

e-Consent design and implementation issues for health information managers

Heather Grain

Abstract

This article outlines and discusses a number of e-consent issues concerning an individual's access to information held in electronic health records. Through research conducted with general practices and health consumers, the following issues have been identified: limitation of health professionals' access to records; the ability of the individuals to limit access to their records and to indicate the circumstances within which access would be permitted; the degree of the health professional's awareness of restricted or total access to a patient's record; audit trails through which an individual can track the path of a record; and the individual's nomination of an agent authorised to control access to their record. These issues affect system developments and Health Information Managers, and key challenges to Health Information Managers in the electronic health record environment are also highlighted.

Keywords: *Electronic health records; consent; e-consent; health information management; professional change.*

Activities surrounding electronic health record (EHR) system definitions and developments are occurring throughout Australia (*Whole of Health Information and Communication Technology Strategic Plan 2003 – 2007*, 2003), in individual sectors of the health industry (ISO/TC215 2003), and at a national level (NHIMAC 2001). These initiatives will impact upon health information management (HIM), particularly the management of the processes for consent to access electronic health information in a shared EHR environment (Primary and Coordinated Care Health Services Division 2002a).

EHR for integrated care (ICSHR) is defined by the International Standards Organisation as

... a repository of information regarding the health status of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users. It has a standardised or commonly agreed logical information model which is independent of EHR systems. Its primary purpose is the support of continuing, efficient and quality integrated health care and it contains information which is retrospective, concurrent and prospective (ISO/TC215 WG1 2004).

Developments in sharing health information

In the 1980s, the Australian public rejected the introduction of the Australia Card because it was considered to be open to manipulation and misuse. Today it is accepted that there is a need to ensure that health information initiatives are acceptable to the major stakeholders, and this concept forms part of the guiding principles of HealthOnline (NHIMAC 2001). Australia's EHR of the future is being developed and informed by a process of wide consultation and trials to investigate both the practicality of alternative solutions and the implications of change (*HealthConnect 2003a*). The *HealthConnect* projects involve creating the ability for service providers at all levels of health care to share information; this involves sharing in community services, general practice and diagnostic services at tertiary levels and across local, state and national boundaries (*HealthConnect 2003b*). Every

effort is being made to find solutions that are practical and meet consumer, service provider and economic needs. These initiatives, although still in their infancy, share certain common concepts that provide sufficient basis for future planning by health information managers.

Controlling access

Health consumers need to be able to control who has access to their health information and to understand the implications of restricting access to their information (*Position Paper on the Federation Paradigm 2004*). This access control is a central principle of the Clinical Information Projects of *HealthConnect* (Primary and Coordinated Care Health Services Division 2002b). Access to the physical record is controlled in the current system, but it is impractical to restrict access to specific elements of that record. Consumers see the potential to limit access to specific segments of health information within a complete health record as a significant improvement on the existing paper system.

e-Consent project

The Primary and Coordinated Care Health Services Division of the Department of Health and Ageing undertook a research and development project in e-consent as part of a body of work focused on the improved integration and coordination of health service delivery. Figure 1 outlines the scope of this project.

The work described here was part of the project undertaken by the Collaborative Centre for e-Health (CCeH). This Centre was established at the University of Ballarat to focus on research and development in the application of electronic technologies for the delivery, access, education, and coordination of healthcare in Australia (Collaborative Centre for e-Health 2002). The CCeH project involved investigating implementation issues for e-consent from a technical perspective (how it could be done) and from a practical perspective (what practical issues might be identified by general practitioners [clinicians] and by health consumers). This article centres on these practical issues of implementation.

