NHS CONNECTING FOR HEALTH EVALUATION PROGRAMME

An evaluation of the adoption of the NHS Care Record in secondary care

APPLICATION FORM - VERSION 2

CONTENTS

After completion this form should be returned to:

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B15 2TT

I. SUMMARY OF PROPOSAL

BOX 1: CODE & TITLE OF PROJECT (as advert)

NHS CFHEP 005 Evaluation of the adoption of the NHS Care Record Service in secondary care

BOX 2: APPLICANTS (NOTE: Section IV should also be completed for ALL applicants)

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BOX 3: POTENTIAL REVIEWERS

Please suggest three people who we might approach to review this proposal. Please include their area of expertise and full contact details, including email:

Name:	**Dr Maureen Baker**
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BOX 4: SUMMARY OF RESEARCH

ABSTRACT OF RESEARCH. No more than 200 words covering the following topics: aims of project; research subject group; sample size, type and location; methods of working.

Aims: We aim to conduct a:

- Formative evaluation of the national implementation of the National Health Service's Care Record Service (NHS CRS) in secondary care and to use the findings to inform the continued roll-out of the NHS CRS
- Summative evaluation of the impact of the NHS CRS on the quality, safety and efficiency of healthcare delivery.

Research subject group: Participants will consist of key stakeholders and organisations involved in and/or affected by the introduction of the new electronic healthcare record; these include patients and carers, 'frontline' healthcare staff, administrative staff, IT support staff and management teams.

Sample size: Up to five hospitals in each of the three NHS CRS implementation clusters.

Type and location: Hospitals across England.

Methods: A theoretically informed multi-faceted quantitative and qualitative evaluation using the principles of a stepped wedge design to sample hospitals, and integration of realistic evaluation and Cornford et al's evaluation framework to assess the effects of introduction of the NHS CRS. Six complementary work packages will be pursued:

i. Implementation, deployment and organisational learning
ii. Attitudes, expectations and experiences of patient, professional and managerial stakeholders
iii. Organisational consequences of implementation
iv. Assessment of costs of NHS CRS implementation
v. Assessing error, safety and quality of care
vi. Organisational consequences and implications for future IT deployments and evaluations.

BOX 5: TIMESCALE

Proposed starting date: June 2008

Proposed duration: 2 Years 6 Months

BOX 6: ETHICS

(NOTE: Ethical approval is not necessary at the application stage, however, projects cannot begin until the necessary approvals are in place.)

Is Ethics Committee approval needed? Yes

If yes, do you foresee any problems with obtaining ethical approval? No

Are research governance requirements applicable to this study? Yes

BOX 7: COST

Total Research Grant Requested from this programme (i.e. 80% FEC): £1.5m

BOX 8: ADVERTISING

Where did you see the advert for this project? We were emailed a copy of the tender document by NHS Connecting for Health Evaluation Programme

II. DETAILS OF PROPOSED RESEARCH

Detailed outline of proposed research (see attached notes for guidance).

Abbreviations

CDSS	Computerised decision support systems
CPOE	Computerised physician order entry
CUI	Common user interface
DCR	Detailed Care Record
ECG	Electrocardiogram
EHR	Electronic health record
EPR	Electronic patient record
ERDIP	Electronic Development and Implementation Programme
ETP	Electronic Transmission of Prescriptions
GP	General practitioner
ICRS	Integrated Care Record Service
IT	Information technology
LSPs	Local Service Providers
N3	National Network for the NHS
NHS	National Health Service
NHS CFH	NHS Connecting for Health
NHS CFHEP	NHS Connecting for Health Evaluation Programme
NHS CRS	NHS Care Record Service
NICE	National Institute for Health and Clinical Excellence
NLOP	National Programme for IT Local Ownership Programme
NPfIT	National Programme for Information Technology
NPSA	National Patient Safety Agency
NSF	National Service Framework
PACS	Picture Archiving and Communications System
PCT	Primary Care Trust
PDS	Personal Demographic Service
PERIC	Patient Electronic Record Information and Consent
PI	Principal Investigator
SCR	Summary Care Record
SE	Standard error
SHA	Strategic Health Authority
SPO/THO	Structure Process Outcome/Technical Factors Human Perspectives Organisational Context
SUS	Secondary Uses Service

1. INTRODUCTION AND OVERVIEW

The effective and efficient storage, retrieval, sharing and secondary analysis of routinely collected patient data can be greatly facilitated by healthcare organisations moving from paper based record systems to digital systems. Electronic health record (EHR) systems therefore, appropriately, lie at the heart of attempts currently being pursued in many countries to reform or transform healthcare systems. NHS Connecting for Health's (NHS CFH) National Programme for Information Technology (NPfIT) is the most ambitious and expensive IT-based healthcare reform currently being undertaken anywhere in the world and the successful implementation, adoption and integration of the multi-faceted NHS Care Record System (NHS CRS) is fundamental to the success of this Programme if it is to realise its potential of improving the quality, safety and efficiency of healthcare delivery. Electronic health record systems are however potentially disruptive technologies altering many aspects of healthcare professionals' routine working practices and patients' experience of care; of particular relevance is that the successful integration of such systems into routine models of care, particularly, in the context of perceived top-down or 'imposed' solutions (as opposed to those which are home-grown) has been shown to be far from straight-forward.

This proposal brings together a multi-disciplinary team of academics and clinicians with considerable expertise and experience of quantitatively and qualitatively evaluating IT-based healthcare reforms and, furthermore, a detailed understanding of NHS CFH and NPfIT. We seek, in undertaking this evaluation, to build on our recent and on-going work. This includes an international overview of the literature for NHS Connecting for Health Evaluation Programme (NHS CFHEP), Phase 1 of which has recently been completed, which investigated and contrasted the theoretical and empirically demonstrated health benefits of IT solutions. This included, amongst other things a review of EHRs and a detailed case study of the implementation and adoption of the NHS CRS in secondary care (NHS CFHEP 001). We also draw upon our ongoing evaluation of NHS CFH's Electronic Transmission of Prescription (ETP) scheme (NHS CFHEP 004), an on-going large cluster randomised controlled trial evaluating the impact of a novel IT-based approach to reducing prescribing errors (funded by the Patient Safety Research Programme, the precursor to NHS CFHEP) and a range of other on-going qualitative, descriptive and experimental studies evaluating the potential, scope, role and effectiveness of IT-based approaches to delivering healthcare (see CVs).

Building on this previous work, we plan to undertake a theoretically informed multi-method (i.e. comprising both quantitative and qualitative approaches) formative and summative, context rich, evaluation of the implementation and effects of introducing the NHS CRS. Our formative evaluation will, we hope, provide crucial insights into how the continuing roll-out of the NHS CRS can be adapted to ensure the best chances of its successful adoption and subsequent positive impacts on professional working practices and patient outcomes; these latter considerations are the focus of our summative evaluation. Our proposed approach is packaged into six complementary work packages, which reflect a rich and nuanced understanding of key questions of scientific and policy interest in relation to EHR systems in particular and large-scale IT deployments in healthcare more generally.

Recognising that aspects of the NHS CRS and the implementation strategy are still in development, we appreciate the need, if successful, to work very closely with NHS CFH and NHS CFHEP, particularly during the first few months of the project, to develop a more detailed understanding of the key components of the NHS CRS and the evolving approaches that will be taken to implementation. This more detailed understanding will be used to further refine the overall approach here described into a more fully developed evaluation strategy.

Section 2 provides background information and the rationale for our proposed approach and we then, in Section 3, proceed to detail the key aims and objectives of our proposed work. Section 4 provides a description of our proposed methods and the six work packages. Sections 5-10 provide more detailed information on the proposed timeline, project team, research governance considerations and justification for requested resources to support this work.

2. BACKGROUND

2.1. Policy context to introduction of IT into healthcare

There is increasing governmental recognition of the all too often large gap between the desired and actual provision of quality healthcare.(1;2) This gap may result in various threats to patient safety,(3) which have important consequences for patient morbidity and mortality; these deficiencies of care also have considerable financial implications.(4;5) Several policy documents in the UK have recognised this threat and highlighted the need for a range of strategic approaches aimed at improving quality of care.(6;7)

Increasing understanding of the extent of variations in care and the high risk of iatrogenic harm associated with many aspects of healthcare delivery has rightly catalysed interest into better understanding the disease burden posed by medical errors and variations in quality of care and, importantly, what can be done to improve the quality and safety of healthcare delivery.(8) Fundamental to these deliberations has been recognition of the importance of systems approaches, which shift the centre of attention away from blaming the individual to considering how organisational context may contribute to errors,(6;9) and it is this, in part at least, that has focused attention on the potential now offered by developments in IT hardware and software capabilities (see Appendices 1 and 2).

In 1998, the Department of Health published *Information for Health*, a technology strategy for the NHS with a commitment to implement electronic health records.(10) This was followed by the *NHS Plan* in 2000, a programme of reform with the aim to develop and optimise NHS care services.(8) *National Service Frameworks (*NSFs*)* form part of the *NHS Plan* and comprise a set of national standards to guide implementation of the *NHS Plan* in specific service areas. The Government further established several agencies charged with quality improvement in the NHS such as, for example, the National Institute of Health and Clinical Excellence (NICE),(11) a governmental agency charged with developing and disseminating guidelines of clinical excellence to NHS service providers. Similarly, in 2001, the National Patient Safety Agency (NPSA) was established as a designated Strategic Health Authority (SHA) with the aim of promoting patient safety in the NHS.(12)

One of the priorities outlined in the NHS Plan was developing IT strategies for the NHS, which resulted in several subsequent reports by the Department of Health on this topic.(13;14) Ultimately, in 2002, the first details of the National Programme for Information Technology (NPfIT) were published, this describing a plan of action to introduce new IT systems throughout the NHS;(15) the NPfIT is currently the most ambitious national IT venture of its kind.(16) Responsibility for delivering NPfIT was in 2005 transferred from the Department of Health to NHS CFH, an Arms-Length Body, which also has responsibility for coordinating procurement of IT systems for the NHS more generally.(17)

2.2 Electronic health records

Electronic health records are the central components of most large scale IT initiatives in healthcare internationally (see Appendix 3). Although they may take various forms, with varying levels of functionality,

the common underlying idea is to have comprehensive and readily available health information on individual patients that is accessible to and modifiable by a variety of users throughout the healthcare system. This vision has thus far proven to be somewhat elusive and, if successful, the NHS CRS will be the first successful national implementation of an EHR system in the world.

We have recently conducted an extensive review of the literature for NHS CFHEP in relation to IT and its impact on the quality and safety of healthcare. Our review indicates that, in theory, IT applications have enormous potential to improve the quality of healthcare delivery. There is however a distinct lack of high quality empirical evidence of the effectiveness of the vast majority of systems including EHRs. However, key theoretical benefits have been argued to include, among others, increased efficiency, better quality of information, improved security, safer patient care, patient empowerment, improved data availability and increased time efficiency by decreasing time spent on, for example, administrative tasks.(18) Table 1 describes the main theoretical benefits associated with use of EHRs and Table 2 provides a summary of the key findings from systematic reviews evaluating EHRs.

Table 1: Key theoretical benefits of electronic health records

Attribute	Benefit
Immediate and universal access to the patient record	Increased efficiency (e.g. reduced time spent pulling charts and duplicate history taking etc). Increased quality (better information at the point of care). Substantial improvements in access for patients.
Easier and quicker navigation through the patient record	More efficient point of care assessment and data abstraction
Increased legibility and comprehensiveness, through computer-aided history taking systems and better formatting (e.g. templates)	Better quality information to aid clinical decision making and shared care; fewer errors in patient management (e.g. mis-prescribing)
Secure record keeping	No lost records, fewer unnecessary waits or missed appointments, aiding informed patient care. Enhanced patient satisfaction.
Standardisation of care among providers within the organisation	Through better recording and sharing of information and linkage to computerised decision support systems
Reduction of paperwork, documentation errors, filing activities	Removes duplication, reduces processing time, decreases personnel costs
Coding efficiency and efficacy	Improved data quality and consequently improved measurement of health indices and processes e.g. Payment by Results
Alerts for medication errors, drug interactions, patient allergies	Safer patient care
Ability to electronically transmit information to other providers (assessments, history, treatments ordered, prescriptions, etc.)	Fewer delays, more efficient and integrated patient care. Enhanced patient satisfaction.
Availability of clinical data for use in quality, risk, utilisation, analyses	Better monitoring of quality and efficiency
Availability of non-clinical data	Easier management of costs, performance and workflow
Availability of data for audit and research, both locally and nationally	With downstream benefits for patient care through facilitating monitoring of standards of care, quality improvement activities and research

Adapted from: Healthcare Information and Management Systems Society (2007)(18)

Table 2: Evidence from systematic reviews on electronic health records

Author	Aim	No. studies	Key results	Conclusion
Chaudrhy et al (2006)(19)	To systematically review evidence on the effect of IT on quality, efficiency, and costs of healthcare	257	EHR is more frequently examined in the outpatient setting; after implementation of the EHR, there was a relative decrease of 9% for total office visits; there is an absence in the literature of key data on the financial context of capitation believed to be an important factor in defining the business case for EHR use	The benefits of IT appear to depend greatly on the quality of the implementation and the level and type of decision support technology. One potential benefit of EHR systems is a reduction in morbidity through improved patient safety
Clamp and Keen (2005)(20)	To summarise literature about the value of EHR	70	Positive evidence of process change associated with EHR; evidence that EHR can increase time costs, particularly for clinicians; In many papers the evidence was not decisive; no compelling evidence that EHR reduce the incidence of adverse drug events, or that the introduction of EHR increases or decreases consultation time.	The positive effects of EHR in some specific clinical settings are clear, but there are many areas where the understanding of costs and effects is limited
Delpierre et al (2004)(21)	To analyse the impact of EHR on medical practice, quality of care, and user and patient satisfaction	26	Use of an EHR was perceived favourably by clinicians; a positive impact of EHR on preventive care was found; evaluations found that positive experiences were as frequent as experiences showing no benefit; no study analysing the impact of EHR on patient outcomes reported any benefit	EHR increased user and patient satisfaction, which might lead to significant improvements in medical care practices. However, the studies on the impact of EHR on patient outcomes and quality of care were not conclusive. Alternative approaches considering social, cultural, and organisational factors may be needed to evaluate the usefulness of EHR
Hogan and Wagner (1997)(22)	To review the published evidence on data accuracy in EHR	20	Studies reported highly variable levels of accuracy; variability arose from differences in study design, in types of data studied, and in the type of EHRs; differences confound interpretation in the literature	This review showed that the understanding of data accuracy in EHR does not correspond with its importance. Description and accuracy in EHR must be measured, and ways to improve it must be investigated
Jordan et al (2004)(23)	To assess the completeness and correctness of morbidity coding in computerized general practice records in the UK	24	Variation in the methodology and quality of studies, and problems in generalisability; A consistent finding was that quality of recording varied between morbidities.	Completeness and correctness of data entry may rely on the enthusiasm of individual practices and of general practitioners. Hence, variations in the accuracy of EHR will be present among general practices. Like Thiru et al, they noted the lack of well-defined data quality standards and the need to correct this if better measurement of data quality in primary care EHR was to be established
Poissant et al (2005)(24)	To examine the impact of EHRs on documentation time of physicians and nurses and to identify factors that may explain efficiency differences across studies	23	The use of bedside terminals and central station desktops saved nurses, respectively, 24.5% and 23.5% of their overall time spent documenting during a shift; Studies that conducted their evaluation process relatively soon after implementation of the EHR tended to demonstrate a reduction in documentation time in comparison to the increases observed with those that had a longer time period between implementation and the evaluation process	This review highlighted that a goal of decreased documentation time in an EHR project is not likely to be realised. It also identified how the selection of bedside or central station desktop EHRs may influence documentation time for the two main user groups, physicians and nurses
Thiru et al (2003)(25)	To systematically review measures of data quality in EHR in primary care	52	Variability in methods prevented meta-analysis of results Prescribing data were generally of better quality than diagnostic or lifestyle data	The lack of standardised methods for assessment of quality of data in electronic patient records makes it difficult to compare results between studies. Studies should present data quality measures with clear numerators, denominators, and confidence intervals. Ambiguous terms such as "accuracy" should be avoided unless precisely defined.

Adapted from: The Impact of eHealth on the Quality and Safety of Healthcare - A systematic overview and synthesis of the literature. Report for the NHS Connecting for Health Evaluation Programme (Project: NHS CFHEP 001) (2008) (26)

2.3. The NHS Care Record Service (NHS CRS)

2.3.1 Aims of NHS CRS

The NHS CRS represents an ambitious visionary programme for the implementation of a large scale complex EHR. It is in many ways the backbone of the entire NPfIT – its successful implementation is therefore extremely important to the success of the Programme as a whole.(26) The primary aim of the NHS CRS is to implement an EHR that will replace the existing mix of paper-based and electronic records. Other key NPfIT applications such as Choose and Book (an online appointment booking service) and the ETP scheme will in due course integrate with the NHS CRS.(27) In addition, it is anticipated that the NHS CRS will allow patients to see and input into their own health records through HealthSpace, thereby allowing them greater control of their personal records than has hitherto ever been possible.(28) The NHS CRS thus aims to provide a live, comprehensive, interactive record service that will be accessible 24 hours a day, seven days a week. When fully developed, it will function across healthcare organisations supporting planned, emergency and unscheduled care.

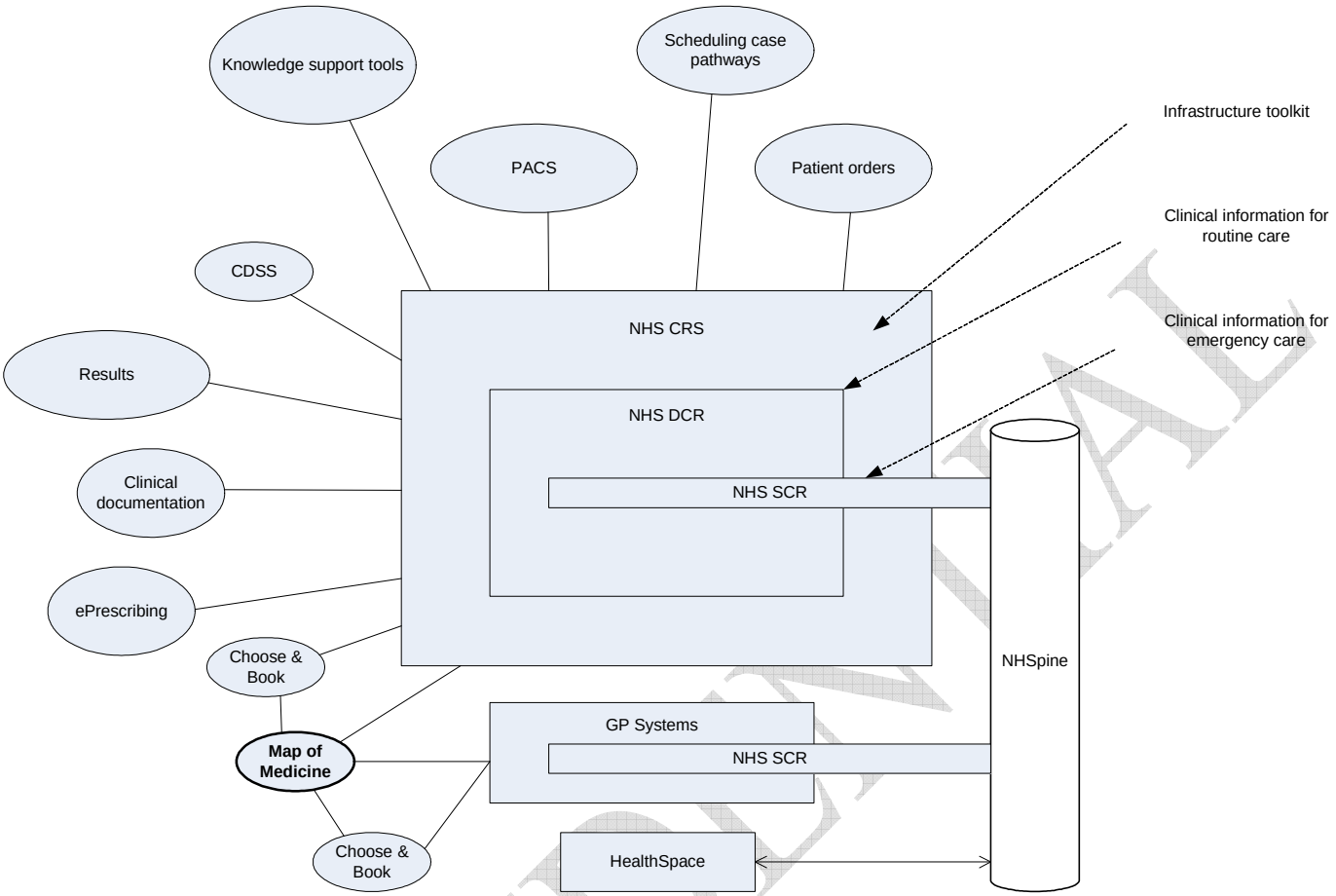
2.3.2 Structure of NHS CRS

The NHS CRS is planned to consist of the following key components:

- National Spine, containing the basic capabilities of the system (29)
- National Network for the NHS (N3), allowing electronic data exchanges across organisations (30)
- Personal Demographics Service (PDS), containing demographic patient details (31)
- Images in Picture Archiving and Communication Systems (PACS) (32)
- Summary Care Record (SCR), which is held on the National Spine and contains a record of essential clinical information
- Detailed Care Record (DCR), containing comprehensive clinical information on individual patients seen and managed in secondary care
- Secondary Uses Service (SUS) for integration of data from different sources and then making this available for audit and research purposes.(33)

Figure 1 represents a schematic model of the NHS CRS. How exactly the physical components of the NHS CRS will integrate with other aspects of the NPfIT and other NHS IT systems (e.g. GP clinical systems) is however not yet entirely clear.(16) The diagrammatic representation below may therefore need some modification as further details of the NHS CRS and, in particular, the DCR emerge.

