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EQUIPD Evaluation of Quality Improvement for People with Diabetes

Study Title: An evaluation of quality improvement collaboratives aligned to a national audit to improve the uptake of insulin pumps for people with diabetes

Short Study Title: Evaluation of Quality Improvement for People with Diabetes (EQUIPD)

IRAS Number: 316162

ISRCTN: https://www.isrctn.com/ISRCTN82176651

REC Reference: IRAS 316162

Sponsor: University of Northumbria at Newcastle

Funding Source: NIHR HSDR

Protocol Version: 2.0

Protocol Date: 22.05.2023

This study is funded by the NIHR (151848). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

The EQUIPD study will at all times comply with current government and HRA advice regarding COVID-19. The Sponsor will ensure study activities will be amended as required in accordance with the latest guidance.

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1. KEY CONTACTS:

Study enquiries	
Randomisation:	https://lictr.leeds.ac.uk/webrand/ Tel: 0113 343 2290
SAEs/RUSAEs/protocol violations:	Michael.sykes@Northumbria.ac.uk

Chief Investigators

Michael Sykes, University of Northumbria at Newcastle Michael.sykes@northumbria.ac.uk	**Robbie Foy, University of Leeds (Co-lead)** r.foy@leeds.ac.uk

Funder

National Institute for Health and Care Research	
Evaluation, Trials and Studies Coordinating Centre University of Southampton Alpha House, Enterprise Road Southampton SO16 7NS Email: netspostawardsetup@nihr.ac.uk Tel: +44 (0)23 8059 5586	Study reference: NIHR151848

Sponsor

University of Northumbria at Newcastle	
laura.hutchinson2@northumbria.ac.uk First Floor, Pandon Building, Northumbria University, Newcastle upon Tyne, NE1 8ST, United Kingdom	Study reference: CRP01987/401729

Co-Investigator

Professor Tracy Finch	
University of Northumbria at Newcastle Tracy.finch@northumbria.ac.uk	

Co-Investigator

Dr Bob Young	
National Diabetes Audit Bobyoung@doctors.org.uk	

Co-Investigator

Dr Alex Berry	
DiabetesUK Alex.berry@diabetes.org.uk	

Co-Investigator

Dr Naomi Holman	
Imperial College, London N.holman@imperial.ac.uk	

Co-Investigator – Lead for Health Economics

Dr David Meads	
University of Leeds D.Meads@Leeds.ac.uk	

Co-investigator –Patient and Public Involvement

Dr Kat Ellis	
K.Ellis@Ucl.ac.uk	

Co-Investigator

Dr Jenny McSharry	
National University of Ireland - Galway Jenny.mcsharry@NUIGalway.ie	

Co-Investigator

Dr Sarah Alderson	
University of Leeds s.l.alderson@leeds.ac.uk	

Co-Investigator

Dr Bethan Copsey	
University of Leeds B.Copsey@Leeds.ac.uk	

Co-Investigator

Prof Amanda Farrin	
University of Leeds A.Farrin@Leeds.ac.uk	

Clinical Trials Research Unit:
Lead Methodologist

Professor Amanda Farrin	
Clinical Trials Research Unit (CTRU) University of Leeds, Leeds, LS2 9JT	**Email:** A.J.Farrin@leeds.ac.uk **Tel:** 0113 343 8017

Trial Statistician

Dr Bethan Copsey	
Clinical Trials Research Unit (CTRU) University of Leeds, Leeds, LS2 9JT	**Email:** b.copsey@leeds.ac.uk Tel: 0113 343 6049

CTRU Project Delivery Lead

Thomas Willis	
Clinical Trials Research Unit (CTRU) University of Leeds, Leeds, LS2 9JT	**Email:** t.a.willis@leeds.ac.uk **Tel:**

Senior Trial Manager

Dr Lauren Moreau	
Clinical Trials Research Unit (CTRU) University of Leeds, Leeds, LS2 9JT	**Email:** l.a.moreau@leeds.ac.uk **Tel: 0113 343 7588**

Data Manager

Alison Fergusson	
Clinical Trials Research Unit (CTRU) University of Leeds, Leeds, LS2 9JT	**Email:** a.fergusson@leeds.ac.uk **Tel:**

2. CONTENTS

3. TRIAL SUMMARY AND FLOW CHARTS

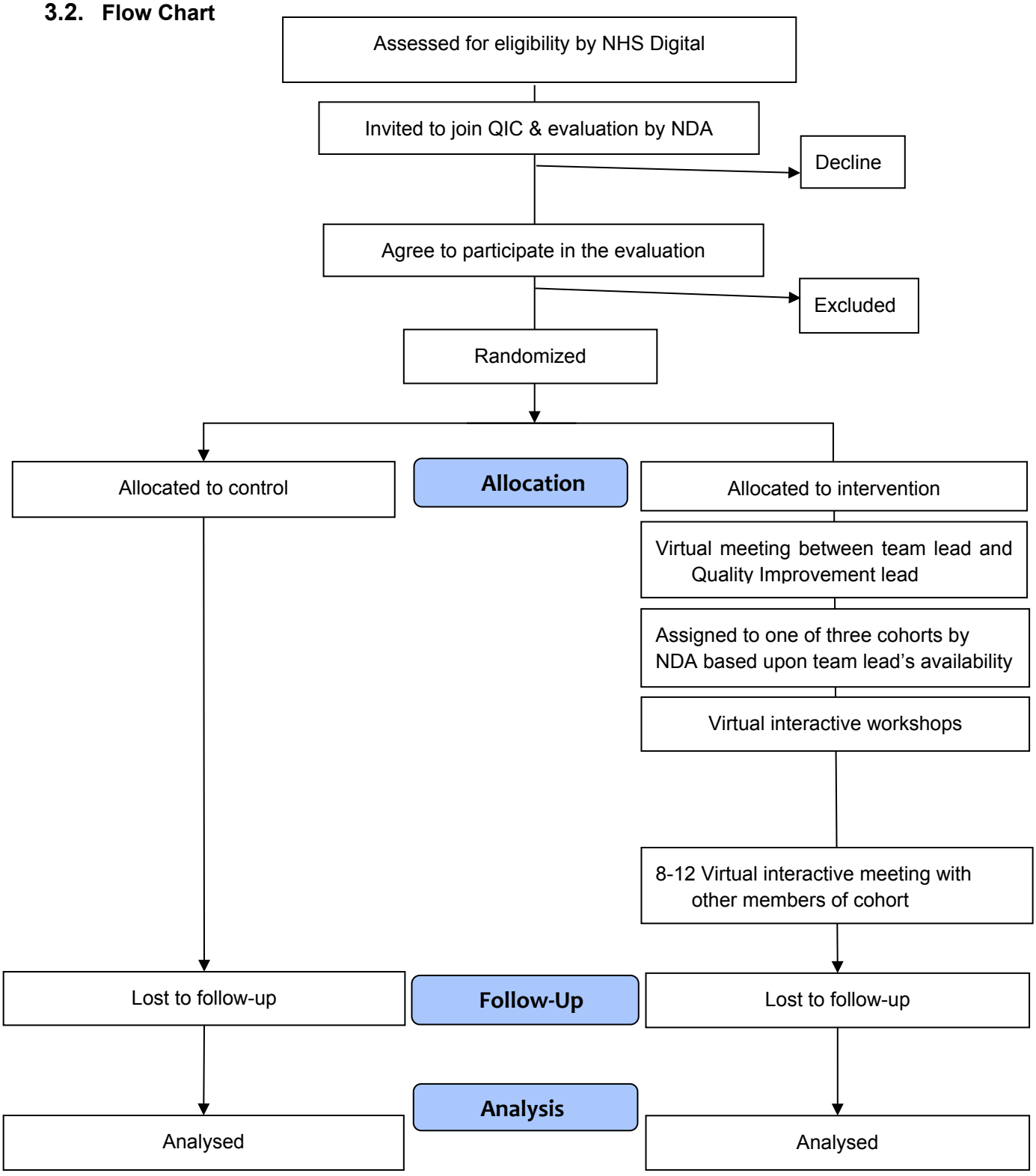
3.1. Trial Summary

Trial Title	**An evaluation of quality improvement collaboratives aligned to a national audit to improve the uptake of insulin pumps for people with diabetes**
Trial description	People with type 1 diabetes and raised glucose levels are at greater risk of retinopathy, nephropathy, neuropathy, cardiovascular disease, sexual health problems and foot disease [1]. Since 2008, NICE has recommended continuous subcutaneous 'insulin pump' therapy for people with type 1 diabetes whose HbA1c is above 69 mmol/mol [2]. Insulin pump use can improve quality of life [3], cut cardiovascular risk [4] and increase treatment satisfaction [5]. About 90,000 people in England and Wales meet NICE criteria for insulin pumps but do not use one [6]. The National Diabetes Audit (NDA) has identified increasing insulin pump use as a key improvement priority [1]. Progress has been slow and insulin pump use also varies markedly by deprivation, ethnicity, sex and location [1]. Whilst patient preferences are important, much variation is likely to be attributable to staff and local organisational factors [7]. Limited capabilities of healthcare providers to mount effective responses to feedback from national audits, such as the NDA, undermines efforts to improve care [8]. We have worked in partnership with patients and carers, national audits and healthcare providers to co-develop a theoretically and empirically-informed quality improvement collaborative (QIC) to strengthen local responses to feedback. Piloting has demonstrated feasibility, acceptability, appropriateness, scalability and fidelity of delivery, receipt and enactment of target behaviours [9]. The NDA plans to roll out the QIC to all specialist diabetes teams but its effectiveness and value for money are unknown. We will evaluate a QIC to improve the uptake of insulin pumps following NDA feedback. Study objectives are to: • Evaluate the effectiveness of NDA feedback with QIC compared to NDA feedback alone; • Understand intervention implementation, engagement, fidelity and tailoring of actions; • Estimate value for money of NDA feedback with QIC. Our research questions are: • Does a QIC delivered alongside NDA feedback increase insulin pump use, and equality of use, compared to standalone NDA feedback? • How do participants engage with, and respond to, the QIC?

