EUROPEAN COMMISSION

ELECTRONIC HEALTH RECORDS IN EUROPE: a shared vision for tomorrow

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Alan Garfield, Chair, Computer Graphics and Interactive Media
University of Dubuque, Dubuque, Iowa 52001
agarfield@dbq.edu, 563.589.3717
Software Interface Engineer, Donegal Medical Systems, Ireland, EU

Introduction

Efforts to develop an electronic health record, variously called EHR, EMR (electronic medical record), EPR (electronic patient record), EHCR (electronic healthcare record), GEHR (good electronic health record), and HCR (healthcare record) have been underway in many parts of the world for many years. In the United States, independent doctors, followed quickly by insurance companies (then by managed groups such as HMOs and finally by the federal government's DHHS the Department of Health and Human Services) have initiated the lead.

And what a lead from the United States… the Health Insurance Portability and Accountability Act (HIPAA) of 1996. This act established new government regulations to advance healthcare information standards. Through HIPAA, a set objectives and a structure for deliverables matched with timelines to see the process through have been mandated, including:

- the NCVHS (National Committee on Vital and Health Statistics) whose function is to recommend healthcare information standards for adoption by the DHHS.

- the NPRM (Notice of Proposed Rule Making) process to review each standard and major recommendation from the NCVHS.

- a process to publish and gather public comments and evaluate how to craft final regulations.

- an implementation timeline (2 years minimum) for the DHHS to distribute these standards by covered entities (providers, health plans and clearing houses) with small covered entities allowed three years for implementation.

Though people might be similar, and their medical needs might be thought of as standard, point in fact is that the evolving nature of the EHR in our country is quite different from that in the rest of the world. This is so for various reasons, not the least of which involve different political and economic forces. The EU's social policy now covers healthcare for every European citizen, even as that citizen travels from one country to another. Medicare and HMOs in the US do not take the same spin on healthcare and pharmaceutical payments as each federated state does in the EU. It is, therefore, natural to assume a different (sometimes parallel) evolution of EHR healthcare standards in Europe (and the rest of the world).

This paper will briefly outline what the author sees as some of the most exciting directions in this field of trying to establish a ubiquitous EHR outside of the United States.

Why do we need an EHR in the first place?

The first item of business that needs to be addressed is the basic question – why? Why do we need to establish an electronic version of what has obviously worked good enough for years, generations, centuries? I think the answer was most succinctly nailed down by Dr. Charles Boelen in his keynote address at the Dublin 1998 WONCA conference:

> We have to address the galloping fragmentation between the different parties and players on the world stage of healthcare delivery.

"Galloping fragmentation". What a powerful phrase. He was telling the world conference of general practitioners what they knew all too well … frequently the information to help the patient was there, but it wasn't accessible, legible nor organized to be useful.

In 1999, Dr. Peter Branger, Erasmus University Hospital in Rotterdam, underscored the issue at the TEHRE conference (London) when he stated:

> The quality of communication between healthcare professionals greatly influences the quality of patient care.

Branger cut to the quick and made sure that, from his perspective at least, the reason is not solely administrative nor economic, but quality of care for the patient.

Studies of older and current systems have been completed and they demonstrate, with little pride, that incomplete decision-making has gone on for too long. Now it is time to develop and incorporate an accurate, historical, and powerful EHR.

Standards: GEHR, SGML, and XML

In Europe, then, a great deal has been learned from these efforts, but no standard, solitary implementation of any published efforts to produce a recognizable standard has taken place so far. In fact, over the last decade, the approach to standardization in Europe has moved away from a minimum shared dataset to a feature rich, standard record with the need for its own specific architecture. The desired European EHR architecture will be an information model or framework for the construction of electronic health records. It has been defined by the European Standards Committee (CEN) as:

> …a model of the generic features necessary in any electronic healthcare record in order that the record may be communicable, complete, a useful and effective ethic-legal record of care, and may retain integrity across systems, countries and time. The Architecture does not prescribe nor dictate what anyone stores in their healthcare records. Nor does it prescribe nor dictate how any electronic healthcare record system is implemented. …(It) places no restriction on the types of data which can appear in the record, including those which have no counterpart in paper records. …details like "field sizes", coming from the world of physical databases, are not relevant to the electronic healthcare record Architecture.