Figure 1: Schematic model of NHS CRS



2.3.3 Procurement and implementation strategy

The national approach to procurement of services and delivery will take place at a local level and is still, to an extent, under negotiation. The general steps envisaged by NHS CFH as roll-out proceeds are summarised briefly below:

- **Strategic development planning (Stage 1):** Here, the Trust assesses its readiness against defined criteria such as financial readiness, availability of trained staff and shareholder support. The Trust then prepares a Business Case and a Project Initiation Document that needs to be approved by the NPfIT.
- **Pre-deployment workshops (Stage 2):** In this stage, technical and clinical transformation and organisational readiness issues are identified. The Trust needs to prepare a Compliance Status Report (what is required before the trust can proceed) and a Location Resolution Plan (a detailed plan of the tasks and resources needed to achieve compliance).
- **Location preparation (Stage 3):** During this stage, the trust produces a joint Development Plan with the LSP in order to outline the preferred local approach to deployment and to identify the order in which various NHS CRS features will be introduced.
- **Product deployment (Stage 4):** This is the final stage before "going-live". During this period, the Trust implements new care processes, monitors and manages change activity and holds staff training. Trust and the LSP will build system interfaces, manages data migration and undertake system and user testing. At this stage Trust prepares the Completion Report. Once this is approved the Trust is ready to "go-live".
- **Go-Live (Stage 5):** During this stage, the trust starts using NHS CRS services. On-site support is handed over to the Trust's IT Helpdesk with support from the LSP. Redundant legacy systems are decommissioned.

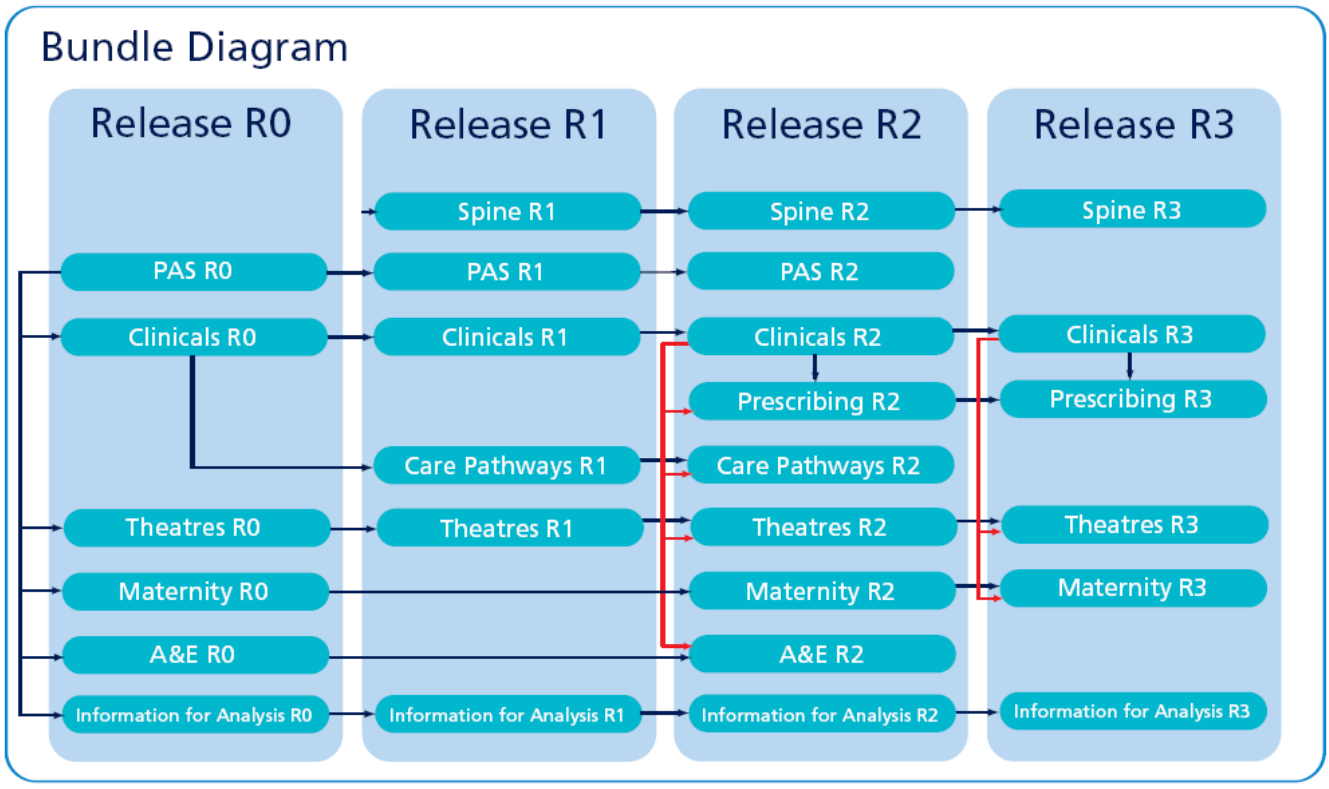
Originally, NHS CFH had divided England into five geographical clusters. This has changed since the introduction of the National Local Ownership Programme (NLOP), which was designed to increase local responsibility for implementing systems and implemented in April 2007.(34) Now the original five "clusters" have become the three "Programmes for IT" and NHS CFH has appointed Local Service Providers (LSPs) to support the roll-out of IT systems for the NHS organisations in each of these. The SHAs are intended to drive the programme delivery through their Senior Responsible Officers, via PCTs and Trusts. The SHAs in each cluster group together to manage their regional NPfIT, although the governance arrangements are still being developed for this.

The clusters and their corresponding LSPs are:(34)

- Southern Programme for IT: Fujitsu
- London Programme for IT: British Telecom
- North, Midlands and East Programme for IT: Computer Sciences Corporation.

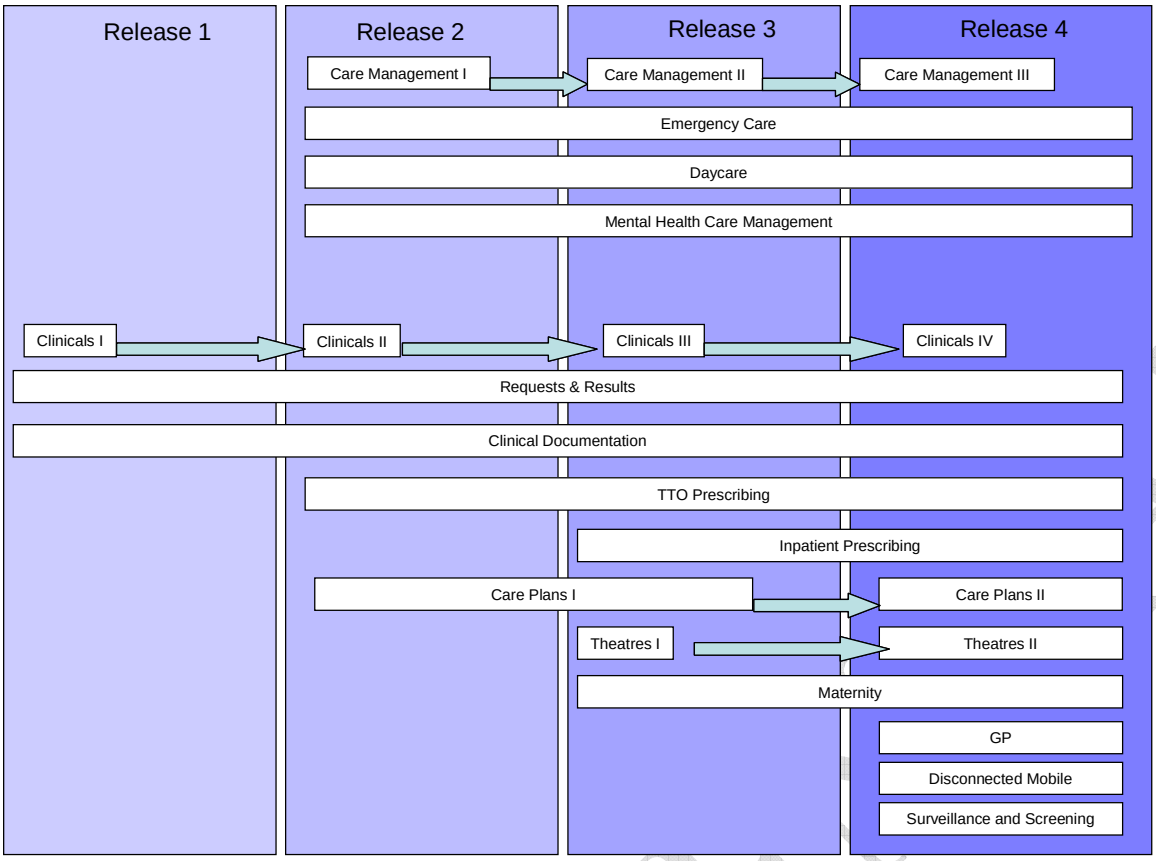
It is planned that implementation of the NHS CRS into secondary care settings will be conducted in a staged approach, this involving initial assessment of the readiness of the Trust for implementation of various levels of service, and culminating in an actual date when the system will finally be up and running.(35) Each cluster has proposed a phased implementation framework that will see incremental functionality available as a sequence of releases are undertaken.(36) LSPs in the London and Southern Programme are planned to use different functionalities of the Cerner Millenium Software, whilst the North, Midlands and East Programme will use Lorenzo Software. The timings of implementation of releases vary with the software in question. Note that according to E-Health Insider (no 311, 25.1.08) Fujitsu may be renegotiating with the Southern programme and may lead to Cerner linked to best of breed clinical systems such as pharmacy. Whatever the truth of this, it illustrates the need for the evaluators to have a flexible approach which can accommodate such changes. Figures 2 and 3 below illustrate the intended phased implementation of the two software applications.

Figure 2: Diagram of the intended phased implementation of Cerner Millenium Software in London



Adapted from: Step by Step Towards the Future. The 'R Series' Release Map Leading Towards a Cerner Millennium® Solution for Acute Trusts (2007) (36)

Figure 3: Diagram of the intended phased implementation of Lorenzo Software



Adapted from: Draft IMT planning paper (2007) (37)

As can be seen from Figures 2 and 3, releases across systems vary with regard to their features. For example BT Cerner R0 includes “Theatres and Maternity”, whilst these do not appear until R3 in Lorenzo. This is further complicated by likely divergence in timings from the planned schedule. For example, Trusts may decide to not implement releases immediately after they have become available or the implementation of the whole release (or parts of it) may slip. This may further be complicated by some sites already having functioning computer systems in several of these areas and potential resulting issues with data migration that may initially slow down the system. This has important implications for our planned evaluation in terms of measuring quality and safety improvements and will be discussed in more detail in the method section below.

The planned implementation model as described above is necessarily somewhat idealised and simplified. In reality we expect to find a more dynamic local context-dependant picture emerging as sites and LSPs seek to manage their way through the challenges associated with implementation.

2.3.4 Core and additional NHS CRS services available to Trusts

Key elements of the NHS CRS, together with associated support, are designated as “core” and are funded centrally as part of the NPfIT. The services are available to Trusts at no charge.(35) Trusts can however also purchase the following additional services:(35)

- Services that add extra-features to the NHS CRS
    - Pathology
    - Document Management
    - Financial Payment
    - Dental
    - Pharmacy
    - Stock Control
    - eHealth (electronic access to patients, telecare and video conferencing).

- Professional services
    - Professional services to assist Trusts with activities supporting technical and clinical transformation, whether or not these come within the direct scope of the NHS CRS programme. These may include workshops, training, presentation materials and provision of experienced resources.

- Catalogue services
    - Trusts have the opportunity to purchase related IT products and applications at competitive rates without the need to go to tender.

2.3.5 The consequence of the NHS CRS for Trusts and the delivery of care

Given the disruptive nature of the technology, and the transformative ambitions it holds, it is anticipated that the introduction of the NHS CRS will have considerable consequences for the work practices of individuals and teams as well as for the workflow in hospital trusts. It is likely to impact and reshape the way individuals, clinical teams and indeed the whole organisation functions. This disruptive and transformative capacity also poses the most significant risks to the successful implementation and adoption of NHS CRS. The NHS therefore needs to plan strategically for the introduction of the NHS CRS. To facilitate this planning, NHS CFH has defined a set of Trust activities under the heading of “Clinical transformation”,(35) these including:

- **Awareness and communications:** Trusts need to appoint a Communications Lead and seek and incorporate user feedback
- **Process planning and redesign:** Trusts need to assess how the new system will affect current practices and plan how new work practices may be constructed
- **Tracking and managing benefits realisation:** Ways of assessing the usefulness of the new system
- **Training:** Trusts need to assess training needs of users of the new system and deliver training.

Trusts will be responsible for securely migrating data from the old system onto the new system, which is preceded by a technical site survey designed to assess if their current IT resources are appropriate for the

new system.(35) Trusts will also be responsible for establishing a variety of internal structures to ensure a smooth introduction of the new system in sites. These will include local programme managers, co-ordinators and local champions to set clear standards and facilitate change throughout each stage of the implementation programme. It is planned that administrative support will be established in the form of a dedicated Project Office. The NPfIT has developed a Cost Model to help Trusts estimate the cost of these activities.(35)

2.3.6 Current status of the use of the NHS CRS

The planned implementation of the NHS CRS is imminent.(16) Four PCTs have since Spring 2007 been piloting the SCR under the "early adopter" programme.(38) The introduction of the NHS CRS into secondary care is, however, yet to come, and substantial implementations are likely to begin in the second half of 2008 and early 2009, although a number of Trusts already have aspects of the selected products implemented. For example, PACS has already been successfully implemented in all English Trusts. In addition, Queen Mary's Sidcup NHS Trust and the Taunton and Somerset NHS Foundation Trust have "gone live" with the Cerner Millennium patient administration system in November 2007 and January 2008, respectively.(39;40)

Other Trusts are already using some elements of the NHS CRS. For example, the Medway NHS Trust in Kent and some London Trusts, such as Imperial Healthcare NHS Trust, plan to skip implementation of Cerner Release 0 and start this year with Release 1.

Also of relevance is the north-south divide in terms of the major suppliers to secondary care (Lorenzo in the North, Cerner in the South and London). As noted above, differences in the products, and in the rate of delivery of elements within each product, may lead to different approaches being taken in the two parts of the country. Of particular interest is the fact that Cerner is an existing product, undergoing adaptation and development, while Lorenzo is a new product being developed from scratch is of potential importance. In terms of pace of delivery, Computer Sciences Corporation is currently agreeing a re-phasing of delivery of elements within the Lorenzo product. Such events, if they continue to occur, would have significant impact on the timing of post-implementation evaluation of affected clinical processes.

A further complication that may be of importance is that additional suppliers may be providing, now or in the future, certain elements of the NHS CRS locally, so that comparability of product within as well as between regions may prove problematic. The "Additional Suppliers Capability and Capacity" tendering process will probably mean that such local differences remain in place for some time to come.

2.4. Theoretical, methodological and evaluative considerations

2.4.1 Overall theoretical views on implementation strategy

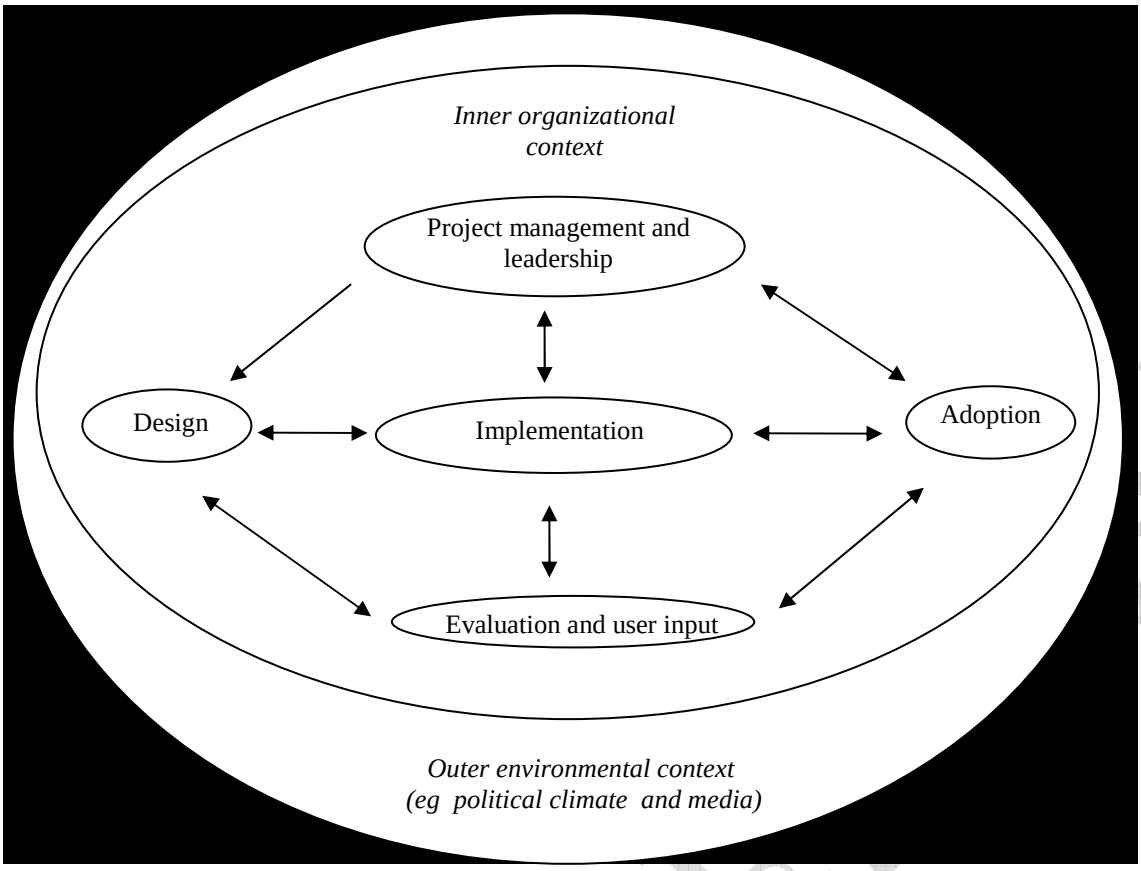
The majority of previous work on the implementation of information systems in all sectors – i.e. not only in healthcare – strongly suggests that implementation and adoption are more likely to prove successful if sufficient attention is paid to socio-technical factors. These factors include:

- Ongoing multi-disciplinary end-user input throughout all stages of development and implementation of the new system in order to capture real requirements and promote a sense of ownership among proposed adopters.
- The visible commitment of management to new systems and their implementation.
- Careful attention to structural, organisational and professional challenges that arise as a result of the introduction of the new system, and to the inevitable (and desirable) realignments and changes that follow. Not all desirable and beneficial changes can however be predicted and planned for.
- Continuous evaluation cycles that give voice to the multiple interests and can capture and evaluate the emerging work practice, technological infrastructure, attitudes and opinions.

