Medical Infobahn for Europe
A. Hasman et al. (Eds.)
IOS Press, 2000

Systems of evidence-based healthcare and personalised health information: some international and national trends

Colin Gordon[a], J.A. Muir Gray[b], Ben Toth[c], Mario Veloso[d]
[a]*Royal Brompton & Harefield NHS Trust, UK*
[b]*Institute for Health Sciences, Oxford, UK*
[c]*NHS Information Authority, UK*
[d]*CENTIS, Lisbon, Portugal*

Abstract. In Europe, North America and elsewhere, growing interest has focussed on evidence-based healthcare systems, incorporating the deployment of practice guidelines, as a field of application for health telematics. The clinical benefit and technical feasibility of common European approaches to this task has recently been demonstrated. In Europe it is likely that, building on recent progress in electronic health record architecture (EHRA) standards, a sufficient state of maturity can be reached to justify initiation within CEN TC251 of a pre-standards process on guideline content formats during the current 5th Framework of EC RT&D activity. There is now a similar impetus to agree standards for this field in North America. Thanks to fruitful EC-USA contacts during the 4th Framework programme, there is now a chance, given well-planned coordination, to establish a global consensus optimally suited to serve the world-wide delivery and application of evidence-based medicine. This review notes three factors which may accelerate progress to convergence:

(1) revolutionary changes in the knowledge basis of professional/patient/public healthcare partnerships, involving the key role of the Web as a health knowledge resource for citizens, and a rapidly growing market for personalised health information and advice;
(2) the emergence at national levels of digital warehouses of clinical guidelines and EBM knowledge resources, agencies which are capable of brokering common mark-up and interchange media definitions between knowledge providers, industry and healthcare organizations;
(3) the closing gap in knowledge management technology, with the advent of XML and RDF, between approaches and services based respectively on text mark-up and knowledge-base paradigms.

A current project in the UK National Health Service (the *National electronic Library of Health*) is cited as an example of a national initiative designed to harness these trends.

Keywords. Evidence-based healthcare, guideline, digital library, knowledge, standards, citizen.

1. Introduction

In Europe, North America and elsewhere, growing interest has focussed on evidence-based healthcare systems[1], incorporating the deployment of practice guidelines, as a field of application for health telematics. There has been clear evidence for some time that the application of clinical practice guidelines can significantly improve healthcare process and outcome. Shareable telematics methods have been proven to offer a practicable and effective means of routinely delivering these benefits. The clinical benefit and technical feasibility of common European approaches to this task has now been demonstrated.[2,3]

The EC 4th Framework RT&D project **Prestige: Guidelines in Healthcare** created telematics applications in 6 EU countries, based on a common technology which enables *evidence-based clinical practice guidelines* to be disseminated, used and consulted as part of the delivery of healthcare to the individual patient and citizen.[4] The project unified and validated a set of methods, tools and systems which form a *European knowledge space for clinical practice guidelines* - a many-to-many communication medium linking the numerous providers of European guideline knowledge and the varied healthcare sectors and information infrastructures within which care is locally delivered. The technical approach centred on the creation of a suite of generic tools and components based on a shared set of conceptual models, capable of interfacing with existing legacy implementations of the Electronic Health Care Record (EHCR). This approach makes it possible for clinical guidelines created by a variety of European bodies to become available for consultation by clinicians in many

practice settings. Industrially, it enables existing vendors to add value to their existing product, capitalising on the heavy recent investments in advanced implementations of the EHCR. The project defined a common an Interchange Format (IF), based on its conceptual models, for exchange of guidelines between authors, tools and applications in a standard BNF-defined text file format.

Core elements of Prestige technology include a model of guideline knowledge which enables its content to be encoded with specially designed authoring tools in a common, structured format; a software module, the Protocol Manager, which can be integrated in legacy systems to derive patient-specific recommendations from guidelines and an EHCR; and a set of tools and interface definitions allowing guidelines to be written with and converted across different clinical terminologies and healthcare business settings.

