

Protocol Based Care Evaluation Project¹

***Report for the National Co-ordinating Centre for
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¹ The contribution of nursing, midwifery and health visiting to protocol-based care and its variants on organizational, patient and staff outcomes, quality and costs of care. This study did not investigate the costs associated with protocol-based care; a team from the University of Sheffield is conducting a cost evaluation SDO/79/2004.

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The Report

1 Introduction

1.1 The Report

This report provides details of two complementary research studies that were conducted in parallel,² which investigated protocol-based care. One study was a case study evaluation that explored nurses', midwives' and health visitors' role and contribution to protocol-based care, and the other an ethnography that studied protocol-based care and decision-making. Where appropriate, separate details about each study are given and where relevant, information from both studies has been integrated.

Throughout this report nurses, midwives, and health visitors are referred to as nurses or nursing; unless there has been a particular need to distinguish between them.

1.2 Policy context: Modernisation

In the United Kingdom (UK) 'protocol-based care' was developed as a policy initiative embedded in the government's modernisation agenda. It is ten years since the National Health Service (NHS) began its journey of modernisation instigated by the publication of *The New NHS. Modern. Dependable* (DH 1997). This document laid down the government's vision for an effective and efficient patient-centred health service. Subsequent publications have developed this vision into a blueprint for high quality service provision, correspondingly there has been considerable investment in the infrastructure to support such activity (e.g. *A First Class Service* DH 1998, *The NHS Plan* DH 2000). *The NHS Plan* (DH 2000) describes the government's strategy for reform and has been elaborated on in subsequent documents including *Investment and Reform in NHS Staff* (DH 2001), *The NHS Plan Implementation Programme* (DH 2001), and most recently *Improvement, Expansion and Reform: Priorities and Planning Guidance 2003-2006* (DH 2003). Key goals of the quality agenda include the promotion of evidence-based practice and patient centred-care in order to improve patients' experiences. The proliferation of guidelines and protocols are visible confirmation of an increasing emphasis on an NHS founded on

² At the request of the NIHR SDO Programme these studies have been reported together.

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evidence of 'what works'. As such, protocol-based care fits within the government's vision for modernisation.

In 2000 it was anticipated that by 2004 the majority of NHS staff would be working under agreed protocols:

....identifying how common conditions should be handled and which staff can best handle them. The new NHS Modernisation Agency will lead a major drive to ensure that protocol-based care takes hold throughout the NHS. It will work with the National Institute for Clinical Excellence, patients, clinicians and managers to develop clear protocols that make the best use of all the talents of NHS staff and which are flexible enough to take account of patients' individual needs. (p83 NHS Plan DH 2000)

The goal of integration of protocol-based care into care delivery is evident in the development of national standards. For example, the National Service Framework (NSF) for Mental Health (1999) and more recently those developed to support the care of people with long term conditions (2005) explicitly identify the development of service protocols as an approach to implementing standards.

In response to this changing policy context, health professionals' roles have also been evolving because of the recognition that a more flexible team response is required, and traditional professional boundaries revised. *Making a Difference* (DH 1999) outlines the contribution that nurses, midwives and health visitors can make to delivering this agenda through for example, nurse-led clinics, nurse prescribing and nurse-led primary services. *Freedom to Practice— dispelling the myths* (DH & RCN 2003) also considers the potential of nursing to the improvement of the patient journey through new ways of working and the blurring of professional boundaries.

In summary, the current NHS policy context emphasises the need for health services to be driven by evidence of clinical and cost effectiveness, to improve patient safety and consistency of care and to co-ordinate services across professional and environmental boundaries. From a policy perspective protocol-based care is a mechanism for facilitating standardisation and the expansion and extension of the nursing workforces' professional practice.

Despite the political enthusiasm for protocol-based care there has been little systematic evaluation of its impact on roles, practice, patients and organisations; particularly across multiple sites. This report presents the findings from a case study evaluation and a decision-making ethnography, which addressed some key questions about the practice of protocol-based care.

2 Evidence review

2.1 Approach

As the methodological framework for this study is realistic evaluation (see section 3), the literature review for this study has been conducted based on the principles of realist synthesis; a recently developed approach derived from realistic evaluation (Pawson 2006, Pawson et al 2005, Pawson & Tilley 1997). In contrast to traditional systematic reviews, which focus on evidence of effectiveness, narrowly focused questions and defer to the hierarchy of evidence, a realist review follows an iterative, inclusive and broader process (Pawson et al 2004). Specifically realistic inquiry has a particular approach to causality, which acknowledges the complexity and non-linearity of interventions. For Pawson (2006) the 'nature of causality in social programmes is such that any synthesis of evidence on whether they work, will need to investigate how they work' (p25). Therefore the fundamental question is: what is it about this programme that works, for whom, how and in what circumstances? For this study the question then becomes; how do certain causal *mechanisms* (particular type of protocol, and practices they prompt) operate in particular *contexts* (e.g. in particular clinical settings or circumstances) to create certain impacts or *outcomes*. A realist synthesis attempts to integrate plural forms of evidence to unearth information on mechanisms, contexts and outcomes.

Fundamentally a realist approach claims that *interventions are theories*, which are based on a hypothesis that postulates 'if we deliver a programme in this way or we manage services like this, then we will bring about some improved outcome (Pawson et al 2004, 2005; Pawson 2006). The aim then is '...to articulate underlying programme theories and then to interrogate the existing evidence to find out whether and where these theories are pertinent and productive. Primary research is examined for its contribution to the developing theory...' (p74, 2006).

A realist synthesis follows similar stages to a traditional systematic review, but with some notable differences (see Table 1):

- realist synthesis derives its focus from a negotiation between commissioners and the researchers (in this case through the brief and contractual expectations).
- The search and appraisal of evidence is purposive and theoretically driven with the aim of refining theory.
- The process is iterative.
- The findings focus on explaining to the reader why (or not) the intervention works and in what ways, to enable informed choices about further use and/or research.

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Using realist synthesis principles to conduct this literature review was thought to be appropriate for three reasons. First it complements the methodological and theory driven approach of the study ensuring integrity, second, the literature about protocol-based care is diverse and varying in quality; the findings from conducting a traditional systematic review would be limited in number of studies reviewed and their applicability, and finally it is important to acknowledge the existence of the complex context of the NHS in order to gain a deeper, realistic understanding of the development and contribution of protocol-based care.

Table 1. Approach to evidence review

Define the scope of the review	Identify the question	<p>What is the nature and content of the intervention (protocol-based care)?</p> <p>What are the circumstances or context of its use?</p> <p>What are the policy intentions or objectives?</p> <p>What are the nature and form of its outcomes or impacts?</p> <p>Undertake exploratory searches to inform discussion with review commissioners/decision makers</p>
	Clarify the purpose(s) of the review	<p>Theory integrity – does the intervention work as predicted?</p> <p>Theory adjudication – which theories around the intervention seem to fit best?</p> <p>Comparison – how does the intervention work in different settings, for different groups?</p> <p>Reality testing – how does the policy intent of the intervention translate into practice?</p>
	Find and articulate the programme theories	<p>Search for relevant ‘theories’ in the literature.</p> <p>Draw up list of programme theories.</p> <p>Group, categorise or synthesise theories.</p> <p>Design a theoretically based evaluative framework to be ‘populated’ with evidence.</p>
Search for and appraise the evidence	Search for the evidence	<p>Decide and define purposive sampling strategy.</p> <p>Define search sources, terms and methods to be used (including cited reference searching).</p> <p>Set the thresholds for stopping searching at saturation.</p>

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	Appraise the evidence	Test relevance – does the research address the theory under test? Test rigour – does the research support the conclusions drawn from it by the researchers or the reviewers?
Extract and synthesise findings	Extract the results	Develop data extraction forms or templates. Extract data to populate the evaluative framework with evidence.
	Synthesise findings	Compare and contrast findings from different studies. Use findings from studies to address purposes(s) of review. Seek both confirmatory and contradictory findings. Refine programme theories in the light of evidence including findings from analysis of study data.
Draw conclusions and make recommendations		Involve commissioners/decision makers in review of findings. Draft and test out recommendations and conclusions based on findings with key stakeholders. Disseminate review with findings, conclusions and recommendations.

(adapted from Pawson et al 2004)

For this study the process of theory formulation began with a synthesis of policy and research literature, the theories and working propositions are then refined through data analysis and interpretation.

2.2 Programme theories and theoretical framework

The first stage of the synthesis involves the identification of concepts, programme theories and framework development. Realism as a philosophy of science is situated between the extremes of positivism and relativism (Pawson & Tilley 1997). As such it is a pluralistic empirical enquiry. Furthermore, 'theory' is construed and defined differently from positivistic interpretations. For realist synthesis an intervention is a theory, because they are always based on a hypothesis; if we do X in this way, then it will bring about an improved outcome.

The focus of this review and research has been informed by the commissioner's requirement, an initial review of the literature undertaken for the proposal (Rycroft-Malone et al 2004) and key policy developments.

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To this end the framework was constructed around the following four theory areas:

- What are the properties of protocol-based care and protocols?
- How are protocols developed?
- What is the impact of protocol-based care?
- How is protocol-based care implemented and used?

These areas need to be related to outcomes and stakeholder issues; as such each area contains additional review questions:

2.2.1 Properties of protocol-based care and protocols

1. What is protocol-based care?
2. What are protocols and what types/models of protocol based care are used in practice?
3. What patient care issues/topics are covered by protocol-based care?

2.2.2 Development of protocols

4. How are protocols developed?
5. What forms of evidence underpin the development of protocols?
6. How does the method of protocol development affect use?

2.2.3 Impact of protocol-based care

7. How does protocol-based care impact on patient and organisational outcomes?
8. How does protocol-based care impact on nurses, midwives and health visitors' role and contribution?
9. How does protocol-based care impact on nurses' decision-making?
10. How does protocol-based care impact on multi-disciplinary decision-making and interaction?

2.2.4 Implementation and use

11. What approaches are used to implement protocols and how does this impact on their use?
12. What are the facilitators and barriers to protocol-based care?

Based on the evidence review related to the four areas and set of linked questions, a number of initial explanatory propositions were developed. These propositions have variable evidence bases, depending on the strengths and limitations of the existing literature. The propositions are not intended to be firm hypotheses, but working theories that guide the

research. These are then revisited and developed through the research process and study findings.

2.2.5 Searching the literature

In a realist synthesis literature is purposively sought to answer the review questions and interrogate the initial hypotheses (Pawson 2006). This included searching electronic health databases, including the Cochrane Trial Register, Medline, Embase, Cinahl, Assia, Psycinfo. Snowballing and hand searching was also be used. Additionally, existing connections with, for example the Care Pathways Review Board, the National Electronic Library for Health (NELH) and Royal College of Nursing (RCN) Forums of practice and the Royal College of Midwifery (RCM) Learning, Research and Practice Development Department, were used in order to uncover grey literature and information embedded in practice. The literature about protocol-based care is vast. Applying the principle suggested by Pawson (op cit) searching and retrieval stopped when there was sufficient evidence to answer the questions posed. Evidence has been included if it is relevant to the theory areas and questions.

2.3 Theory area 1 – Properties of protocol-based care and protocols

2.3.1 Defining protocol-based care

The term protocol-based care was developed by policy makers and first used, but not defined, in the NHS Plan (DH 2000). Having emerged relatively recently in policy documents and the literature, protocol-based care is a poorly defined and understood concept. Concepts and terms related to protocol-based care, such as protocols and care pathways are used, often interchangeably. The Modernisation Agency has suggested that protocol-based care provides clear statements and standards for the delivery of care locally (NHS Modernisation Agency 2002). However, this statement lacks clarity, and implicitly conflates protocols, statements and standards, when arguably these could be conceptually and practically discrete. On the other hand it does indicate that protocol-based care is concerned with standardisation of care, and local delivery. As such protocol-based care could be viewed as an umbrella term, which encompasses a range of clinical care processes, including statements and standards as well as other approaches including care pathways, patient group directives, algorithms, clinical guidelines and procedures (Rycroft-Malone et al 2004).

In an attempt to define this umbrella term, Ilott et al (2006)³ conducted a multi-method concept analysis. The aim of the analysis was to clarify 'what is protocol-based care', and also highlight the inter-relationships between different types of standardised care for nursing practice. The analysis drew

³ University of Sheffield team conducting a parallel project about protocol-based care – to be completed 2008

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on multiple sources of evidence including a content analysis of policy documents, exploration of the literature, and the findings of interviews with opinion leaders. Through inductive analysis of data the authors' report that they were able to distinguish key features of protocols, care pathways, and clinical guidelines (despite opinion leaders using terms interchangeably), which enabled them to define protocol-based care as follows:

The term protocol-based care may be applied in two ways: firstly, in generic settings where multi or unidisciplinary staff standardize clinical care processes and secondly, in specialist settings where authority for clinical care processes is delegated to those working in expanded roles. In both contexts staff follow rules codified in documents such as protocols, care pathways and clinical guidelines, which aim to standardize health care delivery and outcomes. These documents do this in subtly different ways, by varying the specificity and scope in which they have an effect upon the processes of clinical care. Staff retain responsibility for using them appropriately and for obtaining informed patient consent. (p550)

Illott et al (2006) ask readers to test, challenge and further refine their conceptualisation and as this is the most definitive exploration of the concept of protocol-based care to date, there are two issues that emerge from the definition that are worth examining further. First, the authors appear to separate the application of protocol-based care into standardisation of care processes, and delegation. Illott et al (2006) do not state whether they consider these applications to be mutually exclusive or clarify what is meant by 'generic' settings, however in practice it is possible that both applications could co-exist. For example, triage and delivery of patient care through computerised management protocols by practice nurses, fulfils both applications (Richards et al. 2002); it is a generic setting (general practice), and also involves the delegation of tasks from general practitioner (GP) to nurse through standardised processes. Additionally it is worth noting that most of the references to delegation of tasks and jobs through the use of protocols come from policy documents, which indicate the political enthusiasm for this approach to care delivery.

Second, the definition states that in protocol-based care staff follow codified rules, which has connotations of an imperative. A dictionary definition of a rule is 'a regulation or principle governing conduct or procedure within a particular sphere' (Oxford Concise English Dictionary 2004). Whilst there are some exceptions, for example patient group directives for prescribing and some algorithms, in practice, practitioners are rarely 'bound' to follow protocols. Arguably 'rules' may not be a generally applicable term across all types and variants of protocols, and thus not necessarily a defining feature of protocol-based care per se.

In summary, a number of questions about protocol-based care still require answering, including whether protocol-based care is greater than the sum of its parts, or, more straightforwardly about delivering care based on a particular type of protocol(s)? Or, is there something particular about the way in which the protocols are used, by whom, and in what contexts, which distinguish protocol-based care from other service delivery initiatives such

as guideline implementation? The outcome of this research will include developing this conceptualisation, by for example teasing out the influence of context on standardisation and delegation, and by evaluating the different ways in which various protocols are used and by whom.

Currently some emerging defining features of protocol-based care include:

- standardisation of care delivery across healthcare contexts and patient groups.
- Incorporating codified and/or formalised information for care delivery.
- Particularising care delivery to the locality.
- Enabling the delegation of work between healthcare professionals.
- Enabling nurses (and others) to work out of their traditional scope of practice (e.g. prescribing).
- The potential to involve different members of the healthcare team.

These features will be revisited, developed and refined throughout the report.

2.3.2 Defining protocols

The lack of clarity about what protocol-based care is probably stems from the challenges there are with defining what protocols are. As Currie (1999) highlights there are a number of terms used in the literature and in clinical practice to describe the tools used to manage and standardise clinical care processes (see Table 2). However, within and across these terms there is a lack of agreement and inconsistency in use, with for example 17 different terms encompassing the concept of clinical pathways (de Luc et al 2001). Additionally some authors conflate different types of protocols within papers and studies, for example Elliot et al (2006) use the terms algorithm based sedation guideline, guideline and algorithm interchangeably. The lack of consistency in the use of terms adds to the problem of defining what protocol based care (PBC) is, and what it might encompass.

While all these care approaches are aimed at delivering the best patient care, they offer different processes for achieving this. For example, care pathways have been described as both a tool and process; can be condition or procedure specific, as well as symptom based and generic (e.g. Campbell et al 1998, De Luc & Currie 1999, Currie & Scrivener 2002, Morris 2003). In contrast, an algorithm has been described as a specific step-by-step tool to direct practitioners as to the absolute course of treatment for a particular aspect of care or decision (Hadhorn 1995).

Table 2. Clinical care processes – terms evident in the literature and practice

Anticipated recovery path	Protocol
Care map	Clinical indicator
Care pathway	Clinical guideline (local and national)
Integrated care pathway	Case management plan
Clinical pathway	Algorithm
Clinical protocol	Patient group directive
Critical paths	Standard
Expected recovery path	Procedure
Anticipated recovery path	
Care map	

Within the literature there have been a number of attempts to clarify the similarities and differences between some of the commonly used clinical care processes including clinical guidelines, protocols, care/clinical⁴ pathways, and algorithms (e.g. Long 1994, Hadhorn 1995, Duff et al 1996, Antrobus 1996, deLuc & Currie 1999, European Pathway Association (EAP) 2005, Ilott et al 2006, De Bleser et al 2006). The nature of this literature is diverse including full or partial concept analyses (e.g. De Bleser 2006, Ilott et al 2006), literature reviews (e.g. Duff et al 1996), and opinion pieces (e.g. Antrobus 1996). However a number of potentially defining characteristics emerge, which are:

Standardisation and organisation of care – all these clinical care processes standardise and organise care for patients, and/or conditions:

- clinical guidelines have been defined as systematically developed statements to assist practitioner and client decisions about appropriate health care for specific clinical circumstances (Institute of Medicine 1992).
- Care pathways as a way of organising care for a well defined group of patients during a well defined period of time (de Luc & Currie 1999, EAP 2005, De Bleser et al 2006).
- Protocols as a means of formalising how to perform a specific procedure (Ilott et al 2006).
- Algorithms as a step-by-step procedure and instructions for clinical decision-making and/or problems (Society for Medical Decision Making 1992, Morris 2003).

⁴ De Bleser et al (2006) suggest that care pathways should be called clinical pathways. The terms care pathway and clinical pathway will therefore be used interchangeably here.

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Specificity - Whilst standardisation and organisation are common to all these care processes the degree of specificity between them varies. Algorithms provide very detailed information, usually presented in a flow chart, of what to do at each step of a decision making process (Hadhorn 1995). Protocols also provide detailed information about a particular process or procedure but do not usually have the same degree of detail as algorithms (Duff et al 1996). Clinical guidelines have less operational detail than algorithms, being made up of recommendations that describe different aspects of the patient's condition and appropriate management options (Grimshaw & Russell 1993). In contrast, a care pathway could be described as a hybrid of an algorithm, protocol, and guideline. A care pathway will generally cover the whole of the patient journey for a specified period of time (e.g. pathway for a 5-day stay for coronary bypass graft surgery), and may also contain protocols, algorithms and standards within it (Whittle 2006, Ilott et al 2006).

Prescriptive vs. descriptive – In their conceptualisation De Blesser et al (2006) suggest that the more specific or detailed the content of the 'clinical pathway', the more prescriptive it becomes. As such an algorithm would be prescriptive, whereas a clinical guideline, by virtue of the fact it contains less operational detail, would be more descriptive than prescriptive. Being more prescriptive also means that practitioners are more restricted; they have less decision-making latitude. Swinglehurst (2005) is adamant that a distinction should be made since 'protocols' are far more dictatorial and allow for less 'individual judgement' than do 'guidelines'. For Swinglehurst, protocols amount to a set of rules which must be followed whereas guidelines are there to help decisions be made. However, arguably whatever approach is used to guide and standardise care, practitioners should exercise appropriate clinical judgement to particular circumstances or for individual patients.

Applicability – Different types of clinical care processes may be applicable at different levels of the health care system. For example, clinical guidelines are developed nationally but can also be developed locally, at which point they may become a protocol or local guideline (Duff et al 1996). A protocol or local guideline is then the result of the adaptation of the national guideline for use in the local context (Long 1994). Similarly, care pathways tend to be developed locally so that care processes can be particularised to the specific context. Whilst locally developed, there is a national database of care pathways through which developers and users share examples (<http://www.library.nhs.uk/pathways/>). In contrast algorithms may be locally or generally applicable, depending on their clinical focus. For example an algorithm on pressure ulcer risk assessment should be based on available national clinical guideline evidence about appropriate assessment, but may also require the addition of information about the local pressure relieving resources available for staff to use.

Evidence-base – The proliferation of guidelines, protocols, and care pathways are evidence of the political emphasis on evidence based practice. The implication of this is that these 'tools' are based on evidence of clinical (and cost) effectiveness. Duff et al (1996) state that the key defining

attribute of a clinical guideline is that it is based on research evidence. National clinical guidelines, such as those developed by the National Institute for Health and Clinical Excellence (NICE) and the Royal Colleges (e.g. <http://www.rcn.org.uk/publications/>) do incorporate (where available) research evidence into recommendations. However it is less clear how these recommendations may be translated locally into protocols and care pathways, and therefore how diluted the research evidence base becomes.

For now, the term protocol-based care will be used to describe standardised care delivered by guidelines, pathways, protocols or local guidelines, and algorithms. Reference to other approaches, such as patient group directives, will also be made where appropriate.

2.3.3 Patient care issues and topics covered by protocol-based care

Protocol-based care covers a wide spectrum of topics and care processes. The list is extensive and includes, for example; genetics (e.g. Campbell et al 2000), vascular surgery (e.g. Abu-Own et al 1999), mechanical ventilation (e.g. Ely et al 2001, Grap et al 2003, Elliot et al 2006), orthopaedics (e.g. Gregor et al 1996), stroke care (e.g. Kwan & Sandercock 2003), postnatal care (e.g. MacArthur et al 2002 & 2003), minor injuries (e.g. Macduff et al 2001), mental health (e.g. McQueen & Milloy 2001), end of life care (e.g. Hockley et al 2005), telephone triage (Richards et al 2002), pressure ulcer prevention (Wilborn et al 2006), treat and refer (e.g. Snooks et al 2004 & 2005) and nurse prescribing (James 2004, DH 2000b). These examples include the use of different types of protocols; however the majority of the protocol-based care published literature focuses on the use and evaluation of care pathways, then guidelines, and less frequently on protocols and algorithms.

As protocol-based care covers a variety of patient care issues and topics, it consequently spans different clinical settings, from specialist units such as intensive care (e.g. Flynn & Sinclair 2005), cardiac surgery (e.g. Hancock & Easen 2006), and obstetrics (e.g. Hayward-Rowse & Whittle 2006) to general settings such as elder care wards (e.g. Main et al 2006), nursing homes (e.g. Hockley et al 2005), primary care (e.g. New et al 2004), mental health (Jones 1999a & b) and hospital care (e.g. Wilborn et al 2006). There are examples of care pathways in the national electronic libraries for health database that do focus on boundary spanning issues, such as patient transfer (<http://www.library.nhs.uk/pathways/>). Atwal and Caldwell (2002) also report the development and evaluation of an integrated pathway for care of people with fractured neck of femur, which includes the patient pathway from admission to the accident and emergency (A&E) department to discharge from the orthopaedic ward. Similarly Jones (1999b) developed a care pathway for in-patients with schizophrenia that described care from admission to discharge to the community mental health team. However these examples are sparse and tend to be confined to the care pathways literature, additionally it is not clear how much pathways such as these have been evaluated. Boundary spanning protocol-based care

is a neglected issue, but one that will become increasingly important in the NHS with the widespread development and implementation of electronic patient records, and better integration between health and social care provision.

Whilst there is some literature that explores protocol-based care to inform complex care issues, such as end of life care (e.g. Hockey et al 2005, Watson et al 2006), and mental health service provision (e.g. Lacko et al 1999, McQueen & Milloy 2001) this represents a small proportion. The majority of the published literature tends to focus on managing procedural care issues such as weaning of mechanical ventilation (Blackwood 2003, Blackwood et al 2004).

2.3.4 Summary

Standardised care approaches are widely used in service delivery and care management, however the term protocol-based care is poorly understood and conceptualised. Similarly there is little clarity about the standardised care approaches; what they are, and a lack of agreement and consistency in the way terms are used.

Drawing together the features of the literature reviewed thus far, the following characteristics of protocol-based care emerge:

- standardisation and organisation of care processes across a wide variety of care settings and patient care topics,
- localises care delivery through the use of care pathways, protocols, guidelines, algorithms (and other approaches such as patient group directives) and by particularising evidence to the local context,
- varies in the degree of specificity and prescriptiveness of formalised and/or codified information,
- has the potential to involve all members of the health care team, and facilitate the sharing of roles and responsibilities between them.

In order to develop a more robust understanding of the nature of protocol-based care and refine the emerging propositions (see below) there is a need to explore these issues in the reality of the practice context, in relation to the way that protocol-based care has been enacted by health care professionals, and through larger scale evaluation over multiple settings.

2.3.5 Initial propositions

Based on the literature reviewed and summarised above, the following propositions have been developed about the properties of protocol-based care. These are revisited throughout the research process and report.

Table 3. Theory area: Properties of protocol-based care initial propositions

- A clear understanding about the purpose and nature of protocol-based care by potential users will determine the extent to which standard care approaches are routinely used in practice.
- The properties of standard care approaches, such as degree of specificity and prescriptiveness, will influence whether and how they are used in practice.

2.4 Theory area 2 – Development of protocols

2.4.1 How are protocols developed?

Integral to ensuring the delivery of the modernisation and evidence-based practice agenda has been an encouragement for practitioners to develop and use standardised approaches to care. Indeed one of the defining characteristics of care pathways has been stated as ‘an explicit statement of the goals and key elements of care based on evidence, best practice, and patient expectations’ (European Pathway Association, 2005 <http://www.e-p-a.org/index2.html>). However the potential to standardise and improve care is predicated on an assumption that the standardised approaches used are based on (good quality) evidence, and that health care professionals accept and use them as written.

There is a variable amount of information in the literature about how the different care management approaches have been, or should be developed. There is now a well established body of literature about the development of national clinical guidelines in both the presence, and absence of research evidence (e.g. www.nice.org.uk, Rycroft-Malone 2001, Grimshaw & Russell 1993). However, there is a less developed evidence base about the most appropriate methods and approaches for developing local guidelines, care pathways, protocols, and algorithms etc., which constitute protocol-based care.

There is some guidance about how to develop protocol-based care tools and processes from both national organisations such as the NHS’s Modernisation Agency(MA)/NICE and the UK’s National Pathway Association (NPA), and from individual authors (e.g. Venketasubramanian 2001, Harrison 1998, Duff et al 1996, Hadhorn 1995). For example, the NPA outlines an approach to care pathway development that focuses on the process aspects of pathway development such as measuring current practice, structure for meetings, and audit tool development. There is less emphasis on finding, appraising and collating the various evidence sources that may comprise a care pathway. In contrast DeLuc et al (2001) present a detailed approach to care pathway development in a handbook. Similarly the MA/NICE (2002)

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has developed guidance about the key steps in developing protocols, which include:

1. Select and prioritise a topic
2. Set up a team
3. Involve patients and users
4. Agree objectives
5. Build awareness and commitment
6. Gather information
7. Baseline assessment
8. Produce the protocol
9. Pilot the protocol
10. Implement the protocol
11. Monitor variation
12. Review the protocol

Such guidance is a mixture of process and practical information, and whilst not comprehensive, it does offer an overall structure and starting point. It is unclear however on what evidence base such guidance has been developed, and whether these steps have been adopted in local development processes.

Currie and Harvey (2000) suggest that the development of integrated care pathways (ICPs) offers staff a way of adapting and owning the evidence through providing a forum for peer review, debate and negotiation that facilitates consensual decision-making about the content of the pathway. However there is also evidence to indicate that these benefits may not necessarily be realised. Jones (1999) carried out an in-depth interview study with 29 psychiatrists, social workers, mental health nurses, psychologists, occupational health nurses and social workers over a 12 month research project that included the development of a mental health care pathway. The author describes reluctance from all disciplines in engaging in the development process, and a significant amount of time being spent in individual (rather than group) discussions to agree content.

Generally, descriptions about how protocols are developed at a local level are limited. For example, Chadha et al (2000) describe a study that evaluated the effectiveness of protocols in improving hospital care (process and outcome) for women with menorrhagia and those with urinary incontinence. The authors state that national Scottish guidelines were adapted into local protocols, but do not describe the process of adaptation. Similarly Lee et al (2002) report on a trial that evaluated the effects of a care protocol used by community nurses to support nursing home staff in the care of patients with chronic obstructive airways disease. A care protocol was developed as part of the intervention, however, no information is provided about the process or approach to development. Likewise Julian et al (2007) state they adapted national professional body guidelines into an integrated care record for managing menorrhagia without further indication about how this was done. Whilst there are exceptions (e.g. Quirke et al 1997, Morton & Oomen 1998, Cunningham & Gould 1998, Manias et al

2005, Goodman 2006) this lack of detail is representative of the protocol-based care literature as a whole. Consequently questions remain about what are the appropriate methods for protocol development, and whether the development approach affects its use.

2.4.2 Evidence base of protocols

Common to the guidance documents about protocol development is the principle that existing national level evidence is used and adapted for local use (e.g. De Bleser et al 2006, Johnson 1997). The MA/NICE guidance clearly states that the identification and prioritisation of the topic for protocol development should be based on NICE guidance, National Service Frameworks (NSFs), and the Department of Health's (DH) strategies and modernisation initiatives. Presumably the political emphasis is on ensuring that the impact of nationally developed guidance is maximised. For example, the Myocardial Infarction National Audit Project (MINAP) (Birkhead 2003) provides performance data to demonstrate how national standards in an NSF, in this case for coronary heart disease, can be implemented locally with demonstrable positive outcomes for patients. Results indicate that approximately 70% of patients receive thrombolytic treatment within 30 minutes, an increase of over 20% on figures collected a year earlier (Birkhead 2003). In this example, local units and Trusts take national standards and have typically developed integrated care pathways (to facilitate the meeting of specific targets, such as hospital (door) to the start of the thrombolytic treatment (needle) time (Currie & Scrivener 2002). While MINAP provides data to support local implementation of national evidence through protocols, there has been minimal systematic evaluation of exactly how and why this occurs. Additionally in reality there will be issues that are not underpinned by national level evidence but are driven by local priorities, and thus for which the evidence base has to be generated locally.

Perhaps unsurprisingly given the paucity of information available about how protocols have been developed locally, there is a corresponding lack of detail in the literature about the nature of the evidence base upon which protocols are developed.

2.4.3 Development process and impact on use

Authors have argued that guidelines will only be used by healthcare professionals if they feel that they have been part of their development or local application (Greenhalgh 2002, Mitchson & Cowley 2003). However there is limited information about development process and use and impact on use in the literature. For example, de Luc (2000) suggests that pathways have a potential role to play in acting as a vehicle for change because they focus attention on processes involved in their development such as multidisciplinary working, which in itself may be more beneficial than observed changes to care or practice. However in this pathway evaluation the author does not adequately describe the development process or its outcomes, and does not provide an account from evaluative data to support

the suggestion. In contrast Appleton and Cowley (2004) using a case study approach to explore health visitors' use of formal guidelines in their practice speculate that one of the reasons the guidelines were not being used was because they had not been involved in the development of the guidelines and so lacked ownership of them. Similarly Rees et al (2004) suggest that one of the reasons for the lack of uptake of a joint working integrated care pathway was because staff had not been involved in development work.

2.4.4 Summary

Whether standardised care approaches impact on practice and patient care is likely to be partly dependant on the way in which they are developed and the evidence base used in the development process. There is some available guidance on development processes, however this is general and it is not clear how this has been used to develop standardised care approaches locally. Furthermore authors that have developed protocols locally tend to provide limited information about the development process. It is therefore unclear how the development process might affect the subsequent implementation and use of resulting standardised approaches to care because of the limited empirical data.

2.4.5 Initial propositions

Table 4. Theory area: Development of protocols initial propositions

- Protocols that are developed through a systematic, inclusive and transparent process may be more readily used in practice.
- Protocols that are based on a clear and robust evidence base are more likely to impact positively on outcomes.
- Locally developed protocols may be more acceptable to practitioners and consequently more likely to be used in practice.

2.5 Theory area 3 - Impact of protocol based care

Empirically, the impact of protocol-based care has received the most attention. A large number of individual studies, using experimental or quasi-experimental designs report whether interventions, primarily care pathways, protocols and algorithms, have impacted on patients and organisations in terms of for example, improved patient outcomes, reductions in length of stay, enhanced multi-disciplinary working and improved record keeping. This work has been conducted across a variety of clinical topics and settings, including; genetics (e.g. Campbell et al 2000), vascular surgery (e.g. Abu-Own et al 1999), mechanical ventilation (e.g. Ely et al 2001, Grap et al 2003, Blackwood 2003 & 2007), nutrition (Wøien & Bjørk 2006), orthopaedics (e.g. Gregor et al 1996), stroke care (e.g. Sulch et al 2002; Kwan & Sandercock 2003) and postnatal care (e.g. MacArthur et

al 2002 & 2003). This aspect of the protocol-based care literature is huge and variable, therefore the principles of realist synthesis have been followed, which were outlined earlier (Pawson 2006). Specifically the literature has been sampled to answer specific questions about the impact of protocol based care on patient outcomes, staff contributions and roles, clinical decision-making and the organisation. In reality many papers include information about two or all of these aspects. To that end the following considers a number of different approaches to protocol-based care, clinical topics, settings and patient and staff groups.

2.5.1 Impact on patient and organisational outcomes

Broadly, the reported impact of protocol-based care on patient and organisational outcomes is mixed; the findings from both experimental and non-experimental research demonstrate a mixture of positive, some, or no impact. This variability is evident irrespective of clinical topic or setting. For example, Karkouti et al (2006) implemented a protocol for the prompt identification and management of cardiac surgical patients with excessive blood loss in a before and after study involving 1875 patients. Their findings showed an improvement in clinical outcomes and a reduction in complications. However as the authors themselves highlight, it is not possible to identify which of the components of the protocol were more effective than others, and even if protocol implementation did improve outcomes, it is possible that this was not due to any particular components of the protocol but due to improvements in the overall care of bleeding patients owing to the presence of a targeted treatment protocol. In contrast DeLuc (2000) in a quasi-experimental study evaluated the impact of two process care pathways in one NHS Trust; a midwifery led maternity pathway (n=198) and a breast disease pathway (n=173). In a comparison of care delivered before and after the introduction of the two pathways there were mixed results. Statistically significant improvements were found in some aspects of care (e.g. number of days to report mammogram, length of post-natal stay) and no improvement in others (e.g. length of time waiting for therapeutic treatment, number of mothers breastfeeding). Interestingly the author also points to some findings that whilst not statistically significant, were considered to be clinically significant such as number of cancer patients having their care discussed at formal multidisciplinary meetings. Furthermore it is suggested that the development and introduction of the care pathways provided the opportunity and space for the multi-disciplinary team to meet and discuss service delivery and that in itself may have prompted practice changes (rather than the content of the care pathways per se).

Randomised controlled studies evaluating protocol-based care should, in theory, be able to disentangle cause and effect and minimise the potential for bias. For example, Sulch et al (2002) in a randomised trial evaluating a stroke rehabilitation care pathway (n=76) with standard care (n=76) in a UK stroke rehabilitation unit found that some care processes, particularly assessments and investigations, were statistically more frequently conducted in the care pathway group. Other patient management processes

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such as the prescription of certain medications, planning for pressure area care and continence were not found to be significantly different between patients receiving standard and care pathway care. Additionally in a previously reported trial no benefit had been shown in terms of length of stay and mortality in patients with stroke (Sulch et al 2000). Furthermore the authors acknowledge that whilst this pragmatic trial demonstrated some impact on outcomes these cannot be definitively linked to the implementation of the care pathway. As such, in the example it can be concluded that the use of care pathways to manage stroke patients in hospital may be associated with both positive and negative effects on the processes of care and clinical outcomes (Kwan & Sandercock 2003).

Table 5 presents examples of studies that have sought to evaluate the impact of protocol-based care on patient outcomes. They have been purposively selected in order to demonstrate the variable nature of the research evidence base concerning protocol-based care and the often contradictory findings. The possible reasons for this variability and the wider implications of this body of research are considered below.

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Table 5. Examples of studies evaluating impact on patient outcomes

Aim	Type of protocol-based care	Intervention	Methods & sample	Findings	Comments
To examine the effect of an algorithm-based sedation guideline developed in a North American Intensive Care Unit (ICU) on the duration of mechanical ventilation of patients in an Australian ICU (Elliott et al 2006).	Algorithm guideline for use by nurses vs. standard practice.	Introduced using multi-faceted implementation strategy.	Quasi-experimental - pre-post comparison involving 322 patients in a 14 bedded ICU. Primary outcome duration of ventilation.	No reduction in the duration of mechanical ventilation.	No details about implementation strategy Using United States (US) based guidance, question whether appropriate for the context. Authors suggest practice may have already been optimal.
To develop, implement and test a new model of community post-natal care based on a package of care. (McArthur et al 2002 & 2003).	10 evidence-based guidelines for common postnatal health problems.	Guidelines symptom checklists. Planned visits based on need.	Cluster randomised controlled trial. 36 general practices randomised; 17 intervention practices – 801 women returned data, 19 control practices – 702 women returned data. Number of physical health measures.	Improved health outcomes for women receiving evidence-based guideline care at 4 & 12 months, particularly psychological health.	Model of care implemented as a package so difficult to disentangle which elements may be more effective than others.
To evaluate the effects of a care protocol used by community nurses to support nursing home staff in the care of people with chronic obstructive pulmonary disease (COPD) Lee et al 2002	Protocol	Protocol and training of community nurses in the contents of the protocol and COPD	Matched randomised case control trial. 45 nursing homes in an area of Hong Kong. 89 older people participated. Data collected on functional, respiratory and psychological outcomes pre and post intervention.	Experimental group had significant improvements in psychological well-being. No significant differences in functional or respiratory outcomes.	Not known how nurses used the protocol. Do not know about context of care and whether transferable to other countries/ systems.

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To evaluate a sedation protocol that transfers decision making authority for analgesia and sedation to nurses in a paediatric ICU (Alexander et al 2002)	Protocol	No details given – mention educational sessions prior to implementation.	Retrospective chart review over a period of 5 months when patient on the protocols compared to when the same patient was receiving conventional care. 10 patients in the paediatric ICU. Number of days ventilated, number of days in the unit and hospitalised, and severity of illness. Amounts of sedation and analgesia used.	Use of the sedation protocol moderated the severity of under-sedation incidents.	Small sample.
To evaluate the introduction of a nurse-led electrical cardio-version service in a day surgery unit (Currie et al 2004).	Protocol	Training in advanced life support.	Prospective audit. Waiting times, success of procedures and complication rates.	Sinus rhythm restored in 92% of cases included in the audit. Waiting times reduced.	Impact of protocols on changing service delivery and delegation to nurses of doctors' tasks/roles.

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Survey research evaluating care pathway activity shows that staff do see pathways as an approach to facilitate the implementation of evidence-based practice, which is relevant and targeted to local needs (Currie & Harvey 2000). However the above studies, which are characteristic of the literature as a whole, highlight a number of issues. First, protocol-based care does not necessarily result in a positive impact on patient and/or organisational outcomes. In many studies when there might be an improvement in one type of outcome (e.g. an organisational outcome such as length of stay, cost savings) there are no significant changes to other outcomes (e.g. patient outcomes such as complications, co morbidity etc) (e.g. Calligaro et al 1995, Gregor et al 1996, Grap et al 2003, Panella et al 2003, Kent & Chalmers 2006, Marchisio et al 2006, Julian et al 2007). However authors do report that protocols can be influential (even if this effect is not statistically significant), whether this is in raising awareness of key care issues, or in providing the opportunity for staff to tackle issues together. Second, little is known about the mechanisms of how and why protocols may impact on outcomes. This may be partly explained by the fact that interventions and the nature of the protocols themselves tend to be poorly explained. Third, and related to the other points, impact measures within studies have tended to be very specific and limited to a few key clinical and organisational indicators, thus neglecting the potential impact on other variables, such as process, workforce and professional aspects. Fourth, research activity has focused on the impact on specific clinical settings and rarely tracks between care settings, for example, between primary and secondary care (Currie & Scrivener 2002). Finally, whilst there is research that takes into account patients' clinical outcomes, limited attention has been focused on patients' experiences of care whilst being cared for by protocols. Some studies evaluating the impact of protocols have developed and/or included a measure of patient satisfaction (e.g. Chou & Boldy 1999, DeLuc 2000, MacArthur et al 2002), but these examples are sparse.

It has been suggested that protocol-based care increases patient and carer involvement (e.g. McQueen & Milloy 2001, Modernisation Agency 2002), through, for example, better sharing of information. Findings from a study that explored the experiences and views of a range of professional staff using care pathways in their everyday practice, reported patient benefits including better professional-patient communication (Currie & Harvey 2000). For example, having pathways at the bedside enabled patients to see what was planned for them, and to challenge particular courses of action. However this study, because it was reliant on interviews with professionals, was unable to elucidate the mechanisms that facilitate better communication and whether this is a precursor to improved participation (Rycroft-Malone 2002). Holloway (2006) reports on a pilot study to develop and implement a care pathway for people with Parkinson's disease (PD) in which participants and their carers were included. This evaluation, whilst demonstrating little change to outcomes, reported that people with PD and their carers were generally enthusiastic about the pathways, particularly the section of the pathway that facilitated active engagement in their own care. Similarly Nemeth et al (1998) in a study tracking the development of a

pathway identified that if patients are involved at an early stage, their experience of the patient journey and particular care priorities are more readily incorporated. While the belief that the development and implementation of protocol-based care provides a mechanism for patient-centred care and participation makes sense, at present there is little empirical evidence to support this link. This highlights the need for research into patient and carer issues, more specifically, to ascertain how they have been involved in protocol development and implementation, as well as determine their perspectives on care being guided by protocols.