One key challenge for the NPfIT is that it is widely perceived by healthcare professionals, not withstanding NLOP, clinical leads etc., as centrally led and distant from its user community. This may adversely impact on implementation and adoption if individuals/institutions perceive it as being imposed on them, thereby generating resentment amongst at least some professionals. This is reflected by surveys, which show a certain degree of local alienation and scepticism towards the programme.(41;42) In order to address these issues, an appreciation of the multi-faceted impact of the NHR CRS, increased end-user input (i.e. doctors, nurses and allied healthcare professionals) with visible results, and continuous evaluation and feed-back is crucial.

Our background work has resulted in the development of a model of the spread and adoption of IT innovations in health service organisations, which is based on *Diffusions of Innovations in Health Services Organisation* theory (see Figure 4).(43) This emphasises the importance of user involvement throughout the commissioning, design and deployment process and also emphasises the importance of both internal and external factors in shaping beliefs, attitudes and experiences of end users in engaging with new technological deployments. Given the intense media scrutiny and charged political environment surrounding NHS CFH and NPfIT, we are aware that the macro cultural dimensions are likely to far more important in the context of deployment of NHS CRS than is likely to be the case with many other IT-based innovations.

Figure 4: Infusion of eHealth Innovations in Health Services Organisations Model



One of the key developments in our model is the application of *Diffusions of Innovations in Health Services Organisation* theory to IT and the more comprehensive inclusion of design and evaluative considerations.

As our model is based on available evidence in relation to IT-based interventions, it may be used for viewing the different components and contextual aspects of the infusion of the NHS CRS as an intervention in the NHS as a complex organisational environment. We use the term *infusion* to depict the active spread of the innovation in the organisation and include the process of becoming established throughout the NHS.

We use this model to inform the conceptual integration of both questions and findings such as, for example, what is done in adopter sites to facilitate the implementation of the NHS CRS, and what more may be done. It may be used as a general conceptual framework for both qualitative and quantitative components of our evaluation. In addition, the proposed project may also provide with an opportunity to empirically test our model in an integrated way.

2.4.2 Health informatics and evaluation

There is little experience with large scale national IT systems in healthcare anywhere in the world and there is as a consequence little published evidence on evaluations of their implementation. But there is nonetheless an emerging relevant body of work on approaches to evaluate IT-based interventions which is of some relevance to our deliberations on evaluative considerations, particularly in emphasising the need to move away from a simplistic focus on randomised controlled trials to the use of rigorous scientific

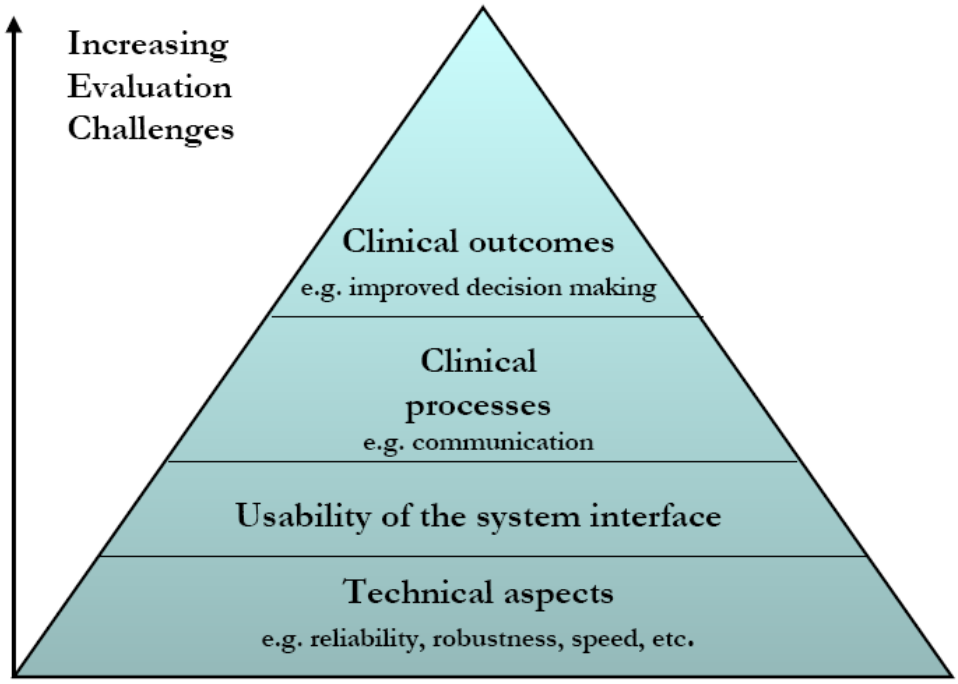
approaches that also allow a more holistic appreciation of contextual and explanatory factors, which may be crucial in determining the success or failure of the implementation strategy.(44-46)

As IT-based interventions such as the NHS CRS and the healthcare setting in which it is to be implemented are both complex, it is now increasingly accepted that evaluation activities need to be multi-faceted. This is often expressed in terms of employing multi-method approaches that integrate quantitative and qualitative components. The value of combining the two lies in the resulting ability not only to determine if something works (or results in changes in the desired direction), but also in the ability to explain why it works (or conversely why it fails to work). However, past evaluations of IT in healthcare have been largely one-dimensional.

Our systematic review on IT and its impact on the quality and safety of healthcare found that in relation to EHRs robust longitudinal evidence for the effectiveness of such systems is lacking. Existing investigations have been mainly quantitative in nature and although qualitative evaluations exist, relatively few evaluations have combined these approaches.(47;48) This may help to explain why in the past the introduction of new IT-based systems into healthcare organisations has proved problematic. The literature contains numerous examples of failed ventures, which can to a large extent be explained by a lack of attention being paid to human factors.(49;50) For example, Sicotte and colleagues describe the introduction of EHRs into four US hospitals;(51) staff refused to use the system feeling that it did not fit in with existing care processes.

In 2001, when Clamp and others evaluated Integrated Care Record Service (ICRS)(52) – a precursor concept of the current NHS CRS as part of the Electronic Development and Implementation Programme (ERDIP) of the NPfIT (see Figure 5) – they attempted to explore the system features arguing "…if a system does not operate satisfactorily at the technical level, then it will not be used, and the evaluation of the next three levels cannot occur". They asked four basic questions: i. Is the EHR technically sound?; ii. Is the EHR useful and usable?; iii. Does the EHR improve communication?; and iv. Does the EHR assist operational decision making? They found a. patient coverage, b. completeness of data, c. accuracy of data and d. timeliness of data problematic and a barrier for evaluation. However, they concluded that although EHR and ICRS are very different concepts; there are many similarities and more importantly: "They are both complex change management projects. The challenge surrounding change management are more significant than the technical issues involved". Whilst offering useful insights, this approach does however somewhat over-simplify the multi-faceted and evolving inter-relationship between technology, work processes and organisational and clinical outcomes, a point we elaborate on below.

Figure 5: The South Staffordshire ERDIP Programme Evaluation Hierarchy



During 2003-2006, Fulop and colleagues evaluated the processes and outcomes of implementing NHS IT programmes in four acute hospitals Trusts in England.(53) Their objective was to describe the progress and perceived challenges in implementing the NHS information technology programme in England. This was a qualitative study based on case studies and in-depth interviews, with themes identified using a framework developed from grounded theory. The authors concluded that this method of data collection resulted in a detailed appreciation of stakeholder perceptions of challenges and potential ways of addressing these.

Greenhalgh and colleagues are currently conducting an evaluation of the "early adopter" programme, where four PCTs are piloting SCRs.(54) This is also a mainly qualitative evaluation, which involves investigating the views of key stakeholders including GPs, nurses, patients and the public, practice managers and other clinical and administrative staff.

During the initial stages of our evaluation we plan to conduct, expand and update the literature review presented in this protocol. This will include a specific search for relevant European literature utilising the EFMI Evaluation Website, which is a very useful resource of existing IT evaluations in healthcare with details of evaluations from a range of countries, which may prove to be of some benefit in relation to our planned evaluation. We therefore plan to formally search the EFMI database using a variety of search terms in the context of updating our literature review at the onset of this project.

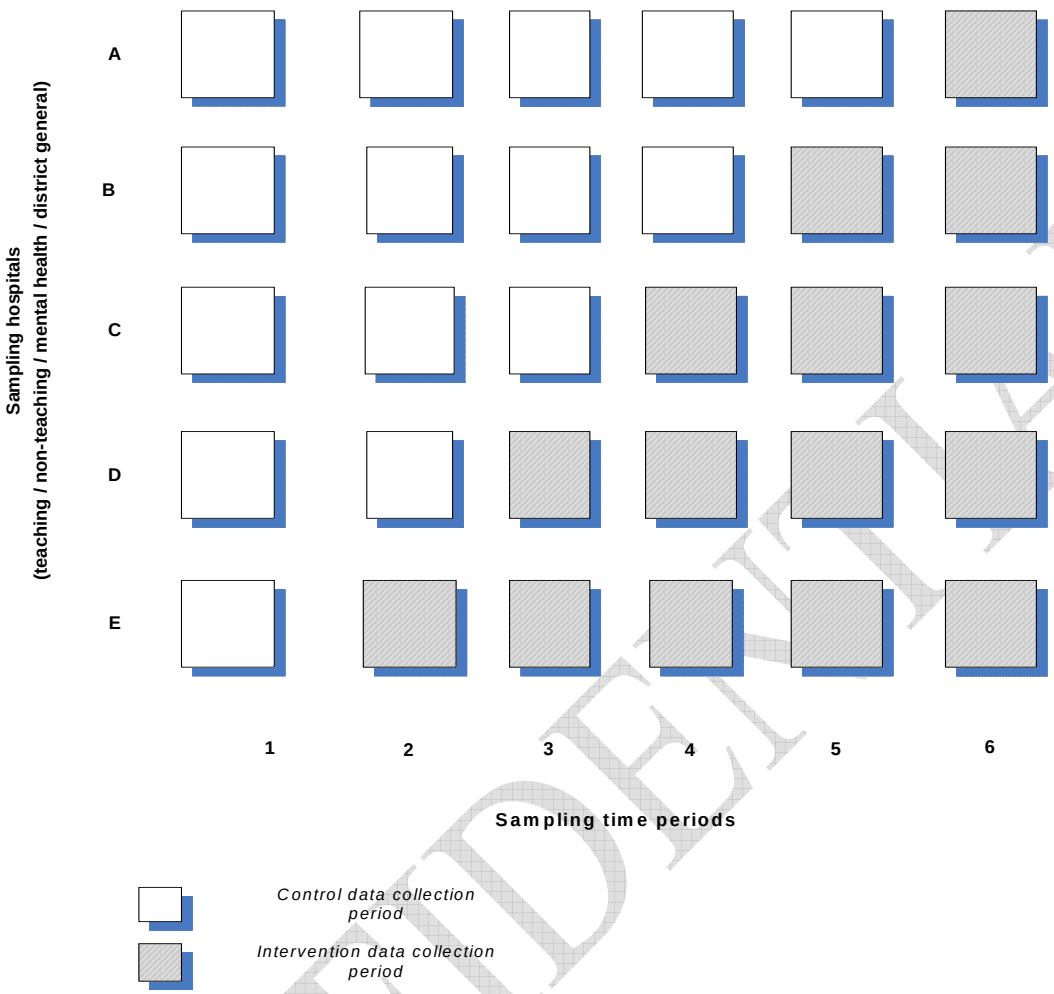
2.4.3 Overall methodological approach

Considering the issues outlined above, in order to gain a sufficiently rounded and dynamic understanding of the introduction of the NHS CRS, we propose to employ a mixed methodology evaluation that uses the principles of a stepped wedge design to select hospital sites within each of the three clusters, with data generation and analysis being informed by realistic evaluation considerations. We will, in partnership with NHS CFH, aim, where possible, to sample a range of hospital sites including teaching, non-teaching, mental health, district and general hospitals.

2.4.3.1 Stepped wedge design for sampling hospitals

Randomised controlled trials provide a robust methodological approach for evaluating the effectiveness of interventions, but they are not always ethical (i.e. when there are concerns regarding the lack of equipoise) or technically feasible; these concerns are relevant to the implementation of NHS CRS. The phased introduction of the NHS CRS corresponds conceptually to a stepped wedge design, where clusters of subjects are allocated sequentially to receive a new intervention (see Figure 6).(55) In the usual application of a stepped wedge design the clusters would be allocated randomly, but this is unlikely to be practical in the current context. The timing of its introduction in different hospitals will, as discussed above, be determined by operational considerations. Also, in an ideal stepped wedge design trial, all clusters (i.e. hospitals in this case) would have observations taken at each “step” of the trial. In practice, the unavailability of relevant comparable routinely collected data and limited research resources makes this infeasible. Within each cluster that is sampled, however, there will, as a minimum, be an opportunity to undertake baseline measurements for selected quantitative variables and obtain a corresponding set of post-intervention measurements; there may however also be the opportunity to undertake a series of measurements before and after the intervention (i.e. a time series element) and undertake comparisons with control sites that have yet to implement the intervention (see Figure 6), both of which would add considerably to the rigour of the analysis.

Figure 6: Stepped wedge design demonstrating a phased roll-out of the intervention (i.e. NHS CRS into hospitals) and the opportunity for comparisons with control sites yet to receive the intervention

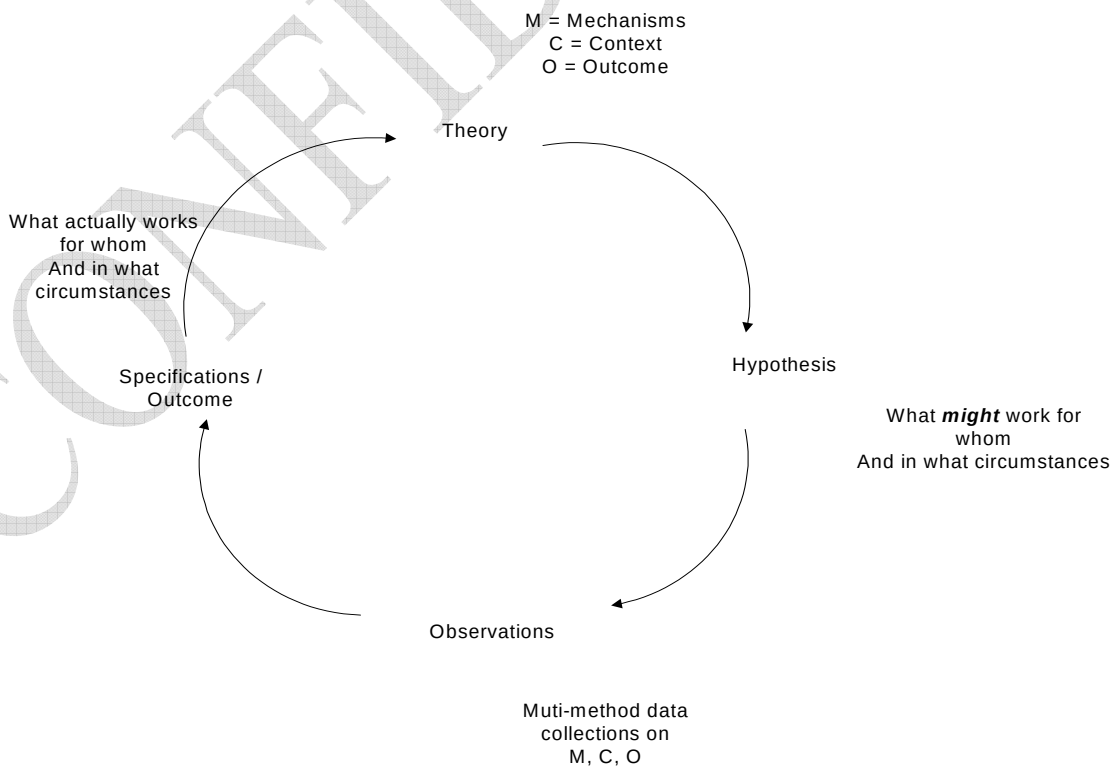


The data generated will thus consist of before and after measures from a sample of clusters (hospitals), together with data from control sites, within each of the three LSPs. For each cluster there will also be data on the timing of the intervention. For most of the quantitative variables we anticipate some degree of between cluster variability. Thus, the primary approach to analysis will be through random effect (otherwise known as multi-level) modelling.(56) The hospitals will be fitted as random effects with fixed effects for the LSPs. The timing of the interventions for each cluster will also be included in the model, initially as a linear term, but with exploratory analysis of alternative models.

2.4.3.2 Realistic evaluation

The main strength of realistic evaluation is the attempt to link the specific contexts and mechanisms in a way that has perhaps not been considered in the past.(57) What works in one site under certain circumstances will not necessarily work in another site. The main issue is thus not only whether a measure worked (as outcomes), but also how did it do so or, conversely, why it failed to work when logic dictated otherwise. Results of conducting evaluations in a realistic way should be that the contexts (structures) that trigger certain mechanisms are identified providing useful knowledge for future programmes. The research task is testing theories of how programme outcomes are generated by specific mechanisms in contexts. This task involves making intra- and inter-programme comparisons in order to see which *context-mechanism-outcome* configurations are effective. This can help to inform *what works for whom and in what circumstances*. Figure 7 below illustrates the realistic evaluation cycle.

Figure 7: The realistic evaluation cycle



Adapted from: Pawson R & Tilly N (1997)(58)

We propose using realistic evaluation as a conceptual framework for analysing both qualitative and quantitative data, and plan to use Cornford et al's framework (discussed below) to inform our approach to data collection and analysis. A key question to answer in this respect will be, "Which mechanisms of the NHS CRS work for whom under what circumstances?" In order to answer this question, we will examine context -mechanism-outcome configurations for causal relationships. If these can be effectively determined, then contexts under which the implementation of the NHS CRS worked well may be re-created in other settings (i.e. other hospitals) and consequently determine outcome. Conversely, contexts in settings where the implementation of the NHS CRS worked less well can help to identify barriers to achieving desired outcomes.

Examining the introduction of the NHS CRS in terms of context-mechanism-outcome (structure-process and outcome) configurations is likely to be most complete by employing both quantitative and qualitative methodologies. For example, context may best be investigated by qualitative means investigating issues such as organisational culture, the wider political environment and individual attitudes. Investigating outcomes, on the other hand, will also need a quantitative component including a measurement of outcomes such as rates of errors, healthcare professional time spend and rates of unnecessary repeat tests.

2.4.4 Cornford et al's evaluation framework

Cornford and colleagues' evaluation framework combines Donabedian's causal chain of quality of healthcare (consisting of a structure-process-outcome triad) with socio-technical factors including system function, human perspective and organisational context.(59) According to Donabedian,(60) quality of care is a function of: i. structure (e.g. organisational traits and resources); ii. processes (activities and interactions between healthcare professionals and patients); and iii. outcomes (the difference in a patient's health status as a result of care). The model is presented as a matrix with structure, process and outcome on one axis and system functions, human perspectives and organisational context on the other (see Table 3).

Table 3: Cornford et al's evaluation framework

	System functions	**Human perspectives**	**Organisational setting**
Structure (Context)	Technical structures of legacy and new NHS CRS systems	Stakeholder attitude and opinion; professional roles	History, resources and skills within organisation. Environmental constraints
Process (Mechanisms)	Systems in use, operational characteristics	Human work processes and care giving that draws on NHS CRS functionality	Organisation's ability to embrace and support change through implementation activities.
Outcome	Systems performance, usability, reliability and integrity	Changes in healthcare delivered	Organisational learning in respect of EHR, IT management; organisational transformation.

This model addresses Donabedian's three classic aspects from the perspective of the technology used, the people involved in the work process, and the institutional setting. The framework thus encompasses technical, individual and team, and organisational perspectives and serves to address the long-term prospects of a system – its sustainability within a technical, social and organisational context – as well as changes to the means for the delivery of care and to established work practice. Use of the framework can help in this study to focus on organisational consequence, and to lead our evaluation activity beyond a few narrow or de-contextualised measures.

The advantage of this framework for studies of the implementation of NHS CRS is that it frames a broad set of evaluation targets and perspectives that combine social and technical perspectives and that encompass qualitative and quantitative approaches. It must, however, be understood as just a framework within which specific data gathering approaches can be located, and we certainly do not claim that it alone offers the elusive integration of the technical and social, qualitative and quantitative elements. The framework can however, as shown here, guide evaluation activities and the choice of criteria, serving as a flexible template within which specific evaluation criteria and methods can be located, and related one to another in analysis. The framework is particularly relevant to the study of the key goal of reducing error through its compatibility with Reason's model that sees errors as having roots in technical, individual, group and organisational failures, with the emphasis directed towards the latter end.

