CRITICAL ISSUES FOR ELECTRONIC HEALTH RECORDS

CONSIDERATIONS FROM AN EXPERT WORKSHOP

Peter Singleton MBA, Claudia Pagliari PhD and Don E. Detmer MD, MA





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About the authors

Peter Singleton is Principal Research Fellow at the Centre for Health Informatics and Multi-professional Education (CHIME) at University College London (UCL); he is also a Director of Cambridge Health Informatics, a healthcare policy consultancy.

Claudia Pagliari is Senior Lecturer in Primary Care at the Centre for Population Health Sciences, University of Edinburgh, where she leads the Interdisciplinary eHealth Research Group and co-directs the MSc programme in Health Informatics, in collaboration with the Royal College of Surgeons of Edinburgh.

Don E. Detmer is Emeritus Professor and Professor of Medical Education, Department of Public Health Sciences, University of Virginia; President and CEO, American Medical Informatics Association; and Visiting Professor of CHIME, University College London (UCL) at the time of the workshop. Don is a past Trustee of the Nuffield Trust.

Claudia Pagliari organised the workshop, Don Detmer facilitated the discussions and Peter Singleton acted as rapporteur. All contributed to the preparation of this report.

Acknowledgements

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The views expressed in this report are the responsibility of the authors, although they seek to reflect the opinions and expertise of the participants at the workshop and their subsequent contributions. We thank all the participants for the generous provision of the time, both to attend the workshop and provide comments on drafts of the report and the workshop proceedings.

Foreword

The Government has rightly put information technology development at the heart of NHS reform. However, it is vital that the substantial sums being invested are used to provide care that is as effective and efficient as possible.

As part of its ongoing research programme, the Nuffield Trust has been engaged in a series of activities focused around new health technologies, and in 2007 published the findings from research on the emergence and implications of personal health records.

This latest report, on electronic health records (EHR), is based on an expert seminar hosted jointly by the Nuffield Trust and the Wellcome Trust. In it, authors Peter Singleton, Claudia Pagliari and Don Detmer very usefully outline the key issues surrounding EHR implementation, and suggest key priorities for delivering EHR systems that will benefit patients and health professionals alike.

I do hope that you will read this report with interest, and will continue to engage with the Trust's work programme in this and other areas. We appreciate the support of the Welcome Trust in this work.

Dr Jennifer Dixon Director, The Nuffield Trust

1. Executive summary

At a workshop in November 2007, experts from the academic, practitioner and policy communities identified a number of critical issues relating to the use and impact of electronic health records (EHRs), EHR systems and associated public policy.

From these issues, seven key requirements were identified for successful systems implementation, integration and maintenance. For progress to be assured regions, nations and the global health community must be engaged intelligently and iteratively. The requirements include:

- 1. A clear 'vision' of the role of EHR and related information and communications technology (ICT)-aided healthcare interventions, supported by sub-component plans capable of assuring engagement of five key stakeholder groups:
 - patients including informal care-givers
 - the public including citizens, the media and public representatives
 - professionals, including
 - clinical practitioners and allied health professionals
 - health informaticians, ICT technologists and technicians
 - managers/administrators/regulators/private payers
 - suppliers (application vendors, systems integrators, etc).
- 2. Clear and consistent communication (relevant messaging) of EHR content and meaning. This includes terminologies, classifications and standards to assure interoperability without loss of meaning, including relevant contextual content.

¹ These include information governance policies and strategies that are informed by a sound understanding of the multiple types, functions and uses of patient data and the long-term implications of record linkage, as well as by stakeholder consultation. These strategies must be sufficiently flexible to respond to changes in clinical need and risk.

- 3. Systems that are able to aggregate, assess and manage the current base of knowledge and then ...
- 4. deliver that knowledge through decision support in a timely manner at the point of care. This is seen as critically important for both clinicians and patients (including their informal care-givers).
- 5. Systems that develop and support relevant workforce education and training.
- Systems that support innovation in healthcare by enabling access to reliable data for research in the core sciences, as well as facilitating continuous improvements in healthcare quality.
- 7. Strategies for harnessing both experiential learning and opportunities to obtain evidence of the impact on quality, efficiency and safety.

All of the above assume that an information and communications infrastructure will be there to offer secure delivery of relevant information and knowledge on a right- and need-to-know basis. It is likely that this agenda will require another 20 years to reach maturity in a number of nations or regions of the world.

The group recognised that EHRs are embedded within complex sociotechnical and organisational systems. Successful realisation of the vision of EHR will require a great deal of change; strategies and tactics that fail to approach implementation as appropriate for complex adaptive systems will be less likely to be successful.

2. Introduction

This report is based on discussions at a workshop entitled Critical Issues for Electronic Health Records, which took place at the Nuffield Trust and the Wellcome Trust in London in November 2007, and on subsequent research and consideration by the authors.

The main objectives of the workshop were to bring together leading academics, policy-makers and research sponsors involved in EHR research, strategy and implementation, in order to:

- share knowledge and expertise from diverse areas of study in relation to EHR, to generate a high-level overview of core issues, harness synergies between diverse areas and consider wider implications
- seek an expert consensus on priorities for strategic planning, implementation and research around EHR
- identify new areas of interest and debate, for example around unintended consequences and societal impacts.

3. Summary of the workshop

Context

Electronic health record (EHR) projects have the potential to increase the quality, efficiency and outcomes of healthcare through better maintenance, availability and linkage of patient data. They also offer opportunities to improve the personalisation of care (for example via linkage to decision support), public health and service planning (through monitoring trends), and to promote medical knowledge and innovation (through research using large datasets).

However, evidence illustrating both the benefits for care quality and safety and the risks to data security remains sparse. Effective implementation of EHR is dependent on a host of socio-technical factors operating at the organisational, professional and patient levels, which remain worthy of serious scholarship.

Linkage of person-specific health records, and the potential integration of data from other sectors (including social care, criminal justice, tax and commercial), raises ethical questions around individual rights for privacy in the 'surveillance society', while the potential integration of genetic data raises questions over ownership and identity. Gaining a comfortable social consensus around these issues remains a policy challenge.

There are also challenges around interoperability of systems and databases, and for effective knowledge management, as new data streams become available (for example mobile symptom monitoring) and as both care and care records become increasingly complex.

In view of the complexity of EHR systems as a topic, discussion of these issues has been inherently fragmented, with in-depth analysis of technical, regulatory or socio-technical issues taking place most frequently within particular enclaves of expertise, typically in exceptional institutions or settings. This acts as a barrier to 'big picture' thinking and

makes it difficult to develop and agree upon packages of recommendations that are relevant to and interpretable by generalist policy-makers, while recognising the diverse interests of the healthcare and research communities.

Aims

The workshop was designed to facilitate the sharing of ideas and establish high-level perspectives on critical issues for electronic health records relevant to healthcare practice, informatics practice, research and policy.

Approach taken

The exercise included a pre-meeting consultation inviting ideas and opinions, as well as presentations, group discussions and structured opinion-seeking during the workshop.

