

Managed Convergence Towards High Quality Electronic Healthcare Records in Europe: The PROREC Initiative

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1. Introduction

In the Single European Market, health care equipment and systems should be built to assist communication between functions and across countries, and any analysis of quality of care and health service costs must be comparable and reliable. Past experience indicates that a single unified Healthcare Record that is valid for all purposes and acceptable by all users, is not attainable. Nevertheless, it is crucial that a consensus and common understanding of the Healthcare Record is reached [1].

Several projects under the former Third Framework Programme of the European Commission (1990-1994) that were related to the Electronic Healthcare Record have tried to reach (part of) this ultimate goal, however not without major difficulties due to the various characteristics of the individual European countries with respect to the differences in Healthcare Systems, technical backgrounds, possibilities, etc.

In the Fourth Framework, the Electronic Healthcare Record is a mayor issue again, and a considerable number of projects are addressing this topic. Meanwhile, quite a number of activities are carried out at regional, national or international level, in- and outside the EU's boundaries, by industry and institution-based experts in the domain. As a consequence, there is a mayor need for actions aiming at a better information exchange in order to arrive at a better understanding of each others activities, and to reach a higher level of harmonisation.

This urgent need is not only perceived by the actors in the field, but is also strongly present in the minds of many politicians. They cherish the vision that relevant healthcare data of a patient could be available upon request anywhere within the European Union. The availability of these data is deemed to be a requirement for the benefit of many parties: as well for the patient, as for the economy, and the society as a whole.

2. Is there a market for high quality electronic healthcare records in Europe ?

The Bangemann report [2] just illustrated the need and necessity to build a European-wide market in order to ensure the rapid emergence of efficient European information infrastructures and services, that will be able to address the already started revolution

of the information society. Focusing in the health care domain, and building upon the insight provided by MEDIREC [3, 4, 5], it is to be expected that an increased target market for electronic health care record systems will be to the benefit both for European health care and for the European industry.

However, the current status on electronic healthcare records is this of a highly fragmented market, with major differences. As examples, approx. 2/3 of Norway General Practitioners use EHCR systems, in UK the rate is also high, due to central funding, in Finland or France the rate is 1/3 or less. There are 5 different vendors supplying EHCR systems to Norwegian GPs, 60 in Belgium. None of the Norwegian system are offered in Belgium and vice versa.

The main characteristics of this market are [6]:

- a large variety of market actors: end-users (physicians, nurses, mid-wives, ...), health care organisations (GP, independent nurses, clinics, ...), health care authorities, software and service suppliers, hardware manufacturers, system integrators. A particular importance in this market is recognised to the credit of the SME's, answering quickly to the users' demands, creating jobs, adapting themselves quickly, creating effective economic tissue, presenting alternative to large companies offer.
- a lack of recognised or implemented standards: CEN/TC251 is doing an enormous effort, but it will take some while to turn the outputs into the results the TC deserves.
- international and regional differences in administrative rules and practices, and in legislation
- shortness of vision: to establish an open market, one must believe in it. And one must believe in EHCR systems. It is our impression that the vision is not yet adequately established today, perhaps not even in the minds of all the major decision makers in this area.
- a lack of a common conceptual approach to the electronic healthcare record,
- each country is considered as an independent market.
- the issue of multi-linguality is not always recognised (specifically by overseas' industries)
- the organisation of health care differs over countries and time.

Several factors must be established in order to build a European-wide market for EHCR systems [7, 8, 9, 10, 11, 12, 13] .

- standards for electronic healthcare record (systems) should be made largely known and implemented: The standardisation effort should enable the interoperability at three levels: within the complete information system of the health care organisation, between two different instances of a same EHCR system, located within different health care organisations, and even within different countries, between two different EHCR systems. However, it should also allow to customise and adapt the solutions to the local uses, rules, languages and customs.