As a simple primary route through data the model allows consideration of how technical structures link to human work process and create organisational outcomes – a simple diagonal similar to that used on the South Staffordshire ERDIP studies described above (see Section 2.4.2).(54) Such a reading of data might produce a clear understanding, but it is more likely that tracing such a simple chain of understanding will raise questions or pose contradictions (for example, how come "good" technology did not lead to "good" human process, or vice versa; how was a fragile and incomplete technology accommodated and made useful by human participants?). Resolving such a contradiction will then require a shift of attention to some other aspect of a system – perhaps in technical outcomes (for example, non-use of certain functionality), or be found in the prior attitudes of certain stakeholder groups. Considering the interaction (inter-relations) between the conceptual cells achieves a deeper level of understanding (a hermeneutic reading of research data) by moving from understanding parts to understanding wholes and back again.

We now outline the application of the framework to the work proposed.

2.4.4.1 Structure: The established characteristics of the situation under study. "The things we have".

Structure is sometimes referred to as "the causal past",(61) representing significant initial conditions that an innovation such as NHS CRS must relate to – current resources and actors, and the characteristics of the work setting and healthcare institution – and with which it must combine to become embedded.

System functions

In the case of NHS CRS we consider the technical components used to implement the service, both as already established and as delivered as part of the implementation activity (e.g. Lorenzo, Cerner Mllenium). Technical elements offer specific functionality, and may displace others, for example computer-based test orders replacing those done by paper. Part of the innovation represented by NHS CRS is thus an innovation in structure, the introduction of new technical means and resources. And, as we know, technical components can prove problematic – computers crash and hang, networks go down, data transmission is not always reliable and data are not always preserved.

Human perspectives

Here we identify the various stakeholder groups who come to use or experience NHS CRS, including healthcare professionals (doctors, nurses, pharmacists etc.), healthcare managers, technical support staff, technology suppliers, and not least patients and carers. Each of these stakeholder groups bring key elements of structure, for example for healthcare professionals in their professional formation and training, their ethical tradition, as well as attitudes, desires and expectations in the face of change in general, and technology led change in particular.

Organisational context

Here we consider the institutional and management structures through which NHS CRS is developed and rolled-out, as well as the established culture and working style of the various institutions. Past experience of large scale IT implementations in hospitals suggests that success draws strongly from distinctive managerial strategies pursued over extended periods of time, but equally on the wider context within which an institution is set – for example, the stability of the local labour market. We also know that prior positive experience of technology can build a strong legitimacy for future innovation.

2.4.4.2 Process: The way things work and are worked out; how parts interact or operate to perform individual and collaborative tasks. "The things we do"

Process is concerned with the activities that occur within a hospital setting as they relate to the delivery of care. This process is to some degree under the influence of human participants through their professional training and experience, but is equally conditioned by the structural characteristics of the technology employed. Most significantly for our study is how process changes as a result of the implementation of the NHS CRS, and how this is negotiated and worked out as a part of an extended implementation activity. The real significance of NHS CRS will be found not in the technical characteristics of the supplied technology and its designed functionality, but in the activity of accommodating it and negotiating it into use.

System functions

The study will focus on the way that the technical components work together as a system, how they manipulate and process data, and how correct, valid and trustworthy they are in day to day use. Prior studies suggest that such systems are not stable or given as operational technology, but even at the best demand constant attention to maintain the technical process at the desired level of performance. Similarly they need attention to become and maintain acceptance within the social environment; for example, attention to assessing and monitoring reliability and safety of the technical system (an embedded evaluative process).

Human perspectives

Here the framework allows us to focus on the main stakeholder groups as identified above: healthcare professionals, healthcare managers, technical support staff, technology suppliers, patients and carers). Each group, taken alone, will present their own distinct account of what it means to work with and through the new NHS CRS systems and which we will capture through qualitative research. More significantly perhaps is the ways in which NHS CRS may change the relations *between* the various stakeholders, both in the short term and in the longer term. Shifts in the timing, pace and location of work, and the ability to reorganise work processes or rely on technical resources (e.g. in prescribing) may have both positive and negative consequences.

Organisational context

Here we consider NHS CRS as an intervention or contribution to the overall organisation and to its operational development. Previous studies emphasise the challenge that any particular hospital must face when adopting major information systems and the long and extensive (almost unending) implementation that it requires. Getting from "here" – which for most hospitals will be established, functioning, well understood and tolerably safe working practices based on a mix of paper and discrete IT-based systems, as well as the accumulated years of experience of all the main actors – to "there",, a brave new world of integrated information management with effective decision support – must be understood as a significant process in itself. In these terms NHS CRS is not an end state that is achieved after a discrete effort, but is more suitably understood as an enduring process of change and for which the organisation must be prepared and committed.

2.4.4.3 Outcome: The consequences of an innovation, what endures, how care is experienced. "The things that happen"

Traditionally outcome is associated with measures of patient's health status as a consequence of a process of care, but here outcome is extended to include the enduring state of technology, of professional interests and for the healthcare organisation itself.

System functions

For the technical components outcome is expressed principally in their ability to continue to operate within the environment, to be considered to maintain their status as relevant, applicable and reliable participants

in the healthcare setting – allowed to stay – welcome. This is of course not the usual use of the term "outcome" in healthcare, but in this case, as with other new and challenging technologies, it is indeed a primary consideration.

Human perspectives

Once again, we consider the main stakeholder groups. For each group we will assess their overall feelings about their work with the new system, their sense of achievement or satisfaction in doing their job or receiving care. It is here that a more traditional notion of "outcome" can be found – with outcome reported in terms of patient satisfaction, adherence to care pathways, or satisfaction with informational resources available. We also must recognise the perception gaps that occur between the "ideal" care records system and the actual one that they experience. The tensions between these two provide a useful perspective from which to assess outcome.

Organisational context

The organisational outcome reflects the institution wide response to the implementation and use of NHS CRS. At one extreme we may find the NHS CRS can become just "one of the things we do", achieving over time the status of an embedded, taken for granted, characteristic of the hospital (infusion). At the other, may be a more problematic situation in which aspects of NHS CRS are rejected or never get beyond a "project" status. Another related outcome measure for hospitals is their developing level of understanding of what it takes to implement and adsorb new technical elements in the care process and to reform work flows and work practices,

2.4.5 Integrating the methodologies

When integrating the methodologies discussed above, our model of the *Infusion of eHealth Innovations in Health Services Organisations* will we hope contribute to our understanding of how the NHS CRS arrives and is accommodated within and integrates within secondary care settings. It will inform our thinking in relation to information systems as socio-technical systems and the ways in which this is implemented, adopted, diffuses and then infuses within organisations. This will furthermore allow us to compare and contrast the ideals and realities of deploying technologies.

Whilst the stepped wedge design will be used to inform recruitment of study sites and to quantitatively assess the impact of the introduction of the NHS CRS, realistic evaluation and Cornford et al's evaluation framework will inform the qualitative component of the current study.

2.5 Methodology of evaluation

As described above, our fundamental understanding of how information systems arrive and are accommodated within healthcare settings is based on a socio-technical understanding that addresses the technology within the context of use and as part of the care-giving practices of the various stakeholders.

We see the implementation of technology within an initiative such as NHS CRS as a diffusion process, in which, over time, systems, ideas and understandings move through the community; different parts of the community experience and relate to the system in different ways at different times. We thus take a constructivist view in which technology is given meaning through the practices which people develop around it – see, for example, Orlikowski's concept of a "technology in practice".(62) This approach has certain consequences for the evaluation task: In contrast to "normal" health evaluation tasks and randomised controlled trials we need to take very seriously people, and their attitudes and opinion, and the ways in which these change over time. Realistic evaluation provides us with a conceptual model of context (or in this case contexts), mechanisms, and outcomes, and asks us to focus as much on mechanism as on outcome. This approach is very compatible with the classic approach of Donnabedian, reflected in his concepts of structure, process and outcome. These themes are then applied to this research through Cornford et al's *Structure Process Outcome/System Factors Human Perspectives Organisational Context (SPO/SHO)* framework, which draws on both Donabedian and socio-technical models. The framework serves in particular two distinct purposes in this research, and thereby helps to retain the focus of the work. The first is to systematically collect data (both quantitative and qualitative) on context/structure, process/mechanisms, and outcomes across the technical, human and organisational domains. The second purpose is to allow such data to be drawn into an analysis that will always look beyond any single cell (be it technical, human, outcome or structure). Meaningful insight is drawn from understanding of the inter-linkages. This work will necessarily be built on co-ordinated complementarities of quantitative and qualitative methods. Our focus on human activity systems with technology draws us to incorporate a number of stakeholder groups (including patients) and explore over time their attitudes, expectations, experiences and work practices.

Our proposed evaluation thus investigates the NHS CRS adoption in a way that will allow us to both capture what should be ideally adopted (the systems as designed and built), while comparing it with what is actually occurring (the systems as adopted and used) and in this way help to identify and minimise the risk of the NHS CRS project.

We will assume that individual Trusts will adopt the NHS CRS when they achieve the readiness criteria (Stage 1). Therefore how the evaluation sites are selected is largely determined by the Trusts. However, in order to adopt a systematic approach to our evaluation we plan to use the principles of a stepped wedge design using alternative approaches to selection as a randomised approach is not likely to be achievable.

Our primary objective for the evaluation is to determine what is happening during the implementation of the NHS CRS in secondary care and what consequences this has for patient care, NHS organisations and the people working and being cared for within these Trusts. This will include examining what might work for whom and in what circumstances. This will also provide insight on what might not work and in what circumstances; this will we believe prove valuable for NHS CFH for reconsidering implementing

approaches in order to keep the project on track for a successful closure; this should also provide valuable information on potentially transferable lessons for other IT deployments.

We plan a pragmatic, but systematic approach to selecting aspects of NHS CRS adoption for evaluation. We will use both qualitative and quantitative observations (data collections) although we fully appreciate that the cost of obtaining reliable and accurate data within the project time frame needs to be critically assessed during each stage of the project. For instance, obtaining data on prescribing errors would be feasible while determining adverse events or fatalities directly attributable to the NHS CRS would, in view of the relative infrequency of such events and the difficulties in determining causal relationships, be extremely difficult. Our initial approach would be to determine if the “new system” introduced by the NHS CRS is equally safe as the “old system”.

In our analysis we will first frame theories in terms of propositions about how mechanisms are fired in contexts to produce outcomes. This will lead to hypothesis generation and testing so as to allow refinement of the measurements and observations we undertake (see Figure 7).

3. AIMS AND OBJECTIVES

3.1 Key aims

The main aims of our proposed project are to inform the roll-out of NHS CRS with a view to ensuring that this is successfully used and has the maximum chances of introducing benefits whilst minimising harm. In doing so, we will:

- Identify benefits and negative impacts of the new system across a variety of dimensions that are reflected in our work packages
- Liaise with NHS CFH throughout the project in order to inform both local implementation and national roll-out of the NHS CRS.

3.2 Key objectives

The call for proposals presents some indicative research questions, but indicates that this listing is "neither exhaustive nor exclusive". In preparing our bid we have undertaken some reworking of the themes directly identified in the call, and present our broad understanding of the research questions in the work packages described below. Table 4 (below) provides a mapping of the original research questions to this work breakdown, noting that some of the original questions are mapped to two work packages. The table also indicates the principal data gathering activities as associated with each work package. More generally, we see these work packages as closely related and, where appropriate, as sharing theoretical approaches, field work activities in data collection, and analytical themes.

The specific objectives that we propose to focus on are to:

Work package 1: Implementation, deployment and organisational learning

- Identify and document the implementation strategy in use and its justification, and the balance of planned versus emergent change supported.
- Identify the stages through which implementations proceed, both planned and actual, and the criteria used to progress between stages.
- Identify assimilation gaps and the strategies used to address them
- Identify relevant activities and deliverables at each stage (process and outcomes)
- Assess how safety, patient care and organisational context is incorporated in to implementation activity
- Identify examples of organisational learning and the development of new competencies (technical and evaluative)
- Feedback all the above to support the continuing roll-out of NHS CRS.

Work package 2: Stakeholder attitudes, expectations, engagement and satisfaction

- Explore key stakeholders' (i.e. including patients/carers, healthcare professionals and managers) attitudes and expectations of the NHS CRS in secondary care before it is introduced

- Explore their early experiences of the NHS CRS
- Explore their perceptions once the system has become established and, where applicable, once they have become experienced users of the new system
- Feedback all the above to support the continuing roll-out of NHS CRS in secondary care.

Work package 3: Organisational consequences: organisational workflow, professional role and data quality transformations

- Explore how human resource transformations occur in terms of evolving professional roles and remits
- Explore how workflows transform
- Investigate the impact of NHS CRS on the IT literacy of the staff involved
- Understand the changing IT training needs of healthcare professionals
- Investigate the impact of introduction of NHS CRS on data quality.

Work package 4: Assessment of costs of NHS CRS implementation

We seek to:

- Assess exceptional introduction per-provider costs
- Assess annual (recurring) per-provider costs
- Develop evaluation frameworks to assess the impact of NHS CRS on costs
- Validate cost categories with local providers and with NHS CFH
- Make recommendations about a core dataset for NHS CRS evaluation post-implementation.

Work package 5: Assessing error, safety and quality of care

- Investigate whether the introduction of the NHS CRS results in improvement in medicine reconciliation on admission to, and discharge from, hospital
- Investigate whether the introduction of the NHS CRS results in improvement in availability of clinical records
- Investigate whether the introduction of the NHS CRS results in improvement in availability of clinical test results in secondary care outpatient and inpatient settings.

Work package 6: Organisational consequences and implications for future IT deployments and evaluations

- Summarise and integrate the findings from the previous five work packages
- Identify barriers and drivers that shape the implementation process and drive the diffusion of NHS CRS within the health community
- Relate findings to the overall objectives of the NHS CRS and NHS CFH – e.g. for seamless care, efficiency gains, error reduction, guideline adherence, disease surveillance etc.
- Assess the degree of transformation of the healthcare system that NHS CRS and associated projects may lead to

- Draw conclusions in respect of governance and communications strategies related to implementations of this scale and complexity
- Identify relevant target audiences for this research, and their specific needs and interests
- Prepare reports and other materials relevant to these audiences and from which they can draw in future work.

4. DETAILED METHODS AND WORK PACKAGES

4.1 Research scope

In line with the objectives set out in the call for proposals (NHS CFHEP 005) we propose to focus on ***evaluating the implementation, adoption and integration or infusion*** of the NHS CRS into hospital, mental health and specialist community settings. We seek to develop a rich picture of the evolution of the ***structure*** and ***process*** in secondary care in evaluation sites as a result of the adoption of the NHS CRS and as a consequence of its interactions with other deliverables of the NPfIT such as PACS, ePrescribing, Choose and Book and clinical decision support systems (CDSS). We will build this picture by collecting qualitative and quantitative data as NHS CRS adoption unfolds in the evaluation sites. We will collect formative and summative data on structural changes in the organisations (how the human resource configurations change), process changes (how the care pathways change), system changes (how the supplier refines the system), organisational perspective changes (how the organisation responds) and the consequences for patient care.

Only implementation (adaptation) and maintenance (evolution) phases of the NHS CRS system life-cycle are within the scope of this research, not requirements elicitation (exploration) or design (technical development) phases. However, much design at the organisational and work practice level does remain in scope, a central feature of any system being put to use.

4.2 Overview of work packages

We provide below an overview of the work packages that we aim to pursue and then provide a more detailed discussion of each of these work packages below; Table 4 provides a mapping of the original research questions onto the planned work packages (see Appendix 4 for the research questions suggested in the NHS CFHEP 005 tender).

- **Implementation, deployment and organisational learning (Work package 1):** We propose to study the way NHS CRS is rolled out, and actual experiences of implementation (e.g. technical, clinical and organisational issues).(63-65) This Work package also considers and explores the effect of the macro and local context, and well as sense of organisational learning or development of (new) core competencies including technical skills and evaluative capacity.
- **Attitudes, expectations and experiences of stakeholders (Work package 2):** We propose to study the attitudes and expectations of the various stakeholder groups over time, including patients/carers, managers, IT service providers and healthcare professionals. This work package will allow us to explore the changing attitude as multiple initiatives and systems come to impose on healthcare professionals.
- **Organisational consequences (Work package 3):** In this work package we propose to shift the focus from the processes of implementation of the NHS CRS itself to the evolving organisational consequences expected, for example, in improved data quality, more efficient workflow or new organisational roles and responsibilities.

- **Assessment of costs of NHS CRS implementation (Work package 4):** This work package focuses on the formative assessment of implementation costs of the NHS CRS.
- **Assessing error, safety and quality of care (Work package 5):** This work package will consider key quantifiable benefits in relation to improving quality and/or safety of care in exemplary areas.
- **Organisational consequences and implications for future IT deployments and evaluations (Work package 6):** This final work package is concerned with a final integration of findings to provide the overall summative element in the evaluation and to explore the overall transformative contribution of NHS CRS beyond the national roll-out. This work package will thus also integrate our findings with a critique of how the system has developed and the interfaces that have occurred, and use this contextual information to make recommendations for implementation and evaluation of future large-scale IT deployments in healthcare.

We wil recruit up to five secondary care sites from each of the three implementation clusters. Whilst the detailed sampling strategy will be developed in association with the NHS CFH/NHS CRS implementation teams, we will, where possible, seek to sample so as to ensure sites with a range of types of providers (e.g. teaching/non-teaching, mental health, etc.), predispositions to IT implementation and the extent to which they have already implemented aspects of the NHS CRS or software to support similar tasks. We note however that sampling will have to accommodate the uneven pace of roll-out, and the particular choices made at any given site as to which modules to implement. Given the project timing, and in order to serve our formative aims in the evaluation, we expect that our sample will draw in particular on early adopters and advanced implementers. The geographical sampling will ensure that we will have sites using the range of systems and system suppliers.

For the sampling and recruitment of sites we will follow a multi-stranded strategy using various contacts. In particular we will liaise with Chief Information Officers at the Strategic Health Authorities, as well as the leads responsible for the NHS CRS roll-out within the LSP's and at NHS CFH. Recruitment at the site (hospital) level will be led through contacts with the trust Chief Executive and the Director of IT (or equivalent).

Individual participants at each site selected will either be approached in person (where feasible) or by telephone in order to enquire whether they are interested in participating in the study and if so whether they would prefer a face-to-face or telephone interview. If they agree to be contacted again, they will receive written information on the project outlining what participation will involve. Interested participants will be given/sent a consent form, which they will be asked to return in a reply paid envelope. Upon receiving the completed consent form, a researcher will contact participants in order to arrange a suitable time for an interview.

All Work packages are based primarily on data collection undertaken in these selected sites, though Work package 6 extends the work to include other stakeholders. The first three Work packages in particular have been designed to allow data collection activities to be closely coordinated.

Once the study sites have been identified and recruited, we will then move to the specific recruitment for the various Work packages. Table 5 below summarises the individuals and roles we will target, and the number of interviews we expect to undertake in each case for Work packages 1, 2 and 3. We will seek to collect data for Work packages 1, 2 and 3 in a coordinated manner using, as far as is possible, the same researchers and the same respondents.

Work packages 1 and 2 have a temporal dimension. In the case of Work package 1 this is to document the recent history that leads up to the implementation of the NHS CRS and then to follow the unfolding activities of implementation. In the case of Work package 2 it is to track changes in attitude, expectations and satisfaction during implementation. In order to capture this temporal dimension we expect to interview key respondents for Work package 1 and Work package 2 twice over a period of time – in general 4-8 months apart. In some cases we may interview three times, or follow up by telephone. We will also maintain contacts with key managers on a regular basis by telephone so as to remain up-to-date with events at the study sites.

Work packages 1 and 2 will share some of the same respondents in the category of managers, and IT support providers. Work package 2 and 3 will share some of the same respondents in the category of heath care professionals. That is, when undertaking the case study of stroke in Work package 3 we will interview the relevant healthcare professionals in respect of their attitudes and perspectives etc. Approximately 50% of the respondents in Work package 2 can in this way be drawn into the Work package 3 study.

