



eHealth - The Electronic Health Record

A Position Paper

Prepared by the Patients' and Citizens Task Force, EHTEL

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Prepared by the Patients' and Citizens Task Force
of the
European Health Telematics Association (EHTEL)

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Preface

In ideal world, the patient would be in total control of the healthcare that he or she receives and take decisions regarding the way in which they are treated. In reality they can only do this with the support of professionals and with the provision of accurate and timely information. Given that we do not live in a perfect world and that professional time is both expensive and limited, patients increasingly rely on peer support groups to advise them.

It is against this background that EHTEL's Patient and Citizens Task Force was established. It is a unique group within the European eHealth community consisting of individuals who are patients in their own right or who represent patient groups but who are also highly qualified from a strategic, technical and managerial perspective within health and medical informatics. At the highest level, it has two main aims: to influence other stakeholders in the ICT and healthcare areas and to empower other patient groups.

Currently, most discussion about the development of eHealth systems happens between the developers and national institutions while there is very little interaction between those organisations and the patient. A key role for the Group is therefore to provide a forum to canvass patient opinion and to communicate these views to the stakeholders described above

Roles for the Group

The Task Force has two audiences for its work: the key stakeholders in the eHealth/ICT community such as developers and national institutions and, separately, patient organisations. In broad terms, the Task Force has a number of roles to perform in relation to each of these audiences as described below:

A vital activity for the Task Force is in ensuring that stakeholders such as politicians, national health authorities, professional medical and nursing groups and also system developers are made aware of the patient position in relation to eHealth. There is a common feeling that, "we're all patients anyway so we understand the patient view". This is a typical reaction from most national stakeholders and the fact that it is promoted demonstrates a clear misunderstanding of what a patient is and what his/or her view on a particular issue is likely to be. It is commonly used to circumvent the patient view.

Firstly, we are **not** all patients. The vast majority of people are fit and well and go through life as healthy **citizens** who occasionally fall ill and, temporarily, become patients. Others may suffer from chronic diseases or conditions that do place them in the position of being both citizens and patients throughout their lives. Views and opinions offered on the delivery of healthcare by healthy citizens will be very different from those offered by the same individuals when they are undergoing treatment.

It is important therefore that constant and ongoing patient orientated issues are available to policy makers and others in order to ensure that important decisions encompass the needs and requirements of the patient. For eHealth to succeed, acceptance by patients – both short and long term – is vitally important.

Thus the Task force seeks to interact with the national stakeholders across the European Union either directly or by encouraging the involvement of patient organisations in the decision making process. It can do this in two ways: by providing consultancy services to stakeholder groups and by producing position papers that address the many different aspects of eHealth development.

To some degree the issues raised in this paper can be viewed as a “wish list”. However, we view them as an important starting point in the identification of matters that require further investigation and development. They now need to be moved forward either as formal programmes of work or through political lobbying. It is important to note that the views in this paper are not “set in stone” and will be revisited over time to ensure that they accurately reflect changes in the delivery of healthcare and the management of related information.

It is in this context that the following position paper has been prepared.

A Summary of Our Position

In summary our position in relation to the electronic health record is as follows:

- The patient has the right to expect that his or her privacy is respected and protected and that the EHR is handled with due regard to professional duties of confidentiality
- Controls for the reinforcement of privacy should not be weakened for the purposes of reducing costs
- The patient should be considered to be the master of the Electronic Health Record
- Patients should give their consent to the sharing of their personal information although this should be a simple and straightforward process supplemented by regular reviews. This process should also contain a facility for patients to be informed about the uses to which their information is to be put.
- The patient should retain the right (with recognised authority) to intervene if they are concerned abuses of privilege by others when sharing information.
- The right to opt out from having information shared should be available although individuals doing so should recognise that it could have a detrimental effect on their healthcare.
- Such an opt out should not be used as a method for denying individuals the right to treatment or care
- Technical innovations should be explored to handle specific situations where the patient may wish to have information withheld from certain organisations or individuals.
- The EHR should include electronic communications (eg emails where permitted) as part of the record
- The use of innovative methods of recording consultations should be investigated.
- The EHR should only be accessible by healthcare professionals who are under a duty of confidentiality.
- Managers and administrative staff should only have access to personal medical information on an exception basis and only after they have signed an appropriate confidentiality agreement.
- The systems processing and transmitting the EHR should be the subject of formal testing and accreditation in order to ensure their integrity.
- Patients should have unfettered access to their records and provided with assistance to understand them. The provision of a summary record should be considered.