The task of integrating this added-value functionality into several existing systems was successfully completed in all six national pilots, with convincing results from practical validation. The applications demonstrated the versatility of the project's generic technology and the range of healthcare contexts in which it can be usefully deployed:

- implementing national standards for cervical screening and influenza vaccination in Dutch primary care;
- a hospital system for guideline-aided management of epilepsy in Portugal;
- applications for managing Type 2 Diabetes mellitus in primary care centres in Portugal and UK, and for GPs managing chronic asthma in the UK;
- hospital cardiology systems for managing angina patients in UK and Germany;
- long-term management of anticoagulation therapy in a regional health network in Denmark;
- supporting a provincial health authority's primary cervical screening and influenza vaccination programmes in Italy.

Implementing the systematic use of evidence-based guideline poses serious challenges in terms of organization and change management as well as technology. An important result of this project was the creation of shareable methods and a growing community of shared experience.

In 1999 the consortium founded and launched the Prestige Association at a public seminar in Lisbon as an international open forum for the guideline telematics community. The Association will be represented in March 2000 at a national invitational consensus workshop being held in Boston, Mass., and will co-host a consensus meeting in London in spring 2000 to coincide with the launch in the UK of the **National electronic Library for Health** [www.nelh.nhs.uk].

2. Plotting the path to the standards process

What needs to be standardised and why?

After decades of r&d in knowledge based systems for healthcare, there are currently no ISO, CEN or ASTM standards for declarative knowledge representation. Experience from Prestige suggests, however, that approaches to *knowledge representation* issues may in many cases be efficiently subsumed under generic *conceptual modelling* methodologies, with UML as the overarching standard, and the XML family of standards as an efficient communication medium.

This approach has recently been taken with encouraging results in the work of the CEN TC251 Working Group1 on a suite of standards for the in electronic health record architecture (EHRA). The team opted for UML for the representation of the core model and XML as the medium for document and message formats derivable via an automated process from that model. They pointed out the benefit of the approach in permitting a syntax-

independent definition of a model capable of providing a basis for a variety of implementation-specific and mutually mappable formats.[5]
Discussion forums such as the workshops of the Prestige project and the Prestige Association (involving dialogues with the projects and actions T-IDDM, ProGuide, Prodigy-3, EON and InterMed), expert panel sessions at AMIA98 and AMIA99, topic sessions at MIE, and a forthcoming USA consensus Meeting (Boston, March 2000) attest to the vigour of interest in the field of guidelines telematics and the value of forums for exchanging experiences within a growing international community.[6] They do not, however, as yet provide evidence of and clear momentum towards a single common approach. The tasks of implementing clinical guidelines with telematic are complex and multiform. Current evidence does not suffice to tell us that there is one best way and that we know what this is. We also lack evidence about the technical and conceptual scope of useful and desirable commonality. In the following section we analyse some key issues and options in this domain.

Development and dissemination of guidelines.
Guideline authors have followed the example of EBM by establishing explicit methodologies for guideline development. So far however little has been done to render explicit the processes of deriving recommendations from evidence, or the ways in which it is expected that guidelines are to be used. Many guideline authors probably envisage their use as a generic educational background resource, rather than for case-by case consultation, and their documents are formulated accordingly. Some guidelines (e.g. those produced by SIGN in Scotland) are explicitly declared not to be intended for direct use in practice but only as a basis for deriving local guidelines where issues of cost-effectiveness and resource availability will be taken into account. The methodology for producing locally adapted guideline is even less well defined than that for the national materials they use as their basis. It would probably be salutory for all concerned if guideline authors were to be more actively involved in the design and implementation of procedures for disseminating and applying their recommendations.

Integration of guidelines into practice.
There is clear evidence that guideline implementation can improve practice, especially when delivered through patient-specific prompts. Computer systems linked to an EHR (and to other key services, notably for prescribing and orders/communications) have proved in several setting effective tools for achieving this result. This does not mean that decision support in the consultation is the only effective way to communicate guideline knowledge. Efficient web-based resources for educational and reference consultation of guidelines, evidence and literature, in various hours and locations, are likely to remain equally indispensable to maintaining the quality of healthcare delivery. Standard mark-up for search and browsing is not less important than standard KR for decision support.

Knowledge-representation and functional requirements of a shared guideline format.
Several benefits are possible from common approaches and convergence towards standards.

- *Many to many guideline dissemination.* Guideline authors will benefit from a knowledge representation standard (backed by shareable, standard-compliant authoring tools) which makes their material usable in multiple sites on multiple clinical information systems platforms.
- The benefit increases in the case of guidelines designed for cooperating use by multiple care agents.
- Vendors and users of clinical informatics platforms have greater incentives for installing guideline implementation capabilities if high quality guideline material is available from several reputable authors in a common format.