Initially all participants were sent an information sheet outlining the aims and scope of the meeting and were invited to submit ideas by email under the following headings:

- opportunities
- barriers
- challenges
- key sources of evidence
- unanswered questions for EHR.

At this stage participants were asked to respond to the questions with particular reference to their own area of expertise, in order to maximise the inclusion of diverse perspectives.

Several participants were also asked to prepare presentations for the workshop focused on specific issues such as human and organisational factors, the evidence base, technical factors, ethico-legal arguments, global perspectives, safety issues, issues for research, surveillance and e-government, and patient ownership and control. Topics and speakers are listed below, in order of presentation:

¹ Karl Stroetmann and Graeme Laurie also prepared presentations for circulation only. All presentations may be accessed online at www.ehealth.ed.ac.uk/ehrsummit.php

Table 1. Topics and speakers

Professor Don Detmer	Electronic health records and EHR systems: policy snapshots 1990 to 2030
Professor Denis J. Protti	eHealth: a global view of commonalities – critical issues for electronic health records
Professor Justin Keen	How useful is the evidence on EHR?
Professor Trisha Greenhalgh	Philosophical issues in EHR research in organisations
Professor Perri 6	Confidentiality challenges for electronic health records
Professor David Bates	Critical issues for EHRs: safety and quality
Professor Trisha Greenhalgh	Embedding EHR in practice – human and organisational factors
Dr Claudia Pagliari	Engaging and empowering patients and the public
Peter Singleton	Ethico-legal issues for EHR
Dr Phillipe Boucher	Electronic medical record systems in developing countries
Professor Frank Sullivan	Secondary uses for research, innovation and population health
Dr Dipak Kalra	Key architectural challenges for electronic health records

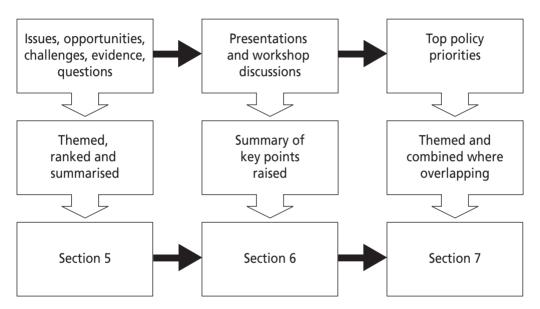
Presentations were followed by group discussions, which were minuted for future reference. A list of critical issues discussed on Day 1 was prepared and presented at the beginning of the second day, to refocus the discussion and to support those attending only on the second day.

Towards the end of the second day, the participants were asked to write down their opinions of the trigger questions introduced at the outset. The opinions expressed by the participants (together with those submitted by others who could not attend) were later collated by the authors and categorised around conceptual themes as part of the development of this report.

As a final exercise prior to adjournment, each delegate identified his or her top choice for the key EHR issue, in a round-robin fashion.

A summary of the presentations and subsequent discussions was also developed after the meeting and sent out to the presenters and delegates, in order to ensure that the notes reflected the opinions intended to be expressed as well as to allow further commentary and to support submission of any additional evidence.

Figure 1. Structure of the EHR workshop



While the authors take full responsibility for the final document and any errors that may appear, we express our gratitude for the extensive contributions of all of those who participated.

4. What do we mean by an electronic health record?

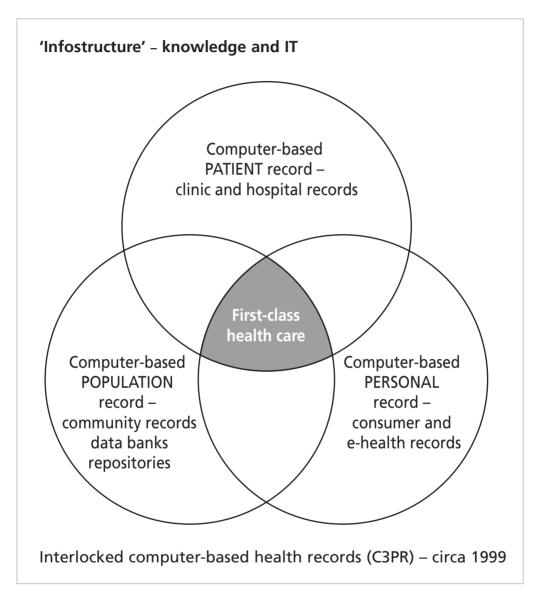
Approaches in the workshop

It was clear from the outset that speakers used the term 'EHR' to refer to a wide range of developments and projects, from in-house technologies to national infrastructure programmes. However, the discussions gave rise to no sense of dissonance when these different interpretations were used, suggesting its acceptance as a generic term. There was an acknowledgement that EHR projects vary in their objectives, contexts, potential impacts and funding, but participants' emphasis on 'vision' and 'leadership' indicates that what is most critical to any given project is being clear about what is to be delivered, what is to be achieved, and the changes and actions required to make this a reality.

Early in the meeting Professor Detmer sought to ground the discussions in a shared understanding of the scope of EHR by highlighting three main categories of 'infostructure' evident in healthcare today (see Figure 2). While these have been described using other terms, they are efficiently summarised as:

- the electronic or computer-based *patient* record (EPR, often called the electronic medical record or EMR), which is the formal record kept by a GP, hospital or other care facility
- a *personal* health record (PHR) that an individual patient may keep for their own benefit or share with their clinicians or others through a web link
- the population or community record which, when freed from unique personal
 identifiers, can support the management of the care system, monitor threats such as
 public epidemics or have other research uses such as pharmaco-epidemiology.

Figure 2. Infostructure for first-class healthcare



Source: Professor Detmer, from his workshop presentation.

How has EHR been defined?

Many definitions of EHR appear in the literature. These are effectively compatible but vary in emphasis; for example on the EHR as a source of information or on its clinical functions or its value for healthcare. They also vary in their representation of the clinical and chronological scope of the record and the primary stakeholders involved. The term is also used to describe the systems within which the records are held and managed.

In some contexts EHR has even been used to describe broader interventions such as clinical decision-support systems (in which patient data and medical knowledge converge), or indeed higher-level health information technology strategies.

This variation inevitably reflects the perspectives of the different organisations involved and the multiple types of EHR in existence (see Box 1). Such perspectives also influence the scientific study of EHR; for example different research questions and methods may be applicable if it is being approached as a piece of technology, a quality improvement intervention or a means of organisational redesign, which will in turn be influenced by different research philosophies and traditions.¹

In addition to broad definitions, a large number of different terms have been used to describe EHR in its various forms and contexts (see Box 2). The range of such terms, and the inconsistency with which they have been used, has tended to complicate communication about the topic.

Several taxonomies have been developed to address this problem, such as the one offered by Professor Protti in Box 3, which considers both the sources and control of the record. However, in practice even these narrower terms are being used interchangeably and there is a growing consensus on the value of using EHR as generic descriptor.