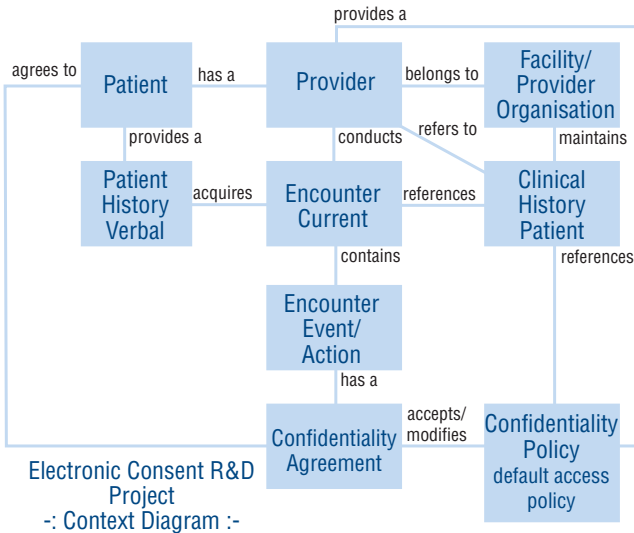


Figure 1: e-Consent Project Context Diagram (Primary and Coordinated Care Health Services Division, 2002a)

Use cases

In order to support these research and development activities, a catalogue of use cases was commissioned; this was to provide a set of consistent, 'real world' examples upon which researchers could base activities involving modelling, design, and functional testing (Clarke 2001). The use cases covered the following general situations:

- 'straightforward' instances:
 - Case 1 – doctor requests and receives a diagnostic test result.
 - Case 2 – hospital provides a discharge summary to a patient's GP.
 - Case 3 – submission of information to a voluntary register
- complex cases:
 - Case 1 – elderly hip replacement
 - Case 2 – especially sensitive data
 - Case 18 – emergency cardiac episode (as expanded to cover workflow) (Clarke 2000).

Frameworks for e-consent

Various frameworks for e-consent were identified. The 'opt-in' approach was used in this project, as it was the preferred option for consumers at this time. This process requires the consumer to opt specifically to have their information included. The research objective was to identify the functional issues, and the methods suited to providing a practical means for the implementation of e-consent in the Australian shared electronic health record environment.

The prototype system

The CcH project developed a prototype system involving data entry screens interfaced to 'Medical Director' software to record access permissions for the consumer and to identify role-based access rules that could be applied within the system. The prototype allowed the consumer to establish a standard 'profile' of their access permissions, so that there was no need to

restate the information at every visit – only to confirm that the protocol was still acceptable. The prototype allowed the provider and the consumer to review permissions for individual care events or the whole consumer access permission profile. It was also used to demonstrate how a system might handle the use cases provided for the project.

The process was tested in a 'demonstration' environment where the prototype was shown in a workshop setting to a group of clinicians (18 participants) and separately to a group of health consumers (seven responses in addition to comments from the Consumer Health Forum), who provided feedback on the acceptability of the process in the active healthcare environment. It was difficult to gather a suitable group of health consumers, so the processes and networks of the Consumer Health Forum were used to disseminate the demonstration material and to solicit comments. Comments were received from chronic disease, the elderly, mental health and Indigenous health consumer representatives.

e-Consent issues

It is recognised that more extensive research is required in this area and that the MediConnect and HealthConnect trials will further inform knowledge. Box 1 shows the specific issues of access control demonstrated by the use cases and considered in this research (Collaborative Centre for e-Health 2002).

Box 1: e-Consent issues investigated

Issue: The right to limit access, to all or specific health information, to all or specific individuals, roles or organisations

Example: *Details of my AIDS test may be available to the pathologist but not to the clerical or nursing staff at the diagnostic organisation.*

Comment: This example shows restrictions of a specific element of health information to a specific role within an organisation.

Example: *I could also restrict all access to any of my health information by Sarah Wilson (a nurse who is also my neighbour).*

Comment: This is an example of restriction to an individual, not specifying any single element of my health information.

In both cases the provider who initiated the health information will always have access to it. Once information is seen by an individual it is always available to that individual, because a record of the information available to support that health professional's decision making must be maintained.

Issue: The ability to indicate that an item or items of health information is to be restricted in some way, but that in an emergency this restriction is or is not to apply

Example: *I might decide that in an emergency I don't mind if Sarah Wilson sees my health information.*

Issue: When information is restricted the person from whom it is to be kept is not aware that there is information that is missing.

