

# Towards a better understanding of delivering e-health systems: a systematic review using the meta-narrative method and two case studies

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## Glossary of terms/abbreviations

A&E	Accident & emergency
ANT	Actor-network theory, a theoretical approach in science and technology studies
CGB	Clinical Governance Board
CHIME	Centre for Health Informatics and Multiprofessional Education
CSCW	Computer supported cooperative work, an academic field within human-computer interaction studies
DSS	Decision support system
DSN	Diabetes specialist nurse
EHR	Electronic health record
EMIS	Egton Medical Information Systems
EPR	Electronic patient record
FMEA	Failure modes and effects analysis, a prospective methodology for analysing potential risks
GP	General practitioner
Hba1c	Haemoglobin A1c (glycated haemoglobin), a measure of long-term blood glucose control
HFMEA	Healthcare failure modes and effects analysis, a variant of FMEA specific to healthcare
HIS	Health information systems
HTA	Hierarchical task analysis
IE6	Internet Explorer 6
INR	International normalised ratio, a measure of blood clotting speed
IS	Information systems
IT	Information technology
LMWH	Low molecular weight heparin, a class of anticoagulant medication
NCLASPS	North Central London Anticoagulant and Stroke Prevention Service
NHS	National Health Service
NPfIT	National Programme for IT
OSCE	Objective structured clinical examination

PAS	Patient administration system
PCT	Primary Care Trust
RCA	Root cause analysis, a retrospective methodology for analysing critical incidents
RCT	Randomised controlled trial
SOP	Standard operating procedure
SWIFT	Structured What-If Technique, a prospective methodology for analysing potential risks

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# 1 Introduction

The introduction of 'e-Health' has profound consequences for how health services work and for patient outcomes, but also through organisational and service delivery changes. We sought to characterise these to inform how to promote the successful implementation and management of e-Health technology, something of particular importance in the context of the National Health Service's Connecting for Health programme.

Electronic patient records (EPRs) and related technologies like decision support systems (DSSs) are often depicted as the cornerstone of a modernised health service. According to many policy documents and political speeches, they will make healthcare better, safer, cheaper and more integrated. Lost records, duplication of effort, mistaken identity, drug administration errors, idiosyncratic clinical decisions and inefficient billing will be things of the past. [1,2]

There is good evidence that the use of e-Health technologies is leading to changes in the organisation and delivery of health services. [3,4] Changes are occurring in the organisation of patient care in both specific clinical settings and in the ways in which patient care is managed across organisational boundaries. Equally, there is evidence that new services can be introduced without discernible benefits and some authors criticise visions of a technological utopia. [5-7] They argue that 'failed' programmes are common and even 'successful' initiatives are plagued by delays, escalation of costs, scope creep, and technical problems.

This highlights a key characteristic of information technologies that distinguishes them from some other health technologies: benefits do not automatically arise following implementation, but are only observed if the behaviour of users changes. Interventions are a combination of technology and organisation. We took as our starting-point that health information technologies are socially and organisationally embedded, used by people in particular contexts for particular social acts. They are socio-technical systems. [8]

Much existing research is on the implementation of new systems. Our programme of research was designed instead as a series of case studies on systems that are already in use. We looked in depth at two e-Health systems. Our first system is for patients on anticoagulation drugs: instead of attending hospital to have their treatment monitored, new technology means that patients can go to a community-based clinic. Our second system involves storing a diabetic patient's notes on a computer network so that GPs, hospital

doctors and other healthcare professionals can all access them easily. We planned to cover a third system, a computer tool used by a GP with a patient to help explain the risk factors for heart disease and strokes, but the main data collection had to be abandoned after long delays in obtaining local R&D permission; some description of the system's history is given. These three examples were chosen for their diversity: they cover different technologies, different parts of the country, different NHS and commercial stakeholders, different conditions and different patient experiences.

**Monitoring and adjustment of anticoagulation therapy:** The North Central London Anticoagulant and Stroke Prevention Service (NCLASPS) aims to provide safe and effective anticoagulation therapy. Optimised prescription requires an individual drug regime to avoid both under-coagulation leading to the risk of stroke and over-coagulation leading to the risk of haemorrhage. Previously, patients were treated in a hospital outpatient setting. The new scheme involves patients attending community settings, including community pharmacies or nurse-led clinics at GP surgeries. It relies on remote access to a computerised decision support tool and an associated electronic health record (EHR). The decision support tool records the clotting characteristics of a patient's blood, which are used to guide prescription decisions, and is complemented by the electronic record that enables healthcare professionals to have access to relevant and current information concerning the patient. The service began with GP practices in 1995. It was first piloted in 2002 in a community pharmacy. [9]

**Electronically mediated diabetes care:** A northern English Primary Care Trust (PCT) uses the Phoenix SystmOne EHR. Around two thirds of GP practices use SystmOne and it is also used in a number of secondary care settings, including the diabetes service at the local General Hospital. EHRs are shared between all sites in the network, including out-of-hours services. The system includes an enhanced communication function, so for example hospital clinicians are alerted to referrals and other significant health events (e.g. patient being seen out of hours). The SystmOne software is one of the system choices provided by local service providers to primary and secondary care within Connecting for Health (the Department of Health agency formed in 2005 to deliver the NHS National Programme for IT).

**Risk communication in cardiovascular disease:** The Laindon Model decision support tool is a package to model survival given cardiovascular disease risk factors. It was developed as an aid to risk communication and shared decision-making in primary care consultations. The target issues are smoking cessation and decisions about cardiovascular disease drug treatments. The model generates expected survival presented in a number of graphical, statistical and

verbal ways to communicate lifetime risks. The package was distributed to all practices in Thurrock PCT.

These services were selected to represent a range of e-Health solutions being adopted in the NHS. The three systems have been implemented to varying degrees and all have been and continue to undergo further development, reflecting the nature of many e-Health systems. These services also exist within the context of a rapidly changing NHS. Such change, both technological and organisational, is an endemic part of what we are studying. Many before-after studies on e-Health ignore this broader context of constant change, but we explicitly identified it as part of what needs to be understood. [10]

This was not a single, large study using a set method across different sites within a hypothetico-deductive framework. Instead, the approach we proposed in the original protocol describes three broad case studies and multiple "mini" case studies of a methodologically diverse nature to focus on different aspects of what are complex systems. This was an exploratory approach and we adopted the hermeneutic circle as a heuristic, in which our understanding of e-Health systems generically is established with reference to the specific examples, and our understanding of the specific examples is established with reference to our global findings. Thus, we iteratively and repeatedly compared our preliminary analyses of each part of the research programme (e.g. a task analysis of NCLASPS) with our emerging understanding of the individual e-Health systems as a whole, and of e-Health systems in general.

Our protocol described five *overlapping* stages. (1) A review of the literature using the meta-narrative approach. (2) A document-based analysis of the systems. (3) Our main data collection: ethnographic, observational work following patient or healthcare professional journeys. (4) A set of "mini" case studies to focus on particular areas using an array of methodologies, including an analysis of the ethicolegal sequelae; an economic analysis of how costs can shift between primary and secondary care; a study of role transformations and how they affect professional relationships; an assessment of training needs etc. (5) Interactive feedback with patients and other stakeholders.

The review (stage 1 in the protocol), which grew to be a bigger task than originally planned, is described in section 2. Sections 3 to 5 then describe the work in our three settings. Document-based descriptions of the systems (stage 2 in the protocol) informed the subsequent work and are represented in the introductions of each of those sections (sections 3.1 and 3.2; section 4.1; and most of section 5, respectively).

For Stages 3 and 4, to quote our original protocol, "we will adopt an iterative and reactive method where the research will adapt to the

findings so as best to be able to study the hidden and unexpected consequences of e-Health.” Broadly, how we adapted our research plans was to carry out more Stage 3 work in case study 2 and more Stage 4 work in the NCLASPS setting. This reflects how SystmOne in case study 2 represents a more dispersed system supporting a broader set of roles, whereas NCLASPS has some degree of centralisation in its governance, training support and other issues. In case study 2, we focused on two observational studies: the first expanded on our understanding of how the system worked, allowing a second larger study following patient journeys. With NCLASPS, while ethnographic and observational work, generally following healthcare professionals, was carried out, the work hewed closer to the multiple “mini” case studies description. However, we sought to keep these methodologically diverse approaches and different research questions connected to the overall picture in this report. Sections 3 and 4 are divided by the key distinct data capture regimes, with the different issues (professional relationships and role transformations, training needs *etc.*) addressed throughout as appropriate. Given its methodological differences, Section 3.5.4 covers the ethicolegal analysis separately.

Stage 5 is not presented separately, but was an important part of how we checked the validity of our work. As discussed in sections 3.3.1 and 3.3.2 in more detail, we chose to work closely with stakeholders in a model of co-production of knowledge. This allowed us to spread Stage 5 right through our work, with repeated presentations back to participating stakeholders. This was mostly to involved healthcare professionals, but also to other stakeholders, including PCT commissioners, software developers and patient representatives. In particular, the existing Clinical Governance Board structure in NCLASPS readily allowed, in that setting repeated, interaction with a group including various different participating healthcare professionals, commissioning bodies (PCT representatives), the software team and patients. In practice, interest in our work varied between stakeholders and not all offers of dissemination were accepted. However, at best, we were able to go back to a variety of stakeholders in a variety of different ways, on a regular basis, and present and discuss our research findings as they emerged.

The first and third case studies describe bespoke systems. To understand these and their use requires the sites of the case study to be identified, as we have done in this report. The sites concerned (NCLASPS for case study 1, and Dr Martin’s general practice in Laindon for case study 3) have given their permission to be so identified. In contrast, case study 2 is concerned with an off-the-shelf software package used quite widely in NHS England. For this case study, there was no particular reason to identify the site (PCT and

general hospital) involved, and we have left this anonymous in the report.

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## 2 A meta-narrative literature review of the electronic patient record in organisations

In our initial proposal, we proposed a meta-narrative literature review focusing on the ways in which service delivery is affected by the integration of e-Health with clinical and management practice. At that time, there were already over 20 systematic reviews on the electronic patient record (EPR) covering hundreds of primary studies. These included scoping reviews published as part of the same NHS Service Delivery & Organisation funding stream that supported our work. However, these reviews covered a relatively narrow body of literature, largely on experimental studies with quantitative designs. A broader literature on organisational aspects of the EPR was known to exist and yet to be largely uncharted.

We undertook a new systematic review to map, interpret and critique a broader range of evidence. We favoured sensemaking over cataloguing: we saw the key task as teasing out the meaning and significance of the literature rather than producing an inventory of every paper published on the topic. We sought to characterise methods and approaches of value for our own and others' work.

The broader literature we sought to cover proved to be even larger than we had expected. To make the review manageable, we focused on the EPR, excluding other technologies like decision support, although we suggest many of our findings generalise beyond the EPR.

The term 'electronic patient record' is used to mean different things: from an isolated file of computer-held information on a single patient, with or without decision support functions, to a national, networked database oriented towards secondary uses such as research, audit and billing. As technologies move on, so does the scope and purpose of the EPR. Rather than impose a rigid definition, we chose to track how the definition changed through time and how framings of the EPR inspired different theoretical approaches, study designs and empirical insights.

Our research questions were:

- What bodies of knowledge and research traditions are relevant to understanding EPRs in organisations?

In each of these traditions:

- What are the key concepts (including taken-for-granted assumptions about the nature of the problem), theories and methodological approaches?
- What are seen as the seminal theoretical works and the high-quality empirical studies?
- What are the main empirical findings and what has been concluded from these?

When comparing across the different traditions:

- To what extent are the assumptions, approaches, findings and conclusions of the different traditions commensurable?
- What higher-order insights can be gained from the study of the agreements and disagreements between them?

Further details of this review have been published separately. [11]

## ***Method***

We used the meta-narrative method as a way of systematically making sense of complex, heterogeneous and conflicting bodies of literature. This is a relatively new method, described in detail previously. [12-15] A meta-narrative embraces a shared set of concepts, theories and preferred methods (including an explicit or implied set of quality criteria against which 'good research' is judged). Researchers within any particular meta-narrative tend to know about and cite one another's work (even if to contest it), attend the same conferences, publish in the same journals, and accept broadly similar criteria for judging validity and rigour.

After an exploratory, informal searching phase, we identified provisional research traditions (each of which appeared to be driven by a different meta-narrative about the EPR) and approached each with six questions in mind:

- a. What are the parameters of this tradition, i.e. its scope, its historical roots, its key concepts and assumptions, and its theoretical basis?
- b. What research questions (in what priority) have scientists in this tradition asked about the EPR?
- c. What methods and instruments have they used to answer those questions, and by what criteria has methodological quality of primary studies generally been judged?
- d. What are the relevant empirical findings from the quality literature in this research tradition?

- e. How has the tradition unfolded over time, i.e. in what way have the findings of earlier studies led to refinements in theory and/or influenced the design and direction of later empirical work?
- f. What are the strengths and limitations of this tradition, and in the light of these, what is its likely overall contribution to the body of knowledge on this topic area?

Our searching became progressively more systematic as the emerging meta-narratives served as a powerful focussing device for refining some areas of enquiry and rejecting others. There was considerable discussion among the research team as to what were the key meta-narratives for our research question, and the extent to which they were truly separate and independent of one another. The selection of papers in each meta-narrative was driven by interpretive judgement rather than a formal checklist of inclusion criteria. Some papers focussed centrally on the study of the EPR in organisations and were thus clearly relevant; others were not about the EPR and clearly irrelevant. But many papers occupied a middle ground, providing ideas, findings and insights that had a bearing on the review even though they were not actually about the EPR.

Our initial list of meta-narratives was somewhat different to that in the results below; it changed iteratively as data emerged from later phases of the review (for example, meta-narratives 3 to 5 were initially classed as a single meta-narrative and we made what were probably arbitrary distinctions between meta-narratives 6, 8 and 9 since some authors had sought to cross-fertilise between them). But as in the previous meta-narrative review on the diffusion of innovations, [12,13] we found that even a 'draft' meta-narrative map was a major breakthrough that enabled us to emerge from what we had previously labelled as "the swamp" (a feeling of being submerged in, and weighed down by, an opaque mass of data). [13] Once this early map was in place, we pursued references to find the books and/or papers that were seen as seminal influences by researchers within each tradition, using three very generic criteria:

1. Is the paper part of a recognised research tradition – that is, does it draw critically and comprehensively upon an existing body of scientific knowledge and attempt to further that body of knowledge?
2. Does the paper make an original and scholarly contribution to research into electronic patient records in organisations?
3. Has the paper subsequently been cited as a seminal contribution (conceptual, theoretical, methodological or instrumental) by competent researchers in that tradition?

We used these seminal sources to distil the 'normal science' of the paradigm (core concepts, theoretical models, and preferred methods and instruments). From the seminal sources, we extracted

(separately for each tradition) a set of quality criteria for primary studies. We then used 'snowballing' search techniques, both manually by searching references of references, and electronically by using citation tracking software to identify later papers that had cited a seminal source. We also undertook selected, focused searches of electronic databases, for example on named authors or key words (such as "structuration"). We placed these additional empirical studies, reviews and commentaries in historical order to build up the detail of the meta-narrative.

In the appraisal phase, we judged primary studies in each tradition according to the quality criteria set by experts within that tradition, as set out in seminal sources. Reassuringly, we found that studies with comparable design tended to be judged similarly whatever the research tradition (for example, an ethnographic case study would be judged by similar criteria and standards whether undertaken in organisational sociology or HSR – namely, authenticity, plausibility, demonstrable links between raw data and interpretations, researcher reflexivity and so on). Furthermore, while all traditions whose methodological toolkit included (say) the ethnographic case study classified this as a high quality method, those traditions whose toolkit did not include this method were dismissive of any work based on it, regardless of the research question being considered.

We developed a data extraction form to summarise the research question, theoretical basis, study design, validity and robustness of methods, sample size, nature and strength of findings, and validity of conclusions for each empirical study. We initially planned to produce inter-rater agreement scores by comparing how two independent researchers classified the study design, relevance and so on. However, the reality was that this classification was not 'extracted' from the papers by benchmarking against a predefined and non-negotiable set of criteria. Rather, the judgement criteria emerged through dialogue among researchers as the meta-narratives took shape. For this reason, data extraction forms were iteratively redesigned throughout the project; some papers included in one tradition were subsequently moved to another; and papers initially rejected as irrelevant to our research question were sometimes retrieved when their place in the wider field of research became clear. By the end of the study, it was evident that 'data extraction' was a highly constructivist process in which we sought consensus within the team, but for which a quantitative measure of inter-rater agreement at any particular time was meaningless.

## **Main findings**

### **2.1.1 Overview and historical roots**

In total, we considered some 5000 abstracts. We included 528 sources in a final report (as yet unpublished) and present a summary of results here. We divided these 528 sources into seminal ('paradigm-defining') works on the EPR in organisations, systematic reviews on the EPR in organisations, empirical studies on the EPR in organisations, and background sources. 'Background sources' are books and papers used for a variety of reasons, including (a) an 'upstream' theory or approach which was not directly influential to EPR work but was drawn upon by those in an EPR tradition; (b) empirical studies that were not about the EPR in organisations but which we included 'for interest' (usually as good examples of particular methodological approaches where direct examples on the EPR were lacking), and (c) policy documents.

Table 1 shows an audit of the seminal sources, systematic reviews and empirical studies on the EPR in organisations included in this review. As in the previous metanarrative review on diffusion of innovations [14], the most fruitful source of papers was 'snowballing' (pursuing references of referencing or using citation-tracking, usually via Google Scholar, to see which subsequent articles had referenced a key source). Seminal papers were often found in the references of references, and forward citation tracking these seminal papers (through Google Scholar) enabled us to identify many additional empirical papers, especially recently published ones. Systematic reviews were most commonly identified by database search, though most of the larger reviews were already known to the research team. Empirical papers were very often identified in the reference lists of other papers in the same tradition. Because of the highly heterogeneous literature and our previous finding that hand-searching journals was an inefficient way to identify good papers, [14] we did not hand search any journals for this review. We have not undertaken a systematic analysis of our 'background sources', since their use was a subjective (largely 'editorial') decision.

**Table 1: Origins of key sources used in the review**

	<b>Seminal papers/books</b>	<b>Systematic reviews</b>	<b>Empirical studies</b>	<b>TOTAL</b>
Electronic database search using search strategy	2	11	8	21 (13%)
Electronic database search using named	2	0	2	4 (2%)

author				
Backwards citation searching (references of references)	25	3	43	71 (43%)
Forwards citation searching	1	2	22	26 (16%)
Previously known to research team	10	6	12	27 (16%)
Social networks of research team (asking colleagues etc.)	3	2	4	9 (5%)
Serendipitous	6	0	3	9 (5%)
TOTAL	49	24	94	167 (100%)

*'Background' sources listed in the references are not included in this table. The above table only records each paper once, in terms of the first category we placed it in. For example, if we already knew about a paper and subsequently found it in a reference list, we classified it as 'known to research team'. The unit of analysis for this table is the study – hence if one study led to three papers, only the major paper is represented here.*

Table 2 below describes the systematic reviews and empirical studies in more detail. We found a complex and heterogeneous literature characterized by diverse philosophical assumptions about the nature of reality (ontology), how that reality might be known (epistemology) and the preferred research approaches and study designs (methodology). Adapting previous taxonomies, [16,17] we identified four main philosophical positions:

- *Positivist*, which assumes an external and knowable reality that can be objectively measured; an impartial researcher; and the possibility of producing generalisable statements about the behaviour of the natural and social world;
- *Interpretivist*, which assumes a socially constructed reality that is never objectively or unproblematically knowable; and a researcher whose identity and values are inevitably implicated in the research process;
- *Critical*, which assumes that the social order is inherently unstable and involves the domination of some groups by others (such as women by men, workers by capitalists, or patients by health professionals) and takes the purpose of

research as at least partly to help dominated groups challenge their position in society;

- *Recursive (or integrative)* which assumes that subject and object, micro and macro, social structure and human agency are reciprocally related, and that the purpose of research is to explore the flux between these various dualities over time.

These four positions, described further in Appendix 1, overlap somewhat. For example, recursive approaches such as structuration theory were initially developed to build links between the polarised worlds of positivism and interpretivism. [18] Leaving aside the philosophical small print, this pragmatic taxonomy provides a useful shorthand for describing in broad terms where the researchers in any particular tradition were coming from and how they (implicitly or explicitly) defined 'rigorous' research.

There were multiple existing systematic reviews of the health information systems literature (meta-narrative 1 below) but not in the other meta-narratives. Thus, we restricted our analysis of the health information systems literature to those prior systematic reviews but had to consider primary studies otherwise. Our sample of primary studies is thus skewed towards the non-biomedical literature, so the statistics that follow should be interpreted accordingly. The 94 primary studies (written up in 129 papers) outside the health informatics literature were philosophically pluralist and methodologically diverse, with a predominance of case studies of different types (Table 2).

**Table 2: Breakdown of systematic reviews and primary studies**

	Number of studies/reviews
SYSTEMATIC REVIEWS (MOSTLY FROM META-NARRATIVE 1)	
Review of reviews using Cochrane methods with some qualitative analysis <sup>#</sup>	1
'Cochrane' review restricted to RCTs with a statistical meta-analysis	1
'Cochrane' review restricted to RCTs but no meta-analysis	4
'Cochrane' review of other quantitative designs but no qualitative analysis	6
'Cochrane' review of quantitative designs with some form of qualitative analysis	9
Qualitative review using realist method	1
Other qualitative or narrative review	2

TOTAL SYSTEMATIC REVIEWS	24
PRIMARY STUDIES (THESE EXCLUDE META-NARRATIVE 1*)	
Organizational case study	
Single site ( <i>i.e.</i> main goal was understanding within the case)	18
Multi-site ( <i>i.e.</i> a key goal was comparison across two or more cases)	20
Ethnography of situated practice*	12
Actor-network analysis†	19
Participatory study	
Action research	4
Co-design‡	2
Qualitative study (interview, focus group or both)	5
Quantitative study	
Quantitative survey alone	2
Quantitative survey supplemented by in-depth qualitative interviews	2
Before and after study	1
Randomised controlled trial	1
Other study design	
Empirical philosophy‡	4
Discourse analysis	2
Simulation study	2
<b>TOTAL PRIMARY STUDIES</b>	<b>94</b>

# *This review of reviews included all Cochrane reviews covered here, plus 14 additional systematic reviews on specialist aspects of EPR use*

\* *Detailed ethnography of the fine-grained detail of clinical (or administrative) work, often using techniques such as video or computer screen capture, and drawing on Garfinkel's ethnomethodological approach [19] and situated action theory*

† *Mapping and analysing a dynamic network in which both people and technologies are 'actors'*

‡ *A form of action research with a stronger technical element, effectively participatory workplace redesign alongside technical (re-)development (sometimes called 'techno-methodology')*

‡ *Mainly theorising but based on a small amount of empirical data (usually from ethnography of situated practice)*

*The unit of analysis for empirical studies in this table is the study – hence if one study led to three papers, only one of these is 'counted' here. The only exception is one study in which a complete re-analysis of the data was undertaken using a different theoretical perspective; this study has been double counted in the table.*

## **2.1.2 Meta-narrative 1: Health information systems (HIS)**

Health informatics is the application of computers to clinical work, and health information systems (HIS) research is the study of the systems which support such work. [20] This predominantly positivist tradition is rooted in quantitative approaches and came to be strongly influenced by evidence-based medicine; the preferred design is the randomised controlled trial. Much (though not all) of it has assumed that the benefits of a well-designed EPR are intrinsic and self-evident. The key challenge has been seen as getting the design right, implementing the technology, and ensuring clinician use. While there is a large literature within health informatics on technical design, this is separate from the literature on the implementation and use of such systems. In the latter, at least until recently, neither the technology nor its social context was considered in depth. Empirical studies were grouped together by systematic reviewers in meta-analyses.

We found 24 systematic reviews covering over 2000 primary studies, each measuring the impact of the EPR on some aspect of care. Of particular note is a 600-page 'review of reviews' embracing the EPR and other technologies. [21] This found that, while some primary studies and some but not all systematic reviews showed positive benefits from the EPR, the nature and magnitude of benefits were not

consistent across studies, nor were there clear findings on how benefits might be maximised or what their opportunity cost might be.

The HIS literature has begun to move beyond studies that are restricted to measuring impact to address how context mediates and moderates this impact. A recent systematic review sought to relate the impact of EPR systems to contextual variables. [22] This suggested a significant difference in the likelihood of success between local 'home grown' EPR systems (developed in an ad hoc way by clinicians close to operational detail) and 'off the shelf' systems. 'Home grown' EPR systems typically emerged slowly, at the pace of local enthusiasm and need. Some impressive examples of systems associated with improved quality were found, but the reviewers concluded "these [home-grown] interventions are by nature not widely generalisable" (p. 5). 'Off the shelf' EPR systems, on the other hand, were often acquired as part of a strategy for rapid change. These systems typically failed to meet expectations and incurred problems of fit with the detail of work practices.

### **2.1.3 Meta-narrative 2: Change management studies within health services research**

Researchers in the change management tradition are usually upbeat about the benefits of the EPR but assume these will only be realised if the change process is properly managed. [23-25] We found 16 empirical studies, most case studies, each of which considered the impact of a range of potential enabling or constraining factors on a project to implement a new system. Studies consistently showed that introducing the EPR is a complex task. It requires a well-articulated vision and strategy, strong leadership, adequate resources, good project management, an enabling organisational culture, effective communication, and attention to human resource issues. Even with these preconditions present, success is not guaranteed.

### **2.1.4 Meta-narratives 3 & 4: Information systems**

Information systems (IS) research is a heterogeneous tradition that emerged in business schools to consider the role of technology. It embraces a longstanding tension between positivist and non-positivist approaches. In IS research overall, the literature is dominated by the former. However, we found only three empirical studies in positivist IS research relevant to our review. These form meta-narrative 3. These all demonstrated that model-based analyses of the determinants of EPR success left much of the observed variance unexplained.

The interpretivist perspective holds that the use, design and study of information systems is fundamentally a hermeneutic (meaning-making) process rather than a rationalistic, decision-making one.

[26] We found 11 studies in this tradition (meta-narrative 4), including papers that drew on institutional theory, [27] symbolic interactionism, [28] organisational sensemaking [29,30] and 'soft systems' action research. [31] Findings were consistent: there are multiple, conflicting framings of the EPR by users, some of which are explained by deeply-held institutional values; these contrasts partly explain the low adoption of the EPR. 'Successful' implementation requires accommodation between perspectives. Externally-imposed deadlines and technical requirements constrain the process of mutual adaptation by which technologies and work processes become aligned. While these retrospective studies offer explanations for failed EPR projects, we note there is little research on how interpretivist approaches might be used proactively to shape effective implementation.

### **2.1.5 Meta-narrative 5: Information systems (technology-in-practice approaches)**

Most studies in this tradition are linked to the work of Orlikowski and her team who applied Giddens' structuration theory [32] to the introduction of technologies in organisations. Barley suggested that a new technology introduced into the workplace is an 'occasion for structuring'. [33] He suggested that a structurational approach to the EPR could show how this technology might shape and support new roles and new ways of collaborative working that would then become routinised, with positive impacts on clinical outcomes. Our findings suggest that these hopes have yet to be realised. Eight empirical studies identified provide examples of abandoned EPR systems; [34] widespread disruption of routines and mismatch of expectations; [35,36] continuing dependence on paper or ad hoc, non-integrated EPR systems; [37] and distortion of organisational response by the prevailing context of a nationally-imposed programme. [38]

Orlikowski and colleagues have demonstrated that individuals, working collectively around common tasks in organisations, actively and explicitly shape both technologies and work routines in a way that is mutually adaptive. [39] In relation to the EPR, this adaptation often does not happen, at least not smoothly or unproblematically. Key influences on the structuration process include the affordances of the technology (the latent "action possibilities" in the technology, i.e. its qualities that allow an individual to perform an action [40]), constraints of time and space, the conflicting meanings attached to the EPR by different groups, patterns of human action and interaction associated with them, and how different 'genres' of medical records are used. 'Failed' EPR projects may be explained by adverse changes in the structuring of work consequent on introducing new technology, the fact that knowledge is linked in complex ways to identities and social practices, and limitations of the technology. As the CSCW

literature (meta-narrative 6, below) has also shown, healthcare work is complex and dependent on the coordinated practice of multiple actors.

### **2.1.6 Meta-narrative 6: Computer-supported cooperative work (CSCW)**

CSCW developed from human computer interaction studies and considers the collaborative use of computers by people in the workplace. [41] It draws pragmatically on positivist, interpretivist and recursive approaches. The preferred research design is the ethnography of situated micro-practices (localised detail of what is done) of collaborative work, focusing on such things as the sequential ordering of utterances or actions. We found 11 empirical studies on the EPR in this tradition; in addition, meta-narratives 7, 8 and 9 draw on CSCW principles.

These ethnographies have illustrated that collaborative clinical work involves the ordering and coordination of tasks, which requires real-time processing of local information. They show that clinical knowledge is often tacit, context-bound and ephemeral rather than codifiable, transferable and enduring. In 'failed' EPR projects, technical designers typically missed these subtleties and produced artefacts that fitted poorly with the situated nature of knowledge and the micro-detail of clinical work. Paper records, being flexible, portable and tolerant of ambiguity, support the complex work of clinical practice remarkably well. CSCW studies have highlighted a telling paradox that high-tech healthcare environments such as intensive care units often make extensive use of paper charts, white boards, sticky notes and oral communication.

Despite its apparently negative conclusion that the EPR is often less fit for purpose than paper, the CSCW literature on the EPR is not anti-technology. It has shown that humans can be very creative in overcoming the inherent limitations of technologies through workarounds. This tradition surfaces and values the 'hidden work' that achieves positive outcomes despite the inflexibility of technology. The EPR can provide multiple views and framings of the data hence can potentially tolerate the ambiguities inherent in interprofessional work and make the work of different professional groups more visible to others. [42] There is considerable scope for more flexible and technologically sophisticated forms of the EPR to overcome current limitations. However, for this to happen, technology (re-)design must occur in intimate proximity to the work process and actively involve users of the EPR. [43,44] CSCW researchers have recognised two potentially conflicting work processes: immediate clinical care (primary uses) and tasks such as audit and research which are one step removed from the clinical

encounter (secondary uses). [45,46] When used as a formal tool, the EPR often slows down the clinical encounter, but it greatly accelerates secondary uses of clinical data. Rather than promising that the EPR will “save time”, a more honest message would be that creating accurate clinical records requires the sacrifice of time and effort by front-line clinical and administrative staff, but that this is (sometimes) justified by wider benefits in terms of efficient business processes, governance and research. Appropriate incentive structures are needed to ensure that those who do the work reap appropriate rewards. [47]

### **2.1.7 Meta-narrative 7: Critical sociology**

This meta-narrative draws on the work of feminist scholars and the philosopher Michel Foucault on power. [48,49] In sum, technologies reflect the interests and values of those who produce them, hence power struggles between bosses and workers, clinicians and managers, men and women, and the state and the citizen are played out partly through the design and use (or non-use) of technology. [50] The EPR may be a focal point around which disputes of professional jurisdiction are fought.

We found nine studies from a feminist perspective and three from a Foucauldian one. Feminist studies have demonstrated that EPR designers sometimes failed to understand or fully incorporate the work practices of female staff with relatively low status in organisations, especially front-line nurses. They have shown that nurses’ work (which is largely unpredictable, close to the patient and difficult to codify) maps closely to what the CSCW community view as articulation: the situated actions of creative human agents that can potentially bridge the gap between the formal and informal, the social and technical. Thus, while some findings appear largely negative, these papers also offer a more positive insight: that there is an important but subtle territory of hidden work by groups such as nurses, administrators and data entry clerks.