¹ See Professor Greenhalgh's presentation at www.ehealth.ed.ac.uk/ehrsummit.php

Box 1. Some definitions of 'electronic health record'

Article 29 Data Protection Working Party (European Union): a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form and providing for ready availability of these data for medical treatment and other closely related purposes.

California Telemedicine & eHealth Center (CTEC): an electronic record composed of health *information* regarding an individual patient that exists as part of a complete system designed to provide access to, and management of, such information. *The EHR is developed and managed by the health facility or provider.*

HIMSS (Healthcare Information and Management Systems Society): a secure, real-time, point-of-care, patient-centric *information resource for clinicians*. The EHR aids clinicians' decision-making by providing access to patient health record information when they need it and incorporating evidence-based decision support. The EHR automates and streamlines the clinician's workflow, ensuring all clinical information is communicated, and ameliorates delays in response that result in delays or gaps in care. The EHR also supports the collection of data for uses other than clinical care, such as billing, quality management, outcomes reporting and public health disease surveillance and reporting.

International Organization for Standardization (ISO): TC 215: a *repository* of information regarding the health of a subject of care, in computer-processible form.

UK Department of Health: the *concept* of a longitudinal record of a patient's health and healthcare to combine information from primary healthcare with periodic care from other institutions.

US Institute of Standards and Technology: a longitudinal collection of patient-centric, healthcare *information*, available across providers, care settings and time. It is a central component of an integrated health information system.

US National Alliance for Health Information Technology: an electronic record of health-related *information* on an individual that conforms to nationally recognised interoperability standards and that can be created, managed and consulted by authorised clinicians and staff across more than one healthcare organisation.

Box 2. Examples of terms used to describe aspects of EHR

CPR	Computer-based	patient record

CPRS Computer-based patient record system

CCR Continuity of care record

CMR Computerised medical record

DMR Digital medical record

EHR Electronic health record

eMAR Electronic medication administration record

EMR Electronic medical record
EPR Electronic patient record
ECR Emergency care record
ICR Integrated care record

IEHR Interoperable electronic health record

LHR Longitudinal health record or lifetime health record

PCR Patient care record
PHR Personal health record

PMR Personal medical record or patient medical record

SCR Summary care record

PHR

Box 3. Key categories of electronic record²

EMR the electronic record in a physician's office; in one setting

EPR the electronic record in a hospital or facility; in one organisation

EHR the longitudinal electronic record of an individual that contains data from multiple EMRs and EPRs; shared and/or interoperable across settings

the internet-based record under the full control of the patient (citizen)

² As described by Professor Protti in his workshop presentation: see www.ehealth.ed.ac.uk/ehrsummit.php

Within this report we will take the broader view of the term 'EHR', conceiving it as:

- an overarching term to describe digitised patient and healthcare information and the systems into which they are embedded
- in an idealised framework, an integrated set of digital healthcare records and systems that may operate across settings and over time and is supported by high-level communication, knowledge management and decision support technologies³
- as a transformative technology with the potential to improve healthcare delivery and medical innovation through integrating institutions and silos of information.

How do EHR programmes vary internationally?

Since the publication of seminal policy reports in the last decade, the EHR has become universally regarded by governments as an essential tool for maximising the quality, safety and efficiency of healthcare in the modern age. For this reason implementing an EHR is central to the overall eHealth strategies of most nations, although countries vary widely in terms of the necessary infrastructure, systems, funding, and the duration of their planning efforts.

In many countries, local clinical records systems have been in use for some time. However, most national e-health programmes are geared towards achieving the long-term vision of a fully integrated care record, while attempting to deliver centrally-held summary care records as an intermediate step.

Although a number of common EHR 'journeys' have been observed, there is wide variation between countries in the extent to which certain issues have been taken into account. These include maximising point-of-care access, ensuring standards and interoperability, monitoring uptake, evaluating outcomes and managing organisational change. Notable success stories in places such as Denmark, Hong Kong, the US (Department of Veterans Affairs) and Andalucia, Spain, are underpinned by effective clinical engagement in EHR design, standards, and change management.⁶

³ The long-term vision represented in major European and US policy documents.

⁴ Institute of Medicine (2001) Crossing the Quality Chasm: A new health system for the 21st century. Washington DC: The National Academies Press.

⁵ HIMSS (2008) Electronic Health Records: A global perspective. Available at www.himss.org/content/files/200808_EHRGlobalPerspective_whitepaper.pdf

⁶ See Professor Protti's workshop presentation, drawing on reports from OECD, WHO and other sources, available at www.ehealth.ed.ac.uk/ehrsummit.php

EHRs are being implemented in several developing nations. However, this can present new challenges relating to infrastructure (such as variable power supply), finance, population factors (such as mobility, a high disease burden), culture (such as name structures), care delivery models (for example, the use of lay workers) and reporting requirements (non-governmental organisations (NGOs), aid agencies and government). To address these factors EHRs need to be tailored to local needs and culture, costs minimised though adopting open-source and open standards, and privacy protected through more consistent data protection legislation.⁷

Table 2. Key features of EHR strategy in a sample of developed nations

Country	EHR approach	Notes/comments
England	National – cross-settings; possible integration with social care as well.	The scale of the programme (£12.6bn) covers a radical change of ICT across different care settings to improve recordsharing, though there seems to be less emphasis on supporting transformation of care.
Wales – IHR	Unscheduled care only.	Individual health record extracted from GP system and made available in other care settings.
Scotland – ECR	Unscheduled care only.	Emergency care record extracted from GP systems now available via 'NHS 24' for unscheduled care settings. Patient access some way off. Fully integrated care records are a distant goal, but examples of integrated care records exist, in particular, clinical domains such as diabetes, where the Scottish Care Information – Diabetes Collaboration system brings together multi-sector patient data.
Netherlands – EMD/WDH	Unscheduled care only.	Making information on medications more widely available and making GP records available for unscheduled care.

 $^{7\,}$ See Dr Boucher's presentation on EHR in developing nations, available at www.ehealth.ed.ac.uk/ehrsummit.php

Country	EHR approach	Notes/comments
Finland – HER	Developing inter- connectivity to standards.	SAINI project – focus on interconnectivity of systems in Finland; supported by FinnWell, a programme of technology-related projects in healthcare.
		National components: image archive, patient record system, electronic prescription, Citizen's Health Portal.
Czech Republic – IZIP	Integration between settings, but sub-national at present.	Patient-controlled, privately managed but in conjunction with GHIC-CR, a state insurer. Now with 2m patient records in five years. Reduces duplicated tests and treatments.
Canada	National – building infrastructure with focus on interoperability rather than national record.	'Infoway' addresses need to provide infrastructure to permit electronic communications between healthcare providers.
Hong Kong	Regional – integration across hospitals, possibly to include primary care (mainly private).	Focus is on interoperability, bringing together records from different parts of the area, rather than a summary record per se.
France – DMP	National infrastructure to support patient-controlled records.	SmartCard-based; opt-in, but failing to gain public buy-in
Australia	A national Individual Electronic Health Record (IEHR), based on summaries of health events.	May be developed nationally or through state-based collaboration. So far has focused on patient and professional identifiers and clinical terminologies. IEHR is intended to include patient self-care information. Opt-in approach planned.
USA – Veterans Affairs	Specific sector – integration of settings.	'Single health economy' – focus on healthcare standards and improving performance.