	• Is the QIC cost-effective? The study comprises an efficient cluster randomised trial using routine NDA data with parallel process and economic evaluations.
Short title	Evaluation of Quality Improvement for People with Diabetes (EQUIPD)
Trial Design	Efficient cluster randomised controlled trial using routine NDA data with process and economic evaluations
Key inclusion criteria	Teams providing specialist diabetes care to adults with type 1 diabetes in England and Wales
Planned Sample Size	120 teams
Treatment duration	15 months
Follow up duration	18 months
Planned Trial Period	34 months
Primary Outcome Measure	The proportion of adults with type 1 diabetes and raised glucose levels(HbA1c above 69 mmol/mol) starting and continuing to use insulin pumps for at least three months within an 18-month follow-up period.
Secondary Outcome Measures	Change in blood glucose levels as measured by HbA1c in people with type 1 diabetes and raised glucose levels between the latest measurement in the 12 months preceding the start of the intervention and the latest measurements recorded during the study period.
	Any record of insulin pump prescribing, including for periods shorter than three months.
	Insulin pump use sustained over at least six months.
Intervention	The intervention comprises QIC delivered alongside the NDA, involving virtual coaching sessions, workshops and multisite facilitation, and delivered as part of the new NDA contract. The control comprises standalone NDA feedback.
Process evaluation	We will: • Describe how implementers engage with the QIC intervention overall to support improvement activity and how context influences this work (implementation and engagement).

	• Assess fidelity of delivery, receipt and enactment of the QIC intervention (fidelity). • Describe how teams enact tailoring (tailoring). Our theory-informed, integrated process evaluation will comprise semi-structured interviews, surveys, documentary analysis and observation, with work package level analysis and synthesis.
Economic evaluation	We will evaluate value for money of NDA feedback with QIC by: • Conducting a micro-costing of the quality improvement collaborative and local improvement strategies; • Estimating the cost-effectiveness of NDA feedback with QIC versus feedback alone; • Estimating the budget impact of NHS-wide QIC roll-out. We will collect data through NDA data extraction, interviews, surveys and observations.

3.2. Flow Chart



4. GLOSSARY OF TERMS

Term	Definition
Audit and feedback	Involves measuring care delivery and outcomes and providing a recipient with a summary of their performance over a specified period of time
BCT	Behaviour change techniques
DiabetesUK	A national charity
DTM	Decision tree model
Fidelity	Adherence to intervention specification
HbA1c	Haemoglobin A1c or glycated haemoglobin, made when the glucose sticks to red blood cells, is a measure of glucose control. A high HbA1c indicates too much sugar in your blood.
HQIP	Healthcare Quality Improvement Partnership
ICER	Incremental cost-effectiveness ratio
ICC	Intra-cluster correlation co-efficient
Insulin pump	A continuous subcutaneous insulin infusion, including those used as part of a closed-loop system.
Insulin vials	Bottles containing insulin that are used in insulin pumps
Implementation	the uptake of evidence-informed practice into regular use
ITT	Intention-to-treat
NDA	National Diabetes Audit
NHS	National Health Service
NHS Digital	A national organization involved in the collection and analysis of healthcare data
NICE	National Institute for Health and Care Excellence
NPT	Normalisation process theory
PMG	Project management group
PSC	Project steering group
QIC	Quality Improvement Collaborative
QALY	Quality-Adjusted Life Year
Specialist team	A team providing secondary care to people with diabetes
SOP	Standard operating procedure
Tailoring	The selection of implementation strategies so as to address the unique needs of a given change effort
TIDieR	Template for intervention description and replication
Type 1 diabetes	Type 1 diabetes causes the level of glucose (sugar) in the blood because the body cannot produce enough of a hormone called insulin, which controls blood glucose.
Virtual outreach sessions	a trained person meet with providers through the internet or telephone to educate providers about the clinical innovation with the intent of changing the provider's practice.
Virtual educational workshops	Meetings held through the internet (e.g. MSTeams) targeting stakeholders to teach them.

Virtual facilitated meetings	A group of providers meet through the internet or telephone and are supported by a trained person to foster a collaborative learning environment to improve implementation.
WP	Work package

5. BACKGROUND

5.1 Introduction

Over 192,000 people in England have type 1 diabetes, almost half of whom have HbA1c levels above 69 mmol/mol that put them at greater risk of retinopathy, nephropathy, neuropathy, cardiovascular disease, sexual health problems and foot disease [10]. NICE recommends continuous subcutaneous insulin infusion ('insulin pump') therapy for people with type 1 diabetes whose HbA1c is above 69 mmol/mol despite receiving a high level of care [2].

Insulin pump use can improve quality of life [3], reduce cardiovascular risk [4], and increase treatment satisfaction [5]. Yet the National Diabetes Audit (NDA) demonstrates slow and unequal progress in uptake of insulin pumps; around 90,000 people who meet NICE criteria are not prescribed insulin pumps (NDA). Pump use varies markedly by locality (2% to 47%; 10), by deprivation (16.3% most deprived; 23.8% least deprived; [10]) and by ethnicity (for example, the national census records 7.5% of people in UK as Asian, but they represent only 2.3% of people on insulin pumps; [1]). The NDA has identified accelerating the uptake and equality of insulin pump use as a key priority in reducing mortality and morbidity [1].

The NDA is one of around 60 national audits in England [11]. Funded by NHS England, it provides feedback on recommended processes of care (e.g. proportions of people with diabetes having foot checks) and attainment of treatment goals (e.g. blood sugar or blood pressure control) to specialist teams. Feedback highlights areas for improvement to stimulate change. Whilst audit and feedback has shown modest improvements on care delivery [12], there are considerable opportunities to improve the impact of national audit programmes such as the NDA by, for example, incorporating goals and action plans for change [13]. However, a common challenge amongst those leading national audits is that even well-designed feedback may only have limited impact in the absence of robust local quality improvement arrangements. For example, we found no improvements in care from enhanced feedback reports in two trials embedded within a national audit programme which aimed to reduce inappropriate blood transfusions; a major reason for the absence of any improvement was the lack of effective local responses to feedback [14]. Evidence (e.g. [15, 16]), theory [17] and stakeholder prioritised hypotheses [18] highlight an opportunity to increase the effectiveness of national audits by enhancing the ability of feedback recipients to mount concerted quality improvement.

The Healthcare Quality Improvement Partnership (HQIP), the main commissioner of English national audits, states that, "health care providers require additional support to make best use of performance feedback data. This is likely to be most effective as part of a coordinated regional or national improvement programme" [15]. Several frameworks propose that significant improvements in care can only be achieved by launching and coordinating quality improvement efforts across all levels of healthcare systems (national, organisational, team, and individual) [19, 20]. Whilst national audit may provide the impetus for change at clinical

team and individual levels, there is often insufficient local organisational capability to enable change by, for example, systematically aligning actions to barriers to, and levers for, improvement [17]. Local quality improvement may also be undermined by a lack of motivation to change [17, 19, 22], limited opportunities for improvement actions [9, 19] and poor adaptability to local organisational context [21]. HQIP guidance states “national clinical audits need to be put into the local context to inform action plans addressing areas where quality improvements can be made” (p8; [15]).

Our proposal will evaluate a quality improvement collaborative (QIC) that supports providers to improve by selecting actions tailored to local contexts and generating organisational commitment for change.

5.2 Evidence explaining why this research is needed now

This study responds to calls to implement insulin pumps (NDA, 2021), to increase the effectiveness of national audit [12, 21], to define the content and cost of quality improvement collaboratives [21, 22] and to investigate the effectiveness of tailoring strategies [23, 24]. In seeking to address use and equality of use of insulin pumps, our proposal also addresses NHS England’s recent strategy, Core20PLUS5 [25], which aims to improve care for the most deprived 20% of the national population and address locally identified inequalities through quality improvement.