The three studies from a broadly Foucauldian perspective link the introduction of the EPR with the rise in managerial surveillance and control of clinical work. They draw on Foucault’s metaphor of the panopticon, the increasing capacity for large-scale surveillance of human activity, supported by technology but also embodied and policed by the actors concerned. The story is more complicated, however, than an inexorable growth in the oppression of clinicians by management, aided by technology – not least because Foucault’s definition of power was a more fluid and generative one than this. One ethnographic study, for example, showed that not only did nurses successfully defend their professional practice in the face of a technical system that sought to ‘managerialise’ it, but also that managers accepted the nurses’ account of what was valuable and

actively colluded with the latter's resistance to a poorly-designed technology. [51]

### **2.1.8 Meta-narrative 8: Actor-network analyses**

Actor-network theory (ANT) is built on a recursive philosophy. [52] It holds that people and technologies are linked in networks, and that the focus of research should be the network's changing relationships and what emerges from these, rather than either the people or technologies themselves. ANT has been applied in numerous ways, often in combination with other theories. An actor-network analysis is a special type of case study in which researchers define and explore a dynamic network of people and technologies as it evolves over time. We found 12 such studies, all of which drew on CSCW as well as ANT, plus two empirically-informed theoretical papers. [53,54]

Many findings in this meta-narrative are conceptual: they invite us to think differently about the EPR, EPR user, and the context in which the EPR is implemented. The EPR is not merely a container for information: it accumulates and transforms work (is 'constitutive' of it), and is thus an actor (or 'actant') in the network. The studies demonstrated that the socio-technical network in which the EPR is embedded is highly dynamic and inherently unstable. An actor-network can be stabilised to some extent when people, technologies, roles, routines, training, incentives and so on are aligned. This alignment is achieved (or attempted) through 'translation', which involves the four stages of problematisation (defining a problem for which the EPR is a solution), interessement (getting others to accept this problem-solution), enrolment (defining the key roles and practices in the network), and mobilisation (engaging others in fulfilling the roles, undertaking practices and linking with others in the network). [55] EPR projects 'fail' when the elements in the network fail to align, when efforts at translation fail. Codes and standards inscribed in the EPR and its infrastructure may help to stabilise the network and thus shape and constrain clinical work. The various actor-network analyses describe the struggles (successful or not) of groups of actors who have sought to define and inscribe particular codes and standards into particular technologies, and show how once these have become part of the network, they are hard to reverse and shape clinical work.

### **2.1.9 Meta-narrative 9: systems approaches to risk and integration**

Another research tradition draws on safety-critical systems research and insights from other industries (notably aviation) to address the role of the EPR and user in complex healthcare systems. Such systems are characterised by advanced technology, tight coupling

and a high level of uncertainty, and are thus vulnerable to unpredictable, catastrophic failures. [56] Accidents arise, rarely but inevitably, from the accumulation of such things as 'minor' errors of judgement, flaws in technology, and small incidences of disrepair or damage. [57] Successful high-reliability organisations are characterised by mindfulness, an ever-present awareness among staff of the possibility of error and the ongoing measures that must be taken to minimise it; over-reliance on technical systems may erode this.

We found 22 primary research studies in this tradition, along with an interdisciplinary literature review. [58] Overall, this meta-narrative provides evidence that while EPRs may contain features that protect against error, they also introduce new risks of their own, including cognitive overload, loss of overview, errors in data entry and retrieval, excessive trust in electronically-held data, and the tendency to conflate data entry with communication within and between care teams. [59,60]

One body of work proved hard to categorise into a single meta-narrative because its authors explicitly sought to work across different research traditions, but we have included it here. This work has been developed by a Norwegian group who drew on CSCW, ANT, and systems theory to study large, networked EPR systems and the challenges of standardisation, integration and scalability within these (see for example [61-5]). These studies suggest networked EPR systems are not unproblematically scalable. The tension between standardisation (which helps stabilise the network) and contingency (which reflects and responds to local needs and priorities) can never be resolved; rather, it must be actively and creatively managed, and this gets harder as the network gets bigger. As predicted by complexity theory, over-assiduous efforts to 'standardise' or 'integrate', especially on a sizeable scale, are likely to create disorder elsewhere in the system. [66] Because of unintended consequences and the loss of potential for using information in a locally meaningful and situated way, large-scale distributed EPR systems are likely to be less efficient, less cost-effective, less safe and the information they contain less trusted, than smaller, more local systems. [61-63, 65]

## ***2.2 Synthesis***

Because this heterogeneous literature is based on different philosophical assumptions, a meaningful synthesis must not merely summate the findings of different meta-narratives but present the tensions between them. We consider seven key themes, each of which has inherent tensions. Most but not all of the tensions are between studies which take a positivist approach (broadly, meta-narratives 1 and 3) and those which take an interpretivist, critical or

recursive one (broadly, meta-narratives 2 and 4-9), though some traditions (notably CSCW) embrace more than one position.

### **2.2.1 The EPR**

The first tension is between 'the EPR as tool or container' and 'the EPR as actor'. Positivist traditions tend to take an essentialist, functionalist and determinist view of the EPR: it has inherent properties which will do certain tasks, and if implemented properly, will more or less predictably improve the process and outcome of the clinical encounter. In contrast, non-positivist traditions view the EPR either as a social construction (whose meaning and purpose is a matter of interpretation) or as a fluid and flexible artefact which 'acts' (to use the language of ANT) in particular, situated and constantly changing contexts. If these latter two views are accepted, it follows that the impact of introducing an EPR cannot be predicted from its essential properties, and hence that studies which seek to 'determine the (generalisable) impact of technology X on outcome Y' have limited value.

Positivist traditions hold that the patient's condition and journey comprise a single reality to be represented in the EPR, and hence seek a single ideal, agreeable form of the record. Multiple 'front ends' of the record are allowable (for example, nurses might be more interested in some data fields and doctors in others), but the underlying reality represented by the record is generally considered to be unitary, context-free and unproblematic. Interpretivist and recursive traditions hold that the very notion of an agreeable EPR is problematic. As one seminal paper put it, the EPR's bodies are multiple. [67]

Research traditions differ in the emphasis they place on the material properties of the EPR. Positivist reviews typically offer comparisons of the general format 'EPR present' versus 'EPR absent'. The interpretivist literature has placed more emphasis on the meaning of the EPR in the eyes of users than on what the EPR can and cannot do in particular conditions of use. In contrast, research in recursive traditions (technology-in-practice, ANT and much of CSCW) place the material properties of the EPR (and indeed, the material properties of paper and so on) central to their analysis. Critical sociology and ANT studies assume that power relationships are (at least to some extent) built into the structure and data models of the EPR. For example, ANT gives us the metaphor of software as "frozen organisational discourse". [68]

### **2.2.2 The EPR user**

There is a tension in the literature between a cognitive view of the human subject (the user as an information-processor or decision-

maker) and a relational view (the user is defined primarily by their position within a socio-technical system). The former explains non-use of the EPR in terms of a 'knowledge', 'skills' and 'motivation' gap (attributes of the individual) for which much of the solution lies in providing information, training and incentives. The cognitive view assumes, broadly, that the outputs of a group of people using technologies will be the sum of their individual inputs. The latter views the EPR user as inextricably linked to (indeed, embodying and reproducing) wider social structures, institutions or socio-technical relationships and thus sees the collective as more than the sum of its parts. While different language is used in different traditions ('ensemble', 'situated', 'embedded', 'accommodated', 'networked'), there is much common meaning and all place greater emphasis on system-level approaches than on interventions aimed at the individual.

One key difference between two traditions that otherwise have much in common – technology-in-practice (meta-narrative 5) and ANT (meta-narrative 8) – is the treatment of the human agent. Technology-in-practice draws on structuration theory and places human identity and agency central to the analysis; it offers theory about what agents 'know' (crucially including internalized social structures). ANT, in contrast, considers agency to be a product of the network rather than something intrinsic to the individual actor, hence such things as knowledgeability and motivation are only weakly and indirectly theorized. [69]

### **2.2.3 Organisational context**

A striking difference between research traditions is their treatment of context. The tension might be expressed as 'context as the setting within which the EPR is implemented' and 'context as the EPR-in-use' (reflecting a difference in focus between 'the organisation as the place where work happens' and 'the process of organising, wherever it happens'). The positivist literature views context as a conglomeration of confounding variables, which must either be carefully quantified and modelled, or controlled for in a RCT design. Critical research traditions also tend to view context as an external reality, made up of economic and social structures that constrain action.

The recursive (and, to some extent, interpretivist) research traditions have a more inclusive and fluid view of context. Context is seen as an emergent property of action, constituted by, and therefore inextricable from, an activity involving people and technologies. These traditions do not see themselves as studying 'technologies' and 'contexts' separately but technologies-in-use. Indeed, this inseparability of the EPR from its context is a defining characteristic of literature that adopts a recursive philosophy.

## 2.2.4 Clinical work and knowledge

The tension here might be expressed as 'clinical work as decision-making' versus 'clinical work as situated practice', and between 'knowledge as transferable facts' versus 'knowledge as information-in-context'. Positivist traditions tend to view clinical work as largely reducible to a series of decisions, and it follows that decision support technologies will help clinical work so long as they are properly implemented. The alternative view is that clinical work is less about decision-making than about addressing the ongoing, local question "what to do next?", [70] and since healthcare work is personalized, exception-filled and context-bound, "the nature of health care work sets natural limits to the possibilities of IT to revolutionize this work" ([71], p. 337). This alternative literature suggests that gains in the quality of care with EPR systems are likely to be relatively modest, incremental, local, and based on the study of articulations and workarounds, though this view still recognizes the efficiency savings which EPR systems offer for secondary uses.

Different traditions in EPR research dispute the extent to which information placed on the EPR can be extracted from its context and transferred to a different context while still retaining meaning. The biomedical literature sometimes talks of "information superhighways" that will make clinical information instantly available in a way that transcends the context in which that information was originally collected. [72] The idea that meaning is transmitted unproblematically along with data underpins many large-scale EPR programs, but critics claim this is a flawed assumption. [73] The CSCW, technology-in-practice and ANT literatures all offer evidence that clinical data must be interpreted in context and 'framed' before they become meaningful. Thus, while positivist studies of collaborative clinical work view it as largely to do with the exchange of information between distributed decision-makers (human and technological), interpretivist and recursive models place much greater emphasis on communication, one aspect of which is contextualising work (prioritising, highlighting, comparing, interpreting, negotiating and other tasks not achieved simply by placing information on an electronic platform that is accessible by multiple users). [46,74]

## 2.2.5 The process of change

The tension here is between the 'logic of determinism' versus the 'logic of opposition'. [75] Taken to its extreme, the logic of determinism is technology-focused, causalist (technology X will produce output Y) and fundamentally linear; it assumes that the human interactions and organisational context will operate on the same formal and predictable technical principles as the technology

itself. In such a model, the change process is one of good project management setting clear strategic goals and ensuring that all parties work towards these. The logic of opposition is fluid, contingent, and contains inherent and unresolvable tensions. These tensions are variously expressed in terms of 'competing institutional logics', [76] the need for 'accommodation', [31] 'sensemaking', [77] 'negotiating knowledge between different communities of practice', [78,79] or 'translation' [52] – approaches which have conceptual common ground. [80] If this logic is adopted, it follows not merely that the change model will be neither linear nor predictable, but also that there will be conflict involved. While good project management is a sine qua non, the key task is to manage an essentially political process in a flexible and reflexive way.

One aspect of the process of change that is addressed differently between positivist and interpretivist/recursive traditions is design. In the latter, Hartswood and colleagues offer a particularly eloquent exposition of the principles of co-design and call for the development of 'shared practice' between designers and users. [74] Berg talks of "growing" rather than building information systems and working to achieve synergy between three fundamental (re-)design tasks: the technical system, the primary work process and the secondary work process. [71]

### **2.2.6 The impact of change – and the definition of success**

The EPR tends to be introduced as part of a programme whose success is generally measured by some sort of evaluation. The key tension here is between 'success as objectively and prospectively defined' and 'success as socially negotiated and context-specific'. Positivist traditions generally assume that 'success' can be measured unproblematically in terms of metrics [81] and that transferable 'success factors' can be deduced from empirical studies.

The interpretivist, critical and recursive traditions problematise the very notion of success (it will, for example, be defined differently by different stakeholders). [82,83] These traditions recognise that the most immediate and easily measurable impacts of a new EPR system (such as increased time to enter data) may fail to capture more subtle or distant potential benefits (such as the easier production of aggregated data). Hence, just as the 'success' of a project may be talked up for political reasons, so 'failed' projects should not be dismissed unquestioningly. [82] Critical traditions argue that the success of an EPR project also has an ethical dimension, asking who has the power to define what counts as success; and whose interests are (and are not) represented in the evaluation. [83]

## 2.2.7 Complexity and scale

A final tension in the literature is between 'the bigger the better' and 'small is beautiful'. The former view is frequently expounded in the HIS literature. Progress in this meta-narrative is defined in terms of shifting from parochial departmental strategies to institutional, national and even international ones, and the concomitant need to explore new, trans-institutional information systems architectures and standards. [84] Policy decisions in many countries have tended to accept this view and used it to justify large-scale EPR initiatives. [7]

The alternative view is that efficiency gains and economies of scale will never be realised because of the trade-off in loss of local, contextual detail (and hence, loss of knowledge) and the magnification of political disputes between stakeholders. This view runs across most of the CSCW, technology-in-practice and ANT literature and is captured in the Law of Medical Information: "the further information has to be able to circulate (i.e. the more diverse contexts it has to be usable in), the more work is required to disentangle the information from the context of its production. The question that then becomes pertinent is; who has to do this work, and who reaps the benefits?" [85] While this rule helps to explain the failure of numerous large-scale EPR initiatives, a more nuanced version of it is needed to account for the examples of successful ones.

## *Discussion and recommendations*

Many existing EPRs appear built on six assumptions: that the EPR (a) is primarily a container for information about the patient; (b) can potentially be integrated seamlessly and unproblematically into clinical work; (c) will increase the effectiveness and efficiency of clinical work; (d) will drive changes in how staff interact with the patient and one another; (e) should replace most if not all forms of paper record, which are old-fashioned and limited; and (f) will provide greatest added value the more comprehensive and widely distributed it is.

Much of the literature covered in this review suggests, conversely, that (a) the EPR can be conceptualised as an 'itinerary', 'organiser' or 'actor'; (b) seamless integration between different EPR systems is unlikely ever to happen because human work will always be needed to bridge the model-reality gap and re-contextualise knowledge for different uses; (c) while secondary work (audit, research, billing) may be made more efficient by the EPR, primary clinical work is often made less efficient; (d) the EPR may support, but will not drive, changes in the social order of the workplace; (e) paper will not

necessarily disappear as it offers a unique level of ecological flexibility; and (f) smaller, more local EPR systems may often (though perhaps not always) be more efficient and effective than larger ones.

The meta-narrative method has shown that 'conflicting' findings in this large and heterogeneous literature can be fruitfully expressed in terms of tensions relating to the nature of the EPR, the context in which it is implemented and used, and the way success in an EPR program is defined and pursued.

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### **3 Case study 1: The North Central London Anticoagulation and Stroke Prevention Service (NCLASPS)**

The North Central London Anticoagulation and Stroke Prevention Service (NCLASPS) is an established integrated care service that embraces hospital outpatient departments and over 30 community sites. The service is based around the need to monitor individuals on anticoagulation therapy, principally warfarin. Patients on warfarin require regular monitoring, usually achieved by attending a clinic about every 6-8 weeks. These entail a blood test to determine how quickly the patient's blood is clotting. This is expressed through the international normalised ratio (INR), the ratio between the time taken for the patient's blood to coagulate and that for a normal sample. The normal range for INR is 0.8-1.2. The target INR in a therapeutic context will vary, but is typically between 2, 2.5 or 3. Based on an individual's target INR and their actual INR on testing, their dose of warfarin may be varied. Higher doses of warfarin increase the INR.

Details of how the service operates vary from site to site. In some cases, primary care staff – community pharmacists, GPs or practice nurses – run clinics. In other cases, there is an outreach service whereby pharmacists from the Whittington Hospital run community-based clinics. Other patients attend the Whittington as outpatients.

The service uses two key pieces of technology. All sites use a bespoke electronic healthcare record system incorporating decision support software to aid warfarin dosing. This was developed in CHIME and is accessed via a web browser. Community-based sites use point-of-care coagulometers: this is off-the-shelf technology allowing near-patient INR testing. Outpatient clinics use lab testing of INR, which is more accurate when INR levels are very high.

NCLASPS has certain key organisational features. There is a Clinical Governance Board (CGB) that acts as a central coordinating mechanism, bringing together professionals from different disciplines and multiple organisations: cardiology, haematology, hospital and community pharmacists, GPs, PCT managers and commissioners, patient representatives, software developers, researchers and other experts. NCLASPS also provides training for anticoagulant practitioners running clinics. The Board is chaired by the lead clinician, Prof. David Patterson (hereafter DP, a co-author of this report).

## ***Anticoagulation***

There are several clinical conditions for which treatment or prevention includes giving a drug to reduce the ability of the blood to clot, an anticoagulant. Examples include stroke, mechanical heart valve replacement, venous thrombosis in the leg, and certain kinds of abnormal cardiac rhythm. The National Audit Office estimated the annual cost of stroke alone in England is about £2.8 billion for direct care provided by the NHS and £5.2 billion when informal care is included. [86]

The commonest oral anticoagulant is warfarin, which is highly effective but only if the level of anticoagulation is kept within a narrow safety range. Under-coagulation (i.e., over-anticoagulation) may result in unintended and sometimes dangerous haemorrhages. Under-treatment may risk a recurrence of the condition that the therapy was intended to prevent. A balance has to be found in the daily dose of warfarin, which is difficult to do well by human judgement alone. The metabolism of warfarin varies greatly between patients. Changes to the patient's health or medication can impact on the stability of the anticoagulation.

Anticoagulation may be required for life, as with patients with mechanical heart valves. In these cases, a high target INR is used (2.5 or greater). Warfarin is commonly used long-term for atrial fibrillation to reduce the likelihood of stroke. Other treatment options are available here: aspirin can be taken instead, but is much less effective. Warfarin is sometimes used for shorter periods: for example, to prevent deep vein thrombosis after surgery where warfarin may be taken for a year. Low doses of warfarin are used to prevent clotting around a central line.

Warfarin inhibits the vitamin K-dependent synthesis of active forms of certain blood clotting factors. As such, vitamin K reverses the effects of warfarin. Foods containing high levels of vitamin K therefore counteract warfarin. Many antibiotics affect the action of warfarin: either directly (for example, metronidazole reduces the metabolism of warfarin) or indirectly (by reducing the natural bacterial flora in the colon, which produce significant quantities of vitamin K). Heavy use of alcohol affects the metabolism of warfarin, increasing INR. Numerous other drugs and some foods can interact with warfarin, while periods of ill health can also affect the patient's INR. Not all these interactions are well-characterised: the swine flu pandemic occurred during the course of data collection and the clinical team observed what appeared to be an unexpected short term INR increase in patients following the swine flu vaccine.

Alternative anticoagulants exist. Warfarin is a synthetic derivative from coumarin, first discovered in plants. Other coumarin derivatives

are sometimes used. The low molecular weight heparins (LMWHs) are the main alternative to the coumarines. They have more predictable pharmacokinetics and anticoagulant effects, although still require some monitoring. These have to be injected and are much more expensive than warfarin. A third class of drugs, the direct thrombin inhibitors, show promise as possible replacements for warfarin and LMWH. However, only a few are in clinical use, they remain comparatively expensive and often require injection. Dabigatran, which can be orally administered and also does not require monitoring, has been licensed in the UK for DVT prophylaxis following orthopaedic surgery, with trials on further uses ongoing.

As with all drugs, successful treatment with warfarin requires good concordance from the patient. Obviously, if a patient does not follow dose instructions, this can create problems. Patients are generally prescribed some mixed set of warfarin tablets. Dose options are standardised in the UK, including 1mg (brown), 3mg (blue) and 5mg (pink). Patients follow a dosing regimen set by their anticoagulant practitioner. As such, unlike with most medication but in common with insulin treatment in diabetes, there is a disconnect between the prescriber and the individual who sets the dose.

While most UK patients attend clinics, it is notable that Germany and some other countries have largely moved to a patient self-management model and there are pilot projects elsewhere in the UK for such. There are a range of patient self-management models and a very small number of NCLASPS patients (at the time of our data collection) self-manage. While the UK has different models across the country, we can also note that the Netherlands has a national, centralised anticoagulation service, showing the possible variation in organisational arrangements.

### ***Key organisational features from a research perspective***

Wensing and colleagues conducted a systematic review on organisational strategies to improve patient care. [87] They identified that professional performance is improved by revised roles for non-physicians and the use of computer systems for knowledge management; patient outcomes are improved by multidisciplinary teams, integrated care services, and computer systems; and cost effectiveness is improved by integrated care services. NCLASPS incorporates all of these features: revised roles for non-physicians, computer systems, multidisciplinary teams and an integrated care approach. NCLASPS relies on technology, both the electronic healthcare record (with decision support) and the near-patient coagulometers. How they work in practice, and how they work with each other are key areas of research.

## **Method**

We used a range of methodologies to study NCLASPS and its technology, and valued the ability to triangulate results across methodologies. [88] We also valued the length of time afforded by the study as it allowed us to see how changes in the system unfolded. [89] Taking a socio-technical perspective, we considered the service as a whole even if a particular facet appeared remote from any issues of technology.

We were rooted in an ethnographic approach and an idea of the co-production of knowledge by the researchers and participants. This involved interviews (structured and unstructured), observation (participant and non-participant), document analysis, audit and a range of iterative analytic processes derived from risk management, all resting on a close co-operation with the clinical team at the Whittington Hospital and the software team at CHIME.

### **3.1.1 Co-production of knowledge**

Throughout the project, we sought a close co-operation between researchers and participants (chiefly, the clinical team, including administrative staff, and the software team behind the service) in a spirit of the co-production of knowledge. [90,91] Members of the clinical team were also an integral part of the research team and adopted a reflexive and inquiring approach during their clinical practice. DP is head of the clinical service, a co-applicant on the project grant and a co-author of this report. Ashik Shah (AS) heads the service in Barnet and is a co-author of this report. Members of the clinical team have been doing PhDs within CHIME. There was a joint purpose of ongoing service improvement and research, which we embraced. The links between the software team and the research team are even closer, with the software team being in the same research department as most of the researchers on this case study.

The research findings were continuously fed back to the clinical and software teams (individually and through the CGB) and clinical practice and software design evolved as a direct result of research findings over the course of the grant. This was particularly the case with the risk management methods used (compare [91]). This included the formal presentation of preliminary findings to both the CGB and to an educational event for anticoagulant practitioners (attended by a range of anticoagulant practitioners from the Whittington Hospital and several PCTs, and also by patient representatives).

Relationships between the clinical and software team are very good and friendly, with both being cooperative and eager to assist the research project too. Within the research, we occasionally note

differences of opinion between the clinical and software teams, but note that these never involved any rancour.

This co-production approach, we believe, improves the validity and immediate applicability of the research. However, we recognise that it runs contrary to a tradition of objectivity that seeks to distance researcher from research participant. There are pros and cons to different methodological approaches (as discussed in section 2) and the fluid ethnography utilised here, while better able to capture real organisational behaviour, does carry the risk of being biased in favour of the service members participating in the research. Can we do justice to all the stakeholders' perspectives while data collection is situated in a close working relationship with certain stakeholders? We have taken a reflexive approach, as popular in the interpretivist literature summarised in section 2, to try to counter any bias.

### **3.1.2 Risk management methodologies**

We used a variety of analytic techniques from clinical risk management – task analysis, prospective hazards analysis and root cause analysis – to probe the workings of the service, both from a risk management perspective and more generally. These entail several formal steps in developing descriptions of the service (including observation and interviews) and then working from these with team members (in interviews and in groups). These are described in their own section (3.5) below.

### **3.1.3 Participant ethnography**

In addition to the specific techniques above (described in detail in section 3.5), researchers (Dr Henry Potts (HP), Dr Lacey Colligan (LC), Dr Janet Anderson (JA), Dr Jackie Nicholls (JN)) and clinician-researchers (DP, AS) were participant and non-participant observers of the service. This was both in the sense of clinical tasks – DP and AS worked as clinicians in the service throughout the research period, while LC and HP were non-participant observers of some clinical work directly – and through a variety of meetings, of both a formal and an informal nature. Informal, unstructured conversations and interviews were carried out with the clinical team (healthcare professionals and administrative staff), other healthcare professionals in the local health ecosystem and the software team. Apart from those elements of the research in section 3.3.2, there were no set interview schedules: rather, the work was ethnographic, with unstructured interviews obtained as and when possible, and as and when appropriate with involved staff and stakeholders, with field notes being made as soon as possible after these and all other activities. Unstructured interviews sought to probe what happened in

the service, and why. We used the theoretical approaches described in section 2 to help pose lines of enquiry.

The most significant formal meetings were of the Clinical Governance Board, which met regularly, approximately twice a year across the duration of the research grant. The CGB is a diverse body with those attending typically numbering around 20. These include

- staff in the service employed at the Whittington:
  - mainly pharmacists; but also generally
  - a cardiologist;
  - a haematologist;
  - an administrative staff member; and
  - sometimes a nurse
- healthcare professionals in the service employed outwith the Whittington Hospital Trust, mainly:
  - GPs; and
  - Community pharmacists
- stakeholders – patient representatives
- stakeholders – PCT representatives), both commissioners and clinicians
- software team members, who may be clinicians or computer scientists by background
- various observers
  - chiefly healthcare professionals in related services;
  - JN (in a legal advisory role); and
  - members of the research team.

Also significant were training and education events for anticoagulant practitioners. There were approximately annual, continuing professional development, refresher events, called for anticoagulant practitioners in the community, also attended by Whittington staff, patient representatives and members of the research team. They were larger than CGB meetings with around 70 attendees.

The most significant informal meetings were between the clinical and software team. There was ongoing, constant contact between members of the clinical and the software team and it was not possible to cover all of these, but various meetings were attended in a participant observational manner.

Informal contact between the research team with the rest of the clinical and software team were frequent, although these focused on the more senior members of the clinical team based at the Whittington and the software lead in CHIME. Where possible, meetings or conversations were held after significant events, e.g. negotiations around the service extending to a new PCT, a major critical incident or after CGB meetings.

Further informal meetings/interviews with others in the local healthcare economy – GPs, hospital doctors, a community pharmacist, a relevant pharmaceutical company representative, a physiotherapist, several local researchers, representatives of commercial health informatics organisations – not directly in NCLASPS also took place.

### **3.1.4 Documents & audit**

A range of documents were analysed. In particular, these included the Standard Operating Procedure for the service (in various different versions), materials considered at and minutes of the CGB, and Department of Health literature pertaining to anticoagulation.

The CHIME software in use in NCLASPS records data on patient encounters. This data was routinely analysed within the service (and such analyses were included in our documentary analysis) and further analyses were carried out for research purposes. To date, the number of visits at which each patient's INR is out of range is analysed per centre. The research team also had access to this data. There were up to about 1000 patients in the service during the period of data collection, with data available on every clinic visit.

## ***Results – detailed description of service***

As part of a case study method, in this section we provide a rich description of the service and its history.

Traditionally, patients on warfarin have attended hospital outpatient clinics where the patient attends for a venous blood sample. A stable patient then leaves the hospital and receives further communication by phone or post. Other patients have to wait for their INR result and to see the anticoagulant practitioner (the entire process taking a few hours and perhaps a whole morning). Multiple blood samples are analysed in batches to determine INRs. This is cost-effective, but introduces the possibility of errors when samples are mixed up. Based on the INR, the anticoagulant practitioner gives the patient a new dosing regimen and a date for the next appointment (a stable patient will have a longer gap until that next appointment than an unstable one). For stable patients, their dosing regimen may be unchanged for many months. If the practitioner sees the patient in

person, they can discuss any changes in the dosing regimen and may also wish to ask the patient questions to ascertain why their INR has changed and/or educate the patient about anticoagulant use.

Initiation on warfarin is a more complex process as it can take some time to determine the right dosing regimen for a patient. This is often done when the patient is a hospital inpatient for whatever condition has necessitated the use of warfarin.

The history of NCLASPS begins when DP, a cardiologist, took over the anticoagulation clinic at the Whittington Hospital. Note that while cardiologists frequently deal with conditions requiring anticoagulant treatment, anticoagulation clinics are usually run by a haematologist. The clinic was initially small, but increased in size over the years, creating a significant management issue. Patients were seen by junior doctors. Dosing decisions were based on the doctor's own experience and the use of algorithms (available on paper). Junior doctors rotated through the department fairly often and were generally fairly inexperienced in pharmacodynamics and warfarin dosing. They would tend to make "over-steering" errors. This is where the practitioner over-compensates for a raised INR by decreasing the warfarin dose too much, leading to the next INR result being too low, or vice versa. In the early 1980s, DP sought to computerise the dosing advice given to doctors. A standalone piece of decision support software, only for use with long-term anticoagulant users, was developed by a software company on a contract basis. This system then supported non-physicians working as anticoagulant practitioners. A skilled nurse from Germany, with greater experience of nurse-led behaviours than was the usual case in the UK at the time, became involved in the clinics. She was trained as an anticoagulant practitioner, against considerable local opposition.

The aforementioned software company went bankrupt and a version 2 of the system was developed in co-operation with the Clinical Operational Research Unit (CORU), an academic department at UCL. A Doctor of Medicine student evaluated the system and trialled its use by nurses. The service was then expanded to an outreach model in which a hospital nurse ran clinics in GP surgeries. The nurse used the decision support system to determine dosing, while the GP wrote the prescription. Note the software at this point was not networked. Within the anticoagulant service, this model was felt to be successful for patients and in terms of improved GP involvement. However, GPs were resistant to nurse-led clinics and concurrent changes in the health service (the introduction of GP contracts and then PCTs) produced an environment not conducive to further developments.

Because of the lack of progress with a GP practice model, it was decided to explore the option of running clinics in community

pharmacies. A collaboration was begun with an individual, independent community pharmacist, who has continued to support developments with the anticoagulation service and is now an active member of the NCLASPS Clinical Governance Board. He initially chose to run anticoagulation clinics purely out of interest, but payment from the relevant PCT was subsequently arranged. In this new model, the community pharmacist generates the dosage recommendation, but the warfarin prescriptions are still written by GPs.

It was decided to develop the DSS software with the addition of a networked electronic healthcare record. This EHR is focused on anticoagulation treatment, i.e. recording INR results and warfarin dosing, but with space for free-text notes. However, at this time, NHSNet excluded community pharmacists, so a separate dial-up service had to be developed to allow networking. This worked poorly, with the community pharmacist involved thus using it erratically and preferring not to use the EHR 'live' during consults, as intended, but retrospectively after running a clinic. Attempts to improve the dial-up failed, forcing the development of new software. This CHIME system, a networked EHR with DSS, was in use throughout the period of data collection (with the exception of Camden PCT), with a major software revision (HeartBeat) introduced at the beginning of 2010, just as this study ended, and rolled out over the year.

Note that the DSS is not configured to handle response to temporary changes to a patient's INR. The anticoagulant practitioner must identify whether an INR change has a temporary cause. If so, they must ignore the advice from the DSS and use alternate algorithms available on paper to handle these cases. These paper-based algorithms are also available should the electronic system fail.

The pharmacy chain Boots became involved around 2001 with an interest in testing the waters around the introduction of supplementary prescribing by community pharmacists. An enthusiastic PCT pharmacy manager at the time helped push developments along, but the introduction of supplementary prescribing, where a non-physician prescribes warfarin, raised concerns in some quarters.

The involvement of community pharmacists drove the development of formal training and testing of anticoagulant practitioners (provided by the Whittington Hospital). NCLASPS anticoagulant practitioners now have to undergo a programme including lectures, practical work and clinic observations. While relatively new, continuing professional development (CPD) and requirements for re-certification are still being developed. Testing involves an objective structured clinical exam (OSCE, a type of *viva voce* exam), an exam format unfamiliar to pharmacists but well-established for medical students. A formal qualification system was needed to support the supplementary

prescriber model. However, over the course of this study, the use of supplementary prescribing has fallen away. Various non-physicians continue to run anticoagulant clinics and instruct patients on dose changes, but the prescription for warfarin has largely remained with a doctor.

