International Journal of Medical, Medicine and Health Sciences
ISSN: 2517-9969
Vol:1, No:12, 2007

The PARADIGMA Approach for Cooperative Work in the Medical Domain

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***Abstract*—**PARADIGMA (PARticipative Approach to DIsease Global Management) is a pilot project which aims to develop and demonstrate an Internet based reference framework to share scientific resources and findings in the treatment of major diseases. PARADIGMA defines and disseminates a common methodology and optimised protocols (Clinical Pathways) to support service functions directed to patients and individuals on matters like prevention, post-hospitalisation support and awareness. PARADIGMA will provide a platform of information services - user oriented and optimised against social, cultural and technological constraints - supporting the Health Care Global System of the Euro-Mediterranean Community in a continuous improvement process.

Keywords - Decision Support Systems, Ontology, Healt Care, Clinical Pathway

I. Introduction

PARADIGMA (PARticipative Approach to DIsease Global Management) is a pilot project of EUMEDIS, a regional MEDA project for the development of the Euro-Mediterranean Information Society. PARADIGMA aims to develop and demonstrate an Internet based reference framework to share scientific resources and findings in the treatment of major diseases, and started in June 2003.

Resolutions of the World Health Organisation suggest that population-based medicine has to become the new approach to patient care, co-ordinating medical resources for patients across the entire health care delivery system, and indicate new technologies as powerful means to support its enactment. Population-based medicine, including Disease Management, is a structured response to a set of problems of healthcare systems which results in:

- reduction of costs in the health care environment by means of the improvement of performances (dia-gnosis and therapy pathways, hospitalisation, etc.);
- redirecting of services and capabilities towards the consideration and care of the overall needs of the patient-person and not only focusing on the purely medical needs of the clinical-case;
- creating a network of care structures, aimed to compare schemes and experiences in medical practice, for continuous information exchange and improvement;
- increasing patient satisfaction by providing, in less time, the best practice and more complete assistance to take care for the whole needs related to a patient's disease;
- enhanced synergy under the organisational, cultural, informative and formative point of view, enhancing the quality of care processes and, most of all, the quality of a patient's life.

The PARADIGMA approach to Disease Management, viewing patients as entities experiencing the clinical course of a disease (rather than their care as a series of discrete episodes or as fragmentary encounters with different parts of the healthcare system), is fully in line with the above guidelines.

PARADIGMA choses to concentrate on expertise from the following Health Care domains, whose main aspects, from prevention to follow-up, will be addressed to define optimal practice, according to specific social, cultural, technological and organisational conditions:

- Profilaxis of thrombo-embolism and monitoring of anticoagulant treatment
- Prevention focused, infant death reduction from pregnancy to the first year of life
- Colorectal cancer prevention and treatment
- Evaluation and improvement of performance in intensive care.

The reason for this choice has to be found in the relevance these themes have in the Euro-Mediterranean community.

The PARADIGMA environment is based on two main technological components: the **Ontology** and the **Navigator**. In the ontology the whole domain, or that part of it significant to the specific context to be supported, is described both according with a standard enterprise modeling methodology (CIMOSA [1] – ENV40003 [2]), and according to a well-defined ontology theory [3].

The outline of the paper is as follows. Section 2 deals with the PARADIGMA's project strucuture. In this section the core architecture of the Care System under development is illustrated. Section 3 introduces the methodological approach adopted in PARADIGMA and illustrates the architecture of a tool, the Navigator, which supports service functions directed to the different types of system users. Lastly, section 4 contains some conclusions and suggestions for future research.

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II. Project Structure

PARADIGMA's objective is to support Disease Management improvement, focusing on needs and characteristics of patients, workforce and structures. The structure of the project previews the subdivision of the activities in a sequence of phases (Fig. 1).

