The PROGEMM Approach For Managing Clinical Processes

Kerstin Maximini, Martin Schaaf
University of Hildesheim,
Institute for Mathematics and Applied Computer Science
Data and Knowledge Management Group
P.O. Box 101363, D-31113 Hildesheim, Germany
{k_maximi, schaaf}@dwm.uni-hildesheim.de

Abstract

*In medical healthcare two contrasting tendencies can be observed. On the one hand, recent technological advancements allow maintaining a quality in medical treatment that was hardly to imagine some years ago. On the other hand, the investment in newer medical devices and the necessary training of the physicians is highly cost intensive and can be hardly regained without proper management of the clinical processes. This is the aim of the PROGEMM (**PR**ocess-**O**riented **GE**neric **M**anagement of **M**edical Knowledge) approach that is presented in this paper. PROGEMM combines the specification and execution of structured workflows combined with highly flexible and knowledge-intensive tasks. It assists physicians as well as other medical professionals in their daily work and, because it is based on the widespread DICOM (Digital Imaging and Communications in Medicine) standard, provides a platform for collaboration among physically dispersed physicians.*

1 Introduction

Due to the tremendous progress in health care over the last years, there is a gap between the achievable medical treatment and what most clinics currently accomplish. Recent technological advancements require constant training of the physicians in order to maintain a certain quality. This is especially true for *health care organizations (HCOs)* with high fluctuation of the employees. Sophisticated devices like *Nuclear Magnetic Resonance (NMR)* are very expensive and, in times of increasing cost pressure, regaining the investment usually requires them to be shared between multiple clinics. Thus, physicians at different locations can be considered as loosely coupled societies that must be supported by a proper collaboration infrastructure. Although more and more HCOs rely on computer-based support that ranges from simple electronic guides to intelligent assistant systems facilitated by technologies like *Case-Based Reasoning (CBR)* [6][7], most of the current approaches are isolated focusing only on particular tasks of the medical treatment of patients. They are not integrated into to the overall clinical workflow and do not consider the cooperation aspects among physicians. As a result, maintaining the patient records requires a lot of effort and even in the case of a well-documented medical treatment it is very common that particular diagnosis tasks are executed multiple times. Furthermore, patient records typically do not capture information from communication sessions (e.g. face-to-face communication) between physicians, which are important results from the execution of agile medical processes.

In this paper we present the PROGEMM (**PR**ocess-**O**riented **GE**neric **M**anagement of **M**edical Knowledge) approach that aims to support the specification, maintenance, and execution of clinical processes. A major objective of PROGEMM is to support the execution of structured workflows as well as knowledge-intensive tasks that cannot be fully described in advance. The latter is extremely important because experience with our partners in Brazil and Germany has shown that physicians require a high degree of freedom for processes based on their medical expertise. Furthermore, it was necessary to avoid the introduction of more or less formal document standards for the information flow between particular tasks. The PROGEMM approach should not enforce physicians to follow a predefined methodology.

PROGEMM is currently under development by the University of Hildesheim in Germany, and the Fedaral University of Santa Catarina (UFSC) in Brazil and will be evaluated by at least three HCOs in both countries, namely two radiological hospitals ("Radiologische Gemeinschaftspraxis Dres. Buddenbrock, Blasinger, Benz", in Germany and "Clínica de Diagnóstico Médico por Imagem SC/LTDA (DMI)" in Brazil) and one general hospital ("Regional Hospital of the Upper Itajai Valley (HRAV)" in Brazil).

In the first section we will give a brief introduction of the initial situation, the different types of processes, and the scenarios that motivated the development of PROGEMM. In section 3 a more technical description is provided with focus on the *DICOM Standard (Digital Imaging and Communications in Medicine)* that has been adopted for storing and transferring information about patients gained during execution of clinical processes. We

will conclude with the evaluation plan of PROGEMM and additional work that has to be carried out in the near future.

2 Processes from the Medical Domain

PROGEMM has been developed for supporting a variety of processes in clinics. We basically distinguish between the following types of processes.

Guidelines: Following the definition proposed in [1], guidelines are "… an attempt to distill a large body of medical expertise into a convenient, readily usable format."

Clinical Practice Guideline: "A predefined policy that allows a health care organization to manage patients with a certain presenting condition in a standardized manner. More extensively: systematically developed statements to assist practitioner and patient decision about health care for specific clinical circumstances." [2]

Organizational Processes: In our terminology, an Organizational Process is in fact a patient management process, e.g., starting with the patient's registration in a radiological hospital and including steps like image acquisition and image interpretation, the writing of the report, and the transfer back to the referring physician. Organizational processes are general descriptions and do not include patient specific information.

