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intr oduction

- Increasing life expectancy, improved survival in people with acute and long-term condition and a greater array of available treatment options are combining to place an increasing burden on healthcare organisations internationally.
- This picture is particularly true of the economically developed world where high salaries for healthcare professionals and ever increasing public expectations contribute to the challenges facing governments trying to contain spending on healthcare provision and planning.
- There is now a substantial body of research, both domestic and international, identifying considerable shortfalls in the current provision of healthcare.
- Key issues emerging from this literature are substantial variations in the quality of healthcare and the considerable risks of iatrogenic harm.
- These failings contribute in a major way to the high rates of potentially avoidable morbidity and mortality, and healthcare expenditure.
- There have been substantial developments in information technology (IT), hardware and software capabilities over recent decades and there is now considerable potential to apply these technological developments in relation to aspects of healthcare provision (the application of IT in this way will henceforth be subsumed by the term eHealth).
- Of particular international interest is the deployment of eHealth applications, with a view to improving both the quality and safety of healthcare delivery.
- Whilst these eHealth applications have considerable potential to aid professionals in delivering healthcare, use of these new technologies may also introduce significant new risks to patients.
- Also of concern is that even when high quality interventions are developed, they frequently fail to live up to their potential when deployed in the “real world”; a major factor contributing to this paradox is perceived professional resistance to their introduction and use.
- Given that the National Health Service (NHS) is now committed to the largest eHealth based modernisation programme in the world, it is appropriate and timely to critically review the international eHealth literature with a view to identifying lessons that can usefully be learnt with

respect to the development, design, deployment and evaluation of eHealth applications.

Aims And oBJectives

- We were commissioned by the Patient Safety Research Programme (which now no longer exists and whose remit has in part been subsumed by the recently created NHS Connecting for Health Evaluation Programme (CFHEP)) to produce a systematic overview of the literature examining the effectiveness of IT (eHealth) applications to improve the quality and safety of healthcare.
- This initial phase of our work focuses on evidence relating primarily to:
 - the storage and retrieval of medical information
 - tools to support healthcare professionals in making clinical decisions
 - ways of promoting the effective development, deployment and use of eHealth applications in routine healthcare settings.
- Our future work will seek coherently to expand on this report by encompassing other facets of eHealth not covered in this report; these include: patient identification devices; consumer informatics; telecare; and eLearning.

methods And for mActive wor k

METHODS

- We conducted a systematic search and critique of the empirical literature on eHealth applications and their impact on the quality and safety of healthcare delivery and synthesised this with relevant theoretical, technical, developmental and policy relevant literature with a view to producing an authoritative and accessible overview of the field.
- Whilst we drew on established Cochrane review principles to systematically search for, critique and synthesise the literature, this approach needed to be adapted in several respects to produce a meaningful umbrella review of the literature (see below).
- Searching the literature was complicated by the lack of internationally (or indeed in some cases nationally) agreed terminology relating to eHealth applications, the lack of agreed definitions of quality and safety, and the consequent poor indexing of these constructs in databases of published literature.
- In order to undertake a thorough review of the literature, we therefore

needed to undertake initial developmental work to formulate a comprehensive search strategy.

- Using the set of comprehensive Medical Subject Headings (MeSH) and free text search terms developed, we systematically searched major medical databases over a 10-year period (1997–2007) to identify systematic reviews, technical reports and health technology assessments, and randomised controlled trials investigating the effectiveness of eHealth applications. The specific databases searched were:
 - MEDLINE
 - EMBASE
 - The Cochrane Database of Systematic Reviews
 - Database of Abstracts of Reviews of Effects
 - The Cochrane Central Register of Controlled Trials
 - The Cochrane Methodology Register
 - Health Technology Assessment Database and NHS Economic Evaluation.
- In addition, we searched key national and international databases to identify unpublished work and research in progress.
- The systematic reviews were then subjected to critical review using the Critical Appraisal Skills Programme (CASP) approach, this being adapted for use for eHealth applications.
- These reports of high quality evidence form the essential core of our proposed *NHS Connecting for Health Database of Systematic Reviews and Randomised Controlled Trials in eHealth*.
- To provide a broader appreciation of the context of this work and furthermore to aid conceptual development and interpretation of findings, we supplemented this systematic search for empirical evidence with a more emergent approach to identify relevant background and theoretical literature in relation to the essential concepts underpinning this overview—namely: eHealth; quality; safety; and the National Programme for Information Technology (NPfIT). This involved drawing on our personal databases of relevant papers, identifying seminal papers and reports as well as searching the grey literature.
- The overall body of literature identified was too diverse to make any meaningful quantitative synthesis of the literature desirable, nor was it possible. Rather, we chose to qualitatively synthesise the literature drawing on the relevant preliminary conceptual work to guide this narrative synthesis.

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- Our overall assessment of the volume and strength of evidence in relation to key findings are summarised in this executive summary using a modified version of the World Health Organization's Health Evidence Network (WHO HEN) system for public health evidence, which grades evidence into three main categories:
 - strong (consistent, good quality, plentiful or generalisable)
 - moderate (consistent and good quality)
 - limited to none (inconsistent or poor quality).

