IS DIGITAL MEDICINE A STANDARDS NIGHTMARE?

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ABSTRACT

As technology has increased, one industry that has been slow in implementing technology is the healthcare industry. Doctors, with handheld devices, going room to room with real time information on each patient is not a reality in most hospitals today. Implementation has been slowed by multiple standards for healthcare data, and the HIPAA act that has brought up security issues for patient data. Also, research is being done in two non-convergent fields. This paper describes the standards and the problems with developing healthcare information systems.

Keywords: Healthcare MIS, Health Level 7, Medical Information Bus, Digital Imaging Communications in Medicine, Data Communication Standards, Digital Medicine.

INTRODUCTION

Healthcare management information systems are some of the most complex systems developed today. Healthcare providers, from individual doctors to hospital HMOs, want more technology integration into the system providing real time data analysis and the possibility of enhancing medical knowledge. Sharing that knowledge can lead to what many describe as "digital medicine" where stored clinical data can generate medical knowledge which can be widely distributed, incorporated into decision support systems, and lead to more effective medical practices (Shaffer, Kigin, Kaput, Gazelle 2002).

In order to achieve digital medicine, the collection of medical information to be retrieved and analyzed is necessary in real time. The equipment that monitors patients, the information recorded by nurses and even the images created in x-rays and MRIs must be stored in the system so that doctors can review all the data relevant to a patient to determine the proper treatment. Three standards specific to the healthcare field exist that healthcare information system developers must incorporate into any project so that data can be collected and stored. Any healthcare system developed incorporates these standards, which are still being developed and improved, plus standard networking protocols, and government induced standards for personal information security due to the recent Health Insurance Portability and Accountability Act (HIPAA). Medical Informatics is a new discipline which is directly influencing the development of information system in healthcare. Traditional MIS must recognize the problems in development of healthcare information systems, and the joint research possibilities with Medical Informatics researchers in solving many of the yet to be resolved issues of data collection and analysis in helping make digital medicine a reality.

This paper will examine three aspects related to the problems in developing healthcare information systems. The first aspect will be the security and privacy issues associated with digital medicine. The second aspect will be the standards for data collection that have been developed, specifically the Health Level Seven (HL7) data model standard, the Medical

Information Bus (MIB) standard for portable medical devices, and the Digital Imaging and Communications in Medicine (DICOM) standard for medical images. Finally, the last aspect will be the need for more joint research into the system architecture and need for a complete architecture of a medical information system that can lead to digital medicine.

PRIVACY AND OTHER RESTRICTIONS ON HEALTHCARE INFORMATION SYSTEMS

The communication standards developed for healthcare equipment and information, specifically the clinical and administrative data generated in hospitals are still developing and, now with the HIPPA requirements, can be the major success or failure factor of any installed healthcare information system. HIPAA has created an urgent need for common standards in the data exchange within hospitals and to external insurance suppliers. HIPAA requirements for security requires all involved with administering patient information to implement basic safeguards to protect electronically stored health information from unauthorized access, alteration, deletion, and transmission. With wireless technology being implemented in hospitals, the security of information on those wireless networks is necessary for HIPAA compliance. In order to make digital medicine a reality, access to patient information from other healthcare workers is necessary without revealing private information.

To create decision support systems and medical knowledge bases will require careful consideration on the uses of patient data which are restricted under HIPAA. Anyone who has visited a doctor recently has signed waiver forms on the privacy of their medical records. Individual privacy concerns could hamper development or implementation of a real time knowledge base.

HEALTHCARE INFORMATION SYSTEM DATA MODEL AND COLLECTION STANDARDS

In health care, specifically hospitals, the different electronic systems that have to connect to a real time information system that can provide doctors with timely information on patients poses an almost overwhelming communications problem. Each piece of equipment that monitors a patient should be capable of electronic data interchange within the hospital's network. Standards have been developed for the equipment that allows electronic data interchange. These standards are capable of providing a software developer the necessary tools that could allow for a fully integrated health care system that not only dealt with the patient records, but with the real time information on the patient's status while in the hospital. Doctors could use this information to provide better medical care.

Three standards are available for the system developer. The Health Level Seven (HL7), the Medical Information Bus (MIB or IEEE P1073), and Digital Imaging and Communications in Medicine (DICOM) all have had an enormous impact on health care information systems and patient care. Each of these standards impacts the data gathering and exchange of information within a health care information system. Wireless communications also presents a new security threat for the network systems, and also HIPAA compliance. So far, a new security standard for healthcare MIS has not been developed.