Example: *If I arrive at the Emergency Department and Sarah Wilson is working there she would be asked, as she logs in to the computer system, whether she needs access*

to 'emergency only' information. This question should be asked every time she brings up a new patient so that there is no apparent difference between the processes relating to whether an individual patient has or has not 'masked' information.

Comment: If I've indicated that specific information is not to be made available in any circumstance, that information can be accessed only by the original provider of that service and any others I've specifically nominated as being permitted to see that information.

Issue: Audit trail of all who have seen my information.

Comment: Consumers would be able to see (i) details of all individuals who have looked at my information; and (ii) which elements of my information they have seen.

Issue: Use of Agents. Consumers want to be able to nominate agents who can act on their behalf regarding access to their health information

Example: *My mother doesn't understand health terminology or processes. She uses me to 'translate' and generally prefers to know only what pills to take or exercises to do, rather than to understand her medical state.*

Comment: This is the case for many people in our society. Many others prefer to understand as much as possible. The use of agents must allow for management of both of these possibilities.

Outcomes of the consultation process

Particular issues arose consistently throughout the consultation workshops with clinicians and consumers. Box 2 indicates the results obtained from the consultation process. Each stakeholder group indicated its specific concerns, and these sometimes represented opposing requirements.

Box 2: Issues arising from e-consent research (Collaborative Centre for e-Health 2002).

Concept: Consumer's right to limit access.

Issues relevant to:

Clinicians and service providers:

There is a feeling among clinicians that explaining the consumer's responsibility and risks when they limit access will add to the time of a consultation.

There will be a need to document formally the explanations given. This may impact upon the cost of health service provision.

Consumers:

Most consumers believe that they should currently be told the implications of sharing (or not sharing) specific health information with other health service providers.

Will the consumer be considered a 'risk taker' for health or life insurance purposes if they limit access to their health information?

Some consumers prefer not to know the details in their health record.

Health Information Managers and system designers:

The ability to access specific parts of the record only, and to restrict access to individual staff members, will present new challenges to management in password allocation, password groups, and the management of access roles.

The effects on electronic health record architecture will all need to be clearly identified.

These changes are also likely to mean that computer systems will need fast and simple methods for change of user identification (ID) and that all users will need

individual IDs, rather than the group logins often used at the moment.

Concept: Special access rules may be required for emergency situations, and the consumer may want to change these access rules over time.

Issues relevant to:

Clinicians and service providers:

There will be a need for the clinician who is aware of information that has been blocked (generally the clinician the patient saw about the problem) to advise the patient if their health status changes in such a way that it would be best that the information is no longer masked or that it should be made available in an emergency.

The legal position of the clinician, if they do not provide such a warning, is yet to be defined clearly.

Health Information Managers and software developers:

Thought needs to be given to provision of decision support tools to clinicians to make this process easier.

There will need to be policies and protocols that clearly define 'emergency'.

Concept: Restricted access, including complete blocking, means that the person from whom information is restricted has no idea that the information is available

Issues relevant to:

Clinicians and service providers:

In regard to complete information, the status quo will not change. Clinicians need to remember that they do not necessarily have all information now and will not know whether they have all information in the future.

Consumers:

Consumer education needs to be more extensive to assist in their decision making about information to be shared. Such education needs to include an understanding of both clinical and confidentiality issues.

If the consumer wants to restrict information more than is currently restricted they will need to go back to the original clinician to ensure that all consequences are explained.

Software developers and consumers:

Consumers may want to change access restrictions (open them up) at any point-of-health care. Consideration must be given to enabling consumers to change levels of restrictions away from the point of care provision.

If the consumer wants to restrict information more than it is currently restricted they will need to go back to the original clinician to ensure that all consequences are explained.

Health Information Managers:

Consideration will need to be given to how an organisation will treat the records (both paper and electronic) of a patient who wants information restricted within a specific health care team. This cannot be done at the moment.

