



A Patients Charter for eHealth Information Systems

Prepared by the Patients' and Citizens Working Group, EHTEL

A Patients Charter for eHealth

Prepared by the Patients' and Citizens Working Group
of the
European Health Telematics Association (EHTEL)

EHTEL is an organisation dedicated to helping all stakeholders in eHealth by sharing their experiences with partners and by learning from others. Its role develops by informing interested parties about eHealth developments in Europe and beyond and contributes to discussions at EU level on interoperability, eHealth and telemedicine issues.

PATIENTS AND CITIZENS TASK FORCE

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Preamble

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 which hold increasingly detailed levels of clinical information, remotely monitor vital signs, enable diagnosis and treatment from a distance 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. However, to the extent that contractual relations, which can be influenced by the patient, impact on or even replace state supervision and responsibility, new requirements for the protection of the individual's rights emerge.

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, which will sometimes necessitate training to increase their knowledge. Given that we do not live in a perfect world and that professional time is both expensive and limited, patients increasingly rely on patient organisations to advise them and provide knowledge through "Patient Schools" and as information conduits and bridge builders.

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. The Task Force also comprises highly qualified members with 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 mentioned.

The Task Force believes that National healthcare authorities across the European Union should work to formalise and harmonise guidelines relating the use of eHealth systems and the processing of the Electronic Health Record (EHR)... We further believe that national authorities should seek to consult the patient about the implementation of eHealth systems in a true and meaningful way. An important tenet of our discussions are that concepts and opinions that are acceptable to citizens in good health may be viewed very differently by those who experience ongoing healthcare as part of, for example, chronic disease management.

In the paragraphs below we present our views on various aspects of the design and implementation of eHealth information systems.

Finally, this Charter represents an umbrella document that brings together a number of position papers in specific areas of EHealth activity. Reflected in this version are the Task Force's position in relation to the EHR, Homecare and Patient Safety.

The Patients' Charter for EHealth Information Systems

Access To Appropriate Information

Increasingly politicians and national health authorities promote the concept of the patient becoming a partner in their healthcare. In addition, new and sophisticated electronic systems (eg health portals) have the potential to provide much more comprehensive information on health and treatment. In the main, these are to support professionals in their work but do also offer the opportunity to better inform the patient. Most patients will either not have routine access to these systems or understand how to operate them. We believe, however, that this rich source of information should be made available to the patient in order to support his or her understanding of diagnosis, the treatments available and the benefits associated with the suggested form of treatment together with details of success rates and waiting times. The patient needs information to help to decide on the course of treatment to take but cannot make that decision without sufficient knowledge. Accordingly, appropriate time and assistance has to be made available to help the patient.

EHealth systems should be operated in a supportive and respectful manner. In working with facilities such as health portals the patient needs to be assured that the information is complete and accurate and, very importantly, not selective so as to promote a commercial organisation's products or services, or indeed a public sector policy or initiative. In support of the above information on health, prevention of diseases and care must be certified in order to protect citizens from inappropriate or false information. It must also be possible to identify the source of the information stored or processed by an eHealth system, particularly where such information is published on the Internet. To this end, the Task Force supports the EC Guidelines for Quality Criteria for Health Related Websites.

In keeping with the same principle, the patient should be allowed open access to their individual electronic health records. However, for such access to be meaningful the information needs to be held in a form that is easily understandable to the patient. Where this is not possible for accepted clinical or technical reasons (eg coded) the facility should exist for patients to have entries in their records translated and explained to them. We understand that 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. Equally, in keeping with the principle of respect, the patient should also have the right "not to know".

We recognise that much more information about patients is transferred by electronic means either between professionals or between patient and professionals. Accordingly, for the individual EHR to be comprehensive and complete, we advocate the storage of communications such as emails (where permitted) as part of the EHR. In order to support this, it is important that all systems are interoperable in order to promote such completeness.

Finally, where treatments are complex or where patients may have difficulty remembering the advice given to them by health professionals, the Task Force would like to see the use of innovative methods of recording consultations using such technologies as video or mpeg. We recognise that such recording would have to be undertaken with the consent of both patient and professional.

Security and Safety of Information Systems

With the increasing reliance on information systems, either as record management or decision support or, indeed, as patient monitoring systems, the Task Force is concerned that the reliance placed on the integrity of these systems has to be undertaken in an environment of formal trust and assurance. Patients and health professionals must be able to have complete confidence in the accuracy of the information held, processed and presented. It must also be fit for the purpose for which it is to be used. We believe that any eHealth system that has the potential to harm a patient should be treated as a safety critical system and be subjected to rigorous and independent testing before being deployed for the purposes of patient care. To that end, the Task Force endorses the general principles of the Luxembourg Declaration on Patient safety, though it believes that it does not refer in sufficient detail to information systems. We believe that the European Commission should take responsibility for driving harmonisation in this area seeking endorsement from the appropriate authorities within individual Member States.

We believe that the design, development and maintenance of eHealth systems should be subject to constant quality control procedures. This should encourage the development of hardware, software and data standards and we believe that work should be undertaken by the European Commission to promote consistency across the Union, particularly in these days of open borders.

