c} levels,[145,146] diabetes quality of life[148] and self-efficacy.[150] The study by Wdowik *et al.*[155] assessed a range of outcomes, which included diabetes knowledge, HbA_{1c} levels and attitudes and beliefs.

Those conducted with school personnel (*n* = 6)

All interventions except one involved some element of education, either through didactic lecture-style presentations delivered by diabetes educators[149] or by way of self-directed learning through CD-ROMs.[147] For school nurses diabetes education was part of continuing education programmes.[153,154]

Two studies assessed diabetes knowledge before and after the intervention and both took into account teachers' previous experience of looking after a child with T1D. The study by Siminerio and Koerbel[149] reported that only 38% of participants had experience of a student with diabetes, whereas 100% of the teachers in the study by Husband *et al.*[147] had such experience. Two studies[153,154] evaluated school nurses' levels of competence after attending continuing education programmes.

Two further studies assessed teachers' confidence in attributing class learning and behaviour problems to hypothetical students with T1D (analogue experiment) when varying levels of information about the hypothetical students with T1D was provided.[151,152]

Theoretical underpinnings

Of the 11 interventions reviewed, only two[150,155] were explicitly reported as theory based.

The study by Wdowik *et al.*[155] utilised the theory of reasoned action and social learning theory and developed an expanded health belief model. The conceptual frameworks for the pilot study by Faro *et al.*[150] were based on both social learning theory and developmental theory.

Narrative summary: intervention studies – stream 1

The 11 studies investigated different types of interventions and used different outcomes to assess their effectiveness and are therefore too diverse to combine in a meta-analysis. Instead, the findings are reported as separate narrative summaries for those interventions conducted with children and young people with T1D and those conducted with school personnel. Tabular summaries of the findings of the included intervention studies are provided in *Tables 12* and *13* respectively. More detailed information on the studies can be found in *Appendix 3* (see *Findings of intervention studies conducted with children and young people with type 1 diabetes* and *Findings of intervention studies conducted with school personnel*).

Children and young people with type 1 diabetes

Three studies[145,146,148] described child-focused interventions (one used a case management approach, one targeted blood glucose management and insulin dose adjustment and the last targeted school-based care and diabetes-related education) and were facilitated by the school nurse. Of these, two showed improved quality of life[146,148] and in the short term all three appeared to have an effect on glycaemic control.

TABLE 12 Summary of findings of intervention studies conducted with children and young people with T1D

Study, country, design and aims	Outcomes (measures)	Findings
Izquierdo *et al.* 2009,[146] USA RCT, two arms To test the feasibility and effectiveness of telemedicine to improve care of children with T1D in schools	HbA_{1c} (primary), urgent encounters, diabetes QoL (PedsQL 3.0), generic QoL (PedsQL 3.0)	*6-month follow-up* HbA_{1c}: I group (+) Urgent encounters: I group (+) Diabetes QoL: overall between-group difference (–); TBS: I group (+), UC group (–); TAS: I group (+), UC group (–) Generic QoL: PFS: UC group (+) maintained at 12 months; EFS: I group (+), UC group (+) *12-month follow up* Diabetes QoL: TBS: I group (+), TAS: UC group (+), I group (NFC) Generic Q0L: PFS: UC group (NFC); EFS: I group (NFC), UC group (+) between 6 months and 12 months
Nguyen *et al.* 2008,[145] USA RCT, two arms To determine if school nurse supervision of blood glucose monitoring and insulin dose adjustment would lead to improvements in HbA_{1c} levels in paediatric patients with poorly controlled T1D	HbA_{1c} (primary)	*3-month follow-up* HbA_{1c}: I group (+)
Engelke *et al.* 2008,[148] USA Before-and-after study To implement and evaluate a school-based case management programme for children with chronic illnesses	Diabetes QoL (PedsQL 3.0) (primary), % meeting goals	*1-year follow-up* Diabetes QoL: 6% change (–); TBS 18.3% change (+)% meeting goals: ↓ episodes of hypoglycaemia (65%) and hyperglycaemia (54%), a HbA_{1c} value of < 7% (27%) and teacher/staff completing diabetes management training (100%)
Faro *et al.* 2005,[150] USA Before-and-after study To conduct periodic diabetes care visits in school with the goal of promoting optimal management of diabetes for high-risk youth	Self-efficacy (R 25-item SED) (primary), HbA_{1c}	*Post test* SED: (–) HbA_{1c}: (–)

TABLE 12 Summary of findings of intervention studies conducted with children and young people with T1D (*continued*)

Study, country, design and aims	Outcomes (measures)	Findings
Wdowik *et al.* 2000,[155] USA Controlled trial To develop and evaluate a *Control on Campus* programme for college students with T1D	Diabetes knowledge (ID 12 items), HbA_{1c}, attitudes (ID 82 items), diabetes self-care behaviour (ID eight items)	*Post test (immediately after the third* Control on Campus *programme session)* Diabetes knowledge: I group (+), C group (–) HbA_{1c} (knowledge of recent result): between-group difference (+) BGM: between-group difference (+); I group (+), C group (–) *3-month follow-up* Diabetes knowledge: I group (+), C group (–) HbA_{1c} (knowledge of recent result): I group (+) Attitudes: social influence construct: I group (+)

BGM, blood glucose monitoring; C, control; EFS, emotional functioning subscale; I, intervention; ID, investigator designed; NFC, no further change; PFS, physical functioning subscale; QoL, quality of life; R, revised; SED, Self-Efficacy for Diabetes tool; TAS, treatment adherence subscale; TBS, treatment barriers subscale; UC, usual care; urgent encounters, urgent visits to school nurse for diabetes-related problems and urgent calls to the diabetes centre; ↓, decrease; (–) indicates that the specified outcome was not statistically significant; (+) indicates that the specified outcome was statistically significant in the hypothesised direction.

A fourth study, facilitated by a paediatric nurse practitioner, showed no change in self-efficacy as self-reported by parents and care providers.[150] One study[155] investigated the diabetes knowledge of university students using a 12-item measure specifically designed to test components of the intervention. However, the authors reported only on the content validity. The authors reported that knowledge was improved as a direct result of the intervention and was maintained at follow-up.

Quality of life was measured in two studies[146,148] using the Paediatric Quality of Life Inventory (PedsQL) 3.0 T1D module.[156] This is a 28-item instrument with five subscales: diabetes symptoms, treatment barriers, treatment adherence, worry and communication. Both studies found significant improvements on the treatment barriers subscale, which assesses the extent to which children experience pain during finger prick or insulin injections, embarrassment about having diabetes, arguments about patient care and difficulty complying with their diabetes plan. The study by Izquierdo *et al.*[146] also found a significant improvement in the treatment adherence subscale, which assesses the extent to which children experience difficulty with taking blood glucose tests, taking insulin injections, exercising, tracking carbohydrates/exchanges, wearing their medical alert bracelet, carrying a fast-acting carbohydrate or eating snacks.

Three studies[145,146,150] measured HbA_{1c} levels. Two studies[145,146] showed significant improvements in the HbA_{1c} readings over a 3-month[122] and 6-month[146] period following the intervention, whereas the other[150] showed no change. A further study[155] showed a significant increase in the number of university students who knew their recent HbA_{1c} results. The study by Faro *et al.*[150] showed limited success in trying to achieve a HbA_{1c} value of $< 7\%$.

TABLE 13 Summary of findings of intervention studies conducted with school personnel

Study, country, design and aims	Outcomes (measures)	Findings
Husband *et al.* 2001,[147] Canada RCT, two arms To determine whether a CD-ROM teaching tool increases teachers' diabetes knowledge and confidence	Diabetes knowledge (ID 17 items) (primary) Confidence (ID four items)	*7-week follow up* Diabetes knowledge: I group (–) Confidence: I group (+) There was no significant difference in confidence pretest scores between the control and the intervention groups
Siminerio and Koerbel 2000,[149] USA Before-and-after study To assess diabetes knowledge and needs of school personnel and to determine the effectiveness of the '5 Cs of Diabetes' programme	Diabetes knowledge (ID 10 items)	*Post test* Diabetes knowledge (+)
Cunningham and Wodrich 2006,[152] USA Analogue experiment (allocated) To examine the effect of providing teachers with varying levels of information about T1D	Perceived confidence (ID)	*Post test* Confidence: (–)
Wodrich 2005,[151] USA Analogue experiment (random assignment) To investigate the effects of disclosing information about T1D with implications for classroom learning and behaviour	Perceived confidence (ID)	*Post test* Confidence (+)
Bullock *et al.* 2002,[153] USA Cohort study To determine whether attendance at specific continuing education programmes increased the competence of school nurses who enrolled on and completed the programmes	Perceived competence (ID 35 items)	*Post test* Perceived competence: between-group difference (+)
Bachman and Hsueh 2008,[154] USA Programme evaluation To develop and evaluate an online continuing education programme to educate school nurses in how to manage care for children with diabetes in schools using current practice principles outlined in *Helping the Student with Diabetes Succeed: a Guide for School Personnel*	Perceived competence (ID)	*Post test* Perceived competence (↑)

C, control; I, intervention; ID, investigator designed; (–) indicates that the specified outcome was not statistically significant; (+) indicates that the specified outcome was statistically significant in the hypothesised direction; ↑, increase.

The effect of the intervention on health service use was measured in two studies. This section of the analysis for the study by Izquierdo *et al.*[146] was poorly reported but indicated that urgent visits to the school nurse for diabetes-related problems and urgent calls to the diabetes centre decreased significantly and that there were fewer hospitalisations and emergency department visits. In contrast, the study by Faro *et al.*[150] did not show any significant difference in the frequency of hospitalisation or emergency department visits.

Only one study[155] was conducted with young people studying at higher education establishments. The findings showed that education sessions that were based on an expanded health belief model and social learning theory had an impact on self-management behaviour, knowledge and attitudes.

School personnel

There is evidence that education-based interventions for school personnel can improve knowledge and confidence although, of the two studies in this review on education-based interventions,[153,154] one showed no effect, which could be attributed to the fact that all of the school personnel in the intervention already had experience of caring for a child and young person with T1D and therefore already possessed a good level of knowledge of diabetes.

Two studies[147,149] conducted their interventions with school personnel using validated, purpose-designed measures. One study[149] showed a significant improvement in diabetes knowledge (only 38% of teachers had experience of children with T1D) and another[147] showed no change in general diabetes knowledge or in knowledge of hypoglycaemia (100% of teachers had experience of children with T1D).

Methodological quality: intervention studies – stream 1

The methodological quality of the three RCTs is presented in *Table 14* and summarised in this section.

In two[145,147] of the three RCTs the school was the unit of randomisation and not the children and young people; therefore, blinding was not applicable. For all RCT studies further details were not provided with regard to the randomisation process or concealment. The studies did not report power calculations. Although sufficient details were provided on the interventions, use of validated measures and whether control and intervention groups were comparable at baseline, only two studies provided information on

TABLE 14 Quality of randomised intervention studies

Study and country	Randomisation and concealment	Blinding	Sample size and use of power calculation	Comparability of groups at baseline	Length of follow-up and attrition	ITT	Risk of bias
Izquierdo *et al.* 2009[146] USA	Unclear, unclear	Not applicable	41, no	Yes, apart from mean body mass index, which was lower in the intervention group	1 year, not reported	Not reported	Unclear
Husband *et al.* 2001[147] Canada	Unclear, unclear	Not applicable	44, no	Yes	7 weeks, 37/44 completed (84%)	Not reported	Unclear
Nguyen *et al.* 2008[145] USA	Unclear, unclear	Not applicable	18, no	Yes	3 months, two dropped out of the control group	Not reported	Unclear

follow-up rates.[145,147] However, no details of whether an ITT analysis was undertaken or identification of any confounding factors were included. The study by Husband *et al.*[147] followed up patients only at the end of the intervention at 7 weeks whereas the study by Izquierdo *et al.*[146] followed up participants for 1 year; however, the fidelity of the intervention was poor. The intervention was not able to begin until midway through the school year, which meant that during the summer vacation, at the 6-month time point, the intervention stopped until school resumed. The authors acknowledge that this could have potentially minimised the effect of the intervention.

In the study by Wdowik[155] the participants were non-randomly allocated to the intervention and control groups. This lack of concealed randomised allocation increases the risk of selection bias. The sample was small ($n = 21$) and no information on whether a power calculation had been calculated was provided. The authors did not describe how allocation occurred and the composition of sex, years in college and living arrangements differed between the groups. It was intended that each participant attend three sessions each lasting for 2 hours and an additional individual session. However, only 50% of participants attended this individual session. Therefore, the fidelity of the intervention is called into question.

There was limited and variable quality evidence to address the research question determining the effectiveness of interventions to optimise children's diabetes self-care and management at school. Three studies[148–150] utilised a before-and-after study design to evaluate participants before and after the introduction of the intervention. In this type of design it can be difficult to account for confounding factors and differences in the care of the participants apart from the intervention of interest. There was a high reliance on self-report measures without discussion of their limitations, and in one study[150] school nurses were used as proxies for children.

In summary, children benefited from interventions to support their diabetes management at school. School nurse support was effective at 3 months and telemedicine in school settings may be an option worth investigating further, especially if there is not a school nurse on site. Interventions to increase the knowledge and confidence of children and staff in managing diabetes in school settings had some positive short-term effects but longer follow-up is required. Overall, the amount and quality of intervention research in school settings is limited, with studies having an unclear or high risk of bias. It is difficult to draw any conclusions at present and further well-designed studies are required.

Non-intervention studies: stream 2

The purpose of stream 2 was to explore the experiences of children and young people with T1D and those involved with their diabetes care and management in an educational setting. The key features of included studies,[94,133,135,136,138,157–207] organised into subgroups of studies with distinct populations, are summarised for children, young people and parents in *Table 15*, students in *Table 16*, school personnel in *Table 17* and school health-care personnel in *Table 18*. The detailed tabular summary (authors, aim, country, sampling and sample characteristics, data collection and methods) for these subgroups can be found in *Appendix 3* (see *Study characteristics for non-intervention studies: stream 2*).

Children, young people and parents ($n = 27$)

Nine studies focused on children and young people,[157–164,174] eight focused on parents[94,165–171] and 10 focused on children, young people and parents.[172,173,175–182]

Design

Seventeen studies used a survey design[158,160,163–171,174,175,177–179,182] and 11 studies used a qualitative approach.[94,157,159,162,172,173,175,176,178,180,181] One study employed a mixed-method design, using a survey followed by qualitative group interviews.[161] The majority of the included papers were published in 2007 or 2008 ($n = 11$). Sample size varied from 2 to 499 participants, with the exception of the Diabetes, Attitudes, Wishes and Needs (DAWN) Youth WebTalk study,[174] which recruited 1905 young people and 4099 parents of children with T1D.

TABLE 15 Study characteristics for non-intervention studies (stream 2): children, young people and parents

Study and country	Design	Participant details	Age (years)	Quality appraisal[a]
Nabors *et al.* 2003,[161] USA	Interviews, survey	105 children from day and summer camps	Mean 10.11 (SD 2.2), range 6–14.6	ABCDEHI
Bodas *et al.* 2008,[164] Spain	Survey	414 children from summer camps	Target range 6–16	ABCEFI
Peters *et al.* 2008,[158] USA	Survey, review of clinic records	167 children from diabetes's clinic	Mean 12.8 (SD 2.5), target range 8–17	ABCDEFGHI
Lehmkuhl and Nabors 2008,[160] USA	Survey, pilot study	58 children from summer camp	Mean 11.5 (SD 1.0), target range 8–14	ABCEHI
Tang and Ariyawansa 2007,[175] UK	Survey	11 children and 11 parents from diabetes clinics	Target range 12–16	ABCEFHI
Wang *et al.* 2010,[157] Taiwan	Interviews	Two children, NS	Aged 14 and 15	ABCDEFGHI
Newbould *et al.* 2007,[180] UK	Interviews	26 children and 26 parents from GP practices	Mean 11.7, target range 8–15	ABCDEFGHI
MacArthur 1996,[163] UK	Survey	15 children from diabetes clinics	Target range 10–16	ABCHI
Clay 2008,[179] USA	Survey	75 children and 75 parents from diabetes clinics	Mean 13.3 (SD 2.8), target range 8–18	ABCDEFGHI
Schwartz *et al.* 2010,[178] USA	Survey	80 children and 80 parents from diabetes clinics	Target range 5–12	ABCEH
Hema *et al.* 2009,[162] USA	Self-completion diaries	52 children from summer camp	Mean 13.02 (SD 2.66), target range 8–18; 8–12 years: $n = 19$, 13–18 years: $n = 33$	ABCDEFHI
Peyrot 2009,[174] Brazil, Denmark, Germany, Italy, Japan, the Netherlands, Spain, USA	Survey	1905 children* and 4099 parents,** part of the DAWN Youth WebTalk study	*Mean 21.3 (SD 2.4), target range 18–25 **Mean 10.5 (SD 4.2), target range 0–16	ABCDEFHI
Carroll and Marrero 2006,[159] USA	Focus groups	31 children from physicians' offices	Mean 14.9, target range 13–18; 13–14 years: 45%, 15–16 years: 35%, 17–18 years: 20%	ABCDEFGHI
Waller *et al.* 2005,[181] UK	Focus groups	24 children and 29 parents from diabetes clinics	Mean 13.07 (SD 1.59), target range 11–16	ABCDEFGHI
Hayes-Bohn *et al.* 2004,[176] USA	Interviews	30 children and 30 parents from diabetes clinics	Mean 17.3, target range 13–20	ABCDEFHI
Wagner *et al.* 2006,[182] USA	Survey	58 children and 58 parents from summer camp	Mean 12 (SD 1.9), target range 8–15	ABCDEFHI
Amillategui *et al.* 2009,[177] Spain	Survey	152 children* and 167 parents** from paediatric units of nine hospitals	*Mean 10.68 (SD 1.92), target range 6–13; 6–9 years: 29%, 10–13 years: 71% **Mean 10.37 (SD 2.15), target range 6–13; 6–9 years: 35%, 10–13 years: 65%	ABCDEFHI

continued

TABLE 15 Study characteristics for non-intervention studies (stream 2): children, young people and parents (*continued*)

Study and country	Design	Participant details	Age (years)	Quality appraisal[a]
Barnard *et al.* 2008,[173] UK	Interviews	15 children and 17 parents registered on the Roche Diagnostics insulin pump user customer database	Mean age 12.07 (SD 2.71), target range 9–17	ABCDEFGHI
Low *et al.* 2005,[172] USA	Interviews	18 children and 21 parents from diabetes camps and a regional paediatric endocrinology practice	Mean age 13.9 (SD 2.2), target range 11–18	ABCDEFGHI
Wilson and Beskine 2007,[167] UK	Survey	73 parents via a survey on the UK Children with Diabetes website	< 5 (11%), 5–11 (55%), > 12 (34%)	ABCDEH
Amillategui *et al.* 2007,[166] Spain	Survey	499 parents from diabetes clinics	Target range 3–18; 3–6 years: 12%, 7–10 years: 26%, 11–14 years: 38%, 15–18 years: 24%	ABCDEFGHI
Pinelli *et al.* 2011,[171] Italy	Survey	220 parents from 15 diabetes units	Mean 10, target range 8–13	ABCDEFI
Hellems and Clarke 2007,[169] USA	Survey	185 parents from diabetes clinics	Target range 5–18	ABCDEGHI
Jacquez *et al.* 2008,[168] USA	Survey	309 parents from diabetes clinics	Mean 11.83 (SD 3.70), target range 4–19	ABCDEFGI
Lewis *et al.* 2003,[170] USA	Survey	47 parents from diabetes clinics	NS	ABCEI
Yu *et al.* 2000,[165] USA	Survey	66 parents from a paediatric endocrinology unit	Mean 12.7 (diagnosed at ≤5 years), mean 12.6 (diagnosed after 5 years)	ABCDEFGI
Lin *et al.* 2008,[94] Taiwan	Interviews	12 mothers from diabetes clinics	Mean 8.4, range 7.3–9.2	ABCDEFGHI

DAWN, Diabetes, Attitudes, Wishes and Needs; GP, general practitioner; NS, not stated; SD, standard deviation.

[a] Quality criteria key: A, clear statement of the aims of the study; B, adequate description of the context for the study; C, clear specification of research design and its appropriateness for the research aims; D, reporting of clear details of the sample and method of recruitment/sampling; E, clear description of data collection; F, clear description of data analysis provided; G, attempts made to establish rigour of data analysis; H, discussion of ethical issues/approval details; I, inclusion of sufficient original data to support interpretations and conclusions.

TABLE 16 Study characteristics for non-intervention studies (stream 2): students

Study and country	Design	Participant details	Age (years)	Quality appraisal[a]
Ramchandani *et al.* 2000,[133] USA	Survey	51 students (42 valid) from five hospital diabetes centres	Mean 20.1 (SD 1.6), range 18.4–25.7	ABCDEFHI
Balfe 2007,[183,207] Balfe and Jackson 2007,[184] Balfe 2009,[185,186] UK	Interviews, research diaries	17 students from five university health centres	Actual range 18–25	ABCDEFGHI
Wdowik *et al.* 2001,[187] USA	Survey	98 students from 22 college health providers	Mean 24.4 (SD 7.4)	ABCDEFGHI
Wdowik 1997,[136] USA	Focus group,* interviews**	*10 students from one university health centre, **15 students attended pre-college workshop at local diabetes centre representing nine colleges across seven states	*Target range 18–35 (two > 24 years) **Target range 19–22	ABCDEFHI
Geddes *et al.* 2006,[138] UK	Case notes	55 students, referrals over a 10-year period to one hospital diabetes centre	Target range 18–24	ABCDEFGH
Ravert 2009,[188] USA	Survey	450 students indicating T1D on graduate surveys	Mean 20.3 (SD 1.6), target range 18–25	ABCDEFI
Wilson 2010,[189] UK	Interviews	23 students, no details provided	Actual range 17–19; 17 (30%), 18 (44%), 19 (26%)	ABCEFGHI
Miller-Hagan and Janas 2002,[190] USA	Interviews	15 students, advertisements placed in one university	Mean 22.4, actual range 18–40	ABCDEFI
Eaton *et al.* 2001,[135] UK	Interviews	22 students from one university medical practice	Mean 20, target range 19–21	ABC

SD, standard deviation.

[a] Quality criteria key: A, clear statement of the aims of the study; B, adequate description of the context for the study; C, clear specification of research design and its appropriateness for the research aims; D, reporting of clear details of the sample and method of recruitment/sampling; E, clear description of data collection; F, clear description of data analysis provided; G, attempts made to establish rigour of data analysis; H, discussion of ethical issues/approval details; I, inclusion of sufficient original data to support interpretations and conclusions.

TABLE 17 Study characteristics for non-intervention studies (stream 2): school personnel

Study and country	Design	Participant details	Experience	Quality appraisal[a]
Amillategui *et al.* 2009,[177] Spain	Survey	111 teachers of children with T1D attending the paediatric units of nine public hospitals	Experience of teaching a child with T1D 100%	ABCDEFHI
Greenhalgh 1997,[191] UK	Survey	85 teachers of children with T1D who attended a diabetes clinic at a local hospital	Experience of teaching a child with T1D 96%	ABCDE
Bowen 1996,[192] UK	Survey	30 teachers, school nurse assigned to five schools	Had taught a child with diabetes 20%, not linked to specific children with T1D	ABCDEFGHI
Alnasir and Skerman 2004,[193] Latif Almasir 2003,[194] Bahrain	Survey	1140 teachers from 49 randomly selected schools	Not linked to specific children with T1D	ABCDEF,[193] ABCDEFI[194]
Gormanous *et al.* 2002,[195] USA	Survey	463 teachers from schools in one US state	Not linked to specific children with T1D	ABCDEHI
Tahirovic 2007,[196] Bosnia and Herzegovina	Survey	83 physical education teachers, all schools within the region included	Not linked to specific children with T1D	ABCDEFH
MacArthur 1996,[163] UK	Survey	11 teachers linked with children from one local diabetes centre who took pre-lunch injections at school	Experience of teaching a child with T1D 100%	ABCHI
Boden *et al.* 2012,[197] UK	Interviews	22 teachers and five health-care professionals from13 primary schools with a child with diabetes in the school (currently or who had left very recently)	No experience 9%, currently teaching 46%, indirectly involved 9%, taught in previous year 27%, taught a child although no longer in school 9%	ABCDEFGHI
Nabors *et al.* 2008,[198] USA	Survey	247 teachers from five elementary schools in one city	Not linked to specific children with T1D	ABCEFGHI
Lewis *et al.* 2003,[170] USA	Survey	65 teachers; 222 schools in three counties were randomly selected to participate in the study	Not linked to specific children with T1D	ABCEI
Rickabaugh and Salterelli 1999,[199] USA	Survey	32 physical education teachers linked with 25 children with T1D from schools across three states	Had taught on average four children with T1D	ABCDEGHI
Chmiel-Perzynska *et al.* 2008,[200] Poland	Survey	52 teachers; part of a wider survey	Currently teaching or had taught a child with diabetes, not linked to specific children with T1D	ABCDE

[a] Quality criteria key: A, clear statement of the aims of the study; B, adequate description of the context for the study; C, clear specification of research design and its appropriateness for the research aims; D, reporting of clear details of the sample and method of recruitment/sampling; E, clear description of data collection; F, clear description of data analysis provided; G, attempts made to establish rigour of data analysis; H, discussion of ethical issues/approval details; I, inclusion of sufficient original data to support interpretations and conclusions.

TABLE 18 Study characteristics for non-intervention studies (stream 2): school health-care personnel

Study and country	Design	Participant details	Experience	Quality appraisal
Fisher 2006,[201] USA	Survey	70 school nurses from a convenience sample of 115 schools	Experience of children with T1D 63%; number of children with T1D: 0 (37%), 1 (31%), 2 (21%), 3 (6%), 4 (3%), 5 (1%)	ABCDEGHI
Guttu *et al.* 2004,[202] USA	Survey	21 counties, 19 provided school nurse services	Each county was characterised as having a good nurse–student ratio (1 : < 1000) or a fair to poor nurse–student ratio (1 : > 1000 students)	ABCDEI
Joshi *et al.* 2008,[203] USA	Survey	43 school nurses from schools in one US state	Not provided	ABCEH
Nabors *et al.* 2005,[204] USA	Survey	38 school nurses from schools in three US states	Experience of children with T1D 87%; number of children with T1D NS	ABCDEHI
Wagner and James 2006,[205] USA	Survey	132 school counsellors, attendees at two school counsellor association annual meetings	Experience of children with T1D: 83% had a child with diabetes in their school, 14% did not know if there were children with diabetes in their school Number of children with diabetes: average of four	ABCDEFGHI
Schwartz *et al.* 2010,[178] USA	Survey	28 school personnel linked with children from a hospital diabetes centre, 20 schools represented. School nurses 85%, dieticians, teachers and other (15%)	Experience of children with T1D 63%; number of children with diabetes: 0 (5.9%), 1–2 (27.5%), 3–4 (41.2%), 5–10 (13.7%), >10 (11.8%)	ABCEH
Darby 2006,[206] USA	Interviews	11 school nurses (RN 6, CNP or APN 2, LPN 3) helped pupils with CSII therapy, survey of local schools across three counties	Experience of children with T1D 100%; number of children with T1D: 1–4	ABCDEFHI

APN, advanced practice nurse; CNP, certified nurse practitioner; LPN, licensed practical nurse; NS, not stated; RN, research nurse.

a Quality criteria key: A, clear statement of the aims of the study; B, adequate description of the context for the study; C, clear specification of research design and its appropriateness for the research aims; D, reporting of clear details of the sample and method of recruitment/sampling; E, clear description of data collection; F, clear description of data analysis provided; G, attempts made to establish rigour of data analysis; H, discussion of ethical issues/approval details; I, inclusion of sufficient original data to support interpretations and conclusions.

Setting

Fourteen studies were conducted in the USA,[158–162,165,168–170,172,176,178,179,182] six in the UK,[163,167,173,175,180,181] three in Spain,[164,166,177] one in Italy[171] and two in Taiwan.[94,157] One further study, the DAWN Youth WebTalk study,[174] was conducted across eight countries (Brazil, Denmark, Germany, Italy, Japan, the Netherlands, Spain and the USA).

Just under half of the studies recruited participants from paediatric outpatient diabetes clinics within local hospitals. The study by Pinelli *et al.*[171] drew its sample from 15 separate diabetes units and Amillategui *et al.*[177] recruited from clinics within nine separate hospitals. Six studies completed their research at day and summer camps for children with T1D.[160–162,164,172,182] Two studies recruited from general practitioner (GP) practices/physicians' offices,[159,180] one study sought volunteers through the UK Children with Diabetes website[167] and another recruited those registered on the Roche Diagnostics insulin pump user customer database.[173] The remaining three studies did not specify such details.[157,169,170]

Participants

Overall, the age range covered was 3–20 years, with the exception of the DAWN Youth WebTalk study,[174] in which the mean age of the young people was 21.3 years. Five studies included children aged ≤ 5 years[166–169,178] and six were aimed only at adolescents/teenagers.[157,159,163,169,175,181] Most interventions were aimed at children and young people in a specific age range, for example 8–13 years, 6–16 years and 5–18 years. One study did not specify the age of the children.[170]

The sex of the sample was reported in 19 studies[94,133,157–162,164,165,167,171,172,174,176,177,179,181,182] and, with the exception of the study by Hayes-Bohn *et al.*,[176] in which the study participants were exclusively female, the proportion of females ranged from 31% to 75%.

Eleven studies noted the ethnicity of the sample[158–162,166,168,172,176,180,182] and reported that the majority of the participants were Caucasian (80–100%). The study by Jacquez *et al.*,[168] however, reported on an ethnically diverse sample (61% Hispanic white, 19% non-Hispanic white, 19% African or Caribbean American, 1% other ethnicity). Only one study[168] reported on social class.

A number of studies specified the insulin regime that the children and young people were on.[94,158,159,167,168,181,182] Three studies focused on those on insulin injection[158,163,182] and two studies focused on those on insulin pumps,[172,173] with the study by MacArthur[163] specifically reporting on those children and young people who took lunchtime injections in school. Six studies provided details of the proportion of children who were on pumps or MDI regimens,[159,167,168,172,173,182] ranging from 29%,[168] 48%[159] and 50% ($n = 1$)[182] on pumps to 60% on pumps or MDIs.[167] Twenty studies[94,160–162,164–167,169–171,173–181] did not report this information.

Three studies reported the length of time in years since the initial diagnosis of diabetes was confirmed: 6–14 years,[159] 1–11 years[160] and 1–12 years.[171] Ten studies reported the length of time since diagnosis as a mean value, which ranged from 3.3 to 7.8 years.[94,162,166,168,171–173,176,180,182] Four studies included only children and young people who had been diagnosed for at least 1 year.[157,158,176,181] The DAWN Youth WebTalk study[174] reported age at diagnosis, whereas the study by Yu *et al.*[165] divided the sample into those diagnosed at ≤ 5 years (early-onset diabetes) and those diagnosed aged ≥ 5 years and the study by Tang and Ariyawansa[175] looked at those diagnosed at < 5 years and those diagnosed at > 10 years. Eight studies[162,170,192,193,195–198] did not provide this information.

Students (n = 9)

Design

Three studies used a survey design[133,187,188] and five studies used a qualitative approach.[135,136,183–186,189,190] One study employed a retrospective survey using case notes.[138]

All of the included papers were published between 2000 and 2010 with the exception of that by Wdowik *et al.*, which was published in 1997.[136] The studies that were qualitative had sample sizes ranging from 15–25. Sample sizes for surveys varied from 51[133] to 450.[188]

Setting

Five studies were conducted in the USA[133,136,187,188,190] and four in the UK.[135,138,183–186,189]

The participants were recruited using a variety of methods, including from hospital diabetes health centres,[133,136] from those registered at university health centres,[135,136,138,183–187] through wider surveys of postsecondary institutions[188] and through advertisements with the use of snowballing techniques.[190] One paper did not provide any details of how the sample was recruited.[189]

Participants

The majority of studies were conducted with university or college students aged from 18 to 25 years. However, several studies included postgraduate students within their sample[133,188,190] and others did not specify the year of study of the participants.[113,163,165]

The sex of the sample was reported in nine studies[133,135,136,138,183–190] and the proportion of females ranged from 52% to 73%. Four studies noted the ethnicity of the sample[183–186,188,190] and reported that the majority of the participants were Caucasian (80–100%). None reported on social class.

Four studies specified the insulin regime that the students were on[133,138,183–186,190] and in three of these those on pumps ranged from 6% to 36%.[133,183–186,190] Two studies included a small number of student with type 2 diabetes (T2D)[187,190] and separate results were not reported for those with T1D.

Six studies reported the length of time in years since the initial diagnosis of diabetes was confirmed. In four of the studies this was 3.5 months to 17 years,[190] 6–20 years,[135] 3 months to 13 years[187] and 8–10 years.[189] One study reported the length of time since diagnosis as a mean value of 11.8 years.[187] The study by Balfe[183–186,207] reported that all respondents had been living with diabetes for at least 1 year and 14 respondents had been living with diabetes for > 6 years. Three studies did not report this information.

School personnel (*n* = *12*)

Design

Of the 12 studies with school teachers as the main participants, 11 used a survey design[163,170,177,191–196,198–200] and only one used a qualitative design.[197] The majority of the included papers were published between 2002 and 2012 (*n* = 8) with the remaining four being published between 1996 and 1999.[163,191,192,199] Sample size varied from 11[163] to 1140.[193] However, excluding these two extremes, the mean number of participants for the remaining 10 studies was 155.

Settings

Three studies were conducted within primary schools in the UK,[197] Poland[200] and Spain[177] and one within a secondary school in the UK[163] and two studies investigated school personnel within both primary and secondary schools in the UK.[191,192] One study was conducted in Bahrain in primary, intermediate and secondary schools,[193,194] a further three within elementary schools in Bosnia and Herzegovina[196] and the USA[195,198] and one in elementary, middle and high schools in the USA.[170] The study by Rickabaugh and Salterelli[199] did not specify the type of school. It should be noted here that children enter formal education at 4 years in the UK whereas in other European countries children tend to start formal education when they are 6 or 7 years old. This could be viewed as a confounding factor when making comparisons between international studies.

Participants

Four studies investigated school personnel in relationship to specific children with T1D for whom they were responsible and who were recruited from paediatric units of local hospitals.[163,177,191,197] The only details given for the children with T1D in these studies was age, with a mean age of 10 years in one study[177] and an age range of 10–16 years in another study.[163]

Eight studies were not linked with specific children with T1D and the school personnel were recruited through a school nurse assigned to five schools,[192] from all schools within a specific geographical location,[193,194,196] from a random sample of schools within a specific geographical location[170,195,198,200] and with the assistance of physicians, support groups, physical education teachers and diabetes-related newsletters.[199]

One study looked specifically at physical education teachers[196] and another study included special education teachers (22%).[198]

*School health-care personnel (*n *= 7)*

Design

Six studies with school HCPs as the main participants used a survey design.[178,201–205] Only one study[206] used a qualitative design. All of the included papers were published between 2004 and 2010 ($n = 7$). Sample size varied from 11 to 132 respondents.

Settings

All seven studies were conducted within the USA. The exact school setting was not specified in three of the papers[201–203] but the remaining four included children from kindergarten,[178] elementary,[178,205,206] junior,[178,205] middle[178,204–206] and high school[178,204–206] settings.

Participants

The majority of the participants were school nurses; however, one study explored the knowledge and beliefs of school counsellors regarding students with diabetes.[205] The minimum number of school HCPs in an individual study was 11[206] and the maximum number was 132.[205] In four of the studies the number of school HCPs who had experience of working with children with T1D was noted,[201,204–206] with this detail not specified in the remaining three papers.[178,202,203]

Narrative summary: non-intervention studies – stream 2

A tabular summary of the findings of the non-intervention studies included in stream 2 is provided in *Appendix 3* (see *Study methods, quality appraisal and summary of results: stream 2*). The question being asked in stream 2 was, 'What are the views on the barriers to and facilitators of providing optimal care and management of children and young people with T1D in educational settings?' Using Ritchie and Spencer's thematic framework analysis approach,[144] themes associated with the barriers to and facilitators of providing optimal care and management of children and young people with T1D in educational settings were developed from reading an initial set of papers, with reference to best practice guidelines and with consideration of the research questions. These were barriers and facilitators associated with (1) self-management in school, (2) self-management in college/university, (3) school culture, (4) school-based facilities, (5) the role of the school nurse and (6) the role of school teachers.

In the following sections the findings are reported with an integrated discussion.

Barriers and facilitators associated with diabetes self-management in school

Children and young people with T1D spend most of their time during the day at school. Best practice guidance[26,128,129] sets out optimal ways for insulin administration and blood glucose monitoring to be integrated into children's daily school life, as well as allowing snacks to be eaten during class time so that pupils with T1D can participate fully in all school activities. Despite clear policy and best practice guidance on self-management in schools, some children found that managing their T1D in school was stressful and that there were unnecessary barriers to self-management,[177,181] especially when experiencing low blood glucose levels (hypoglycaemia)[161,162,177] or high blood glucose levels (hyperglycaemia).[162]

Insulin regime

Children and young people on twice-daily insulin may not need insulin to be given during school hours. In the UK and the USA there is a move towards more intensive management of MDIs and CSII therapy,[26,208] especially for those aged > 11 years.[26] Many children may need special accommodation as these regimens require a greater level of education, support and involvement.[209] Insulin pumps are attached 24 hours a day and deliver set doses of rapid-acting insulin continuously, but a pupil with T1D will need to 'boost' the dose at mealtimes having worked out the amount of carbohydrate eaten.[124] Pupils who have an insulin pump report that this makes life much easier at school, the pump enabling them to feel more 'normal' and independent in front of their peers at school.[157,167,173]

The percentage of pupils who needed to administer insulin by injection at school on a regular basis varied, ranging from 7–54%.[164,166,167,171,175,177,180] Most parents (89%) reported that their child had required insulin administration at school at some point during the previous year.[169]

It is recognised that, although some pupils will be able to administer insulin on their own, others will need supervision. In addition, some will need someone to administer the insulin for them, especially younger children.[122,123,129] The support of administration of insulin during the school day is therefore an important facilitator for those who are not yet at the stage of undertaking this activity themselves. When insulin was administered in school, between 46% and 97% of children[157,164,169,173,180] self-injected, especially older pupils who attended secondary/high school.[167,169] For a small minority of children it was the school nurse (18%)[179] or a member of school staff (1–6%) who administered the injection.[164,167,171,179] For younger pupils (2–32%) it was the young student's parent who came into school to give an injection or administer a bolus if the child needed insulin and no one at school was trained and/or allowed to administer insulin.[164,157,167,169,171] For example:

> *[My father] just came to school several times each day because he was worried about me. He came to school to help me test my sugar, inject insulin, and bring my lunch. Sometimes, he just came to make sure I was okay. The record times he came to school in one day was six.*
>
> *p. 262*[157]

In certain instances, however, pupils occasionally had to go home if nobody was available to administer insulin.[167] When this was not possible a small minority reported that treatment modifications were made because of a lack of co-operation from the school.[164,166] It has also been reported that a small number of pupils were not allowed to inject insulin whilst in school.[175]

Some pupils who self-injected (20–49%) were supervised whilst taking their insulin.[167,179] This was usually the role of medical personnel or a designated member of the school staff.[169] Younger children required more support,[164] especially if they were in kindergarten/nursery or infant/elementary school.[169] Pupils appreciated being reminded by the teaching staff to administer their insulin.[179]

Blood glucose monitoring

Most children with diabetes need to monitor blood glucose levels at school at least once a day, for example at lunchtime or before physical activity. Blood glucose levels may need to be monitored more regularly if their insulin needs adjusting or when there are symptoms of hypoglycaemia or hyperglycaemia. Depending on the school's layout, expecting a student to go to a centralised clinic or office may be unsafe or may result in excess time out of class or cause unnecessary delays in treatment.[210] When in doubt, taking immediate action is important to prevent symptoms of severe hypoglycaemia such as coma or seizures and to prevent students from missing class time.[129]

The percentage of pupils on insulin injections who needed to test their blood glucose during school hours was between 58% and 75%.[161,164,166,171,175,177] This figure was higher for younger pupils (< 6 years of age)[166] who had been diagnosed for < 2 years[164] and for those on an insulin pump.[167]

Many pupils can check their own blood glucose level, especially older pupils, and will need a suitable place to do so. Younger children may need adult supervision to carry out the test and/or interpret test results. However, other pupils need to have this task performed by a school nurse or trained diabetes personnel. All pupils, even those who can independently perform blood glucose monitoring, may need assistance when experiencing low blood glucose.[33,122,123,129] Having the support necessary to undertake blood glucose monitoring within a school setting is another important facilitator. Younger pupils (kindergarten/nursery through to junior/middle school) reported that they needed assistance with blood glucose monitoring during school hours.[164,169] This was usually the role of medical personnel[167,169] or a designated member of the school staff,[161,164,167,177] peers[177] and in some instances parents.[167,169] Older pupils attending high/secondary school generally required less assistance.[167,169]

A small percentage (9%) of children across all ages were forced to reduce the number of blood glucose measurements because of lack of co-operation from school staff. This figure was highest (18%) in those pupils aged < 6 years.[166] In some instances pupils reported that they were being prevented from managing their diabetes in school.[178]

Barriers and facilitators associated with school culture

It is recommended that all children and young people with diabetes should have an agreed individualised care plan (ICP) in the UK and an IHP and Emergency Care Plans for Hypoglycemia and Hyperglycemia in the USA. Such plans, when in place, can act as important facilitators for diabetes self-care. Issues such as providing suitable locations for blood glucose monitoring and insulin administration, allowing the pupil to leave the classroom to access the restroom and water, provision for appropriate storage of medical supplies, nutritional needs including provision for meals and snacks and participation in physical activity programmes and extracurricular and social activities should all be laid out in such documents. However, between 31% and 46% of pupils did not have a written care plan.[167,168,178]

School policies generally apply to the entire student body within a particular school and do not often consider the child and young person with T1D and their need to perform diabetes self-management at school.[176,180] In some schools there are generic policies for all children and young people with diabetes that fail to take into account individual needs. For example, one parent said

> *Not every kid will be comfortable testing in an open classroom. Not every kid will feel comfortable going to the nurse's station to do that . . . I think kids should have more freedom to test, to manage their diabetes according to their comfort level.*
>
> *p. 168*[176]

School nurses felt that a care plan for emergencies was important for facilitating the care of a pupil with T1D in the school environment.[204] The majority of school nurses reported that they had developed written care plans and those who had worked for longer as a school nurse were more likely to report that they had done so.[204]

Availability of appropriate locations to perform blood glucose monitoring and insulin administration

Children with diabetes may need to leave the class for a variety of diabetes-related reasons. Specific arrangements need to be in place so that children can manage their glycaemic control in a timely and appropriate way. During hyperglycaemia the student should be allowed extra bathroom breaks and ready access to extra drinking water.[128,208] The inherent school culture in relation to child autonomy varies by age group, with younger children tending to stay in the same class all day, older children moving around classes and, in post-compulsory education, an adult learning model of self-motivated attendance being adopted.

It is up to each school, as set out in the IHP and ICP, to determine where pupils will be allowed to undertake blood glucose monitoring and insulin administration. The recommendations suggest that the school provides privacy during blood glucose monitoring and insulin administration if this is what the student would prefer, or permission for the student to check his or her blood glucose level and take appropriate action to treat hypoglycaemia in the classroom, or anywhere that the student is in conjunction with a school activity. It is unusual, and may be inappropriate, for a pupil to have to use a first aid room to take his or her insulin if he or she is happy to inject discreetly at the table or the first aid room is a long way from where the pupils eat.[124]

Pupils with T1D described having to leave the classroom when blood glucose levels drop to go to the school nurse's office or another location to take a blood glucose test, inject insulin or have a snack as cumbersome,[176] uncomfortable[159] and inconvenient.[176,181] Missing lessons because of unstable blood glucose levels and having to stay in the school nurse's office until their blood glucose is stabilised means that school work has to be 'made up' in their own time.[159]

Most pupils reported that they were allowed to access the bathroom when needed[168] but in some instances teachers may become angry or yell at pupils when they need to leave the classroom because of their blood glucose levels.[159] Only 30–54% of pupils were permitted to check their own blood glucose in the classroom,[167–169] increasing to 74% for pupils at high school.[169] For those not allowed to perform blood glucose monitoring in the classroom, a number of alternative locations are provided, which include the medical room,[167] school office,[167] head teacher's office[167] or anywhere.[167] Pupils have been shown to demonstrate significantly better glycaemic control when they are given the flexibility to decide where to perform self-care behaviours.[182]

With regard to insulin administration, pupils reported problems with a lack of a private location within the school where they could administer injections.[168,175,180] Locations provided or chosen by pupils included first the aid/medical room or health office[167,175,176,180] toilets/cloakroom,[167,175,180] a classroom,[168,175] 'wherever I have my lunch', the school dining room,[163] a cupboard in the school office,[163] a school office,[167] the lockers between classes[182] and the head teacher's office.[167] One young girl commented: 'There is one place, the first aid room, but there's all windows about where the playground is, so there is no place you can do it without people seeing you (p. 1079).[180] However, some pupils reported being happy with their usual place.[163]

Ability to take regular snacks

It is recommended that a pupil with T1D be given permission to be able to eat a snack during the day (which may include being able to eat in the classroom or before exercise)[26,56,127] so that diabetes self-care can be facilitated. Most pupils with T1D took a snack to school[175] but some reported that they were not allowed to eat snacks when they needed to.[176,180]

The timing of school lunches was also a commonly reported problem.[180] To facilitate a pupil with T1D, schools may need to make special arrangements for lunchtime. For example, if the school has staggered lunchtimes, pupils with T1D may need to be at the front of the queue at the canteen and have their lunch at the same time each day,[124] otherwise blood glucose levels can become difficult to control. Only 25% of primary school teachers and 38% of secondary school teachers appreciated that pupils with T1D should not be late for a meal.[191]

Access to and participation in physical education lessons

Staying healthy is important for optimal glycaemic control and pupils with diabetes need to have the opportunity to be fully integrated into every part of the school day, which includes physical education lessons and team or individual sports. However, children and young people require more intense glycaemic management to participate in physical sports that require or use a lot of energy. With support to maintain optimal glycaemic control before, during and after sport, it is considered a positive thing for pupils with T1D to participate and keep fit. Participation alongside peers and friends also helps children with diabetes to see themselves as similar to others.

To maintain blood glucose levels within the target range during extra physical activity pupils will need to adjust their insulin and food intake. To prevent hypoglycaemia they also may need to check their blood glucose levels more frequently while engaging in physical activity. To facilitate this process all school personnel supervising physical activity should be trained in the management of hypoglycaemia and hyperglycaemia and emergency supplies and extra snacks should be readily accessible at all times.[123,124,129,209]

Although some schools have strategies in place to enable pupils with T1D to participate in sport at school,[166,180] others find it difficult, especially with regard to being able to have a snack beforehand,[159] and some parents stated that their assistance and presence was required during and/or after school sport,[171] especially for younger children,[161] and in some instances their children were not allowed to play sports such as football.[170] It was felt that participation in such activities could be facilitated if a nurse was still on site[160] as supplies were often locked in the nurse's office.[159] Older children felt that their coaches needed to be more knowledgeable about diabetes.[161]

Extracurricular activities

Pupils with diabetes must not be excluded from any school activity on the grounds of their condition.[121,124] Only in certain rare instances may it be advisable for a diabetes team to recommend to a school that a young person should not go on a school activity.[211]

Parents reported that their child's diabetes affected their decisions regarding extracurricular activities.[182] In some instances parents/guardians were asked to act as chaperones on field trips, especially for younger children,[169] but parental attendance should not be a prerequisite for participation by pupils with diabetes.[128]

Parents mentioned that school action or care plans needed to include ideas for after-school care,[161] although school nurses, especially those with less experience, did not believe that they should.[204] Parents suggested that keeping snacks around during after-school activities and making sure that someone can open the nurse's office if a child needs diabetic supplies would improve opportunities for children with diabetes to participate in after-school activities with peers.[161]

Even though teachers felt that all children with T1D should be allowed to go on extended trips with the school,[191] between 15% and 20%[164,166,167,177] of parents reported experiencing difficulties from the school over responsibility of the children during 1-day trips, especially for children under 10 years of age,[164,166] with greater problems for trips that extend over several days.[166] In some instances parents reported that their child was not allowed to participate in outside school trips unless accompanied by a parent or a school nurse,[170] whereas in other instances schools have specific policies in relation to medication on school trips and work with families to ensure that children and young people can participate.[180] School nurses reported that planning for management during 'out of town' trips was critical.[204]

Feeling different

The school culture, rules and regulations and individually tailored diabetes plans were vitally important factors in children's optimal diabetes self-management whilst at school. Getting the balance right so that children do not feel different and yet can have the flexibility that they need to manage their diabetes in an optimal way is highly challenging. Nonetheless, pupils with diabetes in school settings often expressed a feeling of 'being different' from their peers because of their T1D.[157,175,178,180,197,204] They also expressed being embarrassed if they 'had a hypo'[157,178] or when they had to monitor their blood glucose or take medication at school.[178,181] These feelings can act as barriers to positive diabetes self-care behaviours in school.[203] In an attempt to not appear different from their peers young people compromise their diabetes self-management by choosing not to alleviate their symptoms.[157] Some pupils reported that they did not like peers watching them inject.[181] On the other hand, some pupils stated that they did not mind others seeing them take their insulin.[163]

Some parents (26%) reported that their child was bullied/picked on at school because of their diabetes[167] and a small percentage of pupils themselves reported problems with their peers such as diabetes-related bullying or teasing.[157,175,182] This was more of a problem for older pupils in high/secondary school.[167] As a result, pupils managed the need to have peers around them who knew about their diabetes and the emergency management strategies by telling one or two close friends who they felt that they could trust[180] to keep the diabetes a secret from most of their peers.[157,161] Some talked about such peers as a diabetes 'buddies' who, with training, would be able to recognise hypoglycaemia, alert staff, prompt self-care, buffer teasing and escort the student to the nurse.[182] When age and level of HbA_{1c} were taken into consideration, pupils who received help from trained peers were found to have a significantly higher quality of life in the school environment.[182]

The type of support that pupils felt that they needed from their peers varied with each individual pupil. Examples included providing support when they were 'low',[160,161] providing encouragement to follow their medical regimen at school,[161] having an understanding of dietary-related issues,[160,161] supporting them if they felt unwell,[160,161] helping them walk to the nurse's office[160,161,182] and providing general emotional support.[161] In contrast, some children felt most comfortable managing on their own at school and not discussing their care with others.[161]

Even though most pupils informed their friends about their condition they still felt that friends' knowledge could be improved if they were given more information about diabetes,[161,164] in particular about the availability of juices or glucose[164] and hypoglycaemic episodes.[175]

Using diabetes as an excuse

Teachers reported that they felt that some pupils would use diabetes as an excuse for not working,[178] for example 'drinking a juice so blood glucose will be high and they can miss an educational test' (p. 122),[204] or would mismanage their condition on purpose.[197]

Pupils themselves admitted to using their diabetes as an excuse at times to get out of class. One of the 13- to 14-year-olds admitted:

> *Sometimes I leave class 10 minutes before the end because it is almost lunch and I can feel my blood sugar getting too low, but I know I could wait. I have a pass in my assignment book that says I can get a drink or use the bathroom whenever I want. Sometimes when there is nothing to do I get a pass to the bathroom and walk really slowly.*
>
> *p. 250*[159]

Barriers and facilitators associated with school-based facilities

Food availability at the canteen

The nutritional needs of pupils with T1D in school need to be considered and are facilitated when school cafeterias provide healthy choices and nutritional information about the foods served.[98] The nutritional needs of pupils with diabetes do not differ from the needs of pupils without diabetes; however, the timing, amount and content of food, especially carbohydrate content, require consideration.

Some pupils, parents and school nurses felt that food choices provided in the school canteen, vending machines and classrooms that are conducive to healthy diabetes management were limited[176,203] and that ensuring that snacks and appropriate foods are available can reduce barriers to good control at school.[204] Pupils reported that they would benefit from more healthy food and drink options,[166,170,174] from prominent and consistent information about prepared food and from developing nutritional analyses for all foods available in the cafeteria as a way of helping to choose meal options in the cafeteria.[176] As a solution, some pupils in some instances had to take their own lunch to school.[178] Some parents reported that schools were not able, or did not consider it their responsibility, to modify diets to enable children with T1D to eat a school lunch.[166]

Increasingly, older children are taught to count their carbohydrate intake and adjust their insulin accordingly. This means that they have a daily dose of long-acting insulin at home, usually at bedtime, and then insulin with breakfast, lunch and the evening meal and before substantial snacks. The child is taught how much insulin to give with each meal, depending on the amount of carbohydrate eaten. They may or may not test blood glucose levels before the meal to decide how much insulin to give.[122,123] Parents sometimes reported having trouble obtaining nutritional information about foods served and portion sizes from their child's school. This makes it difficult to plan ahead whether using a constant carbohydrate approach or the insulin-to-carbohydrate ratio.[208] Only 7% of pupils reported that their school cafeteria made the carbohydrate content of prepared foods available.[182]

Accessibility of own snacks and supplies

For optimal diabetes care in school, diabetes supplies and equipment [e.g. Glucogel® (BBI Healthcare, Bridgend, UK), glucose drinks and some complex carbohydrate to treat hypoglycaemic episodes] should be accessible to the student at all times.[120,122,128] Pupils considered that having test kits and snacks available whenever they needed them was important.[161] HCPs felt that schools should rethink policies that prevented children from having easy access to their medical equipment.[197]

It is recommended that diabetes supplies and equipment should be stored in appropriate locations or kept with the pupil (those who are deemed self-sufficient and capable).[120,122,128] Pupils reported that medication or items related to diabetes were stored in a variety of places, for example with the pupil,[163,179,180] in another room in school, in a classroom, in the school office,[180] in the nurse's office[179] or in the secretary's/teacher's office/desk.[179] School nurses felt that they could better support pupils if they could have ready 'access' to snacks and testing kits as well as appropriate medical supplies.[203,204] However, one pupil reported: 'My school won't keep my supplies for my diabetes in the nurse's office. They make me go to the hospital if I'm low. If I had to wait too long I would die' (p. 218).[161]

Pupils who were able to carry their own medication used it when they perceived the need, without seeking permission.[180]

Parents of the majority of pupils (65–80%) reported that diet-related accommodations were made for their child, which included allowing the child to keep snacks in the classroom or office (in case of hypoglycaemia) and to eat a snack in class during the child's prescribed snack time. However, only 14–16% of parents reported medical accommodations allowing the child to keep insulin injection materials or a blood glucose monitor in the school office.[165]

Availability and accessibility of glucagon

In the UK NICE guidelines recommend that parents and, when appropriate, school nurses and other carers should have access to glucagon for subcutaneous or intramuscular use in an emergency, especially when there is a high risk of severe hypoglycaemia, and that they should be offered education on the administration of glucagon (p. 41).[26] In the USA the recommendations state that hypoglycaemic remedies, for example glucagon, should be supplied by parents/guardians and that the school nurse or trained diabetes personnel need to know where it is stored and have access to it at all times.[33,129,208] Only a small number of teachers who had taught or were currently teaching a pupil with T1D declared that they knew what glucagon was (43%), knew when glucagon should be given (23%) and knew how to give glucagon (15%).[200]

Pupils reported that they had experienced at least one hypoglycaemic event during school hours (65–75%),[169,171] that the event had been managed well (86%) and that a blood glucose test had been carried out (79%).[171] Most episodes were treated with fast-acting carbohydrate[169,171] with the help of medical personnel, school staff or parents.[171] Some pupils are able to manage an episode of hypoglycaemia by themselves (2% younger pupils, 18% older pupils).[169,171]

Glucagon was found to be available at school for between 34% and 49% of pupils.[164,166,168] A high percentage of both children (60%)[164] and parents (64%)[166] felt that glucagon should be readily available, together with a person who was aware of how to administer it.

Only 10% of children had experienced a serious hypoglycaemic episode at school.[166] In only a very small number of cases was a call made to the emergency services (3%[171]) or glucagon administered.[169]

Flexible accommodation with examinations and educational tests

In the USA the American Association of Diabetes Educators recommends alternative times and arrangements for academic examinations if a student is experiencing hypoglycaemia or hyperglycaemia.[127] However, in some European countries, older children have reported (23–39%) that if they experienced hypoglycaemia events before or during an examination they did not have the opportunity to do it again.[164,177]

Barriers and facilitators associated with the role of school health-care personnel

The main difference between the UK and the USA is the provision of a school nurse. There are no specific recommendations regarding the role of the school nurse within the UK guidelines. The US guidelines recognise the school nurse as the most appropriate person in the school setting to provide care for the student with diabetes. Each pupil with T1D should have permission to see the school nurse and other trained school personnel on request.[128]

Support from school health-care personnel

Despite the policy intent, many US schools do not have a full-time nurse and sometimes a single nurse covers more than one school.[170,212,213] Even when a nurse is assigned to a school full time, she or he may not always be available during the school day, during extracurricular activities or on field trips. For example: 'A school nurse in the building 100% of the time would also be incredibly helpful. It is very difficult for me to monitor and assist my diabetic students when I am in another building across town' (p. 121).[204]

Just under 50% of children[164,166] felt that a nurse should be available daily during school hours to help with the management of diabetes. Parents also expressed concern about the presence of a daily on-site nurse[170] as opposed to a health aide, who they felt was unable to provide adequate care.[176] The number of pupils reporting that their school had a school nurse on site varied widely from 21% to 95%,[164,168,169,177,179] with a smaller percentage working full time.[161,169] However, children reported that, even if they had a school nurse assigned to their school, the nurse did not come to the school every day and they worried about what might happen if they 'got very low' and no one was there to help them.[161] Those nurses who did come every day were not always on site all day and this caused problems for some children as supplies were often locked in their office.[161]

The National Association of School Nurses endorses a nurse-to-student ratio of 1 : 750.[202] Over 80% of school nurses felt that the number of school nurses available across schools for pupils with T1D was inadequate and that a school nurse should be available on school premises during the school day if a pupil with T1D is enrolled.[178] Guttu *et al.*[202] demonstrated that a significant correlation existed between increased presence of school nurses and services provided to children with diabetes. School nurses who felt knowledgeable about diabetes were significantly more likely to report that adolescents with diabetes needed more support at school.[204] The types of services/support that school nurses provided included making sure that insulin injections were administered,[160] helping with blood glucose monitoring,[160,161,201] having a snack available,[160] having juice available,[160] helping with lows[160] and having supplies for testing available.[160] Younger children reported that they needed more support from school nurses.[161]

Some pupils (57%) reported that they received support from school counsellors for a non-medical, diabetes-related problem, but of those only 66% felt that the school counsellor knew enough about diabetes to be helpful.[182] School counsellors (87%) indicated that they had received no specific training about diabetes, yet 40% had reportedly worked directly with students with diabetes. Those who reported that they had received diabetes training had better knowledge and more helpful attitudes.[205] Many, however, endorsed items that would hinder their ability to serve students with diabetes, for example counsellors were neutral or agreed with unhelpful statements such as 'diabetes restricts extracurricular activities' (35% did not disagree) and 'the most appropriate place for children with diabetes to test blood sugar is in the nurse's office' (87% did not disagree).[205]

School nurse diabetes education, training, knowledge and skills

Some young people felt that school nurses were well educated about diabetes whereas others felt that the nurses' knowledge could be improved,[176] but that they should not be the ones providing all of the information.[161] In particular, children wanted nurses to learn to distinguish between when they were 'very low' (about to have a hypoglycaemic episode) and when they were just a 'little low'.[161]

The majority of school nurses (94%) reported that they had up-to-date diabetes reference materials in their office,[201] with some nurses obtaining information about T1D from the internet and professional books and magazines.[203] Just over one-third (36%) of school nurses reported that they had attended a conference on diabetes during the past year.[201] Nonetheless, one-third of school nurses perceived their own level of diabetes knowledge to be low to average.[203] The reported barriers to acquiring new information for school nurses were time constraints (37%) and lack of access to education/regular updates and inadequate training (28%).[203]

School nurses rated themselves as moderately confident in providing diabetes care and education (self-efficacy).[201] Self-efficacy was significantly higher if they were currently participating in the care of children with diabetes, when there were pupils with T1D in the school system and when they were supervising pupils with blood glucose meter testing.[201] However, only 20% felt adequately prepared to assist a child with hypoglycaemia.[178]

Parents reported concerns about CSII therapy in school relating to testing, bolusing and pump management.[172] As well as being completely unfamiliar with pumps or CSII therapy,[172] the biggest challenge faced by school nurses was learning to count carbohydrates when a pupil was on CSII therapy;[206] when they first encountered a pupil on CSII therapy they mentioned being scared, intimidated and overwhelmed as a result of lack of education about and experience with this new technology.[206]

Communication between schools and diabetes health-care providers

Having regular appointments with health-care providers, written communication between the health-care providers and the school nurse regarding management needs for school, and increased information exchange between the two was seen as something that would be beneficial.[197,204] However, communication between the health-care team and the school nurse was reported to occur often or very often for only one-quarter of nurses.[178] Health providers were often difficult to reach and were too busy to respond to questions.[203] Suggestions for improvement included improving the retrieval of useable information by school staff, such as a specific website where such information was quickly and easily downloadable;[197] the use of other electronic media such as frequent transmission of electronic blood glucose readings, medication regimen updates and messaging could also be key components of patient and physician communication with school nurses.[203]

Barriers and facilitators associated with the role of school teachers

Communication between parents and teachers

School nurses reported that parents were poor at communicating with teachers.[204] One of the most frequent issues specified by parents concerning their level of satisfaction with the management of their child's diabetes during school hours was better communication between parents and schools.[170] Some parents were overprotective and expected the school 'to do absolutely everything' and had a confrontational style of communicating with school personnel.[197]

Most teachers are informed that a child or young person has diabetes;[165,166,170] however, not many physical education teachers are reported to be aware. One parent commented that 'J's teacher didn't know for two years that he was diabetic even though I'd written a letter' (p. 286).[181]

Some parents reported experiencing problems at school after they had informed the school about their child's condition.[166,177,180] This affected as many as 30% of children aged 3–6 years and 7% of children aged > 14 years.[166] In a very small number of cases a child was not accepted into his or her chosen school[166,177,180] or had to change schools.[166,177]

Understanding of teachers

School staff can be instrumental in assisting children to manage their diabetes at school or they can be unsympathetic and unaware of the serious nature of the condition.[180] Some pupils reported that teachers lacked understanding when they needed to leave the class because of their blood glucose levels. For example, one child shared: 'The teachers accept what is going on, except for the teacher I have right before lunch. I have to leave a lot because that is when I get the lowest and he gets really ticked at me' (p. 250).[159]

Understanding teachers were those who (1) were flexible in allowing children and young people to test their blood glucose,[161] (2) allowed them go to the nurse's office in the middle of a class or test,[161] (3) included snack times for the entire class based on the schedule of pupils with diabetes[176] and (4) kept a supply of juice or snacks for pupils with diabetes to use during an emergency.[176] Some pupils (14–45%) reported that they were not allowed to snack in class when they needed to[168,175,182] or that teachers delayed them attending the nurse's office to treat hypoglycaemia.[182]

Support from teachers

The greatest support that pupils received at school came from teachers.[161,164,166,177] However, some teachers spoke of constant surveillance whether in the classroom, in the playground or when supervising pupils with T1D off-site on school trips.[197]

Pupils reported that their teachers made sure that they had their insulin injections,[160] helped them with insulin dosage algorithms,[182] helped with blood glucose monitoring,[160,164,182] had a snack available (62%),[160] reminded them to eat a snack,[161,182] had juice available,[160] helped with lows,[160] had supplies for testing available,[160] helped them to follow a meal plan at lunchtime (17%),[160] helped them to recognise when they were beginning to experience a low (58%),[160] sent them to the nurse right away if they were low (66%),[160] let them test when they needed to (79%),[160] provided a drawer in the classroom for diabetes supplies,[182] read books about diabetes[182] and walked them to see the school nurse.[161]

A small number of children reported that they put off or delayed checking their blood sugar at school, or some even avoided checking their blood sugar altogether, because their teacher might get angry.[158] This finding was significantly associated with adherence to dietary and insulin regimes for children aged 8–11 years but made no difference for adolescents aged ≥ 12 years.[158] Children with good glycaemic control who were satisfied with the support that they received from school were significantly more likely to maintain good glycaemic control than those who were dissatisfied.[160]

As well as the more formal policies a range of strategies and administrative procedures were put in place in a number of schools to care for and monitor children with diabetes. For example, an asterisk was added to a pupil's name in the register to remind class teachers (and to notify supply teachers) that they had a child with special health needs in their class, and emergency documents and health-care information, accompanied by photographs, were positioned at key points within the school.[197]

Liability

School personnel may worry about liability should something go wrong; however, if a member of staff carries out treatment using the agreed procedures and care plans and has received regular training then he or she will be covered by the local authority insurance and cannot be held liable for accidents.[124] A high proportion of school personnel (65%) have expressed concerns about potential liability when caring for pupils with T1D in school,[178] related to concerns surrounding exposure to and interaction with children's bodies, especially other people's children.[197] Some parents reported having difficulties with school staff in the daily management of diabetes, with a small number encountering a refusal to allow self-management of pupils whilst at school.[171,197] Health professionals reported that some teachers were afraid of administering insulin injections, with a minority having a broader belief system in which medical issues were not, or should not be, in their remit. As a consequence, this behaviour would influence the type of insulin regimen that a child was put on.[197]

Teachers' diabetes knowledge and skills

In general surveys (no direct experience of a pupil with T1D) the level of diabetes knowledge was significantly better for women, science teachers, those who did not drink alcohol, those with an ill family member and those who had unsatisfactory perceptions about their general health.[193,194] As would be expected, teachers who had previous experience of diabetes were significantly more likely to know about hypoglycaemia,[196] correctly define hypoglycaemia and know the correct treatment.[195] Having family and friends with diabetes was also of significant benefit in terms of being able to correctly identify symptoms of diabetes and hypoglycaemia and select appropriate treatment for low blood sugar.[195] Teachers with no direct experience of a pupil with T1D felt that they needed more information and advice on diabetes.[192,195] Knowledge levels of regular and special education teachers were similar.[198]

When diabetes knowledge was assessed for teachers in schools in which there were pupils with T1D, between 27% and 40% were found to have adequate knowledge.[191] Primary school teachers were found to have significantly better knowledge than secondary school teachers.[191] The majority of teachers knew what a blood glucose meter was (98%) but only about half (46%) felt that they knew how to operate one; however, they still felt that their knowledge was sufficient.[200]

School nurses felt that school staff needed to improve their diabetes knowledge and that this could reduce barriers to good control at school.[204] Both children and parents felt that teachers had a basic knowledge about T1D and that they were adequately trained to care for children to manage T1D,[166,177,178] although sometimes they reported concerns that there was confusion at school between T1D and T2D.[167]

Pupils reported that they would like teachers to be better informed about diabetes and to have better knowledge about diabetes to help the pupils manage their diabetes in school.[161,176,177] The lack of education was described as being problematic.[176] For example, one adolescent said: 'I don't get the feeling at all that the teachers would know what to do if I fainted or something. If my blood sugar went really low' (p. 167).[176]

Recognising a hypoglycaemic episode

The biggest concern of diabetes HCPs was the ability of teachers to spot the onset of hypoglycaemia and react quickly.[197] Teachers were confident in their ability to be able to recognise the signs of hypoglycaemia (70–71%)[192,200] but were less confident that they would be able to cope with emergencies that arise with blood sugar levels (42–63%).[192,200] Just over one-third of parents[166] and just over 50% of pupils[164] believed that school personnel would be able to recognise a mild hypoglycaemic episode. In the majority of cases the children themselves had been able to resolve such an event, with the greatest proportion of these children being in the ≥ 14 years age group.[166]

Physical education teachers

It is important that staff in charge of physical education or other physical activity sessions be aware of the need for pupils with T1D to have glucose tablets or a sugary drink to hand and be able to recognise the signs and symptoms of hypoglycaemia. In general, pupils reported that they felt that sport coaches needed more education about diabetes[161] but that, for the majority of younger pupils, they were able to recognise the symptoms of hypoglycaemia (63% for those aged < 10 years, 14% for those aged > 14 years).[164] When this was the case, this was really appreciated, for example one adolescent said: 'when I got low when I had swimming practices and stuff, my coach, you know, he'd call me out of the pool. He could tell when I could get low because I couldn't swim straight' (p. 167).[176]

Physical education teachers whose school was attended by at least one pupil suffering from T1D were significantly more likely to have been taught about T1D, to be interested in learning about T1D and to know about hypoglycaemia.[196] Physical education teachers who had experience of teaching a pupil with T1D were not very familiar with diabetes and exercise guidelines and were uncertain about the effects of exercise on long-term blood glucose levels, or about exercise limitations that exist for children with T1D, and none was sure about the optimal HbA_{1c} range for children with T1D.[199]

Education and training

To be able to give appropriate care, staff members need an appropriate level of diabetes education, and this should be relevant to activities that take place on the premises as well as those associated with participation in school trips and camps.[126] It is important that when staff agree to administer blood glucose tests or insulin injections they are trained by an appropriate health professional.[26,98,129,214] Not all pupils, especially young children, will recognise hypoglycaemic symptoms with every episode. All school personnel directly responsible for pupils with diabetes should be educated about signs and symptoms of high and low blood glucose levels.[26,56,122,123,208]

In the USA, three levels of training are suggested:

1. all school personnel should receive training that provides a basic understanding of diabetes, training on how to recognise and respond to the signs and symptoms of low blood glucose (hypoglycaemia) and high blood glucose (hyperglycaemia) and information about who to contact immediately in case of an emergency
2. additional training for school personnel who have responsibility for the student with diabetes throughout the school day (e.g. classroom, physical education, music and art teachers and other personnel such as lunchroom staff, coaches and bus drivers)
3. in-depth training for school staff members designated as trained diabetes personnel and providing routine and emergency care for each student with diabetes from a diabetes trained HCP such as the school nurse or a certified diabetes educator.

Pupils and parents frequently indicated that training in diabetes management would help school staff,[159,170,176,180] especially in how to deal with an emergency diabetes situation.[166,174] When training had taken place it had been the child's parents who had provided it in just under half of cases, and it took the form of an informal conversation, review of educational materials or consultation with a health-care provider.[82] Pupils whose parents reported that school personnel had received training had significantly better HbA_{1c} levels (on controlling for age and type of insulin regime) than those with untrained school personnel.[82]

Only one in five teachers who taught a pupil with T1D, however, expressed a willingness to participate in free training on diabetes.[200] Those teachers who had undergone formal training expressed that this had been both a confidence-building exercise and a panic limitation exercise. The most useful type of training that was offered was in relation to tackling specific diabetes-related issues and different types of things to manage in the classroom.[197]

Most teachers (82%) had received written information about children's diabetes;[167] however, only 22% of both regular education and special education teachers indicated that they felt well informed regarding diabetes.[198] Pupils and parents felt that teachers should receive written instructions to improve the management of T1D and to improve integration at school,[164,166] in particular information about the symptoms and steps to be followed in case of hypoglycaemia, more information about diabetes in general and information regarding the optimal management of emergencies,[177] which should be kept in the classroom and in the common areas.[164]

Teachers who were responsible for pupils with T1D reported that they received the majority of their information about T1D from parents.[191] Secondary school teachers also obtained information from other sources: radio, television, other school staff, teaching literature, newspapers and magazines.[191]

Barriers and facilitators associated with self-management at college/university

Just over half of students (55%) reported that having diabetes interfered with being a student,[135] with the majority (71%) of students finding it more difficult to manage their diabetes in college than in high school,[133] although they learned to overcome these difficulties with time and experience.[186] Students' own perception of blood glucose control at college was variable, ranging from 'better' (36%) to 'worse' (33%), 'no change' (26%) and 'didn't know' (5%).[133] Clinicians' rating of metabolic control was also variable, ranging from 'improved' (30%) to 'worse' (30%) and 'no change' (39%).[133] Assessment of HbA_{1c} readings between high school and college[133] and between the first year and the last year of attendance at university[138] showed no significant change. However, the prevalence of retinopathy was found to have increased from 10.9% to 14.5% by the time that students had finished university.[138]

The reasons selected for any type of change (positive or negative) in college students' diabetes control were diet, exercise, frequency of blood glucose monitoring, increased responsibility, irregular schedule, fear of hypoglycaemia, alcohol use, no parental involvement and contact with health-care provider.[133] Students had difficulties balancing the effects of having diabetes with the student lifestyle.[135] Some students reported reduced participation in social events[189] whereas others felt that having diabetes did not affect their social life.[135] The lack of a perceived routine in university was considered a barrier to effective self-management,[136] with students reporting little or no time to engage in practices such as blood glucose testing,[135,136,184,187,189] exercising,[135,136,187] eating snacks during the day[187,189] and injecting in a suitable environment.[189] Inadequate finances was also cited as a barrier to successful diabetes management[135,136] and depended on how much extra support students received from parents or whether they lived in halls of residence of not.[135] Psychosocial issues were also identified as barriers to diabetes management. These included the inconvenience of diabetes management, motivators for managing diabetes, and social support issues.[136] Students with a positive attitude and good intentions may be unable to engage in desired self-care behaviours when significant barriers or negative emotions are present.[187]

In a desire to appear normal[136,185,189] students try to avoid hypoglycaemia in a social situation[183,189] and often make a conscious decision to 'run high' rather than keep their blood glucose at the recommended level.[189] Many students (especially first-year students) drank alcohol in a way that was risky for their diabetes control in order to identify as 'normal' young students. In a further attempt to appear normal most students acknowledged that they were not as adherent to diet recommendations as they thought they should be.[136,207] It was felt that being a student could affect the type of food eaten, as eating a few more pizzas and take-away meals was all part of being a student.[135] Furthermore, many T1D students did not plan ahead for meals and snacks.[136]

The majority of students reported that they engaged in alcohol consumption practices whilst at university,[135,183,188] often consuming five or more drinks in one sitting.[188] Drinking perceptions included 'students with diabetes can drink if they are careful', 'drinking is the primary social activity at this university' and 'the peer pressure to drink is strong'.[190] There was evidence that as students experienced transitions within university their attitudes towards the risks of drinking changed and, in many cases, their drinking decreased substantially after the first year.[183]

Students reported the following strategies when engaging in alcohol consumption practices: eat before and/or during drinking,[136,183,188,190] keep track of the number of drinks consumed,[188] determine in advance not to exceed a set number of drinks,[136,188,190] avoid drinking games,[188] have a friend let you know when you've had enough,[188] alternate non-alcoholic and alcoholic beverages,[188] pace drinks to one or fewer per hour,[188] choose not to drink alcohol,[190] drink an alcohol lookalike (non-alcoholic beer, punch, etc.)[188] to avoid or diffuse peer pressure,[190] limit the frequency of going out to parties and bars,[190] drink with trusted friends[136,190] who understand the symptoms of low blood sugar that would mimic intoxication[136] and check or monitor blood glucose levels.[184,190] Students reported that they usually tested at home, in more private spaces, before and after going out, rather than while they were out.[184]

Younger students mainly engaged in alcohol consumption practices that were risky for their diabetes control in public spaces where they felt that there would be a risk to their identities as normal young people if they did not engage in these practices.[183] Younger students were more likely to rely on a friend to let them know when they'd had enough and to keep track of how many drinks they were having.[188] In contrast, the strategies of pacing drinks and avoiding drinking games were more common among older students.[188]

Students felt that they did not receive adequate support from their college or university and/or their diabetes team to enable them to balance the demands of further education and the management of their condition.[189] Some students preferred to continue to receive care from their diabetes team in their home town.[135]

Methodological quality: non-intervention studies – stream 2

The methodological quality of the non-intervention studies (stream 2) is presented in *Appendix 3* (see *Study methods, quality appraisal and summary of results: stream 2*) and summarised below.

The overall quality of the papers in the non-intervention stream varied. Although 55 (100%) studies identified the study aims, fewer studies ($n = 45$, 82%) provided sufficient detail about sampling and recruitment. A total of 55 studies (100%) provided an adequate description of the context of the study and 55 (100%) studies provided a clear specification of the research design.

The information provided about data analysis was variable. Although 51 studies (93%) provided a clear description of data collection, only 39 (71%) provided a clear description of data analysis. Questionnaires were analysed using descriptive and inferential statistics to examine the proportions of participants responding in a particular way, with inferential statistics being used to investigate the strength of associations. When the method of qualitative data analysis is given, it is described as being content analysis or thematic analysis.

Many studies used investigator-designed questionnaires and most of these studies ($n = 26$, 47%) often involved non-validated questionnaires or did not give enough detail to appraise whether the measures were valid, reliable and reproducible, and did not attempt to discuss how rigour had been established. Overall, generalisability was considered to be limited or not possible.

Ethical issues were discussed in 45 studies (82%). In total, 49 studies (89%) included sufficient original data to support the interpretations and conclusions.

Overarching synthesis of findings from streams 1 and 2: stream 3

Overall, the interventions in stream 1 aimed to provide additional targeted help and support for children to enable them to self-manage their diabetes in schools or to increase knowledge and awareness of school nurses and staff and to encourage better communication with diabetes professionals. These foci broadly match with children's and parents' views and experiences of what needs to be done to optimise children's diabetes self-management in educational settings.

We produced an overarching synthesis matrix that juxtaposed barriers and facilitators alongside results of interventions (*Table 19*). Although some evidence maps across, there are important gaps between what children, young people and parents say are barriers to optimal diabetes self-management in school and robustly evaluated interventions that seek to tackle these issues.

TABLE 19 Overarching synthesis matrix: streams 1 and 2

Views on barriers and facilitators		Interventions that address barriers or build on facilitators	
Barriers	**Facilitators**	**RCTs**	**Non-RCTs**
Self-management in school: insulin regime			
Lack of support for insulin administration,[164,166,175] especially for younger children[157,162,164,167,169,171]	Support for insulin administration for younger children[164,179,167,171]	Supervision of insulin administration by school nurse for those pupils with poorly controlled T1D[145]	None identified
Self-management in school: blood glucose monitoring			
Lack of assistance with blood glucose monitoring, especially for younger children[166,178]	Assistance with blood glucose monitoring and the interpretation of results for younger children[164,167,169,177]	Blood glucose reading checked by school nurse for those pupils with poorly controlled T1D[145]	A school-based diabetes care programme involved a review of school blood glucose readings with the pupil and the school. Concerns about the in-school management plan were addressed when needed[150]
Self-management at college/university			
Infrequent contact with health-care provider;[189] alcohol use;[135,183,190] lack of perceived routine with little or no time to engage in self-care practices;[135,136,184,187,189] poor adherence to dietary recommendations;[136,207] inadequate finances[135,136]	Ability to balance diabetes and the student lifestyle;[133,135,186] strategies in place when engaging in alcohol consumption[136,183,184,188,190]	None identified, research gap	The intervention 'Control on Campus' aimed to increase knowledge and improve the attitudes of students with T1D[155]

TABLE 19 Overarching synthesis matrix: streams 1 and 2 (*continued*)

Views on barriers and facilitators		Interventions that address barriers or build on facilitators	
Barriers	**Facilitators**	**RCTs**	**Non-RCTs**
School culture: school care plans			
Generic polices that that do not take into account the needs of pupils with T1D;[176,180] pupils do not have written care plan[167,168,178]	School nurses felt that individual health-care plans that set out the components of diabetes care in school were important[204]	None identified	A school-based case management approach involved the development of an IHP and an emergency action plan with specific goal setting as appropriate for each pupil[148]
School culture: suitable locations			
Lack of a private location for insulin administration and blood glucose monitoring[168,175,180]	Access to a private location for insulin administration and blood glucose monitoring[163,167,168,182]	None identified	None identified
School culture: regular snacks			
Not being allowed to eat snacks when needed[176,180]	Permission to be able to eat a snack during the day as required[165,175]	None identified	None identified
School culture: participation in physical education lessons			
No strategies in place to enable participation in sport at school[159–161,170,171]	Strategies in place so that pupils can participate in sport at school[166,180]	None identified	None identified
School culture: extracurricular activities			
Lack of support during after-school activities;[169,182] problems with pupils being allowed to participate in school-day or extended trips[164,166,167,170,177]	Parents and school nurses felt that school care plans should include strategies for after-school care;[161,204] specific policies in place in relation to school trips[180]	None identified	None identified
School culture: feeling different			
School nurses felt that pupils being made to feel 'different' from their peers acts as a barrier towards self-care[157,203]	Support from peers considered important;[160,161,180,182] pupils felt that peers being informed about their condition and having information about diabetes was important[161,164,175]	None identified, research gap	None identified
School-based facilities: food availability at the canteen			
Unhealthy choices available in the school canteen;[176,178,203] lack of information about foods served, portion sizes and carbohydrate content of foods available[182]	Ensuring that snacks and appropriate food and drink are available;[174,166,170,204] nutritional labelling on food choices[176]	None identified	As part of the school-based diabetes care programme pupils and school nurses were provided with school menus that included carbohydrate servings for all food items listed so that they could easily ensure that students' individualised meal plans were followed in school[150]

continued

TABLE 19 Overarching synthesis matrix: streams 1 and 2 (*continued*)

Views on barriers and facilitators		Interventions that address barriers or build on facilitators	
Barriers	**Facilitators**	**RCTs**	**Non-RCTs**
School-based facilities: accessibility of own snacks and supplies			
Pupils prevented from having easy access to supplies and equipment at all times[165,203,204]	Diabetes supplies and equipment to be stored at appropriate locations and accessible at all times[161,180,197]	None identified	None identified
School-based facilities: availability and accessibility of glucagons			
Lack of remedies and trained personnel for treatment of severe hypoglycaemia[164,166,168]	Availability of glucagon for the treatment of severe hypoglycaemia and personnel trained in its administration[164,166]	None identified	None identified
School-based facilities: flexible accommodation with examinations and tests			
Pupils unable to retake examinations if experiencing hypoglycaemia or hyperglycaemia[164,177]		None identified	None identified
The role of school health-care personnel: support			
Lack of adequate daily support from the school nurse[161,204]	Availability of a school nurse every day during school hours,[164,166,170] especially for younger children;[161] support from the school counsellor for non-medical diabetes-related problems[182]	Supervision of insulin administration and blood glucose readings checked by the school nurse for those pupils with poorly controlled T1D[145]	None identified
The role of school health-care personnel: communication with health-care providers			
Poor communication with health-care providers and the school nurse[178,203]	Having regular appointments with health-care providers and written communication between the health-care providers and the school nurse regarding management needs for the school and increased information exchange between the two was seen as something that would be beneficial[197,204]	The telemedicine intervention involved the school nurses being able to exchange graphical and tabular blood glucose measurement information with the diabetes centre nurse practitioner[146]	A school-based diabetes care programme sought to strengthen collaboration between school health personnel and the children's diabetes centre staff to resolve diabetes-related school problems and enhance diabetes management[150]
The role of school health-care personnel: diabetes knowledge and skills			
Nurses reported low levels of diabetes knowledge;[203] pupils felt that knowledge could be improved;[161,176] difficulties in getting to grips with CSII therapy;[172,206] nurses rated themselves as moderately confident;[201] nurses feel inadequately prepared to assist a pupil with hypoglycaemia[178]		None identified, research gap	A school-based diabetes care programme sought to increase confidence of school nurses;[150] a continuing education programme sought to increase the competence of school nurses;[153] an online continuing education programme sought to increase the competence of school nurses[154]

TABLE 19 Overarching synthesis matrix: streams 1 and 2 (*continued*)

Views on barriers and facilitators		Interventions that address barriers or build on facilitators	
Barriers	**Facilitators**	**RCTs**	**Non-RCTs**
The role of school health-care personnel: education and training			
Lack of time to access education and regular updates[203]	Access to up-to-date information;[201] diabetes knowledge and skills updated on a regular basis[201]	The telemedicine intervention made available an 18-module educational curriculum for school nurses[146]	A school case management approach provided training to all school nurses that reviewed the principles of case management[148]
The role of school teachers: communication with parents			
Teachers unaware that a pupil has T1D;[181] problems experienced as a result of informing the school about a pupil's T1D[166,177,180]	Teachers informed that a pupil has T1D[165,166,170]	None identified, research gap	None identified
The role of school teachers: understanding of teachers			
Lack of understanding when pupils need to leave the classroom to manage their diabetes;[159,182] pupils not allowed a snack in class[168,175,182]	Awareness of the needs of pupils with T1D in their classroom[161,176]	None identified	None identified
The role of school teachers: support from teachers			
Fear of liability of school staff[197]	Teachers prepared to support a pupil with diabetes on a daily basis[158,160,197]	None identified	None identified
The role of school teachers: diabetes knowledge			
Lack of diabetes knowledge of school personnel;[161,176,177,199,204] diabetes HCPs' biggest concern was the ability of teachers to spot the onset of hypoglycaemia and react quickly[197]	Both children and parents felt that teachers had a basic knowledge about T1D and that they were adequately trained to care for children to enable them to manage their T1D.[166,177,178] Teachers felt that they had the skills necessary to deal with emergency situations,[192,200] pupils felt that physical education teachers needed to be able to recognise the signs and symptoms of hypoglycaemia[164,176]	The telemedicine intervention made available an 18-module educational curriculum for school personnel;[146] a CD-ROM teaching tool containing basic diabetes information targeted at teachers to improve their knowledge and confidence of T1D[147]	The '5 Cs of Diabetes' lecture-based programme for school personnel seeking to improve diabetes knowledge;[149] school-based diabetes care was implemented that involved diabetes education for pupils and school personnel within the context of daily diabetes management for pupils with problems with persistent hypoglycaemia or hyperglycaemia[150]
The role of school teachers: education and training			
Pupils and parents felt that school personnel would benefit from receiving written information about T1D;[164,177] teachers unwilling to participate in diabetes training[200]	The majority of information about diabetes received from parents;[191] training in diabetes management for school staff seen as beneficial,[159,170,176,180,182] especially in how to deal with an emergency diabetes situation[166,174]	None identified, research gap	An investigation of the effects of disclosing information about T1D with implications for classroom learning and behaviour[151,152]

Implications of the systematic review findings for EPIC intervention development

Evidence from the systematic review helped with our understanding of the significant challenges that children and young people with T1D face when away from their parents and attending school, college or university. At the project proposal stage we had already specified that we would develop a T1D educational intervention primarily focusing on children and young people. Nonetheless, review findings also pointed to the significant and unmet needs of schools, teachers, school nurses and health-care assistants, and insufficient communication between parents, teachers and diabetes professionals in supporting pupils to optimally self-manage.

Best practice guidelines provided a template for the implementation of optimal support of children and young people in schools and wider educational settings, but there were obvious failures to translate best practice into local school policies and practices.

We opted not to widen the EPIC intervention focus to address all identified gaps. The following issues were flagged as being particularly important for EPIC intervention development, with a primary focus on blood glucose and insulin self-management by children and young people:

- young people at university lacked wider lifestyle information on living with diabetes
- children and young people at school wanted to fit in and be seen as 'normal' and not defined by their diabetes
- in a school context, children's perceptions of 'normal' were different from the dominant discourse of 'normalisation of medicines management and insulin as a social enabler' highlighted in *Chapter 2*
- children and young people found making appropriate food choices whilst at school challenging and often did not know how many carbohydrates they had consumed whilst at school
- pupils and parents felt that school personnel would benefit from access to written information about T1D
- school friends and peers would benefit from access to written information about T1D.

The next chapter reports the intervention development phase of the EPIC project.

Chapter 4 Stage 2: EPIC intervention development

Introduction

In this chapter we report findings from stage 2 of the EPIC study to develop an age-appropriate child-centred diabetes information pack and diabetes diaries for children and young people ('the intervention') to support the appropriate use of blood glucose monitoring to optimise management of and concordance with their insulin regime.

The empirical evidence base for developing the EPIC intervention came partly from previous work conducted for the IMP.[1] In addition, contextual work commenced in the IMP was extended in the EPIC study with a specific focus on diabetes information available to children and young people with T1D and their families. Specific aspects of this work have been reported in full in *Chapters 1–3*. Extended qualitative fieldwork informing intervention development is presented in this chapter.

We then report the process of integrating the evidence, expert opinion and children's feedback to develop the EPIC diabetes information pack and diabetes diaries. EPIC intervention programme theory and logic are explained at various key points of intervention development.

Evidence from the Information Matters Project

The empirical basis for developing the EPIC intervention was informed by all stages of work in the parallel IMP.[1] In *Figures 9* and *10* we summarise the key evidence from the IMP[1] and cross-reference the appropriate chapters for a full account of the work previously undertaken.

Evidence from the EPIC project

The empirical evidence base for developing the EPIC intervention was further informed by extending contextual work previously undertaken as part of the IMP and refocusing specifically on diabetes-related health information available to children and young people with T1D and their families, as shown in *Figure 9*.

Please see *Chapter 3* for the systematic review and *Chapter 2* for the extended analysis of the content of clinical guidelines and a comparison between these guidelines and selected children's diabetes resources and for the extended CDA of children's diabetes information.

Key evidence from these streams of work is summarised within each chapter and reproduced in a summary table of key evidence informing intervention development (*Table 20*).

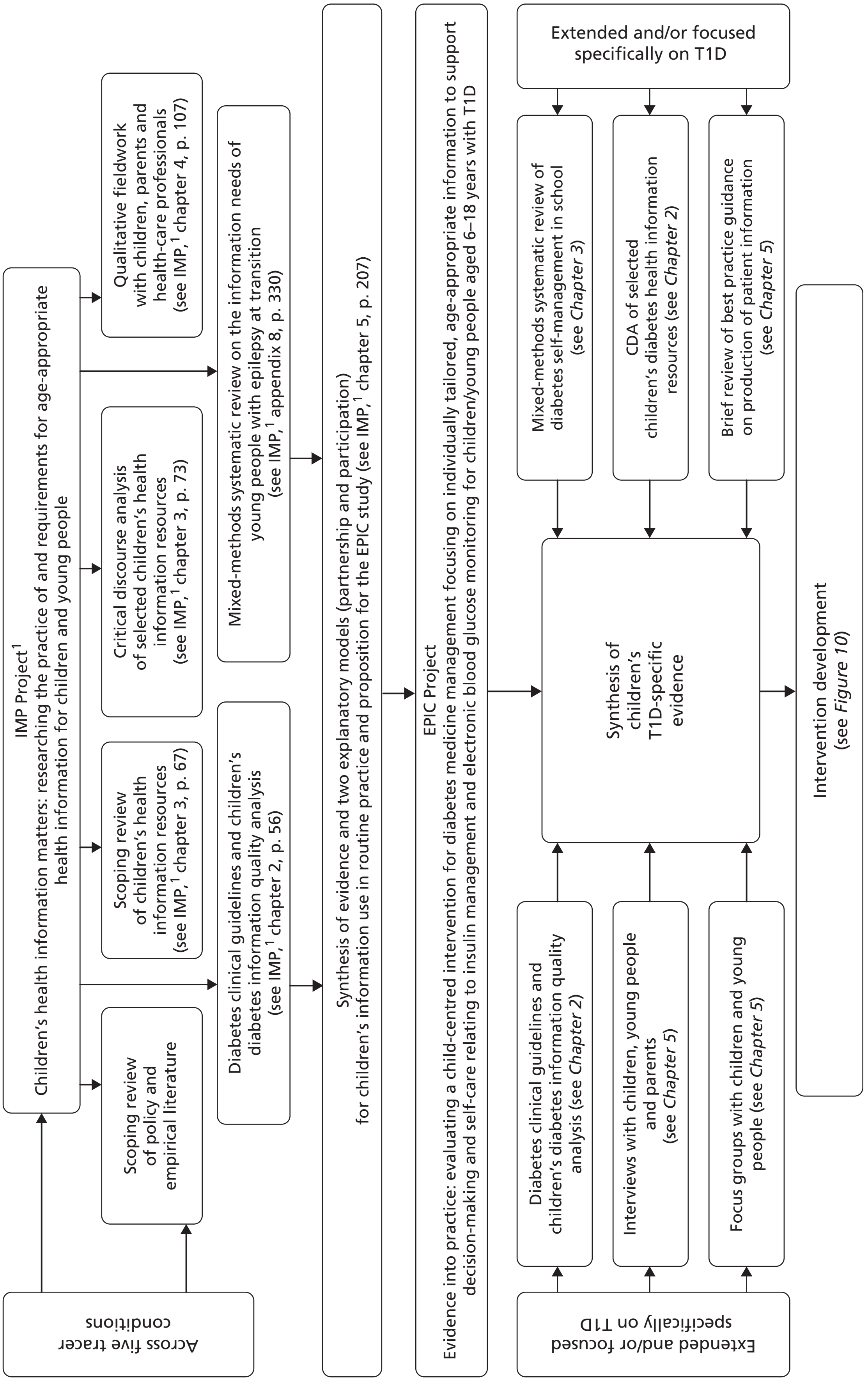


FIGURE 9 Flow diagram of evidence informing EPIC intervention development.