Table 4: Mapping of the original research questions to six work packages

Work Packages		*Issues covered*	*Original research questions*
WP 1	**Implementation, deployment and organisational learning**	The means by which the NHS CRS is rolled out, and actual experiences of implementation (broadly understood). The work package considers and explores the effect of the macro and local context on implementation activity, as well as organisational learning and development of (new) core competencies including technical skills and evaluative capacity.	*OA-1* OA-6 OA-7 OA-8 OA-9 PC-B-4
WP 2	**Stakeholder attitudes, expectations, engagement and satisfaction**	The attitudes and expectations of the various stakeholder groups, including patients/carers, managers, administrative staff, IT service providers and healthcare professionals.	PC-C-1 OA-3 *OA-4* OA-5 OA-10
WP 3	**Organisational consequences: organisational workflow, professional role and data quality transformations**	The evolving organisational consequences, foreseen and unforeseen, for example in relation to data quality, changed workflow, end-to-end seamless care, and new organisational roles and responsibilities.	OA-1 OA-2 OA-4 *OA-9* *OA-12*
WP 4	**Assessment of costs of NHS CRS implementation**	Providing a formative assessment of implementation costs of the NHS CRS.	*PC-B-2* *PC-C-3* OA-13 OA-11 OA-12
WP 5	**Assessing error, safety and quality of care**	The relevant issues of error, safety and quality of care are established and base-lined.	PC-A-1 PC-A-2 PC-B-1 PC-B-2 PC-B-3 PC-C-2 PC-C-3
WP 6	**Organisational consequences and implications for future IT deployments and evaluations**	A final integration of findings to provide the overall summative element in the evaluation and to explore the overall longer-term transformative contribution of NHS CRS beyond the national roll-out.	

Questions are identified as in the Call for Proposals pages 5 and 6, PC= patient Care, OA = Organisational Impacts, HCP = Healthcare professionals.

Table 5: Mapping Respondents to recruitment tasks and Work Packages

Research Respondents	***Overall Project***	***WP 1***	***WP 2***	***WP 3***
Software Suppliers	1*Interview			
Politicians				
"The wider public"				
Individuals to be recruited on a Cluster/ SHA basis				
CIO of SHA	Ongoing contact			
LSP leads	Ongoing contact			
LSP roll out teams		Interview and ongoing contact		
Individuals to be recruited as part of site recruitment				
Trust Chief executive	Ongoing contact			
Director of ICT	Ongoing contact			
Individuals to be recruited per site within and across Work Packages include the following:				
Members of the implementation planning team (including the chair, two clinical members and one IT manager)	Ongoing contact with Chair	2*interviews		
LSP person primary responsible		2*interviews		
Trainers (*2)		2*interviews		
Patients/Carers 6* (for qualitative interviews/surveys)			1*interviews (onsite or telephone)	
Patients (for collecting clinical information)				Care record reviews
Healthcare professionals *6 • Allied *2 • Doctors *2 • Nurses *2			2* interview (with 50% overlap to WP3 - stroke)	1* interview (with 50% overlap to WP2)
Administrative staff			2* interview	2* interview
IT support personnel		2* interview	2* interview	
Healthcare and technical managers			2* interview	
IT service providers		2* interview	2* interview	
Members of professional bodies				
Units to be recruited include the following:				
Stroke wards			(also provide respondents for WP2)	Observation and interview
Accident & emergency department			(also provide respondents for WP2)	Observation and interview
Human resources department				Interview/ documentation

4.3 Work package 1: Implementation/deployment and organisational learning

4.3.1 Background

Systems of the complexity and scale of NHS CRS do not just appear in healthcare settings, or establish themselves in use, on the simple basis of their technical functionality.(66) Rather they need to be, to some degree, managed into use through a phased and often cyclical set of deliberate activities that link the technical, the work practice and organisational aspects. However, it is well understood that systems cannot be comprehensively managed into use, and some balance of planned versus emergent change should be expected and welcomed. That is, systems are negotiated into use within work practices with the participants in those practices, not imposed on them. The ways in which this activity is approached will have fundamental consequence for developing attitudes and the way systems are used.(62;67;68) Activities required during this period include communication with potential users and a sharing of the new vision, various forms of training and preparation, physical installations, work process redesign, and changeover from one way of working to another. Collectively, these activities are usually spoken of somewhat loosely as implementation. Perhaps the most frequently cited explicit implementation model in recent information systems literature is that of Zmud, Cooper and Kwon presented in a number of related papers.(64;69)

The model draws on the literature of diffusion of innovation and establishes the focus of concern for implementation as fundamentally an issue of innovation in organisational settings as much as the technical establishment of a working system.(70) The significant difference between a technology's physical diffusion (what is often referred to as acquisition), and its actual degrees and styles of use (what we call adoption) is termed the *assimilation gap*.(71) However, as below, adoption can be usefully understood in more fine grained terms – e.g. acceptance, routinisation, infusion.

This is the model of implementation used here to structure data collection and analysis. As shown in Table 6 below, the perspective is presented in terms of process and product (outcome) views, compatible with the Cornford et al. framework and able to be addressed in term of the their dimension – e.g. implementation of technology and systems functions, of new human work activities, and of organisational change.

Table 6: Process product view of implementation based on a staged diffusion model, with approximate mapping to NHS CRS (64;69)

Stages	**Model Activities**		**Trust based activities** As per NHS Care Records Service Guide to Planning and Preparation (35)	
	Process	*Product (outcome)*	*Process*	*Product (outcome)*
Initiation	Scanning of problems and opportunities and IT solutions	Match of IT and Problem	Negotiate and explore readiness to participate	Trusts own strategic development plan
Adoption	Rational and political negotiation	A decision to invest and commit to change	Assess formal readiness; Prepare Business case; Run pre deployment workshops	Business case Project Initiation Document Compliance Status Report Local Resolution Plan
Adaptation	Develop, install, maintain	Application available for use	Location preparation; Prioritization of CRS features; Select preferred approach to Implementation; Build system interfaces; manage data migration, undertake testing; Negotiate/design new care processes	Joint development plan with LSP Completion Report
Acceptance	Organisational members induced to commit to usage	Application in use ("GO Live")	Ongoing staff training and support; Monitor change activity	
Routinisation	Use encouraged as a normal activity	Governance systems adjusted to account for the application	Start to use NHS CRS; On site support handed to trust; Redundant legacy systems decommissioned	
Infusion	Benefits for 'higher level aspects of organisational work' from comprehensive and integrated use	Use to fullest potential		

4.3.2 Aim

The aim of this work package is to study the ways NHS CRS is rolled out (implemented) within clusters and within individual healthcare organisations.

4.3.3 Objectives

We seek to:

- Identify and document the implementation strategy in use and its justification, and the balance of planned versus emergent change supported.
- Identify the stages through which implementations proceed, both planned and actual, and the criteria used to progress between stages.
- Identify assimilation gaps and the strategies used to address them
- Identify relevant activities and deliverables at each stage (process and outcomes)
- Assess how safety, patient care and organisational context is incorporated in to implementation activity
- Identify examples of organisational learning and development of new competencies (technical and evaluative)
- Feedback all the above to support the continuing roll-out of NHS CRS.

4.3.4 Methods

This work will be undertaken at two levels, that of the cluster/region/LSP, and that of the healthcare organisation.

Preliminary work will be based on document review and interview with the technical developers and the implementation teams at the LSP.

Design

The design of this work package allows for the collection of data from the LSP/Region and from the healthcare organisation. Thus the approach will allow a picture of the degree of variation between the approach in regions, and within regions by individual healthcare organisations. Given the temporal character of implementation and adoption, the design allows for a regular data collection activity over a period of up to one year per site.

Sampling

At each site (note that where possible we will use the same people as in work packages 2 and 3, discussed below.)

- Four members of the implementation planning team including the chair, two clinical members and one IT manager
- Two members from the LSP who have primary responsibility for this implementation site
- Two trainers or support staff (in house, LSP or contracted).

Data generation

This work package will be based on semi-structured face-to-face interviews. The interview guide will be based around the declared implementation strategies and time frames used in the cluster/region, and the Cooper and Zmud model described above. We will also collect, where possible, relevant institutional documentation, publicity materials and training resources.

Regular follow-up telephone interviews/emails will be used to maintain contact with identified people and to obtain an account of the implementation momentum.

Key issues to be explored

As identified in the discussion of the background to the work package, the key issues we identify are as follows:

- Choice of implementation strategy at LSP and Region
- Choice of implementation strategy at site
- Implementation phasing, timing and resourcing
- Check-points and phase transition processes
- Development of organisational capacity to manage technology and exploit it in healthcare work
- Balance of resources between site and LSP
- Composition of implementation team
- Linkage of implementation management to wider healthcare community
- Aspects identified by stakeholders as good or poor practice.

We plan to consult healthcare professionals when developing topic guides for interviews. These healthcare professionals will include both junior and senior nurses, doctors and allied health professionals.

4.3.5 Data analysis

The data collected will allow within LSP/Region and between region comparisons. This analysis will be supported by the use of a fairly formal interview guide, giving an ability to make comparative statements about individual sites. The work, together with data collected in work packages 2 and 3 will allow an analysis that explores the relationship between local context (structure), the NHS CRS programme, and the LSP resources. We envisage that the primary focus of data analysis here (in contrast to Work packages 2 and 3) will be more on the relationships between the technical elements and the organisation, expressed in terms of processes of deployment, and outcomes of usable live systems, and systems in organisational use.

4.4. Work package 2: Stakeholder attitudes, expectations, engagement and satisfaction

4.4.1 Background

Various examples of failed EHR implementations across the world support the importance of considering and addressing stakeholder views of the new system.(49;50;72) In the context of the NHS CRS, these stakeholders do not only include healthcare professionals (i.e. doctors, nurses and allied healthcare professionals), but also managers, IT service providers and patients/carers.

Patient/carer perspectives, although crucial for the success of the NHS CRS, are often neglected in large scale evaluations of interventions in healthcare. This is however arguably the most important stakeholder group with potentially most to be gained from implementation of the NHS CRS. Existing investigations have mainly been conducted in primary care and UK studies indicate that patient perspectives towards EHRs are largely positive.(73;74) However, important patient concerns surrounding the confidentiality of EHRs have been identified. As part of the ERDIP, mentioned above, the Patient Electronic Record Information and Consent (PERIC) project, found that many patients have concerns relating to access of those who are not directly involved in their care such as receptionists and social workers.(75) The project also found demographic differences in attitudes, with females being most concerned about these issues and older people being least concerned. In addition, the "Share with Care" project, which is also part of the ERDIP, found that patients wish to be asked for consent whenever information is shared.(76)

Healthcare professionals comprise another key stakeholder group whose attitude to the introduction of the NHS CRS is crucial to its ultimate success. Of concern, however, is that several surveys show relatively negative perceptions of healthcare staff towards the NPfIT.(41;42) Again, confidentiality issues were found to play a major role and radical changes in work practices that are likely to result from the introduction of the new system may also contribute to re-considering the relative perceived value of the NHS CRS over the old system. Investigations from outside the UK have further uncovered some concerns relating to EHRs negatively impacting on the clinician-patient relationship and computers as a physical barrier for healthcare professionals to orient themselves towards the patient.(77-79)

Conversely, it has been argued that time savings as a result of the introduction of EHRs may increase both provider and patient satisfaction by reducing waiting times and speeding up care processes.(80;81) It has also been argued that EHRs may result in increased patient empowerment. However, a recent UK study has found that patients' desire to be empowered through computer usage may be negligible.(82)

4.4.2 Aim

The aim of this work package is to explore key stakeholder attitudes, expectations, engagement and satisfaction in relation to the introduction of the NHS CRS in secondary care over time.

4.4.3 Objectives

We seek to:

- Explore key stakeholders' attitudes and expectations of the NHS CRS in secondary care before it is introduced
- Explore their early experiences of the NHS CRS
- Explore their perceptions once the system has become established and, where applicable, once they have become experienced users of the new system
- Feedback all the above to support the continuing roll-out of NHS CRS in secondary care.

4.4.4 Methods

In order to obtain a thorough understanding of the introduction of the NHS CRS in secondary care, we will seek to obtain an insight into the perspectives of a range of stakeholders. Gaining insights into a variety of key stakeholder perspectives is important as the introduction of the NHS CRS may have different impacts in different contexts. This is crucial for hypothesising about causal relationships relating to the context-mechanism-outcome sequence.(57) In particular, we will seek to identify contextual barriers to adoption and generalisable contextual facilitators for the widespread embracing of the NHS CRS among key stakeholders.

Participants

We propose to explore the perspectives of:

- Patients and, where relevant, their carers
- Healthcare professionals (i.e. doctors (including junior doctors), nurses (including nurse prescribers), pharmacists and allied health professionals)
- Managers
- IT service providers
- IT support personnel
- Administrative staff.

Recruitment

Participants will be recruited from sites that implement the NHS CRS. Given that there are three geographical areas implementing the new systems, we will aim to recruit from up to five sites (hospitals) in each of these areas (15 sites in total). As sites involved are likely to vary in relation to local arrangements and preferences, approaches to recruitment of participants will be flexible, being negotiated with key contacts and gatekeepers at each site.

Whilst healthcare workers and clinicians may be approached directly by the team, patients will be recruited with the help of recommendations of clinicians or ward sisters and, if applicable, from expert panels at individual sites.

Sampling

We will aim to recruit the following range and approximate number of participants from each of the 15 sites (where possible, these will be the same individuals as in Work package 1):

- Six healthcare professionals (2 allied health professionals (including pharmacists), 2 doctors and 2 nurses)
- One manager
- One IT service provider
- One IT support personnel
- One administrative member of staff
- Six patients/carers.

Maximum diversity sampling will be employed and in so doing we will aim to sample staff working in a range of clinical areas, and patients with a range of long-term conditions.

The views of staff involved in the direct utilisation of the new system as a means of delivering care and those supporting the introduction of this new system will be obtained by interviewing healthcare staff, support staff, providers and managers.

We see patient perspectives as being a very important part of this work and an essential complement to those of the healthcare community and IT professionals. Studying this group will offer an important opportunity to gain insights into how care is experienced and understood as new systems and work practices come into use.(26) Through including patients we will be able to capture an often overlooked perspective on perceived changes in quality of care associated with introduction of an electronic health record. We expect these interviews to be relatively brief and straightforward, justifying the effort and costs involved in conducting them.

In total, we are thus proposing to undertake approximately 240 interviews (plus those that are serial interviews) and expect that these numbers will lead to saturation and generalisability beyond the settings in which these data are collected.

The overall purpose of this Work package is not to obtain a representative statistical sample of interviewees; rather, our proposed sampling is purposive, issue driven and does not make claims about the direct generalisability of findings. This is a defining characteristic of qualitative research where the aim is to explore emerging issues important to and perceptions of individuals in order to obtain a more in-depth understanding of how the new system is received and accommodated within work situations. The sample size will therefore be guided by theoretical saturation with the end of recruitment of participants determined by the point at which no new themes are emerging. In giving the approximate numbers of individuals to be interviewed, we have merely given an indication of the numbers that we expect will lead to theoretical

saturation. We will continue data collection until this point is reached. Should a greater amount of interviews than expected be required, we will, as suggested, aim at redeploying resources until theoretical saturation is reached. In the (unlikely) case of such a scenario occurring, this decision would be taken in conjunction with the Independent Project Steering Committee.

Data analysis will be iterative and guide future sampling. Thus, when recruiting participants, divergent views will actively be sought and we will encourage and give permission to subjects to describe any perceived strengths and limitations of the new system. Although recruitment is most likely to be facilitated through gatekeepers and contacts, we will attempt to build on this approach through open access and give individuals who want to be heard a chance to be involved. This will most likely happen through inviting comments by email and announcements/presentations at the sites in question.

Design

This work package will employ qualitative methods incorporating a longitudinal element in order to capture the temporal dimension of stakeholders' experiences. Qualitative enquiry is ideally suited for exploring subjective experiences and allowing participants to raise issues of personal significance as they experience change. The richness of data obtained is expected to result in a much more in-depth picture of adoption behaviour than could ever be obtained by using quantitative methods alone. The longitudinal element is likely to be important as participants' attitudes towards the new system are likely to change over time as they experience the transition from the old system to the establishment of the new system. This design is powerful in that it can capture change as it happens from the perspectives of key individuals.

Procedures

Data collection

We will employ two methods of data collection including face-to-face and, where appropriate and convenient, telephone interviews. As it is likely that the introduction of the NHS CRS will influence stakeholder groups in different ways, interviews with patients will be more structured than those with other key stakeholders.

With the exception of patients, we plan to conduct interviews with the same individuals at two and, where relevant, three time points during the implementation of the NHS CRS in order to capture the temporal component:

- Early perceptions at baseline
- Perceptions during early use
- Perceptions in more established use.

Our focus will be on perceptions during early and more established use; these interviews are expected to last around 30 minutes each.

Patient interviews are expected to be briefer than interviews with other stakeholders at around 10-20 minutes each. Here, questions will be more structured to give participants guidance, whilst still allowing time and space for elaboration.

We acknowledge that the proposed number of interviews is relatively large, but feel that this quantity is necessary to obtain an adequate insight into potentially important issues at each site and from each viewpoint. In order to keep the workload manageable, we will however try, wherever possible, to synchronise data collection activities in Work packages 1-3.

Key issues to be explored

The issues to be explored in the methods of data collection outlined above will slightly vary among groups. Key issues to be explored in healthcare professionals, managers and administrative staff include:

- Attitudes to NHS CRS (over time)
- Perceptions of efficiency, safety and convenience
- Integration into wider work processes
- Changes in work practices (deliberate and emergent)
- Consequences for communication and interaction
- The national roll-out (possible adaptations/alternative models and recommendations).

Key issues to be explored in IT service providers and IT support personnel include:

- Attitudes to NHS CRS (over time)
- Perceptions of efficiency, safety and convenience
- Integration of NHS CRS into existing systems (data transfer)
- Continuing support
- The national roll-out (alternative models and recommendations).

Key issues to be explored in patients include:

- Attitudes to NHS CRS (over time)
- Satisfaction
- Perceived impact on patient care
- Acceptance and use of the new system
- The national roll-out (alternative models and recommendations).

As in Work package 1, we plan to consult healthcare professionals when developing topic guides for interviews and questionnaires. These healthcare professionals will include both junior and senior nurses, doctors and allied health professionals.

4.4.5 Data analysis

Making use of both formative and summative methods is expected to result in a rich contextual picture of how key stakeholders perceive the introduction of the NHS CRS into secondary care over time.

Data analysis will consist of comparing data within individuals, perspectives (including patients and professions), and within and across sites. Cornford and colleagues' evaluation framework will guide these efforts and provide with structure.(59;83)

Due to the volume of data and in order to keep bias to a minimum, we will seek to analyse the data with the help of two experienced researchers who will use NVivo 7 software to facilitate coding. In doing so we expect the survey data to take significantly less time than data obtained from interviews.

We expect the analysis of data collected in this work package to result in detailed recommendations that can inform both NHS CFH's current implementation efforts and the national roll-out of the system.

4.5 Work package 3: Organisational consequences: organisational workflow, professional role and data quality transformations

4.5.1 Background

Adoption of NHS CRS in acute trusts is intended to be "disruptive" in the sense that it will replace the existing paper and IT-based systems and practices. The NHS CRS is not however a "disruptive technology" in the sense in which this was originally described by Christensen in 1997, as NHS CRS is not an *unexpected* new technological development.(84) Rather, it is a planned introduction of innovation. In this work package, we seek to evaluate the *acceptance* of NHS CRS technology innovations (*adoption*) by healthcare workers and seek to understand how they incorporate this technology in to their everyday practices. We plan to explore the comprehensiveness and the sophistication of use of the NHS CRS and the extent to which its full potential is realised and embedded in the organisational infrastructure, i.e. the extent to which the technology *infuses* into the NHS. NHS CRS adoption is not expected to be smooth; some components of it will be introduced in some departments first and these are then to an extent expected to *diffuse* within the broader healthcare organisation. Diffusion of NHS CRS is thus another facet of our inquiry. As Christensen described it, disruptive technology lacks refinement, often has performance problems because it is new, appeals to a limited audience and may not yet have proven application. This has some resonance with the current reported state of affairs of the NHS CRS.