Other international examples may be found in recent reports such as HIMSS (2008).8

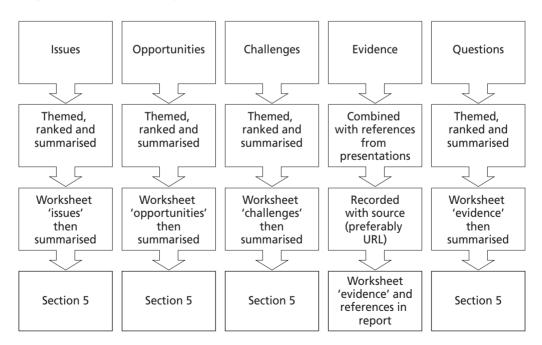
⁸ HIMSS (2008) *Electronic Health Records: A global perspective*. Available at www.himss.org/content/files/200808_EHRGlobalPerspective_whitepaper.pdf

5. Summary of the workshop responses

This section reviews responses to the pre-workshop consultation and includes comments from participants and other invited experts who were unable attend but wished to contribute their thoughts. Some divergence in terminology was noted throughout the workshop and this has been 'harmonised' by the authors.

Responses were grouped by the authors into themes for each area (Issues, Opportunities, Challenges and Questions). Many of the points raised are also reflected in the subsequent sections of this report, even if not directly referenced or quoted.

Figure 3. 'Theming' of responses received



The responses for each area are summarised/paraphrased below, with elaboration only for the top three themes in each section. The number of responses is given in parentheses; it is worth noting that most participants offered more than one response under each heading.

Issues

The most important theme that emerged was the need for **clarity on the focus/vision** for the EHR (17 responses). The responses were quite varied, but generally addressed improving the quality and safety of patient care by increasing access to valid patient information and reducing error, and improving decision-making at the point and time of care through use of decision support software. A careful blend of system support and professional judgement is needed to minimise variation where best practice is clear, without stifling either innovation or patient-centred care and related local realities. For the present, at least, flexibility is needed to meet local needs and practices (where appropriate) and acknowledge vested interests.

Stakeholder engagement (both public and professional) was identified as an issue in 14 responses. Engagement of professionals is needed to clarify and foster mutual understanding of the objectives of EHR and how adaptation of practice habits will be an element of meeting future needs. Equally, the public need to be engaged so that they support, or at least accept, the changing use of medical records through computerisation and the wider shared benefits to both individual care and society through improved standards and the better understanding of health factors and effective healthcare delivery. A better engagement with the public may be necessary to underpin continued use of 'implied consent' or support opt-out dissent mechanisms. This may itself require a more thorough understanding of public attitudes, to inform policy decisions and to help to redefine the social contract underpinning the provision of healthcare and the use of EHR data.

Concerns around **security and confidentiality** elicited 12 responses. They focused not only on secure handling of data, but also on reassurance of the public that there are effective access controls that would be rigorously enforced. This requires an understanding of the controls and how they would be applied, including auditing and monitoring of access to data, with prompt and significant disciplinary measures being taken routinely whenever breaches occur.

¹ It is worth noting that the workshop took place immediately after the UK Revenue & Customs Service (HMRC) announced that CDs containing personal details of 25 million benefits claimants had been lost in the post: see http://news.bbc.co.uk/1/hi/uk_politics/7103566.stm

Eleven responses addressed **systems interoperability**, both at a technical level for inter-system communication and a semantic level so that clinical information recorded was not distorted by transformation between systems and between care settings. Data quality rather than quantity is the key here and data standards are a crucial solution.

Other topics raised as key issues include:

- **insufficient evidence** of the impact of EHR (balancing the desire for proof with the pragmatic need for progress)
- the need for relevant informatics **education and training**
- managing data quality (for example, human influences on coding)
- engaging concerns relating to public trust
- effecting **culture change** within the professions and the NHS generally (including leadership)
- managing the variable **definitions**, **terminologies** and **concepts** of EHR
- managing costs
- ensuring continuing access to EHR data for **legitimate research use** while protecting patient confidentiality.

Opportunities

Enhanced **quality and safety** was a key opportunity theme in 23 responses. This focused particularly around decision support to reduce or eliminate errors through a more timely access to relevant knowledge. It also covered other opportunities to gain more effective use of knowledge for care delivery, such as having better access to medical record banks facilitating hypothesis generation and a productivity gain in meaningful research findings.

Greater **efficiency** was articulated in ten responses, though more as offering a better use of resources, through eliminating errors and enabling earlier, more effective, interventions (based on better understanding of what works best and when, rather than simple cost-containment). **Improving the patient experience** through enabling more timely access to appropriate care was also noted.

Patient involvement was noted as an opportunity in nine responses, though as distinct from public engagement mentioned earlier in this report. Here it referred to the capacity of EHRs to empower patients through a more direct involvement in their own care (especially for the chronically ill rather than accident victims or terminally ill patients).

Direct patient access to one's own health record via secure web portals was regarded as particularly useful. This includes the ability to track progress on markers, such as blood pressure or laboratory results, which are highly valued by patients.

Better research as an opportunity gleaned nine responses. It reflects the prospects for greater knowledge and understanding resulting from:

- much broader datasets across populations
- smaller disease-specific databases (for example, genotypic and phenotypic influences on health and disease)
- greater access to more detailed real-life data such as post-market surveillance reporting of medication use and side effects
- the potential for much larger samples of valid patient information that expose how
 care is actually delivered versus the model of practice as informed by randomised
 clinical trials (RCTs).

Other opportunities suggested by individual participants included using open-source systems and methods to lower costs, and harnessing experiential learning around EHR implementation.

Challenges

Stakeholder engagement, with 21 responses, was seen as being the biggest challenge. Written responses on this topic were brief, but made reference to a range of different stakeholders: public, patients, professionals (particularly GPs), politicians, managers and members of the media. Common issues were engaging the public so as to support the move to EHRs without erosion in trust, engaging practitioners sufficiently to motivate changes in work processes necessary for adoption, and engaging policy-makers to maximise access to patient databases for care quality improvement and formal research.

Concerns were expressed in 11 responses around the challenge of establishing and/or maintaining the **trust of the public** in the new systems, especially with respect to the security of their personal data. This has often been a stumbling block for EHR projects, although a number of 'emergency care' EHR systems have been implemented without apparent difficulty, perhaps as the context and benefits are easy to describe.

Ten responses touched on achieving **culture change** as a theme in terms of adopting new ways of working and new priorities for care. This is crucial to the actual adoption of the EHR as a central support to adopting new processes for care as against simply its

implementation as an IT project. It should be noted that national EHR projects are yet to be proven as a cost-effective use of resources in terms of saving lives and improving patient care, as few have been fully implemented for long and major evaluations are scant.