- In certain cases (albeit with regard to strict limitations) the clinician should have the right to veto access where access to the information might have a harmful effect on the patient.
- All electronic communications and records about a patient's health, medical care or personal information should be prepared and handled in a confidential and discreet manner.
- The provision of a log-book showing who has accessed the EHR and what actions they have taken is considered to be an essential safeguard.
- Every eHealth system should have an associated security policy that clearly describes how the confidentiality, integrity and availability of records will be preserved. This should be freely available for patients to access. System administrators should not have the right to access personal medical data.
- As part of the development process, system specifications should be produced which explain (in an easily understood form) how the system works and what measures have been taken to protect the patient.
- National healthcare authorities across the European Union should work to formalise and harmonise guidelines relating the use and processing of the EHR.
- These fundamental rights should apply to legal representatives of patients when the patients are unable to act for themselves

Introduction

The emerging world of eHealth can be defined as the application of information, communication and video technologies to the delivery of timely, professional and safe healthcare. Systems now exist that hold increasingly detailed levels of clinical information, remotely monitor vital signs, enable remote diagnosis and treatment and more recently have facilitated surgery by professionals located thousands of miles away from the patient. While supporting professionals in the delivery of healthcare, eHealth information systems also have the potential to empower the patient.

Information systems now pervade the healthcare system and these are being developed at a local, national and international (European) levels. Regardless of where these systems are developed, three key issues remain unaffected: patients have the same problems, the demands on the healthcare system continue to increase and the principles against which information is managed increase in complexity.

One of the most significant and common developments within healthcare across the European Union is the electronic health record (EHR). This manifests itself in a variety of forms ranging from a detailed general record capturing clinical detail at the primary care surgery, through specialist clinical databases for particular areas of care, to the more general patient administration record created and held at the acute and secondary care hospital. In the main, the various classes of electronic health records are maintained separately and with little electronic linkage between them. This situation is, however, changing rapidly as information and communications technology improves and matures and the benefits of creating an integrated record become clearer.

A good example of these developments is the “Connecting for Health” Programme in the UK NHS. As part of this ambitious IT programme, it is proposed to create a shared patient record divided into two levels: the detailed record and the summary record. These are described on the CfH website¹:

“The NHS Care Records Service will help NHS organisations in England to store patient health care records on computers that will link information together quickly and easily. It will be introduced gradually from 2006, over the next few years.

Today, this information is usually stored in a number of places and a variety of ways – including paper, computers and film. Getting access to full patient information quickly can prove difficult. In the future, each patient will have a personal electronic NHS Care Record which can be quickly accessed by health care professionals legitimately involved in the patient’s care. It will be made up of Detailed Care Records and a Summary Care Record.

Instead of having individual health records in all the different places patients receive care, NHS organisations *which normally work together* (EHTEL italics) in a region will share a Detailed Care Record for each patient. Detailed Care Records will be developed over several years, starting from 2006.

Patients will also have a Summary Care Record, available to those treating the patient anywhere in England. At first, the Summary Care Record will contain basic information such

as allergies, adverse reactions to medications, and current prescriptions. In due course more information will be added, and discussions are ongoing about the content of these records. The Summary Care Record will deliver continuity of care for patients across England. “

Whilst noting the potential advantages of this project for the patient, the concerns over its ability to deliver have been drawn to our attention. Furthermore, it is interesting to note that there has does not appear to have been any co-operation between the UK project and those in other Member States leading to a potential for costly duplication.

Privacy and the need for Dissemination of Personal Information

In general patients are aware of the fact that as part of their treatment and care information about them is being prepared and processed electronically. In most case cases they will have little or no understanding of how information about their identities, treatment or medication is stored, transmitted or processed. Nor will they be aware of who has access to this information.