The difference between the particular types of processes lies mainly in their different degree of formality. While *Guidelines* are usually weakly structured comprising a set of recommendations how to maintain a certain quality in medical treatment, *Organizational Processes* are highly structured; their individual steps can be fully described in advance.

2.1 Application Scenarios

In cooperation with our radiological partners in Brazil and Germany, several scenarios have been identified that are characteristic for the medical domain. In the following we present these scenarios and show that they can be regarded as combinations of the described process types above.

Scenario 1: Supporting a radiologist throughout a patient visit

The first application scenario is the support of a radiologist during a patient visit, starting with the registration of the patient and finishing with the writing of the final examination report. The particular sequence of activities during examination of the patient depends on the current situation and is described by a set of guidelines, which are proposed to the physician during enactment of the patient visit. By using a CBR approach, such a proposal can be facilitated by experiences from former visits.

This is an example for an organizational process (*patient visit*) dynamically refined by several guidelines (e.g. *knee_MR_examination*).

Scenario 2: Supporting a radiologist on the examination of a difficult case

A radiologist has to provide a report based on NMR images of a patient's knee, providing the diagnosis for a supposed, complicated pathology of the cruciate ligaments, muscular structures, or the meniscus. This is a very difficult task and only very experienced radiologists can perform it without problems, since one must spend extra care to examination best practices and must know exactly where to look at the radiological images.

For this scenario, it is assumed that the radiologist is working on a workstation connected to PROGEMM, which instantiates the specific task by providing guidelines for this specific examination, called *knee_NMR_cruciateLigament* or *knee_NMR_meniscus* from the database (possibly from a distant radiological centre). PROGEMM helps by guiding through the examination process. The steps and the parts of the image and anatomical structures, which have to be examined more carefully, are indicated; normal and pathological parameters for the structures being examined are presented.

During this scenario we are dealing exclusively with guidelines proposed to the radiologist. It is therefore an example for the combination of highly knowledge-intensive processes and the major achievement of PROGEMM is decision support.

Scenario 3: Supporting a general physician in an outpatient primary care unit

In an outpatient primary care unit, such as a in Latin America, the physician is confronted with a patient showing symptoms which probably are related to a pathology that is difficult to diagnose and which the doctor has never encountered before. The doctor knows that some examinations must be performed to confirm or rule out diagnostic hypotheses - but does not know exactly what to do next.

To solve this problem the doctor presents the data stored about the current patient to PROGEMM, which proposes a guideline and/or suitable patient workflows of other patients related to the situation presented by the current patient. Based upon these process descriptions, PROGEMM builds up a new patient workflow suggesting the next steps should be an electrocardiography and an angiography of the patient as well as a consultation of a cardiologist.

In case the doctor considers this a good solution, he/she sends the patient workflow together with the patient data to the next general hospital, which in turn responds with a schedule for the examinations and the consultation of a cardiologist. The workflow data is then available at the hospital and will continue to get processed when the patient arrives.

This scenario illustrates guidelines dynamically refined by organizational processes (e.g. examination and consultation).

Scenario 4: Supporting automation of the healthcare workflow when the outcome of an examination shows that the patient has a different condition than was initially expected.

A patient shows up at the neurology department of a general hospital with a cognitive impairment, which suggests that he or she was victim of an ischaemic stroke. With respect to this situation, PROGEMM creates an appropriate patient workflow starting with a standard computer tomography. The examination of the tomography may show a brain area that presents a slightly reduced radiological density, which would confirm the first diagnosis. The neurologist enters the result of the examination and the workflow is extended automatically by PROGEMM with the next therapy steps. In case the patient has been classified as outpatient, the next steps may be simply speech therapy sessions. After some sessions, it is assumed that the doctor does not see any improvement and chooses to perform a NMR scan and a dynamic computed tomography. These steps are inserted manually into the patient workflow. Both examinations may indicate the likelihood of a low-grade astrocytoma, a brain tumor.

When the doctor enters this information into the PROGEMM system, it adapts the patient workflow - canceling the speech therapy sessions scheduled for the next four months - and suggests admitting the patient and performing a stereotaxic biopsy to confirm or rule out the presence of a tumor. If the neurologist agrees with the suggestion, the workflow steps for the patient's admission and scheduling of the stereotaxic biopsy are generated and distributed to the responsible physicians or are executed automatically.

In this scenario an organizational process is combined with clinical practice guidelines reflecting the manual intervention of the physician as well as other organizational processes depending on the results of the intermediate examinations.