2.5.2 Impact on nurses', midwives' and health visitors' role

A national survey reviewing UK care pathway activity across acute and primary care NHS Trusts identified the key role nurses, midwives and health visitors play in the development and implementation of protocol-based care as pathway facilitators (Currie & Scrivener 2002). Documents such as *Freedom to practise-dispelling the myths* (DH & RCN 2003) and initiatives such as *The Changing Workforce Programme* and *The Collaboratives* all point toward the re-configuration of services to ensure an improved patient journey. In this case, it is the contribution that the clinical team as a whole makes, rather than the role each profession takes. As *Freedom to practise-dispelling the myths* outlines, nurses, under agreed protocols have expanded their roles in assessing, diagnosis, treatment, prescribing and discharging patients. Clearly, this has significance for the autonomy, professional identity and capacity of nurses, midwives and health visitors⁵, and the collaboration of the clinical team.

Research indicates that protocols provide nurses with legitimacy of their knowledge, and as such they tend to adhere closely to written guidance (in contrast to medical colleagues) (e.g. Manias & Street 2000). Manias and Street (2000) suggest that this is also a way to assert power in decision making. Furthermore there is evidence to suggest that following protocols and guidelines enables nurses to practise autonomously (Manias et al 2005). Indeed it has been suggested that pathways, for example, may remap professional boundaries by creating new roles and responsibilities (Pinder et al 2005). This remapping through the development of standardised care approaches has resulted in the successful development of new service delivery initiatives such as nurse led clinics (Porrett et al 2003, Woodward et al 2006). Additionally nurses taking on prescribing through the use of patient group directives (Latter et al 2005 & 2007) provide further evidence of the delegation and redistribution of roles within the healthcare team. Generally nurses report satisfaction with being engaged in these extended roles (e.g. Latter et al 2005, Blackwood & Wilson-Barnett 2007). Some of these issues are explored further in the following sections.

⁵ The generic term nursing and nurses will be used to refer generically to nurses, midwives and health visitors, unless a distinction is warranted.

2.5.3 The impact of protocol-based care on nurses' clinical decision-making

Whilst the current NHS policy context highlights the need for health services to be driven by evidence of clinical and cost effectiveness, it also emphasises nurses as active decision-makers (*Information for Health* DH 1998, *Making a Difference* DH 1999). Central to this is the notion that nurses will be knowledgeable doers, drawing on the best available evidence to assist them in choices they make and the judgements which inform them. A number of different 'technologies' have been developed within health services to assist decision-making including protocols, guidelines, algorithms, patient group directives etc. The body of decision-making literature is large and indicates that nurses could be making decisions as frequently as every 30 seconds (Bucknall 2000), however, there is a lack of research examining whether and how decision technologies affect clinical decision-making.

One of the aims of protocol-based care is to simplify, standardise and streamline the decision-making process (Modernisation Agency 2002, Crouch 2002, Rycroft-Malone 2002). If health care delivery is conceived as a system of decisions ranging from, for example, a decision as to whether or not to take diagnostic blood samples to decisions about which drugs to administer to patients, then the protocols are designed to help the decision maker to come to a decision which is the 'best' (Closs & Cheater 1997). The simplification of the decision-making process by the use of protocols is thought to be achieved by rationalising the information that is used by practitioners to make judgements and ultimately decisions (Thompson & Dowding 2002). However as yet it is unknown whether protocols do, in the reality of practice, simplify clinical decision-making. As Tavakoli et al (2000) indicate clinical decisions are frequently problematic because they involve: "(a) integration of complex information from a variety of sources; (b) imperfect or incomplete information; (c) the presence of uncertainty; (d) a complex interaction between the clinician and the patient, each of whom may bring widely different values to the decision; and (e) a growing imperative to take account of costs and effectiveness of alternative strategies" (2000, p. 112). So whilst protocol-based care aims to simplify and standardise practice in the reality of the clinical context practice decision-making guided by protocols will likely be more complex and dynamic.

2.5.4 Decision making

The studies that have examined nurses' decision-making in clinical practice in relation to the use of evidence and protocols demonstrate that decision-making processes are poorly understood and mapped (e.g. Thompson et al 2001a&b; Bucknall in press 2007). McCaughan et al (2002) studied nurses' use of clinical 'information' (rather than use of protocols per se) in their decision making using mixed methods within a case study approach. They found that whilst nurses made many decisions about varied issues (see Table 6) they rarely used formal sources of information such as guidelines

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and protocols. In hundreds of observed decisions only four involved the use of protocols, though there were a larger number of instances in which nurses referred to a text based source. In this study nurses tended to rely on human sources of information, such as a credible, knowledgeable colleague (McCaughan et al 2002, Thompson et al 2001a&b).

Table 6. The Focus of Decisions in Acute Care Areas (McCaughan 2003)

- Dressings
- Pressure sore monitoring/prevention/use of devices
- Checking/monitoring observations/fluid intake/output
- Patient hygiene
- Patient mobility
- Patient positioning
- Infection control
- Nutrition
- Intravenous/oral fluids
- Timing of pre-medications (in conjunction with theatre staff)
- Patient compliance, for example, medication
- Referral to colleague/senior nurse/doctors/clinical nurse/specialists/therapists/pharmacist
- Referral to relatives/involvement of relatives, especially at times of patient admission and discharge
- Interpreting results, mainly blood tests and exercise tolerance tests
- Decision to document care given
- Bed management
- Staffing/skill mix/allocation of patients to team/delegation to juniors
- General administration of ward, for example, checking drug stock levels
- Staff development
- Supervision/training of staff

Furthermore they found that nurses' decision making is very rarely a lone activity. Often decisions are come to by 'committee' either formally or informally (McCaughan, 2000; McCaughan et al 2002, Thompson et al 2001a&b). This is also a finding from other decision making research (e.g. Manias et al 2004).

2.5.5 How protocol-based care impacts on decision-making

There is a very limited amount of research that has focussed *specifically* on how protocols and their variants affect nurses' decision-making. Manias et al (2005) evaluated 12 newly qualified nurses' use of protocols in their medication management activities using non-participant observation and post observation interviews. Amongst other findings the researchers found that structured protocols enabled nurses to practise autonomously, because they could make clinical judgements without having to follow-up with doctors in the first instance. Similar findings are reported by other investigators (Offredy 1998, Manias et al 2004, Blackwood & Wilson-Barnett 2007). For example Manias et al (2004) in an ethnographic study involving 6 nurses in a critical care setting found that policies and protocols provided an additional means for nurses to assert their power in decision making. Nurses would actively seek evidence in the form of protocols and clinical trials to support their knowledge and decisions. In doing so they could legitimise their knowledge to those around them, especially doctors. On the other hand, a study exploring the perceptions of intensive care nurses to policies, protocols and guidelines found that there was a fear that protocols were 'taking the thinking out of nursing' and that they deprived inexperienced nurses of an opportunity to develop decision making skills (Flynn & Sinclair 2005).

Bucknall (2007) indicates that much of the decision science literature explores the association between the formalised decision-making techniques, such as protocols, and human judgement methods based on intuition, experience and professional insight. The above studies indicate that for nurses protocols may formalise decision-making in an authoritative way. In an evaluation of nurse-directed protocolised-weaning from mechanical ventilation findings show that protocols help junior nurses feel confident in areas of practice where they lack experience because they provide safe guidance (Blackwood & Wilson-Barnett 2007). Conversely more senior and experienced nurses did not find protocols useful because they had already internalised their own weaning style and resented restrictions (in the form of structure) on their autonomy. Dowie (1996) in a study exploring the use of decision trees in the context of intensive care found that nurses do not directly use decision trees but rather keep them to hand as a reference of standards that they can use to increase the confidence they have in their own decisions.

These findings raise interesting issues with respect to experience and professional insight, and as Bucknall (2007) suggests individual decision-making behaviour may in fact change over time, irrespective of the nature of the protocols being used. For newer or inexperienced nursing staff the

role of protocols would be in providing some structure to practice and decision-making, once they become more experienced and confident, the protocols may become part of intuitive practice, at this stage being 'forced' to use them may be viewed as a hindrance.

The policy imperative to streamline and standardise care through protocol-based care implies that decision-making a) can be prescribed, and b) factors other than evidence are unlikely to influence decision-making. However there is evidence to suggest that many sources of information are likely to influence decision making. For example Hancock and Easen (2006) in a study exploring nurses' decision making when extubating patients following cardiac surgery found that despite the use of an unwritten physiologically based protocol for weaning, factors other than best evidence influenced their decisions. Other sources of information included personal, cultural and contextual factors including relationships, hierarchy, power, leadership, education, experience and responsibility. The study illustrates the complexity of decision making, which is characterised by tangible and intangible elements. As such, having a protocol in place is unlikely on its own to ensure safe practice and high quality decision-making.

2.5.6 Impact on multi-disciplinary team decision-making and interaction

It has been suggested that protocols are way of mediating communication between health care team members (Manias and Street 2000). Using an ethnographic approach and drawing on post-modernist theories of power Manias and Street (2000) were able to explore nurses' and doctors' use of policies and protocols in a critical care setting. Findings included that nurses and doctors place different values on policies and protocols to inform their knowledge. Nurses tended to adhere to written guidelines and used them to mediate their communication with doctors and other nurses. Doctors placed little value on existing protocols and policies and relied on knowledge from past experience, education and information gained from journals. These findings are common to other studies (e.g. Ely 1998, Lawton & Parker, 1998, Parker & Lawton 2000, Blackwood et al 2004, Jones 2004, McDonald et al 2005). For example Parker and Lawton (2000) in a large scale questionnaire survey found that doctors saw protocols as decision making tools rather than prescriptive rules in contrast to nurses who felt violations to protocols were inappropriate regardless of the outcome to patients. Similarly McDonald et al (2005) in a study of doctors' and nurses' attitudes to using guidelines within the context of patient safety and the operating theatre found that doctors were 'rule breakers' and nurses 'advocates of standardisation'. Findings showed that doctors rejected written rules and adhered to the unwritten rules of what constitutes acceptable behaviour for members of the medical profession. In contrast, nurses viewed guideline adherence as synonymous with professionalism and criticised doctors for not complying with them. Various reasons are offered for these different perspectives including the differences in professional norms and values about what constitutes safe practice. The implication for the ambition of

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protocol-based care is that standardisation of patient care may not be achievable in the context of multi-disciplinary working.

An ethnographic study examining nurses' accountability in the context of clinical governance found that multidisciplinary and on occasions interdisciplinary decision-making about individual patients was shaped by guidance such as protocols and templates (Savage & Moore 2004). Other studies indicate the limited potential of protocols in enhancing multi-disciplinary working in practice by increasing rather than reducing interprofessional tensions (e.g. Atwal & Caldwell 2002, Pinder et al 2005) even when in theory there is a positive view about joint working and the role of protocols (e.g. Rees et al 2004). Further research is required to explore nurses', doctors' and allied health professionals' (AHPs) use of protocols in different types of units and settings. Uncovering the different decision-making roles and processes of healthcare team members in the delivery of protocol-based care may enable implications to be drawn about nurses' contribution to protocol-based care (in relation to their colleagues) and also about their professional identity, accountability and responsibility. Focussing in-depth on clinical decision-making in relation to protocol-based care should also provide additional evidence about whether this is a mechanism for enhancing teamwork and streamlining patients' care by integrating healthcare roles, knowledge and skills towards common care and treatment goals. As Bucknall et al (2000 & 2001) comments, organisations and researchers have ignored the impact of contextual influences on practitioner's decision making. It therefore seems important to incorporate the study of context in research exploring protocols and decision-making.

2.5.7 Summary

The evidence for the impact of standardised care processes on practice, patient and staff outcomes is variable. Even within studies there may be a demonstrable effect on one type of outcome, but no significant changes to others. There are questions about whether it may be the components or characteristics of the particular protocol or the process of implementation that influence impact, or both. However there is evidence to indicate that standardised care approaches can be influential, if only to raise awareness about particular issues or as an opportunity to bring clinical teams together. Findings from research also show that protocols can enable nurses' autonomous practice, support junior or inexperienced staff and can be a vehicle for asserting power. However this is counterbalanced by a perceived risk that using such tools limits and restricts thinking; a view shared by doctors and nurses.

2.5.8 Initial propositions

Table 7. Theory area: Impact of protocol-based care

- The impact of protocol-based care will be influenced by the type of protocol being used, by who is using it/them, how, and in what circumstances.
- More senior and experienced nurses will be less positive than junior and/or inexperienced nurses about using standardised care approaches.
- The impact on decision making will be influenced by practitioners' perceived utility of standardised approaches to care.
- Protocol-based care will impact on the scope and enactment of traditional nursing roles.
- Protocol-based care has the potential to enhance nurses' autonomy and decision-making latitude.
- The impact on patient care will be influenced by the characteristics and components of the protocol and factors in the context of practice.

2.6 Theory area 4 - Implementation and use

2.6.1 Approaches to implementing protocols

Protocols have the potential to mediate the implementation of evidence into practice, arguably however their effectiveness will depend on whether (or not) they are successfully implemented. Implementation of evidence into practice is acknowledged to be a complex and challenging undertaking (e.g. Greenhalgh 2004, Rycroft-Malone et al 2002) and whilst the evidence base about implementation is large, there are no clear indications as to the effectiveness of particular methods and approaches.

Like other protocol-based care issues, approaches to implementation have received varying attention across the different types of protocols. The implementation of clinical guidelines has been extensively researched, however a systematic review of guideline dissemination and implementation concluded that there was an imperfect evidence base to support decisions about which dissemination and implementation strategies are likely to be efficient under different circumstances (Grimshaw et al 2004). The findings of the review indicate that some strategies may have more promise than others in getting evidence into practice. Broadly these include educational strategies, feedback on performance, mass media campaigns and facilitative approaches (e.g. education outreach and opinion leadership) (Grol & Grimshaw 2003, Grimshaw et al 2004). Other reviews have also highlighted the potential of strategies such as the importance of the format and delivery of the guideline and recommendations (e.g. clear wording and specific

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recommendations), education and training (that is interactive and delivered by opinion leaders), the role of change agents (such as facilitators) and having a dedicated project lead (Thompson et al 2007; Richens et al 2004). However these approaches need to be evaluated within different contexts and across the different professional groups. For example, the Grimshaw et al (2004) review only includes evidence from randomised controlled trials of guideline implementation, and studies included tend to focus on physician (rather than nurse and allied health professionals) behaviour and practice. Thompson et al's systematic review (2007) focussed specifically on the use of research by nurses, not on guideline or protocol implementation per se. Further research is recommended to enable more informed choices about the use of the various strategies in the presence of different barriers and facilitators.

In contrast to the evidence from systematic literature reviews there are numerous studies evaluating the local impact of care pathways, protocols, algorithms, and guidelines, which outline implementation approaches (e.g. Jones 2000, Atwal & Caldwell 2002, Appleton & Cowley 2004, Goodman 2006, Watson et al 2006, Hayward-Rowse & Whittle 2006). Whilst these studies tend to be small scale, variable in quality and detail, there is an indication of the sort of implementation approaches that have been used to encourage the uptake of standardised care tools. Broadly these are:

- Education and training
- Action research
- Documentation
- Dissemination

each of these are explored further below.

Education and training

The most commonly reported approach to the introduction of protocol-based care tools into practice is some form of education and training, although generally these descriptions lack detail. Authors describe both informal and formal approaches. For example, Goodman (2006) outlines the implementation of a protocol for weaning patients off mechanical ventilation by educating staff about how to follow the weaning flow chart. Education was carried out by both formal presentations and talking to nurses one-to-one. Similarly Quirke et al (1997) used the sedation protocol that had been developed locally as an education tool, which was introduced by the research and development nurse through individual teaching sessions as well as more formal teaching sessions.

Some studies link the nature of the education and training with the implementation outcome (e.g. Rees et al 2004, Snooks et al 2004). For example Rees et al (2004) when attempting to implement an integrated pathway to enhance joint working in a primary care mental health trust in Scotland describe each team attending an 'away day' in which training and practical case study examples were given (no further details are provided). However the findings of the evaluation, which was conducted by

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interviewing staff about their experiences, indicated that there was confusion about the implementation plan and who was taking the lead. In this case the pathway was not being routinely used in practice and whilst it is not possible to make a direct link between the nature of training and lack of use, it may have been a contributory factor.

Overall whilst a commonly used approach, questions remain about what are the most appropriate and effective teaching and learning strategies for protocol-based care implementation, who should carry these out and in what settings. Furthermore given the multifaceted nature of changing practice, how education and training fits in with other strategies and context appropriate approaches warrants further investigation.

Action research

A number of studies report the implementation of protocols; specifically care pathways, using an action research methodology (e.g. Jones 2000 & 2004, Hockley et al 2005, Watson et al 2006, Atwall & Caldwell 2002). Within the action research approach a number of different context specific strategies are used. For example Hockley et al (2005) and Watson et al (2006) describe the implementation of an integrated care pathway for the last days of life in eight nursing homes over a 5 year period using key local champions, action learning sets, collaborative learning groups, training sessions, and on-going advice and support. They report positive outcomes, although highlight the challenges of implementation in the context of nursing home care. Similarly Jones (2000) used facilitation and informal training sessions within an action research study to implement a schizophrenia pathway with variable results. As Hockley et al (2005) comment, action research is particularly suitable for identifying specific problems and developing context appropriate solutions, however its effectiveness for protocol implementation has yet to be fully evaluated.

Documentation

A further approach to ensuring the use of protocols has been to introduce or modify documentation to incorporate process and practice changes. For example, in the study about end of life care outlined above, Hockley et al (2005) found that the introduction of integrated care pathway documentation provided a focus for change. Goodman (2006) introduced a protocol as part of patient documentation situated in patient records.

Dissemination

The introduction of protocol-based care approaches through dissemination is apparent in some reports. For example, Appleton & Cowley (2004) through case study research identify that health visitors' use of formal guidelines for identifying and assessing families involved no active implementation strategy, but the introduction of the guidelines by managers; presumably through passive dissemination.

2.6.2 Facilitators and barriers to protocol-based care

The facilitators and barriers to implementing evidence and new ideas are well documented (e.g. Rycroft-Malone et al 2002, Greenhalgh et al 2004, Dopson & Fitzgerald 2005). These include issues about the nature of the evidence itself, the way in which processes and approaches are facilitated, the influence of key actors and contextual factors such as resources, leadership and culture. In relation to protocol-based care specifically a number of factors are evident in the literature that reportedly influence the implementation and/or use of these care process tools, which are outlined below.

Standardisation

A number of authors report a perception of standardisation as having a negative impact on whether protocols are used (e.g. Partington 2006, Flynn & Sinclair 2005, Blackwood et al 2004, Jones 2004,). For example, Jones (2004) found healthcare professionals articulated a tension between the aim of care pathways (in this case for mental health) and the need to conceive the care for people with schizophrenia as an individualised entity. This perception influenced whether or not the care pathway was used in practice. Similarly Partington (2006) suggests that one of the challenges to implementing care pathways in palliative care homes is in allowing care to become a series of tick boxes, which abstract the patient.

Linked to standardisation is the use of clinical experience and professional skill (e.g. Appleton & Cowley 2004, Blackwood et al 2004, Flynn & Sinclair 2005). For example Flynn and Sinclair (2005) report on a focus group study with intensive care nurses (n=17). The nurses in this study did not implement endotracheal tube suctioning protocols fully because they reported using their clinical judgement. These nurses attached importance to experience and valued it over an ability to follow a protocol. These findings are similar to research conducted with medics who reveal a reluctance to relinquish decision-making control through use of protocols and guidelines (Parker & Lawton 2000). As Flynn and Sinclair (2005) point out there may be a legal implication of not following existing guidelines, protocols and policies; professionals would need to be in a position to defend their decision-making.

However, in contrast to the perceived negativity of standardisation, it has also provided the impetus for the development of a care pathway (Kent & Chalmers 2006). In this example the need to standardise care delivery and documentation for admission and discharge in adult mental health services appeared to galvanise stakeholders towards a common goal. The authors however do not report whether the resultant care pathway is being used and how it is being perceived.

Champions and leads

The presence and support of champions and project leads appears to influence the successful implementation and use of standardised care approaches (e.g. Currie & Harvey 2000, Hockley et al 2005, Watson et al 2006, Blackwood 2003 & 2004). For example Watson et al (2006) and

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Hockley et al (2005) describe the critical role that key champions played in supporting the facilitation of an integrated care pathway for the last days of life in nursing homes. In this implementation project champions were appointed in each participating nursing home (n=72) who were also supported by a clinical nurse specialist acting in a research fellow role. Key facilitation activities included training sessions, collaborative learning groups, and monthly support meetings with key champions, on-going advice and support. The authors report that this approach was critical in highlighting and overcoming local obstacles to pathway implementation, but also that such an intense approach whilst necessary to support staff and encourage implementation, is resource intensive. In contrast, other authors report challenges in implementation and use when there is lack of support and/or a person acting as a local champion (e.g. Rees et al 2004, Snooks et al 2005, Kent & Chalmers 2006). Not only does support appear to be important in the early stages of development and implementation but also as an on-going resource. These issues are unsurprising when considering the literature on implementing evidence into practice, which indicates the need for credible local project leads and/or change agents (Dopson et al 2002, Harvey et al 2002, Rycroft-Malone et al 2004).

Context

Blackwood (2003), using the case of protocolised weaning, highlights the potential importance of context in implementing protocols. In this example the author questions why, whilst in the US nurse-led protocolised weaning is normal practice, its introduction in the UK has been slow. In this analysis a number of contextual factors are explored including that the evidence may not be transferable across different settings; the research evidence on the effectiveness of protocolised weaning comes from the US where practice and systems differ from the UK. Furthermore the way that intensive care units organise themselves differs between countries; the US has separate units with similar patient populations, which enables the tailoring of guidance to those patient populations, in contrast the UK has mixed patient populations making adherence to one weaning protocol difficult. Such factors highlight the potential importance of contextually relevant and appropriate approaches to protocol-based care.

2.6.3 Summary

Evidence indicates that approaches to implementation that have the scope to identify and address the complexities of use may be more successful in encouraging the uptake of protocol-based care approaches than those that do not. Furthermore integrating protocols within existing systems and processes may facilitate their use. However there is evidence to indicate that approaches to standardising care may also inhibit use because of a concern about a lack of scope to individualise patient care. Additionally certain contextual factors may facilitate or inhibit the use of standardised care approaches, although what these factors are requires further investigation.

2.6.4 Initial propositions

Table 8. Theory area: Implementation and use

<ul style="list-style-type: none"> Interactive and participatory approaches and strategies to implement standardised approaches to care may influence whether or not they are used in practice.
<ul style="list-style-type: none"> The support of a facilitator or project lead may increase the likelihood of the on-going use of standardised care approaches.
<ul style="list-style-type: none"> Embedding the standardised care approach into systems and process may facilitate use.
<ul style="list-style-type: none"> Some contexts will be more conducive to using standardised care approaches than others.

2.7 Summary and theoretical framework

The evidence review not only illustrates the variable nature of the evidence base about protocol-based care but also the many questions that remain. As each section above described, questions remain about the nature, benefits and impact of protocol-based care on roles, and service delivery, about the nursing contribution to development and delivery, and about related practitioner and team issues.

Whilst there are strengths and weaknesses in the evidence-base about protocol-based care, consistent with realist methodology, a number of working or initial propositions have emerged. These propositions (summarised in Table 9) are to be evaluated by the research questions (section 3).

Table 9. Summary of initial propositions

Theory area	Initial propositions
1) Properties of protocol-based care and protocols	<p>A clear understanding about the purpose and nature of protocol-based care by potential users will determine the extent to which standard care approaches are routinely used in practice.</p> <p>The properties of standard care approaches, such as degree of specificity and prescriptiveness, will influence whether and how they are used in practice.</p>
2) Development of protocols	<p>Protocols that are developed through a systematic, inclusive and transparent process may be more readily used in practice.</p> <p>Protocols that are based on a clear and robust evidence base are more likely to impact positively on outcomes.</p> <p>Locally developed protocols may be more acceptable to practitioners and consequently more likely to be used in practice.</p>

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3) Impact of protocol-based care	<p>The impact of protocol-based care will be influenced by the type of protocol being used, by who is using it/them, how, and in what circumstances.</p> <p>More senior and experienced nurses will be less positive than junior and/or inexperienced nurses about using standardised care approaches.</p> <p>The impact on decision making will be influenced by practitioners' perceived utility of standardised approaches to care.</p> <p>Protocol-based care will impact on the scope and enactment of traditional nursing roles.</p> <p>Protocol-based care has the potential to enhance nurses' autonomy and decision-making latitude.</p> <p>The impact on patient care will be influenced by the characteristics and components of the protocol and factors in the context of practice.</p>
4) Implementation and use	<p>Interactive and participatory approaches and strategies to implement standardised approaches to care may influence whether or not they are used in practice.</p> <p>The support of a facilitator or project lead may increase the likelihood of the on-going use of standardised care approaches.</p> <p>Embedding the standardised care approach into systems and process may facilitate use.</p> <p>Some contexts will be more conducive to using standardised care approaches than others.</p>

The study's overarching theoretical framework is therefore based on the four theory areas, their corresponding propositions, key stakeholder outcomes, and by the Promoting Action on Research Implementation in Health Services (PARIHS) Framework (Kitson et al 1998, Rycroft-Malone et al 2002 & 2004a) (see Figure 1). The framework has been inductively and empirically developed to represent the interplay 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 (Rycroft-Malone et al 2004b, McCormack et al 2002, Harvey et al 2002). The three elements: evidence, context and facilitation are each positioned on a high to low continuum. 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 (high evidence), the quality of context (high context), and, appropriate facilitation (high facilitation). The framework is particularly relevant to this study because:

- The policy imperative underpinning protocol-based care is about improving the care of patients by facilitating the use of evidence in practice. Understanding the factors that influence this will be important in determining the contribution of protocol-based care to patients, staff and the organisation. This framework will provide a conceptual guide for mapping these issues.

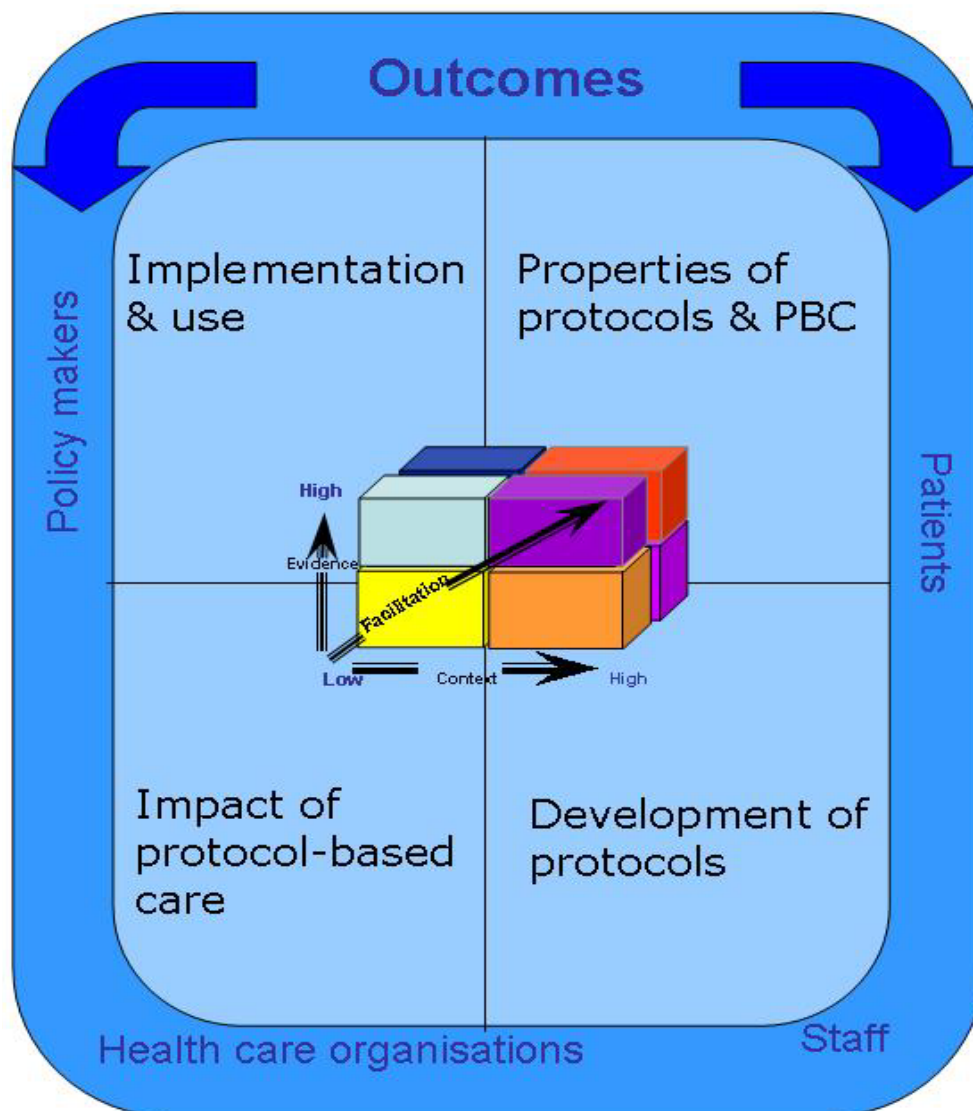
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- Understanding the role of context will be key in evaluating the contribution of protocol-based care. The adoption of this conceptual framework will complement the methodological framework of Pawson and Tilley (1997) and the case study methodology of Yin (1993 & 1994). Thus both the conceptual and methodological frameworks will acknowledge and value the role of context, and its component parts (e.g. culture, teamwork, leadership, resources) in the delivery of protocol-based care.

- It facilitates the gathering of individual (e.g. practitioner and patient) experiences as well as appreciating the fit with the broader context of care delivery.

The framework has integrated both the theory areas, propositions and the evidence-based practice framework and has been used to guide the conduct of this project from idea development, selection of methodology and methods, analysis and findings interpretation.

Figure 1. Theoretical Framework



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The study's theoretical framework comprises the 4 theory areas, which play a role in protocol-based care. The enactment of protocol-based care has the potential to impact on stakeholder outcomes: patients, staff, organisations, and policy makers. Implicit in the framework is the notion that protocol-based care is about introducing new practices, which is a function of the nature of the evidence underpinning the new practice (protocols etc.), the readiness and quality of the context into which they are to be implemented and used, and the processes by which they are implemented. The theoretical framework integrates these components.

3 Methodology and Methods

This section describes the research design and methods used to conduct the research. Following a summary of the research aims and questions, there is an in-depth description of the methodological framework, research design, sampling criteria, and data collection methods. As this final report combines the findings of two research projects, which used complementary but different methodologies; where appropriate the approach used for each project is detailed separately.

3.1 Research Questions

Fundamentally as the findings from the evidence review show, the evidence base for protocol-based care is variable. Therefore the research studies were designed for description, exploration and explanation. As such, the overall objective of these two studies was to evaluate protocol-based models of care and contribute to the practice and academic evidence base by addressing the following research questions:

3.1.1 Case study evaluation

1. What is the impact of protocol-based care on patients, professionals and organisations?
2. How do nurses, midwives and health visitors contribute to protocol-based care?
3. What are nurses', midwives' and health visitors' experiences of using protocol-based care?
4. What are patients' experiences of being cared for through protocol-based systems of care?
5. What factors inhibit and facilitate the implementation and use of protocol-based care?

3.1.2 Decision making study

1. How do protocols affect the clinical decision-making process?
2. Does protocol based care influence multidisciplinary decision-making?
3. What are the areas of multidisciplinary decision-making in protocol-based care?
4. What professional and organisational influences affect the nurse's role in multidisciplinary decision-making using protocols?
5. How does protocol-led clinical decision-making impact on patients' experiences?

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These questions dovetail with the theory areas in the theoretical framework and initial explanatory propositions.

Given the research brief and exploratory questions and propositions about protocol-based care needing to be addressed, the researchers aimed to evaluate a number of intermediate (as opposed to summative) outcomes at various levels. Findings from these studies have a number of implications for intervention studies (see sections 5.6 & 6.5). However, outcomes of interest for these studies included:

- Patients – experiences and perceptions of protocol-based care, including involvement in care.
- Professional – in relation to ‘impact on staff’, including nurses’, midwives’ and health visitors’ experiences and perceptions of, and role in, protocol-based care, including impact on identity, autonomy and clinical freedom, impact on team working.
- Organisational - for example, length of stay, throughput, and workforce specific, e.g. recruitment and retention, staff configuration, role changes.
- Protocol specific– impact on practice, roles and if local audit or evaluation data available; specific protocol’s impact on outcomes.
- Process – use of protocol-based care in practice, including implementation and utilisation factors, including those that capture temporal aspects of change.

The costs of protocol-based care are being evaluated in a parallel project being conducted by the Institute of Work Psychology at the University of Sheffield.

3.2 Research approach

3.2.1 Methodological framework

In order to address these questions, and build on the evidence synthesis reported earlier, realistic evaluation was used as the overarching framework for both the case study evaluation and decision-making study (Pawson & Tilley 1997). This framework acknowledges the importance of context to the understanding of why interventions and strategies work, for whom, how, and in what circumstances. Realistic evaluation’s explanatory proposition is that programmes work (have successful *outcomes* - *O*) only in so far as they introduce appropriate ideas and opportunities (*mechanisms* - *M*) to groups in the appropriate social and cultural conditions (*contexts* - *C*). Thus, realistic evaluation activity attempts to outline the relationship between *mechanisms*, *outcomes* and *context*. Pawson and Tilley (1997) argue that such an evaluation consists of interplay of individual and institution, agency and structure and of micro and macro processes. This is important in considering the framework’s relevance to this proposal; the NHS is a complex system of interconnected, interdependent components (Iles and

Sutherland 2001) including people, rules, processes, social and financial capital, and structures. Furthermore, improving practice through the introduction of approaches such as protocol-based care is a complex and challenging undertaking involving the same components. It is important to acknowledge the existence of the complex context in the design of this study in order to gain a deeper, realistic understanding of the development and contribution of protocol-based care. The transferability of the findings from this work will also be enhanced by conducting the study within a framework that enables a rich description of contexts and of the contingent relationships between them and mechanisms with outcomes.

3.2.2 Research design

The choice of research design and methods employed in this research study was influenced by the need for exploration, description, and explanation and a requirement to capture data about the use of protocols in the reality of the practice context. Therefore case study (Yin 1993 & 1994) was the method of choice for both studies. However in order to address the questions of the decision-making study, data collection methods from the ethnographic tradition were used (described in more detail in section 3.2.5 below).

Case study, which has its roots in ethnography, enables a focus on contemporary phenomenon (i.e. protocol-based care) within its real life context, when the boundaries between phenomenon and context are unclear. Furthermore case study provides an opportunity to utilise multiple methods and to study and understand the experiences of different stakeholder groups (Yin 1993). As such, it is an approach that is methodologically complementary to Pawson and Tilley's framework, which advocates the use of multiple methods to data collection, and recognises the importance of context.

The evaluation of protocol-based care requires descriptive and explanatory case study work, in order to describe the practice and contribution of nurses, midwives and health visitors to protocol-based care. In order to address the research questions and assist in explanation building and transferability of findings, multiple comparative case studies were included.

Cases – definition

A 'case' was defined as a particular clinical setting, for example, a cardiac surgical unit (CSU) and the 'embedded unit' of that case the use of a particular variant of protocol based care, for example, the care pathway. In this way, the care pathway (and other variants of protocol-based care) could be studied in the real life practice context and their impact (on patient, staff and organisational intermediate outcomes) and the contribution of nurses (in relation to the multi-disciplinary team) more readily evaluated. The variants of protocol based care to be studied were determined by the criteria described below and refined according to an initial review of the literature (Rycroft-Malone et al 2004).

3.2.3 Sampling

Sites were purposively sampled in order to maximise rigour in relation to the qualitative concepts of applicability and transferability rather than issues of generalisability (Morse & Field 1996; Lincoln & Guba 1985). Lincoln and Guba (1985) suggest that qualitative inquiry is judged in terms of the extent to which its findings can be applied in other contexts or with other respondents.

Sampling criteria were informed and directed by the findings of the initial review of the literature, the theoretical framework, research questions and the progress of the Sheffield research team⁶. Sampling was based on a replication argument; that is, each case was selected so that they a) predict similar results or b) provide contrasting results but for predictable reasons (Yin 1994). In this way, if arranged effectively within the multiple case design, the set of propositions could be evaluated over the cases. This approach enabled the selection of later sites to pursue different theoretical or practical propositions. For example, emerging findings from early case study work indicated that the nature of nurses' roles and level of autonomy may influence the way in which protocols and their variants were used in practice (e.g. walk in centre). It was therefore important to ensure that later sites included nurses practising in extended and expanded roles to further evaluate this theory (e.g. general practice).

Case study evaluation sampling criteria

A number of sampling criteria were used:

1. *Active involvement in the development and implementation of protocol-based care.* To ensure maximal opportunity to study protocol-based care it was important to access and work with sites who state they are actively engaged in it. In relation to Yin's (1993) characteristic of exemplary case and the use of replication logic, cases that, it is hoped, will be information rich were accessed. These were identified through informal networks and through our links in the field; for example the Care Pathways Review Board, the NELH and RCN Forums of practice and the RCM Learning, Research and Practice Development Departments.
2. *Nature and variants of protocol based care used in different contexts.* Care pathways for example appear to be the most commonly utilised type of protocol-based care; as such they appeared to warrant study in different contexts.
3. *Key policy and practice issues.* Being attentive to on-going policy and practice issues was important in ensuring contemporary findings. For example, with the planned increase of nurse and midwife prescribing it seemed important to consider the inclusion of an evaluation of nurses' use of patient group directives (PGD).

⁶ We entered into discussion with the team at the University of Sheffield (who are conducting a protocol-based care study in parallel to these studies) about site selection to ensure various clinical contexts and service delivery models were included across all studies.

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4. *Organisation and delivery of care.* Studying different service delivery models across varying contexts, amongst other advantages, has the potential to offer new insights into the contextual determinants and influences on protocol-based care.
5. *Different clinical specialities.* In order to enable the study of practice related to groups of clients with differing conditions and thus differing protocol-based care issues, varied clinical specialities and settings were sampled.
6. *Fit with key health targets* was considered in order to enhance the transferability of the findings to wider NHS initiatives, for example focussing on issues that arise from the local implementation of key guidelines and National Service Frameworks.
7. *Ensuring sites reflected the UK's population* - to ensure the capture of different and diverse perspectives of NHS service users.

Decision-making study – sampling criteria

The decision making study was designed in response to the call to address two of the research priority areas identified by United Kingdom Clinical Research Collaboration (UKCRC); diabetes and cardio-vascular disease. A decision to focus on two sites was made so that decision-making in relation to protocol-based care could be studied in depth, within the available timeframe. Consistent with an ethnographic approach, focusing on just two sites, one in relation to the care of people with diabetes and the other to the care of people with cardiovascular disease enabled a prolonged period of time in the field. The criteria that informed purposive sampling for the decision-making study included:

1. Care delivered to people with diabetes and cardiovascular disease (re UKCRC priorities)
2. Active involvement in the development and implementation of protocol-based care (as described above)
3. Ensuring sites reflected the UK's population (as above)
4. Sites included the use of a number of different types of standardised approaches to care, to ensure the capture of what occurs in the reality of the practice setting.

Site descriptions for both studies can be found in Section 4; 4.1.1, 4.1.2 and Appendices 1 and 2.

3.2.4 Data collection

Case study evaluation

A major strength of utilising a case study approach is the opportunity to use various sources of evidence to understand what is being evaluated. Method triangulation was used to enhance the credibility and transferability of the conclusions drawn from data (Jick 1983, Yin 1994, Seale 1999). The unique characteristics of the different data collection methods allowed more pieces

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of the jigsaw to emerge; enabling a more complete picture of protocol-based care to be developed and the generation of theory.

The following data collection methods were used within each site:

- *Non-participant observation* of a sample of protocol-based care interactions. Primarily these focused observations occurred between nurses and patients in situations where practice was being guided by the use of a standardised care approach (i.e. care pathway, protocol, PGD, local guideline etc.). These observations were guided broadly by Spradley's (1980) nine dimensions of observation, including space, actors, activities, objects, acts, events, time, goals and feelings (see Appendix 3 for an example). However the researcher was also attentive to other issues and cues relevant to each of the observations and the particular context in which they took place.

Sampling of interactions was pragmatic and occurred by two main routes. First, periods of general non-participant observation raised researchers' awareness about occasions that might be observation opportunities. Second, staff will be asked to alert researchers to observation opportunities. Observations were written up as field notes.

Clinical areas were visited during a variety of shift times spanning different days of the week. Additionally, the researcher's maximised the opportunity to attend protocol-based care relevant meetings.

- *Semi-structured interviews* with patients in each of the case study sites were conducted to capture patients' experiences of protocol-based care. Patients interviewed were those who had been the subject of observation of nurse-patient care episode as specified above. Patient experiences and outcomes were evaluated by focusing interviews on patients' views on the care episode, including their views on quality of care, whether information was shared and whether they were involved (if they wished to be) in protocol specific issues.
 - When data collection commenced in site 2 (walk-in centre – WIC-) it became apparent that in some cases a face-to-face interview was not practical because patients were leaving the setting immediately on discharge. This was also the case in the pre-operative assessment (POA) clinic, birth centre (BC) and general practice surgery (GPS). We therefore built into the design the potential to conduct telephone interviews, which ensured that the opportunity to follow-up patients was not lost. Telephone interviews have been shown to be an effective method of data collection when recruiting patients within a continually changing environment and for multi-site research (Barriball et al 1996, Musselwhite et al 2007). Ethics approval for this addition was sought and granted.

These interviews, as with all the interviews described below, were audio-recorded and later transcribed verbatim (see Appendix 4 for examples of interview schedules).