Our study is distinct from on-going trials: A search of the WHO trials registry identified four current feedback facilitation studies in different contexts using different intervention components from our proposal. These concern colorectal oncology in the Netherlands [26], suicide risk reduction in the US, [27]), perinatal care in Nepal [28] and diabetes care in Australia [29]. Zoungas et al [29] aim to reduce HbA1c in people with type 1 or type 2 diabetes by delivering a 60-minute quality improvement tutorial illustrating different quality improvement approaches, ‘'change champion'' videos, instructional videos and peer-led online forums.

We have developed the QIC over the past five years [9]. Intervention development [30] included multi-method co-design to understand current responses to national audits and further co-design of a stakeholder-, theory- and evidence-informed intervention to support recipients. The specified QIC is illustrated in the logic model (Appendix). The intervention creates the capability, opportunity and motivation to address local influences upon performance, select improvement strategies, develop organisational commitment and collaborate with peers. The intervention differs from Zoungas et al [29] in terms of intervention context (Australia vs England), intervention delivery (largely didactic vs facilitated collaboration and interactive education), in content (e.g. the use of tailoring, the development of commitment) and in our multi-layer use of theory.

We have explored feasibility, acceptability, appropriateness and fidelity of the intervention when delivered as an adjunct to two national audits (NDA [1] and National Audit of Dementia [31]). We recently delivered the intervention to 28 diabetes teams, and used interviews and observations to explore feasibility, appropriateness, fidelity and scalability. We found that the Behaviour change techniques [35] identified in the manual were delivered by facilitators. There was evidence for fidelity of enactment of target behaviours. Participants reported positive attitudes towards the intervention and that the intervention was appropriate [9]. We propose that the intervention is now ready for a definitive effectiveness evaluation [32].

The study aligns with the NDA's commissioned timetable, such that sites will be randomised to intervention receipt in either January 2023 or July 2024.

5.3 Dissemination, outputs and anticipated impact

We will deliver a rigorously conducted evaluation of the effectiveness of feedback with QIC, estimating effects on care (uptake of insulin pumps) and patient outcomes (HbA1c control). We will show whether feedback with QIC improves equality of care by age band, sex, ethnicity and deprivation. Our analysis of intervention implementation, engagement, fidelity and tailoring will guide interpretation of WP1 trial findings, explain influences on effectiveness and support replication. We will describe how specialist diabetes teams engage with, and respond to, the QIC. This will help others to develop the content and delivery of interventions to support feedback recipients to improve care, as advocated by HQIP, the commissioner of national audits. We will describe how teams tailor to local influences and which strategies they align to which influences. This provides important knowledge which the NDA and others interested in improvement can use in adapting our intervention. The lack of evidence about costs or cost-effectiveness is a major hindrance to informed policy and funding decisions [24]. Our economic evaluation will provide national audit providers and commissioners with important information to inform resource allocation. Our micro-costing of the QIC will provide a template for planning and later studies.

Our study will directly influence the NDA, through key staff involvement in this proposal. We will leverage established collaborative links with HQIP (the main commissioner of national audits), and national (e.g. Q Community) and regional (e.g. NIHR Applied Research Collaborations) networks to identify pathways to informing the quality improvement activities. We will describe the intervention and the study findings via a virtual webinar and animated videos. We will engage with diabetes specific networks (e.g. Diabetes Clinical Networks; Diabetes UK Professional conference) in order to share learning, in particular about the barriers and facilitators teams identify and the actions they selected and enacted to address these influences. We will also provide information in a format and delivery mode accessible to the target audience, by using social media delivered animations to stimulate interest in our work, building upon effective dissemination and linkage to high-impact organisations (e.g. Diabetes UK, NHS England, Meta-Lab). We will engage with audit and feedback researchers via the Audit and Feedback Meta-Lab (http://www.ohri.ca/auditfeedback/), to share our study plans and emerging lessons through Meta-Lab seminars and annual meetings. We will provide an internationally focused webinar to the global network of national diabetes audit providers, and providers of other national audits. To target academic and clinical academic audiences, we will publish in peer-reviewed journals to describe the trial and process evaluation protocols, intervention fidelity, trial findings, the process evaluation, the tailoring evaluation, stakeholder engagement, and the economic evaluation. Our budget covers seven open access articles. We will also summarise our work within the NDA annual report and make plain English summaries of findings available online for relevant patient groups as well as our trial participants. As our work progresses, we will keep under review emerging opportunities and means to optimise and monitor impact.

6. TRIAL AIMS, OBJECTIVES AND ENDPOINTS

6.1. Aim

To evaluate a Quality Improvement Collaborative to improve the uptake of insulin pumps

following National Diabetes Audit feedback

6.2. Objectives and Endpoints

We will:

- Evaluate the effectiveness of NDA feedback with QIC compared to NDA feedback alone;
- Understand intervention implementation, engagement, fidelity and tailoring of actions;
- Estimate value for money of NDA feedback with QIC.

Trial Primary Objective and Endpoint

Objective	Endpoint	Method of data collection
To evaluate the effectiveness of NDA feedback with QIC compared to NDA feedback alone in increasing the use of insulin pumps (primary outcome)	The proportion of people with type 1 diabetes and raised glucose levels (HbA1c above 69 mmol/mol) and not prescribed insulin for a pump in the previous year, starting and continuing to use insulin pumps for at least three months within an 18-month follow-up period. We agreed this primary outcome after deliberations involving the NDA and our patient and clinical co-applicants. It is compatible with NICE guidance [2], represents the specific behaviour targeted by the NDA feedback, addresses a priority for patients and policy makers, and is most likely to promote improved glycaemic control. Our denominator population will be all people identified through the national audit before the intervention period (baseline) who have an HbA1c level above 69 mmol/mol and were not prescribed insulin for a pump in the previous year. The numerator population for the primary outcome will comprise those people who have started and become established on insulin pumps, ascertained by two or more prescriptions for insulin vials	Data routinely collected as part of the National Diabetes Audit

	for use in a pump at least three months apart.	

Secondary Statistical Objectives and Endpoints

Objective ***What is the effect of experimental therapy compared to usual care, on:***	**Endpoint**	**Method of data collection**
To evaluate the effectiveness of NDA feedback with QIC compared to NDA feedback alone at improving blood glucose control of people with type 1 diabetes	Change in blood glucose levels as measured by HbA1c in people with type 1 diabetes and raised glucose levels between the latest measurement in the 12 months preceding the start of the intervention and the latest measurements recorded during the study period.	Data routinely collected as part of the National Diabetes Audit
To evaluate the effectiveness of NDA feedback with QIC compared to NDA feedback alone in increasing the number of people who start using insulin pumps.	Any record of insulin pump prescribing during the 18month study period to people with (HbA1c above 69 mmol/mol) and not prescribed insulin for a pump in the previous year.	Data routinely collected as part of the National Diabetes Audit
To evaluate the effectiveness of NDA feedback with QIC compared to NDA feedback alone in increasing sustained pump use	The proportion of people with type 1 diabetes and raised glucose levels(HbA1c above 69 mmol/mol) and not prescribed insulin for a pump in the previous year, starting and continuing to use insulin pumps for at least six months within an 18-month follow-up period.	Data routinely collected as part of the National Diabetes Audit
To evaluate the effectiveness of NDA feedback with QIC compared to NDA feedback alone at reducing inequality of insulin pump uptake by age, sex, ethnicity and deprivation level.	The difference in insulin pump use for greater than 3 months in people with an HbA1c greater than 69 by: • ethnicity, • sex, • age, • deprivation.	Data routinely collected as part of the National Diabetes Audit

Cost-effectiveness Objectives and Endpoints

Objective	Endpoint	Method of data collection
To conduct a micro-costing of the quality improvement collaborative and local improvement strategies	Estimated costs for NDA feedback with QIC and for feedback alone; variance in costs across centres	NDA routine data, interviews, surveys and observations
To estimate the cost-effectiveness of NDA feedback with QIC versus feedback alone	Incremental cost per Quality-Adjusted Life Year (QALY); Net monetary benefit Supplementary analyses estimating cost per change in blood glucose and cost per uptake in pump use	Model based incorporating data from literature reviews of previous evaluations, results from the trial
To estimate the budget impact of NHS-wide QIC roll-out	Plausible budgetary impacts of the intervention	Model based

Embedded Process Evaluation Objectives

Objective	Endpoint	Data required & how is it being collected?
Describe how implementers engage with the QIC intervention overall to support improvement activity and how context influences this work	Intervention implementation and engagement	Interviews, surveys, documentary analysis and observation
Assess fidelity of the QIC intervention	Fidelity of intervention delivery, receipt and enactment [37]	Interviews, surveys, documentary analysis and observation
Describe how teams enact tailoring	Degrees and types of intervention tailoring	Interviews, surveys, documentary analysis and observation

7. DESIGN

EQUIPD is an efficient cluster randomized controlled trial with parallel process and economic evaluations using routine NDA data. 120 specialist diabetes teams will be allocated on 1:1 basis to either control (NDA feedback alone) or intervention (NDA feedback plus QIC) arms.

