## Outsourcing in the Healthcare Industry: Information Technology, Intellectual Property, and Allied Aspects

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#### Abstract

The healthcare industry is being impacted by advances in information technology in four major ways: first, a broad spectrum of tasks that were previously done manually can now be done by computers faster, better, and at lower costs; second, some tasks can be outsourced to other countries using inexpensive communications technology; third, detailed analysis of longitudinal and societal healthcare data can now be analyzed in acceptable periods of time; and fourth, the best medical expertise can be made available to patients without the need to physically transport the patient to the doctor or vice versa. Still, there are many healthcare situations in which face-to-face interaction is the only practical way to render medical assistance. After considering a number of healthcare scenarios in which one or more of the co-authors were involved, this paper concludes that healthcare will increasingly use a portfolio approach comprised of three closely-coordinated components seamlessly interwoven together: healthcare tasks performed by humans on-site; healthcare tasks performed by humans off-site, including tasks performed in other countries; and healthcare tasks performed by computers without direct human involvement. This three-pronged approach will lead to better healthcare services at the most cost-economic rates; further, it will gradually incorporate some of the principles of the 24-Hour Knowledge Factory framework. Organizations that impede or otherwise restrict the use of this multifaceted approach will see higher healthcare costs, and will gradually become less competitive in the global marketplace, as is happening with non-adapting organizations in several other sectors of the economy. Finally, this

paper deals with intellectual property and legal aspects related to the proposed three-pronged healthcare services paradigm.

## 1. Introduction

Advances in computing and communications technologies are dramatically altering the healthcare landscape around the world in a number of ways such as:

Enabling detailed analysis of healthcare data to elicit underlying trends and interrelationships;

Facilitating storage, transmission, integration, and retrieval of healthcare records;

Enabling healthcare professionals to render assistance to patients separated by significant geographic distance from each other;

Monitoring the safety of medical procedures and pharmaceutical drugs; and

Bringing the latest healthcare information to the attention of healthcare professionals and others

In this paper, we take five operational scenarios, one from each of the five illustrative categories delineated above. In each operational scenario, at least one of the co-authors of this paper played a significant role and therefore possesses first-hand knowledge of that healthcare application. The operational scenario is analyzed, post-facto, from the viewpoint of diagnosing what subset of tasks can be handled by evolving information technologies without significant human intervention, what subset needs to be performed onsite by humans, both now and in the foreseeable future, and what subset can be potentially performed by humans located at a significant distance from the patient.

Based on the above analysis, we postulate that the future healthcare industry is unlikely to adopt a mono-operational scenario in which all the tasks occur onsite (as happened in the past), offsite, or by machines alone. Instead, the healthcare industry will gradually adopt an operational model in which there is a seamless and symbiotic combination of all three modes of operation.

After examining the future healthcare industry model from multiple perspectives, we conclude that we need a new approach to intellectual property in order to adequately safeguard the interests of the relevant constituencies. Based on the forces that will motivate the change, we further assert that healthcare organizations that are unwilling to adapt and embrace the evolving three-faceted work paradigm will be at a competitive disadvantage to their peers. National, state, and local medical regulatory agencies will need to respond to market pressures in order to support the long-term interests of both medical professionals and patients in their respective jurisdictions.

# 2. Comprehensive Analysis of Healthcare Data

One out of eight women in the US will develop breast cancer during her lifetime. Early detection is a woman's best defense against breast cancer, which is 97% curable when detected and treated at an early stage. Mammography is the gold standard for screening for breast cancer. With the trend towards people living longer lives and taking proactive measures on their health, the demand for

mammography is increasing at a significant pace. Unfortunately, 10% - 20% of the cancers currently detectable by a screening mammogram are missed by the human radiologist, allowing the disease another year to progress. In addition, there is a high degree of liability on radiologists due to missed diagnoses. To mitigate this problem, some radiology screening centers employ two radiologists to read each case. This approach involves significant cost to support an additional radiologist, reduces the number of total mammograms that can be performed within a center, and is problematic due to the shrinking numbers of radiologists in the field of mammography, especially in the U.S.

Based on the latest information available on the FDA website, there were 8,832 FDA certified mammography centers and 13,511 accredited units in the US (October 2006). In the year 2006, there were 34.6 million mammograms performed in the U.S. alone, which translates into a total market of \$5 billion (at \$150 per mammogram). Globally, there are over 200 million mammograms per year, which translates to a market running into several billions of dollars per annum. As the population of women over 40 increases and the awareness of proactive health measures, such as mammograms, get enhanced, the number of mammograms increases every year. However, a decrease in mammogram centers and the number of radiologists in this field are negatively correlated with the demand.

The area of mammography and the aspect of errors in diagnosis (both false positives and false negatives) have been studied in detail by many researchers (Berlin, 2005;Ghate et al. 2005; Gilbert et al.; 2006; Khoo et al. 2005; Sickles et al. 2002; Skaane et al. 2006).