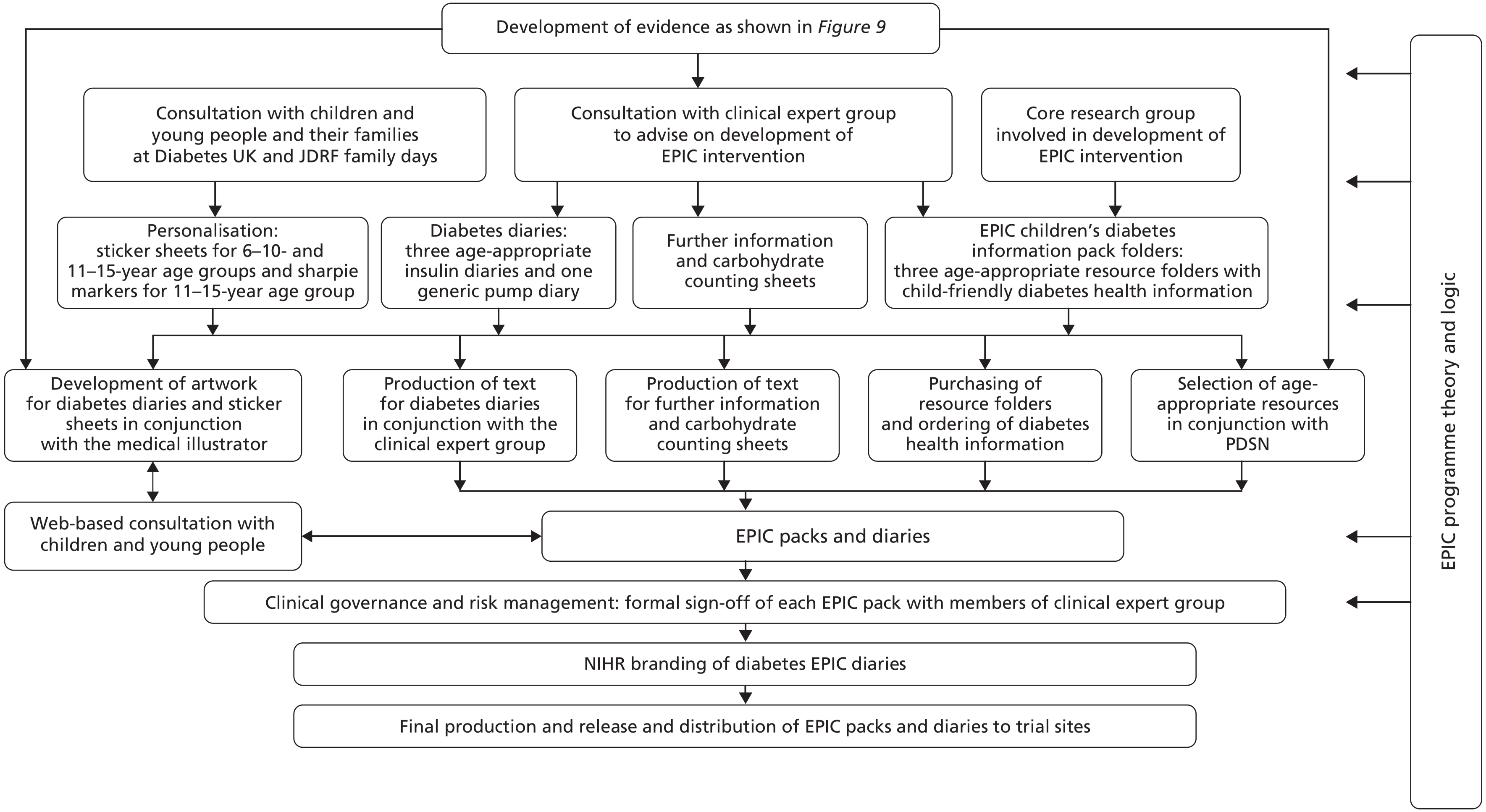


FIGURE 10 Flow diagram of EPIC intervention development elements and processes.

TABLE 20 Table of selected evidence used to develop the EPIC diaries and information packs and underlying programme theory and logic

Stream of evidence	Evidence from the IMP	Translation into EPIC intervention and programme theory
Conceptual model development	• Development of integrated conceptual model (MRC framework, PARiHS and biopsychosocial anthropological model)	• Same model used in EPIC project
Comparison of diabetes clinical guidelines and key messages in children's diabetes information	• Keeping a diabetes diary is the central component of optimal diabetes self-care and management • Children's diabetes clinical guidelines set out optimal ranges for HbA_{1c} • Children's diabetes information was not always consistent with clinical guidelines for self-monitoring of blood glucose and did not appear to be consistently based on gold standard evidence-based guidelines • Children's diabetes information resources were far less specific than clinical guidelines for self-monitoring of blood glucose, and presentation of key information and messages was sometimes vague and open to interpretation	• Development of age-appropriate diaries for children and young people as a central component of the wider EPIC information intervention • Need to screen diabetes information resources for quality and not select vague or inaccurate resources for inclusion in the EPIC packs • EPIC intervention to fit with current children's diabetes guidelines and pathways with minimal manipulation of current service
CDA of sample of children's diabetes information	• Involve children and young people in the production of health information • Insulin is presented as a social enabler and the dominant discourse is to 'normalise' the condition • Choice of images and text in children's health resources is very important • Producers of children's health information need to take specific account of the meanings that may be attributed by child readers to the location and portrayal of children and their families in images • It is also important to consider the additional unintended meanings that can be attributed to the way that text is written and presented to the child • Findings demonstrate the importance of involving children and young people in the production of health information to establish whether key messages conveyed are received and interpreted as intended • There are three different types of empowerment: medical empowerment, patient empowerment and identity empowerment	• Children actively involved at key stages of EPIC intervention development • Normalisation discourse translated/continued in EPIC intervention • Consideration given to the meaning and context of images and text in EPIC packs and diaries. Realistic and true-life stories regarding insulin administration and use presented in the EPIC packs • Process evaluation designed to capture whether key meanings and messages are received and interpreted as intended • Process evaluation designed to explore whether young people feel 'empowered' or not • EPIC packs and diaries to be actively promoted and described to children and young people with T1D by the PDSNs involved in their care • Launch events in trial sites to convey child-centred and age-appropriate communication techniques and intention to integrate packs and diaries into routine clinical encounters and actively promote them

TABLE 20 Table of selected evidence used to develop the EPIC diaries and information packs and underlying programme theory and logic (*continued*)

Stream of evidence	Evidence from the IMP	Translation into EPIC intervention and programme theory
	• Empowerment depends not only on how well the child or young person understands the information that he or she receives through the presentation of facts and advice, but also on the discourse used to convey these facts	
Qualitative fieldwork with children, parents and HCPs across five tracer conditions	• Children's preferences for presentation of information vary by age • Age-appropriate information is important • Younger children liked cartoons • Children and young people wanted realistic and meaningful information that fits with their age, circumstances (family, home, school, college) and differing health needs along condition-specific trajectories • Information should be high quality, relevant, contemporary and shared at key information points, e.g. diagnosis, starting school, changing school, growing up with the condition, lifestyle issues and transition to adult care • Written information is required to support verbal information given in consultations and needs to be more detailed (not basic) but less scientific (use of lay language) and up to date • Children generally placed greater importance on the format, presentation and relevance of the resource and less importance on the type (leaflet, book, website, DVD), although children and young people generally disliked detailed textbooks • Children's health information needs changed over time and updating was required at key time points	• Three separate EPIC packs were created with age-appropriate information for three different age groups (6–10 years, 11–15 years and 16–18 years) • EPIC packs to be individually tailored with information added or removed from the packs as appropriate • Personalisation of the packs taken into account • Realistic and true-life stories were presented in the EPIC packs in written and audio (DVD or CD-ROM) formats, with signposting to appropriate websites • Real-life photographs for older children and cartoons for younger children
Scoping review of children's health information resources	• Information resources were of variable quality and many lacked child-centred, age- and culturally appropriate and accurate information • There was limited information on growing up with the condition and transition and access to services	• All information presented in the EPIC packs was assessed for quality • Information on lifestyle issues was sourced and included in the EPIC packs for 11–15 year olds and 16–18 year olds

continued

TABLE 20 Table of selected evidence used to develop the EPIC diaries and information packs and underlying programme theory and logic (*continued*)

Stream of evidence	Evidence from the IMP	Translation into EPIC intervention and programme theory
Scoping review of policy and empirical literature	• In policy, children's health information is conceived as a key component of teaching children and young people to manage their condition • No conclusions could be drawn about the most effective ways to design, deliver and evaluate the use of children's educational and health information interventions to promote choice, self-care and decision-making	• EPIC packs and diaries fulfil policy requirements • The EPIC project was designed to evaluate the usefulness and effectiveness of a new information resource for children and young people with T1D
Mixed-method systematic review of the information needs of young people with epilepsy at transition	• Age-appropriate communication and child-centred approaches to managing clinic appointments are critical success factors for engaging children and young people • Teenagers with epilepsy disengage with services when the focus is not on them and their needs, or if the focus of communication is between the clinician and their parents • Many young people with epilepsy enter adult services ill-equipped to self-care and manage their epilepsy	• The EPIC packs were designed to be tools that would enable discussion between health-care providers and children and young people with T1D in clinical and home settings • Active facilitation of the EPIC intervention by diabetes professionals using age-appropriate and child-centred communication and techniques • Consideration of the clinic context for implementation of the EPIC packs
Overarching synthesis from the IMP	• Proposition • A new theory of the critical success factors for successful translation of children's health information into routine NHS practice was developed	• Proposition and theory used in EPIC intervention development, RCT and process and economic evaluation
Stream of evidence	• Evidence from the EPIC project	• Translation into EPIC intervention and programme theory
Guidance on producing patient information	*Conveying information*: • ensure that clinical evidence base is accurate and up to date • avoid technical vocabulary • use short sentences • use headings *Intended readers*: • take into account patients' reading skill/level • relevant to target audience and meets their needs • target readership clearly stated • take into account lived experiences	• All principles used to inform EPIC intervention development

TABLE 20 Table of selected evidence used to develop the EPIC diaries and information packs and underlying programme theory and logic (*continued*)

Stream of evidence	Evidence from the IMP	Translation into EPIC intervention and programme theory
	Content: • space for recording personal information and questions • named space for readers' notes • point to additional sources of support and information *Authors*: • appropriate authorship • user involvement (i.e. patients, carers) • involve HCPs • clear statement of authors and agencies involved • clear statement of persons or entities who financed the document • publication should be independently reviewed and approved by an expert *Presentation*: • good-quality paper, good use of colour and good layout • well presented • logo of issuing body • date information was produced	
Extended comparison of diabetes clinical guidelines and key messages in children's diabetes information	• Diabetes diary is conceived as a key element in children's optimal diabetes self-care and management • Every child with diabetes is encouraged to complete the diary every day, look for trends and administer their insulin dose accordingly • The most recently published children's diabetes information resources most accurately reflect optimal diabetes self-care clinical guidelines • Insulin management varies for different children and young people depending on factors such as lifestyle (e.g. exercise, diet), cognitive ability, culture, age, weight, school issues, adherence/concordance with treatment, child and parent choice and consultant's preference • The risk of long-term complications is not mentioned in diabetes information for younger children aged 6–10 years and 11–15 years	• As above • Diabetes self-management information in the EPIC packs and diaries reflected current high-quality and accurate guidance on optimal diabetes self-care • EPIC packs designed for all types of insulin regime • Diabetes clinical guidelines on children's optimal self-management used in the RCT and process evaluation as best practice benchmark • Post hoc acknowledgement that children's diabetes information does not reflect the risks of poor self-management; process evaluation designed to explore risk perceptions • Clinical risk management and governance process followed

continued

TABLE 20 Table of selected evidence used to develop the EPIC diaries and information packs and underlying programme theory and logic (*continued*)

Stream of evidence	Evidence from the IMP	Translation into EPIC intervention and programme theory
	• There is a need to update the content of children's diabetes health information to reflect the updated gold standard clinical guidance of 2009[33] • Children's diabetes health information did not usually carry a quality badge indicating that it was suitable for use in the NHS and it was unclear what (if any) quality assurance processes had been followed	
Extended CDA of selected children's diabetes health information	• Greater understanding of how insulin is represented throughout the texts as a social enabler • Children and young people with T1D want to be seen as 'normal'; they do not want to be different from their peers • Authoritarian voice is used to convey important information • Risks and long-term complications of diabetes do not feature highly, especially in information for younger children • Adult diabetes information is explicit about long-term risks and complications • Branding of information resources legitimises and instils confidence	• As above • Key 'normalisation' discourse adopted – insulin as a social enabler; if children and young people optimally self-manage with insulin their lives will be 'normalised' • Authoritarian voice used to convey top 10 tips for optimal self-management in the diabetes diary • Post hoc acknowledgement that children's diabetes information does not reflect the risks of poor self-management; process evaluation designed to explore risk perceptions
Mixed-methods systematic review of diabetes management in educational settings	• Young people at university lacked wider lifestyle information on living with diabetes • Children and young people at school wanted to fit in and be seen as 'normal' and not defined by their diabetes • In a school context, children's perceptions of 'normal' were different from the dominant discourse of 'normalisation of medicines management and insulin as a social enabler' highlighted in *Chapter 2* • Children and young people found making appropriate food choices whilst at school challenging and often did not know how many carbohydrates they had consumed whilst at school • Pupils and parents felt that school personnel would benefit from access to written information about T1D	• Wider lifestyle information and information about managing diabetes at university included in the 16–18 years pack • Portable information packs and hand-held EPIC diaries, which included 'sick-day rules', were produced • Exploration of 'normalisation' built into the process evaluation • Diary covers did not reflect 'diabetes' as a discourse so would be seen as a diary and not a diabetes diary • Carbohydrate counting charts developed and included in EPIC packs • Written guidance for children and young people included in the pack encouraging them to share information with friends and teachers as appropriate

TABLE 20 Table of selected evidence used to develop the EPIC diaries and information packs and underlying programme theory and logic (*continued*)

Stream of evidence	Evidence from the IMP	Translation into EPIC intervention and programme theory
	• School friends and peers would benefit from access to written information about T1D	
Focus groups with children and young people	• Children wanted diabetes information resources that are organised and that reflect how diabetes is experienced in 'real' life • Children wanted age-appropriate and interesting images/formats • Children wanted to be able to choose from a wide selection of resources that reflect individual interests and lifestyles beyond the specific diabetes focus • Children wanted information to be organised into sections • Those aged 6–10 years wanted information on diagnosis and basic diabetes management and how the body worked • Those aged 11–15 years wanted information on growing up and their changing body and things that happen to them as they grow up • Children aged 6–15 years primarily wanted to receive information from their PDSN • Some wanted information on carbohydrate counting • Diabetes diaries need to use appropriate non-technical language with sufficient space to record information	• As above • EPIC packs were designed to be individually tailored to meet each child's needs • EPIC folders were chosen with partitions to organise information into sections • The content of age-appropriate EPIC packs was designed to match age-appropriate information preferences • EPIC packs were designed to be integrated in routine diabetes NHS care pathways and actively promoted by PDSNs/diabetes teams • Carbohydrate counting sheet produced for the EPIC packs • Age-appropriate diabetes diaries were designed with non-technical language and with space to record information
Interviews with children, young people and parents	• Diabetes information needs to vary by age group • Provision of written information was appreciated and individual information leaflets for quick access to relevant information were preferred to more comprehensive textbooks (all ages) • Information preferences included timely information through the diabetes journey and individually tailored and appropriate information resources that were appealing for the intended audience (all ages) • Information provision was patchy with most received around diagnosis • Children and young people receive/like to receive most of their information from PDSNs	• As above • A variety of leaflets, DVDs and small booklets were included in the age-specific EPIC packs • Children and young people would receive the EPIC pack and diary at any stage of their diabetes journey • EPIC packs could be added to as necessary and outdated information could be removed • Age-appropriate programme theory developed

continued

TABLE 20 Table of selected evidence used to develop the EPIC diaries and information packs and underlying programme theory and logic (*continued*)

Stream of evidence	Evidence from the IMP	Translation into EPIC intervention and programme theory
	• Parents primarily took responsibility for the diabetes management of younger children • Children were taught to take more responsibility as soon as appropriate and especially when attending school • Younger children wanted information about the causes of diabetes • All children and young people expressed the need for individually tailored, age-appropriate and updated information as needs changed over time • The size of a diabetes record diary is important; children need to be able to write in it and young people want to be able to put it in their back pocket • Young people needed information on a wide variety of lifestyle issues such as alcohol, pregnancy and taking part in sporting activities • Most children, young people and families were not aware that information was available in other formats, e.g. DVDs, and were not confident about knowing where to look on the internet for accurate information	
Consultation with clinical expert group	• Clinical experts acknowledged the information gap, approved the sizes of the EPIC diaries and suggested that a separate insulin pump diary would be needed for children and young people on insulin pump therapy • The clinical experts confirmed that lifestyle issue leaflets should go into the 11–15 years age group pack as well as the 16–18 years age group pack • Clinical experts confirmed that the EPIC packs and diaries needed to slot into routine diabetes care	• Four EPIC diabetes diaries were produced (three for insulin injection and one for insulin pump therapy). The sizes of the insulin diaries were A5, A6 and A7. The universal insulin pump diary was A5 in size • As above • The EPIC RCT trial was designed to integrate into routine diabetes care and existing care pathways
Consultation with children and young people	• Children and young people approved the sizes of the EPIC diaries and images used within them • Children and young people provided information for ‘top tips’ in the EPIC diaries	• The EPIC packs and diaries matched with children’s and young people’s preferences • ‘Top tips’ on diabetes self-management using an authoritarian voice were included in each of the EPIC diaries

Best practice guidance and empirical evidence on producing health information

We also consulted best practice guidance and empirical evidence on producing health information and, although little evidence was located specifically on producing children's health information, some general best practice principles were helpful in conceptualising the design features that constitute a 'good' information resource[64,74,215–221] (*Box 28*). We used these principles in age-appropriate ways to develop the EPIC intervention (see *Figure 10*).

BOX 28 Guidelines for producing patient information leaflets

Conveying information:

- ensure that clinical evidence base is accurate and up to date[215–217]
- avoid technical vocabulary[74,218]
- use short sentences[218]
- use headings.[74]

Intended readers:

- take into account patients' reading skill/level[216,219]
- relevant to target audience and meets their needs[217]
- target readership clearly stated[220]
- take into account lived experiences.[64]

Content:

- space for recording personal information and questions[220]
- named space for readers' notes[220]
- point to additional sources of support and information.[220,221]

Authors:

- appropriate authorship[215]
- user involvement (i.e. patients, carers)[217,218,220]
- involve HCPs[216,220]
- clear statement of authors and agencies involved[218,220]
- clear statement of persons or entities who financed the document[218,220]
- publication should be independently reviewed and approved by an expert.[221]

Presentation:

- good-quality paper, good use of colour and good layout[220]
- well presented[215,217]
- logo of issuing body[218,221]
- date information was produced.[218,221]

Qualitative fieldwork with children and young people and their families

We sought to conduct approximately three focus groups (see *Focus groups*) and 20 interviews (see *Semistructured interviews with children, young people and parents*) to explore children's perspectives on currently available children's diabetes information resources and to ascertain the diabetes information needs of children and their families and how and when they use diabetes information resources to support decision-making concerning choice and self-care. We also sought to interview children and young people with T1D who live away from their families in the short, medium or long term (the 'hard-to-reach' population). We had previously conducted 11 interviews with parents and eight interviews with children and young people with T1D for the IMP.[1] For the purposes of intervention development, a further 12 interviews with children and young people, with or without their parents, were undertaken to gain additional perspectives on diabetes information use and preferences.

Various approaches were used to identify children and young people with T1D and their parents and recruit them into the study. The study was registered with the MCRN, the Diabetes Research Network (DRN), the Children and Young People's Research Network and the Clinical Research Collaboration Cymru (CRC Cymru) (now the National Institute for Social Care and Health Research Clinical Research Centre) to utilise their resources and expertise in gaining access to study sites and facilitating recruitment. Children and young people with T1D aged between 6 and 18 years were recruited from hospital outpatient clinics in sites not involved in the subsequent RCT and in locations that could potentially provide an opportunity to recruit from a range of socioeconomic and ethnic groups. This process was facilitated by the MCRN and CRC Cymru.

Focus groups

Focus group method

Age-appropriate focus groups[222] were facilitated to gain an in-depth understanding of what and who influence children and young people in terms of conveying T1D information and health messages and to capture their views on types and preferred formats of diabetes information resources.

Sampling strategy for focus groups

Children and young people with T1D aged between 6 and 18 years were recruited to participate in the focus groups. Our sampling strategy was to identify 8–10 children for each focus group across three age groups: 6–10 years, 11–15 years and 16–18 years. Local diabetes HCPs, with the support of MCRN nurses, identified children and their families, who were then sent a study information pack on behalf of the EPIC research team. Children and their families who were interested in participating completed contact forms and returned them to the research team who then made contact and arranged attendance at the focus groups. Focus groups were conducted in suitable, local, child-friendly venues, for example leisure centres.

It is widely recognised that engaging children and young people with T1D in group activities related to diabetes, particularly outside the clinic setting, is notoriously difficult. Children live with diabetes on a day-to-day basis and dislike it spilling over into their social life. Recruiting them to participate in a research study is even more challenging given the need to work through third parties, for example HCPs, whose enthusiasm, commitment and goodwill are imperative to facilitate the process.[223] The final participant numbers are described in *Focus group findings*.

Facilitation of focus groups

Focus groups were structured around a range of age-appropriate and child-centred activities to facilitate interactions with and the contribution of children (see *Appendix 4*, *Example of focus group schedule: children aged 6–10 years*). The focus groups were video recorded and lasted for approximately 2 hours, excluding time for refreshments/debriefing. Photographs were taken of data collected on wall charts. Two researchers were present; one facilitated the discussion whilst the other operated the video recorder.

MCRN nurses supported administration and registration. Participants received travel expenses and a £20 high street voucher as a ‘thank you’ for their time.

Resource selection for focus groups

Media sources of information (e.g. DVDs, television, internet, books, leaflets) were used to stimulate discussion with children (the scoping exercise of currently available children’s health information has been reported in *Chapter 2*). A selection of available age-appropriate diabetes information resources was chosen to provide a contrast between different types of format (see *Appendix 4*, *Information resources used as part of the focus groups*).

Thermometer rating scale task

During the focus group session, the facilitator asked a question about what kind of diabetes information children and young people would like to receive in a specific context and how they would like to receive it. The thermometer rating scale task involved showing children and young people a large printed thermometer rating scale, which was placed on the wall, and a range of laminated images of possible providers and types of diabetes information. The resource images included leaflets, books, DVDs, a support group, a home telephone, a mobile telephone, a photograph of a nurse, a photograph of a doctor, an internet messaging board, a web forum and an e-mail.

Following presentation of the ‘provider’ image, children and young people had to say or demonstrate what they thought of the method of communicating the specific type of diabetes information in a specific context. Children would shout a number from the thermometer rating scale or demonstrated with laminated ‘thumbs up’ or ‘thumbs down’ signs to indicate whether they liked getting information in that way or not. Consensus agreement was reached before the facilitator placed the appropriate image on the wall-mounted thermometer. At the end of the provider rating task the facilitator summarised the findings and asked the children whether they wanted anything changed. The facilitator then displayed the final agreed image position on a thermometer rating scale using sticky tack (*Figure 11*).

FIGURE 11 Wall-mounted ‘thermometer’ for rating scale task.

Qualitative analysis of focus group data

Focus groups were video recorded and the audio data transcribed verbatim. Ritchie and Spencer's[144] thematic framework analysis approach was used to analyse the data using ATLAS.ti™ software (version 6.2.27, ATLAS.ti, Berlin, Germany). This involved the following five steps: familiarisation (reading transcripts and listening to tapes in detail to gain an overview of content), thematic analysis (developing a coding scheme), indexing (applying the codes systematically to the data), charting (rearranging the data according to the thematic content to allow comparative analysis) and mapping and interpretation (defining key concepts, delineating the range and nature of phenomena, creating typologies, finding associations, providing explanations and developing strategies). Guided by this approach, coding of focus group data was conducted by two researchers and discussed with other members of the team. The a priori coding framework of interest was broadly information types, characteristics and preferences.

Focus group findings

Two focus groups were conducted, one each with the 6–10 years age group and the 11–15 years age group, with the focus group for the 16–18 years age category being a face-to-face interview as only one participant attended this session. An additional focus group with the 6–10 years age category was planned because of the low response rate in this age category, but a face-to-face interview was conducted as only one participant attended the second focus group. Additional demographics are displayed in *Table 21*.

Three overarching themes emerged from the focus group data, suggesting that children and young people would like health information to provide real narratives and images, be tailored to their own age and individual lifestyle and organised into sections.

Real narratives and images

A preference for information presenting real narratives and realistic (as opposed to cartoon) images of children and young people was a strong theme. For example, when referring to the book *Becky has Diabetes* for the 6–10 years age group and *Getting a Grip on Diabetes* for the 11–15 years age group, participants stated that:

> *It was good, because it was about a day, and she injects her insulin . . . . It shows you people injecting insulin and it's real.*
>
> *6–10 years, girl 1*

> *It's like showing a real girl with diabetes.*
>
> *6–10 years, girl 2*

> *It's helpful for someone who's new to diabetes, because it tells you how she does it at home and tells them how they could possibly do it at home.*
>
> *16–18 years, boy 1*

> *It might be a story but it's actually some information . . . . I like looking at stuff like, like stories, like you can get like, from other people sort of thing.*
>
> *11–15 years, girl 1*

TABLE 21 Focus groups conducted by age

Age category	Target *n*	Actual *n*
6–10 years	7–10	4 (2 boys and 2 girls) plus 1 interviewed (boy)
11–15 years	7–10 (max. 12)	12 (7 boys and 5 girls)
16–18 years	7–10 (max. 12)	1 interviewed (girl)

Information tailored to age and lifestyle of the individual

The importance of tailoring health information resources to age and lifestyle emerged as a result of showing children and young people resources intended for use by their age group:

> *Because it's* [Streetwise *leaflets] more like a booklet, it's not thin and . . . it's got a lot more information in it [smoking, drugs, solvents, help advice, contact numbers] . . . yeah I think I'd pick that one up.*
>
> *16–18 years, girl 1*

> *you know as soon as you see it* [Streetwise *leaflets], what it's about really, and also it's not like filled full of cartoons all over it, it's got one or two pictures, which is okay, so you sort of know it's aimed around you know what age level sort of thing that's . . . well, teenage years.*
>
> *11–15 years, boy 4*

When reviewing the resources shown, participants often identified resources as being 'too young', 'too old' or 'adult'. It was clear that children's and young people's preferences in the 6–10 years and 11–15 years focus groups did not always 'fit' with the ubiquitous target age bands set by the information producers:

> *I would have when I was younger but not now no [*T1 *magazine, JDRF].*
>
> *11–15 years, boy 5*

> *plain and boring and no pictures . . . For adults [named NHS trust leaflet].*
>
> *11–15 years, girl 5*

> *Like six or seven . . . cartoony . . . When I was little but not as much now [*Getting Started with Diabetes, *BD Medical – Diabetes Care].*
>
> *11–15 years, girl 1*

> *But the cartoons, err, are well drawn but seem to be for younger children. And they distract you, and you're looking more at the cartoons rather at what's actually in the book [*Managing our Diabetes, *Roche].*
>
> *11–15 years, boy 4*

Children appeared very conscious of the connection between age group and what would be considered appropriate in terms of information, for example the balance of text and words to pictures, drawings or cartoons running through the text, with younger children preferring less text:

> *Well, especially on some of these like, something like that which has pictures, which makes you understand it quite a lot more.*
>
> *6–10 years, boy 3*

> *I would read it [*Type 1 Diabetes in Children, Adolescents and Young Adults, *Ragnar Hanas] but I wouldn't really enjoy it because it's just basically lots of text and not much pictures.*
>
> *6–10 years, girl 2*

One boy described being given a diabetes diary in which to record his blood glucose readings but found that it was not geared to his age and as a result he didn't understand it and stopped using it:

> Boy: *Well, I tried it, but it was, erm, it was like, I ended up just. I filled it in, but I didn't really understand it, I just saw it as I was just putting numbers on a piece of paper really. So it was more.*
> *I still think it was very, err, mature and adult, it was going into all these like . . .*

> Researcher: *Technical details was it?*
>
> Boy: *Yeah, which I was all right with, but it just, as soon as you start hearing hyperglycaemic and all that you know, you tend to switch off.*
>
> *11–15 years, boy 4*

Younger children (6–10 years) commented that a diabetes record diary that was suitable for their age group needed to have spaces that were big enough to write in:

> *I don't think that you could write a lot in it because it is so small. It's too small gaps [*Hangin' with Hu-mee, *Eli Lilly].*
>
> *6–10 years, girl 1*
>
> *I had one of those. Err, but not like the book, but a diary type of thing, but the gaps were bigger on mine.*
>
> *6–10 years, boy 1*

Information organised into sections

Older children (11–15 years) wanted to be able to turn directly to information of interest through the use of an index page, and having clearly labelled sections was a useful feature of thicker information booklets and resource folders:

> *It's [resource folder developed by Gwent Healthcare NHS Trust] actually pretty good. Um, it's very well organised, yeah, everything has got nice sections in it, so like, travelling with diabetes, um, then it's got an index which tells you what it's about, before you actually even look at it.*
>
> *11–15 years, boy 4*
>
> *I thought this book [resource folder developed by Gwent Healthcare NHS Trust] was quite useful to me, it's in sections but you can always find what you want.*
>
> *11–15 years, boy 3*

Overall likes and dislikes with regard to diabetes information

A summary of the overall likes and dislikes of children and young people with T1D by age category is presented in *Table 22*.

Thermometer rating scale task: information type and provision preferences

Findings from the thermometer rating scale task are presented by age category. Children in the 6–10 years focus group identified a preference for receiving information about T1D from their diabetes HCP. They wanted to know more about what caused T1D and how injecting insulin helped to make them feel better. The order of preference for other forms of information provision was the internet, leaflets, books, support groups, e-mail, web forums, DVDs, message boards and by telephone.

Similar patterns of information type and provider preference were identified by young people in the 11–15 years focus group. This age group wanted to have more information about growing up and their changing body and things that happen to them as they grow up. The consensus was that they preferred to obtain information about T1D from their diabetes HCP followed by the internet and web forums, leaflets, books, internet message boards, by e-mail and by telephone.

As previously reported, individual interviews were undertaken with a 10-year-old boy and a 16-year-old girl because of their lone attendance at separate focus groups. They also participated individually in the thermometer rating scale task and presented different preferences from those identified by children and young people in the focus groups. The 10-year-old boy preferred to obtain information about T1D from books, closely followed by diabetes HCPs and support groups. His order of preference for other forms of information provision was the internet, leaflets, DVDs, by home telephone and by mobile telephone.

TABLE 22 Focus group summary of overall likes and dislikes with regard to diabetes information by age group

Age category	Likes	Dislikes
6–10 years	Colourful Cartoon characters Factual Information in sections Real children with diabetes Real pictures, especially of children injecting insulin	Lots of words Too much text and no pictures
11–15 years	Sectioned information Contents page Good information Real-life pictures Not too many pictures – too distracting Tips Other people's stories	No pictures Too many cartoons – distracting Plain Lots of information, including cartoons, that is too young for them, etc. Paragraphs of information Too long Too much information
16–18 years	Reflects lifestyle issues, e.g. diet and drinking alcohol Booklets about carbohydrate counting rather than leaflets because they contain more information	Too little information in thin leaflets

He said he would not use e-mail, web forums or internet message boards as sources of information. In line with the 6–10 year olds in the focus group, he wanted more information on what actually happened inside the body, especially what the pancreas did.

The 16-year-old girl preferred to obtain information about T1D from leaflets, followed by support groups and DVDs. Her order of preference for the other forms of information provision was websites, by e-mail, diabetes HCPs, books, by home telephone and by mobile telephone. She said that she would not look for information on web forums. She specifically wanted more information about carbohydrate counting.

Findings from these two single interviews emphasise that children and young people have very individual and age-related preferences concerning the type and mode of information provision. Choice may also depend on their relationship with their PDSN and engagement with their diabetes team.

Summary of the focus group findings relevant to EPIC intervention development

- Children wanted diabetes information resources that are organised into age-appropriate packs and that reflect how diabetes is experienced in 'real' life.
- Children wanted age-appropriate and interesting images/formats.
- Children wanted to be able to choose from a wide selection of resources that reflect individual interests and lifestyles beyond the specific diabetes focus.
- Children wanted information to be organised into sections.
- Those aged 6–10 years wanted information on diagnosis and basic diabetes management and how the body worked.
- Those aged 11–15 years wanted information on growing up and their changing body and things that happen to them as they grow up.
- Children aged 6–15 years primarily wanted to receive information from their PDSN.

- Some wanted information on carbohydrate counting.
- Diabetes diaries need to use appropriate non-technical language with sufficient space to record information.

These key findings are incorporated in the summary table of evidence informing EPIC intervention and programme theory development (see *Table 20*).

Semistructured interviews with children, young people and parents

We also undertook additional contextual interviews to inform intervention development.

Interview method

A generic qualitative approach[224] with in-depth semistructured face-to-face interviews with children and key family members was used to gain a greater understanding of their diabetes information needs, with an emphasis on medicines management and service delivery. We arranged interviews in a suitably convenient location for the family, for example at home, on a NHS site hospital ward, in an outpatient or other clinic or in a primary care setting. Interviews were conducted individually or jointly with the parent of a child or young person with T1D.

Sampling strategy for interviews

Children and young people aged 6–18 years with T1D were recruited to take part in the face-to-face interviews.

For the recruitment of the 11 parents and eight children and young people interviewed as part of the IMP, see *Chapter 4* (p. 107).[1] The sampling strategy for the EPIC interviews was to identify 10–12 children and young people across three age groups: 6–10 years, 11–15 years and 16–18 years. Children and young people and their families were identified by local diabetes HCPs with support from CRC Cymru nurses. Children and young people were sent a study information pack on behalf of the EPIC research team and those who were interested completed contact forms and returned them to the research team. Interviews were arranged in a convenient location for the family, which in all but one case was the family home (see *Appendix 4* for an example of an interview schedule).

An additional five parents were recruited when their child attended one of the diabetes focus groups. These parents were interviewed either on the day of the focus group at the location where the focus group was held or in their home on a separate day.

Children and young people classified as 'hard to reach'

'Hard-to-reach' children and young people with T1D who lived away from their families in the short, medium or long term were conceptualised in the funder brief as those who were homeless, who had experience of places such as youth offender institutions and who were socially marginalised. Additional recruitment strategies were employed to try and access such children and young people. One national press release, co-written by the Involving People representative on the study, was picked up by the *Big Issue*, teletext and other regional newspapers. We also used local press releases (one in South Wales and one in North Wales) and advertisements on electronic university noticeboards (Cardiff University and Bangor University). Both Welsh- and English-language press releases were distributed to press agencies in Wales. The research team also asked PDSNs at EPIC trial sites if there were any patients on their caseloads who fulfilled the criteria of 'hard to reach'. Children and young people who were interested were asked to contact the research team and study information and consent forms were sent to those who responded. Once completed consent forms had been received, arrangements were made to conduct a face-to-face or telephone interview at a mutually convenient time.

Challenges with regard to 'hard-to-reach' interviews

Every possible effort was made to recruit children and young people with T1D who lived away from their families in the short, medium or long term, but only three individuals responded. Respondents included a child who boarded at a private fee-paying boarding school (child 18), a teenager who had been away by herself on holiday (child 16) and a student living away from home at university (child 17). These children and young people all had ongoing contact with their families and the diabetes service.

The final sample therefore did not capture the theoretical characteristics of the 'hard-to-reach' children and young people as originally conceptualised. Nonetheless, they had all lived away from home in the short, medium or long term and self-managed their diabetes without constant parental oversight. We included these participants as they could potentially add an additional perspective to our overall understanding of the different contexts in which children and young people manage their diabetes.

Resource selection for interviews

A selection of age-appropriate paper-based diabetes health-related information that had been used in the focus groups was taken to the interviews to prompt discussion (see *Appendix 4*, *Information resources used as part of the focus groups*).

Qualitative analysis of interview data

Interviews were digitally recorded and transcribed verbatim. Ritchie and Spencer's[144] thematic framework analysis approach was used with ATLAS.ti software. Initially, three transcripts were read and reread by the two researchers and the major themes that were related to the research questions were noted. A coding frame was then developed in discussion with the research team. This initial coding frame was applied to five different transcripts and amended during this process to include new emergent issues. Using the revised coding framework, all transcripts were then coded or recoded.

The coding framework represented three overarching areas of investigation, closely aligned to the study objectives, namely information needs, information characteristics and information preferences (*Box 29*). Interview transcripts were coded by two researchers and discussed with other members of the research team.

BOX 29 Coding framework

Information needs for self-care of diabetes, with specific reference to blood glucose management and insulin monitoring

(a) Information on what causes diabetes.
(b) Updating of information as needs change.
(c) Issues concerning the wider family.
(d) Information on practical strategies to manage diabetes within one's lifestyle.
(e) Other people's experiences.

Information characteristics: how children, young people and parents learn about diabetes

(a) How was information received and in what type/format.

Information preferences: how children, young people and parents would like diabetes information presented to them

(a) Timely information through the diabetes journey.
(b) Written information to back up verbal instructions.
(c) Individually tailored and age-appropriate information resources.
(d) The appeal of images on information resources.
(e) Types of information.

Semistructured interview findings

Eighteen interviews were conducted with children and young people, seven of which were conducted jointly with the mother. An additional 11 interviews were conducted separately with a parent of a child or young person with T1D; only one interview was with a father. Additional demographics are detailed in *Tables 23* and *24*.

TABLE 23 Numbers of children and young people interviewed by age group

Age group	*n*
6–10 years	7
11–15 years	5
16–18 years	6 (including 3 hard to reach)
Total	18

TABLE 24 Breakdown of diabetes interview respondents (children and young people with or without parents)

Child	Parent	Sex, age group, time since diagnosis
Child 1		Boy, 6–10 years, > 2 years
Child 2	Mother of child 2[a]	Boy, 6–10 years, > 2 years
Child 3	Mother of child 3	Girl, 6–10 years, < 2 years
Child 4	Mother of child 4[a]	Boy, 6–10 years, > 2 years
Child 5	Mother of child 5	Girl, 6–10 years, > 2 years
Child 6	Mother of child 6	Girl, 6–10 years, > 2 years
Child 7	Mother of child 7	Boy, 6–10 years, < 2 years
Child 8	Mother of child 8[a]	Boy, 11–15 years, < 2 years
Child 9	Mother of child 9[a]	Girl, 11–15 years, > 2 years
Child 10	Mother of child 10	Girl, 11–15 years, > 2 years
Child 11	Mother of child 11	Boy, 11–15 years, < 2 years
Child 12		Girl, 11–15 years, > 2 years
Child 13	Mother of child 13[a]	Boy, 16–18 years, > 2 years
Child 14	Mother of child 14[a]	Girl, 16–18 years, > 2 years
Child 15	Mother of child 15	Boy, 16–18 years, > 2 years
Child 16		Girl, 16–18 years, > 2 years
Child 17		Boy, 16–18 years, > 2 years
Child 18		Boy, 16–18 years, < 2 years
Parent interviews		
Mother F1[a]		Boy, 6–10 years, > 2 years
Mother F2[a]		Boy, 6–10 years, < 2 years
Father F3[a]		Girl, 16–18 years, > 2 years
Mother F4[a]		Boy, 16–18 years, > 2 years
Mother F5[a]		Girl, 16–18 years, > 2 years

a Parent interviewed on their own.

Diabetes information needs

Most diabetes information was given to children and young people at diagnosis, and if children were very young diabetes information was primarily aimed at their parents.

In the following sections quotes are designated a code indicating the unique number of the child, his or her age group, if interviewed for EPIC, whether he or she had been diagnosed for > 2 years or < 2 years and sex.

What causes diabetes?

Younger children (6–10 years) relied on parents for information and did not have any particular information needs that they were able to express. When prompted whether they had asked questions of the health professionals involved in their care they answered 'yes' but could not recall what these questions had been about:

> *It's probably about more detail on how, like, diabetes actually start.*
>
> *Child 6, 6–10 years, > 2 years, female*

> *I know one question is, how did I get my diabetes.*
>
> *Child 5, 6–10 years, > 2 years, female*

Updating of information as needs change

In some instances there was a need for updated information as children and young people developed, insulin regimens changed, carbohydrate counting was started or self-management skills were increased:

> *Well for me, because my insulin regime's changed so much my information has had to be changed so much. So for me growing up, the information I've needed has never really decreased, you know . . . I've had to be told about how this insulin works, how you're going to do it, so the information for me has always been kind of new and I've still always needed bit more.*
>
> *Child 14, 16–18 years, > 2 years, female*

One young man talked about the information provided when he changed to a multiple-dose regimen:

> *It was like a leaflet I think at the time and about three or four weeks later I went on the DAFNE [Dose Adjustment for Normal Eating] course so it was kind of like just to get me a bit used to it before I went on the course and then I went on the course and it explained it fully.*
>
> *Child 13, 16–18 years, > 2 years, male*

> *I probably need to know more stuff about carbohydrate counting and stuff like that.*
>
> *Child 12, 11–15 years, > 2 years, female*

Newly diagnosed children recognised that they would need information in the future: 'But maybe about different regimens like . . . because I am on the "basal bolus" but maybe about is there another regime that might fit me better than that one' (Child 8, 11–15 years, < 2 years, male).

Some children liked to have specific information about where to inject and site rotation: 'I like the part where it shows you where you can do it, that's quite handy' (Child 6, 6–10 years, > 2 years, female, commenting on *Growing up with Diabetes*, BD Medical – Diabetes Care, p. 16).

Issues concerning the wider family

Some parents wanted more information about going on holiday, especially abroad, and about research into T1D:

> *Well we did have some information as well but that's the one thing as well, we haven't got information for children on-going away on holiday or that sort of thing.*
>
> *Mother of child 5, 6–10 years, > 2 years, female*

> *The only thing like I've just stated there, research, research put into the diabetes care, the feedback from that you don't seem to get anything, other than what you read in the paper and then you don't know whether its 100% right or, so on that score you don't probably get enough to what's going on in the background, research and . . .*
>
> *Father F3, 16–18 years, > 2 years, female*

A mother of a newly diagnosed child specified the need for more information on diabetes-related long-term complications:

> *if he doesn't take care of himself. Its little things like he'll walk round the house with no shoes on and we say to him, you know, you really need to wear shoes because . . . 'Well why?' and there's nothing there to show him or tell him why, we can't . . . there's nothing to provide that information to explain why they go blind, why they can . . . have amputee . . . you know, their legs amputated or their feet amputated, because they can get gangrene as a result if they don't take care, there's no . . . nothing out there, and I know you don't want to scaremonger but sometimes it would be handy to have that information to be able to say, 'Well look [name of child]' you know 'this is why, because if you don't do this in years to come this is what could happen'.*
>
> *Mother F2, 6–10 years, < 2 years, male*

Information on practical strategies to manage diabetes within one's lifestyle

As young people grow up they require information about managing diabetes in the context of more adult-oriented activities. The topic of alcohol was often raised by young people:

> *Everything I want to know are like, what happens with alcohol? What happens with you go out? What do you need, you know for the things that you do, do you know what I mean? I mean, there are things in my head that I need.*
>
> *Child 16, 16–18 years, > 2 years, female*

> *I'd probably talk about all the drinking and stuff, when I went to the clinic on Monday because I play youth rugby now and we've all got permission to drink in the rugby club so obviously I'll ask the question and they said one or two pints that'll be fine but you've got to, you know you always have to monitor your bloods and stuff but when you go to a certain limit, five or six pints, then you can start worrying about it because your bloods are going to shoot up and then go straight down or it depends what alcohol you actually drink, it could go straight down but I've talked to them about it and I've got enough information for myself.*
>
> *Child 15, 16–18 years, > 2 years, male*

However, some teenagers would have liked information about alcohol consumption at an earlier stage:

> *there was two occasions and I'd drank quite a lot, fainted, got took in to hospital and stuff like that and it was all sorted and obviously I told the hospital about it and they'd given me leaflets like pre-hand saying about what . . . smoking and drinking and stuff like that could do to your diabetes in the long run but it was only after that I'd . . . had these two . . . episodes that they gave me the information . . . in a way that wasn't their fault because I was too young to drink anyway so they might have though well there's. . . no real reason I've got to tell her all this yet, . . . but . . . I think it might have been nice for them to just get those key points just in case because a lot of teenagers these days are drinking a lot younger than they should be so I think they should be kind of aware of that and just highlight the key points.*
>
> *Child 14, 16–18 years, > 2 years, female*

Becoming pregnant and having children were other lifestyle issues considered by young people:

> *I might have, like about problems that I could face. I think that sort of thing, having children and that's a big one that I'm a bit worried about . . . The whole having children thing because I read in a magazine, you have to keep your blood sugar between this and this or you could have problems. I think that is something I would be worried about when I'm older.*
>
> *Child 16, 16–18 years, > 2 years, female*

Young people also needed information about managing diabetes while playing sport. One young man would have liked more information at diagnosis about playing rugby:

> *Yeah because I wasn't really sure when I was younger what was going to happen, I thought I was going to give up rugby, you know I only just started rugby literally that year, I only just started playing rugby and had two months of playing rugby and I just loved it and back in the day when I was diagnosed I would have liked to have had something like that just so I could have reassurance that everything was going to be fine and I could live the lifestyle I wanted to live.*
>
> *Child 15, 16–18 years, > 2 years, male*

Other people's experiences

Some families regularly received booklets from diabetes charities (JRDF and Diabetes UK) and they appreciated reading stories about celebrities and 'normal people' with T1D who were doing well:

> *When I was first diagnosed, probably to the age I was about 13, 14, I got booklets sent me every week or every month, just like latest news, you know, and they tell you about like celebrities that had it and stuff so you kind of thought oh there are people out there, you know, that are doing well for themselves that have got it which that kind of was a nice thing to read at that age because for me I knew nobody else that had it so knowing other people had it and just kind of being able to read it myself, you know, and . . . it was . . . that was good . . . That was really good because it had . . . normal people telling you their stories which was really nice as well.*
>
> *Child 14, 16–18 years, > 2 years, female*

> *Yeah, I do, really, yeah, easy to read [*On the Level, *Diabetes UK] and lets me know of the sort of the stuff my age would, find interesting, well I do anyway.*
>
> *Child 16, 16–18 years, > 2 years, female*

One family registered with Diabetes UK since diagnosis regularly received *Tadpole Times*, a magazine aimed at children aged 4–10 years. The child particularly liked reading letters and stories from other children with T1D:

> *I like the ones where they tell the stories.*
>
> Child 5, 6–10 years, > 2 years, female

> *It's the letters you like as well don't you, she'll come out and she's read it and she'll say mummy there's somebody like me that's doing this and I say well you're not the only one.*
>
> Mother of child 5, 6–10 years, > 2 years, female

Children and young people also enjoyed reading 'people's stories' in *Balance*, a Diabetes UK magazine for parents:

> *people's stories about how you can still do, how they coped going to like hot places on holiday and keeping their blood glucose level under control, about alcohol and more injections and that, is it worth it.*
>
> Child 8, 11–15 years, < 2 years, male

> *Sometimes it might have stories in about people's hypos . . . And I might, it might catch my eye, and look at it . . . Yeah, to see how they handled it.*
>
> Child 9, 11–15 years, > 2 years, female

> *That would make it more interesting, like the* Balance *one [magazine] that . . . my mum reads it more than me. I sort of have a glance through, and if she sees something that she thinks I'll like, I'll have a read, but, that would be, I would have preferred that, yeah.*
>
> Child 17, 16–18 years, > 2 years, male

Although most children and young people viewed the magazines as interesting and informative, some commented that they tended to cover positive stories that did not always match personal experience, which can make young people feel worse:

> *I don't think they realise that the people that weren't doing so good would have thought well no that just makes me feel even worse because it makes you feel like you're doing something totally wrong then. So yeah, hearing . . . negative stories as well as the good would have been helpful for me.*
>
> Child 14, 16–18 years, > 2 years, female

Information characteristics

Children, young people and parents received information about T1D from:

- PDSNs
- child-focused age-banded magazines (Diabetes UK, JDRF)
- peer support groups
- parental support groups
- leaflets (NHS trust in-house leaflets, charities, pharmaceutical companies)
- DVDs
- the internet
- social networking sites
- specialised books (e.g. carbohydrate counting)
- insulin injection teaching aids [e.g. JRDF teddies (Ruby and Rufus), Medtronic lion (Lenny the lion) or an orange]
- educational diabetes camps and activity fun days.

Information preferences

Timely information through the diabetes journey

Some children and parents had received a lot of information at diagnosis and felt that this had helped them to understand diabetes (*Box 30*).

Others felt that they had continued to receive adequate information:

> *I think it's all readily available to be honest if I want it, it's given to me in my checks usually. I've got about ten leaflets on feet for diabetes, but usually if they're introducing me to something they'll give me all the information on it. But then if I'm still not satisfied I can go and ask or search it on the internet, see what's available and ask them about it.*
>
> *Child 13, 16–18 years, > 2 years, male*

Written information to back up verbal instructions

One young girl liked receiving written information that backed up verbal instructions:

> *Every time I've gone to the doctors, well when its changed [insulin regime] they've always kind of wrote down on A4 just basically the outlines, you know the main points I need to know like . . . yeah personally I like how they write it down for you instead of just kind of giving you a leaflet because obviously that's for everyone in general then and you don't know if that's really going to work for you or not.*
>
> *Child 14, 16–18 years, > 2 years, female*

BOX 30 Examples of timely information through the diabetes journey

> *Yeah, yeah that was quite a lot of information. I understood diabetes quite well at the end and went through it all.*
>
> *Child 8, 11–15 years, < 2 years, male*
>
> *We have got loads and to be honest I can't say hand on heart that we read everything but every question we had got answered and I did read some stuff and find out things that I wouldn't have thought to have asked about like some of the problems you can get if you inject in the same area over a long period of time and that sort of thing. We were perfectly happy with the amount of information we were given.*
>
> *Mother of child 7, 6–10 years, < 2 years, male)*
>
> *Yes we were given leaflets and books, obviously it was a shock when we first got told that she was diabetic so it's all a bit of a haze and because she was quite small there were lots of things that we didn't read straightaway because we were just dealing with what we were told by the nurses to be honest and most of the information came from the diabetic team without whom we probably wouldn't have survived.*
>
> *Mother of child 6, 6–10 years, > 2 years, female*
>
> *Yes basically we had this box of all different leaflets and things but we were given so many different I really . . .*
>
> *Child 18, 16–18 years, < 2 years, male*

Individually tailored and age-appropriate information resources

Younger children were often not forthcoming when asked whether they had read any diabetes information specifically for their age group. Sometimes information had been given directly to parents and the children had not seen it:

> *Not really, no they were just adult ones . . . Like . . . I could have read them if the thing . . . but I knew I probably wouldn't understand it . . . I wouldn't understand it as good as I would if they were children ones.*
>
> *Child 3, 6–10 years, < 2 years, female*

> *Well they do give you a piece of paper but I don't know about if it is saying something because they hand it over to my mum, I don't get a chance to see it.*
>
> *Child 4, 6–10 years, > 2 years, male*

> *I think they gave my mum and dad a lot of information because I was so young I think it was a bit, I think I wasn't, they didn't consider me independent, which I wasn't, so they gave my mum and dad a lot of information I think at the time to see how to control it rather than me controlling it.*
>
> *Child 13, 16–18 years, > 2 years, male*

When age-appropriate information had been given, particularly at diagnosis, it was well received:

> *It is, very helpful [*Diabetes Made Simple, *Novo Nordisk] . . . Well, it tells you how the diabetes started and . . . how you can't have certain things, and how to take your insulin and blood sugars . . . And it seems that there's not a lot of writing on each of the pages, but kind of one or two messages on each page. If it's bright and colourful, people like to read it and that it gives probably your first bit of information that you might get.*
>
> *Child 6, 6–10 years, > 2 years, female*

> *In my mum's house I've got one but it's for, I got it when I first got it, it was a dog and you had to write stuff you knew about diabetes to help the dog but I don't look at it any more . . . it had questions so you would learn about it, like what's the difference between carbohydrate and sugar and stuff like that.*
>
> *Child 12, 11–15 years, > 2 years, female*

> *but they gave him a nice book that came with his pen, with a rucksack and everything and lots of information for children . . . its really . . . simple terms and it actually . . . to be honest at the beginning it made me understand it, because sometimes the adult information's just 'whoosh' too much . . . and it gave me that really, basic, basic understanding, and he's taken that into school to show his teacher and things, you know so they've got the real basics and then you go on to look at it in more detail afterwards.*
>
> *Mother F1, 6–10 years, > 2 years, male*

> *Yeah he had booklets, he had all the information . . . but he was eight years old, he knew he had a pancreas and he knew it wasn't . . . it had given up working, but it would start to work again for a little while, so he understood the honeymoon period . . . and then he understood when it was going to sleep, you know, it was giving up work again, but the . . . the booklets that they have at that age are pretty good.*
>
> *Mother of child 13, 16–18 years, > 2 years, male*

Young people commented that they preferred having a smaller diary that they could fit into their back pocket to record their blood glucose readings in:

> *then I started having more formal little books and smaller books as well which could easily fit in the pocket, I find that useful and handy.*
>
> *Child 15, 16–18 years, > 2 years, male*

> *I did have a diary but that was only because the size of it was smaller so I could fit it in my jacket pocket. But yeah that was the main reason I picked it because it was quite thin and small and it was easy to put in your pocket at school and get out quite easily. Whereas some of the others were thicker and I couldn't.*
>
> *Child 18, 16–18 years, < 2 years, male*

However, data indicated that parents thought that there was a gap in information resources for young people aged 11–15 years. Information targeted at younger children was no longer appealing and information for older children was seen as 'too old':

> *She's at that in-between stage, there's a big difference between eleven and sixteen . . . what might be appropriate for sixteen is not, that is a big range but I think that's important as well, to let people know it's not frightening because you can be very scared of all the medical conditions and this, that and the other and you've got to take it seriously but not you know, get the balance.*
>
> *Mother of child 6, 6–10 years, > 2 years, female*

> *Yes even just looking at the faces of them on the front I would think this is more aimed towards seventeen upwards and yet that . . . [*Living with Diabetes, *BD Medical – Diabetes Care] . . . Yes I mean a lot of it isn't applicable, driving and learning to drive, well he's years away from that yet, going out to parties and clubbing, years away from that, drinking and alcohol, definitely years away, smoking never, never, and recreational drugs, never. So yes I think maybe something in between that again looks a little too young front cover wise so I think between ten and fourteen, fifteen [*Growing up with Diabetes, *BD Medical – Diabetes Care].*
>
> *Mother of child 11, 11–15 years, < 2 years (newly diagnosed), male*

The appeal of images in information resources

The front cover of an information leaflet was important to young people. If it was not appealing they would not look inside:

> *This [*Living with Diabetes. A Guide for Teenagers, *Abbot Diabetes Care] looks more like something you'd find with the computer rather than diabetes, it looks like earphones, oh listen to music, I don't know, I'd look at it and just go yeah it might be informal but it's not an attraction, I wouldn't want to read it at all. It looks more like instructions.*
>
> *Child 15, 16–18 years, > 2 years, male*

Specific questioning concerning pictures in booklets and the helpfulness of illustrative content elicited positive responses from children:

> *Like books with like pictures in and like interesting text to read about the picture and that . . . well a bit like a cartoon.*
>
> *Child 2, 6–10 years, > 2 years, male*

> *Yes, it's a bit hard to get to grips with this book with [name of child], you know there's too much words and not enough pictures.*
>
> *Mother of child 5, 6–10 years, > 2 years, female*

> *No it's more as if, if it had pictures in there it would stand out more to me.*
>
> Child 11, 11–15 years, < 2 years, male

> *It's nice that it's got nice pictures so and it explains it.*
>
> Child 6, 6–10 years, > 2 years, female

Types of information

The different types of information included individual leaflets, DVDs/CD-ROMs and websites (provided by diabetes charities, pharmaceutical companies or diabetes equipment manufacturers). Participant preferences for each type of information are described in the following sections.

Individual leaflets

> *I'd rather find a leaflet just specific on one topic, I'd like just one leaflet saying about leaving home or one leaflet about driving, it would be so much easier.*
>
> Child 15, 16–18 years, > 2 years, male

> Interviewer: *So you like lots of different leaflets on a particular thing as opposed to a big book like that with lots of pages.*
>
> Child: *Yes, because there's not too much information like in one leaflet.*
>
> Child 10, 11–15 years, > 2 years, female

> *I think the problem when, you're at that sort of age, I would have, if somebody gave me something, sort of like, just a leaflet, I'd read it, but if it was a big book or something that I had to go off and do to get the information, I think I'd so something like 'oh yeah' and sort of left it, but if they sort of gave it, not too much writing, then that would have been better for me.*
>
> Child 17, 16–18 years, > 2 years, male

DVDs/CD-ROMs

Most families, when asked, said that they had not watched a DVD about T1D. As one mother commented:

> *It would be a nice idea if you had a DVD or something along the lines where it's children talking about their experiences. I mean not ten hours long, just three or four different people having five minutes at a time.*
>
> Mother of child 15, 16–18 years, > 2 years, male

However, one child began doing his own blood glucose monitoring after watching a similar-aged child do it on a Diabetes UK DVD:

> Mother of child 7: *Yes and do you remember when we saw the little video clip of the girl, what was she doing? What was the girl doing on the DVD . . . she was doing her blood test wasn't she?*
>
> Child: *Yes.*
>
> Mother of child 7: *And can you do your blood test now? Do you remember when you saw the girl doing it and then you went and did your own?*
>
> Mother of child 7: *It was really good actually because the DVD had a little girl about [name of child]'s age doing her own blood test in school, it really helped him get the idea that he could do that too.*
>
> Child 7, 6–10 years, < 2 years, male

Another child commented:

> *Sort of, it was just basically the people . . . there's all with diabetes and how they've done it and . . . like there was ones young and there's . . . people that are like in . . . teenagers, and how they dealt with it . . . So it was good to . . . because you knew erm, when you grow up, and you know what you've got to do.*
>
> *Child 3, 6–10 years, < 2 years, female*

Websites

Children and young people were asked if they visited websites or internet sites about T1D. Many had but most were cautious about the reliability of the information provided:

> *I'd prefer to talk to a nurse because she's like there so it's more believable and stuff . . . . Yes because on like Wikipedia people write it like themselves so you don't really know if you can trust it properly or not.*
>
> *Child 12, 11–15 years, > 2 years, female*

> *or try and go on Google and you never know how reliable all that sort of stuff is, web.*
>
> *Child 17, 16–18 years, > 2 years, male*

There was also a lack of interest on behalf of the child even when sites were recommended by diabetes HCPs:

> *I haven't been on there for ages I literally just keep away from some of them because you get too much information if we go on to the wrong site. There have been some websites that have been suggested for her but she's not really very interested.*
>
> *Mother of child 6, 6–10 years, > 2 years, female*

Summary of interview findings relevant to EPIC intervention development

- Diabetes information provision was patchy with most information received around diagnosis.
- Children and young people receive/like to receive most of their information from PDSNs.
- Parents took primary responsibility for the diabetes management of younger children.
- Children were taught to take more responsibility as soon as appropriate and especially when attending school.
- Younger children wanted information about the causes of diabetes.
- All children and young people expressed the need for individually tailored, age-appropriate and updated information as needs changed over time.
- The size of a diabetes record diary is important; children need to be able to write in it and young people want to be able to put it into their back pocket.
- Young people needed information on a wide variety of lifestyle issues such as alcohol consumption, pregnancy and taking part in sporting activities.
- Information leaflets for quick access to relevant information were preferred to more comprehensive textbooks.
- Most children and young people and their families were not aware that information was available in other formats, for example DVDs, and were not confident about knowing where to look on the internet for accurate information.

These key findings are incorporated in the summary table of evidence informing EPIC intervention and programme theory development (see *Table 20*).

The next section moves on to report the methods and processes used in the design and production of the EPIC children's diabetes information packs and diaries.

EPIC children's diabetes diary and information pack development

Once a better understanding of children's preferences concerning types and formats of diabetes information was achieved and the available evidence on developing children's diabetes information was identified, EPIC intervention development moved from the theoretical to the practical stage. However, the empirical evidence was continually revisited to ensure that the content and design of the intervention were evidence based.

The original aim was to develop an individually tailored, age-appropriate information intervention to optimise blood glucose monitoring and insulin titration. Analysis of contextual evidence undertaken for the IMP[1] and the EPIC study suggested that the NHS lacked a suite of high-quality, factual and age-appropriate diabetes diaries, the core component of optimal children's insulin self-management. NHS children's diabetes information provision was also found to be ad hoc, with most information being given at diagnosis when many children were too young to understand it. We therefore took a consensus evidence-based pragmatic decision to produce a suite of diabetes diaries and three age-appropriate and individually tailored diabetes information packs that aligned with primary school, secondary school and post-compulsory education age bands (6–10 years, 11–15 years and 16–18 years respectively). Using a lower age of 6 years was a pragmatic decision based on the fact that the youngest age of child who we had ethical approval to include in the research study was 6 years.

The processes and selected evidence involved in the development of the EPIC diabetes diaries and information packs are shown in *Figures 9* and *10* and *Table 20*. To refine what the 'intervention' would look like in practice we first worked with a clinical expert group.

Ongoing consultation with a clinical expert group

A clinical expert group (for details of members see *Members of the children's diabetes clinical expert group for the EPIC trial*) was convened to advise on the development of the EPIC diaries and to clarify:

- strengths, weaknesses and gaps in current children's diabetes information provision and service delivery
- the need for a new set of age-appropriate diabetes diaries and quality-assured information packs to fill known gaps
- the aims, purpose and anticipated outcomes of the EPIC intervention
- options for type, structure, format and clinical content
- current best/standard practice in children's diabetes documentation
- risk management and clinical governance
- implementation, facilitation and delivery of the intervention in routine clinical practice
- training needs in use of the packs and diaries through launch events.

The group confirmed the need for diabetes diaries and the proposed size of diaries. Members made suggestions about the key areas that information packs should cover and felt that lifestyle issues should be included in the 11–15 years pack as well as in the 16–18 years pack. Separate information was required for children and young people on different types of insulin regime (e.g. insulin pumps).

Development of the EPIC intervention content and associated programme theory and logic

The core EPIC research group met regularly to develop the EPIC intervention and associated programme theory and logic. The group comprised the two principal investigators (PIs), a media specialist, a children's diabetes specialist nurse, a sociologist, two research officers and a research assistant.

As reported in *Chapter 1*, two theoretical models of age-appropriate partnership and participation, and the critical success factors for implementation of children's health information in routine clinical practice were developed at the end of the IMP[1] (see *Tables 1* and *2*). A theoretical proposition was also refined, that for optimal translation of children's health information and participation in care:

> *High quality, age-appropriate and accessible children's health information, valued by health care professionals, children and parents, and shared using child-centered, facilitative and partnership approaches to care and service delivery, will be more highly used and a more effective component of complex interventions to optimize children's long-term condition management.*
>
> *p. 207*[1]

With reference to the study proposition and the theoretical models of partnership and participation and the critical success factors for implementation of children's health information in routine practice, the group refined the scope and purpose of the EPIC intervention, which took the form of a children's diabetes information pack in a folder and a diabetes diary. The diabetes diary (to be produced by the team) was conceived as the central component to optimise children's blood glucose monitoring and insulin management. At the same time, thoughts were focused on how the intervention was intended to work (programme theory) and the sequence of events and 'fit' of the intervention with routine clinical care (programme logic).

The core research group commenced intervention development with a set of evidence-based principles for developing patient information (see *Table 20*) and initial elements of programme theory and logic (*Box 31*) derived from key contextual work and selected evidence (summarised in *Table 20*) and in ongoing consultation with the expert group. The EPIC diabetes information packs and diaries were intended to increase children's self-efficacy in diabetes self-management with a specific focus on blood glucose monitoring and insulin management in the following ways:

- active promotion of the pack and endorsement of children's ownership, and ongoing active referral to the EPIC pack and diabetes diary by diabetes professionals and parents would indicate to children and young people the high value that professionals and parents placed on the diary and pack
- by owning and personalising an individually tailored and age-appropriate EPIC pack, children and young people would be more likely to access it and use the quality-assured information to inform their decision-making about daily self-management of their diabetes, and would refer to this information in the first instance rather than waiting to speak with a PDSN or waiting to raise a question about self-management at the next clinic appointment
- by recording their blood glucose readings regularly on a daily basis in their age-appropriate diabetes diary children and young people would be able to identify trends and manage their diet and lifestyle by titrating their insulin dose accordingly to achieve optimal glycaemic control
- the dominant discourse of 'normalisation' of diabetes and use of insulin as a social enabler would motivate children to optimally manage their diabetes
- age-appropriate behaviour change towards optimal glycaemic control was viewed in the context of the lives of children and their families at home and school, etc.

Once clarified, a logic model was developed and refined (see *Chapter 7*, *Figure 35*, which reports the process evaluation).

Further, more nuanced age-appropriate aspects of the programme theory were articulated once the EPIC packs and diaries had been developed; these are presented in *Further refining the age-appropriate elements of the programme theory and logic of the EPIC children's diabetes diaries and information packs*.

The next task was to decide what the EPIC packs should look like, what they would contain and what information resources would need to be produced in-house.

BOX 31 Developing an initial EPIC intervention programme theory and logic

The EPIC diabetes information packs and diaries would:

- be *paper based* but also include appropriate DVDs and reference lists of books and websites (because of cost and to increase accessibility to all children)
- be *age-appropriate* – three different packs (look and content) to align with key school milestones (6–10 years, 11–15 years and 16–18 years)
- be *child-centred and owned by children and young people* – the packs were developed to reflect age-appropriate preferences for information and presented to the child to be used by the child
- be *individually tailored* – information not felt to be appropriate could be removed by parents and/or diabetes HCPs and information that local diabetes HCPs felt was missing could be added over time
- cover both *genders* **–** images and range of information included for both boys and girls, partly because we did not have sufficient resources to produce additional versions and mainly because currently available information is mostly not gender specific
- continue the *discourse of 'normalisation' and insulin as a social enabler* and use an *authoritarian voice* when appropriate to convey key health messages
- *contain essential and comprehensive diabetes self-management information* – the group purposively selected key high-quality and age-appropriate published resources covering the fundamental diabetes self-management issues reflecting NICE guidelines, including *diabetes diaries* to record blood glucose measurements and insulin dosage, which were produced by the research team in conjunction with a medical illustrator
- *images* chosen for the covers of the diaries *deliberately did not reflect diabetes* so that children and young people would be encouraged to take the diary to school without feeling embarrassed
- *the size of the diaries* – large enough to write in for children in the 6–10 years age group, small enough to fit in the back pocket for the 16–18 years age group
- *be quality assured* – the content was assessed to align with key messages in NICE guidelines and signed off as appropriate for use in the NHS by designated diabetes experts using a standard clinical risk management approach
- be designed to *fit into routine diabetes practice and care pathways* and to be actively *delivered and promoted by PDSNs*
- children, young people and parents would use *information from the EPIC pack* as and when required to *support children's diabetes self-management at home and at school*
- children, young people and parents would *use the EPIC diary on a daily basis* to record blood glucose readings and titrate insulin doses and would take it with them wherever they went
- children, young people and parents would *access the EPIC pack if they had a query* concerning their diabetes self-management *before contacting a diabetes HCP, to see if they could optimally self-manage independently and without delay*
- recordings in the EPIC diary would be shared in clinic with diabetes HCPs.

Ongoing consultation with children, young people and their families

Members of the core EPIC study research team attended a number of events organised by diabetes charities, Diabetes UK and the JDRF and had permission from the organisers to seek children's and young people's opinions regarding the draft images and sizes of the EPIC diaries. A sheet was also distributed to ascertain what information (apart from space to record blood glucose readings and insulin dosage) they would like in the diaries and what top 10 tips they would give children and young people with T1D to help them look after themselves.

Additional consultation and advice was provided by a young university student with T1D (an advisor to the EPIC project) and a mother of a teenager with T1D (on the EPIC project steering group committee).

Development of artwork for the diabetes diaries and sticker sheets in conjunction with the medical illustrator

In the interviews and focus groups the two younger age groups, 6–10 years and 11–15 years, expressed a preference for cartoon characters that related to them. The medical illustrator also had experience of developing artwork for children's health-related projects and designed the cartoons for the youngest age group to cater for their preference for round shapes and bright colours and fun characters that looked like soft toys, which children felt were reassuring and safe, and so that they did not reflect 'diabetes' as the discourse on the outer cover.

The cartoons and colours for the 11–15 years age group were designed to appear more complex and grown-up whilst still looking fun and being in accordance with popular television cartoons for a similar age range.

The 16–18 years age group considered cartoons to be childish and irrelevant to them as young adults. They were interested in the opinions of other teenagers and considered photographs to be more appropriate. Photographs of students were taken, which conveyed camaraderie and support for one another. The models were local teenagers studying for their A levels, who were paid a £10 fee. Each individual photographed signed a level 2 consent agreement to allow us to use the photographs for the EPIC project only.

Diabetes diaries

Three age-appropriate blood glucose monitoring and insulin management diaries [age ranges 6–10 years (*Figure 12*), 11–15 years (*Figure 13*) and 16–18 years (*Figure 14*)] and a specific diary for all age groups for children and young people on insulin pumps (*Figure 15*) were developed.

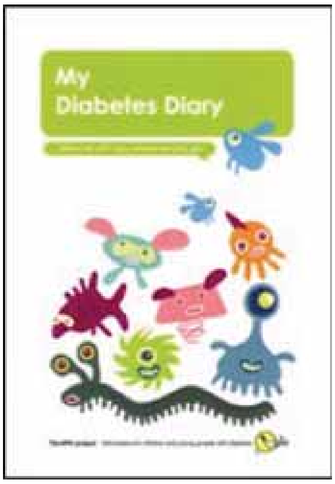


FIGURE 12 EPIC diary for children and young people aged 6–10 years.

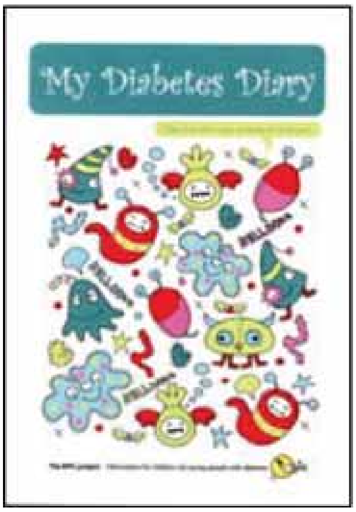


FIGURE 13 EPIC diary for children and young people aged 11–15 years.

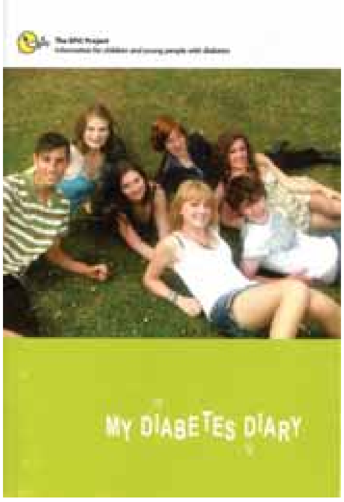


FIGURE 14 EPIC diary for children and young people aged 16–18 years.

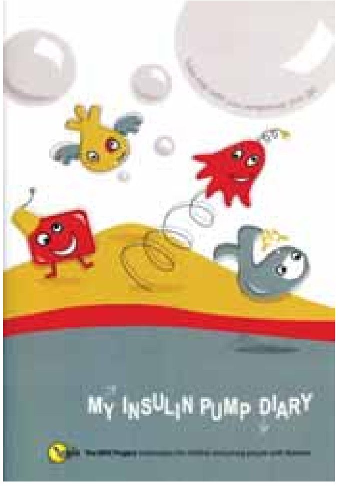


FIGURE 15 EPIC for children and young people on insulin pumps.

Production of text for diabetes diaries

Continuing the discourse of ‘normalisation’ and using an authoritarian voice, clinical information (e.g. sick-day rules) for the diaries was developed in conjunction with the members of the clinical expert group.

‘Top tips’ for optimal diabetes self-care, provided by children and young people with T1D, were highlighted on the bottom of the diary pages. Development of the pump diary necessitated additional support from children’s diabetes specialist nurses from two local NHS trusts.

The final EPIC diaries contained key health and self-management messages that were intended to motivate positive diabetes self-management behaviours in children and young people. The language used in each diary reflected the age of the target audience. It was anticipated that children and young people would carry the EPIC diary with them at all times and use it on a daily basis to optimise self-management. A reminder to this effect was added to the diary covers: ‘Take me with you wherever you go’ was printed on the front of the 6–10, 11–15 and pump diaries, and ‘Always take your diary with you’ was printed on the back of the 16–18 diary.

Personalisation

Sticker sheets that matched the images on the front of the EPIC diaries (*Figures 16* and *17*) were added to the 6–10 pack and the 11–15 pack. The 11–15 pack also contained a coloured permanent marker pen.

The purpose of the stickers and pen was to encourage children to personalise the pack, hence giving a sense of ownership. The assumption was that, if children felt ownership of the EPIC pack, they would be more likely to use it routinely when they needed to check out information and learn about diabetes.

Signposting to further information, branding and carbohydrate counting sheets

The EPIC team developed age-appropriate further information sheets, which contained details of books and websites. An EPIC logo sticker was placed on the front of each folder.

A carbohydrate counting sheet for children and young people who undertake carbohydrate counting as part of their daily regimen was developed by the EPIC research team in conjunction with the medical illustrator.

FIGURE 16 Sticker sheet for the EPIC diary for children and young people aged 6–10 years.

FIGURE 17 Sticker sheet for the EPIC diary for children and young people aged 11–15 years.

Production of text for further information and carbohydrate counting sheets

The content and text for the further information and carbohydrate counting sheets was developed in conjunction with the members of the clinical expert group.

EPIC children's diabetes information pack folders

Three age-appropriate children's diabetes information packs (age ranges 6–10 years, 11–15 years and 16–18 years) were prepared for children and young people on insulin injections and pumps.

Purchasing EPIC age-appropriate pack folders

Resources for the 6–10 years and 11–15 years age groups were presented within a transparent folder comprising a number of different compartments with colourful tabs to label each compartment (*Figure 18a* and *b*). The folder for the 16–18 years age group was a grey portfolio with a number of different compartments with tabs to label each compartment (*Figure 18c*).

Selection of age-appropriate diabetes resources in conjunction with paediatric diabetes specialist nurses

The scoping exercise of currently available children's health information, reported in *Chapter 2*, identified 120 different resources for children and young people with T1D aged from 6 to 18 years. The resources were organised into the three age ranges used in this study and, taking into account quality assurance and children's and young people's preferences and information needs, a selection of age-appropriate resources was purposively chosen for each information pack in consultation with a PDSN. These selected resources included age-appropriate paper-based information, DVDs and an additional information sheet listing age-appropriate books and websites. The contents of the three age-appropriate packs are shown in *Boxes 32–34*. These resources were quality assured against NICE guidelines (see *Chapter 2*) and approved by members of the clinical expert group.

Web-based consultation with children and young people

To provide children and young people with ongoing opportunities to engage in the process of intervention development a website was set up where children and young people could comment on the colours, images and content of the diabetes diaries. Partner children's charities and Roche (who have 8000 children and young people signed up to receive regular newsletters) agreed to include an advertisement inviting children and young people with T1D to provide some feedback on various aspects of the evolving EPIC diabetes diaries. The advert guided children and young people to the EPIC project website

FIGURE 18 EPIC packs. (a) 6–10 years; (b) 11–15 years; (c) 16–18 years.

BOX 32 Contents of the EPIC pack for 6–10 year olds

1. Book and DVD: *Lenny Explains Diabetes* (Medtronic in conjunction with Bayer Healthcare, 2009).
2. Booklet: *Growing up with Diabetes* (BD Medical – Diabetes Care, 2009).
3. Magazine: *Tadpole Times* (Diabetes UK, autumn 2009 – updated).
4. Booklet: *Hangin' with Hu-mee* (Eli Lilly in conjunction with the Royal College of Nursing, 2007).
5. Booklet: *Diabetes Made Simple* (Novo Nordisk, written by C Pesterfield, diabetes specialist nurse, Addenbrooke's Hospital, 2005).
6. CD-ROM: *Type 1 Diabetes with the JDRF Glucose Gang* (JDRF, sponsored by Novo Nordisk, 2008).
7. Leaflet: *Carbohydrate Awareness Guide, Food Index* (Roche/Accu-Chek, 2005).
8. EPIC 6–10 further information sheet (EPIC team, 2009 updated).
9. EPIC diary (6–10 years).
10. Carbohydrate counting sheet.
11. Welcome to your EPIC pack letter (parent).
12. Welcome to your EPIC pack letter (child).
13. EPIC sticker sheet (6–10 years).

BOX 33 Contents of the EPIC pack for 11–15 year olds

1. Booklet: *Living with Diabetes* (BD Medical – Diabetes Care, 2009).
2. Magazine: *On the Level* (Diabetes UK, autumn 2009).
3. Magazine: *T1* (JDRF, issue 2, 2008).
4. *Streetwise* series of leaflets (Eli Lilly, in conjunction with the Royal College of Nursing): *Body Piercing and Tattoos with Diabetes* (2006), *Drinking Safely with Diabetes* (2006), *Emotional Wellbeing with Diabetes* (2008), *Exercise with Diabetes* (2006), *High Blood Glucose with Diabetes* (2006), *Home Blood Glucose Testing with Diabetes* (2006), *Hypos with Diabetes* (2006), *Sex and beyond with Diabetes* (2006), *Sick Day Rules with Diabetes* (2006), *Top Tips for School with Diabetes* (2006), *Travelling with Diabetes* (2006).
5. Booklet: *Managing your Diabetes* (Roche/Accu-Chek, 2005).
6. CD-ROM: *Type 1 Diabetes with the JDRF Glucose Gang* (JDRF, sponsored by Novo Nordisk, 2008).
7. Leaflet: *Ethan, Type 1 Diabetes and Adolescence* (Sanofi Aventis, 2009).
8. Leaflet: *Carbohydrate Awareness Guide, Food Index* (Roche/Accu-Chek, 2005).
9. Leaflet: *Making the Jump to Insulin Pumps* (Roche/Accu-Chek, 2008).
10. EPIC 11–15 further information sheet (EPIC team, 2009 updated).
11. Carbohydrate counting sheet.
12. Welcome to your EPIC pack letter (parent).
13. Welcome to your EPIC pack letter (child).
14. EPIC sticker sheet (11–15 years).
15. Sharpie permanent marker pen.
16. EPIC diary (11–15 years).

BOX 34 Contents of the EPIC pack for 16–18 year olds

1. Booklet: *Living with Diabetes. A Guide for Teenagers* (Abbott, 2008).
2. Booklet: *Living with Diabetes* (BD Medical – Diabetes Care, 2009).
3. Magazine: *On the Level* (Diabetes UK, autumn 2009).
4. *Streetwise* series of leaflets (Eli Lilly, in conjunction with the Royal College of Nursing): *Body Piercing and Tattoos with Diabetes* (2006), *Drinking Safely with Diabetes* (2006). *Emotional Wellbeing with Diabetes* (2008), *Exercise with Diabetes* (2006), *High Blood Glucose with Diabetes* (2006), *Home Blood Glucose Testing with Diabetes* (2006), *Hypos with Diabetes* (2006), *Sex and beyond with Diabetes* (2006), *Sick Day Rules with Diabetes* (2006), *Top Tips for School with Diabetes* (2006), *Travelling with Diabetes* (2006), *Feet with Diabetes* (2006).
5. Booklet: *What is a Hypo*? (Sanofi Aventis, 2008).
6. Booklet: *Making Connections* (Diabetes UK, 2009).
7. Leaflet: *Know the Score* (Roche/Accu-Chek, 2005).
8. DVD: *Type 1 Diabetes: Journey of a Lifetime* (Diabetes UK, 2008).
9. Leaflet: *Carbohydrate Awareness Guide, Food Index* (Roche/Accu-Chek, 2005).
10. Leaflet: *Making the Jump to Insulin Pumps* (Roche/Accu-Chek, 2008).
11. EPIC 16–18 further information sheet (EPIC team, 2009 updated).
12. Carbohydrate counting sheet.
13. Welcome to your EPIC pack letter (parent).
14. Welcome to your EPIC pack letter (child).
15. Sharpie permanent marker pen.
16. EPIC diary (16–18 years).

(see www.epicproject.info) and they were asked for their consent (and parent/guardian consent if < 16 years of age) to take part in web-based activities such as choosing which image they liked best out of a selection.

In total, 33 children and young people responded. The website consultation showed that the diary covers created by the medical illustrator were liked by both girls and boys. For example, the 11–15 diary cover was preferred by 21 of the 33 respondents (11 boys and 10 girls between the ages of 6 and 15 years) and the 6–10 diary cover was preferred by the other 12 (4 boys and 8 girls between the ages of 6 and 18 years). Comments from the website consultation included the following:

> *It is colourful and fun for kids [chose 11–15 diary cover].*
>
> *Girl, 6–10 years, website consultation*

> *it is cute and the writing is fancy [chose 11–15 diary cover].*
>
> *Girl, 6–10 years, website consultation*

> *Boy x found it hard to choose – he liked both pictures, in the end went for the predominantly blue one, as it is a 'boy colour' [chose 11–15 diary cover].*
>
> *Parent/guardian of boy, 6–10 years, website consultation*

Further refining the age-appropriate elements of the programme theory and logic of the EPIC children's diabetes diaries and information packs

Overarching elements of intervention programme theory and logic have already been flagged when appropriate in previous sections of this chapter (see *Table 20* and *Box 31*; see also *Chapter 7*, *Figure 35*).

We again used the two theoretical models and proposition to better understand what age-appropriate care and partnership approaches mean in a children's diabetes context in order to further refine age-appropriate aspects of the intervention programme theory and logic.

Specific age-appropriate aspects of the programme theory and logic of the diabetes diaries and EPIC packs

EPIC pack for the 6–10 years age group

For children aged 6–10 years parents take the leading role in managing their diabetes. The emphasis of the information in the 6–10 years pack is on the condition itself and family-centred care. Self-care in diabetes medicine management should increase over time with the help of others (parents and diabetes professionals), with an expectancy that by the time children with T1D reach secondary school they will be able to self-manage their blood glucose testing and insulin management.

EPIC diary for the 6–10 years age group

Children in this age category wanted a diary that was big enough to hold and write in (*Figure 19*). The 6–10 years diary was therefore presented in A5 size. In the case of younger children, parents usually help complete the diabetes diary and teach their children over time to take on this responsibility. Children at the upper end of the 6–10 years age range could choose the 11–15 years diary instead of the 6–10 years diary if they wished. Information could be added to the pack over time to accommodate changing needs.

FIGURE 19 Image of a child aged 6–10 years engaging with the EPIC pack (photograph posed by model: © EPIC project).

EPIC pack for the 11–15 years age group

For children and young people aged 11–15 years, self-efficacy in diabetes medicine management is continually being developed. However, they would not be expected to be fully independent in their diabetes management. The assumption was that children and young people will become more independent in diabetes self-management but will still require some help from parents, other family members, friends or peers (*Figure 20*).

New/reminder information may improve communication between child and parent and possibly improve the child's understanding in a way that would reduce child and parent conflict in terms of shared decision-making about diabetes medicine management. The information contained in the 11–15 years pack was presented to help children and young people become expert in their self-care, enabling them to test their blood glucose levels and understand more about insulin administration.

EPIC diary for the 11–15 years age group

Children in this age group said that they preferred a smaller-sized diary than that produced for 6–10-year-old children but they wanted it still to be big enough to write in. The 11–15 years diary was therefore presented in A6 size. The expectation was that children and young people in the 11–15 age group would complete the diary more independently than those in the younger age group. If children were at the lower or upper end of the age bracket they could choose a diary from one of the other age categories.

FIGURE 20 Image of a child aged 11–15 years engaging with the EPIC pack (photograph posed by model: © EPIC project).

EPIC pack for the 16–18 years age group

In young people aged 16–18 years, self-efficacy in diabetes management should be established, with young people responsible for their own diabetes management. The assumption is that these young people would be expert and autonomous in their diabetes management and would be making choices about treatment independently of their parents. Information contained in the 16–18 years pack was selected to help the young person be expert in self-care, enabling him or her to test his or her blood glucose levels and understand more about titration of insulin administration. The information selected, for example information on lifestyle issues, driving, going to university and leaving home, reflected the changing information needs of young people.

EPIC diary for the 16–18 years age group

Previous consultation with young people in the 16–18 years age group showed that they wanted a diary that was small enough to fit into a back pocket (*Figure 21*) or in their blood glucose meter wallet. The 16–18 years diary was therefore presented in A7 size. The expectation was that these young people would complete the diary independently. It was intended that the diary would be taken everywhere and used on a daily basis to optimise self-management.

EPIC pump diary: all ages

Previous consultation with health professionals and children and young people on an insulin pump found that, to accommodate all of their needs, the diary would need to be fairly large. Therefore, as this was a universal diary, the size adopted was A5.

FIGURE 21 Image of a young person with the EPIC diary in a back pocket (photograph posed by model: © EPIC project).

Clinical governance and risk management

Clinical governance and risk management processes included formal sign off of each EPIC pack, diary and carbohydrate counting sheet by members of the clinical expert group. The clinical expert group signed off the EPIC packs and diaries as being appropriate for use in the NHS.

A disclaimer was developed in conjunction with the legal departments of both Cardiff University and Bangor University (*Box 35*) and was placed as a footer on the further information sheets.

National Institute for Health Research NHS branding

It was considered important that the EPIC diabetes diaries carried the NHS brand to indicate that they had not been produced by a pharmaceutical company or a third-sector organisation. Following an application and assessment process, permission to use the NIHR NHS logo on the back page of each EPIC diary was granted by the Programme Manager: Communications NETSCC (NIHR Evaluation, Trials and Studies Coordinating Centre), Service Delivery and Organisation. Additional wording was requested for the back page, which read 'This diary has been developed by the EPIC Project Team at Bangor and Cardiff Universities, June 2009. The EPIC Project is funded by the National Institute of Health Research (NIHR) Service Delivery and Organisation (SDO) programme. www.epicproject.info.'

Final production and distribution to sites

The EPIC diaries were printed by a local company. Additional quality-assured contents of the EPIC packs were obtained from producers at no cost. The final production, compilation, release and distribution of the EPIC packs and diaries to trial sites was organised by the EPIC researchers. Trial sites received regular stocks of packs ready to distribute.

The next chapter reports the RCT to determine the effectiveness of the EPIC intervention.

BOX 35 Disclaimer

1. Information resources and links are for general information purposes only and do not replace the need to consult with a health care professional or GP.
2. The EPIC project does not accept responsibility or liability for the content of, or information contained within, both the EPIC information resource pack and the websites produced by external companies, individuals or other providers. The project does not necessarily support the views they express or guarantee the accuracy of the information they provide.

Chapter 5 Stage 3: randomised controlled trial

Introduction

The focus of this chapter is on reporting the pragmatic RCT to determine the effectiveness of the suite of quality-assured, individually tailored and age-appropriate EPIC packs and diabetes diaries that were developed for the EPIC project and described in *Chapter 4*. A protocol reporting the trial design and methods has previously been published[30] (see *Appendix 1*). The embedded process evaluation is reported in *Chapter 7*.

Methods

Participants and setting

Children aged between 6 and 18 years with a diagnosis of T1D attending secondary care clinics and outpatient departments in the UK were eligible for inclusion in the trial. Participants were recruited from the paediatric diabetes clinics of 11 district general hospitals in England and Wales between 16 February 2010 and 11 August 2011. The inclusion philosophy was to recruit willing children and young people when possible and exclude children or young people only if being in the trial would be detrimental to their social, emotional or physical health. The exclusion criteria were needle phobia; any significant social or emotional problems when such problems, in the opinion of the clinical team, would be likely to impair a child's ability to take part in the trial; any significant physical or intellectual impairment that, in the opinion of the clinical team, would be likely to impair a child's ability to take part in the trial; or an inability to communicate in an age-appropriate way in written and spoken English.[30]

Ethical approval and governance

Ethical approval for the trial was granted by the Multi-centre Research Ethics Committee for Wales on 18 December 2008. The trial was registered with the Current Controlled Trials number ISRCTN17551624. The trial was overseen by an independent steering committee and data monitoring and ethics committee. The membership of each is listed in *Appendix 5* (see *Membership of the EPIC trial steering group and EPIC data monitoring and ethics committee*).

Selection of recruitment sites

The EPIC project was adopted by the DRN, MCRN and CRC Cymru. The adoption by these research networks meant that the research team was guided by the managers of the research networks regarding which diabetes centres to contact. Sites were selected in which there was support available from MCRN nurses, CRC Cymru Children and Young People's Research Network nurses or local research nurses. Four recruitment sites in Wales and seven in England were thus selected.

The EPIC trial launch events

The EPIC trial was launched at each site before recruitment of participants and following initial meetings with the local PIs, PDSNs and research nurses. The launch event had three key aims:

- to ensure shared clarity about site expectations, the key roles of people and to clarify the trial design and processes
- to convey the type of individual tailoring, active facilitation and integration (i.e. programme theory and logic) which we envisaged that diabetes staff would deliver when using the EPIC packs in routine practice and follow-up
- to clarify the key elements of data collection for the trial and the process evaluation.

It was during the launch events that most of the Approach Manuals (also known as Standard Practice Manuals) were completed by either the local PI or the PDSN.

Recruitment

All children, young people and their parents who met the inclusion criteria were sent a covering letter and age-appropriate EPIC project information sheet by the local research nurse or PDSN 1 week before a clinic visit inviting them to participate. Those who actually attended the scheduled clinic were approached to ask if they would like to participate, although numbers of children consented was usually limited by research nurse capacity on the day. Written assent or consent to take part in the trial and process evaluation was taken either by the PDSN or the research nurse, depending on the individual clinic organisation. Additional parental consent was obtained for children aged < 16 years and, as appropriate, if parents of young people aged > 16 years completed parent outcome questionnaires.

Randomisation

Following consent, baseline data were collected. Randomisation was performed after baseline data collection by the research nurse or PDSN, who either logged into the remote, secure, web-based randomisation service provided by the North Wales Organisation for Randomised Trials in Health and Social Care (NWORTH) Clinical Trials Unit or telephoned one of the EPIC staff to access the randomisation service for them. Participants were randomised into one of two arms, either to receive an EPIC pack or to have usual care. The child or young person was presented with the EPIC pack if he or she was allocated to the intervention arm of the RCT.

The randomisation process uses a sequentially randomised dynamic adaptive algorithm.[225] For each participant randomised the likelihood of his or her allocation to each treatment group is recalculated based on the participants already recruited and allocated. This recalculation is carried out at the overall allocation level, within stratification variables and within stratum level (the relevant combination of stratification levels). By undertaking this recalculation the algorithm ensures that balance is maintained within acceptable limits of the assigned allocation ratio while maintaining unpredictability. The randomisation process was weakly stratified for centre, age of child (6–10 years, 11–15 years and 16–18 years), sex and time since diagnosis (< 2 years and > 2 years).

The allocation ratio was 2 : 1 in favour of the EPIC pack (intervention) arm to gain more experience of the intervention.

Randomisation groups

Both groups

Either the PI or the PDSN at each diabetes centre completed an Approach Manual so that there was a record of standard care at each site at the beginning of each centre’s involvement in the RCT.

All centres were given the EPIC RCT step-by-step guide, which outlined the procedures for the administration of the trial. The ‘treatment as usual’ service delivery was not altered by the trial. All of the children and young people recruited into the trial attended their clinic appointments and had routine HbA_{1c} blood tests carried out as normal. As well as receiving the EPIC pack, which was intended to be actively facilitated and integrated into routine care, children in the intervention arm received usual care from their clinicians. Clinical data were extracted by the research nurses at the sites, anonymised, tagged with a unique trial number and returned to the trial centre.

EPIC pack: intervention arm

Age-appropriate EPIC diabetes diaries and packs were available for 6–10 year olds, 11–15 year olds and 16–18 year olds. The EPIC packs were intended to be individually tailored for each child and actively introduced and promoted to children and young people by the PDSN in diabetes clinics during routine consultations. The intention was for diabetes professionals to provide parents, children and young people with active, ongoing, child- and family-centred and age-appropriate support by integrating use of the EPIC packs into routine care to support diabetes self-management at home. An age-appropriate letter to child recipients was included in each EPIC pack outlining how to use the diabetes diary and pack to optimise diabetes self-management at home.

For each child who received an EPIC pack as part of the intervention arm the research nurse filled in a clinical report form (CRF) to record which elements of the pack were given or removed and to determine if anything else was added.

Usual care: non-intervention (control) arm

The children in the usual care arm of the trial did not receive the individually tailored EPIC information intervention. A record of the 'usual care' that they had previously received was recorded on the appropriate CRF (one of the four EPIC substitution forms).

Outcome measurements and assessment

The primary outcome measures that we selected were diabetes self-efficacy and quality of life (diabetes PedsQL[156]). We do, however, report HbA_{1c} measurements, generic quality of life, routinely collected NHS/child-held data, costs, service use, acceptability and utility as secondary outcomes.

Children and young people (if appropriate with the support of parents) completed a baseline questionnaire recording sociodemographic variables and patient characteristics. The PedsQL,[156] a paediatric quality-of-life measure (generic, diabetes and parent versions), was completed by children and parents. The European Quality of Life-5 Dimensions (EQ-5D), a measure of health-related quality of life, was completed by parents (as a proxy measure) as well as by the child or young person. Children and young people aged < 16 years completed the EQ-5D youth version. Parents and young people aged > 16 years completed the EQ-5D adult version.

Follow-up questionnaires, focusing on process and outcomes, were administered at 3 and 6 months (including data on health service use, episodes of diabetic ketoacidosis and all hospital admissions for acute complications). Non-responders received telephone and postal reminders after 2 and 4 weeks.

Baseline and subsequent HbA_{1c} measurements, blood glucose monitoring, readings and insulin dose were taken from routine test results and hand-held records when the participants attended routine 3- to 4-monthly clinic visits. Routine test results were recorded on the CRF by the research nurse or PDSN. Pre-intervention baseline characteristics related to diabetes duration and diabetes administration were also collected to characterise participants and to identify cofactors for predefined analysis.

Additional data collection for health economic analyses will be detailed in *Chapter 6*.

The selection of the primary outcome measure for the trial was guided by a NIHR-commissioned systematic review,[7] which recommended that measurement of HbA_{1c} levels (a glycaemic control measure) is not the appropriate primary outcome on which to assess the benefits of an intervention designed to more directly affect behaviour and self-management.

Following completion of follow-up data collection, 60 children and young people were interviewed (40 from the intervention group and 20 from the control group) to gain a further understanding of implementation issues and children's and young people's views and experiences of the EPIC packs and diaries if allocated to the intervention group or their experiences of usual care if allocated to the treatment-as-usual group. The participants were selected for interview on the basis of, for example, age, sex, ethnicity, diabetes regime, time since diagnosis, intervention or control group (for further details see *Chapter 7*).

The acceptability, impact and implementation of the new EPIC pack in practice within an existing diabetes service was assessed by inviting diabetes professionals and research nurses associated with the care of the children and young people in the trial to complete a semistructured questionnaire. The results are presented in *Chapter 7*.

Sample size calculation

Using as a guideline the systematic review of educational interventions targeting psychological effects and glycaemic control (HbA_{1c}) for children with diabetes conducted by Hampson *et al.*,[7] we aimed to detect a standardised effect size of 0.4 in our primary outcome measure. Allowing for a 10% dropout rate we calculated that we needed to recruit 252 children and young people with T1D. We employed a 2 : 1 randomisation strategy and initially aimed to randomise 168 children and young people into the intervention arm and 84 children and young people into the non-intervention arm, stratified by age, sex and length of time since diagnosis (< 2 years and > 2 years). We reviewed our sample size calculations in April 2011 and, after consultation with our data monitoring and ethics committee, applied for permission to extend our recruitment period and target sample to recruit up to 100 extra participants to counteract the effect of a higher dropout rate than was anticipated.

Data handling

Anonymised raw data were returned to the trial centre, logged and sent on to the NWORTH Clinical Trials Unit where they were scanned into an electronic form using the Teleform™ scanning system (URL: www.cardiff-teleform.com/html/digital_vision.html; Digital Vision, Highland Park, IL, USA). These data were then exported to the research databases held in Predictive Analytics SoftWare (PASW) Statistics (version 18.0; SPSS Inc., Chicago, IL, USA).