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- *Tracking patient journeys through multiple interviews* was used with variable success (see Appendix 5 for a fuller reflection on this and for study limitations). One of the main aims of protocol-based care is improving the patient's journey. Research suggests that there are many challenges to capturing useful and representative information about patients' experiences of care (Edwards & Staniszewska 2000, Edwards 2001, Staniszewska & Henderson 2004). More specifically this research indicates that patients' a) experiences transform over time, for example a negative perception of an aspect of care can transform into a positive evaluation, b) are keen to maintain a positive image of their care, and c) have a strong need to make sense of their care experiences. This, coupled with an aim of protocol-based care – improving the patient journey, presented a timely opportunity to obtain a longitudinal perspective on patient experiences and for assessing how protocol-based care impacted on the co-ordination and delivery of care.

The approach used was to interview patients in each site more than once during their episode of care. The timing of these interviews was determined in collaboration with patient participants and their length of stay.

- *Semi-structured interviews* with nurses, midwives and health visitors were conducted to capture their experiences about being involved with and contributing to protocol-based care within the specific clinical setting. Where possible these interviews took place with practitioners who were involved in the focussed observations described above, thus providing multiple data sources on specific practices. Interviews were also conducted with other nurses, midwives and health visitors who were involved in protocol-based care activities within the setting but who had not taken part in the observations. The aim of the interviews was to explore their role in protocol-based care, local developments, including data on the benefits and drawbacks, facilitators and barriers, and the potential for further developing and improving this form of care delivery. Additionally, in considering the impact of their role in protocol-based care, questions about professional identity, responsibility and autonomy were included (see Appendix 4 for interview schedule).
- *Semi structure interviews* were conducted with other key stakeholders, including doctors, allied health professionals, and managers, including those from clinical practice, audit departments and administration. These stakeholders were identified through a snowballing approach to sampling. These interviews explored perceptions about the contribution that protocol-based care made to issues such as patient care, roles, and outcomes. These interviews were also used to investigate views on the facilitators and barriers to protocol-based care and how it could be further developed and improved (see Appendix 4 for interview schedule).
- *Documentation* was collected in each site where available in relation to a) the particular type of protocol care being evaluated and b) the clinical context(s). This provided background information with which to

contextualise findings, provide insight into facilitators and inhibitors of protocol-based care and aid explanation building.

- *Locally collected data*, such as audit information were collected in each site if available and if sites were willing to share it.

3.2.5 Decision-making study

As with the case study evaluation, and consistent with ethnography, the decision-making study included multiple data collection methods. Within each site the following methods were used:

- *Participant observation* of nursing and multi-disciplinary activities. The advantage of using participant observation was getting as close as possible to decision-making, its flexibility to adapt to and/or follow-up events within the context and in the real time of practice. The researchers took on the role of observer as participant (Burgess 1984, Robson 1993, after Gold 1958), which enabled them to ask questions, have discussions and probe into the clinical decisions and care delivery, and the way in which protocols may be influencing these processes. Where appropriate these observations and discussions were audio-recorded, but consistently all were recorded in field notes.
- *Semi-structured interviews* with the practitioners that were involved in observations were conducted. These interviews were focussed around particular incidents and issues that arose during observation as well as the exploration of views in general about protocol-based care. This included questions about how decision-making is affected by protocols; including simplification and standardisation, and what affects decision-making using protocols in the reality of clinical practice. Interviews and discussion with nurses and doctors included an exploration of issues such as autonomy, responsibility and professional identity. To some extent and in keeping with methods from the ethnographic tradition, the focus of these interviews evolved as the study progressed.
- *Interviews* with patients were also conducted. Patients interviewed were those who had participated in observation as specified above and took place as soon as possible and appropriate after this. Patient experiences were assessed by focusing interviews on patients' views on the care episode, whether information was shared and whether they were involved (if they wished to be) in decision-making processes.
- *Non-participant periods of observation* of general ward/unit/clinic 'life' were conducted in order to capture information about the clinical context of protocol-based care, care delivery, and the dynamics of the multi-disciplinary team. Clinical areas were visited during a variety of shift times spanning different days of the week.
- *Comprehensive field notes* were written during and after being present in the clinical settings. Consistent with ethnography these notes provided a rich description of what occurred in clinical practice and the context of practice, as well as personal reflections and interpretations.

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- *Feedback sessions* in sites were conducted following preliminary analysis and as consistent with ethnography; on an on-going basis. This allowed the participants to reflect on findings as well as allowing the researchers to fill any gaps in the knowledge or understanding which existed. This feedback was built into field notes and audio recordings as appropriate.
- *Documentation* was collected in each site where available in relation to a) the particular type of protocol care being evaluated and b) the clinical context(s). This provided background information with which to contextualise findings, provide insight into facilitators and inhibitors of decision-making using protocols and aid explanation building.

3.2.6 Data analysis – case study evaluation

Consistent with case study methodology each case is regarded as a 'whole study' in which convergent evidence is sought and then considered across multiple cases. As such, a pattern matching logic, based on explanation-building, was used as a data analysis framework (Yin 1994). This strategy allowed for an iterative process of analysis across sites and enabled an explanation about protocol-based care to develop over time. It was important to ensure that data analysis reflected the variety of data sources and the potential insight that each could offer in addressing the research questions, i.e. through triangulation.

Qualitative data were content analysed following the approach described by Huberman and Miles (1984 & 1998) and Yin (1994) in which data are 'made sense' of through coding, developing themes/patterns/clusters, discovering relationships, and developing explanations. In practice this meant an inductive process whereby data were broken down into codes within each data set (i.e. interviews, observations, documents) and within each site. Codes were then developed into themes, and these themes considered across the five sites. Yin (1994) calls this cross-case analysis. In this way the difference and similarities were highlighted and comparisons made in order to assist explanation building (Yin 1993 & 1994). This approach enabled a comprehensive picture about protocol-based care to be developed. Data analysis was conducted by three members of the research team and in a way that enabled the challenge and/or confirmation of coding, theme development and interpretation. This form of 'member checking' (Lincoln and Guba 1985) was conducted to enhance the credibility of the study's findings. Data analysis was managed in QSR Nudist (v5).

3.2.7 Data analysis - decision-making study

Data analysis for the decision-making study combined traditional ethnographic and the research analysis approach described above. Consistent with a traditional ethnographic approach, some analysis took place in the field, in that the ethnographer was constantly thinking about the larger meanings behind what they were seeing rather than blindly recording (Hammersley & Atkinson 1995). This means that some of the raw data has an analytical nuance. After the fieldwork period, the two

ethnographers from each field site immersed themselves in the data and, through meeting and discussion arrived at interpretations across site data.

To complement this, data (in the form of, field notes, verbatim quotes, transcribed interviews and the thoughts of the ethnographers) were fed into 'data tables'. The development of these tables was similar to the coding process described above, but remained flexible throughout the analysis period, in keeping with the principle of ethnography, to allow the data to inform their structure rather than a structure being imposed upon the data. Some of the categories in the table were designed to complement the emerging themes of the case study evaluation; others were specifically identified through inductive analysis of field data. Whilst data in this form may appear to be structured and easy to navigate, it nevertheless remains true to ethnography by not favouring any particular thematic area and not forcing data into codes, but rather creating new codes (of equal importance) right through to the end of the analysis process.

3.3 Integration of findings across studies

As requested by the NHS Service and Delivery Organisation Programme, the final report presents the research findings of themes across sites and studies, based on the theoretical framework questions of what works, for whom, how, and in what circumstances.

The main findings from the focussed ethnography that specifically evaluated decision-making are described in a separate section entitled impact of protocol-based care on nurses' decision-making. Additional findings from the ethnography are integrated into other sections of the findings chapter because they are relevant to the use of standardised care approaches more broadly. Data extracts are clearly labelled to enable distinctions to be made.

3.4 Ethics

Both research studies were guided by research and governance framework requirements and codes of ethics (RCN 2004; Association of Social Anthropologists <http://www.theasa.org/ethics.htm>). Multi-site Research Ethics Committee (MREC) approval was sought and given for each study. Additionally the case study evaluation required site specific approval before proceeding locally. For both studies this was a lengthy and time consuming process.

In practice the ethical issues of particular importance to both studies were informed consent, and anonymity. Each potential participant was given information about the study and an appropriate period of time allowed to lapse to before consent sought. A consent form was signed by each research participant, which included an acknowledgment that they had been sufficiently informed about the nature of the research and how they were participating, where appropriate they consented to being audio-recorded, and understood they could withdraw from the study at any time without providing a reason. Anonymity was assured by each site and participant

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being given an identity code (case study evaluation) or pseudonym (decision making ethnography). All data were stored in a locked filing cabinet at the RCN Institute, Oxford, and electronic files password protected on project dedicated laptops.

4 Findings

4.1 Introduction

In this chapter, findings from the case study evaluation and decision making study are presented. As detailed in section 3 the methodologies of the two research projects were complementary in that they used similar data collection methods, but were different in approach and focus. Consequently a description of the sample and summary of data collection activities undertaken in each project are presented separately.

4.1.1 Case study evaluation

A total of five sites were purposively sampled using the criteria detailed in section 3. A summary of site characteristics is presented in Table 10, which provides information to help contextualisation findings (for a more detailed description of each site see Appendix 1).

A variety of methods were used during data collection including focused non-participant observations, semi-structured interviews with patients, practitioners and key stakeholders, field notes as well as collection of relevant documentation (for a more detailed description of data collection methods see section 3). A summary of data collected across and within the five sites is presented in Table 11. A variety of stakeholders took part in the study including nurses, midwives, health visitors, doctors, managers, support staff and patients.

Findings that emerged from data collected in the case study sites are presented as a whole in chapter 4. Where variations within and across sites occurred these are highlighted and discussed.

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Table 10. Case study evaluation sites description summary

Site	Location	Patient population	Capacity	Admission	Staff (included in data collection)	Physical environment
Cardiac surgical Unit (CSU)	Large teaching hospital, acute trust in outskirts of large city	Mainly Caucasian population	12 ward beds & 8-12 cardiac recovery beds	Cardiothoracic surgical & some diagnostics procedures	Nurses, doctors & physiotherapists	Large ward divided in 3 zones with a nurse station & up to 9 beds. Curtains provided privacy for most patients. There were 3 single rooms mainly used for MRSA* patients.
Walk-in centre (WIC)	Inner city walk-in centre near an A&E at the local district general hospital, primary care trust	Diverse population with large proportion of ethnic minorities	Average attendance summer 2005 was 59 patients per day. Maximum 104 and minimum 9	Unscheduled care (range of minor illnesses and injuries)	Nurses, GPs & receptionists	The centre is based in a porta cabin near an A&E department. Consultations take place in individual rooms with medical equipment & a computer
Pre-operative Assessment Clinics (POA)	Large teaching hospital, acute trust in outskirts of city	Diverse population with one in five people in the community belonging to an ethnic minority	Usually half day clinics with between 3 to 10 patients, depending on demand	Scheduled surgery ranging from specialist urological surgery to general surgery	Nurses & doctors	Most clinics usually use a few bays within a related specialty ward with a bed & curtain for privacy. Some clinics take place in a consultation room
Birth Centre (BC)	Large Foundation Trust hospital on two sites in outskirts of city	Diverse population, with large proportion of ethnic minorities	Around 50 – 70 births a month	Women booked at the Centre for their birth	Midwives and obstetricians	Based on a ward of the maternity unit, away from main delivery suite. 4 birth rooms & one 6 bedded postnatal ward area, with 1 room for consultations
GP Surgery (GPS)	GP practice in suburbs of a large city	Mainly Caucasian population	Busy surgery run by 7 partners & 2 associate GPs providing multiple clinics and services	Patients within a particular catchment area need to register with the practice	GPs, practice & district nurses, midwives, health visitors, community matron & smoking cessation adviser	Practice is based in spacious, purpose built premises with consultation rooms & space for housing a full complement of employed and attached staff

* MRSA: Methicillin Resistant Staphylococcus Aureus - an antibiotic-resistant infection.

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Table 11. Summary of data collected within and across case study evaluation sites

Activity		Cardiac Surgical unit (CSU)	Walk-in Centre (WIC)	Pre-operative assessment clinics (POA)	Birth Centre (BC)	GP Surgery (GPS)	TOTAL
Non-participant observations		11	8	10	4	11	44
Post-observation interview with healthcare professional		10	7	8	4	9	38
Post-observation interview with patient		6	5	6	6 (2 patients not observed)	8	31
Patient journey	Number of patients recruited	2	2	2	0	2	8
	Follow-up interview with patients	6 (3 interviews each)	4 (2 interviews each)	4 (2 interviews each)	0	4 (2 interviews each)	18
Interviews with key stakeholders		15	8	14	8	15	52
Collection of written documentation related to protocol based care		e.g. Audit results, Patient journal, Patient information booklet, Physiotherapy discharge advice, Internal magazine, ICP	e.g. Referral audit, Antibiotics' use audit, Nurses vs. GPs throughput, Nurses' essential competencies list	e.g. Patient information, anaesthetic questionnaire, examples of ICPs, NICE guidelines, Urology proforma	e.g. Women's information leaflet, Trust newsletter, copy of All Wales Pathway	e.g. Patient information leaflet, Pregnancy women notes, new staff induction and training	Yes
Field notes	Actual field notes collected	Yes	Yes	Yes	Yes	Yes	Yes
	Days present at site	21	22	17	32	16	76

4.1.2 Decision making study

Additional funding was granted to study decision-making and protocols in a further two sites. The two sites were purposively sampled to cover the care of people with diabetes and the care of people with cardiovascular disease; in line with the priority areas identified by UK Clinical Research Collaboration.

The Diabetic and Endocrine Unit is situated in a large city teaching hospital, which contains several small, independently functioning units (see appendix 2 for further details). The busiest of the functions is that of a 'normal' diabetes clinic where patients come to be seen either by Doctors or Specialist Diabetic nurses. In addition, the unit contains a four-bed ward that accommodates patients who have come in for day-long tests

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administered by the endocrine team. The department also houses a Diabetes Eye Complication Screening Service, dietician clinics, erectile dysfunction clinics, podiatry clinics, lipid clinics and diabetic ante-natal clinics. The busiest part of the clinic is the pre-assessment clinic in which patients have their blood-pressure, weight, height and blood-glucose measured.

The Cardiac Medical Unit is part of one of the largest cardio-thoracic hospitals in the United Kingdom (see Appendix 2 for further details). Once a specialist and referral hospital it has recently become a primary service and since then, the number of admissions to the unit has increased. The unit is divided into two wards on the second floor of the hospital. The first ward is for seriously ill patients, high dependency patients and the second bay for patients having routine procedures and shorter hospital stays.

The primary methods used were participant observation of nurses and multi-disciplinary activities, semi-structured interviews with practitioners and patients, comprehensive field notes and feedback sessions following preliminary analysis.

A variety of stakeholders such as nurses, doctors, support staff and patients took part in the study as described in Table 12. Researchers spent approximately 50 days in each site.

Table 12. Summary of decision-making ethnography participants

Participant type		Diabetic & Endocrine Unit	Cardiac Medical Unit
Nursing staff	Health care assistant	4	4
	Staff nurse	7	12
	Senior/charge nurse	2	5
	Specialist nurse	7	0
Medical staff		2	4
Patients		13	4
Total		35	29

Findings from the decision-making study are presented in the section titled 'impact on decision-making.' Where findings are relevant to other sections data is also integrated with case study evaluation findings⁷.

4.2 Properties of Protocol-Based Care

4.2.1 Types of standardised care processes – case study evaluation

In order to explore protocol-based care as it is used in the reality of the clinical context and across the NHS, we purposively sampled sites to enable the capture of the different ways that protocol-based care tools are being

⁷ Findings from the decision-making ethnography will be more fully disseminated in published papers.

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used. As Table 13 shows, there were various different types of approaches being used within and across sites, which addressed many clinical topics and patient issues. Furthermore these care approaches cover the breadth of care delivery from diagnosis to intervention and treatment.

Table 13. Types of standardised care approaches within and across case study sites

Protocols by site	Name	Type	Format	Location	Users
Cardiac Surgical Unit (CSU)	Multidisciplinary pathway for cardiac surgery	Integrated care pathway	Patient notes	Patient's bedside	Medical & nursing staff, physiotherapists & all other AHPs
Walk-in Centre (WIC)	Teleguide triage algorithm	Algorithm	Electronic	Computer	Initially developed for telecare, used by nurses on face to face care
	Clinical guidelines	Guidelines	Paper	Central paper folder	Nurses
	Ambulance service protocol	Protocol	Paper	Central paper folder	Ambulance & WIC staff
	Patient group directives	Protocol	Paper & attached paper trail	Individual copy	Nurses
Pre-operative assessment clinics (POA)	Guidelines for adult pre-operative investigations	Guidelines	Paper	Central paper folder/board	Nurses & doctors
	Blood pressure algorithm for adult diabetic and non-diabetic patients	Algorithm	Paper	Central paper folder	Nurses & doctors
	Policy for pre-operative starvation and drug administration	Policy	Paper	Central paper folder	Nurses & doctors
Birth Centre (BC)	Clinical pathway for normal birth	Care pathway	Paper	Midwives' station	Midwives
GP Surgery (GPS)	Asthma protocol	Protocol	Paper	Clinic paper folder and shared electronic folder	Nurses
	Routine care for healthy pregnant women's flow chart	Flow chart	Paper	Paper folder and patient's notes	Patient, midwives & all other health care professionals
	Stop Smoking protocol	Protocol	Paper	Clinic paper folder and shared electronic folder	GP, nurses & stop smoking advisor
	Leg ulcer care pathway form	Leg ulcer care pathway form	Paper	Patient held	District nurses and health care professionals at hospital
	Pre-school core health visiting guidelines	Guidelines	Paper	Central paper folder	Health visitors
	Hypertension protocol	Protocol	Paper and electronic, linked to QOF	Central electronic folder	Doctors, nurses & receptionists

In some sites there were a number of different tools being used, this enabled us to explore whether the type of standardised care approach affected the way that it was used. For example, not only was there a variety of approaches being used but these were also delivered in different ways across and within sites. While most were paper-based, some were computer-based, most notably the algorithms in the walk-in centre (WIC), and the SOFIs (electronic protocols related to the Quality and Outcomes Framework – QOF) in the GP surgery (GPS). As will be described in later sections, computer-based delivery did impact on the way they were used in interactions with patients as compared to paper-based approaches being used within the same site.

4.2.2 What is protocol-based care?

As the term protocol-based care is relatively new and mainly confined to policy documents, we explored the meaning of it with health care professionals. Generally, and perhaps unsurprisingly, the term 'protocol-based care' is not one that was recognised. In order to elicit information from interviewees about what protocol-based care might mean and entail, researchers' shared the Modernisation Agency's definition. Following this interviewees were variously able to describe its purpose, for example standardisation, and constituent components, for example following protocols and guidelines:

It's a way of standardising care for patients that everybody gets what is considered state of the art care; it takes a way the sort of randomness that you can find in different practises and it takes away the divergence, by using protocols you're deliberately following guidelines that guide you in decision making...

General Practitioner at GPS - GPSS07

Consistently interviewees used the words 'standardise' or 'standard' when describing the purpose of protocol-based care, some also referred to standardisation based on research or evidence:

...a bunch of people get together and research it and you know get information and it's a standardised way of doing something to ensure effective care is delivered

Staff nurse at Pre-operative assessment clinic (POA) – POAN01

I think protocol-based care is care that's guided by evidence and that evidence gives you structure to deliver care

Practice development nurse at CSU– CSUS02

Some of the constituent elements of protocol-based care were also referred to, specifically protocols and guidelines. Interestingly given the breadth of standardised care approaches being used within sites, interviewees tended to describe protocol-based care as following protocols and/or guidelines, and then proceeded to describe what protocols and guidelines are.

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Generally protocols were viewed as prescriptive; something that should be followed, a check list that determines a course of action:

Whenever I think of a protocol I always have this picture in my head of a flow chart and you know you just kind of, it's like a decision tree and you just go through the whole thing depending on where the decisions take you...I think of them as more prescriptive.

Senior nurse at POA – POAS01

In contrast guidelines were viewed as being more flexible because they allowed greater decision-making latitude:

The difference is if you use the word guidelines there is more room for using your professional judgement. You have to justify it, but you can actually use your professional judgement more

Former manager at WIC – WICS03

Some interviewees described the tension between standardisation and individualisation depending on what approach they were using. For example, because protocols were perceived to be prescriptive and therefore potentially restrictive, they may conflict with what was felt to be best for the patient. In contrast because guidelines were viewed as 'something to guide you' rather than something you had to adhere to, they could be adapted to the particular circumstances of the patient or situation:

There's a subtle difference and I think it allows for the intelligence and decision making of the individual involved, because a protocol is a one size fits all and that doesn't always work.

General practitioner at GPS – GPSS03

4.2.3 Purpose of protocol-based care

As described above there was a consensus that protocol-based care aimed to standardise care. The potential to deliver a standard or a minimum standard of care was viewed as important in the context of, for example, the increasing use of agency staff, lack of experienced staff and fluctuating staffing numbers.

And at that particular time we had a lot of new staff, staff coming from overseas and a very junior level of staff generally, so I think it was something [ICP] that was put in place also to help those people to have something to follow and refer to.

Cardiac directorate manager at CSU – CSUS04

In this way protocol-based care had the potential to make explicit the particular standards of care that were expected with respect to various

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clinical conditions and procedures in specific contexts, which staff could refer to if new to and/or unfamiliar with the setting.

Additionally the potential of protocol-based care to deliver a minimum standard of care was viewed as an important purpose in its own right. This helped ensure for example, a degree of consistency when patients were handed over between staff members, teams and departments such as that seen in the pre-operative assessment clinics.

4.2.4 Summary

- In this study protocol-based care encompassed a variety of different standardised care approaches, patient conditions, and care delivery. It was difficult to ascertain whether protocol-based care is more than delivering care with the use of particular standardised care approaches. As such, when referring to data and findings the term standardised care approach(s) will be used and the term protocol-based care used more cautiously.
- Whilst interviewees were not familiar with the term protocol-based care, they did describe the purpose of it as enabling the standardisation of care.
- Protocols and guidelines were the most commonly referred to care approaches.
- Protocols were viewed as restrictive, whilst guidelines allowed more flexibility and decision-making latitude.
- Standardisation was perceived to be important in the context of staff changes and turnover, and as a mechanism to improve the consistency of care.

4.3 Development Of Standardised Care Approaches

4.3.1 Drivers for initiating standardised care approaches

There were a number of different drivers or motivating factors behind the development and introduction of standardised care approaches in study sites. A number of themes emerged across the sites, which are described below.

4.3.2 Standardisation of care

Standardisation of care and the minimisation of practice variation were reported as the main reasons for the initial development of protocol-based care tools across all sites. For example, in the cardiac surgical unit a number of different interviewees mentioned the variation in consultants' practice, which existed prior to the development and introduction of the integrated care pathway (ICP)

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I mean we have five surgeons who to all intents and purposes operated in quite a different way and that had created some difficulties for the nursing staff.

Cardiac Directorate manager at CSU - CSUS04

Additionally PBC was also used to guarantee a standard of care when developing a new service. For example algorithms (see table 13) were introduced in the WIC with the aim of developing a standard of care:

The idea of them [algorithms] was that you could kind of standardise the care that was being given to the patients in the consultation.

Nurse practitioner at WIC - WICS05

Similarly at the GP surgery, a recent merger between two primary care trusts (PCT) had resulted in a fragmented health visiting practice. In response the core pre-school Health Visiting Guidelines (see table 13) provided an opportunity to agree a minimum level of care and uniformity across the newly merged Health Visiting Service:

So we had an opportunity I think, being a new PCT, with lots of different people, to actually reflect on what was evidence based so that we could come up with, as a minimum, what we should be doing across the whole PCT.

Health visitor professional Lead at GPS - GPSS12

Standardised care approaches were also developed as a way of providing a standard of care in a context of frequent staff changes; as an approach to maintain a certain level of care. For example the integrated care pathway in the CSU was introduced at a time when temporary nurses were being often employed:

It also coincided with the time when we were just starting to use agency nurses and we were quite concerned about our standards of care and so by having these more subtle things in the pathway [.....] any registered nurse should be able to come and look after a patient.

Former ICP project manager at CSU - CSUS13

Maintaining a standard level of care in cases of regular staff fluctuation was also a driver for protocol-based care in the Pre-operative assessment clinics (POA). Some POA clinics are run by permanent nurses, however, many clinics are run by ward nurses on a rota basis; therefore nurses will only run a clinic sporadically. Junior doctors also move from clinics every four to six months. As such these clinics are being run by staff who are not necessarily experienced in the speciality. Additionally high turnover of staff is common in this site. Protocols and guidelines (see table 13) were perceived to be instrumental in maintaining a standard level of care amongst continual staffing changes with varying levels of experience and expertise:

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We have a very transient workforce [...] protocols are useful when [...] you've got a high turnover [...] so you need to give them strict guidance of how to operate.

Assistant director of Nursing at POA - POAS11

4.3.3 Improving documentation

The improvement of documentation was also perceived to be a motivating factor, for example, restricting the duplication of notes was a main driver underpinning the development of the ICP in the CSU:

I think it was – the initial, if I remember correctly was the old issue of twenty different people write 20 different notes, repetitive things, repeating things, all in different places, no central point where everybody goes and looks at it and there it is.

Head nurse at CSU - CSUS06

However, in this example the ICP did not necessarily result in less duplication. The ICP was segregated into professional groups' sections, whereby each professional would complete their 'own' documentation section within the ICP; many times duplicating notes. This was observed when a patient was being admitted to the ward. Initially, the nurse filled in the 'nursing section' of the ICP. Later on, the senior house officer (SHO) completed the 'medical section' with the patient. Many of the question areas were covered by both practitioners (e.g. medical history, life style); however, the SHO did not consult the nurses' section before doing his clerking and as a result there was repetition.

In terms of the ICP, the SHO did explain that he was following a procedure and he pre-empted the usual feeling patients have about answering the same questions endless times.

(Field notes excerpt, CSU)

4.3.4 Improvements to service delivery

New approaches to delivering NHS services

The development and introduction of protocol-based care initiatives was, in a number of sites, aimed at improving service delivery either in response to national policy initiatives or local issues. For example the WIC and the Birth Centre (BC) are examples of how new services and sometimes extended nursing roles (e.g. WIC) can be linked to the introduction of standardised care approaches. WICs are perceived to be an approach to relieving pressure on access to primary care (Maheswaran et al, 2007). WICs were developed as a nurse-led service providing information and treatment for minor conditions without the need for appointments. In this study protocol-based care (PBC) was central to the development of the services delivered by the WIC, and to the new nursing roles that emerged from this new type of service delivery:

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We were creating a completely new service [referring to WIC], an extension of NHS Direct if you like and it was a completely new concept in terms of service delivery and also in terms of nursing roles.....[...] The government set specific areas and each centre did their own protocols.

Former PBC Champion at WIC - WICS02

The care pathway in the BC was introduced when the centre opened in 2005, to support midwifery led care for women expected to have normal labour and birth. Prior to being used in the BC, it was piloted for a short-time on main delivery suite (DS). The pathway was adapted from the All Wales Labour Pathway (Fox, 2004) which was developed by a multi-disciplinary steering group in response to increasing levels of intervention during labour. All NHS Trusts in Wales have been using the Pathway to manage the care of low risk women in normal labour since 2004. The BC was established to provide more choice for women over where they gave birth and who cared for them; in line with government policy (National Service Framework, DH 2004). Care is led by the midwives and the pathway was viewed as an essential 'piece of the jigsaw' to support normal birth.

It takes a range of things to support midwives to work to provide 'normal' care, and the pathway is one of these things.

Lead for Normal Birth at the Trust, BCS03

Improving referrals

There were also examples of protocols being developed to improve communication about patient referrals. For example staff in the GP surgery and the local acute NHS trust working in partnership with the Practice had introduced the Oxford Hip Replacement Score Protocol. This protocol was intended to select patients who would most benefit from hip replacement operations. The protocol was part of the referral process. The following excerpt taken from an observation exemplifies how the protocol is used and explained to the patient (P) by a general practitioner (GP):

<GP> can you notice the difference between the knee and the hip pain?

<P> yes because the pain on the hip is been there for a while but the pain in the knee is only recent. I know have to use my walking stick at home.

<GP> would you like a new hip?

<P> I don't really want to, aren't I a bit too old for that?

<GP> not as old as some that do get it done. But I think we might need a second opinion from our colleagues at the hospital. Can you move your hip?

<P> well, getting in and out of bed is a struggle, my knee is always stiff and sore.

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<GP> I think what we'll do, is do and don't tick list that the orthopaedic team has devised to assess who should get surgery. You self assess what you can and can't do and then they see if an operation is necessary or not.

(GP – patient observation at GPS, GPSObs02)

In the WIC, the streaming protocol had been introduced to formalise and improve referrals between WIC and A&E department. The protocol clarified the conditions that could be treated at the WIC and those that should be referred to the A&E department, and vice versa.

Quality & Outcomes Framework

Additionally the Quality and Outcomes Framework, which is the annual reward and incentive programme detailing GP practice achievement results provided the motivation for much of the protocol development and use in the GP surgery. The QOF awards surgeries achievement points for managing some of the most common chronic conditions (e.g. asthma, diabetes), the amount of extra services offered (e.g. child health and maternity services), how well organised the practice is, and how patients' view their experience at the surgery. Participation is voluntary and has been in place since 2004 (The information centre for health and social care, 2007 -www.ic.nhs.uk/services/qof -). At the GP surgery existing protocols (usually paper-based) had been improved and adapted into electronic flowcharts (called SOFIs) which practitioners needed to 'tick off' during consultation:

I think QOF has driven us very hard down the SOFI line, but they've been very much in relation to QOF and I can't think of a single SOFI that we've got on a clinical area which isn't QOF. [...] We've always had clinical protocols, but it's certainly sharpened the pencil on existing ones that we've had have been reviewed and new ones have been developed.

Practice Manager at GPS - GPSS06

Waiting times

The government detailed in the NHS Plan (DH 2000a) that by 2005 the maximum wait for a hospital operation would be 6 months, falling to 3 months by 2008. As part of this drive to reduce waiting times the government invested £20 million from the Modernisation Fund (DH 1999 - www.dh.gov.uk/en/Publicationsandstatistics/Pressreleases/DH_4025308 -) to provide new equipment, booking systems and new operating theatres. As a result of this government initiative, Site 3 started to standardise its POA services across the trust. PBC tools were instrumental in attempting to standardise the service.

4.3.5 Local drivers

Whilst national drivers were important, in most sites examples of clinically driven and led developments were also reported. For example, staff in the WIC determined the need for nurses to provide treatments and initiated the development of Patient Group Directives:

Well we met the main PCT pharmacist and we said what we thought we'd need to prescribe and why.

Former PBC champion at WIC - WICS02

Additionally in the GP surgery, doctors and nurses would decide whether a particular clinical condition needed to be managed through standardised care tools:

We'd sit down and decide that we'd need a protocol for managing a certain clinical condition or the nurses or somebody would need a protocol. We'd sit down with the nurses, we'd dig up the evidence.

GP partner at GPS - GPSS03

Similarly in the POA some clinical teams would identify clinical conditions which could potentially benefit from PBC. They would then approach the ICP coordinator to support them in the development of those tools:

The clinical teams themselves can come to us and say they feel that, you know, they would like to develop a care pathway for a given condition and we support them.

ICP coordinator at POA - POAS13

4.3.6 Risk management

Reducing the potential for error was also reported as a motivator for PBC development and a mechanism by which recurrent and potential errors could be addressed and rectified:

So you know, if I felt I was compromising somebody's care because I didn't have enough time or whatever, then I should be professionally filling one of those out [risk forms].....And they do get looked at, yes. You know, and also that actually helped formulate some of these policies and guidelines [...] Particularly, if it's a recurrent problem that's happening or error that's happening..

Community midwife at GPS - GPSN06

PBC was viewed as an important tool for managing clinical risk. In some instances, PBC originated from a necessity to address complaints about poor episodes of care, or incidents where patients had been exposed to undue risks:

Developing care pathways in response to maybe high level of complaints, so it can come from corporate, there could be

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concerns from above about a particular condition and then we negotiate with the respective clinical team to say we feel an ICP can help to improve the quality, in for example the management of acute myocardial infections.

ICP coordinator at POA - POAS13

It happens through incidents as well, we've had an incident and that's been one of our responses to the incident, that we think actually we need to have this either in a policy or a guideline

PCT Head of Operations & Nursing at GPS - GPSS09

National risk management initiatives were also reported as motivators of the introduction of certain PBC tools, for example:

To be honest the driver with those [guidelines for the care of vulnerable groups] specifically was CNST [clinical negligence scheme for trusts] requirements, which we were required to demonstrate that we had guidelines in place to support that.

Community midwife manager at GPS - GPSS15

4.3.7 Financial drivers

In the GP surgery two financially driven motivators also emerged, which include incentives, and efficiency. For example the financial reward attached to QOF achievement points was a key driver for the development, improvement and use of standardised care approaches:

We had standards and we had protocols it [the introduction of QOF] just meant that we definitely get penalised if we don't do these things. Whereas before it was optional, but most practices that are trying to provide a good level of care had protocols anyway, but now with QOF you actually lose money if you don't follow the protocols.

General practitioner at GPS - GPSS07

Additionally, controlling or minimising costs and delivering a particular service in a more cost effective way, while maintaining the quality of care, was sometimes perceived by practitioners as the driving force behind PBC:

We've changed the way we work, but only to make it more cost effective [...] we used their protocol and questionnaire as a self-assessment tool for the over 75s. So then we could actually filter out those people who didn't need to be seen, because we've got a huge number of elderly.

Senior practice nurse at GPS - GPSS10

Probably the guidelines are, you know, there to reduce the cost of the health visiting service I would have thought, because the service has been cut, what we actually deliver. I would have thought with a combination of monetary terms

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and with the Hall Four guidelines, I would have thought it's both of those things together really.

Health visitor at GPS - GPSN11

4.3.8 Summary

A number of factors were identified that motivated the development and introduction of standardised care approaches in sites.

- Standardisation of care and the minimisation of practice variation were reported as the main reasons for the initial development of protocol-based care tools and approaches.
- Improving documentation and avoiding duplication was cited a driver in one site.
- PBC was developed to support service delivery initiatives by improving primary care access (WIC), decreasing waiting times (POA) and managing chronic conditions (GPS).
- On occasions PBC was instigated by local needs and led by local health care practitioners.
- Managing clinical risk and potential or recurrent errors were also drivers for the development of PBC.
- Financial rewards and controlling or minimising costs were also seen as important in the development of PBC.
- Reducing intervention in labour was an incentive for PBC development at the Birth Centre.

4.4 Approach to development

Generally, standardised care approaches appeared to have been developed in an ad hoc way, with little organisational support for individual leads.

There is quite a set pathway, that the documentation has to go through, but I learned that through experience, rather than somebody actually sitting with me and saying OK, this is how you do it, this is what you need to do, this is the way you need to lay it out, these are the various groups, these are the contacts. I kind of had to find that out as I went. Obviously there were people that I asked, but there was no strategy for it. It was me being practical and having to go out and find that information, rather than it being readily available if you like.

Pre-operative assessment lead in POA – POAS01

The development of standardised care approaches was described in a broad way by participants rather than with specific details. Data shows that resources and time were invested in the development and implementation of standardised care approaches, but not necessarily into ongoing

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monitoring, reviewing and updating. It was described in terms of who was involved, how were they involved, what evidence was used and what processes of approval were undertaken. There was no reference to specific development frameworks such as the Modernisation Agency 12 steps approach (MA/NICE 2002).

Generally, standardised care approaches were developed following a similar pattern:

1. Identifying project lead or champion
2. Identifying examples of good practice in other trusts or sometimes, countries
3. Finding best available evidence in the topic or best practice when evidence was lacking
4. Involving and influencing relevant stakeholders and expert groups
5. Undergoing the approval process
6. Implementing and monitoring

This development process was sometimes intensive lasting from a week (expert input for Blood pressure algorithm at POA) to a couple of months (clinical guidelines in WIC) to two years (complete development and implementation of ICP at CSU).

4.4.1 Project lead

The importance of having a project lead or champion dedicated to the development and implementation of standardised care approaches became evident in most sites. In the main, champions were experienced senior nurses who were ex-practitioners or still practising, had been part of the team, and were perceived as experts in the area. This meant that they tended to be respected, had authority and credibility within the multidisciplinary team.

I think the champion who introduces it is quite important... She's got a lot of credibility. [...] she was always seen as the expert in tissue viability[...] So she had very good standing among the practitioners in the PCT. So when she's introducing things like her leg ulcer guidelines and the wound formulary and she's got link nurses on board. [...] She's quite an enthusiastic person and very knowledgeable and so people were really keen.

Community matron at GPS – GPSN10

I feel that by the virtue of her post [Pre-operative assessment lead] and influence, she has managed to convince people around her, because I think she is respected.

ICP coordinator at POA – POAS13

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An exception to nurses as leads was in the GP surgery where GPs led in specific areas of care and worked together with senior nurses in the development of protocols. One interviewee commented that in his experience when medical practitioners led the development of standardised care approaches this improved the chances of use.

I've got all of the ICPs in thoracics where we've actually got a consultant who took over leading on it.

R: Does it make a difference who actually does it [role of champion]?

Yes, it's quite a palpable difference, you know. There's much more uptake and everyone gets on board, yes, yes.

ICP coordinator at POA – POAS13

In two sites (WIC and CSU) there was a full time dedicated lead developing and implementing the standardised care approaches. However this was only the case in the initial stages. More commonly project leads and champions took on this role in addition to their clinical or managerial workload.

They [champions]... they don't have extra time, they don't have extra resources, it is just in addition to their jobs. With some senior nurses, I think they do have some kind of time within their job that they have to do quality improvement initiatives like that.

ICP coordinator at POA – POAS13

When these leads and champions left their role or the unit, replacements were generally not forthcoming.

The staff attrition is another factor, where we lose champions and when we lose champions then you just find the ship sinking really so to speak.

ICP coordinator at POA - POAS13

Whereas the people who just want to keep doing what we've always done and don't want the extra work don't volunteer for things really. A lot of it is down to volunteering.

Community matron at GPS – GPSN10

A key part of the champion's role was to liaise with stakeholders and agree on the concept, content and format of the standardised care approach. This is described further below.

4.4.2 Stakeholder involvement in development

Multi-disciplinary team involvement

Involving practitioners and experts groups was reported as the most challenging task in the development of standardised care approaches. In general, the lead would work independently; developing a draft based on information from best practice in other trusts and sometimes research

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evidence. Once this has been developed the multi-disciplinary team and expert groups were usually consulted to provide advice and feedback (an exception to this was a bottom-up approach to development in the GP site discussed later in this section).

That's what tends to happen, you get the idea or see that there's a need for something and we'll put a draft together and then go to various other people who I feel should be involved, need to be involved, guidance from them and then it's more of a collaboration at that point.

Pre-operative assessment lead at POA – POAS01

Usually, the lead worked with different professional groups separately and tried to reach a consensus on what to include in the tool. This was evident in the development of the POA protocols and guidelines, and at the CSU where this separate consultation resulted in a professionally 'segregated' ICP.

In reality, you know, that [multi-disciplinary team meetings] wasn't going to work. So the approach that I took would be to work with individual teams and once the nitty gritty had been sorted out, would then be to make sure that everybody knew as to where we got to and if there were any comments.

Former ICP champion at CSU - CSUS13

An example of this compartmentalisation of professional groups' input/contribution in standardised care approaches emerged in the BC. The normal birth pathway was exclusively developed, implemented and used by midwives because normal birth was viewed as their provenance. Obstetricians were not consulted in the development of the pathway even though the transfer of women from the BC to their care at delivery suite was a possibility. Their lack of involvement had resulted in problems when women had to be transferred from the BC to the delivery suite in emergency cases.

They (obstetricians) seem unhappy that there are not big sections in the pathway to write down everything that had happened to the woman. This is one of the main problems they've raised when we've had to transfer women down to delivery suite.

Midwife at BC – BCS05

I think going back again there should be more inclusion of the rest of the organisation, and I think they (obstetricians) know about it and have become used to it, because obviously when the women are transferred down from the BC to DS they, you know, they've seen the care pathway or protocol etc, although I think generally we should have made more general awareness across the rest of the midwifery work force.

Director of Midwifery at BC – BCS02

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Patient involvement

Patient and user involvement at the development stage was not common.

Well patients would not know evidence based practice. Bearing in mind that NICE and Prodigy and stuff like that weren't around [then], I'm not saying the Expert Patient Programme isn't valid, but I think it was hard enough to find out robust research from clinical trials let alone that.[...] there was no patient involvement in the production. It was done on clinical merit really.

Former manager at WIC – WICS03

An exception to this was patient involvement in practice nursing, midwifery and health visiting guidelines at the GP site. Developers had used available patient groups (e.g. parenting forums, National Childbirth Trust (NCT) local groups, users groups set by the trust) to comment on new guidelines, with success.

We've been fortunate in that we've been able to get together a user panel of women who've used our services. There's six of them altogether, representing each of the different demographic groups that you might meet in the community and we've set up a system whereby they meet four times a year and we're able to take pieces of work or draft guidelines [...]So that they can sort of voice their view, because that's what it's all about really, meeting their needs. They often flag up things that professionals may not have thought about, what's important for them.

Community midwife manager at GPS - GPSS15

4.4.3 Challenges

Changes in practice

In most sites the development of standardised care approaches involved changes to practice. Changing practice was viewed as a difficult goal, which seemed to raise practitioners' levels of anxiety.

Any change programme or implementation people's anxieties take over. We only had a small amount of that, but you do need to explain and communicate for those that hadn't been involved in the process.

Professional Health visiting lead at PCT in GPS – GPSS12

Engaging practitioners early on was reported as an effective way to deal with potential problems. In the GP site practitioners were consulted early in the development of the Pre-school Core Health Visiting Guidelines.

I have to say the development of the pre-school guidelines in the first place was very bottom up. Although it was led by

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the health visitor professional lead at that time in each PCT, it was very much practitioner led.

Community service manager at PCT in GP site – GPSS13

A 'bottom-up' approach was perceived as a way to facilitate ownership of the standardised care approach. Health visitors interviewed reported their involvement in developing and auditing the guidelines. Discussing and debating issues early on in the process, ensured understanding and was an opportunity to resolve tensions about the use and impact on practice.