Concept: Audit trail available for consumer review and access monitoring

Issues relevant to:

HIM and system developers:

This will necessitate the use of individual passwords by all who have a need to see a patient's record, including coders, nurses, allied health professionals, etc.

The responsibility for administration of this system will be significant and, in a hospital environment, would probably rest with the health information manager, who is in the best position to understand all the implications surrounding access.

The rights of the care providers and administrators also need to be considered.

The ability to quickly change user ID (without logging out of the system) was mentioned earlier; it becomes absolutely crucial here.

Concept: Agents. The concept of agents is completely foreign to hospital information management practice, although it has existed in an informal manner in the general practice community where the patient and family are often well known.

Issues relevant to:

Health Information Managers, clinicians and software developers:

The implications of this process are wide and still evolving, as are the legal implications.

Consumers:

There will need to be considerable education on this issue, on how it will work, and what will be the limitations. The implications for children and adolescents are particularly complex.

Ongoing trials

It is clear that the approaches desired by clinicians and consumers differ in many cases. The clinicians' concerns over the ability to implement an approach that will not intrude upon the consultative process are shared by health consumers. The practical impact of these issues and their relative importance to the implementation of shared electronic health records in Australia are being tested through the Clinical Information Project of HealthConnect (HealthConnect 2003a). It seems likely that it will take many trials and the investigation of alternative approaches before workable processes are identified that suit all stakeholders. Irrespective of the results of these trials, there seems no doubt that the EHR will change the practice of HIM in the future.

Opportunities for the Health Information Management (HIM) profession

The introduction of EHRs and the gradual replacement of paper-based records will offer many opportunities and challenges to the HIM profession. The consumer's right to limit access is not a conceptual change from how the system works today. There are, however, many perceived differences, and the challenge will be in obtaining acceptance by both clinicians and consumers. Clinicians will need to understand that consumers 'don't always tell them everything', and how important it is to inform consumers of the risks when not sharing information with them. Consumers will have to take responsibility for their decisions on information restriction, because computer systems will be able to prove what data consumers chose to share or restrict.

The operation of emergency access to restricted information is one that will need to be tested further, particularly the procedures which enable consumers to change the restriction. To implement the lifting of an episode-specific access restriction at the time of an emergency is a simple process; however, for the consumer wishing to add a new restriction to a pre-existing event the process is not so simple. In this latter case, in order to create a restriction the consumer may need to return to the original service provider who initiated the information, so that the provider can explain the consequences of restricting access. It is also important for

the consumer to understand that any change that occurs can not affect the people and places to which information has already been released. It is clear that changes in access privileges after the event will be more difficult to manage. The Health Information Manager's professional responsibilities may extend to include access control education of service providers, consumer agents, and health consumers. It also seems likely that the members of the profession could be key participants in the development and oversight of procedures for updating access profiles and procedures for health care organisation staff at many levels.

Establishment and maintenance of profiles for access, no matter how simple in concept, will necessitate considerable administrative effort, as will the monitoring of audit trails. The introduction of EHR systems, with their inherent need for consumer-controlled access processes, offers an exciting potential extension to the Health Information Manager's role in the health care system.

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Heather Grain AssDipMRA, GradDipDP, FACHI

Lecturer in Health Informatics
Department of Health Information Management
School of Public Health, Faculty of Health Sciences
La Trobe University, Victoria, Australia
Email: H.Grain@latrobe.edu.au

Ms Grain is a member of Consumer Health Forum, a representative on the *MediConnect* Technical Working Party and a member of the *HealthConnect* Clinical Information Project Quality Management Committee. She is Vice-Convenor of the International Standards Organisation Technical Committee 215 – Health Informatics Working Group on Health Concept Representation, and acted as the consumer specialist for the CcEH project on e-consent, funded by the Department of Health and Aged Care, to inform e-consent access processes for electronic health records. She is also a fellow of the Australian College of Health Informatics.