These three standards encompass data standards (HL7), communication standards (MIB) and digital imaging standards (DICOM). Software vendors must rely on all three of the standards to get a complete medical system useful for hospitals. These real-time systems are available, but with old equipment, hospitals can't switch directly to the new systems. That is why most healthcare software developers work with the equipment manufacturers to develop drivers for the older equipment. With each custom 'driver', the software vendor must expand the system and the potential of incompatibility increases. Each standard is described below focusing on the problems of each in terms of security, incompatibility and implementation.

Although these standards are widely known in the Medical Informatics field, they are not commonplace terminology in the MIS field. Networking protocols, such as TCP/IP and Ethernet are used in healthcare systems, but are only the transport protocols, not the implementation (MIB) or the data standards (HL7 and DICOM). Since healthcare information systems must integrate with other systems, such as insurance companies and government agencies, the standards for data models and data access become more important to the success of a healthcare information system. Since most MIS researchers do not understand these standards, a short description of each standard is given.

Health Level 7 (HL7)

The HL7 committee was founded in 1987 in an attempt to develop standards for the storage and exchange of clinical, financial and administrative information generated by such hospital areas as laboratory, pharmacy, admissions, etc. It was designated as an accredited standards developer by ANSI (American National Standards Institute) in June of 1994. HL7 has grown from its modest beginnings to become "*the*" standard for vendors and most prominent hospitals the world over. It essentially is a protocol for electronic data exchange, defining transmission transactions for patient registration, insurance, billing, orders and results of laboratory and physiologic tests, imaging studies, observations, nurses' notes, diet and pharmacy orders and inventory/supply orders. In 2002, the National Committee on Vital and Health Statistics (NCVHS) recommended HL7 as the primary Patient Medical Records Information (PMRI) message format standard. That same committee adopted DICOM, NCPDP SCRIPT (from the National Council for Prescription Drug Programs) and IEEE 1073 (MIB) be recognized as standards for specific PMRI market segments.

HL7 is very flexible, being an "open system," which has led to some confusion and vendor "sales pitch stretch" as far as the issues of connectivity and "HL7 compliance" are concerned. In relation to the seven layer OSI model, HL7 is a seventh layer, application standard. It defines the data to be exchanged, sets timing of such exchanges and manages error messages between applications. It assumes compatible protocols for layers 1-6 and herein lies one of the difficulties of "HL7 compatibility" insofar as different I.T. routes may be taken in those layers to reach the application layer. Different systems from different vendors for aspects of the information system for a hospital could be incompatible in the other layers, especially the network layer.

The flexibility of the HL7 standard-which gives rise to this compatibility issue- is important because the level of care, demographic patient base, payer mix, content of physician versus respiratory therapy orders, etc. differs from institution to institution. Data fields differ widely from hospital to outpatient surgical center to multi-speciality clinic office. In its latest version (HL7 3.0), the issue of flexibility has received considerable attention and indeed is being scaled back as the problems of compatibility abound. ("The reduced optionality will greatly help HL7 to approach plug and play specificity. The slogan for Version 3 is, "optionality is a four-letter word."") (Health Level Seven Organization, 2001) Thus, an ongoing attempt to streamline the collection and retrieval of "static data," which HL7 represents, promises even more in the way of "plug and play" which the medical as well as general public has come to expect. Indeed, HLV3 as it is known represents a complete "rethinking" of the delivery of clinical information, as it is built around the concept of a single object model, the HL7 Reference Information Model (RIM.) The HL7 Board of Directors has proposed this as the solution to :

> "*The most intractable barrier to the application of information technology in healthcare has been the lack of standards for exchanging fine-grained, highly*

heterogeneous, structured clinical data among information systems. The strength
of Version 3 messaging is the exchange of fine-grained data without bilateral
negotiations." (Health Level Seven Organization, 2001)

It is felt that the adoption of HL7 V3 with its RIM which allows for the use of 96 hierarchical message descriptors (HMDs) that delineate specific message types which can be "implemented as a unique, but compatible XML schema" will advance the cause of a single, integrated suite of standards for health care informatics around the world. So far, the only evidence that this may come true is the adoption of HL7 by the NCVHS as the message standard.