By 2006 and the start of data collection, developments with community pharmacies had overtaken models based on GP practices. In that year, there were discussions with PCTs to use a model in which a practice nurse runs an anticoagulant clinic, under the supervision of a GP, and four Islington GPs were early supporters. While the model encourages close involvement by the GP – notably the practice nurse and the GP both receive anticoagulant training – most practice nurses operate fairly autonomously. Also by this time, another local hospital, the North Middlesex, adopted the software. The Whittington outpatient service is now entirely led by one trained nurse. The service was also challenged by the National Programme for IT (NPFIT) and there were initially concerns expressed that NPFIT would force the adoption of a worse electronic healthcare record system than was being used.

NCLASPS are keen to encourage annual reviews of anticoagulation patients to consider whether they should remain on warfarin and with what target INR, remain on anticoagulation but switch to an alternate anticoagulant or cease anticoagulation treatment. This decision needs to reflect the patient's need for anticoagulation, their INR control and other factors in the patient's life that can affect good coagulation control. These reviews, NCLASPS believe, are best carried out by GPs, although some are carried out by hospital doctors. However, in practice, few reviews are carried out.

Over the course of this study, two further PCTs have joined NCLASPS. A pharmacist outreach model was arranged with Barnet PCT where Whittington pharmacists run anticoagulation clinics at community sites in Barnet. In Camden PCT, involved GPs run anticoagulant clinics using an off-the-shelf EHR/DSS called INRstar from Sullivan Cuff Software, the market-leading DSS for warfarin management in the UK primary care sector. This system is not networked. The Whittington Hospital is paid to provide training and governance services, including the involvement of Camden PCT and participating GPs in the Clinical Governance Board.

Barnet PCT had approached the Whittington service in part because of the cheaper service offered compared to the existing local hospital outpatient service. A contract was agreed with details including around the handover of patients from that outpatient service to NCLASPS. This included detailing a minimum dataset for patients entering NCLASPS. Initial rates of patients entering NCLASPS service

were low, but numbers eventually reached expected levels, with the Barnet service becoming the largest in NCLASPS.

Camden PCT first approached the Whittington looking for training to support their GP model using INRstar. NCLASPS proposed that Camden PCT might want to adopt the CHIME system. Camden PCT considered this, but raised concerns that could not be settled in protracted negotiations. A contract was agreed along the original proposed lines, with the Whittington providing training and governance. This was the first time that a service not using the CHIME software had joined NCLASPS.

At the end of data collection, over 1000 patients were being managed in the service.

### **3.1.5 NCLASPS is a successful service**

This study was not intended as an evaluation of NCLASPS, but to determine how NCLASPS works and how technology is used within the service. We take as a starting point that NCLASPS is a successful service based on four criteria:

- *Clinical outcomes:* The primary outcome measure for an anticoagulation service is time in range for patients' INR results. Results from NCLASPS show that INR control in community patients is good with respect to external standards, and as good as current and historical performance of the Whittington Hospital outpatient service.
- *Financial status:* NCLASPS is profitable for the Whittington Hospital.
- *Service user feedback:* Patients are generally satisfied with the service and an evaluation of patient experiences by Barnet PCT for NCLASPS in Barnet was very positive. [92]
- *Commissioner feedback:* PCTs involved with NCLASPS report satisfaction with the service. During the service's existence, it has continually grown with more PCTs joining and no PCT has ever withdrawn from the service.

In July 2009, the Clinical and Academic Department of Cardiovascular Medicine at the Whittington Hospital achieved a Customer Service Excellence award from the Government. NCLASPS received specific feedback, being deemed "an excellent example of best practice" and it was commended to the Cabinet Office as an example of transformational practice.

## ***Risk management approaches***

We used a variety of risk management approaches to explore the NCLASPS case study. This was for two reasons. First, we had always planned to focus on risk, safety and ethicolegal issues as part of our approach of “mini” case studies described in our protocol. Our literature review had further shown a particular gap in the prior research around investigating e-Health systems in this manner. Secondly, a broad systems approach is widely accepted in clinical risk management studies. The methodologies available in this area offer a way of studying how e-Health systems really function.

Electronic health records and decision support are widely seen as improving patient safety, but the literature is surprisingly sparse on demonstrations of this, with evidence in some cases of increased risks. [58,59,93,94] The literature review in section 2 repeatedly found patient safety being cited as a driver for the adoption of e-Health, yet few studies tackling the issue directly and little overlap with the existing clinical risk management literature. The disconnect between optimism and practice can be seen in contemporary developments in the National Programme for Information Technology (NPfIT). Improvements in patient safety have always been part of the argument for NPfIT and yet we were able to obtain by Freedom of Information requests previously unpublished reports jointly commissioned by Connecting for Health and the National Patient Safety Agency (unrelated to this project) that criticised NPfIT for failing to adopt good risk management practices itself. The NCLASPS case study represented the best opportunity to investigate a live e-Health system using these methods.

Following on from section 2, we felt it was valuable to trial different methodological approaches to studying the socio-technical nature of e-Health systems. Risk management methodologies offer a systems approach to analysing services and the use of technology therein. They thus align with our theoretical framework of the socio-technical system. We believed they would allow us to explore the use of technology in new ways, as well as focusing on key outputs of safety and quality.

However, there are many competing risk management methodologies and which are most suitable to analysing e-Health systems is untested. Outside of health, there are well-established areas of research in human-computer interaction as it relates to safety, most notably in the aviation industry, with some case studies in a health context, notably the case of the Therac-25 radiation therapy machine in the mid-1980s. Most clinical risk management, however, has been focused on group working recognising the complex interactions involved in clinical risks. Thus, we sought to

compare different methodologies and their suitability in the context of a complex service that uses technology in a variety of ways.

Patient safety can be a delicate subject. We largely view the NCLASPS service as operating at a high standard of quality with a good risk profile. We acknowledge the willingness of the clinical and software team to participate in exercises of this nature.

A comprehensive task analysis was performed, focusing on the community-based, outreach service in Barnet. We developed both a sequential task analysis or flowchart [97] and a Hierarchical Task Analysis (HTA). [98] We then undertook two prospective hazards analyses: one using the healthcare failure modes and effects analysis (HFMEA) procedure [99] and one using the Structured What-If Technique (SWIFT). We also carried out root cause analyses on critical incidents that occurred in the Barnet service during the research period.

A medico-legal analysis was carried out by JN. This consisted of an analysis of the service using both traditional legal research methods and the case study method, based on the data collection methods described above.

### **3.1.6 Task analysis**

We carried out two matched task analyses of the Barnet service. This work is described in greater detail elsewhere. [100] Process mapping is a central component of quality improvement efforts in healthcare. [101] Process maps are used to assist workers to identify areas to intervene to improve safety and quality, a task that involves examining the process from a new perspective in order to discover where the greatest risks exist. Process maps are external representations of the system and become tools for problem solving, reasoning, and decision-making about risks and improvements. However, there is little discussion in the literature about the choice of mapping methods to use or about the possible influence of the type of process map on the perception of safety problems. Research from different traditions has provided evidence that the way information is organised and displayed affects people's performance and interaction with that information. [102,103] The type of external representation used for quality improvement work in healthcare is likely to be crucial in ensuring the effectiveness of the quality improvement work that is carried out.

We examined NCLASPS clinics under the Barnet model using two different types of process maps: a sequential flow diagram and a hierarchical task analysis diagram. We chose these two different diagrams because they represent the two main ways of organising task information diagrammatically. [98] By doing both, we gain a deeper understanding of the service being mapped and can compare

between the two approaches. We investigated whether practitioners identified the same safety concerns on the sequential flow map and HTA, and practitioners' judgments of the usefulness of each. Sequential flow diagrams and HTA diagrams are fundamentally different. Flow diagrams present the discrete steps in a process sequentially, in the order in which tasks are accomplished. HTA results in a hierarchical diagram that organises work by goal, not by procedural step. High level goals are achieved by carrying out a number of sub-goals, so dependencies are represented in the hierarchical structure. HTA does not generally specify when things need to be done, although the diagram can be annotated with instructions about the required order. Despite being widely used in other disciplines, HTA is not used extensively in healthcare.

## **Method**

### *Producing the external representations*

We developed the sequential flow and HTA diagrams using standard methods [97 and 98 respectively]. Two senior pharmacists and an experienced clinic pharmacist in NCLASPS participated as subject matter experts. Two interviews were conducted with each of the senior pharmacists to gain knowledge of the processes. The clinic pharmacist provided a talk-through and explanation of the patient management process and demonstrated how the DSS operated. One researcher (LC) attended a training session for new anticoagulant practitioners. Protocols, policies and other documents were also analysed.

Draft diagrams were produced. The content of the two diagrams was controlled to ensure that they each had the same number of steps and covered the same aspects of the clinic processes. The diagrams were reviewed for accuracy by one of the prior senior pharmacists and the diagrams amended accordingly (see Appendix 2).

### *Using and evaluating the external representations*

#### *Participants*

The five pharmacists and two administrators who worked in the NCLASPS Barnet service at the time participated in this phase. None had participated in the mapping process described above. Their length of employment ranged from four months to four years.

#### *Procedure*

Participants received information about the study and signed consent forms. An interview was conducted with each participant. These were audio taped with agreement. There were three parts to the interview. First, without looking at the diagrams, participants were asked about their views of safety and quality problems in the service. Secondly,

they were shown the diagrams individually in a counter-balanced order. They received an explanation of the diagram, were invited to review it for accuracy and then to indicate any areas of the process that were outside of their knowledge of the system and any areas where they perceived there to be safety or quality problems. When the second diagram was presented, they were informed that the diagrams contained the same information but were not prompted to circle either the same or different concerns on the second diagram.

Thirdly, participants completed a short questionnaire about which diagram they would prefer in different improvement contexts, namely:

- If they had to explain their work to someone outside the service;
- If they had to discuss a problem with a colleague;
- If they had to explain their work to a manager in order to gain more resources;
- If they had to discuss their work with an assessor; and
- If they were planning safety improvements.

They were also asked which diagram was easier to understand and which would be easier to update. Interviews were transcribed and analysed using an inductive thematic analysis.

## Results

### *Initial perceptions of quality and safety without using a process map*

Before seeing the diagrams, six participants cited between two and six issues each. One participant did not identify any problems. Patient safety concerns were categorised as administrative, clinical or co-ordination across healthcare boundaries (Table 2). The most frequent concerns (9) noted were associated with the clinical work. Safety risks arising from the difficulty of co-ordinating patient care across the boundaries of the healthcare system were also commonly noted (6).

**Table 3: Quality and safety concerns elicited during interviews**

Area of concern identified	Number of participants	Service function
Limitations of software – <i>e.g.</i> diary management, INR values allowed, acknowledgement of team communications	4	Clinical

Availability of backup from doctor or specialist for difficult cases	3	Clinical
Gaining information from other healthcare providers such as GP, PCT or laboratory	3	Co-ordination across healthcare boundary
Follow-up of patients who do not attend an appointment	2	Administration
Availability of information following discharge from hospital ward	2	Co-ordination across healthcare boundary
Lack of training to identify additional health problems in patients	1	Clinical
Patients' understanding of medication instructions	1	Clinical
Suitability of patients referred to the service	1	Co-ordination across healthcare boundary

*Perceptions of quality and safety when using the process maps*

All participants stated that they understood both the sequential flow diagram and the HTA. Two pharmacists noted a missing step (reflecting a difference particular to one clinic location). All other participants reported that the diagrams accurately reflected the system as they knew it.

Safety problems circled on the two diagrams were categorized as administrative, referring to the process of enlisting patients, or clinical, referring to patient monitoring. There were no concerns about co-ordination across clinical boundaries. Table 4 summarises areas of the process identified as problematic for each process map. More safety and quality problems were identified in relation to clinical than administrative work. Clinical processes were only highlighted on the sequential flow diagram whereas both administrative and clinical processes were highlighted on the HTA. More safety problems were identified using the HTA, but this difference did not reach statistical significance: sign test comparing the flow diagram to the HTA for administrative tasks,  $p = 0.25$ , and for clinical tasks,  $p = 1.0$ .

**Table 4: Quality and safety problems identified on sequential flow diagram and hierarchical task analysis**

Diagram	Administrative task step (sequential) or goal (HTA)	Clinical task step (sequential) or goal (HTA)	Total
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	Obtain patient list	Invite patient	Schedule patient	Obtain medical history	Obtain INR	Determine dose & duration	Conclude appointment	
Sequential flow diagram	0	0	0	0	3	4	1	8
Hierarchical task analysis	2	1	1	3	1	2	1	11

Participants were generally not consistent in circling the same areas of the process on both maps. Only one participant circled the same part of the process on both diagrams. The participants' identification of risk also varied between the open-ended questions asked prior to seeing the diagrams and those indicated during the work with the diagrams. For example, the participant who did not mention any concerns when asked without the diagrams did indicate two concerns on the HTA.

The results of the questionnaire showed that the HTA was clearly preferred for discussing a problem with a colleague, but the sequential flow diagram was preferable for detailing other problems. The HTA was perceived as being easier to develop to a further level of detail.

### **Discussion**

Practitioners' perceptions about risks differed depending on whether they were reflecting on those risks without a process map, working with a sequential flow diagram or working with a hierarchical diagram. The results suggest that the type of representation chosen for use in quality improvement work is important because improvement efforts will be influenced by how the process is represented. We suggest that improvement efforts might need to be based on more than one type of representation to ensure that all aspects of the process are captured, as was done here. Using both sequential and hierarchical diagrams might yield a more comprehensive view of the process than using one alone. [104] There was no obvious advantage to HTA or sequential flow for capturing the specifically technical elements used in the clinic.

What a representation captures is clearly important. Here, co-ordination across organisational boundaries was not represented in the process maps. Both diagrams were focused on tasks performed by the practitioners within the bounded context of the clinic, but risks often emerge just outside those boundaries in the patient's behaviour and in the liminal zone between different care services.

Communication and liaison across organisations and the movement

of patients between services were cited as some of the biggest problems when participants were asked open-ended questions without the diagrams.

Two central questions must be decided early when constructing a process map: defining the system boundary and the granularity required. We decided to define our system by the entry and exit of a patient under care of NCLASPS. However, problems were perceived and experienced at the boundaries of the system. To ensure important aspects of the process are captured, we recommend construction of a process map proceed iteratively with emerging information about where the risks in the system are located. Preliminary investigation into risks identified through incident reporting and interviewing clinicians will be necessary to determine where the boundary of the process map should be set, and this might change as the mapping process continues.

The other key decision is granularity. The HTA method includes a stopping rule for formalizing how much detail is represented. [98] There is no similar guidance for flow diagrams, with the possibility that some parts of the process might be shown in more detail than others, biasing subsequent improvement work. A further practical difficulty is how to represent maps as their size increases quickly. An electronic representation can be easier to revise, particularly with a hierarchical map. [106]

Which of these methods healthcare professionals choose to use will probably be a pragmatic choice based on the time available and ease of use. We found the two diagrams each had advantages and disadvantages. The HTA was highly structured, thus easier to produce graphically and easier to revise as the mapping progressed. It offered flexibility in representing important goals which do not correspond to specific acts at specific times but which represent ongoing issues that could be triggered at any time, such as seeking help from a peer, or tasks that are purely cognitive. HTA is also more useful in representing tasks that do not have to be performed in a specific sequence or are optional, like patient education. On the other hand, the timing of some parts of the work was much easier to handle within the flow diagram. The flow diagram was harder to adapt because additional details have to be added within the process steps, creating branches and loops. The information gleaned from the SOP was easier to represent with the HTA, but information gained from interviews and observations was easier to represent with the flow diagram.

Despite HTA being little used in healthcare, we found it was as readily accepted as the flow diagram. The HTA was preferred by participants for discussing their work with a colleague, suggesting that the representation of goals in the HTA is important in providing

context and enabling people with similar expertise to improve the system. Healthcare work is driven by the need to achieve the goals of patient care despite variability in the patients, the demands on the service and the support available, both technological and social. The representation of those goals in the hierarchical structure of the HTA is therefore important, especially if communicating with others who understand those goals. The unpredictability of healthcare and the professional autonomy of practitioners are also better encompassed by the HTA with its focus on the goal to be obtained rather than the precise method.

This study was exploratory and was limited by a number of factors. The size of the sample was constrained by the small number of people in the service with sufficiently detailed knowledge to participate. In order to compare the two diagrams, content had to be standardised, but it is possible that the diagrams are most effective at representing different parts of the process. The clinic setting examined involved tasks that were relatively well structured and well defined. This work could be extended by examining different clinical systems with different clinical demands and different professional groups. We recognise, in particular, that the differing autonomy of different healthcare professions in different roles has implications for whether a flow diagram or HTA should be preferred.

### ***Conclusions***

The layout of a process map can influence practitioners' perceptions of quality and safety problems in a process. It is important to consider the most suitable type of process map to use and whether to use more than one representation in order to capture different aspects of clinical work. Although the process map is often seen as a preliminary step to quality improvement work, it is a vitally important aspect of how that work proceeds.

### **3.1.7 Prospective hazards analysis**

We undertook two matched prospective hazards analyses: HFMEA and SWIFT. Both start with a task analysis (as above) and seek to identify prospectively possible hazards and counter-measures in a system.

Compared to other safety-critical industries, healthcare has not always recognised the importance of prospective techniques, focusing more on retrospective methods. [106] The use of prospective hazards analysis is more advanced in the US hospital system, with the Veterans Affairs Patient Safety Programme having adapted failure modes and effects analysis (FMEA) for a healthcare context [99] and the mandating of such techniques. There has been less uptake within the NHS, despite examples of the benefits in identifying risks and

improving processes (e.g. [107]). Few examples in socio-technical systems exist.

Prospective hazards analyses can be resource intensive and calls on healthcare professionals' time are usually great. Less intensive techniques have been developed, like the Structured What-If Technique (SWIFT), [108] that aim to achieve most of the results of older techniques in a fraction of the time.

Despite common usage, the validity and reliability of these methods has been questioned. [109] We compared two prospective hazards analysis techniques to triangulate between them for a better picture of risks and allowing a comparison between the results of the two methods as a measure of their validity.

### ***Method***

We ran two sessions with matched volunteers from the clinical and software teams, using the same facilitators, sequentially on one day: SWIFT first, HFMEA second. The two groups of participants were matched in terms of role and seniority: each group consisted of one senior pharmacist, two junior pharmacists, one administrator and one member of the software team. (None of the pharmacists involved had been participants in the previous task analysis study.) By running the sessions sequentially, we could ensure no contact between the two groups.

We used two experienced facilitators to run the HFMEA and SWIFT sessions. They were provided with the task analyses produced previously and briefed further about NCLASPS through a series of meetings with the research team and senior members of the clinical team. We chose to use the same facilitators for both sessions to control for any effects caused by facilitator choice. However, this opened the possibility of a carryover effect, with what the facilitators did in the second session being influenced by what they had heard in the first session. The facilitators were aware of the experimental design and sought to counter any such effect, but this effect could decrease any differences between the two techniques.

Both sessions were carried out in the same room with refreshments provided. The SWIFT took 2 hours. The HFMEA took 6 hours (including a half hour break for lunch). Two of us (HP, JA) were non-participant observers, taking notes through the day. Both sessions were audio recorded with consent. Participants and facilitators completed feedback questionnaires at the end of both sessions.

#### *SWIFT & HFMEA*

SWIFT and HFMEA both produce documentary outputs. The SWIFT produced a series of flipchart sheets, transcribed to a three-page document. This identified 55 top-level risks, of which three were

identified as being of particular importance. The breakdown by section of the task analysis is shown (Table 5).

**Table 5: Number of risks identified by SWIFT**

<b>Task analysis section</b>	<b># risks</b>	<b># most important risks</b>
1.1 Obtain patient list for community-based clinic	12	1
1.2 Invite patient	7	0
1.3 Schedule appointment	5	1
2.1 Obtain recent medical history	11	0
2.2 Obtain INR	5	1
2.3 Determine dose and time until next appointment	10	0
2.4 Conclude appointment	5	0

The HFMEA output is more complicated. It identified 72 top-level risks. It rates risks on a matrix (as used in the Whittington Hospital) and identifies whether it is valuable to proceed with further analysis or not. This occurs when the risk is sufficiently severe, there is no existing control mechanism and an error would not be immediately obvious. There were 12 risks with a 'proceed' decision and the highest severity rating (Table 6).

**Table 6: Number of risks identified by HFMEA**

<b>Task analysis section</b>	<b># risks</b>	<b># with 'proceed' decision</b>	<b># with 'proceed' decision and most severe</b>
1.1 Obtain patient list for community-based clinic	8	3	1
1.2 Invite patient	12	4	1
1.3 Schedule appointment	13	9	2
2.1 Obtain recent medical history	14	7	1
2.2 Obtain INR	5	2	0
2.3 Determine dose and time until next appointment	8	7	4
2.4 Conclude appointment	12	10	3

A spreadsheet was prepared listing the risks identified by each method by section. Two researchers (HP, JA) independently

compared the lists of hazards identified by the methods and decided whether there was a match in the other list, a partial match or no substantial match. We then jointly considered all disagreements and reached consensus.

*HFMEA/SWIFT vs. other evidence sources*

The SWIFT and HFMEA outputs can also be compared with the multiple additional data sources from the wider research. In addition, in our observations of the SWIFT and HFMEA groups, we also noted references to hazards that did not make it to the final outputs of each process.

**Results**

*Observations/participant feedback*

The sessions appeared to run well. The meetings were good-tempered, constructive and enjoyed, with all participants contributing. Facilitator and participant feedback showed high levels of satisfaction with both methods, with participants and facilitators confident that nearly all major hazards had been captured.

*HFMEA vs. SWIFT*

Overall, while the HFMEA and SWIFT results clearly overlap in many areas, there is substantial non-matching (Table 7).

**Table 7: Comparison of HFMEA and SWIFT**

<b>Section</b>	<b>SWIFT</b>	<b>HFMEA</b>
1.1 Obtain patient list for community-based clinic	3 match 1 partial match 12 no match	2 match 1 partial match 5 no match
1.2 Invite patient	1 match 2 partial match 4 no match	2 match 3 partial match 7 no match
1.3 Schedule appointment	0 match 1 partial match 4 no match	0 match 1 partial match 12 no match
2.1 Obtain recent medical history	6 match 2 partial match 5 no match	5 match 4 partial match 5 no match
2.2 Obtain INR	4 match 1 partial match 0 no match	4 match 0 partial match 1 no match

2.3 Determine dose and time until next appointment	1 match 4 partial match 5 no match	1 match 4 partial match 3 no match
2.4 Conclude appointment	2 match 0 partial match 3 no match	2 match 1 partial match 9 no match
<b>TOTAL</b>	<b>17 match</b> <b>11 partial match</b> <b>33 no match</b>	<b>16 match</b> <b>14 partial match</b> <b>42 no match</b>

For both SWIFT and HFMEA, less than half the hazards identified were identified by the other method. Both methods highlight more and less serious hazards. The SWIFT picked out three key areas to be addressed first. Two of these were identified in the HFMEA (although they are not seen there as high risk) and the third, while having no good match in the HFMEA, is a broad concept that covers similar territory to a number of HFMEA-identified hazards. This may suggest that, on the important issues at least, HFMEA adequately captures issues revealed by the SWIFT.

The HFMEA procedure divides hazards into those with and without a proceed decision. The risk matrix rating can then be used to split the 'proceed' hazards into those presenting the highest risk and others. The HFMEA produced 12 'proceed' hazards with the highest rating: none of these had matches in the SWIFT, 5 had a partial match and 7 had no match. There are 30 further 'proceed' hazards: 8 of these had a match in the SWIFT, 3 had a partial match and 19 had no match. On these results, the SWIFT is not an adequate replacement for the HFMEA.

#### *HFMEA/SWIFT vs. other evidence sources*

Both the HFMEA and SWIFT differ substantially in terms of hazards recognised compared to other data sources. Root cause analyses (see next section) and ethnographic work identified communication between NCLASPS and other healthcare services, particularly GPs, as a key problem area. This also featured in the process map interviews, although other findings there fit the SWIFT/HFMEA results better. Other work also identified patient understanding as a central issue; we note patient understanding was raised in discussion in the HFMEA group, but was 'parked' in the discussion as it did not readily fit the structure of the process and was subsequently not included in the final results.

Governance Board observations included considerable discussion over the choice of coagulometer in the clinic and procedures to quality assure the machines. General health and safety issues, *e.g.* the suitability of the physical space for a clinic, also emerged. These were largely absent in the SWIFT or HFMEA.

Other work also hinted at issues around hygiene and sharps safety. In the context of blood samples being taken, we would normally expect hazards analysis to pay some attention to such issues, but they were never mentioned in either the HFMEA or SWIFT. It is also notable that no mention was made of possible mismatches between the electronic record and the patient's personally held record.

#### *Hazards pertinent to the software*

A number of specific hazards were identified around the software. The biggest problem comes when the system is unavailable, as has been noted in other work. [92] Established mechanisms are in place during such times.

A key hazard identified revolves around the decision of the practitioner to agree or disagree with the DSS or to use instead the paper algorithms. Expanding the electronic system to cover the advice in the paper algorithms has not been a priority. What was surprising was that the software team member of the group was unaware of the paper algorithm and its extensive use.

The coagulometers are unconnected to the computers hosting the software, so the practitioner has to manually transcribe the INR reading to the software. USB-enabled coagulometers exist, although this would require software development. When inputting results, there is a time out function to prevent unauthorised access to the system if the practitioner is away from the computer. However, the time pressure of the time out system was seen as potentially problematic in itself.

If an individual erroneously inputs an INR value, this cannot be later altered. This is to ensure a clear audit trail for the data and prevents anyone tampering with the data or retrospectively changing it. However, it also freezes errors. In practice, anticoagulant practitioners will enter a corrected INR result immediately after the erroneous value and, within the practitioner community, it is understood that two different INR values immediately following on from each other indicates that the first was a mistake in data entry. However, this is not explicitly stated in the record and the decision support tool does not know to discount the first value. It was suggested that it would be useful if the system can allow the changing of previous values, but where the change is recorded for audit purposes and can be commented.

Issues arose around annual reviews. Having the system create automated letters to request reviews from GPs was supported. Other suggested functionality included a system automatically blocking out weekends and public holidays to prevent appointments accidentally being made on these dates. Improved support for re-scheduling appointments and tracking non-attendances were also proposed.

Practitioners have a checklist of questions to ask patients in an appointment about their recent medical history, and those referring patients into the service should also have a checklist to complete. The HFMEA group suggested using mandatory data fields to enforce these, although how practical this would be is unclear. The use of mandatory data fields to improve referral into the system, which is commonly poorly done, was popular, but outwith the current software.

### ***Discussion***

This was a small study working under a number of constraints. The size of the clinical service meant that only two groups of 5 participants each could be used. The comparative design required both sessions took place on the same day. We used the same facilitators for both sessions, leading to a possible contamination effect. We used a briefer HFMEA procedure than is often recommended. While this does reflect the real pressures in clinical contexts on professionals' time, a longer HFMEA may have captured more risks. The use of a more thorough HFMEA is congruent with our recommendations.

The substantial number of non-matches demonstrates, as with other research, [109] that these prospective techniques cannot be relied upon to be comprehensive. They find many significant hazards, but they do not find all potential hazards and healthcare services should not be complacent and presume that a single HFMEA or SWIFT is sufficient. Not only do the SWIFT and HFMEA show poor concordance with each other, but they showed even poorer concordance with a multitude of other data sources around hazards in the service. A central problem here is that of scope. Both SWIFT and HFMEA are based on the task analysis and that required a decision on scope to be taken. It is easy to define the scope to be those elements of the service directly under the service's control (the 'drunk under a lamppost' problem). However, root cause analyses and interviews strongly indicate that the most serious problems occur when patients are in or between multiple services. It is important to bear in mind how decisions on scope at an early stage of work (here, the process map) can have effects down the line.

SWIFT and HFMEA view processes as sequential series of acts. The central role of patient education gets lost in a sequential analysis and

thus gets lost in the SWIFT and HFMEA structures. Here, a cognitive work analysis framework may be more useful. [110] Likewise, issues around the suitability of premises or the correct functioning of the coagulometer get omitted. There was some indication of whole categories of hazards being overlooked. For example, issues around sharps safety were not mentioned in either group. This may reflect the disciplinary background of group participants: doctors or nurses are more familiar with these issues.

### **Conclusions**

Both the SWIFT and HFMEA were useful activities that raised important hazards for consideration. They were welcomed by staff members. However, the substantial number of non-matches between them and with other sources of evidence about hazards demonstrates that these methods are not comprehensive. We suggest that these techniques should not be used in isolation, but should be one tool among many within an ongoing safety strategy.

It is important to consider questions of scope carefully and flexibly. Choices over scope should be justified with respect to other sources of evidence (e.g. retrospective hazards analysis). We suggest that clinical and research teams need to act with fuzzy boundaries: that is, one should not reject issues as being out of scope – rather, these need to be recorded and reviewed regularly to see whether the scope needs to change.

Specific hazards associated with the technology were identified. Familiar compromises in electronic health record design were seen, e.g. the use of timeouts. We also saw the clear use of established workarounds by the clinical team.

### **3.1.8 Root cause analysis**

Root cause analyses were carried out on critical incidents that occurred in the Barnet service during the research period. Root cause analysis (RCA) is a retrospective problem-solving method. It involves describing in detail the events around a critical incident, the identification of possible unsafe acts, identification of the possible root causes of these, and consideration of changes that could be made to improve the system.

The modern application of RCA in healthcare takes a systems approach. It seeks to understand a causal chain whereby the immediate causes of an adverse event can be understood to be themselves symptoms of an underlying problem, which often lie at a systems level. By investigating far enough back along the causal chain, we hope to be able to determine how best and most efficiently to make changes to prevent future adverse events. RCA has the

advantage of being rooted in real cases, as compared to the hypothetical thinking required in the prospective hazards analysis techniques above. However, the analysis of real cases may also not systematically cover all the potential risks in a system and the nature of RCA means that replication is hard to demonstrate.

Incidents were identified in cooperation with the clinical team. HP led the analysis in collaboration with other researchers (Pippa Bark (PB), JN, LC) and the clinical and software teams. The root cause analysis involves an iterative process of examining medical records and unstructured interviews with involved individuals in NCLASPS. It was impractical for the researchers to directly approach involved individuals outwith NCLASPS, but members of the clinical team had on some occasions done so as part of their initial investigations of events.

RCA involves analysing specific, actual incidents. Each case study involves patient and healthcare practitioner identifiable information, often of a sensitive nature. As such, care needs to be taken in using these analyses in feedback to the clinical team and stakeholders, and in the presentation of research findings. Results presented here are pseudonymised, with details changed and cases mixed.

Three root cause analyses were carried out in detail. A number of further cases were considered briefly. These were selected as being recent and felt by the clinical team to be significant. In selecting these cases, a number of further cases, within and outwith Barnet, were considered briefly. Each root cause analysis yielded a document of between three and four and a half thousand words. Each consisted of the following sections: a narrative describing events leading up the adverse event, the event itself and the immediate aftermath; the nature of the adverse event; the unsafe acts that occurred and a consideration of their causes; and a consideration of the ultimate root cause.

The RCAs were fed back to the Whittington-based clinical team and Clinical Governance Board, who found them valuable and there is a desire to adopt RCA as a routine practice, although RCA has not yet embedded itself in routine practice. The first RCA was also presented at an educational event for anti-coagulant practitioners across NCLASPS and was again well received.

The three detailed cases all involve bleeding events or possible bleeding events. As an anti-coagulant, the usual adverse event associated with warfarin is bleeding. None had long-term, serious effects, although all potentially could have. In particular, INR results of 6 or higher were observed, which are associated with a mortality risk.

## **Software issues**

Many specific issues arise from the analyses. We first discuss those specific to the technical elements of the service. The analyses elucidated a number of issues around use of the CHIME software: workarounds (see meta-narrative 6 in the literature review), how its records are a communicative genre fully understood only through the implicit knowledge of users, [39] and suggestions for improvements. In none of the cases did any of these software issues have any central role in the adverse events.

One patient was recorded as being on a warfarin dose of 1.75mg, but a free text section of the system then explains that the patient should take 2mg on weekdays and 1mg at weekends. This is an average dose of 1.71mg, with some variation over the week. Warfarin doses in 0.25mg increments are not available and breaking tablets in half is discouraged. [111] Warfarin has a long half-life as its mechanism of action is to inhibit the vitamin K-dependent synthesis of various clotting factors. Thus, it does not affect circulating clotting factors: these have varying half-lives from 60 hours for thrombin to 4-6 hours for factor VII. The terminal half-life of warfarin is approximately one week, but the effective half-life is around 20-60 hours. Combined, this means that warfarin is long-acting, allowing a dosing strategy where the dose changes between weekday and weekend. This is established practice and is considered to support good patient compliance by making the dosing easy to follow.