We welcome the implementation of incident reporting procedures – similar to those employed by the pharmaceutical industry – and technology should be exploited to enable patients to contribute to these schemes and be trained in their use. Allied to such incident reporting should be the requirement to ensure that all eHealth information systems should have properly implemented and managed audit trails and should be the subject of constant monitoring for incorrect operation or abuse.

Further requirements for the promotion of safety with eHealth systems are:

- National health technical infrastructures should be exploited to promote warnings for patients and professionals alike.
- Marking and other schemes should be developed to indicate good quality information sites on the Internet and World Wide Web (see also Access to Appropriate Information above)
- National health technical infrastructures should be exploited to help in the identification of *bona fide* healthcare professionals in support of Directive 2005/36/EC on the recognition of professional qualifications.
- All staff operating eHealth information systems should be properly trained in their use.
- Training programmes for patients should be organised (possibly through patients organizations) in order to acquire a core understanding of eHealth knowledge. Adequate resources should be provided for this.
- Adequate fallback procedures should be in place in the event of a system failure.

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Mastery of the Medical Record

There has been much discussion over the years about who is the owner of the individual personal/electronic health record. Regardless of whether this matter is ever finally settled and owners, custodians or administrators formally defined, the Task Force's position remains unchanged from that published in the original Charter published in 2003. This was clear in its view that the patient was to be the master of the personal file with the ultimate power to decide how it was used.

Our primary issue relates to the sharing of information. Patients should give their informed consent to the sharing of their personal information although this should be a simple and straightforward process supplemented by regular reviews. In the extreme, patients should have the right to opt out from having information shared although individuals doing so should be made aware that it could have a detrimental effect on their healthcare as a result of healthcare professionals not necessarily having access to relevant facts about the patient or their condition. That said, such an opt-out should not be used as a method for denying individuals the right to treatment or care.

In the course of our discussions, we have become aware of technical innovations, such as the masking of certain data, and it would seem right to explore their exploitation for use in specific situations where the patient may wish to have information withheld from certain organisations or individuals.

There will also be times when inaccurate or false information is recorded about a patient. We see it as a fundamental right that the patient should have access to information held about them at any point of contact with the healthcare system and, if such incorrect information is discovered, the patient should be able to have it deleted or corrected. As a minimum, they should be able to prevent its circulation. It is recognised that this could conflict with the rules applied to healthcare professionals and thus it may be necessary to retain a secure copy of the original data.

Whatever systems are developed to manage the correct and respectful sharing of information the Task Force considers that the patient should retain the right (with recognised authority) to intervene if they are concerned abuses of privilege by others when sharing information.

Other principles relating to the mastery of the medical record are:

- All patients should know what information is held about them, where it is held and who is responsible for it. It must be possible to identify the source of the information stored or processed by an EHealth system in order to validate the quality, reliability of information according to established international transparency criteria
- 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.
- Where necessary, a data tracking infrastructure must be in place to ensure that information stored about a patient can be identified, located and accessed by that individual
- Facilities should exist to alert patients when information about them is to be destroyed and to provide them with the right to conserve that information if they so wish.

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Privacy and Confidentiality

Privacy and confidentiality are terms that are often misunderstood and often used in the wrong context. For our purposes privacy recognises the right of the patient to remain a private person, only imparting information when choosing to do so. Once information has been shared with, in the context of this Charter, a health professional the patient places a duty of confidentiality on that professional to respect the sensitive information that has been given.

The patient therefore 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. Accordingly 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.

Within that context, and with reference to our earlier comments regarding mastery of the patient's electronic record we believe that the following principles should apply to the privacy and confidentiality of the medical record:

- As a private individual the patient has the right to approve how his or her information is processed or shared.
- EHealth information systems must operate within national laws governing data protection and/or in accordance with EC Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- 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 and should be created in line within accepted international standards for data security i.e. ISO 17799.
- System administrators should not have the right to access personal medical data.
- 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.
- Controls for the reinforcement of privacy should not be weakened for the purposes of reducing costs

Dignity and Respect

The potential for eHealth developments to improve the quality of life for older people, disabled people and patients affected by chronic diseases and other conditions are enormous. Monitoring of vital signs that was once only possible by having the patient moved to a specialist centre can now be undertaken remotely. Equally, the straightforward process of simply watching over older and infirm patients can now be undertaken from a distance and without the need for routine but expensive visits by a health professional or carer to the patient's home.

The advantages are easy to identify. More time at home increasing the quality of life, less expensive professional time is used in undertaking monitoring that can now (with the help of emerging technology) be placed in the hands of the patient. Patients in remote areas can be provided with access to fast remote support and the potential exists to help the patient remain at home for longer thus vastly increasing the quality of life.