NHS CONNECTING FOR HEALTH AND THE NATIONAL PROGRAMME FOR INFORMATION TECHNOLOGY

- The NPfIT is the most comprehensive, ambitious and expensive eHealth based overhaul of healthcare delivery ever undertaken.
- This Programme has its origins in the 1998 Department of Health strategy *Information for Health*, which committed the NHS to lifelong electronic health records for everyone with round-the-clock, on-line access to patient records and information about best clinical practice for all NHS clinicians. Officially launched in 2002, the Programme is a 10-year initiative aimed initially to create the infrastructure, tools and environment through which it is possible to deliver:
 - a longitudinal electronic patient record (from “cradle to grave”) accessible to multiple users throughout the NHS; this (ie NHS Care Records Service or NHS CRS) together with the dedicated NHS broadband (National Network for the NHS or N3) and the national database on which these records will be held (the *Spine*); represents the backbone to the Programme
 - a service through which prescriptions can be transferred electronically from the general practitioner and other prescribers to pharmacists (Electronic Prescriptions Service) and integration with NHS CRS (Electronic Transmission of Prescriptions or ETP)
 - an electronic appointment booking service enabling general practitioners to electronically book hospital appointments (Choose and Book).
- The Programme has, however, subsequently been expanded to include amongst other things:
 - a Picture Archiving and Communication System (PACS)
 - GP2GP, which is a system that enables transfer of patient records between general practices

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- Quality Management Analysis System (QMAS), which automates assessment of GP practice performance against criteria included in the new GP contract
 - ePrescribing.
 - Whilst these represent the headline deliverables of the Programme, our scoping of the field has identified a number of other related eHealth projects or applications which, although officially falling within the scope of the National Knowledge Service (such as ePrescribing and computerised decision support systems), are also within the remit of NHS CFH and are therefore also closely inter-connected with the delivery of the Programme.
 - Originally managed directly by the Department of Health, oversight of NPfIT transferred in 2005 to a newly created Arm's Length Body, namely NHS CFH.
 - Foremost amongst the roles of NHS CFH is responsibility for nationally procuring systems and services that will be needed to ensure delivery of NPfIT.
 - Given the extremely high level of public expenditure, the Programme has and continues to attract considerable public, professional, legal, financial, political and international scrutiny.
 - In addition to it being the most comprehensive, ambitious and expensive eHealth reform programme in the world, it is also likely to be the most influential and its success or failure is likely to have major domestic and international consequences for many years to come.

EXPLORING, DESCRIBING AND INTEGRATING THE FIELDS OF QUALITY, SAFETY AND eHEALTH

- eHealth is a relatively new and rapidly evolving field and so many of the concepts, terms and applications are still in a state of flux.
- There is furthermore no agreed definition of eHealth, with some researchers using this to relate primarily to the area of consumer informatics, whereas others use it more generically to refer to any of the ways in which IT can be employed to improve delivery of healthcare. For the purposes of this review, we considered it important to use an inclusive definition and chose to use Eysenbach's definition as the basis for our work, as adapted by Pagliari:

'eHealth is an emerging field of medical informatics, referring to the organisation and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical

development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology.’

- Whilst the number of eHealth applications is potentially endless, these can nonetheless be divided into three broad domains relating to key activities they support:
 - storing, managing and sharing data
 - informing and supporting clinical decision-making
 - delivering expert professional and or consumer care remotely.
- The effective commissioning, development, deployment and routine use of eHealth applications is a cross-cutting area that impacts on each of these three domains.

Quality

- There are no internationally agreed definitions of healthcare quality.
- Most frameworks of quality currently in use do, however, incorporate the following key dimensions of care:
 - effectiveness of treatments
 - appropriateness of means of delivery
 - acceptability
 - efficiency
 - equity.

Safety

- Whilst there are no internationally agreed definitions of patient safety, adaptations of the National Patient Safety Agency’s definition of ‘patient safety incidents’ are increasingly being used. This, in its original form, states that:

‘A patient safety incident is any unintended or unexpected incident which could have harmed or did lead to harm for one or more patients being cared for by the NHS.’

- There are a number of patient safety taxonomies currently in existence, however, our scoping of this literature found that the Joint Commission on Accreditation of Healthcare Organizations *Patient Safety Event Taxonomy* is the most comprehensive and clinically relevant in that it incorporates five key primary areas:
 - impact of medical error

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- ❑ type of processes that failed
 - ❑ domain, ie the setting in which an incident occurred
 - ❑ cause or factors leading to the safety incident
 - ❑ prevention and mitigation factors to reduce risk of recurrence and or improve outcomes in the case of a further incident.