Finally, there were concerns expressed over the chances of fully **realising the benefits** of EHRs due to issues such as

- lack of financial resources, the necessary tools and systems, or time (presumably before funding or political will runs out)
- a lack of clear standards
- the possibility that political and other motivations may frustrate delivery of an effective EHR
- the requirement for good data quality to populate the EHR
- current limitations in education and training for professionals
- the essential need for effective leadership to see EHR projects through to completion
- the need to overcome perverse incentives and simple professional resistance to change
- the risk that EHRs might increase health inequalities, by providing better access to those who already have good access to care.

Unanswered questions

Participants had been directed to consider this item from their own stakeholder perspectives, so the responses reflected a range of academic and pragmatic questions. These largely echoed the issues and challenges previously discussed. However, additional questions identified were:

- Should systems be implemented in a 'big bang' manner or through a more evolutionary approach?
- How important are the motivations of the various key stakeholders?
- How can equality of access to the benefits of EHRs be assured?
- How do we define anonymisation (or 'good enough' anonymisation)?
- How do we plan to use genetic information beyond individual treatment? How do we manage this for families?

- What is the public understanding of the implications of genetic data in the EHR?
- Can we establish a 'social contract' to define and support likely future use of EHR data and how can this cover different attitudes to privacy across the population?

Questions were also raised around the future status and use of EHR as linkage to social and criminal databases becomes increasingly possible and likely.

6. Key points from presentations and discussions

The 'vision thing'

- The vision for EHRs has been changing over time, but needs to bring together the needs of patients, professionals and the population in order to transform care and improve health; the EHR is fundamentally different from the paper record.
- Medicine is developing rapidly and health informatics needs to develop faster –
 there is a core distinction between just the technology (ICT) and the use of
 information to support healthcare (informatics). EHRs are needed to support a
 'learning healthcare system', providing feedback to different levels of care delivery.
- EHR projects are complex programmes introduced into complex adaptive systems;
 a broad approach to interpretation and evaluation is needed it is not a simple
 IT intervention.
- Greater patient input via electronic PHRs (ePHRs) may radically change the landscape; both of EHRs and of how care is delivered. Commercial players such as Google and Microsoft may bring new impetus and change public expectations.
- Requirements for an EHR can vary widely depending on the type of healthcare
 economy and the state of the wider economy. For example, developing countries
 will have very different needs from those of developed countries, which normally
 have established IT and healthcare infrastructures.
- The importance of integrating data (records) and knowledge (evidence) to support decisions that impact on quality and safety needs to be stressed. (Examples include clinical decision support (CDS) and computerised physician order entry (CPOE).)

Privacy and confidentiality

- Privacy concerns are a key issue, though perhaps one that attracts disproportionate
 media coverage; many people assume records are shared already; generally few
 people choose to opt out of EHR systems when implemented (contrasting with the
 figures suggested by polls).
- Privacy issues are often framed in unhelpful metaphors or terms: 'patient consent' overlooks the need for social benefits; 'striking a balance' between individual and public benefits or risks suggests that one can be offset against another, whereas a 'settlement' which avoids the worst of both extremes might be a more helpful perspective; 'secondary uses' often suggests that research and other quality initiatives are somehow optional and unnecessary to care quality improvement.
- There needs to be a clear 'social contract' around the use of medical records in modern medicine, setting out both the controls on and the benefits from wider data-sharing.¹ There needs to be more emphasis on 'stewardship' of medical records (by which we mean that the holders of data have a duty to use it wisely in the best interests of the data subjects, not just to keep it safe) to meet both confidentiality needs and developing safer, better care.
- There are aspects of use that will be difficult for the citizen to be properly informed about and hence to grant consent. This may require some aspect of 'authorisation' rather than a simplistic consent process. A more nuanced approach is needed, to avoid breaching confidentiality on the one hand and to maintain an effective healthcare system on the other.
- Professionals need effective training and support to assist them in making good
 judgements, rather than legalistic 'guidance', which can fail to recognise that security
 risks are influenced as much by user factors as technical controls.
- Providing patient choices may be the best way to gain trust and provide acceptance.
 It is also possible to take steps to 'de-identify' data while still keeping it useful for research requiring specific consent as well may deter such protections.

¹ The English NHS Care Records Service offers a 'Care Record Guarantee', which details a range of controls to reassure the public: see www.connectingforhealth.nhs.uk/nigb/crsguarantee

Evidence base and economics

- While it is evident that secondary analysis and linkage of EHRs has had benefits
 for research, there remains comparatively little rigorous research demonstrating
 the benefits or disadvantages of EHRs for the quality, outcomes and costs of
 patient care. Where such evidence exists, it tends to come from singlesite/organisation projects; often where EHR is only one part of a broader
 intervention such as a decision support tool.
 - There is less evidence about the effects of national EHR programmes which is where most EHR resources are currently being focused. The lack of impact studies partly reflects the fact that it is difficult to determine the effects of EHR alone because of the existence of parallel changes elsewhere in the system, as well as changing timescales, which make evaluation projects difficult.²
- Evidence (mainly from the USA) is generally focused on evidence from a few key institutions,³ and often on internally developed systems rather than commercial off-the-shelf (COTS) products (an interesting research question in itself). COTS may be weaker on decision support than in-house systems, perhaps as these are poorly adopted/implemented in practice.
- Network effects mean that benefits may not be realised until much of the implementation has taken place and been embedded in practice – this may take years to achieve.⁴
- The lack of clear economic benefits makes it difficult to build a solid business
 case for EHR, though this still needs to be done. There is clear evidence of
 benefits from some successful projects;⁵ but it is hard, though not impossible, to
 generalise from this.

² Car, J, et al (2008) The Impact of eHealth on the Quality and Safety of Healthcare. NHS Connecting for Health Evaluation Programme. Available at: www.pcpoh.bham.ac.uk/publichealth/cfhep/documents/ NHS_CFHEP_001_Final_Report.pdf

³ For example Vanderbilt, Massachusetts General Hospital, Brigham and Women's Hospital, the Veterans' Administration, LDS Hospital/Intermountain Healthcare – as described by Professor Detmer in his presentation Electronic Health Records and EHR Systems: Policy snapshots 1990 to 2030.

⁴ Stroetmann, KA et al (2006) eHealth Is Worth It: The economic benefits of implemented eHealth solutions at ten European sites. Luxembourg: Office for Official Publications of the European Communities. Available at: http://ec.europa.eu/information_society/activities/health/docs/publications/ehealthimpactsept2006.pdf

⁵ Stroetmann, KA et al (2006) eHealth Is Worth It.

- There is a lack of high-quality research on consumer tolerances and attitudes to wider use of health records.⁶
- The costs, risks and benefits of EHR are still not fully understood and there has been insufficient application of economic expertise to the analysis of business cases to inform policy and practice.

