The Role for Engineers in Health Care Information Systems

Ram D. Sriram and Steven J. Fenves

Introduction

Spending on health care in the United States continues to grow at the rate of over 7% per year, expecting to reach $2.8 trillion by 2011, around 17% of the Gross Domestic Product. Escalating health care costs are impeding U.S. industry's ability to compete globally. As an example, according to a USA Today article, General Motors spent $4.5 billion on health care in 2002. The cost to the consumer was $535 on each of the several million GM vehicles sold that year. The lack of interoperability of health care information is a major contributor to this cost. Therefore, the current desire for further extensions of health care coverage by the industry in general needs to be accompanied by decreases in health care costs, brought about by higher levels of interoperability among health care providers.

In this context, it is worth noting that healthcare and manufacturing share many similar organizational, technological and informational issues. Thus, several of the technologies developed for the manufacturing sector for improving interoperability are potentially transferable or adaptable to the health care sector so as to provide an infrastructure for the accelerated and enriched development of improved organizational, technological and information support methodologies.

Two areas of health care of interest to mechanical and industrial engineers are: (1) Health care informatics and (2) Medical devices. Health care informatics deals with all the processes or "software" of the health care enterprise: modeling, design, simulation and implementation of health care information systems, support and control of manufacturing and its associated supply chains, and information and data management both in clinical practice and biological research. Medical devices deal with all the products or "hardware" of the enterprise: the characterization, design, manufacture, testing and metrology of medical devices at scales ranging from large equipment to nano-scale drug delivery mechanisms.

This paper focuses on the information technology aspects of the health care enterprise. We start our discussion with a survey of the major issues and then describe several projects designed to explore the transference potential, undertaken under the auspices of the Manufacturing Metrology and Standards for the Health care Enterprise program in the Manufacturing Engineering Laboratory (MEL) of the National Institute of Standards and Technology (NIST). For further information about the program and associated publications and references see http://www.mel.nist.gov/publications/publications.cgi with sriram as author and health care as the keyword.

Major Issues

Electronic health records will help reduce health care costs. The major enabler of health care information sharing is the Electronic Health Record (EHR), containing all the

relevant patient health care data in a shareable form. In health care delivery, the EHR serves integrating functions similar to that of the Bill of Materials (BOM) in manufacturing.

The penetration of EHRs into health care settings is low and spotty. While large health care institutions have significant investments in EHR-based computer systems, it is estimated that only 5% of the family physicians in the U.S. use an EHR system in their daily practice. For a majority of health care settings (especially small clinics) paper-based records and fax-based communications is still the norm. The available EHR systems are deemed to be too expensive for the many small health care facilities.

Information exchange standards are needed for effective use of EHRs. EHRs and other health care interoperability efforts depend critically on standards. Messaging and information exchange standards (e.g., HL7, E1460, E1467, E1381, E1394, IEEE 1073) are intended to permit the integration of the various health information systems into an EHR. Specifically, HL7 messaging standards allow disparate health care information systems to communicate with each other. ANSI's HL7 has recently released a first version of an EHR functionality specification and ASTM has recently released a specification for the exchange of patient information for continuity of care purposes such as transfer and referrals.

There are significant gaps and overlaps in the standards covering EHRs. They both contribute to the major problem pertaining to clinical informatics: the lack of interoperability among information systems implementing the standards. There are several standard development organizations working on improving the effectiveness of health care information exchange. Potentially, there may be several standard development organizations working in the same, or in related areas. However, for the most part there has been no systems view tying the various parts of the health care informatics domain together.

Many challenges to information exchange exist. One challenge in broadening the range of health care informatics is that health care providers have been using several legacy vehicles to enter, store, and relay information about patients. Electronic exchange of health care information in general and EHR in particular needs to recognize the diversity of techniques in use. Furthermore, the large archives of longitudinal patient records must be accessible and incorporated into any new system. Importing this legacy information is expensive and time-consuming, but essential for medical and legal reasons and for providing quality.