Integrating eHealth, quality and safety

- Integrating the fields of eHealth, quality and safety clearly demonstrates the numerous ways in which technology has the potential to improve the efficiency of many facets of healthcare delivery through, for example, helping clinicians to readily access comprehensive information on their patients, aiding monitoring of their conditions and the treatments being issued, reducing inappropriate variability in healthcare delivery, and proactively identifying and alerting clinicians to threats to patient safety.
- This integrating of these domains however also highlighted the many ways in which introduction of new eHealth applications could inadvertently increase risks.

mAin findings

- Our searches retrieved a total of 46,349 potentially relevant publications from which we selected a total of 414 relevant publications for inclusion, comprising of 67 systematic reviews and 284 randomised controlled and controlled clinical trials.
- The volume of primary and secondary literature is large, rapidly expanding, poorly collated and of very variable quality; as a result the literature surrounding eHealth poses unique challenges to synthesis and interpretation.
- In synthesising the available evidence, we used the following generic approach in relation to different eHealth applications and their related considerations:
 - ❑ clarifying definitions, description and scope for deployment
 - ❑ drawing on our conceptual maps to reflect on the potential benefits and risks of each application
 - ❑ identifying the empirically demonstrated benefits and risks, using exemplar subject areas and or detailed case studies on issues that are of direct or potential future relevance to NHS CFH
 - ❑ based on a synthesis of the above, highlighting the policy, clinical and

research implications for the individual areas of interest with a view to realising the potential that eHealth has to offer.

MAIN OVER-ARCHING FINDINGS

Our main overarching findings are considered below:

A ripe environment for information technology in healthcare

- Given the serious financial and resource implications of ageing populations, improved survival from a range of acute and long-term disorders, and the ever-increasing array of treatment options now available, health services need to find new, more cost-effective ways of delivering care.
- Also of relevance are rising public expectations for accessible, timely and high quality care, and the associated epidemiological and health services work demonstrating considerable and at times very worrying variations in quality of care between healthcare providers.
- In parallel with these demographic transitions and concerns about the future funding of state-run health services, there have been dramatic advances in both hardware and software capabilities, such that technology now plays an integral part of the lives of most people in economically developed societies and this is increasingly also true with respect to those living in the less economically developed world also (witness the spread of mobile phones, or personal computers for example).
- It is the coming together of the need to find novel personalised cost-effective solutions and the development of technological capabilities that have created an environment in which the development of IT applications in relation to healthcare have been able to proliferate.
- Given that these trends are, for the foreseeable future at least, set to continue and the considerable commercial interest associated with these developments, we anticipate that the number of IT solutions being developed and the range of conditions or indeed behavioural factors for which they may have a role and the speed with which they become available will continue to increase rapidly. At present Europe has a global competitive advantage in the eHealth industry with an opportunity for this to become one of the largest in the health sector with a turnover of over £8 billion or 5 per cent of the total health budget by 2010.

A vast and rapidly expanding body of literature that is poorly indexed, appraised and ordered

- In many ways, it is encouraging—given the relatively nascent fields of eHealth, quality and safety—that there is now such a large body of academic work at the intersection between these relatively immature fields of enquiry. As noted above, this reflects the real sense of opportunity that these technological innovations can positively impact on care provision, patient outcomes and cost.
- As is also noted above, however, the relative infancy of these fields does pose a number of difficulties for researchers working in this field and those wishing to interpret this evidence. The inter-relatedness of many of the technologies being developed and the different contexts in which these have been developed and deployed adds to the complexity of producing meaningful taxonomic frameworks and assessing likely effectiveness and generalisability.

Evidence of variable quality that is difficult to interpret

- Our formal assessment of the quality of empirical evidence has demonstrated that the field of eHealth research is of varying quality.
- Another point of concern relates to the outcome measures that have been used in eHealth research. Relatively few studies reported on safety outcomes when evaluating new technologies, whilst others sometimes failed to assess the most salient dimensions of quality. Cost-effectiveness was furthermore rarely formally studied, even though new eHealth applications are frequently promoted as being ‘cost-saving’.
- Many of the studies revealing the clearest evidence of benefits emanate from academic clinical centres where developers of new applications have also been directly associated with the evaluation of these technologies. This double role of developer and evaluator or researcher (and in some cases also being a user) of an application represents a noteworthy conflict of interest and leads to the potential for appreciable information bias. But perhaps more importantly, it may influence the findings of studies through dynamics that are not monitored or accounted for, such as the degree of motivation or computer literacy of end-users of these applications and the extent to which they contribute to design and re-design of an application that is under evaluation. These so-called “home-grown” applications are the ones that have invariably demonstrated evidence of greatest benefits. It

is however unclear how effective these applications would be if employed in other environments.

The vast gap between theoretical and empirically demonstrated benefits

- Our synthesis of evidence on the impact of IT on quality and safety of healthcare has demonstrated a vast gap between the theoretical and empirically demonstrated benefits.
- Although seminal reports on quality and safety of healthcare invariably recognise IT as one of the main vehicles for making radical improvements in delivery of healthcare, our work shows that realising these will require substantial effort and time. Most of the technologies are at present supported only with either face validity and or modest or weak empirical evidence. There is thus the need for much more evaluation of promising technologies, which unless adequately academically studied, may not “mature” to the extent that is needed for these to realise fully their potential when deployed in every-day clinical settings.
- The paradox is that whilst the number of IT applications in healthcare and software programmes is growing (high dissemination), we still have insufficient understanding of how, why, and under what conditions, such interventions might work (low evaluation). Healthcare needs IT solutions that are both theoretically- and empirically-based.

