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Guidelines in Healthcare: the experience of the *Prestige* project

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Abstract. The paper reports the work and results of *PRESTIGE*: **Guidelines in Healthcare**, a large EU project designed to applying ICT to assist the application of clinical practice guidelines.

PRESTIGE: Guidelines in Healthcare [a project in the EC's Telematics Application Programme (DG XIII C4), December 1995-May 1999] is one of the most extensive initiatives yet undertaken worldwide to apply information and communication technology to assist healthcare professionals in the daily application of evidence-based guidelines of best practice. The project has been a collaboration of 30 organizations from eight countries, representing all the key players whose contribution is essential to this initiative: national and international bodies which are authors of standard clinical guidelines, health authorities, associations of clinical professionals, commercial system suppliers in primary and secondary care, academic centres, hospitals and health centres. The project has created clinical applications in six countries, linked to established clinical IT environments, with programmes for validation in routine practice. The aim of the project is "an installed and sustainable healthcare telematics infrastructure that supports dissemination and application of research based and consensus based guidelines, that in turn supports best practice for routine clinical care".

This undertaking involves a challenging combination of cultural, technical and organizational change. European health services are, however, increasingly accepting the goals as essential and committing themselves to mobilising the necessary policies and resources to carry them through.[1]

Some of the component tasks in this agenda for which *PRESTIGE* sets out to prove workable solutions are:

- The need to add new modules of functionality to a range of existing clinical IT environments in existing healthcare settings;
- The need to raise the existing level of implementations of the Electronic Patient Record, to provide a data infrastructure able to support patient specific application of guideline recommendations through individualised care planning over time;
- The need to incorporate new person-machine interactions within the process of the patient consultation in a workable and acceptable manner, and to fit the process of applying evidence in practice;
- The need for a shared methodology to convert the text of published clinical guidelines, and the intentions of their authors, into a formal, machine-readable semantic structure capable of being reliably combined with computerised clinical data to generate recommendations for action;

- The need for a sound, sustainable process for maintaining, disseminating and locally adapting electronic versions of clinical guidelines.

The PRESTIGE Consortium

CENTIS	WHO DiabCare, Munich
Hospital de Egas Moniz	Mainz University Heart Centre
Anestesia, Reanimação e Nurologia	OSE
UNINOVA	SAPHIS
Health Region of Lisbon and Tejo Valley	Bull France
	Danish Institute for Health Services
Royal Brompton & Harefield NHS Trust	County of Funen
	Gentofte Hospital
MIG, University of Manchester	LHV
UK WHO DiabCare Office	SMS Cendata
NHS IMC, UK	NHG
Sowerby Unit, Newcastle University	MIE, University of Nijmegen
Siemens Nixdorf Healthcare Solutions	Modena Local Health Unit
Royal College of Radiologists	THETA
AAH Meditel Ltd.	SIMG
Bromley Hospitals NHS Trust	Linkoping University Hospital

The rationale for a European collaborative initiative of this kind is both industrial and clinical.

Industrially, the development of common reusable components of technology provides vendors of clinical practice systems in national markets with an affordable path to adding major functionality and added value to their product in areas where national healthcare providers and users demand continuous improvements in its support for delivery of healthcare quality.

Clinically, the creation of a common electronic format for protocols provides international and national professional consensus bodies with a route for more effective dissemination and implementation of best practice standards which can 'plug and play' on a variety of clinical software platforms at the point of care. PRESTIGE's results should accelerate movement towards sound and workable European standards to make this vision a reality.

In the following we set out some key points in the technical results achieved to date.