Control arm teams will receive the intervention after the study period, but prior to data analysis, as part of the NDA contract.

7.1. Intervention arm

Teams allocated to the intervention arm will receive standard NDA feedback and the QIC to promote the uptake of insulin pumps. Standard feedback comprises an annual national report and site-level reports in the form of a dashboard that can be filtered by team.
The NDA will deliver the QIC through the NDA Quality improvement lead, the NDA Clinical lead, the Diabetes UK Engagement lead and clinicians with expertise in improvement and insulin pump use.

The QIC (Appendix C: Logic model) supports participants to specify local goals, consider key local influences on care, select improvement actions aligned to these, and develop organisational commitment to the improvement actions. These components are delivered through two virtual workshops (6 hours in total), two virtual outreach sessions (30 minutes in total) and 8 to 12 virtual facilitated multisite meetings (8 hours).

We will ask the team to attend workshops and ensure a team member attends at least 8 of the multisite meetings. Teams are supported over a 15-month period. Only identified, invited members from participating sites will have access the virtual workshops and meetings. Delivery will be in three parallel cohorts of 20 teams, with each cohort forming a 'collaborative.' Learning will be shared between cohorts by the facilitator. Teams will be asked to identify a replacement if any team member leaves. The replacement will be offered a 30-minute one-to-one call to support within-team discussions about the intervention.

7.2. Control arm

Teams allocated to control will receive standard feedback from the NDA alone. Within current arrangements, all specialist diabetes teams are expected to respond and act upon feedback according to their own clinical governance and quality improvement arrangements. However, these are not specified or directly supported by the NDA and responses tend to vary markedly between teams.

Teams allocated to the control arm will be offered a QIC 3 months after intervention delivery is completed.

7.3. Follow-up

We have chosen an 18-month follow-up period for two reasons. First, it reflects the duration of the QIC, plus 3 months to assess sustainment. Second, it allows for a latent period for teams engaging with the QIC to consider, plan and initiate changes in clinical practice.

8. CLUSTER ELIGIBILITY

8.1. Inclusion criteria

Specialist diabetes teams, including diabetologists, nurses and other specialist staff based in English NHS trusts or Welsh Health Boards which accept invitation to participate in the QIC.

8.2. Exclusion criteria
None.

9. PATIENT ELIGIBILITY

9.1. Inclusion criteria
Our eligible patient population will be all people identified through the national audit before the intervention period (baseline) who have an HbA1c level above 69 mmol/mol and were not prescribed insulin for a pump in the previous year.

9.2. Exclusion criteria
None.

10. TRIAL PROCEDURES

10.1. Cluster Identification
Each cluster will be a clinical team providing specialist care to adults with diabetes. NHS Digital have identified 164 specialist diabetes teams. Specialist teams will be invited both to be part of the QIC and to participate in the evaluation by the National Diabetes Audit.

10.2. Cluster Consent
Clinical leads will give consent on behalf of their specialist diabetes teams. The NDA holds contact details for all specialist teams. As part of usual care, the NDA will email all specialist teams to invite participation in the QIC. The invitation will be directed to the clinical leads at each site and will describe the aim, content and delivery of the QIC. The invitation will describe that they will be allocated to be part of the QIC either in January 2022 or July 2024. The invitation will ask them to provide the names, roles and emails of two people who will form the sites' QIC team. The invitation will also describe the evaluation and ask whether they, as a team, wish to be included in / excluded from the evaluation. During the initial virtual meeting with the team lead, discussion will identify a potential third member of the QIC team.

10.3. Cluster Randomisation
Participating specialist teams will be randomised after agreement to participate and confirmation of eligibility. Allocation of specialist diabetes teams (clusters) to intervention or control will be undertaken independently by the Clinical Trials Research Unit (CTRU) using the CTRU automated 24-hour randomisation service. Specialist diabetes teams will be randomised on a 1:1 basis either to receive the intervention (starting in 2023) or waitlist only (receiving the intervention after the trial follow-up period ends in June 2024), using a computer-generated minimisation programme with a random element.
Minimisation factors will be:

- Baseline proportion moving onto a pump in the 15 months prior to the intervention period (above or below median)
- Size of target patient population in specialist team (above or below median)
- Previous participation in the QIC pilot (yes or no)

Following randomisation, the Clinical team lead will be informed of the cluster allocation and training will be scheduled. Each cluster will be given a unique identifier (ID) site code, which will be used on all relevant trial documentation.

10.4. Cluster Withdrawal from Intervention Participation

Clusters can withdraw from participating in the intervention at any time without having to give a reason. If a team withdraws consent to participate, clarification will be sought on whether withdrawal is from the intervention, or from the evaluation.

10.5. Cluster Withdrawal of Consent to Provide Data

Clusters which wish to withdraw from the intervention remain required to submit their data to the NDA. Teams who have agreed to take part in the evaluation will not be able to withdraw their NDA data from the analysis.

10.6. Patient Consent and Withdrawal (from NDA)

Individual patient consent will not be required. No additional patient data will be collected beyond what is already collected as part of the NDA.

If patients do not wish to have their data recorded in the NDA, patients can withdraw using the National Data Opt-Out electronic form (National data opt-out - NHS Digital) at any time. This will result in no further data being collected. The national opt-out does not remove previously collected data.

11. STUDY INTERVENTION

11.1. Intervention Delivery

The intervention will be delivered through two virtual workshops (6 hours), two virtual outreach sessions (30 minutes) and at least 8 out of 12 virtual facilitated multisite meetings (8 hours). Delivery will be by the National Diabetes Audit Quality Improvement Lead, the DiabetesUK Engagement Lead, the National Diabetes Audit Clinical Lead and clinicians with expertise in improvement and insulin pump use. The intervention will be delivered virtually via Microsoft Teams and Google JamBoard.

The logic model outlines the target behaviours that the intervention seeks to implement. It also describes the mechanisms that influence their implementation and the behaviour change techniques intended to address these mechanisms.

11.2. Intervention content

Intervention content and delivery are described in the TIDieR framework [38] (Appendix B) and logic model (Appendix C). Intervention content and delivery is described in an intervention manual. In summary, the intervention seeks to implement target behaviours:

- To specify a goal
- To analyse influences upon care
- To link influence to the improvement action
- To collaborate
- To review feedback
- To engage stakeholders
- To link the work to priorities

- To consider existing work

It is anticipated that enactment of these target behaviours will provide the informational appraisal to select effective actions and generate organisational commitment needed to bring about those actions.

11.3. Monitoring adherence to the intervention

WP2b will draw on the logic model and the fidelity assessment approach of Lorencatto et al to assess the extent to which intervention active ingredients are delivered by intervention facilitators and received by specialist diabetes teams and targeted behaviours are enacted as intended.

11.4. Contamination

We recognise the potential for contamination between sites. Whilst we anticipate this to be minimal, we will actively monitor and describe potential contamination sources (e.g., occurring through conferences and regional networking). Access to the intervention sessions will be restricted. During intervention sessions, we will ask participants to avoid actively sharing intervention experiences beyond the collaborative group during the evaluation period and detail the potential impact of contamination.

11.5. Blinding

Allocation concealment is not feasible in this trial. We will maintain a log of those unblinded to allocation. This will include the intervention delivery team and those research team members who need to know allocations to undertake the study. The NDA Executive will be aware of allocations through the contracted update reports describing the QIC work stream.

The intervention supports teams to engage local patients to identify potential barriers and actions to improvement, as such patients may not be blinded to involvement in the intervention arm.

12. STANDARD CARE

All teams will be given the opportunity to receive the intervention, and all teams will continue to get standard feedback describing National Diabetes Audit data. It is not possible to support all teams at once. We will therefore randomly allocate half to receive the intervention from January 2023, and half from July 2024. Teams that choose not to be included in the evaluation will receive the intervention in July 2024, alongside the control group.

Standard feedback comprises an annual national report and a dashboard describing pump use as a proportion of caseload, identifying the selected sites and other sites across England. It also describes performance in pump and non-pump users in terms of care process completion and treatment target achievement for the site and all sites. The national report describes key recommendations, methodology, participation and data quality information, differences in pump use by ethnicity, age, sex and deprivation and a national-level description of the data described at site-level. The national report and site-level spreadsheet are publicly available on the NHS Digital website.