At one point, it was considered developing a calendar system for the CHIME software whereby it created a calendar to aid the patient to follow a more complex dosing schedule. This was abandoned as being too complex for patients to follow.

While such a dosing regime is an established practice, it constitutes a workaround that the data is recorded in the CHIME software as it is: with a figure for the dose and a free text note. Experienced anticoagulant practitioners are familiar with this arrangement and understand that a stated dose in a 0.25mg increment will be achieved by some dosing schedule along these lines. However, the software assumes that the patient is actually receiving 1.75mg each day, rather than a varying dose that averages to 1.71mg.

In one case, the attending pharmacist complained that the electronic record contained little indication of the patient's understanding of warfarin treatment. Free text notes in the electronic record may sometimes be underused.

Another workaround was observed. The Whittington clinical staff explained that, when there was a contact with the patient outside of a normal clinic visit, i.e. without an INR result being recorded, they

could not create a new dated entry in the software as the system would complain about the lack of an INR result. Thus, additional contacts, e.g. a patient ringing up with further details about something, are recorded by editing the record for the previous clinic visit and appending the notes, with a date manually added (but occasionally forgotten). This workaround was unknown to the software team until revealed by this RCA process. They expressed the view that this workaround is unnecessary and poses risks (particularly apparent if the data of appended comments is unclear). The new HeartBeat software should better handle this issue, which may also become important if such contacts outside of clinics need to be recorded for reimbursement purposes.

### ***Systems issues***

The RCAs remind us that warfarin is a dangerous drug with a high rate of complications. Changes in INR are not always easy to explain, even in retrospect. Patient actions are critical to all three RCA narratives. These are dependent on the patient's understanding of warfarin treatment, which reflects on patient education. This is not just determined by NCLASPS. Patients may be on warfarin for many years or decades. Their understanding may reflect education they received and experiences they had many years ago, when practices in managing anticoagulation treatment may have been different. Throughout the RCA process and the wider research, the importance of patient education was repeatedly expressed, yet patient education in practice struggles to get the attention needed. Limited patient contact time in busy clinics is a challenge here. We also need to consider the role of informal carers. In one case, the patient's spouse managed most of his/her healthcare needs. Education needs to involve informal carers. It can be easy to mistake a patient's competence as reflecting a good support system around them. In such cases, involvement of carers is vital.

One patient was described as being "institutionalised" on warfarin: that is, of being very concerned about taking warfarin and the risks of not doing so, but not necessarily with a good understanding of warfarin treatment. In one case, a patient was taken off warfarin appropriately for a 10 day period due to external factors producing a temporary and dangerous rise in INR. The patient was re-stabilised on warfarin subsequently. This led to a period of a few days when the patient's INR was below the target range. For a patient with atrial fibrillation or some other conditions, this short period of below-target INR has very small risks associated with it and the approach taken is clinically justified to deal with the far greater risks of a high INR. However, the patient involved was concerned and distressed about this short period not taking warfarin. This represents a particular area of focus for patient education.

Repeatedly and critically, the RCAs revealed poor communication between NCLASPS and other services, particularly GPs. Periods of ill health and changes in medication can both affect INR control, with antibiotic prescribing a particular issue. Generally, it would be advisable for GPs observing significant changes in health state, or starting new medications with the potential to interact with warfarin, to ensure that NCLASPS is aware of these changes and able to act accordingly. An anticoagulant monitoring service can then test the patient's INR sooner and more frequently than otherwise planned over this period of change and alter the warfarin dose as necessary. NCLASPS can also directly advise GPs over possible drug interactions and other issues pertaining to anticoagulation. However, the RCAs showed examples of GPs not effectively communicating to NCLASPS directly or relying on the patient to tell NCLASPS in a timely manner and this not happening. Patients were often unable to supply NCLASPS with the details of GP actions, e.g. not being able to say what antibiotic they started. For example, in one case, a patient had been started on an antibiotic on a Thursday by a GP and had then attended the GP surgery on the following Saturday with an apparent complication possibly involving a bleed. The patient was told to stop the antibiotic and warfarin and to attend the hospital for several blood tests after the weekend. The patient appeared at the community-based NCLASPS clinic on the following Tuesday (there was no clinic on the Monday) without an appointment or a referral letter, but with hospital request forms for various haematology tests excluding INR. The patient was unaware that s/he should have attended the hospital for these tests and did not know what antibiotic s/he had taken. There was no communication from the GP direct to NCLASPS.

The challenges for NCLASPS in communicating effectively with other health services were also seen. On one occasion, a patient was sent to a hospital accident and emergency (A&E) service on the grounds of a very high INR and further complications. The attending pharmacist wrote a referral letter and rang ahead. The patient subsequently reported a long wait at A&E and that no venepuncture INR test was performed that evening (note that the community-based clinic coagulometer gives an unreliable result at high INRs and a venepuncture test is recommended), although a referral for a venepuncture test the next day was given. The RCA did not cover events at A&E, but the NCLASPS clinical team would have preferred the venepuncture INR test to have been done that day and vitamin K treatment considered (vitamin K administration counters the effects of warfarin). A&E do not feedback to NCLASPS in these instances; they presumably send a letter to the patient's GP. The NCLASPS team report similar instances where they feel A&E treatment of patients with high INRs was not optimal.

Patients may raise issues with anticoagulant practitioners that prove not to be related to their anticoagulant treatment. Standard practice is to advise the patient to consult their GP or some other healthcare professional about these issues, but there is rarely any direct communication to or relationship with the GP. Patients may contact their GP about issues pertaining to anticoagulation where NCLASPS would probably better be able to help. It is an unsatisfactory situation where the patient needs to know themselves who they should approach, but that is the situation while there is poor contact between GPs and NCLASPS.

In one case, while there was concern within the clinical team about a lack of communication about changes in the patient's medication, there was a lack of consensus about what best practice would be. Likewise, there was a lack of consensus for best practice on related issues. For example, it is difficult to define what levels of ill health should prompt a patient to contact anticoagulant monitoring services. There are few apparent guidelines on these issues: it is not possible to promote best practice to other HCPs while there is uncertainty over what best practice is. If there is inconsistent practice, patients moving between anticoagulation services will hear inconsistent information. Advice appears to be that the patient should contact anticoagulation services when the patient takes any new medication, but much of the time the medication change would not have any affect on INR and it is unclear whether the service is resourced to cope if all these events did lead to contacts.

Although NCLASPS clinics work on an appointment system, one case demonstrated the importance of clinics being able to respond to patients appearing without an appointment. Community-based clinics have low staffing levels and generally there is no-one else to take over in such situations, leading to delays either for the patient without an appointment (who may have an urgent problem) or for those patients with appointments. This is less of an issue with outpatient clinics.

While there is a Standard Operating Procedure, the research team also saw considerable implicit knowledge among staff in dealing with common exceptions from standard protocols. There was much 'hidden work' by administrators to keep the service running smoothly.

One particular issue arose with a patient prescribed an antibiotic as a rescue course. That is, the patient is at particular risk of getting infections and so has a repeat prescription for an antibiotic with instructions to take it at the first signs of an infection. This means that there may be long gaps between the antibiotic being prescribed, when it is dispensed and when it is taken. It was unclear what information the patient was given about possible interaction with

warfarin when the drug was prescribed or when it was dispensed. Even if the information given at these times was optimal (which seems unlikely), the long gap raises the likelihood that the patient will forget the information. The recurrent but sporadic use of a medication complicates warfarin monitoring. That the drug is not taken all the time, but is regularly used, places it in a liminal state, so a patient may be inconsistent when asked about what drugs they regularly take. Rescue courses of medication are workarounds that have many advantages, including prompter treatment of infections and greater convenience for the patient. However, the lower control over their use raises risks and some would argue that they should not be used. In this case, a rescue course was done as a repeat prescription, a situation further reducing direct clinical input. In a patient on warfarin where a drug interaction is likely, it may have been an unwise approach.

### ***Recommendations arising out of RCA***

NCLASPS should consider how better to communicate with GPs. NCLASPS has specialised expertise that would be of value to GPs and other healthcare professionals. A new web interface accompanies the new software, HeartBeat. It has been suggested that the front page of this could be promoted within the local health economy and provide links to advice for GPs and other HCPs, plus details on how to contact NCLASPS. There is a widespread sense that GPs are poorly educated in anticoagulation: this was repeatedly raised in Clinical Governance Board meetings, was reported by NCLASPS staff and by GPs external to NCLASPS encountered in the research.

It is unclear how easy it is for patients, GPs, hospital staff, dispensing pharmacists and others to contact NCLASPS. NCLASPS staff commented that it can be difficult to contact some GPs. In both directions, it would be useful to determine if contact details are clear and easily found. Are all modalities utilised (phone, fax, e-mail, post)? Is out-of-hours contact clear?

Patients frequently go between GP and NCLASPS with nothing more than verbal instructions. Encouraging referral letters is important. NCLASPS should request details from GPs instead of relying on the information the patient knows alone. NCLASPS practitioners should become practised in writing referral letters, and it might be possible to build pro forma referral letters into the HeartBeat software. Referrals from NCLASPS should be more explicit about what is recommended: for example, explaining that coagulometer results are unreliable for INRs above about 6 and that a venepuncture test is indicated; and explicitly asking for feedback to be given to NCLASPS (and how that can be done). Patients may benefit from the greater use of written instructions.

Guidelines as to what should be done by NCLASPS practitioners in emergency situations may be of value. For example, when should patients be referred directly to a hospital-based INR clinic rather than to A&E?

Record keeping within NCLASPS could be reviewed. In some cases, local record keeping could have been better. There is always a balance in these things, and it is recognised that the practitioner always remembers more than can ever be recorded, which is one reason why continuity of care is important.

## **Results**

Patients with a better understanding of warfarin treatment would have improved the three cases studied in depth. While services should not rely on patients, they remain the best placed individuals to ensure good communication and information sharing. Services should not see patient's actions as failings on their part, but as failings on the part of the anticoagulation service and other HCPs to adequately educate the patient. The patient has a central role as a final barrier to actions, but can only fulfil that role with appropriate education, direction and support from healthcare services. Services need to consider what they realistically expect from patients, and why patients are unable to achieve those expectations.

It is necessary to check patient education is up-to-date. Services need to recognise that patient education does not generally cover 'exceptional' circumstances, as occurs in the cases considered here, and patients are not equipped to reason from first principles as to what to do. Can different kinds of patient education be produced?

Often, cases are seen where a patient moves between different health services – GP, NCLASPS, community pharmacist, hospital cardiology, hospital A&E – without any co-ordination. Individual actions taken, individual pieces of advice given to the patient may have been good, but there is no or little communication between the various players and poor integration of services. Cases were seen where no-one took responsibility to see a patient and his/her INRs through to conclusion. Within NCLASPS, it may be useful to clarify what responsibility the service takes for its role in supporting and communication with the other stakeholders. GPs are reluctant to get involved in anticoagulation issues, yet are best placed to take a holistic view. On the other side, the pharmacist anticoagulation practitioners struggle to engage with GPs well. Achieving communication and a sharing of expertise seems crucial.

In two of the cases analysed in detail and in others considered briefly, the root cause is arguably that the patient should not have been on warfarin. Warfarin is a dangerous drug and its benefits are not necessarily greater than its risks. Many patients would be better

on alternative treatment, most often aspirin, providing a much lower level of anticoagulation but with few associated risks. The failure of anyone to review these patients further highlights communication issues between clinical services. However, it is important to note a bias in a RCA approach performed within NCLASPS. Within an anticoagulation service, there may be patients who should not be on warfarin. What we cannot see are those patients who should be on warfarin but are not.

### 3.1.9 Medico-legal perspectives

Healthcare professionals may be reluctant to participate in initiatives to move care from the hospital setting closer to the patient due to fear of increased liability and vulnerability to litigation. [112,113] This concern is understandable in the increasingly litigious context of healthcare and further analysis is required to shed light on how liability changes in community-based care. In other contexts, the extension of roles for healthcare professionals raises the potential for increased exposure to litigation based on professional negligence. [113] Thus, it seems reasonable that the perspective of professionals in NCLASPS may be one of concern around their being exposed to a risk of negligence litigation and indeed such concerns were voiced. We began by attempting to clarify the extent to which existing law, specifically of negligence, applies to changes in the delivery of anticoagulation services. We then considered the aforementioned set of critical incidents which provided further illumination.

#### ***Negligence: the law***

Section 18 of the Health Act 1999 imposes a statutory duty of quality on the NHS, including all PCTs. This duty reflects the beginning of an increasingly explicit focus on quality in the NHS [114,115] and exists alongside the common law duty of care already owed to patients, embodied in the common law of negligence. Most medical negligence claims are based on breach of the common law duty of care.

Negligence is the legal device used to assess whether an acceptable standard of care has been provided. To succeed with a claim, the injured party needs to demonstrate the existence of a clinician-patient relationship with attendant duty of care, that the duty was breached and that the breach caused the injury. Legally, the usual starting point for assessing negligence is the *Bolam* test (*Bolam v Friern HMC*) [116] which states that,

*a doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art*

However, following the judgment in *Bolitho* (*Bolitho v City & Hackney Health Authority*) [117] there is a codicil to *Bolam* in that the experts relied upon have to be able to demonstrate that their opinion has a

logical basis. However, to date, the practical effect of Bolitho appears to have been relatively limited. In addition to legal guidance, professional codes of conduct inform the setting of appropriate standards of professional care even if legal negligence is not at stake.

### ***Duty of care in anticoagulation models***

In hospital-based anticoagulation services, it is self-evident that the consultant in charge owes a legal and professional duty of care to all patients under the care of the service. It is equally uncontroversial that each of the participating healthcare professionals – nurses, pharmacists and GPs – owes a legal and professional duty of care to their patients. Similarly, in the outreach setting all of the participating healthcare professionals owe a legal and professional duty of care to their patients. These include the consultant in charge of the service. It is settled law that the duty of care is non-delegable so a key question is what is the extent of the consultant's duty and how may this be met in practical terms. Implicit in this is the need to explicate the duties, roles and responsibilities of other team members.

To summarise, the potential categories of defendant to an action for negligence brought by a patient treated in the hospital or community setting include:

- any of the involved professionals individually (cardiologists, haematologists, hospital pharmacists, community pharmacists, GP, practice nurse);
- any of the employers of those professionals via the doctrine of vicarious liability, (independent pharmacies, GP practices, NHS Trusts);
- the provider unit directly (PCT, independent pharmacies, GP practices, NHS Trusts).

In theory, both individual clinicians and their employers may be found liable in negligence to their patients, although in practice most legal cases are not brought against NHS Trusts directly, rather they are actions brought against Trusts who are held to be vicariously liable for the acts of their employees.

It is worth commenting further on this less commonly raised issue of direct liability. The Trust may become legally responsible for the negligence of its employees either through the concept of vicarious liability or as a result of the hospital's non-delegable duty to its patients. [118] In this situation, the claim would be that the healthcare providers themselves were negligent, for example, by failing to provide adequate numbers of adequately trained staff [119]. Other examples might be if there were no proper procedures

to check that equipment was working properly or that staff were properly kept up to date with medical developments. [120]

Thus, a situation could arise where no individual professional might be held negligent but the provider itself could be. Although the courts are yet to fully consider the question, it seems that when assessing whether a NHS Trust has been negligent the usual (*Bolam*) test for negligence will not apply, i.e. a Trust will not necessarily have a defence just because they are acting at a level other Trusts act at, if the judge decided those standards to be unreasonable. [121]

Applying this to the NCLASPS outreach models, it seems unlikely that the existence and use of distributed anticoagulation models elsewhere would assist the provider unit in a defence.

### ***Standard of care – outreach services and commissioned services***

Once the existence of a duty of care is established, the central question is what is required in order for the duty to be fulfilled. In broad terms in the context of NCLASPS, three features seem likely to have the greatest impact on the standard of care:

- the physical remoteness of the consultant in charge of the service and the distributed geographical spread of the service;
- allied to which, the expanded role of trained community practitioners (nurses, pharmacists, GPs); and
- the use of an electronic DSS and associated EPR.

These broad areas formed the backdrop for a preliminary risk assessment which highlighted some potential areas where uncertainty might arise about how the duty of care could or should be adequately discharged.

### ***Preliminary risk assessment – potential threats to standard of care***

NCLASPS has been developed through close cooperation between hospital and community-based professionals. The service is regularly reviewed by the Clinical Governance Board. CGB meetings and interviews with various staff have revealed areas of concern. Some of these concerns reflected ethico-professional uncertainties around how the system changed what was required of practitioners in the community. Other concerns revealed points at which the standard of care could be compromised and potentially lead to legal liability based on negligence. Concerns raised included:

- Inappropriate selection of patients for the community-based service;
- Failure to initiate anticoagulation;
- Failure to adjust the prescription of warfarin correctly;

- Failure to take account of prescriptions for comorbid diagnoses;
- Failure to follow-up referrals back to the hospital clinician;
- Documentation failure at start of anticoagulation plan;
- Computer failure either of the EHR or the DSS;
- Human error in using either the EHR or DSS leading to negligent advice;
- Non-contacting GP;
- Non-attending patients – failure to send reminders;
- Inappropriate briefing of locum staff;
- Mixed paper/electronic records – failure to record, incomplete and/or inaccurate records, confidentiality breach;
- Training – quality, auditing of records, relationship to complaints, near misses;
- Definition of accountability;
- Regularity of review by the assessing clinician;
- Self-dosing patients – failure to understand information.

We begin considering how, in general terms, the law of negligence might be applied to NCLASPS. Taking *Bolam* as our starting point, in seeking to defend any claim of negligence, NCLASPS professionals would need to be able to find an acknowledged expert to opine that, in any given instance, the processes of monitoring and managing a patient's INR were within a range of acceptable practice. A claim for negligence could be founded on breach relating to any of the potential risks identified above.

Further to Lord Browne-Wilkinson's judgment in *Bolitho* indicating a need for experts to apply their minds to the question of comparative risks and benefits, evidence would also need to be adduced to show that this balancing act had been considered and addressed appropriately. Operational details for NCLASPS are laid down in the Standard Operating Protocol (SOP). The SOP is subjected to ongoing refinement and monitoring through the CGB, which presumably should go some way to satisfying the consideration of risks and benefits referred to in *Bolitho*. Both the algorithm which supports clinicians and the SOP are a form of guideline and therefore might help to define the standard of practice to the extent that they are consonant with the emerging evidence base.

In the context of a new distributed service, a further question to be considered is how will technology impact a provider's legal liability where some use it and others do not? Sokol and Molzen suggest that,

in the US at least, because healthcare has not uniformly embraced IT, the courts will re-examine the standard of care and how to shape it. [122] Courts could become less concerned with accepted professional norms and more willing to judge against technology-driven standards. It is open to debate as to whether similar arguments might apply in the UK.

In the absence of legal precedent it is not entirely clear what standard of care would be applied to determine negligence. Would it be the standard of care of the ordinary skilled cardiologist and if so, how might this be defined in the context of distributed care involving the use of an electronic system? Always the challenge for the courts when making a standard of care assessment is to legally evaluate the delivery of healthcare in ways that encourage appropriate conduct without creating a pressure towards the practice of unduly defensive medicine.

On a traditional view, the courts have, in general, been reluctant to impose arbitrary standards of care preferring to allow the medical profession itself to define its own standards of care by reference to accepted custom and practices and this is effectively the thinking behind *Bolam*. However, it is plausible that the advancement of technology at a time when public confidence in the medical profession has been undermined and deference to the profession is being eroded may lead to a weakening of judicial deference to medical customs and potentially more robust use of *Bolitho* based judgments.

### ***Negligence and consent***

One risk identified concerns the issue of consent to anticoagulation therapy and to community-based treatment. It is axiomatic that if there is to be 'consent' then there must be 'choice' and choice is rooted in the general principle of autonomy, that is the right of the individual to determine what will happen to them, subject to the rights of others. Our starting point is the fundamental principle that any medical treatment given to competent patients should be based on consent and that such consent should be 'informed'. If there is any suggestion that a patient lacks capacity (in a legal sense), the issue of consent comes into sharper relief. The basic lawful test of competence is long established in common law and was recently codified in the Mental Capacity Act (2005). It requires that the patient can:

- understand the information;
- remember the information;
- weigh the information;
- communicate his/her decision.

Assessment of competence is both time and decision-specific. Self-evidently, it is not acceptable to ask a patient to sign a consent form if they have not had the likely consequences of agreeing explained so that they fully understand what is being proposed and what the alternatives are. We found some suggestion that some patients struggled to fully grasp the dynamics of the changed system of delivery entailed by NCLASPS.

Typically, negligence involving consent will occur when a clinician fails to tell a patient about the risk of a particular complication but what is unclear is the scope of the notion of consent to treatment. The leading authority is the case of *Sidaway v Bethlem Royal Hospital Governors* [123] that effectively says that the *Bolam* test applies to determination of liability so a doctor would escape liability if the information given would be endorsed by a responsible body of medical opinion, although following *Bolitho*, there will be cases where it is so obvious that a warning should have been given, irrespective of expert support for non-warning, that it defies logical analysis.

The potentially greyest areas here concern patient consent to undertake warfarin therapy in the first instance and to be managed via care in the community. The complex interplay of factors that influence anticoagulation means that an important part of clinical care is to ensure that at the start of anticoagulation treatment patients receive sufficient information and counselling to understand how the treatment works and how they need to cooperate with the clinical team. Unsurprisingly, we became aware that these understandings were not always reached.

The question of whether a patient was suitable for community management was raised and led to a need to distinguish between clinical suitability and social suitability. Whereas some patients were deemed clinically 'suitable' achieving an understanding of their condition and its management taxed the limits of what they could cope with. While the majority of patients were able to additionally cope with understanding a new system of care, for some this was not always achieved. The complexity of understanding how hospital services, GPs and pharmacists co-operated to provide their care left some patients confused. Most patients welcome the opportunity to receive care closer to their home in the community. Strictly speaking this is not an issue of consent either legally or professionally – in general, a NHS Trust may choose how to provide services – but it does raise the ethical question concerning whether patients with limited understanding of a fairly complex treatment regime are best served by a complex system of community care.

### ***Negligence and information giving***

Patient uncertainty as to how the system operated overall was unsurprising given that many professionals also either expressed similar concerns or else behaved in ways which indicated a sub-optimal understanding of their role. We found that the SOP is silent on the role that a GP should play in community-based treatment, which could be viewed as an oversight in relation to any claim for negligence on the part of the provider. Equally, the Service Specifications consider communications initiated by the patient or the anticoagulant practitioner but do not explicitly address the scenario of a GP needing to initiate contact leaving the matter of when to instigate communication to an individual GP's professional judgment.

It is these sorts of situations that we suspect underlie the finding that GPs repeatedly reported feeling under-confident in anticoagulation issues. The PCT has a responsibility to provide a safe system of healthcare and therefore failure to provide adequate training could, in theory, render vulnerability to a claim of negligence against the PCT, although, in practice, this would be unlikely to be pursued.

### ***Negligence and treatment across system boundaries***

A very real concern held by GPs appears to centre on concerns regarding failure to recognise the need for specialist support and being vulnerable to a claim of negligence for failing to refer appropriately. Legally, a GP's actions would be assessed by reference to the skills expected of a GP, not those of a cardiologist. [124] So whereas a GP might not be deemed negligent in failing to know how precisely to manage a warfarin-dependent patient, they could be deemed negligent for failing to refer the patient to the anticoagulation service.

Several of the critical incidents we examined revealed evidence of sub-optimal care across geographical and professional boundaries. Many concerns centred on communication of untoward events often allied to co-morbidities suffered by a patient. The issue of managing a patient's anticoagulation therapy in the context of their other co-existing health ailments posed many difficulties. For example, there was evidence of at least two categories of failure to include NCLASPS in the communication loop. One set of failures related to failing to initiate appropriate investigations for patients on warfarin; a second set concerned referring patients for investigations to confirm suspected diagnoses but failing to notify NCLASPS. On the standard test for negligence, both such failures could potentially fall short of practice that would be endorsed by a responsible GP.

It is fundamental to good medical practice that a patient whose care is being transferred from one setting to another is accompanied by the transfer of full relevant information. We were disconcerted to find

evidence that the transfer of information across care settings did not always happen despite requests for information from the receiving clinicians. Such failures to provide information appear to be tantamount to negligent practice and certainly would violate professional ethic codes and guidance.

### ***Negligence and delegation***

In relation to the delegation of care to community-based professionals, there is clearly a requirement for the hospital consultant to take steps to ensure, as far as reasonably possible, that the community healthcare professionals to whom care is delegated are appropriate.

It is a matter of speculation as to how the burden of reasonableness might be discharged, but strategies such as the provision of adequate training (and training records) as well as fall back procedures and suitable checks (*e.g.* audit data) and balances would go some way towards providing a defence. But what would constitute adequate training? Assuming that the content of the training in terms of knowledge and skills is uncontroversial the main issue seems to be the rigour with which any initial and ongoing assessment processes that verify the competence of the trainee are implemented. However, delegation is a two-way process and the professional delegee, be they GP, nurse or pharmacist, has a professionally imposed duty to practice only within spheres in which they are competent.

A trained, competent delegee who in exercising their professional role adheres to the procedures laid down by NCLASPS should, in the normal scheme of things, be delivering an acceptable standard of care. But where does this leave a clinician who follows advice proffered by the DSS but faces a claim of negligence? Would they in defence be able to claim to be 'following orders' from the hospital? Several issues fall to be considered. Of course, it is incumbent on the community-based professionals to check that they correctly understand the instructions for using the DSS (a requirement of particular salience if the instruction seems unusual). Hence the ruling in cases such as Dwyer may assist the consultant in charge of the service should there be failure of the DSS leading to the provision of manifestly unlikely advice. [125]

### ***Conclusions***

Expanding a hospital-based anticoagulation service into a community-based service requires health care professionals in both settings to assume different responsibilities for quality of care. Consonant with this are potential changes to the risks to healthcare quality and to the way in which an acceptable standard of care is defined. These reflect a general problem of defining complex conduct

prospectively, that of how to establish risk spreading and how to establish knowable standards of legal conduct. While these uncertainties remain, our findings provide further insight into the fact that changes in ways of delivering services generate professional concerns about roles and responsibilities. Although these concerns may be partially mitigated by stringent clinical governance procedures, the division of responsibilities across settings suggest a need for even greater clarification of the relative roles of all involved parties.

### **3.1.10 Overall conclusion of risk management work**

We conclude three broad results from the risk management methodologies used: about the utility of these methods, about the presence of workarounds in system use, and about the main challenges to patient safety in the service.

These methods were valuable in illuminating details of the service and allowing the clinical and software team to develop the service, but these methods are not individually reliable. A clinical service seeking to ensure high quality, be it one using technology intensively or not, should use a range of different risk management methods and not assume any one approach is comprehensive. In particular, issues of scope need careful consideration throughout the process.

Within that context, the methods proved able to capture issues about the involved technologies as well as their broader contexts. Clinical, administrative and computing staff members were all brought into this line of work and, generally, found the tasks given them achievable and reported positively on their experiences of using these tools. In fact, our participants were generally more positive about these methods than the finding from our results that suggests they are not individually reliable. Stakeholders, when results from these methods were presented to them, also welcomed this approach. Discussing safety issues can be a delicate subject and that is particularly the case with retrospective analyses of clinical incidents. We found NCLASPS staff at the Whittington happy to embrace root cause analysis, although it was a much greater challenge to jump over organisational boundaries and involve those employed elsewhere. Thus, we argue that all of these methods are readily usable in e-Health systems and can reveal useful findings.

These methods have revealed various workarounds in system use. These workarounds are well-established and highly familiar to the clinical team. They represent potential hazards, but there was no evidence of any actual problems having occurred. They are largely unknown to the software team, notwithstanding the close working relationship between clinical and software team. Moreover, the key role of the paper algorithm is not fully appreciated in the software

team. More broadly, many situations do not fit the SOP, but are readily handled through processes reliant on the implicit knowledge in the clinical and administrative staff.

The prospective techniques focused on what happens in NCLASPS, where mistakes happen but are generally corrected. The retrospective approach of RCA captured the problems around NCLASPS and it was these that represent the greatest threats to patient wellbeing. Problems occur in the gaps between organisational boundaries. Patients are caught in a non-communicating triumvirate: secondary care services focused on stroke prevention, NCLASPS focused on keeping the patient's anticoagulation in a target range, and the GP with the most holistic view of the patient's general health handling a range of co-morbidities. Difficulties with information transfer when care is managed by several parties have been reported by others investigating anticoagulation therapy. [126] The technology has solved problems for a community-based anticoagulation service, but the hopes that a community setting would improve communication across these organisational boundaries have not yet been fully realised. The problems of organisational boundaries may reflect the outreach model used in Barnet PCT, as opposed to using community pharmacists or GPs to run the anticoagulation clinics. Anecdotally, these arrangements have not been as successful as hoped. The community pharmacists running the anticoagulation clinics tend not to be patient's regular pharmacist. GPs running clinics may not be the patient's regular GP. However, further work is needed within these models.

We propose that a useful focus for future technological developments is in supporting communication across organisational boundaries, starting with the proposed GP annual review system.

## ***Results – general***

In order to understand the service more broadly, we analysed our ethnographic field notes, our own experiences of the service and the results from the specific risk management methodologies discussed in section 3.5. We took a grounded theory approach to all the material in order to identify general themes. These were discussed within the local research team to achieve consensus. We drew on theoretical perspectives identified and developed in section 2, the literature review.

NCLASPS is a successful, socio-technical service that has evolved bottom-up over many years. There is a close working relationship between the clinical and software team, and with researchers. The service has grown through a facilitative, partnership model, based now on the Clinical Governance Board. The development of the

service has frequently been driven by local champions, and frequently been slowed by organisational resistance, often because of other ongoing changes in the organisations involved. The development of the service has depended on historical contingency, on ad hoc events.

In the ANT meta-narrative in the literature review, we introduced Callon's model of translation as consisting of four stages: problematisation, interessement, enrolment and mobilisation. [55] We can apply this model to the development of NCLASPS and the work of its Clinical Governance Board. Problematisation dates back to the 1990s and developments at the Whittington Hospital when DP and others sought to move beyond the hospital outpatient model of anticoagulation monitoring. Those stakeholders within the CGB have already been through a process of interessement; the Board represents a context in which enrolment and mobilisation successfully take place. We can see the contract negotiations between NCLASPS and PCTs as being a process of interessement in which the terms of the PCT's involvement are defined. The facilitative environment of the Board and the successful working of the systems (technical and social) are supportive of successful enrolment and mobilisation, but these moments of translation are also possible because there has been prior successful problematisation and interessement.

Other stakeholders have not become involved in the CGB and we can see that as a failure of interessement. Other actors in the form of local hospital Trusts, who broadly agree on the nature of the problem, choose not to accept the Whittington as a focal actor defining NCLASPS as an obligatory passage point. [127] Other hospitals offer alternate solutions with themselves as alternate primary actors. They are in financial competition with the Whittington, so there are strong financial pressures not to accept the centrality of the Whittington.

There has also been repeated resistance from GPs, individually and collectively, to become involved in NCLASPS. Here, the failure of interessement is more complicated. GPs generally recognise their lack of skills in anticoagulation, but they also view anticoagulation control as somebody else's problem. They are reluctant to take on additional work without additional recompense (again, financial arrangements can interfere with interessement) and fear legal liability deriving from being more involved. Ironically, we believe GPs already carry considerable liability. GPs generally prescribe warfarin, although dosing decisions are taken by NCLASPS or other anticoagulation monitoring services. This is a familiar workaround in the NHS whereby GPs sign prescriptions for drugs without full knowledge or control over their use. This is a very useful workaround, but raises issues given the act of prescribing means the GP has taken on some liability. Given the repeated problems that

occur because of poor communication between GPs and NCLASPS, it would be in GPs' interests to become more involved in anticoagulation monitoring. GPs are key to the future development of NCLASPS, as the service itself recognises. There is ongoing work to support GP-led annual reviews of patients on warfarin. However, to date, these have largely failed to happen.