- harmonised healthcare rules and regulations: ideally, there would be few differences in national rules and regulations. The differences that are to be maintained, should be well defined and specified, so that the effort needed to make different national versions of the systems is reduced to a minimum.
- support of European suppliers: As in other sectors, the new market requires that all actors are equipped to participate successfully, or at least that they do not start with significant handicaps. All should be able to operate according to clear rules, within a single, fair and competitive framework. European suppliers, often SME's, are, unlike big non-European companies not used to compete in a wide and open market. They may however, possess both valuable knowledge and interesting products made for smaller markets, that it would be valuable to make available on a broader scale. To have them acting in an open European market, It is necessary to provide them with a support, both in order to obtain the necessary level of investment and to guide their demarche.
- consensus on what should be understood by a European Healthcare Record: it is necessary to establish a European consensus on what a EHCR system is, what it can do, how it shall do it, and what it may and should contain.

3. The LISBON Declaration

During the AIM Final Conference (Lisbon, 6-11/12/94), the feelings of users and experts in the field have been formalised in what now is known as the LISBON Declaration. The Declaration may be seen as a summary of the worries and hopes of the European medical informatics community with respect to electronic healthcare records, and is the true starting point of the PROREC initiative.

It is recommended that the Member States, through the Commission, promote a framework for action within Europe to further develop common aspects of the Electronic Health Care Records based on the following:

1. The EHCR is the nucleus of the relationship between the patient, the HC delivery system and all its professionals. As such, a EHCR should be the core of the new generation of Health Information Systems.

2. The main objective of the use of any EHCR must be to improve the quality of care by having the record and its associated information always available for the HC professionals when needed at the point of care.

3. The use of EHCR's should lead to direct benefits for the professionals by making their work more efficient. This will arise from supporting the diagnostic process, enhancing HCR accuracy and completeness, improving medical knowledge and disease management, and allowing better preventive care and patient handling.

4. Within HC systems, either at European, national, regional or local level, the use of appropriate EHCR's will also contribute to adequate planification and resource management, facilitation of the continuity of care, registration of healthcare interventions, improvement of epidemiological and morbidity information, and hence, a more cost-effective care process.

5. *The European citizen shall by means of any EHCR have (1) guaranteed right of access to the HC he is entitled for, (2) right of access to his individual data and related services, (3) the effective protection of his right of free circulation with respect to the confidentiality of his individual data.*

6. *Further actions and developments on EHCR's should be based upon standards and consensus that ensure interoperability, and allow EHCR's coming from different origins to be reliable, communicable, recognisable and comparable.*

7. *A role of the Health Telematics European Industry is to tackle the need for the development of new products in a huge growing market, offering the enabling technology to fulfil user requirements. Multimedia, 3D images, interchange formats, message contents, linguistic barriers and suitable user interfaces are among the challenges to be developed in a framework of confidentiality and security for patient data.*

8. *The use of EHCR's will require the adequate management of "cultural changes" in all parties involved towards, amongst others, technological innovations, patterns of practice, education and training. Active participation of all parties, including European, national, regional and local Health Authorities in the definition and promotion of the use of EHCR's is mandatory.*

9. *The effective co-operation between all interested parties including users, professionals, authorities, industry, standardisation bodies and others at a European level and through a process of managed convergence towards European EHCR's, would benefit from the set-up of an appropriate Structure based on existing organisations that could promote that mission.*

10. *In order to achieve these goals and to encompass the future, Member States individually and through the Commission should encourage common efforts and policies through adequate resource allocation, focusing on the European EHCR, and leading us to patient-centred HC systems.*

4. The PROREC initiative

PROREC is a Concerted Action sponsored by the Commission of the European Union (contract HC 1110 HC) under the Fourth Framework Programme. The main goal is to promote and co-ordinate the European wide convergence towards comprehensive, communicable and secure Electronic Healthcare Records (EHCR). This will be achieved by co-ordinating and supporting the European Commission's Telematics Applications for Health projects and other initiatives in the area of EHCRs, both nationally and internationally. The main objective of this initiative is that in a reasonable time scale compatible EHCR systems are installed in all Member States such that health care data originating from various sources are communicable and understandable. Also, it is expected that through PROREC initiatives such as CEN/TC251 at the one hand, and EC Informatics programmes at the other hand, meet their purpose of providing standards and highest quality research to enhance the care process for patients and users. But perhaps even more important, PROREC's aim is to

reach all actors in the field, such that even the smallest initiative taken “independently” by some organisation, company or user-group, contributes effectively to the common objective.