13. ASSESSMENTS/DATA COLLECTION

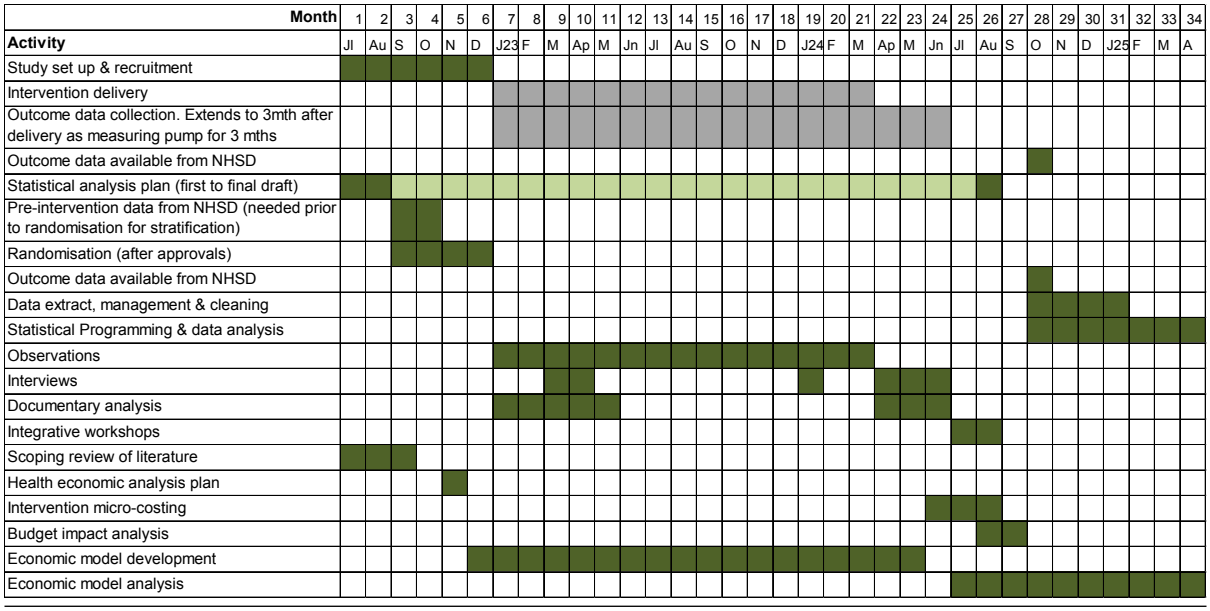
13.1. Data Handling

Trial outcomes and demographic data will be assessed using routinely collected individual patient data which is already extracted for the NDA. A statistician (Copsey) will be embedded within the NDA team at NHS Digital and undertake the analyses on individual patient-level data with supervision both within NHS Digital (Holman) and by the senior trial statistician (Farrin).

13.2. Data Sources

Vial prescription data and HbA1c measurements are extracted from GP clinical systems via the General Practice Extraction Service; the practice must approve the extraction. Specialist diabetes services submit caseload data and additional HbA1c and pump use data through the Clinical Audit Platform. People will be identified as receiving care from a specialist service if they are included in the caseload data provided through the Clinical Audit Platform or where linkage with Hospital Episode Statistics indicates that they attended diabetes/endocrinology outpatient appointments in the relevant time period.

13.3. Schedule of events



13.4. Cluster Screening Data

Data will be summarised on the number of specialist teams invited to participate, agreed to participate, and are randomised.

13.5. Cluster Baseline Data

For randomised clusters, based on data from the NDA, we will summarise the baseline proportion of patients moving onto a pump in the 15 months prior to the intervention period, the size of target patient population in specialist team. We will also summarise the number and proportion of teams who previously participated in the QIC pilot. The target patient population will be people who have an HbA1c level above 69 mmol/mol and were not prescribed insulin for a pump in the previous year.

13.6. Intervention Data

For the intervention sessions, data will be collected on the timing, mode of delivery and

duration of each session. Data will also be collected on the attendance at each session (by team and job title). Intervention content will be assessed as described in the fidelity assessment. Participant engagement will be assessed as described in the process evaluation.

13.7. Patient Baseline and Follow-Up Data

All patient-level data will come from the NDA. We will summarise the age, sex, ethnicity and deprivation of patients in the target population. We will extract data from the 15 months prior to randomisation and the 18 months following randomisation.

From the audit data, we will define a closed cohort of participants who have an HbA1c level above 69 mmol/mol and were not prescribed insulin for a pump in the previous year. For this cohort, we will examine:

- The number of people who have started and become established on insulin pumps, ascertained by two or more prescriptions for insulin vials for use in a pump at least three months apart (primary outcome)
- HbA1c between the latest measurement in the 12 months preceding the cluster randomisation and the latest measurements recorded during the study period (18 months post randomisation)
- The number of people with any record of insulin pump prescribing, including for periods shorter than three months.
- The number of people who have sustained insulin pump use, ascertained by two or more prescriptions for insulin vials for use in a pump at least six months apart

13.8. Unscheduled events

13.8.1 Withdrawals

The study team will make every effort to ensure that any specialist team who wishes to withdraw consent for further involvement in the QIC is defined and documented. Data collected will include, but not be limited to:

1. Date of withdrawal;
2. Reason for withdrawal, optional.

Where a team withdraws from the QIC, we will continue to analyse data on an intention-to-treat basis. Patients will not be able to withdraw from the trial; however, they can withdraw their consent for their data being collected by the NDA through the National Data Opt Out (National data opt-out - NHS Digital). Opting out through this process prevents any further data on being collected but previously collected data is maintained.

13.8.2 Deaths

Patient deaths will not be reported during the trial period. However, deaths will be recorded as part of the NDA. Deaths will be summarized in the final analysis, including date and cause of death.

13.9. Definition of End of Trial

The end of the trial is defined as the date of the end of the follow-up period for the last specialist team randomised.

14. SAFETY REPORTING PROCEDURES

14.1. Definitions

Term	Definition
Adverse Event (AE)	An adverse event is; · any unintentional, unfavourable clinical sign or symptom · any new illness or disease or the deterioration of existing disease or illness
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: · results in death · is life-threatening · requires inpatient hospitalisation or prolongation of existing hospitalisation · results in persistent or significant disability/incapacity · consists of a congenital anomaly or birth defect Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Related Unexpected Serious Adverse Event (RUSAE)	The National Research Ethics Service (NRES) defines related and unexpected SAEs as follows: · 'Related' – that is, it resulted from administration of any research procedures; and · 'Unexpected' – that is, the type of event is not listed in the protocol as an expected occurrence.

14.2. Expected Adverse Events/ Serious Adverse Events (non-reportable)

Events fulfilling the definition of an AE or SAE will not be reportable in this study unless they fulfil the definition of a Related and Unexpected Serious Adverse Event (RUSAE).

15. HEALTH ECONOMICS

Objectives: To estimate value for money of NDA feedback with QIC.

This will include:

Conducting a micro-costing of the quality improvement collaborative and local improvement strategies;

Estimating the cost-effectiveness of NDA feedback with QIC versus feedback alone;

Estimating the budget impact of NHS-wide QIC roll-out.

Design: We will conduct an economic evaluation comparing NDA feedback with QIC versus feedback alone to increase insulin pump uptake. We will collect data through NDA data extraction (WP1) and through interviews, surveys and observations (WP2).

WP3a: Micro-costing

Sampling and data collection: We will interview and/or survey the QIC delivery team and members of the intervention and control teams to map out the resources required to deliver the intervention. These are likely to span intervention refinement, delivery and response activities. We will create a record of consumable costs incurred (e.g. virtual delivery licence costs, printed material) and staff time (and grade) required, for intervention adaptation and delivery (NDA team). We will interview 15-20 intervention arm participants to understand costs associated with participation (e.g. NHS staff time for attending virtual sessions). We will also cost additional activities that result from the intervention (e.g. meetings with stakeholders, local team training, additional consultations with patients). The interviews will take place after the virtual workshops and outreach sessions and at the end of intervention delivery. We will sample teams based upon initial performance. We will interview 8-12 members of control teams to assess costs associated with feedback alone.

Analysis: Staff time will be costed using national database unit costs [42] and combined total costs will be estimated for NDA feedback with QIC and for feedback alone. We will seek to capture the variance in costs that might occur across centres and incorporate this uncertainty in the analysis. We will also empirically estimate the denominator sample for deriving the per patient intervention cost.

WP3b: Cost-effectiveness

Design: This evaluation will be model based and adopt the perspective of the health and social care provider. Analysis will be presented over a range of time horizons but, data permitting, a lifetime horizon will represent the base case.

Data collection and sampling: The evaluation will adhere, as far as possible, to the NICE reference case [51]. We will not collect or analyse individual-level or centre-level data but will use existing published evidence and liaise with the trial statisticians for the required aggregate data to parameterise the model. There are several reasons for not analysing individual-level data: we do not want to duplicate work undertaken by the statistician as this might lead to inconsistencies; we do not plan to collect individual-level quality of life or health care resource use data; and a majority of the benefit of insulin pump use in terms of costs and QALYs are likely to be incurred beyond the trial follow-up (i.e. need to be modelled).