Variable data quality is an unavoidable part of clinical care. Concerns were frequently expressed about the data quality of patients being referred into the service, in particular around identifying patients who are unsuitable for a community-based service. However, by definition, this relates to the behaviour of those outside the service, representing a difficult problem to solve. Transfers into NCLASPS from another anticoagulant service may represent an income loss for that other service, again putting finance in the way of integrated services. In one contract, a minimum data quality/completeness was agreed for transferrals into NCLASPS. However, this proved difficult to meet, contributing to a very low rate of transferrals, below anticipated numbers. A decision was taken to compromise on data quality/completeness, but there were concerns later that this had caused too many problems given the added workload for NCLASPS practitioners to fill in missing data and the risks to patients. Such data quality issues represent a general problem for healthcare services sharing electronic data. We echo earlier work that data quality needs to be recognised as important, but that it cannot be expected to be perfect, and that choices and compromises have to be made around what can be achieved. [128]

Research described in the literature review from the ANT meta-narrative, notably [66], and beyond (e.g. [65]), argues that there is an unavoidable tension between standardisation (which helps stabilise the actor network) and contingency (which reflects and responds to local needs and priorities). This tension must be actively and creatively managed, which gets harder as the network gets bigger. We see this tension played out repeatedly in NCLASPS. The service repeatedly fragments, but effort is made to standardise practice, with debate playing out within and around the Clinical Governance Board.

There are local issues on a clinic by clinic nature. For example, over the course of data collection, there was considerable effort put towards standardising which coagulometer to use in clinics, and to ensuring that this standard would be the more modern device with improved accuracy at high INRs. Some expense was involved if a new coagulometer needed to be purchased and that expense largely fell on the PCTs. The price of a new meter was not great compared to other costs in the service, with a meter costing somewhat below £1000. However, even relatively small costs can present an obstacle when unexpected and/or not budgeted. Over several months, peer

pressure within the CGB led to common adoption of the recommended meter. Except, near the end of the data collection clinic, it came up in discussion at a Board meeting that one clinic was using a related but slightly different product from the same manufacturer because they had a higher volume of results to process. This was a sensible solution for a local issue, but illustrates the constant pressure for fragmentation.

On a larger scale, the individual contracts between NCLASPS and the PCTs, while following a common model, are highly contingent and reflect a variety of issues, including prior local relationships between the Whittington Hospital Trust and PCTs; when the contracts were drawn up (with NCLASPS having learned from earlier negotiations and applying that experience in later negotiations); and differences in what the PCTs wanted. The different local systems encompassed by NCLASPS, notably the system used in Camden PCT with different and non-integrated software, reflect that history of contingent decisions.

The different Whittington/PCT negotiations have tended to focus on different issues: e.g., there was far more focus on network security in one discussion than in any other. These differences do not appear readily explainable in terms of the needs of the PCTs' different populations. Therefore, these variations may indicate sub-optimal behaviour: if a particular issue is given much more focus in a current negotiation than a past one, that may suggest either it is being given an inappropriate level of attention currently (to the detriment of other issues) or was given too little attention previously. We suggest some of this variation may reflect the lack of a knowledge base in the PCTs when it comes to complex technology (compare also [129]), an issue that has been one of the rationales behind the new NHS Technology Adoption Centre.

Much of the fragmentation is in the form of workarounds for the software. Again, these are understandable on a pragmatic level, but they are also associated with potential risks. Notably, despite their close working relationship, these workarounds and key service elements are unknown to software team.

The question of standardisation is linked to the bottom-up design of the service. NCLASPS is consciously set up to be facilitative, with the Clinical Governance Board seeking to bring stakeholders to consensual decisions. Generally, the past literature [22] and our own prior work [130] support such a bottom-up approach in comparison to the top-down approach that has characterised NPfIT. However, the bottom-up approach has limits, as with the failure to involve some stakeholders in the Clinical Governance Board. The relationship between bottom-up and top-down forces is complex and a simple dichotomy between e-Health services developed bottom-up or top-down may miss this complexity.

Two examples serve to demonstrate how top-down forces could be more or less helpful to NCLASPS. During the course of this study, the National Patient Safety Agency (NPSA), a national body promoting patient safety, issued recommendations on the use of anticoagulation. These recommendations carried great weight with NCLASPS stakeholders. They motivated action and were a frequently referred to in discussion at CGB meetings. The ability of the NCLASPS service and software to satisfy NPSA recommendations and to provide the information to demonstrate that a PCT was satisfying the recommendations were and continue to be key selling points for NCLASPS, encouraging continued cooperation with the service, its ethos and its bodies (namely the CGB). Note here the utility of an electronic healthcare record to support secondary uses of data, as described in the literature review, to allow PCTs to demonstrate they are satisfying the NPSA recommendations. The CGB was and is a useful arena for PCTs to share knowledge with each other and to gain expert knowledge from clinicians about how to satisfy the NPSA recommendations.

Thus, the NPSA recommendations were a valuable top-down force that promoted better anticoagulation treatment and were beneficial to NCLASPS in achieving their aims. The NPSA recommendations and their content were not a surprise. They grew out of the same concerns around anticoagulation services that have driven the development of NCLASPS. The key clinical staff in NCLASPS are part of the same anticoagulation actor-network as the authors of the NPSA recommendations. There is a connection between the micro-level of NCLASPS and the macro-level of the NPSA and its recommendations. [131] Some NCLASPS clinicians even directly contributed to the development of the NPSA recommendations.

In contrast, an unexpected top-down dependency arose around Choose & Book and web browsers. The NCLASPS software works through a web browser. In development of the new HeartBeat software, a problem was discovered with how it displays on Microsoft Internet Explorer version 6 (IE6). Extended blank sections can appear in the text on IE6. While no text is lost, an extended blank section may lead the reader to think that there is no more text as the text they can see finishes before the end of the screen. This could lead to the user failing to notice some crucial text. The problem arises because IE6 does not follow various international web standards. [132] It is also considered as having poor security, an important issue in a healthcare context. It proved too difficult to alter HeartBeat to both avoid this problem on IE6 and to work within modern web standards on other browsers.

IE6 is old technology with a diminishing market share, so one option would have been to note that HeartBeat is not compatible with IE6. However, GPs commonly use IE6. This is because, during the data

collection period, the software for Choose and Book, which all GPs are encouraged to use, was only compatible with IE6. (At time of writing, the software is only compatible with IE6 or IE7, with an update for IE8 due soon.) The initial decision to focus compatibility for the Choose and Book software on IE6 is understandable given the browser's dominance some years ago, but the failure to keep up with browser developments, particularly given the criticisms of IE6, has been an ongoing issue. [133] With GPs a key user base for HeartBeat, this represented a major challenge. A workaround was developed whereby Firefox could be installed on GP's PCs with HeartBeat set as the homepage and the Firefox/HeartBeat combination presented as a standalone solution rather than as an alternative browser.

Here, top-down-imposed requirements around one technology, Choose and Book, have led to an unsatisfactory situation around browser options for GPs and an unexpected problem for the development of HeartBeat. The HeartBeat software team worked to international web standards and, from a technical viewpoint, it is IE6 that is widely criticised for not following these. However, this is not to stay that the national decisions around support for IE6 were not rational. It is not known whether the knock-on effect of the Choose and Book software decisions was fully considered. Another example is how the exclusion of community pharmacists from NHSnet much earlier in the project was a major hurdle.

The new HeartBeat software has greatly improved secondary data uses. It offers a data panopticon for users to review their own practice and their clinic's general practice. NCLASPS central personnel see this data as giving them power in negotiations at a patient or organisational level, but the potentially intrusive nature of this technology on individual practitioners is recognised. HeartBeat is not intended to control practitioners, but to allow them to collectively improve. [134]

Not only has the nature and development of NCLASPS been contingent, but even the notion of whether NCLASPS is a success is contingent on what we mean by success. As discussed in the literature review, the nature of success in complex health IT projects is contingent and fluid. [82,83] We argued above that NCLASPS is a successful service on several criteria (good clinical outcomes; profitable; good service user feedback; and good service commissioner feedback). While these are defensible as sensible criteria upon which to judge a service, they are a post hoc selection. Ours was not an evaluation study with pre-defined criteria of success. Moreover, we can trace how success has evolved over time in the history of NCLASPS and how the logic of the service has changed. The initial software was developed to improve decision making around warfarin dosing. The service was then built around the

software to move anticoagulation monitoring away from the outpatient setting and into primary care. The rationale here was that this would reduce the cross-boundary problems whereby decisions or observations in primary care with implications for anticoagulation are disconnected from the patient's anticoagulation therapy.

It is unclear to what extent the NCLASPS approach has improved upon these problems. It would seem most valuable for GPs to be directly involved, but in many cases, GPs have not wished to be involved in the service, which has moved to other models (community pharmacists, or hospital pharmacists on an outreach model). Where community pharmacists have been involved, they could have a critical role in bridging the organisational boundaries if they are also a patient's usual community pharmacist, handling the patient's other prescriptions or over-the-counter medication purchases. However, reports suggest the experience has tended to be that the anticoagulation pharmacists have not been or become patients' usual community pharmacists. We have focused most on the Barnet outreach model. Here, although physically located in the community, a hospital-based pharmacist is the anticoagulation practitioner, so the original goal of involving primary care in anticoagulation is not met. Yet, just because the service has moved away from the earlier goals does not mean it is not a success. The Barnet model has succeeded for other reasons, being both financially successful (profitable for the Whittington, cheaper for the PCT) and very popular with patients. An evaluation of patient experiences in the Barnet service notes the exceedingly positive feedback from patients. [92] Patients praise the convenience of the community setting and shorter waiting times. They also raised other benefits: they prefer the finger-prick blood test to venepuncture, they have more faith in the system when they can see their sample immediately analysed (thus reducing the chance of samples being confused) and they like receiving an instant result.

This fluid model of success and contingent evolution echoes work by Berg [135] and a model where clinical users and technical designers work together, and requirements analysis blurs with R&D and evaluation, in order to produce something fit for purpose. There is not a simplistic cycle of revisions testable under positivist assumptions. Ours was not an evaluation study with pre-defined criteria of success and evaluation studies with pre-defined criteria of success may sometimes be the wrong model for complex, socio-technical services.

Patients also praised the clear, structured paper print-out produced. In considering the role of this print-out and of the record more broadly, it is the interpretivist information systems meta-narrative that provides a theoretical model. We can see the NCLASPS software as an efficient communicative genre [136] for practitioners in the

system and HeartBeat offers improved secondary uses. The record is well designed because it supports the work of NCLASPS. However, the CHIME software does not act as an agent of communication, or a boundary object [37], with other healthcare services. The one way in which the record does become a boundary object is in the production of the print-out for patients. This may carry over to other healthcare professionals when the patient shows them the print-out, but we did not observe this.

### **3.1.11 Conclusion for local context**

Organisational boundaries remain the overriding problem for the service. We suggest that the next phase of development work needs to focus on supporting improved communication over those boundaries.

Annual reviews of patients are recognised as important, but progress here has been slow given GP reluctance to be involved. There is ongoing work to develop a pro forma to be partially populated from the electronic record that can then be given to GPs to help them carry out a review. This idea can be extended: for example, one could imagine a pro forma referral letter for a patient sent to A&E, again partially populated from the electronic record, but editable by the individual anti-coagulant practitioner as required. The design of such a letter could incorporate expertise around good practice for a letter referring a patient to A&E, knowledge that individual anti-coagulant practitioners may not possess.

More generally, we recommend more support for patient education. Training within NCLASPS – both the initial formal anticoagulant practitioner training and ongoing CPD – could cover patient education more and the problems of organisational boundaries.

### **3.1.12 Conclusion for SDO research question**

Our interest in NCLASPS is not simply in terms of improving the local service or similar anti-coagulation services. It is in what the experience of this long-running and mostly successful e-Health system tells us generally about e-Health systems. Are there generic factors apparent that facilitate or hinder e-Health system adoption and use?

NCLASPS again demonstrates the finding seen in earlier research and our review that successful health technology is often associated with “relatively small-scale, practically focused work, based near to the ground and promoted by credible service champions, in local and well-defined clinical communities.” [129; see also 22,137-140] We view the close and ongoing relationship between the clinical and software team as a good approach to tackle the challenges laid out in

the meta-narrative review. Much of the service development has come from key involved personnel. They have acted as change agents, able to bridge different institutional or professional worlds. However, this bottom-up approach has meant that the service has developed where there has been enthusiasm and political will. It has not elsewhere. We also question whether PCTs are well-placed to make evidence based decisions on complex socio-technical systems in healthcare.

Despite the bottom-up approach and close involvement with the software team, we see the inevitability of co-evolution and workarounds, and of localised variation from supposed good practice. The evolution of the service has been contingent on local issues. What constitute success varies between stakeholders and has been re-defined over time. Therefore, we argue, software expertise is needed on an ongoing basis to support this co-evolution and the changing service. You cannot avoid co-evolution or fragmentation, so we argue that it is better to face this situation openly and do so through communication (chiefly achieved here through the CGB) in a facilitative context. We see the Clinical Governance Board and an ongoing reflective approach using research methodologies as valuable mechanisms by which a service can navigate through the process of technological change and co-evolution.

What is less clear in previous research is the relationship between bottom-up and top-down forces, cf. some of our other recent work. [131,141] We note in NCLASPS that, at times, top-down pressure was valuable in promoting service goals. At other times, top-down constraints limited developments. Ultimately, the bottom-up approach struggles to overcome some pressures, notably financial ones. Organisational boundaries constantly featured as problem areas and conflict with the bottom-up approach if interestment fails on an organisational level. We suggest integrated funding and governance structures are important backdrops for such services. [142]

It is too common to use a model of drug development when considering health informatics. As we argued in the meta-narrative review, a drug is the wrong model for a socio-technical service. Health technologies of the type studied necessarily lead to service re-design, so healthcare managers and clinicians should act proactively and plan for service re-design.

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## Case study 2: SystmOne

### ***Background***

Policy makers in England, as in many countries around the world, have invested their hopes and their money in integrated electronic patient records. Records systems for individual clinicians are now commonplace, most obviously for GPs. But integrated records systems, which allow clinicians to view all of a patient's data wherever they are collected, are few and far between. They remain, for the most part, an aspiration for the IT industry and for policy makers.

However, there are a few systems in routine use around the world, and these provide opportunities to establish the realities about integrated records systems. An integrated electronic health record system, SystmOne, is used across various parts of England as one of the accredited systems in the National Programme for IT. In this case study, we consider its use in an NHS Primary Care Trust and general hospital in northern England. While both academics and policy makers tend to emphasise the desirability of integrated records, it is more fruitful to think about the technology of interest here as a fusion of records and digital networks. The key feature of the system, for this study, is not the availability of patient data in clinical settings – it is the fact that data collected in one clinical setting can be accessed in another. We will, therefore, refer to the technology as an EHR network. This differs from NCLASPS in case study 1: although hospital doctors, nurses and pharmacists, community pharmacists, GPs and practice nurses can all access the CHIME EHR, they all do so under the aegis of NCLASPS.

The system in our case study enables the sharing of information between a wide range of healthcare professionals. Medical records include, for example, all consultations, prescribing details, patient and doctor communications, and pathology results. It is also possible to attach documents through scanning. Because data are updated constantly and accessible instantaneously, all healthcare professionals involved in the care of a patient can share information in real time. The EHR features a secure internal messaging service through which healthcare staff can send and receive confidential information about patients, can share the record, send and receive messages from any SystmOne user as well as be alerted to new pathology results.

The link across primary and secondary care is a noteworthy feature of SystemOne. Where GPs and other primary care clinicians used SystemOne, it offers the possibility of GPs accessing hospital data, and hospital staff accessing primary care patient data. It is important to note, though, that GPs select their own practice systems, and a few practices in the area used another system, EMIS. There was no link between SystemOne and EMIS, and hence no possibility for hospital staff to access personal data for patients referred from EMIS practices. We aimed to use this naturally occurring difference in the design of the study. Conversely, it became clear early on that SystemOne was not used extensively in the hospital, and this had a practical consequence – data about patients who used A&E or other services had paper records, and as a result paper medical records were still used for many patients visiting the diabetes service. In secondary care, at least, SystemOne was a partially implemented EHR network.

## ***Our approach***

Given the opportunity to study an EHR network, the principal challenge was methodological. Most studies reported in the health service research literature, and in broader studies of the use of systems by computer scientists, focus on specific settings such as out-patient consultations in health care, call centres or air traffic control rooms. The better studies, as we have argued in section 2, generally use ethnographic methods, seeking to understand whether and how computers influence the way that people undertake their work. The systems used in out-patient consulting rooms and air traffic control centres are, of course, part of larger organisations and larger IT networks. But if the focus of the study is the interaction between the IT system and the user, then it is reasonable to take the view that the wider system is the context for an observational study.

We did not want to use a similar approach here for three related reasons. First, the system in question offered an opportunity to study an EHR network – studying individual users would require us to ignore the novel and interesting feature of the system. Second, the literatures on computers in the workplace are full of good studies, and it was not obvious that another study was needed, particularly in an era of large scale digital networks. Third, there are few detailed studies of the effects of digital networks in health care, and therefore an opportunity to contribute to the literature, for technologies that seem bound to be important in the future. (That is, even the most sceptical would have to accept that large scale digital networks are not going to go away. The Internet and mobile networks are not about to disappear. There is, then, a need to generate evidence and

arguments about the costs, risks and benefits of digital networks, just as there is for any health technology.)

So, what method would be appropriate? There are many methods available for studying networks (see section 2 for an overview), ranging from mathematical studies of the structure and dynamics of large scale networks to sociological studies of societies and political science studies of institutions. We considered a social network analytic study, but discussions with NHS staff holding relevant data were unproductive: it was simply not possible to obtain quantitative data about the use of the network, desirable though this would have been.

At the start of the study we made three decisions. The first was that we would design a process tracing case study. [143] We wanted to understand the ways in which EHR networks were used in processes of care. We wanted to tease out, if possible, the effects of networking of records. The second decision was to keep the technology in focus. Academic social science studies have historically tended to emphasise the social effects of technologies, but treated the technology itself as a 'black box'. Conversely computer science and engineering studies – human-computer interaction studies are a good example – tend to focus on features of the technologies being studied. The aspiration here was to produce a study that focused on the way the EHR network was used, but be able to relate it to features of the network. The third decision was based on the fact that very few such studies were reported in the academic literature – we decided to undertake a pilot study, to test out a method, and then use the experience gained to design a further study.

A small proportion of the funding for this work (less than 5%) was initially earmarked for a "mini" case study on how costs can shift between primary and secondary care. To do this, we had planned to analyse data from the diabetes register for patients living in the PCT area. While there was local clinical support for this approach, the PCT eventually decided that they were unable to make the data available, curtailing this line of work.

## ***First study***

The essence of the first study was to observe the use of the system, SystemOne, in a range of clinical settings. It was a pilot study of a method, and an exploration of the kinds of data that could be obtained using the method. The findings were necessarily preliminary, and are to be interpreted cautiously.

The method was a straightforward one, where clinicians' use of the network was observed in each setting – the point in the consultation process where it was used, and what it was used for, e.g. for

reviewing or entering information. In addition we undertook a small number of interviews with key clinicians. A range of settings were observed, including diabetes clinics in primary care, a diabetes clinic in secondary care, a foot clinic in secondary care, a dietetic clinic in secondary care and a dietetic clinic in a community setting. We expected to observe differences in the use of the system for patients referred from GP practices using SystmOne and using EMIS: the former would have primary records available in all settings, the latter did not. We asked clinicians about any aspects of the consultation that we did not understand, or could not easily observe, immediately after a consultation, or at the first convenient moment during a clinic. For example, clinicians would sometimes write something down on paper, even though they had a patient's record in front of them on a screen – why? Interviews were conducted with four diabetes specialist clinicians.

The next section reports on the findings from the observational work. The second section discusses additional issues raised by the health care professionals who were interviewed.

## ***Results of observations***

### **3.1.13 Use of EHR network prior to the consultation**

Use of the computer prior to the consultation varied between settings, and it was clear that this was influenced by both the nature of the setting and the personal style of the health care professional impacted. The appointments system within SystmOne was used by diabetes specialist nurses (DSNs). The system showed the DSN who was due to attend, when they arrived and how long they had been waiting. In addition, it provided a direct link to a patient's electronic health record. Of the 10 consultations undertaken by a DSN, patient records were reviewed on two occasions before the patient came into the clinic room.

In secondary care settings, it proved to be difficult to observe clinicians using SystmOne prior to a consultation. All, however, told us that this was an important element of their work. The consultants spoke of the frustrations when the patient was registered at a general practice that did not use SystmOne. When a patient's record was shared across primary and secondary care, the consultant could familiarise themselves with patients prior to a consultation, for example to see how they were being managed within primary care, whether they had seen other specialists, and current medications. Thus one told us:

*I don't do a lot of gathering of information while the patient's there. I tend to do that before they come in.*

The dietitian's main contact with patients' electronic records was prior to a clinic. This was because she was reluctant to use the computer during the consultation:

*I am very conscious of it not being a distraction to the consultation. Our consultation is very much about focusing on the person.*

The main reasons for accessing SystmOne were to ensure that the information she received on paper referral forms was up to date, particularly regarding blood test results or changes in medication, and more generally gathering any further information that may be relevant for a consultation.

Observations revealed that within the foot clinic, individual patient records were rarely referred to prior to a patient entering the room. Although the appointments system was operational, unlike other settings within secondary care, observations suggested that it was not actively used. The staff would instead leave the room and go to the waiting area to ask who was waiting.

It is worth noting here that the health care professionals within secondary care indicated that their use of SystmOne prior to a consultation would be supplemented by the use of paper records. This is an issue that will be returned to later.

### **3.1.14 Use of SystmOne during consultations**

There was a clear difference between the use of SystmOne during consultations in primary care and those in secondary care.

#### ***Use of SystmOne in primary care***

Reviewing patient records suggested that the EHR network was integral to consultations in primary care. This finding was confirmed through observations of the DSN. During a clinic appointment she would spend the majority of the time entering data on a Diabetes Summary Template – a summary screen tailored to diabetes services – including data such as weight, blood pressure and blood test results. She would also undertake some administration tasks. Any additional consultation notes tended to be brief and were entered whilst the patient was in the room. Although she expressed concern at typing whilst the patient was in the room, she felt there was not enough time to type between appointments.

Although the DSN did not make prior use of the EHR prior to an individual consultation, there was evidence that she would refer to previous entries and other elements of the record if it was required. For example, she would occasionally refer to previous consultations and communications to answer patient queries about their care. She would often check to see if the doctor had put a note on the computer and would also look in a patient's journal to ascertain dates

of referrals to other services if necessary. In two instances, she scanned previous communications and letters that were on the system to answer a patient's query about previous consultations.

### ***Use of SystemOne within secondary care***

Within secondary care, the use of SystemOne varied by clinician. Its use did not appear to constrain the structure of the consultation, although it did impact on the nature of the appointment making process. Use of SystemOne was dependent on personal style, the confidence of a health care professional in using the system, and whether the patient was registered with a general practice that used SystemOne. If the patient was not registered with a general practice that used SystemOne, the EHR was hardly used within the consultation. For these patients, their EHR contained only previous outpatient appointments and blood test results. The lack of a shared EHR resulted in the consultant spending some of the appointment gathering patient history, particularly around their medication. Observations revealed that in these cases, the consultant would possibly update medications on SystemOne and would then enter brief consultation notes. Little other use was made of the EHR.

There was some evidence that consultants used SystemOne to gather information about patients' previous consultations, medications and other treatments. This was particularly noticeable during foot clinics, on occasions where a consultant was required to assist a podiatrist.

There was a difference between those health care professionals who did not like to use the computer in the consultation and those who felt it necessary to input the data simultaneously. One consultant spent much of the consultation inputting data, and wondered whether the computer was used too much in the consultation: it may divide attention from a patient. Yet it may be necessary to input information immediately as memories faded soon after a consultation. Conversely, one health care professional explicitly expressed dislike for using the computer within the consultation. Observations revealed that in this case use of SystemOne was indeed limited.

Observations revealed that almost all health care staff within secondary care did not use SystemOne to access pathology results, but would instead use the hospital PAS system. Interviews revealed that this was mainly due to familiarity with the hospital system, and earlier availability on PAS (the two systems not being directly linked, data being moved from PAS to SystemOne in batch transfers). In addition it was felt that it was easier to obtain information for a wider range of results on the hospital system and that the nature of the interface on SystemOne – the number of clicks required – made it difficult to access the information required.

### ***Use of paper records alongside SystemOne***

There was a noticeable difference in the use of paper records between health care staff in primary and secondary care. Observations within primary care revealed that very little paper was used. The consultation focused around the electronic template on SystemOne. Referral forms for the dietician, podiatrist, optometrist and blood test forms were the only observed uses of paper within the consultations. In contrast, observations revealed that paper records were a constant feature of consultations within secondary care. As one consultant commented,

*you have to have confidence in a system before you're prepared to throw away that sort of historical paper record.*

Alongside hospital records, the foot clinic and dietetics had their own separate paper records. Within the former, these records were often used as a reference point to gather patient details when filling out referral forms. Little information was, however, entered in these records. Observations of dietetics revealed an extensive use of paper records, including referral forms and an assessment template. This was the result of department policy alongside having no access to SystemOne within community settings. The dietician who was observed is, currently, the only member of staff within the dietetics department who uses SystemOne. The consultants that were observed frequently referred to the hospital paper records alongside SystemOne. This was primarily to clarify details about previous consultations or because there was limited information in a patient's EHR.

Discussions with health care professionals based in secondary care revealed their frustrations at the duplication of effort. Since not all departments within secondary care used SystemOne, there was a necessity to enter details into the written paper record. For each patient, therefore, a copy of the SystemOne record was printed off and placed in a patient's case note. A hard copy of a patient's SystemOne record was also sent to the GPs of those patients who were not registered at a SystemOne practice. A further duplication of effort occurred with blood test results. Clerical staff would enter the details on SystemOne alongside the consultants reviewing the paper results.

### **3.1.15 Health care staff views**

#### ***Use as a communication tool***

There appeared to be a difference between primary and secondary care in the use of SystemOne as an internal communication tool. Primary care staff used the system extensively. The Tasks system was used to convey messages and queries between doctors, nurses

and clerical staff. In the Diabetes Centre, it was pointed out that face-to-face communication with other professionals was easy, and so the Tasks system was not usually needed. In addition, hospital staff were more comfortable using the email system, so this tended to be used in preference to SystmOne.

### ***Potential benefits***

Those interviewed believed that SystmOne enhanced patient care. With both secondary and primary care using the system it allowed for better patient management, by enabling access to the whole patient record and through being able to communicate with health care professionals across both primary and secondary care.

Those involved in clinical audit described how SystmOne could potentially be a very powerful tool in tackling local inequalities in the provision of care. The audit process could be utilised to ensure appropriate referrals to secondary care and also highlight those suitable for discharge from secondary care.

### ***Frustrations***

Those who were interviewed were clearly frustrated that SystmOne was a powerful system that was not being used to its full potential. One frustration stemmed from the fact that it was not used universally, and that some staff were better than using it than others. There was, for example, awareness that some staff were not keen to use EHR and that some doctors refuse to make entries on it. Instead they dictate their information for administrative staff to enter. It was felt that this resulted in incomplete records and made it difficult to ascertain specific information at times.

Several staff expressed concerns that the diabetes template – the tailored screen – was constantly changing. Although there were message screens when a user first logged on to inform about the changes, it was felt that these did not help clinicians to understand exactly how the changes would impact on the system.

The interface was described by a number of staff as not intuitive. Staff within secondary care were, for example, frequently observed as being unable to enter data on a patient's EHR when someone else was using it. Staff would then need to remember to log out and then re-enter a patient's record to be able to save data.

Training had been considered by almost all the health care professionals as an issue – there was not enough of it. Most staff described how they picked up tips by watching colleagues, and were not convinced that they were using the network to its full potential.

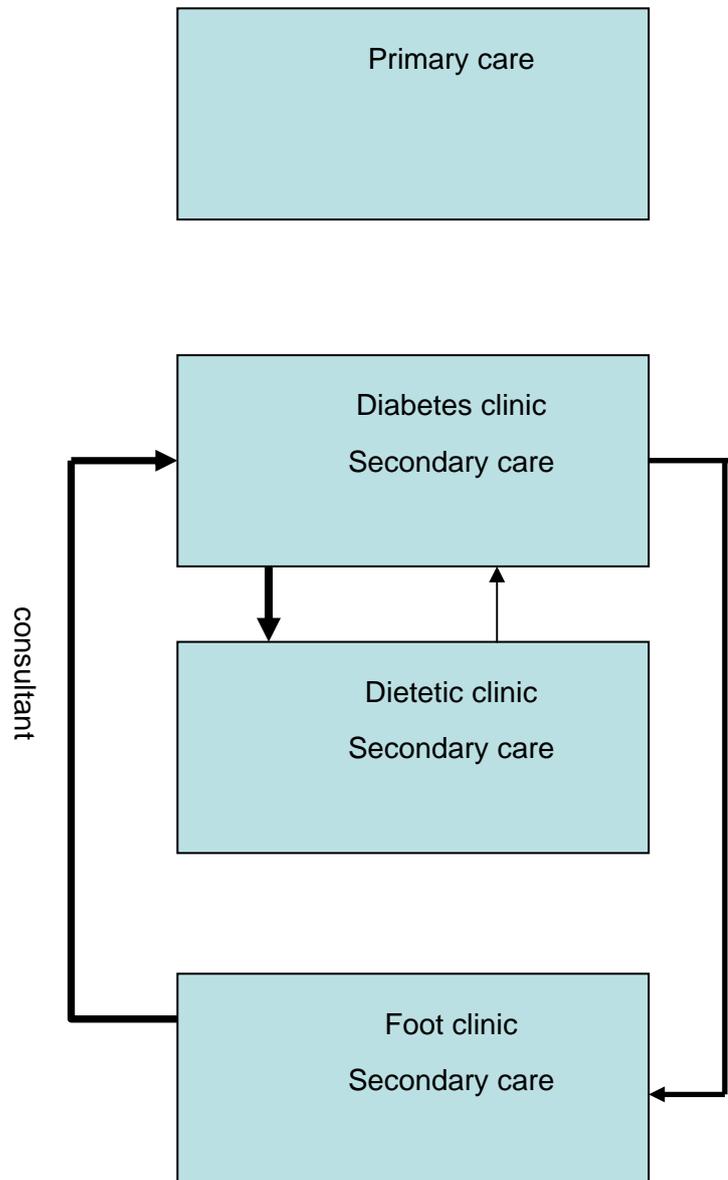
Figure 1 illustrates how HCPs within different settings refer to entries made on a patient's electronic health record from a variety of

settings. The thickness of the arrow reflects the level of usage of the EHR. For example, within a consultation in the diabetes clinic within secondary care, there is a relatively high level of usage of SystmOne, with the health care professional seeking to understand past actions within primary care, dietetics and the foot clinic. Having an understanding of what occurs across these settings necessarily impacts on patient care and management.

Figure 2 illustrates the usage by health care professionals for a patient who is not registered with a SystmOne practice. In this case, the system is used only within secondary care and the level of impact which the system can have on patient management is limited.



Use of SystmOne by health care professionals to refer to previous entries on a patient record and the level of impact on patient treatment and management.



*The depth of the arrow reflects the level of usage among different health care professionals within different setting. A deeper arrow reflects greater usage of the shared EHR, and (possibly) greater impact on patient care.*

### 3.1.16 Concluding comments

The first study provided some useful insights into how and where SystmOne was used. The evidence indicated, for example, that the

potential benefits of SystmOne were influenced by what occurs at the primary-secondary interface. They were also influenced by whether, and how, health care professionals use it as a means of communication. The evidence also implies that its potential to improve patient care was limited within other settings. The second phase of the study would aim to utilise these insights in order to gain a deeper understanding of how SystmOne was used in the care of people with diabetes.