Before data analysis, validation checks were performed on the randomisation database to minimise the risk of bias in reporting. All randomisation stratification variables were reviewed and validated against both the CRFs and, when discrepancies were found, against source data before they were included in the baseline data sets.

All research data were subject to extensive cleaning, initially at the point of accepting the scanned data for face validity against completed forms and again by statistical processes checking for consistency between time points and data fields following a predefined data management plan following the Clinical Trials Unit data management standard operating procedures.[226]

Imputation and treatment of missing values

To protect the trial from bias resulting from dropouts, a full assessment of missingness was made and an appropriate imputation strategy developed. If demographic data remained missing after source data verification they are shown in the descriptive analysis table (see *Table 25*) and then imputed using the modal class for that variable for further use in the analysis. Missing quality-of-life data were defined as missing items within a subscale or scale (item missing), a missing subscale or scale within a time point or a time point missing. *Appendix 5* (see *Subscales imputation strategy for the Paediatric Quality of Life Inventory*) contains the imputation flow chart for the trial.

Scoring and imputing the Paediatric Quality of Life Inventory measures

The PedsQL generic scale is composed of 23 items that are combined to form four subscales: physical functioning (eight items), emotional functioning (five items), social functioning (five items) and school functioning (five items). The PedsQL diabetic scale is composed of 28 items that are combined to form five subscales: diabetes (11 items), treatment barriers (four items), treatment adherence (seven items), worry (three items) and communication (three items).

If ≤ 50% of items within each subscale were missing the subscale was scored as described in the manual instructions; otherwise, the subscale was set to missing. For cases in which, after this imputation, all subscales were complete the total generic and diabetic scores were calculated by appropriate linear combinations of the subscales.

For participants who still had missing subscales we assessed the number of missing subscales at each time point. If a participant had completed at least 60% of the subscales for the child self-report and parent's proxy (i.e. 11 subscales or more) at a time point, the missing subscales were imputed by a 'single' multiple imputation (MI) of subscales within time point. This imputation used all outcome subscales plus age, sex, centre, length of time since diagnosis and group as predictors. We adopted the fully conditional specification (FCS) technique to MI[227] using PASW Statistics. This is an iterative Markov chain Monte Carlo method in which missing values are sequentially imputed at each iteration until convergence is achieved. Once the subscale imputations had been run, missing time points were counted. If a participant had completed < 60% of the subscales the instrument was considered missing. Had there been > 20% of time points missing a MI treatment (five MIs across time points of all related outcome subscales plus age, sex, centre, length of time since diagnosis and group, or if > 50% of time points missing 10 MIs) would have been run. As only 15% of time points were missing at the 3-month follow-up and 6% at 6 months, we then used another single run of imputations of subscales within time points using all outcome subscales plus age, sex, centre, length of time since diagnosis and group.

Finally, total scores were obtained by a using a linear combination of the imputed subscales for each module.

Imputing European Quality of Life-5 Dimensions health utility scores and visual analogue scales

If one item in the health utility score was missing then the missing item was imputed using a weighted mean of the completed items; otherwise, the score was set to missing. We then followed the same procedure as for missing subscales within the PedsQL, this time using complete PedsQL, EQ-5D and EQ-5D visual analogue scale (VAS) scores and age, sex, centre, length of time since diagnosis and group as predictors.

Imputing the glycated haemoglobin measure

If follow-up data were not available for HbA_{1c}, we imputed data using five MIs across time points of the measure using the same FCS technique as for the quality-of-life measures.[228]

Statistical analysis

We described the characteristics and demographics of the sample at baseline. When there was very sparse demographic information (e.g. ethnicity, for which 96% of participants were in one category), we combined categories to sustain analyses.

Differences between treatment groups were analysed using the mixed-model approach to repeated measures analysis of variance, adjusting for any differences in baseline measurements. We estimated parameters for two fixed factors: the two time points (3 and 6 months) and treatment group. Centre was included in the model as a random factor. We also included the interaction between treatment group and time point to examine whether any observed differences between treatment groups varied across the different time points. These analyses examine changes in the quality-of-life measures (youth/adult EQ-5D, PedsQL generic and diabetes-specific health measures) over baseline, using both a pairwise comparison, studying change across individuals, and a cohort analysis comparing overall change in group means. In addition, we compared the intervention and control groups at the 3- and 6-month time points, separately, by means of unadjusted and adjusted models, adjusting for the same variables that showed differences in baseline measurements as previously. We used a two sample *t*-test and the analysis of covariance (ANCOVA), respectively, for this modelling. This provided a sensitivity analysis to assess how robust the conclusions were using the main approach. Bonferroni corrections were made to significance levels to account for multiple comparisons in the analysis of the subscales of the primary outcome measures (nine subscales for each parent and child report PedsQL at two time points, therefore $0.05/36 = 0.0013$ is the significance level accepted for those measures). Any significant results discovered should be interpreted with this in mind.

Multiple regression analysis was planned to identify factors that predict good outcomes within and between groups. This course was not pursued on advice from the independent steering committee in light of the main results of the trial.

Cost-effectiveness analysis

We undertook a cost–utility analysis in which costs were in monetary terms and outcomes were in preference-based non-monetary units, quality-adjusted life-years (QALYs). The area under the curve method was used for calculating QALYs, weighting survival by quality-of-life weights measured using the children's EQ-5D self-reports. We compared our findings with the unofficial NICE ceiling of £30,000 per QALY. Discounting was not necessary given the time period. Bootstrapping was used to provide an estimate of the probability distribution of the cost-effectiveness ratio, its confidence interval (CI) or variance in the ratio. This analysis and the subsequent results are presented fully in *Chapter 6*.

Protocol violations

There were 29 instances in which the trial team withdrew participants' data from analysis after randomisation but before any analysis was carried out (see the results section). One instance was a second randomisation of a participant in error by a research nurse, coinciding with a migration of web servers in the trial centre, leading to a failure to detect the second instance of randomisation. The other 28 withdrawals arose after a new centre joined the trial and, in error, randomised 17 participants before taking baseline measures. Young people and their parents were sent from clinic with baseline measures for self-completion. In some cases these baseline measures were not completed and in others completion took place several weeks after the clinic and therefore after the packs had been distributed in the trial arm. Once the situation had come to light, the investigators, in consultation with the trial statistician, decided to exclude the participants from the main analysis to protect the trial from any bias that might have been introduced by the baseline questionnaire being completed after the results of the randomisation were known. We decided to continue with data collection from these participants in order to perform a sensitivity analysis to assess any bias that might have occurred as a consequence of the decision to remove them post randomisation. To further protect the trial from bias, and to ensure good practice at all of the centres, a quality audit of the baselining process against time of randomisation was undertaken. This revealed 11 further cases in which young people had been sent home with their baseline questionnaires rather than completing them in clinic as per protocol. For consistency these data have also been removed from the primary analysis and included in the sensitivity analyses.

Sensitivity analyses

Sensitivity analyses were performed to assess whether participants who did not adhere to the protocol or who were lost to follow-up threatened the validity of the trial. The first of these analyses is a true ITT analysis conducted on all randomised participants.[229] These analyses were designed to assess the robustness of the imputations described earlier and the decision about which cut of the data to define as the primary analysis. The sensitivity analyses indicate whether the results and conclusions are likely to change if different assumptions or methods had been used. The mixed-effects models were run on four hierarchical subsets of the originally randomised participants: (1) all randomised (fully imputed, ITT analysis), (2) excluding the protocol violations (fully imputed), (3) excluding loss to follow-up and protocol violations (i.e. main analysis, fully imputed) and (4) complete case analysis (no imputation).

Results

Trial recruitment and Consolidated Standards of Reporting Trials

In total, 1105 potential participants were screened by trial site nurses for possible entry to the trial. Of these 1105, 146 (13.2%) were not eligible according to trial eligibility criteria, 335 (30.3%) declined to participate after being given a letter of invitation and trial information sheet and 287 (26.0%) were missed in clinic or did not join the trial for other reasons. In total, 337 (30.5%) were initially randomised but 29 of these (8.6%) were withdrawn from the analysis because of protocol violations, including one randomisation duplication. A sensitivity analysis of the data including these participants is provided in *Appendix 5*. In total, 308 participants were therefore considered to be legitimately randomised trial participants. However, a further 15 (4.5%) provided no follow-up data at all and were therefore also excluded from the primary analysis. *Figure 22* illustrates the Consolidated Standards of Reporting Trials (CONSORT) diagram for the trial. These data are presented more fully by centre in *Appendix 5* (see *Eligibility exclusions at screening by centre: CONSORT eligibility data* and *CONSORT data: number of eligible participants who did not join the trial by centre*).

Accuracy and validation of randomisation stratification variables and baseline demographic information

Data verification revealed misclassifications in only two of the stratification variables: age group and length of time since diagnosis. One participant was randomised to the 16–18 years age group instead of the 11–15 years age group and another was randomised to the 11–15 years age group instead of the 16–18 years age group. The date of diagnosis in some cases varied between the clinical perspective and the perspective of the child or his or her parents. At randomisation 74 participants (22%) reported a length of diagnosis of ≤ 2 years, of whom 48 were allocated to the intervention group and 26 to the control group. For the 263 participants reporting a diagnosis period of > 2 years, 176 were allocated to the intervention group and 87 to the control group. At validation the clinical date of diagnosis was adopted as being a more reliable record of the diagnostic timing. This difference increased the number of participants with a length of diagnosis of > 2 years to 314 (207 intervention and 107 control allocations). *Table 25* shows the demographic characteristics used to stratify the randomisation both at randomisation and after validation and removal of those participants for whom a protocol violation had been noted.

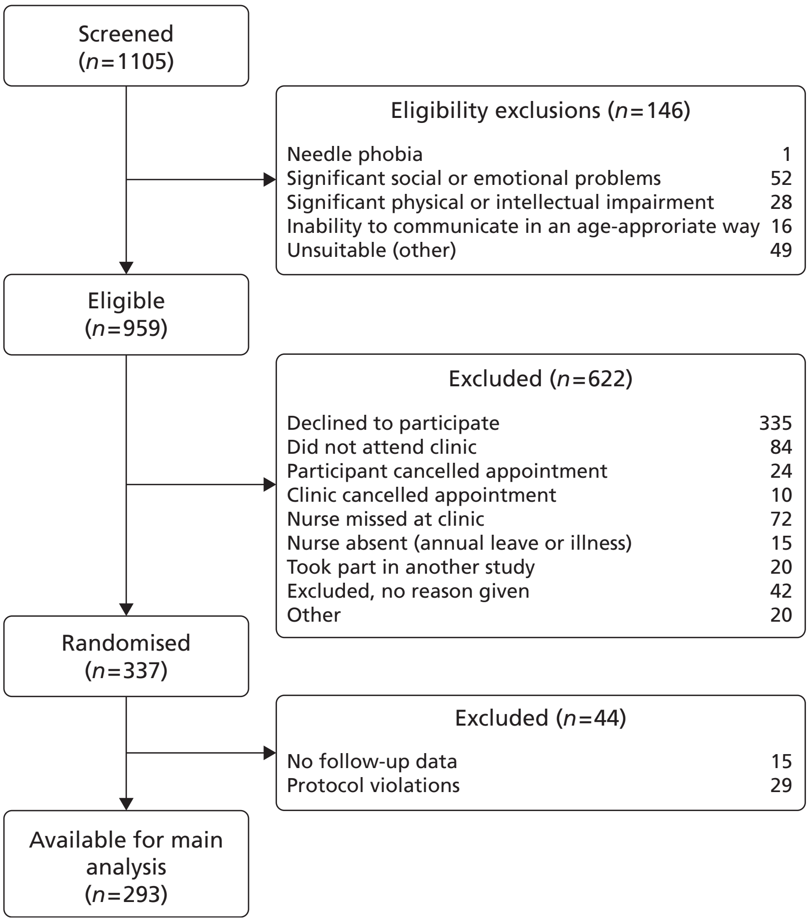


FIGURE 22 The CONSORT diagram, from screening to analysis.

TABLE 25 Stratification characteristics of randomised participants and participants after validation by group

Characteristic	Participants			
	Randomised, *n* (%)		Analysed, *n* (%)	
	EPIC pack	TAU	EPIC pack	TAU
n	223 (66)	114 (34)	190 (65)	103 (35)
Time since diagnosis (years)				
≤ 2	16 (7)	7 (6)	11 (6)	7 (7)
> 2	207 (93)	107 (94)	179 (94)	96 (93)
Age group (years)				
6–10	78 (35)	40 (35)	67 (35)	36 (35)
11–15	103 (46)	53 (46)	92 (48)	50 (49)
16–18	42 (19)	21 (18)	31 (16)	17 (17)
Sex				
Male	105 (47)	55 (48)	85 (45)	49 (48)
Female	118 (53)	59 (52)	105 (55)	54 (52)
Centre code				
Y	23 (10)	11 (10)	20 (11)	9 (9)
L	23 (10)	11 (10)	19 (10)	10 (10)
B	18 (8)	10 (9)	15 (8)	10 (10)
A	25 (11)	11 (10)	23 (12)	11 (11)
Q	21 (9)	11 (10)	20 (11)	10 (10)
I	6 (3)	2 (2)	5 (3)	1 (1)
T	18 (8)	10 (9)	18 (9)	9 (9)
U	26 (12)	14 (12)	23 (12)	14 (14)
O	29 (13)	15 (13)	25 (13)	15 (15)
N	16 (7)	9 (8)	16 (8)	9 (9)
S	18 (8)	10 (9)	6 (3)	5 (5)

TAU, treatment as usual.

Baseline characteristics were collected from three different sources: child self-report questionnaires, parent proxy questionnaires and the CRFs, as reported by the research nurse. All of the baseline characteristics were validated using the same methods as for the stratification variables. Any discrepancies found between the three sources of information were first reported to centres for verification of the data. After the centres had verified the data, if a discrepancy still remained in one of the questionnaires, data were accepted from the two source questionnaires that showed agreement. If all three types of questionnaire differed, discrepancies were resolved by consultation with the chief investigators after examining any other data available.

Baseline demographics and diabetes-related characteristics of trial participants

Of the 293 participants analysed, 159 (54%) were female and 134 (46%) were male. Participants ranged in age from 6 years to 18 years 9 months [mean 12.5 years, standard deviation (SD) 3.1 years] and were predominantly white (96%). The majority of the participants (83%) lived in an owner-occupied dwelling. In total, 26 (9%) lived in a private rented dwelling and 25 (9%) were renting from an association or local authority. Baseline questionnaires for the 16–18 years age group included a question about employment status. In total, 20 (42%) of the 48 16- to 18-year-old participants were at secondary school, 22 (46%) were in college, five (10%) were employed and one (2%) reported being unemployed. For analysis purposes we distinguished between those participants receiving full-time education and the rest, combined into an 'other' category. *Table 26* shows all of the demographic data for those randomised and analysed and any category consolidation made for analysis purposes.

TABLE 26 Baseline demographic characteristics of randomised and analysed participants

Demographic characteristic	Randomised ($n = 337$), *n* (%)	Analysed ($n = 293$), *n* (%)	Variable as used in analysis ($n = 293$), *n* (%)
Sex			
Male	160 (47)	134 (46)	134 (46)
Female	177 (53)	159 (54)	159 (54)
Age (years)			
Range	6–19	6–19	6–19
Mean (SD)	13 (3)	13 (3)	13 (3)
Ethnicity			
White British	315 (93)	280 (96)	280 (96)
Other	3 (1)	2 (1)	13 (4)
Other white background	1 (0)	1 (0)	–
White and black Caribbean	1 (0)	1 (0)	–
White and Asian	1 (0)	1 (0)	–
Other mixed background	4 (1)	4 (1)	–
Indian	4 (1)	3 (1)	–
Pakistani	1 (0)	1 (0)	–
Other Asian background	7 (2)	–	–
Missing	–	–	–
Education and employment[a]			
Secondary school	20 (32)	20 (42)	20 (42)
Further education college	32 (51)	22 (46)	22 (46)
Other	6 (10)	5 (10)	6 (13)
Employed	2 (3)	1 (2)	–
Unemployed	3 (5)	–	
Missing			
Living situation			
Owner-occupied house/flat	268 (80)	242 (83)	242 (83)
Privately rented house/flat	28 (8)	26 (9)	26 (9)
Housing association/local authority	32 (9)	25 (9)	25 (9)
Other	2 (1)	–	–
Missing	7 (2)	–	–

a Includes participants in the 16–18 years category ($n = 63$ for all randomised participants and $n = 48$ for the analysed participants).

The mean length of diagnosis was 7 years 6 months (SD 3.8 years, range 8 months to 16 years 7 months). *Table 27* shows the diabetes characteristics of those randomised and those finally analysed.

A total of 254 (87%) participants were on insulin injections whereas 39 (13%) were on CSII therapy. Of those on injections, over half [140 (55%)] had insulin injections four times a day, 28 (11%) had insulin injections at least five times a day, 24 (9%) had insulin injections three times a day, 60 (24%) had insulin injections twice a day and two (1%) had only one injection a day. The insulin dosage ranged from 8–150 mmol/l (median 40 mmol/l). Almost half of the participants [139 (47%)] monitored their blood glucose concentration four times a day, with 86 (29%) reporting monitoring five or more times a day, 47 (16%) testing three times a day, 12 (4%) testing twice and five (2%) testing once a day. Two (1%)

TABLE 27 Baseline diabetes characteristics of randomised and analysed participants

Diabetes characteristics	Randomised ($n = 337$), n (%)	Analysed ($n = 293$), n (%)	Variable as used in analysis ($n = 293$), n (%)
Time since diagnosis (years)			
Range	0.8–16.7	0.8–16.7	0.8–16.7
Mean (SD)	8 (4)	8 (4)	8 (4)
Missing	1	–	–
Type of insulin administration			
Injections	293 (87)	254 (87)	254 (87)
Pump	43 (13)	39 (13)	39 (13)
Missing	1 (0)	–	–
Insulin regime[a]			
Once a day	2 (1)	2 (1)	2 (1)
Twice a day	71 (24)	60 (24)	60 (24)
Three times a day	27 (9)	24 (9)	24 (9)
Four times a day	160 (55)	140 (55)	140 (55)
Five or more times a day	33 (11)	28 (11)	28 (11)
Insulin dosage (mmol/l)			
Range	8–150	8–150	8–150
Median (IQR)	41 (25–60)	40 (28–61)	40 (28–61)
Missing[b]	5	3	3
Blood glucose tests			
None	4 (1)	2 (1)	2 (1)
Once a day	8 (2)	5 (2)	5 (2)
Twice times a day	14 (4)	12 (4)	12 (4)
Three times a day	52 (15)	47 (16)	47 (16)
Four times a day	153 (45)	139 (47)	139 (47)
Five or more times a day	96 (28)	86 (29)	86 (29)
Missing[b]	10 (3)	2 (1)	2 (1)

IQR, interquartile range.
[a] Insulin regime of patients on insulin injections.
[b] These missing values were imputed for inclusion in analyses.

participants reported that they did not test their blood glucose concentration and two (1%) did not report any information.

Post-randomisation data loss

Randomisation for the EPIC trial was performed in a ratio of 2 : 1, with 223 participants randomised to receive the pack and diary and 114 randomised to the control group. Losses resulting from protocol violations and losses to follow-up totalled 33 from the pack arm and 11 from the control arm. These losses were not significantly different [χ^2 (1) = 1.76, $p = 0.18$] across the two arms of the trial.

We assessed differences for various baseline characteristics between participants followed up [293 (87%)], participants lost to follow-up [15 (4%)] and participants withdrawn by the trial team [29 (9%)]. The results are presented in *Table 28*, which shows no differences between the groups except for the characteristics of 'ethnicity' and 'education and employment', for which differences are the result of a large number of missing values for those variables arising from one centre.

The post-randomisation CONSORT diagram (*Figure 23*) illustrates these data by trial arm.

TABLE 28 Baseline characteristics of participants by whether included in the final analysis

Characteristics	Included in final analysis ($n = 293$), n (%)	Protocol violations ($n = 29$), n (%)	Lost to follow-up ($n = 15$), n (%)	Significance (p-value)[a]
Demographic characteristics				
Sex				
Male	134 (84)	18 (11)	8 (5)	0.219
Female	159 (90)	11 (6)	7 (4)	
Age (years)				
Range	6–9	7–18	6–18	
Mean (SD)	13 (3)	13 (4)	12 (3)	0.720
Ethnicity				
White British	280 (89)	20 (6)	15 (5)	< 0.001
Other	13 (59)	9 (41)	–	
Education and employment[b]				
Secondary school	20 (100)	–	–	0.020
Further education college	22 (69)	9 (28)	1 (3)	
Other	6 (75)	2 (25)	–	
Missing	–	3 (100)	–	
Living situation				
Owner-occupied house/flat	242 (90)	19 (7)	9 (3)	0.061
Privately rented house/flat	26 (93)	1 (4)	1 (4)	
Housing association/local authority	25 (78)	2 (6)	5 (16)	
Missing	–	7 (100)	–	

continued

TABLE 28 Baseline characteristics of participants by whether included in the final analysis (*continued*)

Characteristics	Included in final analysis ($n = 293$), n (%)	Protocol violations ($n = 29$), n (%)	Lost to follow-up ($n = 15$), n (%)	Significance (p-value)[a]
Diabetes-related characteristics				
Time since diagnosis (years)				
Mean (SD)	8 (4)	8 (4)	7 (4)	0.627
Missing	–	1	–	
Type of insulin administration				
Injections	254 (87)	25 (9)	14 (5)	0.931
Pump	39 (91)	3 (7)	1 (2)	
Missing	–	1 (100)	–	
Insulin regime[c]				
Once a day	2 (100)	–	–	0.259
Twice a day	60 (85)	5 (7)	6 (8)	
Three times a day	24 (89)	3 (11)	–	
Four times a day	140 (88)	14 (9)	6 (4)	
Other	28 (85)	3 (9)	2 (6)	
Insulin dosage (mmol/l)				
Range	8–150	12–111	17–102	
Median (IQR)	40 (28–61)	22 (18–47)	49 (35–60)	0.208
Missing	3	2	–	
Blood glucose tests				
None	2 (50)	1 (25)	1 (25)	0.067
Once a day	5 (63)	2 (25)	1 (13)	
Twice a day	12 (86)	2 (14)	–	
Three times a day	47 (90)	2 (4)	3 (6)	
Four times a day	139 (91)	8 (5)	6 (4)	
Other	86 (90)	6 (6)	4 (4)	
Missing	2 (20)	8 (80)	–	
HbA1[c] (%)[d]				
Range	5.9–14.0	6.3–13.4	6.5–10.9	
Mean	8.7	8.9	8.9	

IQR, interquartile range.

a Chi-squared, Fisher's exact test or Kruskal–Wallis chi-squared as appropriate.

b Includes participants in the 16–18 years category ($n = 48$).

c Insulin regime of patients on insulin injections.

d Pooled estimates.

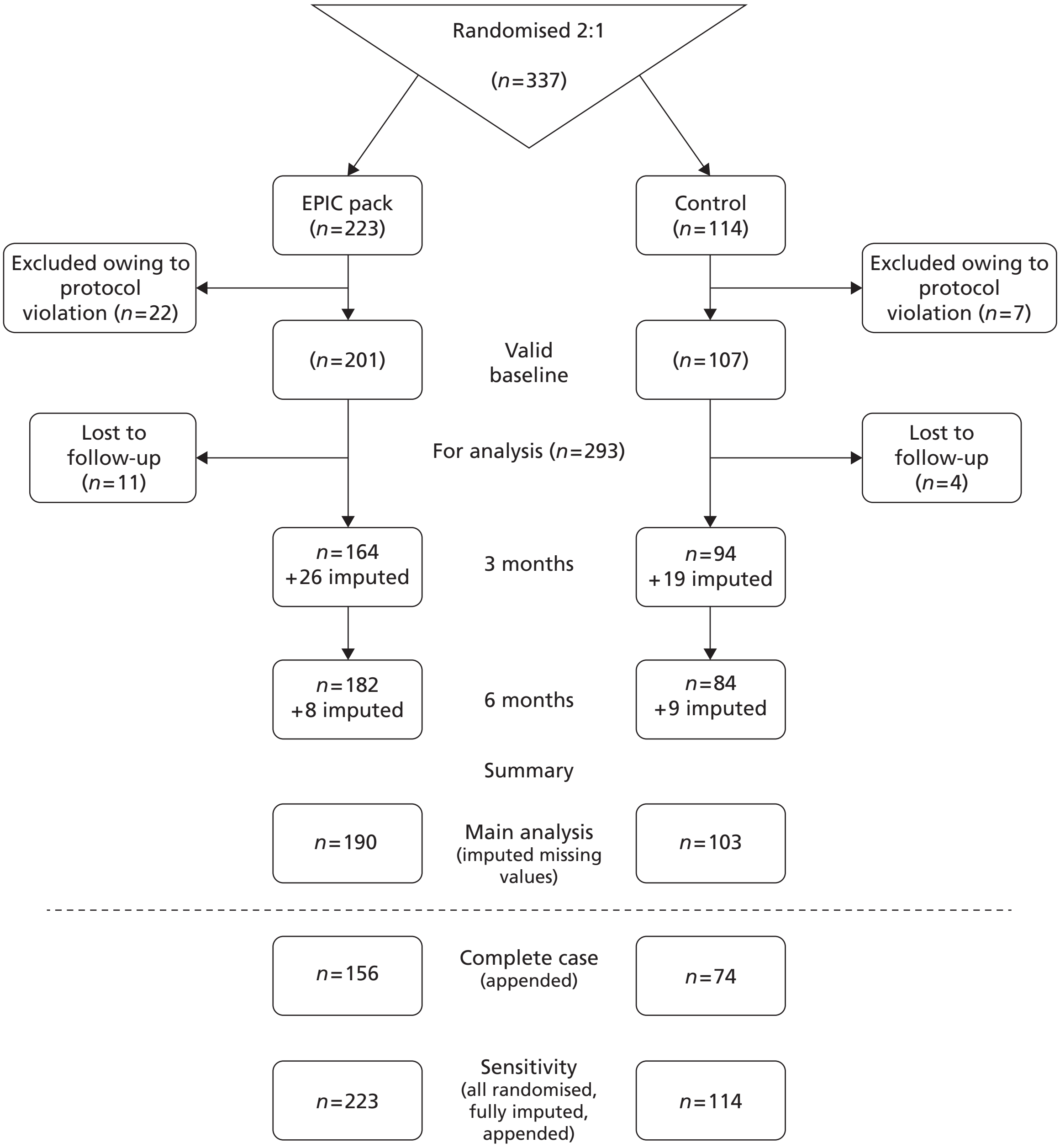


FIGURE 23 The CONSORT diagram showing missing data, from randomisation to analysis.

The demographic profile of the participants in each arm of the trial

Table 29 shows that the demographic and diabetes-related characteristics of participants were very similar in the intervention and control groups. There were slight differences between the two arms of the trial for education and employment status and current living situation. Fisher's exact test was performed to assess differences in education and employment and the chi-square test was used to compare the living situation in the two groups. No significant differences were found [Fisher's $p = 0.650$; χ^2 $(2) = 2.54$, $p = 0.281$].

TABLE 29 Baseline characteristics by treatment arm

Characteristic	EPIC pack ($n = 190$), n (%)	TAU ($n = 103$), n (%)
Demographic characteristics		
Sex		
Male	85 (45)	49 (48)
Female	105 (55)	54 (52)
Age (years)		
Range	6–19	6–18
Mean (SD)	12 (3)	13 (3)
Ethnicity		
White British	179 (94)	101 (98)
Other	11 (6)	2 (2)
Education and employment[a]		
Secondary school	13 (42)	7 (41)
Further education college	13 (42)	9 (53)
Other	5 (16)	1 (6)
Living situation		
Owner-occupied house/flat	156 (82)	86 (83)
Privately rented house/flat	20 (11)	6 (6)
Housing association/local authority	14 (7)	11 (11)
Diabetes-related characteristics		
Time since diagnosis (years)		
Range	1–17	1–16
Mean (SD)	7 (4)	8 (4)
Type of insulin administration		
Injections	167 (88)	87 (84)
Pump	23 (12)	16 (16)
Insulin regime[b]		
Once a day	2 (1)	–
Twice a day	41 (25)	19 (22)
Three times a day	14 (8)	10 (11)
Four times a day	95 (57)	45 (52)
Other	15 (9)	13 (15)

TABLE 29 Baseline characteristics by treatment arm (*continued*)

Characteristic	EPIC pack ($n = 190$), n (%)	TAU ($n = 103$), n (%)
Insulin dosage (mmol/l)		
Range	8–129	10–150
Median (IQR)	41 (29–61)	40 (25–61)
Missing[c]	2	1
Blood glucose tests		
None	1 (1)	1 (1)
Once a day	4 (2)	1 (1)
Twice a day	7 (4)	5 (5)
Three times a day	31 (16)	16 (16)
Four times a day	89 (47)	50 (49)
Other	57 (30)	29 (28)
Missing[c]	1 (1)	1 (1)
HbA_{1c} (%)		
Range	5.9–14.0	6.0–13.7
Mean[d]	8.8	8.6

IQR, interquartile range; TAU, treatment as usual.
a Includes only the 48 participants in the 16–18 years category; other age groups were assumed to be in school.
b Insulin regime of patients on insulin injections.
c These missing values were imputed for inclusion in analyses.
d Pooled estimates.

Clinical effectiveness results

At baseline (before randomisation) the outcome variables were measured for the whole group. PedsQL diabetes scores were 75.3 (SD 14.3) for the child self-report and 66.93 (SD 15.5) for the parent proxy. The generic scale of the PedsQL was 82.4 (SD 12.8) for the child self-report and 76.7 (SD 14.9) for the parent proxy. The EQ-5D health utility mean score was 0.90 (SD 0.15) for the child-self report and 0.84 (SD 0.18) for the parent proxy and the mean VAS score at baseline was 81.3 (SD 17.8) for the child-self report and 81.9 (SD 17.4) for the parent proxy. *Table 30* shows the unadjusted summary results for all of the quality-of-life measures at the 3- and 6-month time points. A comparison of the parent proxy and child-reported quality-of-life measures is presented later in this chapter (see *Child self-report and parent proxy comparisons*).

TABLE 30 Unadjusted results for outcome measures at the 3- and 6-month time points: child self-report and parent proxy

	EPIC pack		TAU		Difference (pack – TAU)			
Outcome variable	Mean	SD	Mean	SD	Mean	SD	95% CI	*p*-value[a]
Child self-report								
PedsQL: generic module								
Total score – 3 months	82.23	13.39	80.37	14.39	1.87	13.75	−1.45 to 5.18	0.268
Total score – 6 months	82.49	13.48	83.58	12.98	−1.09	13.30	−4.29 to 2.11	0.504
PedsQL: diabetes module								
Total score – 3 months	74.16	13.37	72.70	14.09	1.46	13.63	−1.82 to 4.74	0.382
Total score – 6 months	73.76	15.21	75.41	13.58	−1.65	14.66	−5.18 to 1.88	0.359
EQ-5D								
3 months	0.87	0.20	0.85	0.22	0.02	0.21	−0.03 to 0.07	0.499
6 months	0.87	0.19	0.88	0.18	−0.01	0.18	−0.05 to 0.04	0.758
EQ-5D VAS								
3 months	81.64	17.43	78.76	17.32	2.88	17.39	−1.30 to 7.07	0.176
6 months[b]	81.07	17.44	76.98	20.44	4.09	19.44	−0.61 to 8.78	0.087
Parent proxy								
PedsQL: generic module								
Total score – 3 months	78.00	13.69	77.80	13.65	0.20	13.68	−3.10 to 3.49	0.906
Total score – 6 months	78.59	13.91	76.60	14.72	1.99	14.20	−1.43 to 5.41	0.252
PedsQL: diabetes module								
Total score – 3 months	65.31	14.80	67.30	14.10	−1.99	14.56	−5.50 to 1.52	0.265
Total score – 6 months[b]	66.55	15.78	67.32	13.23	−0.77	14.93	−4.36 to 2.83	0.675
EQ-5D								
3 months	0.81	0.20	0.82	0.22	−0.01	0.20	−0.06 to 0.04	0.639
6 months	0.83	0.20	0.84	0.18	−0.01	0.19	−0.06 to 0.03	0.582
EQ-5D VAS								
3 months	81.34	17.44	81.63	16.43	−0.29	17.09	−4.41 to 3.83	0.890
6 months	81.57	18.35	80.55	17.55	1.02	18.08	−3.33 to 5.37	0.645

TAU, treatment as usual.

[a] Two-sided *t*-tests at the 5% significance level.

[b] Unequal variances assumed.

Paediatric Quality of Life Inventory diabetes module

The primary outcome measure in this trial was diabetes self-efficacy as measured by the PedsQL diabetes module, which showed non-significant results favouring the pack at 3 months and treatment as usual at 6 months in the child-self report and treatment as usual at both time points for the parent proxy for the unadjusted analysis. For the child self-report measure the difference between the pack and treatment as usual was 1.46 at 3 months and 1.65 at 6 months and for the parent proxy the differences were 1.99 and 0.77 respectively. There were no significant differences between the groups for any of the subscales of the module (see *Appendix 5*, *Unadjusted models by time point* and *Analysis of covariance: adjusted model by stratification variables and their baseline values by time point, child self-report*).

After the data were adjusted for baseline score and the stratification variables, the child self-report scale still showed no significant differences between the groups. After Bonferroni adjustment no PedsQL diabetic module subscales reported significant differences. However, two subscales showed a trend to significance, with the treatment adherence subscale at 6 months favouring treatment as usual ($p = 0.009$) and the worry subscale at 3 months favouring the intervention arm ($p = 0.008$) in the ANCOVA (see *Appendix 5*, *Analysis of covariance: adjusted model by stratification variables and their baseline values by time point, child self-report*).

Figures 24 and *25* illustrate the results of the linear mixed-effect models analysis and *Table 31* shows a summary table for the primary analysis, with more details provided in *Appendix 5* (see *Mixed-effect models*).

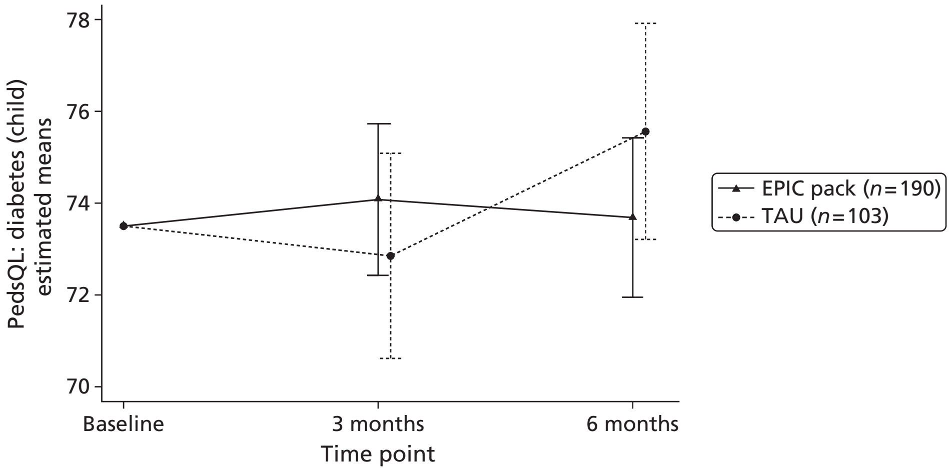


FIGURE 24 Child self-report estimated mean PedsQL diabetes scores and 95% CIs over time adjusted for baseline score and stratification variables by randomisation group. TAU, treatment as usual.

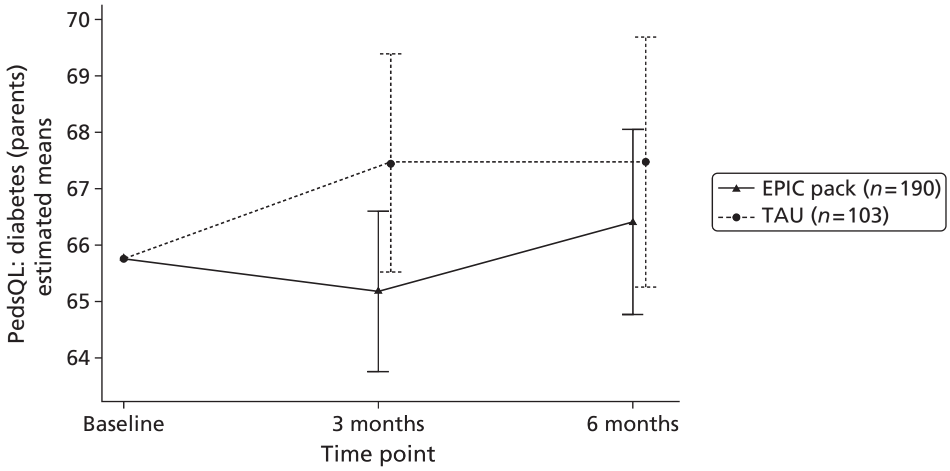


FIGURE 25 Parent proxy estimated mean PedsQL diabetes scores and 95% CIs over time adjusted for baseline score and stratification variables by randomisation group. TAU, treatment as usual.

TABLE 31 Mixed-effect models: adjusted model by stratification variables and their baseline values

Outcome variable	Covariates significant at 5%	*p*-value	Difference (pack – TAU) Mean	SE	95% CI	*p*-value
Child self-report						
PedsQL: generic module						
Total score	Baseline score	< 0.001	–0.96	1.10	–3.13 to 1.21	0.384
	Time point	0.038				
	Treatment group by time point	0.024				
PedsQL: diabetes module						
Total score	Baseline score	< 0.001	0.32	1.26	–2.80 to 2.16	0.798
	Treatment group by time point	0.02				
EQ-5D	Baseline score	< 0.001	0.00	0.02	–0.03 to 0.04	0.960
	Sex	0.014				
	Time since diagnosis	0.009				
EQ-5D VAS	Baseline score	< 0.001	1.10	1.70	–2.26 to 4.45	0.520
	Age	0.045				
Parent proxy						
PedsQL: generic module						
Total score	Baseline score	< 0.001	0.94	1.15	–1.33 to 3.20	0.512
PedsQL: diabetes module						
Total score	Baseline score	< 0.001	–1.68	1.09	–3.82 to 0.47	0.125
	Age	0.037				
EQ-5D	Baseline score	< 0.001	–0.03	0.02	–0.06 to 0.01	0.178
EQ-5D VAS	Baseline score	< 0.001	–1.34	1.54	–4.38 to 1.69	0.385
	Sex	0.023				

SE, standard error; TAU, treatment as usual.

Baseline score was the only significant predictor of both the 3-month score and the 6-month score in all subscales and in the total measure of the diabetes module of the PedsQL, but there was some indication that centre could be a significant factor in the barriers to treatment, worry and communication subscales (see *Appendix 5*, *Analysis of covariance: adjusted model by stratification variables and their baseline values by time point, child self-report*).

After adjustment for baseline score the parent proxy data revealed a non-significant difference in favour of the treatment as usual arm at 3 months but this difference had lessened by 6 months. Significant baseline covariates in predicting 3-month values were baseline PedsQL diabetic score ($p < 0.001$) and age ($p = 0.039$). At 6 months the only significant factor was baseline score ($p < 0.001$).

The only two subscales showing a trend to significant results were the diabetes symptoms subscale ($p = 0.034$) and the treatment adherence subscale ($p = 0.025$) at 3 months, both favouring the treatment as usual group. Neither of these results were significant after Bonferroni correction was applied.

Paediatric Quality of Life Inventory generic module

The unadjusted results for the PedsQL generic module at 3 and 6 months (see *Table 30*) showed no significant differences between groups for either the child self-report or the parent proxy measure. The results were virtually identical between the groups at 3 months but were beginning to diverge by 6 months in favour of the treatment as usual arm for the child self-report and in favour of the EPIC pack for the parent proxy measure.

Figures 26 and *27* show that these results remained the same after adjustment for baseline score and stratification variables. Baseline score was the only significant covariate ($p < 0.001$) at the 3- and 6-month time points for the child self-report scale. None of the generic subscales showed significant differences between the groups after adjustment for multiple testing. The mixed-effect models (see *Table 31*) reported very similar findings.

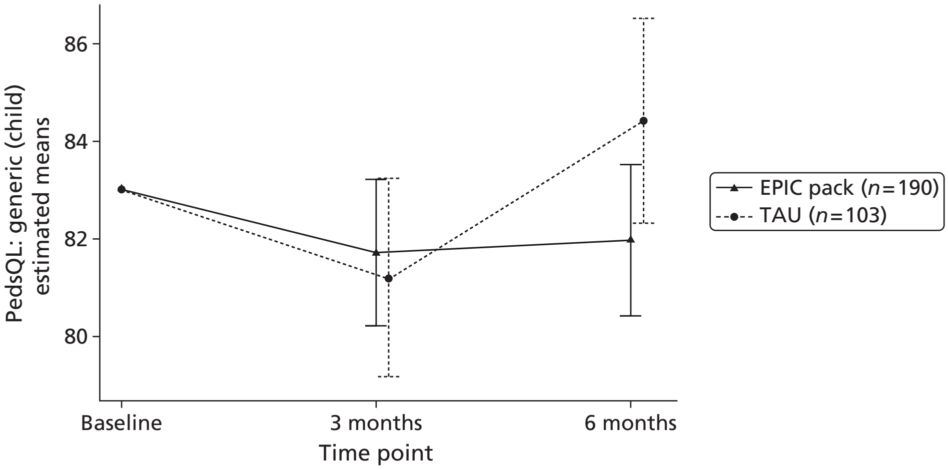


FIGURE 26 Child self-report estimated mean PedsQL generic scores and 95% CIs over time adjusted for baseline score and stratification variables by randomisation group. TAU, treatment as usual.

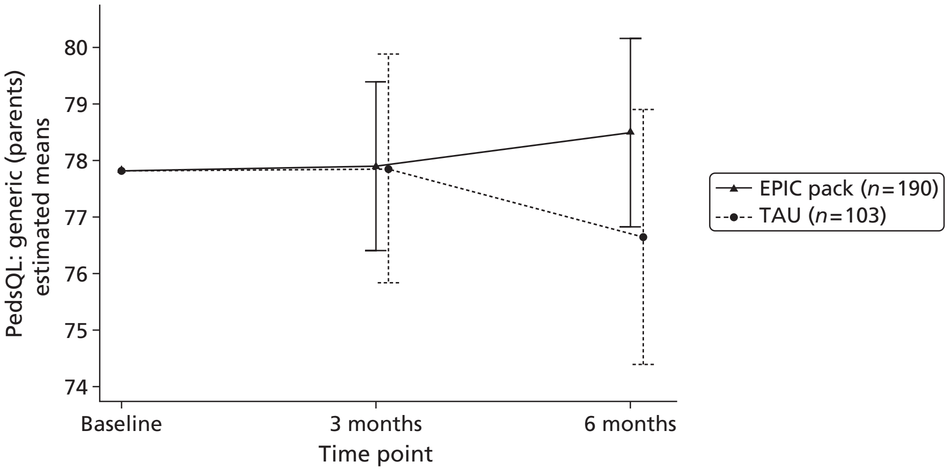


FIGURE 27 Parent proxy estimated mean PedsQL generic scores and 95% CIs over time adjusted for baseline score and stratification variables by randomisation group. TAU, treatment as usual.

Tables 32 and *33* summarise the results of the adjusted analysis for the child self-report and parent proxy report respectively. The covariates that were significant at the 5% level are indicated. All other stratification variables were included in the analysis but did not prove to be significant contributors to the models described. Further details of these analyses are presented in *Appendix 5* (see *Analysis of covariance: adjusted model by stratification variables and their baseline values by time point, parent proxy* and *Child self-report and proxy comparisons*).

European Quality of Life-5 Dimensions health utility scores

The mean (SD) EQ-5D score for the whole group at baseline was 0.90 (0.15). The unadjusted EQ-5D scores (see *Table 30*) for both child self-report and parent proxy were very similar between groups and invariant over time.

Parents reported mean (SD) EQ-5D scores of 0.82 (0.22) at 3 months and 0.84 (0.18) at 6 months in the control arm and 0.81 (0.20) and 0.83 (0.20), respectively, in the treatment arm. At baseline parents reported a mean (SD) score of 0.84 (0.18).

The child scores were slightly higher than the parent proxy scores, with 0.85 (SD 0.22) at 3 months and 0.88 (SD 0.18) at 6 months in the control arm and 0.87 (SD 0.2) at both the 3- and 6-month time points in the treatment arm.

TABLE 32 Analysis of covariance: adjusted model by stratification variables and their baseline values by time point, child self-report

Outcome variable	Covariates significant at 5%	*p*-value	Difference (pack – TAU)		95% CI	*p*-value
			Mean	SE		
PedsQL: generic module						
Total score – 3 months	Baseline	< 0.001	0.40	1.26	–2.08 to 2.87	0.751
Total score – 6 months	Baseline	< 0.001	–2.32	1.31	–4.90 to 0.264	0.078
PedsQL: diabetes module						
Total score – 3 months	Baseline	< 0.001	1.25	1.37	–1.45 to 3.95	0.363
	Centre	0.048				
Total score – 6 months	Baseline	< 0.001	–1.72	1.45	–4.57 to 1.13	0.235
EQ-5D[a]						
3 months	Baseline	< 0.001	0.01	0.19	–0.04 to 0.06	0.642
	Time since diagnosis	0.024				
6 months	Baseline	< 0.001	–0.01	0.16	–0.05 to 0.03	0.598
	Time since diagnosis	0.047				
	Sex	0.002				
EQ-5D VAS[a]						
3 months	Baseline	< 0.001	0.69	15.01	–2.93 to 4.30	0.708
	Age	0.009				
6 months	Baseline	< 0.001	1.70	16.64	–2.31 to 5.71	0.405

SE, standard error; TAU, treatment as usual.
a Residuals not normally distributed.

TABLE 33 Analysis of covariance: adjusted model by stratification variables and their baseline values by time point, parent proxy

Outcome variable	Covariates significant at 5%	*p*-value	Difference (pack – TAU) Mean	SE	95% CI	*p*-value
PedsQL: generic module						
Total score – 3 months	Baseline	< 0.001	–0.12	1.25	–2.59 to 2.35	0.925
Total score – 6 months	Baseline	< 0.001	2.11	1.40	–0.64 to 4.86	0.132
PedsQL: diabetes module						
Total score – 3 months	Baseline	< 0.001	–2.28	1.19	–4.62 to 0.06	0.057
	Age	0.039				
Total score – 6 months	Baseline	< 0.001	–1.02	1.39	–3.74 to 1.71	0.464
EQ-5D[a]						
3 months	Baseline	< 0.001	–0.03	0.18	–0.07 to 0.02	0.210
	Age	0.041				
6 months	Baseline	0.001	–0.02	0.19	–0.07 to 0.02	0.312
	Sex	0.025				
EQ-5D VAS[a]						
3 months	Baseline	< 0.001	–1.52	14.64	–5.04 to 2.01	0.398
	Sex	0.049				
6 months	Baseline	< 0.001	–0.92	15.1	–4.55 to 2.72	0.620
	Sex	0.049				

SE, standard error; TAU, treatment as usual.

a Residuals not normally distributed.

Figures 28 and *29* illustrate the EQ-5D child self-report and parent proxy results, respectively, after adjustment for baseline score and stratification covariates. There are no differences in the child scores between the groups whereas the parent proxy scores, although not significantly different, do show consistency of direction, with those whose child was receiving the intervention pack reporting worse proxy values for the ED-5D.

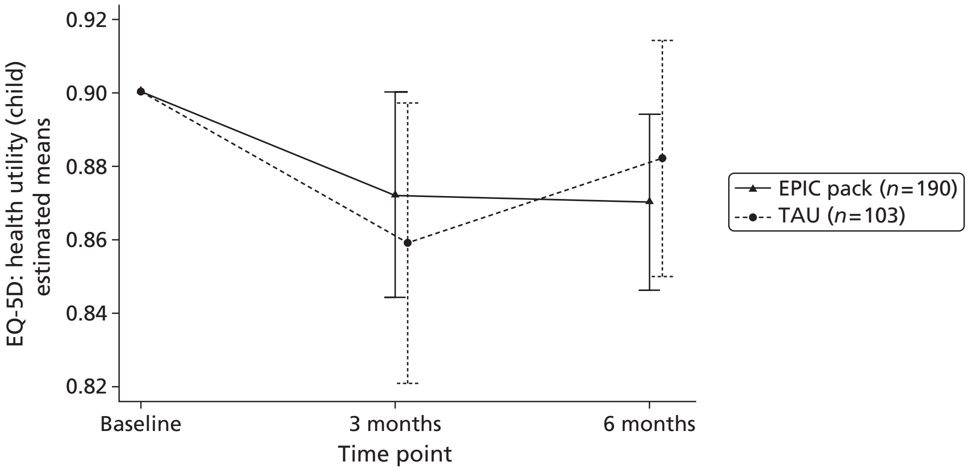


FIGURE 28 Child self-report estimated mean EQ-5D health utility scores and 95% CIs over time adjusted for baseline score and stratification variables by randomisation group. TAU, treatment as usual.

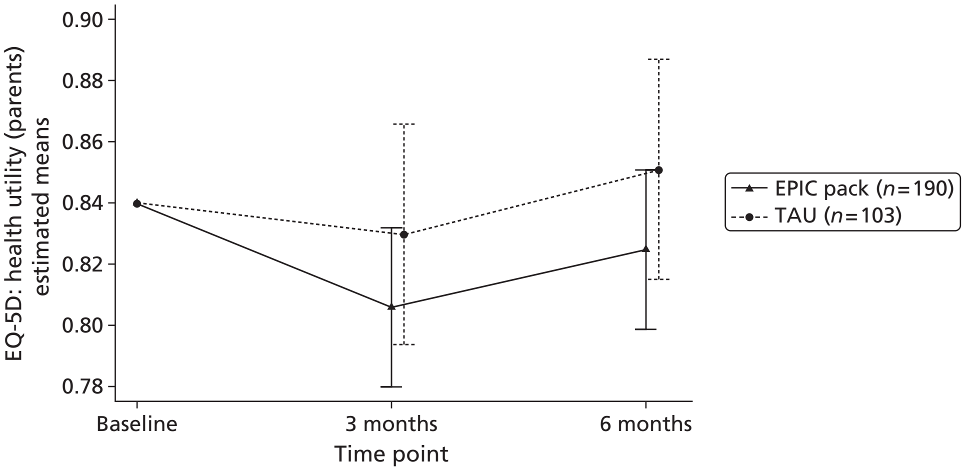


FIGURE 29 Parent proxy estimated mean EQ-5D health utility scores and 95% CIs over time adjusted for baseline score and stratification variables by randomisation group. TAU, treatment as usual.

European Quality of Life-5 Dimensions visual analogue scale scores

The unadjusted parent- and child-reported VAS scores were not significantly different between the two arms of the trial.

Baseline score was a significant factor ($p < 0.001$) in predicting both 3- and 6-month VAS scores for both children and parents. Once that and the other baseline stratification variables had been accounted for the EQ-5D VAS findings were the same as the findings for the other outcome measures with no significant differences between groups.

There was no treatment group by time point interaction suggesting no evidence of differences between the groups over time (*Figures 30* and *31*).

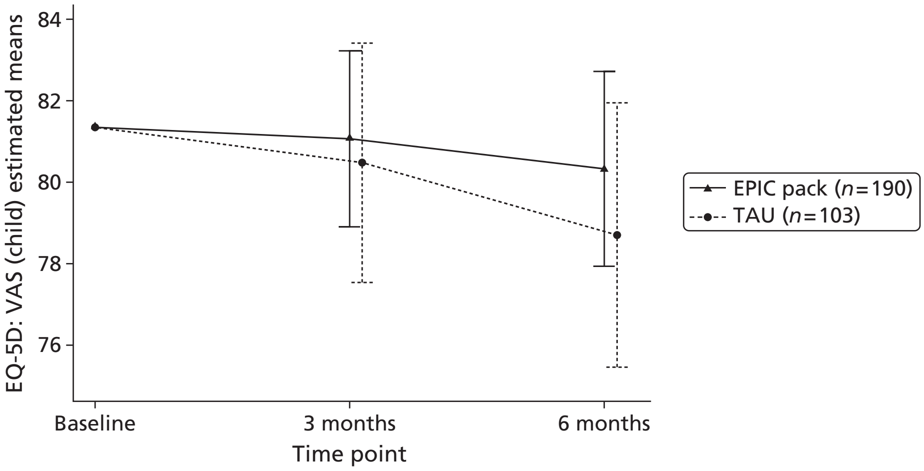


FIGURE 30 Child self-report estimated mean EQ-5D VAS scores and 95% CIs over time adjusted for baseline score and stratification variables by randomisation group. TAU, treatment as usual.

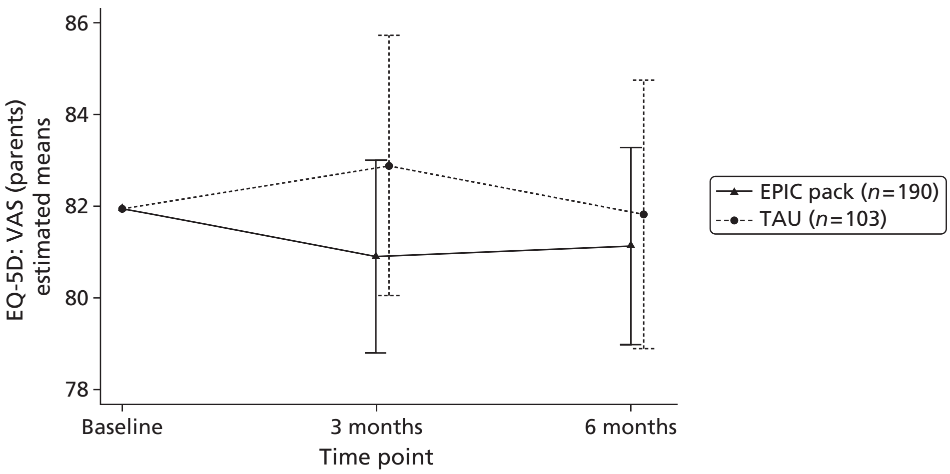


FIGURE 31 Parent proxy estimated mean EQ-5D VAS scores and 95% CIs over time adjusted for baseline score and stratification variables by randomisation group. TAU, treatment as usual.

Glycated haemoglobin results

Participants started the trial with a mean baseline HbA_{1c} score of 8.70% (SD 0.06%). The mean HbA_{1c} score remained virtually unchanged during the follow-up period [8.62% (SD 0.06%) at both 3 and 6 months]. *Table 34* shows the pooled effect estimates and their 95% CIs for all of the covariates and interaction terms included in the linear mixed-effect model. No significant differences in HbA_{1c} between treatment groups were found.

The only significant covariate at either 3 or 6 months was baseline score, showing that baseline values are a good predictor of HbA_{1c} at follow-up. Thus, for example, a participant who enters the trial with a HbA_{1c} value of 9.70 is expected to end the trial with a value that is 0.72 units [95% CI 0.64 to 0.80] higher than the value for a participant who enters the trial with a HbA_{1c} value that is 1 unit lower (i.e. 8.70), and that value would be expected to lie between 9.34 and 9.50.

TABLE 34 Mixed-effects model: pooled effect estimates for HbA_{1c} after adjusting for stratification variables and baseline score

	Estimate	SE	95% CI	*p*-value
Intercept	2.27	0.38	1.53 to 3.01	< 0.001
HbA_{1c} (baseline)	0.72	0.04	0.64 to 0.80	< 0.001
Age	0.02	0.02	–0.02 to 0.06	0.296
Sex (male)	0.04	0.11	–0.18 to 0.25	0.716
Time since diagnosis	–0.02	0.02	–0.05 to 0.01	0.157
Time point	0.02	0.11	–0.19 to 0.23	0.851
Treatment group (EPIC pack)	–0.02	0.14	–0.31 to 0.27	0.904
Treatment group by time point	–0.04	0.14	–0.31 to 0.23	0.765

SE, standard error.

Sensitivity analyses

Sensitivity analyses were performed to investigate whether including participants in the analyses who were lost to follow-up, withdrew or did not adhere to their protocol changed the earlier conclusions drawn from the results of the primary analysis. The sensitivity analyses were conducted by repeating the primary analyses on the total scales using different sample sizes that were selected hierarchically ($n = 337$, all randomised participants; $n = 308$, randomised participants excluding protocol violations; and $n = 193$, participants with available outcomes at all time points) and comparing these results with the primary results. These main effects models are reported fully in *Appendix 5* (see *Sensitivity analysis*).

There were no significant differences between the results of the sensitivity analyses and those of the primary analyses. In the case of all randomised participants the reported means and standard errors were very slightly lower than or identical to those reported in the main analysis for the PedsQL measures and very slightly higher than or identical to those reported for the EQ-5D health utility and VAS scores.

The mean difference in primary outcome between the two trial arms was –1.14 (95% CI –3.59 to 1.32) for the child self-report and –1.43 (95% CI –3.51 to 0.66) for the parent proxy, compared with –0.32 (95% CI –2.80 to 2.16) for the child self-report and 1.68 (95% CI –3.82 to 0.47) in the main analysis.

The results from the analysis of all randomised participants excluding those with protocol violations followed the same pattern and we found no differences in the outcome measures between this analysis and the primary analysis (whether the results favoured the intervention or treatment as usual). However, when comparing the results of the complete case analysis with the results of the primary analysis we found that the estimates in the primary analysis were slightly lower for all outcome measures. The only non-significant difference in outcome results was found for the child self-reported EQ-5D VAS.

Child self-report and parent proxy comparisons

Baseline child self-report measures showed significant correlations with the parent proxy measures, ranging between 0.59 and 0.75. The mean and median scores for the PedsQL generic module, the PedsQL diabetic module and the EQ-5D were significantly higher for child self-report than for the parent proxy. We formally assessed these differences by performing a paired two-sample t-test if data were normally distributed and the Wilcoxon signed-rank test if data were skewed, which in all cases yielded a p-value of < 0.001. The exception was the VAS for which the parent proxy reported a higher but non-significantly different median VAS score (86) from the child self-report (80) in the treatment as usual arm ($Z = –1.014$, $p = 0.310$).

Summary statistics and correlation coefficients for the pre-intervention baseline clinical outcome measures for the child-self report and parent proxy report by treatment arm are presented in *Table 35*. The full breakdown by subscale is provided in *Appendix 5* (see *Child self-report and proxy comparisons*).

As the parent proxy and child self-report measures are supposed to both be measuring the quality of the child's life, albeit from differing perspectives, we further examined the data using a Bland–Altman approach.

TABLE 35 Pearson (*r*) and Spearman (ρ) correlation coefficients for the pre-intervention baseline clinical outcome measures for the child-self report and parent proxy report by treatment arm

	Description							
	EPIC pack (*n* = 190)				TAU (*n* = 103)			
Outcome measure	Child self-report	Parent proxy	*r*	ρ	Child self-report	Parent proxy	*r*	ρ
PedsQL: diabetes module								
Range	26–100	12–96			35–96	31–95		
Mean (SD)	74 (15)	66 (15)	0.65[a]	–	73 (12)	66 (14)	0.59[a]	–
PedsQL: generic module								
Range	43–100	25–100			33–100	35–100		
Mean (SD)	84 (12)	78 (15)	0.65[a]	–	82 (13)	78 (14)	0.75[a]	–
EQ-5D: heath utility score[b]								
Range	0.2–1	0–1			0.2–1	0.3–1		
Mean (SD)	0.9 (0.2)	0.8 (0.2)			0.9 (0.2)	0.8 (0.2)		
Median (IQR)	1 (0.8–1)	0.8 (0.7–1)	–	0.56[a]	1 (0.8–1)	0.8 (0.7–1)	–	0.43[a]
EQ-5D VAS[b]								
Range	25–100	25–100			0–100	0–100		
Mean (SD)	83 (17)	83 (16)			78 (19)	80 (19)		
Median (IQR)	90 (75– 95)	90 (76.5–95)	–	0.49[a]	80 (70–95)	86 (74–90)	–	0.55[a]

IQR, interquartile range; TAU, treatment as usual.

a Correlation is significant at the 0.01 level (two-tailed).

b Highly skewed data.

The Bland–Altman plots (*Figures 32* and *33*) revealed a significant bias towards the child self-report showing higher scores for both PedsQL scales at baseline. The mean difference in scores between the child self-report and the parent proxy report was 7.7 (95% CI 6.2 to 9.2) for the diabetes module and 5.6 (95% CI 4.3 to 6.9) for the generic scale.

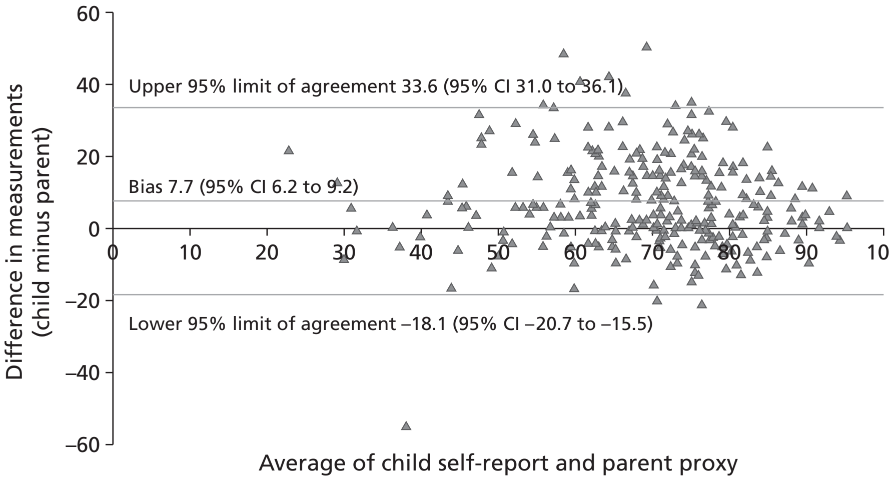


FIGURE 32 Bland–Altman plot for the PedsQL diabetes module: child self-report and parent proxy report at baseline (*n* = 289).

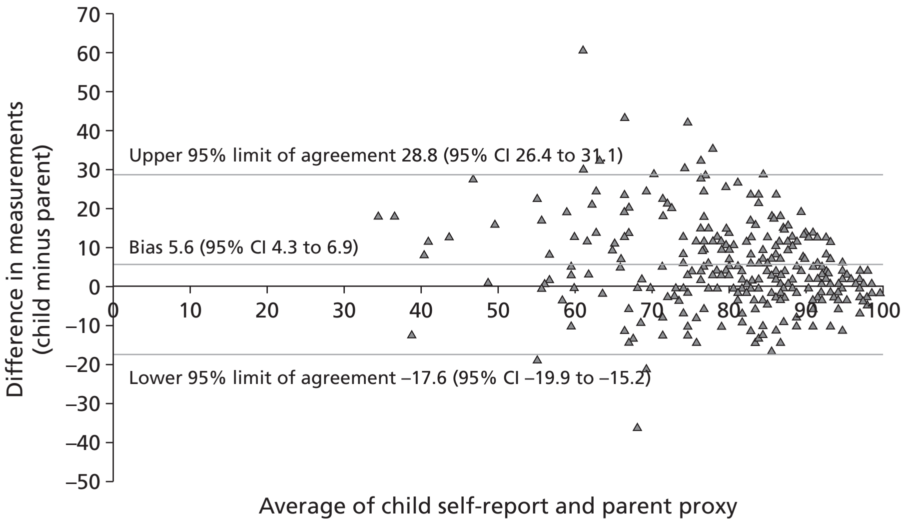


FIGURE 33 Bland–Altman plot for the PedsQL generic module: child self-report and parent proxy report at baseline ($n = 289$).

We also computed the Bland–Altman plots at 3 and 6 months' follow-up and found the same pattern, with a difference in mean scores between the child self-report and the parent proxy report of 8.8 (95% CI 6.8 to 10.7) for the PedsQL diabetes module and 5.1 (95% CI 3.4 to 6.8) for the PedsQL generic module.

Statistical discussion

The diagnostic evaluation of the ANCOVA models (see *Tables 32* and *33*) was fully appraised. When these models were fitted we found that the majority of them were reasonably well fitting; however, models using EQ-5D data violated the assumption of normality of the error terms. This was due to the high degree of skewness of the data, demonstrating a ceiling effect towards the best state of quality-of-life outcome. We applied a square transformation, which barely improved the error terms. Therefore, it was decided to perform the analysis on the raw scores to aid interpretation. However, the results from this analysis, presented in *Table 26*, should be interpreted with caution. Only significant covariates are presented in the table although all were included in every analysis. Adjusting the models for baseline and stratification variables changed the direction of the effect for three of the outcomes. We conclude that the non-significant results across time points favouring the EPIC pack for the EQ-5D and VAS child self-report and the PedsQL generic module parent proxy report are due to a genuine 'no difference' rather than an effect of underpowering the trial. The only significant finding observed was for the PedsQL diabetes module at 3 months for the parent proxy report, which, given the other weight of evidence of no effect, is likely to be a type I error.

With random effects and unbalanced data (our case), the test of fixed effect is difficult and mixed models are more appropriate.

Our sensitivity analyses were designed to quantify any bias resulting from the exclusions that we made in the primary results and to detect any bias arising from non-random dropout by eligible participants. These analyses support the results of the primary analysis, confirm the robustness of the imputations and allow us to conclude that we did not introduce systematic bias by our exclusion and imputation decisions.

The Bland–Altman plots for the EQ-5D also revealed a small but significant bias towards the child self-report showing a mean difference of approximately half a point (see *Appendix 5*, *Child self-report and proxy comparisons*); however, these data were drawn from a highly skewed distribution that demonstrated a strong ceiling effect and therefore these results should be interpreted with some care. The main use of the quantification of observed bias between parent- and child-reported quality of life lies in the ability to accurately adjust one measure to use when the other is missing from a data set.

Although it was initially planned to perform subgroup analyses to investigate potential predictors of outcome, they were not carried out following the recommendations of the data monitoring and ethics committee (DMEC) to avoid data dredging and to not compromise the effort made during the recruitment stage to achieve and maintain the power of the trial.

There is a clear finding that providing participants with the tailor-made EPIC information pack provides no advantage compared with treatment as usual in terms of quality of life. This finding was consistent across all of the unadjusted results and also once adjustment had been made for baseline values and the stratification variables. The linear mixed model also revealed that there was no underlying effect of time on the results. The consistency of the findings across time and analysis technique confirms the robustness of our conclusions.

In the next chapter the findings from the health economic evaluation are reported.

Chapter 6 Stage 3: health economic analysis

Introduction

In this chapter we first explain the revised economic objective as the trial found no evidence of effect, provide an overview of the existing economic evidence relating to supporting children and young people living with T1D, describe the measurement of outcomes and costs included in the economic evaluation plan for the EPIC project and, finally, report the EPIC project intervention costs and the types and frequency of contacts with primary and secondary health-care services, patterns of service use and associated costs by the intervention and control groups over the 6-month study period. We report a range of health-related consequences including diabetes-related quality of life (PedsQL diabetes module), generic quality of life (PedsQL generic module), generic health-related quality of life (EQ-5D) [child completed and parent proxy completed, measured at baseline (before randomisation), 3 months and 6 months] and HbA_{1c} measurements taken routinely in clinic.

Economic analysis objective

The primary objective of the health economics analysis was, from a NHS perspective, to assess the cost-effectiveness of a child-centred, age-appropriate information pack intervention for the management of children and young people with T1D, alongside the EPIC RCT, as described in the EPIC protocol.[30] However, the RCT results reported in *Chapter 5* showed no significant difference between the intervention group (EPIC pack) and the treatment as usual group for the primary outcome measure of diabetes self-efficacy and quality of life (PedsQL diabetes module) or for the secondary outcome measures [HbA_{1c}, generic quality of life (PedsQL generic module) and generic health-related quality of life (EQ-5D)]. Because of the absence of any statistically significant differences in any of the outcome measures we report a cost–consequence rather than a cost–utility analysis. Our reporting of the economic analysis in the EPIC project is consistent with NIHR publishing guidelines,[230] our published standard operating procedure for economic evaluation alongside RCTs[231] and published technical guidance.[232,233]

Economic evidence

In 2006 Murphy *et al.*,[97] in their systematic review, found no papers addressing the cost-effectiveness of child-centred, age-appropriate information for children and adolescents with T1D. Since then our own more recent as yet unpublished review of existing health economics evidence found three studies[234–236] that address economic issues in this field, one of which is relevant to UK practice, although none was a cost-effectiveness study. In the UK, Gregory *et al.*[234] conducted a cluster randomised trial of the development of a psychosocial intervention for children and teenagers with diabetes [the Development and Evaluation of a Psychosocial Intervention for Children and Teenagers Experiencing Diabetes (DEPICTED) study]. They hoped to conduct a cost-effectiveness study but, as with our study, there were no significant differences in their main outcome measure (HbA_{1c}) and so they conducted a cost-minimisation study. In the USA, Rodgers *et al.*[235] conducted a RCT of the impact of a preconception counselling programme for teens with T1D (READY-Girls) on patient–provider interactions, resource utilisation and cost. In another US study, Fischer *et al.*[236] undertook a RCT of nurse-run, telephone-based outreach to improve lipid control in people with diabetes.

Health economics methods

Measurement of consequences

Measurement of diabetes-specific health-related quality of life

The main outcome measure in this cost–consequence study was the PedsQL diabetes module, a validated quality-of-life measure for children with diabetes.[156] The choice of outcomes was informed by a NIHR-commissioned systematic review[97] recommending that HbA_{1c} (a glycaemic control measure) is not the appropriate primary outcome on which to assess the benefits of an intervention designed to more directly affect behaviour/self-management and quality of life.

Measurement of child-specific general health-related well-being

In this cost–consequence study we also assessed children's and young people's general health-related well-being (one of the secondary outcomes planned for this trial)[30] by means of the PedsQL generic module questionnaire, a validated general well-being questionnaire developed for children and young people.[156] Further details about the PedsQL generic module questionnaire are provided in *Chapter 5*.

Measurement of generic health-related quality of life

Our interest in measuring health-related quality of life as an important outcome measure in this trial led us, after consideration of a range of health-related quality of life measures such as the Health Utilities Index, Short Form questionnaire-12 items and EQ-5D,[237] to choose the EQ-5D as our source of preference-based utility weights for any potential QALY gains from this intervention.[237,238] QALYs measure health gain in terms of survival (in years), weighted for health-related quality of life.[237] We calculated the difference in mean QALYs between the intervention (EPIC pack) group and the control (treatment as usual) group.

Measurement of glycated haemoglobin

Glycated haemoglobin levels were measured routinely at clinic visits in all children and young people in the EPIC trial, with HbA_{1c} levels (percentages) recorded at baseline and 3 and 6 months. Further details about the HbA_{1c} measurements are provided in *Chapter 5*.

Measurement of type and frequency of health-care service use by children and young people with type 1 diabetes

We collected the frequency of primary and secondary health-care service use by all children and young people participating in the EPIC trial. These data were collected using a Client Service Receipt Inventory (CSRI)[239,240] at baseline (before randomisation) and at 3 and 6 months. The CSRI was completed by children and young people with the help of a parent or guardian when necessary. The CSRI provided a structured record of the type and frequency of consultations, visits to emergency departments and outpatient clinics and inpatient stays.

Measurement of costs

EPIC information pack intervention cost

All versions of the EPIC information packs and diaries were costed by age group and insulin administration route (injection or insulin pump) by recording the quantities and costs of materials used to produce the folders, printed materials, stickers, diaries (this included the costs of printing the diaries but the costs of researcher time to produce the diaries were not included), etc. and recording on self-completed questionnaires the additional time in clinic taken by the PDSNs to explain the purpose of the packs and how they were to be used by children and young people in the intervention group. In reality, few packs were actually given out by PDSNs and so the time recorded on the questionnaires is likely to have been used to answer children's questions, as reported subsequently in the process evaluation (see *Chapter 7*).

Based on the information reported by the PDSNs on the time taken in clinic to explain the purpose of the packs, we estimated the mean additional time taken in clinic by PDSNs and the corresponding unit cost. Using this unit cost we generated a mean total unit cost for the EPIC information pack intervention, weighted to reflect differences in the costs of pack materials for the different age groups and different routes of insulin administration (i.e. injection or insulin pump). Subsequently, we calculated the mean total intervention cost for the EPIC trial, weighting the total unit cost for the EPIC information pack intervention by the number of children and young people in each age group in the trial.

Costs of health-care service use

We undertook the cost–consequence analysis from a NHS perspective. This included primary and secondary NHS service costs. We applied national average unit cost estimates to these health-care services, drawn from published sources including *Unit Costs of Health and Social Care 2011*[241] and *2010–11 Reference Costs*.[242] All costs are in 2010–11 pounds sterling. As we followed participants for only 6 months, discounting was not necessary.[232]

Cost-effectiveness and cost–consequence analysis

Murphy *et al.*[97] strongly recommend that cost-effectiveness is considered as an outcome in RCTs as none of the studies in their review of psycho-educational interventions with adolescents addressed cost-effectiveness. As mentioned earlier, a cost-effectiveness study was initially planned for the EPIC trial;[30] however, because of the absence of a statistically significant difference in any of the outcome measures used, as reported in *Chapter 5*, we undertook a cost–consequence analysis rather than a cost–utility analysis as initially planned. Cost–consequence analysis is a variant of cost-effectiveness analysis in which we present an array of components of the incremental costs (e.g. health service use costs) and consequences (e.g. health-related outcomes), comparing the two treatment arms in the trial (i.e. EPIC pack group vs. treatment as usual group), without aggregating these results into a cost-effectiveness ratio or a cost–utility ratio.[232]

Analysis of consequences

We calculated and used change from baseline scores for the analysis of the PedsQL. For the analysis of the ED-5D data we integrated outcomes (EQ-5D utility index scores) over time for individuals by calculating the area under the curve (a standard approach to QALY calculation[233]) to produce the incremental mean QALY difference between the intervention (EPIC pack) group and the control (treatment as usual) group over the 6-month study period.

Analysis of costs

We compared the frequencies and costs of health service use by children and young people in the intervention group and the control group over 6 months. As the distributions of both frequencies and costs were skewed, we compared frequencies using a non-parametric test (Mann–Whitney U-test) and costs by bootstrapping (1000 replications). We used Microsoft Excel version 2010 (Microsoft Corporation, Redmond, WA, USA) and IBM SPSS Statistics (version 19.0; IBM Corporation, Armonk, NY, USA) for our analysis.

We also compared the types and frequencies of service use by children and young people in the 3 months before baseline (pre randomisation) between the two groups.

Sensitivity analysis

Economic evaluation uses sensitivity analysis to investigate how sensitive the findings are to basic assumptions. In our cost–consequence analysis our base-case results are based on the assumption that the EPIC child-centred, age-appropriate information packs were administered by PDSNs. We present sensitivity analysis to determine the effect of including intervention costs encountered if packs are administered by consultants in clinic instead of PDSNs, assuming that the average additional time taken in clinic by consultants remains the same as for PDSNs.

Results

Health economics sample

The economic analysis was based on 233 of the 293 children and young people (80%) used in the effectiveness analysis. We excluded 60 children and young people who had incomplete data on costs and service use. Out of our economic sample of 233, imputation was used for seven children and young people (five intervention, two control) who did not complete the PedsQL at baseline or at 3 or 6 months; eight children and young people (six intervention, two control) who did not complete the EQ-5D at one or more of these time points; 14 parents (10 intervention, four control) who did not complete the PedsQL at one or more of these time points; and 26 parents (18 intervention, eight control) who did not complete the EQ-5D at one or more of these time points. The methods of imputation of these missing values for the economic sample ($n = 233$) were the same as for the full sample in the effectiveness analysis ($n = 293$), as described in *Chapter 5*. *Table 36* summarises the characteristics of the economic sample at baseline and *Table 37* shows the frequency of contacts with primary and secondary health-care services by the 233 participants in the 3 months before baseline. The mean PedsQL scores and EQ-5D utility scores for both child self-report and parent proxy report, HbA_{1c} levels and days lost from school for diabetes reasons and for other reasons at baseline were similar in the intervention group and the control group (see *Table 36*), as were the mean frequency of service use in the 3 months before baseline (see *Table 37*). We found no significant differences in frequency of contacts with primary and secondary health-care services by trial participants between the intervention group and the control group (see *Table 37*).

Costs of producing and distributing the individually tailored, age-appropriate information packs

Table 38 shows the unit costs of producing the individually tailored, age-appropriate information packs (see *Appendix 6* for detailed cost information). As the EPIC packs were mostly given out by research nurses, and this time was not recorded, our best estimate is that the additional time taken by PDSNs was used to answer children's subsequent questions about the pack. A few PDSNs did report that they spent time with children going through the pack, but many did not promote the pack as intended. The mean total intervention unit cost of producing and administering the EPIC information packs was £185 (administered by a PDSN taking 13.21 minutes in clinic). This cost included the cost of the materials and the marginal additional costs of prolonged staff time in clinic explaining the use of the packs. The mean total intervention unit cost was weighted by the appropriate number of children and young people in each age group to generate a mean total intervention cost of £181 for the EPIC trial (a little lower than the mean total intervention unit cost of £185).

TABLE 36 Baseline characteristics of trial participants ($n = 233$) by group

Characteristic	Intervention group ($n = 158$), n (%)	Control group ($n = 75$), n (%)
Demographic characteristics		
Participants in each age group (years)		
6–10	58 (37)	25 (33)
11–15	74 (47)	39 (52)
16–18	26 (16)	11 (15)
Sex		
Male	69 (44)	37 (49)
Female	89 (56)	38 (51)
Age (years)		
Mean (SD), range	12 (3), 6–9	13 (3), 7–18
Ethnicity		
White	150 (95)	75 (100)
Other	8 (5)	0 (0)
Education and employment[a]		
Secondary school	12 (44)	6 (55)
Further education college	11 (41)	4 (36)
Other	4 (15)	1 (9)
Living situation		
Owner-occupied house/flat	135 (85)	62 (83)
Privately rented house/flat	14 (9)	6 (8)
House/flat rented from housing association/local authority	9 (6)	7 (9)
Diabetes-related characteristics		
Time since diagnosis (years)		
Mean (SD), range	7 (4), 1–17	8 (4), 1–16
Type of insulin administration		
Injection	136 (86)	65 (87)
6–10 years	49 (36)	21 (32)
11–15 years	66 (49)	33 (51)
16–18 years	21 (15)	11 (17)
Pump	22 (14)	10 (13)
6–10 years	9 (41)	4 (40)
11–15 years	8 (36)	6 (60)
16–18 years	5 (23)	0 (0)

continued

TABLE 36 Baseline characteristics of trial participants ($n = 233$) by group (*continued*)

Characteristic	Intervention group ($n = 158$), n (%)	Control group ($n = 75$), n (%)
Insulin regime		
Once a day	2 (1)	0 (0)
Twice a day	29 (21)	13 (20)
Three times a day	11 (8)	5 (8)
Four times a day	81 (60)	38 (58)
Other	13 (10)	9 (14)
Insulin dosage (mmol/l)		
Median (IQR), range	41 (29–60), 8–129	40 (28–59), 12–112
Missing	2 (1)	1 (1)
Blood glucose tests		
None	1 (1)	0 (0)
Once a day	2 (1)	1 (1)
Twice a day	6 (4)	3 (4)
Three times a day	22 (14)	12 (16)
Four times a day	78 (49)	37 (49)
Other	48 (30)	21 (28)
Missing	1 (1)	1 (1)
HbA_{1c} (%)		
Mean,[b] range	8.7, 5.9–14.0	8.4, 6.0–11.5
Outcomes, mean (SD), range		
Child self-report		
EQ-5D utility score	0.91 (0.15), 0.19–1.00	0.92 (0.12), 0.52–1.00
EQ-5D VAS	83.72 (16.39), 25–100	78.57 (18.05), 0–100
PedsQL generic module	84.27 (12.15), 43.48–100	81.69 (12.98), 32.61–100
PedsQL diabetes module	74.33 (14.39), 31.55–100	74.09 (12.06), 36.61–95.54
Parent proxy		
EQ-5D utility score	0.85 (0.17), 0.03–1.00	0.83 (0.18), 0.26–1.00
EQ-5D VAS	83.49 (16.26), 25–100	80.77 (19.32), 0–100
PedsQL generic module	78.11 (14.55), 25.00–100	77.46 (15.19), 34.78–100
PedsQL diabetes module	65.74 (15.07), 11.61–95.54	65.54 (14.11), 31.25–94.64
Days lost from school		
Diabetes reason	1.46 (3.07), 0–20	2.40 (8.49), 0–70
Other reason	1.46 (4.28), 0–40	1.17 (1.83), 0–8

IQR, interquartile range.

a Includes only the 38 participants in the 16–18 years category; other age groups were assumed to be in school.

b Pooled estimates.

TABLE 37 Frequency of contacts with primary and secondary health-care services by the 233 participants in the 3 months before baseline

	Intervention ($n = 158$), mean, median (min., max.)	Control ($n = 75$), mean, median (min., max.)	Mann–Whitney *p*-value[a]
GP consultations			
GP consultations (at the surgery)			
Diabetes reasons	0.19, 0.00 (0, 3)	0.11, 0.00 (0, 2)	0.369
Other reasons	0.52, 0.00 (0, 11)	0.55, 0.00 (0, 10)	0.728
Total (diabetes and other reasons)	0.71, 0.00 (0, 11)	0.65, 0.00 (0, 10)	0.776
GP consultations (home visits)			
Diabetes reasons	0.00, 0.00 (0, 0)	0.01, 0.00 (0, 1)	0.147
Other reasons	0.01, 0.00 (0, 1)	0.00, 0.00 (0, 0)	0.491
Total (diabetes and other reasons)	0.01, 0.00 (0, 1)	0.01, 0.00 (0, 1)	0.589
A&E			
Diabetes reasons	0.05, 0.00 (0, 2)	0.04, 0.00 (0, 2)	0.525
Other reasons	0.06, 0.00 (0, 2)	0.05, 0.00 (0, 1)	0.902
Total (diabetes and other reasons)	0.11, 0.00 (0, 2)	0.09, 0.00 (0, 2)	0.611
Outpatient visits			
Diabetes reasons	0.83, 1.00 (0, 5)	0.97, 1.00 (0, 6)	0.246
Other reasons	0.09, 0.00 (0, 2)	0.11, 0.00 (0, 5)	0.534
Total (diabetes and other reasons)	0.92, 1.00 (0, 6)	1.08, 1.00 (0, 11)	0.412
Inpatient and day case			
Inpatient stay, diabetes reasons (count);	0.07, 0.00 (0, 2)	0.09, 0.00 (0, 1)	0.420
Inpatient stay, diabetes reasons (no. of bed-days)	0.22, 0.00 (0, 7)	0.31, 0.00 (0, 5)	0.404
Inpatient stay, other reasons (count)	0.02, 0.00 (0, 1)	0.00, 0.00 (0, 0)	0.231
Inpatient stay, total (diabetes and other reasons) (count)	0.09, 0.00 (0, 2)	0.09, 0.00 (0, 1)	0.790
Day case, diabetes reasons (count)	0.03, 0.00 (0, 1)	0.03, 0.00 (0, 1)	0.952
Day case, other reasons (count)	0.01, 0.00 (0, 1)	0.00, 0.00 (0, 0)	0.491
Day case, total (diabetes and other reasons) (count)	0.03, 0.00 (0, 1)	0.03, 0.00 (0, 1)	0.836

no., number.
a Significant at 5% significance level.

Unit costs

Table 39 shows the published unit costs used in this cost–consequences study and their sources.

Type and frequency of health service use by children and young people with type 1 diabetes

Table 40 summarises the type and frequency of service use by children and young people in the EPIC trial. No significant differences were found between the groups for type or frequency of service use over the 6-month study period.

TABLE 38 Costs in 2011 UK pounds of producing the EPIC information packs and distributing them to participants in clinic by PDSNs

	6–10 years		11–15 years		16–18 years		
	Injection	Pump	Injection	Pump	Injection	Pump	Mean
Intervention cost							
Intervention pack cost per unit (£)[a]	11.57	16.67	12.09	17.19	22.07	28.29	
Unit cost for additional clinic appointment time (on average 13.21 minutes) with PDSN (£)[b]	166.66	166.66	166.66	166.66	166.66	166.66	
Total intervention unit cost (£)	178.23	183.33	178.75	183.85	188.73	194.95	184.64[c]
Intervention cost for the EPIC trial[d]							
Number of children and young people in the EPIC trial who received an information pack	49	9	66	8	21	5	
Total intervention unit cost (£)	178.23	183.33	178.75	183.85	188.73	194.95	
Total intervention cost[e] for the EPIC trial (£)	8733.27	1649.97	11797.5	1470.8	3963.33	974.75	180.95

a The intervention pack cost per unit includes the cost of the EPIC age-appropriate diabetes diary (including the costs of materials used to produce the diary and printing but not the costs of researcher time for producing the diary).
b PDSNs mostly did not promote or facilitate the EPIC packs as intended. Research nurses mainly gave out the packs and their time is not costed.
c Mean across all age groups.
d A total of 158 participants in the intervention group received the EPIC pack: age 6–10 years: injection $n = 49$, pump $n = 9$; age 11–15 years: injection $n = 66$, pump $n = 8$; age 16–18 years: injection $n = 21$, pump $n = 5$.
e The total intervention cost refers to the sum of the age-appropriate EPIC pack cost per unit and the average additional clinic appointment time cost incurred by the PDSN.

TABLE 39 Unit costs of health service use in UK pounds for 2010–11 with sources[a]

Health-care resource	Unit	Unit cost (£)	Details and source
GP (clinic)	Visit	53	Per clinic consultation lasting 17.2 minutes[b]
GP (home visit)	Visit	121	Per home visit lasting 23.4 minutes (includes travel time)[b]
A&E attendance	Attendance	106	Treatment not leading to admission[b]
Clinical psychologist	Consultation	135	Per hour of clinic contact[b]
Secondary care			
Hospital outpatient clinic	Consultation	Various	Costed by speciality[c]
Day surgery	Procedure	Various	Costed by procedure[c]
Hospital inpatient episode	Bed-day	Various	Costed by procedure[c]

a NHS costs to nearest pound, including salary, employers' costs, overheads and capital costs.
b From Curtis.[241]
c From Department of Health.[242]

TABLE 40 Frequency of contacts with primary and secondary health-care services by the 233 participants over the 6-month study period

	Intervention ($n = 158$), mean, median (min., max.)	Control ($n = 75$), mean, median (min., max.)	Mann–Whitney p-value[a]
GP consultations			
GP consultations (at the surgery)			
Diabetes reasons	0.17, 0.00 (0, 3)	0.15, 0.00 (0, 3)	0.277
Other reasons	0.74, 0.00 (0, 11)	0.80, 0.00 (0, 6)	0.488
Total (diabetes and other reasons)	0.91, 0.00 (0, 11)	0.95, 0.00 (0, 6)	0.843
GP consultations (home visits)			
Diabetes reasons	0.14, 0.00 (0, 5)	0.09, 0.00 (0, 2)	0.371
Other reasons	0.01, 0.00 (0, 2)	0.00, 0.00 (0, 0)	0.491
Total (diabetes and other reasons)	0.15, 0.00 (0, 5)	0.09, 0.00 (0, 2)	0.299
A&E			
Diabetes reasons	0.18, 0.00 (0, 3)	0.18, 0.00 (0, 5)	0.758
Other reasons	0.13, 0.00 (0, 3)	0.08, 0.00 (0, 1)	0.579
Total (diabetes and other reasons)	0.31, 0.00 (0, 3)	0.25, 0.00 (0, 5)	0.335
Outpatient visits			
Diabetes reasons	1.13, 1.00 (0, 8)	1.13, 1.00 (0, 4)	0.667
Other reasons	0.16, 0.00 (0, 4)	0.38, 0.00 (0, 10)	0.334
Total (diabetes and other reasons)	1.29, 1.00 (0, 8)	1.51, 1.00 (0, 13)	0.432
Inpatient and day case			
Inpatient stay, diabetes reasons (count)	0.06, 0.00 (0, 2)	0.04, 0.00 (0, 1)	0.709
Inpatient stay, diabetes reasons (no. of bed-days)	0.15, 0.00 (0, 4)	0.12, 0.00 (0, 5)	0.717
Inpatient stay, other reasons (count)	0.03, 0.00 (0, 2)	0.01, 0.00 (0, 1)	0.553
Inpatient stay, total (diabetes and other reasons) (count)	0.09, 0.00 (0, 2)	0.05, 0.00 (0, 1)	0.506
Day case, diabetes reasons (count)	0.05, 0.00 (0, 1)	0.08, 0.00 (0, 2)	0.604
Day case, other reasons (count)	0.01, 0.00 (0, 1)	0.01, 0.00 (0, 1)	0.966
Day case, total (diabetes and other reasons) (count)	0.06, 0.00 (0, 2)	0.09, 0.00 (0, 2)	0.500

no., number.

[a] Significant at 5% significance level.

Costs of health-care service use by children and young people

Table 41 shows the mean costs of the primary and secondary health service use by children and young people in the intervention and control groups over the 6-month study period. We undertook 1000 bootstrapped replications to produce a bootstrapped 95% CI around our estimates of the mean difference in total costs of service use by children and young people between groups. The mean total cost (NHS costs including pack and administration costs) was £136 (bootstrapped 95% CI –£52 to £296) higher for the intervention group (mean total cost £702, SD £558) than for the control group (mean total cost £566, SD £664), but this difference was not significant. Also, there was no significant difference between groups for primary or secondary care service use costs.

TABLE 41 Costs of primary and secondary health service use by the 233 participants in the EPIC trial over the 6-month study period

Type of cost	Intervention ($n = 158$), mean (SD) (£)[a]	Control ($n = 75$), mean (SD) (£)[a]	Mean difference (bootstrapped 95% CI) (£)
Primary care sector			
GP consultations			
GP consultations (at the surgery)			
Diabetes reasons	9 (25)	8 (30)	1
Other reasons	39 (74)	42 (64)	–3
Total (diabetes and other reasons)	48 (76)	50 (69)	–2
GP consultations (home visits)			
Diabetes reasons	17 (68)	11 (49)	6
Other reasons	2 (19)	0 (0)	2
Total (diabetes and other reasons)	18 (70)	11 (49)	7
Total primary care costs (GP consultations surgery + home visit, all reasons)	67 (111)	61 (90)	6 (–22 to 32)
Secondary care sector			
A&E			
Diabetes reasons	19 (54)	18 (68)	0.41
Other reasons	14 (48)	8 (29)	6
Total (diabetes and other reasons)	33 (73)	27 (78)	6
Outpatient visits			
Diabetes reasons	291 (281)	291 (250)	0.29
Other reasons	30 (100)	67 (222)	–37
Total (diabetes and other reasons)	322 (311)	358 (360)	–37
Inpatient and day case			
Inpatient stay, diabetes reasons	65 (297)	63 (360)	1
Day case, diabetes reasons	25 (113)	42 (172)	–16
Day case, other reasons	10 (97)	14 (122)	–4
Day case, total (diabetes and other reasons)	35 (153)	56 (208)	–20
Total secondary care costs	454 (524)	504 (648)	–50 (–226 to 103)
Total primary and secondary care costs	521 (559)	566 (664)	–45 (–242 to 124)
Intervention cost	181 (4)	0 (0)	181
Total cost	702 (558)	566 (664)	136 (–52 to 296)

a Costs rounded to the nearest pound.

Consequences

We present a range of relevant health-related consequences for the EPIC trial. These are the primary outcome measures of diabetes self-efficacy and quality of life (PedsQL diabetes module) and the secondary outcome measures of generic quality of life (PedsQL generic module), generic health-related quality of life (EQ-5D) and HbA_{1c}. *Table 42* shows the mean scores for the PedsQL diabetes and the PedsQL generic module for both child self-report and parent proxy report. The change in mean child-reported PedsQL

TABLE 42 Mean child- and parent-reported PedsQL generic scores and PedsQL diabetes scores ($n = 233$) by group

Outcome measure	Intervention (n = 158), mean (SD)				Control (n = 75), mean (SD)				Difference in mean change scores between groups[b] (bootstrapped 95% CI)
	Baseline	3 months	6 months	Change in mean score between baseline and 6 months[a]	Baseline	3 months	6 months	Change in mean score between baseline and 6 months[a]	
Child measure									
PedsQL generic score	84.27 (12.15)	83.95 (13.07)	83.58 (12.95)	–0.69 (10.14)	81.69 (12.98)	82.21 (14.81)	84.67 (12.80)	2.97 (11.01)	–3.66 (–6.47 to –0.75)
PedsQL diabetes score	74.33 (14.39)	75.11 (13.65)	75.07 (14.81)	0.74 (12.90)	74.09 (12.06)	74.73 (13.92)	78.37 (11.91)	4.28 (11.90)	–3.54 (–6.56 to –0.12)
Parent measure									
PedsQL generic score	78.11 (14.55)	79.14 (13.87)	79.23 (13.71)	1.12 (12.74)	77.46 (15.19)	78.30 (14.27)	77.82 (14.34)	0.36 (11.89)	0.76 (–2.35 to 3.77)
PedsQL diabetes score	65.74 (15.07)	65.58 (15.09)	66.90 (15.65)	1.16 (12.63)	65.54 (14.11)	68.14 (14.83)	68.25 (13.89)	2.71 (11.84)	–1.55 (–4.92 to 1.69)

a Change in mean score = (mean score at 6 months) – (mean score at baseline).
b Difference in mean change scores between groups = (mean change score for intervention) – (mean change score for control).

diabetes score between baseline and 6 months was 0.74 (SD 12.90) for the intervention group and 4.28 (SD 11.90) for the control group, yielding a mean difference of –3.54 (bootstrapped 95% CI –6.56 to –0.12). The change in mean parent-reported PedsQL diabetes score between baseline and 6 months was 1.16 (SD 12.63) for the intervention group and 2.71 (SD 11.84) for the control group, yielding a mean difference of –1.55 (bootstrapped 95% CI –4.92 to 1.69).

For the PedsQL generic module, the change in the mean child-reported score between baseline and 6 months was –0.69 (SD 10.14) for the intervention group and 2.97 (SD 11.01) for the control group, yielding a mean difference of –3.66 (bootstrapped 95% CI –6.47 to –0.75). The change in mean parent-reported score between baseline and 6 months was 1.12 (SD 12.74) for the intervention group and 0.36 (SD 11.89) for the control group, yielding a mean difference of 0.76 (bootstrapped 95% CI –2.35 to 3.77).