Analysis: Economic evaluation outcomes are typically reported as incremental cost-effectiveness ratios (ICER) or net (monetary or health) benefit. Net (monetary) benefit is a

rearrangement of the ICER and estimated as: (λ x QALYs) – Costs, where λ is the willingness to pay threshold per health gain (in the case of NICE, £20,000-£30,000 per QALY). The primary analysis will present incremental net monetary benefit for NDA feedback with QIC versus feedback alone.

The value for money of insulin pumps has been evidenced by previous clinical and cost-effectiveness research, summarised in systematic reviews. This evidence was of sufficient weight to lead to a positive recommendation from NICE [2].

The current evaluation will not seek to re-estimate the value of the technology and will not therefore build a de novo economic model of type 1 diabetes. Instead, the evaluation will estimate the value of the alternative implementation strategies alone. As such, this evaluation uses the general principles of value of implementation [43]. A targeted review of the relevant published literature, NICE appraisals and guidelines will seek to identify trial and model-based economic evaluations of insulin pump cost-effectiveness in the UK context. Several of these are available [44, 45] as well as reviews in the area [46]. We will work with the research team to define selection criteria; these may include study quality, population and comparator match to the NHS and most recent data. We will use selected studies to identify the most plausible estimates of net benefit along with (if appropriate) other candidate estimates to use in scenario analyses.

We will extract information on the study context, economic evaluation design, approach to costing along with evaluation outputs such as estimates of costs, QALYs, net health benefits and net monetary benefits (and associated variance around these) of insulin pump use.

The value of the intervention will be defined as the most plausible incremental net benefit of insulin use (versus no use, i.e. multiple daily injections) multiplied by the probability of uptake, minus the costs of the improvement strategy for each arm. The probability of uptake will be derived from adjusted statistical estimates (e.g. as odd ratios). We will explore the development of a simple decision tree model (DTM) to estimate cost-effectiveness which will use value for money (i.e. lifetime net benefit) as model pay-offs and allow us to incorporate probability of pump prescription and probability of sustained pump use. We will conduct extensive deterministic sensitivity analyses to test analytical assumptions and the values adopted. We will define distributions around analysis parameters (strategy cost, probability of uptake, net benefit of insulin use) and conduct a probabilistic sensitivity analysis. Some studies [47] report confidence intervals or variance around cost-effectiveness estimates which could be used for this purpose. Where these are not available, we will use existing studies to inform assumptions around likely distributions.

The analysis will report the incremental net benefit of NDA feedback with QIC versus feedback alone, and the probability that the QIC is cost-effective. We will also seek to explore the heterogeneity of value across key sub-groups (e.g. deprivation levels), thus providing distributional estimates of cost-effectiveness [48, 49].

We will also conduct supplementary cost-effectiveness analyses using cost per change in blood glucose and cost per uptake in pump use as the estimates of effect. We will write an analysis plan and follow new CHEERS guidelines in reporting [50]. A NICE willingness to pay threshold range of (£20,000-£30,000) per QALY will be assumed and discounting beyond year one will be at the NICE recommended rate (currently 3.5%).

WP3c: Budget impact

Data collection and sampling: We will use NDA data describing the incidence of those patients with type I diabetes who do not currently use an insulin pump. We will use the costs estimated in WP3a to determine the budget impact of intervention roll out across the NHS.

Analysis: Costs over year one and subsequent years (relevant time horizons will be agreed with the team but likely to include 2-5 years) will be estimated with costs post year one being subject to a discount rate. Scenario analyses will test assumptions made and values incorporated in the analysis, from example, around type 1 diabetes prevalence and incidence and the sustainability of intervention training.

16. STATISTICAL CONSIDERATIONS

16.1. Sample size

We plan to recruit 60 specialist teams per arm, each including an average of 600 patients with type I diabetes with HbA1c>69 mmol/mol not using a pump within the previous year. This will provide 90% power to detect a 7% increase in the proportion of those patients moving onto a pump for at least three months (3% in the control arm and 10% in the intervention arm) at a 5% significance level after adjustment for clustering and loss to follow-up.

Determination of clinical significance took into account comparisons and ranges of effects from the Cochrane review of audit and feedback (ref), advice from Experts by experience, funder expectations and clinical perspectives about maximum feasible improvement. We considered it plausible and feasible that specialist diabetes teams could initiate an insulin pump and provide support for an average of one extra person a week. We assumed an ICC of 0.14 to account for clustering by specialist team, a coefficient of variation of 0.72 to account for variation in the number of patients per team and 10% loss to follow-up. Estimates for the clustering effects, cluster size and control arm proportion are based on the most recent NDA data available from 2019-20.

16.2. General Considerations

Statistical analysis is the responsibility of the CTRU Statistician. A detailed SAP will be written in accordance with the CTRU SOPs and finalised and agreed by the appropriate members of the research team before any analyses are undertaken. A two-sided 5% significance level will be used for statistical endpoint comparisons.

17. STATISTICAL ANALYSIS

17.1. Analysis Populations

17.1.1 Frequency of Analyses

We will use all available data from all randomised specialist teams, according to a detailed pre-specified plan finalised and agreed by the research team before any analyses are undertaken. We will conduct all analyses on the intent-to-treat (ITT) population, in which all specialist teams and patients will be included in the analysis according to the group to which they are randomised, regardless of intervention adherence.

We plan no interim analyses; we will conduct a single final analysis after the end of the follow-up period, when fully cleaned data are available from the NDA. Blinded interim reports will be presented to the PSC containing descriptive information on site recruitment and intervention adherence.

17.1.2 Summary of Screening, Baseline Data and Flow of Patients

A cluster CONSORT diagram will depict the flow of specialist teams and patients through the study.

Summary statistics will be presented for baseline data by treatment group using means, standard deviations, medians, minimum, maximum, and quartiles for continuous variables, and counts and percentages for categorical variables. Summaries will be presented at the specialist team level where appropriate.

We will compare characteristics of patients lost to follow-up with those not lost to follow-up to assess for attrition bias.

17.1.3 Summary of Intervention Data

Quantitative summaries of intervention delivery will be presented, including timing and mode of delivery of sessions, uptake, and engagement.

17.1.4 Outcome Analysis

Primary outcome analysis

The primary ITT analysis will compare the primary outcome between trial arms, using mixed effects logistic regression, with patients nested within specialist teams, and with specialist teams treated as a random intercept, adjusting for patient-level and team-level covariates (including patient age, sex, ethnicity, deprivation and team-level stratification factors). Estimated mean odds ratios will be reported with 95% confidence intervals, p-values and intra-cluster correlation coefficients.

Subgroup analysis

Planned exploratory subgroup analyses will explore potential moderators of primary outcome treatment effect using key baseline factors - age, sex, ethnicity, and deprivation. This will indicate whether the QIC contributes towards reducing inequalities in care. Subgroup analyses are exploratory, providing estimates of the direction and size of any interactions.

Secondary outcome analysis

For binary secondary outcomes (any insulin pump prescribing, sustained insulin pump prescribing), mixed effects logistic regression will be used, using the same approach as for the primary outcome.

For continuous secondary outcomes (glucose levels measured by hbA1c), mixed effects linear regression will be used and estimated mean differences will be reported with 95% confidence intervals, p-values and intra-cluster correlation coefficients.

17.1.5 Missing Data

Although we expect the level of missing data to be small, we will investigate patterns of missing data and reasons for missing data. We will compare the proportion of missing data between intervention and control groups.

We will build a multiple imputation model assuming data is missing at random for the primary outcome. As a sensitivity analysis, we will also consider a scenario where participants with missing outcome data are assumed not to move onto an insulin pump.

18. PROCESS EVALUATION

18.1. Design

Our theory-informed, integrated process evaluation will comprise semi-structured interviews, online surveys, documentary analysis and observation, with work package level analysis and synthesis.

Theoretical approach: The evaluation will draw upon the same theories applied in developing the QIC intervention: Organisational readiness to change theory [20] to describe the target behaviours undertaken by intervention recipients; Normalisation process theory (NPT) [32] to explore how to implement the target behaviours in teams. Behaviour change techniques (BCTs) [33] describe delivery.

The process evaluation will investigate whether hypothesised mechanisms for achieving change in both professional behaviour (what intervention recipients do) and patient-level outcomes (the use of insulin pumps) are evident when the QIC is used in practice, and what wider (and perhaps unanticipated) factors affect these mechanism-outcome relationships.

The logic model outlines the BCTs intended to trigger NPT mechanisms within the QIC intervention and targeted behaviours of specialist diabetes teams. WP2b will draw on this logic model and the fidelity assessment approach of Lorencatto et al to assess the extent to which intervention active ingredients are delivered by intervention facilitators and received by specialist diabetes teams and targeted behaviours are enacted as intended.