Active stakeholder engagement in development was also reported in the CSU where ongoing discussion about the ICP helped resolve practitioners' anxieties and increased chances of attaining ownership.

Communication helped in all the departments that it was not only presented, but also discussed and repeatedly discussed and as the project went on all the stages where X [project lead] was were highlighted in meetings. So that everybody could follow how far she was with the project. [...] So that the anxieties were dealt with and people were much more willing to accept and implement it.

F grade nurse at CSU – CSUS11

Buy-in

The level of ownership and buy-in to the particular standardised care approaches being developed varied across sites and professional groups. This was, in some sites, evident at the development stage. For example, the lead at CSU had to persuade medics to be involved and accept the ICP.

X [project lead] would liaise with surgeons about it, with the doctors about it, would regularly come to meetings telling us about it, so involve us in the process and it was a challenge to try to get them all onboard and not to write anymore in the buff notes for the doctors but to use this pathway to write in the pathways. [...] then of course she had to talk to the physicists, the way this pathway would work for them, to be used. There was lots of discussion and I think persuasion as well for the surgeons.

F grade nurse at CSU – CSU11

This reluctance was evident three years after implementation when a multi-disciplinary team met to discuss the review of the ICP (medical representatives had not attended this meeting), as the following excerpt shows:

The practice development nurse brings up the biggest hurdle to the ICP in his eyes: medical representation and engagement in the ICP. They talk about improving the medical section of the ICP by trying to liaise with them and find out what they want. It is mentioned that although now the medical section isn't used as it was intended it was developed by

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consultants and especially anaesthetists. But now everyone agrees that engaging them in the process of reviewing the ICP is a problem.

The clinical manager steps in and says that a negative attitude towards them is not useful and that the rest of the team should go ahead with their changes and try to liaise with consultants in their monthly meetings. They agree to raise specific issues in the consultants meetings. The discussion goes towards education of SHOs in their induction day and they agree that it's difficult for SHOs to have any ownership of the ICP because they stay in the ward for very little time.

Multi-disciplinary meeting at CSU – CSUObs111

Another example of stakeholder resistance occurred in the walk-in centre when nurse prescribing was being introduced. Nurses reported that pharmacists were resistant to the idea of nurses prescribing, and this had resulted in a protracted process of PGD development and introduction. This reluctance continued for several years.

Time

Engagement of practitioners seemed to be important for gaining ownership, as described earlier. However, in most cases practitioners were expected to volunteer and participate in developing standardised care approaches as an addition to their clinical workload.

We've been having meetings just within the working day really. You just need to schedule them in with everything else. Nobody is taking any of your other work off of you to allow you the time to do that.

Community matron at GPS – GPSN10

Practitioners reported being stretched with their clinical commitments and therefore participating in development processes was not viewed as a priority. An interviewee intimated that volunteers tended to be always the same people with a 'forward thinking attitude'.

Within the PCT there are certain people who get involved in things and it tends to be the same people. The same people get involved with different things that are going on. The people that get involved are usually the people who are quite forward thinking, aren't scared of change, quite keen to develop service.

Community matron at GPS – GPSN10

4.4.4 Evidence underpinning standardised care approaches

There were a variety of sources underpinning standardised care approaches. Mostly, protocols, guidelines and algorithms included in the study were founded on some form of research evidence, which was then adapted locally. Whilst not an exhaustive list, some examples of evidence included:

- Research articles: ICP at CSU and Antenatal care protocols at GPS

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- Research reports: Pre-school core Health visiting guidelines at GPS
- Research papers: Screening for Intrauterine Growth Restriction at GPS
- National guidelines: asthma protocol at GPS, Normal Labour Pathway
- NHS Prodigy website⁸: WIC clinical guidelines
- NICE guidelines: Guidelines for pre-operative testing at POA
- Nursing and Midwifery Council Code of professional conduct: PGD on vaccination at GPS
- NSF: Guidelines for the management of Diabetes Mellitus in pregnancy, labour and the immediate postnatal period and Pre-school Core Health Visiting Guidelines at GPS
- World Health Organisation guidelines: diabetic protocol at GPS
- DH publications: Antenatal screening for rubella susceptibility at GPS
- Expert committee reports: Drug misuse and dependence guidelines on clinical management at GPS
- Books and manuals on clinical skills: WIC clinical guidelines and Midwifery guidelines at GPS

Generally, whenever national guidelines were available these were adapted to suit local needs.

Is you've got the NICE guideline [on pre-operative assessment investigations], then developed our own slightly tighter guidelines, grey in a lot of areas, they left too much to be decided by the clinician, specific guidance, so we drew up our own.

Pre-operative assessment lead at POA – POAS01

In contrast, there was a perception that developing standardised care approaches locally was duplicating work and wasting resources

I can't understand why people are paid so much money to write protocols in every different area in the UK. Why can't there be national protocols for instance? If we're all giving oral Vitamin K, why can't we just have a national database almost or something? It just seems when you go to a different area again it's been written again by somebody else.

Health visitor at GPS - GPSN11

Sometimes, evidence was not available on all aspects of health care. In these instances, consultant or nurse experience and/or consensus and best practice were used.

⁸ Prodigy website is described as a source of clinical knowledge for the NHS about the common conditions managed in primary and first contact care. Practical and reliable, it helps healthcare professionals confidently make evidence-based decisions about the healthcare of their patients and provides the know-how to safely put these decisions into action. (<http://www.cks.library.nhs.uk/>)

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Some standardised care approaches were a simple compilation of procedures. For example the nurse in charge protocol at WIC detailed the responsibilities of triaging and managing the centre. The ambulance protocol, at the WIC, itemised a list of conditions that could be treated at the WIC. Both these examples were based on consensus (within and across services) about what was the best way to deliver care.

4.4.5 Updating

As mentioned above, the need to keep up with the development of the evidence base for practice was important for practitioners. For them it was essential that standardised care approaches were up to date so that they were useful and relevant to clinical practice:

The [morning] after pill, for a while, we, our PGD said that we still had to supply medicines one to be taken immediately and then one twelve hours later but actually in terms of the national guidelines, they have been changed and you could give two pills stat...so if you were a nurse prescriber you could give anybody two pills stat but if you were following our PGD, even though it was old and out of date, you had to do the twelve hour. I mean both had similar results except that probably people might forget the other one.

Nurse consultant at WIC – WICS04

Usually, the updating process was lengthy as several groups needed to authorise changes. Also it was sometimes not possible to update them due to lack of resources (e.g. lack of a lead).

I know that we've got district nurses and practice nurses and some really good nurses that go beyond their remit and get involved with writing or working towards aspects along these lines, but really you need somebody in a post like mine really to do these sort of clinical aspects.

Tissue Viability nurse specialist at GPS – GPSS14

4.4.6 Implementation

Data shows that in all sites, a considerable amount of effort and resources were invested in the implementation of standardised care approaches. Typically, leads would be responsible for initiating the introduction of a particular standardised care approach through uni-disciplinary or multi-disciplinary meetings, training sessions, workshops and event launches.

We had a big launch at a venue in X that the neighbouring trusts came to as well and I did a presentation of the guidelines, what the changes were, what it incorporated and the pathway [Leg ulcer pathway]. We had them printed and bound [...] so that was distributed together with leaflets and an assessment form. That was very well attended; we had about 120 nurses and practitioners over the whole day.

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Tissue viability specialist nurse at PCT in GPS – GPSS14

The introduction of the ICP at the CSU appeared to have been particularly successful. The lead gradually implemented the ICP over a two year period. Training sessions for junior doctors and nurses were initially planned and new members of the staff had one-to-one sessions with the project. The gradual introduction also involved an ongoing audit and regular meetings with staff where necessary changes and action plans were discussed.

Some of that [implementation] may well be within that two years timeframe. Because I think there were certain guidelines and so on which the lead was able to introduce at different stages, so she didn't wait, probably quite intelligently didn't wait to get the whole thing together as a complete package or pathway at one time. There were certain bits of it that she could pick off at certain stages. Yes, so you know, guidelines around some of the medications for example, they were able to be introduced into practice perhaps a bit ahead of the whole pathway coming out.

Cardiac directorate manager at CSU – CSUS04

Similarly the initial implementation of the algorithms in the WIC consisted of a mentoring scheme and specific training on the IT system with the lead.

I mean when I think back from the beginning we had one particular nurse [lead] that was there that, her role was also to do with the CAS [clinical assessment system - algorithm] training and training up newer nurses when they came on board.

Nurse practitioner at WIC - WICS05

In addition, most standardised care approaches would be sent (via mail or electronically) to practitioners to create an individual or collective resource.

However, after this first impetus the dissemination of the existing standardised care approaches seemed to slow. For example, three years after the introduction of the ICP at CSU the lead had moved on and the ICP was simply introduced to new doctors and nurses as 'paperwork' with little or no reference to the underpinning guidelines. This was also observed in the GP site where the leg ulcer pathway was described as 'paperwork':

You know, in a lot of places when you start a job, you're sort of taught the task say, but then you know there is a protocol or you're shown the paperwork to go with it. So that you work through, like a sort of formal piece of paperwork, like in the leg ulcer pathway.

Staff nurse at GPS – GPSS11

A particular difficulty in disseminating standardised care approaches was observed in the POA clinics where there were frequent staff changes. Paradoxically, standardised care approaches aim to minimise variation in this kind of clinical settings. Most clinics were run by temporary nursing

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and medical staff, therefore the availability of standardised care approaches where clinical supervision and experience was not always available could have been a benefit. However, as the data shows, it was difficult to keep the frequently changing staff aware of their existence; many of the interviewed staff were unaware of the existence of the standardised care approaches. The lead tried to inform practitioners through multi-disciplinary meetings, emails and face to face contact; but she ultimately relied on nurses in the clinics to raise awareness, which was not always successful.

We kind of rely on the people who work in the clinics to just say these are the guidelines that we work to. It is a huge problem [...] because I don't have the time to just keep going and repeating everything. It really does rely on there being somebody in each pre-op clinic who is there consistently so that they can keep raising awareness to the new staff as they come through. In a lot of areas we don't have that.

Pre-operative assessment lead at POA – POAS01

An exception to maintaining an effective introduction of standardised care approaches were the patient group directives at the WIC. At the time of their introduction in 2001, PGDs were linked to a rigorous examination process. In 2005, PGDs had been incorporated into nurses' competencies assessment.

It's taken me nearly the whole five months to be signed up for these [PGDs], but now I am, yes. So I've been watched and had to give explanations and I've been taken through competencies. [...] and then we get sent on a PGD study day at the beginning as well, so it means that they're taking it all seriously, yes.

F grade nurse at WIC - WICN07

A rigid and structured implementation and dissemination strategy was attached to the PGDs with the pharmacy department undertaking regular audits and providing training sessions when deficiencies were identified. In April 2005, an internal audit of antibiotic use and supply on PGD found that some nurses were prescribing outside of the terms of the PGD. Its recommendations included:

- Remind staff of the importance of documenting a full drug history, allergy status, details of the consultation and an accurate and legible record of supply
- Educate all staff on the legal and clinical requirements of PGDs
- Increase opportunities for training and competency assessment in line with Trust PGD Policy
- Investigate all consultations not meeting the legal requirements of a PGD and/or which may have compromised patient safety.

The PGDs were the only mandatory standardised care approach observed in this study; so whether this is related to the strict implementation regime or the fact that their use was mandatory is difficult to ascertain.

4.4.7 Summary

Findings about how standardised care approaches were developed showed that:

- Generally, standardised care approaches were developed in an *ad hoc* way without reference to specific development frameworks but following a similar pattern.
- Project leads or champions tended to be experienced senior nurses, with the exception of medical leads in the GP site. Their role seemed to be instrumental in the successful development and implementation of care approaches.
- In general, the lead would work independently consulting practitioners and experts' groups at draft stage (patients were generally not consulted).
- Actively involving stakeholders was reported as a challenge, particularly in achieving a consensus of what to include in the care processes. Different professional groups were consulted separately resulting in compartmentalised input, and, inevitably 'segregated' tools.
- Data show several challenges which needed to be managed in the development process: anxieties about changes in practice derived from standardised care approaches, lack of time to collaborate in development and difficulty in attaining ownership; this was particularly the case with medics and pharmacists where the leads were nurses.
- There were a variety of sources underpinning standardised care approaches, however most were founded on some form of research evidence (national guidelines when available) which was then adapted locally.
- Practitioners emphasised the importance of keeping up with the development of the evidence base for practice, however it was not clear if and how they did this.
- Data shows that resources and time were invested in the development and implementation of standardised care approaches, but not necessarily into ongoing monitoring, reviewing and updating (with the exception of PGDs).

4.5 Impact Of Protocol-Based Care

4.5.1 How standardised care approaches were used

As previous sections show, the nature and purpose of protocol-based care was described by participants as an approach to standardising care. The following section describes how standardised care approaches were actually used within practice settings.

Overall, the use of standardised care approaches across all seven sites could be described on a continuum ranging from implicit to explicit use (see Figure 2 for examples). For example there were instances where during their interactions with patients nurses (and doctors) explicitly referred to protocols (see Table 14 for examples). The use of the algorithms (for various conditions including for sore throat, rash, urinary tract infections) in the walk-in centre is illustrative of this. The algorithms were computer

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based and when nurses were referring to them they tended to do so alongside patients; talking the patient through the various stages of the algorithm via the computer screen. In contrast, there were many occasions where it was not obvious that available standardised care approaches were being used to explicitly guide care. For example in the POA clinics whilst there were protocols for ordering patient tests, nurses did not always refer to them, but used principles from them to apply to particular patients; justifying why they had not used the protocol in those instances.

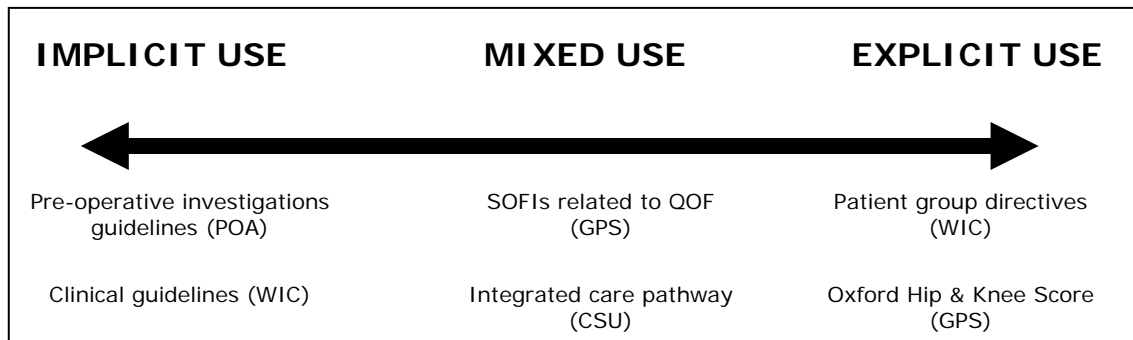


Figure 2. Examples of how standardised care approaches were used

Table 14. Examples of explicit use of standardised care approaches

Site	Example of standardised care approach	How it was used
CSU	Pre-operative checklist included in ICP	Nurses and patients go through a list of questions together before surgery to make sure the patient is ready.
WIC	Algorithms	Nurses tended to refer to algorithms with the patient during consultation to check that nothing had been missed. They could also be part of the patient notes and computer-generated advice for particular conditions can be printed off and handed to the patient.
POA	Protocols and guidelines	Nurses would sometimes consult a table on long term medication to advice patient what medication needed to be continued or discontinued on the day of surgery.
BC	Part 1 of Labour Pathway	Midwives would discuss with women how their care would progress if they were in active labour following the first consultation.
GPS	Oxford Hip and Knee Score	GPs always discuss with patients the need to complete the score before to assess their suitability for surgery before referring them to the orthopaedics department

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		for assessment.
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Both the implicit and explicit use of standardised care approaches manifest in the following ways.

Check list and reference

Consistently across the case study sites nurses used standardised care approaches as checklists and a reference source; prompting what they need to do next, how, or as a check post shift or procedure. This finding emerged from both observation and interview data. For example:

They're like checklists for their care, a patient who's had a C section all the info you find is ticks in the checklist. Individual care plans, how can they be individual if you have the same format for everyone, this is in line with NICE guidelines 2004.[...] It seems that it's more regimental, you slip into going through the checklist and miss out important things. We use to work from top down, psychological state, diet, breastfeeding, etc.

Midwife at GPS – GPSS04

Sometimes these checklists were used during interactions with patients:

She introduced the algorithm to the patient by saying she was going to check in here – the computer – whether she'd overlooked anything. She asked questions about rash, head trauma, which she hadn't asked before – so it could be said she was using it as a checklist to make sure all avenues were explored.

(Field note excerpt, WIC)

In contrast, nurses described referring to available standardised care approaches after a procedure or more commonly at the end of a shift:

I would say most of the time it's supposed to be done in the middle maybe of the shift, but most of the time it's done maybe after the shift, when you want to check.[...] When you're ready just to cross-check to see you've done everything you're supposed to do for the patient for that day or for the shift... it just prompts me as to things that I haven't done.

Staff nurse at CSU– CSUN04

As the above indicates, frequently nurses described this as a way of ensuring they had not missed any thing. Some doctors also recognised the utility of a checklist to ensure issues were not overlooked. Consequently the standardised care approaches were also acting as memory aids.

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They're [pre-assessment guidelines] very useful in ensuring that the significant interventions are not missed, like an aide memoir if you like.

Senior nurse at POA – POAS13

The use of the approaches as checklists sometimes helped nurses organise care, what to cover in interactions or the shift. Whilst this was recognised as a benefit by some senior staff, there was a perception that this was useful for junior staff:

It [care pathway] gives them a framework...with some junior staff it does give them a framework to work around.

Senior physiotherapist at CSU– CSU05b

It [care pathway] is a structure and it helps me not to forget anything that I need.

Senior House Officer at CSU – CSUS01

I think for example the first part...when you look at the pathway and there is the questions 'is the women in the latent stage, is she in established labour' it's really easy to plan...it gives you a firm plan of how to look after the women and what you next step should be.

Midwife at BC – BCS01

Interestingly these comments, which were made by various multi-disciplinary staff members, were from the two sites using a care pathway (coronary artery bypass surgery pathway and normal labour pathway). It may be that more broadly scoped protocols provide a useful framework to work within, rather than a prescription for care.

In addition to providing a check list to ensure nothing had been missed, standardised care approaches were also used to ensure processes and procedures had been done correctly; as a reference. Nurses described having something to refer to gave them confidence that what they were doing or had done, was correct.

Well, the guidelines are there to follow; if they were not there it would be difficult to see what is wrong and what is right. For example, if you didn't have the guidelines and parameters to interpret bloods when they come back from the lab then you wouldn't know what to do.

Staff nurse at POA– POAS10

Similarly if there was a disagreement, or practice was being questioned by colleagues, nurses would report referring to available standardised care approaches as sources of information to confirm that what they were doing was according to the protocol.

If there was a disagreement or if people were working differently then you have got that kind of prop to fall back on

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and say well no, actually the protocol says this or this says this or we shouldn't be doing this or we should be doing this.

Treatment staff nurse at GPS– GPSS11

Tick box mentality

Whilst the idea that standardised care approaches were useful as checklists to prompt, jog memory or organise care, there was a negative perception that using them in this way could also encouraged a tick box mentality to practice. This perception was voiced by doctors and nurses across sites.

But I think that all that ticking makes people focus on the proforma more than anything else. They don't think outside the box, something you can do when you write your notes.

Junior Doctor at POA - POAN02

I could say it was like a tick box but I would practice differently in that I would be looking at the patient and saying OK what's all your symptoms and obviously writing my history on the screen and maybe going to the algorithm.

Nurse practitioner at WIC, WICS02

However whilst there was a concern about standardised care approaches being restrictive, nurses reported continuing to use their clinical judgement even when they were referring to or using such tools.

I mean we follow protocols for things like all our chronic disease monitoring because there are set things we need to do to ensure we've got our QOF points really... it's like a tick box exercise really..but when you actually do them with patients you need to be able to think on your feet and as long as you've got a good rationale for the reasons why you may deviate from what you've done before, I think that's all right.

Community matron at GPS, GPSN10

We were able to over-ride the system [algorithm] but we had to stipulate why we didn't follow it. You still have to use your clinical skills and understanding of a condition. Because anyone can read what algorithms ask and advice but only a nurse is able to interpret what is written and what she sees in the patient.

G grade nurse at WIC, WICS02

Both these examples demonstrate that nurses, if they did use their clinical judgement in particular situations, would need to provide a rationale for doing so.

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Learning tool

There were also reports of using available protocols as learning tools. This appeared to be particularly relevant in the case of students, new or newly qualified staff.

I think it's extremely useful for people like our newly qualified members that come into the area, our people we newly appoint to teams and they're fantastic for that sort of reason.

Professional Health Visiting lead in PCT at GPS - GPSS13

It was felt that they help staff because they give them an idea of what is expected in terms of care delivery and standards in that particular setting. In some sites the particular standardised care approaches available for use were included in induction materials and processes (e.g. the integrated care pathway was introduced as the required paperwork at CSU and the patient group directives were part of the competencies' assessment in the WIC)

Internalisation and experience

Some of the above evidence begins to highlight the role that clinical judgment plays in decision making and the role it plays in how standardised care approaches are used in the reality of the practice setting. Standardised care approaches were believed to support rather than remove the need for practitioners to make judgements; both nurses and doctors expressed this view. Additionally, the role of experience also emerged as important, and is clearly linked to making appropriate judgements. For example a midwife using the normal labour pathway commented:

It gives us leeway to rely on other midwifery skills like observation. You get to learn more about how women are in different stages of labour.

Midwife at BC, BCM02

The idea of learning and developing experience was a common thread in data from all seven sites (see section 4.7 for more information on impact on decision making). When staff were new to the clinical setting, or newly qualified they would tend to frequently refer to the available standardised care approaches, as they became more familiar with them and more confident, they would either stop referring to them or only refer if they were presented with an unusual situation.

The algorithm was a new thing to me when I first started here so I was quite mechanistic in terms of following it, clicking on all the buttons [computer based]. So after a while I got very familiar with the algorithm and then it's all making sense and I don't click it so much.

Senior nurse at WIC – WICN05

Some nurses described this process of learning and familiarity as 'internalisation'. This process of internalisation may also account for what was described above as the implicit use of standardised care approaches.

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Nurses may not be explicitly using the various approaches and tools available to them, however with practise and learning over time, the contents become embedded and so implicitly available when practising; as this excerpt shows:

If this admission [done by an E grade] is compared to X [admission done by student nurse] which was also an admission, you can see the difference in style and amount of information which is given to the patient. [...] I realised that what nurses have informally been telling me is logical and true. They go through the pathway in almost everything they do but only use it physically when they need to seek information from the patient which needs to be recorded there and then (e.g. pre-operative checklist or discharge planning). At the beginning of this observation I thought that the ICP was only being implemented when the nurse was writing in it or asking questions from it, but all of her interaction was guided by it.

(Field note excerpt, CSU)

It was also suggested by more senior nurses that part of being senior is anticipating the sort of questions and issues that are contained in protocols and guidelines, that is, they should know the information contained in them by virtue of their experience.

4.5.2 Summary

Generally there was a consistency across sites concerning how standardised care approaches were used; their use could be described as being on a continuum from implicit to explicit, which included:

- as a check list to prompt what to do next and/or how to do it, or as a check that everything had been accomplished.
- Sometimes these check lists were used during interactions with patients or after procedures, but more commonly tended to be used at the end of the shift to ensure nothing had been missed.
- Practitioners highlighted the danger of using standardised care approaches like checklists as encouraging a tick box mentality.
- Whilst some doctors and most nurses recognised the utility of having an available 'check list', there was a recognition of the need to use standardised care approaches in conjunction with clinical judgement.
- New, newly qualified staff and students were felt to benefit most from protocols and their variants, to that end in some sites they were included in induction and education materials.
- Standardised care approaches were believed to support rather than remove the need for clinical judgement.
- Using and becoming familiar with the various tools and approaches was referred to as internalisation, which may have accounted for nurses' implicit use.
- There was an expectation that more senior nurses, by virtue of their experience, should already know the information contained in such tools.

4.6 Impact on Nurses' Role

The development and introduction of standardised care approaches had impacted on nurses' roles in two main ways; enabling the extension of traditional nursing roles and related to that, autonomous practice (see Table 15 for examples). These findings emerged from data collected in the walk-in centre, pre-assessment clinics, birth centre, GP surgery and diabetes clinic.

Table 15. Examples of impact on roles

Site	Standardised care approaches enabling role extension
WIC	The clinical guidelines and algorithms facilitated the development of nurses' skills in examining and diagnosing. The patient group directives enabled them to extend their role to treating patients without the need to consult GP colleagues to obtain prescriptions. Nurses expressed pride that the WIC was a nurse-led service.
POA	The pre-operative assessment guidelines and protocols helped run nurse-led clinics enabling nurses to make decisions about what tests to order, how to interpret results and ultimately to make decisions about fitness for surgery.
BC	The normal labour pathway supported the development of a midwifery-led service for healthy pregnant women.
GPS	Protocols enabled nurses independently run clinics on the management of chronic diseases such as asthma, diabetes and hypertension. These nurses would be responsible for diagnosing, monitoring patient status and recommending GPs appropriate medications to be prescribed.
Diabetes Clinic (ethnography)	Protocols facilitated clinical nurse specialists to run clinics and performing tests and procedures independently.

4.6.1 Role extension

Standardised care approaches had enabled nurses to extend the roles that they had been traditionally trained for by taking on new tasks and developing new skills. This was particularly evident in nurse-led clinics and units such as the walk-in centre, pre operative assessment clinics, and GP surgery. The development of protocols, pathways and guidelines had facilitated nurses taking on roles such as diagnosing, prescribing, ordering tests, deciding on treatments, which meant that nurses were able to run clinics independently. Furthermore, as described earlier, the development of the midwifery led service in the birth centre was partly facilitated by the introduction and use of the normal labour pathway, which supported midwives' role.

I can ask for an ECG [electrocardiogram] regardless of what the doctor thinks because it's in the guidelines. It's up to me

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to decide what tests need to be done whether it's a Chest X-ray, ECG, lung function. I can do that.

F grade nurse at POA - POAN08

You couldn't run the clinic without them [protocols]... it ensures that the standard of the clinic, because anybody could run a clinic, but you've got to know exactly what you're doing and what things you have to do.

Senior practice nurse at GPS - GPSS10

Nurses in the walk-in centre were prescribing using patient group directives (PGDs). A nurse manager described the development of the nurse-led walk-in centre and how, over time nurses had begun prescribing:

The time when I was working at the WIC we were creating a completely new service, an extension of NHS Direct if you like and it was a completely new concept in terms of service delivery and also in terms of nursing roles...When we started staff didn't have the competencies as they have today because the role of nurse practitioner didn't exist then...We were seeing patients diagnosing but we couldn't treat we had to refer to the GP for prescription. So we wanted to be able to prescribe the most effective medication for the minor illnesses..... it was good if you were new to treating patients from start to finish.. without having to refer to doctors for them to write prescriptions alone...The introduction of PGDs was good because nurses didn't need to refer patients to them so they were able to move things smoother and GPs didn't have such a large case load.

Former PBC champion at WIC - WICS02

As the above quote demonstrates, the ability to be able to prescribe through PGDs also impacted on service delivery in that nurses were able to see patients from diagnosis to treatment without having to refer to a doctor. Whilst GPs were available at every shift for patients who were not easily diagnosed or to prescribe those medications PGDs did not cover, the fact that nurses were able to prescribe in many cases ultimately relieved doctors' workload.

The perceptions of participants was that role extension, through the use of standardised care approaches such as protocols and PGDs was a positive thing because they did enable more seamless care for patients and it gave nurses autonomy by supporting their role. Clearly these findings, and those described in the following sections also have implications for nurses' professional identity, which are discussed in greater detail in section 5.4.1.

4.6.2 Autonomy

Nurses described their ability to practice autonomously as a positive benefit.

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When I look back it was a bit scary in the beginning, you know as everyone would be looking to see how the birth centre took off and if we could work independently of the main delivery suite...so I think it [the pathway] did help me.

Midwife at BC - BCS05

I think what attracted people to the Walk in Centre was that it was a new service, very exciting, that they felt that they could work autonomously, that they could push their professional boundaries, that they weren't always allowed to do in other settings.

Former manager - WICS03

It is difficult to report whether it was the standardised care approaches that facilitated autonomous practice, or the practice environment that supported nurses practising autonomously. In the sites in this study, nurses were able to practice autonomously because of their role (they tended to be more senior, and/or be independent practitioners - e.g. clinical nurse specialists, midwives and health visitors) and because services were nurse-led. The development and introduction of standardised care approaches facilitated the enactment of both nurse-led service delivery and provided nurses with protection to work outside their traditional scope of practice.

4.6.3 Litigation

In those examples where nurses' roles had expanded beyond the scope of traditional nursing practice, standardised care approaches were viewed as a 'safety net' against any potential litigation. If things go wrong, having demonstrated following the protocol provided a back-up, and if required, legal protection. This was a common perception amongst many nurses who were interviewed.

I think it [guideline] helps me because you need a guideline for safety reasons. Otherwise you can make assumptions which are not correct, the guidelines are there for everyone to follow so we all do the same. [...] at a time we used to be able to sign forms but as it is a legal document and taking blood is an invasive procedure we're responsible for that. I like to follow protocols because if I make a mistake no-one will back you up but you can always refer to the protocol.

Staff nurse at POA - POAS10

Documenting you can say as per protocols and as per guidelines, that backs you up if ever anything went to court...it's a safeguard really.

Student midwife at GPS - GPSN07

There was a sense that nurses were more open to liability when they practised with greater autonomy. Additionally nurses described feeling that following these tools gave them an assurance, and therefore confidence:

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that what they were doing was correct or appropriate not only for themselves, but for the safety of patients.

From a safety point of view...these policies should be written on best practice and if someone deviates from them then I want to know why, because otherwise you're putting the woman at risk.

Community midwife at GPS – GPSN06

However one participant felt that protection was an inappropriate motivation:

They're being used incorrectly here. They're used as an excuse to protect incompetent nurses; protocols don't give competence but confidence.

Acting lead nurse at WIC – WICS06

4.6.4 Confidence

As the above indicates nurses also reported that using standardised care approaches gave them confidence;

We were guided by the pathway, but it makes you feel confident because it gives you an idea what to do.

Staff nurse at CSU – CSN07

However it tended to be more junior nurses that articulated this benefit, or senior nurses suggesting that this was more of an advantage for junior staff than senior. Additionally some junior doctors reported this advantage:

You feel much more confident if you've got something there to refer to.

House officer at POA – POAS03

However there was also a counter argument to confidence building, which was that standardised care approaches could provide a false sense of security. This was expressed by the minority of participants who were doctors:

It removes the need to look at the patient and also provides a false sense of security. That's the reason why I don't adhere to it [care pathway].

Consultant at CSU – CSUS09

They can perhaps give you a false sense of security because at the end of it you kind of think everything is fine, when in fact there might actually be something quite serious, but it's just not come up.

General Practitioner at WIC – WICS09

4.6.5 Summary

The impact on nurses' roles with the introduction of standardised care approaches was important:

- Standardised care approaches had enabled nurses to extend the roles for which they had been traditionally trained.
- The use of protocols, pathways, algorithms and PGDs facilitated nurses diagnosing, ordering tests, prescribing and deciding on treatments.
- The extension of nurses' role had the potential to streamline care and reduce doctors' workload by taking over specific tasks and jobs.
- Standardised care approaches were perceived to provide legal protection for working beyond the traditional scope of practise.
- Nurses derived confidence from using these tools and approaches; however it was felt by a minority of doctors that this could also lead to a false sense of security.

4.7 Impact on decision making

The following sections describe the main findings from the focussed ethnography that specifically evaluated the impact of protocol-based care on nurses' decision-making. Additional findings from this ethnography are integrated in other sections of the findings chapter.

The research was conducted in two sites: a diabetes outpatient clinic and a cardio- thoracic unit (see section 4.1.2 and Appendix 2 for fuller description). The *primary* data collection method in both sites was 'observer as participant'. Essentially, this meant that the researchers spent extended periods of time in each field site, recorded observations, talked with staff and patients during observation and visits, followed journeys, explored differing contexts (from training sessions to patient consultations) listened to language used, noted tones of voice, noted rivalries and social interactions.

In the clinical practice setting decisions were observed to be a frequent part of the daily lives of nurses. Standardised care approaches, on the other hand, had to be explored more specifically as their use was not always obvious. As such, their use was more often discussed in audio-recorded semi-structured interviews and reflections on observations. Field notes were recorded in diaries where appropriate, however occasionally note taking during observation was not possible where intrusions upon a certain situation was not desirable, in these situations writing up of notes took place after observation and outside of the clinic area. The following describes the findings that emerged from the data of both sites, where there are differences between sites, these are noted.

4.7.1 Nature of decisions and decision-making

In order to provide a context to understanding if and how standardised care approaches impacted on decision making it is important to provide a general

sense of the nature of nurses' decision making in these two sites. Data show that the variety and number of decisions made by nurses during the period of observation was large. Decisions varied according to many differing and interacting factors.

Broadly, decisions ranged from medical and treatment decisions, for example specialist nurses making decisions about whether patients needed to have a day in a ward having glucose tolerance tests, or a change to the dosage of their insulin (in the diabetes outpatient unit), to time management decisions, such as nurses using certain short-cutting and time-saving heuristics (across both sites). The diversity of the types of decision making necessarily means that often decisions were complex including social as well as health related dimensions. For example one nurse in the diabetes unit used her prior knowledge of a particularly uncommunicative patient's family to ascertain how she would tackle a piece of information gathering related to the young patient's health. She then interpreted this information based on prior knowledge of the ways in which both the patient and mother answered questions, and then finally decided how to give information and advice to the patient. In this example there was a complex interaction of multiple elements, including knowledge of the patient and family, health and social factors, and the use of communication and clinical skills. Additionally, across nurses' practice in both sites, the distribution of decisions that nurses make was uneven. For example, quiet periods involved very few (obvious) decisions and nurses may have used the time to catch up on paper work or other routine work. Busy periods involved multiple decisions in a very short period of time, for example during cardiac arrest situations in the cardiac medical ward.

In the reality of the clinical practice setting the nature of nurses' decision making in both sites was bounded and influenced by many factors; including the potential of standardised care approaches. In both sites there were a variety of standardised care approaches available for use in decision making.

4.7.2 Types of standardised care approaches used

Data shows that nurses' decision-making was variously informed by formal and informal protocols. For example, a number of formal protocols were available in the cardiac medical unit, including:

- Integrated Care Pathway
- Cardiac Mobilization program
- Diabetic Care Plan for Cardiology/Medical Patients
- Radistop protocols
- Additive Information for MRSA care plan
- Treatment of Colonised infected Skin Lesions
- Treatment of MRSA positive patients
- Primary PCI Process Map
- Cardiac Rehabilitation Primary Angioplasty sheet
- Primary Angioplasty follow-up sheet

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- PTCA/STENT Care Plan

and in the diabetes outpatient unit:

- Guidelines for treatment of hypoglycaemia
- Guidelines for glucagon tolerance test
- Guidelines for glucose tolerance tests
- Sick day rules
- Screen for abnormal glucose tolerance in pregnancy
- Guidelines for treatment of diabetic foot ulcer
- Trust's diabetes clinic pre-assessment sheet
- Impotence questionnaire

In reality nurses also referred to internal and informal protocols. For example a lipid clinical nurse specialist in the diabetes clinic had written a practice manual that she had developed for her own use (no one else in the department had read the manual). There was also a perception that locally developed internal protocols were more useful than those developed by external agencies. For example a staff nurse in the cardiac medical unit commented that *'the protocols that come from external sources don't give any information about the procedures except what to do. The ones written by nurses in the hospital include not only what, but why.'* (Linda⁹)

Additionally in both sites nurses used unspoken rules of thumb and local ways of working as informal protocols. For example in the cardiac medical unit local ways of doing things were an important part of a nurse's acculturation to the hospital setting. One new nurse said she tended to do things the way other nurses around her did things, saying that *As long as it is not wrong it is important to adapt to local customary ways of working* (Nancy). Additionally in feedback sessions nurses described feeling 'deluged' with protocols making it practically difficult to use everything available. In this context, most senior nurses stated that the protocols which were 'internal' were more respected because they were relevant to the everyday realities of practice.

How informal and formal standardised care approaches were used is described in the following sections.

4.7.3 Impact of standardised care approaches on decision-making

Whilst access to sites was negotiated based on the site's reported use of various protocols in practice, data from this ethnography show that across both sites nurses were rarely observed referring to 'formal' standardised care approaches. Nurses reported their reliance on multiple sources of information in decision-making, the potential utility of protocols, the actual use of protocols, and the factors that mediated their use. These findings are described below.

⁹ Pseudonyms used

4.7.4 Sources of information informing decision making

As described earlier, nurses' decision making was informed by a variety of factors. The knowledge and information that nurses' used to inform their decision making in this study were varied including intuitive, clinical and social and human factors.

'Instinct'

In discussion with a senior practicing nurse in the cardiac medical unit the researcher asked whether there were any tools that nurses rely on when they make decisions:

Instinct definitely. Definitely instinct. Instinct, knowledge, experience and also support from colleagues as well have a great impact. Sometimes when you make a decision you just need somebody just to say, yes, that is the right thing to do. You know it is the right thing to do but you just need somebody else to say yes. Yes that is right, just as back-up really. Also some sort of written guidelines or so just to what you should be doing. Gut instinct also. Most of our experienced nurses will say: I have a bad feeling here....

Di – nursing sister – cardiac medical unit

As this nurse indicated, the reliance on 'instinct' was something that came with experience. Often the senior nurses made it a point to explain that nurses, particularly those with less experience, should pay close attention to the slightest changes in patients. The clinical records reflect conclusions and decisions based on watching, looking and seeing, i.e., 'observations.'

...the senior nurses... they are the ones that seem to know instinctively when something is not right, but I would say the younger ones, the newer qualified ones, they rely on obs and stuff.

Margaret – health care assistant - cardiac medical unit

An example of the potential importance of observing patients was evident in the following example captured during observation: Susan (a senior nurse in the cardiac medical unit) was insistent that a doctor examine a particular patient because she felt something was not right with his pacemaker, however the patient seemed fine to the doctor. The doctor asked for tests after much persistence by Susan. Tests revealed abnormalities and he apologised for not responding more quickly to her concerns. She said she could tell something was wrong because the patient was too quiet and not "himself".

Interaction with colleagues

There was also a reliance on interactions with colleagues for information to inform and/or support decision making (rather than standardised care approaches). Generally nurses referred to more experienced nurse colleagues for information.

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At some point we probably all will look [at the protocols and guidelines], but I would say it is probably weeks, if not months, that I personally will go and look in there and probably an awful lot of the nurses here and it is probably the more newly qualified nurses will tend to come to the more senior nurses and ask their advice rather than go to the policies and things like that.

Georgia – senior nurse - cardiac medical unit

Within the diabetes clinic, whilst most nurses were more senior than those in the cardiac medical unit (see staff participant characteristics Table 12), the issue of having and using experience in decision making was also evident, for example:

No, there's no guideline. I can't guarantee, hand on heart, that if a junior nurse had seen Mrs S that they would have taken the same [lowered her insulin]. No, they may not have. I can't say that, I'm not sure, but I know that if maybe a senior doctor had seen them, I would hope that they would also have looked at the whole of the situation and said this may potentially be an unsafe situation. The difference being with – because I've actually taken some precautions that I'm actually going to bring her back, whereas if I wasn't as experienced.....I could look at that and say I don't need to see her for a year, she's got perfect diabetes control, but I know that's not perfect.

Gemma – specialist diabetic nurse - Diabetes unit

However alongside the reported reference to more experienced colleagues for information, some nurses suggested that experience may not necessarily mean safe or appropriate care, and that practice should be informed by protocols:

Because even if the person is experienced, they may not be following correctly the guidelines, so to be safe, it would be better to have the protocol alongside.

Joanne – pre-assessment nurse - diabetes unit

As the above indicates the primary approach to knowledge exchange and acquisition in both sites was person to person. Observation data also supports this finding. Nurses tended to discuss decisions with each other, to confirm appropriate decision making; as a type of 'informal audit'. Decision making was a social activity, especially during a shift with nurses of mixed experience and knowledge. In this context referring to a protocol was a last resort because it took time, and nurses found it quicker to talk to each other.

Patients

In the diabetes unit nurses were also using information gained from patients as a source of evidence in decision-making. As staff in the unit

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were caring for patients with a chronic condition, patients were, in most cases, not visiting the clinic because of an acute or immediate need. Nurses' decisions were rarely linear from a diagnosis to treatment, which meant nurses' decisions were rarely formulaic. They were caring for patients in the context of a sustained relationship which had generally been developed over time. As such, the interactions that took place between nurses and patients primarily focussed on information gathering and sharing; for example:

R: I'm also interested in the amount of information which Jackie told you, which was just tons. She told the stories.

Florence: all the nurses will tell you the same, it's like going to see a hairdresser, so if you do have problems and I think this is the only place for a patient to relax. If you allow them sometimes to give you information, you give them information they give you much more. This is the principle I work on. So sometimes they do talk and if they do have problems, maybe there's nobody they can talk to when they come to the nurse.

Florence – specialist diabetic nurse - Diabetes unit

This point was also reiterated in the feedback session where specialist nurses explained that they shared knowledge amongst them about specific patients, which had often been built up over a number of years. This meant that often certain patients were encouraged to see certain nurses in order to utilise particular social or cultural skills and knowledge.

In this site patients' experience was used as one piece of the evidence in decision-making:

You know, the patients know themselves, especially when they are going to go hypo, they know the level from where they'll start feeling sort of.....it was normal, but to him it's not because he know that when he gets there that it's not good for him.

Joanne – Pre-assessment nurse - Diabetes unit

This finding also relates to the influence of the context of decision-making, which is explored in more detail in section 4.7.6 below.