## ***Second study***

The design and methodology of this second study was informed by the findings of the first study. The first study found: settings where the use of SystmOne was extensive and others where it was limited; and settings where the use of SystmOne appeared to have greater potential to impact on patient care than others. Alongside these findings, methodological weaknesses and limitations of the study design emerged. For example, our first study did not observe health care professionals prior to their clinics/consultations properly, yet interviews with health care professionals suggested that this was a crucial time period in which information regarding a patient's treatment and management was gathered.

The design of this study was based on two observations. First, we believed that it was possible to compare patients whose GPs use SystmOne with those who use more traditional practice systems (*e.g.* EMIS) and identify differences in behaviour in consultations between them. Second, we decided that the 'static' approach of observing patients in clinics did not yield the data we needed. We decided, instead, to follow patients – to move with patients as they encountered clinicians in the course of a visit to the Diabetes Centre, in order to allow us to trace their journeys through care processes. Two groups of patients were identified and recruited to the study:

- Patients who attended the Diabetes Centre within the local General Hospital for the first time, because of complications with their diabetes. This typically involved seeing a number of clinicians over the course of a single visit, and offered the opportunity to track the use of newly entered data in the course of the visit;
- Patients whose treatment at the Diabetes Centre at the local General Hospital was ongoing.

The study design drew, in part, on established observational methodologies. Of particular relevance here are: the study conducted by Crosson and colleagues, [144] who used participant observation, in depth interviews and key informant interviews to evaluate the process of implementing an electronic medical record in a primary

care setting; Ventres and colleagues, [145] who undertook participant observation and interviews to observe the effects of an EHR on physician patient encounters; and, participant observation used as a way of understanding working practices in primary care settings (for example, [146,147]). Equally, our strategy of following patients as they moved from consultation to consultation had few antecedents in the health service research or health informatics literatures. We therefore adopted the 'process tracing' approach from case study methods. [143]

We observed nine patients. During our observations we recorded:

- Basic features of the physical environment in which a consultation was undertaken, including the location and accessibility of computer terminals. Whether SystemOne (or other EHR) was used prior to or following a consultation with a patient.
- When SystemOne (or other system, such as PAS) was used within a consultation. This included details of whether the professional looks at the EHR prior to consultation, at what time points within a consultation the EHR was used, how long the consultation lasted, and whether the EHR was used after a patient left the consultation.
- What information was collected within a consultation and how much of this information was recorded electronically.
- To what extent previous entries and consultations were referred to.
- How SystemOne (or other EHR) was used as a means of communication with other clinicians. We noted when the EHR was not used as a means of communication between clinicians, and what other forms of communication were used.
- How SystemOne (or other EHR) was used in communicating with, and providing information to, patients.

During consultations observations were recorded as a series of brief notes – it was felt that it was not appropriate to sit in a clinic writing extensive notes. The aim of the note taking was to provide prompts to help us understand the organisation of the consultation. Where useful, immediately following the observation of each consultation, brief interviews with the health care professional observed were conducted. These were used to validate the data collected and seek individuals' own interpretations of events.

The data recorded within a consultation, and where it was entered in the record, were noted. This would, it was anticipated, allow insights into the elements of the electronic health record that were most useful during a consultation. We would also seek to detail whether

any specific laboratory testing was ordered following a consultation, given the observation about the separation of PAS and SystmOne in the first study. In addition, any alterations to medication will be recorded to evaluate whether the availability of complete prescription/medication result in timely alterations to medication and/or timely ordering of specific laboratory testing.

We undertook a thematic analysis, consistent with approaches used in case studies, and which we judged appropriate to the data we were able to collect. The following account accordingly presents our results by theme, starting with the process of accessing and sharing patient data, and moving on to information gathering, clinicians' use of the EHR network, and the use of paper records.

As the following detailed account shows, our expectations were only partially met. In particular, the distinction between patients registered with GPs who used SystmOne and those using EMIS were not as clear cut as we expected. The reasons why provided one of the key insights from the study.

### **3.1.17 The process of setting up a shared electronic health record**

As we noted earlier, SystmOne was already established locally at the time of the study. Each patient who arrived at the Diabetes Centre for the first time had to be registered, and in practice this involved a process of giving permissions for clinicians to access data entered in other places, *e.g.* clinicians needed to gain permission to access data collected by a GP. That is, the formal process of gaining consent to access personal data had to be undertaken at the point that a patient arrived in secondary care: there was no 'global' permission that allowed all clinicians to access a patient's data.

A doctor at the Diabetes Centre explained that if a GP surgery uses SystmOne, the GP can see patient information from all of the other healthcare services using SystmOne automatically. But in order for other services, such as the Diabetes Centre, to be able to access information about a patient from other services, a "share" needs to be set up on the system. It is the service from which the information is being shared that needs to set up the share. For example, for staff at the Diabetes Centre to be able to view information inputted by the GP, the GP surgery needs to set up a share with the Diabetes Centre for that patient. A member of administrative staff explained that she registered patients on SystmOne a few days before their first appointment at the Diabetes Centre and was prompted by the system to send a task to the GP surgery requesting them to share the patient's record.

### ***Gaps in knowledge and execution of this process***

Of the nine patients from surgeries that had SystmOne who were observed during this study, four did not have a shared record set up from the GP surgery to the Diabetes Centre. Two of these patients were from a GP surgery which reported that they used SystmOne to a very limited extent. They used it to look at tasks sent from other services but did not use it during patient consultations or to record any information. They used EMIS for this. Therefore, if the SystmOne record had been shared for patients from this surgery there would have been little benefit. The fact that the GP surgeries had not set up shares could be due to a breakdown in communication or could be because the patients' consent had not been gained to set up a share. It is known that at one of the surgeries, patient consent was not routinely requested for a share to be set up so in this case it must have been due to a breakdown in communication.

When a share had not been set up from the GP surgery, this was not always recognised and acted upon by staff at the Diabetes Centre immediately. One doctor expressed surprise at not being able to access the records of a patient whose surgery he knew used SystmOne, but did not take any action based upon this. One patient was observed to have appointments with a doctor and a nurse before the nurse at his next appointment realised a share had not been set up and sent a task to the GP surgery requesting one.

A member of administrative staff reported that she set up a share on SystmOne with the GP surgery when she registered a patient. According to a doctor at the Diabetes Centre, the GP can see the information inputted by other services, including the Diabetes Centre, by default. If this is the case, it was not necessary for her to set up this share. That is, some users of the EHR network did not fully understand the relationship between "sharing" and access to a patient's record.

As a result, the network was not being used on occasions when it was available for use.

### ***Patient consent***

In addition to the "sharing" requirement, there was also a requirement to obtain a patient's consent for a clinician to access his or her data. There was some confusion regarding the consent process. A member of administrative staff at the Diabetes Centre said there had been debate regarding whether explicit or "implied" consent was needed and she believed that there had been a range of opinions regarding this among senior medical and PCT staff. This person was unclear regarding the outcome of this debate. She said at the Diabetes Centre they request explicit consent. When a patient comes to their first appointment, they are given a consent form. The

member of administrative staff believed that this was to gain consent for the record to be shared from the Diabetes Centre to the GP surgery. If the patient did not wish to consent, she would remove the share that she had set up on the system between the Diabetes Centre and the GP surgery. However, according to a doctor at the Diabetes Centre, the GP can view information inputted by other services by default. He said that the consent form was used at the Diabetes Centre because there had been a lot of concern around consent issues when the system was implemented and because they did require consent to share information with other service providers such as district nurses.

Although they had a system to request consent at the Diabetes Centre, a member of administrative staff said that staff quite often forgot to ask patients to complete the form on their first visit. A podiatrist said that the podiatry service did not require patients to complete a consent form before they share their records on SystemOne. A GP said that his surgery does not currently ask consent from patients to set up a share to the Diabetes Centre or other services.

The suggestive evidence is that there were differing beliefs regarding the need for patient consent: there was no single protocol covering all clinicians and services. There was also some confusion regarding the process of gaining patient consent for different services to share information. When a service had a policy of requesting consent this was not fully implemented in all cases. The need for patient consent needs to be clarified and applied consistently across services using a shared record. The system of gaining consent may need to be simplified to make it workable in practice. A doctor at the Diabetes Centre explained that a system of "Enhanced Sharing" is being considered for the future, in which consent only needs to be given at one point in the system rather than separate services needing to set up shares.

### **3.1.18 Information gathering**

#### ***Comparison of information gathering by the doctors at the Diabetes Centre for patients with and without shared electronic health records***

Doctors at the Diabetes Centre were observed to use the shared record on SystemOne when it was available to access information regarding patient history and the management and treatment of their diabetes. They all read previous entries from the GP, practice nurses and Diabetes Centre staff in the Journal which suggests they found this a useful source of information. The extent to which they referred to other parts of SystemOne varied between individual clinicians. In some areas of patient care, including medication and blood pressure

management, there was some evidence that the use of the shared record provided more accurate and detailed information than other sources for the clinician to use in their clinical decision-making. In other areas, such as gaining information from other specialities, the evidence was more limited.

**Current medications:** When patients' records were shared from the GP surgery to the Diabetes Centre on SystmOne, the doctors at the Diabetes Centre looked at SystmOne to find out what medications the patient was taking. They looked at the Current Issues and Repeats screens or the Current Issues Overview on the Diabetes Summary. They sometimes checked this list with the patient to ensure it was accurate. When new patients' SystmOne records were not shared, doctors at the Diabetes Centre asked the patients what medications they were taking and the dosage. Some patients brought their current prescriptions or medication boxes with them to show to the doctor and some told the doctor what they were taking from memory. The use of the shared record on SystmOne enabled the doctors to have a quicker and more accurate source of information about the patients' current medications.

**Changes in medication:** There was some evidence that when patients' records were not shared from the GP surgery to the Diabetes Centre, the doctors found out about changes in medication from the patients. For example, a doctor asked a patient whether his dose of blood pressure medication has been increased as he previously advised. A patient told a doctor that he re-started taking medication for high cholesterol a month ago. When the record was shared from the GP surgery to the Diabetes Centre, the doctor was able to refer to changes in medication on SystmOne. For example, when a patient explained she had been given a new medication for digestive problems, the doctor referred to the Journal to identify what medication this was and also identified which medication she changed from. He referred to the Repeat templates screen to discuss a medication which the patient used to take which it would be useful for her to re-start. The use of the shared record on SystmOne enabled the doctors to have a more detailed and reliable source of information about medication changes than having to rely on the patient's memory.

**Blood pressure:** The use of the shared record gave the doctors at the Diabetes Centre better quality information regarding the monitoring of blood pressure over time. This information could inform decisions regarding medication and treatment.

For a patient with a fully shared record, a doctor at the Diabetes Centre brought up a graph of her blood pressure readings over a period of time on SystmOne. This included readings taken at her GP surgery. He could see from this that her high blood pressure reading

on the day of the clinic was a “blip” and that her blood pressure was generally coming down which is what they had been working on. For another new patient with a shared record, a doctor referred to previous entries in the Journal from the GP regarding the management of her high blood pressure and commented that her current reading was significantly better than previous readings at the GP surgery.

For a patient whose record had not been shared from the GP surgery to the Diabetes Centre, the patient told the doctor that the GP took his blood pressure 6 weeks ago and it was lower. The doctor could not view this blood pressure result on SystmOne. At a second appointment with this patient, the doctor looked at the stamped templates in the paper notes to compare the patient's blood pressure today with that at his previous appointment at the Diabetes Centre. He did not have access to the reading taken at the GP's surgery in between.

When the doctors had access to the shared record, they could access more accurate information about the patients' blood pressure readings over time to inform their clinical decisions.

**Information from other specialities:** On two occasions, doctors were observed looking up entries from Podiatry on SystmOne for patients whose records were shared. Doctors were observed on several occasions to ask patients without a fully shared record when their last Podiatry review was.

For patients whose records were not shared on SystmOne, information from other specialities was accessed by doctors at the Diabetes Centre by reading letters filed in the paper notes. This was observed for one patient who told the doctor he had had a transient ischaemic attack last year and for another patient who had seen an orthopaedic consultant. The doctors were able to access the relevant information from the paper notes in these cases.

Most specialities in the hospital do not use SystmOne, so even if a patient has an EHR, information from other specialities may not be available on the system and may need to be accessed in the paper medical records. However, it is sometimes possible to access this information from SystmOne via the GP surgery. A doctor was observed referring to the Communications screen on SystmOne and was able to view an endoscopy report and image which had been scanned into SystmOne. The doctor commented that SystmOne can be useful in accessing information via the GP in this indirect “triangular” way. He said the other specialist services would not send reports to the Diabetes Centre but would always send them to the GP so if they input or scan them into SystmOne, other services can access them.

**New patients with and without a shared record:** On patients' first appointments at the Diabetes Centre, doctors were observed to take a history from all patients regarding their diabetes and its management. The information they needed to gather from the patient varied, depending on whether they had a shared record to refer to. When there was a shared record available, the doctors referred to it regarding medication. They referred to previous entries made by the GPs and practice nurses regarding the management of health issues including the patients' blood pressure, weight and cholesterol readings over time. The doctors were observed having to ask patients who did not have a shared record when they had last seen their GP or practice nurse; how often they saw them and what medication they were on. They had to rely on the patient to tell them about management of health issues such as blood pressure.

**Differences between individual doctors in information gathering using the shared record:** The extent to which the doctors used SystmOne to refer to information for patients with a shared record and the way that they used the system, did vary considerably dependent on the individual doctor. In a consultation with a new patient, one doctor was observed to look at the paper referral form but apart from that referred exclusively to SystmOne for information. In his consultations with patients with a shared record, this doctor was observed to gather information from varied sources within SystmOne. He looked at the Journal to see previous entries from other professionals and at the Repeat and Current template screens at medication but he also looked at the Diabetes Summary and Family History screens. He used more advanced features of SystmOne such as its ability to create graphs showing weight, cholesterol and blood pressure readings taken over a period of time. These used readings taken at the GP surgery as well as the Diabetes Centre so were a good example of the use of shared records to inform clinical reasoning.

Another doctor was observed to gather information from a range of areas of SystmOne: the Diabetes summary, journal, current issues of medication and pathology report. He also used the communications screen to find a report from another specialist service which had been scanned into SystmOne by the GP.

A third doctor was observed to use SystmOne in a more limited way in a consultation with a new patient. He looked only at the Repeat templates screen regarding medication and at the journal entries to view previous entries from the GP surgery, information regarding a medication change and to try to find information regarding a scan and operation the patient had recently had. He did not look elsewhere on SystmOne to try to find this information. He used the paper notes extensively to refer to: looking for information from other specialties and to look at her Hba1c result and other

observations on the stamped template. When he could not see the stamped template in the notes, because it had been filed in a different section to usual, he went to ask the Health Care Support Worker where it was rather than looking at the results which had been inputted on SystmOne.

This difference may be due to a difference in training, confidence in using SystmOne or individual style. Doctors and nurses at the Diabetes Centre commented that more training was needed on the use of SystmOne. One doctor commented it was important so that it was used more consistently by different staff and so that they understand the system's capabilities.

### ***Differences between Professional Groups in information gathering using the shared record***

The doctors referred to SystmOne prior to the patient coming into the consultation and often referred to it during the consultation. When the nurses had a pre-arranged appointment with a patient, they were observed to refer to previous entries in the Journal on SystmOne before seeing the patient. One nurse was also observed to try to look at the Diabetes Education Template. However, on two occasions observed there were problems with the computer loading very slowly or freezing while the nurses were trying to access information on SystmOne prior to seeing the patient. On one of these occasions, the computer took ten minutes to load before the nurse could log onto SystmOne. She chose to look at a paper print out of the SystmOne record of her previous consultation with the patient which she had in the paper notes instead.

When they were asked to see patients during the doctors' clinics, the nurses were not observed to look at SystmOne before seeing the patient. They were not observed to refer to SystmOne during consultations with patients at any time. They explained that they did not use SystmOne during the consultation because the computers in the consultation rooms where they see patients are slow to load. Also, one nurse explained that because she has to log on using a smartcard, if she logs out of the computer in her office to log in in the consultation room, she loses the history of the patients she has seen that day. She finds this list an easily accessible way to go back to the records of patients she saw earlier. Before smartcards were introduced she could retain this information. After seeing patients during the doctors' clinics, nurses were observed to read the entry just written by the doctor in the consultation notes before recording their own consultation. Overall, the nurses were observed to refer to SystmOne less often than the doctors to gather information.

During the podiatry appointments that were observed, very limited use of the shared record for information gathering was noted. This

varied between individual podiatrists. Two podiatry appointments were observed in which the podiatrist had access to a shared record. During one of these appointments, the podiatrist looked at the patient's recent appointment with a Diabetes consultant on the journal, as well as at the previous podiatry entry. She said she found the shared record most useful when there were problems that she needed to look into and also found it useful to be able to check medication. She found the ability to store photos on SystemOne very useful as she could look at how feet had been previously, when another podiatrist may have been treating the patient, and the progress that had been made. Another podiatrist chose an option to look only at the history of podiatry appointments on SystemOne rather than at the full shared record. Another podiatrist who was observed at a GP surgery which did not use SystemOne, said that when a patient did have a shared record she sometimes looked at Hba1c and other blood test results, medications and progress on referrals. She would look at entries from the district nurse if she was sharing wound management care with them. She found the shared record particularly useful as a source to check information with patients who have dementia.

One GP appointment was observed with a patient who had a shared record. The GP did not refer to any paper records. He looked at the consultation notes from the patient's last appointment at the Diabetes centre on the journal. He discussed this appointment with the patient. He referred to the blood pressure reading taken at the Diabetes Centre and took the patient's blood pressure again. The GP said he found referring to the consultation notes from recent appointments at the Diabetes Centre useful so he can reinforce advice given at the Diabetes Centre rather than giving contradictory advice and if the patient is unclear about an issue, he can re-explain advice given at the Diabetes centre. He also finds it useful to look at recommendations for medication changes.

**Duplication of information gathering between different health professionals in the Diabetes Centre:** When patients were seen by a doctor and then a nurse during the same clinic at the Diabetes Centre, the nurses were not observed to refer to the record of the doctor's consultation on SystemOne before seeing the patient. They sometimes did not have access to the paper notes as the doctor retained these. They had a brief discussion with the doctor regarding the purpose of them seeing the patient and gathered information from the patient during the consultation. There was some duplication of information gathered by the doctor and the nurse. Nurses were observed to use a paper assessment form with patients and to repeat initial assessment questions which the doctor had already discussed such as the patient's medication; family history; diet; driving; hypos and recent eye tests. It was sometimes useful for the same area of

diabetes care to be discussed with the patient by the doctor and nurse if the subject was covered in more detail as a result or if the advice given was reinforced for the patient. For example, although the doctor and nurse both examined one patient's injection sites, the nurse looked at those on his legs which the doctor had not examined. The nurse also reinforced the doctor's advice that the patient's medication would not cause hypos. However, if the nurse had seen a record of the doctor's consultation, it could reduce the likelihood of her giving advice that was inconsistent with that given by the doctor. For example, a doctor was observed to ask a patient to record his blood glucose readings for the two weeks prior to his next appointment. The nurse saw him immediately afterwards, without reference to the doctor's advice, and asked him to increase his blood glucose testing and keep a record from the current time. If the nurses referred to a record of the areas of care that the doctor had just discussed, time may be saved as they would only need to repeat those areas of assessment that they considered necessary.

**Missing information:** Staff at the Diabetes Centre were often observed to look for information on SystmOne which was unavailable. This was usually because the patient was from a surgery that did not use SystmOne or because their individual record had not been shared. They therefore had to look for information in the paper record. However, another type of information was often missing from SystmOne. This was the pathology results. Doctors and Health Care Support Workers at the Diabetes Centre routinely looked at patients' pathology results. They were often not available to view on SystmOne. A GP also reported he was not always able to view pathology results on SystmOne at his surgery. Staff referred first to the Pathology Report screen on SystmOne. If the results were not available, the doctors at the Diabetes Centre and the GP could always access them on the ICE pathology system. This took a short additional period of time.

The Health Care Support Workers reported that they were not allowed to access the ICE system. They used to do so and were unclear why this was no longer possible. Health Care Support Workers were observed having to leave the consultation room in order to phone the hospital pathology department to find out when patients last had blood tests and what the results had been. This added several minutes to the consultation time. One Health Care Support worker explained that if she knew a Hba1c test needed to be done, she would do this at the beginning of the consultation because the results took about ten minutes to process. She would do the other tests and observations with the patient while the result was processing. If she had to phone pathology to find out if a Hba1c test was needed, it delayed the whole process.

It was unclear why pathology results were not being transferred consistently from the ICE system to SystmOne. Staff from the Pathology Department said they were transferred onto ICE and SystmOne as part of the same process but that results sometimes did not show on SystmOne until a few hours later than on ICE. This did not explain why they could not be viewed in SystmOne when the blood test had been done a week or several weeks previously. Whether the pathology results could be viewed on SystmOne was not related to whether their GP surgery used SystmOne or whether they were a new or follow up patient at the Diabetes Centre. Although Health Care Support Workers and doctors were aware of the inconsistent transfer of these results, the Diabetes Centre Co-ordinator was not aware of the difficulty. She had believed that the results were automatically transferred to SystmOne and available to view.

### **3.1.19 Recording on SystmOne**

Almost all recording on SystmOne by health professionals at the Diabetes centre was observed to be carried out immediately after the consultation. The doctors and nurses recorded their consultations in different ways.

#### ***Doctors at the Diabetes Centre***

At the Diabetes Centre, the doctors who were observed mostly recorded in the "Consultation notes" on SystmOne after the patient consultation. They wrote a detailed summary of the consultation including information regarding patient history, lifestyle, medication, test results, contact with other health professionals and management of diabetes. This appeared to have enough detail that another health professional referring to it could gain clear and accurate knowledge of what had been discussed and agreed in the consultation. They noted advice given and actions to be taken.

They were observed on several occasions to write information and advice in the consultation notes which was specifically intended for the GP to read and act upon. For example, a doctor requested the GP to refer the patient to an educational programme and several doctors were observed typing advice for the GP about future medication options and dosages.

Only one doctor was observed on one occasion to input an item of data in the current Diabetes templates. Another doctor commented, "I'm guilty of not using the templates." His comment suggests that there was an expectation for the doctors to use the templates. A nurse had commented that the information entered into the templates is Read coded so can easily be used for audit. This may be the advantage to using them rather than recording in free text in the

consultation notes. One doctor was observed using a new version of the template which he was piloting.

### ***Nurses at the Diabetes Centre***

Nurses at the Diabetes Centre record their consultations on SystmOne after the consultation with the patient. They were observed doing this immediately after the consultation although they said they sometimes have to do it later in the day if the clinic is busy. The nurses did most of their recording in the "New assessment" and "Education" Diabetes Templates. They made extensive use of these detailed and highly structured templates. These templates provide menus of issues relevant to the assessment and management of diabetes. For example: Injection sites, Hypoglycaemia, Diabetes and Monitoring, Diabetes and Long-term Complications, Insulins. Each of these is broken down into many sub-sections which have comments and tick boxes to complete regarding the assessment and management of that particular aspect of diabetes care. The nurses said that they found the templates were a good prompt for the areas they should discuss with patients and record. One nurse explained that nurses work through a process of identifying problems and planning care and that the templates offer, "pointers of care" – a checklist of what areas to cover and record. Colleagues can then see which sections of the templates have been completed for a patient and what still needs to be completed. They recorded additional information in the consultation notes on SystmOne. The information recorded in the templates can be viewed in the journal. It appeared to be a clear, accurate and detailed record of the consultation.

One nurse commented that the templates were time-consuming to complete. The time the nurses spent recording on the templates after a consultation with a patient was significantly more than the doctors spent recording in free text in the consultation notes. The approximate time that the doctors spent inputting in SystmOne after a patient consultation ranged from 2 to 10 minutes. The approximate time that the nurses spent inputting data after a patient's consultation ranged from 7 to 22 minutes.

One nurse commented that the Diabetes templates were not specific enough to the Diabetes Centre. Another commented that they were not set up well for nurses in some ways. She gave the example of blood glucose testing, which nurses do a lot of work around managing. She explained there is no template with spaces to enter individual blood glucose results for different times of day. There are only spaces to enter blood glucose ranges, which do not provide useful information about fluctuating levels of blood glucose. These are clinically necessary to improve blood glucose control. They currently have to record individual results in "Consultation notes" and when this information is transferred into the journal the font type

changes and affects the formatting so you can no longer see which reading relates to which time of day.

### ***New templates***

One nurse commented that she thought the care plan format being introduced in a new version of the templates would be useful as nurses currently have to complete care plans for particular issues on paper. A doctor at the Diabetes Centre was piloting the new Diabetes templates. These are based on the "Year of Care" model which is a care planning approach. They include goal-setting with the patient and identifying the methods through which the goals will be worked towards. He demonstrated how the templates are designed to enable goals and methods to be identified using the patient's own terms (in free text). These are then categorised for audit purposes. There is a box to tick labelled, "Method cannot be met" which is intended to be used to identify if a lot of patients have similar unmet needs so that this can guide commissioning on a local level.

### ***Podiatry***

The Podiatry service exclusively used SystmOne to record information. They recorded no information in paper records. They still used a paper referral system but apart from that, they used a totally paperless system. Podiatry have their own templates which the podiatrists said covered everything that was necessary. The "Treatment Episode" template is structured into "Subjective: Presenting Complaint; Objective and Action sections. There is also an "Annual foot review" template. They have sections within the podiatry templates for recording patients' medications and specialists that they are seeing. This is so they have a record of this information for patients who do not have a shared record on SystmOne.

The podiatry service uses the appointments system on SystmOne. When they use this at a GP surgery, even if it is a surgery that uses SystmOne, the podiatry appointments system is not linked to the GP surgery's system so they cannot use it to tell when a patient has arrived. A podiatrist reported that at the foot clinic at the Diabetes Centre, they use the hospital PAS system for appointments and also book it onto the podiatry SystmOne appointments system. A community podiatrist was observed booking a patient his next appointment on SystmOne while he was there and printing off and giving him the appointment letter.

### **3.1.20 Use of paper systems to refer to, record in and communicate with other health professionals alongside SystmOne**

The Health Care Support Workers always recorded the results from their assessment of the patient (weight, height, urine test result, blood pressure, blood glucose, Hba1c) in a stamped template in the paper notes and in the Diabetes data entry template. This is an example of duplication in recording. The Health Care Support Workers took the paper notes through to the doctor so they were always available for the doctors to refer to and record in during their consultations with patients. The GP referrals to the Diabetes Centre are received as paper copies so the doctors often referred to these prior to and during their initial consultation with a patient. All of the doctors were observed to refer to the paper notes to some extent. When patients did have a shared record, some doctors were observed to look at the information available on SystmOne regarding their diabetes management and treatment and information from other specialities. Others looked for much of this information in the paper records even when it may be available on SystmOne. This could be because the paper records were there for them to refer to and they have always done it that way; it could be a lack of conviction that the information would be available in SystmOne or a lack of training or confidence in where to look on SystmOne.

The doctors were observed to make brief notes in the paper record during the patient consultation and then write up the consultation more fully in the "Consultation Notes" on SystmOne after the consultation. After a clinic, the administrative staff printed out copies of the doctors' consultation notes to put in the patients' paper records.

When the doctors asked a nurse to see a patient during the same clinic, they were observed on one occasion to give the paper notes and referral to the nurse so she had these available to refer to during her consultation. On two occasions the doctor retained the paper notes so the nurse did not have these available to refer to during her consultation. The nurses used a paper initial assessment form in their first consultation with a patient and then transferred this information onto SystmOne. During follow up consultations they rarely made any notes during the consultation. The nurses all print out copies of their consultation notes from SystmOne to sign and put a paper copy in the nursing notes and the medical notes. This is because they are concerned that they need to have a signed copy of their notes to meet their professional documentation standards and so that other departments who do not use SystmOne have access to a copy of their notes in the paper record. The nurses had recently been instructed by a senior nurse that they must also print out any phone

contacts they have with patients that they record on SystmOne, sign the printed copy and put it in the paper notes. One nurse commented, "It's gone from a paperless system to creating more paper."

The question of whether a paper copy of documentation needs to be printed out to be signed has not been resolved consistently. The nurses believe they need to do this in order to meet their professional standards. One doctor and a podiatrist were observed stamping the hospital's paper notes with a printed message to look in SystmOne for the consultation notes and signing this. Podiatrists in community settings did not sign their documentation as they were using a paperless system. The GP who was observed did not print out his consultation notes from SystmOne to sign. He e-mailed a prescription to the pharmacy but said he would need to print this out to sign, for legal reasons, and the pharmacy would collect it from the surgery. The issue of the need to print out documentation to sign needs to be resolved across services and professional groups so that practice is consistent and unnecessary duplication of records is reduced.

Paper forms were used for a number of systems of communication at the Diabetes Centre. Doctors and nurses completed a paper form to go to the appointments clerk to arrange follow up appointments and the appointment was then made on the hospital appointment system (PAS). Paper forms were given to patients to take to the GP or hospital pathology department to have blood tests done.

It can be seen from this description that the staff at the Diabetes Centre continue to use paper records to refer to; to record in and to communicate with other health services alongside SystmOne. They refer to and record in the paper notes partly because other services do not use a shared record. Their use of the paper records sometimes appeared to be due to habit or lack of confidence in using the electronic record. Concerns regarding the need to have signed paper copies of documentation have not been resolved consistently across services and professional groups. The use of SystmOne and paper records results in duplication of recording which involves increased time and effort.

### **3.1.21 Verbal communication at the Diabetes Centre**

Within the Diabetes Centre, staff usually communicate verbally as this is a convenient and immediate way of sharing information. The doctors were often observed to ask the nurses to see a patient during their clinic if an issue arose that they wanted the nurse to follow up. For example, advice regarding insulin injections; insulin regime or supply of a blood glucose monitor. On two occasions a health care support worker was observed to go to ask the doctor if he wanted a

new Hba1c test to be done if she was unsure whether the last one was recent enough. A doctor was observed to go to check with a nurse if she had made a referral to the smoking cessation service that she had spoken to a patient about at his last appointment. A nurse went to ask a doctor for advice regarding why a patient's missed insulin dose had not adversely affected her blood glucose readings. This was an immediate and convenient way of gaining information. On one occasion a nurse was observed to send a task to a doctor within the Diabetes Centre to ask if he wanted a patient to continue on a medication. The doctor was not at the Diabetes centre that day for her to ask him in person.

Several staff were observed to phone other departments in the hospital when they required information: a Health Care Support Worker phoned the hospital pathology department to ask for blood test results; a nurse phoned the hospital pharmacy and went to collect a patients' medication for him; a doctor phoned the hospital drug information service to ask for advice regarding side effects.

### **3.1.22 Use of tasks and other forms of communication between the Diabetes Centre and GP surgeries**

#### ***Doctors at Diabetes Centre***

A member of administrative staff explained that after a clinic, the doctor gives her the paper notes for the patients they have seen during the clinic. If the patient is from a SystmOne surgery, she sends a task to tell the GP that the patient has attended the Diabetes Clinic and to refer to the Journal for the consultation notes. They have a list at the Diabetes Centre of which surgeries use SystmOne and the member of administrative staff said she knows which they are anyway. During the study, the administrative staff found that one of the GP surgeries which they believed used SystmOne fully, in fact only used it to look at tasks.

If the patient is from a non-SystmOne surgery, the administrative staff print out and send a copy of the consultation notes to the GP by post. A member of administrative staff said this is quicker than before they had SystmOne as they do not have to type up all the GP letters and get the doctor to check and sign it or to make any amendments before they send them out. Now they just print them out and the doctor signs them so they are often sent to the GP on the same day as the clinic. (Although the time between the consultation happening and the letter being sent to the GP has reduced, and the amount of time the administrative staff spend typing has also been reduced, it may be that the time spent by doctors recording on the system after a consultation has increased).

### ***Nurses at Diabetes Centre***

When the nurses had consultations with patients which were not during the doctors' clinics, different methods of information-sharing with the GP were observed. One nurse was observed to send a task to the GP to inform them that she had reviewed the patient and for them to see the journal for information. She also requested them to share the patient record with the Diabetes Centre. At an appointment over a month later, his record had still not been shared which suggests the possibility that this task had not been read. Two consultations were observed for patients from SystmOne surgeries during which the nurses recorded on SystmOne and but took no further action regarding sharing the consultation notes with the GP, *i.e.* did not send a task to tell the GP that they had seen the patient. One of these patients was from a surgery which only uses SystmOne to refer to tasks but does not use it during patient consultations so it is unlikely that the GP would access the nurses' consultation notes unless a task was sent requesting them to do so.