NHS CRS adoption will result in a large scale health service redesign, making it important that we study the socio-technical features of the NHS CRS. Coiera has proposed four rules for socio-technical informatics, namely:(85) i. technical systems have social consequences; ii. social systems have technical consequences; iii. to design socio-technical systems, we must understand how people and technologies interact; and iv. we do not design technology, we design socio-technical systems. The first two of these are particularly relevant to our evaluation, whereas the latter is more relevant to IT system designers (and are

not considered any further here). We briefly expand on these two relevant rules below in the context of possible implications for NHS CRS:

- **Technical systems have social consequences:** NHS CRS will change how people work and the new ways of working will create new roles and existing roles may disappear resulting in job redundancies. Transformations of professional roles are inevitable. The educational and training demands may not match the existing workforce profiles resulting in undue pressure on existing staff to change, leading to anxieties and insecurity among staff. These organisational transformations could be highly disruptive. This may adversely affect staff morale and have a negative impact on NHS CRS adoption.
- **Social systems have technical consequences:** NHS CRS may be well-designed and effective, but this is no guarantee that it will be used. Use is likely, to an extent, to be influenced by the prevailing local culture within Trusts. The factors that may help overcome any prevailing negative attitudes include existence of local champions and proactively fostering a climate that supports innovation. Users may also reject systems because of poor usability or safety or security concerns. User interface design has an impact on data quality and the NHS CRS could degrade or improve the data quality with resulting patient safety and quality implications.(86;87) NHS Common User Interface (CUI) is expected to safeguard such concerns.(88)

A given milestone in the NHS CRS adoption trajectory can be viewed in the context of its dominant innovation perspective (implementation, adoption, diffusion, infusion etc) enabling us to loosely map each stage to a wealth of information available from recent systematic reviews, including ours.(70;89) Our field data therefore can be mapped to research evidence in systematic reviews though the dominant innovation perspective of the NHS CRS adoption trajectory at the time of data collection. This will, we believe, serve as a useful aid to interpretation of our findings.

In this work package we propose to evaluate the stroke pathway (as an exemplary workflow package) in each of the evaluation sites.(90;91) Management of strokes in the NHS has undergone a dramatic change recently and with the adoption of the NHS CRS and introduction of Map of Medicine® further changes in care pathways are likely. The dynamic nature of this environment makes it an ideal platform for us to evaluate various transformations in professional roles, data quality, training needs, quality of data entry and record content, IT literacy and workflows.

4.5.2 Aim

To evaluate the organisational level transformations during NHS CRS adoption process.

4.5.3 Objectives

Using stroke as an exemplar long-term condition, we seek to:

- Explore how human resource transformations occur in terms of evolving professional roles and remits

- Explore how workflows transform
- Investigate the impact of NHS CRS on the IT literacy of the staff involved
- Understand the changing IT training needs of healthcare professionals
- Investigate the impact of introduction of NHS CRS on data quality.
- Investigate the impact of introduction of NHS CRS on quality of data entry and record content

4.5.4 Methods

Data will be collected from people (participants) and systems (computer databases) both directly and indirectly involved in the stroke pathway. We plan to undertake three stages of sampling, i.e. before adoption, during the early phase of implementation and when NHS CRS has reached a reasonable stability (with regards to system modification and adaptation). Both qualitative data (interviews, questionnaires) as well as quantitative data (job roles and data quality statistics) will be collected, thereby allowing us to build a rich picture of the organisational and data quality transformations that occur.

Data related to role transformations will be obtained from the respective human resource departments of the participating hospitals. Workflows are now recorded in the form of protocols and Patient Group Directions, these being written directions relating to the supply and administration (or administration only) of prescriptions only medicine by certain classes of healthcare professionals. It provides a legal framework for para-medical staff to participate in the medicines management process thereby improving the throughput of, for instance, stroke pathway. In this pathway early therapeutic intervention is likely to reduce long-term disability of stroke patients. Data on IT literacy and IT training needs are collected by qualitative methods (interviews and questionnaires). Data quality considerations will relate to validity, completeness, reliability, coverage, accuracy and timeliness in the recorded information. These data will be collected by record reviews using structured templates. Data quality in electronic records largely reflects the quality of data entry. Record content analysis is therefore important and this will be evaluated by auditing the number of essential data categories entered by the user in the electronic record.(92)

Participants

- Range of healthcare professionals and support staff involved in the stroke pathway

Systems

- PAS system
- Radiology system
- Laboratory system
- Electronic records
- Prescribing system.

Documents

- Job advertisements

- Training programmes
- Different versions of stroke protocols and pathways.

Recruitment

Participants will be recruited and systems selected from sites that implement the NHS CRS. Given that there are three geographical areas implementing the NHS CRS, we will aim to recruit from three accident & emergency departments of acute Trusts in each of these. This will, as discussed above, be achieved by initial networking with NHS CFH, LSP and acute Trusts.

Sampling

There are two dimensions to sampling, namely with reference to the accident and emergency departments (human resources, care pathways, IT literacy of the staff involved) and to patients with stroke (data quality). We will sample approximately 10-20 stroke patients from each site. Data will be collected from computer systems (for data quality and record content) and from all the staff who were involved in the management of each patient (IT knowledge, training etc.). Data on changing job profiles, training programmes and stroke management protocols will be obtained from each of the participating accident and emergency departments.

Design

Data on IT knowledge and training will be collected by interviews and questionnaires. Data relating to changing job profiles will be obtained from the human resources departments. Data on data quality will be obtained from systems by database inspections using both manual and automated methods. Data on record content will be obtained by auditing the number of essential data categories (Table 7) recorded in the electronic records.

Table 7: Categories of clinical data

Category	***Components***	***Examples***
Identifiers	Demographics, Identity codes	Name, date of birth, NHS number
Patient findings	History Observations	Description from patient Subjective: symptoms Objective: clinical signs
Assessment (hypothesis)	Assessment	Diagnosis
Plan (hypothesis)	Plan	Proposed treatment, tests

Actions	Therapy, referrals, tests Information shared, follow-up	Actual therapy, initiated, tests ordered
Modifiers	Who recorded data, when, Certainty, severity	Who made the observation, when, certainty

Adapted from: Health Informatics: Information and Communication (2002) (93)

Procedure

We will employ qualitative methods to capture temporal dimension of skills and knowledge transformations. This information will be triangulated with documentary data collected in regard to skills and knowledge transformations. Several pre-selected data sets will be inspected for validity, consistency, timeliness and accuracy. We will use data customised quality probes to explore the quality of electronic patient data.(94) The concept behind the data quality probe is the notion that mismatched clinical data recorded represent poor data quality (Figure 8). The number of essential data categories recorded will be audited by inspection of records by trained researchers.

Figure 8: Examples of two-item data quality probes

		DATA ITEM B	
		Present	**Absent**
DATA ITEM A	**Absent**	**A+B must be present.** e.g. Patients with hypertension must have had a BP measure **Probe**: Patients with hypertension and no BP measure	**A is present + B is absent.** e.g. Patients with penicillin allergy should not be prescribed penicillin. **Probe**: Patients Px penicillin who are allergic
	Present	**A is absent + B is present.** e.g. Patients without heart disease should not be taking long acting nitrates **Probe:** patients on long acting nitrates with no record of heart disease	**A and B are mutually exclusive.** e.g. Men recorded as having had a hysterectomy. **Probe:** Non-females with a recorded hysterectomy.

Adapted from: Healthcare Computing (2004)(58)

For this evaluation data quality probes needs to be designed and that will require clinical, informatics and computational input. Some of the data quality probes can be easily constructed by reference to stroke

protocols while others relating to various clinical contradictions specific to the stroke pathway need to be designed. We are confident our team has resources to do this task.

Key issues to be explored

The key issues addressed in this package relate to organisational and data quality transformations. They are:

- Does data quality improve or show degradation?
- Will there be a mismatch of skills and knowledge required for proper use of the system and that is available?
- How disruptive is the associated organisational change in terms of new staff recruited and needing to familiarise with new care pathways?
- Does the quality of data recording (entry) improve?

As in Work packages 1 and 2, we plan to consult healthcare professionals when developing topic guides for interviews and questionnaires. These healthcare professionals will include both junior and senior nurses, doctors and allied health professionals.

4.5.5 Data analysis

Formative and summative data analysis will result in a rich contextual picture of organisational transformations induced by the NHS CRS adoption. Data relating to various organisational transformations are qualitative and they need to be first be analysed by standard categorisation methods (open coding, selective coding and theoretical coding etc). The emerging themes will then be further analysed with reference to the Cornford et al framework to determine rational conclusions. As mentioned before, what works for whom and when, is important information for the future NHS CRS roll-out programme of NHS CFH. We will first postulate mechanisms, contexts and outcomes of observations that we plan to make and then, during analysis, using realistic evaluation methods we will seek to critique our observations in relation to our hypotheses; findings will be presented in relation to what is likely to work, in which context and for whom. This will help us to formulate detailed recommendations that inform both the NHS CFH's current implementation efforts and the national roll-out of the system.

4.6 Work package 4: Assessment of costs of NHS CRS implementation

4.6.1 Background

It is widely assumed that adoption of NHS CRS will benefit patients, healthcare professionals, managers and planners in the NHS, and these key perspectives are addressed in the earlier described work packages in this proposal. This Work package examines the expectation that the NHS may benefit economically in terms of savings in cost and time, for example, from cutting out paper-based transactions, replacing paper-based filing and storage by automatic filing and archiving systems, improved workflow and reduction in errors. The complexity of the programme being implemented necessarily poses a complex

evaluative challenge. Current research specifically concerned with the evaluation of implementation of NHS CRS in the UK is limited,(95) and comparative quantitative studies evaluating different forms of EHR are virtually unknown.(96;97) Bowns, Fulop and Chaudhry suggest that the few reports of NHS CRS evaluation that exist rarely gave a full account of costs involved and many evaluations are simplistic and incomplete.(96) Previous evaluations of IT systems have used some form of 'before and after' comparison of costs, taking a healthcare providers perspective.(95) Most studies of the effects of PACS and EHRs have included the initial costs of implementation and some have also included the costs associated with operation and maintenance.(98;99) Studies have measured various combinations of space requirements, staff time, staff productivity, transcription times, turnaround time, test completion time, test order rate, test repeat rates, drug costs, revenue gains, length of stay, return on investment and impact of improved coding on revenue.(95) Fulop and Chaudhry identified a number of technical concerns with the existing evaluations, a key limitation being that the comparative technology was not clearly started in many studies.(95;97)

There is no standard evaluative framework in place to assess the costs of EHR implementation and implementation of an EHR on this scale is unprecedented. We appreciate that very little or almost no previous work is available on this subject and we will therefore need to develop appropriate measurement techniques.(100) Given the stature and the status of this project we believe that this additional work is both possible and justified.

The central function of this work-package will be to assess the implementation costs, and develop a framework for costing that can be rolled out to trusts as NHS CRS is implemented, taking into account the different combinations of required and optional packages available at different phases of implementation of the different NHS CRS systems (discussed above). We will measure the costs of implementation of NHS CRS at early and later adopter sites, and will address both initial 'exceptional introduction per-provider costs' and 'annual recurring costs' for the NHS CRS packages being introduced.

Furthermore, expectations of new system may not be met if the technical specification of the system does not meet the demands of the service, such that costs savings may not be realised. When a new electronic record/CPOE system was introduced into a UK NHS trust, the researchers found that it took the same time for the researcher to access paper records from before the electronic record as it did the computer ones after the electronic record's introduction – the server was overloaded, so it was hard to access in the day and still very slow in the evenings and weekends.(101)

The most extensive and most rigorous quantitative study carried out in the UK in this methodological area was one to establish the net costs to secondary care of a hospital-wide PACS that comprised digital acquisition, storage and transmission of radiological images via a hospital-wide network to 150 workstations.(102) 'Before and after' comparisons and time series analyses were carried out at Hammersmith Hospital (London, UK), and comparison with five other British hospitals where PACS was not

being installed. The cost analysis considered implementation costs and changes in key elements of hospital running costs, including the impact of changes in the length of inpatient stays. Running costs increased for equipment and maintenance, computer staff, utilities and radiographers, and reduced for clerical staff, healthcare assistants, dark room technicians, radiology times, films and chemicals and clinician time.(99)

4.6.2 Aim

To provide a formative assessment of implementation costs of the NHS CRS.

4.6.3 Objectives

We seek to:

- Assess exceptional introduction per-provider costs
- Assess annual (recurring) per-provider costs
- Develop evaluation frameworks to assess the impact of NHS CRS on costs
- Validate cost categories with local providers and with NHS CFH
- Make recommendations about a core dataset for NHS CRS evaluation post-implementation.

4.6.4 Methods

There is uncertainty around the actual roll-out of specific modules of the NHS CRS packages, such that we cannot yet design a detailed evaluation for any individual region, nor develop a comparison between regions. Due to these uncertainties, we are not currently in a position to specify our data collection sites, which may have their own confounding elements of any such design.

Instead, we present the more general issues of how to measure the costs of implementation of NHS CRS, and propose to develop a number of compatible approaches, assess the available data and evidence that is generated in the implementation process as well as by our other work-packages. Our key deliverable from this work-package will be a validated framework of measures that can support further implementation activity and help to prioritise modules in the roll-out.

A range of different approaches can be used to estimate implementation costs, including analyses of routine data, financial transactions and direct observation of resource use. The range of methods includes task completion times, work sampling, direct observation, activity monitoring, diaries and qualitative techniques.

In summary, we will collect data on the following per-provider cost categories:

Exceptional introduction per-provider costs, including:

- Hardware

    - Servers and back-up servers, network installation, PC workstations, laptop computers, printers
    - LAN upgrades and wireless access
    - Ergonomic equipment (keyboards, workstations, monitor stands etc)
    - Interfaces to other systems (e.g. PAS, registration, scheduling, pathology, radiology, pharmacy)
- Software (initial purchase and support)
- Training suites
- Technical support staffing and personnel coverage to support CRS implementation
- Project and change management teams (including aspects such as workflow process redesign)

Annual (recurring) per-provider costs, including:

- Software (annual licensing, support and periodic upgrades)
- Hardware (support, upgrades and maintenance)
- Costs of user accounts for support staff
- Long-term technical and system support administration staffing in support of CRS (new employee hire, duties covered by existing staff).

We will report on variability in both categories of costs at individual sites to provide formative assessment of implementation costs. During the implementation process, we will examine our cost categories, and validate them with local providers and with colleagues at NHS CFH to ensure that we are including all costs appropriately. We will also consult with external experts, such as the British Computer Society Health Informatics Forum.

Development of evaluation frameworks to assess the impact of NHS CRS on costs

We will develop a set of costing frameworks that will allow the team, as part of the study, and Trusts, as part of implementation, to evaluate implementation of NHS CRS. These frameworks will be sensitive to the specific NHS CRS packages, the specific package releases in use, the mix of core and optional packages, as well as the specific needs of the range of clinical settings to be evaluated.

This work-package will develop a set of costing parameters that can be integrated into future versions of the NHS CRS to allow more responsive and less labour intensive evaluation of costs.

Data collection

Data will be collected from each provider where the NHS CRS is adopted. Most of the data parameters listed will have to be collected proactively as part of this evaluation (such as training costs). This can be measured by direct valuation of resources used.

4.6.5 Data analysis

Unit costs will be attached to resource use. The annual equivalent capital cost of the NHS CRS system will be obtained (using a combination of technology implementation, running and annual equivalent replacement costs) so that the overall annual NHS CRS running costs can be estimated for an NHS trust. This set of estimations will be carried out in consultation with NHS CFH.

Key assumptions in costing methods (such as process measurement methods, unit costs and differences between centres, changes in running costs over time) will be tested in one- and two-way sensitivity analysis.

Integration with other work packages

Work package 4 will be integrally linked to the other work packages. Assessing quantitative measures of cost of implementation will allow us to explore early and later costs of the system and compare users' perceptions obtained from Work package 2 with actual costs. The qualitative work being carried out in Work package 2 will help us to understand reasons for variability in implementation costs and how best to manage these. Integration of qualitative and quantitative measures will provide essential formative data on implementation costs that can inform later stages of the roll-out. Integration of data on prescribing safety from Work package 5 will also allow us to link implementation costs with performance data.

Specific formative aims within this work package are to develop a framework to identify provider-specific implementation costs, comparing different NHS CRS systems; comparing the same system being implemented in different hospitals; and comparing implementation of systems in different service delivery environments. These comparisons will therefore allow us to learn, during the early stages of implementation, how best to proceed with the continuing roll-out of these systems.

The data collected during these formative evaluations will be examined to assess which parameters are most informative, reliable, transferable and critical assessors of implementation, to allow us to develop a reduced dataset for future implementation assessment. This will allow future modelling of performance without having to carry out extensive primary data collection. This reduced dataset will also be used to inform evidence-based procurement of NHS CRS packages.

This evaluation provides us with the opportunity to deliver both a formative and summative assessment of the costs of implementation of this complex intervention, using prospective observational data. The integration of data from this Work package with data on user perceptions, patient safety and organisational implementation parameters will influence specific deployment of the NHS CRS, and provide generalisable lessons for future deployment of IT initiatives in the NHS.

4.7 Work package 5: Assessing error, safety and quality of care

4.7.1 Background

We have extensive experience of undertaking assessments of quality and safety in secondary care settings. For example we have done studies involving observation of medication errors,(103) chart review to detect medication related problems and studies of the quality and safety of information provided by hospitals at the time of patient discharge.(104;105) Also we have experience of using the methodology required to assess medicines reconciliation at hospital admission and the use of chart review to detect adverse events in hospitals.(106;107)

Challenges

The call for research suggests a number of aspects of quality and safety that we might investigate and our team has the necessary expertise to undertake this work in a methodologically robust manner. There are challenges however because the earlier releases of the NHS CRS do not contain all of the important safety features and undertaking rigorous assessments of quality and safety is very time consuming and requires build-up of high levels of trust with participating hospitals. Therefore before going on to describe the research that we might do us part of this work package we describe below some of the issues that need to be considered.

The first challenge is that the NHS CRS will be delivered in four releases, probably over a period of three or more years. Consequently the releases that we assess are likely to be the first two or three, which are the most basic, offering a bedrock for some later developments; as such we would not, within the timescales of this evaluation, expect to observe many of the potential benefits in safety and quality of care that NHS CRS can offer. These are more likely to appear in later release, such as advanced inpatient prescribing and decision support.

The second challenge is that the two NHS CRS systems being studied – Cerner Millennium and Lorenzo – provide different functionalities in different releases. It is therefore difficult to find areas of enquiry that can be applied across the different programmes/systems within the timeframe of this evaluation. For example, Cerner offers Maternity and Theatre functions in its first release, however Lorenzo will not provide these until their third release, probably two to three years later. In contrast, Lorenzo Release 2 has an electronic patient discharge option, which would be valuable for assessing discharge reconciliation. Both systems plan inpatient prescribing to be in their third release (described as R2 in Cerner), so there is the potential for this to be measurable within the study period.

A third challenge is that it is well recognised that new technologies can cause new forms of harm. These have recently been highlighted with respect to computerised physician order entry (CPOE) in the USA.(108) However there are ample other examples from areas such as software control of radiotherapy, which have led to fatal under-dosing or overdosing.(109;110) In our design we will need to be alert to the unexpected in any aspect of the implementation.

In the light of these challenges we have outlined below some of the approaches we propose to take to assess the impact of the NHS CRS on quality and safety. If awarded the contract to undertake the study, we will work closely with NHS Connecting for Health to decide exactly how to undertake studies given the availability of different releases (and functionalities) of the NHS CRS in different parts of the country. Also, in visiting acute Trusts as part of the evaluation we will use our interviews with front-line staff and managers to try to pick up any examples of new errors resulting from the introduction of the NHS CRS. We will alert NHS Connecting for Health to any potential problems and will be prepared to alter our plans for evaluation to focus on any emerging safety issues.

Areas of quality and safety that we plan to evaluate

We have the ability to assess changes in almost all of the quality and safety outcomes outlined in the call for research. As noted above, however, the early releases of the NHS CRS likely to fall within this study period may not have a great impact on clinical quality – we expect many of these benefits to follow later. Therefore, while we will look at a wide variety of quality and safety outcome measures, we propose to focus on those outcomes that are most likely to be influenced by the earlier stages of introduction of the NHS CRS. We do not expect significant health outcomes to be detectable within the timeframe and budget, so we will focus on indicative process measures which are linked to risky activities. As medication errors are one of the most common forms of error, which can have significant consequences for health, our work will lean towards them. In addition, work in this field can yield robust quantitative data which allows the testing of hypotheses. Below we provide background information on the following aspects of quality and safety that we plan to evaluate:

- Medicines reconciliation on hospital admission
- Availability of laboratory results, electrocardiograms (ECGs) and other investigations in hospitals. In particular we would expect faster reporting of abnormal and out-of-range results which would impact on safety and quality of care
- Completeness of information provided at hospital discharge
- Clinical and medication errors

In addition

- We will look at whether the introduction of the NHS CRS improves the scheduling of operating theatre sessions (see Work package 4 for further details), and whether the frequency of cancellations changes, and the duration of delays are reduced.
- We will work with NHS CFH to agree on other quality and safety outcome measures that it would be useful and feasible to track during the roll-out of the NHS CRS. We will particularly look for local audits and assessments of the effects of implementation of the NHS CRS.