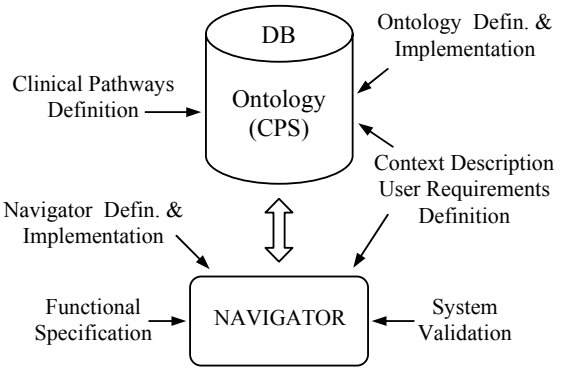

Fig 1 Project Structure

The first phase is made up of the following activities: Context Description, User Requirements Definition, and Ontology Definition and Implementation. The context description provides formalisation of the "as is" reality at the start of the project. The user requirements definition provides a definition of a set of possible use scenarios, from which to derive the related user requirements. Both the activities concern the specification of organisation, processes, resources, information of the reality of pilot sites. All the knowledge acquired in these steps will be stored in a structured dictionary of concepts called **Ontology**. An ontology is a reference framework, i.e. a shared view of parts of the world (the Disease Management System domain) which provide conceptualisations that are agreed upon by people engaged in collaborative actions.

The shared nature of these conceptualisations allows people or programs to communicate effectively and supports the development of information systems by building interoperable components that view and manipulate information in a unified, clearly defined and consistent manner.

The second phase is made up of Clinical Pathway Schema definition. Clinical Pathway Schemata (CPS), modelling management processes for disease in a generalised context, provide guidelines for the description of disease processes within the Ontology. In the CPS, the scientific, technological, organisational and human aspects of medical practices are related into a network of activities with their mutual relations. The next step to be afforded is the definition of a certain number of specific *Clinical Protocols*, focusing the CPS on the diseases under analysis.

Clinical Pathway Schemata and Clinical Protocols will be integrated in the ontology that will be stored in a structured way in a relational database management system integrated in the PARADIGMA environment.

The next phase of the project concerns the *Functional Specifications* of the PARADIGMA Navigator. It comes from comparing, in a significant number of medical structures, the "as is" situation and the expected services and facilities, with procedures and protocols defined inside each Clinical Protocol.

The Navigator provides a set of disease oriented and context adaptive services, developed and integrated according with functional requirements and technological constraints, based on a user friendly "navigation" of the ontology and of information stored on several local data bases, seen as one.

The Navigator infrastructure is provided by a software application based on the WEB technology that will communicate with the relational databases provided by the PARADIGMA infrastructure.

The last phase of the project provides the activities of validation, test an tuning for the entire system. System Validation against user requirements, performed in several verification steps, is the basis for former optimisation of Navigator services.

III. Methodological Approach and Technical Solutions

The PARADIGMA framework will make provision for suitable user interfaces both to input data (electronic forms, questionnaires, guided interviews, etc.) and to navigate (user and context oriented interfaces, customised functionalities, aimed training, etc.) the framework itself. Moreover, IT and Health Care expertise are needed to benchmark, customise and use existing commercial tools, both for formalising the Ontology and for implementing Navigator functionalities.

A. Ontology Definition

Analysis methods and modelling methodologies will be applied to care practice and human interaction, beginning with an analysis of the relevant disease management variables, in terms of their implications for the design and operation of the overall structure of the work system and related processes. All this involves systematic analysis of organisation key characteristics: available technology, professional profiles, behavioural models of all involved humans, social and cultural aspects of the overall environment. Once the key characteristics of the overall care system have been determined, they, in turn, prescribe many of the factors that need to be customised into the individual jobs, specific work processes and human interfaces.

The project will develop an extensible and modular ontology to meet two main objectives, the resolution of the heterogeneity of the digital assets and the support for those involved in the health care system [4].