3 The PROGEMM Architecture

From the scenarios described above it becomes clear that support for the specification and execution of clinical processes must integrate traditional, process-centered workflow technology as well as flexible approaches for knowledge-intensive workflows. For the technical realization we have chosen to tailor the process-centered software engineering environment (PSEE) *MILOS (Minimally Invasive Long-term Organizational Support)* [5] that was intended for supporting software development processes. However, clinical processes can be considered as somewhat similar because both follow a basic methodology but require a high degree of flexibility at each particular step. The advantage of MILOS is its support of multiple alternative methods for individual processes. It allows the decision, which method to choose, to be deferred to the execution time of the workflow. Furthermore, such a decision can be retracted or, even better, the entire process can be redefined at any time.

For PROGEMM, the *Organizational Processes* and *Clinical Practice Guidelines* are defined as native MILOS processes. The *Guidelines*, which cannot be described in advance in the sense of individual tasks having a specific ordering relation, are stored as abstract processes acting as indicators, only. They are configured during execution time. Here, we extended MILOS by the CBR retrieval engine orenge [10] that assesses previously executed workflows according to their relevance with respect to the current context (e.g. the diagnosis). For *Guidelines*, the support of PROGEMM is restricted to assisting the physician in selecting the next steps to execute. Another necessary change of MILOS was to break the workflow control paradigm based on the transfer of documents between particular process steps. Instead, we have only a global document that is the DICOM-based *electronic patient record (EPR)* that acts as a repository for each information item associated to a patient. This does not only include written documents but also informal pieces of data like emails, chat logs, or speech recordings, which contain important information elicited during enactment of the agile clinical processes.

From a conceptual perspective, the PROGEMM architecture consists of three main components as shown in Figure 1.

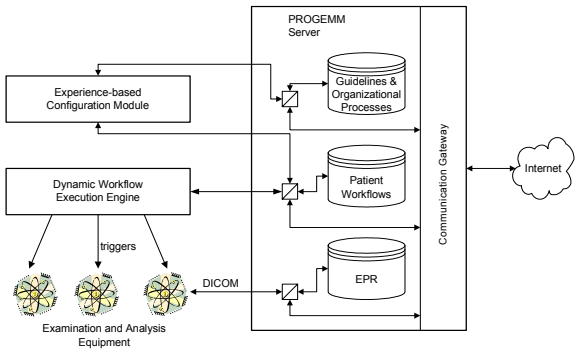

Figure 1: PROGEMM architecture

PROGEMM Server: As a distributed medical data server the *PROGEMM Server* provides transparent access to distributed guidelines, organizational processes, patient workflows, and patient data stored in Electronic Patient Records. It is a multi-database with repositories over several participating hospitals or clinics and is served by a set of central instances (portals) hosted by selected service providers enabling a transparent view over all data stored in the multi-database. On the one hand, the *PROGEMM*

Server supports the exchange of data between the hospitals in terms of sharing experiences, but on the other hand a strict security concept is implemented.

Experience-based Configuration Module (ECM): Guidelines and organizational processes are represented in the same way, so that they can be defined with the same tools and stored in the same database. The major task of this component is the configuration of an individual patient workflow. To perform this task, guidelines, organizational processes, and stored patient workflows are used. Suitable and fitting processes can be retrieved from the appropriate databases and adapted to the current needs by using adapted case-based reasoning technologies.

Dynamic workflow execution engine: This component processes instances of patient workflows, configured by the ECM. Depending on the usage site, it triggers examination equipment like analysis software tools or image modalities.

From the generic process descriptions, PROGEMM successively generates a patient workflow that can be seen as an instance of an organizational process, adapted to the concrete situation of a given patient. So in comparison to the corresponding generic organizational process it can include additional steps; likewise it is possible that steps are skipped. Because PROGEMM relies on the widespread DICOM data exchange interface it is possible to enable the collaboration of physically dispersed medical partners.

3.1 Introducing the DICOM Standard

An important difference between the PROGEMM approach and typical WFE implementations is that the entire document flow is restricted to particular records of the EPR, which can be considered as a kind of repository that collects all data about a patient during his or her medical treatment.

In recent years, a data and exchange format for patient data and radiological images called *DICOM* has been established, defining on the one hand a data format for EPRs in radiological hospitals and enabling, on the other hand, the exchange of data between medical devices, the EPR, diagnoses stations, printers, etc.

