Methods of Information in Medicine
(to appear)

Model-Based Design of Trustworthy Health Information Systems

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Introduction

Quality and affordability of healthcare delivery represents one of the major challenges in the 21st Century. While other information-intensive industries have developed and deployed standards-based, pervasive information infrastructures, information technology (IT) penetration in healthcare is still surprisingly low. Healthcare has been characterized as a 'trillion dollar cottage industry' that is still dependent upon paper records and fragmented, error-prone approaches to service delivery. There are many indications that the 20th Century healthcare delivery practice is unacceptable. According to a landmark National Academies Study [1], over 98,000 Americans died and more than one million patients were injured due to process and systems failures in health care. The Picker Institute survey [2] pointed out that 75% of patients considered the health care system to be fragmented, convoluted, plagued by duplication of effort, poor communication and conflicting advice. These inefficiencies have resulted in double digit inflation of cost of health care worldwide.

However, there is an emerging vision for the future of healthcare [3] that can bring dramatic change in the quality and cost of health care. This new vision is characterized by:

- engaged patients with access to a large volume of health-related information online who actively contribute to the health decisions made,
- providers who serve patients as coach-consultant,
- personalized medicine guided by genomics and
- agile, evidence-based care with automated, patient-specific alerts.

This vision is not only a matter of correct policy or business decisions. The introduction of new technologies, such as ubiquitous, wireless telecommunication, web portals as secure bi-directional conduits for communication and documentation of care delivery and advanced clinical decision support systems with automated event monitors, are all required enablers. These technologies need to be tried and deployed requiring innovation and serious investment. But why would health care move in this direction with the outdated fee for service reimbursement model that does not penalize for inefficiency? According to Masys, there are several forces at work that push the healthcare industry towards radical change [3] including:

- the dramatic increase in the amount of information required for making health decisions,
- the rapidly growing use of Internet worldwide,
- genome research that opens up opportunity to provide personalized healthcare,
- medical errors caused by failures in information management.

It has been increasingly recognized that IT can indeed make a huge difference by enabling the creation of disruptive technologies that can change health care [4]. Personal health records (PHR) are predicted to be a game changer by creating informed and engaged patients. PHRs are owned and controlled by patients, contain electronic medical records created by providers, as well as patient entered information and all other relevant data such as insurers and authentications. By owing and controlling PHR, patients will have a stronger position on the health care market. The future significance of PHRs has been recognized by the largest IT technology companies, led to new service offerings, such as Microsoft's HealthVault and Google Health.

A revolution has started up in real-time medical decision support systems as well. Increasing number of research prototypes and early commercial instances of decisions support systems are being developed with new capabilities: they can integrate patients' clinical data and patient-specific medical information in the decision process and have the ability to operate according to formalized and validated care protocols. The advent of these systems is a significant step toward evidence-based, personalized health care that can be easily adapted to changing best practices.

The cost of health care for aging population has become a major concern. Recent advances in wireless sensor networks have made it possible to deploy wearable sensors on the bodies of patients in at-home setting, allowing continuous monitoring of physiological signals (such as ECG, blood oxygen levels) and other health related information (such as physical activity levels). This technology offers unique opportunity for shifting healthcare outside a traditional clinical setting to a patient/home-centered setting.

Progress in these new, transformational applications of IT in health care is predicated on the availability of technical solutions for some extremely hard problems:

- implementation of security and privacy requirements in Health Information Systems (HIS) and
- availability of design technology that can guarantee safe operation in the extremely dynamic and rapidly changing health care environment.

A primary concern is that privacy and security requirements for HIS are frequently expressed in vague, as well as contradictory, complex laws and regulations. Engineering of complex software systems that are functionally complete, able to adapt to the changing healthcare environment and can adopt to changing security and privacy related laws and regulations is hard, if not impossible to solve using conventional software and systems design technology. To address this problem, model-based methods offer a revolutionary way to formally and explicitly integrate privacy and security goals into HIS architectures. End-to-end architecture modeling, integrated with formal privacy and security models, offer new opportunities for HIS system designers and end users.

The goal of this Special Issue is to provide a source of reference for the ongoing and future research by sampling the new intellectual directions and by exposing the present and expected challenges brought about by the engineering of trustworthy HIS. This Special Issue has been organized based on the Workshop MOTHIS 2007 – Model-Based Design of Trustworthy Health Information Systems conducted as satellite event of the 10th International Conference on Model-Driven Engineering Languages and Systems MoDELS 2008 in Nashville, USA in October 2007.