- Vendors' development costs may be reduced if common software components, designed to exploit common knowledge formats, can be used within different clinical systems.

Despite these potential benefits, there is little evidence of a clear trend towards conceptual consensus among interested parties, while there are countervailing signs of intensifying competition between proponents of inferencing and authoring technologies based on rival KR models.

Possible ways forward.

This impasse could be overcome by establishing a LINUX-like community sharing development of an open-source inferencing component implementing the semantics of a standard knowledge model. Likely agencies with the influence and authority to broker and lead the adoption of such *de facto* common approaches may be the public-sector and public-interest guideline dissemination agencies and warehouses (in the UK, such candidate agencies are the National Institute for Clinical Excellence and the National Electronic Library for Health). Such a development would generate expanded business opportunities for added-value products linking guideline-driven inference services to EHR platforms, and for the creation of advanced knowledge authoring and management environments.

Progress towards a common model may to some extent be partitioned into a set of sub-problems, such as:

a) An interface for EHR queries.
b) A grammar for expressing criteria which are capable of being tested by means of EHR queries.
c) A grammar for specifying recommended healthcare actions.
d) An algorithm specification for methods used to compute a result or value, which may form a component of a recommendation (e.g. a drug dosage, a risk stratification score, a diagnostic assessment conclusion).
e) An object model for expressing the compositional structure of a protocol and the criteria governing the lifecycle of the use of a protocol and its parts.
f) An interface for connecting a component implementing the semantics of items (b),(c), (d) and (e) and a host clinical information environment.

Consensus on any one of the above topics will begin to yield some of the clinical, business and public-interest benefits identified above.

Several of these issues are interlinked with other areas of current health informatics standards work. Delivery of item (a) depends on standards for EHR architecture. Delivery of item (b) and (c) depends on standards for clinical activity and workflow definition. Items (a), (c) and (e) all imply demands (some of them novel) on the range and expressiveness of clinical terminology schemes.

The standards processes for EHR architecture and terminologies have reached a more mature stage than those for the topics discussed here, so that we can share their methods and build on their existing results, even if the latter are not fully sufficient for our needs.

A preliminary solution for item (a) above could probably be constructed on the basis of emerging standards results for EHCR architecture, and by similar consensus processes including both technical and clinical testing of candidate standards, with equivalent testing of the integrity of knowledge transfer across different systems. Any draft version of a standard comprising items (a) to (f) inclusive above should be accompanied by a joint initiative - as suggested above; a current, national pilot action is outlined below - to create an open-source, public-domain software inferencing module implementing their combined semantics.

Organizational approaches to consensus development and standardization of guideline-sharing formats.

Interest in health informatics for clinical guidelines now far exceeds the evidence base justifying any one approach as the way of the future. Many interesting results exist but all of

these (including our own experiences reported above) remain limited in respect of either (a) prolonged exposure to live clinical use (b) complexity of knowledge content supported (c) dependencies on a technology platform and host system, or (d) proof of use and content sharing across multiple and varying environments. It remains to be established that the healthcare community can learn to master the combined organizational and technological challenges of safely maintaining and managing over time large digital corpuses of complex shared guideline knowledge. For these reasons, approaches to consensus development and standardisation in this domain still need to proceed cautiously and with deliberation.

3. 'Docuknowledge': the closing gap between text and knowledge

The new standards and technologies of XML and RDF (Resource Description Framework: http://www.w3.org/TR/NOTE-rdf-simple-intro) are beginning to provide a much more powerful set of platforms and media for exploiting the possibilities of the Web as a knowledge medium. XML offers a pathway for progressively extending the computerised processing and exploitation of hypermedia documents. RDF enables XML documents to contain embedded, machine-understandable (that is, explicitly modelled and structured) data and metadata content, which can be processed by intelligent software agents and uploaded and downloaded from and to database repositories. An XML document store or database can thus provide:

- highly searchable document content suited for structured browsing,

coupled to

- fully structured data and knowledge sufficient to support the requirements of intelligent clinical management and decision support systems.