Potential users of eHealth data include:

- Patients
- Doctors
- Nurses
- Managers
- Pharmacists
- Doctors’ support staff such as secretaries or receptionists
- Dispensing assistants
- National health organisations
- Insurance companies or other reimbursement agencies
- Researchers
- Drug companies

The possible uses of such information include:

- Direct and obvious patient care
- Financial analysis
- Governmental analysis of prescribing patterns
- Commercial analysis of prescribing patterns
- Epidemiological studies
- Pharmaceutical vigilance
- Health reporting

With the exception of the first of these information uses (direct care) the vast majority of patients will be uninformed and unaware of the uses to which their personal information is put. In some cases, such processing will be anonymous and will focus on aggregated data. In other cases, data will be “pseudonymised” allowing processors to identify individual cases where they feel it is appropriate.

The crux of the matter is that, in the main, patients remain ignorant of who sees their personal information and to what purpose it is put. In many cases, organisations (which have legitimate access to eHealth data) may assume that the patient has, by the fact of seeking treatment, given implicit consent (see below) for their information to be used for the greater good of the administration of healthcare and improved drug development. This is a difficult area requiring a delicate balance between operational efficiency and the basic principles of patient involvement and consultation. The responsibility for defining when implied consent is acceptable and when explicit consent is essential is a key task for national healthcare authorities in EU Member States to define in consultation with patient representatives.

In addition, there is often confusion between the terms, “privacy” and “confidentiality”. Professional staff often assume that they are the guardian of the patient’s privacy and do not discuss this issue with him or her. However, by definition – and as a private individual – only the patient can define the level of privacy (possibly the amount of information he/she is prepared to have shared with others) required. The patient then places a duty of confidentiality upon the professional concerned to respect that requirement.

Accurate record keeping and the controlled dissemination of such information are crucial to the provision of effective healthcare. Furthermore, the development of electronic patient records for treatment of current conditions supported by a birth-to-death electronic health record provides a potent tool for effective treatment of patients and one that would be/is welcomed by them. Potential benefits includes timeliness of information (there when it is needed), increased accuracy, fuller histories for new professional staff treating the patients and the potential to support cross-border flows.

From the patient perspective, however, privacy is paramount. The potential for information to flow into areas that the patient may not be aware of and may not approve of is always present, as is the desire of researchers and commercial organisations to have access to such information. Thus safeguards need to be in place to reassure patients that professional duties of confidentiality are being met and that formal arrangements for obtaining consent are established. Our position is not to obstruct appropriate and proper use of information but to ensure that basic rights regarding privacy are respected and met. In return we expect our rights to be respected and not weakened for the purposes of cost-cutting.

Ownership and Control of the Electronic Health Record

There has been much discussion and debate regarding which individual or organisation owns a patient’s health record. One possible candidate is the clinician, but in an age where the health record is compiled by a large number of professional staff, it is difficult to identify a single owner. Another possible owner is the national authority responsible for administering the healthcare system. Another view is that the record is owned by the insurance institution with which the patient is registered. Another, possibly less convincing argument (but more relevant to electronic records), is that the record is owned by the administrators of the related information systems.

Discussions around ownership of the EHR can be important in the legal context but from the patient’s view of privacy they can be misleading. It is not who owns the record but who has

ultimate control over how the information is used that concerns the patient. As there is one common component – the patient - that links all of the information in the EHR, regardless of who placed it there, this would seem to be the obvious individual to exercise the necessary control over the use of the data.

This principle is embodied in the Patient’s Charter for eHealth Information Systems² published by this Task Force in 2003 where it was clearly stated that the patient should be the master of his or her (medical) file. Our position remains the same in this regard.

Consent to Share Personal Medical Information

The requirement for information to be shared between clinicians and professions allied to medicine is clearly necessary for the effective treatment of the patient. However, as to whether they have an absolute right to do so without the consent of the patient concerned has been debated at some length across the European Union. A major issue is the question whether the patient should give his or her explicit consent to the release/sharing of their information or whether the seeking of treatment provides implicit consent for the information to be shared. Also, if explicit consent is required, does this have to be given at each individual consultation?

Associated with implied consent is the question of whether the patient should have the right to “opt out” from the system by exercising a right to refuse to have any information shared with any organisation outside of the one currently treating him or her. This, in turn, raises the question of whether such an “opt out” has to be a blanket provision ie no sharing in any circumstances or whether it is an option to be exercised on specific occasions.