Nurse and doctor decision making

At the time of data collection in the cardiac medical unit there were a number of junior doctors with only one or two years' experience. Observation of ward activity and team dynamics indicated that the 'nursing' team consisted of nurses and to some degree; the less experienced doctors. Junior doctors relied on the nurses for insight as much as the nurses relied on them. The decision making processes with teams of relatively new doctors and experienced nurses took on an organic quality in that they emerged from their developing relationships and interactions. Although emergency situations, such as cardiac arrest, relied on decision making within the hierarchy of prescribed roles. In most cases the collaborations

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relied on mutual respect for each others' knowledge and experience. In contrast the more experienced doctors seemed to ask nurses about how patients were doing, but they took more control and consulted less before making clinical decisions. According to the nurses patient care decisions in this site tended to be made collaboratively:

Our decisions would be probably in collaboration with the medical teams. In the mornings when the doctors do their ward round they start ...they will ask us about the patient, whether they are well enough to go home, what do we think. We will sometimes make a decision ...because obviously the doctors are not there all the time with the patients, and if we don't feel the patients are ready to go home...The doctors may decide that they don't agree with this but nine times out of 10 they do.

Pippa – senior practice educator - cardiac medical unit

In the diabetes unit, because of the way that the various professionals contributed to patient care, decision making tended to be more of an individualised activity. Interestingly in this unit nurses appeared to have more decision-making latitude because of the nature of their role, and relative autonomy in comparison to those working in the cardiac medical unit. The following provides an example of a doctor referring a patient to a nurse for decision about appropriate treatment:

R: I went into the appointment with Dr David.....who said that it basically was your decision and that he was approving that. Which one of you actually makes the decision...?

Monica: Well I'd already made the decision. But because David had initially referred him to me, purely to get the medications right and get him established on the Testo gel, it's a kind of courtesy to say actually I don't think this is the right thing and I want to put him on the injection. Are you happy with that? So that was a professional courtesy, rather than a clinical decision if you like.

Monica – Endocrine specialist nurse – diabetes unit

There were also examples in which joint decisions were made between doctors and nurses about patient care, for example:

R: would you ever discuss treatment with him (the doctor)?

Monica: Yes

R: so it would be a joint opinion whether someone needed something.

Monica: Yeah, he might say something and I might disagree (laughter). Yeah, we do have this – it's an open – with all of the doctors here, and we have a meeting after the clinic, on a Thursday we would discuss patients if we weren't sure what

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to do or what the best thing was. I would use them for advice; they would use me for advice, so it's a mutual thing.

In this site in addition to nurses' role and experience, their scope of practice also determined the extent of decision-making latitude. The following example related to independent prescribing and the need for further training, until which point the nurse remained dependent on a doctor's advice:

Now at this moment, because I'm not actually an independent prescriber, but I'm doing a prescribing course, if I was an independent prescriber I'd maybe say look, you need to be taking these ones instead. That's why I have to say go back to the GP....so even though I know, I've got the education and the information onboard, I can't actually physically – I can only advise to do that.

Gemma – specialist diabetes nurse – diabetic unit

In these examples, whilst nurses described decision making alongside or with medical colleagues, there was no evidence of standardised care approaches overtly informing these decision making activities.

4.7.5 Utility of standardised care approaches

Nurses in both studies did report conditions and situations where standardised care approaches may, and did, have utility.

For the inexperienced

Protocols are guidelines for new nurses and backup for experienced ones.

Pippa – senior practice educator - cardiac medical unit

Standardised approaches to care were perceived to be more helpful to new, inexperienced nurses. A senior nurse said she used to be “shallow and narrow” and relied on the guidelines and other standardised procedures when she first started. Now she feels she has internalised all the procedures and relies on senior staff when she is unsure of something. There is a sense that:

Guidelines and protocols are there for staff in the beginning of their careers and when they are unsure and lack the depth and breadth of knowledge to make decisions.

Linda – Staff nurse - cardiac medical unit

For non routine procedures

Protocols were said to be useful and helpful for nurses handling non-routine procedures and when other medical staff are unavailable to help or unable to help.

I used a protocol yesterday to determine the aspirin loading level for a patient with a chest tube. I read the care plan and

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spoke to the doctor who was not sure about the loading dose either. So I looked up the protocol...it was helpful.

Robin – staff nurse -cardiac medical unit

Interestingly as seen in the excerpt, the first response was to ask a colleague rather than refer to the protocol. In this case the decision as to what to do was clear but the technical aspect was in question; the loading dose. Robin said the guidelines were useful when you need to remember how to do something specific and exacting.

Data from observation and coffee room conversations between nurses in the cardiac medical unit suggested that nurses recognised that protocols were there to guide decision making during procedures. However they did not have the time to look at them during a procedure and they did not provide enough substance to motivate nurses to look at them except when needed. Most of the nurses in this site only looked at protocols when they have to do something they had not done in a long time.

Protection and accountability

In addition to the informal confirmation of decision making through interaction as described above, standardised care approaches were also viewed as a way to protect nurses if their judgement might be in question. For example a nurse in the cardiac medical unit commented that it was good to have an authority's procedures in place so that a nurse (or doctor) is covered in case a procedure is questioned because *you can prove you followed the standard procedure* (Pippa – senior practice educator). Nurses also reported that this was the reason they consulted with protocols after procedures; to check that their decisions fell within the directives of any particular protocol or guideline, which they described *as part of covering themselves* (Di).

There would be repercussions if we have undertaken something that should have been done a certain way and we haven't done it and there is consequence has happened, there has been an adverse incident or something, I mean they are going to come back and say look this is protocol, what happened?

Georgia – senior nurse – Cardiac medical unit

Similarly in the feedback session in the diabetes unit nurses commented that whilst protocols could be controlling, they could also be protective in terms of accountability.

Appropriate or 'best' practice

Within the diabetes unit protocols were reportedly being used to ensure appropriate care in a context of reduced staff numbers:

For our unit things aren't very stable at the moment...where all the blood tests and diagnostic tests are done...what's happened there is we don't have a lot of staff and we have to

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make sure that we have a way of giving the results, which is safe and appropriate.

Millie – nurse consultant - diabetes unit

However within the cardiac medical unit an interesting perception emerged about the difference between best practice and standard practice. Observation and informal discussions with nurses suggested that protocols existed to encourage adherence to a standard, but not necessarily best practice. Nurses in this site felt that best practice evolved from daily decisions made on the ward and guidelines and protocols were not linked with best practice. Individual experience and the experiences of identifiable others was more influential and determined best practice on the unit. The protocols were perceived as impersonal and therefore they had less authority in the practice setting.

As a guide

Where standardised care approaches were reportedly used to inform decision making, they were used as guides because of the need to use them flexibly and particularise them to particular patients and/or situations. For example in the diabetes unit protocols existed which dictated certain measurements or dosages (e.g. Glucose Tolerance Test), which did not remove nurses' need for decision-making. The hypoglycaemia protocol dictated the amount of lucozade to give a patient with low blood sugar but it did not account for those patients who had their own food or methods of raising blood sugars. Nurses, instead of the decision 'how much lucozade should I give (which is answered by the protocol)' had a different decision to make; 'shall I use the protocol or not?' One nurse confidently stated that before the protocol was there they all knew how to deal with a hypoglycaemic patient.

Similarly nurses reported that protocols should be used flexibly and as supportive information rather than prescriptive, for example

I would see it (protocols) as a support because I am a bit, I always err on the side of caution, and I would never do anything that I didn't think was safe or was not normal practice.....some nurses get paranoid with protocols and feel they have to follow it no matter what.

Linda – staff nurse - cardiac medical unit

Additionally other nurses reported that if necessary they would modify or adapt protocols to particular patient's experiences and the local context.

Furthermore some nurses ignored existing guidelines and protocols if they felt confident in their existing practice. For example, Linda sought out a protocol for the removal of an arterial line [post procedure]. It recommended the use of a clear plaster without gauze after line removal, but she had used gauze because she believed it was better for the wound. She said the reason the protocol suggested clear gauze is so that the wound could be observed, however she felt the way she had done it was better.

She was confident in her decision and knew why she had made her choice. She did not think the protocol was wrong, it offered another way of doing it.

4.7.6 Influences on use of standardised care approaches

A number of issues emerged in both sites that influenced whether and how standardised care approaches were being used, including individual and contextual factors.

Internalisation

Whilst nurses described standardised approaches to care being helpful to new and/or inexperienced nurses, the counter to this was that as nurses became more experienced they 'internalised' procedures and protocols, and then relied on their memory and/or clinical judgement.

But it depends what I am not clear on. There are different protocols that I refer to, but the thing is, like blood pressure protocol, I know by heart the standard, what the blood pressure should be, what is the target for the different patients...

Isabella – Lipid nurse specialist – diabetes clinic

The nurses describing internalisation and their use of clinical judgement were nurses who were more senior. These also stated that if they were confronted with a new situation or were unsure about any procedure or process they would consult available protocols:

I don't think much about protocols unless I am doing something for the first time or something I've not done in a long time, then I approach them like an instruction manual, not a must do

Robin – staff nurse – cardiac medical unit

Scope of standardised care approaches

In both sites there was evidence that standardised care approaches have the potential to cover only a small or limited part of the decisions that need to be made about patient care.

As described earlier, many of the patients in the diabetes unit had been coming to the unit for a long time and living with a chronic condition made them expert patients. Many of the decisions observed centred on the relationship patients have with their condition and related complexities. For example, it was not enough for a nurse to look at one young man's sugars and prescribe more insulin without also understanding that this was going to upset him. Instead she wanted to understand why he was not managing his sugars better himself. As the nurse ascertained, the reasons were partly to do with a form of self-destructive behaviour brought about by the way in which the patient's diabetes manifested itself in his sporting life. In this example (as in many others in this site) whilst there may have been a

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protocol to manage the clinical issue about drug titration, the wider issues were complex.

This finding was particularly evident in the diabetes site, and relates to the nature of the patients, the service being delivered and the skill and experience of the nurses' working there.

Accessibility

How accessible the standardised care approaches were in the clinical setting appeared to impact on whether or not they were referred to. For example in the cardiac medical unit the protocols, guidelines and procedures were scattered in various areas of the wards. However in all cases they were kept in binders in cupboards away from where patients were cared for, and hidden from view:

All the guidelines, policies and most of the protocols are collected in a binder and kept in a cabinet at the nurse's station. Protocols are rarely consulted and many nurses are not sure which procedures are covered by which protocols.

Linda – staff nurse – cardiac medical unit

In contrast where protocols and algorithms were embedded in existing systems or routinely used paperwork they were referred to. For example in the diabetes site the diabetic pregnancy and glucose tolerance test protocols were embedded within patient forms, and/or onscreen algorithms.

Resources

Within the cardiac medical unit there were examples of not being able to fully follow protocols because of a lack of equipment. For example, in one protocol the use of the Femstop device (for vascular closure) was recommended, however it was no longer available within the trust, according to nurses because the hospital was saving money. Instead nurses applied manual pressure after removing an arterial line. There were also other examples of there generally being a lack of equipment in this unit (e.g. syringe drivers, pumps).

Practice context

Summarising some of the context specific issues that have been referred to in the above sections, it appears that there were differences between the sites that impacted on the nature of decision making. The importance of patients taking personal responsibility for chronic illness was obvious in the diabetes unit and in contrast to the majority of patients in the cardiac medical unit who were there for defined events or procedures. There was a lot of evidence in this site that decision making about patient care was a collaborative process between patients and health care professionals.

In contrast to the cardiac medical unit, the diabetes unit had more senior and experienced nurses. This is not surprising given the nature of the service, but in relation to this study, this manifested in interactions with patients and the use by some nurses of high level skills and knowledge in

joint decision making. These nurses also worked more autonomously and had greater decision making latitude than those in the cardiac medical unit.

4.7.7 Summary

A number of issues emerged from the decision-making ethnography about the nature of nurses (and others) decision making with and without the use of standardised care approaches, including:

- Nurses made a wide variety of and number of decisions ranging from medical and treatment decisions to more general decisions concerning care and service delivery.
- The types of decision-making observed were often complex including health and social related dimensions.
- There were various types of standardised care approaches available for use in both sites; however nurses were rarely seen referring to them explicitly in the course of their interactions with patients.
- Nurses tended to draw on informal (such as local ways of working) as well as formal protocols (e.g. particular protocols or guidelines). They felt that internal or informal protocols were more relevant to the everyday reality of practice.
- Nurses rely on various sources of information in decision making, including 'instinct' or clinical experience, interaction with colleagues (particularly senior colleagues), and patients.
- Decision making tended to be a social activity with nurses checking and confirming what they ought to do and informally auditing what they had done.
- Standardised care approaches were perceived to be useful or actually used to inform the decision making with new or inexperienced staff, for non-routine procedures, as a form of protection and demonstration of accountability, to ensure the delivery of appropriate care and as a guide rather than a 'must do'.
- Standardised care approaches tended to be used flexibly, with the need to particularise to patients' situations and the context.
- More experienced nurses reported having internalised protocols and procedures and the relying on their memory and/or clinical judgement.
- There was no evidence that standardised care approaches were explicitly informing team interactions and decision making.
- The use of standardised care approaches in decision making was influenced by a number of issues including:
 - their scope; not all patient issues can be covered by a protocol,
 - how accessible they were; if embedded in routinely used documents or systems,
 - whether there were the resources locally to follow them accurately, and
 - the experience and skills of nurses impact on the quality and nature of the interaction and the approach to decision making,

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- o working in more autonomous roles meant more independent decision making latitude for nurses.

4.8 Impact on professionals' roles and team working

As previous sections show, standardised care approaches had the potential to impact on nurses' roles; findings also suggested an impact on aspects of professionals' roles and team working.

4.8.1 A nurse's thing

A common perception amongst medic interviewees was that protocol-based care is "a nurses' thing":

It's mostly a nurse thing, protocols, you know....it's not a thing that doctors deal with a lot actually.

Anaesthetist at POA – POAS14

And so you will find the doctors are terrible at following protocols on the whole. The nurses are brilliant and that is partly due to our arrogance I suppose and partly due that we simply just haven't got the time to go all through the nitty gritty bits.

General Practitioner at GPS – GPSS02

There's a side of me that thinks well...I'm a doctor, I'm not going to be told by a stupid piece of paper, an algorithm, what to do.

General Practitioner at GPS – GPSS03

Nurses also recognised that protocols and their variants may be more of a 'nurse's thing' than a medic's because, as the above quotes intimate, nurses tend to be better at following rules and regulations:

I think nurses are better at following rules and regulations than the doctors.

Nurse at WIC – WICS02

There were examples of the development of the standardised care approaches being a nurse or midwifery led initiative. For example the use of the normal birth pathway in the birth centre was seen as a midwifery-led initiative by both midwives and obstetricians:

It was really a midwifery initiative...it was up to the midwives to implement.

Obstetrician at BC – BCS07

However, there were examples within and across sites that standardised care approaches had been developed to be used by the multi-disciplinary

team, not only nurses. This included the integrated care pathway at the cardiac surgical unit, the asthma protocol at the GP surgery and the investigations guidelines at the pre-operative assessment clinics. With the exception of the GP surgery, medics were not using them. One of the reasons GPs may have been using the protocols because they were integrated into the Quality and Outcomes Framework, and linked to incentives (this finding is described further in section 4.10). Interestingly General Practitioner interviewees did express their reluctance to follow protocols (as the above quotes illustrate) but were using them through the QOF. However it could be argued that the perception that protocol-based care is a 'nurse's thing' had impacted on whether or not they were an acceptable way to practise. This finding indicates that protocol-based care may be a socially and professionally constructed phenomenon. This issue is discussed further in section 5.

4.8.2 Clarifying and formalising professionals' roles

As described earlier standardised care approaches had impacted on nurses' roles so that in some cases they were able to provide care autonomously from diagnosis to treatment, and as a result had reduced doctors' workload. Findings also suggest that the introduction and use of standardised care approaches tended to formalise each professional's respective roles, rather than necessarily enhance the potential for better team working.

A good example of this finding was seen in the cardiac surgical unit with the development and implementation of the integrated care pathway. Generally an ICP becomes a permanent part of the patient's record and is a multidisciplinary record of care in which all disciplines involved record their notes in a single document. However, the way in which the ICP was developed in this site had resulted in segmentation rather than integration:

Lots of teething problems because it was supposed to be an integrated care pathway that was single documentation used by the multi-disciplinary team, but...the doctors wanted their own section and the physios wanted their own documentation, so it became a bit fragmented.[...] doctors wanted their own section and they wanted it to be a different colour,[...] The physios they had to have the blue because that's what they used.

Practice development nurse at CSU - CSUS02

In this example the ICP was colour coded so that each professional's section was easily identifiable. This resulted in each professional rarely consulting sections that were not their own, a practise that was seen during observations.

'So now we'll go into the paperwork. This is our pathway and all the team writes in it, we have here all the information we need about you. We know if any changes and the doctors use their part and the nurses we use ours. So I'll ask you some questions now.' said the nurse

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Observation of a nurse-patient interaction at CSU - CSUObs04

However as one interviewee in this site commented, the use of documentation in itself is unlikely to engender team work:

I don't think a document would necessarily affect the multi-disciplinary team. I mean you either work well as a multi-disciplinary team or you don't.

Senior physiotherapist at CSU - CSUN05b

Whilst the ICP in this site had resulted in segmentation, an alternative perspective is that it clarified the contribution that each professional team made to the patient's journey through cardiac surgery. Clarifying roles was also seen in the GP surgery. For example, one of the health care teams that consisted of three health visitors and a community nursery nurse underwent a significant change in the way it worked due to the introduction of a Pre-school Core Health Visiting Guideline. The introduction of the guideline, which itself had emerged from a national report, prompted the team to clarify their roles and to delegate tasks to the most appropriate professional, which resulted in an impact on the health visitors' workload.

It's definitely affected the way that we as a team work...we changed the way that we were working. When I started it was very much geographical so we'd each have an area and babies born on certain streets we'd take patches almost. Then we decided actually within our team we've got so many different skills that one family might just not want one person and we could actually use everybody and probably achieve those needs that we found and use the guidelines better.[.....So as a team it's kind of given us very good boundaries for our roles and also let us hand things over to people who have better skills in those areas. So it's good because it points out exactly who should be doing what...

Health visitor at GPS - GPS09

The use of the Quality and Outcomes Framework in this site had also provided the opportunity to re-evaluate each team member's contribution and role.

4.8.3 Summary

Findings about the impact on professional's roles and team working of developing and using standardised care approaches showed that:

- There is a common perception amongst both doctors and nurses that the use of standardised care approaches is a 'nurse's thing' being nursing and midwifery initiatives.
- Nurses reported being better than doctors at following rules and procedures, whilst doctors reported a reticence to using protocols etc.
- In cases where a particular standardised care approach had been developed for multi-disciplinary use, generally doctors were not routinely using them. The exception to this was in the GP surgery, where some

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protocols were linked to the Quality and Outcomes Framework, and for some junior doctors.

- Data shows that the introduction of standardised care approaches formalised and clarified each professional's respective roles and contribution, rather than necessarily enhancing the potential for better team working.
- The potential to clarify roles and contributions was viewed as a positive impact by nurses.

4.9 Impact on patients' experiences

There has been a relative neglect of patients' experiences in previous research related to protocol-based care. This study included the perspectives of patients in an attempt to develop insight into how standardised care approaches might affect the process of care from their position. A number of issues emerged.

4.9.1 Awareness of protocol-based care

Overall patients across all sites were unaware they were being cared for by standardised care approaches, however they are aware that nurses and doctors were following some sort of procedure.

Well, I assume so because of the operation that I'm having I'm sure there'll be a procedure they need to follow, especially because of litigation.

Female patient at Ear, Nose & Throat POA - POAP08

The exception to patients not being aware about the use of standardised care approaches was in the Walk-in Centre. As described previously, nurses in the WIC used on-screen algorithms to guide interactions; the nurse would share the questions on the screen with the patient and they would follow the process together. There was a mixed reaction to this approach:

At the beginning where she took me through lots of steps and says you're basically healthy, you've got no chronic health conditions, no family history of diabetes, all those kind of questions, they were important for ruling out that it was anything serious and although I'd perhaps gone through those questions myself, that's not to say that I would have got that right. There could well have been something I'd totally missed...but if it had turned up something surprising then that would have been the single most useful thing.

Female patient at WIC, WICP03

However as can be seen in this excerpt, it was not necessarily the use of the onscreen algorithm per se, but the number of general questions it contained that the patient was questioning. The same patient stated that liked being involved in the on- screen consultation.

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...a collaborative moment and that was really nice because often you feel like nurses and doctors or medical staff, well I mean they have to sometimes keep the screens away from you because it's got information on that you shouldn't see, but it's much nicer for them to turn the screen.

Female patient at WIC, WICP03

Health care practitioners tended to assume that patients would not be interested in knowing about protocols.

People who walk in through my door are not interested in protocols, they've got no interest whatsoever. They don't know what a protocol is. They don't want to know what a protocol is. They want to know what's wrong with them. 95% of the people that walk in through my door I don't bother with protocols I discuss with them what's wrong with them.

General practitioner at GPS – GPSS07

I suppose they come in and they place themselves in our hands and they don't ask any questions ... if you were to ask a patient if we had a protocol probably doubt very much if they would know whether we had or not.

Di – Senior Nurse – Cardiac medical unit

However whilst patients were often not aware that care was being delivered through protocols etc., patients did experience care guided by them, that is, when used, their care may have been delivered according to the contents of the standardised care approach. For example, in the GP surgery a woman pregnant with her second baby directly experienced the changes that new NICE guidelines had on her maternity care. She was not aware of the NICE guidelines, but she was aware of the changes that had taken place between her two pregnancies.

I think I saw the midwife every four weeks on my first pregnancy. From what I can remember things were done differently, like the measurement of the tummy, I mean obviously it's early days at the moment anyway, but I do remember that. I might be getting things mixed up, whether that was later on in my pregnancy with the first one or not, I don't know...if it was my first one I would be worried that I'm not seeing her so often.

Female patient at GPS - GPSP06

In this example NICE guidance, which had been adopted by this site, recommended a reduced number of patient – practitioner contacts through pregnancy.

Furthermore, if patients had on-going contact with the service because of their condition and/or treatment they became more familiar with the procedures and standards. For example, John a patient from the day case

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unit in the cardiac medical unit had experienced multiple visits and become accustomed to the routines. During his interview he showed high confidence in the care he received and his knowledge of procedures.

Well I am in for an angiogram. I have been in here before and the experience is a straightforward normal procedure, quite happy to go ahead with. I don't know it has just caught me on the hop though. .. The treatment you get in here is good. I know exactly what they are doing; they are testing this, that and the other.

John – male patient – cardiac medical unit

When questioned about the protocols he said that he knew about them and he understood that they were “testing this, that and the other”.

4.9.2 Standardisation

Whilst patients may not have been aware of protocol-based care approaches they did experience standardisation.

I mean it's like a factory conveyor belt, they were churning out the operations upstairs, putting them into the recovery ward, as soon as they recovered, they were down here and they had to have beds ready for them.

Male patient at CSU - CSUP08

Practitioners however recognised that they needed to be flexible and individualise care.

I think that of course the art is to find the right patients to fit in the protocol or to find the right protocols for the individual patient.

General practitioner at GPS – GPSN02

It's a tool like anything else and the patient doesn't like to be treated like an algorithm either, you know what I mean. Because at the end of the day they're people and you go and see a health care professional and you want to be treated as a person, not with someone looking at the screen asking do you have this, 'no', do you have that, 'no'. And the person sitting there wants to be understood and empathised with, they don't want to just a yes/no, tick box.

General practitioner at WIC – WICS09

There were also examples of nurses tailoring care for individual patients. A nurse running the asthma clinic at the GP site adapted the relevant protocol (see table 13) to suit a patient who was due to undergo surgery as the excerpt illustrates:

The nurse advised her [patient] to come along to the clinic just to rule out asthma. She had given her at the clinic a bronchodilator and had measured a peak flow a week ago. The nurse mentioned that under the protocol she should have asked the patient to keep a diary but the patient was due to go for surgery and a diary would have not been practicable [...] In this particular instance it [asthma protocol] was been adapted by the nurse to the particular circumstances the patient was in, however it was still valid and part of it was still followed as necessary.

(Field notes excerpt, GPS)

At the POA, nurses regularly used the guidelines for adult pre-operative investigations (see table 13) to decide what tests patients needed to undergo. However, these guidelines were adjusted to suit patient's needs as described in the excerpt:

When talking with the nurse about what tests she did and why, she says that although the patient wasn't indicated for an ECG (patient was not over 50) she was a smoker and she thought it might be needed.

(Field notes excerpt, POA)

However observations also revealed that sometimes guidelines and protocols were followed irrespective of patients' individual circumstances and needs. For example, a nurse, following a pre-operative assessment checklist in the ICP at the cardiac surgical unit asked a 76 year-old male patient whether he had removed all his make up and nail varnish. Another example was that of a breast cancer patient attending a pre-operative assessment clinic. She had been to hospital for a biopsy a week beforehand and had all her tests done then. She had discussed with the consultant whether she would need to go through the tests again the following week and he had said that it was improbable. On the day of the pre-operative assessment clinic she mentioned this to two nurses; however she went through the whole assessment again.

I was disappointed I had to sit and fill all the forms in again when I'd just done it a couple of weeks ago, I was hoping I could get away without doing that.'

Female patient at Breast cancer POA - POAP03

4.9.3 Involvement in care

Generally, patient interviewees reported being familiar and involved in their care. As indicated above this was particularly the case with patients who had repeated episodes of care. For example:

- Patients at the cardiac-thoracic ward were aware of their 'goals' as described in the ICP. For example patients knew they would be asked to become mobile very shortly after surgery, which was in line with the physiotherapy section of the pathway.
- A patient with chronic obstructive Pulmonary disease at the GP surgery was aware of the need to identify any chest infection early. She had an

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antibiotic prescription ready for when she noticed any changes in her condition. This was in line with NICE guidance about patients being proactive and involved in the management of their condition, and consistent with the approach that the nurse had taken with her:

I'd expect her to contact me if she was coughing more, if her sputum was a darker colour, if she had any pain, if her breathlessness was worse. I've sort of gone through that with her and tried to educate her.

Community matron at GPS, GPSN10

- Women in the birth centre reported that the midwives kept them informed of what was happening, and observations demonstrated that midwives involved both women and partners at all stages of the birthing process.

In addition, the algorithms at the WIC enabled nurses to print out leaflets with information on home care for patients to involve them in their own care at home as shown in this observation:

They returned to their seats [after the physical examination], there was some more conversation about the condition, the nurse mentioned that it was probably as a result of the cold and it should pass within a week or two. With that in mind she gave her some computer-generated advice. When she was giving advice the patient was looking at the screen with the nurse. She was involving the patient in it by asking her to read the advice. She was very thorough about the possible causes of hearing loss. The nurse also took a GP dictionary which she read and shared with the patient to convince her that what she was doing was the right thing.

Nurse – patient observation at WIC – WICObs07

Practitioners also reported the need to involve patients in their care,

That's exactly what the family health needs person is, because what you should be doing is sitting down and asking them what they feel their family health needs are, or what they feel their child's health needs are.

Health visitor at GPS – GPSN09

These descriptions of patient involvement are examples of the way patients' experienced care, rather than being aware of protocol-based care per se.

4.9.4 Different agendas

An interesting finding emerged in the GP site related to the use of protocols within the QOF. The QOF targets were translated into on-screen electronic flowcharts called SOFIs. These protocols covered a range of areas such as hypertension, asthma, depression, smoking, and obesity, etc. They could involve recording of data (e.g. is patient a smoker, patient's BMI), assessments (e.g. depression questionnaire, blood pressure taking) and/or

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referrals (e.g. to the smoking clinic). The following describes how SOFIs were used by GPs and practice nurses.

We are currently using this SOFI system which ensures that the clinician or the administrator collect the codes, asking the questions on the spot during consultation. [...] You had some little window, you had your little list and you said oh I'll do the CHD and the BMI, click this, click that and it goes blink, that would be fine. [...] It's like a flowchart if you like. [...] There are others parts which will offer you a list.

Data manager at GPS – GPSS01

GPs reported that by using the SOFIs they were not necessarily following the patient's agenda.

The patient came in with her own agenda, but I was too busy thinking about what question I should ask them prompted by the protocol..... my mind was sort of bogged down with trying to adhere to these questions on the protocol. I suddenly realised I wasn't giving him chance to ask her own questions. So the protocol in that situation was dominating the consultation and that's not good...if you're not careful it doesn't give the patient, or as it were, it doesn't become their consultation any more, it becomes your consultation.

General Practitioner at GPS – GPSS07

However there were examples of practitioners not following the SOFIs during consultations, but referring to them post-consultation because of the risk of redundant questions.

SOFIs [...] are similar to algorithms and designed to gather data related to QOFs. She [senior nurse – GPSS10] doesn't use them on screen; instead she takes notes while consulting and write READ Codes [clinical data codes] related to the SOFIS after the patient goes. Because the consultation needs to be about the patient not about numbers or questions in a screen.

(Field note excerpt, GPS)

4.9.5 Information provision

Often the delivery of care according to the standardised care approach necessitated information sharing and provision. Some patients felt overwhelmed with the amount of information they received in a short space of time.

So she did all of that with us on the first visit. It was quite a lot to take in.....I mean it was a lot of information.

Female patient at routine health visitor appointment, GPSP09

There were also instances of duplication. Patients complained about the need to tell different practitioners similar things when each one had recorded their answer using the same standardised care tools. This seemed

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to be a particular issue in the cardiac surgical unit and pre-assessment clinics.

Maybe too much to say the same thing over and over and over. I had that nearly all afternoon... I said to my daughter then, I don't know why they don't just fill in what they're asking and then give it to the next one that's coming... I don't know whether it's that they want to find out if you're actually telling the truth.

Patient at pre-admission clinic at CSU – CSUP03

4.9.6 Summary

A number of issues arose concerning the patient's experiences of standardised care approaches. These include:

- patients were not aware they were being cared for by standardised care approaches.
- The exception to this is where standardised care approaches were used explicitly in the interaction, such as that seen in the WIC and GP.
- Practitioners assumed patients would not be interested in knowing they were being cared for by protocols etc.
- Patients did experience care delivered by standardised care approaches even if they were not aware of this. Care was seen to be delivered according to the contents of the tools.
- Patients assumed that practitioners were using procedures, which they became familiar with if they had on-going contact with services.
- Whilst practitioners reported the need to particularise care to patients' circumstances, sometimes patients experienced standardisation, at the cost of individualisation.
- Generally patients reported being involved in their care, and this perception was supported by observation of practice.
- Protocols had the potential to set a professional-led, rather than patient-led agenda.
- Some patients reported feeling overwhelmed by the amount of information they received, and were unhappy about the need to duplicate information in their interactions with different professionals.

4.10 *Impact on organisational outcomes*

A number of organisation level outcomes were perceived to have been affected by the introduction and use of standardised care approaches. These findings are mainly based on interview data and data from audits where available. Additionally, but perhaps not surprisingly given the diversity of sites in terms of settings and standardised care approaches being evaluated, these impacts tended to be site specific or confined to a fewer number of sites than many of the previously reported findings.

4.10.1 Use of resources

There was a perceived impact on finance and time resources.

Cost containment

Standardisation of care delivery had also resulted in standardisation of resources such as medicines, dressings and tests. This was reported as an impact in the GP site, pre-operative assessment clinics, and cardiac-surgery unit. For example, it was perceived that the development of protocols and guidelines that specifically suggested the sort of antibiotics that should be prescribed, the appropriate number of tests patients should have and when, and the type of dressings to be used for particular wounds should have had an impact on containing costs, because they had impacted on the way practitioners were practising.

If I didn't know anything about the guidelines of the investigations I'd probably just start taking blood from everyone and it does cost a lot of money in the lab to try and actually get results or to process blood results for people that doesn't need to have them. Why even take a chest X ray for someone who doesn't need to have it? So it's probably a good thing that we have guidelines and we can stick to them and we can actually order things that really need to be done. There's no point in just doing this because it's written down, because it can cost money to the Trust.

E grade nurse at POA - POAN07

Specifically, some practitioners reported that the development of protocols had facilitated the choice of cheaper products.

They've probably decreased costs because we've standardised prescribing and we try and aim for the cheapest medication or the most cost effective medication.

General Practitioner Partner at GPS - GPSS03

In some cases managers reported that such measures had actually resulted in reduced costs.

I know our antibiotic costs went down.

Former project Manager at CSU - CSUS13

As previously reported the evidence base of the standardised care approaches was variable, therefore it is unclear how developers were making decisions about what resources to standardise.

Workload

As previously described findings have shown the introduction of standardised care approaches had enabled the extension of nurses' roles. For example, at the Walk-in Centre, doctors handed some prescribing responsibility to nurses who in turn are able to deliver a more streamlined

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service to patients. As a result, doctors' workload had decreased and enabled them to deal with more complex patients.

At the GP practice there were several examples of standardised care approaches decreasing professionals' workload, for example,

- Nurses had delegated their responsibility of running Stop Smoking Clinics to specially trained advisors (without any prior health care experience). This had released nurses' time to be able to run chronic condition management nurse-led clinics, which in turn had freed up GPs' workload.
- Health visitors had re-organised the way in which their team worked handing more responsibility to the community nursery nurse, which enabled health visitors to deliver a more targeted service to 'at risk' families.
- Midwives had been able to reduce their face to face contact with healthy pregnant women who did not require intensive midwifery support, which had released their time to increase support for women with more high risk pregnancies:

I get more time as a result of not seeing healthy women so much...the time that we save seeing routine patients is used up in some other way.

Midwife at GPS - GPS04

Referrals

There were three examples of where the introduction of a protocol had impacted, or an intended impact, on more efficient referrals between settings and departments. For example, at the GP site when doctors needed to refer patients for hip and knee surgery, they used the local protocol developed by the orthopaedics department at the hospital because it had a positive impact on the success of the referral.

Any referral for hip or knee surgery, which we would send off without a Hip Scoring would just bounce back - thank you, but do it again. And therefore we are made to implement it, you know, rightly I would say, you know, because it is a useful tool for the specialist services, which could be physiotherapists or orthopaedic surgeons and I accept it's part of our homework before referring patients further.

Associate GP at GPS - GPSN02

In the Walk-in Centre the streaming protocol was intended to make referral from A&E to the WIC and vice versa, more efficient and facilitate the achievement of the 4 hour A&E waiting time. An internal referral audit undertaken in March to April 2005 demonstrated that 98% of patients who attended the WIC were treated or seen by someone on site. Approximately 2% of patients were referred to A&E. Nurses and doctors referred similar numbers of patients with similar outcomes (e.g. admission, follow-up, investigations, treatment or discharge).

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In contrast, receptionists' appropriate referrals were small in comparison with nurses and doctors, highlighting the need for further training for these staff groups.

Additionally at the Pre-operative assessment clinic there was an example of how an algorithm had improved referrals between departments. The blood pressure algorithm had impacted on the number of patients referred to the Blood Pressure Unit from pre-op assessment clinics. The algorithm ensured more successful referrals minimising the likelihood of operations being cancelled because the required tests had not been carried out.

Length of stay

In the cardiac surgical unit the integrated care pathway for coronary artery bypass surgery had been introduced to 'fast track' straightforward cases through the pre-operative and post-operative phases over a five day period. Whilst there was no available routinely collected data to support this finding, the perception was that overall, this was achieved.

I think from an overall length of stay, I think it probably made people more aware, nursing staff more aware of what the goals are, but then again it's also got stuck at being five days and actually we could look at – although some patients are discharged earlier than that, but I think that's seen as the norm, whereas actually we could possibly even reduce that norm now. Obviously that would have a big impact on costs.

Senior nurse H grade at CSU - CSUS07

As the above quote indicates and as other interviewees intimated, it was assumed that because there was a reduced length of stay there was a more efficient use of beds, resulting in greater activity, and more income.

However, the patient population had changed since the introduction of the ICP in 2002; patients had become more complex with an increasing number of co-morbidities and so they were not straightforward cases. As a result, and because the pathway had not been updated, many patients had to come off the pathway as the following excerpt from an internal audit suggests:

The current ICP is based on a patient stay of one day in cardiac recovery unit (CRU) and discharge home on day 5. In reality patient stays are now longer with an increase in both stays on CRU and on the ward. The average length of a patient stay on the cardiac unit for the nine months April to December 2004 was 9.494 days and the average CRU stay was 2.086 days [at time of data collection – June 2005- this was 1.29 to 3.9 at CRU and 6 days at ward]. The ICP also gives a very rigid structure to the patient stay, which many of our patients do not fit into.

Nursing audit of ICP use for cardiac surgery - CSU

Use of the normal labour pathway had not generally impacted on the postnatal length of stay on the BC, although as the Centre was building up

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to full capacity, women were offered some flexibility and choice about their length of stay.

As far as length of stay, that's one thing at the moment where we have the luxury of not worrying about it. However if the numbers go up, then we will have to worry about it.

Senior midwife at BC - BCS03

Performance

As described previously, within the GP site the introduction of the QOF; a component of the new General Medical Service contract, had impacted on use of protocols. The QOF rewards practices for the provision of quality care, and helps to fund further improvement in the delivery of clinical care. It measures practice achievement against a range of evidence-based clinical and organisational indicators. Most GPs and nurses at the practice used the QOFs, health visitors and midwives had not been as involved, but there were plans for both these groups of professionals to collaborate by recording the care they deliver in QOF.

The QOF scheme...I think of it as a performance management scheme..Because they've got this problem really with GPs, that they can't directly control GPs, they've got some fairly blunt instruments, some fairly blunt carrots and sticks....So the QOF scheme has brought in a specific range of quality indicators, both from the clinical side and on the sort of support infrastructure side, which has had payments related to them. So it's not been the main reason why we have clinical protocols because we've always had clinical protocols, but it's certainly sharpened the pencil on existing ones that we've had have been reviewed and new ones have been developed.

Practice manager at GPS - GPSS06

As this practice nurse stated:

It's a financial implication and if they don't meet that target guideline they don't get... the funding.

Practice nurse at GPS - GPSN01

So within this site the protocols were being used because they represented performance targets linked to financial reward.

Yes, this is very target based. This is the carrot and initially the carrots are big and juicy, but you can bet your arse as time goes on, once the GPs are in the harness, the carrots will get smaller and staler and the stick will be more in place.

Data manager at GPS - GPSS01

Streamlining documentation

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Within the Birth Centre it was perceived by midwives that the normal labour pathway had streamlined documentation. The pathway ensured that care during labour and birth was captured on the one proforma and so notes were not duplicated. If care were transferred between midwives, the second midwife would continue to use the same pathway. The lack of documentation was viewed as a positive outcome, as it meant more time could be spent with the woman. However if the woman was transferred from the Birth Centre to main delivery suite (DS), the pathway would no longer be used.

I think the BC midwives find communication between each other easy. They all use the same paperwork, they can see any variations or anything that's happened. It does focus their minds on things that have happened that aren't within the pathway because it's been documented. They've seen the documentation and they know there's an issue. So the fact you haven't got to go through pages and pages of notes, that's a benefit up here. However, it's not a benefit downstairs (DS). The girls downstairs are still expected to read everything that's happened.

Senior Midwife at BC - BCS03

4.10.2 Summary

There were a number of reported organisation level impacts from the use of standardised care approaches, including:

- the standardisation of resources, which meant that practitioners were guided towards the use of particular products and ordering of tests. This was reported to have improved cost containment. However, it was unclear how decisions were made about what resources to standardise.
- The redistribution and therefore reduction of professional's workload. This occurred between doctors and nurses, and within nursing and health visiting teams.
- More efficient processes for referrals between settings and departments.
- An integrated care pathway within one site had impacted on patients' length of stay, and so on more efficient use of beds.
- Within the GP site the QOF had impacted on performance by providing targets linked to incentives.
- Within the Birth Centre the use of the normal labour pathway had resulted in more streamlined documentation.

4.11 Influences On Use

As the description of both the case study evaluation and decision making study findings have begun to show, a number of factors either facilitated or inhibited the use of standardised care approaches within and across study sites. These are summarised below.

4.11.1 Location and visibility

The location of the standardised care approach and its level of visibility also influenced how and whether it was used. In settings where they were more visible, physically close to the patient-practitioner interaction, and/or easily accessible, they tended to be referred to more often. For example as described previously, algorithms in the walk in centre were computer based and were often used as an on screen prompting tool during interactions with patients. A similar finding emerged from GP site data where most staff routinely used the onscreen protocols related to the QOF. In the walk in centre some nurses had copies of PGDs that fitted into their pockets or bags so that they could be quickly and easily referred to at the point of care. Furthermore embedding the care pathways in documentation in both the cardiac surgical unit and the birth centre ensured that, they were used routinely by most professionals (see below for exception). In sites where these mechanisms were not in place the use of the standardised care approaches was patchy. For example in the cardiac-thoracic unit nurses described the location of guidelines, policies and protocols as scattered in various areas, and mainly hidden from view. Similarly in the pre-operative assessment clinics where the guidelines and protocols were in a paper-based manual, they were rarely referred to. The exception to this was with a protocol about 'what tests to order', which was used, and was displayed on the walls in clinical areas.

4.11.2 The nature of the standardised care approach

The flexibility of the standardised care approaches appeared to impact on the way that they were used; however there are contradictory findings with respect to flexibility. For example interviewees in the cardiac surgical unit felt that the care pathway was inflexible because it could not be used with patients who were complex cases (the ICP had been developed for 'straightforward' cases). At the time of data collection there was an intention to revise the pathway to enable it be used with more patients. In contrast, nurses in the walk-in centre were using algorithms, which they described as prescriptive (and so not flexible) and apart from three nurses, they were consistently used, even if only as a checklist at the end of a procedure or patient interaction. Similarly the SOFIs (protocols related to QOF), whilst prescriptive, were used by most staff in the practice. Whether it was the flexibility of the standardised care approach per se that influenced the type and amount of its use, or factors such as the motivation for using them, for example, incentives and being able to run a nurse-led service, is difficult to unravel.