The QIC supports teams to explore influences upon performance, identified using the Theoretical domains framework [34] and to select improvement actions aligned to these influences. Previously identified influences upon insulin pump use include patient factors (e.g. knowledge and skills), staff factors (motivation; beliefs about acceptability to, and consequences for, patients; beliefs about capacity and capability) and contextual factors (e.g. culture, funding, time). The tailoring evaluation (WP2c) will describe the selected improvement actions using the Expert Recommendations for Implementing Change (ERIC) [35] compilation of implementation strategies, and the template for intervention description and replication (TIDieR) framework. WP2 analysis will be ongoing and iterative and draw upon other approaches from implementation science where relevant.

18.2. Objectives

To understand intervention implementation, engagement, fidelity and the tailoring of improvement actions. Guided by the MRC Framework for developing and evaluating complex interventions, we will:

- WP2a. Describe how implementers engage with the QIC intervention overall to support improvement activity and how context influences this work (implementation

and engagement).

- WP2b. Assess fidelity of delivery, receipt and enactment of the QIC intervention (fidelity).
- WP2c. Describe how teams enact tailoring (tailoring).

18.3. Methods

Participants: We will include both specialist diabetes teams (typically including diabetologists and nurses) taking part in the study, and professional staff delivering the QIC intervention.

Sampling and recruitment: We will sample participants from both intervention and control arms, weighted towards the former and aiming to ensure diversity of teams, service settings, and patient population characteristics.
To limit participant burden, we will sample from around half (30) of the intervention teams for interviews, but from all intervention teams for observations and documentary analysis. Documents will include those produced within QIC workshops (for which we will give authors the opportunity to have their data excluded from the analysis) and organisational documents (e.g. local reports with appropriate permissions).
For interviews, we will undertake strategic sampling within the intervention arm, for example, by baseline proportion moving onto a pump in the 15 months prior to the intervention period (above or below median) and number of patients served by the specialist team (above or below median). We will sample from 8-12 control arm teams.

18.4. Data Collection:

We will collect data from both intervention and control (teams assigned to later receipt) arms to explore 'implementation as usual' work for the NDA and any potential contamination between study arms. We will use four qualitative methods: around 60-80 theory-informed, semi-structured interviews, some intervention deliverers will be asked to complete an online survey, analysis of up to around 120 documents and an estimated 55 hours or less of observations. Where appropriate, the data will be used for all three process evaluation objectives (process and engagement, fidelity, tailoring) and the WP3 economic evaluation.
We will interview diabetes team members at multiple time points. The interviews will use a topic guide developed from our aforementioned theoretical approaches, including open questions for exploring barriers, facilitators and mechanisms related to NPT and BCTs. Interviews will also include more tailored questioning, developed from prior analysis of other data sources (documents and observation), and serving as prompts for more detailed investigation. An initial round of around 20 interviews will include both intervention deliverers and intervention arm participants early during intervention delivery to assess intervention engagement, fidelity, and tailoring. A further 40-50 interviews towards the end of the intervention period will seek more reflective data on intervention engagement and perceptions (including tailoring) and data required to complete fidelity assessment. This latter set of interviews will include 8-12 with control arm participants to focus on team experiences of undertaking quality improvement in relation to the NDA in the absence of intervention, thus providing contextual data about 'implementation as usual'. Combined with data from intervention participants, this will also provide scope to explore and understand any contamination across trial arms (e.g. if control participants mention access to QIC intervention documentation).

We will collect up to 55 hours of observational data with intervention participants only, contributing data on implementation, engagement, fidelity and tailoring. This will capture participant descriptions of both planned and completed improvement actions. The observations will include recorded virtual interactive educational workshops, virtual outreach sessions and multisite facilitated meetings. Around two thirds of these data will be captured within the first three months of intervention delivery, allowing later interviews to focus more directly on issues arising from the observations. We will record intervention exercises and monthly virtual facilitated meetings for subsequent structured observational analysis. We will conduct more focused qualitative observations at some sites (identified at interview), to include meetings of implementation teams and meetings with key stakeholders (either in real time or recordings), as available and appropriate.

Around 120 documents for analysis will include materials concerning intervention exercises and activities, including stakeholder maps, logic models, action plans, and summaries of any discussions and meetings available to the research team. We anticipate the majority of these will concern intervention arm participants and provide additional detail for assessing fidelity of delivery, receipt and enactment and understanding tailoring activity. We will seek some documentation for analysis from control arm participants towards the end of the intervention period. These documents will be identified during control participant interviews and requested for inclusion in the study if available. They will likely consist of internal quality assurance reports and will contribute to understanding 'implementation as usual'.

We will use an online survey to collect data from those intervention deliverers who provide brief input into intervention delivery. The survey will be distributed by email within the first three months of intervention delivery.

18.5. Outputs

Data analysis: The process evaluation will take an interpretivist perspective. Analysis of interview and survey data will be iterative, using both inductive and deductive approaches and according to the standard procedures of rigorous qualitative analysis [39, 40]. For example, the fidelity assessment will deductively seek the presence or absence of the enactment of target behaviours; the evaluation of implementation will inductively explore influences on engagement. Documents will be read in parallel by two researchers who will extract data for analysis according to the different process evaluation objectives. For implementation and engagement (WP2a), these documents will be used to develop prompts and more detailed questions within the topic guide when interviewing the team members who authored them. For investigation of tailoring processes (WP2c) documents will prompt questioning about the influences teams identified and how (and why) they linked these to their documented strategies. For fidelity (WP2b), documentary analysis will focus on enactment of target intervention behaviours (e.g. use of the TDF to identify influences; the development of a list of stakeholders for engagement). We will take a more structured approach for observational data, assessing fidelity through coding and comparing the BCTs in the manual with those observed in delivery. In total, 36 hours of the delivered intervention sessions will be coded (12 hours of virtual interactive educational workshops, 12 one-to-one virtual outreach sessions and 12 multisite virtual facilitated meetings). These will be distributed across the delivery period, in accordance with the National Institutes for Health Behaviour Change Consortium recommendations. 80 to 100% adherence to intervention specifications represents 'high' fidelity of delivery, 51 to 79% represents 'moderate' fidelity, and <50% or less represents 'low' fidelity.

Our multi-stage analysis will occur concurrently with data collection to allow for emerging trends found in earlier fieldwork to be explored later. We will share interim analyses with stakeholders to identify additional avenues for exploration in later interviews and documentary analysis. This wider group will include clinicians, people with diabetes, policy leads and implementation scientists.
Integrative analyses: We will undertake workshops for integrative analysis of the different data sources (from interviews, surveys, observation and document analysis) to address the three investigative objectives of the process evaluation: implementation and engagement; fidelity and tailoring (1-2 half-day workshops per investigation). The analysis workshops will explicitly reconnect and explore the data and findings to develop higher level analyses with reference to NPT and organisational readiness (WP2a) and BCTs (WP2b), and the matching of improvement strategies to barriers and facilitators using causal models [41] (WP2c). Project team and stakeholders will be invited to these workshops as appropriate.

19. TRIAL MONITORING

A Trial Monitoring Plan will be developed and agreed by the Project Management Group (PMG) and the Project Steering Committee, based on the trial risk assessment which will consider the safety or physical or mental integrity of the trial participants and the scientific value of the research; this plan may include on site monitoring. This Trial Monitoring Plan will detail the timing and content of reports to monitor trial conduct, implementation, and adherence with CONSORT.

19.1. Project Steering Committee (PSC)

The PSC will provide overall supervision of the study, including study progress, adherence to protocol, patient safety, and consideration of new information. The committee will meet once during the set-up period and at least annually thereafter for the duration of the study. A subcommittee of the PSC will be convened where necessary to monitor safety data.

19.2. Data Monitoring

For patient outcomes and demographic data held by the NDA, the NDA validates, monitors and reports on data quality [36]. Data regarding randomization will be monitored for quality and completeness by the CTRU, using established verification, validation and checking processes.

19.3. Clinical Governance Issues

To ensure responsibility and accountability for the overall quality of care received by participants during the study period, clinical governance issues pertaining to all aspects of routine management will be brought to the attention of the PSC and, where applicable, to individual NHS Trusts.

20. QUALITY ASSURANCE AND ETHICAL CONSIDERATIONS

20.1. Quality assurance

The study will be conducted in accordance with current MRC Good Clinical Practice (GCP) guidelines, UK Policy Framework for Health and Social Care Research 2017 and complies with the Mental Capacity Act (2005), through adherence to CTRU standard operating

procedures (SOPs) and relevant study-specific SOPs.

20.2. Serious Breaches

Investigators are required to promptly notify the Sponsor of a serious breach (as defined in the latest version of the National Research Ethics Service (NRES) SOP). A 'serious breach' is defined as a breach of the protocol or of the conditions or principles of GCP (or equivalent standards for conduct of non-CTIMPs) which is likely to affect to a significant degree the safety or physical or mental integrity of the trial subjects, or the scientific value of the research. In the event of doubt or for further information, the Investigator should contact the Trial Manager at the CTRU.