Other questions surrounding the issue of patient consent to information sharing are:

- Who may be permitted to see personal medical information? Does this include administrative personnel? If so, should they be required to sign confidentiality agreements?
- Does a provider of healthcare have the right to refuse to treat a patient that does not give consent to information sharing?
- Who gives consent if the patient is legally or medically incapable of doing so?
- What assurances should patients have regarding the effective application of rules for information sharing and the level of confidentiality placed upon their records? What provisions need to be made for tracking access to patient records?
- How can the level of confidentiality and information sharing controls be guaranteed to be compatible across organisations?
- How can the level of confidentiality and information sharing controls be guaranteed to be compatible across Member States? How can access rights and consent indicators be checked across borders?

- Should there be special conditions relating to the use of personal medical information by research organisations? If so, what should they be?
- To what degree should the patient be given access to his or her medical record? How can this be achieved?
- Is it appropriate for all types of personal medical information to be shared?

Explicit versus Implied Consent

The debate around consent needs to focus on finding a balance between the ideal position and the pragmatic approach needed for the delivery of effective healthcare. However, any solution needs to recognise the overriding principle that the patient is the master of the file. In our view, the vast majority of patients would be content to accept a position of implied consent (indeed, it is quite likely that they already believe that their records are shared between healthcare providers and support that position). However, we recognise that data protection and related legislation in Member States may prevent this from being acceptable. Thus, it would seem sensible to implement procedures whereby patients indicate their consent in a simple and straightforward manner albeit with regular reviews to ensure that the position remains the same particularly where the patient is diagnosed subsequently with a serious medical condition. Patients should also have the right to retain the right to intervene with recognised authority if they are concerned about any abuse of privilege by others using their records.

Additionally, any consent has to be based on accurate information regarding how the electronic health record is being used and how personal data is being shared. This requirement has always been present in considering explicit consent but our view is that even in a system of implied consent, the patient must be fully informed about the way in which the record is used. To this end we have noted the actions taken by the UK NHS where all provider organisations display posters, issue leaflets and offer support when required.

This latter point is important as a small minority of patients may well require assistance in understanding the technical, legal and ethical issues surrounding information sharing. In our view, healthcare organisations should make suitable provision to ensure that concerned patients can discuss these issues.

Guidance relating to patient confidentiality can be found at the UK's Department of Health website:

<http://www.dh.gov.uk/PolicyAndGuidance/InformationPolicy/PatientConfidentialityAndCaldicottGuardians/fs/en>

Opting Out from the System

Inevitably, there will be some individuals that are not prepared to have their information shared widely for whatever reason. We believe that, in these cases, they should have the right to opt out from having their records recorded electronically and made available across a distributed electronic healthcare network. However, in such cases of blanket opt

out, it must be made clear – preferably by an appropriate clinician – that exercising such an option comes at a price in that the quality of their overall treatment may be affected.

What is not acceptable is for treatment for such individuals to be denied particularly as a method of coercing them into co-operating with the EHR infrastructure. The medical record is a key component in the treatment of patients but it does not necessarily have to be in an electronic or widely distributed form.

This leaves the situation of the individual case where a patient, who is generally content for information to be shared, specifically requests that certain information is withheld. This might relate to a specific episode or in relation to a particular healthcare professional or organisation. We believe that all electronic healthcare infrastructures should make provision for such occasions. In this regard, we were particularly interested to learn of developments in France where it is possible for portions of the EHR to be masked either temporarily or permanently thus leaving the record intact but protected to the satisfaction of the patient.

Content of the Electronic Health Record

We anticipate that the Electronic Health Record planned for implementation across the Member States will be a structured version of the existing electronic records held currently on primary, secondary and tertiary stand-alone systems. We further believe, however, that the new developments present an excellent opportunity for additional information to be recorded. This should include any copies of emails and other forms of electronic communication (where permitted) between clinician and patient (and vice versa) in order to ensure completeness of the consultation record. Additionally, an opportunity exists for space to be made available for the patient to add any comments regarding aspects of their condition and treatment again enhancing the overall holistic quality of the record.

In terms of future thinking, we believe that patients would benefit from the use of recordings of the consultation session in order to be able to remind themselves of the guidance and instructions given to them. This might be in the form of a video, mp3 recording or podcast that might be downloaded. Naturally, stringent security would be required regarding such recordings.