Following a patient consultation, another nurse planned to task the GP to read the notes if the patient was from a SystmOne surgery but said she would also print them out, send a copy by post and fax them a copy to make sure that they got them. She was not confident that they would be referred to on SystmOne. In this case, she wanted the GP to read the notes for a particular purpose: because she was requesting the GP to prescribe test strips and lancets for the patient. Another nurse said that she would send a task to a GP for a particular purpose if the patient was from a SystmOne surgery. In this case, it was regarding prescribing an insulin pen with a higher dose for a patient in a month's time. She said that if his surgery was not SystmOne, she would fax them to request this. The same nurse intended to fax a GP to set up a repeat prescription for testing strips for another patient. This was a GP from a SystmOne surgery but the nurse may not have been aware of this.

One nurse described an example of sharing information using tasks on SystmOne which she would not otherwise share with the GP. This was regarding making adjustments to insulin. She explained that this is done very regularly by the nurses and that she would send a task to a GP from a SystmOne surgery to let him know of an insulin adjustment whereas she would not inform non-SystmOne surgeries of this as it would generate too much paperwork. She also described a patient that she works with who she considers to be quite vulnerable. She and the GP have never spoken or met but send each other tasks regarding this patient and she feels they have a "good working relationship" through sharing information on SystmOne.

There was a lot of variation in how individual nurses used the shared record to communicate with the GP. One nurse described benefits of

using tasks to send additional information to GPs which she would not otherwise share and to build up good working relationships. Some nurses sent tasks to inform the GP that they had seen the patient, others did not, relying on the GP to look at their entry on the journal if they needed to. Some sent tasks if there was a particular purpose to communicate with the GP, such as requesting a prescription. However, the nurses were not always confident that the tasks they sent would be read so sometimes also faxed or wrote to the GP.

On one occasion that was observed, described above, a task that had been sent had not been acted upon, suggesting that it may not have been read. The nurses reported that there was one particular surgery where they believed tasks were not being looked at and another surgery where it was one member of staff's job to read the tasks so if they were away, tasks were not picked up. It could be useful to have a more consistent procedure regarding how SystemOne is used by the nurses to communicate with GPs. The current variation is partly due to the fact that some surgeries use SystemOne and some do not. It was not always clear if the nurses had accurate knowledge of which surgeries used SystemOne and to what extent. They were not confident that tasks sent would be read and so felt the need to use other forms of communication to ensure important messages were received.

### ***Podiatry***

One podiatrist said if she sees a patient at a surgery that uses SystemOne she knows the surgery staff can look at her foot clinic record on the journal if they require. She does not send them a task to do this. If she sees a patient at a surgery that does not use SystemOne, she prints out a copy of her foot assessment to be filed in the patient's notes at the surgery. A podiatrist working at a surgery which did not use SystemOne as its main system communicated with staff at the surgery in the following ways: She printed out a copy of her clinic list to give to the practice nurse on the day of her clinic. This has a very brief description of the purpose of the appointment. The nurse would discuss any patient from this list that she needed to, with the podiatrist. The paper list was then shredded and the nurse recorded any actions on EMIS. If the podiatrist and doctors or nurses at the surgery need to communicate at other times, they leave each other notes and memos. She said this informal communication worked well at this surgery because staff and patients know each other well but in other settings it would not be so effective. Although they are not a SystemOne surgery, one member of administrative staff can access SystemOne at this surgery so if they need more detailed information from the podiatry record, the surgery staff can still access it.

### ***Communication with the patient outside the Consultation***

One patient who was observed was directly involved in the use of SystmOne to manage her treatment. She had access to a list of her current repeat prescriptions online. When a medication was due to run out she could tick this and the medication was prepared for her by the pharmacy. This meant she only had to visit the pharmacy once to collect the medication rather than having to go in to order it too. She found this very convenient, particularly as she had multiple prescriptions so would need to renew something most weeks. She had also sent a request on this system to remove some medications from the list that she was not currently taking and this had been acted upon.

Most communication with patients outside of the consultation was done by phone. During many of the consultations with nurses at the Diabetes Centre they said they would phone the patient after a short period of time to check how they were progressing in testing their blood glucose, to find out what their blood glucose results were and in some cases, to adjust their insulin based on these results. The patients were given a booklet in which to record their blood glucose readings.

Could there be a role for SystmOne in this communication in the future? For example, could there be an option for patients' to record their blood glucose results online and the nurses to be able to access this? One patient who was observed requested a blood glucose monitor that he could download the results from to record them on his computer directly so he did not have to write them down in a book. Another patient brought a print out of a spreadsheet on which he recorded his blood glucose results to show to his doctor. So some patients were observed to prefer to record their blood glucose results on the computer. This could be a useful feature of a shared record. Many patients may be computer literate and may find this option convenient. It was observed that it was sometimes difficult for nurses to arrange a convenient time to phone patients if they were at work or college during the week.

In other cases, a phone call may be a more suitable form of communication: if the patient is not computer literate; because it gives the nurse and patient the opportunity to have a discussion which may be particularly important in some cases, e.g. a nurse was observed saying she would phone a patient in a few days to check how he was managing with his new injected medication. As he was nervous about injecting, a discussion with the nurse would be a more appropriate form of communication in this case.

***Could there be the potential for an electronic record to have an increased role in providing information and explanation for the health professional and patient?***

A doctor who was considering adding a new pain relief medication for a patient was observed to use the "Drug Information" section on SystmOne to try to identify whether it was contra-indicated with another of the patient's medications. He could see that it would be contra-indicated if it was prescribed for a different condition to the one he was planning to prescribe it for but the "Drug Information" section of SystmOne did not provide him with all the information he needed. He had to call the Hospital Drug Information Service for further information.

Doctors at the Diabetes Centre were observed to explain the benefits and side effects of treatments to patients in many consultations. They were observed to explain the evidence base for different treatments. One doctor wrote down a reference to a study for a patient to look up on the Internet. Another doctor showed a patient graphs on PowerPoint to explain his Hba1c level in relation to the national target and to explain weight gain in relation to different treatments.

### **3.1.23 Technical difficulties with the system**

In this short section we note a number of 'minor irritations' with the system, to make the point that apparently small details can have real effects on the ground. There were a number of technical difficulties with the use of a shared electronic record which were observed or reported by staff. The nurses reported that the computers in the consultation rooms that they used opened the system very slowly and so they did not use them during consultations. When a nurse was observed opening the system in one of these rooms, it took ten minutes to load. On other occasions, the system was observed to take several minutes to load in the nurses' office and when a healthcare support worker was opening it for use in the initial consultation room. The system was also observed to freeze on two occasions, once for a minute when a doctor was typing up his consultation and once when a nurse was referring to it prior to a consultation and had to close it down.

A member of administrative staff explained that when SystmOne is on, other programs on the computer, including the PAS system, close after a few minutes which can be very inconvenient. She said the IT department had told her this is because they both run using JavaScript.

The staff member's designation and location should be automatically recorded on SystmOne but the nurses at the Diabetes Centre said

there have been problems with some nurses' designations being changed to inappropriate titles, *e.g.* Public Health Professional. The location is recorded as Diabetes Centre but does not identify where this is based. Therefore the nurses said they have been directed to type this in manually and are typing it into the "Consultation Notes", an example of a workaround become routinised.

A nurse reported that the font type changes when information is transferred from the consultation notes to the journal and that this changes the formatting which can make it impossible to read some types of information accurately, *e.g.* blood glucose results.

A doctor was observed to print out the patient's current medication list from SystmOne to fax to the Drug Information Service. He commented that one of the drugs displayed on screen did not appear on the print out and added it by hand. He was sending the list to the Drug Information service in order to get advice about possible contra-indications before he started a patient on a new medication. If he had not noticed the missing medication and added it by hand there would have been a risk of contra-indications not being identified.

### **3.1.24 Concluding comments**

The system of shared electronic health records was partially implemented. Not all of the GP surgeries in the study area used SystmOne. Of these, fully shared records were not set up for all patients who used the Diabetes Centre so the system was not being fully implemented when it was available for use. This may be due to issues with communication and organisation. As many patients do not have a shared record and as most other secondary care services did not use SystmOne, it was necessary to use paper medical records alongside SystmOne in the Diabetes Centre. When a shared record was available, some clinicians used it extensively to gather information while others used the paper records to a greater extent. The use of paper records as well as a shared electronic record also resulted in duplication in recording. Some staff at the Diabetes Centre were observed to write in both the paper records and the electronic record or to print out their notes from SystmOne to file in the paper notes. The fact that some GP surgeries used shared electronic records while others did not also resulted in the staff at the Diabetes Centre using several systems to communicate with them: using tasks on SystmOne but also faxing and sending the GPs information. Some staff found sending tasks useful but others were not confident that they could rely on them being read and acted upon. It can be concluded that the fact that shared electronic records were only partially implemented and so were used alongside other systems of record-keeping and communication contributed to several issues including duplication of recording; different degrees of use of

the shared record by different clinicians; and a lack of confidence in the reliability of the system for communication.

For those patients who did have a shared record, health professionals were observed to use it to refer to previous entries from staff in primary and secondary care. Doctors at the Diabetes Centre were observed to use it to gather information regarding patient history and the management and treatment of their diabetes. There was some evidence that their use of the shared record enabled them to access more accurate and detailed information regarding areas such as medication, blood pressure and contact with other health professionals which could inform their clinical decision-making. Potential benefits of the use of the shared record for information-gathering included different clinicians giving consistent advice and not repeating areas of assessment unnecessarily. When practical constraints occurred, such as difficulty in accessing SystemOne on a computer, these benefits could not be obtained. Staff were observed to record their consultations in different ways on SystemOne: some used the Consultation Notes and other used the templates. Both methods appeared to produce a clear and detailed summary of the consultation. Staff at the Diabetes Centre were observed to record advice in the shared record that was specifically intended for the GP to read and act upon such as requests for referrals to other services and advice regarding medication. They did use the shared record and tasks to communicate with GPs, despite some concerns about relying on this system of communication. With regard to sharing information with GPs after a patient consultation at the Diabetes Centre, the use of SystemOne was reported to be quicker than the previous system of typing letters, even when notes had to be printed out and sent to GPs who did not use the system.

When there were issues or problems with the use of the system, these were not always addressed across services, so the problem was not resolved or inconsistencies emerged, echoing the local fragmentation described in section 2. An example of an unresolved problem was that pathology results were often unavailable on SystemOne but this issue had not been effectively communicated between different services in order for a solution to be worked towards. An issue which was addressed inconsistently across services was that some staff groups believed it was necessary to print out notes in order to sign them to meet their professional standards of documentation while other services did not do this. The question of whether documentation needs to be signed is an important issue which needs to be addressed consistently across services if implementation of a shared electronic record is intended to replace paper records. There were differing views and practices across services regarding gaining patient consent for their records to be shared. This is an important ethical and legal issue to be considered

in the implementation of shared patient records and needs to be clarified and applied consistently across services.

Overall, for patients who had a shared record there was evidence that clinicians used the shared record to gather information from previous entries by other health professionals. This sometimes gave them more accurate and detailed information than would otherwise have been available to use in their clinical decision-making. However, the fact that the system of electronic shared records was only partially implemented meant that paper records had to be used alongside it and there was a lot of inconsistency in how the different systems were used for information gathering, recording and communication. Where there were issues and problems with the use of the system, these were often worked around on an individual or local level and not resolved consistently across services.

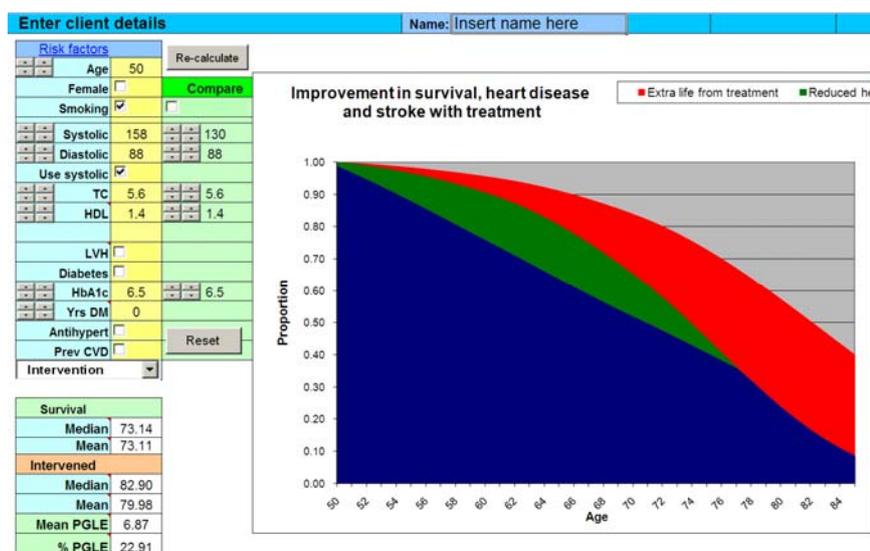
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## Case study 3: Laindon Model

The Laindon Model is a Markov-cycle-tree model of survival given relevant risk factors including smoking status, blood pressure, cholesterol and diabetes. It was developed in Excel and runs in real-time. It was designed for use in consultations by health professionals and to be simple and easy to operate. A GP can input basic patient data and show a prediction of mortality, and how this prediction will vary with certain choices, e.g. giving up smoking or taking statins (see Figure 3).

It was developed by a General Practitioner in Essex (Dr Chris Martin (CM), a co-author of this report), for use in his own practice initially, and then as a tool for more widespread use in the NHS. Given problems in data collection (see section 5.1 below), the account here is based on CM's own experiences and thus we recognise it predominantly reflects one perspective, limiting the generalisability of the results.

### Screenshot of the Laindon Model



### Background

In the early 1990s, CM had become uncomfortable with the existing categorical approach to cardiovascular risk using single cut-off values that were not sensitive to other risk factors. He created a spreadsheet application to aid treatment decision that, by 1995, used the Framingham equations. [148] While this approach felt like a useful step forward, there were still some difficulties. The spreadsheets did not take account of competing causes of death and

estimation of interventions by simply applying risk ratios independently was flawed. Consequently, in 1998, a tool modelling cardiovascular disease but integrated into all cause survival was developed. This was a popular tool in his practice and was adopted by other GPs locally on an informal basis.

The tool was not distributed widely, as the author had concerns about the unproven validity of the tool and possible liability. While the model seemed, on the face of it, to give sensible results consistent with experience, there had been no formal test of its accuracy. Furthermore, the risk of smoking was underestimated by the tool as only cardiovascular disease was modelled.

CM decided to pursue the development of the model more vigorously. In 2000, he became a part-time MSc student at CHIME and there developed a further version that modelled a series of cancers and smoking-related respiratory disease. This was then evaluated against prospective longitudinal cohort data and performed well. [149] It was not until this point (2002) that CM was satisfied enough with the validity of the model to allow its widespread use. Funding to cover the MSc and the opportunity cost of lost income was sought, with £13,000 a year won from the Eastern Region NHS Enterprise Award Scheme. This made up a quarter to a third of the lost income over the course of three years. After that, an additional £10,000 was given by the Essex Primary Care Research Network.

Further development of the model became difficult. There was no indication of uncertainty in the output. A decision was made to pursue a stochastic implementation of the model. After two years working alone, CM returned to CHIME as a part-time PhD student, while continuing to work as a GP. The experience of being a GP and direct involvement in the process of care contributed greatly to the development of the model, yet it also limited opportunities for funding and other support. Most sources of funding were not accessible by part-timers, and there were sometimes maximum age limits. Consequently, between 2005 and 2008, the entire cost was born by CM.

Possibly as a result of media coverage (e.g. [150]), in 2008, a catastrophe risk modelling company interested in the life insurance and pension markets recruited CM to further develop the model, initially part-time but later full-time.

The intended market for the model is now the longevity risk experienced by pension funds, where the increase in life-expectancy over time outstrips the best estimates of life-actuaries in the past, with the result that the reserved funds prove inadequate to support the payment of annuities and, in particular, the defined-benefit schemes that were popular until recent years. In addition, life underwriters can potentially gain a competitive advantage by more

accurately modelling the risk of death in insureds. A more recent model is described elsewhere. [151]

Within the current research project, we had sought to evaluate use of the Landon Model in a primary care practice. Permission was obtained for an observational study from the local NHS Research Ethics Committee. However, there was a delay of over 6 months in subsequently obtaining local R&D approval, due to failings in the R&D office. This delay and the shift in the project away from a clinical setting meant that the planned observational work was no longer possible.

## ***Adoption and spread***

As part of the contractual arrangement of the research funding in 2000, exploitation of any intellectual property rights had to be pursued. An agreement between the NHS Innovations Hub and CM was reached dividing the revenues in proportion to cost borne. A market evaluation was performed with an estimate of the potential pricing made. The model was advertised through the Innovations Hub.

While uptake in terms of purchases of the model was limited, public interest was considerable in terms of media coverage. The model was adopted by a number of GPs and colleagues in the South West Essex area by direct contact with CM. In 2004, Thurrock PCT purchased a site wide license. The software was given to every practice and a series of three training sessions was arranged to which all practices were invited. Approximately half of practices were represented: more than half were GPs, two were nurses and one was a receptionist. A few other practitioners purchased licenses via the Eastern Regional NHS Innovations Hub including GPs, a private physiotherapist and a cardiologist.

Uptake of the model was disappointing and, subjectively, appeared to occur where there was close contact with the model in the working environment. Colleagues in the practice, neighbouring practices and practices joined by registrars leaving the practice became regular users. Little feedback was received from the PCT-wide license on who had adopted the tool, who had tried it out and not adopted it, and those who had not tried it at all. Feedback from some users was received where problems had occurred. These related to the operation of the software. It was written as an Excel spreadsheet and this proved less than ideal as a medium for disseminating a product like this. Protection of the intellectual property required password protection of worksheets in the spreadsheet, which required the application of macros. If macros were disabled by default on a user's machine, a message explained what they needed to do to enable

them. Some organisations do not permit enabling of macros, and some users were not sufficiently familiar with Excel to be able to do this.

Some users had difficulty installing the package and requested help via the Innovations Hub. This was a slow and unsatisfactory experience for all but the most determined users and illustrated the importance of support as part of the package in purchased software. Other factors may create barriers to adoption of new methods and technologies. The 2003 General Practice contract reduced interest in professionals. Targets for payment were set according to values of blood pressure and cholesterol and not according to global risk making the exercise of risk assessment less attractive for GPs. The consultation time that could be spent on risk communication was vired towards the meeting of contractual targets.

### ***Continued development***

Some development funding was received via the NHS primary care research funding that emerged at the end of the 1990s and in the form of an Eastern Region Enterprise Award. Despite this being comparatively generous in historical terms, it covered only a fraction of the real cost of the project. In recent years, the funding environment has become more severe for this kind of 'own account' research. NHS research funding is more focussed on its defined research priorities. Individual clinicians with innovative projects that do not conform to the conventional format of clinical research have a difficult task finding research funds. This is not necessarily a bad thing but raises questions about the role of NHS research funding as opposed to development funding. It is inevitable that innovative ideas on how to improve decision making, delivery of care, service operation or other facets of clinical practice will be generated by individual professionals and employees. Many of these ideas will be of limited value and are unlikely to survive the process of trial and error. However, without the existence of an environment that encourages, or at least does not militate against, innovation, most or all of the worthwhile ideas will not be implemented and the benefits not realised.

Within the NHS, despite the rhetoric of initiatives such as *Shifting the Balance of Power*, [152] the reality has been a considerable increase in centralised control in clinical care and research governance, and while this has had advantages in standardising practice and pulling up inadequate practice in places, it has also had the effect of disempowering professionals and has limited their ability to innovate.

We suggest that the general mind-set of the front-line practitioner has shifted from being focused on managing and developing their

role and being in control of their working environment to one of conforming to centralised definitions and standards and delivering on specified targets. Again, while this has its advantages in standardising care, it may discourage innovation. The development of novel ideas and products entails a certain amount of risk. Many, probably most, ideas will not be successful. A reasonable parallel would be the development of new drugs in the pharmaceuticals industry where very large numbers of potential treatments are trialled before a successful candidate is found. The willingness to pursue a development process with such a high attrition rate requires a highly entrepreneurial spirit that may not be compatible with the delivery of public services which are more focused on proven processes, procedures and products.

In some ways, the private sector may be more suited to the development of innovative ideas. This particular project has been greatly accelerated by interest from the life insurance and pensions industries. Projects of this nature require an organisation that is accustomed to making investments that meet the true cost of development and, at the same time, are willing to accept the risks of failure. The resulting product will be owned entirely by the investing organisation, and while the target market will initially be the finance industry, there will be the opportunity for the technology to trickle back down into healthcare.

## ***Conclusion***

The development of the Landon Model illustrates some of the historical problems with technology development, adoption and dissemination in the NHS, as highlighted by others. [153,154] Despite working well locally, there was little support to promote the system more widely. Key developments in the technology have instead come from serendipitous events and, most recently, the private sector. The most recent development work has been driven by a shift away from frontline healthcare.

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## Conclusion/recommendations

Policy documents and much of the literature invest great hope in e-Health systems to deliver a modern, high quality, safe and efficient healthcare service. Information and communication technology has and can deliver many benefits in healthcare, but realising these benefits has repeatedly proven to be more difficult than expected. e-Health remains a fast-moving discipline and much has changed since this research was originally commissioned. A change in the UK Government has led to new policy, while technological development marches on, for example in the increasing focus on the use of mobile phones and other mobile devices in healthcare.

We have presented above a set of distinct but related pieces of work. In particular, there was a substantial new synthesis of the diverse literature in this field (published in longer form as [11]); there was a set of overlapping “mini” case studies describing the organisational workings of an anti-coagulation service spanning primary and secondary care (some of which has been published in longer form as [100]); and there were two sequential large observational studies on diabetes services across primary and secondary care (partly published as [155]). We sought to apply an iterative hermeneutic circle [156] in which each part of the research adds to the overall picture, but is also interpreted in the context of that overall picture. This section seeks to describe that which is generalisable in terms of factors that facilitate or hinder the uptake and acceptance of information and communication systems in healthcare.

We recognise e-Health systems, such as electronic healthcare records, as being socio-technical. That is, the technology and the organisational context are inextricable. We adopted a flexible and pluralistic methodological approach, rooted in ethnography, in order to learn from organisations using information systems in two services. We also looked at a broader and more diverse literature using a novel systematic reviewing approach.

Our work was exploratory in nature, rather than seeking to test any hypotheses. As such, there was no presumption that the different pieces of work would or would not produce a consistent set of answers. However, the value of case studies lies in the generalisability of the findings and it was our stated intention in our initial protocol “to identify generic factors that facilitate or hinder the uptake and acceptance of information and communication systems by both patients and healthcare professionals.” Policy makers, healthcare staff and fellow researchers have a reasonable expectation of such “actionable” knowledge [157]. How can we design e-Health

systems in organisations so that they work best: have the most impact on patient care, are most efficient and are safe?

But actionable knowledge should not be confused “with prescriptive statements [and] solutions to immediate problems” [158, p. 10]. Conceptual underpinnings and methodology are just as valuable. The research has led us to retreat somewhat from the determinist language of “generic factors” and to offer also some theoretical and methodological observations.

Many papers in the systematic review, particularly the literatures with a positivist grounding, do give concrete recommendations: introducing the EPR in an organisation or organisations requires, for example, a well-articulated vision and strategy, strong leadership, adequate resources, good project management, an enabling culture, effective communication, and attention to human resource issues. None of our data collection contradicts those and they remain the beginning of the approach needed. However, much of the literature and our own work demonstrate the overriding contingent nature of e-Health systems. Such systems are introduced and function within complex existing networks. We can see a recursive relationship – whether one uses the language of technology co-evolution or structuration theory or ANT – between software and hardware on the one hand and users within organisations on the other. This contingency and recursive nature means that the same system introduced in apparently similar hospitals can have very different effects. Complex interdependencies, inherent tensions and high implementation workload should be expected.

Our case studies and literature review agree on much. The development of e-Health systems can reflect past and ongoing contingencies. There are unavoidable pressures for the localisation and fragmentation of services. There is always a co-evolution of the service and the technology, including the use of workarounds. Individuals working within systems can be unaware of how others use shared technology. Definitions of success reflect different perspectives and may evolve over time. Electronic records are not passive containers for information, but actively shape and constrain care.

The persistence of paper in many settings should not be a surprise, although we saw some services that had moved to an almost paperless system. There are tensions around the role of the record. Electronic record systems can result in reduced use of free-text (compare [159]). Communication is a key need for integrated services and we would encourage a greater focus on communicative features in healthcare systems, but communication requires the right organisational context too.

e-Health is often promoted for its contributions to patient safety and improved quality of care, but the evidence base for improvements is weak. We saw that risk management methodologies (task analysis, prospective hazards analysis, retrospective hazards analysis) can be illuminative for studying e-Health technologies and the services using them. However, these methods were not individually reliable.

Generally, healthcare staff were flexible in dealing with these systems, developing workarounds as necessary, but these increased localisation. We recognise the importance of 'hidden work', including by administrators, to keep services running smoothly.

Whether dealing with a novel service using bespoke software and a bottom-up approach, or an off-the-shelf system supporting existing services, organisational boundaries remain problem areas and threaten the provision of high quality care. Organisational boundaries are a particular issue when 'interessement' has failed, and finance structures can be a particular barrier.

GPs have a central role in integrated services. GPs are also generally among the most advanced in using computer systems in the NHS, so their role in e-Health systems seeking to achieve integration is even greater. NCLASPS recognise the key role of GPs, but has an ongoing struggle to involve them. In the SystemOne context, it is notable how, in one case, a hospital doctor accessed results from other hospital departments via the GP record.

Many studies reported in the literature are of implementations. A key departure for us was to investigate systems that are already in place, already part of the messy and *ad hoc* nature of health care. [160] The observation from practice is that implementation is not a once-and-for-all event: implementation is continuous, with new electronic services being upgraded and extended on a regular basis.

We have sought to illustrate some of the richness inherent in functioning e-Health systems. Aspects of individual elements of the research presented will, we hope, resonate with others designing, running or researching other e-Health systems. One of our initial aims was to inform the implementation of Connecting for Health. Some of the authors of this report also worked on an evaluation of Connecting for Health [141, 161], which draws on some of our work here (the literature review) and which offers similar conclusions. If we are to draw out a central conclusion, it is perhaps that there are no easy answers. To quote the title of one of those reports, on the Summary Care Record, the devil is in the detail. [141] Policy makers, healthcare staff and researchers need to consider contingencies, they need to consider the work required or done unseen to make e-Health systems function well, and they need to bear in mind the context around them and how it impinges. The technology cannot be isolated from the broader context. A key difference with the Connecting for

Health evaluation is that the systems under study here were mostly homegrown and sought to develop from the bottom-up within a broader environment designed for the National Programme for IT.

Part of what we recommend is about praxis. You cannot set up a system and then leave it. There needs to be an ongoing effort. That praxis is about communicating with stakeholders on an ongoing basis. It can also include, as seen in the NCLASPS example, the role of ongoing action research.

If we have not supplied all the answers, we hope to have explicated better questions. We have reviewed and explored a variety of methods that can be used either in a pure research context or as part of local improvement activities.

### ***Methodological limitations***

This programme of research was designed as a set of case studies and, within those, additional “mini” case studies focusing on particular issues. We sought to capture a rich description of the messiness of actual, daily practice. We intended an in-depth and valid look at our e-Health systems, based on stakeholder involvement. However, we recognise that by focusing on a few settings and working closely with the clinical teams involved, we were taking a different approach to many studies that prioritise objectivity, generalisability and a quantitative approach. Our reasoning for this approach is laid out in the meta-narrative literature review (section 2). We see different methodological approaches as being complementary. A full understanding of the field will emerge from multiple studies, not any single programme of research.

In this context, we recognise the methodological limitations of our approach, particularly in two aspects: objectivity and sample size. We contest that there is a value in working closely with clinical teams, both in practical terms of carrying out the research and because it allows the researchers to better see and understand real practice. We saw ourselves and the clinical teams as co-producers of knowledge, [91] rather than as researchers and research subjects. There is a threat, however, of the researchers becoming too tied to a team’s own perspective and privileging it above that of other stakeholders or what the data say. In sections 3 and 5, the research team (and co-authors of this report) explicitly included involved healthcare professionals and otherwise previously involved academics. This was a particular issue in section 5 given the problems with data collection. As such, we recognise the possible biases introduced. We sought to combat these through the reflexivity, as favoured in qualitative research, [90; 162] and through ensuring we captured the opinions of other stakeholders.

While we were able in the NCLASPS setting to use audit data covering more than 1000 patients over an extended period, most of the data collection concerned the actions of those employed in health care. The more in-depth approach based on interviews and observations is more manpower intensive, producing a smaller sample size than an equivalently resourced quantitative study. Moreover, within our clinical teams, there were only a small number of involved personnel, even fewer at the senior levels. For example, in the task analysis study described in section 3.5.1, we interviewed the entire team working in Barnet: five pharmacists and two administrators. A larger sample size was not possible (with the task analyses specific to the Barnet arrangements). Given these smaller numbers, we are careful not to draw quantitative conclusions from our work.

Given these limitations, while we believe we have achieved high validity in terms of describing a number of settings, we caution about the generalisability of this work. The results have to be interpreted within the broader literature, which we reviewed in section 2. Moreover, e-Health systems are diverse in nature. As discussed in 2.3.1 with respect to the EPR, but as we believe applies more broadly across all e-Health systems, we reject a positivist, determinist view of technology, the idea that specific properties which will, if implemented properly, more or less predictably yield improvements. Rather, we argue that the impact of an e-Health system cannot be reliably predicted from its essential properties, but rather that systems are fluid and flexible artefacts which 'act' in situated and constantly changing contexts. By this logic, while our own data collection and the broader literature can suggest success factors, applying them in a new context can never guarantee success. Care must always be given to the ongoing process, or praxis, of use. Moreover, we should recognise that even definitions of success are fluid [82,83] and, ergo, not presume that our understanding of success at any time is the same as previously or the same as held by other stakeholders.

While our methodological approach was based on the section 2 literature review, we recognise that that review in itself uses a highly novel approach to systematic reviewing. This is, to our knowledge, only the third meta-narrative review conducted and the review challenged our own ideas of the method. We hope that the proof of the pudding is in the eating and that the review's results are sufficiently valuable so as to prove the method's validity, but we acknowledge that the method may be considered unsystematic by some.

## ***Applied learning for NHS practice***

The late computer scientist, Roger Needham CBE, once said, "If you think technology is the solution to your problem then you don't understand technology and you don't understand your problem either." In looking for generic factors about successful e-health systems, we have come to the conclusion that sometimes we do not understand the problem the e-health systems are trying to solve.

The generic factors are systems that work, within projects with successful interestment. However, what works depends very much on context. The story is more complex than you think, and the story lasts longer than you think. What is misleading are the generic assumptions, e.g. of improved safety. We offer a set of methodological and theoretical tools to allow future researchers and practitioners to better understand their problem and their technology.

We suggest the following generic factors that those working in the NHS should bear in mind:

- a) The electronic record is not merely a container for facts that can be readily agreed about a patient. Records (in whatever medium) support work. Thus, different work may call for different records, and understanding the work will help improve design of the records. Entries in a record reflect their local context. From section 2 and particularly [67].
- b) Communication between healthcare professionals is often more than just an exchange of unambiguous information. There is an important human role in re-contextualising knowledge for different uses. Technology should focus on better supporting communication rather than record keeping alone. Patients move between islands of good practice. From sections 2, 3.5.3, 3.5.5, 4.5.4-6 and also [5,41,43,46,74].
- c) There is considerable implicit knowledge in the staff (healthcare professionals or administrative staff) of any team. Capturing this knowledge is not easy, but overlooking its importance is, particularly the further away those commissioning or designing a new system are from those who carry out the work. From sections 2, 3.5.3 and 4.5.1.
- d) Successful interestment is at the heart of successful e-Health systems, and those involved in e-Health systems should consider barriers, including organisational and financial, to such. Policy makers may find it valuable to consider how the design of the healthcare system and IT strategies impacts on the ability of those developing, deploying and using e-Health

systems to achieve interengagement from other potential stakeholders. From sections 2, 3.5.6 and 4.4-5.