5. The PROREC activities

PROREC promotes the widespread use of Electronic Healthcare Records by co-ordinating the EC’s Telematics Application Projects related to the EHCR, and by installing in Europe a permanent network of centres focusing on the dissemination of information related to electronic healthcare records. The activities envisaged, both on the international as on the national level, can be found on a scale ranging from *informative*, over *advisory* and *monitoring*, to *accreditation*. This is done through organisation, co-ordination and concertation.

Tasks carried out in PROREC along each line are:

5.1 *informative actions:*

- collect continuously information on existing products, methodologies, techniques, projects, studies, etc. related to EHCRs. Focus on EHCR aspects such as communicability, comparability, faithfulness, comprehensiveness.
- perform or initiate studies in particular domains in order to get answers on questions that not have been addressed so far, or that are felt to be out-dated. Depending on the financial possibilities of PROREC at any given moment, these studies can be carried out on explicit demand of it (e.g. by the EC), or may be realised by encouraging researchers and academic staff to devote PhD-theses to relevant issues with respect to the EEHCR.
- disseminate the information as widely as possible, by using various channels and media (scientific associations, user groups, symposia, vendors at the one hand, and bulletins, papers, CD-ROM, on-line databases at the other hand).
- not only concentrate on activities going on in Europe, but take into account important initiatives in the US, Japan and Canada.

5.2 *advisory actions:*

- provide answers to specific questions on demand
- identify missing elements in current efforts and propose modifications
- take a leading position in consultancy efforts towards national and international bodies in the domain of EHCRs

5.3 *monitoring actions:*

- initiate, assist or co-ordinate the working out of check-lists, requirements, functional and technical specifications to which specific products or projects should adhere to in order to contribute as much as possible to the EEHCR-concept
- monitor ongoing or prepared efforts on EHCR along these lines

5.4 accreditation activities

- initiate, assist or co-ordinate the development of rating scales and measurement procedures that can be used to certificate or provide quality labels (with respect to the EEHCR-principles) to existing products. Possible “rules” might be the implementation of specific European Standards, level of user-involvement, etc.
- advise the Member States to discourage the dissemination of products not fulfilling the requirements of the EEHCR.

6. The PROREC centres

Within various Member States, PROREC centres will be set up as non-profit organisations, each of them acting independently, but nevertheless co-ordinated at international level by the PROREC Consortium. PROREC-BE (Belgium) was the first centre to be created.

The role of each centre is

- 1) to collect information in the member state,
- 2) to bring this information to PROREC International,
- 3) to disseminate recommendations from PROREC International in the member state, and
- 4) to conduct local initiatives related to the promotion of the widespread use of EHCRs.

As such, through co-ordination with PROREC International, optimal information flow and utilisation of resources can be guaranteed.

According to the principle of subsidiarity, a national centre may organise itself as most suited to the national habits. The main principle is that the centre will receive money from the Support Action funded by the Commission to initiate the work, but that in their “business plan” (although in principle non-for-profit organisations) adequate measures must be taken to be self-supporting after at least three years.

The activities of each centre are:

6.1 Related to the activities of PROREC International:

- report towards PROREC International on the state of the art regarding medical informatics in the Member State at a regular basis
- respond to specific demands and questions from PROREC International
- implement European initiated studies in the Member State
- co-ordinate and implement the accreditation principles of PROREC International in the Member State
- report to the PROREC national centre’s members on the activities and achievements of PROREC International at the one hand, and other national PROREC bodies at the other hand.