The Right to View Personal Healthcare Information

We believe that once patients have indicated that they are content to have their information held in electronic form and shared within a wider healthcare community (see Explicit versus Implied Consent above) such information should be available to all registered healthcare professionals provided such registration places them under a clear duty of confidentiality. Where it does not, our view is that their employing or contracting authority should insist that they sign appropriate confidentiality agreements before allowing access to the EHR.

To this end we believe that administrative and managerial staff within healthcare organisations should not have routine access to personal medical information unless it is

demonstrably necessary for them to carry out their duties. In such cases our position is that staff should be required to sign confidentiality agreements that specifically address personal medical information. General conditions in employment contracts may not be sufficient in this regard.

This concern might, in part, be addressed by breaking down the information held on e-Health systems into categories such as:

- Administrative data
- Core health/personal medical information
- Summary data collected at the end of a patient encounter

With designated access rights assigned to different classes of user. As an example, a manager may see administrative data but not the clinical details.

Patient Safety and the Electronic Health Record

Integrity of the Electronic Health Record

Electronic information systems now permeate the world of healthcare. In the early days of their implementation considerable care was taken in checking the accuracy of the information they provided. As time has moved on all information systems have become more trusted and those operating in eHealth are no different. However, in this regard, and with the increasing amount of critical and sensitive information that they hold they are as important to patient safety as an item of medical equipment. In this regard it is interesting to note that there is currently (to our knowledge) any system for the testing and accreditation of such systems before they are deployed in the clinical environment. The Luxembourg Declaration on Patient Safety of 2005³ went some way to addressing this issue. Our position is that the principles of the Declaration should be revisited to ensure that any information system that can be shown to have an influence on patient safety is formally accredited. This issue is further addressed in our accompanying paper, “eHealth and Patient Safety”

Patient Access to the EHR

A patient’s right to access information held about them on an eHealth system is fundamental. With information being shared between health professionals and their support staff, it is important for the patient to have assurances that personal information is accurate and that any opinion expressed about either their medical condition or indeed themselves is both accurate and fair.

The long held view that “the doctor knows best” is now being questioned as patients become better informed about their medical condition and as they increasingly discuss treatment regimes and other issues with their professional advisors. Access to one’s own information is a fundamental right and is embodied in the European Union Data Protection Directive (95/46/EC) which stipulates that:

"Member States shall guarantee every data subject the right to obtain from the data controller:

- (a) without constraint at reasonable intervals and without excessive delay or expense:*
 - confirmation as to whether or not data relating to him are being processed ...*
 - communication to him in an intelligible form of the data undergoing processing ..."*

Thus the developers, owners and users of eHealth systems have a moral and a legal duty to provide patients with access to their medical records. Such access must be provided freely and should enable patients to see their information in the exact form in which it is held. The use of dual screens at the time of the patient/professional consultation would enable to see what information was being entered, to requests amendments and to exercise their right to provide explicit consent to its use.

Over and above the right to see information held about themselves, patients need to have appropriate time to view the information and, where appropriate, to have access to a resource which is able to translate any areas as appropriate. This might take the form of a summary record showing high level details of patient demographics and episodes of treatment and care

The patient can have an important role to play in ensuring the accuracy of the medical record by being provided with the facility to view and check the details of his or her own record. Ideally, this would be achieved quickly and conveniently by providing each patient with their own electronic access facility. Indeed, in the UK, this was proposed as a facility within its National Programme for IT. However, there are advantages to the record being accessed in discussion with the healthcare professional in order to explain some of the clinical terms used and also to reassure the patient regarding sensitive elements of the information.

In certain cases (albeit with regard to strict guidelines) we believe that it would be appropriate for the clinician to veto access where access to the information might have a harmful effect on the patient. Such action should be considered very carefully, apply only to specific conditions and should not be used as a method of applying a blanket veto. The right to appeal against any such veto should be an established feature of the procedure.

Clearly, it would not be appropriate for the patient to amend the record but in the event of a query or discrepancy, it would be appropriate for this to be discussed with the appropriate health care professional. This approach would support the principle that the patient is the master of the file. It also has potential benefits for the clinician as well as the patient in that has the potential to reduce errors in the information shared with colleagues (who may have little experience of the patient's personal circumstances).