In medical operations, the ontology is concerned with the use or application of models and data during the whole disease management process. It links goals and (programmed) activities of people to past, actual and future, possible and impossible, states and flows of the physical domain, and links

flows to transformations of signs (structured by means of models) in the information domain. The schemata according to which (and the formats in which) data, models and functions are offered to the users, by the computer networks, are stored in the ontology. The PARADIGMA Ontology is layered at four generical levels as follows:

1. **Core Ontology** core level
2. **Enterprise Ontology** generic level
3. **Health Care Ontology** partial level
4. **Disease Area Ontologies** particular level

- **Core Ontology** states Entities, Relationships and Constraints as basic Concepts, to be applied in the modelling.
- **Enterprise Ontology** introduces new concepts, specialising the Core Ontology ones, which are specific to model a generic Enterprise.
- **Health Care Ontology** states new concepts, defined at partial level, specialising Enterprise Ontology ones, which are specific to model the Health Care Domain. People involved in the PARADIGMA context can use them to build and share a common knowledge on the Health Care Domain.
- **Disease Area Ontologies** state new Concepts, defined at particular level, specialising the Health Care Ontology ones, applicable to the Disease Areas of each Competence Group. These concepts can be used to build and share common knowledge on specific Disease Management.

Moving trough the levels of the Ontology, gradually new and ever more specific concepts are introduced by specialisation of the more abstract concepts in previous levels. These concepts will be used in the phase of definition and formalization of Clinical Pathways.

The diagram in Fig. 2 shows the dependences of the packages that compose the *PARADIGMA Ontology*. The *Enterprise Ontology* depends from *Core Ontology* and *Standard Ontologies*. The *Health Care Ontology* depends from Enterprise Ontology, allowing to derive each of *Disease Area Ontology*.

The Core Ontology (see Fig. 3) comprises three main generic concepts: *Function*, *Object* and *Information*. These concepts are linked to each other by two fundamental relationships: *involved* existing between function and object, and *relevance* linking each of the three concepts to the fundamental concept information.

Function captures the notion of a transformation to a thing or change. Within the organisation, change consists of the execution of functions to objects, e.g., by transforming *inputs (objects)* into *outputs (objects)*, given some conditions verified.

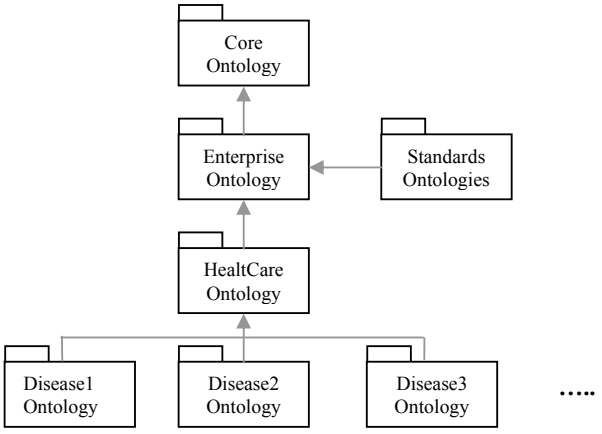

Fig. 2 Paradigma Reference Ontology Levels

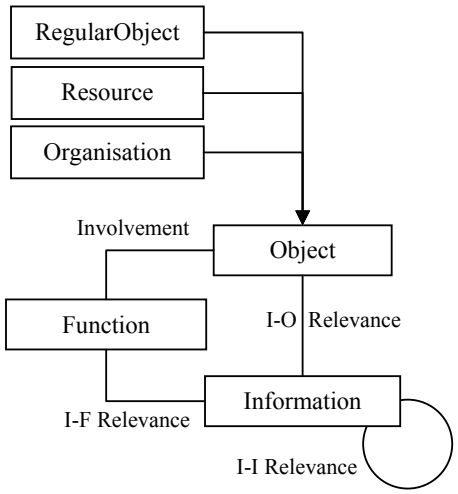

Fig. 3 The PARADIGMA Core Ontology

Object is something, not being available at anytime, that allows the function performing. The concepts RegularObject, Resource and Organisation, extend the core model, as specialisation of the Object basic concept. The fact that a concept (e.g. Resource in Fig. 3) is more specific of another (Object) means that a resource is (ISA) an object, while it is not true the contrary.

Information is a simple or composite characteristic of any core elements, Object, Function or another Information, which are used to constrain them, directly or indirectly.

Relevance means "is related to". Some information is related to objects, other to functions or to information (recursively), thus this relationship has been differentiated into I-O Relevance, I-F Relevance, and I-I Relevance.

Involvement represents the fact that an object can be involved in the application of a function. This involvement can be seen as an input, output or resource for example. Involvement as an output means that the object can be the result of the function.