20.3. Ethical considerations

The trial will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland, and October 2000. The right of the participant to refuse participation without giving reasons must be respected. The participant must remain free to withdraw from the trial at any time without giving reasons and without prejudicing their care or treatment. The trial documentation will be submitted to the identified Research Ethics Committee (REC). The trial must be approved by that REC and receive Management approval from each participating site prior to any participants entering the trial.

20.4. Submission of Study Data

Cluster data

Data from NHS Digital will summarise the baseline proportion of patients moving onto a pump in the 15 months prior to the intervention period and the size of target patient population in specialist team.

Health economics data

Data will be entered into a web-based data base, capturing:

Information from documents and observations describing the number of healthcare workers participating in the intervention (describing both duration and frequency) and their role (including grade where identified).

Information from interviews with intervention and control group participants, including their role and the self-reported time they and their colleagues spent engaging in response to national diabetes audit insulin pump feedback.

Information from observations, surveys and interviews describing time and grade for intervention delivery.

NHS Digital data

Data analysis will be undertaken within NHS Digital. The analysis and outcome will be shared with the study team.

Interview data

All interview data will be audio-recorded, transcribed verbatim and analysed using framework analysis. NVivo software will support the analysis and establish an audit trail.

21. CONFIDENTIALITY

All information collected during the course of the study will be kept strictly confidential and held securely. Patient data will only be accessed via NHS Digital. The CTRU and NHS Digital and University of Northumbria at Newcastle, as sponsor, will comply with all aspects of the 2018 Data Protection Act and operationally this will include

- appropriate storage, restricted access and disposal arrangements for participant personal and clinical details
- people are able to opt out of their data being collected by the NDA using the National Data Opt Out process.
- where anonymisation of documentation is required, sites are responsible for ensuring only the instructed identifiers are present before sending to CTRU.

To ensure confidentiality of the data collected when published, fictitious site names and pseudonyms or study numbers not linked to sites or persons will be used. All identifiable data such as research site names, address, and patient date of birth will be removed. Any data relating to individuals taken from the NDA will be rounded to the nearest 5 to protect confidentiality.

22. ARCHIVING

At the end of the study, data will be securely archived at the University of Northumbria at Newcastle for a minimum of 5 years.
At the end of the study, data relating to the economic evaluation will be securely archived at the University of Leeds for a minimum of 5 years. Data held by the University of Leeds will be archived in the Leeds Sponsor archive facility and site data and documents will be archived at site. Following authorisation from the Sponsor, arrangements for confidential destruction will then be made.

23. STATEMENT OF INDEMNITY

The proposed study is sponsored by the University of Northumbria at Newcastle. The NHS has a duty of care to patients treated, whether or not the patient is taking part in a research study, and the NHS remains liable for clinical negligence and other negligent harm to patients under this duty of care. University of Northumbria at Newcastle, as the employer of the Chief Investigator will be liable for negligent harm caused by the design of the study.

24. STUDY ORGANISATIONAL STRUCTURE

24.1. Responsibilities

24.1.1 Chief Investigator

As defined by the UK Policy Framework for Health and Social Care Research 2017, the Chief Investigator is responsible for the design, management and reporting of the study.

24.1.2 Principal Investigators

For the trial, there will be one site (NHS England), the Chief investigator will remain overall responsibility for the conduct of the study. For the process and economic evaluation, the Principal Investigator at each participating research site will have overall responsibility for the conduct of the study at that site.

24.1.3 Operational structure

The **Project Steering Committee (PSC)** – The PSC, with an independent Chair, will provide overall supervision of the programme, in particular progress, adherence to protocols, safety and consideration of new information. It will include an Independent Chair, no fewer than two other independent members and a patient representative. The CI and other members of the PMG may attend the PSC meetings and present and report progress. The Committee will meet annually as a minimum.

The **Project Management Group** (PMG) comprises of the Chief Investigator, key Co-Applicants, and CTRU staff. The PMG will meet at key points during the study to oversee the study including the set-up, on-going management, promotion of the study and the results.

It is anticipated that the PMG will regularly meet to discuss the study. They will be responsible for the set-up of the study, including gaining ethical and R&D approval, management and overall supervision of the study team, collection and analysis of data, and drafting/finalizing publications. The Chief Investigator will be responsible for the day-to-day running of study.
The CTRU will be responsible for: randomisation, database development and provision (for randomisation and health economics data) and quantitative analysis.

25. PUBLICATION POLICY

The study will be registered with an authorised registry, according to the International Committee of Medical Journal Editors (ICMJE) Guidelines. The success of the study depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated, through authorship and contributorship. Uniform requirements for authorship for manuscripts submitted to medical journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

- conception and design, or acquisition of data, or analysis and interpretation of data,
- drafting the article or revising it critically for important intellectual content, and final approval of the version to be published,
- and that all these conditions must be met (www.icmje.org).

In light of this, the Chief Investigator and relevant members of the PMG will be named as authors in any publication.

The timing of any publication from the programme and this study will ensure scientific integrity is maintained. Individual collaborators must not publish data concerning their participants which is directly relevant to the questions posed in the study until the first publication of the analysis is reported. The publication policy for this study will follow the publication policy agreed by the Project Management Group.

26. REFERENCES

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APPENDICES

Appendix A Source Data Location Plan

Screening & Consent	**Source Data Location/ First Data Source**
List of eligible sites	NHS Digital
NDA: List of sites responding to invitation who agree / decline to participate in the evaluation	NDA QI team at DiabetesUK

Background and team characteristics	**Source Data Location/ First Data Source**
Baseline proportion moving onto a pump in the 15 months prior to the intervention period (above or below median) per team	NHS Digital
Size of target patient population in specialist team (above or below median) per team	NHS Digital
Previous participation in the QIC pilot	NDA QI team at DiabetesUK

Follow-up Data	**Source Data Location/ First Data Source**
The proportion of people with type 1 diabetes and raised glucose levels(HbA1c above 69 mmol/mol) and not prescribed insulin for a pump in the previous year, starting and continuing to use insulin pumps for at least three months within an 18-month follow-up period.	NHS Digital
Change in blood glucose levels as measured by HbA1c in people with type 1 diabetes and raised glucose levels between the latest measurement in the 12 months preceding the start of the intervention and the latest measurements recorded during the study period.	NHS Digital

Any record of insulin pump prescribing during the 18month study period to people with type 1 diabetes and raised glucose levels(HbA1c above 69 mmol/mol) and not prescribed insulin for a pump in the previous year.	NHS Digital
The proportion of people with type 1 diabetes and raised glucose levels(HbA1c above 69 mmol/mol) and not prescribed insulin for a pump in the previous year, starting and continuing to use insulin pumps for at least six months within an 18-month follow-up period.	NHS Digital
The difference in insulin pump use for greater than 3 months in people with an HbA1c greater than 69 by: • ethnicity, • sex, • age, • deprivation.	NHS Digital
Health economics data	**Source Data Location/ First Data Source**
Estimated costs for NDA feedback with QIC and for feedback alone	Interviews
Incremental cost per Quality-Adjusted Life Year (QALY) Supplementary analyses estimating cost per change in blood glucose and cost per uptake in pump use	Systematic review
Plausible budgetary impacts of the intervention	Interviews
Process evaluation	**Source Data Location/ First Data Source**
Intervention implementation and engagement	Interviews, survey, observations and documentary analysis
Fidelity of intervention delivery, receipt and enactment	Interviews, survey, observations and documentary analysis
Degrees and types of intervention tailoring	Interviews, survey, observations and documentary analysis

Appendix B TIDieR Intervention description

Item number		
1.	**BRIEF NAME** Provide the name or a phrase that describes the intervention.	National Audit Quality Improvement Collaborative
2.	**WHY** Describe any rationale, theory, or goal of the elements essential to the intervention.	The development of commitment and informational appraisal to select actions, resonating with the theory of organisational readiness for change [22]
3.	**WHAT** Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers.	The workshop includes slides to increase the coherence and cognitive participation of the target behaviours described in the logic model. These were supported by online materials to support participants to identify influences upon participation using the Theoretical Domains Framework, align these influences to actions and to identify stakeholder influence and interest.
4.	**WHAT** Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	The intervention is described in a manual. The active ingredients are described in the logic model.
5.	**WHO PROVIDED** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	National Diabetes Audit Quality Improvement Lead, the DiabetesUK Engagement Lead, the National Diabetes Audit Clinical Lead and clinicians with expertise in improvement and insulin pump use.
6.	**HOW** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Virtual delivery through MS teams and using Google JamBoard
7.	**WHERE** Describe the type(s) of location(s) where the intervention	Virtual delivery through MS teams and using Google JamBoard

	occurred, including any necessary infrastructure or relevant features.	
8.	**WHEN and HOW MUCH** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Two virtual workshops, two virtual outreach sessions and 12 facilitated, virtual meetings. Participants are expected to attend 8 facilitated, virtual meetings.
9.	**TAILORING** If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Not applicable Note: Tailoring work is undertaken by intervention participants

Appendix C: Logic model prior to refinement