In a pilot project of the UK's **National electronic Library of Health**[78], drawing on recent Prestige results and the proposals from WG1, we are proposing to develop and demonstrate an **eXtended electronic Health Library Format** (XHLF) implemented in XML/RDF, to support the services of targeted content access and retrieval combined with personalised recommendations, made available in appropriate forms for healthcare professionals, patients and citizens.

With collaborating systems vendors, we plan to validate a pilot **eXtended electronic Health Library** [XHL] comprising a suite of national clinical guidelines. Based directly on previous Health Telematics results, a **Personalised Advisor [PA]** module will be created as a public-domain open-source software resource, freely available for incorporation in a number of demonstration system and service configurations. Installed at a website and/or a personal or clinical health system platform, the PA will provide case-specific and personalised recommendation services, using XHLF format guidelines, together with interactive browser screens and/or connection to an EHCRs.

This service will thus be connectable to, and functionally integrated with *distributed healthcare record architectures*. It will, additionally, be integrated in one or more national pilots with *personal health systems*, using telematics and clinical guidelines to support self-monitoring and self-management of long-term therapy in both mobile and home settings - a concept which one of our European partners has called 'medical home banking'.

4. Conclusions: the national digital warehouse and the knowledge-enabled citizen

At least four major contemporary forces drive current thinking about the concept of an Information Society in the domains of healthcare and health:

- The *social and technological effects of the new multimedia and communications technologies*, and especially the World Wide Web in expanding citizens' access to, and

consequently their demand for personal access to information and information services in all fields of life including the domains of health and healthcare;

- The demand from governments, service providers, citizens and patients and service clients, for *continuous improvement in the efficiency and quality of health care and health promotion services*, delivering the greatest possible benefits from biomedical sciences and technologies which are in continuous growth and transformation;
- The world-wide *movement for promotion and practice of evidence-based medicine and healthcare* which has convinced policy makers of the agenda of a 'knowledge-based health service', in which the effective dissemination and application of evidence about appropriate and effective healthcare is seen as an essential strategy to satisfy the increasingly exacting demands noted above;
- The demand for *seamless healthcare*, that is, for a well coordinated service to the individual client from all the sectors and professions of health service he or she may pass through and encounter, both along a care pathway and over a lifetime.

It is estimated that 6% of the EU population suffers from a rare disease, about many of which the patient may well now become more knowledgeable about her/his condition than a busy family physician; rare diseases is one of the EU's key declared health priorities. The advent of the 'expert patient' is likely to revolutionise the clinical relationship between professional and client. Both partners will in future be users of health knowledge services in ways which can enhance the quality of service delivered, while also making the client an active and co-responsible partner in a more cost-effective system of care. Thus, for example, the UK NHS has recently launched its **NHS Direct** web site (www.nhs.uk), which includes an interactive triage advice service for the general public. In the context of this type of initiative, health telematics has the opportunity to enable the coordinated and effective delivery of personalised, evidence-based health information to clinician and citizen alike.

References

[1] JA Muir Gray,. *Evidence-Based Healthcare.* Churchill Livingstone London 1997.

[2] C Gordon and J P Christensen eds., *Health Telematics for Clinical Guidelines and Protocols*, IOS Press 1994.

[3] "Prestige: Guidelines in Healthcare. Final Report, Executive Summary for Publication", European Commission DG XIII, London/Brussels 2000. [www.rbh.nthames.nhs.uk/prestige]

[4] Colin Gordon, Mario Veloso and the PRESTIGE Consortium, "Guidelines in Healthcare: the experience of the Prestige project", Proceedings of MIE99.

[5] David C. Markwell "Validation of a European Message Standard for Electronic Health Records", Proceedings of MIE 99.

[6] Mark A. Musen, Robert A. Jenders, Colin Gordon, Aziz Boxwala, Samson W. Tu, "Sharing Knowledge for Clinical Practice Guidelines: Are We There Yet?" A panel discussion at the 1999 AMIA Annual Symposium. http://smi-web.stanford.edu/projects/kmg/guideline_panel/index.html.

[7] Colin Gordon, "UK backs IT" *Healthcare Information Technology* Autumn/Winter 1999/2000 CCL Commerce, London.

[8] J A Muir Gray, Simon de Lusignan, "National electronic Library for Health (NeLH) ", BMJ 1999;319:1476-1479 (4 December).