Model-Based Design

Model-based development offers a unifying framework with emphasis on developing and integrating design artifacts through precise models rather than informal documents. Models are used throughout the design process, from requirements capture to code generation to test generation. *Model-based software design and verification* facilitates the formal representation, composition, and manipulation of models during the design process. It addresses system specification, model transformation, synthesis of implementations, model analysis and validation, execution, and design evolution.

There are several fundamental advantages of using model-based methods in the design of HIS.

- *Abstractions:* Medical applications define a domain with unique abstractions. PHRs are structured using unique ontology's. Care protocols need to adopt a large variety of abstractions used for describing and characterizing treatment steps, their coordination and their relation to patient states and to the actors of clinical environments. It means that design of HIS's can be hugely simplified by defining well defined, domain specific abstraction layers in the design process that have intuitive meaning, and precise enough to perform formal verifications.

- *Integration:* Healthcare environments and the embedded HIS's are extremely heterogeneous due to the many factors that influence design. A large range of design aspects, such as information flows, organization models, document models, activity and event models, coordination and timing models, policy models, deployment models and others need to be created and related. Integration and management of these interrelated, heterogeneous models is a major challenge. Model-based design environments facilitate this complex task with tools and methods.

- *Automation:* HIS's need to be highly flexible to local needs, procedures and best practices. There is no chance for acceptance of technologies that impose strong restrictions and rigidity on the treatment process. This makes customization an extremely important requirement. Affordability of customizable HIS's require high level automation in translating high-level models (that capture variations) into verified, operational systems. Model-based system generation and verification tools can provide solution for this challenge.

We believe that various flavors of the rapidly progressing model-based software and systems engineering technologies, such as Model Driven Architecture (MDA) [5], the Eclipse Modeling Framework (EMF) [6], Model-Based Security Engineering (MBSE) [7] or Model Integrated Computing (MIC) [8] and others will play a key role in the future of HIS.

Description of Papers

The issue includes four contributions from researchers working on model-based software engineering and its application in HIS.

A. *Formally Defining Medical Processes*
The paper addresses the formal modeling of medical processes, or care protocols. The objective of the authors is to develop and test a method for precise process specification that has solid semantic foundation for conducting formal analysis of the models. The background of the proposed technique is the Little-JIL process definition language originally developed for software architecture modeling. Authors selected chemotherapy preparation and administration as a target application and have shown that their formal representation is able to capture the required complexity; properties can be verified using model checking.

B. *Model-Based Design of Clinical Information Systems*
The paper describes a new framework for the model-based design and implementation of clinical Information Systems. The Model Integrated Clinical Information Systems (MICIS) framework is implemented as a software toolkit that establishes high-level modeling abstractions for representing clinical information flows extended by a range of modeling aspects for the provider's organization, documents, deployment architecture and privacy/security policies. The MICIS generators translate these high level models to an underlying SOA execution platform.

C. *Model-Based Security Analysis of the German Health Card Architecture*
The paper focuses on the methods used by the authors for analyzing the security of the German Health Card System. An essential aspect of any PHR implementation is security. The German Health Cards will include critical, highly sensitive data that will provide major help in healthcare delivery, but need to be carefully protected. The presented analysis of the security architecture of the system is based on UMLSec, the authors' modeling language for security characteristics.

D. *Model-Based Assessment of Data Availability in Health Information Systems*
The core contribution of the paper is the development of a theoretically well established solution for assessing structural qualities of information systems. The authors propose an ontology for describing health information systems and show the practical impact of their method on information management.

Acknowledgement

The editors of this Special Issue wish to thank all those who contributed with submissions and reviews to this Special Issue. In particular we wish to thank Colin Aktinson, Lori Clarke, Sebastian Garde, Michael Hafner, Arie Hasmann, Sebastian Höhn, Frank Innerhofer-Oberperfler, Jan Jürjens, Basel Katt, Ingolf Krüger, Kasimir Kulikowski, Akos Ledeczi, Brad Malin, Sjouke Mauw, Juha Mykkänen, Lee Osterweil, Barbara Paech, Karl-Peter Pfeiffer, Alexander Pretschner, Stephanie Rinderle, Heiko Schuldt, Yuval Shahar, Jan Talmon, Alfred Winter, Florian Wozak, Yuan Xue, Xinwen Zhang. Our special thanks go to the Editor, Reinhold Haux, for his continuous support and encouragement.

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Comment [.1]: Stimmt das?