- PRESTIGE technology functions with local and existing **patient record database** structures. Each application has linked generic PRESTIGE technology to a locally designed implementation of the electronic patient record.
- All applications contain a common **Protocol Manager** (the software component which identifies clinical guideline recommendation relevant to a specific patient). The Protocol Manager is being used in all the project's applications, and is supplied in the form of a developer's source code kit and as an ActiveX control. Its external interfaces have been successfully used to connect it to each application's Operational Front End, Patient Record and Knowledge Server.
- The project has a set of shared and local services for creating and storing **protocol knowledge**. The project has a common conceptual model of protocol knowledge; some applications are sharing database implementations to represent protocol knowledge in the runtime system. Several applications have used the tools **GAUDI (Guideline AUthoring and DIssemination Tool),** which incorporates a terminology server and

model (GRAIL) developed by the GALEN organization. Some applications use the tool **GLEAM (Guideline Editing and Authoring Module)** which has the capability to directly edit the knowledge base of an application. A project-wide Interchange Format for protocols and their associated terminology has been defined and is being used as a common transfer medium between GAUDI, GLEAM and the various project application platforms (see diagram and illustrations below). Partners in one application (THETA I.T.; Modena Local Health Unit, Italy) implemented its own tool (PAT: Protocol Authoring Tool) to edit its protocol knowledgebase.

- The project has produced a suite of generic **Act Management** software (that is, tools for managing shared information on requested and performed activities in a cooperative healthcare environment) and which implements the same conceptual model as the Protocol, Manager and Authoring Tools. These servers have been validated in a HIS environment at Hospital Egas Moniz, Lisbon. Other applications have implemented equivalent, appropriate forms of act management support for the primary care environment.

Guidelines implemented
Cervical Screening (primary care - NL, IT)
Influenza vaccination (primary care - NL, IT)
Diabetes Management (primary care - UK, PT)
Angina Management (primary care, hospital care - UK, DE)
Asthma Management (primary care, UK)
Epilepsy Care Planning (primary care, hospital care - PT, DK)
Anticoagulant Therapy (primary care, hospital care - DK)

Approach to Knowledge Modelling

In its initial phase, PRESTIGE developed a suite of object-oriented conceptual model definitions of the healthcare enterprise, the patient healthcare record and the protocol. The model was used to derive a set of shared component interface definitions, authoring tools and an Interchange Format (IF) for exchange of guidelines between authors and application in a standard BNF-defined text file format.

The approach to knowledge representation is declarative, based on the separation of knowledge structure from knowledge use. A protocol is basically conceived as a compositional hierarchy in which a main protocol (with its entry and exclusion criteria) is composed of a number of component protocols, which may themselves have further components. A leaf node protocol always contains a specification of an act recommended by the guideline. The logic of the protocol - what should be done when - is given by the compositional structure together with *lifecycle criteria* which can be specified for the component protocols and (if required) for the act which they specify.

A practical issue which demanded close attention and consistent handling in the project application was the correct coordination of the protocol model with the local application EPR, its coding system(s), and the working and technical environment of the user healthcare enterprise. This enables a clear division of tasks between:

- **the Protocol Manager,** which uses the standard constructs of the Protocol Model criterion grammar to logically evaluate the criteria specified in a protocol for recommended actions,
- **the Application EPR**, invoked by the Protocol Manager to evaluate a *Subject Phenomenon* expression which may be constructed using coded terminology constructs local to that EPR

- **the host clinical management system,** which can be invoked to assist in performing a recommended class of act specified in a protocol, by activating a corresponding functional service (e.g. communicate a booking request, enable generation of a drug prescription).

The adoption of this layered and partitioned modelling approach thus enables two key architectural and organizational benefits:

- The smooth functional coupling of new generic technology and existing, legacy technology functions;
- A clear framework for adapting and customising a shared (national or international) guideline to use with a locally specified dataset, technical infrastructure and service structure.