Inadequate attention being paid to socio-techno-cultural considerations

- A contributing factor to this gap between theoretical and empirical factors is that many of the applications developed are not fit-for-purpose. Flagging of drug interactions, for example, is potentially a very important benefit given the frequency with which medication errors occur. Studies however repeatedly show that most prompts about drug-interactions are ignored by doctors as they are perceived as clinically irrelevant.
- Greater attention to the design considerations such that they provide grades of advice and support, offer alternatives, and for the most serious issues prevent overriding for example, could greatly enhance the usefulness of such professional support tools and increase the likelihood of these achieving their intended outcomes. This is, however, dependant on these human factors being accorded at least as much priority as the more technical developments, which is where the majority of attention and resources continue to be devoted.
- Following the presentation of the overarching findings we present also a

summary of findings from individual chapters. Our findings' chapters are grouped together in relation to the three main foci of this report, namely the domains of:

- managing, storing and transmitting data
- supporting clinical decision making
- the cross-cutting issue of the socio-techno-cultural dimensions of developing and implementing eHealth applications.

DATA STORAGE, MANAGEMENT AND RETRIEVAL

Health information exchange and interoperability

- Effective and efficient sharing of clinical information is essential to the future development of modern healthcare systems, which are increasingly characterised by the involvement of many specialist healthcare providers, often working from different sites, contributing to the care of individual patients.
- The ideal in this respect is for professionals and patients themselves to have the ability to simultaneously access and seamlessly transfer, contribute to and integrate clinical data from disparate sources.
- The potential gains in relation to improving the quality, safety and overall efficiency of healthcare delivery are potentially enormous, as demonstrated by a recent US-based economic analysis.
- Most UK healthcare settings are however currently characterised by relatively low levels of health information exchange and interoperability (HIEI) capability, this being particularly true of the hospital sector, where paper-based records are still the main means of recording and communicating clinical information.
- The NPfIT has already and will greatly increase the potential for HIEI, for example, through N3 and deployment of the NHS CRS, which will result in the creation of summary and detailed electronic health records that have the potential to be shared, to varying degrees, across healthcare settings and between providers.
- Although NHS CFH's insistence that new eHealth applications must be Health Level Seven compliant—this referring to a voluntary but nonetheless widely used standard for interoperability—thereby assuring a degree of ability to exchange information between systems, is undoubtedly welcome, none of the headline NPfIT applications will achieve the optimum levels of HIEI, with the result that patient safety may needlessly be compromised.

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- The current empirical evidence-base in support of such HIEI considerations is however at present weak in relation to this improving organisational efficiency, practitioner performance or indeed any clinical patient outcomes.
 - Improving HIEI to the optimal level so as to allow seamless transfer and access to data in all settings, whilst probably resulting in cost-savings in the longer run, will inevitably require considerable upfront investment in hardware and software capabilities.
 - An important paradox to further developments in this area is that whilst increasing levels of HIEI are clearly desirable for many reasons, greater availability of data also inevitably increases the risk of threats to data security and breaches of patient confidentiality.
 - Key outstanding issues that face healthcare systems in realising the potential for seamless exchange of information include the need to develop and deploy standard coding structures across all care settings (eg using Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT)), facilitate integration of the increasing amounts of patient-generated data (eg through HealthSpace, home sensors or telemetry devices), and improve secure audited access to electronic records to minimise the risks of breaching confidentiality.

Electronic health records

- The electronic health record (EHR) represents the backbone of all major international eHealth developments currently taking place internationally, including NPfIT.
- The ultimate goal is to have available comprehensive longitudinal health information for all members of the population, with the potential for accessing and contributing to these records by multiple users working across a range of healthcare settings; no country has, however, yet to achieve this comprehensively and if successful, the NHS CRS will be the first in the world to come close to this aspiration.
- Electronic health records range from simple storage devices to those with varying degrees of added functionality, including the ability to electronically prescribe (ePrescribing) and access to computerised decision support systems (CDSSs), which are active knowledge systems, which use individual patient data to generate case-specific advice.
- The main potential advantages of EHRs relate to improved legibility and comprehensiveness of recording information, access by multiple users that

is not geographically-bound (if interoperable), the ability to incorporate professional support tools, and time and cost savings.

- There are, however, important potential risks associated with the EHR, these in the main relating to data security considerations; there is in addition, the concern that clinically important information may be overlooked, particularly in contexts where there is parallel recording of data using both electronic and paper records.
- The empirically demonstrated benefits relating to introduction of EHRs are currently limited to improved legibility, time savings for some professionals (nurses), and the facilitation of higher order functions such as audit, secondary analysis of routine data and performance management.
- Time taken for doctors to enter and retrieve data has in contrast been found to increase; studies have furthermore found that the time disadvantage for clinicians to record and retrieve information did not attenuate with increased familiarity and experience with using EHRs.
- Given the lack of evidence of empirically demonstrated benefits associated with EHRs, it is welcome that NHS CFH is undertaking a comprehensive evaluation of the effects of the introduction of the NHS CRS. This work will help plug an important gap in our understanding of the impact of introducing EHRs.
- There is moderate evidence that EHRs can help improve patient outcomes, particularly in relation to provision of preventative care.
- Standardised and widely accepted measures of data quality in EHRs are lacking and their development should be a priority.
- An important potential national future development for EHRs is the ability to readily incorporate multi-media files such as heart sounds, retinal screens and audio or video recordings of consultations.