4.11.3 Buy-in

The level of ownership and buy-in to the particular standardised care approaches being used varied across sites. In sites where there was buy-in by members of the whole team, whether unidisciplinary or multi-disciplinary (e.g. GP site, Birth Centre), all practitioners tended to use them. In contrast in sites where there was varying levels of buy in – there were varying levels

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of commitment to their use. For example junior medics at the cardiac-surgical unit used the care pathway, but not how it was originally intended to be used as the following excerpt detailing how an ICP was completed shows:

Medical section: The PAC [pre-assessment] section is filled in but Day 0 to Day 5 are all blank; instead medics use the comments section and date their observations. (many people have mentioned already medics' resistance to the ICP, it looks that although change was achieved and doctors are writing in the ICP's pink section [their colour coded section] instead of on their buffer notes they're still refusing to follow the format of the ICP).

Field notes excerpt - CSU

In addition, a number of the medics in the cardiac surgical unit were vehemently opposed to using the care pathway:

The doctors hate it. [...] In fact X [Medical director and consultant] would be a good person to talk to because he hates it [ICP] , hates it with a vengeance.

Pre-admission nurse at CSU – CSUN05a

The opposition by more senior doctors in this site meant that they did not use it, resulting in incomplete documentation and a lack of commitment to be involved in a pathway revision. Whilst these doctors expressed opposition to this particular care pathway, other doctors from different sites stated their dislike of protocol driven care more generally.

Another example of stakeholder resistance occurred in the walk-in centre when nurse prescribing was being introduced. Nurses reported that pharmacists were resistant to the idea of nurse prescribing and this had resulted in a protracted process of PGD development and introduction.

Well we met the main PCT pharmacist and we said what we thought we'd need to prescribe and why. But there was some resistance from them and it took ages to move through the system. We had a lead nurse who finally took it forward and it came into being in 2002.

Former PBC champion at WIC – WICS02

4.11.4 Making a difference

Where practitioners could see that the use of the standardised care approaches were making a difference to their practice, patient care or service delivery they tended to be more readily used. In the GP site, opinion was unanimous that the use of the SOFIs had improved the

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standard of patients' care; this perception was supported by the consistent achievement of targets and high QOF points. In this example it is difficult to disentangle the effects of better standards of care (defined by the targets) and incentives.

The referral protocol for orthopaedics' procedures was another example at the GP site of how standardised care approaches which were perceived to improve care were being consistently used. The referral protocol was initially used with osteoarthritis of the hip and after proven improvement it was extended also to osteoarthritis of the knee as the excerpt of a support letter accompanying the protocol shows:

For over a year X [local area] GPs have been using the Oxford Hip Score in the referral of patients with proven osteoarthritis of the hip. This has been generally well accepted by patients and by clinicians within primary and secondary care. It has led to less patients being unnecessarily referred to hospital for assessment when their likelihood of needing surgery has been low. The conversion rates of patients with the greatest need demonstrated by the score have been seen quickly, with several receiving surgery within four months. We have now agreed that the same prioritization process can happen for patients with proven osteoarthritis of the knee. [...] All referrals must include the Oxford Knee Score from the 1st of April 2004. Un-scored referrals will be returned to you for scoring.

Support letter by GP partner introducing protocol – GPS

In other sites the ability of nurses to be able to practise autonomously and in extended roles appeared to provide a motivation to continue to use available protocols and guidelines. This was particularly the case in the walk in centre with the use of the PGDs and algorithms, in the birth centre where care was completely midwifery led, and in the GP practice where nurses, midwives and health visitors were running clinics.

4.11.5 Time

There was a perception from practitioners in some sites that the use of standardised care approaches was time consuming. In some instances this did not affect whether they were used, for example the QOF related protocols were reportedly cumbersome and time consuming but were used, in other cases it did. For example medics in the cardiac surgical unit reported that they did not have time to complete the ICP documentation.

One of the problems you will find in the post op section is that there are a lot of things which are important [...] and all that is very relevant and all very important, but for the time that you have in the ward rounds and to fill in all these things, it's just not practical.[...] Well you know sometimes there are like thirty patients down there to do in an hour, so thirty in an hour that's two minutes. Now two minutes per patient, well yeah.

Consultant at CSU - CSUS14

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In the walk in centre there were time pressures of a different kind. At the time of data collection a review was being conducted into the number of patients nurses and doctors were seeing each hour. Data shared with the research team indicated that nurses were seeing between 1 and 2 patients per hour with wide variations in numbers seen. Doctors typically were seeing 2.5 patients per hour. As data shows doctors were seeing more patients and this had resulted in nurses being questioned about their practice. It was suggested that some of the algorithms nurses were using were too time consuming to complete, and that nurses should be focussing on increasing patient throughput.

But here they judge you by the number of patients you see per shift and algorithms slow consultation but I'm concerned about my patients leaving happy my consultation room.

F grade nurse at WIC – WICN06

Ironically, nurses in this site would not have been able to deliver this service unless such algorithms and protocols were in place.

4.11.6 On-going project lead

The presence or absence of a dedicated project lead overseeing the development, introduction and use of standardised care approaches appeared to be influential in whether sustained use was achieved. All sites had invested in a lead for the development and initial implementation phases, and in one case this had been sustained for 2 years (CSU). However over time the project leads had moved to other roles or away, and were not replaced. As a consequence there was a lack of monitoring, evaluation and revision of the various standardised care approaches being used, which may have accounted for why use in some sites was variable.

I can't even remember now how long we've been using it , but I mean it's a long time and really there hasn't been anybody, we kept saying oh we should change this we should change that but because there's no ownership, whereas it was X's [former PBC champion] ownership before, there is nobody there to actually say well actually this isn't working or can we alter this so we've just plodded along with it.

Senior physiotherapist at CSU – CSUN06

Usually practitioners had the responsibility to update standardised care approaches in addition to their clinical work.

That is the challenge. They [practitioners] don't, they don't have extra time, they don't have extra resources, it is just in addition to their jobs.

ICP coordinator at POA – POAS13

The exception to this was in the GP site. Here there was a dedicated data manager whose main responsibility was the maintenance and updating of the protocols related to the QOFs.

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I think we're more and more dependent on our IT [...] and our extra QOF money [allowed us to employ a member of staff] So we've now got a data manager.

Practice manager at GPS – GPSS06

In the Birth Centre, the Lead Midwife for Normal Birth was responsible for auditing the use of the labour pathway, dealing with issues which arose from its use and for overseeing plans for its implementation at a second maternity unit within the same Trust and within the main delivery suite. Overseeing use of the pathway was viewed as being part of her overall management responsibility.

The responsibility is mine [...] I try to look at between 10 – 15 sets of notes a month to see how it is being used, and whether there are things being dropped off [...].A fair proportion of my job is defending and standing strong that this is the right way forward for normal, low risk women.

Senior Midwife at BC - BCS03

4.11.7 Consultants' preferences

Standardised care approaches, as described in the drivers' section, were developed in most sites to minimise practice variation and standardise care. However, it was not clear how successfully this goal had been met. This objective, for example, was reached by the integrated care pathway in the cardiac surgical unit when it was first introduced. At the time of data collection, there was evidence that different consultants' preferences were being referred to, as such the use of the pathway was mediated by consultants' preferences.

So I think it was quite good that things were standardised [when ICP first introduced in 2002]. I mean I think things are creeping in that different consultants still want different things, but at the time because they had to sit down, decide these certain things, what was going to be normal and what was going to be abnormal.

Senior staff nurse at CSU - CSUS12

Then he [the nurse] was explaining to me that Mr X's [a consultant] team only put one drain in, all the others put two. Thank god I had Mr X.

Patient at CSU – CSUP03

At the POA clinics the impact of consultants' and anaesthetists' preferences on the use of standardised care approaches was more prominent. Decisions about the relevant pre-operative tests a particular patient would undergo were not always determined by the pre-operative adult investigations guidelines, but by the preferences of the medical team. This was reported by junior nurses and doctors and nurse practitioners in interviews and also it was noted in observations.

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Because again it's what the anaesthetist, the registrar and the consultant will expect to see. They want to see that result [referring to a blood test], even though according to the protocol you wouldn't do it. [...] In terms of the protocols and stuff it's more do the consultants agree with what we do and that sort of thing really.

Urology nurse practitioner at POA – POAN03

I work very much on what I know my consultant has a preference for, what the anaesthetist has a preference for.

House officer at POA - POAS03

She said that all breast cancer patients have Chest X-rays and other patients vary on their conditions and on what she finds on examination but also her decisions are based on what anaesthetists want. This again brings up the discrepancy between consultants and what impact that has on professionals' practice, in this case on investigations.

(Field notes excerpt, POA)

In this site it seemed that the use (or not) of standardised care approaches was influenced by consultants' views and preferences.

4.11.8 Mandatory

Finally whether the standardised care approach was mandatory affected its use. The only example of this was in the walk in centre and the use of PGDs. If nurses wished to prescribe they had to use a PGD, which ensured they were always used.

I have done the course for the [PGD], I have done the study day for the PGD which allows me to give medication, [...] It is an aid for my practice because without the course I cannot really give – if I am going to give any medication I have to call somebody that has already done the course to countersign for me.

F grade nurse at WIC – WICN01

4.11.9 Summary

Factors that facilitated or inhibited the use of standardised care approaches included:

- their visibility and location. In sites where they were more visible, physically close to the point of care and easily accessible, they were more likely to be referred to and used.
- Embedding standardised care approaches in regularly used documentation also increased the likelihood of use.
- The degree of flexibility of pathways and protocols influenced how and if they were used.

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- Where there were varying levels of stakeholder buy-in, the commitment to their use was also variable. Where there was resistance this resulted in lack of use and/or co-operation.
- Where practitioners could see a direct impact on care, practice or service delivery, standardised care approaches tended to be used more readily.
 - This was particularly significant in the GP site where financial incentives ensured the use of protocols.
 - In sites where standardised care approaches were enabling autonomous and nurse-led practise they were used regularly.
- In some cases the use of standardised care approaches were perceived to be time consuming.
- The absence of a dedicated project lead had, over time, led to decreasing or patchy use of protocols, pathways and guidelines.
- Instead of using information contained in protocols and pathways, in two sites consultants' preferences were deferred to.
- Where protocols are mandatory, such as in the case of the PGD, they are used consistently.

4.12 Summary Of Findings And Links To Initial Propositions

The case study evaluation and decision making study enabled the exploration of a variety of standardised care approaches, their impact on practice, and the collection of multiple perspectives. Findings show a mixed picture, which is summarised below. A commentary about how these findings link to initial propositions is then presented.

4.12.1 Properties of protocol-based care

There was a wide a variety of standardised care approaches being used to deliver services, including pathways, local guidelines, protocols, algorithms, and patient group directives across sites, and sometimes within sites. These covered various patient conditions and types of service delivery.

Standardised care approaches were being used by all members of the multi-disciplinary team, but in this study as a consequence of the study's aims, we focused mainly on nurses', midwives' and health visitors' role and contribution. In summary:

- Protocol-based care was not a term familiar to study participants; however they were very familiar with its constituent elements, such as protocols and guidelines.
- The purpose of protocol-based care was identified as standardisation of care.
- Different types of standardised care approaches were perceived to have differing levels of prescriptiveness or flexibility. Protocols for example were viewed as restrictive, and guidelines and care pathways as more flexible.

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- Standardised care approaches were viewed as potentially important mechanisms for making minimum standards of care explicit. This was thought to be particularly useful in contexts where there were frequent staff changes providing newly qualified and/or staff unfamiliar to the setting with a source of information.
- The potential of protocol-based care to deliver a minimum standard, and as a mechanism to improve consistency was also highlighted.

4.12.2 Development of standardised care approaches

Drivers

Standardised care approaches had been developed within sites for a variety of reasons; some of these had appeared to impact on whether and how they were then used in practice (discussed later). The following issues were the main drivers:

- Commonly, the need to standardise care and/or practice variation was cited as one of the main reasons for the development and introduction of protocol-based care tools. Standardisation was motivated in response to the setting up of new services (e.g. the walk-in centre), service re-organisations (e.g. GP site), and frequent staff changes (including doctors and nurses).
- The development and introduction of standardised care approaches in four sites was aimed at improving service delivery in response to national policy initiatives. This included improving access to primary care services (WIC), decreasing waiting times (POA), midwifery led care (BC), and improving the management of chronic conditions through the quality and outcomes framework (GPS).
- Examples of local or clinically led initiatives were also evident. For example, the need to be able to prescribe to deliver the nurse-led service in the walk in centre motivated the development of PGDs, and in the GP site identifying local population needs for protocol development.
- The development and use of standardised care approaches as possible risk management tools were also evident, particularly if there had been patient complaints.
- The need to improve documentation and reduce duplication was a driver in one site.
- In the GP site the potential for financial reward (through the QOF) and cost efficiency had motivated the development of QOF related protocols.

Development Process

Standardised care approaches were developed following a similar pattern in most sites, without reference to a specific development framework and with little organisational support for leads. Issues in this process were:

- The importance of the champion leading on the development and introduction was apparent in most sites. Leads tended to be experienced nurses who would have authority and credibility within the multi-disciplinary team (with the exception of GP surgery). Examples (e.g. CSU and GPS) suggest that success in development and implementation could be related to lead's personal qualities and the way they were perceived within the team.

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- Involving the multi-disciplinary team in developing care approaches was difficult. Commonly, leads would work with different professional groups in parallel at draft stage. However, the level of buy-in was wide-ranging and in some cases medical and pharmaceutical staff's reluctance to standardised care approaches was as an obstacle to its effective development and implementation.
- A 'bottom-up' approach to development and auditing was perceived as a way to facilitate ownership of the standardised care approach in two sites. Discussing and debating issues early on ensured understanding and was an opportunity to resolve tensions about standardised care approaches' use and impact on practice.
- Patients were not usually involved in development of standardised care approaches. However, in one site where 'naturally occurring' patient groups (e.g. NCT groups) were available they were usually consulted.
- Anxiety about changes in practice related to the development and introduction of standardised care approaches was reported as a challenge. This was usually addressed by engaging practitioners in early discussion and debate about what the introduction of the standardised care approach would mean in practical terms.
- Buy-in and early engagement in development seemed to be important in gaining ownership, as described earlier. However, typically practitioners and most leads took part in development activities in addition to other responsibilities. This lack of protected time made it difficult for them to perform the role effectively.
- A variety of sources underpinned standardised care approaches. Commonly, national guidelines, whenever available, were adapted to suit local needs. Other common sources were consultant/nurse experience, consensus and best practice. It was not clear how evidence was gathered or synthesised.
- Updating standardised care approaches was perceived as essential to maintaining their relevance and value to practitioners. However, the process was perceived as lengthy and difficult due, mainly, to lack of resources (e.g. lack of time or lead).

Approaches to implementation

Overall, effort and resources were invested in the initial dissemination and implementation of standardised care approaches, but not necessarily in on-going monitoring, reviewing and updating.

- Mostly, traditional dissemination and implementation approaches such as training sessions, official launches and meetings (team and individual) were used.
- Supporting standardised care approaches with specific training and meetings to discuss changes was successful in most sites; however it did not tend to last after the initial introduction impetus.
- An example of successful on-going monitoring, audit and training emerged in the WIC where PGDs were incorporated into nurses' competencies assessment with the pharmacy department being responsible for auditing and training nurses when deficiencies were identified.

- Implementation was reportedly difficult in an environment where staff changed frequently. Paradoxically, standardised care approaches are considered ideal for clinical settings where new or temporary staff is delivering care. However, in the reality of clinical practice, maintaining transient staff's awareness about relevant standardised care approaches was perceived as a challenge.

4.12.3 Impact of protocol-based care

How standardised care approaches were used

Overall the way standardised care approaches were used within and across sites was highly variable. Generally their use could be placed on a continuum from implicit to explicit use. Explicit refers to their obvious use in interactions with patients, and implicit, to the occasions when nurses (and others) may have been following the principles contained in the protocol-based care tools, but did not overtly refer to them. Interview and observation data showed that the use of standardised care approaches manifest in a number of ways.

- Commonly they were used as checklists and references. They prompted what needed to be done next, how, or (more commonly) as a check that everything *had* been done.
- There were examples of nurses referring to available standardised care approaches during interactions with patients (for example in the WIC), however more commonly they would be referred to after a procedure or at the end of a shift.
- There was a concern by nurses and doctors that using these tools as checklists could lead to a 'tick box mentality'. Observation of practice did uncover some evidence of this.
- Whilst there was a concern about standardised care approaches being restrictive, interview data and observations show that nurses continued to use their clinical judgement even when referring to or using them. As such they were believed to support, rather than remove the need for clinical judgement.
- The role of experience also emerged as importantly linked to making appropriate judgements and decisions. There was an expectation that senior nurses, because they were experienced, should already be aware of the information contained in the protocol-based care tools.
- As such, it was felt that standardised care approaches were particularly useful and relevant for students, new or newly qualified staff. In two sites the standardised care approaches had been linked into induction and training materials.

Impact on nurses' role

Two main impacts of the use of standardised care approaches on nurses' role were found. First, they enabled the extension of traditional nursing roles, and second, they supported nurses' ability to practice autonomously.

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Specifically these findings emerged from the walk-in centre, pre-assessment clinics, birth centre and diabetes clinic.

- By using standardised care approaches nurses were taking on new tasks and developing skills beyond the traditional scope of practice.
- Nurses were able to take on prescribing, diagnosing, ordering tests and in some cases deciding on treatments. The ability to perform these roles meant that nurses were able to run clinics or services independently.
- The extension of roles to incorporate prescribing for example meant that nurses were able to provide a more streamlined service for patients because they did not have to refer to doctors. In turn, this reduced doctors' workload.
- Role extension was viewed as a positive impact, and was linked to nurses' ability to practice autonomously with 'protection'. There was a common perception that standardised care approaches were a safety net against any potential litigation for working in extended roles.
- In addition to the assurance that using standardised care approaches instilled, they gave junior nurses confidence, because they were a reference and guide for ensuring they were practising appropriately. However, some doctors felt that using such tools could also provide a false sense of security.

Impact on decision-making

Findings from the decision-making ethnography showed how nurses make decisions with and without reference to standardised care approaches. Data showed that the variety and number of decisions made by nurses was large, and that decisions varied according to many differing and interacting factors. The types of decisions made were often complex including a melding of social as well as health dimensions. A number of findings emerged with particular relevance to the use of standardised care approaches, including:

- Nurses' decision-making was variously informed by formal and informal protocols. Whilst a number of formal protocols were available in both sites, in reality they were rarely explicitly referred to. Often nurses used local ways of working and internal protocols when making decisions.
- There were a number of sources of information that informed nurses' decision-making, including 'instinct' or clinical experience, colleagues (particularly those that were senior), and patients. Nurses reported that relying on 'instinct' came with experience. In both sites the primary approach to knowledge exchange and acquisition was person-to-person contact; if nurses were unsure they tended to talk to a more experienced colleague (because referring to a protocol would take more time). In the diabetes clinic nurses also used patients' experiences and preferences as a source of information in decision-making. In this site there was evidence to suggest that decision making about patient care was generally a collaborative process between patients and practitioners.
- There was no evidence to suggest that doctors and nurses were using standardised care approaches to enable team-based interaction or decision-making.
- Nurses who worked in more autonomous roles (in the diabetes clinic) had more decision-making latitude.

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- Standardised care approaches were reported as being useful for supporting decision-making when staff are inexperienced (as a reference), when performing non-routine procedures to check on process/detail, for protection if judgement might be questioned, to ensure appropriate care in the context of reduced staff numbers, and as a guide, which then may need to be particularised to the patient and situation.
- As described above there was a perception that standardised care approaches are more useful for inexperienced staff because as nurses became more experienced they 'internalised' procedures and protocols, and then relied on their memory and/or clinical judgement.
- Many of the standardised care approaches only covered a specific aspect of patient care. Therefore their utility for decision making may be limited by the fact that they only have the potential to cover discrete aspects of the decisions that need to be made about patient care.
- If standardised care approaches were not readily accessible they were less likely to be referred to, in contrast, where they were embedded in routine documentation they tended to be used.
- The availability of resources such as equipment stipulated in protocol-based care tools, determined the extent to which they could be followed.

Impact on professionals' roles and team working

Findings from these studies show that standardised care approaches had a limited impact on team working and roles.

- Whilst there were examples of standardised care approaches being developed for use by the multi-disciplinary team, there was a common perception amongst both doctors and nurses that protocol-based care is a nurse's thing and a nursing/midwifery initiative.
- With the exception of the GP site and junior doctors, medics were not obviously using available standardised care approaches. Whilst some GPs expressed their reluctance to follow protocols, they were doing so through the QOF.
- Standardised care approaches tended to formalise and clarify professional's respective roles, rather than enhance the potential for better team working.

Impact on patients' experiences

Data from patient interviews and observations provided a perspective on standardised care approaches from a non-professional view point.

- Apart from in the walk-in centre, patients were unaware of being cared for through standardised care approaches. It was obvious in the walk in centre that nurses were using the on-screen algorithm to guide their consultations; however this was not the case in other sites. Patients did however assume that practitioners were following procedures, which patients became more familiar with if they had on-going contact with a service.
- Some nurses and doctors assumed that patients would not be interested in knowing whether they were being cared for using protocols.
- Whilst generally patients were not explicitly aware that standardised care approaches may be being used, they did experience care that was

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guided by them. That is, when they were used, their care may have been delivered according to the contents of the particular protocol, pathway, or guideline etc.

- Some patients reported feeling overwhelmed by the amount of information they received, which had been determined by the contents of the standardised care approach.
- Some patients experienced standardised care, which at times might have been at the expense of individualisation. However they did report being involved in care and this was seen during observations.
- GPs highlighted the potential conflict between a professional versus patient-led agenda in interactions using the SOFIs. GPs reported that working through the SOFIs meant that the consultation may not be patient centred. The SOFIs cover general health issues (i.e. blood pressure, smoking, diabetes) whereas a patient may have come to into the surgery with a specific and different problem.

Impact on organisational outcomes

Whilst hard data were not available to verify impact on organisational level outcomes, perceived impacts were reported.

- Standardisation of practice had resulted in some cases in standardisation of resources and so cost containment. For example, determining the sort of medicines, dressings, and tests to be used within tools such as care pathways and protocols, had the potential to impact on what was used, how much and when (assuming that such tools were being used). In some cases there was a perception that this had been an outcome, and in one site actual reduction in costs had been noted.
- The potential to re-distribute roles and tasks between doctors and nurses with the introduction of extended role supported by standardised care approaches, had resulted in a reduced workload for doctors in the GP site and WIC.
- The use of referral and streaming protocols had resulted in more successful referrals between settings, and departments.
- In one site, the introduction of a patient pathway was perceived to have impacted on containing, and in some cases reducing, patients' length of stay.
- The introduction and consistent use of QOF related protocols in the GP site had positively impacted on performance and the achievement of targets, which resulted in financial rewards.
- The use of the normal labour pathway was perceived to have streamlined documentation within the birth centre; however this documentation was not being used in the delivery suite, indicating that documentation had been streamlined in one setting within maternity services in this site.

Influences on use

The ability to study in different settings, focussing on various protocol-based care tools from the perspective of different stakeholders and sources of evidence, enabled the identification of factors that either facilitated or inhibited the use of standardised care approaches.

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- Where standardised care approaches are visible, close to the point of care and easily accessible practitioners were more likely to refer to, and use them. Embedding these tools in routinely used systems and documentation also facilitated their use. In sites where visibility and accessibility was poor, the use of standardised care approaches was patchy.
- How flexible standardised care approaches were influenced the way that they were used. In some cases being inflexible had resulted in no or less use. However data from the WIC and GP site shows that a prescriptive standardised care approach did not necessarily result in it being used less.
- Findings showed that there were varying levels of stakeholder buy-in about particular standardised care approaches being used in sites, and about the notion of protocol-based care more generally. In sites where there were varying levels of buy in, there were varying levels of commitment to their use. Generally doctors appeared to be particularly opposed to the idea of protocol-based care.
- If the standardised care approaches made a difference, which practitioners could see, they tended to be more readily used. Significant examples of this finding is the use of the SOFIs, where meeting targets impacted on improved quality of care and financial reward, and in sites where nurses were able to practice autonomously.
- Time to complete or use standardised care approaches sometimes impacted on willingness to use.
- In sites where there was an absence of a dedicated project lead, there was a decreased or patchy use of available standardised care approaches.
- Standardised care approaches that were mandatory, i.e., PGDs, were consistently used.

Findings: link to initial propositions

A number of working propositions were developed from the evidence review and originally presented in section 2; these are now considered in the light of the findings reported in section 4. Consistent with realistic evaluation's approach to theory building, comparisons have been developed by considering context, mechanism and outcome in an iterative way throughout the research process (Pawson & Tilley 1997). The assessment of the propositions has been made by comparing the main finding summaries with each of the propositions in the four theory areas. The results of this comparison are reported as narrative commentaries in the text box below. These commentaries then provide the linkage to a detailed discussion about the differences and similarities that emerged from these studies in comparison to previous research (section 5). This comparison and discussion then links to the summary of 'what works, for whom, how, and in what circumstances' presented in section 5.6.

Initial propositions	Commentary
<ul style="list-style-type: none">• A clear understanding about the purpose and nature of protocol-based care by potential users will	<ul style="list-style-type: none">• Whilst participants were unfamiliar with the term protocol-based care they were clear about its purpose;

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<p>determine the extent to which standardised care approaches are routinely used in practice.</p> <ul style="list-style-type: none"> • The properties of standardised care approaches, such as degree of specificity and prescriptiveness, will influence whether and how they are used in practice. 	<p>standardisation of care. Findings suggest that other factors were more important in determining the extent to which standardised care approaches were used (or not). Furthermore, the drivers for developing and implementing such tools appeared to be important predictors of their sustained use.</p> <ul style="list-style-type: none"> • There was a perception that different standardised care approaches had differing levels of flexibility. Findings were contradictory in terms of whether the degree of flexibility or prescriptiveness influenced whether and how they were used in practice. In some cases the need for flexibility was important, in other examples prescriptive protocols and algorithms were being consistently used, but with the use of clinical judgement. These findings indicate that other factors also impact on the use of standardised care approaches in practice.
<ul style="list-style-type: none"> • Protocols that are developed through a systematic, inclusive and transparent process may be more readily used in practice. • Protocols that are based on a clear and robust evidence base are more likely to impact positively on outcomes. 	<ul style="list-style-type: none"> • A 'bottom-up' approach to development seemed to have an impact on ownership and use in one site; however resources, such as protected time for practitioners to get involved, were usually not available. More commonly, development was ad hoc with practitioners being consulted at draft stage. An inclusive development strategy may have an impact on use; however it is difficult to isolate this factor from others such as the perception about the need to change practice. • Standardised care approaches that were perceived as making a visible difference (e.g. QOF) were relevant to practice were usually being used and reportedly were improving the care provided. Generally, practitioners expected standardised care approaches to be based on robust research and thus to have a positive impact on care. However it was unclear how robust the evidence base was for many standardised care approaches being used.

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<ul style="list-style-type: none"> Locally developed protocols may be more acceptable to practitioners and consequently more likely to be used in practice. 	<ul style="list-style-type: none"> The applicability of locally developed or adapted standardised care approaches was broadly recognised. In contrast, there were examples of nationally developed care approaches which were being successfully used (e.g. SOFIs, algorithms). These findings suggest that other factors in addition to local development might have an impact on use.
<ul style="list-style-type: none"> The impact of protocol-based care will be influenced by the type of protocol being used, by who is using it/them, how, and in what circumstances. The impact on decision making will be influenced by practitioners' perceived utility of standardised approaches to care. More senior and experienced nurses will be less positive than junior and/or inexperienced nurses about using standardised care approaches. Protocol-based care will impact on the scope and enactment of traditional nursing roles. Protocol-based care has the potential to enhance nurses' autonomy and decision-making latitude. The impact on patient care will be influenced by the characteristics and components of the protocol and factors in the context of practice. 	<ul style="list-style-type: none"> The impact of the use of standardised care approaches was determined by a number of interrelated factors including who was using them, how, for what reasons and in what contexts. These factors are difficult to disentangle. Decision making was informed by many sources of information, including informal and formal protocols. Findings demonstrate the difficulty of isolating the influence of any one factor in decision making. The utility of standardised care approaches was believed to be more relevant to junior and new staff. Standardised care approaches had enabled the extension of traditional nursing roles in some sites. Role extension was linked to practising autonomously. More senior nurses had more decision-making latitude. Nurses who had extended their role and who were using standardised care approaches were able to make decisions and enact roles beyond those they were traditionally trained for. Patient care was often delivered according to the contents of a particular standardised care approach. The approach of the individual practitioner determined whether the standardised care approach was used explicitly in interactions with patients.
<ul style="list-style-type: none"> Interactive and participatory approaches and strategies to 	<ul style="list-style-type: none"> Ongoing monitoring and auditing of standardised care approaches

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implement standardised approaches to care may influence whether or not they are used in practice.

- The support of a facilitator or project lead may increase the likelihood of the on-going use of standardised care approaches.
- Embedding the standardised care approach into systems and process may facilitate use.
- Some contexts will be more conducive to using standardised care approaches than others.

seemed to influence use in two sites (CSU, WIC). Providing feedback on and a forum for discussion of (in the form of meetings and/or audits) the use of standardised care approaches during implementation and beyond seemed to facilitate their use as it was originally intended.

- The absence of a dedicated project lead did lead to decreased use of available standardised care approaches.
- Standardised care approaches that were embedded into routinely used systems and documentation facilitated on-going use.
- Some contextual factors, rather than contexts per se, influenced the use standardised care approaches.

The findings provided a richer, complex and more detailed picture of protocol-based care than that found in the existing literature. The initial propositions represented the key issues to emerge from the evidence review, which as the above commentary shows, only partially correspond to the multiple findings reported earlier. The following sections discuss the findings in more detail, before drawing some conclusions about protocol based care in relation to what works, for whom, how and in what circumstances.

5 Discussion And Implications

Protocol-based care is embedded in the government's modernisation agenda and from a policy perspective is viewed as a mechanism for facilitating standardisation and the extension of the nursing workforces' professional practice. The expectation that by 2004 the majority of NHS staff would be working under agreed protocols was ambitious, but signified the political enthusiasm for protocol-based care as a way of working.

To date, there has been a lack of larger scale research exploring protocol-based care as enacted in the reality of the clinical setting. The case study evaluation and decision-making ethnography provide a multi-site evaluation that has shed some light on some key questions. As the findings show, the development, use and impact of standardised care approaches is multi-faceted, and largely context and professionally specific. Key findings from both projects are discussed below, together with their implications. Whilst they are presented as discrete sections they should not be viewed as mutually exclusive issues because there is overlap between them. A number of these issues offer the opportunity for greater theoretical elaboration, which we will continue to do and disseminate in other publications. Finally, a summary of 'what works, for whom, how, and in what circumstances' is presented before recommendations are made.

5.1 Properties of protocol-based care

5.1.1 The nature of protocol-based care

It is perhaps not surprising that the policy discourse has yet to permeate to clinical practice and that the term protocol-based care was unfamiliar to those participating in the study. The term was originally developed by policy makers and not defined (DH 2000). Later, the Modernisation Agency (2002) described the purpose of protocol-based care as providing clear standards and statements for local care delivery. Even if practitioners did not recognise the term; they did articulate its purpose, which for them was about standardisation of care, and sometimes resources. This enabled consistency and a minimum level of care to be delivered in contexts where there were frequent staff changes because they provided a reference. Previously, the main purpose of standardised care approaches has been to impact on improved patient care and/or organisational outcomes through standardisation. This research indicates that standardised care approaches may also be useful context specific information resources for nurses, allied health professionals and some doctors.

There were many different types of standardised care approaches being used within sites, covering various patient conditions and situations, which is consistent with national survey findings and other literature (e.g. Currie 1999, Currie & Harvey 2000). The most commonly used approaches were

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care pathways, local guidelines, protocols, algorithms, and PGDs. Each of these mechanisms was perceived, and did in practise, have differing levels of prescriptiveness, specificity, and applicability. For example algorithms and PGDs were specific and prescriptive and particularly applicable at the level of the patient-practitioner interaction. In contrast, care pathways and local guidelines were broader frameworks for care, with less operational detail contained in them and applicable to care delivery at multiple levels. These findings are consistent with the analysis of the literature presented in Chapter 2 which have been further conceptualised in Figure 3.

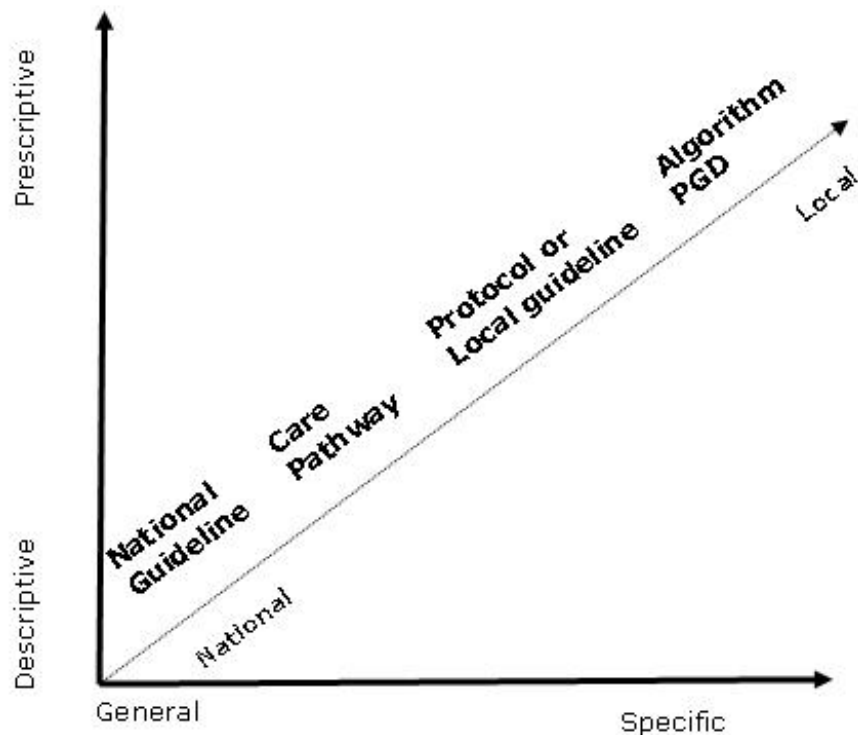


Figure 3. Conceptualisation of frequently used standardised care approaches

This conceptualisation demonstrates that different standardised care approaches can be plotted on axes related to their specificity and level of detail. As such, findings from this research suggest that algorithms and PGDs are highly specific and prescriptive. In contrast care pathways were more general, less specific and descriptive; providing broader frameworks for care.

Findings indicate that the characteristic of the standardised care approach does not necessarily impact on if, and how, it is used. For example nurses were concerned that protocols and algorithms could be restrictive because they were prescriptive; however, generally, they used them (even if implicitly). Critically, it emerged that when using them, they used them flexibly by frequently exercising their clinical judgement. This finding is consistent with Berg's analysis of protocol use in which he suggests such technologies are 'often circumvented, tinkered with, and interpreted' (1997, p1082). Observation of practice revealed this to be the case across all sites

with many practitioners, particularly those with more experience and familiar with the clinical context. Such use has implications for the policy intention of protocol-based care, which is about standardisation. If practitioners use standardised care approaches in a flexible and individualised way, the goal of standardisation is unlikely to be met. These, and other related issues are discussed further below (section 5.4).

5.1.2 Defining protocol-based care

In an early attempt to define protocol-based care Rycroft-Malone et al (2004) suggested that it is an umbrella term that encompasses the use of a variety of clinical care processes. Illot et al (2006) also attempted to clarify 'what is protocol-based care', which resulted in a definition that appeared to separate the application of protocol-based care into standardisation of care processes, and delegation, and introduced the idea of following codified rules. Building on this work, our findings based on self report and observation data enable the development of a more comprehensive understanding of what protocol-based care might be. Given the complex picture of practice that emerged it is difficult to determine whether any of the sites were actually engaged in a way of care delivery that could be called protocol-based care. Certainly practice was being informed variously by the use of standardised care approaches; the key question is whether protocol-based care is greater than the sum of its parts. In our study sites this was not clear.

Findings suggest that protocol-based care could be defined as:

The use of standardised care approaches, which implicitly and/or explicitly inform or guide practice. A standardised care approach is a mechanism that contains codified information about the process and delivery of care in relation to conditions and/or procedures. The purpose of introducing and using standardised care approaches varies from setting to setting. Primarily protocol-based care is concerned with standardising care and resources, and supporting new ways of working. For nurses, they can support them to work beyond their traditional scope of practice and to practice independently. Judicious use of standardised care approaches requires that judgement is exercised in order to individualise care to patients and settings.

In contrast with Illot et al's definition (2006), with the exception of the mandatory use of PGDs to support nurse prescribing, none of the standardised care approaches being used in these sites were either viewed as, or used as, rules. Furthermore, standardised care approaches were not necessarily being used to delegate tasks between doctors and nurses. Clearly it is difficult to separate out these issues but in examples where nurses were practising beyond the traditional scope of nursing practice (e.g. Walk in Centre, Pre-assessment clinics) and as independent practitioners (e.g. midwives and health visitors) it was by virtue of their experience and/or training, the context of practice and approach to service delivery. However in some cases standardised care approaches did support their ability to perform in these roles.

5.2 Development of standardised care approaches

The potential to improve care through the use of standardised care approaches is predicated on an assumption about their underpinning evidence base, and that practitioners accept them and use them as intended. The use of standardised care approaches is discussed further below; the way in which they were developed is explored in more detail here.

5.2.1 Motivation for development

Our findings show that the motivation for the development of standardised care approaches varied within and across sites. Standardisation was important, but so were other factors, including the need to streamline documentation, support the development of new services, for risk management, and as an approach to meet targets. In some sites these motivating factors appeared to influence the extent to which the resulting standardised care approach(s) were used. For example in the GP surgery their wish to deliver care through the Quality and Outcomes Framework had led to the development of a number of protocols; which were consistently used. This use had led to the meeting of targets and subsequent financial reward. In sites where standardised care approaches had been developed to support new ways of working (e.g. Walk in Centre and Midwifery led Birth Centre) they too tended to be used. These findings add to the existing evidence base about protocol-based care use. Previous researchers tend to identify the purpose of developing and introducing standardised care approaches as an approach to improving and standardising care (e.g. DeLuc 2000, Sulch et al 2002, Karkouti et al 2006). Furthermore as Hunter & Segrott (2007) highlight in their analysis of care pathway literature, the development process tends to begin with the selection of an appropriate clinical condition, with a lack of consideration for contextual issues. Our findings indicate that other motivating factors, in addition to improvement and standardisation may be influential. Whilst these are likely to vary from setting to setting, the implication is that identifying and being clear about what the other motivating factors are beyond the need for standardising care about a particular clinical issue or condition, may lead to greater commitment to their initial and sustained use, in practice.

5.2.2 Development process

Whilst there are frameworks and guidance about how to develop protocol-based care tools (e.g. MA/NICE) findings indicate that generally standardised care approaches had been developed in a fairly ad hoc way. However, there was some consistency in process whereby most sites had gone through some form of staged process. However within this process there appeared to be varying amounts of structure. Findings show that existing development frameworks and guidance were not used, and that the development process relied largely on the skills of project leads and champions.

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Role of project lead

Findings indicate that the project leads were pivotal to the development of standardised care approaches in all sites. This is consistent with evidence-based practice literature, which identifies the critical role that a dedicated project lead can have to the success of implementation projects and in the implementation of standardised care approaches (e.g. Harvey et al 2002, Dopson et al 2002 & 2005, Rycroft-Malone et al 2004b, Hockley et al 2005, Watson et al 2006). Previous research indicates that facilitators and project leads have the potential to work with individuals and teams to develop ideas, assist with evidence gathering and particularisation, and implement enabling strategies and processes. These people need to be credible, appropriately skilled, have drive and enthusiasm. Findings from this study show that project leads rarely had dedicated time to devote to the development or implementation of standardised care approaches, but took on this role alongside other commitments. The leads were generally viewed as credible and were respected by colleagues; however they did not necessarily have previous experience of standardised care development or implementation, which is consistent with previous work (Currie & Harvey 2000a&b). Most of the leads were nurses, which may have been significant when it came to facilitating multi-disciplinary buy-in. In the site where there was a nurse lead developing a multi-disciplinary pathway, stakeholder buy in was poor. However it is difficult to assess whether this was because of general resistance by doctors to the idea of the care pathway generally, rather than a nurse lead specifically.

The role of the lead or champion appears to be key, which implies that standardised care projects might be more successful if they were given dedicated time, had the appropriate skills and experience, and the ability to engage key stakeholders at all stages of the process.

Multi-stakeholder buy-in and involvement

The approach to the development of the standardised care approaches did not demonstrate multi-disciplinarity. There appeared to be differing levels of engagement with protocol-based care across and within sites and across and within professional groups. In contrast to the view that the development process provides an opportunity and forum for debate and discussion (Currie & Harvey 2000a&b & deLuc 2000), these findings showed that the leads tended to work with the different professional groups separately. This is consistent with Jones's work (1999) in which he described a reluctance from all disciplines to be engaged with a large amount of time being spent in individual rather than group discussions to agree content. The exception to this finding was in the GP surgery where doctors, nurses, midwives and health visitors worked together to develop a number of the standardised care approaches. It could be that the nature of team working was better developed in this site than in the others, which resulted in more collegiate ways of working.

The issue of buy-in and involvement may have significant implications for use and for policy. There is evidence to suggest that guidelines and pathways, for example, will only be used by healthcare professionals if they

feel they have been part of the development process or local application (Greenhalgh 2002, Mitchson & Cowley 2003, Appleton & Cowley 2004, Rees et al 2004). Such involvement is likely to engender a sense of ownership. As such, standardised care approaches may be less likely to be used if there has been little stakeholder involvement, buy-in and so ownership. Our findings suggest that involvement may impact on the extent of use of some standardised care approaches. However the evidence is contradictory. For example, the algorithms used in the walk-in centre were not developed by the nurses themselves, yet they were used because they gave them confidence to work outside their scope of practice. In other sites standardised care approaches were used by those who had been involved in their development, and not used by others. It is therefore unclear whether involvement in development (or not) results in more or less use; other factors play an equal or greater role in the likelihood of use.