There have been two fundamentally different approaches to the development of EHR architectures. The first is an object-oriented modelling approach, typified by GEHR (Good Electronic Health Record) and its related architectures that originated in Europe. The second is a document-oriented approach based on SGML and is typified by the Kona/PRA model that came from the HL7 special interest group in the US. In 2000, it looked like only the GEHR type object-oriented architecture could fulfil all of the requirements necessary for a globally acceptable EHR information model. However, features of both models recently have been adopted and adapted into the use of XML as an exchange mechanism, and at this moment in time in Europe, it looks as though XML architecture might meet the collection of diverse observations and data structures, constructed by numerous people in various places, over time.

History of the GEHR

The Good Electronic Health Record has had a long history, partly in Brussels and partly in London. Dr. Alain Maskens, a Belgian oncologist, became interested in collecting data in primary care to assess causative factors in cancer. His group of general practitioners in Brussels worked with a mobile group of patients who were multi-lingual. That team developed the HEALTH.one EHR program in the mid-1980s. That software allowed (albeit minimally) structured records to store coded information. As the best of its class at the time (almost the only), the program was taken up in primary and secondary care in a number of EU countries. Dr. Sam Heard, with a group of GPs in London, required health information on the highly mobile inner city practice at St Bartholomew's Hospital. HEALTH.one developed a modular approach with international effort to produce a common and 'good' electronic health record architecture, hence the GEHR.

Between 1991 and 1995, the GEHR project was funded by the EU's Advanced Informatics in Medicine program. The goal was none-other-than to develop an EHR architectural framework for using and sharing electronic health records across different health sectors, systems, countries, and times. The project was a huge undertaking involving clinicians, academics, and IT specialists from 20 state/private organizations in 8 countries. 23 volumes of documentation were published over the 4 years, and a formal object model (the GOM) was developed using the Eiffel programming language.

Developments of an EHR since GEHR

A number of projects related to further developments of the EHR architecture have been undertaken since the completion of the GEHR project in 1995. The most significant of these in Europe are the Synapses, EHCR Support Action (EHCR SupA), and the SynEx projects. Synapses developed what was called a 'federated EHR architecture' to ease the transition from non-GEHR legacy systems. The EHCR SupA project compared the GEHR Version 1.0 model with those from around the world to support the

development of a new CEN extended EHR architecture pre-standard. The SynEx project currently is focused on integrating the work of several European health informatics projects, including Synapses, Galen, TeleNurse, and 14C, to "…facilitate the sharing of EHRs between open distributed computing environments through interoperable middle-ware components". And, as you might imagine, there have been numerous independent definitions/architectures for an all-inclusive EHR proposed, tried, and tested.

Funding Mechanisms for Development of HER

1. 5th and 6th Framework from the European Commission

In Europe, as in the US, resourcing such developments in healthcare does not come cheap. A general understanding of the funding issues explains some of the partnerships and timing constraints placed upon EHR projects. The major research-funding arm of the EU is the framework program, and the 5th Framework's funding from the European Commission just ended in December 2001. The Commission's next Framework, the 6th Framework Programme of Research and Development, has been announced and will be active between 2003 and 2006. It was introduced in the European Council and Parliament for tentative approval in February 2001, and the specific programs were introduced May 2001. FP6, Framework Proposal 6 as it is called, will be a major instrument for the realisation of the European Research Area (ERA)[1].

2. IST 2002 - Information Society Technologies

6th Framework funding will be awarded starting 2003. But to keep existing projects online and to encourage new, short-term projects, the EU has approved the IST Programme for 2002 in all relevant fields and includes, in particular, activities to encourage collaboration between research programs. As such, this year – 2002 – is a transition year, with projects slouching towards the next big 6th Framework Programme.