Computer history taking systems

- Most computer history taking systems (CHTSs) are designed for use by healthcare professionals, although some elicit information directly from the patient, as in the case of pre-consultation interviews.
- Computer history taking systems can be used in a variety of clinical settings and have, when eliciting data directly from patients, proven particularly useful in identifying potentially sensitive information such as alcohol consumption, sexual health and psychiatric illnesses, eg suicidal thoughts.
- Computer-based questionnaires are particularly useful for gathering

important background data prior to the consultation, which can then allow more time for focusing on key aspects of the health problems in the actual consultation. These systems can also save money by reducing administrative costs.

- Speech software and speech completed response computer history taking systems allow adaptability for those with particular needs such as non-English speaking patients, patients with hearing impediments and those who are illiterate.
- There is moderate evidence that data collected electronically tend to be more accurate and contain fewer errors than data captured manually with traditional pen and paper techniques; such data are also more legible.
- The current generation of computers is, however, not adept at detecting non-verbal behaviour; these systems should therefore be seen as not a substitute, but rather an adjunct to the clinical history.
- There have as yet been no comparative studies that have formally assessed the effectiveness and cost-effectiveness of different CHTSs.
- It is important for NHS CFH to carefully consider the considerable potential efficiency gains to be made from incorporating CHTS functionality—particularly if this involves direct entry of data by patients—into future iterations of the NHS CRS. HealthSpace could facilitate this as could a number of other modalities such as touch-screen or voice-recognition equipped computers available in waiting rooms. This will, however, need to be introduced within a clear evaluative context.

SUPPORTING PROFESSIONAL DECISION MAKING

Computerised decision support systems

- There are strong theoretical reasons for believing that improved access to relevant clinical information for healthcare professionals, at the point of care, can translate into improvements in healthcare quality, patient safety and organisational efficiency.
- Defined as software applications that use individual patient data, CDSSs utilise a repository of clinical information (knowledge-base) and an inference mechanism (logic) to generate patient specific output. These applications are highly variable in sophistication, output and the extent to which they can integrate with other clinical information systems.
- Computerised decision support systems have the potential to improve clinical decision making by providing practitioners with real time patient

specific and evidence-based support and by providing individually tailored feedback.

- Although numerous evaluations of CDSSs have taken place, very little consistent and generalisable evidence exists on their ability to improve practitioner performance and patient outcomes; evidence is often limited to particular conditions (eg diabetes and hypertension) or an aspect of clinical care (eg preventative care).
- The use of computerised reminders for provision of preventative care has been empirically demonstrated to be of benefit. However, trials have not assessed patient outcomes as for most preventative care interventions, the time needed to demonstrate an effect on patient outcomes is prohibitive.
- Through a detailed case study investigating the potential of CDSSs to support diagnostic screening we demonstrate how these tools may fail to realise their potential, particularly in relation to complex tasks such as making a diagnosis.
- Computerised decision support systems are largely unregulated in the US and UK due to exclusion from the Federal Drug Administration and Medicine and Healthcare Products Regulatory Agency respectively.
- Without formal quality and safety assurances in relation to CDSS applications, the potential risks to patient safety need to be seriously considered as they may in certain situations inadvertently introduce new errors.
- As CDSSs work best when interfacing with or integrated within existing clinical information systems, and the evidence of benefit is clearest and risk of harm is least for provision of preventative health care, NHS CFH should consider introducing a range of computerised health promotion tools into primary care and with the roll-out of the EHR into secondary care.
- The hope of finding one over-arching message regarding the effectiveness and safety of CDSSs is naïve and should be abandoned. Rather, research should focus on understanding the contexts in which these decision support tools are most likely to prove effective and this should be a priority consideration for NHS CFH as it introduces new eHealth applications with built-in decision support functionality.

ePrescribing

- There is considerable variation in the quality of prescribing. Medicines

management errors are common, costly and an important source of iatrogenic harm.

- ePrescribing is defined as the use of computing devices to enter, modify, review and output or communicate prescriptions. ePrescribing systems are highly variable in functionality, configurability and the extent to which they integrate with other systems.
- ePrescribing has the potential to greatly improve the quality and safety of prescribing, through facilitating cost-conscious evidence-based prescribing and in particular reducing errors associated with knowledge gaps and routine tasks such as repeat prescribing.
- There is moderate evidence that practitioner performance is improved through better access to these guidelines. Patient outcomes are, however, less well studied and when assessed, most studies have not been able to demonstrate a clinical benefit.
- The detailed case study of supported oral anticoagulant dosing revealed some evidence for improved practitioner prescribing performance as demonstrated by improved control; this has, however, not been shown to translate into decreased adverse drug events.
- Evidence of benefit from ePrescribing systems has in the main been demonstrated from evaluations of home-grown systems in a few centres of excellence. Most systems in use are however commercially procured and these systems typically lack the sophistication, clinical relevance and sense of ownership associated with the tailored home-grown systems.
- Poorly designed ePrescribing systems and a failure to appreciate the socio-techno-cultural issues associated with their introduction can introduce unexpected new risks to patient safety.
- In the UK, the Medicines and Healthcare Products Regulatory Agency does not consider ePrescribing systems to be a medical device and does not therefore require these systems to be quality assured. This is an important policy failing that needs to be addressed.
- Further research into the design features, knowledge-bases and underlying algorithms, clinical relevance of output, interoperability of ePrescribing systems and socio-technical factors that enhance use is needed in order to replicate the benefits of ePrescribing that have been demonstrated in US centres of excellence.