Medical Information Bus (MIB)

MIB's scope: "To provide for open systems communications in
health care applications, primarily between bedside medical devices and
patient care information systems, optimized for the acute care setting."
MIB's purpose: "To allow hospitals and other health care providers
to interface medical instrumentation to host computer systems in a manner
that is compatible with the patient care environment." (IEEE MIB Website, 2002)

The critical care areas of a hospital represent a formidable challenge from an information systems standpoint (and from a health care standpoint too, I might add.) This is an area where the requirements for data generation, interpretation, status changes, alarms, safety and reliability, are far beyond those required of typical and "standard issue" computer hardware and software. The number of "device riders" on the "bus" can easily go from one to 7-8-10 within a matter of moments as a patient's status changes rapidly. It is not uncommon for patient monitors to suddenly and quickly increase their displays from simple EKG and temperature to 5-6-7 lines of waveform data, accompanied by a profusion of IMED (intravenous) pumps, a ventilator and cardiac support pumps within minutes. This is the environment where "plug and play" is not a desirable, comfortable, lazy man's feature but a matter of life and death. And indeed this was recognized very early on, in 1984, when the IEEE (Institute of Electrical and Electronic Engineers) founded the committee charged with writing the "Standard for Medical Device Communications." This committee, which produced the family of standards known as IEEE P1073 (MIB) has continued working to this day and needless to say has rewritten the standards several times in a continuing effort to reach a true plug and play environment where the manufacturer, model number, vintage (within reason) of a needed piece of equipment is of no consequence in the overall care/information picture except in so far as it performs its clinically designated task.

MIB is a model that focuses on object orientation- that is entities defined as objects by the MIB model, be they pumps, monitors, ventilators, etc. They may also include patients, doctors, nurses, therapists- in short all the "Virtual Medical Objects" in play at and around the bedside, as defined by MIB, using the Medical Device Data Language (MDDL). Since the objects, information, access to the information and usage /display of the information all are addressed by MIB, it is- in contradistinction to HL7- a full seven layer protocol stack in the OSI model. The lower layers cover the equivalent of what in an office would be covered by Ethernet and TCP/IP- that is the physical connections, topology and transmission protocols. Considerable effort was expended in the area of connections, grounding and safety, given the sometimes less than ideal environment in which these devices must function. Star topology- specified by MIB- can also be viewed as a safety device in so far as it prevents a single cable failure from bringing down the entire local device network (i.e. attached to one patient). MIB also specifies a once per second device polling to ensure prompt failure recognition.

The upper layers of the MIB OSI protocol stack define content, format, structure and syntax of the message in question. This area is of crucial importance for- unlike HL7 which is designed for PC and workstation type equipment, where significant computing power is available and where upper layers are loaded into the machine via the applications- MIB deals with micro controller and micro processor based equipment with little processing power and little if any programmability.   In addition, these devices are mobile, and must be connected and disconnected several times daily by non IT trained clinicians who neither know, nor care to learn, the finer points of network programming.

The upper layer protocol work has progressed slower than the lower. The IEEE has purposely attempted to standardize device classes, such as infusion pumps (the first to be standardized - IEEE 1073.1.3.1) in order to define parameters, attributes and services in a logical fashion. In addition, the Andover Working Group, a consortium of IT and healthcare companies under the direction of HP, has also continued work in this area and indeed has been one of the champions of standards based networks in this area. Finally, it cannot be ignored that MIB devices are by definition FDA regulated, which adds additional engineering, clinical and clerical "hoops to jump through" and which impacts the speed of advance of this work.

Digital Imaging and Communications in Medicine (DICOM)

Soon after the advent of CT (computerized tomography) scanners in the late 1980's, it became apparent that a method of storage and transmission of radiographic and other images more efficient than the traditional X-ray file room was needed. The American College of Radiology and the National Electrical Manufacturers Association formed a joint committee in 1983 to develop interfaces and standards relating to imaging equipment and other medical electronic equipment.   The first version of DICOM was published in 1985 and has undergone several revisions. (DICOM Standard Website at National Emergency Management Agency, 2001)

In its present form, DICOM 3.0 is a full 7 layer OSI protocol stack. This is indeed necessary given the bewilderingly different pieces of equipment from an impressive array of vendors that make up even a relatively unsophisticated radiological department. DICOM 3.0 addresses interoperability and such questions as: commands, information objects (CT scan, barium enema etc.) and their attributes, data element tagging, naming and semantics (interpretation),encoding rules for data stream construction, message exchange, all of which allow applications to establish sessions, transfer messages (data) and terminate sessions.   DICOM 3 allows support of numerous OSI protocol stacks, to include Ethernet, FDDI, ISDN, X.25, TCP/IP and other LAN and WAN technologies.   However, DICOM physical layer protocols specify a 50 pin cable to accommodate the large data transfer requirements inherent in medical imaging.