Politically, differing levels of engagement of individuals and/or professional groups with protocol-based care, is likely to have implications for the government's ambitions. The modernisation agenda, which includes the development of effective and efficient services, is partly founded upon an assumption that practitioners will engage with the notion of standardisation. For example, the development of national guidelines by the National Institute of Health and Clinical Excellence as part of this agenda is predicated on an assumption that these guidelines, once produced, will be used in practice. Findings from these studies, which build on previous research (e.g. Sheldon 2004) show that this may be a misguided assumption. The use of standardised care approaches, such as guidelines and protocols, is in fact a complex and multi-faceted issue, which is not only mediated by individual's behaviour but other bureaucratic, political, organisational and social factors.

Evidence base

A variety of sources of evidence were used to underpin the standardised care approaches, however they mainly drew on existing sources of synthesised evidence, such as national guidelines, national services frameworks, and Prodigy. This raises questions about how national, population level research, can be applied to local, context specific issues (Jones 2000). There was a lack of detail about how (and if) these evidence sources were adapted or synthesised with any other sources of information at local level. Findings indicate that in the absence of research evidence best practice was integrated. Clearly best practice varies from setting to setting, which undermines the aim of standardised care approaches, which is to provide evidence-based standardisation. If local best practice is used, variations will continue to exist.

It has been suggested that in protocol development it is easier to incorporate information that is easy to 'explicate and/or quantify' (Berg 1997, p1085). However it is not possible to judge how and if particular sorts of information and evidence might have been privileged because these were not described. It is therefore difficult to conclude whether the nature of the

evidence base impacts on a) how and if the standardised care approaches are used and b) whether this impacts on outcomes.

One of the intentions of the development and use of standardised care approaches is the potential they have to improve patient care based on robust evidence. Findings show a lack of detail about how evidence is selected, and synthesised, which means that the impact on outcomes would be difficult to trace back to an obvious evidence base. There are also implications for updating standardised care approaches in line with current best evidence. Most of the sites did not have a mechanism for this, which means that practice and process may become quickly out of date.

Patient involvement in development

Numerous policy documents emphasise the role that patients or lay people should have in their care. Our findings show a lack of patient involvement in standardised care approach development. This is consistent with others' research (e.g. Pinder et al 2005). Nominally the patient was at the centre of many of the standardised care approaches; however their experience was determined or prescribed by a professionally led agenda.

5.3 Implementation

Findings show that generally traditional approaches to dissemination and implementation had been used, which included training sessions, official launches, team and one-to-one meetings. These findings are in common with the reports of others (e.g. Goodman 2006, Quirke 2007, Rees et al 2004). Within sites multi-pronged strategies were used, making it difficult to ascertain which had been most successful.

Like standardised care approach development, the project leads within sites played the key role in implementation efforts. However it was evident that whilst effort was put into initial implementation, on-going implementation was not sustained, particularly in cases where project leads left. In the context of a constantly changing environment, and frequent staff changes, dissemination and implementation was reportedly challenging. However, successful implementation was seen in cases where the standardised care approaches had been embedded in documents, and integrated into routinely used systems. This finding is consistent with those of, for example, Hockley et al (2005) and Goodman (2006). Presumably this approach worked because practitioners had to use them in the course of their work. An additional finding to emerge, which adds to previously published work, relates to the use of PGDs in the Walk-in- Centre. In this example the PGDs were incorporated into competency assessment, which was linked to audit and on-going training. This joined up approach to training, assessment and performance management had contributed to ensuring the appropriate and consistent use of PGDs by nurses in this site.

These findings imply that the role of the project lead is not only critical in the development of standardised care approaches but also in implementation. It may be more helpful to view these activities as one

process rather than discrete undertakings. It is unclear what the most successful implementation strategies were; further research is required to evaluate specific interventions, within different contexts, with different standardised care approaches and professional groups. However, findings from one of the sites indicate that a structured, integrated approach to implementation, which involves competency training and feedback on performance, may be effective.

5.4 Use and impact of protocol-based care

For Pinder et al (2005) and Berg (1997) a major concern is that protocols and pathways fail to incorporate the individual experience of the patient or client because they are structured around a sequence of decisions and a standard process. Our findings show that nurses (and some junior doctors) used available standardised care approaches as checklists and references implicitly or explicitly. However findings also show that care was often not obviously informed by available standardised care approaches. As data were collected in the reality of the clinical setting we were able to capture the complexity of protocol-based care practice. It was difficult to separate out the use of such tools, from the context, individual's practice and the patient, and it is difficult to do so in the discussion of them. The paradox is that standardised care approaches present a mechanistic model of practice, yet practice is rarely straightforward or predictable. The following sections discuss some of these issues further by attempting to link mechanism, process and outcome where possible.

5.4.1 Checklists – confidence – new roles

As shown, standardised care approaches were often used by nurses as checklists either during or after processes and procedures; they provided prompts, memory aids or heuristics to organise care. Some junior doctors also used them in this way. Concern was expressed by study participants that their use in this way encouraged a 'tick box mentality', which reflects the perspective of others (e.g., Berg 1997 & 2000, Jones 2004, Flynn & Sinclair 2005, Pinder et al 2005, Partington 2006, Hunter & Segrott 2007). As Partington (2006) suggests, one of the challenges to using standardised approaches is in not allowing care to become a series of tick boxes, which abstracts the patient. Some of our observations showed evidence of this, where patients were asked inappropriate questions because nurses were following a list. Additionally general practitioners working through the QOF protocols felt that consultations may not necessarily be patient-centred. However, for nurses, their use in this way was probably linked to engendering them with confidence, the ability to perform tasks beyond their traditional scope of practice and work in new roles. Furthermore they believed using such tools provided legal protection against potential litigation. In contrast, doctors felt that they provided a false sense of security.

Our findings show that some nurses were taking on prescribing, diagnosing, ordering tests and in some cases deciding on treatments; this practice was

supported by the use of standardised care approaches. Nursing taking on these roles, and practising autonomously was viewed as a positive development. These findings support those of other researchers who found that by following guidelines and protocols nurses led to more autonomous practise (e.g. Manias et al 2005) and to the development of new service delivery initiatives such as nurse-led clinics and services (Porrett et al 2003, Richardson et al 2003, Fitzsimmons et al 2005, Woodward et al 2006). Specifically our findings show that where nurses practised autonomously they were able to deliver more streamlined care because on a patient by patient basis they did not have to refer to, or follow up with doctors. This is consistent with the findings of a national evaluation of independent nurse prescribing in which less reliance on doctors had given nurses greater satisfaction and autonomy and had a positive impact on patient care (Latter et al 2004 & 2007). Research indicates that there is a strong link between professional autonomy of nurses and midwives and their job satisfaction (e.g. Hunter 2004, Mrayyan 2004, Finn 2001).

Whilst this development was viewed positively by our study participants, other's express a different view point. From a sociological perspective, it has been argued that the potentially powerful way that standardised care approaches can shape professional identity, boundaries and work, is often downplayed (Berg 1997 & 2000, Pinder et al 2005). Key to this debate is the legitimisation of particular professional's distinctive bodies of knowledge. Explicating and formalising these knowledge bases through the development and use of standardised care approaches have the potential to subtly affect professional boundaries, and so identities. The introduction of new nursing roles as seen in for example the nurse-led walk-in centre and pre-operative assessment clinics are evidence of these shifting boundaries. The idea of doctor-nurse substitution is politically charged as the government looks for new ways to challenge professional boundaries to modernise the NHS. Systematic review evidence demonstrates that there are no significant differences in health outcomes, process of care and resource utilisation between doctor versus nurse led primary care. In fact patient satisfaction was higher with nurse-led care (Laurant et al 2006). It is likely that nurse led services are here to stay, the role that standardised care approaches play in supporting nurses running such services therefore needs further evaluation within different settings.

5.4.2 Judgement – decision making – adaptation

Protocols, pathways, guidelines, PGDs, and algorithms are technologies that have the potential to assist decision-making. Findings discussed above indicate that in some cases standardised care approaches explicitly informed decision-making. However findings from the ethnography, complemented by those that emerged from the case study evaluation, show that nurses and doctors make many decisions without explicitly referring to available protocols, guidelines and pathways etc. As discussed earlier standardised care approaches appeared to support rather than remove the need for practitioners to make judgements. Consistent with findings from Greatbatch et al's study exploring NHS Direct nurses' use of the computerised clinical

assessment system (CAS) in which nurses tailored rather than followed CAS recommendations, nurses in this study also adapted and individualised the care approaches.

These findings are interesting in the context of some scholar's analysis of standardisation approaches such as guidelines. A guideline has been described as the 'ultimate bureaucratic instrument: it explicates what to do when, in what way and with what means. It categorises patients, each with their own specific stories, into distinctive, homogeneous categories to ensure uniform treatment...' (Berg et al 2000, p766, a view also expressed by Harrison 2002, Harrison et al 2002, Pinder et al 2005). Harrison (2002) and Harrison et al (2002) present a model of medicine that is called 'scientific-bureaucratic medicine'. In this model, personal experience is rejected as the primary source of valid knowledge. Instead:

'...valid and reliable knowledge is mainly to be obtained from the accumulation of research conducted by experts according to strict scientific criteria.' (Harrison, 2002, p469)

Furthermore this model assumes that working clinicians are either too busy or not skilled enough to find and interpret this knowledge for themselves. As such practice should be influenced by the expert distillation of research findings into guidelines and protocols, which are communicated to practitioners for them to use in practice. As Harrison (2002) suggests, the logic of guidelines is algorithmic; that is practitioners will be guided towards particular courses of action based on what ought to be done, thus relegating clinical experience in favour of standardised, research-based approaches to care. As such, practitioner's decision-making is being directed (or controlled) and arguably their professional practice basis eroded. As Berg (1997) suggests protocols (and the like) are not benign devices, their use can have far reaching, and unintended consequences.

Whilst some have expressed a fear that using protocols took 'the thinking out of nursing' (Flynn & Sinclair 2005), paradoxically whilst the aim is to standardise and simplify decision-making processes by rationalising information (Thompson & Dowding 2002), practitioners in this study, particularly those with more experience, either did not refer to them, or used them flexibly. They tended to privilege their own experience, or the experience of others instead of referring to available standardised care approaches. This supports the findings of qualitative research conducted with NHS Direct nurses in which clinical experience was viewed as an important source of information (O'Cathain et al 2004). In this sense our findings support Hammond's Cognitive Continuum view of decision making (1996). He proposes that thinking modes will vary according to the task properties (such as complexity), uncertainty of the task content, and presentation of information.

Consistent with other decision making research, nurses, if unsure, tended to refer to human sources of information, such as a credible and knowledgeable colleague (McCaughan et al 2002, Thompson et al 2001a&b). Fundamentally our findings question whether standardised care approaches can simplify decision making.

These findings, building on others' work, imply that the political assumption underlying protocol-based care, i.e. standardisation, may be mistaken. Practitioners experienced a tension between standardisation and individualisation. Lawton and Parker (1999) suggest that the 'successful implementation of protocols and guidelines in the NHS depends on achieving the right balance between standardising practice and allowing professionals to use clinical judgement.' Furthermore standardised care approaches only cover specific aspects of a patient's care. In the reality of the clinical context, which is complex, unpredictable and multifaceted, protocol-based care tools will need to be, and arguably should be, adapted in use. Findings show that nurses in this research adapted standardised care approaches in response to a number of factors, including:

- patient circumstances and preferences
- their own and others' clinical experience
- contextual factors, such as local ways of working and availability of resources

This judicious use means that it can not be assumed that a standardised care approach will be used in the way that it was originally intended when it is introduced into the real world of practice.

5.4.3 Experience – decision-making – internalisation

The ability to see 'the whole' is viewed as a characteristic of expertise (Benner 1982 & 1984). That is, experts do not make decisions in incremental ways, but by assimilating knowledge holistically. This may explain the findings that show more senior nurses tend not to refer to standardised care approaches, and junior, new and inexperienced nurses (and doctors) find them useful. These findings are consistent with previous research exploring the use of decision trees and protocols (Dowie 1996, Blackwood & Wilson-Barnett 2007). In our research, junior, inexperienced or new staff found available standardised care approaches useful reference guides. However, as Bucknall (2007) suggests decision-making behaviour changed over time. As these staff became more experienced, confident and familiar they referred to them less and less. Some senior nurses described the result of this process as internalisation.

There is a lack of consensus about the role intuition plays in nursing practice. Intuitive-humanist models of decision making suggest that intuitive judgment distinguishes the expert from the novice; the expert does not rely on analytical principles to act. 'Nursing appears intuitive to the outside observer and feels internalized within the practitioner; clinical decisions are the result of an almost unconscious level of cognition' (Thompson 1999, p1224). For senior, more experienced and expert nurses, the question is whether there is a role for the use of standardised care approaches in their practice, and if so what would that be? Some senior nurses stated that if they were faced with new situations they would refer to available protocols. In which case, their potential as a source of information may be useful. Perhaps it is more fruitful to determine who they are *most*

useful for, how and in what situations, and acknowledge that standardised care approaches have their limitations.

5.4.4 Multi-disciplinary team – decision making – roles

Previous research suggests that standardised care approaches have the potential to facilitate greater collaboration between professionals (e.g. Currie & Harvey 2000b). Findings show that standardised care approaches had no effect on team working. In fact there is evidence to suggest that standardised care approaches formalised respective roles, rather than enhanced team working. Previous sections have discussed the professionally segregated care pathway that was developed in one site, in other sites with the exception of the GP surgery; medics were not using available standardised care approaches even if they were applicable to them. Atwal and Caldwell (2002) also report fragmentation of care when they attempted to introduce a care pathway for fractured neck of femur in one UK hospital. As they note the introduction of such approaches, which should integrate care across teams, does not equip professionals with the skills to become effective team players.

Our findings demonstrate that some doctors thought protocol-based care is a 'nurse's thing'. Research suggests that nurses and doctors have different views about adherence to rules and guidelines (e.g. Parker & Lawton 2000, McDonald et al 2005). Doctors have been described as 'rule breakers' and nurses as 'advocates of standardisation' (McDonald et al 2005). Doctors tend to perceive such tools as threats to their professional autonomy, and prefer to exercise clinical judgement (Lawton & Parker 2000). Nurses on the other hand prefer to adhere (McDonald et al 2005). However, our findings provide contradictory evidence, which indicates that not all doctors are rule breakers, and not all nurses are advocates of standardisation. Some doctors, notably junior doctors and General Practitioners working within the QOF used standardised care approaches. Some nurses, particularly those that were senior, more experienced and/or independent practitioners were resistant to using them. In our study junior doctors found standardised care approaches useful information resources, and GPs used protocols because they were incentivised. Some GPs also acknowledged that using them had improved the quality of care delivered to patients. Nurses did not use them because they preferred to use their clinical judgment. This indicates that the different perceptions between doctors and nurses about protocol-based care may not be as clear cut as previously reported. The successful use of standardised care approaches within the multi-disciplinary context may be more a function of the ability to work together as an effective team, than about particular professional views concerning protocol-based care; particularly when those views might be shared amongst individuals across professional groups.

5.4.5 Standardised care approaches – interactions – patients' experiences

As Hunter and Segrott (2007) state, patient and carer experiences are usually overlooked in protocol-based care evaluation and research studies. Previous research has tended to focus on the measurement of clinical outcomes and sometimes patient satisfaction (e.g. DeLuc 2000, Sulch et al 2002) but less on patients' experience of the process of care. This study therefore contributes to the evidence base because it provides a non-professional perspective of the process of protocol-based care through observation of practitioner-patient interactions and patient interviews. Interestingly with the exception of patients in the walk-in centre where consultations were often explicitly guided by on-screen algorithms, patients were generally not aware that they were being cared for by a standardised care approach. However, they often experienced care that was being guided by them, that is, their care had been delivered according to the contents of a particular pathway, protocol, or local guideline. Observations also showed that some patients experienced standardisation rather than individualisation, with inappropriate questioning or duplication of information provision. Here the tension that practitioners felt between standardisation and individualisation manifest in some patients' experience. In other instances nurses circumvented standardised care approaches in order to individualise and particularise them to patients and their experiences.

It has been suggested that protocol-based care can increase patient involvement, through better information sharing (e.g. McQueen & Milloy 2001). The challenges of capturing useful and representative information about patients' experiences of care has been discussed elsewhere (Edwards and Staniszewska 2000). Generally patients in this study reported positive experiences of care, being involved, and that they had been informed (sometimes overly). Observations also captured examples of patient involvement and information provision. However, it is difficult to directly link these outcomes with the use of standardised care approaches per se.

Our study shows that patients' do experience the use of standardised care approaches, even if they are not aware of it. This implies that there is scope for facilitating greater patient awareness of the way their care is being delivered, and improved involvement in the development and use of standardised care approaches. Some practitioners suggested that patients would not be interested in knowing whether their care was being guided by protocols. Our findings, which require further substantiation, intimate that some patients (particularly those who have repeated contact with health services) do have expectations and welcomed the opportunities to be more involved in health care interactions.

5.4.6 Standardised care approaches – standardisation – impact on resources

Perhaps not surprisingly efforts to standardise care, through the development and use of standardised care approaches, had the potential to

impact on use of resources including drugs, dressings and tests. Additionally in some sites there had been redistribution of staff workload through substitution. Essentially it was believed that this resulted in some cost containment. These were self-reported impacts as sites rarely collected data to evaluate such outcomes so it is difficult to make a direct link to the use of particular standardised care approaches. Whether or not a standardised care approach impacts on resources, will depend on the quality of its underpinning evidence base, and how (and if) it is used. As the previous sections have shown, their use can be patchy.

In the United States cost control has been a major factor in driving protocol-based care forward (e.g. Merritt et al 1999), however in the UK the emphasis has been more broadly on standardisation of care, which probably reflects the difference in the way our respective health care systems are funded. Whilst some studies have included the evaluation of cost related outcomes (e.g. Marchisio et al 2006), generally in studies conducted in the UK potential impact on resources has been neglected. Our findings indicate that their development and use probably does impact on resource use and allocation. However, there is a need for systematic evaluation of how and why standardised care approaches impact on resources of various types. It will be important to combine resource impact research with the study of impact on the quality of care.

5.4.7 QOF protocol – performance management – financial reward

Linked to new public management are new arrangements for financial accountability and the measurement of effectiveness (Exworthy & Halford 1999). The Quality and Outcomes Framework rewards GPs for meeting targets related to service quality. The introduction of the protocols developed through the QOF; a component of the new General Medical Services contract, had clearly impacted on GP and practice staff performance. As it is embodied in the GP contract, GPs must attend to it if they are to receive income. It has been suggested that performance indicators, because they are associated with managerialism, have the potential to erode general practitioners' clinical autonomy (Exworthy et al 2003). However our research indicates that if GPs can see a benefit both in terms of financial reward, and for the quality of patient care, they were willing to engage in performance assessment. As Exworthy and colleagues (2003) state this may '*not signal the demise of clinical autonomy per se, rather its re-definition*' (p1502).

5.4.8 Protocols and algorithms –appropriate use- improved referrals

Previously researchers have rarely considered how standardised care approaches might facilitate care and service delivery across settings (e.g. Atwal & Caldwell 2002, Jones 1999b). Whilst there were only a limited number of examples, our findings indicate that the use of protocols and algorithms for referrals between departments within hospitals, and across

settings can improve referral processes and outcomes. The success of the outcome was dependant on appropriate use, and the acceptability of the protocol or algorithm by all parties using it. Clearly, this impact needs further investigation.

5.5 Influences on use

Findings show that the development and implementation of the standardised care approaches tended to lack a systematic, planned approach. Only a small number of study participants recognised the fact that the development and use of standardised care approaches was about the successful management of change. The findings about influences on use relate closely to the literature on the successful implementation of evidence into practice (e.g. Iles & Sutherland 2001, Dopson et al 2002, Rycroft-Malone et al 2002 & 2004b, Dopson & Fitzgerald 2005). A number of key issues are discussed further below.

5.5.1 Ownership

Buy-in and support seemed to be important across all sites, particularly in relation to multi-disciplinary buy in. As described earlier when there was buy-in from the whole team, practitioners tended to use available standardised care approaches. There were two aspects to buy in, which included the idea of protocol-based care generally, and the particular available approach(s) within sites. In the change management and implementation literature ownership is recognised as an important factor (e.g. Iles & Sutherland 2001, Greenhalgh et al 2004). More specifically, Wood et al (1998) indicate that the nature of local relationships is key to the change process. If there are good relationships, common ways forward are more easily developed. Conversely the flow of information and knowledge can be inhibited by professional boundaries (Dopson et al. 2002). This implies that any development and implementation approach needs to include processes that enable team members' involvement and engagement. While good multi-disciplinary working can be a challenge, it would seem that this might be an important factor in the successful implementation of standardised care approaches.

5.5.2 Context

There has been an increasing awareness that there are a number of factors that might make a context more conducive to change, incorporation of new ideas and evidence use (e.g. Iles & Sutherland 2001, McCormack et al 2002). However context is a poorly understood mediator of change (Dopson 2007). A number of contextual factors at the micro, meso and macro levels have been found to be potentially influential, which include hard factors, such as resources and soft factors, such as culture leadership and teamwork (McCormack et al 2002, Gabbay et al 2003, Sheldon et al 2004).

Strategic support is important. Research shows that initiatives that address policy agendas will hold more appeal to local power holders than those that do not (e.g. Dopson et al 1999, Pettigrew et al 1992, Pettigrew 1985). As such, commitment and resources for the initiative are more likely to flow. There is some evidence from our findings to suggest that the development and implementation of protocol-based care lacked strategic support. For example, as described earlier, rarely was a project lead or champion given dedicated or protected time to oversee the development, introduction and monitoring of particular standardised care approaches. Frequently practitioners took on this role in addition to clinical or managerial workloads. Generally if the project lead moved on, they were not replaced. In contrast in the GP site where there was an organisational commitment to the use of the QOF, and GPs could see that it made a difference, this impacted positively on protocol use.

Additionally it was clear that where standardised care approaches had been embedded into an organisation's structures and processes, particularly if that was close to the point of care, this appeared to increase the likelihood of their use. This supports findings from others' research (e.g. Hockley et al 2005, Goodman 2006). As the intention is to move towards an increasing use of electronic records (e.g. DH 1997 & 2005), and portable electronic devices (e.g. Doran 2007, Feldman 2004) the potential to embed standardised care approaches in routinely used systems will increase.

Our findings imply that if organisations have a serious intention to develop approaches to local service delivery such as guidelines, pathways, protocols and algorithms this needs to be supported by appropriate investment in resources and infrastructure. This support and investment needs to occur at all stages of the process, including monitoring of on-going use, and at appropriate levels within the organisation.

5.5.3 Compulsory use

In contrast to the findings in other sites the only standardised care approach being consistently and prescriptively used were the patient group directives in the walk-in centre. Nurses had to use them in order to be able to independently prescribe medications. By implication it could be suggested that making the use of standardised care approaches mandatory, would ensure use. Apart from the political uproar this would cause, as discussed above, decision making latitude and autonomy are valued and important aspects of professionals' roles; and judicious use of standardised care approaches may actually mean more appropriate, patient centred care.

5.6 Overall Summary: What works, for whom, how, and in what circumstances?

As shown, the development and use of standardised care approaches is complex, with many factors inter-relating. In keeping with the principles of realist evaluation the following summarises key points and exemplars in relation to what works, for whom, how, and in what circumstances (Table

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16). In realist evaluation language, these threads provide ‘theories’ that can be used and evaluated by those engaged in the development and implementation of standardised care approaches, and by researchers and other stakeholders wishing to further develop the evidence base. As such, over time, theory development should evolve cumulatively (Pawson & Tilley 1997). Additionally, in accordance with the underpinnings of the theoretical framework, critical factors have been identified for the successful implementation and use of standardised care approaches (Table 17). These are based on the findings of the study and consider them in relation to evidence, context and facilitation (Rycroft-Malone et al 2002 & 2004b). The information in these tables provides the link to the recommendations in section 6.

Table 16.a What works, for whom, how and in what circumstances

What works	<ul style="list-style-type: none"> • Location & visibility: standardised care approaches that are readily available and are highly visible are more likely to be used. • Buy-in: generally when the whole team (multi/uni-disciplinary) has been actively involved in the development of a standardised care approach it tends to be used. • New ways of working: standardised care approaches that supported the development of new services such as nurse and/or midwife led care were consistently used. • New roles: standardised care approaches that enabled the extension of nursing roles tended to be used. • Making a difference: standardised care approaches that practitioners perceived as making difference to their practice and patients were used. • Incentives: standardised care approaches linked to financial rewards were consistently used.
How	<ul style="list-style-type: none"> • Explicit use: some standardised care approaches were being used on-screen and shared with the patient - usually as checklists or prompts. Additionally they could be useful sources of information for some staff. • Implicit use: some standardised care approaches were not explicitly referred to, but their principles may guide care. • Embedded in documentation: some standardised care approaches were embedded in routine documentation, sometimes replacing or complementing patient’s notes. • Embedded in IT systems: some standardised care approaches were part of routine systems and worked effectively as a prompt.
For whom	<ul style="list-style-type: none"> • Mainly nurses, midwives and health visitors: despite existence of multi-disciplinary standardised care approaches, medical staff rarely used them (for exception see below). • Medical staff: some junior doctors found standardised care approaches useful. GPs consistently used QOF related protocols. • Students, newly qualified, temporary and new staff: standardised care approaches were perceived to be a useful heuristics to organising care for those who do not have experience (usually nurses but also medics and AHPs). • Nurses taking on new roles: standardised care approaches gave nurses confidence for delivering care autonomously (e.g. nurse/midwife-led clinics and services).

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In what circumstances	<ul style="list-style-type: none"> • Nurse/midwife-led services: standardised care approaches supporting the running of nurse and midwife-led services and clinics were more likely to be used. • Protection from litigation: when nurses were practising outside their traditional scope of practice standardised care approaches were consistently used because they provided a safety net. • Mandatory: when the use of standardised care approaches was compulsory they were consistently used, and supported with regular audits and training. • Financial reward: for outcomes of use, encouraged commitment to and use of linked protocols. • On-going project lead: the existence of such a role seemed to facilitate active involvement of the multi-disciplinary team. The lead also enabled on-going monitoring of use. • Strategic support: for the development and sustained implementation of standardised care approaches.
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Table 16.b Exemplars: What works, for whom, how and in what circumstances

	What works	How	For whom	In what circumstances
Exemplars	On screen algorithms	Prompt & guide interactions	Nurses & patients	Nurse-led care and services
	SOFIs	Prompts for health screening	GPs & practice staff, & patients	Linked to financial reward
	PGDs	Guide prescribing practice	Prescribing nurses	Mandatory
	Normal birth pathway	Record midwifery care	Midwives & Women	Midwifery care Normal birth
	Healthy pregnant women flowchart (algorithm)	Specifies care & number of contacts Women held notes	Midwives & Women	Midwifery led care Low risk cases
	Pre- school core health visiting guidelines	Specifies care & number of contacts	Health visiting team (HVs & community nursery nurses)	Health visiting services Low risk families
	Standardised care approaches of various types	As sources of information – for reference	Nurses & doctors	New to context and/or role

Table 17. Critical factors for the successful use and implementation of standardised care approaches

Evidence	Context	Facilitation
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<ul style="list-style-type: none">• Base standardised care approaches on high quality research evidence, which can be combined with other types of evidence including clinical experience, patient experience, and local information/data (e.g. about supplies, medicines, investigations).• Use existing research syntheses such as national guidelines, and systematic reviews where available.• Search for existing standardised care approaches, and assess their applicability.• Agree the underpinning evidence base through a process of consensus building.• Maintain an audit trail.	<ul style="list-style-type: none">• Ensure strategic fit and support, e.g. changes to service delivery, development of new roles.• Ensure appropriate and sufficient resources are allocated from initiation to evaluation.• Assess context's readiness for changes to practice:<ul style="list-style-type: none">◦ team work◦ power and authority• Use existing systems and processes.	<ul style="list-style-type: none">• Dedicated project lead with protected time. Credible, respected, skilled and experienced.• Use motivating factors as levers.• Use appropriate incentives if necessary.• Involve all key stakeholders simultaneously.• Ensure implementation is context, and stakeholder specific.• On-going training and evaluation.• Make standardised care approaches visible and accessible.• Embed in routinely used systems, processes and documents.
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6 Conclusion & Recommendations

In the UK 'protocol-based care' was developed as a policy initiative embedded in the government's modernisation agenda for the NHS. From a policy perspective protocol-based care is a mechanism for facilitating standardisation of care based on best practice and the extension of the nursing workforces' professional role. However there has been little systematic evaluation of what protocol-based care is, or its impact on practice, roles, patients and organisations, particularly across multiple sites. Using realistic evaluation as a methodological framework this research has addressed some key questions about protocol-based care as practised in the reality of the clinical setting.

A rich and detailed picture of protocol-based care has emerged. The use of standardised care approaches was seen as important to reduce practice variation and improve service delivery, especially for new and/or inexperienced staff. Additionally findings show that they supported nurses' autonomous practice and the extension of their role beyond the traditional scope of practice. In contrast, whilst there were a number of standardised care approaches that could be used, nurses' (and doctors) either did not obviously refer to them, or used them flexibly to support decision making processes. Other sources of information tended to be privileged and decision making was a social activity.

Overall, our findings demonstrate that the development, use and impact of standardised care approaches is largely context, professionally, and individually specific. Based on the findings and implications of this research, a number of recommendations are made for policy making, management, practice, educators and research.

6.1 Recommendations for policy making

1. Reflecting on the vision:

It was anticipated that the majority of NHS staff would be working under agreed protocols by 2004: this vision has not been realised for various reasons. A reflection on whether the majority of staff *should* be working under protocols should be undertaken. A discerning view about appropriate use is needed.

2. Clarity about terminology:

'Protocol-based care' is a political term not recognised by health service practitioners. Clarity about what is meant and intended may provide a clearer steer to those attempting to develop and implement standardised care approaches locally.

3. Goal of standardisation:

Given the complexities of the health service delivery and the clinical context, complete standardisation is likely to be impossible, and even inappropriate. Clarity about the goal of standardisation and taking a

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stance that encourages judicious use may lead to more receptive stakeholders.

4. Embedding in national standards:

An approach that ensures that standardised care approaches are developed as part of the development processes of, for example, national service frameworks and national guidelines should be encouraged. These could then be particularised by local service providers to their contexts and service delivery processes.

5. Embedding in electronic records:

Capitalising on the potential of electronic records and technologies nationally and locally; it is recommended that creative approaches to the dissemination and use of standardised care approaches through such media are developed.

6. National database:

Investing in the development of a national database of the broader range of standardised care approaches used in the NHS, like that housed in the National Electronic Library for Health for care pathways, would facilitate easy access to relevant resources and potentially reduce the duplication of work. Such a database could also hold development, adaptation and evaluation tools. A network to enable the sharing of examples of good practice would also have utility.

7. Incentives:

Financial incentives might encourage doctors to more fully engage in protocol-based care issues and use. Such incentives may also encourage the engagement of nurses and other allied health professionals.

8. Roles:

Extending the role of nurses in other practises and other service delivery approaches may be possible if supported by the use of standardised care approaches, but only after further research has been conducted (see recommendations for research).

9. Resources:

The successful development and implementation of standardised care approaches is unlikely to occur without the appropriate allocation of resources; nationally and locally. Therefore it is recommended that strategic decisions are taken about the commitment to the protocol-based care agenda.

10. Further research:

Consider investing in the agenda for future research outlined below, and engage key stakeholders in its delivery.

6.2 Recommendations for management

1. Motivators:

Assess and capitalise on the multiple motivating factors there may be to develop particular standardised care approaches, which may vary within settings and stakeholders. Some motivating factors may be particularly important to certain individuals of groups of stakeholders, which could be used as levers for engagement.

2. Strategy:

Foster and ensure there is strategic level support for any development and implementation activity. This needs to include the identification of relevant resources, including finances, time, equipment and personnel.

3. Approach to development:

Ensure that a planned, systematic and comprehensive approach is adopted for development and that a clear audit trail is recorded.

4. Project lead:

Identify an appropriately skilled, experienced, credible and respected project lead. The lead needs to be able to engage all relevant stakeholders in the process. Ensure this person is given dedicated time to take on this role, and that there is succession planning.

5. Evidence base:

Develop a robust and transparent process for evidence identification, synthesis and inclusion. Ensure that there is a built-in process for updates when new evidence emerges.

6. Stakeholders:

Engage key stakeholders in the development and implementation process, which should include patients, service users and where appropriate carers. Finding ways of developing and fostering good multi-disciplinary team working will likely have wider benefits to care and service delivery.

7. Implementation:

Development and implementation should be viewed as aspects of one process. Different implementation strategies are likely to be effective with different standardised care approaches. Dissemination alone is likely to be ineffective. The approach used needs to be matched to the particular setting and stakeholders.

Embed new standardised care approaches in existing systems and documents, and link training, assessment, and performance strategies together.

Ensure that standardised care approaches are visible and accessible.

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8. New staff:

Develop processes to ensure new staff are aware of available standardised care approaches and have access to relevant training to use them. Embed in induction procedures.

9. Incentives:

Consider the use of incentives to encourage engagement in development, implementation and use. As the incentive may vary from profession to profession it is important to clarify what might be appropriate for whom.

10. Evaluation:

Build in mechanisms to evaluate the impact of implemented standardised care approaches. Ensure that these are linked to feedback mechanisms.

11. Time lines:

Allocate realistic timescales to development and implementation endeavours; successful implementation and sustained use will be dependent on comprehensive, systematic strategies that can only be delivered within a realistic time frame.

6.3 Recommendations for practice

1. Judicious use:

Using standardised care approaches judiciously will help ensure that they are individualised to patients' experience and avoid a 'tick box mentality'.

2. Patients:

It can not be assumed that patients are not interested in being aware that their care is being guided by standardised care approaches. Identify how to engage patients and where appropriate carers in standardised care development and use.

3. Team working:

Work proactively to maximise opportunities for team working, particularly multi-disciplinary working. Engage relevant practitioners concurrently in development, implementation and evaluation processes.

4. Practice resource:

Develop standardised care approaches as context specific sources of practice information and as a resource for practitioners. Consider the fact that nurses, doctors and other professionals may find these useful.

5. Streamlining care:

Identify opportunities for streamlining local care delivery through the development and use of standardised care approaches. Standardised care approaches that span settings and/or department boundaries are one potential.

6.4 Recommendations for educators

1. Training:

On-going training and support needs to be offered and undertaken by all staff using available standardised care approaches. Practitioners should not be expected to initiate training opportunities independently.

2. Clinical judgement:

Given the expansion of nurses' roles and their increasing decision making responsibility, teaching student practitioners how to structure decisions by making choices and values explicit seems appropriate.

3. Learning resources:

Available standardised care approaches could be used as learning resources in local training sessions.

6.5 Recommendations for further research

1. Intervention research:

This research (considered together with the findings of the University of Sheffield team's project when complete¹⁰) highlights a number of components that could be incorporated into intervention research. Considering the Medical Research Council's framework for the evaluation of complex interventions, the state of the current evidence base offers the potential for a pilot trial. Specifically, the ideas set out in 'what works, for whom, how, and in what circumstances' could be tested. This should include cost consequence analysis, and process evaluation.

2. Patient engagement:

An evaluation of different approaches to engaging patients in the development and implementation of standardised care approaches. This research should include the range of patients served by the NHS.

¹⁰ There is a potential piece of work to integrate the findings of these two projects.

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3. Nurses' roles:

An evaluation of how role extension through standardised care approaches impacts on patient outcomes. This should include a study of intermediate and summative outcomes.

4. Nurse-led services:

Standardised care approaches play a role in supporting nurse-led care. This finding needs to be investigated further in different settings, and diverse nurse-led services. This research should be linked to practitioner, organisational and patient outcomes.

5. Professional identity:

Our research indicates that one of the outcomes of using standardised care approaches is an effect on professional boundaries and roles. Research using sociological theory could explore how this affects professionals' identity.

6. Incentives:

Further research examining the potential role that incentives could play in engaging practitioners, particularly doctors, in the protocol-based care agenda should be conducted¹¹.

7. Methodology & methods:

Our research shows that protocol-based care is complex; future research should adopt an approach that acknowledges and incorporates this in study design.

8. Social care:

A similar evaluation to this should be conducted in social care.

9. Reporting:

Researchers reporting protocol-based care related research should ensure clarity in use of terms and clearly describe processes and methods.

¹¹ Could link to current SDO projects – 126/128 & 136

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Appendix 1 List Of Advisory Group Members

Case study evaluation

Name	Title	Organisation
Ms Lynne Currie	Project manager Evidence for Practice	Resource Development Institute, RCN Institute
Dr Claire Hawkes	Research Fellow	RCN Research Institute, University of Warwick
Ms Gill Harvey	Senior Lecturer in Healthcare and Public Sector Management	Manchester Business School, University of Manchester
Dr Irene Illot	Research associate	Institute of Work Psychology, University of Sheffield
Mr Tom Isaacs	Patient Involvement Expert	European Parkinson's Disease Association
Dr Sue Latter	Reader in Nursing	School of Nursing and Midwifery, University of Southampton
Ms Claire Morrell	Director of quality improvement	Quality and safety Institute, RCN Institute
Mr Malcolm Patterson	Research Fellow	Institute of Work Psychology, University of Sheffield
Dr Sophie Staniszewska	Senior Research fellow	Research Team, RCN Institute
Dr Paul Yerrell	Senior Research Fellow/ Director Thames Valley Primary Care Research Network	Oxford Brookes University

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Decision-making study

Name	Title	Organisation
Mr Calum Buchanan	Senior Practice Development Nurse	John Radcliffe Hospital NHS Trust, Oxford
Dr Claire Hawkes	Research Fellow	RCN Research Institute, University of Warwick
Ms Marina Fontenla	Research Fellow	RCN Research Institute, University of Warwick
Dr Jan Savage	Independent ethnographer	

Appendix 2 Case Study's Site Descriptions

Site One: Cardiac Surgical Unit

Clinical Setting

This is a 28-bedded cardiothoracic surgical unit (CSU) within a teaching hospital, one of three hospitals within an acute trust in the outskirts of a city, serving a predominantly Caucasian population. The hospital provides acute medical and surgical services, trauma intensive care, services for women and children, and accident and emergency services. An 8-12 bedded (flexible capacity) cardiac recovery unit (CRU) was also part of this site. The services constitute a major cardiothoracic centre in the locality. Patients are referred to the CSU via the cardiologist and a small proportion of patients are referred through Accident & Emergency and other hospitals in the locality. Admission of patients to the CSU during the period of data collection was due to cardiothoracic surgical procedures, pre-operative cardiac medical and diagnostic procedures and for general medical purposes. The use of the ward for diagnostic and medical general purposes was due to bed shortages in other wards.

Cardiothoracic surgical patients' occupied beds in the CSU waiting to undertake aortic valve replacements, coronary artery bypass graft, aortic dissections and thoracic surgery. Once they had surgery they would be transferred directly to the CRU for a minimum period of 24 hours. The CRU incorporates eight ventilated, high dependency beds. The CRU treats patients requiring ventilation and cardiovascular support on a one-to-one or one-to-two basis. In the CRU patients received one-to-one care in an intensive care environment. After 24 hours if they developed no complications they were transferred to the CSU.

Patients were visited by a physiotherapist twice a day, dietician, pharmacist and any other specialists depending on patients' needs. Surgical consultant ward rounds took place twice a day, early morning and evening.

All surgical patients would need full-time support for the first week after discharge. Therefore, discharge destinations varied depending on each patient's circumstances. If patients had a carer they were discharged to their own home and links were established with their GP and community nurse. However if patients had no carers available they were discharged to community hospitals.

The CSU is headed by a G-grade and staffed by four F, eight E, five D grades and two healthcare assistants (A & B grades). Usually there is a student nurse per shift during term time. The minimum staffing level is five trained nurses and one health care assistant.

At this site the focus was on a multidisciplinary pathway for cardiac surgery. The pathway was introduced to establish a minimum standard of care as well as to fast track patients through the system to an average of five days

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from admission to discharge. The pathway is used by physiotherapists, medics, nurses and other healthcare professionals to record all episodes of care for each patient; it is essentially a clinical document. The pathway follows the patient journey from pre-admission at the outpatient clinic to discharge, usually on the 5th day post surgery.

Data collection period

Data were collected during 21 days between August 2005 and February 2006. Morning, evening and weekend shifts were observed.

Interviews

The table below displays the interviewees' identifiers undertaken at site 1.

Type of interviewee	Identifier
Nursing staff*	CSUN01a; CSUN01b; CSUN02; CSUN03; CSUS02; CSUN04 ; CSUN05a; CSUS04; CSUS05; CSUN07; CSUS06; CSUS07; CSUS08; CSUS11; CSUS12; CSUS13; CSUN08; CSUS16
Medical staff*	CSUS01; CSUS09; CSUS10; CSUS14; CSUS15
Allied health professionals	CSUN05b; CSUN06
Support staff	CSUS03
Patients	CSUP01; CSUP02; CSUP03; CSUP04; CSUP05; CSUP06; CSUP07; CSUP08

Observations

The table below displays the identifiers of the observations undertaken at site 1.

Participants observed	Identifier
Nurse and patient	CSUOb01; CSUOb02; CSUOb03a; CSUOb04, CSUOb05a; CSUOb07, CSUOb08
Doctor and patient	CSUOb03b
Physiotherapist and patient	CSUOb05b; CSUOb06
Multidisciplinary team meeting	CSUOb111

Patient Journeys

Two patients were recruited to take part in two further interviews. These patients were CSUP04 and CSUP05.