Despite the growing acceptance of the HL7 standard, interoperability and interchange of health care information remains a barrier due to different degrees of adoption of the revisions of the HL7 standard. While EHR vendors may have developed products consistent with HL7 version 2.5, most implementations are still at versions 2.1 to 2.3. The high cost of integration of health information systems is a barrier that prevents organizations to switch to vendors with lower costs, and newer products.

The above two aspects of transition are highly evocative of what the manufacturing industry has gone through (and is still going through) in the transition from paper-based to CAD-based representation of products and in transitioning from Version X to Version X+1 of the CAD tools.

Systems engineering can aid in development of tools for biology and medicine. Biological systems are characterized by multiple interlinked pathways of interaction at various levels. These levels span the molecular level to the cellular level and to the multi-cellular organism level. The interactions within and across these levels are critical to the fundamental understanding of systems biology (SB), which involves gathering comprehensive sets of data that define and quantify the elements of a particular biological system and computationally analyzing them to establish functional and dynamic connections. Essentially, the goal of SB is to formalize descriptions of these processes and interactions. The state of art in SB and absence of a grand theory open the space of exploration to extending the traditional systems engineering (SE) principles to better understand the challenges of SB. The challenge to industrial engineers is to look into the current computational formalisms available in systems engineering, their limitations, and the requirements for extending these formalisms for developing a deeper understanding of biological functions.

Supply chain inefficiencies result in considerable wastage. In 1996, the study *Efficiency Healthcare Consumer Response* concluded that $11 billion out of the approximately $150 billion biomedical device and equipment market was wasted annually because of health care supply chain inefficiencies. Standards are needed for manufacturing and e-commerce of biomedical devices, for better integration of manufacturing processes with supply chain management and for device integration. Today patient monitoring using medical devices in clinics and homes still requires manual recording of the measured medical data. Some proprietary interfaces exist but require proprietary communication interfaces and protocols. The Medical Information Bus standard, IEEE 1073, is designed for bedside monitoring of hospitalized patients, but there is a lack of similar standards for ambulatory patients in non-critical care facilities. An exemplar standards-compliant interface would simplify the information intake from these devices into EHRs. Clinics, nursing homes, and patients would be able to accurately record patient monitoingr data and benefit from a wider choice of products and their interoperability. Vendors of health care information systems would be able to reduce their device integration costs.

Bioimaging plays a major role in health care and suffers from interoperability issues. Medical imaging is a multibillion dollar industry and is making major strides into current medical diagnosis and therapy. However, there are key technical barriers that are hampering progress in medical imaging. These are: (1) lack of standards for data collection and analysis across different commercial imaging platforms; (2) lack of validated and robust software methods for measurement of change in extracted features such as tumor volume; (3) inadequate physical performance standards and related image quality standards; and (4) lack of technical interoperability standards for ensuring standard image rendering, data storage and retrieval.

Design and production of pharmaceuticals are increasingly being outsourced. With the growing demand for pharmaceutical products to expand life spans and improve the quality of life, the pharmaceutical products sector is poised for steady growth. The high cost of developing new pharmaceuticals and the emergence of generic pharmaceutical manufacturers worldwide have combined to increase the pressure on the US pharmaceutical industry. In addition, a number of commercially successful pharmaceuticals are approaching patent expiry in the coming years and many generic versions of these products will appear shortly thereafter. The outsourcing of small margin pharmaceuticals to low cost production facilities can be a viable alternative. However, any changes in pharmaceutical production processes require Food and Drug Administration (FDA) approval. Therefore the outsourcing of pharmaceuticals or pharmaceutical ingredients requires lossless interchange of process information. There is a need for interoperability standards for pharmaceutical process models or their components. The voluminous documents that accompany requests for FDA approval of pharmaceutical products specify the production process in a non-computable format that precludes the use of FDA computational tools to thoroughly and rapidly evaluate these submissions. Adoption of standards, such as those promoted by the European CAPE-OPEN and its counterparts, in the pharmaceutical industry will also enable development of interoperable process component libraries that are exemplars of validated, special purpose processes. The use of such interoperable libraries could hasten the design of pharmaceutical manufacturing processes.