Our analysis shows no significant difference between groups for the difference in mean change scores for the parent proxy PedsQL diabetes module and the parent proxy PedsQL generic module. For the child-reported PedsQL diabetes module and the PedsQL generic module, our analysis shows that there were significant differences at 95% ($p = 0.05$) between groups for the mean difference in child-reported PedsQL diabetes and PedsQL generic module. The resulting negative mean difference in effect (a mean difference of –3.54 in the change scores between groups for the child-reported PedsQL diabetes module and –3.66 in the change scores between groups for the child-reported PedsQL generic module) is meaningless because the intervention group had a smaller effect in mean change scores over the 6-month study period than the control group, meaning that the intervention was dominated by the control condition, that is, the intervention group did worse than the control group.[233]

Table 43 shows the child and parent-reported EQ-5D utility index scores and QALY gains (if any) ($n = 233$) by group over 6 months. For the child-reported EQ-5D utility scores we calculated mean QALYs of 0.446 over 6 months for the intervention group, a value very close to that of the control group (0.447), yielding negative incremental mean QALYs of 0.001 between groups (bootstrapped 95% CI –0.0209 to 0.0189). Similarly, for parent proxy-reported EQ-5D utility scores we calculated mean QALYs of 0.415 over 6 months for the intervention group, a value also very close to that of the control group (0.418), yielding negative incremental mean QALYs of 0.003 between groups (bootstrapped 95% CI –0.0238 to 0.0188). No significant difference was found in the incremental mean QALYs between groups for either the child-reported or parent-reported measure. The resulting negative values for the incremental mean QALYs indicate that the intervention (EPIC pack) had a smaller effect (measured in mean incremental QALY gain over 6 months) than the control group (treatment as usual). This means that the intervention group was dominated by the control group.[233] Overall, parents' proxy ratings of their child's diabetes-related quality of life (using the PedsQL diabetes module) and generic health-related quality of life (using the EQ-5D instrument) were consistently lower than their child's self-ratings across all time points in both groups (see *Tables 42* and *43*).

Table 44 shows the mean (range) HbA_{1c} levels for children and young people participating in the EPIC trial ($n = 233$) by group. The mean values were similar across the two groups at baseline (8.7 intervention vs. 8.4 control), 3 months (8.6 intervention vs. 8.5 control) and 6 months (8.6 intervention vs. 8.4 control). These values were also similar across all three time points within the intervention group as well as across all three time points within the control group.

TABLE 43 Mean child- and parent-reported EQ-5D utility index scores, mean QALYs and incremental mean QALYs over the 6-month study period by group ($n = 233$)

	Intervention ($n = 158$), mean (SD)				Control ($n = 75$), mean (SD)				
Outcome measure	Baseline	3 months	6 months	Mean QALY over 6 months	Baseline	3 months	6 months	Mean QALY over 6 months	Incremental mean QALYs between groups[a] (bootstrapped 95% CI)
Child-measure									
EQ-5D utility	0.906 (0.151)	0.892 (0.198)	0.880 (0.180)	0.446	0.923 (0.116)	0.879 (0.224)	0.898 (0.162)	0.447	–0.001 (–0.0209 to 0.0189)
Parent measure									
EQ-5D utility	0.852 (0.168)	0.820 (0.199)	0.828 (0.205)	0.415	0.827 (0.175)	0.833 (0.232)	0.854 (0.176)	0.418	–0.003 (–0.0238 to 0.0188)

a Incremental mean QALYs between groups = mean QALYs for intervention group – mean QALYs for control group.

TABLE 44 Mean (range) HbA_{1c} levels for trial participants ($n = 233$) at baseline, 3 months and 6 months by group

	Intervention group, mean[a] (range)			Control group, mean[a] (range)		
	Baseline	**3 months**	**6 months**	**Baseline**	**3 months**	**6 months**
HbA_{1c} (%)	8.7 (5.9–14.0)	8.6 (5.7–14.0)	8.6 (5.4–12.3)	8.4 (6.0–11.5)	8.5 (5.8–14.0)	8.4 (5.4–13.3)

a Pooled estimates.

Sensitivity analysis: diabetes professionals

Although it was mainly research nurses who gave the EPIC packs to children and young people following randomisation and their time was not costed, we recorded that a small number of PDSNs did go through the pack with children, although not always as originally intended. Diabetes professionals also recorded that they experienced longer consultations as children and parents had additional questions following receipt of the pack. Given the assumption that children and young people were seen in clinic by consultants instead of PDSNs [and assuming that the average additional time taken in clinic by consultants was the same as for PDSNs (13.21 minutes)], we calculated that the unit cost for consultants' additional clinic time associated with the EPIC pack was £211.97 as opposed to a unit cost of £166.66 for the same length of average additional clinic time taken by PDSNs. In our sensitivity analysis the mean total cost of service use in the intervention group and the control group was £747 (SD £558) and £566 (SD £664) respectively. This yielded a mean difference of £182 (bootstrapped 95% CI –£9 to £339) in the total cost of service use, which, as was also the case in our base-case analysis, was not significant.

Discussion

Principal findings

We report a cost–consequence study setting out disaggregated findings as there were no significant differences in costs or effects between groups in this trial.

Strengths and weaknesses of this study and in relation to other studies

Our study is set against all of the existing relevant literature that we could find. We have followed systematic and robust methods for the conduct of economic analysis alongside pragmatic trials.

Meaning of this study

The EPIC intervention was a complex, behavioural intervention. It was low cost in terms of the production costs of the tailored information packs and the marginal time required in clinic to explain the packs to children and young people and their families. Marginal time spent in clinic is our best estimate. If the packs were promoted as intended the time taken is likely to be longer. Identifying the effects of such interventions is difficult but is worth attempting.

Unanswered questions

Our analysis showed consistent differences between children's and young people's own reported health state and that reported by parent proxies. This may be worth further exploration in future studies of interventions for children.

Conclusion

Although children's diabetes information is considered an essential component of diabetes care, the EPIC packs and diabetes diaries were no more effective than receiving diabetes information in an ad hoc way. The cost of diabetes information provided as treatment as usual was not estimated and may be considerably more than the cost of the EPIC packs. Although in a disaggregated cost–consequence form, our economic analysis alongside the EPIC trial shows that the EPIC packs and diabetes diaries were no more effective than receiving diabetes information in an ad hoc way. The EPIC packs and diabetes diaries, however, do meet current children's policy requirements, which stipulate that children should receive age-appropriate and quality-assured information, whereas treatment as usual packs may not. As the current diabetes guidelines recommend that children would need to use a diabetes diary as part of their diabetes care pathway, the EPIC diaries fill a gap in current children's provision. In addition, as shown in *Table 38*, the calculated costs per unit of producing the child-centred age-appropriate EPIC packs and diabetes diaries were considerably modest.

In summary, although the EPIC packs may not be any more effective, they do have other quality advantages over ad hoc delivery of children's diabetes information. In light of current policy that children should receive child-centred and age-appropriate diabetes information[13,26,243–245] and the modest costs of producing the age-appropriate EPIC information packs and diabetes diaries, we consider it reasonable to recommend and support the introduction or roll-out of the EPIC packs and diabetes diaries in the paediatric diabetes care setting.

Chapter 7 Stage 4: process evaluation embedded in the EPIC randomised controlled trial

Introduction

The RCT reported in *Chapter 5* maintained adequate power and showed no difference between the EPIC intervention and treatment as usual for the primary outcome measure of diabetes self-efficacy (PedsQL diabetes module) or the secondary outcome measures of HbA_{1c} level and generic quality of life (PedsQL generic module). The focus of this chapter is to use evidence from the process evaluation to explain this overall finding of no difference.

We first report the process evaluation aims, objectives, design and methods.

Evidence from the theory-based embedded process evaluation is used to look for explanations as to why the intervention did not bring about the intended behaviour changes needed to optimise children's diabetes self-management.

We first look at treatment as usual to see whether our assumptions were right and then make some observations about the population of children who participated in the trial. Finally, we look at intervention fidelity organised by three care processes:

1. individual tailoring of the EPIC pack, presentation following randomisation, choice of diary and children's initial reactions
2. daily use of the diary and regular use of the EPIC pack at home and at school by children and young people and their families to optimise diabetes self-care and management
3. promotion and active use of the EPIC pack following randomisation by diabetes professionals.

Next, we report a cross-cutting issue common to all children in the trial – their perceptions of and attitudes to diabetes-related risks and long-term complications.

Throughout the chapter, findings are mapped against the logic and theoretical models to gain a greater understanding of why the intervention did not work as intended. The chapter concludes with a discussion of the strengths and limitations of the process evaluation and recommendations for further research.

Embedded process evaluation

Aims

The aims of the theory-based embedded process evaluation were to:

- evaluate the introduction of an evidence-based diabetes information pack into children's self-care regimes and health-care practice in order to optimise blood glucose meter use and insulin management
- focus on the key contextual variables mediating the implementation and use of the EPIC information pack
- facilitate the gathering of individual (e.g. child/parent or practitioner) experiences as well as appreciating the fit with the broader context of care delivery
- determine the acceptability and feasibility of the EPIC diabetes information packs.

Objectives

The objectives were to:

- describe site differences between routine diabetes information practice and the EPIC packs
- evaluate the use of the EPIC diabetes diaries
- evaluate the usefulness of each information component of the age-appropriate EPIC packs
- describe individual tailoring of the EPIC packs
- evaluate the EPIC pack design, for example the folders, style, visual appeal
- evaluate ease of use and accessibility of the EPIC pack
- describe any self-management changes in blood glucose meter use and insulin management
- describe diabetes HCPs' attitudes/beliefs regarding the EPIC pack
- describe diabetes HCPs' facilitation of the EPIC pack
- describe routine information practice for those children in the control arm
- ascertain the views of parents, children, young people and diabetes HCPs.

Process evaluation design and methods

The mixed-method embedded design (*Figure 34*) included a number of interlinking and sequential elements including theory development, data collection and analysis and synthesis that followed the principles of the MRC framework for the development and evaluation of complex interventions.[42,43] A logic model (to represent components of the intervention and provide a structure for mapping process evaluation evidence to understand why the intervention worked or not as intended) was developed and

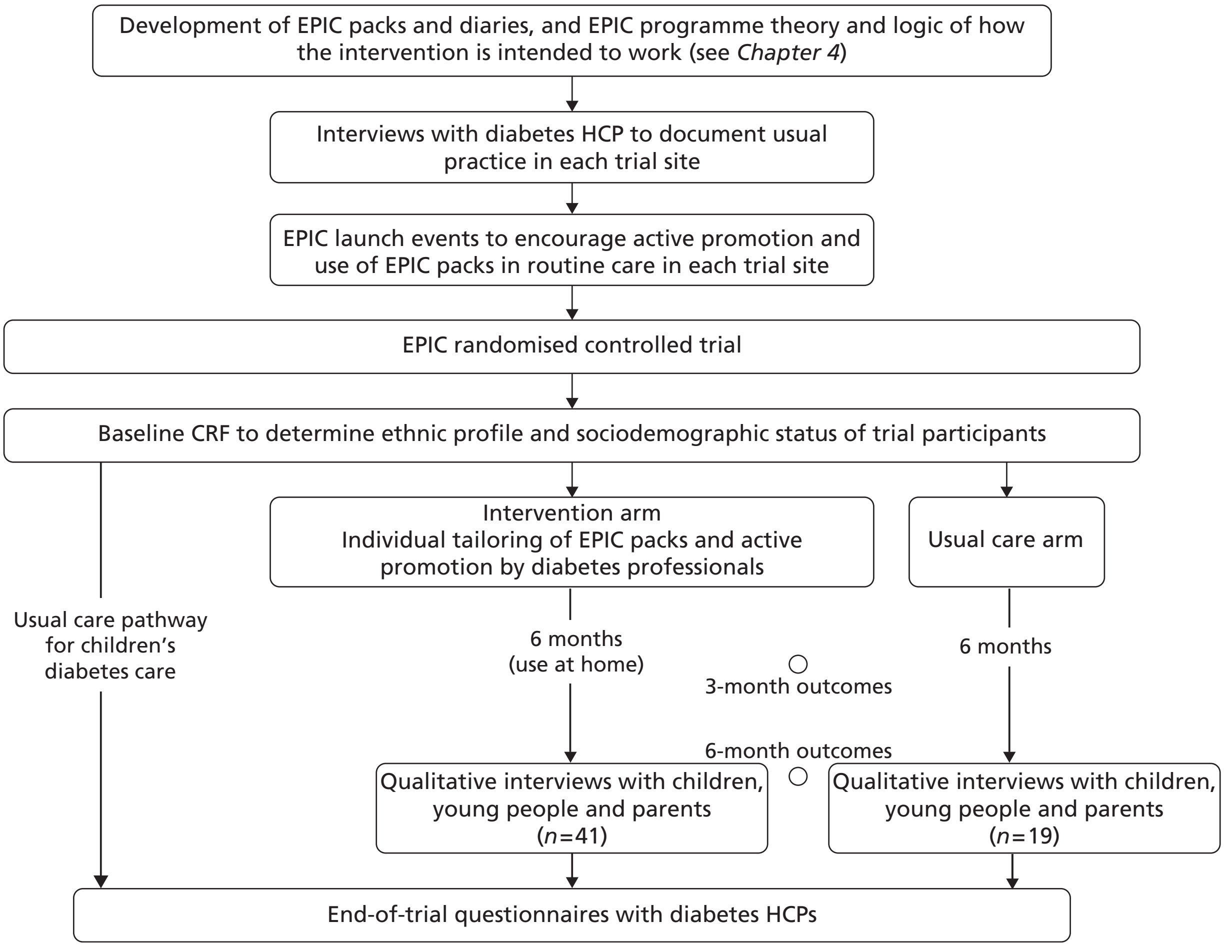


FIGURE 34 Process evaluation design.

refined during the intervention development phase. This model of the 'potential EPIC intervention pathway' is a graphical model that seeks to make explicit the underlying assumptions about causal relationships and EPIC intervention programme theory, and help explain the potential mechanisms of action (*Figure 35*). The logic model needs to be understood in the context of the programme theory and logic reported in *Chapter 4*.

Data collection, target samples and data analysis

The multiple elements of the process evaluation data collection activities, sampling and analysis are summarised in *Table 45*.

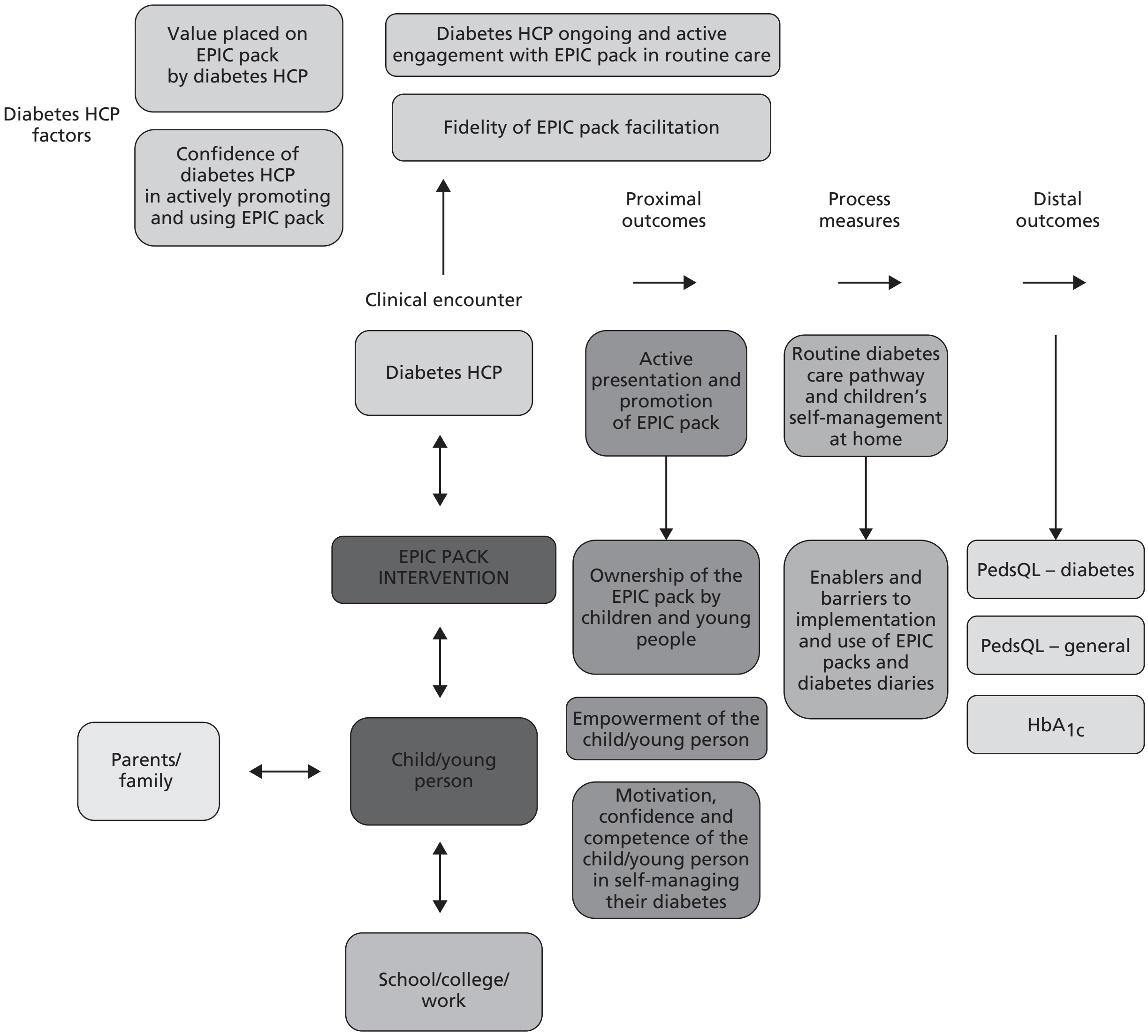


FIGURE 35 Logic model of the EPIC intervention pathway.

TABLE 45 Summary of process evaluation data collection activities, target samples and data analysis methods

	Data collection time point					
	Trial site set-up ($n = 11$)	**Baseline**	**Baseline**	**Baseline to 6 months**	**At disengagement from trial at 6 months**	**At disengagement as trial site**
Data collection element	Structured interview(s) to ascertain usual care	Ethnicity survey	Postcode analysis	Individual tailoring of EPIC pack	Qualitative interviews with children, young people and parents	Attitudes and opinions of diabetes HCPs
Data collection method	Structured interviews, digital photographs	CRF questionnaire	CRF questionnaire	Information substitution report form	Semistructured interviews, photographs of EPIC packs	Team designed and piloted structured questionnaire (53 questions) with open-ended questions. Paper based or SurveyMonkey®
Target sample	One to two key diabetes HCPs in each site	All children randomised	All children randomised	All children receiving the EPIC pack	40 (I)/20(C) Theoretical sampling framework (site, sex, regime, time since diagnosis, ethnicity)	Participating diabetes HCPs and research nurses in 11 trial sites
Purpose	Complete the Approach Manual of usual practice document and photograph children's diabetes information resources	Describe ethnic make-up of sample	Calculate ID for all and subset of those interviewed	Ascertain what information resources were removed or added to the EPIC packs	Describe the views and experiences of the EPIC pack and how they were received and used	Ascertain the views of, attitudes to and opinions of the EPIC intervention and service delivery
Method of analysis	Content analysis of interview transcripts and collation by site in a summary table	Descriptive statistics	TIMS, WIMD, ID	Descriptive statistics (PASW Statistics version 18.0), content analysis of open questions	Digital recording and transcription using ATLAS.ti software, collation of photographs, Ritchie and Spencer[144] framework analysis	Descriptive statistics (PASW Statistics version 18.0), content analysis of open questions
Appendices	Approach Manual (see *Appendix 7*)		Social deprivation scores (see *Appendix 7*)		Age-appropriate interview schedules: I and C (see *Appendix 7*), theoretical sampling frame (see *Appendix 7*)	Questionnaire (see *Appendix 7*)

C, control; I, intervention; ID, English Indices of Deprivation 2010;[246] TIMS, Townsend scores (2001 data);[247] WIMD, Welsh Index of Multiple Deprivation 2008;[248] IND, Index Deprivation.

Application of legal and theoretical frameworks

The overarching theoretical framework is described in detail in *Chapter 1* (see *Figure 2*) and incorporates the MRC framework for complex interventions, ideas from the discipline of anthropology and the PARiHS framework. In addition, two theoretical models are also presented in *Chapter 1* (see *Tables 1* and *2*), that were developed using PARiHS and which represent partnership and participation between children, parents and health services, and critical success factors for the successful translation of children's health information in practice were used to map and interpret evidence from the process evaluation.

EPIC intervention proposition, programme theory and logic

A detailed account of the programme theory and logic can be found in *Chapter 4*. When reporting findings in subsequent sections, relevant elements of programme theory and logic are included in order to interpret the evidence.

Demographic characteristics of participants in the process evaluation

Target recruitment was achieved with the desired theoretical characteristics, with the exception of children and young people from minority ethnic backgrounds.

In summary:

- 13 diabetes professionals took part in interviews to ascertain 'treatment as usual' and the usual diabetes care pathways in each centre (*Table 46*)
- 71 interviews were conducted with children, young people and their parents at the end of their participation in the trial (*Tables 47* and *48* provide detailed demographic characteristics of the sample)
- questionnaires were returned from 32 diabetes HCPs and research nurses at the end of the trial (*Table 49*).

TABLE 46 Local diabetes HCPs who participated in qualitative interviews to establish usual care in each site

Centre code	Information source	Total
Y	PDSN	1
T	PDSN	1
A	PDSN	1
U	PDSN and local PI	2
L	PDSN	1
S	Local PI	1
I	PDSN	1
O	PDSN and local PI	2
Q	PDSN	1
N	PDSN	1
B	PDSN	1
Total	10	13

TABLE 47 Demographic characteristics of children and young people who participated in process evaluation interviews

	6–10 years, *n* (%)	11–15 years, *n* (%)	16–18 years, *n* (%)	Total sample (6–18 years), *n* (%)
Sex				
Female	7 (37)	9 (45)	11 (52)	27 (45)
Male	12 (63)	11 (55)	10 (48)	33 (55)
Number of years since diagnosis				
< 2	4 (21)	4 (20)	2 (10)	10 (17)
>2	15 (79)	16 (80)	19 (90)	50 (83)
Regime				
Insulin injection	15 (79)	14 (70)	17 (81)	46 (77)
Insulin pump	4 (21)	6 (30)	4 (19)	14 (23)
Type of interview				
Child/child and parent (see breakdown below)	18[a]	20	21	59/60 families
Boy only	1	2	7	10
Boy and mother	9	8	1	18
Boy and father	1	1	0	2
Boy and mother and father	1	1	1	3
Boy and other family member	0	0	1	1
Girl only	0	1	2	3
Girl and mother	5	8	7	20
Girl and father	1	0	2	3
Girl and mother and father	1	0	0	1
Girl and other family member	0	0	0	0
Separate parent(s) interview (see breakdown below)				
Mother and father	0	1 couple	0	1 couple
Father only	0	1	0	1
Mother only	2	3	3	8
Total number of interviews	21	26	24	71
Ethnicity				
White[b]	19 (100)	20 (100)	21 (100)	60 (100)

a 19 families interviewed for the 6–10 years age group but one boy ill in bed on the day of the interview.
b The research team aimed to achieve a representative sample according to ethnicity, but only families of white origin agreed to take part in the face-to-face process evaluation interviews.

TABLE 48 Age category, sex and arm in the RCT of the 60 children and young people interviewed

	Intervention, *n*			Control, *n*			
	6–10 years	11–15 years	16–18 years	6–10 years	11–15 years	16–18 years	Total
Female	6	5	9	1	4	2	27
Male	7[a]	10	4	4	2	6	33
Total	13	15	13	5	6	8	60

a Eight families interviewed in the 6–10 years age group but one participant was ill in bed at the time of the interview.

TABLE 49 Clinical roles reported by respondents in the end-of-trial HCP questionnaires

	Clinical role				
	Paediatric diabetes consultant	PDSN	Research nurse	Other[a]	Total
n	7	10	13	2	32

a 'Other' included one associate specialist in paediatrics and one research support officer.

Why did the EPIC intervention not bring about the desired behaviour changes to optimise children's self-care and diabetes management?

In considering why the EPIC pack did not bring about the desired changes in behaviour and improve diabetes outcomes we first look at treatment as usual, then make some observations about the entire population of children who participated in the trial and finally look at intervention fidelity organised by three care processes:

1. individual tailoring of the EPIC pack, presentation following randomisation, choice of diary and children's initial reactions
2. daily use of the diary and regular use of the EPIC pack at home and at school by children and young people and their families to optimise diabetes self-care and management
3. promotion and active use of the EPIC pack following randomisation by diabetes professionals.

Findings are continuously mapped against the logic and explanatory models to gain a greater understanding of why the intervention did not work as intended.

In the following sections quotes are afforded a code indicating the unique number of the child, his or her age group, whether he or she uses insulin injections or a pump and has been diagnosed for > 2 years or < 2 years and sex.

Were assumptions about 'usual care' correct?

As reported in *Chapter 3*, the assumption underlying usual care was that, if children and young people had received any diabetes information, it was most likely to have been from their diabetes specialists around the time of diagnosis, with ad hoc additional paper-/audio-/visual-based information received since diagnosis. The IMP[1] found that much of the information that children received from diabetes HCPs was verbal. Children therefore have to remember what was said and mostly do not have a written record to refer to later if their recall of the information is poor. We assumed that children and young people in the control arm would have received information from their diabetes team as and when it was requested by them or their family, or offered by PDSNs. Many children were also diagnosed when young and so information at diagnosis was likely to be targeted at parents and not children.

In reality, assumptions about 'usual care' were correct. Although it was evident that standard practice and diabetes care pathways varied hugely across sites, even within the same trust (see *Appendix 7*, *EPIC Approach Manual*), doctors, nurses and dieticians across the 11 sites currently provided 'newly diagnosed', 'starter' or 'discharge' information for children and their families using NHS trust-produced information and selected available children's diabetes resources. However, it is likely that practice has changed over time and may not reflect the diabetes information given to children and young people if diagnosed several years ago. In current practice in all 11 sites children were discharged as soon as possible after diagnosis and the basics of diabetes care were covered over a period of time, both in hospital and at home. Specific issues and questions were discussed verbally with the diabetes specialists as and when appropriate. Some of the 11 sites had a tick list regarding what had been discussed and information resources shared whereas other centres did not, and so it is not certain that all children received a comprehensive range of diabetes information that fulfils the current policy aspiration of the right child receiving the right information at the right time.[245]

Children's and parents' views and experiences of diabetes information received as usual care and diabetes diary use

Interviews with children and their parents receiving usual care confirmed that, although it may have been some time since they received any diabetes information resources, some but not all were using a diary as recommended by NICE guidelines.[26] Overall, 63% of children and young people in the control arm of the process evaluation did not use a diabetes diary, with use decreasing with age. Of those interviewed:

- two out of five children in the 6–10 years age group used a diary – in most cases parents kept a diary on behalf of the child
- three out of six children in the 11–15 years age group used a diary
- two out of eight young people in the 16–18 years age group used a diary.

The finding that children and young people in the treatment as usual arm were mostly not using a diabetes diary is important and is a recurring thread that we will pick up again in the EPIC intervention arm.

Post diagnosis, most information was given verbally by the diabetes team and young people had different opinions about how they wanted to receive diabetes information:

> *I would have preferred it written down, so I could remember it, sometimes you have a conversation and you forget it, so . . . .*
>
> *Child P75, female, 16–18 years, injections, > 2 years, centre T*

> *I prefer getting it verbally. Otherwise I just won't read the leaflet kind of thing.*
>
> *Child P28, male, 16–18 years, injections, > 2 years, centre B*

How typical were children, young people and their families in the EPIC randomised controlled trial and process evaluation?

Ethnicity

The majority (93%) of children and young people were white British, with the remaining 7% of other ethnic backgrounds (including 2% who did not specify their ethnicity). These figures on ethnicity are comparable with evidence from the National Diabetes Paediatric Audit 2009–11[249] and suggest that the ethnic make-up of the sample was typical of children with diabetes in England and Wales.

Socioeconomic status

Similar to other studies, such as the DEPICTED study,[250] we identified a recruitment bias towards more affluent families, who may have been more likely to access children's diabetes information from diabetes services and other sources as and when required. For example, 86% of families taking part in the trial were owner-occupiers, which is well above the national average for England (67%) and

Wales (70%). Over-representation of more affluent families indicates a bias towards those who are more highly educated.

Full details of the methods used to determine social deprivation scores for postcodes across England and Wales for children, young people and parents who took part in the EPIC trial (see *Chapter 5*) can be found in *Appendix 7* (see *Social deprivation scores for postcodes across England and Wales*). The social deprivation scores (*Figure 36*) indicate that, although from a range of social backgrounds, the sample was skewed towards more affluent families, with 66% coming from areas that were neither the most deprived nor the least deprived, 11% coming from the most deprived areas and 23% coming from the least deprived areas.

The subsample of children, young people and their families who took part in the qualitative process evaluation tended to be from even more affluent families (*Figure 37*). The highest percentage of families (35%) were from the least deprived areas, with only 6% coming from the most deprived areas, and again this shows a bias towards the middle classes. The remaining 59% came from areas that were neither the most deprived nor the least deprived.

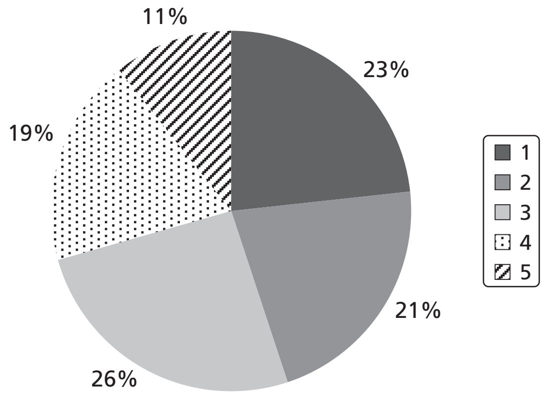


FIGURE 36 Social deprivation scores for the whole sample. Based on Townsend scores from 2001 data.[247] 1 represents the percentage of postcodes that fall into the quintile representing the least deprived areas in England and Wales, based on their rankings from lower layer super output area scores; 5 represents the percentage of postcodes that fall into the quintile representing the most deprived areas in England and Wales, based on their rankings from lower layer super output area scores. Number of postcodes in each quintile: quintile 1 = 73; quintile 2 = 67; quintile 3 = 80; quintile 4 = 59; quintile 5 = 33.

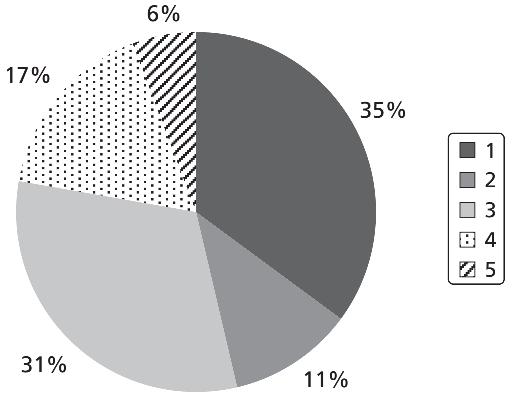


FIGURE 37 Social deprivation scores for the subsample who took part in the process evaluation. Based on Townsend scores from 2001 data.[247] 1 represents the percentage of postcodes that fall into the quintile representing the least deprived areas in England and Wales, based on their rankings from lower layer super output area scores; 5 represents the percentage of postcodes that fall into the quintile representing the most deprived areas in England and Wales, based on their rankings from lower layer super output area scores. Number of postcodes in each quintile: quintile 1 = 19 ; quintile 2 = 6; quintile 3 = 17; quintile 4 = 9; quintile 6 = 5.

Overall diabetes control of children and young people in the EPIC randomised controlled trial and process evaluation

The National Institute for Health and Care Excellence recommends an HbA_{1c} level of < 7.5% (59 mmol/mol) for children and young people with diabetes in the UK.[26] Concern about lack of achievement of the NICE HbA_{1c} target was the main reason why a number of trials to test interventions to promote optimal self-management were commissioned within a similar time frame (including the EPIC trial).

Overall, only 16–18% of children and young people in the trial achieved a HbA_{1c} level of < 7.5% (*Table 50*), with some variation, although not significant, between the two arms of the trial (*Table 51*). These findings are important and show that > 80% of trial participants would need to improve their self-management to achieve the target HbA_{1c} range. Irrespective of allocation most participants were managing their diabetes suboptimally and running the risk of diabetes-related complications. In the 2009–10 National Diabetes Paediatric Audit,[249] only 14.5% of children and young people in the UK were found to achieve the NICE target, with the highest attainment in children aged 0–4 years followed by children aged 5–11 years.

Although there was no age effect in the trial, it is possible that the high number of participants (65%) aged 11–18 years and the challenges associated with this age group may have contributed to the no effect outcome. Ambivalence to optimal diabetes self-management becomes a specific challenge during adolescence. The National Diabetes Paediatric Audit[249] reported that older children are less likely to achieve optimal glycaemic control. Within an anthropological context, evidence shows that as children enter adolescence diabetes management is known to take less priority in their lives, and school, examinations, relationships and peer approval become the foci.[251,252] Ambivalence in young people is not uncommon. Although aware of the need to achieve optimal glycaemic control, their motivation and behaviour is affected by other issues going on in their lives.

Later in the process evaluation we present further qualitative evidence on teenage ambivalence to illustrate their views about receiving and using (or not) the EPIC diaries and packs.

Time since diagnosis

Irrespective of allocation, the mean time from diagnosis was 7 years. Self-management behaviour and motivation would have been deeply embedded for many of the children, young people and their parents, making changes in motivation and behaviour difficult to achieve. The following comments from a teenager

TABLE 50 Pooled estimates of the number of participants with a HbA_{1c} level < 7.5% (59 mmol/mol)

Time point	< 7.5%, *n* (%)	≥ 7.5%, *n* (%)
Baseline	47 (16)	246 (84)
3 months	48 (16)	245 (84)
6 months	52 (18)	241 (82)

TABLE 51 Pooled estimates of the number of participants with a HbA_{1c} level < 7.5% (59 mmol/mol) by treatment as allocated

	Intervention, *n* (%)		Control, *n* (%)	
Time point	< 7.5%	≥ 7.5%	< 7.5%	≥ 7.5%
Baseline	29 (15)	161 (85)	18 (17)	85 (83)
3 months	26 (14)	164 (86)	23 (22)	80 (78)
6 months	32 (17)	158 (83)	21 (20)	82 (80)

receiving treatment as usual indicate that she believed that she had sufficient knowledge and that diabetes self-management had become routine, although, as reported previously, overall children and young people in the trial had HbA_{1c} levels that were higher than the recommended target of $< 7.5\%$ (59 mmol/mol):

> *I don't really look at it [diabetes information] any more because it is just routine, and like reading through it, I read through it again today, just like looking at it, and I was just kind of like, it's a bit boring, I know all this.*
>
> *Child P75, female, 16–18 years, injections, > 2 years, centre T*

EPIC intervention fidelity

In this section we look at intervention fidelity organised by three care processes:

1. individual tailoring of the EPIC pack, presentation following randomisation, choice of diary and children's initial reactions
2. daily use of the diary and regular use of the EPIC pack at home and at school by children and young people and their families to optimise diabetes self-care and management
3. promotion and active use of the EPIC pack following randomisation by diabetes professionals.

Care process 1: individual tailoring of the EPIC pack, presentation following randomisation, choice of diary and children's initial reactions

The EPIC pack was designed to be individually tailored. This approach was welcomed by diabetes professionals who acknowledged that each child's learning needs were different and the age banding of the packs covered several years during which diabetes information needs would change:

> *Because the needs of children and young people and families vary so much it is very difficult to design a pack which is suitable for all in a similar age group. Education needs vary depending on when children/parents are ready to receive it and are ready to learn something new.*
>
> *PDSN, centre Y*

Diabetes team members, usually the PDSN, were asked to use their knowledge of individual children to add or remove information as appropriate. They could also give children in the 11–15 years age range the choice of the 6–10 years EPIC diary or the 16–18 years EPIC dairy if they used an insulin injection diary. Parents were also able to remove contents from the packs. A record was kept of the numbers of items removed or added to the EPIC packs (*Tables 52–54*).

In reality, there was very little individual tailoring. In 86% of cases nothing was removed and in 87% of cases nothing was added.

Interview and questionnaire data provided additional information about individual tailoring of the EPIC packs. Some leaflets and information were taken out by diabetes HCPs if they were deemed unsuitable for the particular child or young person. For example, one PDSN commented on the wide age range covered by the 11–15 years pack and felt that the resources were too advanced for 11 year olds and should be *included* as part of individual tailoring rather than needing to be removed:

> *In 11–15 pack, some information was not applicable to all, i.e. 'Body piercing', 'Sex and beyond', 'Drinking safely'. Felt that this should not be included to all in the age group and should be added as needed not taken out. N.B. Alcohol leaflet does not state that it is dangerous to drink at 11 years if you have diabetes and tattoos and body piercing is illegal at this age. Maybe packs at this age should be more flexible to address individual needs.*
>
> *PDSN, centre T*

TABLE 52 Numbers of items removed from or added to the EPIC packs according to age group

	Age group			
	6–10 years	11–15 years	16–18 years	Total
Number of times 0–5 items removed from the EPIC pack				
0 items	61	74	28	163
1 item	6	7	3	16
2 items	0	6	0	6
3 items	0	3	0	3
5 times	0	2	0	2
Total	67	92	31	190
Number of times 0–5 items added to the EPIC pack				
0 items	59	78	28	165
1 item	3	11	2	16
2 items	4	2	1	7
3 items	1	0	0	1
13 items	0	1	0	1
Total	67	92	31	190

In some instances parents tailored their child's EPIC pack by removing information before giving their child access. For example, the mother of a 14-year-old boy removed three leaflets on diabetes and lifestyle issues from the EPIC pack:

> *I took three books [leaflets] out, but I did give them to him this morning to read, . . . I don't know, because I thought, well I better read them, and see, if I should let him read them, and I did in the end, but initially I took out the one about sex, the one about drinking and the one about tattooing.*
>
> *Mother of child P63, male, 11–15 years, injections, > 2 years, centre A*

Removal of information on lifestyle issues for an age group known to have tattoos (irrespective of whether it is illegal in the UK), to sometimes engage in sex and to drink alcohol, with or without parental consent, could be interpreted as an indicator of adult power over children and overprotection. Some children and young people may pick up on this demonstration of adult power, especially if the information resources are removed in their presence. Linking back to the CDA of children's diabetes information, we suspect that children and young people could therefore be less inclined to use the pack or diary as using the selected information chosen for them is what adults want them to do.

In summary, there were concerns about intervention fidelity at randomisation. PDSNs tailored a minority of the EPIC packs to the perceived needs of the individual children and young people, and this was especially true for children and young people in the 11–15 years age group. PDSNs and parents were more likely to remove the information resources on diabetes and lifestyle – information that had previously been requested by similarly aged children in focus groups as part of the intervention development phase.

Initial introduction, promotion and use of the EPIC pack

The PARiHS framework[41,48] places emphasis on the context of care as a critical ingredient for intervention implementation in practice. The theoretical models in *Chapter 1* (see *Figure 2* and *Tables 1* and *2*), based on the conceptual domains of the PARiHS framework showing partnership and participation and implementation of children's health information, conceptualised that the type of diabetes service model and individual staff would be important factors for optimal implementation to occur (context). In addition,

TABLE 53 Resources added to the EPIC packs

Age group (years)	Resource added	Number of instances
6–10	4-mm needle information	1
6–10	AVIVA Nano Meter School pack	1
6–10	*Basal Bolus* leaflet	1
6–10	*Blood Ketones and Management*	1
6–10	*Getting Started with Diabetes*	1
6–10	*Home Management of Intercurren* [sic]	1
6–10	*Type 1 Discovery*	1
6–10	EPIC pump diary	2
11–15	16–18 years EPIC diary	1
11–15	*A Guide to Basal Bolus*	1
11–15	Annual review pack	1
11–15	*Carb Counting: an Introduction*	1
11–15	*Carbs and Cals* book	1
11–15	*Getting Away*	1
11–15	*Go 4 It* leaflet	1
11–15	*Growing up with Diabetes* leaflet	1
11–15	*HbA_{1c} New Values*	1
11–15	*HbA_{1c} – What Do You Know about* [sic]	1
11–15	Local carbohydrate counting leaflet	1
11–15	EPIC pump diary	1
11–15	Home monitoring diary (not EPIC diary)	2
11–15	*Managing Sick Days*	3
16–18	NHS trust hospital leaflet	1
16–18	11–15 years EPIC diary	1
16–18	Home monitoring diary (not EPIC diary)	1
16–18	Identity cards	1
16–18	*What is Basal Bolus?*	1

staff, children and parents who placed high value on the EPIC packs (evidence) and engaged in active promotion were key to translating and using the EPIC packs in routine care (facilitation).

As indicated in the programme theory and logic model, it was conceptualised that active promotion of the pack and endorsement of ownership and active use of the EPIC pack, containing quality-assured information targeting specific age groups, would facilitate a change in motivation and behaviour towards improved self-management of diabetes. The main elements of behaviour change in the programme theory concerned increased blood glucose monitoring and appropriate insulin titration in relation to diet and activity and a focus on general diabetes self-care and lifestyle management. Behaviour change was viewed in the context of the lives of children and their families in relation to their health, medicines management and self-care. In this context, diabetes self-management was conceptualised as not only being the

TABLE 54 Resources removed from the EPIC packs

Age group (years)	Resource removed	Number of instances	Reason for removal
6–10	*Carbohydrate Awareness Guide*	3	Removed as not previously explained to the child and therefore the leaflet would need a lot of explanation
11–15	*Living with Diabetes*	1	Substituted with another magazine
11–15	*T1* magazine	2	Substituted twice as issue in the pack was out of date (was the Christmas issue)
11–15	*Body Piercing* leaflet	8	Removed as not suitable for the age group according to the PDSN
11–15	*Drinking Safely with Diabetes* leaflet	11	Removed as not suitable for the age group according to the PDSN
11–15	*Emotional Wellbeing with Diabetes* leaflet	1	Removed as not age-appropriate according to the PDSN
11–15	*Sex and Beyond with Diabetes* leaflet	12	Removed as not suitable for the age group according to the PDSN and mother
11–15	*JDRF Glucose Gang* booklet	1	Removed as not age-appropriate according to the PDSN
11–15	*Carbohydrate Awareness Guide*	4	Removed as the information had not been discussed with the participant and someone would need to explain it
11–15	*Making the Jump to Insulin Pumps*	2	Removed as young person not interested in the topic or not deemed suitable by the PDSN
16–18	*Top Tips for School with Diabetes* leaflet	1	Removed as young person no longer attending school
16–18	*Making the Jump to Insulin Pumps*	2	Removed as young people already on insulin pump therapy

responsibility of children but also involving parents, as evidence suggests that children who are supported by parents achieve better outcomes.[253]

As part of the trial set-up in each site we facilitated a launch event to explain the child-centred behaviours and skills that were important in routinely promoting and using the EPIC packs. Written guidance on the appropriate ways to actively facilitate the EPIC packs was included in the trial site manual, and regular newsletters reminded staff of the need to refer back to the EPIC pack, as appropriate, in clinical encounters with children and their families.

Although it was intended that the pack would be initially introduced to children by a member of their diabetes team (context), in reality it was most usual for children to receive the pack from the research nurse and not a member of the diabetes team (see also previous section, which indicates that most packs were not individually tailored as intended). This lack of active and ongoing promotion was disappointing and meant that a key component of the intervention programme theory and fidelity was compromised.

There were both examples of good presentational style (even if not delivered by a diabetes team member as intended) and examples in which very little introduction to the EPIC packs was given:

> *Yeah, she [the research nurse] opened it up [the EPIC pack] and showed me where things are.*
>
> *P60, male, 11–15 years, injections, > 2 years, centre B*

> *we were taken into a room and he was literally just handed a pack, nothing was said about it, it was like, here's a gift, this is for you, it wasn't go home and read it, or look at it or use it, it was just, there's a pack and then he filled in a questionnaire, and that was it, we didn't know if there was going to be anything else to it . . . and he looked at different bits and pieces, but we weren't told to sort of sit and go through it, I had a quick leaf through it, but it wasn't anything that he didn't know already so . . . I sort of, he took it into school to show his friends, he liked the folder and what not.*
>
> *Mother of child P25, male, 6–10 years, injections, > 2 years, centre B*

A 17-year-old young man was not concerned that there had been minimal facilitation of the EPIC pack: 'She [one of the research nurses] just gave it to me . . . I think it was probably quite good just to look at it yourself and take it at your own pace kind of thing (child P43, male, 16–18 years, injections, < 2 years, centre O).

In some cases there was evidence that more than one person introduced the EPIC pack: 'Yeah, she [the PDSN] did do that, and she showed us all the books and things. And . . . the other lady went through it with us too. Just to make sure' (P41, male, 6–10 years, injections, > 2 years, centre T).

Twenty of the thirty-two diabetes HCPs (63%) said that facilitating the EPIC pack prolonged the clinical appointment by 5–20 minutes, but this additional time appeared to be more for the initial randomisation and completion of the baseline questionnaire than for presenting the EPIC pack. Typical comments include:

> *Main issue in clinic was completing the questionnaire. Parents often did not have the time as they needed to get their children back to school. If the clinic was running late this made it easier.*
>
> *Research nurse, centre Y*

> *Moved to another room with research nurse as no time in general clinic to explain/deliver this pack.*
>
> *PDSN, centre I*

Parents and children also visited the clinic every 3–4 months and some were keen not to spend more time than necessary at the clinic to go through the pack. For example: 'Children/parents often want to go back to school so reluctant to look at contents of pack when in clinic. Most prefer to take them home with them' (PDSN, centre Y).

In summary, there were serious concerns about intervention fidelity at handover of the pack to the children and young people. Most EPIC packs were given to the child or young person by the research nurse, independent of the diabetes team and outside of the clinical consultation with the child or young person and their family.

Children's reactions to receiving the EPIC pack

The age-appropriate EPIC packs were designed to be appealing to children in age-appropriate ways. Most children who were interviewed liked receiving an EPIC pack.

Typical comments from children included:

> *Well, I thought it was good because it's nice and big and it fits all the things in, and I think it's good about this string, because then it's easy to take off and put on and it won't snap straightaway [boy talking about elastic string to close the folder].*
>
> *Child P41, male, 6–10 years, injections, > 2 years, centre T*

> *It's all right.*
>
> *Child P34, female, 11–15 years, pump, > 2 years, centre N*

> *I thought there's loads of stuff in it and it's a really nice folder, . . . I was quite impressed.*
>
> *Child P46, female, 16–18 years, injections, > 2 years, centre S*

Most of the diabetes HCPs believed that the EPIC packs were well received by children and young people, with 16 of the 25 (64%) believing that the EPIC packs were useful in generating questions from parents and children. We can therefore say that introduction of the EPIC packs did alter behaviour in a small way in that some children, young people and their parents asked more questions than usual. It is less clear whether diabetes professionals used the packs to stimulate questions from children and young people and their parents. This is important as texts do not 'live' in isolation from the wider discursive context. However user-friendly the EPIC packs and diaries are, this is not enough to make up for a lack of contextualisation if they were given to children and young people without comment or discussion. Simply giving something to someone with good intentions that is well thought through does not constitute giving them 'ownership'.

Typical comments from research nurses about how the children received the packs include:

> *All of the children who received packs were really impressed with the presentation of them and they seemed to appeal to the different age groups equally as much as each other.*
>
> *Research nurse, centre N*

> *I thought the packs were well designed, informative, motivational, well presented and age appropriate. The children I witnessed receiving the packs all responded well to the content. I'm sure the packs will help making learning fun for those patients.*
>
> *Research nurse, centre Q*

> *I personally found that the participation in EPIC was amazing for our children and many more wanted to be involved but we were unable to recruit due to the time restraints of entering the study. I was thrilled to have participated and see the child's face light up on the randomisation when they got a new pack.*
>
> *Research nurse, centre T*

Summary of findings for care process 1

In summary, we found evidence at baseline, which aligned with the logic model and programme theory, that most children and young people found the EPIC packs appealing and that they matched with their age-appropriate tastes concerning types and formats of information.

The theoretical model of the critical success factors shows the importance of context in creating effective partnerships between families and diabetes professionals, and the role of facilitation, which is needed to successfully implement new interventions into practice. When this evidence is mapped against the core concept of partnership and participation, it is clear that many children and young people experienced lower levels of partnership and participation with their diabetes team than was intended when the EPIC intervention was conceived. Insufficient partnership and participation could be another reason why the EPIC packs did not work as intended, as a different style of child-centred engagement with children is required. It was also clear that, without modification of the current model of the children's diabetes care pathway and clinic set-up (logic model), it would be challenging to optimally implement a diabetes education pack such as the EPIC pack. Lack of accommodation of the EPIC packs and diaries by the service and diabetes professionals is crucial. The context was wrong for optimal reception of the text and its use. Texts circulate and sense is made of them in the context of partnership and participation. Something that is simply given to children and young people with an expectation that they will just 'get on' with it (along with their parents) can be interpreted as authoritarian and patronising. There is a sense that the person with diabetes is indeed a 'patient' in the old sense of the word, who must do as he or she is told, even when the text is well presented and age appropriate.

Care process 2: daily use of the diary and regular use of the EPIC pack at home and at school by children and young people and their families to optimise diabetes self-care and management

Within an anthropological context, following initial intensive and practical support at diagnosis, diabetes is a condition that is mostly managed at home by parents and children and young people with regular 3- to 4-monthly visits to a hospital and ongoing contact with a PDSN (programme logic). How parents, children and young people used (or not) the diabetes diary and EPIC pack at home and at school, and whilst children were away from the care of their parents, was of specific interest (logic model).

The intention of the EPIC pack was to align children's self-management with gold standard children's clinical diabetes guidelines so that when children used the EPIC diary and information provided they were motivated to self-manage in optimal ways. The EPIC packs were designed for children and young people to use on a daily basis to help them self-manage common diabetes issues and prevent escalation of situations that may be life-threatening (e.g. severe hypoglycaemia). It was expected that children and young people (and, when appropriate, families) encountering a diabetes self-management issue would access information in the pack to work out the solution for themselves in the first instance before contacting a diabetes HCP if further advice was required.

The key message within the programme theory of the information provided was normalisation of medicine management. Thus, the empowerment of children and young people concerned normalisation of diabetes management, and the images and information presented in the EPIC packs were selected to promote this.

The EPIC pack also included a letter to the child or young person outlining how to use his or her pack and inviting him or her to personalise it to reinforce 'ownership' of the pack. Colourful stickers and/or pens were provided within the EPIC pack, the theory being that children and young people would feel ownership of the EPIC pack through personalisation, thus engendering routine use of the EPIC pack when they needed information about T1D.

Use of the EPIC diary by children and young people and their parents at home/school

The main component of the EPIC pack was a diabetes diary. It was intended that the EPIC diary would be taken out of the 'pack' and used on a daily basis to record blood glucose levels and insulin doses. This information is essential for identifying trends and maintaining optimal blood glucose control. A key message to children and young people was printed on the outside of each diary – 'Take me with you wherever you go' – and this was purposefully written in an authoritative style.

The key discourse used was to present medicine (insulin) as a social enabler, with factual, truthful and reliable information on optimal medicines management. Children's recordings of their medicines management in the diary are ideally shared with diabetes professionals in clinic so that they can advise about strategies for optimal glycaemic management.

In reality, at the end of the 6 months children and young people generally liked the look of the EPIC diaries but this liking for the style and format did not consistently translate into actual daily use as intended. This finding is similar to the finding in the treatment as usual group. In addition, interviews revealed that children and young people were usually, but not always, given an EPIC diary at randomisation. This was disappointing because the EPIC diary was conceived as central to the EPIC pack and the key component for optimal diabetes self-management.

There was some evidence of children and young people taking their EPIC diary with them into school but this was in a minority of cases as most children did not take blood glucose readings at school or inserted the readings from their meters into their diaries at a later time point at home, or their parents would do this for them before clinic visits. Members of the clinical expert group said that not taking a diary to school is fairly common because children tend to forget to bring the diary home; sometimes they have a separate diary to keep in school for lunchtime readings. This lack of use, or very limited use, of a diary in any context, both in the treatment as usual arm and in the intervention arm, is of major concern and provides an explanation of why children's overall diabetes control was poor and why the EPIC pack and diary had no overall effect.

Non- or limited use of the diary is an issue that will be illustrated across all age groups in the following sections, which describe how children and young people and their families – especially the teenagers – have taken the diary home but mostly not used it as intended.

The 6–10 years EPIC diary

Six children in the 6–10 years age group said that they did not remember receiving an EPIC diary. In some cases there was clear evidence that parents were completing the diary for their child and so it is possible that the children had not seen or been involved in completing the dairy. Nonetheless, in this age group we had envisaged that parents would be establishing optimal behaviours at a young age by teaching their children to record blood glucose readings and insulin doses and learning about insulin titration together (programme theory). An example of a completed diary is shown in *Figure 38*.

Positive responses to the 6–10 years EPIC diary and evidence of completion Of the children who received the 6–10 years EPIC diary ($n = 13$), seven said they liked and used it. Although it is not clear whether the diary was completed by her or with her son, a mother of a 9-year-old boy said:

> *we've only literally just finished it . . . I do like the spaces in that one . . . . It's good you get some which are literally half that size, they're kind of more adult geared ones . . . the spaces are big enough as well like I often write little things like the reason you know even though he's that, I can write . . . I've given him that because he's playing out.*
>
> *Mother of child P87, male, 6–10 years, injections, > 2 years, centre O*

A 9-year-old girl said that she used the 6–10 years EPIC diary because it was colourful and had helpful hints (these included sick-day rules and 'top tips' presented at the bottom of the pages):

> *It was handy, because it was like . . ., it was here, it was more colourful in a way, and I enjoyed it better than the others because, I don't know, the others are too long. But I liked that one [6–10 years EPIC diary] . . . . It was good because it said things like remember to check your blood glucose and such like at the bottom.*
>
> *Child P52, female, 6–10 years, injections, > 2 years, centre Y*

FIGURE 38 Completed 6–10 years EPIC diary.

Suboptimal use of the 6–10 years EPIC diary Similar to the treatment as usual group, few children in this age group took their diary to school. Having diabetes was a sensitive issue and some young people wanted to keep it a secret. Despite more positive media coverage of diabetes and how it can be managed, children and young people did not want other children to know as it marked them out as different, not normal, somehow not as good as others. This is linked to wider cultural perceptions about disability more generally, which are much harder to change. The programme theory of 'normalisation' with use of insulin as a social enabler did not fit with some children's representations of still feeling different:

> *No [doesn't take diary to school], because I like to keep my diabetes kind of secret. And like I only tell like my best friends and like I just kind of keep it secret from everyone else and if people ask I just say like, well I'm just diabetic.*
>
> Child P66, female, 6–10 years, injections, > 2 years, centre Q

The 6–10 EPIC diary was also liked, but not used, by another boy in the 6–10 years age category. The mother in this example is completing the diary but deliberates whether she should be encouraging her son to take on this responsibility:

> *I think that's a good diary because there's plenty of room to write in, and [boy's] last book that he got from the hospital was very similar to this. Very similar, same sort of size . . . yeah, but I know [boy] wouldn't fill that in though, would he? I mean maybe we should be encouraging him to fill the diary in himself? He just doesn't want to. He doesn't fill any in . . . we do it for him now ourselves, and he just lets us get on with it . . . he just wants to carry on his life as normal, he doesn't want to be seen as being different to anybody else. Which is fair enough.*
>
> Mother of child P83, male, 6–10 years, injections, > 2 years, centre T

We found a disconnect between some parents and children in their management of the child's glycaemic control: the 9-year-old girl (P52) said that her mother usually filled her diary in to monitor blood glucose levels but her mother admitted that she rarely did so because of their busy family life. Mirroring the findings from the systematic review reported in *Chapter 3*, this girl also struggled to manage her diabetes when away from her family at school as there was no one to do undertake the readings for her and she had not been taught to do it herself:

> Researcher: *Right, and who does that usually? Do you write your bloods down, or does mum do it?*
>
> Girl: *Mum.*
>
> Mother: *But we didn't do much to tell you the truth, we don't. We're supposed to, but I find it difficult you know . . . with all the children and running for the bus and then when they're in school at lunchtime there is nobody to do it at lunch time for her.*
>
> Child P52, female, 6–10 years, injections, > 2 years, centre Y

This example of disconnect between the child's perceptions and the parent's perceptions appears to be a communication breakdown and may signal a need for greater support for the whole family. The 9 year old may benefit from more encouragement to monitor her own levels and fill in the diary herself. There is also an obvious need for more support when at school. This concurs with the findings from the systematic review in *Chapter 3* in which we reported examples of parents of children who should be self-managing going into school to give their children insulin.

Design issues with the 6–10 years EPIC diary The type of shiny paper used caused children in all age groups problems as certain pens did not work. In the next example, a 9-year-old boy and his mother liked the diary and used it for 2 weeks both at home and at school before returning to another dairy because the type of paper used in the EPIC diary made it difficult for the boy to write in it:

> *I used it for 2 weeks . . . but we had a big problem with it . . . the pages, because they were shiny, and it was kept in the kitchen, with cooking grease and things like that and I did tell [son] to write in it, was really hard . . . yeah, if it had different paper inside, it was a fabulous diary. Because he does take a diary to school. And he does it all himself at school, and he did like the diary.*
>
> *Mother of child P41, 6–10 years, injections, > 2 years, centre T*

The boy himself thought that the diary and 'top tips' were very helpful and the diary was taken to school as intended and it is therefore not clear why they did not keep the diary away from cooking grease and swap the pen to one that did work on this paper type. This illustration shows that even a relatively small design issue that can be fairly easily overcome with simple problem-solving and changing the pen type acted as an immovable barrier to implementation and ongoing use.

The 11–15 years EPIC diary

All 15 of the children and young people in this group said that they had received a diary. Similar to the treatment as usual group, the diary was reportedly used by only six of the 15 children and young people, with eight saying that they did not use the diary (one unknown). Again, non-use of the diary is a serious concern and helps explain why the EPIC intervention had no detectable effect. An example of a completed diary is shown in *Figure 39*.

Positive responses to the 11–15 years EPIC diary Some young people liked the tips (key health messages delivered in an authoritarian voice – programme theory) contained within the diary, although the outcomes suggest that reading key health messages alone did not bring about a sufficient change in diabetes self-management behaviour across the sample. For example:

> *Yes, I've noticed the section with the tips at the bottom of each page, a different tip on your diabetes and how to control it. What foods are good and watch your carbs and stuff like that so, there's some good tips on it, so . . . I thought, it was good for the tips that it gave at the bottom but it wasn't especially like . . . the tips were a lot better than the diary that my diabetic nurse gives to me.*
>
> *Child P19, male, 11–15 years, injections, > 2 years, centre Y*

Evidence of using the 11–15 years EPIC diary recordings to titrate insulin as intended Although six young people *said* that they were using the diary, there were few actual examples of young people using the diary as intended.

The teenager in the following example does not say whether he filled in the diary himself, but importantly he used the diary to identify patterns to inform decision-making in his medicine management. This self-management behaviour of looking for trends and self-titration of insulin is a good example of the type

FIGURE 39 Completed 11–15 years EPIC diary.

of behaviour required for optimal diabetes management, and we found very few examples such as this. We do not know if it was the EPIC diary and pack that motivated this behaviour or if it was already an established approach to self-management by this teenager:

> *Good to like see what all my blood sugars were on the days, if I was high or not . . . . And like if I had say had the same meals as I had another day and I could check how many units, and see what my blood was next time and see whether I have to change it.*
>
> *Child P64, male, 11–15 years, injections, < 2 years, centre A*

Suboptimal use of the 11–15 years EPIC diary Young people in the 11–15 years age category and their parents liked the EPIC diary but some parents were still completing it for their children. In this age group the expectation is that young people will be completing their own diary and making decisions about changes to insulin doses with parent supervision decreasing over time (programme theory). In reality, it was not clear whether this age group considered self-titration of insulin to be important. We found that parents were still completing diaries as they felt that it would not get done unless they did it. In addition, young people did not always act on their blood glucose levels. In the following example the parent appears to have done too much for her son, who is at an age when it is appropriate for him to be completing some or all of his diary:

> *it [EPIC diary] was a better laid out one than the one we're using . . . You don't fill it in do you? . . . Otherwise, it wouldn't get filled in would it, any of it? He just does his reading and then he's off.*
>
> *Mother of child P17, male, 11–15 years, injections, > 2 Years, centre Y*

As they grow up some children cannot see the point of changing their behaviour as they consider that their parents are always going to take control anyway so there is no need to bother changing.

The following quote illustrates that, even when young people filled in the diary, they did not always use the information to help with decision-making and medicines management: 'I don't know, I don't actually look at it much, I just . . . write in it and put it back. So I don't really mind how it [diary] looks' (child P60, male, 11–15 years, injections, > 2 years, centre B). From a self-management point of view there is no point filling in the diary if young people do not act on the results and the diary recordings do not prompt a change in insulin dosage.

It may be that by this age some young people are unconcerned about diary presentation as they have been presented with so many over the years. If design is not an issue, more emphasis could be placed on how some form of diary will make their life easier, because it will help them to control their diabetes.

Few children in this age group took their diary to school. For example, a 13-year-old boy said that he recorded his readings on his phone but did not necessarily transfer the readings to his diary when he got home: 'No like, I wrote all my numbers down on like my phone. And I meant to put them down when I got back, but I didn't take the diary no' (child P64, male, 11–15 years, injections, < 2 years, centre A).

For this young man and other young people who do not like disclosing their diabetes or who do not want to carry a separate paper diary, a diabetes phone app may be more appealing, but the technology would need to incorporate automatic information transfer to a home computer so that readings could be shared with parents as appropriate.

Inappropriate reliance on downloading blood glucose readings from the monitor A small number of young people indicated that they did not use the EPIC diary because downloading meter readings to their computer was easier: 'I don't know I just, I rather the easy way of just downloading them [blood glucose readings] on to the computer really' (child P57, male, 11–15 years, injections, > 2 years, centre L). Although downloading meter readings seems to be common, unless young people record on their computer their insulin dose alongside their blood glucose reading and look for patterns and trends they are not going to have the appropriate information to optimally self-manage.

Then again, this notion of optimal self-management (programme theory) is defined by diabetes professionals and it could be that this is part of young people's resistance. It may be that what we are seeing is partly a backlash to never being able to be 'normal' but also to adult power and control. It seems that lip service is paid to empowerment and self-management, when in fact the structures are not really in place to do so (in concrete terms but also conceptually in terms of adult power over children, protecting them from risk and decision-making, etc.). Children and young people pick up on these things and some may instinctively counter-react.

Adults (professionals and parents) may wonder why children and young people do not 'get it', do not do as they are told, do not recognise that optimal self-management is in their best interests, but, for varying reasons, some children and young people might not see it this way but as another way of adults controlling them.

In the following example a parent cancelled a diabetes clinic appointment as the blood glucose readings and insulin management had not been completed either by her or by the young person. They tried to download the readings from the blood glucose monitor but were not able to do so. At the age of 13 years the responsibility for this should ideally be shared with and subsequently taken over by the child.

> *I've had to cancel a couple of appointments, generally because we haven't got the books [diaries] or we haven't had the books [diaries] written down on, and you know, even if I started doing them or, for whatever reasons things have happened, and you know? . . . . I'm not taking you to the appointment, if you haven't got any readings to show people and we haven't got any of the information . . . then . . . we tried to download and there was a problem with one of the machines*
>
> *Mother of child P58, male, 11–15 years, injections, > 2 years, centre L*

This is another example showing that a phone or computer diabetes diary may be preferable to a paper one. The key issue seems to be the easier you make recording, the better. An app can do this, track trends, make suggestions about diet, etc. A PDSN reinforced the children's and young people's evidence that IT-based solutions may be more appropriate for the teenage group: 'The information was very useful, but the teenage groups may respond much better to IT-based information, podcast info, interactive learning-based info, which I appreciate requires investment' (PDSN, centre U).

Design issues with the 11–15 years EPIC diary Although it was intended to offer teenagers in the 11–15 years age group the option to select the 16–18 years diary, only one diary was swapped in this age group. It is unclear whether young people were not offered a choice or whether they opted for the younger version of the diary. The subsample of young people who we interviewed who did not receive the 16–18 years diary specifically commented that the 11–15 years diary cover may be too young for some teenagers, which suggests that they were not given a choice of selecting the older version.

In addition, the following quote illustrates that young people did pick up on the key health messages in the diaries, but nonetheless reading the 'top 10 tips' for self-managing diabetes did not result in sufficient improvements in self-management behaviour:

> *Yeah, I think it's quite nice, it's got all these friendly little pictures on it and these little tips, like these little monsters are telling you, helping you how to control your diabetes . . . . Yeah, I thought that many little kids will like that because it's friendly, to them . . . I think that somebody, like a teenager, some of them will like it, because it's friendly, but I think most would think it's a bit childish, teenagers will, and will want more adult ones.*
>
> *Child P57, male, 11–15 years, injections, > 2 years, centre L*

The 16–18 years EPIC diary

The young people in this age group are still being managed by children's services and are in transition to adult services or have moved into a transition clinic or have left children's services and are being managed by adult services. We were not able to access young people who had already transitioned to adult services and so we interviewed young people who were being seen in children's or teenage transition clinics. The assumption is that at this age young people are able to self-care and manage their diabetes on their own, but within the context of their family and ongoing family support (programme theory).

One female interviewee reported that she did not receive an EPIC diary at randomisation. In this case it is likely that she did not take it home from the clinic appointment as she knew that she would not use it. This example of not wanting a diary to self-manage is similar to what several young people told us in the treatment as usual arm. In addition to hearing about diary use, we were particularly interested in receiving feedback on the size of the diary for this age group as teenagers had requested that the diary be able to fit in a meter pouch or pocket. We found that the 16–18 years EPIC diary was both liked and disliked because of the A7 size.

An example of a completed diary is shown in *Figure 40*.

Evidence of completion of the 16–18 years diary and feedback on diary size Of the thirteen young people in this age group who received the diary, three said that they used it and seven said that they did not. This reiterates that young people are less likely to use a diary over time and especially at the stage when they are supposed to take full responsibility for their diabetes self-care.

A 16-year-old girl was one of three who said that she recorded her readings in the diary, but this particular girl found the space limiting:

> *I filled it in as much as I, it's full now, bit small for me, I generally found the boxes a bit small and my handwriting is quite big . . . I think, because it's a diary there's only so much you can do with it because it's got to be filled in, I do think it needs to be one size bigger because I struggled with that and especially if you've been newly diagnosed the chances are you'd be filling a lot more notes in so you might need a bit more room there, little things like that. But the layout, I think the layout is really good and its all clear.*
>
> *Child P26, female, 16–18 years, injections, > 2 years, centre N*

An 18-year-old boy currently on a pump but who was on insulin injections at the start of the trial found the diary small and his consultant had difficulty reading the content. As seen with a couple of young

FIGURE 40 Completed 16–18 years EPIC diary.

people in the 15–18 years age group, he recorded back-up blood glucose (but presumably not insulin) readings on his computer:

> *The only issue with the [EPIC insulin not pump] diary was that it was quite small wasn't it? And it was sometimes difficult for my consultant to read it, because my writing is awful, to be honest. That's probably nothing to do with the size, but it was okay because I had my computer thing anyway.*
>
> *Child P82, male, 16–18 years, pump, > 2 years, centre S*

We will discuss further the issue of maintaining an e-record rather than a paper diary in *Non-use of the insulin pump diary and substitution with an e-record*.

Suboptimal use, non-use and diary size There was a greater trend towards intermittent or non-use of diaries in this age group. In the following example the diary was kept as intended in the blood glucose meter pouch but was completed twice a week only and not four times a day as intended:

> *Yeah, and I could keep it [diary] like in my [meter] pouch . . . I did it like twice a week. Or something, I'm just like, I don't know . . . . No, I'm just a bit lazy when it comes to that [filling in a diabetes diary].*
>
> *Child P40, female, 16–18 years, injections, > 2 years, centre T*

Another 17-year-old girl stated that she had not used the diary because another diary provided by the hospital was better because it was a bigger size (and easier to find in her bag): 'No, I've not used it. I was going to start using it, but I thought . . . the other one I've been given at the hospital was better to use [*Home Monitoring Diary* by Novo Nordisk]' (child P67, female, 16–18 years, injections, > 2 years, centre Q).

Despite being presumably aware that completing a diary was a central and important part of diabetes self-care, most young people were very open about not using a diary. The mother of one 17-year-old girl reiterated that her daughter would not be able to see a trend if she did not write down her meter readings, but this was not sufficient to persuade her daughter to change her self-care behaviour:

> *It's small enough to go in her pocket because we have struggled to get [girl] to record, she does test, but then doesn't write them down. And what that means is that she can't see a trend . . . and I thought when I saw this, it's quite small . . . but as most things, she tries them for a while, and then stops using them . . . she can't get into the routine of it . . . but I find it a bit small.*
>
> *Mother of child P85, female, 16–18 years, injections, > 2 years, centre T*

Young people generally found the diary appealing but this was not sufficient to motivate them to keep a daily record of their readings to establish trends and optimal self-management:

> *I like that it's little . . . . It's small and cute and pocket size . . . . I don't really take my blood sugar levels enough to use it but if I did take my blood I would write in it, yeah. I'd probably take it with me if I went away, if I went on holiday or something like that. I don't know why I just like to take my blood sugar more when I go on holiday.*
>
> *Child P46, female, 16–18 years, injections, > 2 years, centre S*

This 17-year-old girl was consistently offered diaries but chose not to complete one: 'they offer me a new diary when I'm there but no, I just say I've got an empty one at home already' (child P46, female, 16–18 years, injections, > 2 years, centre S).

Another 17-year-old girl also mentioned that she did not use a diary: 'No. I haven't been using a diary' (child P74b, female, 16–18 years, injections, > 2 years, centre B). Her mother seemed to have accepted that completing a diary was no longer appropriate, when the diary is in fact the central component of good diabetes self-management: 'She's grown out of that . . . for a long time, she's not kept a diary' (mother of child P74b, female, 16–18 years, injections, > 2 years, centre B).

It could be that the notion of a 'diary' is less appealing to older children. A move to an e-format might be more appealing and a name change might also be worth considering. There is no issue with size or space to input readings with an e-format.

The EPIC insulin pump diary

The self-management of diabetes with an insulin pump is different from self-management with insulin injections. Some trial sites were keen to use the pump diaries and in one site a child in the treatment as usual arm was given an EPIC pump diary (*Figure 41*). Other sites seemed to prefer to encourage young people to rely on downloading information from the pump onto a computer. Young people on pumps tended to download information from their pump because it allowed them to view different graphs to inform their decision-making.

Because of resource constraints we produced one EPIC insulin pump diary for all of the age groups (6–18 years). We were aware that it would be difficult to produce a diary that was appealing to such a wide age range, so as well as determining whether the diary was used by children and young people we were interested to see what visual impact the diary had on children and young people of various ages. As predicted, the diary was visually more appealing to younger age groups, thereby reinforcing the importance of age-appropriate resources.

Non-use of the insulin pump diary and substitution with an e-record Only two of five 16–18 year olds using an insulin pump who were interviewed were in the intervention arm of the EPIC RCT and neither used the EPIC pump diary because they downloaded blood glucose results from their meter and information from their pump onto the computer. One 16-year-old girl, for example, said that the pump diary was good but that she preferred to download information onto her computer rather than writing information in a diary:

> *Yeah, I thought it was like, it was good because I was looking at my blood sugars more than I would be . . . . I download it onto my computer . . . . And download my pump . . . I don't print it off usually . . . and my nurse knows my password, so if I tell her that I've uploaded it she can have a look at it and help me . . . it was PDSN that suggested it.*
>
> *Child P81, female, 16–18 years, pump, > 2 years, centre I)*

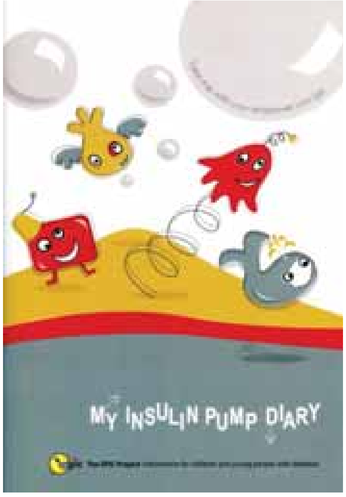


FIGURE 41 EPIC insulin pump diary.

Also, the mother of a 13-year-old girl said:

> *I think the diary is in there [the EPIC pack] but we haven't filled it in because we tend to download things off the computer with her pump . . . when she first had diabetes I filled out the diary religiously because she'd actually learnt such a lot from your diary entry and you could go back when you had a problem and see what happened last time so we haven't used it now because we tend to download and we're pretty much, you know can problem solve without.*
>
> *Child P34, female, 11–15 years, pump, > 2 years, centre N*

We agree with these young people that producing EPIC pump and injection diaries as apps might be an alternative option, although we have no evidence that an app is any more likely to bring about improvements to diabetes self-care and management.

Use and non-receipt of the EPIC pump diary Among sites that did encourage use of a pump diary, the mother of an 8-year-old boy was positive about the diary but again her response suggests that she had total responsibility for the diary, which is appropriate for this age and management of a child with a pump:

> *they were good diaries, the best type I've had actually, really useful . . . I think they were just easier to use, you know because they had the table on the top and then the food underneath. I mean I didn't necessarily fill the food in every day but I mean the actual spreadsheet itself was great.*
>
> *Mother of child P35, male, 6–10 years, pump, < 2 years, centre N)*

Unfortunately, not all families received the EPIC pump diary as intended. As the mother of a 9-year-old girl said: 'I wouldn't like to say, hand on heart, that we definitely didn't get it, I don't remember getting it [EPIC pump diary]' (mother of child P20, female, 6–10 years, pump, > 2 years, centre L).

We also detected issues of intervention fidelity whereby the pump diary was not given as intended to children and young people if they changed from insulin injections to an insulin pump during the life of the EPIC trial: 'Well had to swap [diary] didn't we when I got the pump, but we did [get the 11–15 years EPIC insulin injection diary]' (they did not get the EPIC pump diary) (child P38, female, 11–15 years, pump, > 2 years, centre Q).

Design issues with the pump diary There was only one example of the pump diary being used in the 11–15 years age group. This was a 13-year-old girl who reported a problem with the pen that she used with the diary: 'at the bottom of the page, there was a picture and it was covering up them two boxes, and because of the material it was made out of, the pen wouldn't work on it properly' (child P23, female, 11–15 years, pump, > 2 years, centre A).

There were also examples of the pump diary not being used because the cover was too childish, thereby reinforcing the importance of age appropriateness. For example, a 15-year-old boy said:

> *It doesn't act in an older way. I think it was a bit childish. That's from my point of view, I don't like to be treated as a child, when it comes to diabetes, I would like to be given stuff adult standard . . . . It does look a bit childish . . . I thought it was a bit . . . too much, I think that the one that we've got now, is better . . . . How much you're going to put in, how much bolus you're going to do. I thought that might have been too much details.*
>
> *Child P74a, male, 11–15 years, pump, > 2 years, centre B)*

Summary of key findings concerning implementation and daily use of the EPIC diaries

From a professional perspective, diabetes diaries play an important role in diabetes care because they allow day-to-day evaluation of blood glucose readings and insulin patterns indicative of a potential need to alter insulin dosage, regardless of the insulin regimen being used. Diabetes diaries, used correctly, act as an adjunct to HbA_{1c} measurements, thereby facilitating decision-making by children, parents and diabetes professionals (programme theory). In the EPIC trial there were a number of issues concerning the diary that have with certainty impacted on outcomes. First, not all children received or wanted a diary at randomisation. Second, not all children and families who injected insulin used the diabetes diary as the essential tool to manage the medicine component of diabetes – blood glucose management and insulin titration. The main barriers to using a diabetes diary generally, and the EPIC diary specifically, were lack of interest or motivation, especially by teenagers and some parents, lack of time and lack of practice in how to use a diary because parents filled in diaries on behalf of their children. Some young people seemed to prefer using their phone or computer to record or download readings. Most recently apps have become available for adults, including a diabetes diary app. Importantly, many young people were uninterested in recording and using their readings to manage their diabetes in optimal ways to minimise long-term complications. Third, there were some design issues with the diaries, including:

- the pocket-sized teenage diary, which was designed to match with their exact size preferences and to fit in the blood glucose meter pouch, back pocket or small bag, was too small to record information
- the shiny high-quality paper did not work with some pens
- the images in the 11–15 years diary were too young for older children and the 16–18 years diary was not consistently offered to this age group
- the images in the pump diary (6–18 years) were too young for the older end of the age range.

The theoretical model of the critical success factors for implementation of children's health information shows the importance of the 'value' that children, young people and their parents place on the diabetes diary (evidence-based intervention). It is clear that many children and young people, and some parents, did not 'value' having a diabetes diary as they found it a chore to fill in on a daily basis and there was uncertainty as to who the diary recordings were being made for (i.e. diabetes professionals as opposed to children and young people). This lack of clarity could be addressed by children's diabetes information leaflets making clear who the recordings are for and why they are useful. The child reader has to want to perform the readings him- or herself and experience feeling better because of optimal diabetes management. Diabetes professionals were perceived to place a far higher value on the diary readings and most children and young people and many parents did not value the diary (any diary) as a useful tool to aid self-management at home.

In a clinical context, not using the diabetes diary as intended is the most significant challenge when attempting to optimise diabetes self-management. Comparison of the EPIC findings with the clinical experience of diabetes clinical co-applicants from non-trial sites confirmed our findings. As in the EPIC trial, in their experience many parents attended clinic without their child's diary. Although young people may perform blood glucose monitoring, as in the EPIC trial, they often failed to record the readings in their diary on a daily or even weekly basis. Some children, young people and parents do not use a diary at all or record a few readings over the 2 weeks before their clinic visit. Some young people and parents were found to falsify readings, either because they had not recorded any or because they did not want to present high readings. Also, as with our findings, children, young people and parents did not always act on the results when necessary.

Diabetes co-applicants also provided some external validation that children, young people and parents think that completing a diary is for the benefit of diabetes professionals (also corroborated by non-participative observation in the IMP[1]); hence, it is common to fill in 1 or 2 weeks of readings the day before clinic. This behaviour identifies a critical lack of understanding about what the diary is for: to identify patterns within the profile to inform a change in insulin dosage that fits with optimal medicine management. It also begs the question about ownership of the diary. The diary was perceived by children, young people and parents as being for the benefit of the HCP, and many children, young people and parents neglected to fill it in as they did not consider it to be their diary.

Our EPIC process evaluation findings make clear that diabetes self-management intrudes on every aspect of daily life. Providing a diary alone without other behavioural interventions is unlikely to motivate change or optimise diabetes self-management practice as there are not shared expectations or clarity about the role or importance of the diabetes diary in self-management at home. Some children and parents who started out with optimal self-management seem to lapse over time and new interventions are needed at critical junctures post diagnosis to maintain optimal self-management practice.

In the next section the focus moves to the use of the EPIC pack of comprehensive diabetes information by children and young people at home.

Use of the EPIC packs by children, young people and parents at home

The EPIC packs contained a comprehensive range of quality-assured and age-appropriate diabetes information in various types and formats and a letter to the child/young person indicating that the pack was theirs with some advice on how and when to use it (programme theory). Although we had hoped that the packs would be individually tailored for each child at baseline and over time, as previously reported we found that minimal tailoring actually occurred. It was hoped that the EPIC pack would help with the gradual shifting of responsibility for diabetes self-management from parents to children and young people, depending on their maturity and diabetes care requirements (programme theory). Like the diabetes diaries, the packs contained messages that medicines were a social enabler and that self-management would enable and empower children to experience childhood like other children.

Ownership, personalisation and storage of the EPIC pack at home

In reality, the EPIC packs were almost exclusively used in the home by children and young people, with few examples of parents using the packs with younger children to help with problem-solving. We found that children and young people tended to engage with the EPIC packs on their own, in their home environment, with little or no active help or support from parents or other family members. Although parents were positive about the EPIC packs, some were often put away after an initial ‘look through’, and they were not used as a discussion tool between the parent and child or young person but rather as a reference tool for the child’s or young person’s future use.

Most children and young people took ownership of their EPIC pack in the sense that they held it as one of their belongings and stored it in their bedroom, on their bookshelf or on/in their desk:

> *In my room, on my desk . . . and whenever I need information, I can read some.*
>
> *Child P24, female, 6–10 years, pump, > 2 years, centre B*

> *Well we’ve got like a drawer in like the desk upstairs and it’s in there with all our other piles. So, it’s somewhere we know all the files are so we can just access it easily.*
>
> *Child P19, male, 11–15 years, injections, > 2 years, centre Y*

Some EPIC packs were left in more communal areas of the house such as in the dining room/kitchen: ‘it’s in the kitchen. Because every time if we need to go through, if we ever have a problem it’s easy access type thing, because we have a box on the side with sweets in, that’s my box’ (child P22, female, 11–15 years, injections, < 2 years, centre A).

Other places where the EPIC packs were stored were the utility room, conservatory and upstairs office.

At the end of the 6 months we found that most children and young people understood that the EPIC pack was theirs to keep, but a small percentage of those interviewed did not feel as if they owned the EPIC pack and that they were simply borrowing it from the hospital and that it would have to be returned. This finding suggests that the feeling of 'ownership' of the pack, leading to 'empowerment' to use and reuse the pack, was compromised. The lack of perceived ownership of the pack by children and young people may also reflect their perception of who is in control of their diabetes, that is, diabetes professionals.

For example, the following children and young people said that they did not know that the EPIC pack was theirs to keep. One 13-year-old boy said:

> *I thought it was my pack, but I wasn't sure if it was after the project had finished, if it was going to be returned back to you and then you send it off to somebody else? That's why I kept in mind not to write on it, or anything.*
>
> *Child P57, male, 11–15 years, injections, > 2 years, centre L*

Similarly, a 17-year-old girl said: 'I think everything that was in the pack is still in there, because I thought I had to give it back to the hospital' (child P85, female, 16–18 years, injections, > 2 years, centre T).

Having had the pack for 6 months we found that only a small number of children and young people had decorated their pack to make it personal to them. There were some examples of children and young people using stickers to decorate their 6–10 years (*Figure 42*) or 11–15 years (*Figure 43*) pack. However, there was not much evidence of the Sharpie pen (which was put in the 11–15 years pack) being used to personalise the 11–15 years pack, apart from being used to write the young person's name on the name card on the front of the pack or on the front of the diary. Some children did not want to use the stickers because they were not into stickers (some of the 15 year olds felt too old to use stickers), and other children did not realise that they were stickers as they had to cut them out themselves (they were not precut).

FIGURE 42 Example of personalisation of a 6–10 years pack.

FIGURE 43 Example of personalisation of a 11–15 years pack.

Negative reactions to the EPIC pack

As highlighted previously, many of the children and young people in the EPIC trial have lived with diabetes for an average of 7 years and managing the condition, whether independently or by/with their parents, was part of their life. We also found examples of children and young people who had been diagnosed for < 2 years and who did not want to be reminded in any way that they had diabetes. Confirming CDA findings, young people generally did not want to be defined by their diabetes, and members of the clinical expert group reinforced this finding by saying that they found it very difficult to interest young people in outings with other young people who have diabetes as it is not diabetes that defines them. Overall, we found that as young people grow up, other things are more important in their lives and diabetes seems to take a back seat.

Although the key discourses in the packs were designed to motivate and 'empower' children and young people to self-manage in a variety of ways, some did not feel able to open the packs and were therefore not exposed to the discourses contained within the diaries or comprehensive up-to-date diabetes information. Although the packs were not designed to emphasise a 'difference' and focused on medicines as a social enabler, we found that some children, particularly older children, did not want to be constantly reminded that they were different to children without diabetes. We identified examples of both children and parents who put the EPIC pack to one side or in an inaccessible places such as the attic and 'forgot about it'.

The following quotes illustrate the complex issue of children and young people not wanting to be defined by, or socially involved with, their diabetes. For example, a 12-year-old girl hid her pack behind the bedroom door:

> *I don't want stuff like that to be around . . . this pack is kept behind my door in my bedroom, I never want to see it really. I don't want to properly read through it, I don't want to put stickers on it and make it you know, my best friend, . . . I don't really want to see it.*
>
> *Child P22, female, 11–15 years, injections, < 2 years, centre A*

A girl from the 11–15 years age group explained that she did not visit the websites mentioned in the EPIC pack. She said:

> *If I'm honest, I wouldn't have used them [the diabetes websites listed on the further information sheet]. I mean, I know it's all about trying to help me with my diabetes, . . . I just try and be, not at all socially involved with diabetes, if I can, I shut it out as much as possible.*
>
> *Child P22, female, 11–15 years, injections, < 2 years, centre A*

However this same girl said that she had watched videos on the predominantly social media site YouTube regarding diabetes injections, suggesting that she does utilise the internet for information about T1D from time to time.

Young people also commented on specific information in the pack that did not yet apply to them as a reason for not reading or using the information: 'some of it I haven't read because it doesn't apply to me . . . but obviously the drinking applies to me and the exercise applies to me because I had problems before with that' (child P44, female, 16–18 years, injections, > 2 years, centre S).

This comment was particularly interesting as, apart from information on the risks associated with having tattoos (which may not apply if the young person never intends to have a tattoo), all of the diabetes-specific, well-being and lifestyle information should have been relevant to a 17 year old.

Receiving an EPIC pack on its own, even if actively promoted and integrated into routine care as intended, did not and is unlikely to change the self-care and management behaviours of these specific children and young people. For this group it is obvious that they need additional interventions and support to help them deal with being a child or young person with diabetes.

Examples of positive behaviour change as a result of using the EPIC pack

Apart from the diary, some of the EPIC resources did enable children and young people to make diabetes-related decisions as intended in relation to their self-care of T1D. This was through learning about T1D and gaining knowledge and skills by reading/watching the resources presented in the EPIC pack. The DVD in the back of the *Lenny Explains Diabetes* (Medtronic) hardback book was said to be particularly helpful.

There was evidence that the EPIC pack changed some parents' approach to helping their child look after their diabetes. The mother of a 9-year-old boy said: 'I did involve him a bit more, so yes . . . definitely' (mother of child P42, male, 6–10 years, injections, > 2 years, centre T). The mother of a boy in the 11–15 years age group said: '[taking part in the EPIC project and getting the EPIC pack] made him address his diabetes rather than ignore it' (mother of child P19, male, 11–15 years, injections, > 2 years, centre Y).

A few children and young people stated that information in the EPIC packs had enabled them make a decision about their diabetes self-care. For example, the pump information leaflet provided in the pack helped a young man in the 16–18 years age group decide to move on to an insulin pump regime:

> *I had looked at one [insulin pump] before and I had been drawn to it, but I think the pack gave me a bit more information about the pump, and the quotes as well, I think, because obviously the nurses were trying to talk me into . . . but these were quotes from people who had actually used them.*
>
> *(Child P82, male, 16–18 years, pump, > 2 years, centre S)*

The last illustration also highlights that support and endorsement from peers with similar experiences is important.

In summary, we did find examples in which children's and young people's self-management behaviours and decision-making had changed in response to receiving or using the EPIC pack at home. However, the magnitude of the response was not sufficient to detect an intervention effect.

Supporting children's diabetes self-care and management away from parents

Some young people said that they could see how the pack could help them with decision-making in the future and that they stored the information from the EPIC packs for future use, such as when leaving home and going to university. For example:

> *'Body piercing and tattoos', that would be helpful for me, because I would like a tattoo. 'Drinking safely', that's good. 'Emotional well-being', that's good, 'Exercise', I mean, they're really good. And like these are the ones that I'll consult to, whereas, I will use those more, I'll keep them, you know, say, if I go to university, I'm taking these with me . . . these are just really handy, small, put in your bag.*
>
> *Child P22, female, 11–15 years, injections, < 2 years, centre A*

This illustration is important as it shows that the 12-year-old girl is aware of body piercing and tattoos already and wants a tattoo. This raises the question of why some diabetes professionals or parents removed information on these issues from the EPIC packs. It might be another indication of them being too protective, or they might believe that such information might both inform and promote the desire for body piercing or a tattoo. Nonetheless, some of the young people in the 11–15 years age group already knew about body piercing and tattoos and so the best approach may be to address these issues directly instead of trying to protect them.

In addition, there were a variety of responses regarding diabetes self-care and management at school that are consistent with findings from the systematic review reported in *Chapter 3*. We have reported previously that few children used their diabetes diary as intended at school. In line with programme theory, some children, especially in the 6–10 years age range, did not manage by themselves at school, and had little or no support from school personnel, putting increased pressure on the family to come in at lunchtime to help manage diabetes at school. Other families felt supported at school but had concerns about snacks and the lack of permission from the school to inject in public places such as in the playground or in corridors or classrooms. We found a few, but not many, examples in which the EPIC packs had been used to help improve diabetes self-management at school.

A girl in the 6–10 years age group said that she thought that the *Lenny Explains Diabetes* DVD (Medtronic) was useful and had shown it to her school friend so that she would know what to do if she had a 'hypo': 'showed it to my friend [name of friend], and she thought it was good . . . she can look after me now in school if I'm in hypo and stuff' (child P24, female, 6–10 years, pump, > 2 years, centre B). This girl's mother added that, before watching the DVD, the friend had no idea at all what the implications of diabetes were. The mother said:

> *Now she understands diabetes, she knows what [daughter] needs when she's in hypo, and she knows, [daughter] has taught her how to test her blood sugars because if she's in very, very bad hypo . . . she might not be able to function properly, her mind just goes, and sometimes she can't work out how to do her own BMs [blood glucose monitoring], so [name of friend] has learnt to test her BMs for that scenario. So it has been really helpful to be honest.*
>
> *Mother of child P24, female, 6–10 years, pump, > 2 years, centre B*

Some children shared resources from their EPIC pack with extended family members (e.g. grandmother, great grandmother) and teaching assistants at school. For example:

> *You lent one out to Great Granny didn't you . . . [and] Mrs [name] the teaching assistant and although she helps doing the blood tests and putting carbs into the pump, she said she wanted to understand more about diabetes, she didn't actually know a lot about it so we lent her the books without going into too much technical detail it'll give her the right information [*Lenny Explains Diabetes *(Medtronic) and* Diabetes Made Simple *(Novo Nordisk) booklets].*
>
> *Mother of child P33, female, pump, < 2 years, centre O*

Once young people attend secondary school they are expected to self-manage their diabetes with minimal supervision from teachers. Some young people were confident about managing their diabetes by themselves at school. The following boy, for example, had a belief that he looked after himself at school: 'I just remember myself [to inject insulin or eat a snack at school] . . . . It's [T1D] just part of me' (child P17, 11–15 years, injections, > 2 years, centre Y).

Age appropriateness of EPIC pack

On the whole, children and young people who received an EPIC pack believed that the information resources were appropriate for their intended age group. This was especially true of the 6–10 years and 16–18 years age groups: For example:

> *I think they were suitable for the age that it was supposed to be.*
>
> *Child P56, female, 6–10 years, injections, > 2 years, centre Y*

> *Yeah, like it's more up to date, especially with my age group now, I probably don't do the same things as I did when I was thirteen . . . . I think everything I could pretty much relate to.*
>
> *Child P40, female, 16–18 years, injections, > 2 years, centre T*

However, those in the 11–15 years age group had differing opinions, with some finding the pack too young and others finding the pack at the right level or too old. For example:

> *I think that pack should be for younger people . . . . Maybe like nine to like eleven or something?*
>
> *Child P34, female, 11–15 years, pump, > 2 years, centre N*

> *Yeah, it's got like, all the information that I'd need and it's not too complicated or it's just simple telling you what you need and what to do and like the diary and everything like that.*
>
> *Child P19, male, 11–15 years, injections, > 2 years, centre Y*

> *Because it said body piercing and tattoos, and I'm not going to do that . . . I thought it was maybe like a bit too old . . . I'm thinking because I'm only 13 now, . . . and I'm trying to concentrate on school and not stuff like that . . . I just looked at the first two then thought, no they're too old for me and put them down.*
>
> *Child P57, male, 11–15 years, injections, > 2 years, centre L*

This last reaction appears reasoned and appropriate. This child saw the information and made his own judgement about its appropriateness instead of having this decision made for him by parents or professionals.

Children and young people liked the EPIC pack predominantly because they saw it as an information resource that they could refer to at a later date. Many said that they would like to see the EPIC pack produced for newly diagnosed children. The following is a representative quote by a parent:

> *I personally found that [EPIC pack] a lot more child friendly and I wish I could have had that pack when she was first diagnosed . . . from a personal point of view, I think it would be fantastic if newly diagnosed children and parents got those packs, because it's so daunting when they're first diagnosed.*
>
> *Mother of child P24, female, 6–10 years, pump, > 2 years, centre B*

Signposting to additional information

Some children and young people did not notice the additional information sheet in the EPIC pack listing websites and other resources, but others did acknowledge the sheet and some found the websites of interest and, by viewing them, stated that their level of knowledge had improved.

Summary of key findings with regard to regular use of the EPIC pack at home and when away from parents

The potential impact of the EPIC pack was conceived as ranging from proximal to distal (see logic model). Among the former were enablers to behaviour change, such as perceived ownership of the pack and contents, and increased knowledge and confidence of children and young people in terms of self-efficacy to manage their diabetes at home and when away from their parents and families. In summary, there were a number of issues concerning the use of EPIC packs over time that have impacted on outcomes, including:

- most parents did not appear to actively support and promote the EPIC pack as a way of problem-solving and increasing self-management confidence in their children
- parents may not be integrated into information 'giving' and diabetes care processes sufficiently to feel some sense of ownership of the EPIC pack
- not all children and young people felt that they owned the packs and this may be a result, in part, of hierarchical relationships with diabetes professionals
- many children and young people looked at the EPIC pack at baseline and then stored it as a tool for future reference; hence, confidence in diabetes self-management behaviours (self-efficacy) did not change within the 6 months of the trial
- children and young people did not want to be socially defined by diabetes and some resented receiving the pack.

When mapped against the theoretical model of the critical success factors for implementation of children's health information, there is further evidence that, once taken home, the EPIC packs had a different perceived use and 'value' from that intended. Additional interventions to support parents (facilitation) may have been helpful to show them ways of proactively promoting and using the packs with their children. Within an anthropological context, many children and young people appear to be reacting quite reasonably and rationally to a sense in which they are at the wrong end of power relationships with adults (diabetes professionals and parents), and unless these relationships can be addressed some young people are unlikely to benefit from the EPIC packs unless they are delivered in a different way. Young people also did not want to be defined by their diabetes, which raises interesting questions about the discourses used in currently available diabetes information such as those of normalisation and medicine as a social enabler.

The next section will focus on ongoing promotion and active use of the EPIC packs following randomisation by diabetes professionals.

Care process 3: ongoing promotion and active use of the EPIC packs in routine care by diabetes professionals

Value placed on the EPIC packs by diabetes professionals

As highlighted previously, the PARiHS framework[41,48] places an emphasis on the value of the intervention as a critical ingredient for its successful implementation in practice. In the explanatory model (see *Tables 1* and *2* in *Chapter 1*) implementation was conceptualised to be most successful when the intervention was highly valued by those who came into contact with it. We were therefore interested to know what diabetes professionals thought of, and how they valued, the EPIC packs.