SOCIO-TECHNICAL DIMENSIONS OF DESIGNING, DEVELOPING, AND DEPLOYING eHEALTH APPLICATIONS

Human factors

- The study of organisational issues as they pertain to eHealth innovations is a multi-disciplinary field utilising bodies of knowledge from organisational psychology, change management and human factors with clinical and information technology expertise.
- There is a general consensus that organisational issues are at the root of problems associated with the implementation and adoption of technological innovation in healthcare.
- The nature of human factors (ergonomics) is to understand people and their interactions, as well as the relationships between these interactions, and to improve those interactions in real life settings.
- For human performance and safety considerations to effectively influence the design and project specifications, they need to accommodate the following essential factors for all users: staffing constraints; system operator and maintainer (user) skills; training time available and cost limitations for formal, informal and on-the-job skill development; and acceptable levels of human and system performance when operated and maintained by members of the target population.
- Healthcare has been slow to incorporate human factors considerations into assessments of eHealth applications, despite the mounting complexity of care delivery systems and evidence of resulting risk to patients.
- A well designed user interface is, for example, as important as functionality and reliability in ePrescribing applications. Confusion and frustration with an application interface are enough to impede users' acceptance of an application, with an adverse subsequent knock-on effect on implementation.
- While there is at present no over-arching framework in relation to the implementation and adoption of eHealth innovations, a number of themes have been found to be important, these include: innovation attributes; end-users' attitudes towards the innovation; end-user capacity and competence; communication and concerns; strategic project management and effective leadership; evaluation and continual quality improvement.
- Assessing readiness for technological innovation and fostering readiness appear to be particularly important in relation to technological innovations in modern day healthcare organisations and systems.
- The empirical evidence-base for approaches to strategise implementation

and adoption is at present very limited; this reflects amongst other things, the lack of rigorously conducted prospective studies that allow assessment of effectiveness and processes through which these effects are mediated.

- There is need for further research encompassing design, implementation and adoption considerations in relation to eHealth innovations. NHS CFH needs to ensure that the results of human factors assessments are provided by developers and that the findings of these tests are incorporated into decisions to grant approvals before new eHealth products are introduced into the NHS.
- The EHR, ePrescribing and CDSS systems are examples of complex applications for which it is clearly essential that end-users have been involved in all stages of design, development and deployment.
- Embedding human factors principles and thinking is not free; NHS CFH needs to ensure that adequate time, resources and prioritisation are given to this so as to maximise the chances of success of its various eHealth initiatives.
- Users should be involved in all stages of design, development and deployment of eHealth applications. Feedback from users should not only be facilitated, but must also be actively encouraged so as to ensure that new applications are fit-for-purpose and so as to minimise risks to patient safety.
- Ease of use (“usability”) and fit with working practices is as important as the functionality and reliability of eHealth applications such as the EHR, ePrescribing and CDSSs. Confusion and frustration arising from poor usability interfere with user acceptance, with a subsequent adverse knock-on effect on implementation, which may also endanger the safety of patient care.
- There are important gaps in the literature regarding how best to conduct usability testing with the end-users of eHealth applications such as ePrescribing.

Effective implementation and adoption of eHealth applications

- Most technological innovations fail to realise their potential and this unfortunately has also been true with respect to the history of eHealth applications.
- Major factors contributing to these failures—which may in some cases be spectacular—include the lack of appreciation and attention paid to the human factors issues during product development and socio-technical

factors that subsequently enable innovations to diffuse and embed themselves into healthcare organisations and then be successfully adopted.

- There is a burgeoning change management literature, dating back to the influential *Diffusions of Innovation* theory and stretching to the more recent *Diffusion of Innovations in Health Service Organisations* work. Much of this is however descriptive and so the predictive ability of these models of change management is as yet unknown.
- Using an adaptation of the above and other theories to render them more relevant to the planned dissemination of eHealth applications we used our *Infusion of eHealth Innovations in Health Services Organisations Model* to undertake a detailed case study assessing NHS CFH's current approach to promoting the NHS CRS in secondary care.
- We found this model helpful, particularly in highlighting the need to pay attention to human factors when developing and designing IT solutions and this failure to engage with end-users at this crucial formative stage represents a major weakness of the NHS CRS implementation of plan, as does the continuing lack of clarity over the details of what this will comprise of, the opportunity to trial and gain confidence in using it, ongoing concerns about confidentiality and the lack of a clear timeline for implementation.
- That said, NHS CFH are instituting a comprehensive multi-faceted approach to implementing the NHS CRS which, given the disruptive potential of this innovation with respect to normal working patterns, is very appropriate.
- It is, however, very important that particular attention is now also paid to ensuring that there are ample training opportunities for staff before its actual introduction and real-time support during the actual implementation phase. The success (or failure) of the central plank of the multi-billion pound investment in NPfIT will ultimately depend only in part on technological competence; far more important will be the attention awarded to understanding and managing the socio-technical dimensions and it appears that at present inadequate time, attention and resources have been focused on this latter issue.