Representative NIST/MEL Projects

Assistance to the Office of the National Coordinator for Health Information Technology (ONC)

The Office of National Coordinator (ONC) for Health Information Technology of the Department of Health and Human Services (HHS) is responsible for the deployment of the Nationwide Health Information Network (NHIN). In order to support ONC in the first version of NHIN, where direct interaction between the network and individual health care service providers was contemplated, a prototype tool called the Architecture Deployment Facilitator (ADF) was developed.

ADF was intended to serve as the repository of a set of predefined compatible healthcare IT components, called artifacts, which could then be combined to design, configure and deploy a large variety of healthcare IT system architectures. The design of ADF responded to the evolving nature of the NHIN envisaged by ONC. ADF made absolutely no assumptions about the upper levels of the NHIN architecture and did not impose any constraints on any architecture that may evolve, from the most highly centralized one to the fully decentralized one.

Eventually, ONC decided to concentrate its efforts on the upper-level "network of networks" comprising large-scale health care information service providers (HISPs). In such a system, individual health care service providers will interact with an individual HISP, which will in turn define its interoperability requirements. Thus the "global" repository envisaged for ADF would no longer be needed.

Analysis of Workflow in Physicians' Offices

This pilot study analyzed small physician offices (from 1 to 4 providers) from a workflow perspective. The study, using a combination of a questionnaire, interviews and in-situ observations, was done at 13 small practice physician offices in the Baltimore and New York areas. The offices included both primary care (4) and specialty providers (9). The study aims to provide an overview of potential sources of delays. The data from the offices were used to create workflow maps so as to be able to contrast workflow maps for offices with and without EHR. Workflow maps for specialist offices and primary care physicians were also separated to understand the difference in complexity of the workflow. The study follows the interpretive model of case studies rather than a large sample statistical survey of the practices.

The results of the study show that specialty physicians are more favorable to adopting EHR than primary care physicians. While primary physicians would like to introduce EHR in their offices, the barriers to doing so are greater than those for specialists. The variety of workflows in primary care physician offices is greater than that of the specialists, leading to difficulties in using standardized workflow structures. Primary care physicians would benefit more from EHR provided they could interact with other external entities through the EHR system. Non-standard ways of interaction with external entities and their low level of computerization are leading to the retention of paper-based systems. Without the ability of moving away from paper-based systems, the EHR becomes an extra burden and cost, resulting in low rates of adoption.

Simulation of Health Care Enterprises

A pilot conceptual study examined the benefits to be gained from modeling, simulating and visualizing biological and medical information and processes. There is considerable on-going work in this area, particularly in genomics, but there is a need for a more global outlook and for methodologies that span the spectrum of biological systems from the molecule or cell level to national or international societal levels, for example, for modeling the spread of epidemics. Applications of simulation techniques in the health care industry may be software- or hardware-based.

Software-based simulations include models that represent the behavior of a physical system using computer programs. The following types are included:

- System dynamics simulation using causal relationships that determine system behavior over time.
- Discrete event simulation using events that make step changes in the status of the system over time.
- Agent-based simulation using the behavior of independent entities forming the system to determine the status of the system over time.
- Monte Carlo simulation using random distributions to represent the outcomes of a system's behavior.
- Continuous simulation using differential equations to represent the physical phenomenon being studied.

Hardware-based simulated environments are built for training and assessing clinical skills. This category includes the following types:

- Virtual reality and gaming using interactive three-dimensional computer-based graphics and human interaction devices.
- Patient simulator devices using mannequins that represent the behavior of full or part of a human body.
- Simulated environments using rooms such as patient visit rooms with humans role-playing as patients or operation theatres with mannequins as the patient.