3. How does the IST Programme work?

The IST Programme is implemented through a series of annual work programs, each of which is developed in close co-operation with industry, academia and user organisations. Advice for the programs is provided by the IST Advisory Group (ISTAG) and the Programme Committee. This advice helps define priorities which, with further specifications and consultations, result in the Action Lines described in each work program. The consultation process for the 2002 work program (WP2002) consisted of meetings and workshops that involved more than 400 IST experts from industry and academia. Reports of these meetings can be found on the IST Programme web site (www.cordis.lu/ist).

The program follows the structure of work as defined in Annex I to the Specific Programme Decision (namely "The General Outlines, the Scientific and Technological Objectives and the Priorities"). The WP2002 thus lays out the Action Lines for the Call for Proposals to be published in calendar year 2002 and structures them in a way that reflects the nature of the Programme and its Key Actions.

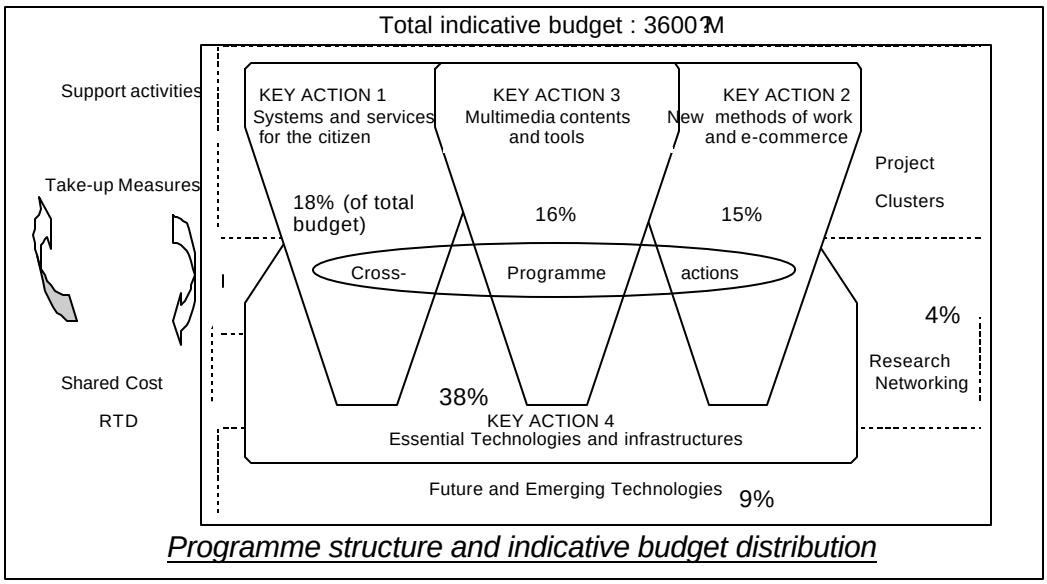
A bit of recent history here. As a result of the first six IST Calls for Proposals between 1999 and 2001, over 7400 proposals were received, requesting funding of over 12.5 billion Euro. Following independent expert evaluation, around 1700 proposals were selected for support from an available budget of around 2.6 billion Euro. (Detailed figures and statistics on participation and results of these Calls are available on the Programme web site including an integrated analysis of the Programme's portfolio of projects - the IPPA report, www.cordis.lu/ist. WP2002 builds on experience gained from these Calls and addresses the future orientation of the Programme to be developed under the Community's next RTD Framework Programme.)

4. IST and Key Actions

The IST Programme is structured around four interrelated Key Actions (KAs), an activity on Future and Emerging technologies in all IST fields and an activity supporting Research networking. The Programme consists of a set of complementary activities that are derived by grouping together the technologies and applications with the greatest affinity or interdependence. In this, each Key Action has, as appropriate, a balance of the complete range of research and development in technology.

I have included the IST diagram of funding below.

[1] http://www.cordis.lu/rtd2002/era/era.htm



Programme structure and indicative budget distribution

5. IST and Standardisation Support Initiatives in Healthcare

Specifically, the IST Programme identifies the following descriptors for health research.

IST2002 - I.1.1 Intelligent systems for the monitoring of health status

Objectives: To improve early illness detection and medical intervention by carrying out medium to long term multidisciplinary research on IST health application systems. The aim is to foster closer collaboration between research activities in areas such as health telematics, biomedical engineering and advanced communication technologies. Longer-term work is also expected on new systems that take into account the results of functional genomics research. Activities will complement the existing clusters on "Ambient intelligence-based systems for health promotion, illness prevention and patient treatment".