Intended ongoing use of the EPIC packs

A key aspect of the EPIC programme logic was that the EPIC packs would be actively integrated into ongoing routine care and diabetes professionals would actively refer to and help children and families to optimally use the EPIC packs during clinical encounters. Diabetes professionals would also frequently update the packs as appropriate for each individual child and young person. The intervention was designed to work without manipulation of service delivery and required the usual level of child-centred communication and facilitation techniques used by children's diabetes specialists. It was also anticipated that diabetes teams would develop child-centred ways of supporting children, young people and their families to use, and continue using, the EPIC packs.

In reality, there was not much evidence of referral to, adding to or active use of the EPIC pack by diabetes specialists for diabetes-related problem-solving with children and young people following randomisation. One consultant said: 'Most patients had nothing further to discuss from the information in my experience' (centre U).

The evidence also showed that children and young people rarely brought their diary or EPIC pack back to clinic (confirming children's evidence) and so there were few opportunities for diabetes professionals to actively promote use of the diary and pack for diabetes self-management problem-solving at home and at school.

Some children and young people said that they did not remember the EPIC pack being discussed further by the diabetes professionals, and some stated that the EPIC pack was not mentioned again at follow-up and gave possible reasons for this. For example, a 17-year-old girl said: 'I can't remember, she [PDSN] might have done I don't want to get her into trouble, I can't really remember it [the pack] being brought up' (child P40, female, 16–18 years, injections, > 2 years, centre T).

A mother described a typical busy children's diabetes clinic and rescheduling of appointments as a reason for staff not referring to the EPIC pack again:

> *Not yet but we've only been once since we've been given that [EPIC pack] . . . because that's the other thing is your appointments, where for example you might want to go every three or four months, you might get pushed to every five or six because their clinics are over subscribed . . . I think they're struggling so I wonder if that's why they don't tend to sort of think 'oh yes I'll ask them how they go on with that pack'.*
>
> *Mother of child P32, male, 6–10 years, injections, > 2 years, centre 0*

Most children and young people said that they would not have minded discussing their EPIC pack in follow-up consultations with their diabetes specialists:

> *Yeah, probably, it would have reminded me about it!*
>
> *Child P74b, female, 16–18 years, injections, > 2 years, centre B*

> *Yeah, I suppose he could have done, really, yeah . . . maybe if the consultant would have actually said to him, 'Have you been through that pack?', he probably would have picked it up and gone through it actually wouldn't he? . . . He does listen to him.*
>
> *Mother of child P83, male, 6–10 years, injections, > 2 years, centre T*

As well as children and young people not bringing their diary back to clinic, the lack of ongoing referral to or active promotion of the EPIC packs within routine consultations is also likely to explain why many children and young people put them aside and forgot about them once home. Children and young people might also find it appealing to have the information there but not feel compelled to always have it handy and use it religiously.

In the following sections we look more closely at diabetes professionals' views on the diabetes diaries and EPIC packs.

Diabetes professionals' views on the EPIC diaries

Most agreed that the EPIC insulin injection and pump diaries were visually appealing and suitable for the target age group (*Table 55*). Diabetes professionals also backed up children's and parent's reports that the diabetes diaries had generally not been used effectively by children, young people and their parents.

Thirteen of twenty-eight diabetes professionals agreed that the children and young people were enthusiastic about their EPIC diaries, but only 11 of 26 agreed that children and young people used the EPIC diaries to record blood glucose levels. This supports children's self-reports that about half used a diary in some way, but not always as intended. Most found the sizing of the EPIC diaries to be appropriate.

Furthermore, confirming the children's and young people's actual use of the diaries, diabetes professionals did not believe that children and young people in the intervention arm were more likely to bring their EPIC diaries to follow-up appointments than previous diaries (*Figure 44*).

TABLE 55 Views of diabetes professionals on the suitability and use of the EPIC insulin injection and pump diaries

	Injection diary, *n*/*N*			Pump diary 6–18 years, *n*/*N*
	6–10 years	11–15 years	16–18 years	
Diary suitable for the target age group	26/29	22/27	21/27	21/25
Diary effectively used	14/25	11/25	6/22	8/22

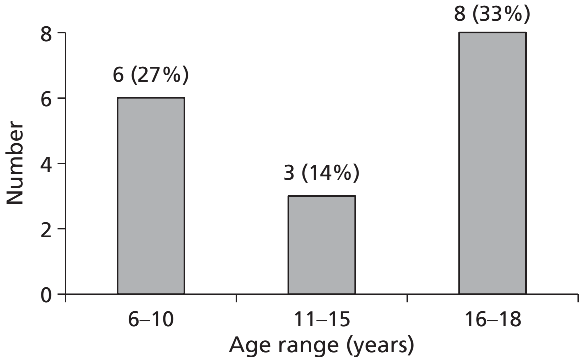


FIGURE 44 Bar chart showing the numbers of diabetes professionals who agreed that children and young people were more likely to bring their EPIC diaries back to clinic.

Diabetes professionals' views on the EPIC packs

The majority of diabetes professionals believed that the EPIC packs were a useful way of ensuring that children and young people received the necessary information. In total, 27 of 29 (93%) diabetes professionals found the 6–10 years EPIC pack appealing and suitable for the target age group, which reduced to 24 of 27 (89%) for the 11–15 years EPIC pack and 24 of 28 (86%) for the 16–18 years EPIC pack. Most diabetes professionals found the EPIC packs to be well designed and easy to handle and the right size for each age group. Most diabetes professionals also believed that the EPIC packs contained the appropriate information for each age group, although the numbers agreeing that this was the case were lower for the older age groups (6–10 years: 20/27 agreed; 11–15 years: 16/26 agreed; 16–18 years: 18/26 agreed).

Nearly two-thirds of diabetes professionals noted that the EPIC packs were useful in facilitating questions from parents and children at baseline; however, this fell to under one-third at 6 months' follow-up.

Summary of key findings concerning diabetes professionals' views and experiences

In summary, together with earlier findings that there was insufficient time to actively promote and show the EPIC pack at randomisation, and that many children were not actively using EPIC diaries and packs as intended once home, the evidence suggests that the current model of diabetes service delivery does not easily accommodate time for ongoing active facilitation or promoting of children's diabetes information as part of routine ongoing care (context).

Although diabetes professionals generally placed a high value on the EPIC resources per se, this did not follow through to the EPIC packs and diaries being actively promoted by diabetes professionals as an essential tool to promote diabetes self-management in children and young people at home.

The next section reports a cross-cutting issue common to all children in the trial.

Cross-cutting issue: perceptions of and attitudes to diabetes-related risks

As noted in *Chapter 2*, few children's diabetes information leaflets, especially for younger age groups, explained the risks of suboptimal diabetes self-management. In interviews with parents and young people, diabetes was described as an 'invisible' illness that nonetheless singled children and young people out as being and feeling different:

> *He was twelve years old [when diagnosed], he was just coming into puberty, and it is a difficult age for girls and boys at that age, and so to get something like diabetes, even though it is an invisible illness, they still feel like they've just been taken out of the equation, and put on a pedestal . . . the dangerous thing is, a lot of children rebel against it at that age, because it does isolate them . . . and they feel like the spotlight is on them.*
>
> *Child P19, male, 11–15 years, injections, > 2 years, centre Y*

In contrast, the EPIC programme theory was about 'normalisation' of diabetes through optimal medicines management. However, normalisation of diabetes seems incongruent with the need to consider a reduction in the risk of diabetes-related complications, the main driver for optimal glycaemic control. Most parents worried about their child's future health, fears that were exacerbated by stories related by others or associated experiences. Young people too are often aware of the existence of diabetes-related complications but do not want to be confronted with them and will resist looking at information about complications:

> *And like, I know, there was a video as well that I got sent, when I first got it, on YouTube, and now if ever I see articles about diabetes, on the thing [TV or computer] I mean, I do get quite annoyed about my diabetes now, it's like the other day, I just saw it, you want me to try and read that, I'm not reading it . . . I mean, I know it's like, annoying when you deal with it every day, to, then read about it and . . .*
>
> *Child P22, female, 11–15 years, injections, < 2 years, centre A*

> *There was a programme on . . . the [diabetes] transition clinic and beyond and the amount of young people in their early twenties that don't go, and the amount of problems they have and the things that can go wrong with it . . . and I said it's on Sky Plus [son] to watch . . . and then I tried to sit him down with his girlfriend to watch it, and she's being like 'oh my God!', and after five minutes he switched it off . . . he has no intention to watch it.*
>
> *Mother of child P29, male, 16–18 years, injections, > 2 years, centre B*

Adolescence has previously been noted as a challenging time for diabetes self-management and many parents had seen the risks that children with diabetes knowingly or unwittingly took. The following mother talked about these issues and considered the risks as self-abuse:

> *They pretend it doesn't exist. Girls use it as a dietary [aid], and a lot of boys just are lazy or just don't want to do it, so they should really [explain risks], not a scare tactic, but if they said look, it's serious, it could affect your kidneys or it could affect this, it is potentially fatal, if they sat through a DVD with them . . . if they've abused themselves, if they get diabetes at 13 and they abuse that until they're 20, it's too late, the damage is already done, so they really need to nip it in the bud when the kids are 13, 14.*
>
> *Mother of child P19, male, 11–15 years, injections, > 2 years, centre Y*

One mother would have liked her child to have received more information in the EPIC pack about the risk of complications:

> *I just think there could be a bit more, information about like, if you don't manage it properly, which I know is scary, the prospects, like at his age now, he sometimes he won't do an injection at school, he'll think, 'oh I don't want to eat my dinner so I won't eat it, so I won't have an injection', but it's like, in later on in years isn't it, you've got to think about it, because I've seen people on the telly and they lose legs and stuff like that . . . and I've said, 'you've got to be careful with your feet and everything', a bit more sort of understanding on what you need to look after. I know it's a bit scary saying, you'll lose your leg or something, maybe not to that extent, but something to just try and make them think it's like long term damage, you're all right now, but it's later on isn't it, you have to think about . . . like we don't like to frighten him about long-term things but we also want to make him aware that he's got to look after himself and do this. Maybe if it was put a bit simpler for him but not to frighten him, I don't know.*
>
> *Mother of child, P30, male, 6–10 years, injections, > 2 years, centre U*

Similarly, the father of a teenage girl felt that it was important that his daughter understood the potential consequences of poor glycaemic control to inform decisions she might make concerning her diabetes self-management:

> *You know, she's getting older, she knows the consequences of not managing it, of not doing the right things, of not going with what the diabetes consultant says, so I know it might seem a little harsh, or it might seem hard or whatever, but, she's got to get on with it. And do it, you know, we can't mollycoddle her and babysit her all the time now.*
>
> *Father of child P51, female, 11–15 years, injections, > 2 years, centre Y*

He realised, though, that his daughter was still at an age at which children 'live for today' and find it difficult to envisage the future:

> *It's down to her, it's all long term isn't it, you know you could manage short term or think that it's okay, but in the long term you've got to think . . . there's no reason that she couldn't live, you know a long and fulfilling life, you know, as a normal person would, until she's 80 or whatever, as long as she manages it and that's the hard part, and when you're sixteen, you know 25 is old. That's a long time away. So you know, it's tough, there's always 'I'll leave it to another day or whatever, I'll begin tomorrow'.*
>
> *Father of child P51, female, 11–15 years, injections, > 2 years, centre Y*

Most parents, however, particularly mothers, wanted to protect their children from receiving information about diabetes-related risks. One mother, for example, said that she had been given some information about later life complications and that it scared her so she put it away in the attic. She did not feel that it was appropriate to have received the information, whereas her husband thought differently:

> *you can't hide from the fact, at least we're aware of what could happen in the future rather than being ignorant to it all, we know he could have problems with his eyes or his feet . . . when he gets older, I'd sooner know about it but [name of wife] wouldn't I don't think.*
>
> *Child P69, male, 11–15 years, injections, > 2 years, centre U*

These data strongly suggest that parents and older children, and sometimes younger children, are aware of the risk of diabetes-related complications but find it difficult to dwell on the possibility of future health problems. To cope with their child's diagnosis most parents need to balance their fears with optimism, for example new treatments or a future cure,[254] and if children are to lead 'normal' lives parents believe that diabetes should not be allowed to dominate or become intrusive.[255] In addition, data from this study suggest that young people struggle to think about complications in the here and now. Nevertheless, given the importance of optimal glycaemic control, children and young people need to make decisions about self-management in possession of all of the facts, which includes the provision of a rationale and age-appropriate information concerning risk.

Discussion

Children and young people in the EPIC RCT had a range of recorded HbA_{1c} levels which showed that, as a group, their diabetes self-management would generally need to improve to achieve the recommended HbA_{1c} levels in NICE guidance.[26] This concurs with a recent report on children's outcomes[25] that highlighted the need for children in England to have better control over their diabetes and lower HbA_{1c} levels.

The low-cost, age-appropriate, innovative and quality-assured EPIC packs and diaries fulfilled all NHS policy imperatives that children and young people should receive high-quality, accurate and age-appropriate information about their condition, self-management and wider lifestyle and well-being issues.[13,26,243–245] Nonetheless, the EPIC pack was no more effective than usual care, in which case most information is provided at diagnosis and thereafter obtained mostly by motivated children and their families on an ad hoc basis from diabetes professionals, charities or the internet. The process evaluation has shown that providing diabetes diaries and information that attracts children is not going to change children's self-management behaviour sufficiently to improve their diabetes-related and general quality of life and HbA_{1c} levels. Additional research, implementation strategies and service redesign are needed to enable children, young people, parents and diabetes professionals to translate the available information into optimal self-management knowledge and subsequent optimal diabetes self-management action. The findings clearly indicate a need to rethink context and the hierarchical relationships between these partners in the context of 'partnership and participation' in diabetes decision-making, self-care and self-management. The key unresolved question is what would work to improve children's diabetes self-management.

In the following sections we discuss the following issues:

- What is the optimal model of child- and family-centred children's diabetes service delivery?
- What is the best way to convey the risks of suboptimal diabetes self-care and management?
- What is the best format to deliver diabetes information to children and young people?
- What are the potential effective behaviour change components of children's diabetes information interventions?
- When is the best time in a child's diabetes life course to deliver diabetes information?
- What can be learned from children's diabetes management from other European contexts?

The state of the art and science regarding children's diabetes care and management is moving fairly rapidly as several other trials, addressing different but related questions, were commissioned at the same time as the EPIC trial. Some trials have now reported and are discussed below, whereas others are still ongoing. We first draw on these key contemporary studies and trials carried out with similar populations of children with T1D in the UK NHS and then compare findings from the European and international literature.

What is the optimal model of child- and family-centred children's diabetes service delivery?

The two theoretical models of participation and partnership and critical success factors for translating children's health information into routine practice (see *Tables 1* and *2*) provided a coherent conceptual guide for mapping evidence against an optimal model of children's information provision in the NHS. At the end of the EPIC project these models can be developed further to add additional diabetes-specific dimensions to help understand partner relationships, communication to children, young people and their parents of the risks of poor diabetes self-management, and the level of lifelong support for lifestyle change that is needed to bring about initial and then sustained behaviour change and improvement in diabetes outcomes.

Effective partnership and participation by children, young people and their parents is a core concept of child- and family-centred care philosophies used in the UK NHS. As in the IMP,[1] diabetes nurse specialists were key to educating and monitoring children, but they had insufficient time and mostly conveyed verbal information whilst completing the usual diabetes checks and listening to children's and parent's updates. In the IMP,[1] observations of children's diabetes clinics reinforced the constant busyness and high flow of children through clinics. We also frequently observed an inspectorial model of monitoring by diabetes professionals whereby the information flow was from the child and parents to the professionals as part of the essential checks of 'compliance' with diabetes regimes. It is, however, highly challenging for diabetes professionals to find the right balance between promoting self-autonomy of the child and family when they are suboptimally managing the child's diabetes and trying to protect the child against negative outcomes, such as retinopathy, that may occur years down the line.

In the context of this model of diabetes service delivery the discourse of 'normalisation' of medicine management and medicines as a social enabler as key messages conveyed in a sometimes authoritarian way to children and young people through diabetes texts warrants further discussion. With hindsight, we constructed texts (the EPIC packs and diaries) that were supposed to motivate and empower children and young people without properly thinking through the power relations between the diabetes professionals and the children and their families, which seem, in some senses, not to have changed very much. Texts alone cannot empower and cannot make the case to children that all of the effort is worth it to meet someone else's notion of 'optimal diabetes self-care and self-management'. This presents a paradox as diabetes guidelines talk about diabetes self-care and management and the need for it to look a particular way.

One of the challenges of recruiting children, especially teenagers with diabetes, to participate in research about diabetes concerns their preference not to be defined by their condition and to be seen as no different from their unaffected peers. They prioritise aspects of their lives other than diabetes care, and peer approval and conformity become increasingly important. Teenagers make up a homogeneous group and the process of constructing identity may come into crisis when they are asked to participate in an activity, such as research, with different demands and expectations.

Many children and young people wanted to keep their diabetes private or secret and disliked taking their blood glucose levels at school and at home. From a professional perspective this behaviour can be interpreted as a clear example of non-compliance and suboptimal diabetes self-management. Our findings, however, provide another explanation for this behaviour and why children did not want to take their blood glucose readings at school or at home or record them in their diary, as the act of doing so marked them out as 'not normal' when all of the diabetes texts are suggesting that if they do as they are told they will be normal. Children, especially as they get older, could see this either consciously or subconsciously as a con.

The key point is that children and young people do not necessarily want to see themselves as 'diabetes patients' for a lifetime who, however nicely it is all dressed up by the diabetes texts, must do as they are told. In effect, there is something of a disconnect between the texts and the good intentions of them to empower children and young people and the existing power relations between children and young people and diabetes professionals, who still want to be or feel responsible for maintaining the ultimate power and authority to protect children and young people from harm. The concept of maintaining ultimate power and authority is difficult because adults (diabetes professionals and parents alike) believe that they are acting in children's best interests. At one level this is true as the consequences of poor diabetes self-management can be devastating, but some of the responses from children and young people presented in the report actually highlight this tension.

Our findings point to an extratextual context of the relationship between children, parents and diabetes professionals as one possible reason why there seems to be a lack of 'compliance' to what children and young people and sometimes parents are being told and what diabetes professionals 'expect' of them. It is this tension in the relationship between these parties that may partly explain why some children, young people and parents become less interested in optimal diabetes self-care and management as they grow older. It may be that they just become fed up with the regimen and having life seemingly defined by diabetes and 3-monthly clinic visits, despite discourses which claim that life can be 'normal' but only if you do as you are told.

At a health service level, manipulating service delivery by increasing the time that the diabetes team have available to listen, teach, discuss and individually tailor diabetes and lifestyle information appears to be a critical success factor for rethinking child–family–professional relationships, along with the adoption of a higher level of child-centred communication and feedback skills.[256] The role of school staff or school nurses in the delivery of an intervention such as the EPIC pack is also an avenue for further investigation.

Our findings concur with the the foreword to the British Medial Association Board of Science report by Aynsley-Green *et al.*[257] into the state of children's services in the NHS, which reiterates that many services still lack a sense of child-centredness and many staff were not sufficiently equipped with sufficient age-appropriate communication skills – especially for teenagers.

Identifying effective interventions to enhance communication to optimise partnership and participation is, however, proving challenging. A recently completed trial, the DEPICTED study,[250] evaluated the effectiveness of a motivational communication skills training programme for diabetes professionals working with young people with T1D and found no difference in outcomes between the intervention group and the control group. Further research needs to be carried out to better understand the mechanisms involved in more effective communication and communication styles that motivate children and young people to engage with professionals as active partners and sustain optimal self-care over their lifetime.

What is the best way to convey the risks of suboptimal diabetes self-care and management?

Many of the children and young people who we interviewed were taking risks with their diabetes-related health but did not convey any significant degree of concern about the potential consequences; indeed, many teenagers appeared uninterested. The communication and acknowledgement of risk to and by children and young people with T1D, and effective interventions to modify behaviour to minimise risky self-management behaviour, remain little understood. Mitigating risk through optimal self-management is a particularly challenging aspect of children's diabetes care as they may not experience the impact of poor early self-management until several years later.

The key unresolved question is why so many children and young people take these risks with their health. It may be that from the perspective of those who do take risks there is too much pressure to adhere to certain diabetes self-management rules, and, indeed, that they are presented as 'rules', for example 'sick-day rules' or 'top 10 tips', in an authoritarian voice rather than good practice guidelines. Some children may feel that they are being lectured at (especially by the more authoritarian texts that we analysed) and may react negatively to the 'know it all' attitude of such texts. For some children and young people, 'authority' is experienced in and through their relationships with diabetes professionals.

Children, young people and parents may feel this pressure and be resentful of the amount of control that is being exerted. They may weigh up the risks in relation to what diabetes professionals expect them to do and take rational decisions about what is acceptable for them. There appears to be a tension between clinical definitions of risk and personal ones. In terms of diabetes information, risk may need to be acknowledged and 'rule-based' authoritarian messages addressed to make the relationship between diabetes professionals and children with diabetes and their families less hierarchical.

Very few children's diabetes information resources that we located – especially for younger children – said anything about the serious risks and long-term complications of poorly managed diabetes. Diabetes information for younger children tended to focus on acute complications of hypoglycaemia and diabetic ketoacidosis. Despite older children asking for 'realism' and real-life stories to make diabetes feel 'real' to them, we found no reports or stories in children's diabetes information about young people who had experience of comorbidities such as retinopathy. However, children and young people may find information for themselves using the internet, and diabetes complications are often mentioned in the national press. Diabetes professionals, and in particular diabetes nurse specialists, tend to start talking about risks on a case-by-case basis when they see the child or young person in clinic.

In a recent study,[258] parents said that they hid issues about complications from their children. This lack of disclosure may also be because parents do not want to think about it. But there is an important issue here about adherence and concordance: if children and young people do not know what could happen if they do not look after their diabetes, they are not making an informed decision to look after their diabetes, or not look after it.

Although it is understandable that parents and professionals may want to protect children from this potentially distressing diabetes knowledge, a central tenet of informed consent is knowing about the benefits and risks of treatment, and the purpose of written information is to back up verbal information on both benefits and risks in an age-appropriate way. Even if children are unable to consent in law, those who can use and understand age-appropriate information still need relevant and truthful information so that they can participate as appropriate in decision-making. In other contexts, parents appear keen to convey potentially distressing information to keep their children safe, such as not talking to strangers and not accepting lifts from strangers. This type of information could be key to breaking down the hierarchical relationship between diabetes professionals, parents, children and young people. Nonetheless, even if the risks of suboptimal diabetes self-care and management have been conveyed verbally by diabetes professionals, children and young people may find the almost wholly 'positive' nature of children's diabetes texts confusing and this may dilute the message conveyed by diabetes professionals.

Another key unresolved question is how to convince children and young people that it is in their best interests to monitor their blood glucose and titrate their insulin dose and live a healthy lifestyle. Discussion with the clinical expert group revealed that opinions differed on the best approach to long-term diabetes risk management. Diabetes professionals felt a sense of responsibility to keep children safe from potentially devastating long-term consequences of suboptimal diabetes self-management. In reality, certain children may not be able to self-manage according to the professional model of optimal self-management for specific periods or even throughout their childhood. Evidence from other studies confirms that, on entering adult services, many young people are unprepared to become a self-managing adult.[22]

However unpalatable from a professional perspective, it could be that children and young people have to experience some ill health and deterioration of their condition before some diabetes risks become real. Perhaps this is where the notion of risk becomes important, as ownership over risks needs to rest with children as well as adults. In wanting to protect children and to do 'what is right', it may be that an authoritarian, and a predominantly empowerment to be normal, approach is undermining the development of some children's own skills and abilities to manage risk. In other aspects of life, children and young people are generally given room to make mistakes and to learn from their mistakes, although the consequences in such cases may not be as serious as they are with diabetes. Otherwise, children and young people do not develop a sense of ownership of risks and this is yet another aspect of life that adults can take control over, perhaps producing some of the reactions of indifference or resistance to the messages about diabetes self-care and management and, as previously suggested, meaning that if children are being empowered by certain texts then in reality it may seem like a con to some of them.

When undertaking non-participant observation in the IMP study,[1] we observed specific instances in which diabetes nurses were negotiating with 'non-complying' children and young people about how they would like to monitor their blood glucose. The logic of this approach was that some blood glucose monitoring was better than none at all. However, little is known about what children and young people define as optimal diabetes self-management or what happens when professionals let go a little of diabetes control and allow room for individualisation and some mistake-making (as long as the mistake is not serious).

Not all children and young people were engaging in suboptimal diabetes self-management. A much smaller proportion appeared to be managing their diabetes more optimally. It is therefore likely that one size will not fit all and some children do respond positively to firm boundaries and an authoritarian voice, even if others do not. As shown in the EPIC trial and other studies, young people may start off with good self-management practice and then reject the 'rules' and authoritarian voice over time. More acknowledgement and further research into these complex issues is needed so that a higher degree of individual tailoring can be achieved.

What is the best format to deliver diabetes information to children and young people?

The intention of any children's diabetes information intervention is that children and their families will respond to it and behave in a different way to optimally manage the child with diabetes (the mechanism). In the EPIC trial we found that a quality-assured and age-appropriate 'pack' of diabetes information compared with providing ad hoc diabetes information over time made no tangible difference to children's self-efficacy or diabetes self-management practices or outcomes within the current service delivery model.

Nonetheless, by providing the EPIC pack diabetes teams can be assured that children have received a standardised and comprehensive range of high-quality and age-appropriate information that can be individually tailored and added to as required over time. The EPIC pack therefore has an added value benefit compared with an ad hoc approach to providing information.

Electronic diabetes diaries

A key finding from the EPIC trial is that some young people did not want a separate paper diabetes diary to carry around when most now 'owned' a mobile phone that they carried everywhere or used iPad-type technology. This kind of technology was not commonly available in 2006 when the study was conceived and it now seems appropriate to support the use of age-appropriate and child-centred electronic phone apps and computer programmes as substitutes for paper diabetes diaries, especially for teenagers.

However, the newly available blood glucose phone apps are designed for adults. Glooko has two products that work together: first, an iPhone app (Android is in development) that logs all blood glucose readings and, second, a cable to connect the iPhone to one of 11 popular blood glucose meters (see www.glooko.com/). An alternative has been produced by iHealth Ventures LLC. Blood Glucose Tracker (iDiabetes™) is an easy-to-use app for iPhone, iPad and iPod Touch to help people control their blood glucose levels (see www.ihealthventures.com/). It helps people to monitor and keep track of their blood glucose levels, insulin dose and oral medication.

Age-appropriate phone apps are now required for children and young people and some consideration also needs to be given to providing a choice of options for children who are becoming increasingly IT literate at even younger ages and maybe IT literate before they have reasonable writing skills.

Further research is required to evaluate the behaviour changes that occur on implementing e-recording devices compatible with personal phones, iPads and computers.

Web-based information

Children and young people did not want to be defined by diabetes and we identified examples in which older teenagers did not want to access diabetes-specific websites and preferred to access diabetes information using social media such as YouTube. This is interesting as YouTube is a general information site that most teenagers will use. It may be that, rather than specialist diabetes websites, there is a need for more general websites to be utilised to convey diabetes information so that the experience is more like researching a topic from a general search engine where one is not constantly reminded that one is different from others.

Individual tailoring and personalisation

Individual tailoring and personalisation were considered to be important parts of the EPIC pack and yet the capacity for individual tailoring, especially adding to the pack over time, and instilling ownership through self-personalisation were not realised. There is a critical lack of evidence in the wider literature on individual tailoring and self-personalisation of children's diabetes information and care. A complementary study is currently under way led by Cooper, which is aiming to develop an Adolescent Diabetes Needs Assessment Tool (ADNAT).[259] The ADNAT study is using computer technology to assess psychosocial and educational needs and individualised support and educational planning. The tool can also be used for monitoring progress over time. When reported, this study has the potential to provide more information on how best to individually tailor education for adolescents, but little is still known about younger age groups or the effect of individual tailoring on diabetes outcomes.

The family as a mediator of children's diabetes control

In the EPIC study the role of parents and the family was found to be an important positive and negative influence on children's diabetes self-management. The EPIC pack was not primarily conceived as a family-based intervention but was intended to be presented to and owned by children as opposed to parents. Although parents are encouraged to hand over responsibility to their children as they mature, inevitably parents acted as ongoing support for their children by filling in the diary and making decisions about changes to insulin management. There is evidence which suggests that children and young people attain better diabetes control when parents continue to give support[253] and further research is needed on how best to achieve a balance so that young people gain the skills they need to live independently. If children and young people live at home it is likely that parents will always be involved with diabetes management to a degree, especially if they are responsible for planning and cooking meals.

A recent trial has focused on the role of family cohesion as a mediating factor in children's diabetes management, finding no effect. In the Families and Adolescents Communication and Teamwork Study (FACTS 2),[260] 300 adolescents aged 11–16 years and parents attended a course focusing on family cohesion, functioning and diabetes skills training, which also covered issues such as adolescent development, communication and conflict resolution skills. The study found no effect of the intervention on family communication or average glycaemic control. There were some improvements in diabetes self-management skills as young people were more likely to adjust their pre-meal insulin boluses, but as in the EPIC study adolescent compliance with daily self-management tasks was suboptimal.

Although we made a considerable effort we were not able to gain a better understanding of how children and young people manage their diabetes for longer periods of time away from their families in more complex social situations (e.g. youth offender institutions). Our understanding is limited to when children and young people are at school and college for part of the day. Important as the family undoubtedly is, there is a potential danger of becoming overdependent on seeing the family as providing the key support for all children and young people in managing diabetes. Some children will be in non-supportive families (not enough time to help, abusive, etc.) and some parents, often for the best of reasons, tended to micro-manage their children's lives and this did little to empower children to take control and feel a sense of ownership where monitoring was concerned. These issues warrant examination in a future study of the context in which children and young people manage their diabetes. It is the essential link between texts and the contexts of their reception that is fundamental to moving ahead with the issue of good diabetes self-care and self-management. At a more philosophical level there is also a need to question how adults define childhood, which has becoming increasingly about protectionism in recent years. Protectionism does nothing to encourage children and young people to be more self-reliant and, as seen in the EPIC study, a common response to this is for children and young people to actively or inactively step back from growing up and taking responsibility. If, on the one hand, children and young people are told to take responsibility but, on the other hand, adults micro-manage their lives, this sends mixed messages about how much we trust them to do the right thing (or allow them to do the wrong thing and learn from it). Professionals generally find this aspect of tailoring an individual approach the most challenging as serious complications of diabetes mismanagement are generally irreversible and constitute an additional lifelong cost of care to the health service.

Children's intensive structured diabetes education programmes

The EPIC pack had at its heart the concept of high-quality and age-appropriate information to reinforce verbal information given by diabetes professionals and self-motivated diabetes problem-solving by children and young people at home. Although the findings from the EPIC study suggest that authority relationships could be an important mediating factor in why some children and young people did not optimally manage their diabetes, other interventions recently or currently being tested are based on more conventional adult to child structured learning and some interventions such as KICk-OFF[29] include compulsory attendance at courses.

The carbohydrate, insulin collaborative education (CHOICE) programme[261] is a structured education programme for children and young people with T1D. Although the programme had no effect on HbA_{1c} levels, it reduced the impact of diabetes on quality of life and increased dietary freedom and adherence. However, these effects reduced over time, suggesting that further support post education is needed. Importantly, children and young people did not have sufficient numeracy and literacy skills to gain optimal benefit from the programme.

Similarly, within the UK education system children and young people are acclimatised to being taught by qualified teachers and learning independently with educational packs, books and resources as part of the national curriculum and with the active support of their parents. With this educational model in mind, at the same time that the EPIC study was conceived, Waller *et al.* were funded to design and evaluate a structured educational programme for 11–16 year olds with T1D called the KICk-OFF course.[29] KICk-OFF is conceptually very different from the EPIC intervention and is based on the adult Dose Adjustment for Normal Eating (DAFNE) course. KICk-OFF follows a structured education model that uses similar principles to how children learn in school and involves children attending six 5-day outpatient courses on carbohydrate counting and insulin dose adjustment. It is due to complete data collection in September 2012. Attendance at all sessions is compulsory and the programme has a different approach to instilling choice and optimal diabetes self-care from the EPIC intervention.

An unpowered pilot study with 48 children and young people indicated that the course format was appropriate. There were no changes in HbA_{1c} levels, body mass index or episodes of hypoglycaemia but children and parents reported improved quality of life ($p < 0.05$). When the full trial is reported KICk-OFF will add valuable information about whether structured education and attendance at courses can bring about the desired behavioural changes required by 11–16 year olds to optimally self-manage their diabetes and maintain an optimal HbA_{1c} range.

Funded around the same time as the KICk-OFF study but focusing on the family, CASCADE (Child and Adolescent Structured Competencies Approach to Diabetes Education) is a cluster RCT[262] of a structured intensive education programme using psychological approaches that maximise engagement, motivation and long-term change, which is due to end in December 2012. The programme focuses on increasing competency in the self-management of diabetes. The programme is delivered to young people aged 8–16 years and their families over four monthly sessions in groups of three to four families. When reported, CASCADE will add to knowledge about the efficacy of delivering family-based diabetes education.

What are the effective behaviour change components of children's diabetes information interventions?

Apart from asking diabetes teams and parents to actively promote the EPIC pack and refer to its contents in routine care and at home (which did not generally happen), and a printed letter within the pack signposting how children and young people could optimally use the pack, there was no additional 'active' behavioural change component focusing on diabetes HCPs', children's or parental behaviour. We know that texts alone will not change behaviour and, as outlined previously, the relationship between children, parents and professionals needs to change to become more of a partnership with a move away from a top-down model of communication, however child friendly it is.

The key question is, 'What else could potentially change children's and young people's behaviour so that they achieve better diabetes self-management?'. Interventions such as Sweet Talk,[263] a text messaging system to support young people with diabetes, have been shown to be effective in reminding young people to check their blood glucose measurements, but more research is needed to see whether behavioural changes are sustained over time, or what other long-term interventions to improve concordance could be beneficial. KICk-OFF[29] and CASCADE[262] may provide more information on what works in terms of behavioural change components of highly complex interventions to optimise children's diabetes self-management.

Given that the consequences of poor diabetes self-management in childhood will lead to life-changing disabilities and costly lifelong care and treatment, one additional line of inquiry worth investigating could be a reward system such as financial incentives for achieving optimal diabetes self-management. One trial site was already awarding vouchers to children and young people when they achieved specific self-management goals.

When is the best time in a child's diabetes life course to deliver diabetes information?

One of the challenging issues with childhood diabetes is that some children receive their diagnosis as babies or young children and their parents would have originally received training and information on how to care for their child at home. Over time parents then teach their children with the support of PDSNs, but by the time that children are old enough to access age-appropriate self-management information they have already learned and adopted sometimes suboptimal diabetes self-care. As with other childhood issues such as obesity, changing established and suboptimal diabetes self-management behaviours and lifestyles is likely to be more challenging as children grow older, especially during the teenage years.

Targeting children at diagnosis or as soon as they reach an age when they can start reading and watching information to help them move towards self-management may also be more appropriate than receiving an information pack many years after diagnosis when self-management and lifestyle behaviours are already learned and hard to change. The Delivering Early Care In Diabetes Evaluation (DECIDE) RCT,[264] which has yet to report, was designed to assess hospital compared with home management in children aged 0–17 years with newly diagnosed diabetes, comparing psychological, social, physical and economic outcomes. DECIDE could potentially help answer questions about the most appropriate places, and the most effective ways, to teach parents and young people about diabetes immediately following diagnosis.

What can be learned from children's diabetes management in other European contexts?

The National Diabetes Paediatric Audit 2009–11[249] identified that, in the UK, only 14.5% of children and young people achieved the NICE-recommended HbA_{1c} target of $< 7.5\%$ (59 mmol/mol) compared with $> 50\%$ of children in Germany over the same period. Reasons for poor outcomes in paediatric diabetes are multifactorial but, when considering the difference in HbA_{1c} outcomes between countries it is probable that culture plays a part. However, the Hvidøre Study Group[265] carried out an international study involving 2873 children with diabetes and concluded that diabetes education, management from the onset of the disease, different attitudes within diabetes teams and different levels of patient empowerment were the factors explaining the differences.

In Germany, for example, where diabetes control is better than in the UK, far more resources are devoted to training at diagnosis. Children and their families often undergo prolonged admission for this purpose, unlike in the UK where children are discharged as soon as possible after diagnosis. The EPIC intervention was probably delivered too late post diagnosis, when children's behaviours were engrained/established and too difficult to change. In Germany separate age-appropriate diabetes education programmes for children aged 6–12 years and young adolescents/young adults, and a programme specifically designed for parents of children with diabetes, have been developed and evaluated in multicentre studies.[266] A child's level of autonomy, developmental stage and diabetes duration determine the type of diabetes education. At diagnosis, the comprehensive education packages are usually delivered on an inpatient basis, with inpatient stays of up to 2 weeks. Individual ongoing education is provided at intervals of 2–3 years, acknowledging the dynamic process of diabetes education. These programmes emphasise translating knowledge into everyday practice, integrating diabetes management tasks into daily routines and providing emotional support for those coping with the condition and its psychosocial consequences.

Despite this commendable approach to diabetes education, however, a 2011 population-based survey[267] undertaken in Germany with 200 parents of 115 children with diabetes aged < 16 years identified a mean HbA_{1c} level of 8.1% (65 mmol/mol), with only 29% of these children achieving an HbA_{1c} of level of $\leq 7.5\%$ (59 mmol/mol), which is still higher than in the EPIC trial. HbA_{1c} levels increased with age, with older age significantly associated with a higher HbA_{1c} level. Similar to this study, the authors conclude that further work is required, including an investigation of factors facilitating the transfer of parents' responsibility and motivation for continued frequent treatment tasks to their growing children.

In the SWEET Project[268] a group of established European and national diabetes organisations have joined forces to improve diabetes management in children and adolescents. This project aims to improve secondary prevention, diagnosis and control of T1D and T2D in children and adolescents by supporting the development of centres of reference for paediatric and adolescent diabetes services across the EU. One outcome is expected to be a Paediatric Diabetes Toolbox, to include recommendations for minimum treatment and care, patient education programmes and training programmes for health professionals. A separate work package of the SWEET Project was to examine the training of HCPs across the EU.[269] They identified that only a minority of EU countries had well-established training for paediatric diabetes multidisciplinary teams, and that in many countries training was not mandatory nor a prerequisite for HCP posts. Germany has invested in a standardised approach to HCP training, and data over the past decade indicate a positive effect on diabetes outcomes. The SWEET Project has developed a curriculum for paediatric diabetes training for HCPs, which is due to be implemented across Europe.

Comparisons with international literature

We have suggested that technology may be an area worthy of further investigation to try and effect an improvement in children's self-management and glycaemic control. A recent American trial[270] demonstrated some positive outcomes using an automated diabetes management system that was integrated into the family management of diabetes in children aged < 12 years ($n = 48$). Children's HbA_{1c} levels and self-management were improved significantly over a 12-month period. Given these encouraging results this study needs replication with a larger cohort. Adolescents were not included in this study and, as previously discussed, present different challenges. A study of the self-management of T1D in 504 young people aged 13–21 years[271] affirmed that collaboration with parents decreases over time, with the most rapid decrease occurring between the early and middle teen years. The findings also suggest that there are elements of self-management that are affected by gender, that is, males may communicate less about their diabetes and perform diabetes activities less frequently than their female counterparts. These results have implications for treatment decisions, for example regimen used, and corroborate our conclusion that 'one size does not fit all', that interventions to improve adolescent self-management may need to be individually tailored.

Report conclusions and implications

Strengths and limitations of the process evaluation

Although children randomised into the EPIC trial appeared to come from more affluent families, a strength of the process evaluation is the broad range of characteristics and experiences of those interviewed. We achieved recruitment targets in both the trial and the process evaluation. Although we conducted over 70 interviews with children, young people and their parents, there were insufficient resources to interview all children randomised in the trial. Nonetheless, process evaluation interviews yielded rich data about why the intervention did not work and cast new light on why the dominant programme theory inherent in children's diabetes information may actually be counterproductive in some children.

Conclusions

Similar to the EPIC study, most of the recently completed trials of interventions to promote children's diabetes self-management conducted in the NHS have found no difference in outcomes. Optimising children's diabetes care and self-management remains an unresolved challenge. In the future, individually tailored, complex and intensive educational and behavioural interventions may be more effective if they are delivered at diagnosis and refreshed at an appropriate age if the child is too young at diagnosis.

The unique contribution of the EPIC study is to cast doubt on the appropriateness of current discourses inherent in current children's diabetes and highlight the inability of current diabetes services to implement a children's diabetes information resource as intended in routine practice.

Implications

The daily use of a diabetes diary to record blood glucose readings and insulin doses is recommended in NICE diabetes clinical guidelines.[26] The NHS as an organisation may want to consider adopting the EPIC diaries to ensure that children have access to an age-appropriate diabetes diary and do not have to rely on one that has not been designed for their age group or on a generic one produced by a pharmaceutical company.

The NHS may want to consider using the template of the age-appropriate EPIC packs to ensure that children and young people receive a comprehensive range of quality-assured diabetes information to meet the policy aspiration of the right child having the right information, even though it is no more effective than receiving ad hoc or limited diabetes information.

More research needs to be undertaken to:

- better understand the disconnection between children's diabetes text and context
- develop age-appropriate apps and e-records as an option for recording blood glucose measurements and insulin management
- develop interventions to reduce risk-taking behaviour by children and young people in relation to their diabetes management
- reconsider what could work to optimise children's self-management of diabetes
- understand how best to reorganise current children's diabetes services to optimise child-centred delivery of children's diabetes information and services.

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Jane Noyes (Florence Nightingale Foundation Chair of Clinical Nursing Research) was chief investigator, contributed to designing the study and intervention development and was the overall project lead and PI at Bangor University.

Lesley Lowes (Reader and PDSN) contributed to designing the study and intervention development, chaired monthly management group meetings, provided clinical expertise as a PDSN and was PI at Cardiff University following the retirement of Professor Anne Williams.

Rhiannon Whitaker (Trial Statistician and Associate Director Clinical Trials Unit, Bangor University) refined the trial design, was the Clinical Trials Unit lead and was the trial statistician following the retirement of Professor Ian Russell.

Davina Allen (Professor and Sociologist) contributed to designing the study, intervention development and analysis and interpretation of the qualitative evidence.

Cynthia Carter (Senior Lecturer in Journalism, Media and Cultural Studies) contributed to designing and undertaking the critical discourse analysis and intervention development.

Rhiannon Tudor Edwards (Professor of Health Economics) contributed to the trial design and led the health economic analysis.

Joanne Rycroft Malone (Professor of Health Services Research and Implementation Science) contributed to designing the study and the process evaluation.

Janice Sharp (Medical Illustrator) contributed to the study design, produced illustrations and artwork for the intervention and contributed to the intervention development.

Deborah Edwards (Research Officer) based at Cardiff University and contributed to data collection and analysis.

Llinos Haf Spencer (Research Officer) based at Bangor University and contributed to data collection and analysis.

Yvonne Sylvestre (Trial Statistician) based at Bangor University and contributed to the statistical analysis.

Seow Tien Yeo (Research Fellow Health Economics) based at Bangor University and contributed to the health economic analysis.

John Gregory (Consultant in Children's Diabetes Endocrinology) contributed to designing the study, intervention development, interpretation of trial outcomes and clinical expertise.

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Appendix 1 Protocols

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BMC Pediatrics

STUDY PROTOCOL **Open Access**

Evidence into practice: evaluating a child-centred intervention for diabetes medicine management The EPIC Project

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Abstract

Background: There is a lack of high quality, child-centred and effective health information to support development of self-care practices and expertise in children with acute and long-term conditions. In type 1 diabetes, clinical guidelines indicate that high-quality, child-centred information underpins achievement of optimal glycaemic control with the aim of minimising acute readmissions and reducing the risk of complications in later life. This paper describes the development of a range of child-centred diabetes information resources and outlines the study design and protocol for a randomized controlled trial to evaluate the information resources in routine practice. The aim of the diabetes information intervention is to improve children and young people's quality of life by increasing self-efficacy in managing their type 1 diabetes.

Methods/Design: We used published evidence, undertook qualitative research and consulted with children, young people and key stakeholders to design and produce a range of child-centred, age-appropriate children's diabetes diaries, carbohydrate recording sheets, and assembled child-centred, age-appropriate diabetes information packs containing published information in a folder that can be personalized by children and young people with pens and stickers. Resources have been designed for children/young people 6-10; 11-15; and 16-18 years.

To evaluate the information resources, we designed a pragmatic randomized controlled trial to assess the effectiveness, cost effectiveness, and implementation in routine practice of individually tailored, age-appropriate diabetes diaries and information packs for children and young people age 6-18years, compared with currently available standard practice. Children and young people will be stratified by gender, length of time since diagnosis (< 2years and > 2years) and age (6-10; 11-15; and 16-18 years). The following data will be collected at baseline, 3 and 6 months: PedsQL (generic, diabetes and parent versions), and EQ-5 D (parent and child); NHS resource use and process data (questionnaire and interview). Baseline and subsequent HbA1c measurements, blood glucose meter use, readings and insulin dose will be taken from routine test results and hand-held records when attending routine 3-4 monthly clinic visits.

The primary outcome measure is diabetes self-efficacy and quality-of-life (Diabetes PedsQL). Secondary outcomes include: HbA1c, generic quality of life, routinely collected NHS/child-held data, costs, service use, acceptability and utility.

Trial Registration: ISRCTN17551624.

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Background

The requirement for health information

People of all ages require high quality information promoting health, self-care and medicines management to help facilitate their engagement in participative models of health care, and assist them in making choices [1-4]. In the United Kingdom (UK) the National Health Service (NHS) Constitution makes clear that patients require information to engage fully and knowledgably in decision-making, and be aware of risks and benefits of treatment options [4].

Policy makers also identify a need for health and social services providers to increase capacity, confidence and efficacy of individuals for self-care and to build social capital in the community [4-10]. The requirement for prevention, early intervention and support for individuals for self-care, and promoting wellbeing for the wider population is a fundamental policy aspiration [4-10]. However, there is uncertainty about the positioning of children, young people and their families within these models and policies and what practical plans and processes exist for successful implementation.

Children's age-appropriate and child-centred health information is likely to be critical to developing self-care and wellbeing as children's autonomy increases with age [9]. Information needs and informed choice are central to the Children's National Service Framework (NSF), (including a standard on medicines management, and the Children's Plan, which make specific reference to the requirement to provide high-quality, age-appropriate, child-centred information in varying formats) [9-11]. There is however little reliable evidence concerning the effectiveness of different types of provision of health information for children and young people. There is even less evidence about types and formats of information which could empower children and young people to make decisions and choices, where appropriate, about aspects of their care [12].

Progress has been made on a UK strategy for service delivery and organisation of medicines for children and young people to facilitate not only a measurable increase in appropriately labelled and formulated medicines and conduct of trials, but also information for prescribers, carers and children [9]. One outcome is the setting-up of the Medicines for Children Research Network (MCRN), [13] which is supporting the EPIC project and linked foundation study the Information Matters Project (IMP), funded by the National Institute for Health Research: Service Delivery and Organisation [14,15].

Broad policy background

The need for child-centred, age-appropriate information on medicines specifically, and self-care management in general, is highlighted when viewed against the broader NHS public health policy context. Children's health policy is centred on the notion of 'family-centred' care with family members providing a large proportion of care, and with children taking on more responsibility for their healthcare as they gain autonomy. The Children's NSF model of children's acute and chronic disease management focuses on educating children/young people in age-appropriate ways to deliver aspects of their own healthcare, and specifically identifies parents as experts [4]. The shift in focus to homecare and community settings requires complex arrangements for medicines and treatments and greater support for parents and children/young people who are administering increasingly complex medicines (eg insulin pumps), and treatment regimes, and who are recommended to adapt their lifestyles to optimise health [9]. Information on self-administration and medicines management is required to support delivery of children's healthcare in various community settings (eg home and school) [9].

The illness trajectories of many childhood conditions now extend into adulthood [16]. There is little information available for young people and their families around transition between child and adult service provision, with many young people seemingly unprepared to manage their own care and live independently [17]. Findings from an overlapping SDO study looking at transition of young people to adult services (TCADS) are expected soon [18]. Available standard patient information is often of poor quality and may not be easily accessible or understandable for children, young people and their families [1].

Policies need to be placed within the context of children and young peoples' lives, illnesses they experience and what best suits their needs. Long-term conditions such as diabetes are commonly treated with medicines and children/young people increasingly take responsibility for their regimes over time, especially during school hours [19]. Children and young people need to be involved with their families/carers and professionals in decision-making about their care-management, including understanding risks and benefits, and specific instructions to ensure optimum effect [9]. Research has been aimed at identifying aspects of structured education programmes, for example comparing their effectiveness, [20] developing innovative curricula, [21] and exploring acceptability to adolescents and their parents and eliciting ideas on how they would set about designing education sessions [22]. There is also work on psycho-educational interventions [23].

Clinical guidelines indicate that high-quality, child-centred information underpins the achievement of optimal glycaemic control with the aim of minimising acute re-admissions and reducing the risk of complications in later life [24]. There is, however, insufficient evidence

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about the effectiveness of information underpinning diabetes education and medicines management for children and young people [25-27]. Likewise tailored, child-centred information could equip children and young people with the knowledge to become expert in diabetes care [23,24].

Building on research evidence determining children and young people's preferred types and formats of information across five tracer groups and associated critical discourse analysis derived from the linked IMP qualitative project, the pragmatic trial protocol reported here aims to fulfil a significant gap in current knowledge concerning children's diabetes information and its use in routine practice to promote optimal self-care and medicines management [28].

Methods/Design

Research aims

The aim of the research is to develop and evaluate an individually-tailored, age-appropriate diabetes diary and information pack to support decision-making and self-care relating to insulin management and electronic blood glucose monitoring for children and young people aged 6-18 yrs with type 1 diabetes, compared with available resources in routine clinical practice.

Objectives

To:

1. Review gold-standard clinical guidelines, currently available information including findings from the linked qualitative IMP study to identify best practice, and types/formats of information most likely to assist age-appropriate decision-making and choices concerning blood glucose monitoring and insulin management.
2. Develop an age-appropriate information intervention (child-centred diabetes diary and information pack) for children and young people, to support appropriate use of blood glucose meters to optimise management of and concordance with their insulin regime.
3. Explore the utility of the child-centred diabetes diary and information pack (in this context utility refers to ease of use and fitness for purpose) within different contexts in which children and young people manage their routine diabetes care (home, school, community) with and without support from parents or healthcare professionals, and in alternative settings.
4. Explore how children/young people with and without their parents, teachers, nurses, doctors use (or not) the diabetes diary and information pack to support decision-making; in particular how children and parents 'self-prescribe' the correct (or incorrect) dose of insulin.
5. Identify similarities and differences between the diabetes diary and information pack developed for adolescents and those available within adult diabetes services.
6. Evaluate the diabetes diaries and information pack within the context of routine diabetes care in relation to patient outcomes (diabetes-specific health-related quality of life, generic health-related quality-of-life, medicine and treatment concordance, acceptability, ease of use, and glycaemic control).
7. Identify gaps in knowledge to inform a future research agenda.

Design

To meet our objectives, which are aligned with the phases of the MRC Framework for RCTs of complex interventions, a four-stage study has been designed [29,30].

Stages 1 and 2 to develop the information intervention have mostly been completed and will be described briefly. This protocol focuses on Stage 3, the randomised controlled trial to evaluate the effectiveness and cost effectiveness of the children and young people's age appropriate diabetes diaries and information packs developed in stages 1 and 2.

The four stages are as follows:

Stage 1. Review and, where appropriate, undertake further work to identify types/formats of information most likely to assist age-appropriate decision-making/choices related to children/young people with type 1 diabetes.

Stage 2. Construct age appropriate diabetes diaries and information packs, and consult with children as appropriate.

Stage 3. Conduct a pragmatic evaluation to assess utility, acceptability, effectiveness and cost effectiveness of the diabetes diaries and information pack.

Stage 4. Undertake data synthesis and comparative analysis of stages 1-3.

Conceptual and methodological frameworks

In addition to using the MRC Framework for designing and evaluating complex interventions, the Promoting Action on Research Implementation in Health Services (PARIHS) framework will be used as the framework for the translation of evidence into practice evaluation [31,32]. The framework has been theoretically and empirically developed to represent the interplay and interdependence of the many factors influencing implementation of evidence into practice. This is explained by a function of the relation between evidence, context and facilitation [32-34]. The hypothesis offered is that for implementation of evidence to be successful there needs to be clarity about the nature of the evidence being used, the quality of context, and, the type of facilitation needed to ensure a successful process. The framework has been used by others to inform the design and evaluation of evidence into practice initiatives [35-37].

PARIHS framework is particularly relevant to this study because:

1. It aims to introduce new diabetes diaries and assembled information packs (evidence) into children's self-care regime and healthcare practice in order to improve blood glucose meter use and insulin management. Understanding the factors that influence its implementation and use will be important in determining the acceptability and feasibility of the information pack (facilitation)-this framework will provide a conceptual guide for mapping these issues.
2. Understanding how the information pack is used in different contexts where children/young people manage their diabetes will be key in the evaluation of its utility and contribution. Applying the framework will allow a focus on the key contextual variables mediating the implementation and use of the information pack.
3. It facilitates the gathering of individual (e.g. child/practitioner/carer) experiences as well as appreciating the fit with the broader context of care delivery.

Plan of Investigation

Stage 1. Review of literature and discourse analysis of currently available children's health information

Literature review

We are undertaking an ongoing systematic review of literature, policy, evidence of cost-effectiveness, best practice clinical guidance and management plans that will run throughout the study. We have used a scoping review of current evidence from the IMP project to inform intervention development and have extended the focus on childhood diabetes diary and information pack development.

Critical discourse analysis of currently available childhood-diabetes information sources

We have used completed IMP project critical discourse analysis findings to inform intervention development and have focused in detail on childhood diabetes. We have explored management of childhood diabetes and focused on blood glucose monitoring and insulin management as a key exemplar concerning medicine management, self-care and concordance. We have also looked specifically for similarities and differences in the discourses and philosophies underpinning children's/young peoples' and adult care pathways and management plans to see how and in what ways medicine management and self-care discourses/philosophies change at key stages across the lifespan. Information sources across all mediums and sectors (eg. NHS, pharmaceutical) were sought. This work established what sources of diabetes information were currently available to children/young people and their families. We have also identified the underlying assumptions of the information sources and their main messages, and we have assessed their applicability in terms of age, disability, ethnicity and gender, and for those children living away from their families. Analysis of the content has identified whether key messages match clinical guidance on childhood diabetes management.

Stage 2. Diabetes diaries and information pack development

Expert clinical advisory group

Towards the end of phase 1, we convened an expert clinical group to discuss what gaps existed in current children's diabetes information, and what new information could be produced within the study budget and time constraints. It was decided that evidence concerning preferred formats and presentation of age-appropriate key health messages would be used to design and develop a series of age-appropriate children's diabetes diaries that record daily insulin management and blood glucose measurements, and carbohydrate counting sheets. In addition, the diary would be central to an age-appropriate information pack of existing diabetes and diabetes-related information resources that were considered high quality in terms of content and identified by children and young people in focus groups and interviews as being attractive and relevant to them in terms of content and presentation.

Evidence from stage 1 (ongoing literature review and discourse analysis) has been used as an empirical basis for developing the age appropriate diabetes diaries and information packs. The diabetes diaries and information pack were designed in conjunction with children/young people, parents, healthcare professionals, and a children's medical illustrator.

Qualitative interviews and focus groups

To establish the context for the development of the diabetes diaries and information packs and their implementation in routine practice, linked with the IMP project, we have conducted 7 focus groups and 48 interviews to ascertain children and young people's views of currently available information resources across 5 tracer conditions including diabetes, and explored children and young people's information needs related to managing their condition and self-care, including diabetes. We also interviewed 52 parents and 11 healthcare professionals and undertook non-participant observations of routine clinical encounters where information is exchanged.

Over the course of the EPIC study, we plan to increase the number of interviews with children and young people with type 1 diabetes to around 20, with the specific aim of including those who live or have lived away from their families in the short, medium or long term (such as summer camp, school trips, foster or institutional care etc) to ascertain children and young people's views and experiences of managing their diabetes in various everyday contexts.

In addition, approximately 20 healthcare professionals drawn from participating trial sites (approximately two from each trial site), will be interviewed to document current routine practice and local clinical care pathways for children with type 1 diabetes in their sites.

Obtaining children and young people's perspectives on various iterations of the age appropriate diabetes diaries and information packs

With permission from the organisers of family days run by children's diabetes charities and support groups, we have asked for children and young people's general views on various iterations of the age appropriate diabetes diaries and information packs. They have commented on artwork, colours, formats, sizes and types of information. We have also used advertisements in charity and Roche family support network news letters and communications inviting children and young people to visit the EPIC Project website. Having given their online consent (and parent/guardian consent if under 16 years of age) children and young people were invited to take part in web-based activities such as choosing which image they liked best out of a selection, and commenting on various iterations of the information resources in production.

Children's diabetes information resources produced for the trial

In an iterative approach, integrating findings from the linked IMP Project, and building throughout stages 1 and 2, we have produced the following range of resources that can be individually tailored for pragmatic evaluation in routine clinical practice-stage 3:

- Three diabetes diaries for children and young people using multiple insulin injections (6-10 years, 11-15 years and 16-18 years);
- One diabetes diary (6-18 years) for children and young people using insulin pumps;
- Child-friendly sheets for recording carbohydrate intake;
- Three age-appropriate information packs containing published diabetes information bound in an age-appropriate folder (6-10 years, 11-15 years and 16-18 years), and
- Stickers and pens for children and young people to personalise their folder.

Stage 3. Trial platform to evaluate the diabetes diaries and information packs in routine practice

Methods

Study design This trial is an individually randomised controlled trial with two parallel groups. The protocol is summarised in Figure 1.

Main hypothesis Children and young people with type 1 diabetes aged from 6-18 years, receiving and using an individually-tailored and age appropriate diabetes diary and information pack will increase their diabetes-related self-efficacy and quality of life at 6 months.

Secondary hypotheses That receiving and using an individually-tailored and age-appropriate diabetes diary and information pack will lead to an improvement in HbA1c, generic health-related quality of life, and a range of care process outcomes, and be cost-effective.

Setting NHS children's, transition, and young adult diabetes clinics, and a range of domestic/community settings (eg family homes and schools).

Site selection and preparation Depending on the size of site and number of children/young people with diabetes type 1, we envisage up to 10 sites (depending on current NHS re-organisation and amalgamation of Trusts) will recruit children and young people. We will be guided by co-applicant clinicians and the MCRN/CRC Cymru research network who have an overall view of available of sites for trials and will have an overall strategic role in supporting research teams to facilitate site and participant recruitment [38].

The age-appropriate diabetes diaries and information pack will be individually-tailored and introduced by nurses/doctors in children and young people's diabetes clinics during routine visits. We will hold a launch event to familiarise healthcare professionals with the information pack in each participating site.

Types of participants

Inclusion criteria

Children age 6-18 years with type 1 diabetes.

Exclusion Criteria

Children/young people with:

1. Needle phobia;
2. Any significant social or emotional problems where such problems in the opinion of the clinical team are likely to impair a child's ability to take part in the trial;
3. Any significant physical or intellectual impairment which in the opinion of the clinical team is likely to impair a child's ability to take part in the trial, and
4. An inability to communicate in an age appropriate way in written and spoken English.

The underlying principle guiding clinicians is that children/young people should be entered into the trial where at all possible and should only be excluded if being in the trial would be detrimental to their social, emotional or physical health, or children/young people or their parents are unwilling to give their informed consent/assent.

Sample size calculation and effect size

A systematic review provides sample size calculations for studies of educational interventions targeting

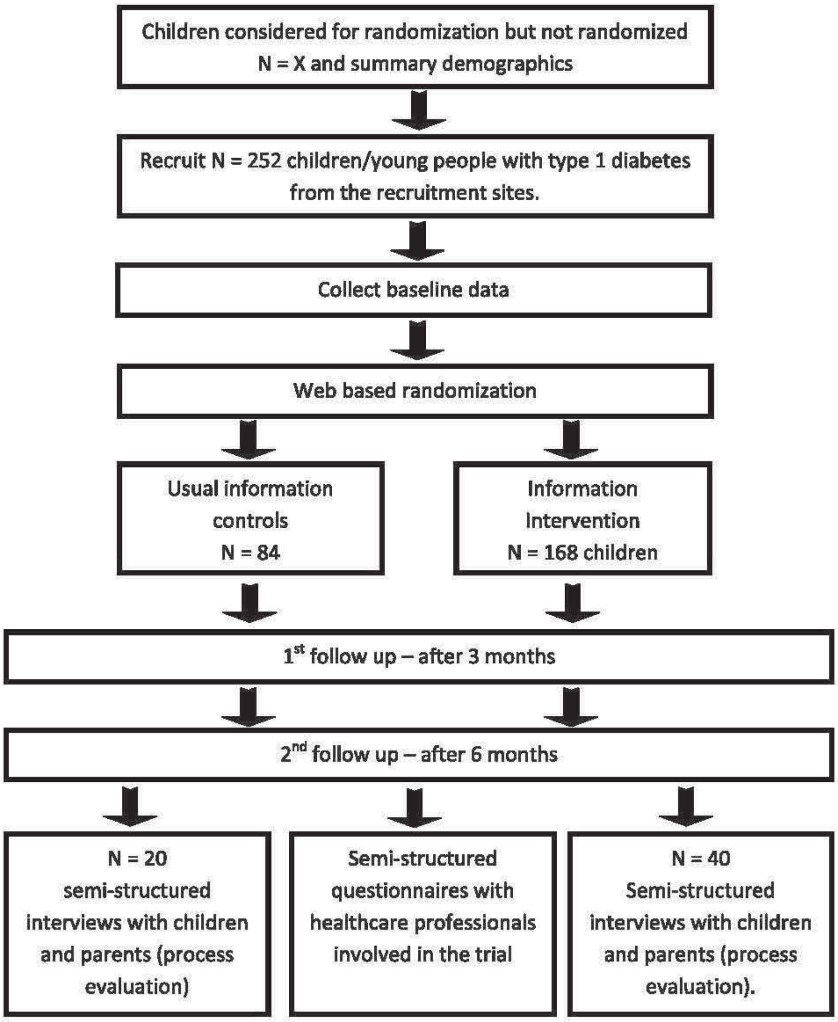

Figure 1 Flow of patients through the trial.

psychological effects and glycaemic control (HbA1c) for children with diabetes [39]. They calculated a total of 130 randomized subjects in order to detect a 0.5 (medium) psychological effect size, with a power of 80% at the 0.05 significance level (assuming equal assignment in the two arms). They report that the effect size for psychological outcomes is more predictable with a median and mean of 0.38 and 0.35 respectively, therefore we will aim to detect an effect size of 0.4.

The sample size is 252 children/young people with type 1 diabetes (this is allowing for a 10% drop out rate, and adjusting for a 2:1 randomisation strategy). In order to gain more experience of the new intervention in routine practice, we will employ a 2:1 randomization strategy and randomise 168 children/young people into the intervention arm and 84 children/young people into the non intervention arm, stratified by age, gender and length of time since diagnosis (<2 years and >2years). Figure 1 shows the flow of patients through the trial.

Recruitment Where appropriate consultants, nurses, or MCRN/CRC Cymru research nurses will send an information pack to a child/young person (and if under 16 years their parent/guardian) attending a clinic one week prior to the clinical appointment. During the clinic visit, the consultant/nurse/research nurse will ask them if they want to take part in the study. If the child/young person agrees to take part in the study, the consultant/nurse/research nurse will take the consent from young people over 16 years, assent and parent/guardian proxy consent from children under 16 years. Children and young people not entered into the trial will receive standard care.

Allocation Children age 6-18 years fulfilling the inclusion criteria and for whom appropriate consent(s) (proxy if appropriate) are obtained will be randomized using an independent web based randomisation service supported by the North Wales Organisation for Randomised Controlled Trials in Health and Social Care (NWORTH).

Randomisation A web-based, password protected, secure adaptive randomisation with a telephone backup has been developed.

168 children/young people will be randomized into the intervention arm and 84 children/young people into the no intervention arm, stratified by gender, length of time since diagnosis (<2 years and >2 years) and age (stratification by age will be into the following age categories: 6-10 years; 11-15 years; and 16-18 years).

Planned interventions

Group 1 - Information intervention An age-appropriate diabetes diary and information pack produced or assembled for the study will be selected and individually-tailored as appropriate to each child/young person depending on their age and diabetes management, and introduced by nurses/doctors and as appropriate other multi-disciplinary team members in clinic during routine visits by children/young people between the ages of 6-18 years with type 1 diabetes. Parents of children under 16 years will be provided with verbal and written guidance on supporting their child's use of the information pack. Parents attending clinic consultations with young people over 16 years will receive the same verbal advice as the young person, and written guidance will be aimed at the young person.

Group 2-Standard practice Children age 6-18 years with type 1 diabetes receiving standard practice will be the 'practice as usual' control group. A manual of standard practice for each centre will be produced. This will help with the comparisons of outcomes at the end of the trial.

Outcome measures

Primary outcome measures Choice of outcomes is guided by a Health Technology Assessment commissioned systematic review recommending that HbA1c (glycaemic control measure) is not the appropriate primary outcome on which to assess benefits of an intervention designed to more directly effect behaviour/self-management [39]. Therefore, the primary outcome measure is diabetes self-efficacy and quality-of-life as measured by the single composite score derived from the Diabetes PedsQL.

Secondary outcome measures Secondary outcomes include: HbA1c, generic quality of life, routinely collected NHS/child-held data, costs, service use, acceptability/utility.

Baseline, 3 and 6 month data collection

Children/young people (if appropriate with support of, or proxy report by parents) will complete a baseline questionnaire recording sociodemographic variables, patient characteristics, and PedsQL (generic, diabetes and parent versions). The EQ-5D will be completed by parents (as a proxy measure) as well as the child/young person.

Follow-up questionnaires, containing the same outcome measures as at baseline, and with an additional focus on process will be administered at 3 months and 6 months, (including data on health service use, episodes of diabetic ketoacidosis, and all hospital admissions for acute complications). Non-responders will receive telephone/postal reminders after two and four weeks.

Baseline and subsequent HbA1c measurements and routinely collected NHS/child-held data will be collected by the clinicians/diabetes nurse specialists/MCRN nurses, or researchers where appropriate. Blood glucose meters will be checked for the previous 250 blood glucose records if considered appropriate by the clinician and if used as part of routine clinical practice.

Implementation, service utilisation and costs

Economic Evaluation

Murphy et al., strongly recommend that cost-effectiveness is considered as an outcome as none of the studies in their review of psycho-educational interventions with adolescents addressed it [39]. We will therefore weigh up the diabetes related costs and consequences of the different interventions (that involve resource use) from an NHS perspective. Contacts with NHS services and resource use will be collected via questionnaire. Costs will be obtained from national sources. Activity will be collected for 6 months.

Process evaluation

Following the intervention, sixty children/young people and parents (as appropriate) will be interviewed by telephone or in person (40 from the intervention group and 20 from the control group) in order to gain further understanding about implementation issues, and user experiences of the intervention diabetes diaries and information packs or resources used in existing routine practice.

Healthcare professionals associated with the care of children/young people recruited to the trial will also be invited to complete a semi-structured questionnaire to determine acceptability and impact of the new diabetes diaries and information pack in practice.

Data handling

SPSS® and Atlas Ti® will be used for statistical, qualitative and healthcare professional questionnaire data handling [40,41]. NWORTH will support data management and processing. Where appropriate, we plan to use an electronic data collection system (TrialSys®) in each centre with an alternative paper-based system [42]. Data will be transmitted securely electronically to the clinical trials unit NWORTH [43].

Data analysis

Statistical analysis Initial descriptive statistics will describe characteristics and demographics of the sample at baseline. We shall compare outcomes between the two groups by analysis of covariance to adjust for possible differences in baseline measurements. This will be repeated at 3 and 6 months comparing intervention and control groups. In addition, longitudinal analysis will consider any changes over time. These analyses will examine changes in the quality of life measures (paediatric EQ-5D, PedsQL generic and diabetes-specific health measures) over baseline, both using a pairwise comparison, studying change on individuals, and a cohort analysis comparing overall change in group means.

Multiple regression analyses will be performed to identify factors which predict good outcomes within and between groups.

Cost effectiveness analysis

We will undertake a cost-utility analysis, whereby costs are in monetary terms and outcomes are in preference-based non-monetary units such as Quality Adjusted Life Years (QALYs). The area under the curve method will be used for calculating QALYs weighting survival by quality of life weights measured using the paediatric EQ-5D instrument. We will compare our findings with the unofficial NICE ceiling of £30,000 per QALY. Discounting will not be necessary given the time period.

Uncertainty

The bootstrap calculation is a useful statistical approach for examining the uncertainty in cost-effectiveness analysis. It is a non-parametric simulation method used when the underlying data has a skewed distribution. The bootstrap method can be used to provide an estimate of the probability distribution of the cost-effectiveness ratio, its confidence interval, or variance in the ratio.

Qualitative data analysis

Interviews will be tape recorded and transcribed. The process analysis accompanying the subsequent evaluation will explore implementation issues and compare the experience of managing diabetes and insulin management and self-care processes between the intervention and control pathways. The predominantly deductive 'framework approach' will be used to categorise qualitative data based on the literature, conceptual framework, the trial design, and the evaluation focus [44].

Healthcare professional questionnaires

Healthcare professionals' questionnaire data will be analysed using descriptive statistics and open ended questions will be subject to content analysis.

Stage 4. Data synthesis and comparative analysis

Data from stages 1 to 3 will be synthesised and subject to comparative analysis.

Ethical arrangements

Ethical approval A favourable opinion has been received from Cardiff Research Ethics Committee. Reference **08/MRE09/57**

Risks and anticipated benefits for trial participants The research carries minimal risk and therefore it is considered appropriate to involve children and young people in evaluating the diabetes diaries and information packs [45].

We have convened an expert clinical advisory group and developed a specific clinical governance and risk management framework with diabetes clinicians to quality assure and 'sign off' children's diabetes information produced for the study as appropriate for use in the NHS (see Figure 2).

Team members with direct contact with children will undergo appropriate Child Safeguarding screening, and follow local child safeguarding procedures in each site.

Consent for participation in the trial Participants will be children/young people between the ages of 6 to 18 years. Young people over the age of 16 can provide their own consent, however consent by proxy (from a parent or guardian) will be obtained for children under the age of 16 years. Assent will be sought from children under 16 years.

Discussion

The multi-disciplinary team and innovative design will ensure that children's needs are made explicit within policy implementation and service delivery, providing generalisable evidence to: 1. Identify types/formats of information to underpin structured education programmes for children with type 1 diabetes. 2. Guide integration of high quality children's information needs within service delivery to facilitate choice in routine clinical practice at national and local levels. 3. Inform decisions about the allocation of NHS resources in relation to service use. 4. Assist the development of a future research agenda related to age appropriate, child-centred information across a range of conditions, in order to fill an identified service delivery and organisation gap.

We have also successfully integrated high levels of participation with children, young people, families and healthcare professionals in the study at various key stages. The study will undoubtedly also yield further useful and valuable evidence on process and outcome measurement generally in a range of children and young people that can be used to inform the design of future trials of information and behavioural interventions generally across a range of tracer conditions. Evidence that addresses the preparation of children in order to

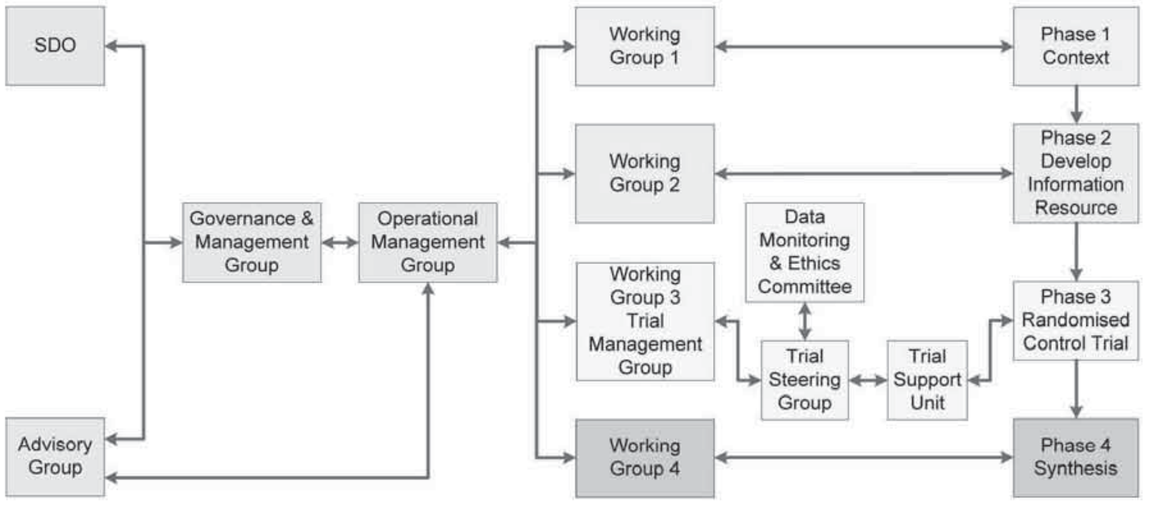

Figure 2 Trial governance and management arrangements.

manage their own care and live independently into adulthood is critical to the NHS agenda

The study complements other children's diabetes studies undertaken by team members and findings will contribute to a developing a wider evidence base with specific reference to children/young people with type 1 diabetes [14,18,46].

We have been asked by NIHR SDO to publish the trial management and research governance framework developed for EPIC.

Trial management and research governance framework

Team management

Drawing on team members' experiences of managing teams, we have adapted a template shared by PB and constructed a management and research governance framework to support the four phases of our study (1. context: review literature and current information 2. develop information pack, 3. randomized controlled trial, 4. synthesis of phases 1-3 and comparative analysis), and to ensure cohesive and effective working between team members (see Figure 2).

Key Groups

Group tasked with overall responsibility and governance: 'Governance and Management Group'

Management and research governance is being overseen by a group composed of the co-applicants named on the bid, led by AW and JN. Co-applicants were chosen to support this application on the basis that they each have established reputations in fields and expertise most relevant to the proposed research, including: systematic review skills, research skills, trials expertise, experience of user groups/working with users, clinical expertise, policy knowledge, services planning and development, management and delivery, multi-agency/disciplinary partnerships, networking and dissemination skills. In addition, co-applicants have specialist roles within relevant clinical research thematic networks (PB, JG, JN) and professional bodies (JG, CJ, ML, JN, AW).

All co-applicants are experienced and effective communicators in their capacity as researchers, clinicians and managers. The majority of us have collaborated previously or are currently collaborating on other projects. While we each bring different discipline and professional perspectives to bear on the objectives we have set, we aim to promote team values with an inclusive approach where differing opinions are respected. Many of us have developed considerable confidence as team leaders in multi-disciplinary/multi-agency settings. The Governance and Management Group will normally meet once a year, and will report to the funder. Additionally, teleconference meetings will be called if required.

Group tasked with day-to-day management: Operational Management Group

Day-to-day management of operational aspects of the programme will be the responsibility of the two PIs working with the two RAs employed for the duration of the study. AW will work with one RA based in Cardiff, meeting face-to-face on a weekly basis and JN with one RA based in Bangor, also meeting face-to-face weekly. This core group of four researchers will be in close contact with each other via a secure web site and will communicate via teleconference or telephone at least every 2 weeks during the 36 months of the programme. They will meet face to face in the early stages to establish working relationships. Our experience suggests this increases effectiveness and efficiency. They will also be in contact with members of the Working Groups, Governance and Management Group and Advisory Group as detailed in the section 'Working together effectively' below. Management of information will be critical to the day-to-day management of the study; common data bases and resources have been set up and it has been important to identify precise division of labour from outset of study.

Working together effectively

Based on previous experience and current models of good practice employed on projects by the co-applicants, we have set up Working Groups. These will give clarity to the roles and responsibilities of the co-applicants who have been costed into the price of the proposed research. They are planned to provide particular advice and guidance to the PIs and RAs in each phase of the study: 1. Context: review of literature and current information 2. Development of the information pack, 3. Randomized controlled trial, 4. Synthesis of phases 1-3 and comparative analysis. Guidance will be related to varying aspects such as range of policy, best clinical practice, child/user-friendly construction of question sheets and so on. Guidance on dissemination of findings will be a key aspect of their role. Individual members of the Governance and Management Group are leading activity in the working groups, working closely with the Operational Management Group. Advisory Group members will be called on for specific expertise, including dissemination skills. Each working group reports to the Governance and Management Group via the Operational Management Group.

Trial Management

The North Wales Organisation for Randomized Trials in Health and Social Care (NWORTH) will support implementation and running of the trial.

Working group three in Figure 2 has been convened as a Trial Management Group, Chaired by LL (co-applicant) that meets monthly by teleconference. Membership includes PIs, ROs, trial statistician, and health economists.

Trial Steering Group

A trial steering group (TSG) has been convened under the independent Chairmanship of Professor Tim Barrett. The TSG includes clinical, academic, parent and young person representation and will meet every six months in person and every six months by telephone conference.

Data Monitoring and Ethics Committee

An independent data monitoring and ethics committee (DMEC) has been convened and chaired by Dr Chris Foy (independent statistician), who will report to Professor Tim Barrett (Chair TSG). The DMEC will meet face to face every six months and virtually every six months prior to the TSG meeting.

Serious Adverse Event Reporting

A serious adverse event monitoring and reporting system has been devised in conjunction with NWORTH.

MCRN and CRC Cymru

The study has been adopted and supported locally by MCRN, Diabetes Research Network, and Children and Young Peoples' Network CRC Cymru.

Additional Stakeholder and lay input

In addition to the clinical expert advisory group described previously, we wish to involve at various stages of the study those people we have already consulted in preparing the research proposal-parents, children, young people-and others such as clinicians, managers and voluntary sector representatives. A number are working with us on the linked IMP project.

Additional stakeholder and lay advice and input will therefore be drawn from people with knowledge and experience relevant to the aims of the project. Previous experience of this type of research by the co-applicants suggests that collaboration, communication and transparency with key stakeholders from the outset will be crucial to the success of the proposed study.

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Research officers: Dr Llinos Spencer, Deborah Edwards and Jacqueline Chandler-Oatts, and Natalia Houndsome. Associate Lecturer Gaynor Williams. The MCRN and Children and Young People's Research Network (CRC Cymru) are providing invaluable local research support.

Professor Tim Barrett is independent Chair of the Trial Steering Group

Dr Chris Foy is independent Chair of the Data Monitoring and Ethics Committee

Rachel Harris, diabetes nurse specialist is independent member of DMEC.

Yvonne Rees-Coleman and Nina Phillips, are independent lay members of the TSG.

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Author's contributions

JN and AW are chief investigators and were involved in the conception of the study. All co-applicants contributed to the design of the study and/or development of the protocol. Artist JS produced illustrations and artwork for the intervention. JN and AW drafted the manuscript with all authors providing critical review and final approval. JN is involved with supervision of students on this project.

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Authors' information

AW and JN (joint-PIs) have track-records in managing research programmes in patient/carer-centred service delivery and organisation.

JN has experience in child health research, health services research and health economics and evidence synthesis.

AW has a specific interest in policy changes in relation to the shaping of new and changing professional roles, identities and relationships, and changing patient engagement with the health services.

PB, as Chair of the Methodology Clinical Studies Group of MCRN will act as formal link between the research team and MCRN and facilitate additional links with the MCRN Endocrinology Clinical Studies Group. As an experienced trial researcher, PB will provide additional input and scrutiny into the running of the trial and data monitoring.

The study demands applied clinical expertise and research. JG (Paediatric Endocrinology) and LL (Children's Diabetes Specialist Nurse) have a joint-research programme into delivering children's diabetes care.

As an academic clinician managing a caseload of children with diabetes, JG will help facilitate recruitment and support the development of a robust risk management framework for the use of the information pack in practice. As an experienced trial researcher, JG will provide additional input and scrutiny into the running of the trial and data monitoring. He will also provide cross-linking with another trial on which he is principal investigator into adolescent diabetes care, thereby adding value by sharing best practice and findings. JG through his membership of British Society of Paediatric Endocrinology has strong links with the MCRN Endocrinology Clinical Studies Group and will facilitate communication on behalf of the study. He also has links with the Diabetes Research Network.

As diabetes nurse specialist and academic, LL will provide advice on clinical governance issues and support the development of a robust risk management framework for the use of the information pack in practice.

CJ is a children's pharmacist and will advise on current policy and practice in relation to administration of children's medicines and the children's British National Formulary. She will advise and support on the development of appropriate risk management procedures with specific reference to medicines, and support the facilitation of translation of the information pack into practice with reference to pharmacy professionals.

ITR is non executive director of the North Wales Clinical Trials Unit which will coordinate trial management and scrutiny. ITR will also oversee statistical aspects. He is also Professor of Clinical Trials, Centre for Health Information Research & Evaluation, Swansea University School of Medicine.

RW is trials unit assistant director (NWORTH) and research statistician. The clinical trials unit will develop randomisation procedures and provide an independent randomisation service, advise on data base development, data storage, and provide data as requested by the data monitoring and ethics committee.

DA has expertise in policy and research concerning transition from child to adult. Her extensive work on policy analysis from a sociological perspective and her depth understanding of theories informing current policy supports her role in advising on these matters in relation to children and young people with type 1 diabetes.

CC (specialist in children, communication and media) will advise on the development of the information pack in terms of content and intellectual structure from a media perspective.

As a member of the Wales Health Economics Group, RTE brings key expertise to the study. She will have overall responsibility for the health economics component of the trial.

Translating evidence into practice is critical to the research plan. J R-M has extensive experience in knowledge translation and utilisation, and will guide translation of theoretical concepts and findings from linked studies to practical application and evaluation in the current study.

As a children's researcher, lead nurse and clinical quality lead in a paediatric clinical trial, ML will provide advice on clinical governance issues and support the development of a robust risk management framework for the use of the information pack in routine practice.

MS will help facilitate publication of EPIC advertisements in Roche newsletters to children and families who have signed up to receive information. He will also provide a link with industry, who produce blood glucose monitors and insulin and are required to produce user friendly product information (currently for adults only). MS will receive no financial reimbursement for supporting the study. Note MS commenced as Managing Director, NIHR Office for Clinical Research Infrastructure (NOCRI), April 2010.

JS, a children's medical illustrator, will produce illustrations and support the design of the information pack.

Competing interests

MS is a former employee of Roche Diagnostics.

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Evidence into practice: evaluating a child-centred intervention for diabetes medicine management: Study Protocol

Lay Summary

Context:

Children/young people need high quality information to support decisions they make about looking after themselves and staying healthy. Most children with type-1 diabetes need injections of a drug (insulin) several times a day. To help avoid complications, they monitor their glucose levels by regularly obtaining a blood-spot from their finger to test in a meter, and keep watch on sugar levels in their food and drink. The design of currently available intensive structured children's diabetes education programmes have been adapted from those designed for adults. They aim to educate children about decisions they need to make about measuring their blood glucose, taking their insulin and caring for themselves. Although researchers are currently evaluating these kinds of education programmes to see if they work, very little is known about the kinds of age-appropriate information likely to inspire children as they grow up to manage their diabetes on a daily basis at home, school, elsewhere in the community or in hospital.

What we propose to do

We will undertake a study to provide a better picture of the kinds of information that is most helpful to children with type-1 diabetes and their families.

About the Study

Using a four-stage design and working with children aged 6-18 years with type-1 diabetes we will:

- Stage 1: Review literature and other existing information for children and their families.
- Stage 2: Develop an age-appropriate information resource. We will ask children/young people, key family members and healthcare professionals to help us develop this information resource.
- Stage 3: Test the resource to establish how helpful and effective it is.
- Stage 4: Combine and report findings and make widely available. We will publish papers and organise a conference emphasising everyone's perspectives. This will ensure maximum impact of our findings amongst health service users, practitioners, managers and policy makers.

Background

Resources to educate and improve medicine concordance and related care for children with Type 1 diabetes currently focus on intensive structured education programmes (1,2). The commissioning of an RCT of intensive structured education programmes by the HTA underlines the importance attached to the programmes' potential (3). NICE and childhood-diabetes competencies in the NHS Knowledge and Skills Framework stipulate that children and their families should receive an age-appropriate individually-tailored intensive structured education programme and high quality, child-centred information to support the achievement of clinical management goals including optimal glycaemic control, minimisation of acute readmissions and risk reduction of long-term complications (4). However, there is insufficient evidence concerning the types/formats of information that could inspire children to manage their medicines and encourage concordance with care plans (7). Moreover, a lack of child-centred research hampers development of effective interventions to optimise long-term management and minimise risk of complications (5–7). We will address these gaps in evidence by producing age-appropriate and individually-tailored children's diabetes information packs. The research will produce findings to facilitate translation of information into practice for children/young people with Type 1 diabetes, producing generalisable findings relating to other long-term conditions.

Type 1 diabetes is the most common form of childhood diabetes. The incidence in children under 5 years doubled between 1985 and 1995 and under 15 years there is an overall increase of around 4% each year (3). Management of diabetes is aimed at maintaining blood sugar levels within the normal range. Most children with Type 1 diabetes need individual insulin regimes, monitoring of their blood glucose and close attention to diet and exercise. Parents, and with increasing age children, are taught to measure blood glucose several times daily, learn how to react to eating, exercise and changes in insulin dosage. Children may be supplied with an electronic blood glucose meter or they may purchase one without a medical prescription. There is little evidence to indicate that children/young people and their families are using blood glucose meters effectively in domestic, residential or education settings. On inspection, the accompanying blood glucose meter user information can be seen to lack a child-centred focus. We will address the absence of appropriate information by developing a child-focused and age-appropriate, information pack focusing on blood glucose monitoring and insulin management. Findings from the evaluation will identify the complexities of using blood glucose meters, children's decision-making processes, insulin management and self-care activities within the context of routine diabetes management.

Conceptual Framework

The proposed research is anchored in the idea that partnership between the public and the UK NHS has the potential to build a healthier society (8). Information on medicines management is regarded as critical to effective partnership (9,10). Generic information derived for adults using equipment such as glucose meters in the management of their medicines is, however, unlikely to be intelligible and accessible to children/young people. If we are to promote partnership then it is important to recognise that children/young people are capable of being partners in the approach to their treatment. As highlighted in the NICE diabetes guidelines: 'information provided should be accurate and consistent and it should support informed decision making' and be 'appropriate for the child's or young person's age, maturity, culture, wishes and existing knowledge within the family' (4). The study has been conceived as a stand alone RCT with sufficient power to detect a significant effect based on effect size calculations from a HTA systematic review of educational and psychological interventions in young people with type 1 diabetes (24). Therefore the study is unequivocally independent of any future research, and will provide outcomes of value to the UK medicines for children agenda in relation to Type 1 diabetes. However, the study will undoubtedly also yield further useful and valuable evidence on process and outcome measurement generally in a range of children and young people that can be used to inform the design of future trials of information and behavioural interventions generally across a range of tracer conditions. The study complements a currently funded study NIHR 08/1745/145, which commenced in March 2007 and is running according to the anticipated project milestones. We will run the two studies in staggered parallel and use data from the completed stages of the currently funded study to complement the proposed study.

NHS context and relevant literature

Changing children's engagement with the NHS

A requirement of participative models promoting health, self-care and medicines management is provision of information to assist patients' choices so that they may engage fully and knowledgably in decision-making, aware of risks and benefits of treatment (9,13–15). There is little reliable evidence concerning the effectiveness of different types of provision of information for children, young people and their carers (16). There is even less evidence about types/formats of information which could empower children/young people to make decisions/choices about aspects of their care, where appropriate (17). Policy makers identify a need for health and social services providers to increase capacity, confidence and efficacy of individuals for self-care and to build social capital in the community. The requirement for prevention, early intervention and support for individuals for self-care, and promoting wellbeing for the wider population is underlined (18,19). Children's information is likely to be critical to developing the notion of self-care and wellbeing as children's autonomy increases with age. Information needs and 'informed choice' are central to the Children's NSF (20), which makes specific reference throughout the ten standards to the requirement to provide high quality, age-appropriate, child-centred information in varying formats, including a standard on children's medicines. Children's medicines information Progress has been made on a UK strategy for service delivery and organisation of medicines for children to facilitate not only a measurable increase in appropriately labelled and formulated medicines and conduct of trials, but also information for prescribers, carers and children (21). One outcome is the setting-up of the Medicines for Children Research Network (MCRN) which is represented on this bid. The need for child-centred, age-appropriate information on medicines management is highlighted when viewed against the broader NHS policy context. Children's health policy is centred on the notion of 'family-centred' care with family (especially mothers) providing a large proportion of care, with children taking on more responsibility for their healthcare as they gain autonomy. Indeed, the Children's NSF model of children's acute and chronic disease management has incorporated the notion of educating children in age-appropriate ways to deliver aspects of their own healthcare, and specifically identifies parents as experts (20). The shift in focus to homecare and community settings requires complex arrangements for medicines and treatments and greater support for parents and children/young people who are administering increasingly complex medicines (e.g. subcutaneous and intravenous regimes) at home (20).

Information relating to safety and administration issues is urgently required to support the contemporary delivery of healthcare. The informed use of unlicensed medicines and off-label usage of medicines for children/young people is unavoidable if they are to access the most effective medicines (20), however comprehensive accessible and timely information about both risk and benefit and decision support are imperative if children/young people are to be active partners in decision-making about healthcare choices. Information around risk is provided by professionals and increasingly by adult and child patients themselves. Quality information is regarded as central to participative models of health citizenship which have emerged (13,14). However, there is uncertainty about the positioning of children and their families within these models and what practical plans and processes exist for their successful implementation. Children's information is likely to be crucial to developing the notion of self-care as children's autonomy increases with age. The illness trajectories of many childhood conditions now extend into adulthood. There is little information available for young people and their families around transition between child and adult service provision (Allen/Gregory/Lowes on SDO-funded exploration of transition from child to adult diabetes services), with many young people seemingly unprepared to manage their own care and live independently. Available standard patient information is often of poor quality. It may be hard to understand, and not easily accessible for young people and their families (9).

Information to support children's medicine management in the context of Type 1 diabetes

Policies need to be placed within the context of children's lives, illnesses they experience and what best suits their needs. Long-term conditions such as diabetes are commonly treated with medicines and children increasingly take responsibility for their regimes over time, especially during school hours. Children need to be involved with their families/carers and professionals in decision-making about their care-management, including understanding risks and benefits, and specific instructions to ensure optimum effect. Research has been aimed at identifying aspects of structured education programmes, for example comparing their effectiveness (22), developing innovative curricula (2), and exploring acceptability to adolescents and their parents and eliciting ideas on how they would set about designing education sessions (23). There is also work on psycho-educational interventions (24). While the research illuminates important aspects of a neglected area of investigation it is clear that structured education programmes for children are based on programmes designed for adults, notably the Dose Adjustment for Normal Eating (DAFNE) programme. The HTA brief (3) states such programmes have been shown to be effective in adults, however a trial is necessary to establish if they have a role to play for children/young people. Our searches also suggest that high-quality, child-centred information underpins the achievement of optimal glycaemic control with the aim of minimising acute readmissions and reducing the risk of complications in later life (4). There is insufficient evidence about the effectiveness of information underpinning diabetes education for children and young people (1,5,6). Likewise tailored, child-centred information could equip children/young people with the knowledge to become expert in diabetes care (4,24).

Aims and objectives

Aim

The overarching aim of the multiple strands of work was to develop and evaluate an individually-tailored, age-appropriate diabetes diary and information pack to support decision-making and self-care with a specific focus on insulin management and electronic blood glucose monitoring for children and young people aged 6-18yrs with Type 1 diabetes, compared with available resources in routine clinical practice.

Objectives

1. To review gold standard diabetes clinical guidelines, currently available diabetes information, including findings from the linked qualitative IMP project to identify best practice, and types/formats of information most likely to assist age-appropriate decision-making and choices concerning blood glucose monitoring and insulin management.
2. To develop an age-appropriate diabetes information intervention (child-centered diabetes diary and information pack) for children and young people, to support appropriate use of blood glucose monitoring to optimise management of and concordance with their insulin regime.
3. To explore the utility of the child-centered diabetes diary and information pack (in this context utility refers to ease of use and fitness for purpose) within different contexts in which children and young people manage their routine diabetes care (home, school, community) with and without support from parents or healthcare professionals, and in alternative settings.
4. To explore how children and young people with and without their parents, teachers, nurses, doctors use (or not) the diabetes diary and information pack to support decision-making; in particular how children and parents 'self-prescribe' the correct (or incorrect) dose of insulin.
5. To identify similarities and differences between the diabetes diary and information pack developed for adolescents and those available within adult diabetes services.
6. To evaluate the diabetes diaries and information pack within the context of routine diabetes care in relation to patient outcomes (diabetes-specific health-related quality-of-life, generic health-related quality-of-life, medicine and treatment concordance, acceptability, ease of use, and glycaemic control).
7. To identify gaps in knowledge to inform a future research agenda.

Plan of investigation

To meet our aim and objectives which are aligned with the phases of the MRC Framework for RCTs of complex interventions, we designed a four-stage study:

Stage 1

Review and, where appropriate, undertake further work to identify types/formats of information most likely to assist age-appropriate decision-making/choices related to children/young people with Type-1 diabetes.

Stage 2

Construct an exemplar information pack, piloting for variations as necessary.

Stage 3

Conduct a pragamatic evaluation to assess utility, acceptability effectiveness and cost effectiveness of the information pack.

Stage 4

Undertake data synthesis and comparative analysis.

Developing the information pack

In line with Department of Health guidance, we will use evidence-based principles to develop the information pack (25,26). There is increasing acknowledgement of the complexity and multifaceted nature of translation of evidence into practice which makes standardisation of information resources challenging (27). Little guidance exists concerning the development of age-appropriate health resources for children – thus, where appropriate, we will adapt and apply general best practice principles (26,28). In line with guidance on the development of information resources for 'lay' people, we will follow a systematic approach and start with a paper-based information pack, which has the potential to be adapted into other formats once the key health messages and content are agreed and its efficacy in routine clinical practice established (26). Where appropriate, we will liaise with the DH 'Information accreditation scheme', Diabetes UK, and Centre for Health Information Quality toolkits (29,30).