Medicines reconciliation on hospital admission

Recent NICE patient safety guidance has highlighted the importance of medicines reconciliation on hospital admission.(106) Errors in prescription medication histories occur in up to 67% of cases on admission to

hospital and up to 27% of all hospital prescribing errors can be attributed to problems with medicines reconciliation on admission.(111;112) Also, interventions have been shown to have a marked impact on improving medicines reconciliation on admission.(106) Of particular relevance to the NHS CRS is one before and after study which showed that the use of a template faxed between the admitting hospital and GP practices reduced numbers of errors from 55 to 17 per 100 patients. In turn, this increased the percentage of treatment sheets written correctly within 24 hours of admission from 45% to 83%.(106)

Given the importance of medicines reconciliation on hospital admission and the likely room for improvement with the NHS CRS we propose to modify an audit tool developed by NICE to undertake assessments of errors in prescription medication histories before and after the introduction of the NHS CRS (comparing with control sites where possible), using some of the principles of a stepped wedge design.(106)

Availability of laboratory results, ECGs and other investigations in hospitals

Lack of availability of clinical test results is an important cause of delays in patient care and harm to patients.(113;114) Problems have been demonstrated in relation to missing laboratory test results and radiographical procedures.(115-119) Also, the importance of having ECGs available was reported in a survey the US.(120)

The vast majority of studies on availability of clinical test results come from the US (ambulatory care and secondary care). Therefore, it is difficult to be certain of the extent of the problem in secondary care in the UK. Nevertheless, anecdotal reports suggest that missing information is responsible for delays in patient care in at least 10% of consultations in outpatient settings. These estimates would be in accordance with figures from the US.(113) Also, it should be noted that the type of information available is important. For example, a study from the US showed that clinicians preferred images rather than written reports for ECGs and x-rays, but opted for written reports for cardiac studies and advanced imaging.(120)

There has been little work done on the impact of electronic medical records on availability of clinical test results at the point of patient care. Nevertheless, one study from the US showed an odds ratio of 0.4 (0.17 – 0.94) for test results being missing where a full electronic record was available compared with having paper or partial electronic records.(114) Therefore the availability of a full electronic record does appear to be associated with better availability of clinical test results.

We will particularly look for cases in which missing or delayed information is safety critical. For example a recent FMEA study conducted by Barber, studying aminoglycoside prescribing in a hospital, found that the lab rang abnormal results straight through to the ward, who made a note on a scrap of paper; sometimes the prescriber would not get the message until hours or even days later. The NHS CRS, linked to pathology, has the potential to significantly reduce the time to corrective action.

We plan to investigate whether the introduction of the NHS CRS in England results in improvement in availability of clinical records and clinical test results (e.g. ECGs) in secondary care outpatient and inpatient settings.

Completeness of information provided at hospital discharge

Failure to convey accurate, complete and up-to-date information across interfaces in care is a major, avoidable risk to patient safety, yet improving care at hospital discharge has recently been described as an "unmet challenge".(121) The National Service Framework for Older People stated that "the current emphasis on providing more care in the community requires better communication than ever between health professionals".(122) Yet the Royal College of Physicians has recognised "serious problems with the validity of clinical information in interim discharge documents that may affect patient care, resource management (and) performance indicators".(123)

Evidence from the US suggests that adverse events occurred in one in five patients discharged from hospital to the community.(124;125) These adverse events include medication side-effects, unplanned readmissions and death. It has been shown that "…at least half of these events could have been prevented or ameliorated if simple measures had been put in place before the patient left the hospital".(121) A recent study that we conducted in the UK showed preventable discharge communication gaps in over 50% of patients readmitted to hospital with medication related problems.(105)

The introduction of the NHS CRS gives great potential for improving the information provided when discharging patients from hospital. As noted above, the Lorenzo system in release two has an option for providing discharge information in an electronic form. We propose to investigate the impact of introducing this system on errors (usually errors of omission) in information provided on discharge from hospital. We plan to do this using some of the principles of a stepped wedge study design.

In order to assess clinically significant gaps in information on hospital discharge communications we will modify an audit tool developed by the Royal College of Physicians.(126)

Investigating changes in clinical and medication errors

There is strong evidence of the benefits of computerised clinical decision support systems (CDSS) in reducing clinical and medication errors, particularly when systems have been well designed.(127;128) There is less evidence, however, that clinical and medication error rates will be reduced solely by the introduction of electronic records, even if these are linked to primary care.

We plan to investigate changes in clinical and medication errors as part of our evaluation, looking at all prescribing activity, whether undertaken by doctors or nurses. Barber, Cornford and Jacklin were commissioned by the NPSA, via the DH Patient Safety Research Programme, to develop a methodology to evaluate the safety of electronic hospital prescribing systems.(101) The work (based on Cornford's

framework and hence compatible with this study), successfully studied a newly installed and a long established system. In addition, since then, Barber has been involved in the evaluation of the JAC system being implemented at Great Ormond Street Hospital. In short, we have a great deal of experience in assessing these systems. It should be noted however that this methodology can be time-consuming and we would need to work with NHS CFH and NHS Trusts to work out what would be feasible within the context of the introduction of the different clinically important elements of the NHS CRS and the availability of local clinical support for undertaking assessments of error rates.

The limited UK work suggests that early incarnations of in-patient prescribing stop about two errors in every 100 prescriptions written.(101) However as we are not sure of the functionality of the planned systems we do not believe it is possible to come up with firm sample size calculations for this work, but if awarded the contract to evaluate the adoption of NHS CRS in secondary care we will undertake pilot work in participating NHS Trusts. This will enable us to design a study to assess changes in clinical and medication errors that is feasible within the funding and support available.

4.7.2 Aim

To determine whether the introduction of NHS CRS results in improvement in a number of aspects of quality and safety of care.

4.7.3 Objectives

To determine whether the introduction of NHS CRS results in improvement in

- The proportion of patients admitted to hospital having errors in prescription medication histories
- The proportion of patient encounters associated with clinically important missing records
- The proportion of discharge communications having clinically significant gaps in information
- The proportion of patients subjected to clinical or medication errors.

4.7.4 Hypotheses

- Taking a conservative figure of 30% of hospital admissions having errors in prescription medication histories we hypothesise that the introduction of the NHS CRS will reduce the error rate to below 15%.(106)
- Taking a conservative estimate of 10% of current patient encounters being associated with clinically important missing records we hypothesise that the introduction of the NHS CRS will reduce rates of missing information to less than 7.5%.
- Taking a conservative figure of 20% of discharge communications having clinically significant gaps in information, we hypothesise that the introduction of the NHS CRS will reduce this rate to less than 10% (see below for sample size calculations).

- Given the relatively limited amount of computerised clinical decision support in the early phases of NHS CRS we do not think it will be possible to demonstrate statistically significant changes in clinical and medication errors.

4.7.5 Design

We will use the principles of a stepped wedge design in which we undertake sampling at four or more time points during the course of the studies, where possible undertaking comparisons with control sites.

4.7.6 Sample size calculations

Any analysis of the data must consider that this is a de facto cluster based design, where the clusters correspond to the individual hospitals sampled. In the absence of any information on the size of the intra-class correlation coefficient that can be expected, sample size calculations are based on information aggregated at the hospital level. Also, as there will be before and after intervention data within each hospital, we will base out sample size calculations on the mean of the changes seen in each hospital, and the standard deviation of these changes. This standard deviation is also unknown since it is determined principally by the magnitude of the between hospital variation (unless this is very small). Nevertheless, we can express it as a multiple of the mean change that we are attempting to detect (ie the reciprocal of the effect size). For effect sizes ranging from 0.8 to 1.5 the required number of clusters, for 80% power to detect changes as statistically significant from zero at the 0.05 level, ranges from 15 to 6 (see Table 8). If the standard deviation is less than two thirds of the mean change (effect size > 1.5) there will in excess of 80% power, even with only 6 clusters.

Table 8: Effect size and sample size calculations

Effect size	Sample size for 80% power
0.8	15
0.9	12
1.0	10
1.1	9
1.2	8
1.3	7
1.4	7
1.5	6

As an example, if the introduction of the NHS CRS reduces the errors in prescription medication histories from 30% of hospital admissions to 15%, the mean change will be 15%. Even if the standard deviation across hospitals of this change in percentage is as high as 10% (effect size 1.5), there will be 80% power at the 5% level of significance with only six hospitals.

If the introduction of the NHS CRS reduces the percentage of patient encounters with clinically important missing records from 10% to 7.5%, the mean change will be 2.5%. If the between hospital standard deviation is the same magnitude as the mean (effect size=1), then 10 hospitals are required for 80% power at the 5% level of significance. If the standard deviation is increased to 3%, then 14 hospitals are required for the same power.

The numbers to be sampled within each hospital will be informed by more complicated sample size calculations using the methods described in Brown and Prescott.(56) In view of uncertainties in the numbers of subjects available, sampling costs and, particularly, the magnitude of intra-class correlations, final sample size calculations will be based on the best information available at the time and will incorporate sensitivity analyses. As a marker at this stage we would expect to be able to collect data on 20 patients for the first three outcome measures outlined above at 10 hospitals at 4 times points during the course of the study. This equates to 800 patients in total for each study.

4.7.7 Methods

Sampling

We will undertake sampling at up to 15 hospitals (five in each cluster), although we may undertake data collection in as few as six hospitals (two from each cluster) for some of the outcome measures depending on the results of more detailed sample size calculations. For the assessments of clinical and medication errors, the time taken to establish the trust of clinicians and set up a study means that it is unlikely that we will be able to work in more than six hospitals when undertaking this part of the evaluation.

Participants

Participants will be:

- Patients admitted to hospital who have had medication histories recorded
- Patients attending hospital outpatient clinics
- Inpatients
- Patients being discharged from hospital

Data collection

Plans for data collection for each of the studies within the quality and safety work package are as follows:

- For patients admitted to hospital we will check their medication histories recorded on admission and compare these with evidence of recent medicines issued according to their primary care records. We will use a data collection tool based on one developed by NICE (106)
- For patients attending hospital outpatient clinics, we will ask clinicians to record any instances whereby clinically relevant information is missing, such as hospital notes, correspondence, laboratory test results, x-rays, scans and other investigations.

- For inpatients, after undertaking initial pilot work, we will undertake assessments of clinical and medication errors using either chart review or direct observation
- For patients being discharged from hospital, we will undertake assessments of the completeness of clinically important discharge information. We will use a data collection tool based on one developed by the Royal College of Physicians.(126)

4.7.8 Data analysis

Initially we will undertake descriptive analyses of the data. When assessing whether CRS is associated with change in quality and safety, as outlined earlier, we anticipate some degree of between cluster variability. Thus, the primary approach to analysis will be through random effect (otherwise known as multi-level) modelling.(56) The hospitals will be fitted as random effects with fixed effects for the LSPs. The timing of the interventions for each cluster will also be included in the model, initially as a linear term, but with exploratory analysis of alternative models.

4.8 Work package 6: Organisational consequences and implications for future IT deployments and evaluations

4.8.1 Background

This final work package is concerned with the integration and presentation of findings from the project and will in this way provide the overall summative element. We see this as necessary as a separate work package to ensure that the final delivery of the project's findings is as complete, integrated and useful as possible, and is communicated to the right people. In this way we hope to be able to support research-informed policy making at both the national and trust level, as well as offering useful insights for the supplier industries. In this aspect the project can be seen as an example of translational research, concerned with moving scientific insights into the practice of healthcare.(129)

In such a multi-method evaluation across such a wide area of interests it could be easy to leave individual aspects of this evaluation to stand alone.(45;130) To avoid this, we will work to connect the various results from Work packages 1-5, with a view to mapping out the wider overall picture and establishing the enduring themes (in realistic evaluation terms, the mechanisms) that offer useful insights to those who will plan, manage and participate in future deployments of healthcare technology. In this respects, we will also seek to draw on the findings from other completed or on-going research on NHS CRS and any indirect or direct evidence that secondary analysis, whether for audit or research purposes, has been facilitated by introduction of NHS CRS.

To achieve this we see the need to pay particular attention, together with NHS CFHEP, to packaging and disseminating the results of the study in forms that are appropriate to and useful for the various potential audiences. In particular, we take a main objective of the project to be to inform future IT deployments within

and beyond NHS CFH and this will require some research in its own right to understand exactly to whom to pass on these messages and how best to achieve this.

This work package will also explore the potential overall transformative contribution of NHS CRS beyond the national roll-out. We say 'potential' since by the time of the end of this project the NHS CRS is unlikely to be fully implemented,(131) nor will sufficient time have passed for the organisations studied to have experienced all the consequential changes. Any such transformation at either the system level, or for individual trusts, will be cyclical and on a longer time frame than this project can capture. Over time we should however expect that the new technology represented by NHS CRS can meet needs previously established, but will change work processes and work flows and thereby create new needs and new potential technical and informational systems.(132) Nevertheless, we do expect by the end of the project to be able to depict the main dimensions of change we observe, and offer an assessment of their strength and significance.

4.8.2 Aim

- To present the overall findings of this evaluation in forms appropriate to and useful for the various identified audiences.

4.8.3 Objectives

We seek to:

- Summarise and integrate the findings from the previous five work packages
- Identify barriers and drivers that shape the implementation process and drive the diffusion of NHS CRS within the health community
- Relate findings to the overall objectives of the NHS CRS and NHS CFH – e.g. for seamless care, efficiency gains, error reduction, guideline adherence, disease surveillance etc.
- Assess the degree of transformation of the healthcare system that NHS CRS and associated projects may lead to
- Draw conclusions in respect of governance and communications strategies related to implementations of this scale and complexity
- Identify relevant target audiences for this research, and their specific needs and interests
- Prepare reports and other materials relevant to these audiences and from which they can draw in future work.

4.8.4 Methods

The work package will use the identified conceptual evaluation frameworks of diffusion of innovation, realistic evaluation and socio-technical approach (Cornford et al. model) to interlink the various elements. The primary concern will be to provide a coherent account of how NHS CRS, its technologies and the associated expectations are accommodated within healthcare organisations, the consequences for patients and their care, and for the healthcare professionals who deliver care. The structure of the work, reflecting

the work breakdown of the project, will be on how implementation activity over time draws in various stakeholder groups, how systems are set to work and their consequences for work processes and workflow as well as how it has effects on the quality and safety of care. The emphasis here on 'how' reflects the realistic evaluation concern with understanding underlying mechanisms.

This work package does not have a substantial empirical element, but we will undertake interviews with relevant persons within NHS CFH, LSPs and Trusts in order to establish who our various target audiences are, and what they would wish to draw from this evaluation work. We see these possible audiences as including healthcare professionals and professional bodies, healthcare managers, technical mangers and support staff in trusts, LSP staff, suppliers, patients and carers, politicians and the wider public. The contribution of the Project Advisory Board and the Independent Project Steering Committee will be very valuable in refining this aspect of the study.

5. OVERALL PROJECT TIMELINE

The overall project timeline consists of 30 months of investigation and evaluation. After careful consideration we have opted to include a Gantt chart showing the scheduling for the evaluation (below). However, recognising the complexity and interrelated nature of the NHS CRS, we provide the project timeline for guidance only in order to permit reviewers envisaging the general course of the evaluation.

It should be noted that we plan a six month set-up phase prior to beginning formal evaluation activities. During this time we plan to liaise with NHS CFH to obtain further clarity and considerably more details into the NHS CRS and its implementation strategy; this will also give us the opportunity to further develop the protocol, obtain Research Ethics Committee and Research & Development board approvals, as well as recruit additional research staff and obtain honorary contracts for them.

The six work packages depend on the speed of implementation and therefore have flexible timelines. However, as a broad guideline, we generally envisage that Work packages 1 (implementation, deployment and organisational learning), 2 (attitudes, expectations and experiences of stakeholders) and 3 (organisational consequences) will run throughout the course of the evaluation in order to obtain baseline (where applicable), early implementation as well as implementation follow up data. Here, due to the focus on qualitative methods, data collection will be flexible and summative. Work packages 4 (performance measures, effectiveness and cost-effectiveness) and 5 (assessing error, safety and quality of care) are on the other hand likely to have a much stricter and more confined timescale due to their strictly quantitative design. Finally, Work package 6 can conceptually be placed at the end of the evaluation project as it will integrate all of the above.

Gantt chart showing key activities for the evaluation of the implementation of the NHS CRS

Months	**1-3**	**4-6**	**7-9**	**10-12**	**13-15**	**16-18**	**19-21**	**22-24**	**25-27**	**28-30**
Ethics and R&D approvals										
Recruitment of staff										
Refine protocol with NHS CFH										
Recruitment of sites										
Baseline data collection										
Field work										
Data collection										
Data analysis										
Writing of report and papers										

6. RISK ASSESSMENT OF PROJECT MILESTONES

There are a number of possible risks to our evaluation of the implementation of NHS CRS; these are detailed in Table 9 below together with the possible impact of these risks on the evaluation and our proposed mitigating strategy if such problems should arise.

Table 9: Risks and mitigating strategy associated with the evaluation of the implementation of the NHS CRS in secondary care

RISKS	IMPACT ON PROJECT	MITIGATING ACTIONS
Delay in the implementation of the NHS CRS	Slippage/delay	Close liaison with NHS CFH with a view to enhancing baseline data collection and undertaking more detailed formative evaluation
Increasingly negative public (media) and/or adopter perception of the NHS CRS	May result in lack of co-operation of key stakeholders	Actively seeking negative attitudes and feeding these back to NHS CFH as early as possible so remediable action can be taken
Lack of local management support for the new system	Difficulty in entering study sites; lack of 'action' at study sites; token usage of systems.	Need to engage with local management and offer them a channel for expressing concerns. Feed back to NHS CFH/NHS CRS. Provide analysis (formative evaluation) that can help deliver approaches to address these issues
Unrealistic expectations and/or major problems with systems leading healthcare professionals to refuse to interact with NHS CRS	Slippage/delay Inability to collect 'outcomes' data	Need to capture and understand the reasons for such problems and feed information back to NHS CFH at earliest opportunity
Problems in evaluation team/staff (e.g. illness)	Inability to keep up with events in all study sites	Robust team approach to organising and managing the work; some budgetary flexibility; new PI or Local-PI or researchers appointed at earliest opportunity and in the interim ameliorative action taken by grant holders, who will collectively ensure that the evaluation is efficiently managed

7. RESEARCH TEAM

We believe our proposed research team is ideally suited for conducting the evaluation of the NHS CRS in secondary care for a number of reasons:

- We have substantial experience in conducting large scale evaluations of IT in healthcare settings employing a variety of relevant research methods
- The diversity of backgrounds (with representatives from both primary and secondary care as well as healthcare professionals and academics) will bring complementary perspectives to bear on the evaluation, thereby enabling us collectively to reflect on the complex manifestations of implementing the NHS CRS
- The group represents healthcare professionals with prolonged experience of *implementing* new health technologies. Ann Jacklin and James Paton have over 20 years experience each of implementing cutting edge technologies and are widely known as early adopters in secondary care.
- Through Ann Jacklin and Charles Vincent on the Project Steering Group and Lord Darzi and Susan Osborne on the Project Advisory group, we already enjoy excellent relationships with Imperial College Healthcare NHS Trust, which will be one of the first-wave adopters of NHS CRS (starting with St Mary's Hospital, followed by Hammersmith Hospital and then Charring Cross Hospital)
- We are aware and indeed expect that the unpredictability of such a large scale intervention may result in changing implementation efforts, which in turn may result in the need to, after careful liaison with NHS CFH and NHS CFHEP, to adapt our proposal. We are, however, confident that we collectively have the skills and experience to manage any such changes both effectively and efficiently.