Fig. 4 shows the specialization at the generic level of the

Information concept.

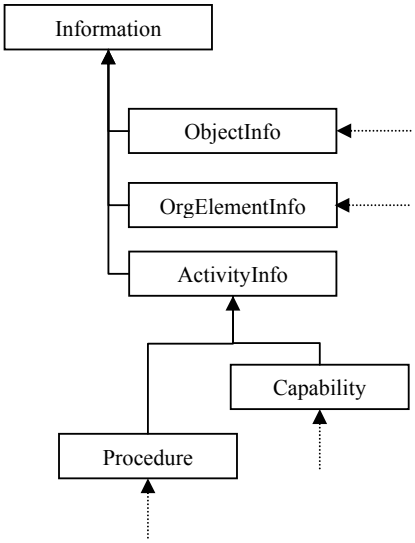

Fig. 4 Ontology fragment at the Generic Level

The PARADIGMA Ontology, especially the components at partial and particular levels, allows people thinking at the abstract level they need for Domain Modelling, without be annoyed by details, as terms and local practices. By using the Reference Ontology at partial level, it is possible to define the conceptual structure of a generic Clinical Pathway, which can be specialized to derive Clinical Pathway templates, less o more suitable for the use in the context of each Disease Area.

As an example of the Partial Level, Fig. 5 shows the fragment which details the concept of ClinicalCapability which is, in turn, a specialization of the concept of Capability at the Generic Level.

Concepts relevant for the Particular Level of the ontology can be obtained by specialization of the Partial Level. Disease Area Ontologies at the Particular Level are specific for each pilot study.

B. Navigator Definition and Implementation

In the PARADIGMA project a participative approach is supported. This means that a certain number of users, virtually working as a group by means of IT, should be able to give each other visibility on problems and possible solutions, to share data and exchange information. An environment enabling such a work approach will, therefore, represent a powerful support to the management and optimisation of operative realities, by supporting decisions and enabling checking alternative operative solutions from all points of view against the final global objective.

To provide integrated support to a variety of different users in a Health Care Structure, a tool, the PARADIGMA Navigator, has been developed. The Navigator should select the most suitable solution to a health care problem from a given set, for specific types of problems, actors and resources, providing for customised user interfaces.

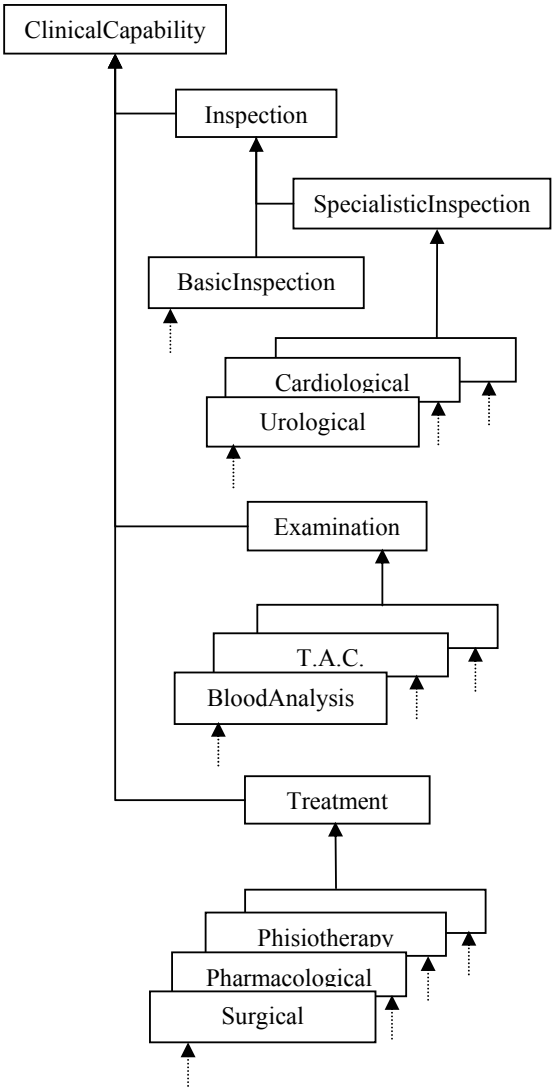

Fig. 5 Ontology fragment at the Partial Level

The Navigator knows, through the Ontology, the way each user approaches the PARADIGMA environment. Furthermore it knows which information (s)he will be given and what other support is needed to accomplish the job.