Security of the Electronic Health Record

Personal health information is a very sensitive resource. Accordingly, for any eHealth system to be acceptable for patients to use, it is essential that they can have trust in the safety and security of their personal information. In order for them to have the confidence to discuss medical and social conditions with their health professional to the full and open extent required, they must have assurances that it will be held and processed securely. In order to reinforce this, we believe that the provision of a log book showing who has accessed the EHR and what actions they have taken should be available for the patient to view.

In the case of ensuring that sensitive personal information is not accidentally or deliberately revealed to unauthorised persons or organisations, system developers need to ensure that strong access controls are installed. Such access controls must include technical checks to validate the authenticity of those seeking to access the system.

Technical considerations aside, the users of the system (which will include doctors and other clinical staff) must have in place appropriate security policies to ensure that the systems are operated correctly and that they and their staff understand the rights of patients to have their information protected. Such policies need to exist in order to ensure that the appropriate security controls are operated correctly.

Patient health must not be put at risk through inaccuracies in the treatment process. Accordingly, and in addition to the issues of confidentiality, patients need to be reassured about an eHealth system's ability to preserve the integrity of the information held about them. System developers and users must assume responsibility for and be capable of demonstrating to the satisfaction of patients that the information held about them is not capable of becoming corrupted. Such assurances must encompass every aspect of the eHealth process including local computers, tokens such as smart cards, network servers and databases operated by insurance and other reimbursement organisations.

To further enhance the trust which patients are asked to place in eHealth systems, clear, open and understandable procedures must be in place to ensure that, in the event of a technical failure, treatment will not be delayed. This is particularly important to ensure that patients are not put at risk through the non-availability of information about them.

Thus for the purposes of security, eHealth systems should be so designed that the following principles can apply:

- All electronic communications and records about a patient's health, medical care or personal information should be prepared and handled in a confidential and discreet manner.
- Every eHealth system should have an associated security policy that clearly describes how the confidentiality, integrity and availability of records will be preserved. This should be freely available for patients to access.
- We are aware that certain ICT staff have privileged access to information held on eHealth systems. It is important that such privileges are not abused and that

personal medical is only accessed when absolutely necessary and only then under the supervision of a medical professional.

- As part of the development process, system specifications should be produced which explain (in an easily understood form) how the system works and what measures have been taken to protect the patient.

Consistency of Approach in Regulating the EHR

In an area as complex as healthcare where large numbers of organisations and individuals are involved there is always a danger that any provisions to protect the rights of patients can be subject to inconsistent interpretation. This is not just an issue within individual Member States but will increasingly become an issue as European citizens travel, live and work across borders and receive treatment outside of their Home State.

It is important therefore that the relevant national authorities seek to introduce and to formalise guidelines in this area. Equally, there is a role for the European Commission in undertaking work to ensure that there is harmonisation across the Member States in the interests of safeguarding patient rights in relation to confidentiality and other issues of safety.

Conclusion

It is becoming clear that developments in the electronic health record are set to increase significantly in the near future. With the patient as their ultimate focus, it is critical that the views of these stakeholders are taken into account when formulating policy and strategy and when designing and implementing new delivery mechanisms and systems. The Task Force believes that without such involvement the potential for eHealth developments to transform the delivery of healthcare (ultimately to the benefit of the patient) will not be achieved.

However, in order for this to happen, it is clear that the major stakeholders such as national authorities have to recognise the importance of the patient voice and to support further work in this area. This includes involvement of patients in policy and planning groups, consultation with system designers and the undertaking of research in key areas such as those described above. There must also be recognition of the need for funding in these areas to enable such activities to move forward.

To date, the Task Force has sought to raise awareness of the patient perspective through presentations and discussion but this is not enough. The time has come to move forward and to begin to take real action in the area of empowering the patient.

References

- 1 NHS Connecting for Health, <http://www.connectingforhealth.nhs.uk/faq/hottopic>
- 2 “The Patients Charter for eHealth Information Systems”, EHTEL 2003, www.ehtel.org
- 3 “The Luxembourg Declaration on Patient Safety”, European Commission



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