7.1 Team members

Aziz Sheikh is an experienced epidemiologist, Professor of Primary Care Research and Development at the University of Edinburgh, GP by background and presently an Honorary Consultant Allergist at the Royal Hospital for Sick Children, Edinburgh. He has extensive experience of a range of quantitative and qualitative research architectures. He and his team have recently completed a systematic overview of the literature as part of the Connecting for Health Evaluation Programme (NHS CFHEP 001) and he is currently grant holder on the PINCER (**P**harmacist-led IT-based **in**tervention **c**ompared with simple feedback in reducing rates of clinically important medication **er**rors in medicines management) trial (). He has considerable experience with evaluating complex interventions and is currently a co-PI on a National Cancer Research Institute programme grant, which has its specific focus on the design, developments and evaluation of complex interventions. He, furthermore, currently leads a complex intervention trial funded by the Medical Research Council/National Preventative Research Institute and is a co-investigator on another complex intervention cluster randomised controlled trial funded by the same funders. **Kathrin Cressswell** is a medical psychologist with an interest in safety; she is currently employed as a qualitative researcher on two studies funded by the Patient Safety Research Programme. **Bernard Fernando** is a GP in Kent with a particular interest in medical informatics and an Honorary Clinical Research Fellow at the University of Edinburgh. He has contributed to a number of academic studies and reviews investigating the role of IT in

improving patient safety. **Robin Prescott** is also based in Edinburgh, where he is a medical statistician and Professor of Health Technology Assessment. He is the trial statistician on the PINCER trial. He has over 30 years experience with designing and analysing data from clinical trials. He is co-author of a book on mixed models, which is the technique used for efficient analysis of cluster randomised trials, as well as over 300 other scientific publications. All of the Edinburgh team will have ready access to the Edinburgh eScience Centre and the University wide multi-disciplinary eHealth Network.

Anthony Avery is Professor of Primary Health Care at the University of Nottingham where he also heads the Division of Primary Care. He has over 13 years experience of research into prescribing and medicines management and is PI on the PINCER trial. In particular he has focused on the role of IT in error prevention. Recent work for the NPSA has identified a number of important flaws in the safety features of GP computer systems and many of Professor Avery's recommendations have been accepted by the NPSA and incorporated into the NPfIT. **Rachel Elliott** is Lord Trent Professor of Medicines and Health at the University of Nottingham. She is an experienced health economist having worked on a range of projects and primary and secondary care settings, including the PINCER trial and is together with Professor Avery a co-investigator on NHS CFHEP 004.

Nicholas Barber is Professor of the Practice of Pharmacy and Head of the Department of Practice and Policy at the School of Pharmacy, University of London. He is also Visiting Professor in Patient Safety at Harvard Medical School. He has extensive experience in evaluating IT systems in healthcare settings. He led a joint MRC/EPSRC research network on the use of technology to improve Patient Safety (with Cornford, Jacklin and Avery) and developed (with Cornford and Jacklin) for the NPSA a methodology to evaluate prescribing systems in secondary care. He has recently secured funding (with Avery, Elliott and Cornford) as PI on NHS CFHEP 004 evaluating the impact of the Electronic Transmission of Prescriptions.

Tony Cornford, who is co-investigator on NHS CFHEP 004, is a Senior Lecturer in Information Systems at the London School of Economics and has wide-ranging experience in evaluating IT-based interventions in healthcare. From this work he has, in collaboration with his colleagues, developed the Cornford framework that we propose to use in our evaluation.

James Paton is a consultant Microbiologist at the Queens Hospital in Burton-on-Trent, a hospital which has pioneered computerisation of many of its clinical functions. He has worked with the NPfIT and based on previous local experiences of implementing an EHR system will provide a valuable clinical secondary care perspective.

Charles Vincent is a psychologist and Professor of Clinical Safety Research Division of Surgery, Oncology, Reproductive Biology and Anaesthetics at Imperial College London where he heads up the NHS' National Institute of Health Research's National Centre for NHS Patient Safety and Service Quality. This has a focus on safety, quality, resilience and reliability of technology, the effective use of IT and investigating the role of NHS managers and staff in enhancing patient safety. **Ann Jacklin** is the Chief

Pharmacist Hammersmith Hospitals NHS Trust and has considerable experience in implanting, running and evaluating IT systems in hospital settings. She is Chair of the UK Teaching Hospital Pharmacists Association and a joint programme lead in the National Centre for NHS Patient Safety and Service Quality at Imperial College Healthcare Trust.

In summary, this proposal brings together a team of experienced academics and clinicians with a substantial track record of collaboratively undertaking implementation and evaluation of IT interventions in healthcare settings. Given our previous successful experiences, and past history of working together, we are confident that we will be able to undertake this evaluation on time and within budget. The basing of research staff within four recognised UK centres of excellence in eHealth will have the additional benefit of promoting significant capacity building in this nascent field throughout the UK.

7.2 Roles of staff employed by the grant

7.2.1 Study Co-ordinator (Edinburgh)

Kathrin Cresswell will be the full-time study co-ordinator where she will work under the direct supervision of Professor Sheikh. Her responsibilities will consist of the day-to-day co-ordination of all aspects of the evaluation, these including:

- Managing communications and meetings of the Project Steering Group, Project Management Group, Project Advisory Board and Independent Project Steering Committee (see below)
- Regular liaison with the clinical co-ordinator and study researchers
- Supporting local teams with data collection and trouble-shooting on as needed basis
- Overall responsibility of Work package 2
- Developing and maintaining an overall project database to help ensure that all activities are completed according to plan
- Contributing to the writing of interim and final project reports.

We believe that it is essential to have a co-ordinator in order to ensure the smooth and successful running of the study, particularly as the proposed research team is large and geographically scattered.

7.2.2 Clinical Co-ordinator and Interface with NHS CFH (Edinburgh/London)

Dr Bernard Fernando will be a (part-time) Clinical Co-ordinator of this evaluation. His day-to-day responsibilities in relation to the management of the project will include:

- Resolving anxieties, fears and concerns about the proposed sampling by discussion with the clinicians
- Providing relevant clinical context and insight into the work to the Study Co-ordinator and Research Fellows during data generation and analysis for each of the six work packages
- Take a lead on co-ordinating Work package 6
- Liaising with the Project Advisory Board
- Assessing possible unreliable and missing data by reviewing clinical care pathways.

In addition, Dr Fernando will act as an interface with NHS CFH and specifically the NHS CRS implementation teams, which we believe will be crucial for ensuring a collaborative partnership between our team and NHS CFH throughout the project. Key activities here will include:

- Discussing technical implementation details with NHS CFH, determining any implications to the project and providing timely feedback to the research group
- Co-ordinate the implementation and evaluation timeline
- Providing technology related feedback to NHS CFH
- Act as an expert reviewer of the NHS CRS (technical) and give feedback to the research group
- Organising regular informal and formal feedback meetings for NHS CFH.

Collaboration will also be important in relation to LSP and we therefore further propose Dr Fernando to:

- Collaborate with developers to see if the systems could be modified for ease of data collection
- Design automated data sampling modules in collaboration
- Collaborate to design data extraction reports needed for the evaluation.

Dr Fernando will further contribute to the writing of the project report.

7.2.3 Project Secretary (Edinburgh)

Professor Sheikh, Dr Fernando and Ms Cresswell will be supported in this co-ordinating role by a full-time secretary who will enable clerical tasks to be undertaken without taking up more expensive researcher time. Day-to-day administrative tasks will include:

- Organisation of meetings and minute taking
- Maintain a Web-based electronic diary of trial meetings and other events
- Correspondence with co-ordinators, researchers and all project committees/boards
- Transcription of qualitative data
- Data input to project database
- Maintaining bibliographic database
- Producing study publicity, newsletters etc.

7.2.4 Research Fellow 1/Research Assistant 1 (London School of Economics)

We plan to appoint a full-time Research Fellow at the London School of Economics, who will work in collaboration with Dr Cornford and Dr Klecun on all aspects of data collection and analysis in the Southern region, and will take a specific lead on co-ordinating Work packages 1 (implementation, deployment and organisational learning) and 3 (organisational consequences). The Research Fellow will be supported by a 0.5 WTE Research Assistant during the main data collection phase of this project i.e. months 12-24 and a 0.3 WTE Secretary for the duration of the project. Regular liaison with the Clinical Co-ordinator and the Study Co-ordinator will be central to this work.

7.2.5 Research Fellow 2/Research Assistant 2 (Nottingham)

We seek to appoint a full-time Research Fellow at the University of Nottingham, who will work in collaboration with Professors Avery and Elliott on all aspects of data collection and analysis in the North, Midlands and Eastern region, and will take a specific lead on co-ordinating Work package 4 (assessment of costs of NHS CRS implementation). The team will have weekly meetings locally with the appointed Research Fellow being involved in all aspects of data collection, analysis and write-up in this work package. The Research Fellow will be supported by a 0.5 WTE Research Assistant during the main data collection phase of this project i.e. months 12-24 and a 0.3 WTE Secretary for the duration of the project. Regular liaison with the Clinical Co-ordinator and the Study Co-ordinator will be central to this work.

7.2.6 Research Fellow 3/Reserach Assistant 3 (School of Pharmacy)

We plan to appoint a full-time Research Fellow at the University of London, who will work in collaboration with Professor Barber on all aspects of data collection and analysis in the London region, and will take a specific lead on co-ordinating Work package 5 (assessing error, safety and quality of care). They will have weekly meetings locally with the appointed research fellow being involved in all aspects of data collection, analysis and write-up of Work package 5. The Research Fellow will be supported by a 0.5 WTE Research Assistant during the main data collection phase of this project i.e. months 12-24 and a 0.3 WTE Secretary for the duration of the project. Regular liaison with the Clinical Co-ordinator and the Study Co-ordinator will be central to this work.

8. PROJECT MANAGEMENT AND RESEARCH GOVERNANCE

We have given considerable thought to the issue of project management and governance and are, particularly in view of the complexity of the intervention and proposed evaluation, very receptive to NHS CFH's advice in this respect. Whilst the exact shape and form of the Project Steering Group, Project Management Group, Local Project Teams, Project Advisory Board and Independent Project Steering Committee are to an extent likely to need to vary in response to issues that arise in the context of different stages of the evaluation, we believe we have an overall structure that will ensure robust local and overall management and which will also allow independent monitoring by the Independent Project Steering Committee, the exact membership of which will be discussed and agreed with NHS CFH. Please find our preliminary project management and governance plans outlined below.

8.1 Project Steering Group

We will convene a Project Steering Group, chaired by Professor Sheikh and comprising all co-applicants to oversee the effective running of this evaluation. This Group will convene on average quarterly for face-to-face meetings and will collectively be responsible for the governance of this project.

8.2 Project Management Group

A Project Management Group, consisting of Professors Sheikh, Avery, Barber, Doctors Cornford and Fernando as well as Ms Cresswell will meet every six weeks by video-conference. This will help to ensure that all evaluation activities are organised and within the timescales set out in the protocol.

8.3 Local Project Teams

Professor Sheikh will have responsibility for the overall day-to-day management of the project. Professor Sheikh will also head the Project Management Group (see below) and will oversee Work packages 2 (Attitudes, expectations and experiences of stakeholders) and 6 (Organisational consequences and implications for future IT deployments and evaluations), which will be co-ordinated from the University of Edinburgh.

Dr Cornford will have overall responsibility for the conduct of the evaluation in the Southern area and for ensuring the overall success of Work packages 1 (Implementation, deployment and organisational learning) and 3 (Organisational consequences) which will be run from the London School of Economics.

Professor Avery will have overall responsibility for the conduct of the evaluation in the North/Midlands/Eastern area and for ensuring the success of Work package 4 (assessment of costs of NHS CRS implementation), which will be co-ordinated by the University of Nottingham.

Professor Barber will have overall responsibility for the conduct of the evaluation in the London area and for ensuring the success of Work package 5 (Assessing error, safety and quality of care) which will be co-ordinated by the School of Pharmacy.

Day-to-day co-ordination of activities will be the responsibility of the:

- Study Co-ordinator (for overall evaluation activities and the conduct of the project)
- Clinical Co-ordinator to provide day-to-day clinical input and liaise on a regular basis with NHS CFH and NHS CFHEP
- Research staff employed by the London School of Economics, who will be working with Dr Cornford
- Research staff employed by the University of London, who will be working with Professor Barber
- Research staff employed by the University of Nottingham, who will be working with Professor Avery.

The Project Co-ordinator and the Research Fellows will have monthly video-conferences and local project teams will meet weekly at their individual sites. In addition the staff at the London School of Economics and School of Pharmacy will work closely as the two groups are only 20 minutes walk apart.

8.4 Project Advisory Board

A NHS CFH Project Advisory Board will be set up with the specific remit to act as a wider resource to keep the team abreast of important policy and strategic developments, concerns and opportunities in relation to NHS CFH and more specifically NHS CRS considerations that will be relevant to the evaluation.

Individuals who have already kindly agreed to be part of this Group include:

- Susan Osborne (NHS CFH National Clinical Lead for Nursing)
- Dr Simon Eccles (NHS CFH National Clinical Lead for Hospital Doctors)
- Marlene Winfield (NHS CFH National Patient Lead)
- Dr Dipak Kalra (Clinical Senior Lecturer in the Centre for Health Informatics and Multi-professional Education at University College London - health informatician with particular expertise in electronic health records)
- Professor Jeremy Wyatt (Head of Medical Informatics at the University of Dundee and a member of the NHS CFHEP Programme Advisory Board
- Professor Lord Sir Ara Darzi (Professor of Surgery at Imperial College)
- Professor Trisha Greenhalgh (University College London and PI on evaluating early adopters of the SCR)
- Jo Partington (Head of Therapies, Imperial College Healthcare NHS Trust)
- Steve Morris (Finance Director, Imperial College Healthcare NHS Trust)
- Professor Peter Sprivulis (Project Lead, Benefits Realisation Study, National E-Health Transition Authority, Australia).
- Sir Muir Gray (Director of the National Knowledge Service)
- Yvonne Pettigrew (NHS CFH National Clinical Lead for Allied Health Professionals and Head of Therapy Services at the University Hospital Birmingham NHS Foundation Trust)

Others who have been approached and who will we hope be joining the Board include:

- Mr Steve Jones (Vascular surgeon, Taunton and Somerset NHS Trust).

We also plan to approach the following:

- Professor Nancy Lorenzi (President of the International Medical Informatics Association and Professor of Biomedical Informatics)
- Professor Michael Kidd (Chair of the World Organization of National Colleges, Academies and Academic Associations of General Practitioners and Family Physicians Working Party on Informatics)
- Dr Paul Cundy, Joint GP IT Committee Chairman, British Medical Association

This will be a largely virtual policy and information sharing group that will convene formally once in the early stages of the project and on an ad-hoc basis thereafter as needed. The Programme Advisory Board will be encouraged to advise on strategically broadening membership to ensure we have input from a full range of relevant disciplines, professional viewpoints and organisational contexts. Since this will largely be a virtual group, we envisage expanding this with local key informants as and when the opportunity arises. For example, we have ready access to a number of health informaticists through the University of Edinburgh's eHealth Group.

8.5 Independent Project Steering Committee

We propose to set up and Independent Project Steering Committee, which will meet six monthly by tele conference to provide independent impartial advice on how the work is progressing. As potential members we propose:

- Professor David Bates as the chair (Professor of Medicine, Harvard Medical School)
- Professor Martin Buxton (Professor of Health Economics at Brunel University)
- Anthony Chutter as a patient representative
- Professor Michael Thick representing NHS CFH/NHS CRS implementation team
- Professor Richard Lilford and Jo Foster representing NHS CFHEP.

We plan to discuss this proposed membership with NHS CFH and NHS CFHEP and obtain suggestions on possible additional/alternative members before formally inviting participation in this Committee. We will be very happy to formally bring additional health expertise onto either the Independent Project Steering Committee as and when the need arises.

9. DISSEMINATION STRATEGY

Effective communication and sharing of our findings will be key to our efforts. We recognise the potential sensitive nature of this evaluation and we will therefore, at an early stage, agree the principles of a dissemination strategy with the funders. We anticipate that this will include the following dimensions:

- Regular feedback to NHS CFH, NHS CFHEP and, in particular, the NHS CRS clinical and technical implementation teams, primarily through the Clinical Co-ordinator, but also through the Project Advisory Board
- Regular feedback to participating hospitals/teams in each of the three geographical implementation clusters, through the local research teams
- Academic presentations and publications through presenting at learned conferences and writing in peer-review journals
- Preparing summary articles for publication in professional journals
- Maintaining a project website which will be accessible to the general public
- Ensuring sharing of relevant information between different NHS CFHEP commissioned projects, both through attending NHS CFHEP Advisory Board meetings, but also more specifically through sharing relevant insights obtained from NHS CFHEP 001 extension (PI Aziz Sheikh), NHS CFHEP 002 (PI Trisha Greenhalgh) and NHS CFHEP 004 (PI Nick Barber).

10. JUSTIFICATION OF RESOURCES

This is a complex multi-faceted evaluation, which is to be conducted across England. We have accordingly developed a costing model for the co-ordinating centre (Edinburgh) and devolved costings for the three collaborating universities (London School of Economics, School of Pharmacy and University of Nottingham) that will be undertaking field work in the three geographical regions in which NHS CRS is being implemented.

10.1 Grant-holders

Funds are requested for appropriate proportions of academic grant-holders time to allow them to co-ordinate the project overall (AS), oversee local data collection and analysis (TC, NB and TA) and undertake the statistical (RP) and health economic (RE) analyses. It is in addition extremely important that we draw on the experiences of other key academics and healthcare professionals with relevant expertise and so modest costs are requested to cover their time (AJ, CV and JP).

10.2 Edinburgh

We seek to appoint a full-time Study Co-ordinator for the duration of the project, who will in addition to servicing the day-to-day management of this project and co-ordinating between sites, will be responsible for leading Work package 2. In addition, we seek to appoint a part-time Clinical Co-ordinator with an established interest in medical informatics to be based in the NHS CFH offices so as to ensure the project team is kept abreast of important developments and facilitate two-way communication; he will in addition be responsible for leading Work package 6. We also seek support for a full-time Research Secretary, who will support all project meetings, data transcribing and day-to-day activities relating to this project.

Non-staff costs include PCs, essential software, a budget to service and for travel to the Steering Group, Independent Project Steering Committee and Project Advisory Board meetings and video-conferencing equipment to enable regular 'face-to-face' contact with the local research teams (the London School of Economics, School of Pharmacy and University of Nottingham already have such equipment). We also request funds for literature retrieval, developing and maintaining the project database, a dissemination budget, this being viewed holistically as including travel to visit local hospitals and meet with the NHS CFH team on as needed basis as well as the usual academic dissemination activities.

10.3 London School of Economics

We seek to appoint a full-time Research Fellow who will take a lead on Work packages 1 and 3, who will, during the main period of field work, be supported by a part-time Research Assistant. We also seek funds for a part-time local secretary to provide essential administrative support and help with transcribing data.

No-staff costs include a PC, essential software, a speakerphone (Edinburgh already has this), an incentive budget to stimulate and support local data collection, and travel costs to undertake field work throughout the Southern implementation area.

10.4 School of Pharmacy

We seek to appoint a full-time Research Fellow who will take a lead on Work package 5, who will, during the main period of field work, be supported by a part-time Research Assistant. We also seek funds for a part-time local secretary to provide essential administrative support and help with transcribing data.

No-staff costs include a PC, essential software, a speakerphone, an incentive budget to stimulate and support local data collection, and travel costs to undertake field work throughout London.

10.5 University of Nottingham

We seek to appoint a full-time Research Fellow who will take a lead on Work package 4, who will, during the main period of field work, be supported by a part-time Research Assistant. We also seek funds for a part-time local secretary to provide essential administrative support and help with transcribing data.

No-staff costs include a PC, essential software, a speakerphone, an incentive budget to stimulate and support local data collection, and travel costs to undertake field work throughout the North, Midlands and Eastern region.

10.6 Project Advisory Board

Given the complexity of the implementation and evaluation, we believe it is important that we draw on the expertise of a wider grouping of policy leads, clinicians and researchers and so we seek funds to support an initial meeting of this Board, regular subsequent tele-conferences and the funds needed to allow for a limited number of additional face-to-face meetings if needed; we also plan to offer a small honoraria as a token of appreciation for their time/expenses incurred.

10.7 Independent Project Steering Committee

Based on successful previous experiences, we envisage that this Committee will in the main convene by international conference call and an appropriate budget is requested to cover the costs of these meetings, with some contingency funds for a limited number of face-to-face meetings should these be requested by the Chair.

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