As in the previous discussion on MIB, the environment of DICOM devices can be less than ideal.   More importantly, the crucial aspect of virtual every byte of information in the reconstruction of images cannot be overestimated. The presence of errors in, or the failure of transmission of but a few bytes out of millions can render an image unreadable as understood in the clinical sense of the word. Indeed, recognizing that digital radiological images vary from 0.064 Mbytes per exam image(nuclear medicine scan) to 32 Mb per exam image(computerized radiography) and bearing in mind that transmission rates via a DS-0 would vary from 59 sec to 76 minutes gives the reader some idea of the magnitude of data accumulation, transmission and the extraordinarily low tolerance for error in this area of medical information technology.

Work continues on the DICOM standard, in particular on interface with HL7, crucial to enable demographic and other data needed for radiological examination to flow smoothly from the "static" to the "imaging" portions of hospital care. Once again, however, the term "DICOM

compliant" needs to be taken with a grain of salt when emanating from a vendor, for the sheer complexity and size of DICOM standards is such that no products currently implement it totally. Thus, careful consideration of the "non compliant" areas is in order and adequate planning for interfacing at those points is mandatory.

RESEARCH POSSIBILITIES IN HEALTHCARE INFORMATION SYSTEMS

Even though these standard organizations are starting to work toward integration of the standards, there are still no interface standards between them. With many hospitals integrating wireless technology, each standard organization must come up with security aspects of the standards that can ensure encryption of the data that meets or exceeds the necessary security requirements for securing the data over wireless networks. Compatibility issues of interfaces for portable equipment within the hospital setting is forcing software vendors and manufacturers to write special 'drivers' for all the possible equipment from all the different equipment manufacturers. Even though the Medical Information Bus (MIB) standard is for the portable equipment, older equipment used in hospitals don't have the MIB interface yet are still used in most hospitals today. Recent research suggesting that medical errors can be reduced with more technology integration also points out the problems with dealing with complex standards, government regulation and policies, and even physicians that are not technically savvy (Chung, Choi and Moon 2003).

Joint research efforts between MIS and Medical Informatics can lead to solutions for building healthcare information systems which encompass the complexity of multiple standards, provide real time/life saving access to information, and still satisfy the business processes of a hospital. Add to the complexity the legacy systems most hospitals have and the complexity of installation without data loss or service interruption multiplies.

Medical informatics has defined the two technology areas that need to converge as information processing methodology (IPM) and information and communication technology (ICT). Convergence and clearly defining the technology areas involved in successful design of healthcare information systems are research areas. Potential research areas have been defined for informatics in the areas of the electronic patient records (which relates to the HL7 standard), system architectures for medical information systems, and medical knowledge bases (Haux, 2002).

As vendors integrate the standards into the systems they sell to hospitals, the complexity of the task to fully automate and digitize all the information that any one patient can generate at one time, and all the data gathering equipment to be tied to the system, along with any image data that is needed in real time by primary and surgical care providers is also compounded by the legacy systems that most hospitals have with patient data that they can't afford not to tie into a new system.

Other areas for future research are defined by research that suggests managed care has limited the technology development and adoption in the healthcare area. A review finds limited literature on technology adoption affected by managed care (Baker, 2002). Integration of wireless technology, for instance, increases complexity of systems by requiring compliance to HIPAA, and requiring data collection and access security problems. Some researchers already recognize problems with wireless technology that they say will hinder the availability in hospitals due to interference with existing medical devices, and no immediate communication of urgent messages (Helsop, Howard, Fernando, Rothfield and Wallace 2003). Technological influence on patient treatments and treatment trajectories can lead to digital medicine. Social medicine researchers are already researching the socio-cultural influence of technology in health care

(Mechanic, 2002). Training in technology is necessary for healthcare workers, especially physicians, to use the technologies most efficiently and effectively. Defining the role of the physician in digital medicine, and therefore the training necessary for the physician has also been an area of research (Howell, 1999).

Most research in this area is from the medical side, while the amount of research in healthcare information systems in MIS is minimal in comparison. The value add from joint research to establish system architecture standards, knowledge base development research techniques, communication standards, system integration with legacy systems, and the potential of developing digital medicine can lead to great advances and rapid solutions to many of the problems outlined in this paper.

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