concl usions And futur e reseAr ch Prior ities

- We have in undertaking this work made four main methodological contributions to this nascent field, namely development of:
 - a very comprehensive search strategy for identifying high quality

primary and secondary literature investigating the impact of eHealth on the quality and safety of healthcare

- integrated conceptual maps of eHealth, quality and safety, which have, as demonstrated in this project, the ability to draw attention to the major potential benefits associated with use of different eHealth applications
- a tool for critically appraising systematic of eHealth applications based on internationally agreed approaches
- a framework with which to consider the planned implementation of eHealth innovations into complex health service organisations.
- This project has also laid the foundations for the future creation of a potentially important international resource—*NHS Connecting for Health Database of Systematic Reviews and Randomised Controlled Trials in eHealth*—that should we believe be of considerable usefulness to all those with an interest in IT and its impact on healthcare delivery.
- The formative work for this project and the review of technical reports and a variety of review documents clearly demonstrate that eHealth applications have the potential to dramatically improve the quality of healthcare delivery; even more importantly, perhaps, there is considerable potential to improve the safety profile of medicine through elimination of both latent and active errors and through promoting real time systems checks.
- The major finding from reviewing the empirical evidence—which is of variable quality—however, is that there is very limited rigorous evidence demonstrating that these technologies actually improve either the quality or safety of healthcare.
- The reasons for this are multi-faceted, these including:
 - a lack of primary research, this to an extent reflecting the assumption that the benefits associated with these applications is obvious
 - using proxy outcome measures as opposed to those that are actually clinically important
 - poorly theorised interventions and studies
 - over-estimating likely effect sizes
 - methodological limitations, particularly the failure to appropriately use cluster designs in studies that are at risk of contamination, poor outcome definition and measurement, and approaching these interventions as the equivalent of simple interventions, which they are typically clearly not

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- ❑ naïve assumptions that these technologies will be equally effective in all contexts
 - ❑ inappropriately short timeframes to study likely health gains
 - ❑ the failure to involve end-users at a sufficiently early stage in the design and deployment process that they can actually influence factors that are likely to increase acceptability of the interventions to clinicians
 - ❑ a failure to pay adequate attention to the socio-technical factors that are likely to be important in relation to the diffusion, implementation and use of these applications.
- Despite these substantial gaps in the evidence-base—which can be filled—we are, on the basis of the theoretical work and empirical evidence reviewed, cautiously optimistic that a number of the eHealth applications being introduced into the NHS through the NHS CFH’s NPfIT are likely to result in significant medium- to long-term benefits to organisation efficiency and patient care.
 - Based on our synthesis of the evidence described above and wider trends within the IT sector, we consider below some key policy considerations:

Interoperability

- The critical importance of ensuring interoperability between the increasingly numerous and diverse applications now commonly used in healthcare settings is widely recognised. Currently, most IT applications in the NHS are not interoperable; that is to say that they cannot exchange information electronically. NHS Connecting for Health is now active (on a global scale) in developing and ensuring interoperability and such efforts need to be sustained at both a national and international level. It is particularly important that agreed standards are enforced across all applications used by the NHS, including those already in use, but particularly in relation to procurement of new technologies to avoid potentially serious problems with information saved in different formats or standards.

Data quality

- Far greater attention needs to be given to the quality of data being recorded by healthcare professionals as this will be crucial to maximising the potential benefits of the introduction of the NHS CRS. Correctness and completeness of data is of utmost importance not just for current clinical care, but even more for future care when many CDSSs and other

applications will critically depend on the quality of the recorded data; inaccurate information may lead to wrong and potentially dangerous recommendations. Accurate data recording of clinical information is also required to ensure effective secondary uses of these data, including applications for paying for episodes of healthcare (such as Payment by Results), needs assessment and public health monitoring, quality measurement, and research.

Commitment to evaluation

- As eHealth is with us to stay and is furthermore very likely to continually expand its role in aiding the management and provision of healthcare, it is vital that we take every opportunity to learn from the largest IT commissioning and deployment project in healthcare in the world.
- NPfIT offers an unparalleled opportunity not just for introducing improvement into the NHS, but also to learn how to implement IT into healthcare and how to further improve it once introduced. The Programme could also have far-reaching implications, not just for England but also for many other countries as they introduce EHRs and other eHealth applications. Linked to this is the potential for economic benefits: as well as the eHealth market in the UK, opportunities may exist to export much of the knowledge and technology developed in the UK.
- Due to the continually evolving nature of IT, it is inevitable that many of the applications currently being introduced will be due for major upgrade, improvement or replacement within the next few years.
- Given the real paucity of evidence, we very strongly encourage NHS CFH to centralise their evaluation programme so that this permeates all aspects of the Programme's development and implementation. Given the historic failure of many previous IT initiatives, such investment will we believe likely to prove a most valuable investment.
- Developing the at-present very weak evidence-base in relation to how to facilitate implementation and adoption is therefore likely to result in significant long-term benefits. Bearing this in mind, we strongly recommend that, wherever possible, implementation proceeds within the context of carefully considered evaluation.