6.2 Related to physicians and other health care workers:

- inform about the various activities going on at both European and Member State level.

- present continuously a state of the art on electronic healthcare record related issues in the Member State
- encourage education and training in the domain
- achieve active involvement in the activities of PROREC
- organise consensus formation from the user point of view at national level

6.3 Related to electronic healthcare record suppliers and other software developers active in health care

- In addition to the objectives mentioned in the previous paragraph:
- inform about the accreditation principles of PROREC International with respect to the elaboration of a common electronic healthcare record in Europe
- provide national variants on those principles in line with national laws and customs
- stimulate co-operation between developers such that information exchange between the various systems becomes possible
- organise comparative studies on the functionality's of the systems

6.4 Related to governmental and public bodies:

- make the government aware of the low level needs of all parties involved, and show that providing facilities to respond to these needs has a beneficial impact on healthcare expenditure
- participate in governmental programs (both at regional and federal level) related to the domain
- give expert advise and have an impact on governmental policies

6.5 Related to citizens:

- draw the attention of the public on how the widespread use of electronic healthcare records will improve the quality of healthcare services, and as a consequence, also their health.

7. The European Electronic Healthcare Record Index

One particular task of PROREC at the international level is the compiling of a large inventory of existing systems and products. This activity is a direct response to a clear user need: the availability of adequate information. The goal of the EEHCRI is to have available to all interested parties an overview of the past, ongoing and future activities in the field of Electronic Healthcare Records, such that duplication of work can be avoided. Meanwhile, important aspects not covered so far, may be easily identified, and appropriate actions taken. Finally, existing products should find their way to the market, while potential buyers can use the catalogue to make a first selection by comparing their needs with the functionalities described with respect to individual systems.

A catalogue will be set up containing all information on existing EHCR-products in Europe, initiatives, projects, legislation, etc. The requirements for such an Index have extensively be discussed in the MEDIREC Concerted Action, and the need for it clearly expressed by the national representatives of various Member States [5].

The principles along which has to be worked are outlined in [11], the most important ones being:

- the EEHCRI must cover a wide range of interested parties. The expectations of parties interested in the development of EEHCR's, and those interested in the use of it, both have to be met.
- it will provide a multi-dimensional view on Electronic Healthcare Record systems in Europe.
- the information needs of all parties have to be analysed precisely, and the Index should account for the results of the analysis. The demands of particular subcategories should be given high priority.
- the EEHCRI will incorporate a twofold policy with respect to standards. First, it should use a standard terminology in describing systems and approaches. Second, it should mention for particular systems and approaches the standards that are addressed (design, implementation, hardware, communication, contents, ...).
- information obtained from third parties have to be judged upon reliability and objectiveness. Developers should be able to find in the EEHCRI information that will enable them to enhance their products and to identify opportunities. A careful balance needs to be established between "benchmark" information and "commercial" information.
- relevant parts of the EEHCRI will be based on the recommendations of authoritative parties entitled to describe in a standardised way the organisational aspects of healthcare in general and the electronic medical record in particular.
- the EEHCRI will contain information that (mostly) indirectly can be used by national and international governmental bodies to know where the answers can be found on questions or problems they (urgently) want to see solved. In addition, the EEHCRI should be a valuable source of information to decide where and in what domains governmental funding or public investments are needed.
- For all systems described, a complete list of functionalities and characteristics should be provided. The functionalities have to be indexed such that a user can identify easily the systems with functionalities and characteristics he is interested in.

The Index will be made available in various formats. The first version will be based on the existing information on that topic within the EC, including the relevant Telematics Applications for Health projects.

8. Who will benefit ?

The intended audience of all the activities of PROREC are the players active in the electronic health care record market: users, software engineers and developers, buyers, vendors, governmental bodies, standardisation bodies, universities and academic centres, patients, and researchers.