DICOM provides an ideal basis for the support of typical processes occurring in radiological hospitals (see section 2.1), both strong and weakly structured processes. Instead of a typical document flow, all processes read from and write into the DICOM-based EPR, which therefore represents the current state of treatment. Thereby, every item within the EPR is formal, but it is not stipulated which item must be stored by which process. Hence, for every patient only the necessary and individually needed information is stored and the execution of two patient workflows, being instances of the same organizational processes, can lead to very different entries in the EPR. Even highly unstructured knowledge like chat-logs between two physicians can be stored within the right context, namely the process.In addition, DICOM provides the sufficient degree of formality for applying techniques like CBR, e.g., to search for other patients, which showed similar symptoms like a current one like described in Scenario 3.

In conclusion, DICOM is the key factor for enabling the support of typical agile processes in the medical domain and thus the following section provides a brief introduction into the basic ideas of DICOM.

3.2 DICOM at a Glance

Since 1983 the *American College of Radiology (ACR)* and the *National Electric Manufacturers Association (NEMA)* are developing the DICOM Standard. It deals with the storage and exchange of digital information between medical image equipment by specifying elements required to achieve interoperability between the equipment. Thus, the goal is to define the information, which gets exchanged between devices and how devices are expected to react to commands and associated data.

To keep track of the elements and to enable expansion, DICOM draws up a model of the real world. Therefore, it uses an entity relationship model, shown in Figure 2. The rectangles are called *information entities* and represent real world objects, whereas the diamonds indicate the relationship between the information entities. The numbers at the arrows show the cardinality of this relationship, e.g., one patient has one or more (1-n) studies.

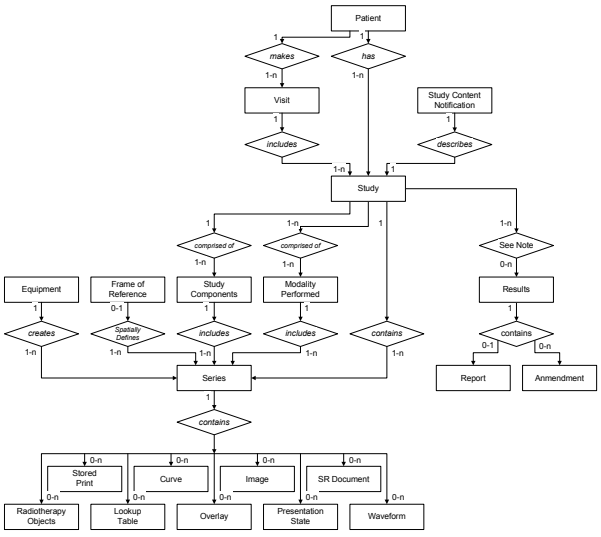

Figure 2: DICOM model of the real world

Roughly speaking, an information entity contains several mandatory and optional attributes, e.g., the informa-

tion entity **Patient** contains attributes like "Patient's Name" and "Patient's Sex" and the information entity **Image** contains attributes like "Image Date", "Rows", "Slice Thickness", and of course the pixel data itself. So, a DICOM image is not only pixel-data but also a characterization of the image. Several information entities are aggregated to one DICOM object.

Example: One Patient named Joe has been in a radiological hospital twice: The first time because of his knee and the second time because he was victim of an ischaemic stroke. So, two studies are associated with Joe: one knee study and one brain study. Each study consists of one or more series, whereby a series is a collection of images. The images belonging to one series have all been performed at the same day and with the same imaging technique, but one study may contain series acquired at different days (e.g. follow-up examinations). Structured Reports, containing information about examination results and findings are also related to Joe.

Nowadays, nearly all vendors of medical devices like computer tomographs and other modalities, EPRs, or printers are forced to be compliant to DICOM to stay competitive. The standard itself consists of 16 basic parts, but there exist several supplements, which handle more specialized issues. The basic parts are not "static", but are updated frequently, e.g., by integrating tested and accepted supplements. For the scope of this paper "DICOM Supplement 23: Structured Reporting" is worth mentioning, because it specifies the transfer of observation data accompanying an image like text descriptions of significant findings. These Structured Reports are used by the CBR component to find patients with similar symptoms and lesions. An overview about DICOM is given in [3] and more detailed information can be found in [4].

4 An Evaluation Plan for PROGEMM

Together with our medical partners, the PROGEMM system will be evaluated as soon as the first prototype with necessary stability is available. Hence, the development of the PROGEMM system is accompanied by the development of an evaluation plan that includes technological, medical, and economic issues as well as workflow evaluation approaches proposed, for example, by the Workflow Management Coalition [11]. The evaluation criteria will be aligned with the four-quality dimension: reliability, functionality, application performance, and system performance.