Proteins Identification

The Hershey Medical Center (HMC) recently discovered that some morbidly obese patients, who were initially diabetic, found themselves free of diabetes after stomach stapling surgery. HMC was interested in understanding the mechanism involved in this process. *Differential Protein Expression Profiling*, which uses mass spectrometry, makes it possible to get a "snapshot" of the biological state of the patient before and after the surgery in terms of relative protein levels. Using this information and various statistical methods and wavelet analysis, we could generate a protein-protein interaction network that can be used to determine the pathways involved in the curing of diabetes.

Evaluating Protein-Protein Interaction Software

The primary goal of this project is to develop metrics for evaluating protein-protein interaction software. We ventured into this by selecting a problem and then evaluating various tools for this problem. The problem we selected involves the interaction of two proteins involved in Alzheimer's disease. We were able to compare the interactions between the proteins at the atomic level by using a geometry-based alignment algorithm. The algorithm aligns the proteins such that their interfaces are interacting geometrically as similarly as possible to the interface of the crystallized complex. Our alignment algorithm can be potentially generalized to the cases in which the protein surfaces to be aligned need to satisfy certain geometric conditions following from biochemical considerations. We tested our *in-silico* experiments with *in-vivo* experiments conducted at the National Institutes of Health (NIH).

Extracting Protein-protein Interaction Sentences from Literature

Protein-Protein Interaction (PPI) information is critical to understanding the function of individual proteins and the organization of entire biological processes. Therefore, current biomedical literature is replete with articles that describe PPI experiments, which specify individual interaction proteins and the corresponding interaction types. Protein interaction databases also have been developed by utilizing these biomedical articles. However, the rapid growth of the literature makes it difficult to manually find the necessary information. In addition, the dynamic nature of biology makes building the ontology or the database more difficult. We undertook the development of a machine learning-based framework called PIE (Protein Interaction information Extraction system), which identifies PPI information automatically from the biomedical literature. PIE consists of two procedures: article filter and sentence filter. In the article filter, documents are roughly classified to reduce the overhead of the second procedure. The AdaCost algorithm with naive Bayes classifiers is used for the article filter, and the SVM classifier

with tree kernels is used to identify PPI-relevant sentences for the sentence filter. Our experimental results confirm that the PPI articles are successfully classified using word-based probability distributions.

Standards for Device Supply Chain Management

Our project was aimed at helping the biomedical device industry in developing standards that will enable the integration and optimization of the value chain performance, ensuring product quality and safety, and providing traceability of medical devices and their components throughout the device life cycle. We contributed to the Health Industry Business Communications Council (HIBCC) in the development of a draft XML-based specification on selected e-business transaction messages. We drafted XML schema documents on invoices and orders to support the HIBCC e-Business standards. The XML schemas provide internet-based e-Business transactions that will free companies from transaction fees using the Value Added Network.

From Image Recognition to Classification

NIST has embarked on a bioimaging initiative as part of NIST's American Competitive Initiative program. One of the components of the bioimaging initiative is "Standards and Validation for Software," undertaken by NIST's Information Technology and Manufacturing Engineering Laboratories. The overall goal is to improve the quality of image acquisition, analysis, and storage through effective standardization, improved software, and rigorous testing. To this effect, we have been working closely with the NIH and other concerned government agencies and industry representatives. The project is intended to support clinical decision making by highlighting deviations from normal conditions through the image analysis of diseased organs and by suggesting potential disease conditions through mapping feature vectors obtained through segmentation of the image onto various disease ontologies. The intention is not to provide a decision aid and not an automated diagnosis. While providing a general framework, the initial project focuses on images captured through wireless endoscopy of the gastrointestinal system. The framework will later be extended to lung cancer image databases.

Acknowledgments and Disclaimer

We would like to thank all the participants in the Manufacturing Metrology and Standards for the Health Care Enterprise Program. Certain commercial software systems are identified in this paper. Such identification does not imply recommendation or endorsement by the NIST; nor does it imply that the products identified are necessarily the best available for the purpose. Further, any opinions, findings, conclusions or recommendations expressed in this material are those of the authors and do not necessarily reflect the views of NIST or any other supporting US government or corporate organizations