Users: Users have demands and priorities, the knowledge of which is crucial for the acceptance of any application, be it an industrial product or the product or tools designed and implemented through a community funded R&D activity. As a consequence, PROREC will focus on the user's needs and demands, and their

involvement in the pre-design phases of the development cycle of particular EHCRs. Their contribution to the failure or success of specific systems will be identified. PROREC will also favour activities that assess continuously their need for education and training.

Software-engineers and developers: their interest with respect to EHCRs compared to other domains in informatics is different from the one of the users. PROREC will identify their acceptance of new engineering tools and programming languages and assess their (perhaps conflicting) interests in a EEHCR.

Buyers: for small EHCR systems, such as GP systems, buyers are also the users. For larger systems such as those particularly designed for hospitals, it is management that decides what system will be purchased. PROREC will keep record on how buyers are looking upon EHCRs in general, and the concept of the EEHCR in particular.

Vendors: here also, developers and vendors do not necessarily imply the same people. A number of companies confine themselves to development only, and make use of independent dealers to distribute their products. In this case, the commercial interests of vendors and developers may differ. Such independent vendors may opt for systems that are easy to sell, even if from a qualitative point of view, these systems are not the most advanced. PROREC will take these attitudes into account and will develop strategies to make sure that vendors do not ignore differences in quality.

Governmental bodies: if the concept of a EEHCR is to be generally accepted, Member States should create a favourable environment for it. PROREC will first contribute to the identification of circumstances that hamper the breakthrough of the EEHCR in particular Member States. It then will propose specific actions within each Member State to remove the barriers related to legal, cultural or financial matters.

Standardisation bodies: PROREC will remain aware at all times of the actual status of standardisation efforts in the domain of medical informatics. For this reason, a liaison with CEN\TC251 will be established. This liaison will lead to an enhanced productivity of both CEN\TC251 and PROREC.

Educational bodies and universities: PROREC will keep track of national and international initiatives on training and education in medical record keeping in general, and the EHCR in particular. Harmonisation of the education in EHCRs for physicians and other Health Care workers will be aimed at.

Patients: it should never be forgotten that all efforts in the domain of Health Care - and the development of a EEHCR should not be an exception - should lead to an improvement of quality and equity in Health Care, as expressed in the WHO declaration "Health for All". Although patients are not directly involved in activities related to the development of a EEHCR, PROREC is aware of the patients' personal interest in EHCRs. Indirectly, PROREC will contribute to "marketing" efforts towards patients favouring the use of EHCRs by their physicians.

Researchers and scientists: PROREC International and its national centres intend to become the central place (information cross road) where researchers and scientists working on ECHR and related domains can find the information they need.

9. Conclusion

Today, health care telematics is a valuable tool for care delivery and health interventions to improve efficiency and quality. Medical records (a term rather out of date that should be replaced by Health Care Record to encompass the future) will be the corner stone in the relationships between the users and patients at the one hand, and with the health care delivery system and its professionals at the other hand. As such, the health care record is nowadays also recognised for being the core element of the new generation of Health Information Systems.

The main objective of the use of any electronic health care record (EHCR) must be to improve patient care. The main objective of a EHCR System should be to get the record and its associated information always available when needed at the point of care for the health care professionals. The direct benefits for the professionals arise from its potential in supporting the diagnostic process, enhancing HCR accuracy and completeness, improving medical knowledge and disease management and allowing better preventive care and patient handling. For the Health Care Systems, the EHCR will support the adequate planification and resource management, the facilitation of the continuity of care, the improvement of epidemiological and morbidity information and with all these tools a cost-effective process of care. The Health Telematics Industry will profit from the need for the development of new products in a huge growing market offering the enabling technology for the user requirements. And finally the European citizen shall have guaranteed their universal right of access to health care, the effective protection of their right of free circulation within a frame work of quality of care in Europe as a global Information Society.

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Short Biography

Dr. W. Ceusters is general manager of Office Line Engineering NV, a small company specialised in Medical Language Engineering. He obtained degrees in neuropsychiatry, informatics and knowledge technology. He is involved in several European projects in the domain of medical informatics, and is one of the founders of PROREC.