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However, it is necessary to recognise that monitoring technologies, by their very nature are invasive in that they are installed in private residences whether they are rooms in a care institution or in a private home. Attention needs to be paid to the way in which such technology is installed, how patients, infirm citizens and carers are treated. These processes need to be managed in such a way as to recognise the respect and dignity of all concerned. In this area, therefore we believe that the following principles should be adhered to:

- The patient must have the right to refuse to use the technology with no repercussions regarding the quality of treatment they receive.
- The patient needs to be in control of the technology and to be able to switch it off when necessary. This is particularly important when considering the area of privacy
- Patients need support in managing eHomecare technology preferably through a single point of contact for all elements
- Controlling authorities need to be clear about ownership and legal responsibilities relating to the technology and to make this clear to the patient
- The benefits and risks associated with the use of eHomecare need to be made transparent to the patient
- The views and needs of the patient need to be taken seriously. Others cannot normally assume this responsibility.
- Education and training for the patient, the professional, carer and, where relevant, family members are essential in order to gain acceptance by the user
- Training needs to encompass not just the use of the technology but also the interactions between professional and patient and, indeed, the support staff who maintain the equipment. Respect and sensitivity are key components in the acceptance of eHomecare
- Socio-economic considerations including ICT literacy, relationships within the family household and the potential for others to assume responsibility for any monitoring and consultation need to be taken into account
- The need for direct human contact needs to be considered very carefully
- Telecommunication networks carrying personal medical information need to be properly secured and appropriate audit trails showing who has accessed such information should be maintained.
- Access controls need to be implemented in items of equipment that could be used by other members of the household
- All equipment installed in the home should be suitable accredited to recognised safety standards and installed to a professional level and in accordance with health and safety directives

Products From The Internet and World Wide Web

Drugs and other healthcare products are increasingly ordered from providers using the Internet and the World Wide Web. These are either prescription items or “over the counter products” ordered legitimately using a doctor’s authorisation or they may be prescription drugs ordered without such official sanction i.e., in the main, illegally. Although there is much to be said about the unofficial ordering of prescription drugs, we consider it outside our remit.

In relation to the use of authorised electronic pharmacies for the ordering of drugs our position is:

- Drugs and other medical products and services, together with accompanying information (e.g. package leaflets), must be provided at guaranteed quality levels
- The origin and source of products must be transparent in order for appropriate liability to be recognised in the case of poor quality, inadequate or false information leading to patient harm
- The distribution of drugs and other medical products across the Internet must be in accordance with respective country laws.

Comments and Complaints

The use of the term “complaint” has negative connotations, but there will be times when a patient is harmed or damaged through a fault or inappropriate use of an eHealth system. This needs to be recognised by national authorities who should, in our opinion, put in place procedures to enable patients to raise issues about the safety and quality of eHealth systems and to receive a response. Such procedures can be viewed as a positive support for the incident reporting systems mentioned earlier in this document.

Procedures will need to make it clear who is responsible for administering them, where they are located and how the patient can initiate a complaint.

We also believe that there is a role for the post of Ombudsperson at the European level supported by a network of other such posts established by national authorities within their respective countries. The Patient and Citizen Taskforce believes that an Ombudsperson would be also there to assist patients in understanding complex IT issues and to serve as an Institution where complaints can be made and followed up.

Compensation

Besides new opportunities, eHealth systems have also created new conditions for patients to be physically harmed or otherwise damaged. These new features need to be recognised in and law governing legal liability and the level of damages available.

Annex – Glossary of Terms

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| Access: | Right, opportunity, or means of finding, using, or retrieving information. |
| Accuracy: | Attributes of software that bears on the provision of right or agreed results or effects. |
| Audit: | An official and methodical examination and verification. |
| Confidentiality: | The characteristic of data and information being disclosed only to authorised persons, entities and processes at authorised times and in the authorised manner. |
| eHealth | The combined use of electronic communication and information technology in the health sector |
| Health Portal | A website containing links to other websites relating to health, disease and illness information. In effect, an index of useful websites |
| ICT | Information and Communications Technology – the bringing together of data storage and transmission |
| Integrity: | The property that data has not been modified by an unauthorised entity and its fit for the purpose for which it is to be used |
| Logbook | An electronic record of transactions showing when a patient record was accessed, amended or corrected by a person and on what date. Otherwise known as an audit trail. |
| Privacy: | The individual rights of a person to protect her or his personal life from the outside world, including the right to be left alone and to decide herself or himself how, what, and to what degree others may dispose of her or his data. |
| Reliability: | <p>The reproducibility of a measure. A measure is reliable if it yields similar results each time it is used on similar samples, or if its components yield similar results for the same or similar samples (compare <i>validity</i>).</p> <p>Set of attributes that bear on the capability of software to maintain a level of performance under stated conditions for a stated period of time.</p> |
| Safety: | Freedom from unacceptable risk or harm. |

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- Security:** The combination of availability, confidentiality and integrity. It can be defined the preservation of the availability, access to, confidentiality and integrity of information.
- Validity:** Used to describe a measurement that reflects what is intended to be measured.

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References:

EC Guidelines for Quality Criteria for Health Related Websites

http://ec.europa.eu/information_society/europe/ehealth/quality/draft_guidelines/index_en.htm

Luxembourg Declaration on Patients' Safety

http://www.eu2005.lu/en/actualites/documents_travail/2005/04/06Patientsafety/

Directive 95/46/EC (page 9)

http://www.eu2005.lu/en/actualites/documents_travail/2005/04/06Patientsafety/



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