Focus:

- minimally invasive personal health systems for illness prevention and/or for health status monitoring of patients including systems based on flexible and smart technologies adaptable to the human body and integrating the possibilities of electrical, optical, chemical, & mechanical sensors. These systems monitor various parameters (bio-signals, location, etc), and when needed, communicate securely with health professionals as well as with intelligent support systems. The focus is on development of new sensor technologies as well as intelligent decision support systems.

- research on knowledge technologies for access and delivery of *personalised* health promotion material based on the current health status and including, where appropriate, health and genetic profile. The problems to address include interoperability of databases containing individual's health information, semantic based knowledge representation, knowledge capturing and retrieval which facilitate compliance with data protection, electronic signature and other information society related legislation.

IST2002 - I.1.2 Systems for health professionals: creating a "Health knowledge info-structure"

Objective: To allow health professionals timely interaction with heterogeneous, distributed, medical and other health related databases. Work will consist of medium to long term research on the development of more efficient and secure "Health Knowledge Info-structure", (i.e. a network of interactive and secure medical and health systems). This will complement the existing cluster on "Ambient intelligence-based system for health professionals"

Focus:

- Advanced navigation tools for health professionals for timely retrieval of vital information including health info-structure tools such as user friendly systems and interfaces as well as mobile systems for ubiquitous, timely and secure access to medical data at the point of care. A midterm strategy is the fostering of closer collaboration between the bio-informatics community and

medical informatics researchers in order to accelerate and validate the results of functional genomics and develop the future forms of clinical systems that will incorporate genetic information.

- Medical knowledge and evidence management, data mining, capturing and retrieval, intelligent interactive environments and interoperability of large health databases, using open source where appropriate. All systems handling person identifiable data must comply with the requirements of the information society related legislation.

6. Other EU Initiatives

Though these are not specifically healthcare identified, these funding programs can be used in conjunction with the IST2002 Programme.

COST framework (see http://cost.cordis.lu) funding links to all IST-related actions, including the established COST-Telecommunications set.

TEN-Telecom and Eureka frameworks (see http://www3.eureka.be/Home/) funding encourages industrial co-operation in down-stream product and pan-European service innovation.

Some EHR case studies…

How does one choose a "favourite" child? Each one of these funded initiatives has a unique salient characteristic which has already contributes to the corpus of the EHR challenge. And each one is still in progress.

1. **Web based multimedia database system for Orthodontic Patient Records. Joint project between universities of Bergen-Norway, Gothenburg-Sweden, Munich-Germany, Thessalonica-Greece.**
   A shared wish to promote internationalized education and case-based learning, the need to promptly retrieve clinical information regardless of where it is stored, and a commitment in keeping good patient records guided four European orthodontic departments to co-operate in order to enter the digital era. This partnership developed a common, distant-access, standardized patient record system to be used by postgraduate students for case-based self-learning and by instructors for teaching. Agreements were made on content, terminology, recording guidelines, and image standardization issues. An international user-centered design group defined user requirements, carried out context analysis and prototyping, and has subsequently continued testing and validating the system. Ortholine, the main tangible product of this effort, is a relational multimedia database systems that contains full records of patients treated orthodontically (c. 100 images each patient) and is available on the Web at: http://ortholine.ifi.uib.no/user/ortholine$.startup (user name and password: "guest" allows limited view-only access.

2. **Middleware solution for supporting operational and healthcare record needs. Joint project between universities in Dublin, Geneva, London, and Rome.**
   This study focused on the importance of integration of existing systems with their own data and mutually incompatible applications into a central healthcare information system for an entire organization, not only traditional medical personnel. Assuming that the structure of healthcare data would be geographically spread over different centers with different levels of complexity, from general hospitals, to clinics, to GPs themselves, this project addressed the inter-operability and inter-working of the systems from the point of view of application-oriented support and business logic. Middleware was chosen to hide complexity, to allow mapping between elements of the model held within the server, and to extend the underlying model. Data from GEHR, CEN TC-251, GALEN, I4C, Synapses and a host of other systems were brought together with the middleware software developed and named SynEx. Additional application functionalities could also be added.