Incentives and motivation

- Barriers to the adoption of EHR have been recognised as poor interoperability, privacy issues and lack of patient engagement, gaining clinician buy-in/the current clinical culture, the role of vendors, and insufficient or perverse financial incentives coupled with the lack of an economic case. On successful projects, these have largely been overcome.
- Patient safety can be significantly improved through appropriate use of IT, but it
 requires institutional and professional commitment to using it effectively. For
 example, decision support must be adopted as part of the way care is delivered if it is
 to be effective. Achieving the right level of interaction takes time and commitment.
- People have evolved complex ways of dealing with the demands of healthcare delivery – simply trying to replace paper with IT often fails when this point is not appreciated, as some functionality may be lost and people may struggle to compensate.
- Stakeholder engagement is critical; change must evolve and involve users in the solution; it may be necessary to change thinking first before implementing an EHR.
- Over-emphasis on consent rather than appropriate protection of the data may deter
 academics from carrying out research, through rising costs and uncertainty over
 gaining approvals to proceed; referring to 'secondary uses' pre-judges the issue and
 undermines public perceptions of the risks and issues involved in using health
 records for research.
- Issues around clinical coding: financial and other incentives may have distorting
 effects the issues around 'upcoding' of treatments in order to increase income are
 well known. Lack of incentives can also be a problem, as shown by the poor quality
 of death certificate completion.

⁶ Singleton, P et al (2008) Public and Professional Attitudes to Privacy of Healthcare Data: A survey of the literature General Medical Council. Available at www.gmc-uk.org/confidentiality/background.asp

Interoperability

- EHR systems must be semantically interoperable clinical information must still be meaningful once transferred, both between systems and between versions of the same software. It must also be gathered consistently if comparative analysis is to be performed effectively.
- There is a need for consistent policies around access to data, patient consent or
 organisational approval. Often these are determined locally in areas within
 countries, and the interpretation of data protection requirements can vary
 significantly between countries, even in the EU where they are supposed to be
 subject to the same European Data Protection Directive.
- Cultural, user and external factors may influence EHR structure, content and coding; as where data fields are influenced by sponsors' recording requirements, or practitioners' attitudes about the sensitivity of particular medical conditions affects the way these are coded. This will have implications for integration within and across nations.

7. Participants' top policy priorities

At the end of the workshop participants were asked to give their top policy priorities as a result of the presentations and discussions during the workshop.

Use and purpose of EHR

- A strategic approach to EHR implementation is needed, focusing on the delivery
 of clinical improvement rather than just management information, and
 demonstrating short-term wins particularly around quality.
- Being able to link archival data is vital for research to understand health over the longer term and to aid effective patient care, and this should be facilitated.
- There is a need to promote the use of EHR for research and to support access for this purpose.
- There is a need to recognise the common purpose of EHR for enabling both research and care delivery; both are integral to improving the quality and outcomes of medicine. In this regard, the distinction between so-called 'primary' and 'secondary' uses can be unhelpful.

Clinical informatics knowledge/skills

- A more strategic approach to capturing organisational learning around EHR is required – individual practitioners, clinical teams and managers require feedback on what works in practice and what doesn't.
- Changing culture and developing the workforce for the future requires education and training.

- There is a need to educate:
 - health professionals, on the implications of EHR for working practices (e.g. new responsibilities around data interpretation and confidentiality)
 - chief executives and boards in how to manage complex EHR projects (including issues such as how to engage staff and develop processes)
- there is a need to train more health informaticians.

Data quality

 Further understanding is needed of how to maximise the benefits of multi-disciplinary (and patient) contribution, while minimising variability in data quality.

Interoperability

- Increasing the interoperability of heterogeneous systems is essential to maximise whole system benefits.
- Standards for EHR are required which preserve syntax/structure and semantics/meaning.
- Professional and technical standards for confidentiality and security need to be agreed and defined.
- There is a need to coordinate standards efforts globally otherwise these will focus
 only on national or 'first world' issues.

Knowledge management

- There is a need to both generate and aggregate evidence of the impacts of EHR. This requires training in the conduct and interpretation of evaluation studies.
- Web-based repositories of EHR experience and studies are needed, but there is the question of who defines quality standards.
- Further integration of medical knowledge sources with EHR systems is needed to maximise potential benefits.

Lessons for implementation

 There is a need to engage clinical leaders and health professionals in the process of developing priorities and plans for EHR adoption.

- Clinicians need to be incentivised to adopt new ways of working, accept short-term disruption and improve data quality. There is also a need to manage perverse incentives against change. This may also apply to other stakeholders.
- There is a need to recognise that EHR implementation takes place within a larger complex adaptive system. Understanding contextual, human and organisational factors is the key to successful implementation.
- There is a need to understand the business case for all players, so as to design systems and tailor incentives for maximum effect.

Public acceptability

- There is a need to establish the basis of a social contract between different stakeholders with respect to data privacy and data use. Further research and consultation is needed to achieve this.
- A better understanding of public attitudes to the use of EHR for research is required in order to inform ethics and governance policies.
- There is a need for wider public engagement over who owns the patient record (or at least who has what rights). The notion of stewardship for ensuring appropriate and careful use of the records is often underplayed against the data subject rights of the individual.
- There may be a gap between the affluent/well-educated and the disenfranchised, who
 may not benefit so greatly from public sector integration. There are always those
 people who do not wish to engage.
- Opt-out should be the default option, both for EHR generally and research (assuming that the individual's identity has been protected through de-identification).

8. Conclusions

Clarity of vision

EHR projects needs to be clearly focused on their principal objectives, not only so that options, approaches and outcomes can be evaluated against these objectives, but also so that the various stakeholder factions can be brought together to achieve them. Broad 'infrastructure' projects that fail to communicate a clear vision of likely benefits may fail to engage stakeholders in the processes of EHR implementation and evaluation.

Scope of EHR

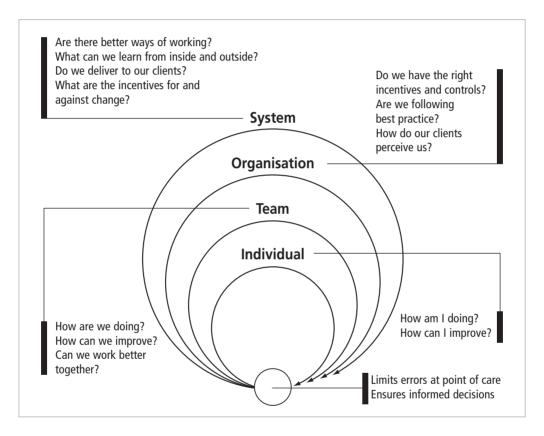
Defining the scope of an EHR is a key part of communicating the vision, but it is also critical for establishing what needs to be done and who needs to be involved. For example, implementing a relatively simple solution such as a central summary record extracted from local GP systems (as has happened in Scotland) is easier than implementing a more comprehensive integrated care record, but also confers less potential benefit. At the same time, more radical developments may deliver far greater benefits, but at far greater risk of getting bogged down in political issues and running up against vested interests. The functional scope of available products may not be immediately commensurate with the vision for transforming care processes and these may require further development and pilot testing before being widely rolled out.