Theoretical framework for translation of evidence into practice

The Promoting Action on Research Implementation in Health Services (PARIHS) framework will be used as the framework to guide conduct of the evaluation (31,32). The framework has been theoretically and empirically developed to represent the interplay and interdependence of the many factors influencing implementation of evidence into practice. This is explained by a function of the relation between evidence, context and facilitation (33,34,35). The hypothesis offered is that for implementation of evidence to be successful there needs to be clarity about the nature of the evidence being used, the quality of context, and, the type of facilitation needed to ensure a successful process. The framework has been used by others to inform the design and evaluation of evidence into practice initiatives (36,37).

The framework is particularly relevant to this study because: 1. It aims to introduce a new information resource (evidence) into children's self-care regime and healthcare practice in order to improve blood glucose meter use and insulin management. Understanding the factors that influence its implementation and use will be important in determining the acceptability and feasibility of the information resource (facilitation) – this framework will provide a conceptual guide for mapping these issues. 2. Understanding how the information resource is used in different contexts where children/young people manage their diabetes will be key in the evaluation of its utility and contribution. Applying the framework will allow a focus on the key contextual variables mediating the implementation and use of the information resource. 3. It facilitates the gathering of individual (e.g. child/ practitioner/ carer) experiences as well as appreciating the fit with the broader context of care delivery.

Pragmatic evaluation of the information resource in routine clinical practice

We plan to undertake a pragmatic randomised controlled design and process evaluation to avoid bias and assess the size of effect, and ascertain the clinical and child-focussed effectiveness, cost-effectiveness, utility and appropriateness of an individually-tailored information resource concerning blood glucose monitoring and insulin management, compared with information resources (if any) currently available in routine clinical practice. The intervention group receives an individually-tailored child-centred information resource concerning blood glucose monitoring and insulin management; the control group continues to follow current standard practice.

Trial Governance

The evaluation will be supported by the North Wales Organisation for Randomised Trials in Health and Social care (NWORTH), part of the Clinical Research Collaboration Cymru, the Welsh component of UKCRC. Standard Operating Procedures will provide the management framework for the trial. An independent Trial Steering Committee and Data Monitoring Committee will provide oversight.

Sample size calculation

A systematic review provides sample size calculations for studies of educational interventions targeting psychological effects and glycaemic control (HbA_{1c}) for children with diabetes (24). They calculated a total of 130 randomised subjects in order to detect a 0.5 (medium) psychological effect size, with a power of 80% at the 0.05 significance level (assuming equal assignment in the two arms. They report that the effect size for psychological outcomes is more predictable with a median and mean of 0.38 and 0.35 respectively – therefore we will aim to recruit 100 children to each arm (200 total) to detect an effect size of 0.4. Allowing for a 10 percent drop out rate we calculated that we needed to recruit 252 children and young people. We employed a 2 : 1 randomization strategy and initially aimed to randomise 168 children and young people into the intervention arm and 84 children and young people into the non intervention arm, stratified by age, sex and length of time since diagnosis (< 2 years and > 2 years). NB. We reviewed our sample size calculations in April 2011 and, after consultation with our Data Monitoring and Ethics committee, applied for permission to extend our recruitment period and target sample to recruit up to 100 extra participants to counteract the effect of a higher dropout rate than was anticipated.

Outcomes

The information pack will be evaluated using multiple methods to capture facilitation, contextual and outcome data. In choosing appropriate outcome assessments, we are guided by comprehensive systematic reviews which recommend that HbA_{1c} is not the most appropriate primary outcome on which to assess the benefits of an intervention designed to more directly effect behaviour or self-management (5,24).

Our primary outcome measure will therefore be a measure of self-efficacy and diabetes health-related-quality-of-life (PedsQol). However, as interventions are integrated into clinical care – ongoing glycaemic assessment is essential as a secondary outcome.

Primary outcome: Diabetes health-related-quality-of-life and self-efficacy measured with Diabetes PedsQol module.

Secondary Outcomes: HbA_{1c} Generic health-related-quality-of-life (paediatric. EQ-5D/PedsQol) Blood glucose levels Frequency of administration of insulin and dose Frequency of severe hypoglycaemia Decision-making and self-management behaviour Utility/acceptability of information resource to children, parents, healthcare professionals Service utilisation and costs.

Economic Evaluation

Murphy et al (24) strongly recommend that cost-effectiveness is considered as an outcome as none of the studies in their review of psychoeducational interventions with adolescents addressed it. We will therefore weigh up the costs and consequences of the different interventions, (that involve information pack use) from an NHS perspective. NB – later changed to a cost utility analysis when the outcome of the trial became known.

Process Evaluation

Qualitative methods will be used to capture data relating to utility and acceptability, such as, concordance, age related decision-making and self-efficacy in using the information resource in different contexts. Capturing such information will facilitate a better understanding of the complexity, interdependence and interplay concerning the 'active ingredients' and implementation/facilitation in practice, and how the intervention and various components work for children/parents/professionals.

Methods

Stage 1. To examine and build on the existing evidence base

Systematic review

Building on completed systematic review findings from NIHR 08/1745/145 (38) to inform the proposed work the aim of the review was to determine the barriers to, and facilitators of, providing optimal care and management for children and young people with Type 1 diabetes within educational settings.

Objectives

1. To undertake a review of the effectiveness of interventions that are conducted within an educational setting that seek to improve the care and management of children and young people with Type 1 diabetes.
2. To explore the experiences of children and young people with Type 1 diabetes and those involved with their care and management in an educational setting.
3. To conduct an overarching synthesis of the first and second objectives to determine the extent to which interventions address the barriers identified by children, parents and teachers and build upon the facilitators for providing optimal care and management of children and young people with Type 1 diabetes in educational settings.

Review design

The review design and approach will be selected once an initial scoping exercise determines the type of evidence.

Integration and extension of critical discourse analysis of currently available childhood-diabetes information sources We will use completed NIHR 08/1745/145 critical discourse analysis findings to inform the current work and extend the scope to focus in-depth on childhood diabetes. We will explore management of childhood diabetes and focus on blood glucose monitoring and insulin management as a key exemplar concerning medicine management, self-care and concordance. We will also look specifically for similarities and differences in the discourses and philosophies underpinning children's/young peoples' and adult care pathways and management plans to see how and in what ways medicine management and self-care discourses/philosophies change at key stages across the lifespan. Information sources across all mediums and sectors (e.g. NHS, pharmaceutical) will be sought. This work will establish what sources of diabetes information are currently available to children/young people and their families. We would also wish to identify the underlying assumptions of the information sources and their main messages, and we will assess their applicability in terms of age, disability, ethnicity and sex, and for those children living away from their families. Analysis of the content will identify whether key messages match clinical guidance on childhood diabetes management (4).

Synthesis of integrated and extended contextual data to inform development of exemplar information pack and diabetes diaries Systematic review, discourse analysis findings and current evidence will be integrated using evidence-based principles and methods developed for synthesising diverse study designs within systematic reviews for public policy (39). Focusing on diabetes, we will devise matrices that juxtapose currently available information for children and their families, children's information needs as identified in their management plans and care pathways against the evidence concerning children's identified information needs and preferred information choices of children and their families, and benchmarked standards for the presentation of age-appropriate health messages to inform development of an exemplar information pack and diabetes diaries.

Stage 2. Development of the diabetes diaries and information pack with children/young people, key family members and healthcare professionals

In consultation with children and clinicians, we agreed to develop a range of age-appropriate diabetes diaries, housed within a wider diabetes information pack of currently available and quality assured information. We will use evidence from Stage 1 to develop the optimum age appropriate diabetes diaries and information packs to optimise blood glucose monitoring and insulin management. Our medical illustrator (Sharpe) will work with the research and advisory teams to incorporate evidence from phase one, and consult with children/young people and key family members to produce age and developmentally-appropriate illustrations to incorporate in the diabetes diaries.

Different versions of the diabetes diaries and information pack may need to be piloted to achieve optimal acceptability for different age groups of children, children whose first language is not English, those with disabilities, and those living away from home etc. We will explore the feasibility of facilitating the information pack and acceptability to children/young people and their families in various contexts and circumstances. We will also undertake interviews with healthcare professionals to develop/pilot facilitation processes within routine practice.

Sampling strategy to develop the diabetes diaries and information packs

Consultation with children/young people We will facilitate three age-appropriate focus groups (age 6–10, 11–14, 15–18 years) to develop/refine the diabetes diaries and information pack. Additionally, we will undertake up to 20 semi-structured interviews focusing on diabetes-specific information needs with children/young people and where appropriate key family members – specifically targeting those living away from home in boarding schools, youth offender institutions, looked-after, disabled and minority ethnic children. Participants will be recruited from defined geographical locations, via our own extensive networks for hard to reach populations, and the MCRN network. Whilst working within the Data Protection Act and the Roche 'Behaviour in Business Code' of practice, we may also consult with children/ young people via the Roche e-mail database to ascertain their views on various iterations of the information resource and if living within the defined geographical locations, where appropriate in accordance with our theoretical approach to sampling we may invite some children and young people to participate in a focus group or interview.

Consultation with professionals We will undertake semi-structured interviews with up to 20 healthcare professionals (nurses/doctors/pharmacists) drawn from fieldwork sites (number will depend on number of trial sites – we will interview a minimum of one professional per site – see trial recruitment below).

Defining control conditions in routine clinical practice

We will explore and define manualised 'standard practice'. This will entail unpacking what (if any) information types/formats children/young people and their families currently use and how it fits into their routine care. This will be translated into a manual of standard practice defining information resources used in routine practice by the control group.

Risk management/clinical governance

We are aware of the risk management and clinical governance procedures when developing individually-tailored information of this type. We will develop a specific clinical governance and risk management framework with clinicians (Lewis/Lowes/Gregory) to quality assure procedures and mitigate the risk of a child being given incorrect information.

Stage 3. Pragmatic evaluation

In an iterative approach, building on phases 1 and 2, we will fine-tune a pragmatic evaluation to test the information pack in routine clinical practice.

Setting: The information pack will be individually-tailored and introduced by nurses/doctors in children's diabetes clinics during routine visits.

Site preparation: We will hold a launch event and workshops to familiarise healthcare professionals with the information pack in each participating site.

Inclusion/Exclusion criteria: The inclusion criteria are children or young people aged between 6 and 18 years with Type 1 diabetes. The inclusion philosophy is to recruit willing children and young people where possible, and only exclude children or young people if being in the trial would be detrimental to their social, emotional or physical health. The exclusion criteria are: needle phobia, any significant social or emotional problems where such problems, in the opinion of the clinical team, are likely to impair a child's ability to take part in the trial, any significant physical or intellectual impairment which, in the opinion of the clinical team, is likely to impair a child's ability to take part in the trial, or an inability to communicate in an age-appropriate way in written and spoken English.

Trial Recruitment: We will continue collaborating with the MCRN to recruit children with diabetes (co-appplicants Brocklehurst – Chair, MCRN Clinical Studies Group, Gregory – links with Paediatric and Endocrinology Clinical Studies Group).

Randomisation: Children age 6–18years fulfilling the inclusion criteria (see trial protocol) and for whom appropriate consent(s) (proxy if appropriate) are obtained will be randomised using a randomisation service.

Facilitation of the information resource

Facilitation in practice will be shaped by the eventual design of the information pack – but we envisage that if randomised to receive the information pack, children will take their individually-tailored information pack home from clinic to use in their routine care. The child's diabetes team will facilitate its use and where appropriate parents will be provided with verbal and written guidance on supporting their child's use of the information resource.

Data collection

Children/young people (if appropriate with support of, or proxy report by parents) will complete a baseline questionnaire recording sociodemographic variables, patient characteristics, paediatric EQ-5D, Peds-Qol (generic, diabetes and parent versions), with follow-up questionnaires focusing on process and outcomes administered at 3 months and 6 months (including data on health service use, episodes of diabetic ketoacidosis, and all hospital admissions for acute complications). Non-responders will receive telephone/postal reminders after two and four weeks.

A sub-sample of 60 children/young people purposively sampled from baseline questionnaire respondents, will be invited to participate in a face-to-face interview, see below. Baseline and subsequent HbA_{1c} measurements, blood glucose meter use, readings and insulin dose will be taken from routine test results and hand-held records when attending routine 3–4 monthly clinic visits.

Data analysis

Initial descriptive statistics will analyse characteristics and demographics of the sample at baseline. We shall compare outcomes between the two groups by analysis of covariance to adjust for possible differences in baseline measurements. This will be repeated at 3 and 6 months comparing intervention and control groups. In addition, longitudinal analysis will consider any changes over time. These analyses will examine changes in the Quality of Life measures (paediatric EQ-5D, PedsQL generic and diabetes-specific health measures) over baseline, both using a pairwise comparison, studying change on individuals, and a cohort analysis comparing overall change in group means. Multiple regression analyses will be performed to identify factors which predict good outcomes within and between groups.

Economic cost utility analysis

The primary objective of the health economics analysis is, from an NHS perspective, to assess the cost-effectiveness of a child-centered, age-appropriate information pack intervention in the management of children and young people with Type 1 diabetes, alongside the EPIC randomised trial, as described in the EPIC published protocol. However, the RCT results reported showed no significant difference between intervention (EPIC pack) and control (treatment as usual) groups for the primary outcome measure of diabetes self-efficacy and quality-of-life (Diabetes PedsQL), or on the secondary outcome measures (HbA_{1c}, generic quality-of-life (General PedsQL) and generic health-related quality-of-life (EQ-5D)). Due to the absence of any statistically significant differences in any of the outcome measures, we report a cost consequence rather than a cost utility analysis.

The Client Service Receipt Inventory was adapted to record additional service use not already contained in the outcome questionnaire (40,41). All contacts with NHS services, (e.g. GP, nurse, pharmacist, doctor, in-patient and out-patients stays) and prescribing will be collected. Costs will be obtained from national sources (42). Activity will be collected for 6 months.

Qualitative interviews

As part of the process evaluation a representative sub-sample of 60 children/young people and key family members will be identified from baseline questionnaires and invited to participate in semi-structured interviews to gain in-depth understanding concerning, for example: Facilitation and use of the information resource, self-efficacy and self-management in different contexts, and decision-making processes – in particular how children/young people and parents 'self-prescribe' the correct (or incorrect) dose of insulin.

Process evaluation questionnaire

Healthcare professionals associated with the care of children/young people recruited to the trial will also be invited to complete a semi-structured questionnaire to determine acceptability and impact of the new information resource in practice.

Qualitative data analysis

Focus groups and interviews will be tape recorded and transcribed in full. Those undertaken to refine the information resource will feedback findings into the development process. The process analysis accompanying the subsequent evaluation will compare the experience of managing diabetes and insulin management and self-care processes between the intervention and control pathways. The predominantly deductive 'framework approach' will be used to categorise data based on the literature, the trial design, and the evaluation focus (43). The analysis process will be thematic and iterative.

Healthcare professional questionnaires

Data will be analysed using descriptive statistics and open ended questions subject to content analysis.

Data handling (quantitative and qualitative)

SPSS and Atlas Ti will be used for data handling.

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Appendix 2 Evidence supporting intervention development

Audit of all organisations and individuals contacted for diabetes information resourcing

Information source	Contact details
Charities	Diabetes UK
	JDRF
	Insulin Dependent Diabetes Trust
Insulin companies	Eli Lilly and Company
	Sanofi Aventis
	Novo Nordisk Ltd
	Medtronic Diabetes UK
	Animas Corporation
Glucose meter companies	Lifescan Ltd
	Roche/Accu-Chek
	BD Medical – Diabetes Care
	Abbott Diabetes Care Inc.
	Bayer HealthCare
NHS trusts	Abertawe Bro Morgannwg University NHS Trust (Singleton Hospital/Neath Port Talbot Hospital)
	Birmingham Children's Hospital NHS Foundation Trust
	Cambridge University Hospitals NHS Foundation Trust (Addenbrooke's Hospital)
	Cardiff and Vale NHS Trust (University Hospital of Wales)
	Central Area of North Wales NHS Trust (Glan Clwyd Hospital)
	Central Manchester University Hospitals NHS Foundation Trust (Manchester Children's Hospital)
	Great Ormond Street Hospital for Children NHS Foundation Trust
	Guy's and St Thomas' NHS Foundation Trust (Evelina Children's Hospital)
	Gwent Healthcare NHS Trust (Royal Gwent Hospital)
	Leeds Teaching Hospitals NHS Trust (St James's University Hospital)
	North East Wales NHS Trust (Wrexham Maelor Hospital)
	North West Wales NHS Trust (Bangor Hospital)
	Nottingham University Hospitals NHS Trust
	Royal Liverpool Children's NHS Trust
	Royal United Hospital Bath NHS Trust
	Salford Primary Care Trust
	Salisbury NHS Foundation Trust
	Sheffield Children's Hospital NHS Foundation Trust
	Stockport NHS Foundation Trust
	United Bristol Healthcare NHS Trust (Bristol Royal Infirmary)
	Waltham Forest Primary Care Trust
	Whipps Cross University Hospital NHS Trust
Non-UK charities/ organisations	American Diabetes Association
	Diabetes Australia
	Canadian Diabetes Association
	European Society for Paediatric Endocrinology

Diabetes information database

Information source	No. of pages	Size	Format	Title	Current, date of issue	Age range	Copy available
Diabetes UK	8	A4	Newsletter (quarterly)	*Tadpole Times*	Y, spring 2007	1	Y
Diabetes UK	12	A4	Newsletter (quarterly)	*On the Level*	Y, autumn 2008	2/3	Y
Diabetes UK	12	A4	Newsletter (quarterly)	*Link Up*	Y, spring 2007	P	Y
Diabetes UK	32	A4	Magazine	*Just for You*	Y, 2004/5	1	Y
Diabetes UK	64	A4	Magazine	*Go 4 It* (newly diagnosed information)	Y, 2004	2/3	Y
Diabetes UK	72	A4	Magazine	*Tots to Teens*	Y, 2007/8	P	Y
Diabetes UK	16	A5	Booklet	*Children with Diabetes in School*	Y, 2005	P	Y
Diabetes UK	20	A5	Booklet	*When your Child Has Diabetes – What Care to Expect*	Y, 2005	P	Y
Diabetes UK	N/A	N/A	Booklet	*When a Child with Diabetes Comes to Visit*	N, U/K	P	NA
Diabetes UK	N/A	N/A	DVD/booklet/leaflet	*Type 1 Diabetes: Journey of a Lifetime* – pilot starter pack of 2000 (newly diagnosed information)	Y, 2008	2/3	Y
Diabetes UK in conjunction with Epilepsy Action	N/A	N/A	Video	*Epilepsy and Diabetes: a Guide for Schools*	N, 2001	P	Y
JDRF (project group Cardiff University and University of West of England, supported by grant from Novo Nordisk)	20	A5	Booklet	*Teenage Diabetes. What Friends Need to Know*	Y, 2007	3	Y
JDRF	10	A5 gatefold	Leaflet	*A Child in your Care Has Type 1 Diabetes*	N, 2005	P	Y
JDRF	16	½ A5	Leaflet	*Your Child Has Diabetes*	N, 2005	P	Y
JDRF	8	A5 gatefold	Leaflet	*Diabetes Doesn't Rule*	N, 2005	3	Y
JDRF	8	A5	Leaflet	*Type 1 Diabetes: a New Diagnosis* (newly diagnosed information)	Y, 2008	P/3	Y
JDRF (pilot sponsored by Accu-Chek)	16	A5	Magazine	*T1*	Y, 2008	2	Y

Information source	No. of pages	Size	Format	Title	Current, date of issue	Age range	Copy available
JDRF International	16	A4	Magazine (quarterly)	*Countdown for kids* – pull-out section	Y, 2008	2/3	Y
JDRF (sponsored by Novo Nordisk)			CD-ROM	*Type 1 Diabetes with the JDRF Glucose Gang*	Y, 2008	2	Y
JDRF			Leaflets (out of production September 2008)	*JDRF . . . Because Insulin is Not a Cure*, *Managing and Monitoring your Blood Glucose*, *Diabetes and the Nervous System*, *What You Should Know about diabetes*, *Diabetes and Foot Care*, *Diabetes and your Heart*, *Diabetes and Pregnancy*, *Diabetes and Dental Care*, *Diet, Exercise and Diabetes*, *Diabetes and your Eyes*, *Diabetes and the Kidneys*	N, 2005	P	Y
JDRF			Type 1 reference folder in blue bag	New diagnosis pack with *TI* magazine, new diagnosis leaflet, Rufus bear with patches Pingu colouring book, cover letter, *JDRF Glucose Gang* DVD, *Diabetes Made Simple* (Novo Nordisk), JDRF newsletter (quarterly)	Y, 2008	1/2/3/P	Y
Eli Lilly (in conjunction with RCN)	6	A5	*Streetwise* collection of leaflets	*Sex and beyond with Diabetes* – 2008	Y, 2008–10	2/3	Y
	8			*Travelling with Diabetes* – 2010			
	6			*Hypos with Diabetes* – 2010			
	6			*Exercise with Diabetes* – 2010			
	6			*Drinking Safely with Diabetes* – 2010			
	6			*Sick Day Rules with Diabetes* – 2010			
	8			*Body Piercing and Tattoos with Diabetes* – 2010			
	4			*Top Tips for School with Diabetes* – 2010			
	6			*High Blood Glucose with Diabetes* – 2008			
	6			*Home Blood Glucose Testing with Diabetes* – 2008			
	6			*Feet with Diabetes* – 2010			
	6			*Emotional Wellbeing with Diabetes* – 2008			

Information source	No. of pages	Size	Format	Title	Current, date of issue	Age range	Copy available
Eli Lilly	38	B6	Booklet	*Hanging with Hu-Mee*	Y, 2007	1/P	Y
Eli Lilly	N/A	B6	Ring-bound booklet	Log book	Y, 2007	1/P	Y
Eli Lilly			CD-ROM	*All about Diabetes*	N, 1999	1	Y
Eli Lilly	48	B6	Booklet	*A Parent/Carer Guide. Bringing up a Child with Diabetes*	Y, 2007	P	Y
Eli Lilly	2	B6	Information card	*Looking after your Insulin Pen*	Y, 2007	1/2	Y
Eli Lilly	18	125 × 143 mm	Book	*Desmond Motor Gets Diabetes*	N, 1994	1	Y
Sanofi Aventis	52	A5	Booklet	*Joe's Rough Guide to Diabetes* (newly diagnosed information)	Y, 2006	3	Y
Sanofi Aventis	20	A5	Booklet	*What is a Hypo*	Y, 2008	3	Y
Novo Nordisk (written by C Pesterfield DSN, Addenbrooke's Hospital)	44	148 × 148 mm	Booklet	*Diabetes Made Simple*	Y, 2005	1	Y
Novo Nordisk (written by J Tuck RCN, Dorset County Hospital)	56	A5	Booklet	*Learning to Live with Diabetes* (newly diagnosed information)	N, 1998	1	Y
Sanofi Aventis	16	A5	Booklet	*Help with Hypos*	Y, 2006	3	Y
Sanofi Aventis (written by Dr P Swift and team at Leicester)	8	A5	Booklet	*Have Diabetes: Will Travel*	N, 1998	2/3/P	Y
Lifescan	2	½ A5	Leaflet	*Children; Helping your Child with Diabetes*	N, U/K	P	Y
Lifescan	N/A	N/A	Training kit	Ultrabox, with One Touch Meter	Y, 2008	1	Y
Lifescan	?	?	Leaflet	*From Glucose to Ganja*	N, U/K	3	Y
Roche/Accu-Chek	48	A5	Booklet	*Managing your Diabetes* (newly diagnosed information)	Y, 2005	1/2	Y
Roche/Accu-Chek	23	½ A5	Booklet	*Know the Score*	Y, 2004	3	Y

Information source	No. of pages	Size	Format	Title	Current, date of issue	Age range	Copy available
Roche/Accu-Chek	12	½ A5	Booklets (generic)	*Time to Test*	Y, 2004	3	Y
	12			*Get the Low Down on Hypos*			
	16			*Making the Jump to Insulin Pumps*			
	20			*What Do You Know about* HbA_{1c}			
	12			*Give your Fingertips a Rest from Testing*			
	16			*Taking the Sting out of Testing*			
	16			*The Inside Story on Diabetes*			
	16			*When Diabetes Gets You Down*			
	12			*Man Talk*			
Roche/Accu-Chek			Ring-bound flip chart	Diabetes information for nurseries, schools and colleges	Y, 2005	P	Y
Roche/Accu-Chek	20	A5	Booklet	*Managing your Diabetes*	Y, U/K	3	Y
BD Medical – Diabetes Care	36	A5	Booklet	*Getting Started with Diabetes* (newly diagnosed information)	Y, 2006	1/2	Y
BD Medical – Diabetes Care	1	A4	Certificate	Self-injection certificate and injection site guide	Y, 2006	1	Y
BD Medical – Diabetes Care	1	A5	Information card	Blood glucose monitoring chart	Y, 2006	1	Y
BD Medical – Diabetes Care	20	A5(L)	Booklet (generic)	*10 Questions about Lipodystrophy*	Y, 2005	3	Y
BD Medical – Diabetes Care	20	A5(L)	Booklet (generic)	*What You Need to Know about Lipodystrophy*	Y, 2005	3	Y
BD Medical – Diabetes Care	2	A5	Two-sided information card	*Hyperglycaemia/Hypoglycaemia*	Y, 2006	1/2	Y
BD Medical – Diabetes Care	2	A5	Information card (generic)	*Facts You Should Know about Needle Reuse*	Y, 2008	3	Y
BD Medical – Diabetes Care	6	A5	Leaflet (generic)	*Getting Away*	Y, 2008	3	Y
BD Medical – Diabetes Care	4	A5	Leaflet (generic)	*Sick Day Rules*	Y, 2008	3	Y

Information source	No. of pages	Size	Format	Title	Current, date of issue	Age range	Copy available
Abbott Diabetes Care	36	15 × 15 cm	Booklet	*Living with Diabetes – a Guide for Parents*	Y, U/K	P	Y
Abbott Diabetes Care	36	15 × 15 cm	Booklet	*Living with Diabetes – a Guide for Teenagers*	Y, 2008	3	Y
Abbott Diabetes Care	?	?	Booklet	*Ketones and Diabetes*	Y, U/K	3	N
Bayer HealthCare			New diabetes pack	Pocket size reference guide (2004), reward poster, Glucolog record diary, book with crayons – *Taking Diabetes to School*, cuddly toy (tiger), ketones urinalysis dipsticks	Y, 2008	1	Y
United Bristol Healthcare NHS Trust	4	A5	A4 sheet	*Sick Day Rules: Information for Parents*	Y, 2008	2/3/P	Y
	4	A5		*Sick Day Rules: Information for Teenagers*	Y, 2008		
	4	A5		*The Yearly Diabetes MOT Clinic*	Y, 2008		
	4	A5		*Holiday Plans*	Y, 2008		
	6	A4(G)		*The Diabetes Team*	Y, 2008		
	4	A5		*Taking Risks*	N, U/K		
	8	A5		*Guidelines for the Management of Children and Adolescents at First Presentation with Type 1 Diabetes Mellitus*	N, U/K		
	6	A4(G)		*Diabetes and your Periods*	U/K		
	1	A4		*Blood Sugar Testing Guidelines*	U/K		
	1	A4		*Exercise and Diabetes*	U/K		
	1	A4		*Night Time Hypos*	U/K		
	1	A4		*Guidelines for the Management of a Child with Insulin Dependent Diabetes (Child Aged 11–18 Years)*	U/K		
	12	A5		*Manage your Diabetes with Attitude and Exercise*	U/K		

Information source	No. of pages	Size	Format	Title	Current, date of issue	Age range	Copy available
United Bristol Healthcare NHS Trust (sponsored by Novo Nordisk)	24	A5	Booklet	*Type 1 Diabetes in the under 5s*	U/K	P	Y
Gwent Healthcare NHS Trust			Folder	*Diabetes. Eating Well and Keeping Active*	Y, 2004	2/3	Y
Gwent Healthcare NHS Trust	28	A5	Booklet	*Diabetes and Sport. Getting the Balance Right*	Y, 2008	2/3	Y
Gwent Healthcare NHS Trust	32	A5	Booklet	*Insulin, Food and Blood Glucose Monitoring Diary*	Y, 2007	2/3	Y
North East Wales NHS Trust	1	A4	Information sheet	*Sick Day Rules*	Y, 2008	2/3	
Stockport NHS Foundation Trust	8	A4	Leaflet	*Diabetes in Five Minutes – a Survival Guide to Going Home*	Y, 2008	2/3/P	Y
Leeds Teaching Hospitals NHS Trust		Print as A4	Information leaflets via website	www.leedsth.nhs.uk/sites/diabetes/	Y, U/K	2/3/P	Y
Birmingham Children's Hospital NHS Foundation Trust	16	A5	Booklet	*Diabetes and Me*	Y, U/K	1/2/3	Y
	2	A4		*MOT Clinic*			
	1	A4		*Foot Care*			
Waltham Forest Primary Care Trust and Whipps Cross University Hospital NHS Trust	16	A4	Leaflet	*From Home to Hospital*	Y, 2006	2/3	Y
Waltham Forest Primary Care Trust and Whipps Cross University Hospital NHS Trust	8	A4	Leaflet	*Type 2 Diabetes in Children and Young People*	Y, 2006	2/3	Y
Waltham Forest Primary Care Trust and Whipps Cross University Hospital NHS Trust	4	A5	Leaflet	*Blood Glucose Testing*	Y, 2006	2/3/P	Y

Information source	No. of pages	Size	Format	Title	Current, date of issue	Age range	Copy available
Royal Liverpool Children's NHS Trust	4	A4	Information sheet	*Dealing with Sick Days*	Y, 2007	2/3	
	3	A4		*Changing Insulin Doses Based on Blood Glucose Tests*			
	6	A4		*Hypoglycaemia*			
Salford Primary Care Trust	5	A4(G)	Gatefold leaflet	*Moving On – a Guide to Transferring to Adult Diabetes Services*	Y, 2008	3	Y
East Suffolk Diabetes User Group	16	A5	Booklet	*Diabetes Type 1*	Y, 2008	2/3	Y
Greater Glasgow and Clyde NHS Trust	45	A4	Information sheet	*Childhood Diabetes – a Guide*	Y, U/K	2/3/P	Y
Greater Glasgow and Clyde NHS Trust	6	A4	Booklet	*Travel and Holiday Information*	Y, 2005	2/3/P	Y
United Lincolnshire Hospitals NHS Trust	2	A4	Leaflet	*Changing to a Basal-Bolus Insulin Regime*	U/K	P	Y
United Lincolnshire Hospitals NHS Trust	2	A4	Leaflet	*Altering your Insulin*	U/K	P	Y
Derbyshire County Primary Care Trust	22	A5	Booklet	Learning disabilities booklet	Y, 2006	2/3	Y
Oxfordshire Children's Diabetes Service	10	A4	Leaflet	Diabetes clinic leaflet	Y, 2008	2/3/P	Y
Oxfordshire Children's Diabetes Service	15	A4	Leaflet	*The Basal Bolus Insulin Regimen for Newly Diagnosed Diabetes*	Y, 2008	2/3/P	Y
Oxfordshire Children's Diabetes Service	3	A4	Leaflet	*What is your* HbA_{1c}	Y, 2008	2/3/P	Y
Oxfordshire Children's Diabetes Service	4	A4	Leaflet	*The Problem with Families*	Y, 2008	P	Y
Oxfordshire Children's Diabetes Service	1	A4	Information sheet	*Blood Ketone Testing*	Y, 2008	2/3	Y

Information source	No. of pages	Size	Format	Title	Current, date of issue	Age range	Copy available
Oxfordshire Children's Diabetes Service	2	A4	Information sheet	*Sick Day Rules for Children with Diabetes*	Y, 2008	2/3	Y
Oxfordshire Children's Diabetes Service	2	A4	Information sheet	*Alcohol*	Y, 2008	2/3	Y
Oxfordshire Children's Diabetes Service	4	A4	Information sheet	*Diabetes Complications Explained*	Y, 2008	2/3	Y
Oxfordshire Children's Diabetes Service	3	A4	Information sheet	*Puberty*	Y, 2008	2/3	Y
West Suffolk Hospital NHS Trust	4	A4	Information sheet	*Golden Rules for Teenagers*	Y, 2007	2/3	Y
West Suffolk Hospital NHS Trust	4	A4	Information sheet	*Golden Rules for Children*	Y, 2007	1/P	Y
Royal United Hospital Bath NHS Trust and Wiltshire Primary Care Trust	39	A4	Information sheet	*Type 1 Diabetes – Information for Families*	Y, 2009	P	Y
Royal Surrey County Hospital NHS Trust	1	A4	Information sheet	*Driving with Diabetes*	Y, U/K	3	Y
Royal Surrey County Hospital NHS Trust	1	A4	Information sheet	*Patient Instructions for Giving Insulin Injections*	Y, U/K	2/3/P	Y
Royal Surrey County Hospital NHS Trust	2	A4	Information sheet	*Multiple Daily Injection Therapy*	Y, U/K	2/3/P	Y
Salisbury NHS Foundation Trust	63	A4	Information folder	Salisbury Child & Adolescent Diabetes Clinic information folder	Y, 2004	2/3/P	Y
NHS Tayside Diabetes Managed Clinical Network	1	A4	Information sheet	*What is Type 1 Diabetes*	Y, U/K	2/3/P	Y
NHS Tayside Diabetes Managed Clinical Network	2	A4	Information sheet	*Growing with Diabetes*	Y, U/K	2/3/P	Y
NHS Tayside Diabetes Managed Clinical Network	4	A4	Information sheet	*Information for Children with Diabetes and their Families*	Y, U/K	2/3/P	Y

Information source	No. of pages	Size	Format	Title	Current, date of issue	Age range	Copy available
University Hospitals of Leicester NHS Trust		Print as A4	Information leaflets via website	www.leicestershirediabetes.org.uk/	Y, U/K	2/3/P	Y
Patient information organisation – Patient UK	6	Print as A4	Information leaflets via website	*Type 1 Diabetes* – www.patient.co.uk/pdf/pilsL553.pdf	Y, U/K	P	Y
Better Health	2	Print as A4	Information leaflets via website	www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Diabetes_Type_1_or_juvenile_diabetes?open, www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Diabetes_issues_for_children_and_teenagers?OpenDocument	Y, U/K	P	Y
Medtronic in conjunction with Bayer HealthCare	48	16.5 cm^2	Hardback book and DVD	*Lenny Explains Diabetes*	Y, 2008	1/2/P	Y
MiniMed (now Medtronic)	57	A4	Spring-bound book	*Teens – Pumping it up* (2nd edition)	N, 1998	2/3	Y
Animas	16	A4	Information pack	*Animas® 2020. The Insulin Pump Made for Just One Kid. Yours* – includes *Hello. We're Animas*, *Get to Know the New Animas 2020 Insulin Pump*, Inset® 30 infusion set, *Improving Control* (JDRF information), *Let us Help You Get Away*, *There's a Whole New Way to Take Control of your Diabetes*	Y, 2007	3/P	Y
Roche/Accu-Chek			Information pack	Includes:	Y, 2005	3/P	Y
	36	A4		(a) *Take a New Path*			
	24	20 cm × 20 cm		(b) *The Insulin Pump that Grows with the Knowledge – Step by Step*			
				Making the Jump To Insulin Pumps			
				DVD – *Pump Therapy – a Personal Perspective*			
Diabetes UK	10	A4	Resource pack for under 5s	Downloadable from website – 10 information sheets related to diabetes and how to share that information with a preschool child	Y, 2009	1/P	Y

Information source	No. of pages	Size	Format	Title	Current, date of issue	Age range	Copy available
Diabetes Monitoring Forum			Information leaflets via website	www.dmforum.org.uk/, log-in details required to access booklets	Y, 2009	2/3/P	
Bournemouth Diabetes and Endocrine Centre			Information leaflets via website (carbohydrate counting information)	www.bdec-e-learning.com/, log-in details required to access booklets			
BD Medical – Diabetes Care	23	21 × 21 cm	Booklet	*Growing up with Diabetes*	Y, 2009	1/2	Y
BD Medical – Diabetes Care	24	21 × 27 cm	Booklet	*Living with Diabetes*	Y, 2009	3	Y
BD Medical – Diabetes Care	24	21 × 21 cm	Booklet	*Caring for a Child with Diabetes*	Y, 2009	P	Y
Diabetes UK – Scotland	62	A4	Booklet	*Making Connections*	Y, 2009	3	Y
Sanofi Aventis	26	A5	Booklet	*Ethan, Type 1 Diabetes and Adolescence*	Y, 2009	2	Y
Roche Accu-Chek			Leaflet	*Carbohydrate Awareness Guide*	Y, 2005	1/2/3	Y
Derby Hospital NHS Foundation Trust	42	A4	Leaflet	Derby hospital information pack	Y, 2009	1/2	Y
Medikidz	34	26 × 17 cm	Graphic book	*What's up with Ella? Medikidz Explains Type 1 Diabetes*	Y, 2010	1/2	Y
Roche Accu-Chek and Royal Devon & Exeter NHS Foundation Trust	12	½ A5	Leaflet	*Diabetes Information For Friends and Relatives of Children with Diabetes*	Y, 2007	P	Y
Bayer HealthCare	1	A4 folded	Leaflet	*Freedom: Around You*, *Studying and Diabetes*, *Travelling and Diabetes*, *Going out and Diabetes*, *Employment and Diabetes*, *Drugs and Diabetes*	Y, 2007	3	Y
Abbott Diabetes Care	22	15 × 15 cm	Booklet	*Living with Diabetes: a Guide for Parents*	Y, U/K	P	Y
Sanofi Aventis	8	½ A5	Booklet	*Going to Secondary School*	Y, 2009	2	Y

Information source	No. of pages	Size	Format	Title	Current, date of issue	Age range	Copy available
Sanofi Aventis	22	25 × 22 cm	Spiral-bound booklet	*I've got Diabetes Too. Living with Diabetes Kids Guide*	Y, 2009	1/2	Y
Sanofi Aventis	16	A4	Booklet	*The All Star Academy, Harry & Sophie's Puzzle and Fun Book*, reward chart	Y, 2009	1/2	Y
Bayer HealthCare	8	½ A5	Booklet	*Going to Secondary School*	Y, 2008	2	Y
Accu-Chek (and Jo Sutton, consultant dietician)	72	A4	Booklet	*Carbohydrate Counting Guide*	Y, 2004	P	Y
Sanofi Aventis	140	½ A5	Spiral-bound booklet	*My Diabetes Diary*	Y, 2009	1/2	Y
Bayer HealthCare	36	A4	Booklet	*Record Diary, Don't Get in a Muddle, Jot Down All your Meter Readings*	Y, 2008	1/2	Y
Roche/Accu-Chek	38	¼ A5	Booklet	*Diabetes Diary*	Y, 2007	1/2	Y
Novo Nordisk	32	½ A5	Booklet	*Home Monitoring Diary*	Y, 2008	3	Y
Medtronic	70	16 × 9 cm	Booklet	*Insulin Pump Daily Journal*	Y, 2006	3	Y
A.Menarini Diagnostics	22	15 × 10.5 cm	Booklet	*GlucoMen LX Log Book*	Y, U/K	Adult	Y
Bayer HealthCare	42	½ A5	Booklet	*Record Diary*	Y, 2009	Adult	Y
Lifescan	36	¼ A5	Booklet	Untitled	Y, U/K	Adult	Y
Home Diagnostics UK	20	17.5 × 10 cm	Booklet	*QuickTick Record Booklet*	Y, 2007	Adult	Y
Sanofi Aventis	64	½ A5	Booklet	*Home Monitoring Diary, Helping Make Sense of Diabetes*	Y, 2008	1/2/3	Y
Bayer HealthCare	24	½ A5	Booklet	*Record Diary, Don't Get in a Tangle, Keep Track of your Meter Readings*	Y, 2007	1/2	Y
MiniMed	60	18 × 12 cm	Spiral-bound booklet	*Carbohydrate Counting. A Primer for Insulin Pump Users to Zero in on Good Control*	Y, 1999	Adult	Y

Information source	No. of pages	Size	Format	Title	Current, date of issue	Age range	Copy available
Insulin Dependent Diabetes Trust	33	A5	Stapled booklet	*For Parents of Children with Diabetes*	Y, 2010	Adult	Y
British Society for Paediatric Endocrinology and Diabetes	7	A4	Self-print from internet	Average Readability Leaflet: *Diabetes Insipidus. Patients Guide*	Y, U/K	Adult	Y
British Society for Paediatric Endocrinology and Diabetes	7	A4	Self-print from internet	Easy Readability Leaflet: *Diabetes Insipidus. Patients Guide*	Y, U/K	Adult	Y
Lifescan	4	A4	Self-print from internet	*UltraMan* comic no. 1 – 'The Paper Chase'	Y, U/K	1/2	Y
Lifescan	4	A4	Self-print from internet	*UltraMan* comic no. 2 – In 'The Pirates Cave'	Y, U/K	1/2	Y
Dbaza.com			CD-ROM	*Diabetes Education for Kids* at www.dbaza.com/dek/index.html – US$40 through company website	U/K	1/2	N
Dbaza.com			CD-ROM	*Diabetes Education for Teens* at www.dbaza.com/ddet/index.html – US$40 through company website	U/K	2/3	N
Nasco Nutrition (www.enasco.com)			15-inch inflatable ball	Toss-up ball with 60 icebreaker questions!	U/K	2/3/P	N
Nasco Nutrition (www.enasco.com)			Video	*Diabetes: a Team Effort* – parents and kids talk about their feelings	U/K	?2/3/P	N

1, 6–10 years; 2, 11–16 years; 3, 16+ years; DSN, diabetes specialist nurse; HP, health professional; N, no; N/A, not available; P, parents/carers; RCN, Royal College of Nursing; U/K, unknown; Y, yes.

Resources: books

Author(s)	Title	Year of publication	Age range
Hanas	*Type 1 Diabetes in Children, Adolescents and Young Adults*, 3rd edn	2006	2/3/P
Hanas	*Type 1 Diabetes in Children, Adolescents and Young Adults: How to Become an Expert on your Own Diabetes*, 4th edn	2009	2/3/P
Llewellyn	*The Facts about Diabetes*	2001	1/2
Sönksen *et al.*	*Diabetes at your Fingertips*	1998	3/P
Mazur *et al.*	*The Dinosaur Tamer and Other Stories for Children with Diabetes*	1995	1/2
Loy and Loy	*Getting a Grip on Diabetes: Quick Tips and Techniques for Kids and Teens*, 2nd edn	2007	2/3
Powell	*Becky has Diabetes*	2004	1
McAuliffe	*Growing up with Diabetes: What Children Want their Parents to Know*	1998	P
Ward	*No Added Sugar: Growing up with Type 1 Diabetes*	2009	2/3
Besser	*Diabetes Through the Looking Glass: Seeing Diabetes from your Child's Perspective: A Book for Parents of Children with Diabetes*	2009	2/3/P

1, 6–10 years; 2, 11–16 years; 3, 16+ years; P, parents/carers.

Resources: websites

Date accessed	Source details	Website	Age range
2 March 2011	Diabetes UK	*My Life – Kids* – www.diabetes.org.uk/Guide-to-diabetes/My-life/Kids/	1
		My Life – Young Adults – www.diabetes.org.uk/MyLife-YoungAdults/	3
		My Life – Teens – www.diabetes.org.uk/Guide-to-diabetes/My-life/Teens/	2
2 March 2011	JDRF (UK)	*T1 Tinies* – www.jdrft1.org.uk/landing.asp?section=24&sectionTitle=Tinies±0%2D8	1
		T1 Tweens – www.jdrft1.org.uk/landing.asp?section=25&sectionTitle=T1±Tweens	2
		T1 Teens – www.jdrft1.org.uk/landing.asp?section=26&sectionTitle=Teens±13%2D16	3
2 March 2011	JDRF (USA)	*JDRF Kids Online* – http://kids.jdrf.org/	2/3
2 March 2011	CBBC Newsround	*Diabetes* – http://news.bbc.co.uk/cbbcnews/hi/find_out/guides/uk/diabetes/newsid_1679000/1679502.stm	2
2 March 2011	BBC	*Health – Diabetes* – www.bbc.co.uk/health/physical_health/conditions/in_depth/diabetes/	3/P
2 March 2011	Children with Diabetes	UK information section – www.childrenwithdiabetes.com/uk	P
2 March 2011	BD Medical – Diabetes Care	*Teenagers with Diabetes* – www.bd.com/uk/diabetes/page.aspx?cat=14152&id=31485	2/3
		Growing Up with Diabetes – www.bd.com/uk/diabetes/page.aspx?cat=14152&id=31494	1/2
		Caring for Children with Diabetes – www.bd.com/uk/diabetes/page.aspx?cat=14152&id=31503	P

Date accessed	Source details	Website	Age range
2 March 2011	Lifescan	*Parents and Kids* – www.lifescan.co.uk/parentskids	1/2
		UltraMan no. 1 – www.lifescan.co.uk/sites/default/files/pdf/Comicpirates-English.pdf	1/2
		UltraMan no. 2 – www.lifescan.co.uk/sites/default/files/pdf/Comic_English.pdf	1/2
2 March 2011	Roche/Accu-Chek	*Kids – What is Diabetes?* – http://kids.accu-chek.co.uk/kids/kids/what-is-diabetes.html	1/2
		Parents – Further Information for Parents – http://kids.accu-chek.co.uk/kids/parents/overview.html#	P
2 March 2011	Novo Nordisk	*For Children* – www.novonordisk.com/diabetes/public/diabetestools/forkids/default.asp	2/3
		For Parents – www.novonordisk.com/diabetes/public/diabetestools/forparents/default.asp	P
2 March 2011	Abbott Diabetes Care	*Young Adults* – www.abbottdiabetescare.co.uk/young-adults	3
		Parents – www.abbottdiabetescare.co.uk/parents-and-kids	P
2 March 2011	Bayer HealthCare	*Helping your Child Ages 3–9* – www.bayerdiabetes.co.uk/sites/aroundu/ages_3–9/index.aspx	P/1/2
		Your Diabetes (10–14) – www.bayerdiabetes.co.uk/sites/aroundu/ages_10–14/index.aspx	2
		Moving Forward (14+) – www.bayerdiabetes.co.uk/sites/aroundu/ages_15/index.aspx	3
2 March 2011	kidshealth.org	*Diabetes Center* – http://kidshealth.org/kid/centers/diabetes_center.html	2
2 March 2011	teenshealth.org	*Diabetes Center* – http://teenshealth.org/teen/diseases_conditions/growth/diabetes_center.html	2/3
2 March 2011	youthhealthtalk.org	*Diabetes Type 1* – www.youthhealthtalk.org/Diabetes_type_1_in_young_people/	2/3
2 March 2011	GrandmaSandy.com	www.grandmasandy.com/index.html	1
2 March 2011	INPUT	*Kids & pumps* – www.input.me.uk/kids-pumps/	2/3/P
2 March 2011	Insulin Pumpers UK	*Current Information on Pump Use in the UK* – www.insulin-pumpers.org.uk/ukissues/	P
2 March 2011	Animas Insulin Pumps (UK)	www.animascorp.co.uk/animas-testimonials.aspx	1/2/3/P
2 March 2011	Deltec Cosmo Insulin pumps (USA)	www.cozmore.com/	–
2 March 2011	Medtronic Insulin Pumps (UK)	www.medtronic-diabetes.co.uk	–
2 March 2011	Accu-Chek Insulin Pumps (UK)	www.accu-chek.co.uk/gb/products/insulinpumps/index.html	–
2 March 2011	Insulin Dependant Diabetes Trust	*Parents and Family* – www.iddtinternational.org/?page_id=1007	1/2/3/P
2 March 2011	Diabetes Australia	*myD for under 25s* – www.ndss.com.au/myD	3
2 March 2011	Diabetes Australia	Website for kids and teens with type 1 diabetes – www.diabeteskidsandteens.com.au/dealingwithd.html	P/1/2/3
2 March 2011	Canadian Diabetes	*Diabetes and You – Youth* – www.diabetes.ca/diabetes-and-you/youth/diagnosis/	P

Date accessed	Source details	Website	Age range
2 March 2011	American Diabetes Association	*Living with Diabetes – For Parents and Kids* – www.diabetes.org/living-with-diabetes/parents-and-kids/	P
		Planet D – www.diabetes.org/living-with-diabetes/parents-and-kids/planet-d/	1/2/3
2 March 2011	Biomation	*The Diabetes Project Films* – http://biomation.blogspot.com/2007/09/diabetes-film.html	2/3
2 March 2011	Contact a Family	www.cafamily.org.uk/medicalinformation/conditions/azlistings/d24.html	P
2 March 2011	European Society for Paediatric Endocrinology	*Parents, Carers and Patients* – www.eurospe.org/patient/English/index.html	P
2 March 2011	Medikidz	*Medical Information for Kids* – www.medikidz.com	2/3
2 March 2011	Runsweet.com	Diabetes and sport – www.runsweet.com/ChildrenAndAdolescents.html	1/2/3/P
2 March 2011	Diabetes.co.uk	*Kids Section* – www.diabetes.co.uk/kids/index.html	1/2/P
1 June 2011	Insulin Dependent Diabetes Trust	www.iddtinternational.org	P
1 June 2011	International Diabetes Federation	www.idf.org/	P/HP
9 January 2012	Great Ormond Street Hospital for Children NHS Foundation Trust	*Living with Diabetes* – www.gosh.nhs.uk/children/general-health-advice/health-features/living-with-diabetes/?locale=en	1/2/3/P

1, 6–10 years, 2, 11–16 years, 3, 16+ years; HP, health professional; P, parents/carers.

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Discourse analysis contextual information

Diabetes UK

Diabetes UK produces magazines for children and young people.

> *1. Who or what prompted you to produce information specifically for children?*
>
> *The magazines (one for children and one for teens) and guides (one for children just diagnosed, one for teens just diagnosed) that [Diabetes UK] produce have been ongoing for a number of years, so I wasn't around when they first started and don't know what prompted them originally. I can talk about why we continue to produce them though.*
>
> *The short answer is, we want to ensure children and young people with diabetes know how to live with their condition in a way that will help them get the best out of life. (We also want this for adults with diabetes, and we have separate publications for them as well!)*
>
> *The information in the magazines and guides aims to help children and young people understand their condition, how to manage it and how to live normal life around it. The information is produced in a way that (hopefully!) engages with the audience appropriately both in terms of the design and in*

terms of giving them the information they want. For example, the children's publications includes lots of cartoons, puzzles, pictures, etc. and is quite text-light. The teen's publications is mostly illustrated with photographs, includes lots of real-life personal experiences from other teens with diabetes, has problem pages, contains a lot of information and covers typical teen issues alongside diabetes (such as smoking, drinking, drugs, relationships, sex, learning to drive, going to uni, getting jobs, moving out of home, etc., etc.).

There is also a supply/demand point of view. The magazines, although free, are only available on subscription and there are around 5,000 on the mailing list for each (the one for children and the one for teens). The introductory guides are bought through a catalogue. We print around 1 year's worth of stock at a time. When they run out, we update/tweak the guide and reprint another year of stock.

2. Did you need to consult anyone when actually producing the information (e.g. doctors, nurses, young people, children, parents)? If you did consult, it would be also helpful to know when you consulted (e.g. beforehand or perhaps also at the production stages)?

There is an internal team of Care Advisors at Diabetes UK who consist of various healthcare professionals. They are fully involved in producing the information advising on content, writing copy, and checking all the text after it's been edited but before it is designed for print.

Young people and teens are also involved in producing some of the copy for the children's magazines it's more a case of them sending in photographs with a bit of news about themselves (for example, they ran a kids marathon). For the teens magazine, teens themselves share their stories of life with diabetes and it's these interviews that make up a key part of the magazine (examples of recent features range from an interview with Harry Potter's stunt double in the latest film, who has diabetes, to an interview with a young ski-racing champion with diabetes who's winning lots of international events).

Each issue of both magazines also include a section asking for readers to email or write in to tell us their news and what they have to say. We don't get much feedback about the actual magazines though we usually just get people saying 'I'm doing this and thought you might like to include my story in the magazine'.

We don't really involve parents specifically in these publications, although they are welcome to feedback their views, too. And we have a separate magazine and an introductory guide specifically for parents/carers of children with diabetes.

Eli Lilly

Eli Lilly produced a series of written leaflets called *Streetwise*. These are aimed at young people with diabetes and cover a range of issues.

Who or what prompted you to produce information for children and young people?

Request for information comes from professionals. Lilly have links with the RCN Paediatric and Adolescent Diabetes Group and new leaflets produced and updated as and when requested by this group. Latest ones on 'tattoos and body piercing' and 'foot care' in response to perceived needs of teenagers/children.

Can you tell me a bit more about how they are produced and the consultation process?

Overhaul of *Streetwise* leaflets about 2 years ago (previous ones out of date – 'too 1980s'). Lilly liaise with the advertising agency who are asked to come up with a number of designs. These were then discussed by the RCN group. In relation to the latest leaflets, the group approved the words and helped make the final selection of designs – those that they felt would appeal to teenagers.

Children/teenagers not directly consulted by Lilly in the production of leaflets, although [name of correspondent at Lilly] felt that the team developing Lilly's latest (adult) range of patient information leaflets would have consulted directly with people with diabetes.

Novo Nordisk

Novo Nordisk produced a booklet for children called *Diabetes Made Simple: a Kid's Guide to Diabetes* (introducing the 'Novo Crew').

Who or what prompted you to produce information for children and young people?

We produce insulin for people with diabetes 1 and have produced information specifically for kids including *Diabetes Made Simple: a Kid's Guide* and *Diabetes, Attitudes, Wishes and Needs (DAWN)*. The follow up to DAWN will go live on the web in two weeks time.

We produced information because kids have different needs from adults. We are aware that we 'are in some respects not good enough' (discussion related to how it must be quite challenging to put high quality information together).

So in putting together the information you did consult?

Yes, historically this has been mainly paediatricians and diabetes specialist nurses.

What about children's voices?

No, however I have been in close contact with the Juvenile Diabetes Research Foundation who are involved with/in partnership with adolescents. So we have access to adolescents' and young people's views. For example, we know that some teenagers experience weight gain when they are say 15 years old (mentioned insulin as being an anabolic steroid); they adjust their insulin dose to just stay alive but not to put on weight. Then we have had reports – from diabetes specialist nurses – that a number of 19/21 year olds are going blind because they are not taking the correct dose of insulin. So we are very interested in teen communication as are the people at JDRF.

Information used within NHS trusts for children and young people with type 1 diabetes

Twenty-two paediatric diabetic specialist units were contacted in the following hospitals to determine what information they gave out to children and young people with T1D as part of their routine care.

Cardiff & Vale NHS Trust

Uses a lot of generic information as part of its children and adolescent information packs:

Managing your Diabetes (Roche)

Getting Started with Diabetes (BD Medical – Diabetes Care)

Hypoglycaemia/Hyperglycaemia (BD Medical – Diabetes Care)

Help with Hypos (Novo Nordisk)

Home Blood Glucose Testingwith Diabetes (*Streetwise*, Eli Lilly)

Sex and Beyond with Diabetes (*Streetwise*, Eli Lilly)

Body Piercing and Tattooswith Diabetes (*Streetwise*, Eli Lilly)

Travelling with Diabetes (*Streetwise*, Eli Lilly)

Exercise with Diabetes (*Streetwise*, Eli Lilly)

What is a Hypo (Sanofi Aventis)

United Bristol Healthcare NHS Trust

Uses generic information and also provides a range of in-house information leaflets:

Hypoglycaemia/Hyperglycaemia (BD Medical – Diabetes Care)

North Wales NHS Trust

Uses generic information and also provides several in-house information leaflets:

Hypoglycaemia/Hyperglycaemia (BD Medical – Diabetes Care)

Getting Started with Diabetes (BD Medical – Diabetes Care)

Managing your Diabetes (Roche)

Birmingham Children's Hospital NHS Foundation Trust

Streetwise collection (Eli Lilly)

Hu-mee collection (Eli Lilly)

Diabetes Made Simple (Novo Nordisk)

Abertawe Bro Morgannwg University Health Board

Getting Started with Diabetes (BD Medical – Diabetes Care)

Streetwise collection (Eli Lilly)

In house leaflets across the different NHS trusts

Sick day rules

Diabetes and your periods

General clinic information (yearly MOT)

Blood sugar testing guidelines

Exercise and diabetes

Night-time hypos

Manage your diabetes with attitude and exercise

Foot care

Information for schools

Appendix 3 Evidence supporting the systematic review

Summary table of reviews of children and young people with type 1 diabetes

Study and country	Type of review	Date range	Age group	No. of studies	Outcomes
Alsaleh *et al.* 2011[100] UK	Qualitative narrative review	1970–2009	Children (7–18 years), young people (18–23 years) and/or parents	6	Insulin pump therapy
[a]Armour *et al.* 2005[101] USA	Systematic review and meta-analysis	Database start–February 2003	≤ 18 years[b]	19 RCTs (in 28 publications)	Family interventions *Outcomes*: metabolic control, parent knowledge
Couch *et al.* 2008[102] Canada	Systematic review and meta-analysis	1982–March 2007	0–18 years	80 studies: 53 RCTs or CCTs, 27 observational studies	Diabetes education *Outcomes*: HbA_{1c}, health service utilisation, complications, skills, self-management/adherence, psychological outcomes, quality of life, school performance
Dean *et al.* 2011[103] UK	Systematic review	January 1980–June 2007	≤ 18 years	17 RCTs	Interventions to enhance medication adherence *Outcomes*: medication adherence
DeShazo *et al.* 2010[104] USA	Systematic and narrative review	August 2008	Children	9 manuscripts, 11 different video games	Educational video games *Outcomes*: self-management
Gage *et al.* 2004[105] UK	Narrative review	Database start–December 2002	9–21 years	62 studies: RCTs ($n = 26$), non-randomised/wait list control ($n = 7$), pre–post no control ($n = 24$), case study ($n = 1$), other ($n = 4$)	Educational and psychosocial interventions *Outcomes*: self-management, behavioural change, metabolic control, utilisation effects, cost-effectiveness
Golicki *et al.* 2008[106] Poland	Systematic review	1966–2007	Children	5 papers, RCTs	Continuous glucose monitoring system *Outcomes*: HbA_{1c}

Study and country	Type of review	Date range	Age group	No. of studies	Outcomes
Grey *et al.* 2000[107] USA	Integrative literature review	1980–1 January 1999	Children, families	41 papers on empirical research	Educational, psychological or family interventions *Outcomes*: none predefined
Hampson *et al.* 2000[108] Hampson *et al.* 2001[7] UK	Systematic review and narrative review (Gage *et al.*[105])	Database start–end June 1999	9–21 years	62 studies reported across 64 papers: RCTS ($n = 25$, 41.9%), pre–post designs with no control group ($n = 21$, 33.9%), studies using non-randomised control groups (9.1%), post intervention only (4.6%), wait list control group (1.6%), case studies (1.6%), other (6.5%)	Educational and psychosocial interventions *Outcomes*: self-management, behavioural change, metabolic control, utilisation effects, cost-effectiveness
Hill-Briggs and Gemmell 2007[109] USA	Systematic review	1990–present	Adults ($n = 21$), children/young people ($n = 21$)	52 studies: quantitative ($n = 36$), conceptual or qualitative ($n = 16$)	Problem-solving as a process or strategy for diabetes self-management *Outcomes*: behavioural change, metabolic control
Kelo *et al.* 2011[73] Finland	Intergrative review	January 1998–August 2010	School-aged children (mean age between 6 and 12 years)	22 articles: quantitative ($n = 12$), qualitative ($n = 9$), mixed methods ($n = 1$)	Self-care *Outcomes*: goals of self-care, content of self-care (knowledge, skills), factors related to diabetes self-care (characteristics of the child, illnesses and self-care, support)
[a]Krishna and Boren 2008[110] USA	Systematic review	1966–2007	Children ($n = 6$), adults	20 articles representing 18 studies	Cell phone interventions *Outcomes*: health outcomes, processes of care
Kucera and Sullivan 2011[111] USA	Review	Not stated	Children or adolescents aged < 18 years	15 articles for cognitive effects (3 review papers, 2 meta-analyses), 7 articles for academic effects (1 review)	Educational implications *Outcomes*: cognitive effects, academic effects

Study and country	Type of review	Date range	Age group	No. of studies	Outcomes
Lawson 2007[112] USA	Narrative review	Earliest 1999–latest 2003	Not stated	6 papers on empirical research	Supporting family health *Outcomes*: none predefined
Murphy *et al.* 2006[97] UK	Systematic review and effect size calculations	January 1999–January 2005 (updated Hampson *et al.*[7])	Children 5–11 years, young people 12–18 years	24 interventions across 27 papers: RCTs ($n = 13$), non-RCTs ($n = 9$), wait list control ($n = 1$), retrospective analysis ($n = 1$)	Educational and psychosocial interventions *Outcomes*: none predefined
[a]Nichols and Norris 2002[113] USA	Systematic review	January 1966–May 2001	School personnel	4 studies: pre–post intervention assessment ($n = 3$), cohort with comparison group ($n = 1$)	Effectiveness of educating school personnel
Northam *et al.* 2005[3] Australia	Integrative literature review	1985–2003	Children, adolescents	14 papers : RCTs ($n = 10$), non-RCT ($n = 1$), uncontrolled ($n = 1$), random assignment to intervention or waiting list ($n = 1$), pre–post intervention assessment ($n = 1$)	Behavioural and psychosocial intervention *Outcomes*: metabolic control
Savage *et al.* 2010[114] Ireland	Systematic review	2004–8	Children, adolescents up to 19 years	29 papers, 14 RCTs	Educational, psychological family interventions *Outcomes*: science of intervention development
Spencer *et al.* 2010[115] UK	Integrative literature review	1988–2008	Adolescents 13–16 years	20 qualitative studies (in 28 publications)	Casual factors of deteriorating metabolic control *Factors*: no factors predefined
[a]Sutcliffe *et al.* 2011[116] UK	Systematic review and narrative	January 1980–May 2009	≤ 25 years	19 papers: RCTs ($n = 9$), randomised cross-over ($n = 1$), case series ($n = 2$), case Studies ($n = 2$), observational ($n = 4$), qualitative ($n = 1$)	Communication technologies *Outcomes*: metabolic control, behavioural change, self-management, psychosocial, cost, frequency of contact
Tolbert 2009[98] USA	Integrative literature review	Within last 6 years	School students	11 studies	Care of students at school and interventions to improve care within a school setting *Outcomes*: all

Study and country	Type of review	Date range	Age group	No. of studies	Outcomes
Urban *et al.* 2004[117] USA	Systematic review	January 1986–November 2003	Adolescents and/or their families	29 studies	Educational and psychosocial interventions *Outcomes*: knowledge, competence, metabolic control
Winkley *et al.* 2006[118] UK	Systematic review and meta-analysis	Databases – not stated; conference proceedings 1997–2004	Children, adolescents, adults	16 RCTs children and adolescents, 13 RCTs adults	Psychological interventions *Outcomes*: glycaemic control
Wodrich *et al.* 2010[99] USA	Narrative review	1960s (1), 1970s (2), 1980s (9), 1990s (15), 2000s (22)	Children, adolescents, < 20 years	49 studies	T1D and school *Outcomes*: school attendance, peer relations at school, classroom behaviour and psychosocial status, cognitive functioning and classroom attention, levels of school achievement, teachers awareness of diabetes, on campus nurses as resource, educational/legal rights afforded to students with T1D
Wysocki 2006[119] USA	Narrative review	Not stated	Children, adolescents	Not stated	Behavioural and intervention methods

CCT, controlled clinical trial.

a Studies included in the review were of T1D and T2D.

b Adults included within some studies.

Search terms presented within the SPICE framework

Quantitative review of the strategies and/or interventions that are conducted within an educational setting that seek to improve the care of children and young people with type 1 diabetes

Setting	Population	Intervention and phenomenon of interest	Comparison	Evaluation
Educational setting in any country 12th/twelfth grade 6th/sixth grade College Diabetes Camp Institute Junior High Kindergarden Kindergarten Nursery Polytechnic Pre School School School Camp Summer camp University	Children/young people with type 1 diabetes, 3–18 years preschool or education, 18–30 years in higher education *School-aged children* P*diatric Child$ Adolescen$ Young person$ Young people Young patients Young women Young men Young adult$ Youngsters Youth Year old$ Teen$ years of age juvenile pube$ adult {and type 1 and/, ages 16, 17, 18) *Condition* Diabetes Diabetes Mellitus	All interventions to promote optimal management of diabetes in school settings: educational, psychosocial, medical, nursing, psychotherapeutic Secondary issues to include programme theory and service delivery	Any comparison of interest including usual care	*Blood glucose monitoring* Glyc*mic control Blood glucose monitoring Blood glucose levels Self monitoring blood glucose Blood glucose testing BG Metabolic glyc*mic control Glucose control SMBG Self monitoring Self regulation Metabolic control Blood sugars Hypos Hyperglyc*mia Low blood sugar Hyperglyaemia High blood sugar *HbA*$_{1c}$ Glycos*lated H*moglobin Glycated H*mogloblin GHb H*moglobin A1c HbA1$_{c}$

Setting	Population	Intervention and phenomenon of interest	Comparison	Evaluation
	Diabetes Mellitus, Type 1 Diabetic Diabetic patients Diabetic control Type 1 or type l DM IDDM Insulin dependent diabetes mellitus Sudden onset diabetes mellitus Auto immune diabetes mellitus insulin deficient diabetes mellitus Diabetes insipidus Early diabetes mellitus Labile diabetes mellitus T1D Juvenile diabetes			Auto controlling gly*emia *Insulin management* Insulin injections Insulin sensitivity Insulin adjustment Insulin replacement Hypoglycemic Agents Dietary behaviour Nutrition Eating patterns Eating behavio*r Carbohydrates Carbs CHO Snacks Snacking Carbohydrate Counting Carb Counting

SMBG, self-monioring of blood glucose.

Qualitative synthesis of the facilitators of and barriers to managing type 1 diabetes within an educational setting for children and young people with type 1 diabetes and those involved with their care

Setting	Perspective/people	Issues of interest	Comparison	Evaluation
Educational setting in any country 12th/twelfth grade 6th/sixth grade College Diabetes Camp Institute Junior High Kindergarden Kindergarten Nursery Polytechnic Pre School School School Camp Summer camp University	Children/young people with type 1 diabetes, 3–18 years preschool or formal education, 18–30 years post-compulsory education *School-aged children* P*diatric Child$ Adolescen$ Young person$ Young people Young patients Young women Young men Young adult$ Youngsters Youth Year old$ Teen$ years of age juvenile pube$ adult {and type 1 and/, ages 16, 17, 18) *Condition* Diabetes Diabetes Mellitus Diabetes Mellitus, Type 1 Diabetic Diabetic patients Diabetic control	*Facilitators of/barriers to*: Problems/support Knowledge of Attitudes to Experiences of Training of staff Compliance Behaviours Knowledge Attitudes Needs Perceptions Concerns Practices Expectations	*Compare children with parents/ professionals* Family Families Siblings Brothers Sisters Parents Mother Father Grandparents Peers School Nurses School Staff Teachers School Psychologists School Counsellors School Nurses School Health Professionals School personnel School Administrators Coaches Teaching assistants Learning support assistant/LSA	*Management* Patient care management Management skills Self-management behaviours Self-management Self-care Care Self-efficacy Self Regualt$ Self monitor$ Self manage$ Self Adheren$ *Medical Management* *Health care routines* *Health related quality of life*

Setting	Perspective/people	Issues of interest	Comparison	Evaluation
	Type 1 or type I			
	DM			
	IDDM			
	Insulin dependent diabetes mellitus			
	Sudden onset diabetes mellitus			
	Auto immune diabetes mellitus			
	insulin deficient diabetes mellitus			
	Diabetes insipidus			
	Early diabetes mellitus			
	Labile diabetes mellitus			
	T1D			
	Juvenile Diabetes			

Search strategies

PsycINFO

Searched 27 June 2011

1. university.m_titl. (13,278)
2. Schools/ (16,489)
3. school$.m_titl. (82,027)
4. institute.m_titl. (1757)
5. nurser$.ti,ab. (3759)
6. kindergarden.ti,ab. (22)
7. kindergarten.ti,ab. (10,465)
8. polytechnic.ti,ab. (198)
9. college.ti. (29,473)
10. (high adj1 school).ti,ab. (41,051)
11. (junior adj1 high).ti,ab. (4859)
12. (pre adj1 school).ti,ab. (2015)
13. pre-school.ti,ab. (1977)
14. grade.ti,ab. (55,400)
15. (educational adj1 establishments).ti,ab. (35)
16. (educational adj1 setting$).ti,ab. (2540)
17. (tertiary adj1 education).ti,ab. (232)
18. (further adj1 education).ti,ab. (743)
19. (higher adj1 education).ti,ab. (10,222)
20. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 (214,647)
21. diabetes.ti,ab. (12,090)

22. diabetic.ti,ab. (3175)
23. DM.ti,ab. (1140)
24. IDDM.ti,ab. (231)
25. T1DM.ti,ab. (48)
26. exp Diabetes/ (8011)
27. 21 or 22 or 23 or 24 or 25 or 26 (14,303)
28. p*diatric.ti,ab. (13,680)
29. child$.ti,ab. (445,255)
30. adolescen$.ti,ab. (135,127)
31. toddler$.ti,ab. (4745)
32. youth.ti,ab. (40,168)
33. teen$.ti,ab. (12,694)
34. youngster$.ti,ab. (2709)
35. juvenile.ti,ab. (15,300)
36. pubert$.ti,ab. (4710)
37. (young adj1 adult).ti,ab. (6028)
38. (young adj1 person).ti,ab. (585)
39. (young adj1 men).ti,ab. (2866)
40. (young adj1 patients).ti,ab. (782)
41. (young adj1 women).ti,ab. (4003)
42. (young adj1 people).ti,ab. (12,719)
43. (years adj2 age).ti,ab. (21,208)
44. (years adj1 old).ti,ab. (10,513)
45. student$.ti,ab. (311,485)
46. exp Students/ (159,324)
47. 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 (867,923)
48. 20 and 27 and 47 (176)
49. limit 48 to (english language and yr='1996 -Current') (129)

MEDLINE

Searched 27 June 2011

1. exp Universities/ (11,972)
2. university.m_titl. (13,947)
3. Schools/ (9353)
4. school$.m_titl. (26,302)
5. exp Academies/ and Institutes/ (5107)
6. institute.m_titl. (5335)
7. exp Nurseries/ (428)
8. nurser$.ti,ab. (3045)
9. kindergarden.ti,ab. (6)
10. kindergarten.ti,ab. (1452)
11. polytechnic.ti,ab. (111)
12. college.ti. (8807)
13. (high adj1 school).ti,ab. (8789)
14. (junior adj1 high).ti,ab. (841)
15. (pre adj1 school).ti,ab. (1395)
16. pre-school.ti,ab. (1386)
17. grade.ti,ab. (112,920)
18. (educational adj1 establishments).ti,ab. (90)
19. (educational adj1 setting$).ti,ab. (455)
20. (tertiary adj1 education).ti,ab. (207)

21. (further adj1 education).ti,ab. (737)
22. (higher adj1 education).ti,ab. (3312)
23. 1 or 2 or 3 or 4 or 6 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 (186,008)
24. exp Child, Preschool/ or exp Child/ (590,330)
25. exp Adolescent/ (657,111)
26. p*diatric.ti,ab. (99,491)
27. child$.ti,ab. (418,384)
28. adolescen$.ti,ab. (85,797)
29. toddler$.ti,ab. (3123)
30. youth.ti,ab. (17,622)
31. teen$.ti,ab. (10,697)
32. youngster$.ti,ab. (946)
33. juvenile.ti,ab. (23,704)
34. pubert$.ti,ab. (12,807)
35. (young adj1 adult).ti,ab. (9037)
36. (young adj1 person).ti,ab. (315)
37. (young adj1 men).ti,ab. (4897)
38. (young adj1 patients).ti,ab. (8286)
39. (young adj1 women).ti,ab. (8137)
40. (young adj1 people).ti,ab. (8241)
41. (years adj2 age).ti,ab. (119,312)
42. (years adj1 old).ti,ab. (48,860)
43. student$.ti,ab. (82,596)
44. exp Students/ (39,373)
45. 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 (1,247,090)
46. diabetes.ti,ab. (164,726)
47. diabetic.ti,ab. (77,850)
48. DM.ti,ab. (14,606)
49. IDDM.ti,ab. (2982)
50. exp Diabetes Mellitus, Type 1/ (29,286)
51. T1DM.ti,ab. (983)
52. 46 or 47 or 48 or 49 or 50 or 51 (206,968)
53. 23 and 45 and 52 (1022)
54. limit 53 to (english language and yr='1996 -Current') (895)

EMBASE

Searched 30 June 2011

1. diabetes.ti. (92,066)
2. diabetic.ti. (46,247)
3. DM.ti. (768)
4. "IDDM".ti. (834)
5. "T1DM".ti. (100)
6. exp Diabetes Mellitus, Type 1/ (40,086)
7. 1 or 2 or 3 or 4 or 5 or 6 (149,700)
8. exp Universities/ (26,143)
9. university.m_titl. (19,207)
10. Schools/ (18,169)
11. school$.m_titl. (32,110)
12. "Academies and Institutes"/ (53,716)
13. institute.m_titl. (6921)

14. exp Nurseries/ (881)
15. nurser$.ti,ab. (3759)
16. kindergarden.ti,ab. (17)
17. kindergarten.ti,ab. (1776)
18. polytechnic.ti,ab. (176)
19. college.ti. (11,327)
20. (high adj1 school).ti,ab. (10,906)
21. (junior adj1 high).ti,ab. (1085)
22. (pre adj1 school).ti,ab. (1853)
23. pre-school.ti,ab. (1839)
24. grade.ti,ab. (154,584)
25. (educational adj1 establishments).ti,ab. (97)
26. (educational adj1 setting$).ti,ab. (554)
27. (tertiary adj1 education).ti,ab. (289)
28. (further adj1 education).ti,ab. (1105)
29. (higher adj1 education).ti,ab. (4232)
30. 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 (315,581)
31. exp Child, Preschool/ or exp Child/ (694,676)
32. exp Adolescent/ (563,727)
33. p*diatric.ti,ab. (140,180)
34. child$.ti,ab. (545,202)
35. adolescen$.ti,ab. (112,076)
36. toddler$.ti,ab. (3951)
37. youth.ti,ab. (21,500)
38. teen$.ti,ab. (13,801)
39. youngster$.ti,ab. (1277)
40. juvenile.ti,ab. (29,147)
41. pubert$.ti,ab. (16,218)
42. (young adj1 adult).ti,ab. (10,993)
43. (young adj1 person).ti,ab. (476)
44. (young adj1 men).ti,ab. (5852)
45. (young adj1 patients).ti,ab. (11,379)
46. (young adj1 women).ti,ab. (10,420)
47. (young adj1 people).ti,ab. (11,099)
48. (years adj2 age).ti,ab. (158,078)
49. (years adj1 old).ti,ab. (74,490)
50. student$.ti,ab. (104,941)
51. exp Students/ (33,446)
52. 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 (1,441,506)
53. 7 and 30 and 52 (726)
54. limit 53 to (english language and yr="1996 -Current") (641)

British Nursing Index

Searched 26 June 2011

1. exp Children/ (2055)
2. exp Adolescents/ (2186)
3. p*diatric.ti,ab. (2013)
4. child$.ti,ab. (14,207)
5. adolescen$.ti,ab. (2457)
6. toddler$.ti,ab. (109)

7. youth.ti,ab. (256)
8. teen$.ti,ab. (936)
9. youngster$.ti,ab. (9)
10. juvenile.ti,ab. (64)
11. pubert$.ti,ab. (39)
12. (young adj1 adult).ti,ab. (59)
13. (young adj1 person).ti,ab. (18)
14. (young adj1 men).ti,ab. (54)
15. (young adj1 patients).ti,ab. (24)
16. (young adj1 women).ti,ab. (119)
17. (young adj1 people).ti,ab. (1333)
18. (years adj2 age).ti,ab. (88)
19. (years adj1 old).ti,ab. (94)
20. student$.ti,ab. (6485)
21. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 (24576)
22. university.m_titl. (280)
23. Schools/ (609)
24. school$.m_titl. (1585)
25. institute.m_titl. (64)
26. nurser$.ti,ab. (126)
27. kindergarden.ti,ab. (0)
28. kindergarten.ti,ab. (5)
29. polytechnic.ti,ab. (14)
30. college.ti. (189)
31. (high adj1 school).ti,ab. (78)
32. (junior adj1 high).ti,ab. (1)
33. (pre adj1 school).ti,ab. (118)
34. pre-school.ti,ab. (118)
35. grade.ti,ab. (163)
36. (educational adj1 establishments).ti,ab. (4)
37. (educational adj1 setting$).ti,ab. (15)
38. (tertiary adj1 education).ti,ab. (3)
39. (further adj1 education).ti,ab. (34)
40. (higher adj1 education).ti,ab. (291)
41. 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 (3323)
42. diabetes.ti,ab. (3687)
43. diabetic.ti,ab. (993)
44. DM.ti,ab. (2)
45. IDDM.ti,ab. (5)
46. T1DM.ti,ab. (0)
47. exp Diabetes/ (2802)
48. 42 or 43 or 44 or 45 or 46 or 47 (4441)
49. 21 and 41 and 48 (27)
50. limit 49 to yr="1996 -Current" (27)

EPIC screening tool

Author: ______________________________ Year: ___________ Reviewer__________

Types of participants
Children / Young People with Type 1 Diabetes ☐
Those involved with care (school staff, school nurses, parents, siblings etc ☐

Setting
3- 18 years pre school or education ☐
18 – 30 in higher education ☐

Issues of Interest
Diabetes care and/or management ☐

Methods
Qualitative ☐
Mixed-methods ☐
Quantitative ☐

Experimental ________________________________

Descriptive ________________________________

Other ________________________________

Intervention or Issue of Interest
____
____
____

Types of outcome measures

Blood Glucose Monitoring ☐

Insulin Management ☐

Quality-of-life ☐

Dietary Behaviour ☐

HbA1c………… ☐

____ ☐

____ ☐

____ ☐

____

To appraise☐ **Exclude**☐ **Seek Further Info**☐

Comments

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Studies excluded from the review

Study	Reason for exclusion
Aanstoot 2009[272]	Educational article not an empirical study, objectives and discussion of the DAWN project
Ahern 1999[273]	Paper unavailable
Anderson 2009[274]	Educational article not an empirical study, psychosocial care for young people with diabetes – DAWN project
Bachman 2000[275]	Not specific to T1D, SchoolhealthLnk – survey of health priorities
Bratina 2010[276]	Descriptive article with no evaluation, description of educational programme for professional caregivers and teachers for children on pumps and continuous blood glucose monitors
Chisholm 2003[277]	School issues not primary focus of research, one item within research instrument not specifically reported on
Cullen 2009[278]	Educational article not an empirical study, food choice in schools
Dalton 2001[279]	Descriptive article no evaluation, school clinics for adolescents – description of service
Edge 2009[280]	Educational article not an empirical study, insulin injections at school
Engelke 2009[281]	Not specific to T1D, case management by school nurses – generic
Evert 2005[282]	Position statement on management in school setting
Evert 2008[283]	Educational article not an empirical study, managing hypoglycaemia in the school setting
Gallivan 2003[284]	Educational article not an empirical study, resources for school nurses/school guide
Gallivan 2005[285]	Educational article not an empirical study, resources for school nurses
Gallivan 2008[286]	Educational article not an empirical study, resources/tips for school nurses
Gallivan 2009[287]	Paper unavailable
Gallivan 2010[288]	Paper unavailable
Greene 2009[289]	Educational article not an empirical study, views of young people on health professionals – DAWN project
Hill 2007[214]	Educational article not an empirical study, development of children's diabetes services for schools at one hospital
Hull 2008[290]	Descriptive article with no evaluation, school nurses – continuing education programme course content
Jameson 2004[210]	Educational article not an empirical study, school nurses – tips/resources
Lange 2009[291]	Beyond scope, summary of all findings of the DAWN project
Lorenz 2003[292]	Educational article not an empirical study, medical management of diabetes in schools
Lorenz 2005[293]	Educational article not an empirical study, medical management needs at school
Lyford 2003[294]	Educational article not an empirical study, diabetes training for schools
Malasanos 2005[295]	Descriptive article with no evaluation, Florida Initiative in Telehealth and Education – remote blood glucose monitoring
Mandali 2009[296]	Educational article not an empirical study, diabetes management in schools
Marschilok 2008[297]	Educational article not an empirical study, management of T1D and T2D in school
Matyka 2010[298]	Educational article not an empirical study, different perspectives of managing diabetes in school
Mellinger 2003[137]	Educational article not an empirical study, diabetes in college students
Olson 2004[299]	Not specific to T1D, school professionals' perceptions of the impact of chronic illness in the classroom
Owens-Gary 2010[300]	Paper unavailable

Study	Reason for exclusion
Patrick 2007[301]	Educational article not an empirical study, diabetes management in schools
Peregrin 2002[302]	Educational article not an empirical study, diabetes curriculum for schools
Radjenovic 2001[303]	Beyond scope, undergraduate teaching students, measured knowledge, comparing computer-based with paper-based training
Rapone 1997[304]	Educational article not an empirical study, description of a school health-care plan
Reading 2005[305]	Educational article not an empirical study, managing medication in schools
Silverstein 2009[306]	Educational article not an empirical study, description of available resources for school nurses
Strachan 2010[134]	Educational article not an empirical study, case study of the death of a university student with T1D
Strawhacker 2001[307]	Educational article not an empirical study, management of T1D – role of school health office
Sullivan 2000[308]	Beyond scope, Professions Allied to Medicine students acting as diabetes coaches
Taras 2009[309]	Educational article not an empirical study, who should administer insulin in school
Thornton 2009[310]	Educational article not an empirical study, role of the school nurse

Findings of intervention studies conducted with children and young people with type 1 diabetes

Izquierdo *et al.* 2009,[146] USA, RCT – two arms

Aim: to test the feasibility and effectiveness of telemedicine to improve the care of children with T1D in schools

HbA_{1c}

HbA_{1c} values decreased in the telemedicine cohort ($p < 0.02$) and the improvement was maintained over the next few months. No significant differences in slopes or within-group slopes were observed after the 6-month time point (the beginning of the summer vacation)

Urgent encounters

Urgent visits to the school nurse for diabetes-related problems and urgent calls to the diabetes centre decreased significantly over time in the telemedicine cohort but not in the usual care group (*p*-value not reported).

Hospitalisations and emergency department visits

There were fewer hospitalisations and emergency department visits in the telemedicine intervention group than in the usual care group (not tested)

Diabetes quality of life

Treatment 1 dimension – assesses the extent to which children experience pain during finger prick or insulin injections, embarrassment about having diabetes, arguments about patient care and difficulty complying with their diabetes plan. There was significant improvement at 12 months on this dimension for the telemedicine group ($p = 0.039$)

Treatment 2 dimension – assesses the extent to which children experience difficulty with taking blood glucose tests, taking insulin injections, exercising, tracking carbohydrates/exchanges, wearing their medical alert bracelet, carrying a fast-acting carbohydrate or eating snacks. There were significant improvements at 6 months for children in the telemedicine group ($p = 0.017$). Usual care showed no significant change during this time but at 12 months the usual care group had improved significantly ($p = 0.29$) and the telemedicine participants remained at levels similar to those at the 6-month time point

Generic quality of life

Physical functioning: improved in usual care group at 6 months ($p = 0.14$) and was maintained at 12 months

Emotional functioning: improved in telemedicine group at 6 months but no further change by 12 months, whereas in the usual care group participants showed an improvement between month 6 and month 12 ($p = 0.034$)

Nguyen *et al.* 2008,[145] USA, RCT – two arms

Aim: to determine whether school nurse supervision of glucose measurement and insulin dose adjustment would lead to improvement in HbA_{1c} levels in paediatric patients with poorly controlled T1D

HbA_{1c}

At the end of the 3-month study period HbA_{1c} levels remained unchanged in the control group but were decreased significantly in the intervention group ($p < 0.0001$)

Engelke *et al.* 2008,[148] USA, before-and-after study

Aim: To implement and evaluate a school-based case management programme for children with chronic illnesses

Quality of life

Quality of life overall: baseline: 65.48 (SD 13.5), end of year: 69.41 (SD 11.9); this was reported as a percentage change of 6%. There was a statistically significant improvement in the treatment barrier subscale ($p = 0.01$, eta-squared = 0.19); this was reported as a percentage change of 18.3%

Percentage meeting goals

The degree of achievement of goals set for each child was examined. Nurses were more successful in achieving goals that were under their control. Percentage of children meeting achievement goals: decrease in episodes of hypoglycaemia (65%), decrease in episodes of hyperglycaemia (54%), HbA_{1c} value of < 7% (27%), teacher/staff complete diabetes management training (100%)

Faro *et al.* 2005,[150] USA, before-and-after study

Aim: to conduct periodic diabetes care visits in school with the goal of promoting optimal management of diabetes for high-risk youth

Self-efficacy

No statistically significant differences were seen between pre-intervention and post-intervention mean scores on the Self-Efficacy for Diabetes tool. Neither were statistically significant differences seen between pre-intervention and post-intervention self-care practices, parent satisfaction with school care, HbA_{1c} levels, family knowledge and competence in diabetes management or frequency of hospitalisation or emergency department visits. Despite the lack of statistically significant outcomes, some encouraging trends were seen. In particular, blood glucose monitoring at home increased and the frequency of insulin administration at school doubled. The need for an intensification of insulin regimens was demonstrated by increased blood glucose monitoring and insulin adjustments in response to documented need. The researcher felt that, had the study been extended for another school year and the sample size been larger, a stronger outcome might have been achieved

Wdowik *et al.* 2000,[155] USA, controlled trial

Aim: to develop and evaluate 'Control on Campus' for college students with T1D

Knowledge

Knowledge was improved as a direct result of the intervention and was maintained at follow-up. Scores in the treatment group increased significantly ($p < 0.001$) from 66.3% (SD 3.4%) correct at pre test to 90.5% (SD 3.4%) correct at post test. Treatment group scores at 3 months' follow-up were 82.1% (SD 3.4%) and remained significantly higher than pre-test scores ($p < 0.001$)

HbA_{1c}

A higher percentage of treatment group participants (91%) than of control group participants (40%) knew their recent HbA_{1c} results ($p = 0.003$). Within the treatment group the change in the number of students knowing their HbA_{1c} result at pre test vs. follow-up was significant ($p = 0.005$)

Attitudes/beliefs

The expanded health belief model consists of 10 constructs and at pre test the mean scores were initially high for both treatment and control groups. The only attitudinal construct that appeared to change over time was the social influence construct. The mean score for the treatment group increased significantly ($p < 0.05$) from 4.1 (SD 0.1) at pre test to 4.5 (SD 0.1) at follow-up

On-campus support

Question: 'I feel support on campus for my diabetes': treatment group participants had significantly higher scores (76%, $p < 0.01$) than control group participants (30%)

Blood glucose monitoring

Question: 'I don't test my blood sugar as often as I should because I am afraid of what I will find': improvement for treatment group participants with 38% showing a decrease in score; control group participants had no decrease in score ($p < 0.05$)

Behaviours

Question: 'In the past week, I tested my blood sugar': mean scores improved for the treatment group from 4.2 (SD 0.3) at pre test to 4.5 (SD 0.3) at follow-up ($p < 0.05$); scores did not change for the control group

Question: 'In the past week I followed my prescribed insulin regime': mean score remained high for the treatment group [4.8 (SD 0.1) at pre test and 4.9 (SD 0.1) at follow-up] but declined from pre test to follow-up for the control group [from 4.9 (SD 0.1) to 4.6 (SD 0.1)] ($p < 0.05$)

Findings of intervention studies conducted with school personnel

Husband *et al.* 2001,[147] Canada, RCT – two arms

Aim: to determine whether a CD-ROM teaching tool increases teachers' diabetes knowledge and confidence

Knowledge of diabetes

There was no significant difference in pre-test scores between the control group and the experimental group for total knowledge. The post-test scores increased for both groups but this was not significant

Knowledge of hypoglycaemia

There was no significant difference in pre-test scores between the control group and the experimental group for hypoglycaemia knowledge. The post-test scores increased for both groups but this was not significant

Confidence

There was no significant difference in confidence pre-test scores between the control group and the experimental group. The post-test confidence scores increased significantly in the experimental group only ($p < 0.016$)

Siminerio and Koerbel 2000,[149] USA, before-and-after study

Aim: to assess diabetes knowledge and needs of school personnel and to determine the effectiveness of the '5 Cs of Diabetes' programme

Knowledge

Overall pre-test score [mean (SD)] was 75 (11.0); post-test score was 94 (4.1). Participants showed a statistically significant ($p < 0.004$) improvement in overall knowledge scores.