Comparative studies to guide procurement decisions

- There is an urgent need for comparative head-to-head studies in relation to IT applications that healthcare systems are considering procuring. It is

somewhat paradoxical that head-to-head rigorously conducted trials are the “gold standard” for evaluation of other health technologies (eg new medicines or surgical interventions) but not eHealth applications.

- While we realise that these may be in some cases difficult as the interventions may be multiple and their pathways to impact complex or subject to effect modification, alternative rigorous methodologies for evaluation can nonetheless be considered. Simple satisfaction surveys and face-validity should not be taken as constituting sufficient evidence.
- Commercial and home-grown applications procured by NHS CFH for the NHS should undergo the same rigorous evaluation as would be expected for new medicines as they may have comparable effects—positive and negative—on patients’ health, the safety of healthcare, costs, and on the overall quality of care. In line with the above recommendation, a European regulatory body comparable to European Medicines Agency could help ensure that rigorous standards for the quality and safety of IT applications (such as ePrescribing applications) are met. Such a body could in collaboration with the European Medicines Agency proactively engage in research on ePrescribing, for example, and compile a list of all important medication interactions and create a priority list for implementation for software developers and then support evaluation.

Developing home-grown applications

- Given the repeated emphasis on the importance of contextual factors it is important to appreciate that evidence from the US is, given the very different healthcare systems in operation, often unlikely to be generalisable to a UK context in any simplistic way.
- Furthermore, given the strength of evidence that home-grown applications produce the best outcomes, NHS CFH should consider supporting development and rigorous evaluation of selected home grown NHS applications over commercial off-the-shelf applications.
- As there are currently over 5,000 different applications in use in the NHS—many home-grown—a mechanism could be developed to try to learn from and support further development of the best of these so that they meet standards expected for use on a larger perhaps national scale.

Staff training and development

- The NHS is Europe’s largest employer with a workforce of over one million people, approximately half of whom operate in clinical roles. Information

technology already impacts on many workers' day-to-day role and it will in the months and years to come set to impact on more-and-more of this workforce in an increasingly profound way.

- Given the acknowledged training needs of this workforce, it is particularly important that every opportunity is taken to promote the relevant knowledge, skills and competencies, for example, beginning in medical and nursing schools, but extending throughout professional working careers.
- Appreciating the structural, organisational and, to a lesser extent, professional challenges that need to be overcome in the deployment should however never be over-looked, particularly when complex transformative technologies such as the NHS CRS are introduced. The need for training in use of new technologies and on-the-job support also needs much greater appreciation.
- Realising the benefits of eHealth applications is, however, likely to be crucially dependant on actively and formally facilitating end-user input throughout the commissioning, design, development and implementation process as this will maximise the chances that aspects of these technologies that are actually clinically useful are developed (for example, ETP) and promote a sense of ownership and buy-in into the technology.
- End-user consultation and feedback should be viewed as an on-going process and should therefore continue after deployment to ensure that problems are identified early, as are possible solutions which can be incorporated into system upgrades.

International collaborations

- Information technology in healthcare is now a top priority in the European Union, US and most Organisation for Economic Co-operation and Development (OECD) countries. This mutual interest provides a strong basis for promoting collaborative endeavours in relation to the development and enforcement of standards and the mutual sharing of lessons and experiences from attempts at IT-based healthcare reform. Such learning is at present suboptimal and evaluation efforts are in some areas duplicated whilst in other areas large gaps remain. International collaborations can help in the development of high quality eHealth applications and also in the evaluation of eHealth applications by making such evaluations less environment-specific and more generalisable.
- We also encourage NHS CFH to prioritise the implementation of

ePrescribing, ideally with CDSS functionality in an integrated way within the NHS CRS within secondary and tertiary care settings and also to improve ePrescribing functionality in primary care.

- We have throughout this report identified a number of areas in relation to specific technologies where further research is warranted. There are, however, a number of broader research considerations that need to be prioritised which we emphasise here, namely:
 - the need for further conceptual development and then international consensus building on use of standardised terminologies to facilitate future primary and secondary work
 - the development of a methodological toolkit to facilitate evaluation of eHealth applications throughout all aspects of the development and deployment life cycle of these technologies
 - the need to encourage researchers to combine rigorous quantitative and simultaneously conducted qualitative assessments when evaluating the effectiveness of new eHealth applications to allow a detailed appreciation of relevant contextual factors that might help better understand the reasons for the success or failure of the intervention to emerge and also, where found to be successful, to allow an assessment of the likely generalisability of the intervention to be made.
- Given the vast gulf between the potential advantages associated with eHealth applications and the actual empirically demonstrable benefits, our major research recommendation is however to ensure that evaluative considerations are centralised within NHS CFH; given the scale of the investment taking place, it is vital that every opportunity is taken to ensure that this public money produces the desired outcomes. In view of the likely timeframe for these improvements to be demonstrated, it is important that this commitment to evaluation continues beyond the end of the 10-year lifetime of the Programme.