Site Two: Walk-in Centre

Practice setting

This is an inner city Walk-in Centre providing unscheduled primary care. It is under a Primary Care Trust which caters for one of the most deprived areas in England. Unemployment is over 13%, the population comprises a

* Clinical and non-clinical staff

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significant (48%) proportion of people from ethnic minorities and it has a higher population of younger people. It was opened in 2000 as part of the government's drive to improve access to primary care, a key strand of the modernisation agenda. The centre is designed to provide one-off consultations only, however, a considerable number of patients for whom access to a GP is difficult repeatedly visit the centre. It is a nurse-led service supported by sessional GPs and frontline receptionists who also are interpreters. It offers health information, advice and treatment for a range of minor illnesses and injuries. It is situated next to the A&E department at the local district general hospital, serving a diverse population with a large proportion of ethnic minorities. The centre is open seven days a week, including holidays, from 7 am to 10 pm.

Patients can be directed to the WIC by their GP, A&E department, Genito-Urinary clinic (only at weekends), ambulance paramedics (specific type of patients might be taken directly to WIC rather than A&E) or self-refer. Patients attending do not have easy access to a General Practice or they may not have a GP. The most common presenting illnesses at the WIC are sore throat, earache, abdominal pain, rashes, stress, coughs and dysuria. Each nurse might see, treat and discharge up to 30 patients a day; overall more than 100 patients are seen daily. Ninety-eight percent of these patients are treated by someone at the centre; only 2% are referred to A&E (information obtained from an internal audit of A&E referral).

Patients arrive at the centre presenting a complaint and usually are seen on a first come, first serve basis. The frontline receptionists, who are not health care professionals, initially assess whether the complaint can be treated at the WIC. For example if the patient reports an accident they will be signposted to the A&E department. They are also able to recognise a series of red flags (e.g. epilepsy, difficulty in breathing, diabetic hypoglycaemia, head injury, chest pain) which would prompt them to urgently contact a nurse to see the patient without delay. Patients' waiting time is variable; however it is usually one hour and a half. The patient will generally be seen by a nurse who will be able to examine, diagnose and treat the condition. Some patients might be referred to the in-house GP or the A&E department. But typically most patients will be seen and treated by a nurse.

A third of patients attending the WIC belong to an ethnic minority and a high proportion of those seen are young men (information obtained from internal audit).

The WIC is managed by an H grade nurse practitioner with an I grade nurse consultant providing staff development support. The centre is staffed by frontline receptionists who also are interpreters and advocates; healthcare assistants, sessional general practitioners, administrators, and (16 full-time and 9 part-time) primary care nurses and nurse practitioners/consultants (F grades and above). The nurses' background includes district nursing, health visiting, general practice, midwifery, ITU, paediatrics, women's health, mental health and emergency department. Nurses work independently as autonomous professionals occasionally requiring help from

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sessional GPs (e.g. when prescribing antibiotics, or for a second opinion). The minimum staffing requirements at the centre is two trained clinicians at opening of service (nurses or GPs).

At this site the focus was on a variety of protocol-based care tools used in the delivery of primary care in an inner city walk-in centre. The tools studied were mainly red flagging/streaming (recently developed and being refined during period of data collection), algorithms, local guidelines, and patient group directives. The protocol-based care tools were mainly used by nurses and it allowed them to see, diagnose and treat patients autonomously. Receptionists also implemented an informal type of protocol which allowed them to recognise 'red flags' or symptoms requiring urgent attention or referral to Accident & Emergency (A&E) department. GPs did not, generally, use protocol based care tools available at the WIC; although they were aware of their existence.

Data collection period

Data were collected during 22 days between August 2005 and February 2006. Early, morning, evening, late and weekend shifts were observed.

Interviews

The table below displays the identifiers of the interviews undertaken at site 2.

Type of interviewee	Identifier
Nursing staff*	WICN01; WICN02; WICN04; WICN05; WICN06; WICN07; WICN08; WICS02; WICS03; WICS04; WICS05; WICN06; WICN08
Medical staff	WICS09; WICS10; WICS11
Allied health professionals	WICS08
Support staff	WICS01
Patients	WICP01; WICP02; WICP03; WICP04; WICP06; WICP07; WICP08

Observations

All observations were of nurse's consultations with patients. The identifiers are as follows: WICOb01; WICOb02; WICOb03; WICOb04; WICOb05; WICOb06; WICOb07; WICOb08.

Patient Journeys

Two patients were recruited to take part in a further interview. These patients were WICP06 and WICP07.

* Clinical and non-clinical staff

Site Three: Pre-operative Assessment Clinics

Clinical setting

This is a large teaching hospital in an acute trust in the outskirts of a city, serving an ethnically diverse population. The Trust provides a range of district hospital services and a full range of medical, surgical and emergency services. One person in five is from a minority ethnic background. This is a population of 1.3 million that encompasses a wide variety of ethnicities, religions and faiths. It also is younger than average, with a high number of immigrants and varying levels of deprivation (Information obtained from site's website).

The study focused on a number of pre-operative assessment (POA) clinics within the hospital. The clinics included were: General Surgery, Plastic Surgery, Gynaecological Surgery, Breast Cancer Surgery, Urology Surgery, Trauma and Orthopaedics Surgery, Maxillofacial Surgery, and E, Nose and Throat Surgery. These clinics were mostly run by doctors and nurses with varying level of autonomy. However, the Urology POA clinic was led by nurse practitioners. There was not a central POA location, instead each specialty run their clinic within their department's premises.

Patients attended these POA clinics within two or three weeks prior to their operation to assess their fitness for surgery. The type of operations varied from 10 minute orthopaedic operations to more complicated surgery. During their appointment, patients would typically see a nurse, a house officer and, depending on the required investigations, they would see a radiologist, a phlebotomist, etc. A thorough medical examination and a series of investigations would be the basis for a decision on fitness for surgery. In some occasions, complex cases were referred to the anaesthetic clinic, run by a consultant and the POA nurse lead, for further investigations.

All clinics take place in different places depending on the specialty. Also the equipment available varies; some have ECG in the clinic others need to send patients to a central department. Bloods can be taken at clinic if staff qualified (doctor or nurse) but tend to be sent to specific department for it.

General Surgery POA Clinic

This clinic deals with surgery on the abdomen and the organs concerned with digestion of food and excretion of waste. It is usually run by rotating staff nurses and junior doctors. Nurses do the nursing assessment and partly the anaesthetics questionnaire. Doctors do the clerking and they order tests. The POA protocols' manual was not in the clinic at the time of data collection.

Urology Surgery POA Clinic

This clinic usually deals with cancers, stone disease (kidney stones), reconstructive surgery of the male reproductive organs and surgery for incontinence. It is a nurse-led clinic run by two permanent nurse practitioners supported by a staff nurse. The staff nurse does the basic

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observations. The nurse practitioners do the nursing assessment, the clerking, the anaesthetics questionnaire, and the ordering of tests. Each nurse practitioner had a copy of the POA protocols' manual.

Breast Surgery POA Clinic

The clinic deals mainly with breast cancer, related procedures and operations. It is run by nurses and doctors with counselling support from a MacMillan nurse. Nurses do the nursing assessment, the anaesthetics questionnaire and fill the blood forms in advance of patients' arrival. Doctors do the clerking and they order tests. The POA's protocols manual is in the clinic and includes up to date protocols and information for patients.

Trauma and Orthopaedics Surgery POA Clinic

The clinic deals with a wide variety of injuries and disorders pertaining to the skeleton and its supporting muscles (musculoskeletal system). It is run by two experienced permanent nurses (F grade) and rotating junior doctors. The nurses order X-rays and blood tests as well as doing the nursing assessment. The doctor does the clerking and orders any additional tests. The POA protocols' manual is in the clinic but does not seem to be central to their work.

Plastics Surgery POA Clinic

The clinic deals with patients who will have cosmetic or reconstructive surgery. It is run by rotating staff nurses and a senior house officer. The nurses do their assessment and the doctor does the clerking and the ordering of tests. The POA's protocol manual was not in the clinic at the time of data collection.

Ear, Nose and Throat POA Clinic

The clinic deals with disorders and defects of the ears, nose (including sinuses), throat, head and neck. This clinic was run by a permanent staff nurse (E grade) and a senior house officer. The nurse does the nursing assessment and orders some tests. The doctor does the clerking and orders additional tests. The POA's protocols manual was not in the clinic at the time of data collection.

Maxillofacial POA Clinic

The clinic is mainly concerned with congenital or acquired diseases, dysfunction, defects or injuries of the mouth, jaws, face, neck and associated regions. This clinic is run by the same nurse as the ENT clinic and a registrar. The POA's protocols manual was not in the clinic at the time of data collection.

Gynaecology POA Clinic

The clinic deals with diseases of the female reproductive system (uterus, vagina and ovaries). This clinic is run by a receptionist, a permanent sister, a staff nurse and a SPR or consultant. Nurses do the assessment and tick blood tests forms but do not sign them due to resistance from laboratory

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staff. Doctors explain operation in detail. There was a POA protocols manual in the clinic.

At this site the focus was on a series of protocol-based care tools. The tools studied were guidelines for adult pre-operative investigations, blood pressure algorithm for adult diabetic and non-diabetic patients, and policy for pre-operative starvation and drug administration. The tools were generally used by nurses; doctors were not aware of its existence.

Data collection Period

Data were collected during 17 days between December 2005 and June 2006. Morning and afternoon clinics were observed.

Interviews

The table below displays the identifiers of the interviews undertaken at site 3.

Type of interviewee	Identifier
Nursing staff*	POAN01; POAS01; POAN03; POAN04; POAS02; POAS04; POAS05; POAN06; POAN07; POAS09; POAN08; POAS10; POAS11; POAS12; POAS13
Medical staff*	POAN02; POAS03; POAN05; POAS06; POAS08; POAS14
Allied health professionals	POAS07
Patients	POAP01; POAP02; POAP03; POAP04; POAP05; POAP06; POAP07; POAP08

Observations

The table below displays the identifiers of the observations undertaken at site 2.

Participants observed	Identifier
Nurse and patient	POAOb01; POAOb03; POAOb04; POAOb06; POAOb07; POAOb08; POAOb09
Doctor and patient	POAOb02; POAOb05; POAOb10

Patient Journeys

Two patients were recruited to take part in a further interview. These patients were POAP05 and POAP02.

Site Four: Birth Centre

Clinical Setting

The Birth Centre is based on a ward on the 1st floor of the main maternity unit, separate from the main delivery suite (which is on the ground floor). It opened in 2005 and is staffed by a core team of midwives, maternity support workers and ancillary staff. Student midwives are rotated to the

* Clinical and non-clinical staff

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Centre and there were plans afoot to have medical students doing their obstetric/gynaecology rotation to spend some time on the Centre. It is managed by the Lead Midwife for Normal Birth at the Trust who reports to the Director of Midwifery. The Centre operates independently of main delivery suite with midwives providing full care of women booked to give birth there. There was no routine obstetric contact. At the time of the study, there were around 50 – 70 births a month, with plans to increase capacity.

It has a separate room for antenatal checks and early labour assessment, a staff room, a patient sitting room, a kitchen (for use by staff, women and their partners), an office for the Centre manager, a six-bedded postnatal ward area, 4 birthing rooms, staff locker-room and toilet and patient bathroom and toilets. There are no beds in any of the birthing rooms, but there are large bean bags, armchairs and a pezzi ball. A cot is also in the room. Each room has an en-suite bathroom and there is also a separate sink in the main room. In one room there is a large birth pool. All rooms have piped entonox and oxygen. There is one neonatal resuscitaire, which is kept in the corridor. There is a large central area within the BC which housed the midwives desk, with two computers, phones, documentation and all Trust policies/procedure manuals etc.

There were twice weekly tours of the Centre for prospective parents that provide an opportunity to ask about care and for the midwives to explain the philosophy of the Centre. This includes that care is non-interventionist (e.g. women who request epidural analgesia or whose labour does not progress as anticipated have to be transferred to main delivery suite), the woman and her birth-partner are actively engaged in decisions about care and the woman is encouraged to be as mobile as possible during her labour. In addition to standard options for pain relief which women can use at the Centre (entonox, birthing pool and IM pethidine), midwives at the Centre can also offer reflexology. At the time of data collection, it was not uncommon for women in early labour to be walking the corridors by the Centre or around the Centre itself.

Antenatal clinics were held every Wednesday for women booked at the Centre. When the study was taking place, this was a new initiative and women who were 36 weeks gestation or more were invited to attend this clinic. Clinic day was the busiest for the Centre, with appointments taking place at around 45 minute intervals. The midwife running the clinic would be supernumerary to the midwives providing labour/birth care. Women who required ultrasound scans or obstetric referral would have to leave the Centre to attend main delivery suite or the scanning rooms. Midwives on the Centre could take bloods, but again, testing was done away from the Centre and women would have to wait for the results.

Data collection period

Data were collected during 32 days between March 2006 and January 2007. Shifts covered included a mix of morning, afternoon and night-time.

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Interviews

The table below displays the interviewees' identifiers undertaken at site 4.

Type of interviewee	Identifier
Midwifery staff*	BCS01, BCS02, BCS03, BCS05, BCS06, BCS08, BCM01, BCM02, BCM03, BCM04
Medical staff*	BCS04, BCS07
Women	BCW01, BCW02, BCW03, BCW04, BCW05, BCW06

Observations

The table below displays the identifiers of the observations undertaken at site 4.

Participants observed	Identifier
Midwife and woman	BCW01, BCW02, BCW03, BCW04, BCM01, BCM02, BCM03, BCM04

Patient Journeys

No patient journeys were undertaken in this site due to the varied length of an individual woman's labour, which in some cases lasted for a 24 hour period from a woman's first admission to the Birth Centre. At recruitment, women in some cases also expressed a wish not to have the researcher present at the actual birth of their baby.

Site Five: General Practice

Practice Setting

The General Practice is a well established practice based in the outskirts of a city. It provides a full range of general practice services including: chronic disease management, screening, children's health, immunisation and family planning.

The practice is run by seven GP partners and two salaried GPs. It also has a large team of supporting staff including a full complement of practice nurses (7), phlebotomists (2), counsellor, secretaries, receptionists, computer operators, practice manager, clinical data manager, research manager and personnel manager. Health visitors (3), a community nursery nurse and midwives are based in the practice building, and regular meetings are held, including primary care team meetings. District nurses (5) provide services for the practice patients and are based at a nearby Health Centre. Sessions are also provided by a visiting dietician, welfare benefits advisor, and drugs worker. And osteopath and acupuncturist work providing weekly services from the practice premises. The practice is open from 8.30 am to

* Clinical and non-clinical staff

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6.30 pm weekdays. Out of hours care is provided by a doctor deputising service and is commissioned by the local Primary Care Trust (PCT).

The catchment area of the practice is fairly compact, covering a population of over 12,000. The majority of patients are in social class three to five and there are many extended families on the register. Unemployment is similar to the national average and there are a small number of patients from ethnic minorities. Around 12% of patients are aged over sixty five and 6% under 5 years old. About 150 babies are born in the practice each year. Although reasonable close to the city centre (3 miles) the practice does not have issues commonly associated with inner city areas, although many of the patients have complex morbidity and social problems (information obtained from Practice documentation).

The practice is an above average achiever for QOFs (Quality Outcomes Framework) points. All Information Technology is fully networked and clinical data is, either, electronically received, managed and stored or scanned and managed. Consultations are recorded electronically.

The practice is run by GP consultation but practice nurses also run minor illness, treatment room, chronic disease management and family planning clinics. Health visitors run baby clinics and midwives see their patients at the practice. A Stop Smoking clinic is also run by an advisor, without health care background.

The minor illness clinic is run by nurses for problems with ears, nose, throat, eyes, cough, women's health, urinary, skin, muscular, stomach upsets and minor infections. Treatment room nurses can help with dressings, vaccinations, minor injuries and screening of blood pressure and urine testing for diabetes. Chronic disease management clinics are run by nurses who specialise in asthma and respiratory illnesses, hypertension and diabetes. Patients can book for these clinics directly and information is provided for them in the patient information leaflet. Patients usually phone to obtain an appointment with a particular healthcare professional. If the patient's GP has no appointments available the frontline receptionist, who is not health care professional, might suggest the patient to see a nurse at a particular clinic. Patients are then seen by the relevant healthcare professional, diagnose, treated and/or referred to other services, for example a district nurse or a specialist appointment at the local hospital.

At this site the focus was on multitude protocol-based care tools used in the delivery of primary care in a busy outer city GP practice. The tools studied were mainly local protocols for asthma, Hip Replacement protocol, Hypertension protocol, Stop Smoking protocol, Routine care for healthy pregnant women flowchart, Pre-school core health visiting guidelines, Leg ulcer pathway, COPD protocol and Quality Outcomes Framework protocols for different conditions. Many other protocol-based care tools were identified during data collection but not observed. For example Patient group directives used in immunisation clinics, Falls' protocol, Drug misuse and dependence clinical guidelines.

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The protocol based care tools were used by nurses, doctors and other practitioners depending on the tool studied. Local protocols on chronic disease and minor illness allowed nurses to run specialist clinics where they would see and diagnose patients autonomously. A smoke cessation worker, without a health care background, was also running the Stop smoking clinic with the support of GPs in prescribing. Health visitors and district nurses followed PCT guidelines in dealing with different situations and clinical conditions. Midwives were following the traditional casework model and using guidelines and protocols derived from the acute NHS Trust.

Data Collection Period

Data were collected during 16 days between May and July 2006. Morning and afternoon sessions were observed.

Interviews

The table below displays the identifiers of the interviews undertaken at site 5.

Type of interviewee	Identifier
Nursing staff*	GPSN01; GPSN08; GPSS08; GPSN10; GPSS09; GPSS10; GPSS11; GPSS14
Medical staff	GPSN02; GPSN03; GPSS03; GPSS07
Midwifery staff*	GPSN06; GPSS04; GPSN07; GPSS15
Health visiting staff*	GPSS05; GPSN09; GPSN11; GPSS12; GPSS13
Support staff	GPSS01; GPSS02; GPSS06
Patients	GPSP01; GPSP02; GPSP03; GPSP04; GPSP05; GPSP06; GPSP07; GPSP08; GPSP09; GPSP10

Observations

The table below displays the identifiers of the observations undertaken at site 5.

Participants observed	Identifier
Nurse and patient	GPSOb01; GPSOb08; GPSOb10
Doctor and patient	GPSOb02; GPSOb03
Health visitor and patient	GPSOb09; GPSOb011
Midwife and patient	GPSOb06; GPSOb07
Smoking cessation advisor and patient	GPSOb4; GPSOb05

Patient Journeys

Two patients were recruited to take part in a further interview. These patients were GPP05 and GPP06.

* Clinical and non-clinical staff

Appendix 3 Decision-Making Ethnography Site Descriptions

Site Six: Cardiology Ward

Clinical Setting

This was a Cardiac MCU (Medical Care Unit) of one of the largest cardio-thoracic hospitals in the United Kingdom. Once a specialist and referral hospital, it has recently become a primary care provider. With this change the number of admissions to the cardiac unit has recently increased.

The specialism is in caring for patients who require cardiac investigations and interventions such as angioplasties, PFO closures, pacemakers and internal cardiac defibrillators. Patients who have heart failure and need medical therapy or the support of an intra-aortic balloon pump are also treated. The unit can provide invasive cardiac monitoring and has a well-established primary angioplasty service, which also provides learning opportunities for new staff.

The MCU is divided into two wards on the second floor of the hospital. The first ward is for seriously ill, high-dependency patients and the second bay is for patients having routine procedures and those who have shorter hospital stays.

Data collection period

Data were collected over 50 days between November 2006 and February 2007. Participant observation involved the researcher being in the clinic for 4-5 hour periods observing and taking notes where possible and appropriate.

Since the ward was active during both day and night and staff worked in shifts so the ethnographer observed different shifts, staying in hospital accommodation to be on site at appropriate times. Morning, daytime, evening and weekend shifts were observed.

Respondents

The table below displays the identifiers of those who take part in research and were present during observation periods.

Type of interviewee	Identifier
Nursing staff	Tina, Gina, Judy, Monica, Robin, Di, Marsha, Nadine, James, Michelle, Hope, Susan, Toni, Nancy, Pippa, Linda, Georgia, Tasha, Mina, Connie, Margaret
Medical staff	Lara (Female SHO), one register, one consultant, one male SHO
Patients	Elizabeth, Harry, John, Ellie (Other patients were observed and consent to observation was received – they are not mentioned by name in the research)

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Observations

All nursing and medical staff were observed interacting with patients and with each other. Doctors' time in the ward was often fleeting making 'consenting' difficult. As such, most observation with doctors was done at times of emergency and collective decision making moments. All nursing staff were also allowed time to talk freely with the ethnographer and most also took part in semi-structured interviews. Nurses and other staff were also observed and questioned during periods without patients present.

All identified patients took part in semi-structured interviews as well as being observed throughout their journey through the clinic (from pre-assessment nurses to specialist nurses, clinics and doctors).

Site Seven: Diabetic and Endocrine Unit

Clinical Setting

The Diabetes and Endocrinology Unit is situated in a large inner-city teaching hospital which serves patients who are both local and, through the provision of specialist care, from further a field. The unit itself is an agglomeration of services clustered around a main diabetic clinic. It is primarily a service for local patients but will take tertiary referrals and patients are accepted from anywhere in the UK. The unit will accept patients with all forms of diabetes and any lipid or endocrine disorders as well as those who are suffering from certain complications caused by any of these conditions (e.g. Erectile Dysfunction and Podiatry clinics)¹². The unit also contained a four bed ward for patients who were admitted for day long screening, monitoring and testing procedures. All patients arrived at the same reception desk and would first be seen by the pre-assessment nurses.

The vast majority of the patients visiting the unit were diabetic out-patients attending their regular six-monthly (or other periodic) check-up. The unit ran two separate clinics each day: a morning and an afternoon session. Patients came by appointment (though patients familiar with procedure would often arrive without appointment to go through pre-assessment procedures before the time of their appointment with the specialist nurses or doctors.

Each patient arrived at the same reception point and was then seated in the waiting area to wait until called by the pre-assessment nurses before being passed on to appointments in the various clinics within the unit. Patients booked in for day-long screenings would have to arrive before the unit opened at 9am to general appointments, and would remain until the unit closed at 5pm. The unit was open 5 days a week and was closed at weekends.

¹² A list of the specialist services provided within the unit is as follows: Lipid Clinic, Endocrine Clinic, Combined renal/diabetes, Combined vascular/diabetes, Combined antenatal/diabetes, Pre-pregnancy counselling for patients with diabetes, Erectile dysfunction service, [Diabetes Eye Complication Screening Service](#), [Insulin pump clinic](#), Nurse led diabetes clinics, Dietician clinics, Podiatry clinics and Psychotherapy clinics.

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The unit also runs a service for in-patients in the hospital with diabetic or endocrine problems. A specialist nurse will go to the various wards within the hospital to see patients and referrals to the unit may also be made from within the hospital. The most common referral from within the hospital is from the ante-natal clinic for patients who need to be screened or treated for diabetes during pregnancy.

The patient's medical record is passed to the nurses as each patient is called and a small slip on which to record weight, height, blood pressure and blood sugar serves as something of a pathway. Individual appointments and visit so to the different clinics and services are recorded in different ways however.

Data collection period

Data were collected over 50 days between November 2006 and February 2007. Participant observation involved the researcher being in the clinic for 4-5 hour periods observing and taking notes where possible and appropriate.

Respondents

The table below displays the identifiers of those who take part in research and were present during observation periods.

Type of interviewee	Identifier
Nursing staff*	Beth, Sarah, Phillipa, Joanne, Rachel, Mike, Lily, Nina, Tina, Gemma, Florence, Isabella, Monica , Georgina, Clare, Millie, Sandeep, Marianna, Winnie, Lara
Medical staff*	Yvonne, David
Patients	Jane, Bob, Ella, Jose, Emily, Nick, Sherice, Layla, Mrs.H, Brian, Fanella, Wendy, Billy (Other patients were observed and consent to observation was received – they are not mentioned by name in the research).

Observations

All nursing and medical staff were observed interacting with patients and with each other. All nursing staff were also allowed time to talk freely with the ethnographer and most also took part in semi-structured interviews. Nurses and other staff were also observed and questioned during periods without patients present.

All identified patients took part in semi-structured interviews as well as being observed throughout their journey through the clinic (from pre-assessment nurses to specialist nurses, clinics and doctors).

* Clinical and non-clinical staff

Appendix 4 Example Of Case Study Observation Format

Observation summary

Identifiers

Date and site	Walk-in centre, 15/08/2005
Observation number	WICObs03
Study numbers	WICP03 & WICN03

Observation's dimensions

Space	Consultation room 6, at the end of the corridor not facing the street. Quiet. The desk is facing the window with a PC on it. The nurse is facing the PC; the patient is sitting to the nurse's left in a chair by the desk. I'm sitting in the examination couch.
Actors	Nurse, patient, researcher
Activities	Talking, typing, looking at the PC
Objects	PC, shoes & socks
Acts	The nurse is asking all relevant questions, from time to time looks to the PC where she's consulting the algorithm. The patient is explaining her problem and showing the blistered feet to the nurse.
Event	routine consultation
Time	15.07 – 15.24 (17 minutes)
Goals	Nurse needs to establish a diagnosis and provide a treatment and/or advice. The patient needs to be reassured to whether the infection is serious and how to tackle it.
Feelings	Relaxed atmosphere, good communication between them and sharing of the PC screen

Walk-in centre description

Skill-mix	2 receptionists, 1 GP, 1 H, 2 G and 2 F grade nurses.
Patient Nos	12 patients waiting, 1 ½ hours waiting. 9 patients had been transferred from A&E to the WIC in this time, only one had been sent to A&E from the WIC.
Atmosphere	Relaxed as there were a good bunch of professionals doing consultations. The afternoon is usually the busiest time of the day.

Patient description

Age	30
Gender	Female
Ethnic background	White
Occupation	Not collected
Type of complaint	Infected blisters

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Observation example WICObs03

Nurse	Hi I'm a nurse at the centre, what is the problem?
Patient	Well, I think I have a feet infection, shall I show you?
Nurse	Sure
Observer description	<i>(The observation starts at 15:07. The patient takes her shoe and sock off, there is an inflamed area by the toes which looks red and painful)</i>
Patient	They started about three weeks ago but they're not healing well
Nurse	They are they still bleeding
Patient	Yes, and yellow stuff comes out
Nurse	Do you have any medical problems?
Patient	No
Nurse	Are you taking any medication?
Patient	No
Nurse	Any allergies?
Patient	No
Nurse	Have you been feeling feverish?
Patient	No
Nurse	Does your family have any medical problems?
Patient	No
Nurse	Do you drink?
Patient	Yes, about 3 glasses of wine a week
Nurse	Can I take your temperature, can you put this under your tongue. When was the last time you had your blood pressure checked?
Patient	Two years ago
Nurse	We'll check it now
Observer comment	<i>(Time is 15:11, she gets the machine and starts the process; at this point the nurse starts using an algorithm, both patient and nurse are looking at the screen, the nurse moved the screen so the p could see)</i>
Nurse	That's perfect <i>(referring to the patient's blood pressure)</i>
Patient	I try! <i>(participants laughs)</i>
Observer description	<i>(The nurse is writing on the PC now. Both are looking at the algorithm, kind of reading it together)</i>
Nurse	Worm, wet injury?
Patient	Yes, What can I do to keep it clean?
Nurse	You can keep a dry dressing on it. Now it's oozing so clean it and then apply the dressing, but you'll also need antibiotics
Patient	I can dress it at home
Nurse	OK, I'll give you some dressings then <i>(nurse gives patient 6 packed dressings she got from a drawer)</i> . Clean it as you usually do and then apply the dressing on top. Try to wear sandals and don't apply alcohol on it. Are your vaccinations up to date?
Patient	Yes
Nurse	If the wound isn't healing contact your GP or come back here
Observer comment	<i>(Time is 15:16, The nurse leaves the room to get the antibiotics. It takes about 8 minutes for her to come back with the GP prescription. In the meanwhile the patient and I talk about the waiting time in the WIC and other small talk)</i>
Nurse	Now you need to take this two antibiotics together for them to work until the end of the pack
Patient	How long will it take to clear up?
Nurse	About a week, but if it doesn't then come back here or go to your GP
Patient	Thanks
Observer description	<i>(End of observation at 15:24. This consultation is the first one that I see patient and nurse looking at the screen together in fact using the algorithm as a way to engage the patient. It is easy to see the use of algorithms in practice as they are in the PC screens and also they are part of consultation notes sometimes)</i>

Appendix 5 Examples of Interview Schedules

Nurse interview schedule: Post non-participant observation

Interviews with nurses were broadly guided by the following topics – however we wanted to ensure the latitude for nurses to raise issues about protocols that are relevant to them, therefore interviews were also conducted with this aim in mind.

- Explore issues that arise from nurses who have been part of observation, and so will be specific to particular interactions which may include topics such as:
 - Communication issues: with patients, other professionals
 - Procedural issues: did they follow the protocol-based care tool? If variations why?
 - General views: perceived usefulness of protocol-based care tool¹³?
- Exploring issues about the protocol-based care tool development
 - Are you aware of when was the protocol-based care tool developed?
 - What was the main motivator/s to the development of the protocol-based care tool (purpose)?
 - Probes: cost control; patient focus; continuity of care; clinical effectiveness; other?
 - Are you aware of how it was developed?
 - How did you first find out about the protocol-based care tool?
 - Who was involved in its development e.g. nurses, other AHPs, patients?
 - Is the protocol-based care tool used across different units/wards?
 - Are you aware of what kind of information was used in the development of the protocol-based care tool?
 - Probes: Research evidence, clinical guidelines; clinical practice knowledge; patient and carer's knowledge; local knowledge (audit, performance data).
- Exploring issues about how the protocol-based care tool was implemented
 - Are you aware if there was a formal implementation project? If yes, who facilitated this process? What was their role?
 - Were you involved?
 - Who else was involved? (AHPs, patients, medics...)
 - Did you feel part of the introduction process?
 - What was the reaction of the team and patients to its introduction? Was everyone happy about its introduction?
 - In your opinion what helped the introduction of the protocol-based care tool?
 - And what issues complicated the introduction of the protocol-based care tool?

¹³ The interviews were structured around different protocol-based care tools identified in each site.

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- Probes: perceived restriction on clinical judgement, perceived as more paperwork, lack of support from staff, lack of leadership, non-compliance
- Is the protocol-based care tool used for something other than guiding patient care?
- Exploring their perceptions about how protocol-based care tool impact on:
 - Their role, e.g. day to day work, clinical freedom and identity
 - Do you discuss patients' care through the protocol-based care tool at admission or through their stay?
 - How does the protocol-based care tool impact on your day to day delivery of patient care?
 - Do you find the protocol-based care tool helpful?
 - Do you find any aspect of the protocol-based care tool problematic?
 - Do you feel the protocol-based care tool affects your clinical judgement?
 - Do you feel the protocol-based care tool affects your autonomy in your role?
 - Do you feel the protocol-based care tool affects your responsibility at work?
 - Influence care delivery, e.g. length of stay, clinical outcomes, costs
 - In your opinion does the use of the protocol-based care tool allow you to provide better care for patients? If so in what way?
 - Do you know whether the protocol-based care tool has improved patient outcomes?
 - Probes: length of stay, quality of care, use of resources
 - Impact on team working
 - How do you think using the protocol-based care tool has affected team work?
 - Has the protocol-based care tool improved communication with doctors and other AHPs?
 - Is the protocol-based care tool valued by all members of the multi-disciplinary team?
- Factors influencing delivery of protocol-based care, e.g.:
 - Contextual factors, e.g. organisational structures, leadership, resources
 - In your opinion is the protocol-based care tool supported by managers? Probe for what level of management (unit, directorate, etc)
 - Are you aware if the resource levels adequate to deliver protocol-based care? (e.g. staffing, time, staff skill-mix, etc.)
 - Individual factors, e.g. skills, experience and knowledge
 - When you first came to work in the unit did you feel you had the right knowledge/skills/experience to use the protocol-based care tool?
 - What do you understand by protocol-based care?
 - In your opinion how does it fit in the broader evidence-based care agenda?
 - Protocol-specific issues, .e.g. perceived credibility, usefulness and applicability
 - Do you think the protocol-based care tool needs reviewing?
 - What is the best/most useful aspect of the protocol-based care tool?

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- In your view, how does the protocol-based care tool compare to the care you used to give before it was introduced? What has changed?

Patient interview topic guide: Post non-participant observation

Interviews with patients were broadly guided by the following topics – however we wanted to ensure the latitude for patients to raise issues about protocols that are relevant to them, therefore interviews were also conducted with this aim in mind.

- Ascertaining whether patients were aware that their care was being guided by protocols:
 - E.g. were you aware before being approached to take part in this study that your care is being guided by protocols?
- Questions will arise from the period of non-participant observation and so will be specific to particular interactions, which at this stage cannot be predicted, but may include topics such as:
 - Degree of information sharing
 - Sharing of notes
 - Protocol-specific issues, such as views on particular procedures that were undertaken because they were part of a protocol.
 - General views on the care episode
- Exploring views on how whether protocols have made a difference to patient's knowledge about what was going to happen to them, when and how.
- Exploring views on how patient's communication with practitioners is influenced by protocol-based care.

Staff interview schedule

Interviews with other stakeholders (e.g. other members of the multi-disciplinary team, managers, etc.) were broadly guided by the following topics – however we wanted to ensure the latitude for stakeholders to raise issues about protocols that were relevant to them, therefore interviews were also conducted with this aim in mind.

These topics were used flexibly depending on who was being interviewed.

- Exploring issues about the nature of protocol-based care delivery within the particular context, e.g.
 - Scope of protocol-based care – across the organisation, and within the particular clinical setting. Does the protocol cross health care settings and/or organisational boundaries?
 - What type of protocols are in existence in the organisation?
 - Is there an overall strategy for protocol-based care delivery within the organisation?
 - Who oversees this activity?
 - Are you aware of any reviews/audit on protocol based care in the past?
- How protocols are developed, e.g.
 - How are topics selected and by whom?
 - What processes are used (timeframe, reviews, groups)?

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- What evidence is used? Probes: Research evidence, clinical guidelines; clinical practice knowledge; patient and carer's knowledge; local knowledge (audit, performance data).
- Who is involved in the development of protocols (what healthcare professionals, patients, carers)?
- How protocols are implemented, e.g.
 - Is there a formal implementation plan developed?
 - Who is involved in this process?
 - In your opinion what helped the introduction of protocol based care in the past?
 - And what issues complicated its introduction?
 - Probes: perceived restriction on clinical judgement, perceived as more paperwork, lack of support from staff, lack of leadership, non-compliance
- Impact on care
 - How impact on care delivered by protocols is measured?
 - What data and how often is it collected?
 - How measurement data is used?
 - Who is accountable for collecting and acting on this data?
 - How is this data fed back to the unit/ward?
- Explore issues in relation to the impact of protocol-based care on organisational issues:
 - What impact has had protocol-based care on recruitment and retention issues – of nurses and doctors?
 - What impact has protocol-based care had on costs (e.g. length of stay, clinical investigations)?
 - What impact has protocol-based care had on time savings (e.g. elimination of duplication of work, etc)?
- Explore issues in relation to care delivered by the team, e.g.
 - How protocol-based care might have impacted on work role configuration?
 - How protocol-based care effects team working?
 - Has the protocol improved communication between nurses, doctors and other AHPs?
 - Has the protocol enabled extended roles for nurses?
 - Has the protocol made a difference to the team?
 - How protocol-based care effects people's autonomy and identity
 - What impact has the protocol had on nurses, doctors and other professions?
 - Do you feel the protocol restricts professionals' clinical judgement?
 - Have you found yourself questioning the protocol at some point? What did you question and why?
- Factors influencing delivery of protocol-based care, e.g.:
 - Contextual factors, e.g. organisational structures
 - Does the protocol have support from the organisation?
 - Is the protocol supported by managers?
 - Who is accountable for implementing the protocol?
 - Are resource levels adequate to deliver protocol-based care? (e.g. staffing, time, staff skill-mix, etc.)
 - Individual factors, e.g. skills, experience and knowledge
 - Do you feel confident when delivering/supporting the delivery of evidence-based care?

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- Do you feel you had appropriate training prior to the introduction/use of protocols/care pathways?
- Do you feel you have the necessary skill/experience/knowledge to deliver/support the delivery of evidence-based care?
- What could help you deliver/support the delivery of evidence-based care more effectively?
- Protocol-specific issues, .e.g. perceived credibility, usefulness and applicability
 - Do you think the protocol needs reviewing?
 - Would you change something about it? If yes, what and why?
 - What is the best/most useful aspect of the protocol?
 - Is the protocol easy to use?
 - Is the protocol easy to understand and follow?
 - Is the protocol easy for patients to understand?
 - How does the protocol compare to the care you used to give before it was introduced? What has changed?
 - How credible do you think the protocol is perceived by healthcare professionals in the team?

Appendix 6 Reflections and Limitations

Reflections on the study methods

Data collection for the case study evaluation and the decision making ethnography took place in seven different clinical settings. This diversity in settings translated to different conditions, services and patient journeys. As a result it became apparent that one approach to collecting data and involving participants would not fit all settings and participants. A number of challenges emerged during fieldwork, which are considered below.

1. Involvement of patients

Recruitment of patients

The study protocol stated a general approach to be taken in the recruitment of patients. However, this approach was adapted to each clinical setting to fit with health care professionals' and patients' needs whilst keeping in line with ethical guidance. In two sites, WIC and BC, the recruitment of users was particularly problematic due to the nature of the services.

In the WIC, patients come in to see a nurse or doctor without a prior appointment, usually waiting over an hour for a consultation after which they are usually discharged. Following this patients were not always willing to spend more time to be interviewed by the researcher. As a result, telephone interviews were introduced in the study design in order to allow patients more flexibility about when they could participate. Ethical approval for this amendment was sought and granted.

This amendment meant that the post-observation interview did not always take place immediately after the consultation, as originally planned, but at a convenient day and time for the patient. The introduction of telephone interviews proved successful not only when recruiting patients but also when recruiting busy health care professionals in this multi-site study.

In the BC another issue arose in relation to recruitment of women. The study focused on the normal labour pathway which was used to guide the care of healthy pregnant women from labour onset to delivery. Recruiting women in labour was not an option because they were in a vulnerable position. Therefore, women needed to be recruited on their 36th gestational week, about a month before they were due to give birth.

Whilst the researcher in this site was an experienced midwife, the study involved observations at an intimate and special time, resulting in added difficulty to the recruitment process. The researcher had to attend antenatal information meetings for several weeks at the BC where she emphasised that women's privacy would be respected at all times and observations would only occur with women's and their birth partner's permission. Perseverance was fruitful and 25 women were recruited to the study, although data were only collected from six women who took part in the study. The main difficulty encountered with collecting data on more women

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resulted from the fact that the observation period could not be planned in advance due to the unpredictability of the onset of spontaneous labour, and had to rely on the researcher's availability to attend the BC over a 24 hour period.

The need for the researchers and the research design to adapt to the reality of the clinical setting was essential in enabling this study to take place.

Patient journey

The study aimed to capture a longitudinal perspective on patients' experiences and how protocol-based care impacted on the co-ordination and delivery of their care. To achieve this, some patients were interviewed more than once during or after their episode of care. Interviewing patients on a number of occasions was intended to allow patients time to reflect and make sense of their experiences in order to obtain more representative and useful information.

In practice, this approach did not seem to have a significant impact in patients' reporting of their experiences. In general, patients had very positive views of their care and this did not change if they were interviewed on a number of occasions. Similarly, if they had a negative experience and they initially voiced it this would remain in subsequent interviews. In some cases, the time between interviews allowed patients to ponder about possible improvements to services and one patient shared a diary he kept of his stay in hospital with the researcher. From a researcher's point of view, the opportunity to revisit issues which surfaced in initial interviews was useful, as sometimes they would gain importance as data collection progressed. Overall, tracking the patient journey was particularly useful for extended episodes of care and for allowing patients 'thinking time' to make sense of their experiences.

2. Recruitment of healthcare professionals

The researchers explored all avenues to persuade potential participants to take part; presenting information about the study in team meetings, individually and via email. Healthcare professionals in all the clinical settings were working under time constraints that had a direct impact on their decision to participate (or not) in the study. Generally practitioners were willing to participate, however in one site there were particular challenges. At the WIC during the data collection period the staff in the centre had experienced a number of different managers and were working with a nearby A&E department to achieve the 4 hour waiting target. As a result practitioners were under great time pressure and did not consider research a priority. Snowball sampling proved to be useful in recruiting practitioners. Being flexible about the post-observation interview, i.e. in terms of timing – not always immediately after observation – and medium – telephone interviews –, also improved recruitment success. Overall, perseverance and flexibility were the approaches that ensured successful field work in the reality of the clinical setting.

Limitations of the study

Both the case study evaluation and the decision making ethnography used interviews as a way to understand how participants used and experienced protocol-based care. Semi-structured interviews are open to criticism because of issues about bias and self report. As the study was funded by the SDO Programme and protocol-based care is a term emanating from the NHS modernisation agenda, there was a potential for social desirability to influence the positive reporting about the topic. In general, however, participants were candid in their views, considering both positive and negative aspects of protocol-based care. In some instances notes, instead of recordings, were used at interviews to facilitate participants to be open about their views. All attempts were made to capture the 'real' opinions and thoughts of participants during interviews. Additionally, observations were included in the study to complement, and triangulate with the self reports; making the findings more robust. The interviews and observations were aimed at capturing how protocol-based care worked in the reality of the clinical setting.

The findings are not generalisable; however readers should assess their transferability to other settings and contexts. By combining multiple interviewers, observers and methods in this multi-site study, the findings become a robust illustration of how protocol-based care tools work (or not) in some clinical settings and for some healthcare professionals and patients. The in depth description of sites and methods (in the main report and appendices), should enable a judgement to be made about transferability.

This research highlights a number of possible ideas that could be tested in interventional research; that is the ideas derived from the data of 'what works, for whom, how and in what circumstances'.

Disclaimer

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Addendum

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