3. **Confidentiality model for a generic EHR was developed to allow for permissions and, when appropriate, overrides. This project was a result of computer science and medical specialists at Teeside University in England.**
   This group combined the British tendency to separate "medical permissions" from "medical information". As such, the single EHR became a single record where all data and information was

stored and managed. It explored how access rights to medical and other data could be represented as coded data with confidentiality permissions. That confidentiality data formed part of a confidentiality system to control access to parts of the EHR. Electronic transfer of data between clinicians (for instance during referral by a GP to a specialist) was enabled by the GP setting permissions to allow the specialist to access the data but not the confidential information. Override mechanisms were planned and executed. Three scenarios were explored and documented where override restrictions placed on sensitive data (usually social in nature) were temporarily removed. Very controversial. This study alone has caused the EU to heighten its awareness regarding security and personal property on data issues.

4. **Documentation and analysis of problems encountered when a British hospital went paperless. This study, directed by an anaesthetist, questions the need for an EHR.**
Since a birth-to-grave record doesn't yet exist on paper, maybe we should examine whether such a record needs to be produced electronically. What's all the fuss about, the author of the report suggests? Before we can move to an EHR, this project suggests that ownership of data, electronically or on paper, be determined. The research concludes that the primary care sector has a clear view that everything is theirs (and that view is supported by the current politics in England of the National Health Service). But most British primary care sites cannot work electronically with acute care or hospitals in England.

5. **Issues and opportunities in using an EHR for GPs and clinicians were examined by the Phoenix Associates Group in England. Secondary (or peripheral) aspects were shown to be as significant in consideration as the primary focus of a meaty EHR.**
This study posed the concept in question as "fitness for purpose". As a concept in healthcare informatics, the reference is both in the quality of the content and the ability to handle the content appropriately. Integral to effective information use (without reference to the complexities of the data form itself), the research found that aspects needed to be considered were typically: professional skill, quality issues, processes, the context of the EHR, and accurate communication of messages based on data.

6. **Radical solution proposing an episode-oriented patient care management with pre-coded, context sensitive data sets to reduce input for the GP. This unique approach, from an Irish company dedicated to the integrity of patient care, anticipates data entry within a protocol-assisted and problem-oriented structured data form.**
Of all the approaches, this seems the most unique. Research is presented to identify points of friction between GPs (public-at-large) and computers, and the solutions incorporate the issues identified. Structured data sets are linked to ICPC, ICD10, and READ codes. Use of these medical databases reduces text entry on the part of the physician, which is a contentious issue identified early on by Donegal Medical Systems. The approach is episode-based and the file(s) remain open (unresolved) until the episode (reason-for-encounter) is resolved. The holistic notion of patient feedback and patient health is unique in this research. Backbone assumptions to this proposal include: (1)the patient's understanding of the nature of a health problem; (2)the patient's own expectations relating to advice or management; (3)the doctor's interpretation of the cause of the problem; (4)the doctor's view regarding certainty or severity of a health problem; (5)the doctor's interpretation of the patient's need for healthcare; (6)the advice, intervention or management offered by the doctor; and (7)the sequential follow up assessment until problem adequately managed.

Conclusion

In this paper, I have endeavoured to introduce European progress in establishing a cohesive, unified EHR. It is well documented in the literature and regularly explored via international conferences. Yet, in spite of huge leaps in technologies, we do not seem to have come up with an appropriate application and matching architecture to encourage clinicians, as a user group, to enter and retrieve information, without the help of others. Perhaps with the advent of mobile technology (handhelds, cell 3G systems, and their progeny), the considerable amount of work done over the last decade will find willing and enthusiastic partners. At the end of the day, like in the United States, the case of the EHR in Europe will clearly have

to support EU policy developments related to sustainable development and to consumer protection of personal data[2] in our 21st century information society.

2 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ L 281, 23 November 1995, p. 31, and Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerning the processing of personal data and the protection of privacy in the telecommunications sector, OJ L 24, 30 January 1998, p.1.