Percentages answering with correct answers to pre-test questions:

1. Sugar is essential for the brain to function: 88%

2. The American Disabilities Act includes children with diabetes: 60%

3. A major concern for the school child with diabetes is the likelihood of developing: 79%

4. A sign of high blood sugar in a child with diabetes may be: 53%

5. A low blood sugar requires: 88%

6. A general rule for treatment of low blood sugar: 95%

7. Children with diabetes need to miss more school days: 92%

8. Glucagon is: 64%

9. Schools can ask parents to waive liability: 77%

10. Children with diabetes should be reprimanded if seen eating a candy bar: 75%

Open-ended responses

The most frequent concerns about having a child with diabetes in the classroom related to having enough knowledge regarding signs and symptoms of high and low blood sugar; being able to recognise and properly treat hypoglycaemia; the lack of preparedness of other school personnel, e.g. substitutes, aides, bus drivers and coaches

Cunningham and Wodrich 2006,[152] USA, analogue experiment (allocated)

Aim: To examine the effect of providing teachers with varying levels of information about T1D

Confidence

Teachers' mean confidence was similar across no disease information, basic disease information and basic disease information + classroom implications (11.93. SD 2.53, 11.59, SD 2.71 and 11.26, SD 3.67 respectively). There was no support for the prospect of enhanced confidence in accommodating a student's needs based on teachers receiving greater information. Years of teaching experience did not improve the model, indicating that years of teaching experience is not a significant covariate influencing the relationship between increased information and generation of disease-specific accommodations. In total, 95% of the sample indicated that they would desire more information and/or assistance about how to better accommodate the learning needs of a student with T1D (there was no difference between the different T1D information levels). In total, 93% would seek additional information from a school nurse, 90% from the student's parents, 60% from the student, 58% from an experienced fellow teacher, 53% from the student's physician, 43% from a special education director or teacher, 34% from a school counsellor and 32% from a school psychologist

Wodrich 2005,[151] USA, analogue experiment (random assignment)

Aim: to investigate the effects of disclosing information about T1D with implications for classroom learning and behaviour

Confidence

The more knowledge that teachers have about the consequences in the classroom of chronic health conditions the more confident they will be in attributing behaviour to chronic conditions ($?^2 = 10.0$, $p = 0.007$, Cramer's $V = 0.38$)

Bullock *et al* 2002,[153] USA, cohort study

Aim: to determine whether attendance at specific continuing education programmes increased the competence of school nurses

In total, 91% reported that the education programme would enhance their ability to manage students with diabetes

Bachman and Hsueh 2008,[154] USA, programme evaluation

Aim: to develop and evaluate an online continuing education programme to educate school nurses in how to manage care in schools for children with diabetes using current practice principles outlined in *Helping the Student with Diabetes Succeed: a Guide for School Personnel*[129]

Perceived competence

Those school nurses who had enrolled and completed the course reported a statistically significant higher level of perceived competence (mean 1.54) than those who had not participated (mean 1.87, $p = 0.0001$)

Study characteristics for non-intervention studies: stream 2

Study, country and aims	Sampling and sample characteristics
Children and parents	
Nabors *et al.* 2003[161], USA To assess children's and young adolescents' perceptions of supportive behaviour by nurses, teachers and friends that allows them to improve their diabetes management at school	105 children recruited at day and summer camps (RR not specified) Age: mean 10 years 11 months (SD 2 years 2 months), range 6 years to 14 years 6 months Sex: female 43% Social class: NS Ethnicity: Caucasian 94%, African American 6% Insulin regime: NS Educational establishment: NS Duration of diabetes: 4 years 4 months to 11 years
Bodas *et al.* 2008,[164] Spain To improve awareness of the needs within school settings of children and adolescents with T1D based on information provided by the students	414 children recruited at summer camps (RR not specified) Age: target range 6–16 years Sex: female 51% Social class: NS Ethnicity: NS Insulin regime: NS Educational establishment: primary school 47%, middle school 48%, high school 5% Duration of diabetes: NS
Peters *et al.* 2008,[158] USA To examine diabetes-related teacher victimisation, the association between teacher victimisation, adherence and metabolic control, and whether these relations differ between children and adolescents	167 children recruited from a paediatric clinic of a major university (RR not specified) Age: mean 12.8 years (SD 2.5 years), target range 8–17 years Sex: female 64% Social class: NS Ethnicity: white 80.2%, African American 13.8%, Hispanic 2.6%, other 2.4% Insulin regime: excluded if they used a pump or if serious psychopathology in the child or parent Educational establishment: NS Duration of diabetes: at least 1 year

Study, country and aims	Sampling and sample characteristics
Lehmkuhl and Nabors 2008,[160] USA To assess children's perceptions of their satisfaction with and support from school nurses, teachers and friends in their classrooms as well as the types of support they needed from each group	58 children recruited at summer camps (RR not specified) Age: mean 11.5 years (SD 1.0 years), target range 8–14 years Sex: female 47% Social class: NS Ethnicity: Caucasian 100% Insulin regime: NS Educational establishment: NS Duration of diabetes: mean 6.7 years (SD 2.9 years), range 1–11 years
Tang and Ariyawansa 2007,[175] UK To identify the difficulties that young people with diabetes may encounter while at school	11 children (55% RR) and 11 parents (55% RR) recruited from diabetes clinic Age: target range 12–16 years Sex: NS Social class: NS Ethnicity: NS Insulin regime: NS Educational setting: secondary 100% Duration of diabetes: diagnosed under the age of 10 years ($n=8$)
Wang *et al.* 2010,[157] Taiwan To obtain an initial understanding of school-based lived experiences of adolescents with T1D	Two recruited (RR not specified): one female (age 14 years), injections three times a day, diagnosed for 1 year; one male (age 15 years), pump, diagnosed for 6 years
Newbould *et al.* 2007,[180] UK To examine the experiences and concerns of young people and their parents in relation to the management of medication for asthma or diabetes whilst at school	26 children (30% RR) and 26 parents (30% RR) recruited from GP practices Age: mean 11.7 years, target range 8–15 years Sex: female 54% Social class: homeowners 81% Ethnicity: white 100% Insulin regime: NS Educational setting: primary $n=12$, lower (5–8 years) $n=1$, secondary $n=13$ Duration of diabetes: mean 4.8 years

Study, country and aims	Sampling and sample characteristics
MacArthur 1996,[163] UK To examine the practice and attitudes of local children who were taking pre-lunch insulin injections at school	15 children recruited from diabetes clinic (88% RR) Age: target range 10–16 years Sex: NS Social class: NS Ethnicity: NS Insulin regime: pre-lunch injections at school Educational establishment: secondary $n = 11$ Duration of diabetes (years): NS
Clay *et al.* 2008,[179] USA To examine problems with medication administration in school	75 children (41% RR) and 75 parents (41% RR) recruited at routine clinic appointments Age: mean 13.3 years (SD 2.8 years), target range 8–18 years Sex: female 31% Social class: NS Ethnicity: NS Insulin regime: NS Educational establishment: kindergarten–3rd grade 11%, 4th–6th grade 25%, 7th–8th grade 23%, 9th–12th grade 41% Duration of diabetes: NS
Schwartz *et al.* 2010,[178] USA To evaluate the experiences of children and adolescents with T1D in school	80 children (62% RR) and 80 parents (62% RR) recruited from University Medical Associates Diabetes/Endocrine Center Age: target range 5–12 years Sex: NS Social class: NS Ethnicity: NS Insulin regime: NS Educational establishment: Kindergarten–12th grade Duration of diabetes: NS
Hema *et al.* 2009,[162] USA To investigate the daily stressors and coping responses of children and adolescents with T1D	52 recruited from summer camp (RR not specified) Age: mean 13.02 years (SD 2.66 years), target range 8–18 years (8–12 years, $n = 19$; 13–18 years, $n = 33$) Sex: female 65% Social class: NS Ethnicity: Caucasian 96%, other (NS) Insulin regime: NS Educational establishment: NS Duration of diabetes: 4.78 years (SD 3.46 years)

Study, country and aims	Sampling and sample characteristics
Peyrot 2009,[174] Brazil, Denmark, Germany, Italy, Japan, the Netherlands, Spain, USA To gain an understanding of the challenges and issues facing young people with diabetes and those with responsibility	1905 children (RR not specified) and 4099 parents (RR not specified) recruited Part of the DAWN Youth WebTalk Study. Age: mean 21.3 years (SD 2.4 years), target range 18–25 years; mean 10.5 years (SD 4.2 years), target range 0–16 Sex: female 60%; 50% Social class: NS Ethnicity: NS Insulin regime: NS (T1D: 94.1%, 98.1%) Educational establishment: NS Duration of diabetes: age at diagnosis: 12.2 years ± 2.3 years; 6.3 years ± 3.9 years
Carroll and Marrero 2006,[159] USA To explore how diabetes influences adolescents' perceptions of quality of life in general and their relationships with parents, peers, school and their physician	31 children recruited from physicians' offices (RR not specified) Age: mean 14.9 years, target range 13–18 years; 13–14 years: 45%; 15–16 years: 35%; 17–18 years: 20% Sex: female 42% Ethnicity: white 90%, African American 10% Educational establishment: NS Insulin regime: injections 52%, pump 48% Duration of diabetes: mean 6.6 years, range 6–14 years; 0–3 years: 26%, 3–6 years: 29%, 6–9 years: 16%, ≥ 10 years: 29%
Waller *et al.* 2005,[181] UK To seek the views of children and adolescents with T1D and their parents regarding the acceptability and design of a new diabetes education programme called the Dose Adjustment for Normal Eating programme	24 children (27% RR) and 29 parents (31% RR) recruited from diabetes clinic lists Age: mean 13.07 years (SD 1.59 years), target range 11–16 years Sex: female 50% Social class: NS Ethnicity: NS Insulin regime: injections 100% Educational establishment: NS Duration of diabetes: diagnosed for at least 1 year

Study, country and aims	Sampling and sample characteristics
Hayes-Bohn *et al.* 2004,[176] USA Diabetes care at school from the perspective of adolescents with T1D and their parents	30 children and 30 parents recruited from outpatient department (RRs not specified) Age: mean 17.3 years, target range 13–20 years Sex: female 100% Social class: NS Ethnicity: Caucasian 84%, African American 13%, Hispanic 3% Insulin regime: NS Educational establishment: NS Duration of diabetes: inclusion criteria diagnosed > 1 year, average 7.7 years (SD 4.1 years)
Wagner *et al.* 2006,[182] USA To investigate the relationships between perceived school experiences, diabetes control and quality of life	58 children (48% RR) and 58 parents (48% RR) recruited from summer camp Age: mean 12 years (SD 1.9 years), target range 8–15 years Sex: female 55% Social class: NS Ethnicity*:* European American 98% Insulin regime*:* pump or MDI 100% Educational setting: public schools 90% Duration of diabetes: mean 5.3 years (SD 3.1 years)
Amillategui *et al.* 2009,[177] Spain To identify the special needs of children with T1D at primary school, taking into account the perceptions reported by parents, children and teachers	152 children[a] (35% RR) and 167 parents[b] (39% RR) recruited from the paediatric unit of nine public hospitals Age: mean 10.68 years (SD 1.92 years), target range 6–13 years (6–9 years: 29%, 10–13 years: 71%)[a]; mean 10.37 years (SD 2.15 years), target range 6–13 years (6–9 years: 35%, 10–13 years: 65%)[b] Sex: female 48%[a], 50%[b] Social class: NS[a,b] Ethnicity: NS[a,b] Insulin regime: NS[a,b] Educational establishment: primary (100%)[a,b] Duration of diabetes: mean 4.25 years (SD 2.90 years); < 3 years: 33%, 3–6 years: 45%, > 6 years: 22%[a]; NS[b]

Study, country and aims	Sampling and sample characteristics
Barnard *et al.* 2008,[173] UK To identify key components of quality of life and assess the impact of insulin pump therapy on children/adolescents with T1D and their parents	15 children (14% RR) and 17 parents (15% RR) recruited from those registered on the Roche Diagnostics insulin pump user customer database Age: mean 12.07 years (SD 2.71 years), target range 9–17 years Sex: NS Social class: NS Ethnicity: NS Insulin regime: pump 100% Educational establishment: NS Duration of diabetes: mean 6.67 years (SD 2.42 years), range 2–12 years
Low *et al.* 2005,[172] USA To explore psychosocial issues related to insulin pump use (CSII) in youth aged between 11 and 18 years	18 children (57% RR) and 21 parents (57% RR) recruited through diabetes camps and a regional paediatric endocrinology practice Age: mean 13.9 years (SD 2.2 years), target range 11–18 years Sex: female 50% Social class: family income (US$): 0–25,000: 4.4%, 25,000–50,000: 11.1%, 50,000–75,000: 33.3%, > 75,000: 50% Ethnicity: Caucasian 100% Insulin regime: pump 100% Educational establishment: NS Duration of diabetes: mean 6.1 years (SD 2.5 years)
Wilson and Beskine 2007,[167] UK To examine how children with diabetes are managing their condition in the school setting using pump therapy and MDIs	73 parents recruited via a survey on the UK Children with Diabetes website (64% RR) Age: < 5 years: 11%, 5–11 years: 55%, > 12 years: 34% Sex: female 59% Social class: NS Ethnicity: NS Insulin regime: pump 60%, MDI 40% Educational establishment: NS Duration of diabetes: NS

Study, country and aims	Sampling and sample characteristics
Amillategui *et al.* 2007,[166] Spain To identify the special needs of children with T1D in schools from parents	499 parents recruited from one paediatric outpatient clinic (RR not specified) Age: target range 3–8 years; 3–6 years: 12%, 7–10 years: 26%, 11–14 years: 38%, 15–18 years: 24% Sex: female 45% Social class: NS Ethnicity: NS Insulin regime: NS Educational establishment: NS Duration of diabetes: NS
Pinelli *et al.* 2011,[171] Italy To determine how Italian parents and school personnel of 6- to 13-year-old children with T1D manage during school hours, including for insulin administration, management of hypoglycaemia and glucagon use	220 parents recruited from 15 diabetes units (100% RR) Age: mean 10 years, target range 8–13 years Sex: female 41% Social class: NS Ethnicity: NS Insulin regime: NS Educational establishment: elementary 65.6%, middle 46% Duration of diabetes: mean 5 years, range 1–12 years
Hellems and Clarke 2007,[169] USA To determine which school personnel currently assist students with insulin administration and management of hypoglycaemia and whether these students are being cared for in a safe manner	185 parents recruited from diabetes clinics (RR not specified) Age: target range 5–18 years Sex: NS Social class: NS Ethnicity: NS Insulin regime: NS Educational establishment: elementary: $n = 58$, middle: $n = 60$, high: $n = 67$ Duration of diabetes: NS
Jacquez *et al.* 2008,[168] USA To investigate parent reports of the diabetes care support their children receive in school, their concerns and knowledge about diabetes management in school and their knowledge of federal laws that protect children with diabetes	309 parents recruited from two outpatient diabetes clinics (92% RR) Age: mean 11.83 years (SD 3.70 years), target range 4–19 years Sex: NS Social class: mean Hollingshead socioeconomic status score 40.94 (SD 10.47) Ethnicity: Hispanic white 61%, non-Hispanic white 19%, African/Caribbean American 19%, other 1%

Study, country and aims	Sampling and sample characteristics
	Insulin regime: T1D: pump 29%, injections 71%; T2D: injections 38%, oral medication 62% Educational establishment: NS Duration of diabetes: 4.37 years (SD 3.62 years)
Lewis *et al.* 2003,[170] USA To identify obstacles to good control of diabetes in the school setting and document the level of support available in various school districts serving the clinic patient population	47 parents recruited from diabetes clinic (RR not specified) Age: NS Sex: NS Social class: NS Ethnicity: NS Insulin regime: NS Educational establishment: elementary 40.4%, middle 29.8%, high 29.8% Duration of diabetes: NS
Yu *et al.* 2000,[165] USA To characterise the academic and social experiences of children with diabetes	66 parents recruited from paediatric endocrinology unit (RR not specified) *Early onset – diagnosed at* $\leq$ *5 years (n = 31)* Age: mean 12.7 years Sex: female 52% Social class: NS Ethnicity: white 94% Insulin regime: NS Educational establishment: NS Duration of diabetes: mean 9.7 years *Late onset – diagnosed at > 5 years (n = 35)* Age: mean 12.6 years Sex: female 51% Social class: NS Ethnicity: white 97% Insulin regime: NS Educational establishment: NS Duration of diabetes: mean 4.2 years

Study, country and aims	Sampling and sample characteristics
Lin *et al.* 2008,[94] Taiwan To explore the essential structure of mothers' life experience when helping their first- to third-grade children with T1D make adjustments at school	12 mothers recruited from children's day clinic (RR not specified) Age: mean 8.4 years, range 7.3–9.2 years Sex: female 67% Social class: NS Ethnicity: NS Insulin regime: injections 100% Educational establishment: first to third grade Duration of diabetes: 3.3 years, range 2–5.8 years
Students	
Ramchandani *et al* 2000,[133] USA To assess the changes in diabetes management and control that occur in the transition from high school to attending college away from home	51 students recruited from five different hospital diabetes centres (31% RR); data used for 42 participants Age: mean 20.1 years (SD 1.6 years), range 18.4–25.7 years Sex: female 64% Social class: NS Ethnicity: NS Insulin regime: injections 92.8%, pump 7.2% Educational establishment: college or university 100% Year of study: freshman 36.6%, sophomore 12.2%, junior 26.8%, senior 14.6%, graduates 9.8% Duration of diabetes: NS
Balfe 2007,[183,207] Balfe and Jackson 2007,[184] Balfe 2009,[185,186] UK To explore the narratives of practice of young university students with T1D	17 students recruited from across five university health centres (11% RR) Age: actual range 18–25 years Sex: female 65% Social class: NS Ethnicity: white 100% Insulin regime: injections 94%, pump 6% Educational establishment: university 100% Year of study: first year: $n = 4$, second year: $n = 9$, third year: $n = 1$, postgraduate student: $n = 3$ Duration of diabetes: at least 1 year; > 6 years, $n = 14$

Study, country and aims	Sampling and sample characteristics
Wdowik *et al* 2001,[187] USA To determine relationships between constructs of the expanded health belief model and to identify characteristics of college students who successfully manage their diabetes	98 students recruited from 22 college health providers (85% RR) Age: mean 24.4 years (SD 7.4 years) Sex: female 57% Social class: NS Ethnicity: white 83%, black/African American 4%, Hispanic/Mexican American 6%, not stated 6% Insulin regime: not T1D ($n = 2$) Educational establishment: college students 100% Year of study: NS Duration of diabetes: mean 11.8 years (SD 6.9 years)
Wdowik 1997,[136] USA To identify factors that affect the ability and motivation of college students to engage in appropriate self-care behaviours for successful management of diabetes	10 students recruited to focus groups who used the student health services or who had seen advertisement in college newspaper (32% RR) Age: target range 18–35 years, only two aged > 24 years Sex: female 80% Social class: NS Ethnicity: NS Insulin regime: NS Duration of diabetes: 3 months to 13 years Educational establishment: college 100% Year of study: NS 15 recruited (75% RR) to telephone interviews who attended a pre-college workshop at local diabetes centre (from nine colleges across seven different states) Age: target range 19–22 years Sex: female 60% Social class: NS Ethnicity: NS Insulin regime: NS Duration of diabetes: 3–17 years Educational establishment: college 100% Year of study: NS

Study, country and aims	Sampling and sample characteristics
Geddes *et al.* 2006,[138] UK To examine the clinical characteristics of, and diabetes management provided for, young people with T1D in tertiary education	55 case notes of students referred to one hospital over a 10-year period (37% RR) Age: target range 18–24 years Sex: NS Social class: NS Ethnicity: NS Insulin regime: basal-bolus 35%, insulin three times a day 3%, insulin twice a day 62% Educational establishment: degree-level study Year of study: NS Duration of diabetes: > 1 year
Ravert 2009,[188] USA To examine the use of nine common alcohol management strategies among college undergraduates with diabetes to determine which strategies predicted alcohol consumption and consequences	450 respondents who had competed a graduate survey who indicated that they had diabetes, were aged < 26 years and had undergraduate status from 123 North American post-secondary institutions Age: mean 20.3 years (SD 1.6 years), target range 18–25 years Sex: female 68% Social class: NS Ethnicity: white 79.6%, black 5.1%, Hispanic 5.6%, Asian 6.9%, Indian 2.4%, other 4.7% Insulin regime: NS Educational establishment: college undergraduates Year of study: first year 28.2%, second year 24.7%, third year 24.7%, ≥ fourth year 22.4% Duration of diabetes: NS
Wilson 2010,[189] UK To explore the experiences of young people managing their diabetes at college or university	23 students recruited (no details provided) (RR not specified) Age: actual range 17–19 years; 17 years 30%, 18 years 44%, 19 years 26% Sex: female 52% Social class: NS Ethnicity: NS Insulin regime: NS Educational establishment: college 30%, university 70% Year of study: NS Duration of diabetes: 8 years 44%, 9 years 30%, 10 years 26%

Study, country and aims	Sampling and sample characteristics
Miller-Hagan and Janas 2002,[190] USA To explore how college students with diabetes perceive and manage alcohol consumption	15 students recruited using advertisements placed in one large north-eastern university (RR not specified) Age: mean 22.4 years, actual range 18–40 Social class: NS Sex: female 73% Ethnicity: white 87%, black 6%, Asian 6% Insulin regime: T1D: $n = 11$, T2D: $n = 4$; pump: $n = 4$, oral: $n = 3$ Educational establishment: sample included graduate students Year of study: NS Duration of diabetes: 8.1 years, range 3.5 months to 17 years
Eaton *et al.* 2001,[135] UK To contact students with diabetes at the University of Leeds to ascertain their, alcohol, smoking and exercise habits and to explore their views on diabetes and factors which influence their ability to maintain glycaemic control	22 recruited from those registered at one university medical practice (47% RR); eight selected for interview Age: mean 20 years, actual range 19–21 years Sex: NS Social class: NS Ethnicity: NS Insulin regime: NS Educational establishment: university 100% Year of study: NS Duration of diabetes: mean age at diagnosis 12.6 years, range 6–20 years
School teachers	
Amillategui *et al.* 2009,[177] Spain To identify the special needs of children with T1D at primary school, taking into account the perceptions reported by parents, children and teachers	111 teachers of children with T1D attending the paediatric units of nine public hospitals recruited (26% RR) Experience of children with T1D: yes 100% School characteristics: primary 100% Staff characteristics: teachers 100% Details of children with T1D: age: mean 10.08 years (SD 2.26 years), 6–9 years 38%, 10–13 years 62%. No further details specified
Greenhalgh 1997,[191] UK To assess school teachers' knowledge of insulin-dependent diabetes in school children aged 5–16 years	85 school teachers of children who attended a diabetes clinic at a local hospital recruited (60% RR) Experience of children with T1D: yes 96% School characteristics: primary: $n = 22$, secondary: $n = 16$ Staff characteristics: primary: head and child class teachers: $n = 25$; secondary: science/biology and PE teachers: $n = 23$, head of year and form teachers: $n = 37$ Details of children with T1D: not provided

Study, country and aims	Sampling and sample characteristics
Bowen 1996,[192] UK To discover whether teachers had the training to cope with the health-related emergencies that may arise with children who have special needs	30 recruited (83% RR) Experience of children with T1D: taught a child with diabetes 20% School characteristics: primary: $n=4$, secondary: $n=1$ Staff characteristics: primary 43%, secondary 57% Sample characteristics: not linked to specific children with T1D
Alnasir and Skerman 2004,[193] Bahrain To study awareness about common health problems in Bahrain Latif Alnasir 2003,[194] Bahrain To assess Bahrani school teachers' knowledge of diabetes	1140 recruited (91% RR); all Bahraini teachers of all disciplines in 49 randomly selected schools Experience of children with T1D: NS School characteristics: NS Staff characteristics: primary teachers 45%, intermediate teachers 25%, secondary teachers 30% Details of children with T1D: not linked to specific children with T1D
Gormanous *et al.* 2002,[195] USA To determine the levels of knowledge about diabetes mellitus among Arkansas public elementary school teachers	463 recruited (64% RR) Details of children with T1D: not linked to specific children with T1D School characteristics: elementary: $n=27$ Staff characteristics: kindergarten–6th grade Experience of children with T1D: student with diabetes in classroom 7%, not aware if students with diabetes were in their classrooms 24%, family member or close friend 42%
Tahirovic 2007,[196] Bosnia and Herzegovina To investigate how far physical education teachers from elementary school understand diabetes and are trained in its management and in the treatment of diabetes emergencies	83 recruited (RR not specified); all schools within the region included Experience of children with T1D: G1: teachers whose school was attended by at least one pupil suffering from T1D; G2: teachers in whose school there were no pupils suffering from T1D School characteristics: elementary: $n=83$ Staff characteristics: physical education teachers Details of children with T1D: not linked to specific children with T1D
MacArthur 1996,[163] UK To examine the practice and attitudes of local children who were taking pre-lunch insulin injections at school	11 teachers of children with T1D recruited from diabetes clinic (82% RR) Experience of children with T1D: all children in school who had pre-lunch injections at school School characteristics: secondary: $n=9$ Staff characteristics: head teacher: $n=4$, form teacher: $n=3$, deputy head: $n=2$, head of year: $n=1$, school nurse jointly with deputy head: $n=1$ Details of children with T1D: age: 10–16 years. No further details specified

Study, country and aims	Sampling and sample characteristics
Boden *et al.* 2012,[197] UK To examine the concerns of primary school staff working with children with T1D and their parents, and to relate these views to the views of health care professionals working with school personnel	22 recruited (88% RR); 25 primary schools were identified as having a child with diabetes either in the school currently or who had left very recently Experience of children with T1D: no 9%, current 46%, indirectly 9%, previous (previous year) 27%, previous (no longer in school) 9% School characteristics: primary: $n = 13$ Staff characteristics: head teachers, teachers and teaching assistants who had managed, or could potentially manage, children with diabetes Details of children with T1D: no details provided
Nabors *et al.* 2008,[198] USA To assess special education and regular education teachers' perceptions of their knowledge about and confidence in meeting the academic and social needs of children with chronic medical conditions (including diabetes)	247 recruited from 15 elementary schools in a Midwestern city (RR not specified) Experience of children with T1D: NS School characteristics: elementary: $n = 15$ Staff characteristics: special education teachers 22%, regular teachers 78% Details of children with T1D: not linked to specific children with T1D
Lewis *et al.* 2003,[170] USA To identify obstacles in the school setting to good control of diabetes and document the level of support available in various school districts serving the clinic patient population	222 schools in three counties were randomly selected to participate in the study; 65 responded (29% RR) Experience of children with T1D: 80% of schools had a child enrolled with diabetes; four schools did not know whether they had students with diabetes enrolled Staff characteristics: NS School characteristics: elementary 27.6%, middle 33.8%, high 35.3%, combined middle/high 3.1% Details of children with T1D: not linked to specific children with T1D
Rickabaugh and Salterelli 1999,[199] USA To explore the attitudes and reported behaviours of participants concerning diabetes and exercise guidelines	Participants included 25 children with T1D and 28 of their parents and 32 physical education teachers. Recruited from across three states (RRs not specified) Experience of children with T1D: had taught on average four (SD 0.9) children with T1D. Had an average of less than one incidence of hypoglycaemia (mean 0.94 events, SD 0.08) in their classes per year School characteristics: NS Staff characteristics: physical education teachers 100% Details of children with T1D: age: mean 12.1 years (SD 0.7 years); sex: female 48%; ethnicity: NS; social class: NS; duration of diabetes: 5.0 years (SD 0.6 years)

Study, country and aims	Sampling and sample characteristics
Chmiel-Perzynska *et al.* 2008,[200] Poland To evaluate the knowledge of primary school teachers in the Lubelskie Province, Poland, about hypoglycaemia and to determine educational needs necessary to ensure that children with diabetes are properly dealt with by their teachers	200/753 (27%) teachers had previously responded to a survey. Of these, 52 were currently teaching or had taught a child with diabetes (26% RR) Experience of children with T1D: currently teaching/had taught School characteristics: primary 100% Staff characteristics: teachers 100% Details of children with T1D: not linked to specific children with T1D
School health-care personnel	
Fisher 2006,[201] USA To measure school nurses' perceived self-efficacy in providing diabetes care and education to children	70 school nurses recruited (61% RR) from a sample of 115 schools in a suburban area in New England. RN 100% Years of experience: 1–5 years: 36%, 6–10 years: 27%, 11–15 years: 19%, > 16 years: 19% Type of school: elementary and middle Experience of children with T1D: 63% Number of children with T1D: 0: 37%, 1: 31%, 2: 21%, 3: 6%, 4: 3%, 5: 1%
Guttu *et al.* 2004,[202] USA To examine the impact of school nurse-to-student ratios on student outcomes	21 counties, 19 provided school nurse services. No further details presented Each county was characterised as having a good nurse-to-student ratio (one nurse to < 1000 students) or a fair to poor nurse-to-student ratio (one nurse to ≥ 1000 students)
Joshi *et al.* 2008,[203] USA To gather nurses' perceptions of the barriers related to diabetes knowledge, communication and management	43 school nurses recruited (RR not specified) from across one US state Sample characteristics: not provided
Nabors *et al.* 2005,[204] USA To examine nurses' perceptions of how to support adolescents with T1D at school	38 school nurses recruited, surveyed from across three states (34% RR). RN 34% Years of experience*:* 6 months to 32 years, mean 8.6 years (SD 6.3 years) Type of school: middle 31%, high 38%, both middle and high 31% Experience of children with T1D: 87% Number of children with T1D: NS
Wagner and James 2006,[205] USA To explore whether training in diabetes for school counsellors is associated with better knowledge and more helpful attitudes to students with diabetes	132 school counsellors recruited, attendees at two school counsellor association annual meetings (83% and 42% RR) Years of experience: NS Type of school: elementary 7%, junior/middle 28%, high 61%, combined 4% Experience of children with T1D: 83% had a child with diabetes in their school, 14% did not know if there were children with diabetes in their school Number of children with diabetes: average of four

Study, country and aims	Sampling and sample characteristics
Schwartz *et al.* 2010,[178] USA To evaluate the experiences of children and adolescents with T1D in school by surveying patients, their parents or guardians and the school personnel directly involved in their care	28 school personnel recruited (RR not specified), linked with children from a hospital diabetes centre. A total of 20 schools represented School nurses 85%, dieticians, teachers and other 15% Years of experience: NS Type of school: kindergarten–12th grade Experience of children with T1D: 62.9% Number of children with diabetes: 0: 5.9%, 1–2: 27.5%, 3–4: 41.2%, 5–10: 13.7%, > 10: 11.8%
Darby 2006,[206] USA To examine the challenges encountered by school nurses when caring for students receiving CSII therapy	11 school nurses recruited who cared for students with T1D on pump therapy (85% RR). Survey of local schools across three counties RN: $n = 6$, CNP or APN: $n = 2$, LPN $n = 3$ Type of school: elementary: $n = 5$, middle: $n = 4$, both middle and high: $n = 1$, both elementary, middle and high: $n = 1$ Experience of children with T1D: school nurses who cared for students with T1D on pump therapy Number of children with T1D: range 1–4 Years of experience: range 2 months to 5 years

APN, advanced practice nurse; CNP, certified nurse practitioner; LPN, licensed practical nurse; NS, not stated; RN, research nurse; RR, recruitment rate.

Study methods, quality appraisal and summary of results: stream 2

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
Children and parents	
Nabors *et al.* 2003,[161] USA	
Aim: to assess children's and young adolescents' perceptions of supportive behaviour by nurses, teachers and friends that allow them to improve their diabetes management at school	
Design: interviews and survey Measure: ID – How is School Scale Data analysis: CCA and descriptive and inferential statistics Quality criteria met: ABCDEHI	Substantive themes: improving staff knowledge, availability of snacks and supplies, help with lows, reminders, support from other people to help them manage their diabetes at school Support: younger children reported needing more support from teachers and nurses
Lehmkuhl and Nabors 2008,[160] USA	
Aim: to assess children's perceptions of their satisfaction with and support from school nurses, teachers and friends in their classrooms as well as the types of support they needed from each group	
Design: survey – pilot study Measure: revised How is School Scale, revised CATIS Data analysis: descriptive and inferential statistics Quality criteria met: ABCEHI	Support from school nurses ($n = 45$): make sure do insulin injections (13%), blood glucose monitoring (42%), have a snack available (69%), have juice available (73%), help with lows (82%) and have supplies for testing available (80%) Support from teachers ($n = 53$): make sure do insulin injections (100%), blood glucose monitoring (4%), have a snack available (62%), have juice available (66%), help with lows (30%), have supplies for testing available (28%), help with following meal plan at lunch (17%), help me to recognise when I am beginning to experience a low (58%), send me to the nurse right away if I am low (66%) and let me test when I need to (79%) Support from others ($n = 49$): help me with blood glucose monitoring (8%), help with following meal plan at lunch (14%), help me to recognise when I am beginning to experience a low (49%), don't give me snacks (39%), find an adult if I look unwell (45%) and walk me to the nurse if I need to go (63%) Extracurricular activities: the support that they received from adult leaders during after-school activities was between 'some' and 'ok' (mean 3.38, SD 1.19) Support: a regression analysis explained 40% of the variance in HbA_{1c} at 6 months (mean satisfaction with support ratings, HbA_{1c} at study entry and the interaction term were significant $F(3,19) = 11.97$, $p < 0.001$) HbA_{1c}: children reporting higher levels of satisfaction with support were more likely to have higher HbA_{1c} at 6 months [beta = 2.16, SE = 0.92, $t = 2.35$, $p < 0.05$]. Children with a higher HbA_{1c} at study entry were apt to have a higher level 6 months later (beta = 6.92, SE = 1.89, $t = 3.67$, $p < 0.001$). The interaction of support and HbA_{1c} was significant (beta = –0.187, SE = 0.60, $t = –3.10$, $p < 0.01$). When satisfaction ratings were higher and HbA_{1c} was lower at study entry, children were more likely to have a lower HbA_{1c} at 6 months

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
Bodas *et al.* 2008,[164] Spain	
Aim: to improve awareness of the needs within school settings of children and adolescents with T1D based on information provided by the students	
Design: survey Measure: ID Data analysis: descriptive statistics Quality criteria met: ABCEFI	School nurse: 21% reported having a school nurse (private schools 51%) and 45% felt that there should be a nurse at school Glucagon: this was available at 34% of schools and 60% felt that someone at school would be willing to inject glucagon Support: younger children received more support than older children, with only a minority reporting that they had to modify their insulin guideline and/or diminish glycaemia controls because of lack of help at school Blood glucose monitoring: 7% of the teachers help the children with blood glucose monitoring (15% for those aged < 10 years) Insulin: 32% need to inject insulin at school (42% < 10 years, 49% private schools) and 47% require the presence of a nurse. Most (97%) self-inject (mother 2%, teacher 1%) Teachers' knowledge: 54% stated that at school they know how to recognise the symptoms of hypoglycaemia and 49% of physical education teachers were able to recognise signs of hypoglycaemia Local school policies: 23% reported that they did not have the opportunity to resist an exam after a hypoglycaemia event Extracurricular activities: younger children reported difficulties in relation to out-of-school activities Information: should be more written information for teachers about the symptoms and steps to be followed in case of hypoglycaemia and information about diabetes in general, and should have emergency information about diabetes in the classrooms and in the common areas. Friends should have information about diabetes and the availability of juices or glucose
Peters *et al.* 2008,[158] USA	
Aim: to examine diabetes-related teacher victimisation	
Design: survey and review of clinic records Measure: DSMP Data analysis: descriptive and inferential statistics Quality criteria met: ABCDEFGHI	Support: mean score for diabetes-related teacher victimisation was 4.35 ± 1.16 (range 4–12) Blood glucose monitoring: whether they put off or delayed checking their blood sugar at school because their teacher might get angry: sometimes: $n = 11$ (7%), often: $n = 4$ (2%), always: $n = 3$ (2%); whether they avoided checking their blood sugar at school because their teacher might get angry: sometimes: $n = 8$ (5%), often: $n = 2$ (1%), always: $n = 2$ (1%) Teacher victimisation was associated significantly with decreased dietary adherence as assessed by the DSMP hypoglycaemia subscale ($r = -0.158$, $p < 0.05$)

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
	For children aged 8–11 years, teacher victimisation was associated significantly and negatively with the DSMP diet subscale ($r = -0.256$, $p < 0.05$), DSMP insulin adherence subscale ($r = -0.343$, $p < 0.01$) and DSMP total score ($r = -0.305$, $p < 0.01$). For adolescents aged ≥ 12 years, teacher victimisation was not associated with any variables
Tang and Ariyawansa 2007,[175] UK	
Aim: to identify the difficulties that young people with diabetes may encounter while at school	
Design: survey Measure: open-ended questions Data analysis: descriptive statistics and numerical content analysis Quality criteria met: ABCEFHI	Self-management skills at school: 64% undertake blood glucose monitoring, 27% administer insulin, 91% take a snack to school, 18% reported feeling different to their friends, 55% reported that their friends already knew about their diabetes and 45% would like their friends to know, especially about hypoglycaemia episodes School-based issues: medical room or toilet to go for blood glucose monitoring, inject insulin, etc. 45% reported a problem with the teaching staff in relation to needing to undertake blood glucose monitoring, administer insulin or eat a snack during a lesson. Only one person reported issues of bullying
Wang *et al.* 2010,[157] Taiwan	
Aim: to obtain an initial understanding of school–based lived experiences of adolescents with T1D	
Design: interviews conducted in Mandarin Chinese Measure: semistructured schedule Data analysis: a Heideggerian hermeneutic phenomenological approach Quality criteria met: ABCDEFGHI	Substantive themes: learning to be master of their disease, learning to find ways to feel comfortable, learning not to be different, learning to not let others (especially parents) worry about them
Newbould *et al.* 2007,[180] UK	
Aim: to examine the experiences and concerns of young people and their parents in the management of medication for asthma or diabetes whilst at school	
Design: interviews Measure: semistructured schedule Data analysis: qualitative analytical procedures and numerical content analysis Quality criteria met: ABCDEFGHI	Self-management skills: 100% took items related to their condition to school, only 12% injected insulin during school hours Accessibility of own snacks and supplies: storage of medication or items related to diabetes was with the young person (38%), in another room in school (16%), in the classroom (42%) or in the school office (4%) Local school policies: all three of the young people who regularly administered insulin during the school day reported problems with a lack of a private location within the school where they could administer injections. Parents were unhappy that school policies meant that behaviours encouraged within the home to ensure good diabetic control, such as regular snacking and blood glucose monitoring throughout the day, could not be continued at school. In total, 50% of parents did not know whether their child's school had a policy regarding medicine (31% said yes and 19% said no)

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
MacArthur 1996,[163] UK	
Aim: to examine the practice and attitudes of local children who were taking pre-lunch insulin injections at school	
Design: survey Measure: ID Data analysis: descriptive statistics and numerical content analysis Quality criteria met: ABCHI	Location of lunch-time injections: a variety of locations were reported including classroom, toilets, medical nurses room, 'wherever I have my lunch', 'in the dining room', 'in a cupboard in the school office' and at home. However, children reported being happy with their usual place Self-management skills: the majority conducted their own injections Accessibility of own snacks and supplies: they all looked after their own pen at school Classmates watching: 12 (80%) stated that they did not mind others seeing them take their insulin
Clay 2008,[179] USA	
Aim: to examine problems with medication administration in school	
Design: survey Measure: ID Data analysis: descriptive statistics Quality criteria met: ABCDEFGHI	School nurse: 87.5% reported that they had a school nurse Self-management skills at school: medicines were kept in the nurse's office (62.5%), in the secretary's/teacher's office/desk (16.7%), in their own bag (15.3%) or other (9.7%). Reminder to take medicines from teacher (6.9%), no reminding needed (86.1%), someone gets me (1.5%), other (8.3%). In total, 76.4% administer their own medicine (nurse 18.1%, teacher/secretary 5.6%, other 8.3%). For 49.3% no one watches when they take their medicine (person who gives it 40.9%, another person 9.9%). A total of 81.9% never miss taking medicine at school, 12.5% miss once a year and 4.2% miss once a month to less than once a week. (Note that summing responses may exceed 100% because more than one response per item could be checked)
Schwartz *et al.* 2010,[178] USA	
Aim: to evaluate the experiences of children and adolescents with T1D in school by surveying patients, their parents or guardians and the school personnel directly involved in their care	
Design: survey Measure: ID Data analysis: descriptive statistics Quality criteria met: ABCEH	Self-management skills at school: treated differently at school: very often 4.2%, often 10.4%, sometimes 31.2%, rarely 22.9%. Accused of using diabetes as an excuse: very often 14.6%, often 6.2%, sometimes 16.7%, rarely 12.5%. Prevented from managing their diabetes: very often 8.3%, often 8.3%, sometimes 12.5%, rarely 14.6%. Felt embarrassed at school experiencing hypoglycaemia or other diabetes-related incidents requiring intervention (22.9%) or when they had to check their blood glucose or take medication at school (27.7%). Generally embarrassed in front of their classmates (11.4%) and felt embarrassed intentionally by school personnel (11.4%) Food availability at the canteen: does the cafeteria have proper food: very often 20.0%, often 40.0%, sometimes 20.0%, rarely 6.7%. Own lunch to school: very often 11.1%, often 11.1%, sometimes 13.3%, rarely 17.8%

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
	Education and training: parents felt that school personnel were adequately trained to care for their children/manage T1D: always 40.0%, usually 20.2%, sometimes 15.6%, rarely 35.2% Support – parent's perspective: making up missed class work and communication with the child's health-care provider when child misses school: always 53.7%, usually 26.8%, sometimes 12.2%, rarely 7.3%. Adequacy of support provided when their child missed school because of a diabetes-related illness or doctor visit: supportive 53.7%, usually supportive 26.8%, sometimes supportive 12.2%, not supportive 7.3%. In total, 30.8% responded that they had to miss work because of the school's inadequacy to care for their child Liability issues: 65% of school personnel expressed concern about the potential liability of caring for these children and adolescents at school Skills of school nurse: 20% felt adequately prepared to assist a child with hypoglycaemia Availability of school nurses: 20% felt that there was an adequate numbers of school nurses and 76% felt that a school nurse should be available on the school premises during the school day if a student with T1D is enrolled School policies: 31% had no policies in their school and 21.6% were unaware of specific policies Interaction with HCPs: communication with the child's health-care team – often or very often by 25%
Hema *et al* 2009,[162] USA	
Aim: to investigate the daily stressors and coping responses of children and adolescents with T1D	
Design: self-completion diaries for 2/3 weeks Measure: what upset me today was/What I did Data analysis: qualitative description Quality criteria met: ABCDEFHI	Identified that diabetes-related issues caused them stress during the school day: younger (8–12 years): $n = 4$ (1.52%), older (13–18 years): diabetes related: $n = 14$ (2.78%) Specifically mentioned a stressor related to diabetes – 'I was really low', I had to take 2 units of insulin'
Peyrot 2009,[174] Brazil, Denmark, Germany, Italy, Japan, the Netherlands, Spain, USA	
Aim: to gain an understanding of the challenges and issues facing young people with diabetes and those with responsibility	
Design: survey Measure: ID Data analysis: descriptive statistics Quality criteria met: ABCDEFHI	Role of school teachers: with regard to areas for improvement, 58% felt that teachers need to be better informed about diabetes and trained how to deal with an emergency diabetes situation Food availability at the canteen: 55% felt that they would benefit from more healthy food and drink options

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
Carroll and Marrero 2006,[159] USA	
Aim: to explore the perceptions of how diabetes influences adolescents' perceptions of quality of life in general and their relationships with parents, peers, school and their physician	
Design: focus groups Measure: open-ended qualitative questions Data analysis: themes generated Quality criteria met: ABCDEFGHI	Substantive themes: personal perceptions of life living with diabetes, impact on parental and peer relationships and impact on school School culture: missing lessons because of unstable blood glucose levels and leaving the class to perform their blood glucose monitoring
Waller *et al.* 2005,[181] UK	
Aim: to seek the views of children and adolescents with T1D and their parents regarding the acceptability and design of a new diabetes education programme	
Design: focus groups ($n = 8$) Measure: semistructured schedule Data analysis: themes generated Quality criteria met: ABCDEFGHI	Adjusting insulin dose depending on their chosen meal. The DAFNE programme requires greater self-management: children would be expected to have the knowledge and self-esteem to test blood glucose and inject insulin during school time Substantive themes were perceived advantages of the DAFNE programme and concerns about the DAFNE programme. Parents were concerned about the commotion in schools ['Secondary schools are hyper. C is frightened he's going to get it [syringe] dropped so he won't take it' (mother)] and the lack of understanding of diabetes and its management, despite efforts to educate staff ['J's teacher didn't know for two years that he was diabetic even though I'd written a letter' (mother)] Location/missing break/classmates watching: children worried about the inconvenience – having to inject in the middle of the hall, the reactions of peers watching them injecting and the prospect of missing out on break time
Hayes-Bohn *et al.* 2004,[176] USA	
Aim: diabetes care at school from the perspective of adolescents with T1D and their parents	
Design: interviews Measure: 12 questions (one school) Data analysis: thematic analysis Quality criteria met: ABCDEFHI	Part of a larger study. Findings for parents and adolescents presented together Substantive themes: knowledge/training of school staff, food offered/available and school rules
Wagner *et al.* 2006,[182] USA	
Aim: to investigate the relationships between perceived school experiences, diabetes control and quality of life	
Design: survey Measure: diabetes quality of life, ID – problems and assistance at school Data analysis: descriptive and inferential statistics Quality criteria met: ABCDEFHI	Bullying: 21% reported problems with peers regarding their diabetes Missing class: 56% reported missing class time for routine, non-emergency diabetes care Food availability at the canteen: school cafeteria made carbohydrate content of prepared foods available for 7%

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
	Support others: 57% indicated that they saw a school counsellor for a non-medical, diabetes-related problem, but only 66% felt that the school counsellor knew enough about diabetes to be helpful Role of teacher: providing a drawer in the classroom for diabetes supplies, reminding child to monitor blood glucose or eat a snack, helping with insulin dosage algorithms and reading books about diabetes. In total, 14% reported that they had experienced problems with regard to diabetes care (testing, snacking, taking insulin, treating lows, etc.) Examples included not being allowed a snack in class and being delayed in going to the nurse's office to treat hypoglycaemia Role of peers: 31% noted that peers provided help as a diabetes 'buddy'. Children reported that buddies recognise hypoglycaemia, alert staff, prompt self-care, buffer teasing and escort the student to the nurse. A total of 56% reported that their classmates had received diabetes training Quality of life: controlling for age and HbA_{1c}, participants who reported trained peers had significantly higher quality of life (mean 82.8) than those with untrained classmates (mean 75.2) [$F(3,45) = 7.01$, $p < 0.05$] Location/HbA_{1c}: 56% reported blood glucose monitoring, treating hypoglycaemic episodes or injecting insulin outside the classroom (e.g. nurse's office, main office, at locker between classes). Children who reported leaving class for diabetes care had a higher HbA_{1c} level (mean 8.4%) than those who indicated that they performed care in the classroom or were unrestricted (mean 7.5%) [$F(4,48) = 17.31$, $p < 0.001$] Education and training: 72% stated that there was a person at their child's school trained to handle diabetes emergencies, usually the school nurse (86%) and 58% of parents stated that their child's school personnel had received training in routine, non-emergency diabetes care. The child's parents had provided that training 48% of the time. The type of training varied, for example an informal conversation, review of educational materials or consultation with a health-care provider. Controlling for age and pump status, children whose parents reported that school personnel had received training had a significantly lower (better) HbA_{1c} level (mean 7.7%) than those with untrained school personnel (mean 8.4%) [$F(3,41) = 5.12$, $p < 0.05$] Extracurricular activities: parents reported that their child's diabetes affected their decisions regarding participation in field trips (29%) and extracurricular activities (27%) and their after high-school planning (11%)

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
Amillategui *et al.* 2009,[177] Spain	
Aim: to identify the special needs of children with T1D at primary school, taking into account the perceptions reported by parents, children and teachers	
Design: survey (postal) Measure: ID Data analysis: descriptive statistics Quality criteria met: ABCDEFHI	Self-management skills: 60% of children, 64% of parents and 65% of teachers reported that child required blood glucose monitoring during school hours, with help needed from teacher (6%), other personnel (2%) and a peer (5%). Between 9% and 11% of children required insulin administration during school hours. In total, 26% of children, 20% of parents and 8% of teachers reported that there had been one, or more than one, hypoglycaemic episode before or during an exam. Children's major concerns included not being able to recognise a hypoglycaemic episode [mean 3.64 (±1.43)] followed by not being able to administer insulin to themselves [mean 3.11 (±1.64)]. In contrast, they seemed to be less worried about the necessity of following a diet [mean 2.29 (±1.41)] or adhering to a strict management timetable [mean 2.31 (±1.39)] as well as about feeling different from their peers [mean 2.36 (±1.48)] Glucagon: 46% of children, 51% of parents and 51% of teachers reported that glucagon was not available at school; 54% of children) would like to have glucagon readily available along with a person who knows how to administer it Role of the teacher: 18% of children, 21% of parents and 4% of teachers thought that the physical education teacher would not be able to recognise a hypoglycaemic episode during physical activities; 70% would like teachers to be better informed about diabetes and 64% would like teachers to have a better knowledge of the steps that they should follow to manage diabetes Support: children reported that they needed support from teachers (68%), peers (68%), other school staff (19%). Parents reported that their child needed support from teachers (71%), peers (80%), other school staff (19%) Local school policies: 39% of children were unable to resit an exam that they had not been able to take because of their disease School nurse: 48% of children reported that there was a nurse at the school Availability of snacks and supplies: 40% of children would like glucose and fruit juices to be readily available Role of teacher: 7% reported that they experienced problems at school when they informed the school about their child's diabetes [in 2% of cases the child was not accepted into the chosen school and in 1% of cases (1/167) the child was forced to change schools] Outside school trips: 16% of parents experienced difficulties in getting the school to accept responsibility for their child during day trips; 86% said that their child undertook the same trips as their peers

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
	Information and resources: 95% of parents, 88% of children and 99% of teachers felt that written information about T1D is needed; 64% of children, 79% of parents and 81% of teachers were convinced about the importance of written information about T1D and that it would improve integration at school; 100% of teachers felt that they need information on the optimal management of emergencies Concerns of teachers: possibility that the children could go into a coma at school and that they would not be able to recognise a hypoglycaemic episode
Barnard *et al.* 2008,[173] UK	
Aim: to identify key components of quality of life and assess the impact of insulin pump therapy on children/adolescents with T1D and their parents	
Design: interviews Measure: adapted Schedule for the Evaluation of Individualised Quality of Life Data analysis: descriptive statistics and thematic analysis Quality criteria met: ABCDEFGHI	Support: children most frequently reported family, friends and school as the discrete life domains that were important for their quality of life
Low *et al.* 2005,[172] USA	
Aim: to explore psychosocial issues related to insulin pump use (CSII) in youth aged between 11–18 years	
Design: interviews Measure: open-ended and informational questions Data analysis: themes generated using a constant comparative method Quality criteria met: ABCDEFGHI	Substantive themes: pump therapy: expectations and benefits, adjustments related to pump therapy, social issues, liabilities associated with CSII, wearing an insulin pump and school-related issues
Wilson and Beskine 2007,[167] UK	
Aim: to examine how children with diabetes are managing their condition in the school setting using pump therapy and MDIs	
Design: survey Measure: open questions Data Analysis: thematic analysis of the context of comments Quality criteria met: ABCDEH	Care plan: 64% of children have a school diabetes care plan Information and resources: for 82% of children the school has written information about their diabetes Self-management skills: all children (100%) perform blood glucose monitoring in school with school staff checking the reading in 82% of cases. In total, 40% gave insulin injections during school and these were overseen for 20%. Help was available if needed for blood glucose monitoring or injecting (67%) Outside school trips: 80% able to participate in all school trips/outings/clubs Bullying: 26% of children were bullied/picked on at school because of their diabetes

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
	Support: younger children required assistance with blood glucose monitoring during school hours from the teacher/classroom assistant, office staff, carer/mother, school nurse, head teacher. Some younger children also needed assistance with insulin injections during school hours, usually from a parent or teacher/classroom assistant ($n = 1$). Older children > 12 years conducted their own blood glucose monitoring and insulin injections Locations: blood glucose monitoring: classroom (22/73), anywhere (19/73), medical room (15/73), school office (7/73), locker room (1/73), computer room (1/73), toilet/cloakroom (3/73), head's office (1/73), side room (1/73), own room (1/73), library/reading room (2/73). Insulin injections: medical room (15/29), school office (7/29), locker room (3/29), toilets/cloakroom (3/29), head's office (1/29)
Amillategui *et al.* 2007,[166] Spain	
Aim: to identify the special needs of children with T1D in schools from the parents' point of view and the difficulties experienced with full integration and to define a series of interventions that may improve the situation	
Design: survey Measure: ID Data analysis: descriptive statistics Quality criteria met: ABCDEFGHI	School nurse: psychologist and nurse 17%, psychologist 44% and nurse 5%; 70% of parents felt that a nurse should be available at the school for the children Role of school teachers: teachers were informed about their children's diabetes (95%) but only 78% of physical education instructors were aware of the children's condition. Some experienced problems at schools after they had informed the school about their child's condition (3–6 years: 30%, 7–10 years: 23%, 11–14 years: 16%, > 14 years: 7%, overall: 17%). Institutions (62%) and teachers (56%) were considered responsible for these problems. As a result, 5% of children were not accepted into the school of the parents' choice and 8% were forced to change school (3–6 years: 20%). In total, 9% admitted experiencing discriminatory behaviour from the school (3–6 years: 23%, 7–10 years: 9%, 11–14 years: 6%, > 14 years: 6%) Self-management skills: blood glucose monitoring required during the school day for 75% of whom 87% were in the 3- to 6-year-old age group; 9% admitted that they were forced to reduce the number of blood glucose measurements because of lack of co-operation from school staff (3–6 years: 18%, 7–10 years: 14%, 11–14 years: 4%, > 14 years: 8%). In 26% of cases insulin injections were carried out during school but only 63% of the children were able to do this by themselves. In 16% of cases treatment modifications were made because of a lack of co-operation from the school Support: the greatest support that the children received at school came from teachers (66%) and peers (63%) Diabetes knowledge: parents felt that teachers had a basic knowledge about T1D (58%); 34% of parents believed that school personnel would be able to recognise a mild hypoglycaemic episode. In 64% of cases the children themselves had been able to resolve such an event, with the greatest proportion (80%) being in the ≥ 14 years age group

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
	Glucagon: only 9.8% of children had experienced a serious hypoglycaemic episode at school, but, according to parents, 55% of schools did not have glucagon available. Parents (64%) felt that glucagon should be readily available, together with a person who was aware of how to administer it Education and training: parents would like teachers to have a better knowledge of the basic steps that should be taken during a glycaemic emergency (75%) and to have a better understanding of the disease (70%) Food availability at the canteen: 27% of the children ate at school of whom 72% could eat anything from the menu. In total, 63% of parents felt that their child's meals were under control. Parents (14%) said that schools were not able, or did not consider it their responsibility, to modify diets to enable children with T1D to eat a school lunch Extracurricular activities: 95% of the children engaged in normal physical activities with their peers, although 51% had had at least one hypoglycaemic episode during these activities. In extracurricular activities, 16% of parents experienced difficulties from the school over responsibility for their child during 1-day trips (3–6 years: 26%, 7–10 years: 27%, 11–14 years: 10%, > 14 years: 7%), rising to 34% when trips were extended over several days Peer support: 61% of children's peers were sympathetic to them and 12% had experienced some form of verbal abuse or mocking (3–6 years: 3%, 7–10 years: 7%, 11–14 years: 15%, > 14 years: 18%)
Jacquez *et al*, 2008.[168] USA	
Aim: to investigate parent reports of the diabetes care support that their children receive in school, their concerns and knowledge about diabetes management in school and their knowledge of federal laws that protect children with diabetes	
Design: survey Measure: ID Data analysis: descriptive and inferential statistics Quality criteria met: ABCDEFGI	School care plan: 45% of children did not have a written care plan School nurse: 45% did not have a nurse at their school Glucagon: 49% reported that their school had a glucagon kit Location: 54% of children were allowed to perform blood glucose monitoring in the classroom and only 50% of children were allowed to perform blood glucose monitoring in special places. Only 21% of children were allowed to administer insulin in the classroom and only 54% of children were allowed to administer insulin in special places Snacking: 84% reported that their child was allowed extra snacks when needed Leaving the class: 81% reported that their child was allowed access to the bathroom when needed

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
Pinelli *et al* 2011,[171] Italy	
Aim: to determine how Italian parents and school personnel of 6- to 13-year-old children with T1D manage during school hours, including insulin administration, management of hypoglycaemia and glucagon use	
Design: survey Measure: ID Data analysis: descriptive statistics Quality criteria met: ABCDEFI	Self-management skills: 54.2% carried out insulin injection during school time. Person responsible for administration of insulin at school was the child (20.0%), a parent/relative (20.0%), a nurse (3.6%), a teacher (2.7%) or another school worker (0.9%). In total, 58.6% carried out blood glucose testing during school time. Treatment of hypoglycaemia during school hours: carbohydrate (66.9%), call to parents (47.1%), self-management (9.6%), call to emergency services (2.9%), other (3.7%). In total, 63.6% had had at least one hypoglycaemic event during school hours; the event had been managed well in 85.7% and a blood glucose test had been carried out in 79.3%. Treatment of hyperglycaemia during school hours: request for parents advice (64.6%), self-management (22.4%), insulin administration (9.3%), correction with pump (3.7%) Glucagon: 40.9% of schools had a refrigerator to store glucagon Understanding of teachers: parents reported difficulties encountered with school staff in the daily management of diabetes [practical difficulties with good diabetes management, checks, insulin treatment, hypoglycaemia (26.3%), underestimation of the impact of diabetes on life by teachers (24.6%), poor knowledge of illness and therapy (22.8%), generic attitude of school personnel to avoid responsibility (15.8%) and the school staff's fears (12.3%) and refusal to allow self-management of children (3.5%)] Extracurricular activities: 54% of parents were required to assist and be present during sport and extracurricular activities (54%)
Yu *et al.* 2000,[165] USA	
Aim: to characterise the academic and social experiences of children with diabetes	
Design: survey Measure: ID interview schedule Data analysis: descriptive statistics Quality criteria met: ABCDEFGI	Role of the teacher: who knows about diabetes: early-onset diabetes: classmates (97%), teachers (100%), administrators (87%); late-onset diabetes: classmates (100%), teachers (97%) and administrators (91%). Accommodation for diabetes: early-onset diabetes: 65% – diet related (52%), medical maintenance (16%), other (13%); late-onset diabetes: 80% – diet related (77%), medical maintenance (14%), other (9%)
Hellems and Clarke 2007,[169] USA	
Aim: To determine which school personnel currently assist students with insulin administration and management of hypoglycaemia and to determine whether these students are being cared for in a safe manner	
Design: survey Measure: ID Data analysis: descriptive analysis Quality criteria met: ABCDEGHI	School nurse: 95% of parents had a school nurse assigned to their child's school, with 69% reporting that this was full time Location of blood glucose monitoring: 49% reported that their child was permitted to check their own blood glucose in the classroom (elementary school 41%, middle school 28%, high school 74%)

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
	Self-management skills: 89% reported that their child required insulin administration at school during the previous year, with 79% injecting their own insulin. Of children in elementary school, 41% injected their own insulin and, of children in high school, 74% injected their own insulin. A total of 75% reported that their child had experienced low blood glucose requiring treatment while at school in the previous year. Most episodes were treated with fast-acting carbohydrate. One instance of severe hypoglycaemia was reported that required glucagon administration Kindergarten to fifth grade: person responsible for child's diabetes care during the school day: medical personnel (88%), teachers and administrators (64%), other school personnel (21%), parent (16%). Person responsible for child's diabetes care during after-school activities: medical personnel (26%), teachers and administrators (40%), other school personnel (2%), parent (71%), no one (2%). Person who helps with blood glucose monitoring: medical personnel (84%), teachers and administrators (40%), other school personnel (2%), parent (19%), no one (3%). Person who helps with insulin administration: medical personnel (74%), teachers and administrators (29%), other school personnel (2%), parent (24%), no one (7%). Person who helps with episodes of hypoglycaemia: medical personnel (88%), teachers and administrators (53%), other school personnel (14%), parent (24%), no one (2%) Middle school – sixth to eighth grade: person responsible for child's diabetes care during the school day**:** medical personnel (97%), teachers and administrators (43%), other school personnel (30%), parent (15%). Person responsible for child's diabetes care during after-school activities: medical personnel (25%), teachers and administrators (37%), other school personnel (10%), parent (52%), no one (18%). Person who helps with blood glucose monitoring: medical personnel (85%), teachers and administrators (12%), other school personnel (0%), parent (30%), no one (15%). Person who helps with insulin administration: medical personnel (53%), teachers and administrators (8%), other school personnel (0%), parent (32%), no one (22%). Person who helps with episodes of hypoglycaemia: medical personnel (95%), teachers and administrators (27%), other school personnel (17%), parent (23%), no one (5%) High school – 9th–12th grade: person responsible for child's diabetes care during school day: medical personnel (81%), teachers and administrators (25%), other school personnel (12%), parent (6%), no one (9%). Person responsible for child's diabetes care during after-school activities: medical personnel (6%), teachers and administrators (16%), other school personnel (22%), parent (25%), no one (46%). Person who helps with blood glucose monitoring: medical personnel (33%), teachers and administrators (6%), other school personnel (0%), parent (13%), no one (54%). Person who helps with insulin administration: medical personnel (12%), teachers and administrators (1%), other school personnel (0%), parent (15%), no one (75%). Person who helps with episodes of hypoglycaemia: medical personnel (75%), teachers and administrators (27%), other school personnel (10%), parent (19%), no one (18%)

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
Lewis *et al.* 2003,[170] USA	
Aim: to identify obstacles to good control of diabetes in the school setting and document the level of support available in various school districts serving the clinic patient population	
Design: survey Measure: ID Data analysis: descriptive statistics Quality criteria met: ABCEI	Extracurricular activities: 20% of parents reported that their child was not allowed to participate in all school activities without restriction. Many parents stated that their child was not allowed to go on school field trips unless accompanied by a parent or a school nurse, and some parents stated that their child was not allowed to play sports such as football Role of teachers: 6.2% of parents stated that they did not know if teachers or did not know if specific child's teachers were aware of their child's diabetes. The most frequent issues specified by parents concerning their level of satisfaction with the management of their child's diabetes during school hours were better staff training about diabetes management, better communication between parents and schools, healthier school lunches and a daily on-site school nurse
Lin *et al.* 2008,[94] Taiwan	
Aim: to explore the essential structure of mothers' life experience when helping their first- to third-grade children with T1D made adjustments at school	
Design: semistructured interviews Measure: interview schedule Data analysis: Colaizzi's six-step method approach Quality criteria met: ABCDEFGHI	Six major themes emerged: worrying about the child's safety, creating a safe environment, building the child's self-care ability, improving academic achievement, assisting with peer relationships and normalising the child's life
Students	
Ramchandani *et al.* 2000,[133] USA	
Aim: to assess changes in diabetes management and control that occur in the transition from high school to attending college away from home	
Design: survey Measure: ID Data analysis: descriptive and inferential statistics Quality criteria met: ABCDEFHI	Findings from open-ended questions not reported Self-management skills: 35.7% reported that blood glucose control was better in college, 33.3% reported that it was worse and 26.2% that it was unchanged (4.8% did not know). In total, 30.6% of clinicians rated the metabolic control of the students as being worse in college, 38.9% rated it as unchanged and 30.6% rated it as having improved. A total of 71% found it more difficult to manage their diabetes in college than in high school, 24% found it easier 5% found it the same. Diabetes was perceived to be significantly more difficult to manage in college than in high school ($p = 0.002$). Neither an increase in the frequency of self-monitoring of blood glucose nor an increase in the number of daily insulin injections was associated with a perceived increased difficulty of diabetes management. The reasons selected for any type of change (positive or negative) in college student's diabetes control were diet ($n = 36$), exercise ($n = 34$), frequency of self-monitoring of blood glucose ($n = 25$), increased responsibility ($n = 24$), irregular schedule ($n = 21$), fear of hypoglycaemia ($n = 17$), alcohol use ($n = 16$), no parental involvement ($n = 13$), contact with health-care provider ($n = 11$) HbA_{1c}: there was no significant change in control between high school and college

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
Wdowik 1997,[136] USA	
Aim: to identify factors that affect the ability and motivation of college students to engage in appropriate self-care behaviours for successful management of diabetes	
Design: focus groups and telephone interviews Measure: structured interview schedule Data analysis: chart of pertinent issues and listing of the responses Quality criteria met: ABCDEFHI	Self-management skills: the five most salient barriers to successful diabetes management cited were scheduling and time management difficulties, stress, hypoglycaemic reactions, diet management constraints and inadequate finances. Psychosocial issues were also identified as barriers to diabetes management. These included the inconvenience of diabetes management, motivators to managing diabetes and social support issues
Wilson 2010,[189] UK	
Aim: to explore the experiences of young people managing their diabetes at college or university	
Design: interviews Measure: semistructured schedule Data analysis: thematic data analysis Quality criteria met: ABCEFGHI	Thematic data analysis identified four main themes: balancing diabetes and further education, adverse diabetes management strategies, reduced participation in social events, and transition to an adult diabetes clinics
Wdowik *et al.* 2001,[187] USA	
Aim: to determine relationships between constructs of the expanded health belief model and to identify characteristics of college students who successfully manage their diabetes	
Design: survey Measures*:* ID – Diabetes College Scale/expanded health belief model Data analysis: descriptive, inferential and analytical statistics Quality criteria met: ABCDEFGHI	HbA_{1c}: only 45.8% provided a self-reported recent HbA_{1c} level Self-management skills: planning snacks, exercising and testing blood sugar were reported with a frequency of between ‘sometimes’ and ‘usually’ Self-management attitudes: survey responses on attitude constructs indicated that participants had good intentions to engage in self-care behaviours. However, intention alone was not enough to result in optimal behaviours, as indicated by the infrequency of exercise reported. Notably, students’ emotions were negative predictors of exercise such that, the more they disliked exercise or felt stressed, out of control or unhappy, the less likely they were to participate. Intention and emotional response were strong predictors of exercise, whereas health importance and intention were predictive of testing blood sugar. Situational factors and emotional response were substantial barriers to optimal diabetes self-care. In this study the attitude constructs most predictive of good diabetes management behaviours included intention and health importance whereas barriers to achieving appropriate outcomes were identified as situational factors and emotional response. Thus, even students with positive attitudes and good intentions may be unable to engage in desired self-care behaviours if significant barriers or negative emotions are present

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
Balfe 2007,[183,207] Balfe and Jackson 2007,[184] Balfe 2009,[185,186] UK	
Aim: to explore the narratives of practice of young university students with T1D	
Design: interviews and follow-up interviews 6 months later, research diaries for 2 weeks Measure: semistructured interview schedule Data analysis: thematic analysis Quality criteria met: Balfe 2007:[183] ABCDEFHI, Balfe 2007:[207] ABCEFGHI, Balfe and Jackson:[184] ABCDEFGHI, Balfe 2009:[185] ABCDEFGHI, Balfe 2009:[186] ABCDEFGHI	Balfe 2007:[183] alcohol: discussion centred around the themes of reasons for drinking riskily, risk anxieties (short term and long term), managing risk and changing attitudes to risk. Many respondents (especially first years) engaged in alcohol consumption practices that were risky for their diabetes control in order to perform identities as normal young students. Younger interviewees mainly engaged in alcohol consumption practices that were risky for their diabetes control in public spaces where they felt that there would be a risk to their identities as normal young people if they did not engage in these practices. There was evidence that as the respondents experienced transitions within university their attitudes towards the risks of drinking changed and, in many cases, students' drinking decreased substantially after their first year Balfe 2007:[207] healthy eating and exercise: discussion centres around the themes of moral practices – concerns about eating healthily and exercising, about 'engaging in the 'right' practices, about temporalities – concerned about exercising and eating healthily to minimise the ability of diabetes to affect their future identifies. Routine – the university environment itself could make a deleterious impact on interviewees' ability to engage in moral disciplinary practices, even for those who wanted to do so. Weight management narratives – using disciplinary regimes to manage weight Balfe and Jackson:[184] technologies defined as insulin pens, insulin pumps and blood testing equipment. Discussion centres around the themes of the use of technology, disadvantages and factors influencing the use of technology. Technologies increased respondents' social and spatial flexibility, providing them with the means to fit their diabetes more easily into their student lifestyle Balfe 2009:[185] being normal: the main finding was that respondents attempted to be 'normal' by engagement with particular body projects: student bodies, toned bodies and healthy bodies. If individuals cannot balance their body projects they get 'identity damage' Balfe 2009:[186] self-management skills: five themes were identified: routine benefits, routines at university, adjustment (achieving a balance between self-care routines and student practices), glitching (glitching describes the involuntary collapse of an entire diabetes self-care routine over an extended period) and crashing (crashers tended to ignore their self-care routines or be overwhelmed by them) In summary, students with diabetes can experience significant difficulties with their self-care routines in university but can learn to overcome these with time and experience

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
Geddes *et al.* 2006,[138] UK	
Aim: to examine the clinical characteristics of, and diabetes management provided for, young people with T1D in tertiary education	
Design: retrospective survey Measure: case notes Data analysis: descriptive and inferential statistics Quality criteria met: ABCDEFGH	Diabetes management: year of referral to local diabetes clinic at hospital was not consistent. Only 10 students (18%) were not using a basal-bolus regimen by the time they left university. Smoking and alcohol consumption of students were seldom reviewed. At the time of initial assessment the mean HbA$_{1c}$ level was 8.8% (SD 2.0%). By the end of their attendance at university this was unchanged [8.7% (SD 1.6%), $p = 0.77$]. Prevalence of retinopathy was 10.9% at the beginning of the observation period but by the end of the observation period this had risen to 14.5%. The frequency of home blood glucose monitoring had not been adequately documented in 13 (24%) of the 55 patients. The frequency of testing in the remainder was variable, ranging from six to eight times per day to once per week. The frequency of mild hypoglycaemia had not been documented
Eaton *et al.* 2001,[135] UK	
Aim: to contact students with diabetes at the University of Leeds to ascertain their alcohol, smoking and exercise habits and to explore their views on diabetes and factors that influence their ability to maintain glycaemic control	
Design: interviews Measure: semistructured schedule Data analysis: themes generated Quality criteria met: ABC	Self-management skills: 22 (55%) reported that having diabetes interferes with being a student. Two main themes were identified: the effects of having diabetes on the student lifestyle (with three subthemes of alcohol, exercise and student budget) and facilities and services
Ravert 2009,[188] USA	
Aim: to examine the use of nine common alcohol management strategies among college undergraduates with diabetes to determine which strategies predicted alcohol consumption and consequences	
Design: survey Measure: ID Data analysis: descriptive and inferential statistics Quality criteria met: ABCDEFI	Alcohol: a majority of respondents (68.0%) reported alcohol use in the previous month, with 41.8% consuming five or more drinks in one sitting during the previous 2 weeks. Respondents reported using the following strategies: eat before and/or during drinking (77.9%); keep track of how many drinks you are having (65.5%); decide in advance not to exceed a set number of drinks (40.1%); avoid drinking games (38.7%); have a friend let you know when you've had enough (30.7%); alternate non-alcoholic with alcoholic beverages (29.4%); pace your drinks to one or fewer per hour (29.6%); choose not to drink alcohol (34.0%); drink an alcohol lookalike [non-alcoholic beer, punch etc. (10.0%)] No significant correlation was found between age and overall mean management strategy use. However, two individual strategies, rely on a friend and keep track, were negatively correlated with age ($r = –0.13$, $p = 0.019$, and $r = –0.11$, $p = 0.047$ respectively) and were therefore more common among younger students. In contrast, the strategies of pacing drinks and avoiding drinking games were more common among older students ($r = 0.11$, $p = 0.047$, $r = 0.21$, $p < 0.001$ respectively)

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
	High alcohol management strategy use in the past year was associated with fewer heavy drinking episodes and fewer alcohol-related consequences. The strategies of avoiding drinking games and pacing drinks were especially strong predictors of reduced consumption and consequences
Miller-Hagan and Janas 2002,[190] USA	
Aim: to explore how college students with diabetes perceive and manage alcohol consumption	
Design: interviews Measure: semistructured schedule Data analysis: constant comparative method Quality criteria met: ABCDEFI	Alcohol: three drinking-related perceptions were especially salient among the participants in this study: students with diabetes can drink if they are careful, drinking is the primary social activity at this university and the peer pressure to drink is strong. Students had varied responses to the social environment and pressure to drink. Three distinct practices emerged: not drinking, experimenting with drinking and drinking within limits. Analysis of students' drinking practices revealed six categories of strategies that students used in an attempt to restrict or limit their alcohol consumption: avoid or diffuse peer pressure; limit the frequency of going out to parties and bars; develop personal rules for the amount of alcohol consumed; check or monitor blood glucose levels; 'cover' the alcohol with insulin and/or food; and drink with trusted friends
School personnel	
Amillategui *et al.* 2009,[177] Spain	
Aim: to identify the special needs of children with T1D at primary school, taking into account the perceptions reported by parents, children and teachers (for further details see Amillategui *et al.*[177] under children and parents section)	
Greenhalgh 1997,[191] UK	
Aim: to assess school teachers' knowledge of insulin-dependent diabetes in school children aged 5–16 years	
Design: Survey Measure: ID – diabetes knowledge Data analysis: descriptive and inferential statistics Quality criteria met: ABCDE	Diabetes knowledge: adequate knowledge of diabetes 35% (40% primary and 38.3% secondary, 27% secondary excluding science and PE teachers). Primary school teachers scored significantly higher marks (40%) than secondary school teachers (38.3%) Sources of information: parents 64%. Secondary school other sources: radio, television, other school staff, teaching literature, newspapers and magazines Diabetic ketoacidosis: manage symptoms of diabetic ketoacidosis 37.6% Policies: detention was an appropriate punishment for misbehaviour by a child with diabetes (53% secondary and 48% primary). Children with diabetes should not be late for a meal (37.5% secondary and 25% primary) Outside school trips: 100% felt that all children with diabetes should be allowed to go on holiday with the school

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
Bowen 1996,[192] UK	
Aim: to discover whether teachers had the training to cope with the health-related emergencies that may arise with children who have special needs	
Design: survey Measure: ID – competence Data analysis: descriptive statistics Quality criteria met: ABCDEFGHI	Hyperglycaemia: 70% recognise signs Hypoglycaemia: 60% recognise signs Competence: 63% competent to cope with emergencies that arise with blood sugar levels Information about diabetes: 86% would like more information and advice
Gormanous *et al.* 2002,[195] USA	
Aim: to determine the levels of knowledge about diabetes mellitus among Arkansas public elementary school teachers	
Design: survey Measure: ID – diabetes knowledge Data analysis: descriptive and inferential statistics Quality criteria met: ABCDEHI	Training: 19% had never received in-service training or education on diabetes Information about diabetes: 79% would like more information Diabetes knowledge: teachers who had previous experience of diabetes were significantly more likely to correctly define hypoglycaemia (65% vs. 45%, $p < 0.05$) and know the correct treatment (37% vs. 13%, $p < 0.05$). Teachers with family and friends with diabetes were significantly more likely than those with no personal exposure to diabetes to correctly identify symptoms of diabetes (49% vs. 29%, $p < 0.05$) and symptoms of hypoglycaemia (60% vs. 38%, $p < 0.05$) and select the appropriate treatment for low blood sugar (21% vs. 12%, $p < 0.05$)
Alnasir and Skerman 2004,[193] Bahrain	
Aim: to study awareness about common health problems in Bahrain	
Latif Almasir 2003,[194] Bahrain	
Aim: to assess Bahrani school teachers' knowledge of diabetes	
Design: survey Measure: ID – diabetes knowledge Data analysis: descriptive and inferential statistics Quality criteria met: ABCDEF,[193] ABCDEFI[194]	Diabetes knowledge: mean 5.34 (SD 2.13), median 5.5 (possible range 1–10). The level of diabetes knowledge was significantly better in females, science teachers, those who did not drink alcohol, those with an ill family member and those who had unsatisfactory perceptions about general health
Tahirovic and Totomanovic 2007,[196] Bosnia and Herzegovina	
Aim: to investigate how far physical education teachers from elementary school understand diabetes and are trained in its management and in the treatment of diabetes emergencies according to their understanding	
Design: survey Measure: ID Data analysis: descriptive and inferential statistics Quality criteria met: ABCDEFH	Training: physical education teachers whose schools were attended by at least one pupil suffering from T1D were significantly more likely to have been taught about T1D (group 1 39%, group 2 20%, $\chi^2 = 5.04$, $p = 0.02$). Physical education teachers in whose schools there were pupils suffering from T1D were significantly more likely to be interested in learning about T1D (group 1 89%, group 2 98%, $\chi^2 = 4.18$, $p = 0.04$)

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
	Hypoglycaemia: physical education teachers whose schools were attended by at least one pupil suffering from T1D were significantly more likely to know about hypoglycaemia ($\chi^2 = 4.178$, $p = 0.040$) Policies: schools in which there were pupils suffering from T1D were significantly more likely to allow pupils to take glucose or food during lessons (group 1 82%, group 2 53%, $\chi^2 = 10.32$, $p = 0.001$). Schools in which there were pupils suffering from T1D were significantly more likely to allow pupils to measure their blood glucose levels during lessons (group 1 71%, group 2 31%, $\chi^2 = 7.58$, $p < 0.05$)
MacArthur 1996,[163] UK	
Aim: to examine the practice and attitudes of local children who were taking pre-lunch insulin injections at school	
Design: survey Measure: ID Data analysis: descriptive statistics and numerical content analysis Quality criteria met: ABCHI	Location: certain area to do the insulin injection: yes: $n = 6$, no: $n = 5$. Reasons for yes mainly concerned the student's privacy, safety and cleanliness. School staff did not think that the children needed to be supervised whilst doing injections at school. In total, 91% ($n = 10$) of the school staff reported that pupils should look after their own pen
Boden *et al.* 2012,[197] UK	
Aim: to examine the concerns of primary school staff working with children with T1D and their parents and to relate these views to the views of HCPs working with school personnel	
Design: interviews Measure: semistructured interview schedule Data analysis: qualitative approach Quality criteria met: ABCDEFGHI	Primary school staff expressed a range of concerns about injecting and blood glucose testing, the ability of children to mishandle their condition, and reactions of parents to school decisions on health-based matters
Nabors *et al.* 2008,[198] USA	
Aim: to assess special education and regular education teachers' perceptions of their knowledge about and confidence in meeting the academic and social needs of children with chronic medical conditions (including diabetes)	
Design: survey Measure: ID – perceptions of knowledge and confidence Data analysis: descriptive and inferential statistics Quality criteria met: ABCEFGHI	Diabetes knowledge: 22.1% of teachers reported being very well informed (rating of 5 or 6) regarding diabetes. There was no difference in knowledge between regular education teachers and special education teachers Confidence: 42.5% of teachers (regular education teachers and special education teachers) indicated being very confident (rating of 5 or 6) in meeting the academic needs of students with diabetes and 43.7% of teachers indicated being very confident (rating of 5 or 6) in meeting the social needs of students with diabetes. There was no difference in confidence in meeting the social needs of students between regular education teachers and special education teachers

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
Lewis *et al.* 2003,[170] USA	
Aim: to identify obstacles to good control of diabetes in the school setting and document the level of support available in various school districts serving the clinic patient population	
Design: survey Measure: ID – 25 items Data analysis: descriptive statistics Quality criteria met: ABCEI	Policies: no policy pertaining to diabetes management 9% ($n = 6$). Students with diabetes did not have activity restrictions 95% Blood glucose monitoring: not allowed to perform blood glucose monitoring while at school 3% ($n = 2$) Availability of supplies: did not have refrigerators available for the storage of glucagon, insulin or syringes (20%). Food and beverages containing glucose were not readily available 3% ($n = 2$) Training: did not have staff trained in diabetes management 17% ($n = 11$)
Rickabaugh and Salterelli 1999,[199] USA	
Aim: to explore the attitudes and reported behaviours of participants concerning diabetes and exercise guidelines	
Design: survey Measure: ID – diabetes and exercise knowledge and attitudes Data analysis: descriptive and inferential statistics (non-parametric) Quality criteria met: ABCDEGHI	Knowledge: parents (36.3%) performed noticeably better on knowledge items than children with T1D and physical education teachers (23.1%). Physical education teachers were also very unsure about the optimal HbA_{1c} range for children with T1D (teachers 100%, parents 32%). Physical education teachers were unsure about what exercise limitations exist for children with T1D (teachers 47%, parents 86%). Physical education teachers were also more uncertain than parents about the effects of exercise on long-term blood glucose levels (teachers 56%, parents 86%) Attitudes: children with T1D and their parents displayed similar attitudes towards diabetes and exercise guidelines, whereas physical education teachers appeared to be less familiar with these procedures and indicated that they were 'unsure' on many responses
Chmiel-Perzynska *et al.* 2008,[200] Poland	
Aim: to evaluate the knowledge of primary school teachers in the Lubelskie Province, Poland, about hypoglycaemia and to determine the educational needs necessary to ensure that children with diabetes are properly dealt with by their teachers	
Design: survey Measure: ID – diabetes knowledge Data analysis: descriptive statistics Quality criteria met: ABCDE	Blood glucose monitoring: 98% knew what a glucose meter is but only 46% reported being able to operate it Hypoglycaemia: 71.3% recognise the signs, 76.9% did not know what blood glucose levels are indicative of hypoglycaemia, 42.3% did not know how they could help a hypoglycaemic child Glucagon: 43.3% did not know what it is used for, 23.1% knew when glucagon should be given, 15.4% knew how to give glucagon Diabetes knowledge: 92% considered their knowledge to be sufficient and only one in five expressed a willingness to participate in free training on diabetes

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
School health-care personnel	
Fisher 2006,[201] USA	
Aim: to measure school nurses' perceived self-efficacy in providing diabetes care and education to children	
Design: survey Measure: SEDE Data analysis: descriptive and inferential statistics Quality criteria met: ABCDEGHI	Support: 62.9% participated in the care of children with T1D and supervised blood glucose meter testing Education and training: 94.3% reported that they had up-to-date diabetes reference materials in their office and 35.7% had attended a conference on diabetes during the past year Self-efficacy: mean SEDE score 36.30 (moderately confident). There was a significant relationship between higher self-efficacy scores and having a diabetes curriculum. However, only nine school nurses reported having a diabetes curriculum Significant findings in this study were the positive relationships between self-efficacy and three variables: (1) participating in the care of children with diabetes, (2) having T1D children in the school system and (3) supervising children with blood glucose meter testing. Regression analysis of self-efficacy on these demographic variables revealed a R of 0.42 ($R^2 = 0.20$), indicating that 20% of the variance in self-efficacy was explained by these factors ($p = 0.01$)
Guttu *et al.* 2004,[202] USA	
Aim: to examine the impact of school nurse to student ratios on student outcomes in a 21-county region with a range of school nurse to student ratios	
Design: survey Measure: percentage of students with T1D known to school nurse Data analysis: descriptive and inferential statistics Quality criteria met: ABCDEI	Availability of school nurse: there was no difference in the percentage of students with diabetes between counties and nurse to student ratios. A significant correlation existed between increased presence of school nurses and services provided to children with diabetes ($r = 0.52$, $p = 0.000$)
Joshi *et al.* 2008,[203] USA	
Aim: to gather school nurses' perceptions of the barriers related to diabetes knowledge, communication and management	
Design: survey Measure: ID Data analysis: descriptive statistics and numerical content analysis of open-ended questions Quality criteria met: ABCEH	Diabetes knowledge: 29% had a low to average perception Source of diabetes information: internet (79%), professional books and magazines (42%) Barriers to acquiring new information: time constraints (37%), lack of access to education/regular updates and inadequate training (28%) Barriers to increasing students' adherence to medical regimen: improper food habits (limited food choice in cafeteria, availability of snacks with high carbohydrate levels) (40%)

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
	Problems faced in helping students cope with T1D: easy access to vending machines (36%), inadequate physician and parent orders (27%), students do not want to be recognised as different to their peers (53%), enhance education of students (42%) Ways to promote better support of children: diet schedules should be modified (32%), improve communication with provider and parents (30%), timely availability of supplies (21%)
Nabors *et al* 2005,[204] USA	
Aim: to examine nurses' perceptions of how to support adolescents with T1D at school	
Design: survey Measure: ID Data analysis: descriptive and inferential statistics, content coding process based on grounded theory Quality criteria met: ABCDEHI	Experience of diabetes: adequate (54%) or high (30%) School policy: 92% had developed written health-care plans for a child with diabetes. Nurses who worked for more years as a 'school nurse' were more apt to report that they had developed care plans for youth with diabetes ($r = 0.22$, $p = 0.025$) Extracurricular activities: 73% did not believe that after-school activities should be included in written health-care plans. Participants with more years of experience as a school nurse were more likely than those with less experience to state that care plans should address after-school activities ($r = 0.25$, $p = 0.012$) Diabetes knowledge: school staff needed to improve their knowledge about diabetes Support from school staff: 98% of nurses agreed that adolescents with diabetes needed more support at school. Nurses who felt knowledgeable about diabetes were more likely than nurses who did not feel knowledgeable to report that adolescents with diabetes needed more support at school ($r = 0.30$, $p = 0.002$) Facilitators of adherence at school: four themes emerged: improving communication among everyone who could potentially help the adolescent at school, educating nurses and school staff, improving parental involvement in school planning and improving support for adolescents Barriers to adherence at school: five themes emerged: issues for teens, issues for school staff, communication, food management and education
Wagner *et al.* 2006,[182] USA	
Aim: to explore whether training in diabetes for school counsellors is associated with better knowledge and more helpful attitudes to students with diabetes	
Design: survey Measure: ID – awareness of diabetes-related issues, DAS version 3, TDKT Data analysis: descriptive and inferential statistics Quality criteria met: ABCDEFGHI	87% indicated that they had received no specific training about diabetes, yet 40% had reportedly worked directly with students with diabetes Knowledge: mean score on the TDKT 10.3 (SD 3.4), indicating a basic understanding of diabetes according to criteria established by the scale's authors. Knowledge deficits were demonstrated by 15% of the sample, basic understanding by 57% and scores indicative of being an effective support for children with diabetes by 28%. Respondents who reported diabetes training had higher TDKT scores (mean 13.04) than those who did not (mean 10.51) [$F(3,90) = 8.62$, $p < 0.01$]

Methods and quality appraisal[a]	Summary results (only results relating to barriers and facilitators are reported)
	Attitudes: mean score on the DAS 3.9 (SD 0.5). Respondents who reported diabetes training had higher DAS scores (mean 4.27) than those who did not (mean 3.96) [$F(3,91) = 6.55$, $p < 0.05$] Awareness: many school counsellors endorsed items that would hinder their ability to serve students with diabetes. Specifically, counsellors were neutral or agreed with unhelpful statements such as 'diabetes restricts extracurricular activities' (35% did not disagree) and 'the most appropriate place for children with diabetes to test blood sugar is in the nurse's office' (87% did not disagree)
Schwartz *et al.* 2010,[178] USA	
Aim: to evaluate the experiences of children and adolescents with T1D in school by surveying patients, their parents or guardians and the school personnel directly involved in their care (for further details see Schwartz *et al.*[178] in the children and parents section)	
Darby 2006,[206] USA	
Aim: to examine the challenges encountered by school nurses when caring for students receiving CSII therapy	
Design: interviews Method: semistructured schedule Data analysis: phenomenological analysis with the process of intuiting and describing at the centre of this analysis Quality criteria met: ABCDEFHI	Eight themes evolved from the data. These were feeling scared, developing trust, knowing your students, working with the children's hospital, teaching and learning, talking the talk, dealing with pump problems and calculating challenges The nurses' responses indicated that they were 'scared' when first caring for students undergoing CSII therapy. However, they were able to work through their fear by using their resources and gaining more knowledge and hands-on experience with insulin pumps. The data also revealed that school nurses who were able to learn the language of CSII therapy and successfully deal with pump problems developed trusting and knowing relationships with students, teachers and parents

CATIS, Child Attitude Towards Illness Scale; CCA, constant comparative analysis; DAS, Diabetes Attitude Scale; DSMP, Diabetes Self-Management Profile; ID, investigator designed; SE, standard error; SEDE, Self-Efficacy in Diabetes Education instrument; TDKT, Test of Diabetes Knowledge.

[a] Quality criteria key: A, clear statement of the aims of the study; B, adequate description of the context for the study; C, clear specification of research design and its appropriateness for the research aims; D, reporting of clear details of the sample and method of recruitment/sampling; E, clear description of data collection; F, clear description of data analysis; G, attempts made to establish rigour of data analysis; H, discussion of ethical issues/approval details; I, inclusion of sufficient original data to support interpretations and conclusions.

Appendix 4 Evidence to support fieldwork

Example of focus group schedule: children aged 6–10 years

	Resources
Introduction – Hi, I'm (name of researcher) and this is (name of researcher). First of all welcome, and thank you all for coming. We've asked you to come here today to talk to us about you, your diabetes and how you look after yourselves. What we're doing today is called a focus group, because we are in a group and we are focusing on some resources and questions about diabetes. What you tell us is important, and we are going to pass that information on, without using your names Have you all signed a sheet to say that you are happy to take part in this focus group? And that you are happy to be video recorded? (Wait for response). Okay. Great. What's important is that everybody has a chance to say something, so the rules are: (1) tell us what you really think, (2) listen carefully and try not to interrupt, (3) respect what others are saying because you won't necessarily agree with each other all of the time and (4) if you need to have a snack during the focus group, there is some food and drink for you on the table over there – so help yourself if you need to. Otherwise we will be having a drink and some snacks at the end of the session. Has anybody got any questions for me? Is everybody okay with this?	• Blu-tack • Rules on a A3 piece of paper ○ Give your honest opinion (let us know/tell us what you really think) ○ Please listen carefully to what others are saying, and try not to interrupt ○ Respect what others in the group are saying ○ Drinks and snacks available for you
Ice breaker – Throw a teddy so that we can learn everyone's name	Soft toy
Question 1 – General warm-up question Have you been given information about what diabetes is, and what did you like about the way you got that information?	None
Question 2 – Show some items from the focus group list and get the child's opinion: *What do you think about this?* *What do you like about it?* *What don't you like about it?* *How could it be more relevant to you?* *Could you be the person in the image?* *Does it matter that you are not like him/her?* *Can you tell me more about that?* *Do you feel as part of a group of kids with diabetes?* *Do you want to be part of such a group?* *What does your syringe mean to you?*	Leaflets from NHS trusts: • Stockport NHS leaflet • Gwent Hospital diabetes folder • Birmingham NHS Trust – *Diabetes and Me* Leaflets from glucose meter companies: • BD Medical – Diabetes Care – *Getting Started with Diabetes* • Novo Nordisk – *Diabetes Made Simple* • Eli Lilly – *Hanging with Hu-mee* (HumaPen) Leaflets from charities: • Diabetes UK – *Tadpole Times* DVD video clips: • *JDRF Gang* DVD • *Tina at Home with Ria* • *Chloe Blood Testing at School*

	Resources
Do you feel that your equipment says something about you as a person? *If so, do you want to express yourself through different colours and styles of syringe?*	Books: - *Becky has Diabetes* - The Facts about Diabetes - The Dinosaur Tamer Websites: - www.childrenfirst.nhs.uk/kids/health/illnesses/d/diabetes.html (Great Ormond Street Hospital for Children NHS Foundation Trust) - www.clubultraman.eu.en/20.php (snakes and ladders game) - www.diabetes.org.uk/guide-to-diabetes/my-life/kids (*Me and My Diabetes*) - www.abbottdiabetescare.co.uk (site unavailable on 31 October 2008, may be updated)
Question 3 – Thinking about the information that you've been given about your diabetes, is there anything that you'd like to know that you're not sure of? *Some people have looked at children's information and some children have said that they haven't had enough help, support or information about:* 1. fitting in 2. friendships 3. standing out 4. how you feel about yourself 5. your lifestyle – school life, coping with injecting insulin, going on holiday without your parents 6. future jobs 7. going out with your friends around the town	- Flip chart - Flip chart pens - Blu-tack
Question 4 – How would you like to be given that information? 1. in a leaflet 2. on a website 3. by e-mail 4. in a book 5. in person through a health professional 6. face-to-face with a person with diabetes (peer support group) 7. in DVD or video format 8. on a web forum 9. on a web message board 10. by text 11. by telephone information service	Thumbs up (×12) and photographs to stick on the 'thermometer' with Blu-tack 1. photo of leaflet 2. photo of a website 3. photo of e-mail sign 4. photo of a book 5. photo of a HCP 6. photo of a support group 7. photo of a DVD/video 8. photo of a web forum 9. photo of a message board 10. photo of a mobile phone 11. photo of a telephone
That's the end of my questions, have you got any questions for me – or does anyone want to say anything else about diabetes information?	
Thank you – Okay! Thank you all for coming, it's been great to meet you all The information that you have given us will stay confidential in that we won't name you on any reports that we write The information that you have given us will help improve the information given to other young people in the future about diabetes	

	Resources
Token – Before you go, we will give you a high street voucher worth £20 for taking part today. Don’t forget to pick it up from us. We’ll ask you to sign a form to say that you have had it	High street vouchers (£20 × 12)
Drink and snacks **–** Feel free to help yourself to a drink and a snack in here while you wait for your lift home	● Diet coke ● Regular coke ● Small bottles of original Lucozade ● Bottled water ● Cereal bars ● Bananas ● Crisps ● Dextrose tablets
Again, thank you very much for your time and opinions. They are much appreciated and very valuable to us	

Information resources used as part of the focus groups

6–10 years	11–15 years	16–18 years
Leaflets from NHS trusts: ○ Stockport NHS leaflet ○ Gwent Hospital diabetes folder ○ Birmingham NHS Trust – *Diabetes and Me*	Leaflets from NHS trusts: ○ Stockport NHS leaflet ○ Gwent Hospital diabetes folder	Leaflets from NHS trusts: ○ Stockport NHS leaflet ○ Gwent Hospital diabetes folder ○ United Bristol Hospital Trust *Sick Day Rules*
Leaflets from glucose meter companies: ○ BD Medical – Diabetes Care – *Getting Started with Diabetes* ○ Novo Nordisk – *Diabetes Made Simple* ○ Eli Lilly – *Hanging with Hu-mee* (HumaPen)	Leaflets from glucose meter companies: ○ Eli Lilly – *Streetwise* leaflets ○ BD Medical – Diabetes Care – *Getting started with Diabetes* ○ Roche Diagnostics – *Managing your Diabetes*	Leaflets from glucose meter companies: ○ Eli Lilly – *Streetwise* leaflets (*Sex and Beyond with Diabetes*, *Drinking Safely with Diabetes*, *Body Piercing and Tattoos with Diabetes*, *Travelling with Diabetes*) ○ Abbott Diabetes Care – *Living with Diabetes – a Guide for Teenagers* ○ BD Medical – Diabetes Care – *10 Questions about Lipodystrophy* ○ Roche Diagnostics – *Know the Score*
Leaflets from charities: ○ Diabetes UK – *Tadpole Times*	Leaflets from charities: ○ Diabetes UK newsletter – *On the Level* ○ JDRF magazine – *T1*	Leaflets from charities: ○ None
DVD video clips: ○ *JDRF Gang* DVD ○ *Tina at Home with Ria* ○ *Chloe Blood Testing at School*	DVD video clips: ○ Diabetes UK DVD ○ Excerpts *Dean & Aimee*	DVD video clips: ○ Diabetes UK DVD
Books: ○ *Becky has Diabetes* ○ The Facts about Diabetes ○ The Dinosaur Tamer	Books: ○ *Type 1 Diabetes in Children, Adolescents and Young Children* ○ *Getting a Grip on Diabetes*	Books: ○ *Joe's Rough Guide to Diabetes* ○ Type 1 Diabetes in Children, Adolescents and Young Adults ○ Getting a Grip on Diabetes
Websites: ○ www.childrenfirst.nhs.uk/kids/health/illnesses/d/diabetes.html (Great Ormond Street Hospital for Children NHS Foundation Trust) ○ www.clubultraman.eu.en/20.php (snakes and ladders game) ○ www.diabetes.org.uk/guide-to-diabetes/my-life/kids (*Me and My Diabetes*) ○ www.abbottdiabetescare.co.uk	Websites: ○ www.diabetes.org.uk/Guide-to-diabetes/My-life/Teens/ ○ www.accu-chekteams.co.uk/en_GB/multimedia/plp/index.html#/growingup/ ○ www.diabeteskidsandteens.com.au/dealingwithd.html ○ www.childrenfirst.nhs.uk/teens/health/conditions/d/diabetes.html (Great Ormond Street Hospital for Children NHS Foundation Trust)	Websites: ○ www.diabetes.org.uk/MyLife-YoungAdults/ (problem page) ○ www.novonordisl.com/diabetes/public/diabetestools/handsoninsulin/default.asp ○ www.bayerdiabetes.co.uk/aroundu/ages_15/index.aspx (day-to-day) ○ www.diabeteskidsandteens.com.au/dealingwithd.html ○ www.runsweet.com/ChildrenAndAdolescents.html ○ Or discuss social networking sites

<table>
<tr><th>6–10 years</th><th>11–15 years</th><th>16–18 years</th></tr>
<tr><td colspan="3">Activity to elicit viewpoints and preferences on the following. Ask them to put their hands up or use the thumbs-up ‘thermometer’:
1. photo of leaflet
2. photo of a website
3. photo of e-mail sign
4. photo of a book
5. photo of a HCP
6. photo of a support group
7. photo of a DVD/video
8. photo of a web forum
9. photo of a message board
10. photo of a mobile phone
11. photo of a telephone</td></tr>
</table>

Example of interview schedule

Preliminaries

1. Names, purpose of study explained simply and clearly (refer to child's info sheet).
2. Thank child/YP for agreeing to take part
3. Consent
4. Remind them its okay to stop interview at any time or not to answer a particular question.
5. Rehearse with child various strategies (whatever seems appropriate)
    - Using red and yellow cards
    - Choose a phrase to use if they want to stop.
    - Choose a phrase to use if don't want to answer a question.
    - Can use a silly word if don't want to answer a question.
6. Ask permission to tape record. Offer child chance to listen back. Or the chance to ask some questions (to be the interviewer) later on. Consider giving child control over tape recorder?
7. You are the expert…. e.g. 'I don't know as much about (condition) as you do. I am very interested to hear your views and experiences.
8. There are no right or wrong answers. We are just interested in what you think and feel about things'.
9. Okay to say 'don't know' and to say if you don't understand.
10. Ask if they have any questions.

Background Questions (warm up)
Q: Perhaps we can start off by you telling me about your school and the things you do there (adapt depending on age)

Q: *And what about when you are not at school or doing homework! What sorts of things do you like doing? Hobbies?* (Adapt according to age)

I'd like to start by finding out about you and your diabetes
1. *I know that children/YP with diabetes have to do things like their blood sugars / keep a diary/ give themselves injections. Can you tell me what you have to do day by day?*

Prompt:

- Use of medicines, equipment used and daily routines?
- What are the most easy/difficult aspects and why?
- What things does child think 'OK' and /or dislike and why?

2. *So far you've been telling me about the kinds of things you have to do. I'm interested to know how diabetes fits in with the rest of your life. How do you find having diabetes affects your everyday life?*

Prompt:

- Sense of health / Spare time
- Friendships / School
- Ideas/plans for future (as appropriate: e.g. boyfriends/girlfriends jobs, leaving home)

3. *As you know, this project wants to find out about the sorts of information children and YP with diabetes need. Can you tell me how you learnt about your diabetes and the kinds of things you have to do to take care of yourself?*

Prompt:

- Who has helped child to learn to look after their diabetes?
- How have they helped?
- What did they teach child?
- How is information used at different stages - at diagnosis, when things change, when making decisions etc? Has the kind of information (and the way people to talk to you about your condition) changed over time?

4. *Have you ever read any books or leaflets about diabetes?*

Prompt:

- Where did the booklets/ leaflets come from?
- How useful were they?
- Age-appropriate / child-centered?
- What do they particularly like about them?
- Which types/formats do they find most helpful?
- (How) do they think the written information could be improved?
- Better use of colour / images/real life stories & experiences?
- More information on psychosocial info (other stuff that is important to them) and less on the bio-medical 'facts'.

5. *Have you ever watched any videos / TV / accessed the internet about diabetes?*
Prompts as above

6. Is there anything about your diabetes that you would like more information on, or you are not sure about?

Prompt (as appropriate):

- Anything missing from currently used information sources?
- Psychosocial information needs met? (Fitting in, being different, identity, fears for the future, lifestyle, school, ambitions?)
- If yes? How would they like these (un-met) needs to be met?
- Explore whether child has misunderstood/overlooked information because of language or cultural issues.