Emphasis on quality

Making 'quality of care' the primary focus seems to be a possible recipe for success, although this requires an admission by governments and the professions that medicine, as currently practiced, is less effective, efficient and safe than it ought to be. The evidence from other industries is that a quality focus drives out inefficiencies, as redundant extra steps or processes inevitably introduce more opportunity for failure. Quality is often a necessary precursor to improved performance.

Once it is accepted that 'quality is king', then the focus has to be on what data is needed to support a quality framework. This will require a focus on standardisation of care processes – where possible and appropriate – and increased emphasis on feedback across the system, actively using records to inform future performance, as shown in Figure 4.

Figure 4. Levels of feedback in healthcare delivery



This diagram helps to emphasise that EHRs in their broadest sense may need to serve a very wide range of different purposes – over and beyond the simple recording of clinical facts, events and opinions. It may be necessary to establish what 'level' of problem is being addressed at the early stages of deployment – it is unlikely to be possible to address the whole gamut of needs from the outset, though hopefully an infrastructure can be developed to support this in the future.

An 'end-to-end' view of care delivery

EHR projects have often focused on reproducing existing ways of working with the aid of ICT (or, worse, instigating change through imposition of ICT). However, EHR has also been described as a *transformative* technology, with the potential to change the organisation and delivery of health services. Workshop discussions highlighting the multiple functions and complex effects of EHR also illustrate the value of adopting a more holistic view of the role of EHR within the care delivery process, and its potential to cater to a range of different needs.

Similar thinking has been useful in the business environment, where many commercial success stories have involved streamlining the delivery of products and services while improving the breadth and quality of customer service. For example Dell introduced greater customisation of their PCs, allowing customers to define what they wanted prior to manufacture, then delivering quickly and at a low cost; this enabled them to win significant market share. Amazon too has placed great emphasis on helping customers to choose books (with some degree of social networking) and integrating the supply chain so that a wide range of books can be provided readily to customers.

This is not to suggest that a slavish following of these business models in healthcare would work, but rather that applying known effective industry techniques may be useful in EHR implementation. Rather than 'de-personalising' healthcare such business methods may, for example, facilitate the delivery of a faster, more responsive, level of care to the majority of patients, while directing the most restricted resources to complex cases requiring a high level of analysis and intervention.

Establishing the 'social contract'

Given the wide range of uses of EHR identified above, it is clear that medical records will not only be used in the context of care delivery, within which ethical and legal issues are so often framed and public attitudes sought.

In Europe, the Article 29 Data Protection Working Party published a paper in 2007 on the use of EHRs.² While its legal arguments may seem odd to the layman, particularly if

¹ See among others McGlynn, EA *et al* (2003) 'The quality of health care delivered to adults in the United States', *NEJM* 348(26), 2635–45.

² Article 29 Data Protection Working Party *Working Document on the Processing of Personal Data Relating to Health in Electronic Health Records (EHR)*. Brussels: European Commission. Available at: http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf

not used to the terminology of European law, it does clearly recognise that the use of medical records is changing and that this requires wider debate and the establishment of new regulatory frameworks.

There is some indication³ that the public may already be anticipating the law-makers, in that they often expect medical records to be used pro-actively in the same way that supermarkets and online stores exploit what they know about their customers to provide a better service, more efficiently.

Ideally, the social contract needs to be framed around a concept of 'stewardship' where health information is used to promote individual and common good, establishing appropriate principles and practices in the use of the information and knowledge to be gained.

Leadership – from the top

There needs to be top-level commitment to the EHR with a clear understanding of why it is needed, and what is needed to get it there, and a realisation that this is a long-term transformative programme (probably of 15 to 20 years' duration) which is mainly about change management and far less about IT delivery *per se.* There has to be both political and management will to support the vision; this may require reinterpretation and reorientation, as circumstances change and disruptions are encountered while people adjust to new ways of working, and systems and procedures bed in.

It is also critical that there is clinical leadership, particularly from the professional bodies, in the process of change. This will require the skills and expertise of clinical informaticians, who can understand both the clinical and the business imperatives for change together with the core concepts and methods of health informatics, to ensure that the desired benefits are actually delivered.

Benefits realisation

There is a definite danger of delivering a fixed IT solution to a changing business problem, especially given the likely implementation timescales. It is vital that clear and tangible benefits are identified, if only to focus stakeholders on the real issues and how those benefits can best be achieved. It is critical to most change management projects that stakeholders understand that benefits may take a long time to become established.

³ Scottish Consumer Council (2005) Health On-line: Public attitudes to data sharing in the NHS.

Focusing on the benefits to be achieved may help resolve the inevitable conflicts that will arise during such a large-scale project due to the existence of vested interests, as well as sustaining impetus during the early adoption phases.

The need for baseline data

If benefits realisation is to be effective, then it presumes that we currently know enough about the health economy and healthcare delivery to measure the gains that a new EHR project will have delivered.

There is a strong 'Catch-22' situation here, in that often one of the drivers for an EHR system is the very lack of such relevant management and planning information in the first place. For example, the Good eHealth report⁴ points out that the economic impacts of EHR can only be extrapolated from estimates, rather than hard financial figures.

A baselining exercise should be one of the first tasks of an EHR project; not only to document the status quo, but critically to determine how well, if at all, the benefits can be gauged as the project rolls out and, if necessary, to inform new data collection procedures. Better assessment of benefits may also help establish when such benefits are likely to accrue and help set expectations accordingly.

Standards and interoperability

It is clear that integration requires clear standards to ensure that information can pass across systems without corruption or misinterpretation. However, medicine is constantly changing and the need for information varies across care settings; for example what is a fairly precise diagnosis in primary care may not be precise enough for treatment in secondary care. For this reason the emphasis should perhaps not necessarily be on the scientific exactness, but more on the appropriateness and accuracy of the data for its purpose, while use outside its original setting may have to recognise the necessary limitations around its generation.

It should also be noted that the issue of 'standards' has dogged computer (and other) systems since they started to be connected. There is always a conflict between proprietary 'standards', which may be used for commercial gain, and 'open' standards, which should

⁴ Stroetmann, KA et al (2006) eHealth Is Worth It: The economic benefits of implemented eHealth solutions at ten European sites. Luxembourg: Office for Official Publications of the European Communities. Available at: http://ec.europa.eu/information_society/activities/health/docs/publications/ehealthimpactsept2006.pdf

be adopted for the good of the industry as a whole but is still geared towards supplier, rather than consumer, interests. Buyers may require a certain set of standards when specifying the products they wish to use, but that does not guarantee that conforming products will actually be available.

Further, many products may adopt a standard, but they may implement it in subtly different ways, so that the products are no longer wholly compatible. Too strong a set of standards may actually inhibit innovation – one only need think of the QWERTY keyboard, both as a standard that is known to be inefficient, but cannot be supplanted, but is also subject to variations (for example AZERTY in France).