- e) Smaller, more local systems may be more effective than large ones. Big is not always beautiful and national strategies should not overlook homegrown systems, nor the effects they have on them. Policy decisions in one area can readily have unexpected results elsewhere. From sections 2, 3.5.6 and 3.6.2; and also [22].
- f) Promises of seamless integration between systems are unlikely to be delivered. We need to recognise the limitations of any technical system compared to the flexibility of human work. [41] Recognising limitations should produce more realistic expectations and the disappointments that have arisen with certain e-Health programmes. [161] From section 2 and particularly [71,73].
- g) Many of the greatest benefits from e-Health systems will come in terms of secondary work and these may be at the cost of less efficient primary clinical work. From section 2.
- h) Technology alone cannot be used to drive changes in how healthcare professionals interact with each other or with patients, but it can support such changes. From section 2.
- i) Paper offers its own affordances and may never disappear. Use paper where it works and recognise the ongoing use of paper in your system. From sections 2, 3.5.2, 4.4.2 and 4.5.2.

What these often require from those in NHS management roles is a change in expectations. Benefits of e-Health systems may be subtle and contingent, and they require ongoing management, not merely good implementation at the start.

However, in looking for generic success factors, we also conclude the importance of local and specific success factors. The message of the sociotechnical approach that we believe e-Health requires is that the context is as important as the technology.

While our two key settings, diabetes and anticoagulation services across primary and secondary care, are significant ones for the NHS, we cannot provide detailed local success factors beyond these. What we do, however, offer a broader readership are theoretical and methodological tools that can be applied in other settings. While the language of some approaches may be daunting for the newcomer, as it was for us initially, we hope section 2 serves as a useful introduction. Many of the approaches laid out there are not complex to use.

Sections 2.2.2 to 2.2.9 lay out the various disciplinary perspectives explored, while section 2.3 offers a set of conceptual questions to

consider when assessing a system. Chapters 3 and 4 explore the application of different methods to our two main contexts. Specific sections therein will be of particular relevance in different circumstances, e.g. the medicolegal perspective in section 3.5.4 or the issues around partial implementation of a system discussed in section 4.5. However, to illustrate how we suggest our findings can support applied learning in the NHS, we have chosen an exemplar of patient safety.

### **3.1.25 e-Health and safety: lessons learned**

We identified patient safety in our proposal as an area warranting a particular focus, and we use patient safety here to illustrate some themes running through our diverse data collection.

e-Health systems have long been seen as core technology for a safer health system [58] and there are high levels of expectation apparent in the literature, [21] particularly in policy documents (e.g. [163]). Improving safety is assumed to save money, which is then used as justification for IT costs. Our literature review found numerous papers littered with assumptions concerning the safety benefits of electronic patient records.

Where research has been carried out, there has often been a focus on medication errors, i.e. an issue that is easily measurable and fixable. There is less work described on new risks introduced by new systems. [58,93,164,165] The disproportionate amount of literature on the benefits that have been realised comes from a small set of early-adopter institutions that implemented internally-developed health information technology systems. These had considerable expertise and implemented systems over long periods in a gradual, iterative fashion. [166]

The financial context can create external factors promoting technology that are in contrast to an evidence-based approach (e.g., [167]), and the introduction of technology can have unexpected costs implications. [168]

In this context, we used a number of standard risk management methodologies in our anticoagulation case study. These produce two sets of conclusions.

First, from a methodological perspective, it proved possible to apply standard risk management methods to a socio-technical context (sections 3.5.1-3.5.3). We received good feedback on the process from clinical staff. Even in a context where the clinical and software team were believed to work together closely, these methods proved valuable in promoting communication between the two groups (section 3.5.2). However, they need to be used with care. Individual

methods are not necessarily comprehensive and a range of methods is advised (sections 3.5.1-3.5.3).

However, a key methodological issue arose, that of scope. Scoping decisions were very significant determinants of what was found. A natural tendency to look at the service separate from its broader context proved dangerous. Retrospective critical incident analysis was more successful in identifying problem areas because it is less sensitive to a pre-defined scope (section 3.5.3). Considering the safety of a system requires thinking beyond the technical aspects, and beyond the service boundaries.

Secondly, in terms of success factors, many of the threats to patient safety that arose, as also in the diabetes case study, were around communication rather than record keeping. We argue for a greater focus on technology that supports communication (sections 3.5.3, 3.5.5, 4.5.4-6), echoing earlier work. [5,41,43]

The routinisation of workarounds was identified as an area of possible risk and we conclude the importance of proactive methods to question routine behaviours (sections 3.5.2 and 3.5.6).

Again something seen in both the main case studies, and the literature review, is this unavoidable tension between standardisation and the contingency of local needs (particularly section 3.5.6). This tension requires active management. Within NCLASPS, the Clinical Governance Board as an organisational structure provided a context in which that could happen. As with prior research, [22,130] systems developed 'bottom-up' may have an advantage here, but we also found that even bottom-up systems still have to work within a broader context. [131] Getting that broader context right, particularly the funding models, is important. [142]

Thus, NHS managers and clinician-managers need to move beyond assumptions that implementing e-Health systems will necessarily and uncomplicatedly improve patient safety; and beyond a focus on implementation as a one-time process. Instead, there is a need for the ongoing management and governance of e-Health systems to realise their potential benefits and to overcome failures of interestment. This is what we mean by a focus on praxis. Such might involve a range of formal risk management tools (critical incident reporting, prospective analyses), but it is also about asking for the right system revisions. The unexpected effects of management decisions a long way from an e-Health system should be considered.

Much of this is readily achievable, but there was some evidence of insufficient knowledge and skills within Trusts (for example, in the contract negotiations around NCLASPS) to best support e-Health. At present, plans to abolish PCTs and replace them with smaller GP

commissioning groups are still being formulated. Without knowing the nature of new structures, we cannot make specific recommendations in terms of roles, but there is a danger of this problem being magnified. The NHS should consider how to provide support where insufficient local expertise is available. We note that the NCLASPS CGB performed well by having both clinical leads and commissioners represented from PCTs.

## ***Recommendations for future research***

As well as recommendations for practice, we also have suggestions for future research in this area. We found the meta-narrative approach useful for drawing attention to overlooked theoretical and epistemological perspectives on e-Health, and this work is now being extended by others (e.g. [169]).

The evidence suggests that future research on e-Health systems should not presume a simple, causalist approach (technology X will reliably produce outcome Y). The knowledge base continues to develop, but we also suggest that parts of it have been systematically overlooked. As discussed at greater length in [11], our findings suggest several areas in which further research is likely to add significantly to the evidence base. Some of these would benefit from secondary research, since the literature already contains valuable findings.

First and foremost, there is an agenda for theory building. It is striking how the alternative approaches to research on the EPR in organisations described in the review and used in our data collection have developed in parallel rather than in dialogue with one another. There is scope, we suggest, for developing creative theoretical and methodological approaches by blending existing theories, e.g. [131].

Second, there is an extensive primary research agenda on what has been called “appreciating situated micropractices” in different clinical settings. [64, p.444] Even with our own observational work, the research conducted to date on the microdetail of collaborative clinical work from an ethnographic perspective comprises a relatively small number of studies. There is much we do not yet know, for example, about what “working knowledge” is or how it is produced in different clinical settings and specialties. [62] The “hidden work” of those close to the patient (e.g., nurses and administrative staff) should be a particular focus in this programme. There is much room for a detailed study of the communicative dimensions of collaborative clinical work, including how staff contextualize and prioritize knowledge for shared use. Our work suggests that there is scope for the greater use of risk management methods in health informatics, but also that these are not individually reliable.

Third, a systematic review is needed on how information systems in health care and comparable settings might be (co)designed in the workplace (i.e., on the proactive application of interpretivist and recursive approaches to maximize the sociotechnical fit of such systems). This literature was partially covered in our review, but we suggest there is a need for a more technically oriented review by an interdisciplinary team with representation from software engineering, design and CSCW, as well as sociology and clinical disciplines. Important insights are likely to be drawn from the computing and design literatures beyond the health care setting. There is also scope for additional primary studies in this area. In our review, we found very few published studies in which a sense-making or soft-systems approach was used prospectively in action research or comparable participatory designs. We recommend that careful thought be given to developing hybrid funding streams from research and service in this area, with a view to developing and disseminating some case examples of what has been called “engaged scholarship” [170] to support the sort of relationships and clinical service development we were able to achieve in some of our own work.

Fourth, the differences between “off the shelf” (commercially developed) and “homegrown” EPR systems, as well as the question of whether and in what circumstances “small is beautiful” in EPR systems, demand further critical exploration. Scale is frequently a challenge in technology: complexity theory argues that efforts to “standardise” may create disorder elsewhere in the system, something magnified by attempts to work on a larger scale. [66] As information moves further away from its local context, it may become harder to interpret. Our review found no evidence that large-scale commercial IT systems in health care produce the benefits anticipated by their architects, and a few high-quality studies suggest that they do not, [61-3, 65] but we also found recent evidence that if EPR systems are developed organically and in-house, scale *per se* may not be a bar to their success. [22]

With our own data collection, we saw both benefits and problems with both approaches. Prospective, theory-driven primary studies of large-scale EPR systems are needed and should be undertaken from an interdisciplinary perspective that includes CSCW, systems design, economics, management studies, and clinical disciplines. Such work could include the question of how small-scale, homegrown, modularized systems that support effective collaborative clinical care in local settings can be interfaced with other small-scale systems so as to achieve multiple objectives (local information sharing, local research, and also secondary uses of data at the regional and national levels). [171] suggests a way forward.

Fifth, a systematic review of the ethics and practicalities of data sharing is needed. We identified some important papers on this topic

in our review, but put them aside because of resource and time constraints. Such a review should cover topics like the balance between technical security and accessibility; [141,161] the nature of the trust relationship among the individual, the clinician, and the EPR; the desire (or not) of patients and citizens to view data concerning them; the changing dynamics of the clinical relationship as information inequality is redressed; and the involvement of patients, citizens, and civil liberties groups in influencing policy in this area.

Sixth, and perhaps as a cross-cutting theme in all the preceding areas, the realpolitik of EPR projects within and among organizations and interest groups should be more explicitly explored. ANT offers one (but not the only) theoretical perspective for addressing this. More generally, Orlikowski and Yates called for more research on the “messy, dynamic, contested, contingent, negotiated, improvised, heterogeneous, and multi-level character of ICTs in organizations”. [172, p. 132] We suggest that sponsors and publishers eschew sanitised accounts of successful projects and instead invite studies of the EPR in organizations that “tell it like it is,” perhaps using the critical fiction technique to ensure anonymity. [173]

Our review also identified some areas where more research does not appear to be needed, either because definitive findings have already been produced in those areas or, for epistemological reasons, because there never will be definitive findings (or any real hope of reducing uncertainty beyond its current level). We believe there are three such areas. The first is simplified experimental studies based on functionalist and determinist assumptions of the general format “What is the impact of technology X on outcome Y?” or variations thereof. We are not suggesting that such designs are never justified but that the circumstances in which they add value are more limited than is often assumed. Second, we believe that surveys of attitudes of patients or staff toward “the EPR” or “computerisation” that are not adequately contextualized have almost no enduring value. Finally, we caution against undertheorized qualitative studies of “failed” (or, indeed, “successful”) EPR projects. Although it is relatively easy to interview a range of stakeholders and ask their views, more studies showing (for example) that leadership and vision are better than no leadership and no vision are unlikely to add significantly to the evidence base. Funding for qualitative case studies of the EPR should be directed at studies that will enrich our theoretical understanding of this uniquely complex field.

## ***Conclusion***

This research programme, review and case studies, cannot provide an exhaustive account of research on the EPR or its implementation

in organisations. Instead, we seek to illuminate and challenge the way that researchers think. The meta-narrative review method has shown that “conflicting” findings in the existing large and heterogeneous literature can be fruitfully expressed as tensions and antinomies relating to the nature of the EPR, the context in which it is implemented and used, and the way success in an EPR program is defined and pursued. Although it is tempting to present the mainstream (traditionally positivist) biomedical literature as incommensurable with studies written from interpretivist, critical, and recursive positions, the latest research suggests a less polarised picture. Studies from both inside and outside the health informatics tradition, for example, are raising questions about both the scalability and the transferability of EPR systems, especially when such systems are developed commercially rather than grown organically as part of an emergent change effort. [22]

Our case studies and the literature depict in-use e-Health systems as being flexible and contingent. They rely on the ongoing work of healthcare staff to bridge the gap between social requirements and technical feasibility, [41] including the common use of workarounds. We suggest a dynamic tension between standardisation and localisation is unavoidable. Evidence from the first case study suggests that an integrated governance board can have a useful role bringing stakeholders together to navigate these co-evolutions of technology and service. The evidence highlights organisational barriers, including funding models, to successful integrated electronic services. Projects rely on the ability of change agents to bridge different institutional perspectives, align their conflicting logics and mobilise implementation effort.

While e-Health systems are complex, and we have discussed several challenges they face, they can be successful.

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## Appendix 1 Meta-narrative review tables

**Table 8: Philosophical basis of different approaches in EPR research**

Partly inspired by previous work [16,17]

<b>Assumptions &amp; VALUES</b>	<b>Positivist</b>	<b>INTERPRETIVIST</b>	<b>CRITICAL</b>	<b>RECURSIVE (INTEGRATIVE)</b>	
				<b>Technology structuration theory</b>	<b>Actor-network theory</b>
<i>Ontology</i> (assumptions about the nature of reality)	A single reality. Knowable, probabilistic	Multiple realities, socially constructed through symbolic interactionism, framing, and sense-making	Multiple socially constructed realities reflecting power relations hence influenced by external forces	Multiple realities enacted by social actors, recursively shaped and constrained by macro social structures of signification, legitimation, and domination and by the materiality of technologies	Multiple realities that are recursively shaped and constrained by actants (people and technologies) in the socio-technical network
<i>Epistemology</i> (assumptions about the nature of knowledge)	Knowledge is objective and dispassionate, and has a direct link to	Knowledge is subjective, context-dependent, value-laden and emerges from the researcher-	Knowledge is subjective, value-laden and critical – i.e. questions	Knowledge is embodied and enacted in particular practices; social structure cannot	Knowledge is embodied, enacted and generated by social actors who

	reality	participant interaction	how and why the social situation arose as it did	be directly measured but can be known indirectly via actors' perceptions, understandings and actions	engage in 'translation' as they seek to achieve their goals through particular practices
<i>Role &amp; reflexivity</i> (assumptions about the role of the researcher)	Researcher is a detached observer of truth; no reflexivity needed	Researcher seeks valid, plausible and reflexive understanding of the meanings ascribed by actors	Questioner of the social order	Researcher seeks reflexive understanding of the recursive relationship between the micro (actors' knowledgeability and practice) and macro (social structure)	Research is a reflexive performance; researcher seeks understanding of action and emergence in a socio-technical network
<i>Methodology</i> (assumptions about what methods will generate 'best evidence')	Observation; quantitative, statistical. There is a hierarchy of research design i.e. one method is inherently 'better' than others	Qualitative, naturalistic; pluralistic (multiple methods preferred to give a rich picture of reality); data analyzed for meanings and perspectives	Participative, qualitative, naturalistic; analyzed for hidden power relations embedded in social structures or language	Qualitative, naturalistic; data analyzed for emergence of actors' understandings and practices and (indirectly) changes in social structures over time	Qualitative, naturalistic, performative; data analyzed for ontologies (things that are brought into being through practice) and the actor-networks from which these emerge
<i>Axiology</i> (what is of value)	Truth: universal and generalisable; prediction	Understanding and description; situated and particular	Challenge, emancipation	Illumination of technologies-in-practice and how these shape	Illumination of technologies-in-practice and how

				and are shaped by social structures	these shape and are shaped by socio-technical networks
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**Table 9. Nine meta-narratives that have driven research on the EPR in organisations**

Research tradition	Disciplinary and philosophical roots	Definition and scope	General format of research question	EPR conceptualized as	EPR user conceptualized as	Context conceptualized as	Example papers (further details in [11])
1 Health information systems	[Evidence-based] medicine, computer science ( <i>positivist</i> )	The study of the storage, computation and transmission of clinical data. Until recently, focus was on benefits of EPRs and how to achieve them	What is the impact of technology X ( <i>e.g.</i> EPR, CDSS, CPOE) on process Y ( <i>e.g.</i> clinician performance) and outcome Z ( <i>e.g.</i> patient health status)?	Container for information about the patient; tool for aggregating clinical data for secondary uses	Rational decision-maker whose cognitive ability sets limits to what can be achieved without computers	Potential confounder which can be 'controlled for' if the right study design is used	See review of 37 previous reviews [21], plus one later publication [22]
2 Change management (within health services research)	[Evidence-based] medicine, social psychology, management	The study of how to achieve organizational-level change in healthcare.	How can we improve the delivery of healthcare and sustain that improvement?	Innovation which, if implemented widely and consistently will improve process	'Resistant' agent who must be trained and incentivised to adopt new technologies and	External milieu of interacting variables that serve as barriers or facilitators to change efforts	[136,174-80]

		<i>(interpretivist)</i>			and outcome of care	ways of working		
3	Inform-ation systems (positivist)	Business studies, psychology, computer science ( <i>positivist</i> )	The study of how organizations adopt and assimilate (or why they fail to adopt and assimilate) information systems	What factors (independent variables) account for the success or failure (dependent variable) of information system X in organization Y?	Unwelcome change, likely to be resisted by individuals and interest groups, and which may fit poorly with organizational structures and systems	Potential adopter who may be actively engaged in the change or resist it; member of group whose power base may be enhanced or threatened	External milieu of interacting variables that mediate or moderate the relationship between input and output variables	[181-3]
4	Inform-ation systems (interpretivist)	Management, sociology, social psychology, anthropology ( <i>interpretivist</i> )	The study of how organizational members make sense of information systems and thereby assimilate them	What meanings does information system X hold for the members of organization Y? How can accommodation be achieved between different views?	Socio-technical change which holds different meanings for different individuals and groups	Stakeholder whose 'framing' of the EPR is crucial to its effective assimilation. Agent whose creativity and energy can be drawn upon in this effort	Scene and setting for an unfolding story; webs of meaning in which organizational actors are suspended	[27-31,184-6]
5	Inform-ation systems: technology-in-	Organizational sociology, social	The study of how social structures	What is the relationship between	Itinerary and organizer whose physical and	Knowledgeable, creative agent for whom social	Generated and regenerated through the	[34-38,188]

	practice	psychology, philosophy ( <i>recursive</i> )	recursively shape and are shaped by human agency, and the role of technology in this process, with a focus on the meso-level of organizational life	organizational actors, technology X, and the organization – and how does this change over time?	technical properties structure and support collaborative clinical work	structures both create possibilities and limit the possible	interplay of action and structure. Researchers do not study 'technologies' and 'contexts' separately but technologies-in-use	
6	Computer supported co-operative work	Computer science, software engineering, psychology, sociology ( <i>recursive</i> )	The study of how groups of people work collaboratively, supported by information technology	How can technologies support the work of multiple interacting people?	Contextualized artefact	Agent who seeks to achieve local goals in collaboration with others and creatively overcomes limitations of formal tools	<i>Either</i> external milieu <i>or</i> an emergent property of action (constituted by, and inextricable from, an activity involving people and technologies)	[42-46,133,189-91]
7	Critical sociology	Sociology, philosophy ( <i>critical</i> )	The study of the relationship between people and the social order and how	What social structures and inherent power imbalances are embedded in	Implicated in micro and macro power dynamics, both within the organization and	Constrained by dominant social structures or discourses; imagined user,	Social and material conditions into which the (inherently	[51,192-5]

			this changes over time, and the role of technologies in this process	technology X – and what impact does this have on social roles and relationships?	more widely (because of the link between knowledge and power)	stereotypes about whom may be built into technologies by designers	unequal) social order is inscribed; a more or less stable structure of macro social relations	
8	Empirical philosophy (actor-network case studies)	Philosophy, sociology, linguistics ( <i>recursive</i> )	The study of socio-technical networks and what emerges from these. Considers how relationships and power shift within the network	How has the network, with its various relationships, work practices and risks, changed as a result of introducing technology X?	Actor in a network	Actor in a network	The EPR and its context together form the network; the one cannot be studied without the other (since the EPR only becomes 'the EPR' as part of the network)	[53,67,134,196-201]
9	Systems approaches to risk management and integration	Systems and management research, drawing on cognitive psychology, CSCW, and ANT ( <i>recursive</i> )	The study, from a systems perspective, of how to promote safety and reduce risk in healthcare	What role in both protecting against and producing error does the EPR play within a complex healthcare system?	Component of complex socio-technical system whose structural features and operational properties, even when designed to protect against error, may come	Component of complex socio-technical system whose structural features and operational properties, even when designed to protect against error, may come	Complex, changing environment which poses potential risks to patient safety	[59,61,64,65,202-6]

					together in unpredictable ways to produce error	together in unpredictable ways to produce error		
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# Appendix 2 Process maps of the NCLASPS Barnet service

## Sequential flow diagram

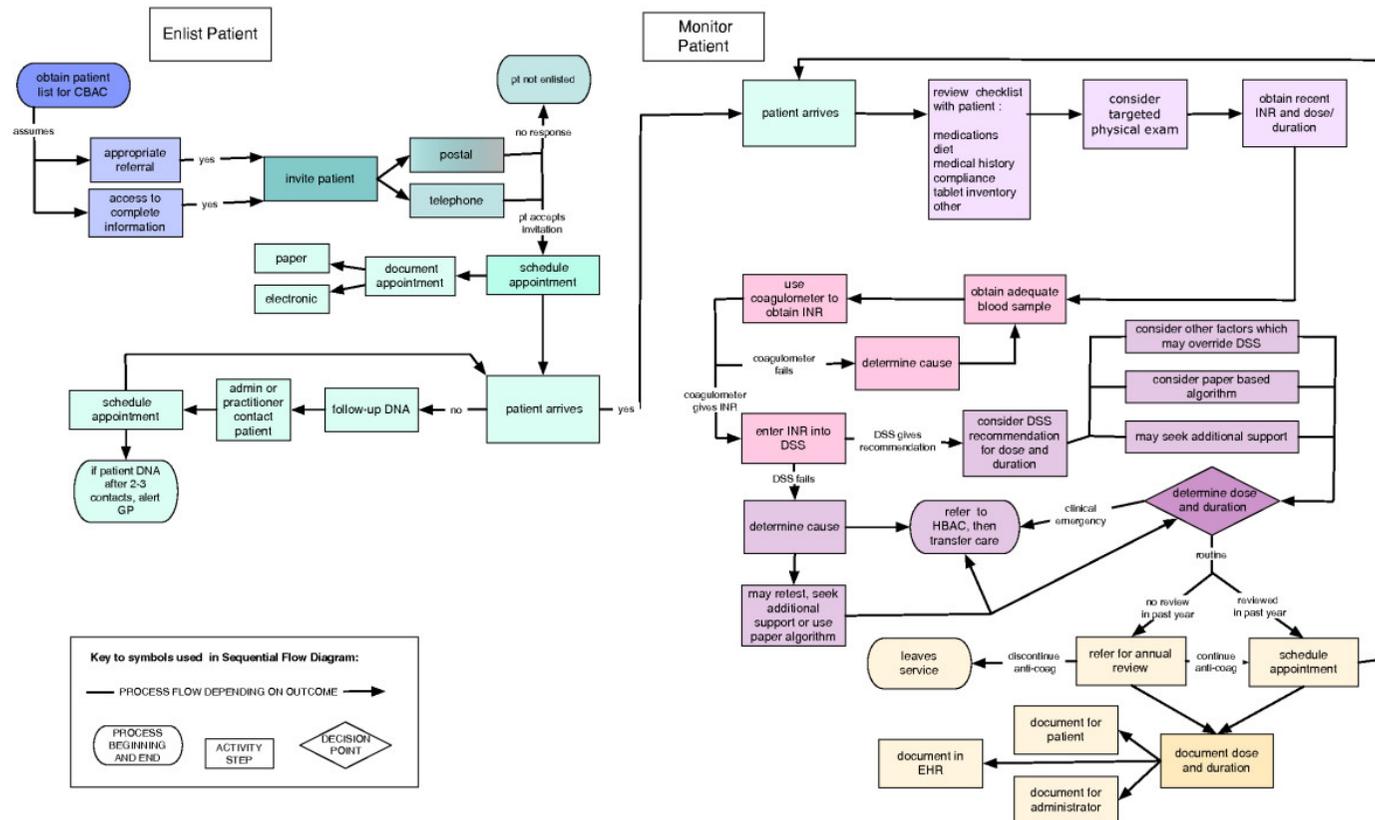
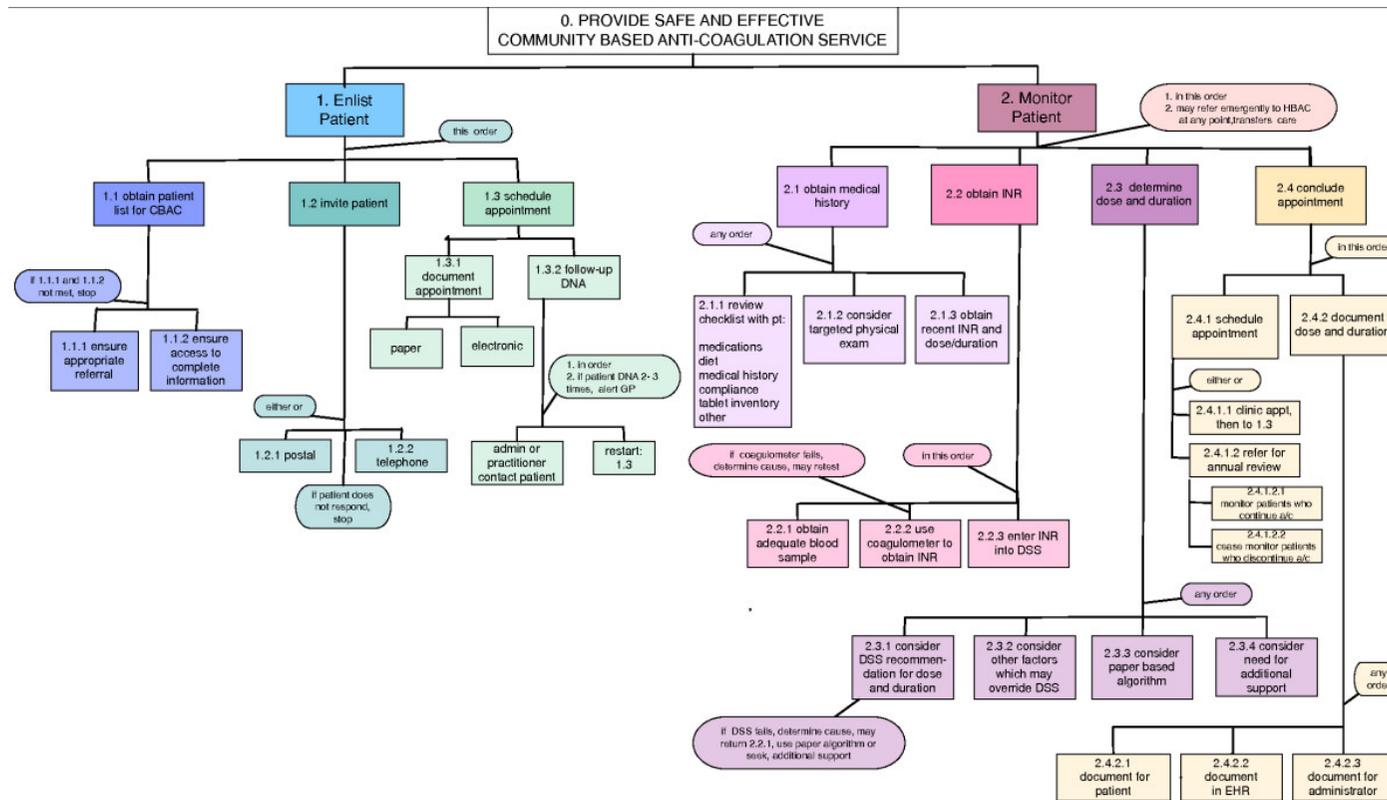


Figure 2. Hierarchical task analysis diagram



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## Appendix 3 MeSH Keywords

delivery of health care  
electronic health records  
review, systematic  
social sciences  
medical informatics  
software design  
decision-making, computer-assisted  
coumarins  
cardiovascular diseases  
diabetes mellitus

## Appendix 4 STARE-HI compliance

During the course of this research, Talmon and colleagues published a set of guidelines on the publication of evaluation studies of health informatics applications, the STARE-HI guidelines. [208] Our work was not designed around these guidelines and we suggest the guidelines largely reflect the epistemological approach of meta-narrative 1 on health information systems (see 2.2.2). Within that context, the table below lists the approximate correspondence between the report sections and the STARE-HI items.

**Table 10: STARE-HI compliance**

STARE-HI items		Case study 1: NCLASPS	Case study 2: SystemOne
1	Title	p. 1	
2	Abstract	Executive Summary	
3	Keywords	Appendix 3	
4	Introduction	3.1-3.2	4.1
4.1	Scientific background	Section 2, 3.1	4.1
4.2	Rationale for the study	3.2	4.1
4.3	Objectives of study	3.2	4.1
5	Study context	3.4	4.1-2
5.1	Organizational setting	3.4	4.1-2
5.2	System details and system in use	3.4	4.1-2
6	Methods	3.3, 3.5	4.2-3, 4.5
6.1	Study design	3.3, 3.5	4.2-3, 4.5
6.2	Theoretical background	3.3, 3.5	4.2-3, 4.5
6.3	Participants	3.3.1, 3.3.3, 3.5.1-3	4.3, 4.5
6.4	Study flow	3.3.3-4, 3.5.1-3	4.3, 4.5
6.5	Outcome measures or evaluation criteria	3.3, 3.5	4.2-3, 4.5
6.6	Methods for data acquisition and	3.3, 3.5	4.2-3, 4.5

	measurement		
6.7	Methods for data analysis	3.3, 3.5	4.2-3, 4.5
7	Results	3.4-6	4.4-5
7.1	Demographic and other study coverage data	3.3-3.6	4.4-5
7.2	Unexpected events during the study	3.6	4.4-5
7.3	Study findings and outcome data	3.5-6	4.4-5
7.4	Unexpected observations	3.5-6	4.4-5
8	Discussion	3.6	4.4.4, 4.5.8
8.1	Answers to study questions	3.5-6	4.4.4, 4.5.8
8.2	Strengths and weaknesses of the study	3.5-6; also 6.1	4.4.4, 4.5.8; also 6.1
8.3	Results in relation to other studies	3.5-6; also section 6	4.4.4, 4.5.8; also section 6
8.4	Meaning and generalisability of the study	3.5-6; also section 6	4.4.4, 4.5.8; also section 6
8.5	Unanswered and new questions	3.5-6; also section 6	4.4.4, 4.5.8; also section 6
9	Conclusion	3.6; also section 6	4.4.4, 4.5.8; also section 6
10	Authors' contribution	pp. 8-9	
11	Competing interests	p. 3	
12	Acknowledgement	p. 9	
13	References	p. 126 <i>seq.</i>	
14	Appendices	Appendices 1-4	

## **Addendum**

This document is an output from a research project that was commissioned by the Service Delivery and Organisation (SDO) programme whilst it was managed by the National Coordinating Centre for the Service Delivery and Organisation (NCCSDO) at the London School of Hygiene & Tropical Medicine. The NIHR SDO programme is now managed by the National Institute for Health Research Evaluations, Trials and Studies Coordinating Centre (NETSCC) based at the University of Southampton.

Although NETSCC, SDO has managed the project and conducted the editorial review of this document, we had no involvement in the commissioning, and therefore may not be able to comment on the background of this document. Should you have any queries please contact [sdo@southampton.ac.uk](mailto:sdo@southampton.ac.uk).