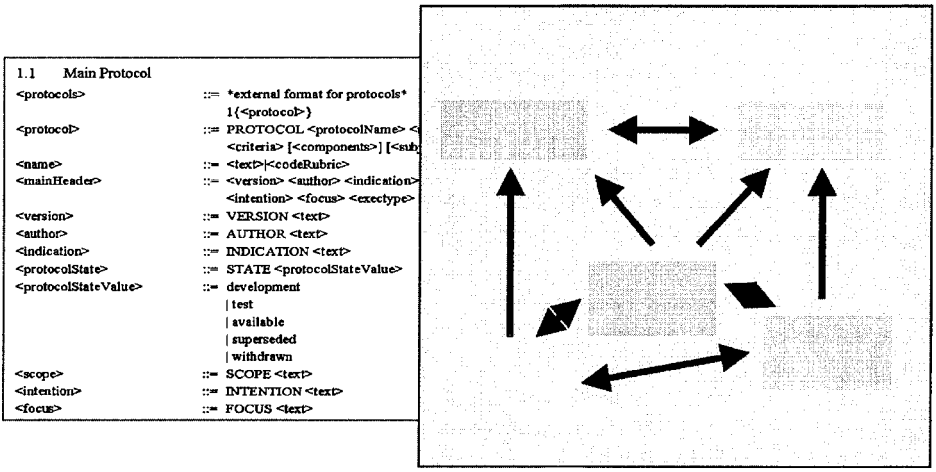

Figure 1. The PRESTIGE Guideline Interchange Format

Lessons and further steps

A major part of the clinical activity in any protocol is collecting datasets (e.g. patient history, current medication, family history, physical examination, test results, etc.) Our model envisaged providing a fully declarative definition of the data capture mechanisms required for such activities (specifying which data items are mandatory or optional, whether existing data items should be displayed and whether these need to be systematically reconfirmed). To date it has not yet been practicable to use such a declarative specification to automatically generate and drive specific data entry dialogue for each act. Our current applications thus comprise either coded dialogs for each act class (a common approach in a hospital clinic) or generic system functions, not tailored to the specific protocol (a common approach in GP systems).

The EC's auditors reported in November 1998 that PRESTIGE had set itself "an ambitious goal" but "demonstrated solutions convincingly". Remarking that the results had "theoretical huge potential" but pointed to two potential bottlenecks: the availability of a supply of guidelines processed into the required format, and the achievement of compatibility and integration between PRESTIGE's technology and existing and used software for the EPR.

We agree these are two key areas where much work remains to be done and a high level of effort will be required. There are still significant conceptual, cultural and clinical lessons to be learned before guideline working groups are routinely able to convert their product in computer-intelligible forms.

Indeed the very agenda of patient-specific application of guidelines in the consultation, although well justified by existing research results, sometimes demands greater explicitness and definition of guideline content than the cautious and nuanced wordings, evolved through consensus and compromise, currently provided in published guidelines. We anticipate that the availability of computer-aided implementation pathways will impact on and feedback into the guideline definition process, and it is desirable and necessary that this should occur.