First validation studies will be performed on the Scenarios 1, 2, and 4 (see 2.1): How PROGEMM supports the execution of processes like described in Scenario 1 and 2 will be evaluated by the "Radiologische Gemeinschaftspraxis Dres. Buddenbrock, Blasinger, Benz" in Germany and the "Clínica de Diagnóstico Médico por Imagem SC/LTDA (DMI)" in Brazil. We have analyzed and modeled typical organizational processes in both radiological hospitals and have modeled several guidelines for radiological knee examinations like *knee_MR_examination, knee_NMR_cruciateLigament,* and *knee_NMR_meniscus*. This has been carefully chosen because knee examinations are one of the most frequent examinations performed in both hospitals. Significant knowledge about these examinations has been already elicited in former projects [8][9].

PROGEMM's ability to support processes like described in Scenario 4 will be examined by the "Regional Hospital of the Upper Itajai Valley (HRAV)", a medium-sized public hospital in Brazil. This evaluation study is much more complicated, because we cannot single out a "typical" examination as the approach can only work with a huge amount of very different patient workflows. So the first step in this evaluation study will be the collection and modelling of patient workflows.

5 Conclusion

In this paper we presented the PROGEMM approach for managing flexible and agile clinical processes by emphasizing the *DICOM Standard* for storing patient data elicited during process execution. While *DICOM* is a necessary technical foundation for the integration of structured workflows and highly flexible knowledge-intensive tasks, PROGEMM consists of several other components that have been only briefly sketched, here.

PROGEMM is currently under development by the University of Hildesheim in Germany and the Federal University of Santa Catarina (UFSC) in Brazil. We expect our approach to improve the daily workflows of both hospitals as well as their collaboration together and with independent physicians who have to send their patients for radiological diagnosis, regularly. For this, we have to increase the number of medical partners, collaborating together via the PROGEMM platform.

Besides technical challenges, also psychological challenges have to be faced: Some health professionals decline the deployment of "intelligent" systems due to ethical reasons, and these physicians must be convinced what is probably the hardest goal to achieve.

6 References

[1] G. Molino. Form Clinical Guidelines to Decision Support. In W. Horn at al,. editor, AIMDM'99, pages 3-12. Springer Verlag Berlin, Heidelberg, 1999.

[2] European Commission, Information Society Directorate-General. Telemedicine Glossary, 3rd Edition. Glossary of standards, concepts, technologies and users. Luciano Beolchi (editor), 2001 Working Document.

[3] Kerstin Faber. *Object-Oriented Implementation of a DICOM-Network Client in SMALLTALK*. Project Thesis, University of Kaiserslautern, February 2000.
[4] Digital Imaging and Communications in Medicine, Homepage. http://medical.nema.org (Verified: March 2003)
[5] Maurer, F., Dellen, B., Bendeck, F., Goldmann, S., Holz, H., Kötting, B., Schaaf, M. (2000). Merging project planning and web-enabled dynamic workflow for software development, IEEE Internet Computing, Special Issue on Internet-Based Workflow - May/June 2000.
[6] Dirk Krechel, Ralph Bergmann, Kerstin Maximini, Aldo von Wangenheim. *A Framework for Radiological Assistant Systems*. Proceedings of the 15th IEEE Symposium on Computer-based Medical Systems (CBMS'02), June 2002 in Maribor, Slovenia. Published by the IEEE Computer Society, Los Alamitos, California.
[7] Fabio Alexandrini, Dirk Krechel, Kerstin Maximini, Aldo von Wangenheim. *Integrating CBR into the Health Care Organization*. Proceedings 16th IEEE Symposium on Computer-based Medical Systems (CBMS'03), June 2002 in New York, USA.
[8] Kerstin Faber, Dirk Krechel, Daniel Reidenbach, Aldo von Wangenheim, Paulo R. Wille. *Modelling of Radiological Examinations with POKMAT, a Process Oriented Knowledge Management Tool*. Proceedings of the 8th Conference on Artificial Intelligence in Medicine in Europe (AIME 2001), July 2001 in Cascais, Portugal.
[9] Kerstin Faber. *The Process Oriented Knowledge Management Tool POKMAT, with an Application to Radiological Knee Examinations*. Diploma Thesis, University of Kaiserslautern, Germany, 2001.
[10] empolis knowledge management GmbH: *The orenge Framework - A Platform for Intelligent Industry Solutions Based on XML and Java*. Whitepaper, empolis knowledge management GmbH, Kaiserslautern , 2001.
[11] Homepage of the Workflow Management Coalition. http://www.wfmc.org/. (Verified: May 2003).