Approx 15 minutes

7. Who do you ask/ where do you go if you have a question or you don't understand something about your diabetes?

Prompts:

- *Charities / Health Professional (literature suggests popular)*
- *Internet / Books/leaflets*
- *Friends / Parents*
- *Chat room etc*

8. What about when you're older, do you think you might have different questions or concerns?

- *Prompt (as appropriate): Girlfriend/ boyfriends*
- *Jobs / work / Going out*

***9.** . What about when something changes with your diabetes – say your care or treatment changes in some way – what kind of information are you given then?*

Prompt:

- If yes, what information were they given?
- How was information communicated?
- **Helpful / not helpful? Gaps?**
- Child or Adult focused?
- **Involvement of child in decisions?**
- Risks? / Side effects?
- Transition?

***S**o far we have been talking about the different kinds of information and where you might go for information.... I'd like to talk a little bit now about how you and your family look after your (name of condition) at home.**

10. *Who does what at home to help you look after your diabetes?*

Prompt:

- Explore current role of child, parents, key family members
- How was it decided who does what and when? Did child have a choice (or not) –
- How have roles and routines changed over time as child grows up?
- How does child feel about their current role? Would they like to do more/same/less of their own care?
- Where medicines/equipment stored, how accessed, by who, permissions (or not) required by child?

And what about at school…

11. *What happens at school - can you tell me what you have to do at school to look after your diabetes?*

Prompt:

- Who does what?
- How do they decide when to take their insulin / do blood sugars?
- Do they check with anyone?
- What happens if they feel unwell?
- Does child take insulin / equip. to school or are they kept at school?
- Has that always been the case?
- Choice / decision-making on part of child?
- Were they involved in planning these arrangements?
- Are they happy with arrangements?

12. *Do your school friends know you have diabetes?*

Prompt:

- How do they look after their diabetes when they are with school friends?
- If their school friends don't know, explore reasons and decision-making.
- What makes it difficult to tell them?
- What would help?
- Do (school) friends see child as 'different'

Okay, we are over half way through now. This is really helpful. Would you like to stop for a minute and have a drink/rest. –

We've talked quite a bit about school, I now want to talk about visiting the hospital / GP surgery and some of the other people who help you and your family look after your (name of condition/medicines/equipment).

***13**. Which doctors, nurses, (other healthcare professionals as appropriate) do you now see about your diabetes?*

Prompt:

- type of consultation? / hospital doctor(s),
- general practitioner, / specialist nurses,
- pharmacists, / physiotherapists
- occupational therapists / play specialists
- Other?

***14**. What do you think about visiting the (doctor/nurse/ other as appropriate)?*

Prompts:

- What's your experience like? (adapt as necessary)
- Child-centeredness (or not) of consultation.
- (How) is information used?
- Do they feel able to ask questions?
- If not, why do they think that is? What stops them asking?
- What would help them feel able to ask?

***15**. When you see the (doctor/nurse/ other as appropriate), who does the talking? **PAUSE**. Do you sometimes ask questions?*

Prompt:

- Is their involvement more than supplying/receiving information? Is their scope to 'tell their story' / explain how they feel/how the condition & treatment impacts on their lives?
- Are they asked what they think is best for them? To what extent are they involved in making decisions about their own care?
- Explore actual examples of child-centered involvement in decision-making, and if/how things have changed over time.
- **If no** – explore child's views/experiences of not being asked what they think is best for them/ preferred options.

We're almost done now, I haven't got any more questions, but maybe you feel there's something you want to tell me that you feel is important, but I didn't ask you?

Is there anything else you would like to say?

Thank you very much for your time and thoughts

Members of the children's diabetes clinical expert group for the EPIC trial

Core team

Deborah Edwards
Llinos Spencer
Jane Noyes
Anne Williams

Invited members

Lesley Lowes, Department of Child Health, University Hospital of Wales, Cardiff and Vale University Health Board

Dr Caroline Roberts, Clinical Psychologist, University Hospital of Wales, Cardiff and Vale University Health Board

Professor John W Gregory, Professor in Paediatric Endocrinology, University Hospital of Wales, Cardiff and Vale University Health Board

Mrs Diane Deeley, Diabetes Specialist Nurse, University Hospital of Wales, Cardiff and Vale University Health Board

Mrs Grace Parfitt, Paediatric Diabetes Specialist Nurse, Aneurin Bevan Health Board

Miss Gill Regan, Chief Paediatric Dietician, Royal Gwent Hospital, Aneurin Bevan Health Board

Dr Carl Taylor, Consultant Paediatrician and Clinical Lead, Salisbury District Hospital, Salisbury NHS Foundation Trust

Mr Chris Headland, National Care Advisor for Wales, Diabetes UK

Appendix 5 Evidence to support the trial

Membership of the EPIC trial steering group and data monitoring and ethics committee

Trial steering group

Professor Tim Barrett (TB), Infdependent Chair of the TSG, Director of the Wellcome Trust Clinical Research Facility, Birmingham Children's Hospital

Professor Jane Noyes (JN), Chief Investigator, Bangor University

Dr Lesley Lowes (LL), Principal Investigator and Paediatric Diabetes Specialist Nurse, Cardiff University

Mrs Deborah Edwards (DE), Research Officer, Cardiff University

Dr Llinos Haf Spencer (LHS), Research Officer, Bangor University

Professor John Gregory (JG), Clinical Professor, Department of Child Health, Cardiff University School of Medicine

Professor Peter Brocklehurst (PB), Director, Institute for Women's Health, University College, London

Mrs Rhiannon Whitaker (RW), Associate Director, NWORTH, Bangor University

Professor Rhiannon Tudor-Edwards (RTE), Health Economist, Bangor University

Miss Nina Phillips (NP), service user representative, Cardiff University

Mrs Yvonne Rees Coleman (YRC), parent representative, Involving People

Data monitoring and ethics committee

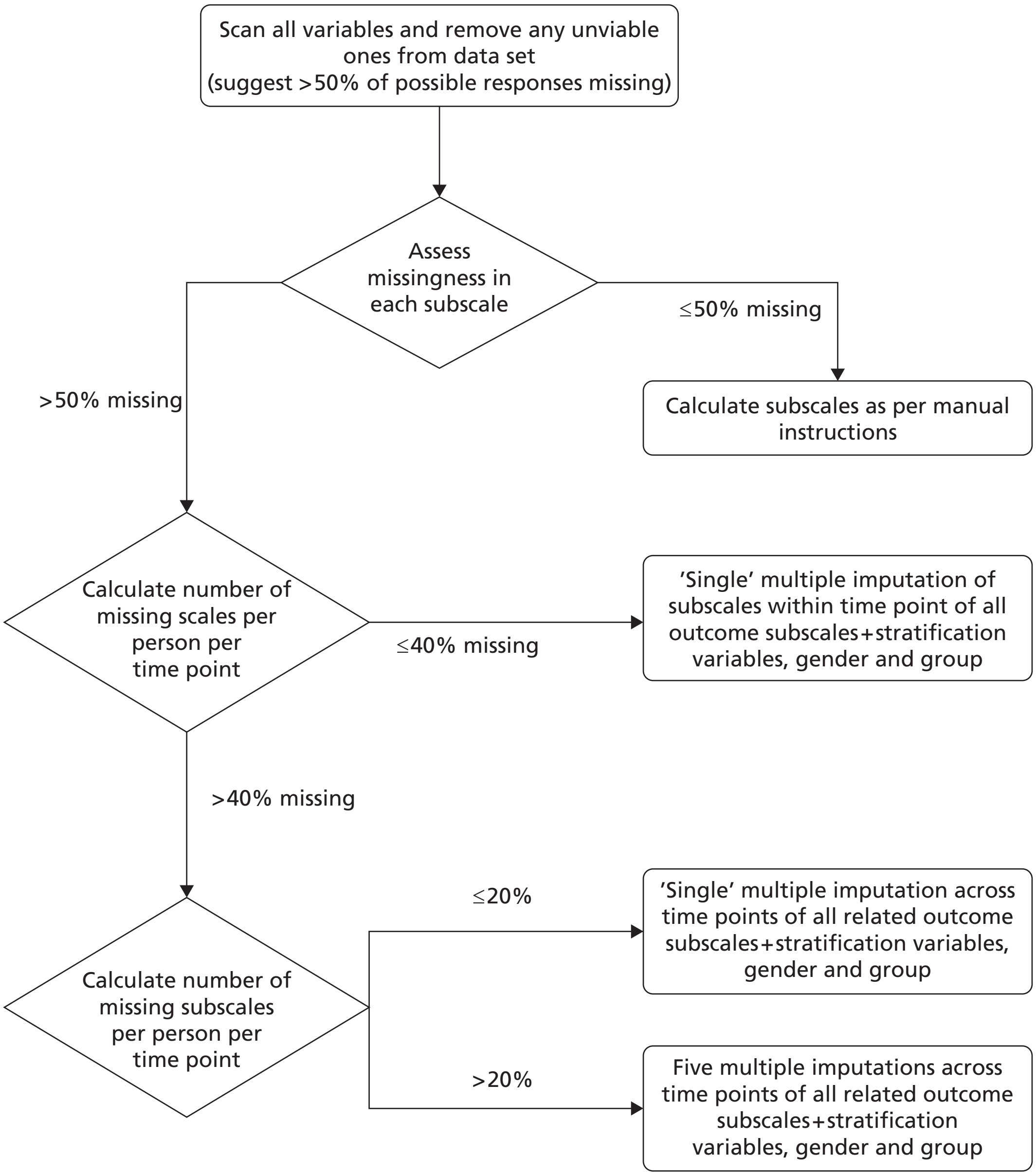
Dr Chris Foy (CF), Statistician and Independent Chair of the DMEC

Rachel Harris (RH), Paediatric Diabetes Specialist Nurse, University Hospital of Wales

Professor John Gregory (JG), Clinical Professor, Department of Child Health at Cardiff University School of Medicine

Mrs Rhiannon Whitaker (RhW), Associate Director, NWORTH, Bangor University (invited representative of the trial)

Subscales imputation strategy for the Paediatric Quality of Life Inventory



Sensitivity analysis

The following table presents the mixed-effects models using four subsets of the originally randomised participants: (1) all randomised (imputed), (2) excluding the protocol violations (imputed), (3) excluding loss to follow-up and protocol violations (i.e. main analysis) and (4) complete case analysis (no imputation)

Outcome variable	Mean (SE)		Mean difference (EPIC pack – TAU) (95% CI)	*F*-value	*p*-value
	EPIC pack	TAU			
All randomised participants (n = 337)					
Child self-report					
PedsQL: diabetes module	72.36 (0.73)	73.50 (1.01)	–1.14 (–3.59 to 1.32)	*F*(1,330) = 0.83	0.362
PedsQL: generic module	81.10 (.63)	81.95 (.89)	–0.85 (–3.00 to 1.29)	*F*(1,329.98) = 0.61	0.435
EQ-5D	0.89 (0.01)	0.89 (0.01)	0 (–0.04 to 0.03)	*F*(1,288.88) = 0.06	0.812
EQ-5D VAS	81.07 (0.99)	81.33 (1.36)	–0.26 (–3.59 to 3.07)	*F*(1,290.13) = 0.02	0.882
Parent proxy					
PedsQL: diabetes module	65.46 (0.62)	66.89 (0.86)	–1.43 (–3.51 to 0.66)	*F*(1,329.85) = 1.81	0.180
PedsQL: generic module	77.24 (0.67)	76.26 (0.93)	0.98 (–1.28 to 3.24)	*F*(1,329.96) = 0.73	0.394
EQ-5D	0.84 (0.01)	0.86 (0.02)	–0.02 (–0.06 to 0.02)	*F*(1,297.92) = 1.01	0.315
EQ-5D VAS	82.01 (0.95)	82.95 (1.32)	–0.95 (–4.16 to 2.27)	*F*(1, 303.38) = 0.33	0.568
Randomised participants excluding protocol violations (n = 308)					
Child self-report					
PedsQL: diabetes module	72.58 (0.77)	73.68 (1.06)	–1.10 (–3.68 to 1.49)	*F*(1,301.96) = 0.70	0.404
PedsQL: generic module	81.10 (0.68)	82.20 (0.93)	–1.10 (–3.36 to 1.16)	*F*(1,301.97) = 0.919	0.338
EQ-5D	0.88 (0.01)	0.89 (0.02)	0 (–0.04 to 0.03)	*F*(1,271.05) = 0.03	0.869
EQ-5D VAS	81.22 (1.03)	81.13 (1.42)	0.09 (–3.39 to 3.56)	*F*(1,272.56) = 0	0.957
Parent proxy					
PedsQL: diabetes module	65.40 (0.64)	67.22 (0.88)	–1.82 (–3.97 to 0.33)	*F*(1,301.85) = 2.79	0.096
PedsQL: generic module	77.70 (0.70)	76.60 (0.96)	1.11 (–1.23 to 3.44)	*F*(1,301.99) = 0.87	0.352
EQ-5D	0.83 (0.01)	0.86 (0.02)	–0.02 (–0.06 to 0.02)	*F*(1,286.18) = 1.2	0.273
EQ-5D VAS	81.71 (0.97)	83.11 (1.35)	–1.41 (–4.68 to 1.86)	*F*(1,291.98) = 0.71	0.399
Randomised participants excluding protocol violations and those lost to follow-up (n = 293)					
Child self-report					
PedsQL: diabetes module	73.88 (0.75)	74.21 (1.01)	–0.32 (–2.80 to 2.16)	*F*(1,287.00) = 0.07	0.798
PedsQL: generic module	81.85 (0.65)	82.81 (0.89)	–0.96 (–3.13 to 1.21)	*F*(1,287.01) = 0.76	0.384
EQ-5D	0.87 (0.01)	0.87 (0.01)	0 (–0.03 to 0.04)	*F*(1,287.04) = 0	0.960
EQ-5D VAS	80.69 (1.01)	79.59 (1.37)	1.10 (–2.26 to 4.45)	*F*(1,287.08) = 0.42	0.520
Parent proxy					
PedsQL: diabetes module	65.80 (0.65)	67.47 (0.88)	–1.68 (–3.82 to 0.47)	*F*(1,286.98) = 2.36	0.125
PedsQL: generic module	78.19 (0.68)	77.27 (0.92)	0.94 (–1.33 to 3.20)	*F*(1,286.91) = 0.66	0.417
EQ-5D	0.82 (0.01)	0.84 (0.01)	–0.03 (–0.06 to 0.01)	*F*(1,287) = 1.82	0.178
EQ-5D VAS	81 (0.91)	82.34 (1.24)	–1.34 (–4.38 to 1.69)	*F*(1,287.01) = 0.76	0.385

Outcome variable	Mean (SE)		Mean difference (EPIC pack – TAU) (95% CI)	*F*-value	*p*-value
	EPIC pack	TAU			
Complete case analysis* (n = *193)					
Child self-report					
PedsQL: diabetes module	75.24 (0.88)	77.20 (1.27)	–1.96 (–5.04 to 1.12)	*F*(1,187.00) = 1.58	0.210
PedsQL: generic module	83.14 (0.72)	84.88 (1.03)	–1.74 (–4.24 to 0.76)	*F*(1,187.03) = 1.89	0.174
EQ-5D	0.89 (0.01)	0.90 (0.02)	–0.01 (–0.05 to 0.04)	*F*(1,187.18) = 0.06	0.801
EQ-5D VAS	81.92 (1.17)	82.84 (1.69)	–0.92 (–5.02 to 3.18)	*F*(1,187.50) = 0.20	0.659
Parent proxy					
PedsQL: diabetes module	66.25 (0.81)	68.59 (1.17)	–2.34 (–5.16 to 0.48)	*F*(1,187.06) = 2.68	0.103
PedsQL: generic module	78.84 (0.88)	78.05 (1.26)	0.78 (–2.27 to 3.83)	*F*(1,187.05) = 0.26	0.613
EQ-5D	0.83 (0.01)	0.86 (0.02)	–0.03 (–0.08 to 0.02)	*F*(1,187.00) = 1.11	0.292
EQ-5D VAS	82.22 (1.04)	82.91 (1.50)	–0.69 (–4.32 to 2.94)	*F*(1,187.22) = 0.14	0.709

SE, standard error; TAU, treatment as usual.

Eligibility exclusions at screening by centre: CONSORT eligibility data

Centre code	Screened	Needle phobia	Significant social or emotional problems	Significant physical or intellectual impairment	Inability to communicate in an age-appropriate way in English	Unsuitable other	Total eligible	Eligible (%)
Y	63	0	0	0	0	4	59	94
L	81	0	0	0	0	1	80	99
B	82	0	5	1	1	5	70	85
A	91	0	4	0	1	4	82	90
Q	76	0	0	0	0	1	75	99
I	62	0	2	3	0	5	52	84
T	68	0	2	3	2	5	56	82
U	174	0	14	7	7	12	134	75
O	178	1	15	5	2	6	149	84
N	145	0	10	9	3	4	119	82
S	85	0	0	0	0	2	83	98
Total	1105	1	52	28	16	49	959	87

CONSORT data: number of eligible participants who did not join the trial by centre

Centre code	Eligible	Declined	Did not attend clinic	Participant cancelled visit	Clinic cancelled visit	Nurse missed participant at clinic	Nurse absent (annual leave or illness)	Taking part in another study	No reason given	Other	Total randomised	Randomised (%)
Y	59	9	3	0	6	0	0	0	7	0	34	58
L	80	17	6	0	4	1	0	0	18	0	34	43
B	70	20	3	4	0	2	0	0	4	9	28	40
A	82	23	5	0	0	0	3	0	13	2	36	44
Q	75	29	10	3	0	1	0	0	0	0	32	43
I	52	44	0	0	0	0	0	0	0	0	8	15
T	56	18	5	0	0	0	0	3	0	5	25	45
U	134	45	20	11	0	15	12	0	0	3	28	22
O	149	42	8	5	0	46	0	8	0	0	40	26
N	119	48	19	1	0	7	0	0	0	0	44	37
S	83	40	5	0	0	0	0	9	0	1	28	34
Total	959	335	84	24	10	72	15	21	42	20	337	35

Unadjusted models by time point: two-sided *t*-tests at 5% significance level

Outcome variable	EPIC pack		TAU		Difference (pack – TAU)				
	Mean	SD	Mean	SD	Mean	SD	95% CI	*t*	*p*-value
Child self-report									
PedsQL: generic module									
Total score – 3 months	82.23	13.39	80.37	14.39	1.87	13.75	–1.45 to 5.18	*t*(291) = 1.109	0.268
Total score – 6 months	82.49	13.48	83.58	12.98	–1.09	13.30	–4.29 to 2.11	*t*(291) = –0.669	0.504
Physical functioning – 3 months	85.36	13.75	82.07	15.76	3.28	14.49	–0.20 to 6.77	*t*(291) = 1.853	0.065
Physical functioning – 6 months	85.51	13.47	86.47	12.54	–0.96	13.15	–4.12 to 2.21	*t*(291) = –0.594	0.553
Emotional functioning – 3 months	75.64	20.56	75.90	21.61	–0.26	20.94	–5.3 to 4.78	*t*(291) = –0.101	0.920
Emotional functioning – 6 months	76.45	20.13	76.52	21.97	–0.07	20.79	–5.08 to 4.93	*t*(291) = –0.029	0.977
Social functioning – 3 months	88.57	15.52	87.07	18.14	1.50	16.49	–2.47 to 5.47	*t*(291) = 0.744	0.458
Social functioning – 6 months	89.54	15.94	89.26	17.18	0.29	16.39	–3.66 to 4.24	*t*(291) = 0.144	0.886
School functioning – 3 months	77.48	18.23	75.40	17.06	2.08	17.83	–2.21 to 6.38	*t*(291) = 0.955	0.340
School functioning – 6 months[a]	76.66	18.08	80.36	15.14	–3.7	16.24	–7.61 to 0.22	*t*(243) = –1.861	0.064
PedsQL: diabetes module									
Total score – 3 months	74.16	13.37	72.70	14.09	1.46	13.63	–1.82 to 4.74	*t*(291) = 0.876	0.382
Total score – 6 months	73.76	15.21	75.41	13.58	–1.65	14.66	–5.18 to 1.88	*t*(291) = 0.919	0.359
Diabetes symptoms – 3 months	64.85	16.62	64.89	18.08	–0.04	17.14	–4.17 to 4.08	*t*(291) = –0.021	0.983
Diabetes symptoms – 6 months	66.18	17.31	66.66	17.59	–0.49	17.41	–4.68 to 3.71	*t*(291) = –0.228	0.820
Treatment barriers – 3 months	79.53	17.69	75.67	19.42	3.86	18.32	–0.55 to 8.27	*t*(291) = 1.722	0.086

Outcome variable	EPIC pack		TAU		Difference (pack – TAU)		95% CI	*t*	*p*-value
	Mean	SD	Mean	SD	Mean	SD			
Treatment barriers – 6 months	77.70	20.54	77.91	19.80	–0.21	20.28	–5.09 to 4.67	*t*(291) = –0.085	0.932
Treatment adherence – 3 months	84.16	14.46	82.96	15.27	1.20	14.75	–2.35 to 4.75	*t*(291) = 0.664	0.507
Treatment adherence – 6 months[a]	82.82	17.15	86.22	13.10	–3.40	14.65	–6.93 to 0.13	*t*(259) = –1.897	0.059
Worry – 3 months	77.40	22.02	73.85	21.81	3.55	21.95	–1.74 to 8.84	*t*(291) = 1.322	0.187
Worry – 6 months	76.36	23.26	78.11	20.47	–1.75	22.32	–7.12 to 3.63	*t*(291) = –0.639	0.523
Communication – 3 months	74.56	18.76	72.26	20.49	2.30	19.38	–2.37 to 6.97	*t*(291) = 0.970	0.333
Communication – 6 months	72.57	21.05	76.22	21.69	–3.65	21.28	–8.77 to 1.48	*t*(291) = –1.400	0.162
EQ-5D									
3 months	0.87	0.20	0.85	0.22	0.02	0.21	–0.03 to 0.07	*t*(291) = 0.678	0.499
6 months	0.87	0.19	0.88	0.18	–0.01	0.18	–0.05 to 0.04	*t*(291) = –0.309	0.758
EQ-5D VAS									
3 months	81.64	17.43	78.76	17.32	2.88	17.39	–1.3 to 7.07	*t*(291) = 1.355	0.176
6 months[a]	81.07	17.44	76.98	20.44	4.09	19.44	–0.61 to 8.78	*t*(183) = 1.719	0.087
Parent proxy									
PedsQL: generic module									
Total score – 3 months	78	13.69	77.8	13.65	0.2	13.68	–3.10 to 3.49	*t*(291) = –0.118	0.906
Total score – 6 months	78.59	13.91	76.6	14.72	1.99	14.2	–1.43 to 5.41	*t*(291) = 1.147	0.252
Physical functioning – 3 months	85.03	14.33	83.22	13.95	1.81	14.2	–1.61 to 5.23	*t*(291) = 1.041	0.299
Physical functioning – 6 months	85.46	13.95	82.27	15.79	3.19	14.62	–0.33 to 6.71	*t*(291) = 1.785	0.075
Emotional functioning – 3 months	65.93	19.78	67.97	21.49	–2.04	20.4	–6.95 to 2.87	*t*(291) = –0.818	0.414
Emotional functioning – 6 months	68.54	20.11	66.66	21.24	1.88	20.52	–3.06 to 6.82	*t*(291) = 0.749	0.454
Social functioning – 3 months	83.21	17.57	82.88	18.86	0.32	18.03	–4.02 to 4.67	*t*(291) = 0.147	0.884
Social functioning – 6 months	83.95	17.55	84.5	18.04	–0.55	17.72	–4.82 to 3.72	*t*(291) = –0.255	0.799

Outcome variable	EPIC pack		TAU		Difference (pack – TAU)				
	Mean	SD	Mean	SD	Mean	SD	95% CI	*t*	*p*-value
School functioning – 3 months	73.6	18.97	73.86	17.66	–0.27	18.52	–4.73 to 4.19	*t*(291) = –0.118	0.906
School functioning – 6 months	72.29	18.7	69.56	17.73	2.73	18.37	–1.69 to 7.16	*t*(291) = 1.216	0.225
PedsQL: diabetes module									
Total score – 3 months	65.31	14.8	67.3	14.1	–1.99	14.56	–5.50 to 1.52	*t*(291) = –1.116	0.265
Total score – 6 months[a]	66.55	15.78	67.32	13.23	–0.77	14.93	–4.36 to 2.83	*t*(242) = –0.420	0.675
Diabetes symptoms – 3 months	57.84	17.38	60.63	16.38	–2.79	17.04	–6.89 to 1.31	*t*(291) = –1.338	0.182
Diabetes symptoms – 6 months	59.19	17.59	59.2	15.56	–0.02	16.91	–4.09 to 4.06	*t*(291) = –0.008	0.994
Treatment barriers – 3 months	66.16	19.8	67.55	20.4	–1.39	20.01	–6.21 to 3.42	*t*(291) = –0.569	0.57
Treatment barriers – 6 months	67.3	20.47	65.69	19.17	1.61	20.02	–3.21 to 6.44	*t*(291) = 0.659	0.511
Treatment adherence – 3 months	75.48	17.57	78.74	16.34	–3.26	17.15	–7.39 to 0.86	*t*(291) = –1.556	0.121
Treatment adherence – 6 months[a]	76.87	18.32	79.37	15.49	–2.49	16.54	–6.48 to 1.49	*t*(241) = –1.231	0.219
Worry – 3 months	66.71	24.4	67.21	22.54	–0.49	23.76	–6.22 to 5.23	*t*(291) = -0.169	0.866
Worry – 6 months	69.39	24.09	73.72	21	–4.33	23.05	–9.89 to 1.22	*t*(291) = –1.537	0.125
Communication – 3 months	66.44	22.61	64.81	24.13	1.63	23.15	–3.94 to 7.21	*t*(291) = 0.576	0.565
Communication – 6 months	65.61	22.45	64.72	23.31	0.89	22.76	–4.59 to 6.37	*t*(291) = 0.320	0.75
EQ-5D									
3 months	0.81	0.20	0.82	0.22	–0.01	0.20	–0.06 to 0.04	*t*(291) = –0.470	0.639
6 months	0.83	0.20	0.84	0.18	–0.01	0.19	–0.06 to 0.03	*t*(291) = –0.551	0.582
EQ-5D VAS									
3 months	81.34	17.44	81.63	16.43	–0.29	17.09	–4.41 to 3.83	*t*(291) = –0.138	0.890
6 months	81.57	18.35	80.55	17.55	1.02	18.08	–3.33 to 5.37	*t*(291) = 0.461	0.645

TAU, treatment as usual.

a Unequal variances assumed.

Analysis of covariance: adjusted model by stratification variables and their baseline values by time point, child self-report

Outcome variable	Covariates significant at 5%	*F*-value	*p*-value	Mean difference (pack – TAU)	SE	95% CI	*F*-value	*p*-value
PedsQL: generic module								
Total score – 3 months	Baseline	*F*(1,277) = 241.56	< 0.001	0.4	1.26	–2.08 to 2.87	*F*(1,277) = 0.10	0.751
Total score – 6 months	Baseline	*F*(1,277) = 168.6	< 0.001	–2.32	1.31	–4.90 to 0.26	*F*(1,277) = 3.12	0.078
Physical functioning – 3 months	Baseline	*F*(1,277) = 78.64	< 0.001	2.03	1.6	–1.12 to 5.19	*F*(1,277) = 1.61	0.205
Physical functioning – 6 months	Baseline	*F*(1,277) = 77.95	< 0.001	–2.04	1.45	–4.89 to 0.81	*F*(1,277) = 1.99	0.160
Emotional functioning – 3 months	Baseline	*F*(1,277) = 169.54	< 0.001	–0.71	2.04	–4.72 to 3.30	*F*(1,277) = 0.12	0.729
Emotional functioning – 6 months	Baseline	*F*(1,277) = 107.75	< 0.001	–0.33	2.19	–4.64 to 3.99	*F*(1,277) = 0.02	0.882
Social functioning – 3 months[a]	Baseline	*F*(1,277) = 162.3	< 0.001	0.51	1.63	–2.70 to 3.72	*F*(1,277) = 0.10	0.754
	Sex	*F*(1,277) = 4.9	0.028					
Social functioning – 6 months[a]	Baseline	*F*(1,277) = 112	< 0.001	–0.66	1.73	–4.06 to 2.74	*F*(1,277) = 0.15	0.702
School functioning – 3 months	Baseline	*F*(1,277) = 254.67	< 0.001	–0.15	1.6	–3.30 to 3.00	*F*(1,277) = 0.01	0.928
	Centre	*F*(10,277) = 2.27	0.014					
School functioning – 6 months[b]	Baseline	*F*(1,277) = 136.95	< 0.001	–5.39	1.73	–8.80 to –1.98	*F*(1,277) = 9.70	0.002
PedsQL: diabetes module								
Total score – 3 months	Baseline	*F*(1,277) = 140.87	< 0.001	1.25	1.37	–1.45 to 3.95	*F*(1,277) = 0.83	0.363
	Centre	*F*(10,277) = 1.88	0.048					
Total score – 6 months	Baseline	*F*(1,277) = 156.81	< 0.001	–1.72	1.45	–4.57 to 1.13	*F*(1,277) = 1.42	0.235
Diabetes symptoms – 3 months	Baseline	*F*(1,277) = 146.41	< 0.001	0.13	1.73	–3.26 to 3.53	*F*(1,277) = 0.01	0.938
Diabetes symptoms – 6 months	Baseline	*F*(1,277) = 116.5	< 0.001	–0.18	1.81	–3.74 to 3.38	*F*(1,277) = 0.01	0.920
Treatment barriers – 3 months[a]	Baseline	*F*(1,277) = 125.94	< 0.001	2.00	1.90	–1.74 to 5.75	*F*(1,277) = 1.11	0.293
Treatment barriers – 6 months[a]	Baseline	*F*(1,277) = 143.66	< 0.001	–2.16	2.04	–6.17 to 1.84	*F*(1,277) = 1.13	0.289
	Centre	*F*(10,277) = 1.91	0.043					

Outcome variable	Covariates significant at 5%	*F*-value	*p*-value	Mean difference (pack – TAU)	SE	95% CI	*F*-value	*p*-value
Treatment adherence – 3 months[a]	Baseline	*F*(1,277) = 45.9	< 0.001	0.11	1.69	–3.22 to 3.45	*F*(1,277) = 0	0.948
Treatment adherence – 6 months[a,c]	Baseline	*F*(1,277) = 72.36	< 0.001	–4.60	1.75	–8.04 to –1.15	*F*(1,277) = 6.89	0.009
Worry – 3 months[d]	Baseline	*F*(1,277) = 154.58	< 0.001	5.79	2.17	1.53 to 10.06	*F*(1,277) = 7.14	0.008
	Centre	F(10,277) = 1.99	0.034					
Worry – 6 months	Baseline	*F*(1,277) = 104.19	< 0.001	0.72	2.37	–3.95 to 5.39	*F*(1,277) = 0.09	0.763
Communication – 3 months	Baseline	*F*(1,277) = 87.84	< 0.001	3.77	2.08	–0.33 to 7.87	*F*(1,277) = 3.28	0.071
Communication – 6 months	Baseline	*F*(1,277) = 76.68	< 0.001	–2.44	2.32	–7.00 to 2.12	*F*(1,277) = 1.11	0.293
	Centre	*F*(10,277) = 1.91	0.044					
EQ-5D								
3 months	Baseline	*F*(1,292) = 67.12	< 0.001	0.01	0.19	–0.04 to 0.06	*F*(1,292) = 0.22	0.642
	Time since diagnosis	*F*(1,292) = 5.13	0.024					
6 months	Baseline	*F*(1,292) = 87.88	< 0.001	–0.01	0.16	–0.05 to 0.03	*F*(1,292) = 0.28	0.060
	Time since diagnosis	*F*(1,292) = 3.99	0.047					
	Sex	*F*(1,292) = 10.09	0.002					
EQ-5D VAS								
3 months[a]	Baseline	*F*(1,292) = 105.9	< 0.001	0.69	15.01	–2.93 to 4.30	*F*(1,292) = 0.14	0.708
	Age	*F*(1,292) = 7.01	0.009					
6 months[a]	Baseline	*F*(1,292) = 85.62	< 0.001	1.7	16.64	–2.31 to 5.71	*F*(1,292) = 0.70	0.405

SE, standard error; TAU, treatment as usual.

[a] Residuals not normally distributed.

[b] Significant difference. Effect size: 0.03 = (|–5.39|/195.26).

[c] Significant difference. Effect size: 0.02 = (|–4.60|/200.15).

[d] Significant difference. Effect size: 0.02 = (|5.79|/305.66).

Mixed-effect models: adjusted model by stratification variables and their baseline values

Outcome variable	Covariates significant at 5%	*F*-value	*p*-value	Mean difference (pack – TAU)	SE	95% CI	*F*-value	*p*-value
Child self-report								
PedsQL: generic module								
Total score	Baseline	*F*(1,287) = 275.48	< 0.001	–0.96	1.1	–3.13 to 1.21	*F*(1,287) = 0.76	0.384
	Time point	*F*(1,287) = 4.36	0.038					
	Treatment group by time point	*F*(1,291) = 5.13	0.024					
Physical functioning	Baseline	*F*(1,287) = 102.7	< 0.001	0.04	1.32	–2.56 to 2.65	*F*(1,287) = 0.001	0.974
	Time point	*F*(1,291) = 5.38	0.021					
	Treatment group by time point	*F*(1,291) = 8.14	0.005					
Emotional functioning	Baseline	*F*(1,287) = 183.67	< 0.001	–0.51	1.83	–4.12 to 3.09	*F*(1,287) = 0.078	0.78
Social functioning	Baseline	*F*(1,287) = 180.7	< 0.001	–0.05	1.46	–2.93 to 2.82	*F*(1,287) = 0.001	0.971
School functioning[a]	Baseline	*F*(1,287) = 271.37	< 0.001	–2.90	1.4	–5.66 to –0.14	*F*(1,287) = 4.264	0.04
	Time point	*F*(1,287) = 4.26	0.040					
	Treatment group by time point	*F*(1,291) = 9.59	0.002					

Outcome variable	Covariates significant at 5%	*F*-value	*p*-value	Mean difference (pack – TAU)	SE	95% CI	*F*-value	*p*-value
PedsQL: diabetes module								
Total score	Baseline	*F*(1,287) = 183.33	< 0.001	0.32	1.26	–2.80 to 2.16	*F*(1,287) = 0.066	0.798
	Treatment group by time point	*F*(1,291) = 5.44	0.02					
Diabetes symptoms	Baseline	*F*(1,287) = 170.03	< 0.001	–0.09	1.55	–3.14 to 2.96	*F*(1,287) = 0.003	0.955
Treatment barriers	Baseline	*F*(1,287) = 173.83	< 0.001	–0.27	1.71	–3.64 to 3.11	*F*(1,287) = 0.024	0.876
	Treatment group by time point	*F*(1, 291) = 4.19	0.042					
Treatment adherence	Baseline	*F*(1,287) = 78.08	< 0.001	–2.38	1.47.	–5.28 to 0.52	*F*(1,287) = 2.599	0.108
	Treatment group by time point	*F*(1,291) = 6.87	0.009					
Worry	Baseline	*F*(1,287) = 2.76	< 0.001	3.23	1.94	–0.60 to 7.05	*F*(1,287) = 2.756	0.098
	Treatment group by time point	*F*(1,291) = 4.88						
Communication	Baseline	*F*(1,287) = 107.11	< 0.001	0.69	1.93	–3.10 to 4.48	*F*(1,287) = 0.128	0.720
	Treatment group by time point	*F*(1,291) = 7.17	0.008					
EQ-5D								
	Baseline	*F*(1,287) = 115.46	< 0.001	0	0.02	–0.03 to 0.04	*F*(1,287) = 0	0.960
	Sex	*F*(1,287) = 6.12	0.014					
	Time since diagnosis	*F*(1,287) = 6.82	0.009					
EQ-5D VAS								
	Baseline	*F*(1,287) = 125.37	< 0.001	1.1	1.70	–2.26 to 4.45	*F*(1,287) = 0.415	0.520
	Age	*F*(1,287) = 4.05	0.045					
Parent proxy								
PedsQL: generic module								
Total score	Baseline scores	*F*(1,287) = 263.76	< 0.001	0.94	1.15	–1.33 to 3.20	*F*(1,287) = 0.66	0.417
Physical functioning	Baseline scores	*F*(1,287) = 93.91	< 0.001	2.22	1.38	–0.49 to 4.93	*F*(1,287) = 2.61	0.107
Emotional functioning	Baseline scores	*F*(1,287) = 142.73	< 0.001	–0.48	1.87	–4.15 to 3.20	*F*(1,287) = 0.06	0.799
Social functioning	Baseline scores	*F*(1,287) = 291.75	< 0.001	0.72	1.45	–2.13 to 3.57	*F*(1,287) = 0.25	0.620
	Age	*F*(1,287) = 5.28	0.022					

Outcome variable	Covariates significant at 5%	*F*-value	*p*-value	Mean difference (pack – TAU)	SE	95% CI	*F*-value	*p*-value
PedsQL: diabetes module								
School functioning	Baseline	*F*(1,291) = 6.81	< 0.001	0.97	1.42	–1.84 to 3.77	*F*(1,287) = 0.46	0.497
	Time point	*F*(1,287) = 5.28	0.01					
Total score	Baseline	*F*(1,287) = 411.62	< 0.001	–1.68	1.09	–3.82 to 0.47	*F*(1,287) = 2.36	0.125
	Age	*F*(1,287) = 4.38	0.037					
Diabetes symptoms	Baseline	*F*(1,287) = 390.43	< 0.001	–1.55	1.29	–4.09 to 1.00	*F*(1,287) = 1.43	0.232
Treatment barriers	Baseline	*F*(1,287) = 269.55	< 0.001	–1.21	1.6	–4.36 to 1.95	*F*(1,287) = 57	0.452
	Age	*F*(1,287) = 5.67	0.018					
Treatment adherence[b]	Baseline	*F*(1,287) = 218.13	< 0.001	–3.48	1.4	–6.23 to –0.72	*F*(1,287) = 6.15	0.014
	Age	*F*(1,287) = 3.75	0.054					
Worry	Baseline	*F*(1,287) = 188.06	< 0.001	–0.77	1.98	–4.67 to 3.12	*F*(1,287) = 0.15	0.697
	Time point	*F*(1,291) = 9.49	0.002					
Communication	Baseline	*F*(1,287) = 155.71	< 0.001	0.67	2.04	–3.34 to 4.69	*F*(1,287) = 0.11	0.742
EQ-5D								
	Baseline	*F*(1,287) = 70.64	<.001	–0.03	0.02	–0.06 to 0.01	*F*(1,287) = 1.82	0.178
EQ-5D VAS								
	Baseline	*F*(1,287) = 170.51	< 0.001	–1.34	1.54	–4.38 to 1.69	*F*(1,287) = 0.76	0.385
	Sex	*F*(1,287) = 5.22	0.023					

TAU, treatment as usual.

[a] Significant difference. Effect size: 0.14 = (|–2.90|/20.09).

[b] Significant difference. Effect size: 0.17 = (|–3.48|/20.09).

Analysis of covariance: adjusted model by stratification variables and their baseline values by time point, parent proxy

Outcome variable	Covariates significant at 5%	*F*-value	*p*-value	Mean difference (pack – TAU)	SE	95% CI	*F*-value	*p*-value
PedsQL: generic module								
Total score – 3 months	Baseline	*F*(1,277) = 229.14	< 0.001	–0.12	1.25	–2.59 to 2.35	*F*(1,277) = 0.02	0.925
Total score – 6 months	Baseline	*F*(1,277) = 167.93	< 0.001	2.11	1.4	–0.64 to 4.86	*F*(1,277) = 2.28	0.132
Physical functioning – 3 months[a]	Baseline	*F*(1,277) = 84.75	< 0.001	1.37	1.55	–1.69 to 4.43	*F*(1,277) = 0.78	0.378
Physical functioning – 6 months[a]	Baseline	*F*(1,277) = 51.11	< 0.001	3.05	1.68	–0.25 to 6.36	*F*(1,277) = 3.3	0.070
Emotional functioning – 3 months	Baseline	*F*(1,277) = 123.68	< 0.001	–2.80	2.08	–6.89 to 1.29	*F*(1,277) = 1.81	0.179
Age		*F*(1,277) = 4.08	0.044					
Emotional functioning – 6 months	Baseline	*F*(1,277) = 97.6	< 0.001	2.06	2.17	–2.22 to 6.33	*F*(1,277) = 0.90	0.344
Social functioning – 3 months[a]	Baseline	*F*(1,277) = 260.98	< 0.001	1.11	1.6	–2.04 to 4.27	*F*(1,277) = 0.48	0.489
Time since diagnosis		*F*(1,277) = 9.47	0.002					
Social functioning – 6 months[a]	Baseline	*F*(1,277) = 180.22	< 0.001	0.44	1.73	–2.97 to 3.85	*F*(1,277) = 0.07	0.798
School functioning – 3 months	Baseline	*F*(1,277) = 224.1	< 0.001	–0.69	1.7	–4.03 to 2.66	*F*(1,277) = 0.16	0.687
Sex		*F*(1,277) = 3.77	0.053					
Centre		*F*(10,277) = 2.01	0.032					
School functioning – 6 months	Baseline	*F*(1,277) = 232.23	< 0.001	2.67	1.67	–0.62 to 5.96	*F*(1,277) = 2.56	0.111
Centre		*F*(10,277) = 2.43	0.009					

Outcome variable	Covariates significant at 5%	*F*-value	*p*-value	Mean difference (pack – TAU)	SE	95% CI	*F*-value	*p*-value
PedsQL: diabetes module								
Total score – 3 months	Baseline	*F*(1,277) = 363.43	< 0.001	–2.28	1.19	–4.62 to 0.06	*F*(1,277) = 3.67	0.057
	Age	*F*(1,277) = 4.29	0.039					
Total score – 6 months	Baseline	*F*(1,277) = 224.35	< 0.001	–1.02	1.39	–3.74 to 1.71	*F*(1,277) = 0.054	0.464
Diabetes symptoms – 3 months[b]	Baseline	*F*(1,277) = 373.25	< 0.001	–2.96	1.39	–5.69 to –0.23	*F*(1,277) = 4.56	0.034
Diabetes symptoms – 6 months	Baseline	*F*(1,277) = 203.33	< 0.001	–0.24	1.6	–3.38 to 2.9	*F*(1,277) = 0.02	0.881
Treatment barriers – 3 months	Baseline	*F*(1,277) = 218.28	< 0.001	–2.68	1.86	–6.33 to 0.98	*F*(1,277) = 2.08	0.151
Treatment barriers – 6 months	Baseline	*F*(1,277) = 157.64	< 0.001	0.39	1.99	–3.54 to 4.31	*F*(1,277) = 0.04	0.847
Time since diagnosis		*F*(1,277) = 4.11	0.004					
Treatment adherence – 3 months[c]	Baseline	*F*(1,277) = 140.33	< 0.001	–3.86	1.71	–7.22 to –0.49	*F*(1,277) = 5.09	0.025
Time since diagnosis		*F*(1,277) = 8.04	0.005					
Treatment adherence – 6 months	Baseline	*F*(1,277) = 152.04	< 0.001	–2.78	1.73	–6.19 to 0.63	*F*(1,277) = 2.58	0.109
Worry – 3 months	Baseline	*F*(1,277) = 126.46	< 0.001	1.22	2.46	–3.62 to 6.06	*F*(1,277) = 0.25	0.621
Age		*F*(1,277) = 4.95	0.027					
Worry – 6 months	Baseline	*F*(1,277) = 126.99	< 0.001	–2.66	2.38	–7.36 to 2.03	*F*(1,277) = 1.25	0.265
Communication – 3 months	Baseline	*F*(1,277) = 111	< 0.001	1.23	2.42	–3.53 to 5.99	*F*(1,277) = 0.26	0.612
Communication – 6 months	Baseline	*F*(1,277) = 115.47	< 0.001	0.37	2.38	–4.32 to 5.07	*F*(1,277) = 0.02	0.875
EQ-5D								
3 months[a]	Baseline	*F*(1,292) = 69.88	< 0.001	–0.03	0.18	–0.07**0.02	*F*(1,292) = 1.58	0.210
Age		*F*(1,292) = 4.21	0.041					
6 months[a]	Baseline	*F*(1,292) = 31.12	< 0.001	–0.02	0.19	–0.07**0.02	*F*(1,292) = 1.03	0.312
Sex		*F*(1,292) = 5.09	0.025					

Outcome variable	Covariates significant at 5%	*F*-value	*p*-value	Mean difference (pack – TAU)	SE	95% CI	*F*-value	*p*-value
EQ-5D VAS								
3 months[a]	Baseline	*F*(1,292) = 110.52	< 0.001	–1.52	14.64	–5.04 to 2.01	*F*(1,292) = 0.72	0.398
	Sex	*F*(1,292) = 3.9	0.049					
6 months[a]	Baseline	*F*(1,292) = 138.87	< 0.001	–0.92	15.1	–4.55 to 2.72	*F*(1,292) = 0.25	0.620
	Sex	*F*(1,292) = 3.92	0.049					

SE, standard error; TAU, treatment as usual.

a Residuals not normally distributed.

b Significant difference. Effect size: 0.02 = (|–2.96|/126.19).

c Significant difference. Effect size: 0.02 = (|–3.86|/191.89).

Child self-report and proxy comparisons

The following table shows the pre-intervention baseline clinical outcome measures and Pearson (*r*) and Spearman (ρ) correlation coefficients for the child-self report and parent proxy by treatment arm.

Outcome measure		EPIC pack ($n = 190$) Child self-report	EPIC pack ($n = 190$) Parent proxy	*r*	ρ	TAU ($n = 103$) Child self-report	TAU ($n = 103$) Parent proxy	*r*	ρ
PedsQL: diabetes module									
Total score	Range	26–100	12–96			35–96	31–95		
	Mean (SD)	74 (15)	66 (15)	0.65[a]	–	73 (12)	66 (14)	0.59[a]	–
Diabetes symptoms	Range	7–100	2–98			25–93	20–95		
	Mean (SD)	64 (18)	58 (17)	0.624[a]	–	64 (14)	57 (17)	6.11[a]	–
Treatment barriers	Range	13–100	6–100			6–100	0–100		
	Median (IQR)	81 (67–94)	69 (55–81)	–	0.542[a]	75 (63–94)	69 (50–75)	–	0.496[a]
Treatment adherence	Range	29–100	29–100			32–100	25–100		
	Median (IQR)	89 (79–100)	79 (68–93)	–	0.551[a]	86 (75–93)	79 (68–89)	–	0.487[a]
Worry	Range	0–100	0–100			0–100	0–100		
	Median (IQR)	75 (58–92)	67 (50–83)	–	0.580[a]	83 (67–100)	67 (50–92)	–	0.266[a]
Communication	Range	13–100	0–100			8–100	8–100		
	Median (IQR)	83 (67–85)	67 (50–83)	–	0.413[a]	83 (67–92)	67 (50–83)	–	0.474[a]

Outcome measure		EPIC pack ($n = 190$)				TAU ($n = 103$)			
		Child self-report	Parent proxy	*r*	ρ	Child self-report	Parent proxy	*r*	ρ
PedsQL: generic module									
Total score	Range	43–00	25–100			33–100	35–100		
	Mean (SD)	84 (12)	78 (15)	0.65[a]	–	82 (13)	78 (14)	0.75[a]	–
Physical functioning	Range	44–100	22–100			38–100	41–100		
	Median (IQR)	91 (84–97)	91 (81 to 97)	–	0.480[a]	88 (81–94)	91 (78–97)	–	0.543[a]
Emotional functioning	Range	0–100	0–100			20–100	20–100		
	Median (IQR)	80 (65–95)	65 (50–81)	–	0.546[a]	80 (70–90)	70 (50–80)	–	0.643[a]
Social functioning	Range	30–100	25–100			20–100	35–100		
	Median (IQR)	95 (85–100)	90 (70–100)	–	0.452[a]	95 (85–100)	90 (75–100)	–	0.702[a]
School functioning	Range	25–100	20–100			20–100	25–100		
	Mean (SD)	77 (17)	71 (19)	0.659[a]	–	74 (16)	71 (19)	0.647[a]	–
EQ-5D: heath utility score									
	Range	0.2–1	0–1			0.2–1	0.3–1		
	Mean (SD)	0.9 (0.2)	0.8 (0.2)			0.9 (0.2)	0.8 (0.2)		
	Median (IQR)	1 (0.8–1)	0.8 (0.7–1)	–	0.555[a]	1 (0.8–1)	0.8 (0.7–1)	–	0.428[a]
EQ-5D VAS									
	Range	25–100	25–100			0–100	0–100		
	Mean (SD)	83 (17)	83 (16)			78 (19)	80 (19)		
	Median (IQR)	90 (75–95)	90 (76.5–95)	–	0.490[a]	80 (70–95)	86 (74–90)	–	0.548[a]

IQR, interquartile range; TAU, treatment as usual.

[a] Correlation is significant at the 0.01 level (two-tailed).

Appendix 6 Evidence supporting the economic evaluation

Total cost of the 6–10 years EPIC intervention pack items per unit for insulin administration by injection

6–10 years EPIC intervention pack items	Quantity	Unit cost (£)	Cost (£)	Details
Sticker sheet	1	0.42	0.42	
Ink for colour printing information sheets	10	0.26	2.60	Ink for printer @ £575.56 for 225 packs; average 10 colour printed information sheets per pack. Calc.: £575.56/2250 = £0.26 per sheet
Paper for colour printing information sheets	10	0.01	0.10	£5 for 500 sheets in a ream; Calc. £5/500 = £0.01 per sheet
Sticky labels	2	0.02	0.04	14 stickers to a page/50 sheets in a box at £14.72. Calc.: £14.72/50/14 = £0.02 per sticky label
Poly pocket	1	0.02	0.02	100 @ £2.36. Calc.: £2.36/100 = £0.02 per poly pocket
JDRF CD-ROM	1	1.50	1.50	
6–10 years diary	1	3.00	3.00	
Postage for *Tadpole Times* magazine	1	0.20	0.20	Postage for 25 @ £5. Calc.: £5/25 = £0.20 per postage
13-part folders	1	3.65	3.65	
Envelopes	2	0.02	0.04	500 @ £7.98. Calc.: £7.98/500 = £0.02 per envelope
Total cost of one pack			11.57	

Total cost of the 6–10 years EPIC intervention pack items per unit for insulin administration by pump

6–10 years EPIC intervention pack items	Quantity	Unit cost (£)	Cost (£)	Details
Sticker sheet	1	0.42	0.42	
Ink for colour printing information sheets	10	0.26	2.60	Ink for printer @ £575.56 for 225 packs; average 10 colour printed information sheets per pack. Calc.: £575.56/2250 = £0.26 per sheet
Paper for colour printing information sheets	10	0.01	0.10	£5 for 500 sheets in a ream. Calc.: £5/500 = £0.01 per sheet
Sticky labels	2	0.02	0.04	14 stickers to a page/50 sheets in a box at £14.72. Calc.: £14.72/50/14 = £0.02 per sticky label
Poly pocket	1	0.02	0.02	100 @ £2.36. Calc.: £2.36/100 = £0.02 per poly pocket
JDRF CD-ROM	1	1.50	1.50	
Pump diary	1	8.10	8.10	
Postage for *Tadpole Times* magazine	1	0.20	0.20	Postage for 25 @ £5. Calc.: £5/25 = £0.20 per postage
13-parts folder	1	3.65	3.65	
Envelopes	2	0.02	0.04	500 @ £7.98. Calc.: £7.98/500 = £0.02 per envelope
Total cost of one pack			16.67	

Total cost of the 11–15 years EPIC intervention pack items per unit for insulin administration by injection

11–15 years EPIC intervention pack items	Quantity	Unit cost (£)	Cost (£)	Details
Sticker sheet	1	0.42	0.42	
Ink for colour printing information sheets	10	0.26	2.60	Ink for printer @ £575.56 for 225 packs; average 10 colour printed information sheets per pack. Calc.: £575.56/2250 = £0.26 per sheet
Paper for colour printing information sheets	10	0.01	0.10	£5 for 500 sheets in a ream. Calc.: £5/500 = £0.01 per sheet
Sticky labels	2	0.02	0.04	14 stickers to a page/50 sheets in a box at £14.72. Calc.: £14.72/50/14 = £0.02 per sticky label
Poly pocket	1	0.02	0.02	100 @ £2.36. Calc.: £2.36/100 = £0.02 per poly pocket
JDRF CD-ROM	1	1.50	1.50	
Sharpie marker pen	1	0.52	0.52	
11–15 years diary	1	3.00	3.00	
Postage for *On the Level* magazine	1	0.20	0.20	Postage for 25 @ £5. Calc.: £5/25 = £0.20 per postage
13-parts folder	1	3.65	3.65	
Envelopes	2	0.02	0.04	500 @ £7.98. Calc.: £7.98/500 = £0.02 per envelope
Total cost of one pack			12.09	

Total cost of the 11–15 years EPIC intervention pack items per unit for insulin administration by pump

11–15 years EPIC intervention pack items	Quantity	Unit cost (£)	Cost (£)	Details
Sticker sheet	1	0.42	0.42	
Ink for colour printing information sheets	10	0.26	2.60	Ink for printer @ £575.56 for 225 packs; average 10 colour printing information sheets per pack. Calc.: £575.56/2250 = £0.26 per sheet
Paper for colour printing information sheets	10	0.01	0.10	£5 for 500 sheets in a ream. Calc.: £5/500 = £0.01 per sheet
Sticky labels	2	0.02	0.04	14 stickers to a page/50 sheets on a box at £14.72. Calc.: £14.72/50/14 = £0.02 per sticky label
Poly pocket	1	0.02	0.02	100 @ £2.36. Calc.: £2.36/100 = £0.02 per poly pocket
JDRF CD-ROM	1	1.50	1.50	
Sharpie marker pen	1	0.52	0.52	
Pump diary	1	8.10	8.10	
Postage for *On the Level* magazine	1	0.20	0.20	Postage for 25 @ £5. Calc.: £5/25 = £0.20 per postage
13-part folders	1	3.65	3.65	
Envelopes	2	0.02	0.04	500 @ £7.98. Calc.: £7.98/500 = £0.02 per envelope
Total cost of one pack (£)			17.19	

Total cost of the 16–18 years EPIC intervention pack items per unit for insulin administration by injection

16–18 years EPIC intervention pack items	Quantity	Unit cost (£)	Cost (£)	Details
Ink for colour printing information sheets	10	0.26	2.60	Ink for printer @ £575.56 for 225 packs; average 10 colour printing information sheets per pack. Calc.: £575.56/2250 = £0.26 per sheet
Paper for colour printing information sheets	10	0.01	0.10	£5 for 500 sheets in a ream. Calc.: £5/500 = £0.01 per sheet
Sticky labels	2	0.02	0.04	14 stickers to a page/50 sheets in a box at £14.72. Calc.: £14.72/50/14 = £0.02 per sticky label
Poly pocket	1	0.02	0.02	100 @ £2.36. Calc.: £2.36/100 = £0.02 per poly pocket
Diabetes UK DVD	1	1.00	1.00	
16–18 years diary	1	1.88	1.88	
Postage for *On the Level* magazine	1	0.20	0.20	Postage for 25 @ £5. Calc.: £5/25 = £0.20 per postage
Portfolio folder	1	8.00	8.00	
Envelopes	2	0.02	0.04	500 @ £7.98. Calc.: £7.98/500 = £0.02 per envelope
Connexions booklet	1	8.19	8.19	Each booklet contains 31 pages printed on both sides in full colour and cone bound. 500 sheets (ream) @ £2.37 and 100 comb binders @ £5. Calc.: total cost for one *Connexions* booklet = (£2.37/500 × 16) + (£5/100 × 1) + (31 colour pages × £0.26 per page colour ink) = 0.08 + 0.05 + 8.06 = £8.19
Total cost of one pack			22.07	

Total cost of the 16–18 years EPIC intervention pack items per unit for administration by means of pump

16–18 years EPIC intervention pack items	Quantity	Unit cost (£)	Cost (£)	Details
Ink for colour printing information sheets	10	0.26	2.60	Ink for printer @ £575.56 for 225 packs; average 10 colour printing information sheets per pack. Calc.: £575.56/2250 = £0.26 per sheet
Paper for colour printing information sheets	10	0.01	0.10	£5 for 500 sheets in a ream. Calc.: £5/500 = £0.01 per sheet
Sticky labels	2	0.02	0.04	14 stickers to a page/50 sheets in a box at £14.72. Calc.: £14.72/50/14 = £0.02 per sticky label
Poly pocket	1	0.02	0.02	100 @ £2.36. Calc.: £2.36/100 = £0.02 per poly pocket
Diabetes UK DVD	1	1.00	1.00	
Pump diary	1	8.10	8.10	
Postage for *On the Level* magazine	1	0.20	0.20	Postage for 25 @ £5. Calc.: £5/25 = £0.20 per postage
Portfolio folder	1	8.00	8.00	
Envelopes	2	0.02	0.04	500 @ £7.98. Calc.: £7.98/500 = £0.02 per envelope
Connextions booklet	1	8.19	8.19	Each booklet contains 31 pages printed on both sides in full colour and cone bound. 500 sheets (ream) @ £2.37 and 100 comb binders @ £5. Calc.: total cost for one *Connextions* booklet = (£2.37/500 × 16) + (£5/100 × 1) + (31 colour pages × £0.26 per page colour ink) = 0.08 + 0.05 + 8.06 = £8.19
Total cost of one pack			28.29	

Appendix 7 Evidence supporting the process evaluation

EPIC Approach Manual

Approach Manual

(Manual of standard practice)

24-03-2010_v.2

For the EPIC Randomised Controlled Trial

2009-2011

Purpose

The purpose of this approach manual is to discover what is routine practice in each of the EPIC Project recruitment sites. This form is to be completed in conjunction with a healthcare professional working at the diabetes clinic taking part in the EPIC Project randomised controlled trial.

1. Name of consultant in charge of diabetes clinic service

2. Name of diabetes nurse specialist

3. Name of hospital

4. Name NHS Trust/Area

5. Method of data collection	**(please tick)**
Face to face interview	☐
Telephone interview	☐
Approach Manual questionnaire sent through the post	☐

Please answer the following questions as honestly as possible.

6. What **type of Diabetes Clinic** do you run? (Please tick and insert number where applicable).

Children's clinic	☐	How frequent is the clinic run?	☐ a month
Transition clinic	☐	How frequent is the clinic run?	☐ a month
Adult clinic	☐	How frequent is the clinic run?	☐ a month
Other type of clinic	☐	How frequent is the clinic run?	☐ a month

If **other**, please write the name of your clinic in this box. Also, if the clinic is not run in the main hospital, please note the **location of the clinic** in this box.

7. **How** are children/young people referred to your clinic?

Children's ward	☐
Accident and Emergency	☐
GP	☐
Other	☐

If **other**, please state in this box.

8. How many times per year (on average) is a child/young person scheduled to **visit your clinic**?

1-2 times per year	☐
3-4 times per year	☐
5-6 times per year	☐
7 or more times per year	☐

9. How many times per year (on average) is the child/young person scheduled to see the **Diabetes Consultant**?

1-2 times per year	☐
3-4 times per year	☐
5-6 times per year	☐
7 or more times per year	☐

10. How many times per year (on average) is the child/young person scheduled to see the **Diabetes Nurse Specialist?**

1-2 times per year	☐
3-4 times per year	☐
5-6 times per year	☐
7 or more times per year	☐

11. Where is **most** of the diabetes care provided?

At the diabetes clinic	☐
In the community/home	☐
On a hospital ward	☐
Other	☐

If **other**, please state in this box.

12. Where **else** is the diabetes care provided?

Please write your answer clearly in this box.

13. Approximately how many children and young people do you have on **your Diabetes Clinic caseload?**

Please write your answer clearly in this box.

14. How many children do you see at each **clinic**?

Please write your answer clearly in this box.

15. **How much time** do you spend with each child during an appointment?

Please write your answer clearly in this box.

16. How many children in your clinic are on **insulin pumps**?

Please write your answer clearly in this box.

17. Do you provide any information to the children/young people on **carbohydrate counting?**

Yes ☐ No ☐

If yes, please describe how you provide this information, and if it is in leaflet form, please append a copy to this approach manual.

18. What is your **routine practice** with regards to presenting children and young people about information about diabetes? *(If written/audio instructions or information are provided, please append a copy with this approach manual).*

Please write your answer clearly in this box.

19. Do you hand out diabetes related **leaflets** to newly diagnosed children/young people?

Yes ☐ No ☐

If yes, please state which leaflets.

Name of leaflet	**Name of leaflet**
•	•
•	•
•	•
•	•
•	•
•	•
•	•
•	•
•	•
•	•
•	•
•	•
•	•
•	•
•	•
•	•

20a. What additional information do you give out as circumstances arise (e.g. travel, driving, starting school)?

Name of information	**Type of information (e.g. leaflet, book, DVD)**
•	
•	
•	
•	
•	
•	
•	
•	
•	
•	
•	
•	

20b. Can you tell me about the availability of the information you provide?

For example:

- Do you pay for any of the leaflets?
- If yes, how are they funded?
- Who provides them and from where are they obtained?
- Are they easily obtainable?
- Who decides on what information is provided e.g. Consultant, CNS or multi professional group (the team)?

20c. If you have more than one clinic or consultant do they identify different information for children and young people to receive, i.e. individual preference?

20d. Do you have any protocols/management plans/care pathways (or other sources of evidence practice e.g. algorithms) that address the information you should provide children and young people?

20e. Who maintains the literature/information in the clinics?

20f. Are information materials combined in anyway e.g. in packs or by age group?

21a. Have you written any of your own diabetes related information?

Yes ☐ No ☐

If **yes**, please describe, and append to this approach manual.

21b. By whom and how was this information developed e.g by individual champion, interested individuals (community of practice) by team, by committee (standard procedures) etc.?

21c. Is it regularly reviewed and updated?

21d. Is this information available across all clinics and routinely given out?

If no, please explain.

21e. Have you evaluated this information? If yes, please describe

21f. Have you either requested feedback from parents/children/young people or received feedback?

If yes, please describe

21g. Do you provide a diabetes diary your own or someone else's?

21h. How are they used by healthcare professionals?

21i. How well do children and young people use them?

21j. Explore whether diaries are age appropriate, child focussed and take account of ethnicity, or gender.

May we have copies please?

22. Do you recommend **books** about diabetes to children and young people?

Yes ☐ No ☐

If **yes**, please state which books and how often you recommend books.	
Book title	How often is this **book** recommended?
•	
•	
•	
•	
•	

23. Do you recommend diabetes related **websites** to children/young people?

Yes ☐ No ☐

If yes, please state which websites and how often you recommend websites.	
Website address	How often is this **website** recommended?
•	
•	
•	
•	
•	

24. Do you recommend diabetes related **websites to the parents/guardians** of children/young people with diabetes?

Yes ☐ No ☐

If yes, please state which **websites** and how often you recommend websites.	
Website address	How often is this **website** recommended?
•	
•	
•	
•	
•	

25. Do you recommend **DVDs** about diabetes to children/young people?

Yes ☐ No ☐

If yes, please state which **DVDs** and how often you recommend DVDs.	
Title of DVD	How often is this **DVD** recommended?
•	
•	
•	
•	
•	

26. Do you recommend **DVDs about diabetes to parents/guardians** of children/young people with diabetes?

Yes ☐ No ☐

If yes, please state which **DVDs** and how often you recommend DVDs.	
Title of DVD	How often is this **DVD** recommended?
•	
•	
•	
•	
•	

27. Have children/young people ever recommended any resources to you that you could pass on to other children/young people/families? If so, please list the resources.

Yes ☐ No ☐

If yes, please write details about title and type of resource.	
Title of resource	**Type of resource** (e.g. leaflet, book, DVD, website)
•	
•	
•	
•	
•	

28. Could you tell me how the information you provide is introduced to the parents/children and young people in the clinic interview?

(The aim is to try and understand the ‘approach’ undertaken in facilitating information provided)

29. Is there anything else that you would like to state about the **routine practice** in your diabetes clinic?

Please write your answer clearly in this box.

30. In your opinion, overall how would you describe the standard practice of information provision for parents/children and young provided by this trust/clinic?

(We are trying to illicit their perspective, and their understanding of children and young people’s needs. Also they may state they could be better, so what prevents this from happening-need to tease out issues as appropriate)

31. Name of researcher collecting this information (if face to face)

32. Date this Approach Manual was completed

d d m m y y

☐☐ ☐☐ ☐☐

On behalf of the EPIC Project team, **thank you very much** for answering these questions.

Please return the completed document, in the **FREEPOST** envelope to:

Dr Llinos Spencer
Data Manager, EPIC Project
Centre for Health-Related Research
Bangor University, FREEPOST BG35
Fron Heulog, Ffriddoedd Road
Bangor, Gwynedd
Wales, LL57 2BR

Example of EPIC project process evaluation interview schedule: 6–12 years

Aim

To gain an understanding from the child of the role that the intervention pack has played in the management of their blood glucose monitoring and their ability to titrate blood glucose levels to the insulin units required.

Approach

Semistructured interview comprising open questions with prompts. The interviews may be conducted at clinic or at home. It will be useful to have a copy of the relevant intervention pack and diary at the interview. Care must be taken as they may have different information in their pack to the sample that we have. It is hoped, and should be requested on organising the interview, that the child's pack and diary would be available to the interviewer. It may be appropriate to interview the child or young person before the parent.

Interview objectives

- To ascertain what aspects of the EPIC intervention pack and its contents assisted the child in taking responsibility for the care of their blood glucose monitoring and insulin units required.
- To ascertain whether the EPIC diary contributed to facilitating decisions about the management of their diabetes with specific reference to self-prescribing of insulin.
- To ascertain how and where the child and their family used the EPIC diary and intervention pack.

Interview procedure

- Thank them for agreeing to this interview (informed consent process previously undertaken before interview).
- Remind child of project/study purpose and restate the purpose of the interview and that our questions relate to the last 6 months since they agreed to be in the trial.
- Ensure that you have an understanding of the child's family circumstances before working through the schedule; record as additional information.

The following are broad topic questions that will be followed up with subsequent questioning that will be appropriately tailored to the individual child's needs.

General warm-up question

- Can you tell me how you are getting on with looking after your diabetes at the moment? Focus on the monitoring of blood glucose levels and determining how much insulin is required.
- How do you like to receive information about diabetes? (prompts – leaflets, books, DVDs, internet)

EPIC-specific questions

General

- What did you think when you were given the EPIC information pack and diary in the clinic?
- Who gave you the information pack?
- Did this person explain it to you and go through it with you?
- If no, would you have liked someone to have gone through it with you?

(Explore how they would prefer the PDSN or consultant to use the EPIC information pack when they meet with the young person.)

Diary specific

- If produced, discuss photographing their material and obtain signed consent.
- Did you use the diary? Discuss use of the diary.

EPIC intervention packs

- What did you think about having all the information together in the EPIC intervention pack?
- Who looks after the pack and the information inside?
- Did you make use of the pack? Explore how.

Impact of information pack and diary

- Have you spent any time away from home without mum or dad since being in this project? Explore how the child managed their diabetes.
- When you are at school or doing activities (perhaps ask first what activities they are doing) do you take any information or your diary with you?
- Do you think your diabetes has got easier to manage in the last 6 months?
- Have you received any home visits from the diabetes team?
- Did the diabetes nurse talk about the pack during the visit?
- Have you spoken to the diabetes nurse over the telephone?
- Did the diabetes nurse talk about the pack during the conversation?
- When you attended follow-up appointments at the hospital did you take the diary and/or pack with you?
- Has the consultant or diabetes nurse talked about the pack at any other hospital appointments?
- If yes, what did they talk about particularly?
- Would you have liked someone to have asked you about the pack? (Explore how they would prefer the PDSN or consultant to use the EPIC information pack when they meet with the young person.)

Invite the child to add any thing further they feel is important.

What are the most important three things you would like to change about the way doctors and nurses help you look after care?

Thank you for your time and contribution to this research project.

Theoretical sampling frame for the child, young person and family process evaluation interviews

Age group (years); number; (intervention : control)	Sampling by centre																		Sampling across sites
	CY		CL		CB		CA		CT		CU		CN		CO		CS		
	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	I	C	
6–10, 24 (16 : 8)	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	Proportions in total sample to be first identified for the following with representative sampling across centres: sex, socioeconomic status, < 2 years from diagnosis, > 2 year from diagnosis, ethnicity, pump users
11–15, 24 (16 : 8)	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	
16–18, 12 (8 : 4)	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	1–2	0–1	
Total, 60 (40 : 20)	3–6	0–3	3–6	0–3	3–6	0–3	3–6	0–3	3–6	0–3	3–6	0–3	3–6	0–3	3–6	0–3	3–6	0–3	

C, control; I, intervention.

Process evaluation diabetes health-care professional questionnaire

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

EPIC Project
Process Evaluation-Healthcare Professional Questionnaire

Principal Investigators: **Professor Anne Williams**
Professor Jane Noyes
Researchers: **Ms Jackie Chandler-Oatts**
Dr Llinos Spencer
Mrs Deborah Edwards

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

EPIC Project-Process Evaluation-Healthcare Professional Questionnaire

Please tick as appropriate

Paediatric Diabetes consultant ☐

Paediatric Diabetes Nurse ☐

Research Nurse ☐

Other, please specify ☐

We are evaluating the appropriateness and utility of information given to children, young people and their parents to promote self-care, blood glucose meter use and optimisation of their insulin regime. Please answer all questions with a black pen marking with an X once in a box on the scale in the right hand columns. For those questions that are not appropriate for you to answer or for which you do not have information please leave blank. Please circle yes or no answer as required. Please answer the questions based on information during the EPIC trial period. Boxes have been provided for free text comments. Please add any additional information on the back page under 'any additional information or comment'

Date ☐☐ - ☐☐ - ☐☐☐☐ i. Centre Number ☐☐☐☐
d d m m y y y y ii. iii.

iv. v. vi. vii. viii. Your initials ☐☐☐

ix. x. xi. xii. xiii. xiv.

Date ☐☐ - ☐☐ - ☐☐☐☐ Centre Number ☐☐☐

	EPIC INTERVENTION GROUP	Strongly Agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree
	Your views on the age-appropriate EPIC insulin injection and pump diaries					
1.	a) I found the 6-10 EPIC injection diary visually appealing and suitable for the target age group					
	b) I found the 11-15 EPIC injection diary visually appealing and suitable for the target age group					
	c) I found the 16-18 EPIC injection diary visually appealing and suitable for the target age group					
	d) I found the EPIC pump diary visually appealing and suitable for 6-18 year olds					
2.	a) Overall the EPIC injection diaries were used effectively by the 6-10 age group					
	b) Overall the EPIC injection diaries were used effectively by the 11-15 age group					
	c) Overall the EPIC injection diaries were used effectively by the 16-18 age group					
	d) Overall the EPIC pump diaries were used effectively by the 6-18 age group					
3.	The EPIC diaries were not very different from diaries we use at the Trust					
4.	The children and young people were enthusiastic about the EPIC diaries					
5.	Children and young people used the EPIC diaries to record blood glucose levels					

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

	EPIC INTERVENTION GROUP	Strongly Agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree
6.	a) Children aged 6-10 were more likely to complete their EPIC diaries appropriately on a regular basis than previous diaries					
	b) Young people aged 11-15 were more likely to complete their EPIC diaries appropriately on a regular basis than previous diaries					
	c) Young people aged 16-18 were more likely to complete their EPIC diaries appropriately on a regular basis than previous diaries					
7.	a) Children (6-10) were more likely to bring their EPIC diaries to their follow up appointments than previous diaries					
	b) Young people (11-15) were more likely to bring their EPIC diaries to their follow up appointments than previous diaries					
	c) Young people (16-18) were more likely to bring their EPIC diaries to their follow up appointments than previous diaries					
8.	a) Children (6-10) were more able than previously to calculate their insulin units correctly with the result from their blood glucose meter					
	b) Young people (11-15) were more able than previously to calculate their insulin units correctly with the result from their blood glucose meter					
	c) Young people (16-18) were more able than previously to calculate their insulin units correctly with the result from their blood glucose meter					
9.	Overall parents found the use of the EPIC diaries aided their intervention in prescribing the correct dose of insulin for their child/young person					

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

10. a) Did children (6-10) experience any difficulty in using the EPIC diaries? **YES** **NO**

(Please circle)

If yes please explain

b) Did young people (11-15) experience any difficulty in using the EPIC diaries? **YES** **NO**

(Please circle)

If yes please explain

c) Did young people (16-18) experience any difficulty in using the EPIC diaries? **YES** **NO**

(Please circle)

If yes please explain

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

11. Did you find the sizing of any of the EPIC diaries appropriate? **YES** **NO**

(Please circle)

If no, please explain

12. Please freely comment overall on the design and use of the 4 separate EPIC diaries (6-10, 11-15, 16-18, & pump)

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

	EPIC INTERVENTION PACK	Strongly Agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree
	Your views on the age-appropriate information packs					
13.	a) I found the 6-10 EPIC intervention pack visually appealing and suitable for the target age group					
	b) I found the 11-15 EPIC intervention pack visually appealing and suitable for the target age group					
	c) I found the 16-18 EPIC intervention pack visually appealing and suitable for the target age group					
14.	a) I only have access to some of the information in the 6-10 EPIC intervention pack to give to my patients in routine practice					
	b) I only have access to some of the information in the 11-15 EPIC intervention pack to give to my patients in routine practice					
	c) I only have access to some of the information in the 16-18 EPIC intervention pack to give to my patients in routine practice					
15.	a) I found that the EPIC intervention packs were bulky and awkward to handle.					
16.	a) The information provided in the EPIC intervention packs, to my knowledge, is the most appropriate information to give to young people between the ages 6-10					
	b) The information provided in the EPIC intervention packs, to my knowledge, is the most appropriate information to give to young people between the ages 11-15					
	c) The information provided in the EPIC intervention packs, to my knowledge, is the most appropriate information to give to young people between the ages 16-18					
17.	I thought that the EPIC intervention packs were well designed					
18.	I had no difficulty in handling the EPIC intervention packs					

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

19.	EPIC intervention packs were well received by parents /carers					
	EPIC INTERVENTION PACK	Strongly Agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree
20.	EPIC intervention packs were well received by children and young people					
21.	I feel that the EPIC intervention packs did not make an overall difference to previous information provision provided by this clinic in the last year					
22.	EPIC intervention packs were useful in facilitating:					
	a) questions from parents and children					
	b) engagement of children and young people in discussion about their management of their diabetes:					
	i. At baseline					
	ii. At 3 month follow up					
	iii. At 6 month follow					
	iv. Between follow ups or at home visits					
23.	EPIC intervention packs provided too much information in one clinic appointment					
24.	The information in the pack was not being provided at the right time for the children or young people					
25.	The EPIC intervention packs ensured that children and young people received all the information necessary for them to manage their diabetes					
26.	The EPIC information packs were not practical for use by the children and young people					

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

27. Was the size of the EPIC information packs an issue for the children and young people? ☐ **YES** ☐ **NO**

(Please circle)

If yes, please explain

28. Please list any important information you felt was missing from the packs for any of the three age groups

Missing information 6-10 EPIC intervention pack	Missing information in the 11-15 EPIC intervention pack	Missing information 16-18 EPIC intervention pack

29. Please freely comment on the design of the EPIC information packs. Feedback is very welcome.

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

	Service Delivery of the INTERVENTION Pack	Strongly Agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree
	Administration and Organisation of packs and diaries					
30.	The EPIC information packs were a useful way to ensure that the child or young person received the necessary information					
31.	Storage of these packs could be a problem within the OPD clinic setting					
32.	Our clinic already provides information to children and young people in a similar 'pack' format					
33.	We will be developing our own packs after this trial					
34.	I did not find it difficult to facilitate these EPIC information packs and diaries to the parent and child as suggested by the project step by step guide provided					
35.	There is not enough time to engage the child or young person appropriately within a child-centered approach in routine consultations at our clinic					
36.	Delivering the EPIC information pack and diary allowed me the opportunity to engage the child/young person more directly in the consultation					
37.	Clinical practice at the clinic closely follows the NICE diabetes guideline 2004					

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

38. Did the EPIC information packs prolong the average clinic appointment?

Please Tick

a) Yes by 5-10 minutes ☐

b) Yes by more than 10 minutes but less than 20 minutes ☐

c) Yes by more than 20 minutes ☐

d) No they did not extend time of clinic appointment ☐

Any additional comments

☐

(Please circle)

39. Are you aware of any impact on the improvement of blood glucose monitoring and insulin management since the children and young people, randomised to the intervention group, have been in the trial? **YES** **NO**

If yes;

i. Are some children or young people from the trial presenting with a more positive attitude towards their blood glucose management since being entered into the trial? **YES** **NO**

ii Are some parents reporting that their child from the trial are managing their blood glucose levels better than before the trial? **YES** **NO**

Date ☐☐ - ☐☐ - ☐☐☐☐　　CENTRE NUMBER ☐☐☐

	CONTROL-Usual information routinely provided	Strongly Agree	Agree	Neither agree or disagree	Disagree	Strongly disagree
40.	There was very little difference between the information we provide and the EPIC intervention information packs					
41.	We give information to children and young people that is appropriate to their age group					
42.	We give children and young people diaries regularly to complete					
43.	During the trial we improved our own routine information resources given to children and young people					
44.	We routinely direct children, young people and their parents to other sources of information not available from the clinic					

(Please circle)

45. Are you aware of any impact on the improvement of blood glucose management since the child randomised to the control group has been in the trial? **YES** **NO**

If yes;

i. Are some children or young people from the trial presenting with a more positive attitude towards their blood glucose management since being entered into the trial? **YES** **NO**

ii. Are some parents reporting that their child from the trial are managing their blood glucose levels better than before the trial? **YES** **NO**

46. Are you aware of any other impact on **any** of the children and young people or parents recruited into this trial? **YES** **NO**

If yes, please explain

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

Service Delivery of Diabetes Care

47. Service delivery for children's diabetes services at this Trust is delivered via (please tick all that apply)

	Please Tick
a) Shared care with the GP (Primary Care)	☐
b) Via Hospital-led outreach clinics nearer to the child's home	☐
c) Via regular home visits from the clinical nurse specialist	☐
d) Via a flexible approach to location of consultations with diabetes nurses and doctors based around the needs of the individual child and their family	☐
e) Via consultant led clinics in the outpatients department at the hospital	☐
f) Other, please specify in the box below	☐

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

48. Does facilitation of a 'child-centered approach' require training? ☐ **YES** ☐ **NO**

(Please circle)

If yes, what core competencies do you think are relevant?

49. Please complete the following sentence

The key principles in encouraging children and young people to self manage their diabetes include;

50. Children and young people in your clinics on average attend

	Please Tick
a) All appointments	☐
b) Nearly all appointments	☐
c) Half of all appointments	☐

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

d) Few appointments ☐

51. Which age group has most difficulty in attendance at clinic? ☐ **6-10** ☐ **11-15** ☐ **16-18**

52. In your opinion what are the key factors in non attendance at your clinics, please tick all that apply:

Please Tick any that apply

a) Lack of motivation ☐

b) Competing lifestyle factors .e.g school, parents work patterns, juggling with other children ☐

c) Distance between home and clinic ☐

d) Transport difficulties e.g. parking at the clinic ☐

e) Cost of travel to hospital ☐

f) Psychosocial issues e.g family background ☐

g) Other, please specify in the box below ☐

Date ☐☐ - ☐☐ - ☐☐☐☐ CENTRE NUMBER ☐☐☐

53. Please add any additional information or comments

Thank you very much for giving time to complete this questionnaire

Please send the completed questionnaire back to Llinos Spencer in the **FREEPOST** envelope provided.

Dr Llinos Spencer
EPIC Project Data Manager
Centre for Health-Related Research
Bangor University, FREEPOST BG35
Ffriddoedd Road, Bangor
Gwynedd, LL57 2BR

If you have any questions please contact Dr Llinos Spencer on **01248 38 3171** or e-mail: **L.Spencer@bangor.ac.uk**

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Date received by EPIC Office	☐☐	☐☐	☐☐☐☐		
Date entered into the database	☐☐	☐☐	☐☐☐☐	Entered by	☐☐

Summary table of usual practice information by centre

Centre code	Clinic information				Caseload	Information provided at diagnosis	Date information was obtained
	Staff	Occurrence	Clinic information	Transition			
Y	One consultant, one PDSN	Clinic main hospital (weekly, AM), satellite clinics (weekly, alternating locations, AM), satellite clinic (monthly, AM), nurse-led clinic (monthly, AM) (majority of care provided in the community/home)	Six to eight children; 30 minutes; seen by PDSN and a medic at each clinic appointment	Not at present	84, 8% insulin pumps, up to 18 years	Newly diagnosed pack produced in-house, which contains Eli Lilly *Streetwise* series and information pack from Roche Diagnostics for newly diagnosed	7 January 2010 with PDSN
L	One consultant, one PDSN	Clinic main hospital (bimonthly, alternating days, AM and PM), nurse-led clinic (monthly), additional clinics as required (majority of care provided in the community/home)	16 children; no set time; PDSN would see approximately 50% of the list	No Adult services: two young adult clinics (one consultant runs a monthly clinic and another consultant a bimonthly clinic for those aged 16–25 years)	105, 0% insulin pumps, up to 16 years	Newly diagnosed pack made up from available leaflets, etc. A large variety of leaflets offered (> 40)	8 March 2010 with PDSN
B	One consultant, one PDSN	Clinic main hospital (weekly, AM), clinic main hospital (bimonthly, PM) (majority of care provided in the community/home)	Six children; 30 minutes, annual review 1 hour; seen by PDSN and a medic at each clinic appointment, annual review by PDSN and dietician	Yes, four times a year for 2 years Adult services: young persons clinic (up to 25 years)	78 paediatric, 11 transition, 9% insulin pumps, up to 16 years	Starter pack made up from available leaflets, etc. Discharge pack made up from available leaflets, etc.	13 August 2010 with PDSN
A	One consultant, one PDSN	Clinic main hospital (six clinics a month) (majority of care provided in the community/home)	Eight children; 20 minutes; varies depending on need	Yes, once every 2 months	85, 7% insulin pumps	Information pack on diabetes team. Drip feed other information as needed on an individual basis. A small variety of other leaflets offered (< 10)	7 September 2010 with PDSN

Centre code	Clinic information				Caseload	Information provided at diagnosis	Date information was obtained
	Staff	Occurrence	Clinic information	Transition			
U	Two consultants, three PDSNs, one play specialist, one youth worker	Clinic main hospital (weekly, PM) (majority of care provided in the community/home), Saturday club in local school (monthly)	14 children (usually see 16–18); 15 minutes with consultant and then rotate around nurse and dietician as needed	Yes, monthly	250, 6% insulin pumps, up to 16 years	Newly diagnosed pack produced in-house. A large variety of other leaflets offered (10–20)	19 May 2010 with PDSN, 19 May 2010 with PI
N	One consultant, one associate registrar, two PDSNs, one dietician	Clinic main hospital (twice a week, PM), dietician once a week, podiatrist once a week, care provided across all settings, diabetes camp every 2 years funded by the charity Candy Free Kids (parent support group)	12 children; 10 minutes	Yes, three times a year in school holidays, up to 16 years	140 paediatric, 66 transition, 22% insulin pumps, 16 years until finish full-time education	JDRF newly diagnosed ‘Kids Sac’, Bayer newly diagnosed bags. A small variety of other age-appropriate leaflets offered (< 10)	14 June 2010 with PDSN
Q	One consultant, two PDSNs	Clinic main hospital (weekly, Thursday AM), extra annual review clinic monthly or alternate fortnightly, separate weekly dietetic clinics	Five to ten; 20–45 minutes		98, three on insulin pumps (two toddlers)	Ward pack, hypoglycaemia, sick-day rules, ketones, correction bolus, information from consultant	14 March 2011 with PDSN
T	Two consultants, two PDSNs	Clinic main hospital (weekly, AM), clinic primary care centre (fortnightly, PM), no dietician cover, care provided across a variety of settings	Between 4–12; 10 minutes for consultant-led clinic and up to 90 minutes in a nurse-led clinic	Yes, once a month	130, three on insulin pumps	Newly diagnosed education pack, loan Diabetes UK DVD, loan book *Type 1 Diabetes in Children, Adolescents and Young Adults: How to Become an Expert on your Own Diabetes*. A large variety of other leaflets offered (10–20)	25 March 2011 with PDSN

Centre code	Clinic information				Caseload	Information provided at diagnosis	Date information was obtained
	Staff	Occurrence	Clinic information	Transition			
O	Two consultants (only one consultant at each clinic), four PDSNs (3.5 FTE), one cognitive–behavioural therapist, one consultant psychologist, one dietician	Clinic main hospital [twice a week, AM (start 08.30), PM (16.00–19.30)], pump clinic main hospital (monthly), satellite clinic (monthly, all day), Friday Club (nurse led with mental health team helping children to cope with diabetes through art and play), majority of care in large hospital (very large rural county), high street voucher given as a reward for positive self-management behaviours	Transition (eight children), evening clinic (seven children), morning clinic (10 children); 15–25 minutes once seen all the team	Yes (weekly, pm), 14–19 years	350 (including those in adult system), 26% (90) on insulin pumps	A small variety of in-house-produced leaflets (< 10) and starter pack (*Getting Started*), *Diabetes Made Simple* (Novo Nordisk), trolley with a variety of information on it readily available for children and young people to choose at clinic along with a selection of diaries (10–20 leaflets)	14 December 2010 with PDSN, 14 December 2010 with PI
I	One consultant, one PDSN	Consultant-led clinic main hospital (weekly), nurse-led clinic (twice a week, Thursday evening 15.30–18.00 and Friday AM)	Between six and eight at consultant-led clinic, which lasts 20–30 minutes; five in nurse-led clinic: Thursday clinic – 30 minutes, Friday clinic – 45 minutes	Yes, twice a year	100–110, 27 on insulin pumps	Developed own A5 packs for infant/junior school and secondary school children. All presented in a Novo Nordisk wallet that is provided free. Contains diary, carbohydrate awareness guide, *Eating Well with Type 1 Diabetes* (Novo Nordisk), lipodystrophy book, *How to Manage at School*, *Foot Care* (general), *Sick Day Rules*, *Help with Hypos*, *Hypo Guide for Schools*, contact details	11 January 2011 with PDSN

Centre code	Clinic information				Caseload	Information provided at diagnosis	Date information was obtained
	Staff	Occurrence	Clinic information	Transition			
						Everybody: 'Kids Sac' (JDRF), *Tots to Teens* (Diabetes UK) > 11s: *On the Level* (Diabetes UK), *Go for It* (Diabetes UK) < 11s: *Tadpole Times* (Diabetes UK)	
S	Two consultants, three PDSNs	Clinics main hospital: < 13 years (weekly, AM), adolescents 13–16 years (weekly, PM) (majority of care provided in clinic setting)	10; 30 minutes	Yes, every third Thursday of the month; 16–18 years	244, 35 on insulin pumps	Newly diagnosed handbook (70–80 pages) (ring binder so that age-appropriate pages can be added or removed), *Getting Started with Diabetes* (BD Medical – Diabetes Care), *Growing up with Diabetes* (BD Medical – Diabetes Care), *Ketones* (Abbott Diabetes Care)	27/06/2011 with PI

FTE, full-time equivalent.

Social deprivation scores for postcodes across England and Wales

From the participants who took part in the EPIC trial (see *Chapter 5*), 334 postcodes were collected across England and Wales to establish social deprivation scores. In Wales, 129 of the 138 postcodes collected were included as deprivation scores could not be found for nine of the postcodes. In England, 183 of the 196 postcodes collected were included as deprivation scores could not be found for 13 of the postcodes.

Several measures of deprivation were investigated. Of these, Townsend scores[247] based on 2001 area statistics, the *English Indices of Deprivation* for 2010[246] and the *Welsh Index of Multiple Deprivation* for 2008[248] were selected as these are the most widely used in health research. Townsend scores are applicable across the UK; however, this measure is based on the 2001 UK census and so has not been recently updated. The *English Indices of Deprivation* and *Welsh Index of Multiple Deprivation* are more recent; however, they cannot be compared across England and Wales as the domains are different in each.

The *English Indices of Deprivation*[246] has seven main domains: income, employment, health deprivation and disability, education, skills and training, barriers to housing and other services, and crime and living environment. The *Welsh Index of Multiple Deprivation*[248] has eight main domains: income, housing, employment, access to services, education, health, community safety and physical environment. Townsend (2001) scores and the 2010 *English Indices of Deprivation* scores were found for England, and Townsend (2001) scores and the 2008 *Welsh Index of Multiple Deprivation* scores were found for Wales. These were all provided by the Public Health Wales Observatory, including additional information: Townsend score, rank, fifth, decile calculated based on England and Wales lower layer super output area (LSOA) data combined. For Wales, postcodes were geocoded to LSOA and then the scores, ranks, fifths and deciles were assigned for all postcodes that were valid. There are 1896 LSOAs in Wales. The English postcodes were converted into LSOA scores.[311] It was possible to establish the nearest corresponding Lower Layer Super Output Area, which is the geographical level that indices of deprivation information has been collected at. There are 32,482 Lower Layer Super Output Areas in England. From the LSOA information it was then possible to find the ranks, fifths and deciles.

The Townsend scores for England were then compared with the more recent indices of deprivation scores using a scatter plot. This information was analysed by Public Health Wales. The indices were looked at in terms of scoring using the following sources:

- the *English Indices of Deprivation 2010 – Technical Report*:[312] 'The most deprived LSOA for each index is given a rank of 1, and the least deprived LSOA is given a rank of 32,482' (p. 51)
- Townsend (2001) scores:[313] 'Positive values of the index will indicate areas with high material deprivation, whereas those with negative values will indicate relative affluence'
- the *Welsh Index of Multiple Deprivation 2008*:[248] 'the most deprived LSOA is ranked 1, and the least deprived 1,896'.

These were all interpreted as below:

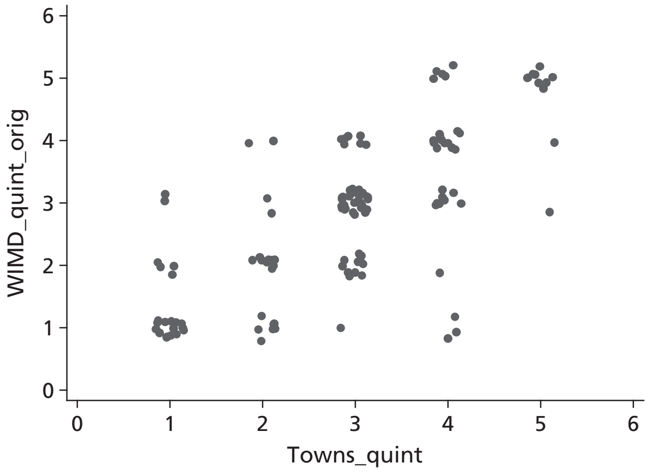
English Indices of Deprivation 2010	more deprived =	= smaller rank (closer to 1)	= smaller quintile (closer to 1)
Townsend scores	more deprived = larger positive score	= larger rank (closer to 32,482)	= larger quintile (closer to 5)
Welsh Index of Multiple Deprivation 2008	more deprived = larger score	= smaller rank (closer to 1)	= larger quintile (closer to 5)

When comparing quintiles, the 2008 *Welsh Index of Multiple Deprivation* and 2001 Townsend scores match closely, For the *English Indices of Deprivation* the quintiles need to be reverse scored and compared with the Townsend 2001 scores. These scores were then interpreted using scatterplots.

Wales scatterplot (using original rankings for the Welsh Index of Multiple Deprivation and Townsend scores)

As noted above, the *Welsh Indices of Multiple Deprivation* quintile 5 is the most deprived (score is high and rank is closer to 1) and Townsend quintile 5 is the most deprived (score is high positive and rank is further away from 1).

Note that the jitter command has been used to separate out the individual points at each co-ordinate (otherwise all of the points at 3,3 appear on top of each other and hence as a single point). Also, note that both axes have been extended to 0 and 6 only to ensure that all of the points at the extremes are displayed after being jittered.

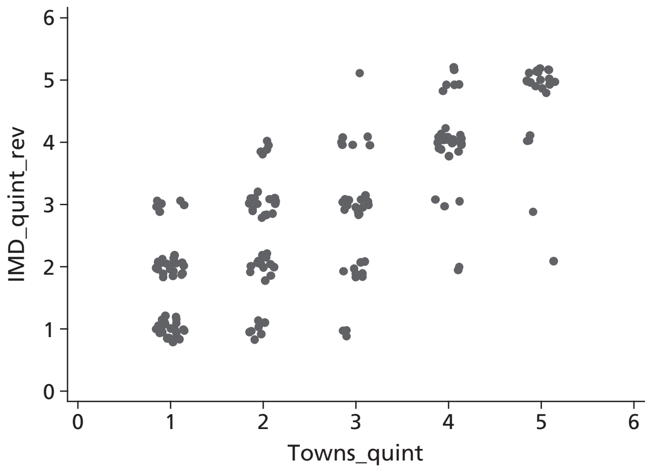


		Townsend				
		1	2	3	4	5
WIMD	5				5	9
	4		2	7	11	1
	3	2	2	28	8	1
	2	4	10	11	1	
	1	15	7	1	3	
					n	%
		Fifth same for both indices			73	57
		Fifth one different			45	35
		Fifth two different			7	5
		Fifth three different			3	2
		Fifth four different			0	0
					128	

England scatterplot (using reversed rankings for the English Indices of Deprivation and original rankings for Townsend scores)

As noted above, the reversed *English Indices of Deprivation* quintile 5 is the most deprived (rank is closer to 1) and Townsend quintile 5 is the most deprived (score is high positive and rank is away from 1)

Note that the jitter command has been used to separate out the individual points at each co-ordinate (otherwise all of the points at 3,3 appear on top of each other and hence as a single point). Also, note that both axes have been extended to 0 and 6 only to ensure that all of the points at the extremes are displayed after being jittered.



		Townsend				
		1	2	3	4	5
IMD	5			1	6	18
	4		5	6	19	3
	3	6	17	15	3	1
	2	21	15	8	2	1
	1	25	7	3		

	n	%
Fifth same for both indices	92	51
Fifth one different	71	39
Fifth two different	18	10
Fifth three different	1	1
Fifth four different	0	0
	182	

From this it was decided the Townsend scores still match closely to the more recent *English Indices of Deprivation* and *Welsh Index of Multiple Deprivation* scores; therefore, to enable a comparison to be made across the UK the Townsend scores were selected to interpret social deprivation.

Social deprivation scores for postcodes across England and Wales for the process evaluation sample

In total, 61 children, young people and families were interviewed, but two young people were from the same family, resulting in 60 postcodes in England and Wales. The Public Health Wales Observatory provided Townsend scores based on the 2001 census for 54 of these 60 postcodes. Using the same processes as for whole sample, Townsend 2001 scores, ranks, quintiles and deciles were calculated based on England and Wales LSOA data combined.

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