It may be that the real requirement is 'interface-ability', rather than interoperability, whereby information can be transferred meaningfully (or at least within the context of what is needed).

We must also remember the effect of users on any standards – the NHS in the UK had mandated Read Codes within Primary Care for many years, but the main problem has been not the differing versions in play, but how users have chosen to code patient conditions, using the particular version they had. It has often been the inconsistency of use which has been problematic, rather than the lack of interoperability of the standards themselves.

9. Closing remarks and caveats

The experts brought together for this exercise were drawn from across the research, policy and practitioner communities and are engaged in both health sector-specific and wider debates on personal data.

Consistent messages were drawn about the need for a clear understanding of, and vision for EHR that is mindful of:

- the underlying complexity involved (multiple functions, users, interactive effects)
- the relevant cultural and behavioural influences (such as public and professional attitudes, behaviours, incentives, training, leadership)
- the challenges of ensuring data integrity, security and systems interoperability
- the need for evidence to inform the selection and implementation of EHR systems and demonstrate benefits
- the importance of clear policies and strategies for effective governance (data privacy, consent and sharing).

As electronic personal data becomes pervasive in the healthcare sector, the potential downstream effects for science (innovation), society (public health) and individual patients (such as personalised medicine) are increasing rapidly. An important message from the workshop was the blurring of distinctions between 'primary' and 'secondary' uses. The essential role of public engagement in informing these debates was a recurring theme.

Important considerations relating to the digitisation of genetic information within the EHR and the potential linkage of EHR data across families or to other sources of electronic personal information (civic and commercial) were highlighted in the initial consultation. However, probably reflecting the composition of the group, these were not major themes of the workshop discussions.

We refer the reader to the *Data Sharing Review Report* recently published by the Information Commissioner's Office and the Wellcome Trust, both of which organisations presented in this workshop. This summarises relevant work on public attitudes to data sharing and uses of genetic data.¹

¹ Thomas, R and Walport, M (2008) *Data Sharing Review Report.* Available at www.justice.gov.uk/docs/data-sharing-review-report.pdf

Glossary of acronyms

CDS	Clinical decision support (system)
COTS	Commercial off-the-shelf (software)
CPOE	Computerised physician order entry
CPR	Computer-based patient record
CTEC	California Telemedicine & eHealth Center
EHR	Electronic health record
EMR	Electronic medical record
EPR	Electronic patient record
EU	European Union
GP	General practice or general practitioner – a primary-care physician
HIMSS	Healthcare Information and Management Systems Society
ICT	Information and communications technology
IHR	Individual health record
ISO	International Organization for Standardization
IT	Information technology
NGO	Non-governmental organisation
NPfIT	National Programme for IT (EHR programme in England)
OECD	Organisation for Economic Co-operation and Development – www.oecd.org
PACS	Picture archiving and communications system
PAS	Patient administration system
PHR	Personal health record
PMR	Personal medical record or patient medical record
RCT	Randomised clinical trial
SCR	Summary care record
VA	(US Dept of) Veterans Affairs
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Attendees and speakers*

Name	Affiliation(s)
Professor Perri 6	Professor of Social Policy, Nottingham Trent University
Professor David Bates	Professor of Health Policy and Management, Harvard Medical School
Kim Beazor	Chief Operating Officer, The Nuffield Trust
Dr Philippe Boucher	Technical Officer, eHealth Division, World Health Organisation
Dr Susan Clamp	Director, Yorkshire Centre for Health Informatics, University of Leeds
Professor Don Detmer	Professor of Medical Education, Department of Public Health Sciences, University of Virginia; President and CEO, American Medical Informatics Association
Alan Doyle	Programme Manager, Populations and Public Health, The Wellcome Trust
Dr Richard Fitton	General Practitioner, Hadfield Medical Centre, Derbyshire
Pat Goodwin	The Wellcome Trust
Professor Trisha Greenhalgh	Professor of Primary Healthcare Director, Open Learning Unit, University College London
Angela Hands	Director – Value for Money Audit, UK National Audit Office
Dame Deirdre Hine	Chairman, BUPA Foundation
Adrienne Hunt	Secretary to UK Biobank ECG, The Wellcome Trust

^{*} All job titles refer to those held at the time of the seminar (November 2007)

Name	Affiliation(s)
Richard Jeavons	Director of IT Service Implementation, Department of Health
Kerry Jones	Policy Manager, The Nuffield Trust
Dr Dipak Kalra	Clinical Senior Lecturer, University College London
Professor Justin Keen	Professor of Health Politics, Leeds Institute for Health Sciences
Ian Miller	Senior Data Protection Manager, Information Commissioner's Office
Dr Claudia Pagliari	Senior Lecturer in Primary Care, eHealth Interdisciplinary Research Group, University of Edinburgh
Professor John Powell	Associate Clinical Professor in Epidemiology & eHealth Group, University of Warwick
Professor Denis J. Protti	Professor of Health Information Science, University of Victoria
Professor Charles Raab	Professor of Government, University of Edinburgh
Professor Michael Rigby	Professor of Health Information Strategy, Keele University
Peter Singleton	Director, Cambridge Health Informatics
Professor Robert Souhami	Emeritus Professor of Medicine, University College London
Karl Stroetmann	Senior Research Associate, Empirica, Bonn, Germany
Veli Stroetmann	Senior Researcher, Empirica, Bonn, Germany
Professor Frank Sullivan	Professor of General Practice, University of Dundee
Professor Michael Thick	NHS Connecting for Health
Professor Peter Wells	Cardiff University
Professor John Williams	Professor of Health Services Research, Swansea University Director of Health Informatics Unit, Royal College of Physicians
Marlene Winfield	NHS Connecting for Health
Dr Louise Wood	Head of Innovation and Industry R&D Relations, UK Department of Health
Naho Yamazaki	Policy Officer, The Wellcome Trust

Other contributors/commentators

Name	Affiliation(s)
Professor Graeme Laurie	Professor of Medical Jurisprudence, University of Edinburgh
Professor Joyce Tait	ESRC Innogen Centre, University of Edinburgh
Professor Jeremy Wyatt	Dundee University
Professor Steve Yearley	ESRC Genomics Forum, University of Edinburgh

CRITICAL ISSUES FOR ELECTRONIC HEALTH RECORDS

CONSIDERATIONS FROM AN EXPERT WORKSHOP

This report is based on an expert seminar hosted by the Nuffield Trust and Wellcome Trust. This seminar brought together health leaders, policy-makers and academics to identify the key priorities involved in research, strategy and implementation of electronic health record systems (EHR).

Critical Issues for Electronic Health Records – Considerations from an expert workshop augments the workshop findings with further comment from the authors and identifies the key requirements for successful EHR systems implementation, integration and maintenance worldwide.

This report will be of interest to all those engaged in researching and implementing EHR systems, as well as those concerned with developing public policy in this important area.

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