When a *User* introduces himself to PARADIGMA via the Navigator, (s)he will be informed of the *tasks* (s)he is allowed and/or required to perform at that moment, according to the clinical protocol description and the resouces that are currently available. The user, then, chooses which *task* (s)he wants to perform and the PSIM Environment will support the chosen task by providing highly visual and computable representations of clinical protocol that are used as a common basis for discussions and proposals, in a way that is coherent, logical and easy to understand.

The Navigator IT infrastructure is the result of the integration of three systems (see Fig. 6):

SPM	System for Presentation Management	[level 1]
SSM	System for Services Management	[level 2]
SKS	System for Knowledge Storing	[level 3]

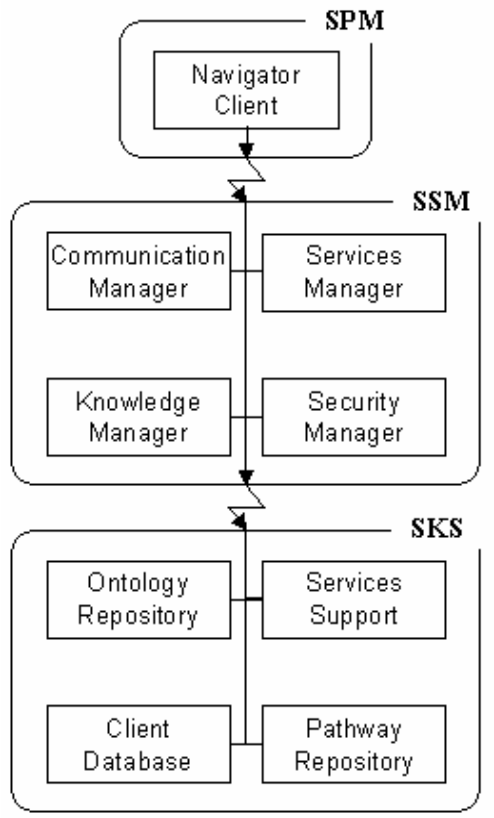

Fig. 6 NAVIGATOR architecture (top level)

The System for Presentation Management at level 1 and the systems at level 2 and 3 are separated by a communication channel (Internet or intranet). Each system works as a stand alone system; the integration of the three systems is made only by means of predefined input/output interfaces.

The System for Presentation Management contains the Navigator Client, a graphical user interface (GUI) which makes available functionalities for the acquisition of the user inputs and for the presentation of specific outputs about activated procedures and services.

The System for Services Management provides an environment to control an to manage the information. It provides many services to define concepts, to exchange information between different systems and to maintain the security of the information.

The System for Knowledge Storing provides an environment to store the knowledge in a structured way. It contains databases which store all the data describing the ontology, the clinical pathways, the clients (users and Pilot Sites features), and the supports for the services at higher level.

The NAVIGATOR infrastructure proceeds through a cyclical flow of request/response that take advantage of predefined and standard system interfaces. The communication protocol among the systems is standard XML.

IV. Conclusion

The Navigator represents the most important software tool which will be developed in the PARADIGMA project, making use of the opportunities that modern ICT offers. It would be a clever interface between the Health Care structure, its processes, data and objectives, and each user (doctor, nurse,…), his job, capabilities, work environment and support tools, making data exchange between several tools possible.

Besides this, the Navigator will provide the PARADIGMA users an easy to use and attractive interface to go through the procedural steps of Clinical Pathways and use the available tools in the process of solving problems.

The following impacts are to be expected from the research and development in the project:

1) the improvement of performances (diagnosis and therapy pathways, hospitalisation, etc.) and the reduction of costs in the health care environment;

2) the creation of a network of care structures, aimed to compare schemes and experiences in medical practice, for continuous information exchange and improvement;

3) the increase of patient satisfaction by providing, in less time, the best practice and more complete assistance to take care for the whole needs related to a patient's disease.

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