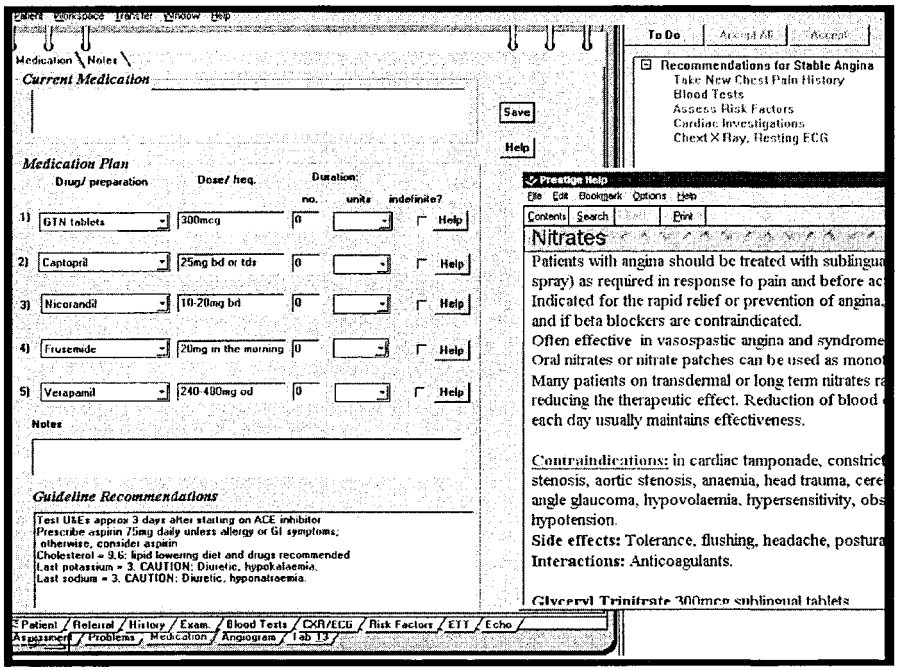

Figure 2. Assistance for medication planning using a guideline for managing Stable Angina

Web technologies can now provide major supports and intermediate steps in progress towards electronic dissemination of guideline knowledge in computer-intelligible form. Some organizations like the USA's Agency for Health Care Policy Research (AHCPR) already make their guidelines available as web documents, although with as yet limited exploitation of the full power of hypertext. The release by the WWW Consortium in 1998 of the Extensible Markup Language (XML) and Resource Description Framework (RDF) standards promise to greatly enhance the capabilities of the Web as a medium for communication of structured clinical knowledge and data.[2] The accumulation of experience from initiatives like *PRESTIGE* in 'full content' guideline knowledge representation should within the next few years provide a solid basis for a fuller standardised structuring of electronic health service knowledge resources in both document and knowledge base formats. In the short term the *PRESTIGE* Association may shortly investigate establishing an XML/RDF version of its existing guidelines Interchange Format.

The second key bottleneck identified by our auditors relates to the cost and difficulty of connecting new functional components based on a common data and knowledge standard to the multiplicity of existing commercial platforms for clinical management in European healthcare. PRESTIGE has gained ground-breaking experience by working on this problem with leading commercial GP system suppliers in four EC States (UK, NL, DK, IT), with close technical consultation with engineers developing next-generation versions of these companies' products. Our project was based on the premise that this exercise is unavoidable and necessary. Support for the practice of evidence-based medicine is a service to the clinician which supplements and must build on the more basic services provided by existing products for practice management and patient data management. The complexity of this existing market and product type precludes any realistic prospect of implementing common services across Europe for guideline implementation through a common new product which would supplant the less advanced approaches currently in use. On the other hand, the progress made by the existing suppliers in developing a more complete, structured and expressive database for the patient record, and the maturing of modular architectures for client PC applications, have meant that some of the systems are now well suited to support the additional level of functionality PRESTIGE can offer.

In an initiative explicitly supported by the European Commission and its auditors, the PRESTIGE consortium launched in March 1999 (at a public meeting in Lisbon, sponsored by Portugal TELECOM, Siemens Portugal and Portuguese health services), the PRESTIGE **Association**, an ongoing, open-membership organization designed to build and extend the community of shared experience and consensus in the domain of technology for guidelines in healthcare. The Association will provide an umbrella for practical collaborations between clinical systems suppliers in different national markets, working along parallel lines to extend the capabilities of their products for supporting evidence-based medicine. It will also act as a forum for the building of alliances between the communities of guideline authors, evidence-based medicine initiatives (such as the Cochrane Collaboration), and the health telematics community, to ensure that in the future guideline developers are aware of and fully able to exploit technology for structured representation and computer-aided implementation of clinical guidelines.[3] It will cooperate with the health service research community to study in further detail the critical success factors and ongoing effectiveness, in terms of process and outcome, of the computer-assisted use of clinical practice guidelines.

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[1] NHS Executive, *Information for Health. An Information Strategy for the Modern NHS 1998-2005.* London 1998.

[2] Cf. the keynote address by Tim Berners-Lee at AMIA98: *Web Phase II: Evolution or Revolution?* [http://www.w3.org/Talks/1998/1108-amia-tbl/slide1-1.htm]

[3] C Gordon, 'Practice Guidelines and Healthcare Telematics: Towards an Alliance', in C Gordon and J P Christensen eds., Health Telematics for Clinical Guidelines and Protocols, IOS Press 1995.