The use of Computer Aided Detection (CAD) techniques in mammography can mitigate the growing shortage of radiologists, as well as reduce or eliminate many of the instances of missed diagnosis. One of the authors of this paper and several of his colleagues have developed new computer-based algorithms that allow a rapid analysis leading to the marking of cancerous and precancerous regions, thereby providing a decision-support diagnostic facility to the radiologist. Using a CAD-based approach in conjunction with a human radiologist allows for the second reading of a mammogram, with the human radiologist actively involved in the process and making the final determination in each case. The advantages of the proposed approach are:

- The capital investment of using a CAD service is significantly less, when compared to that of employing a second radiologist;
- No additional hardware or space requirements;
- Current and previous cases can be made available to the radiologist on line for necessary comparison;
- Minimal footprint in the workspace, allowing multiple radiologists to objectively view and analyze mammograms;
- Results and information can be made available anywhere via the Internet;
- Improvements to the algorithm and core technology can be readily disseminated;
- The approach is consistent with the trend towards teleradiology, allowing radiologists to perform analysis from anywhere, anytime.
- The proposed approach reduces the incidence of second visits and the level of patient anxiety, by providing expert (specialty) second opinions when needed in a timely manner through a teleradiology model.

The proposed approach was developed in 2001 and 2002 (Gupta et al, 2002), and its technology component is described in (Norman and Gupta, 2002). It advocated that instead of taking the mammogram image and its interpretation by the radiologist at the same location, it would be more advantageous to use a geographically decentralized strategy that utilized the following principles:

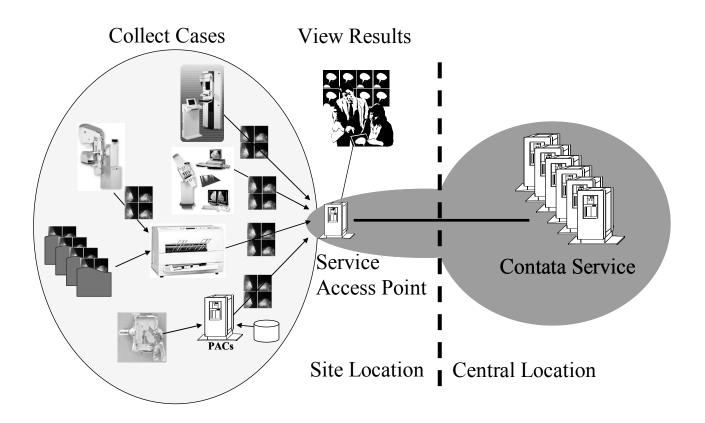
- Taking of the mammogram image by a technician at the location where the patient was available.
- Transmitting the image to a central location where the image was analyzed by advanced data mining techniques and compared with other images.
- Interpretation by a qualified radiologist at the same location where the centralized computing facility is located or at a different place altogether.
- Making the image available, with appropriate privacy and security safeguards, to the patient when she visits other clinics and to appropriate medical personnel with the patient's consent.

Based on unique and patentable distributed computing technology, a peer-to-peer model was implemented; it could act as a pure application service provider (ASP), a pure client application, or any combination in between. The proposed solution could:

- Minimize or eliminate the costs of a "second reader"
- Provide scalability for large, medium and small centers (national and international)
- Support the development of distributed teleradiology systems
- Decrease the liability factor for false readings
- Improve equity of access to radiology services by employing only technicians on-site and performing both human and CAD readings off-site

The proposed technology envisaged a long-term vision of "Image Anywhere", where there is a network of mammography screening centers in shopping malls across the country. A woman could step into a mammography center as easily as walking into a drug store. While the screening was performed at that site, the radiologist could be located hundreds of miles away looking at images from several mammography centers (via teleradiology), and could provide an opinion back to the concerned location within a few minutes of the screening time.

Finally, the proposed architecture and the technology could be readily adopted for use with all other types of medical images, as depicted in Figure 1. After establishing a track record with mammography CAD, the plan envisaged expansion into auxiliary applications (first medical, then non-medical). These include dentistry, CT colonography, and bone cancer detection.



# Figure 1: The integrated architecture for the use of on-site medical personnel, off-site medical personnel, and computer-based techniques for mammography and other medical applications

The above concept was unanimously voted to be the first place winner at the Big Red Venture Fund Innovation Contest (2002), organized on an annual basis by Cornell University. To the best of the authors' knowledge, this is the pioneer instance where the three pronged strategy of using resident medical resources, off-site medical resources, and advanced computational techniques was explicitly delineated; this was done in the context of optimizing the productivity of radiologists, enhancing access to mammography centers by women, improving the quality of interpretation of mammograms, reducing the incidence of errors (both false positives and false negatives), and reducing the costs incurred in performing mammograms.

# 3. Management of Healthcare Records

As healthcare costs continue to rise, researchers are exploring new options for enhancing the process of sharing medical data across disparate information systems, both within and across hospitals and other healthcare facilities. This has the potential to reduce costs by billions of dollars each year, estimated at \$ 77.8 billion dollars for the U.S. alone (Walker et al., 2005), and concurrently improve the quality of healthcare rendered to patients. Each of the entities in the current generation of hospital systems was built to function on an individual basis, with each island of information governed by its own idiosyncratic data model (Shortliffe, 1998). In the U.S., only regional interoperability has been implemented, so far, on an experimental basis (Halamka et al. 2005). The absence of a larger scale interoperable system presents other problems too. For

example, in the case of a plane crash or other catastrophic situation, the manual approach to accessing large numbers of patient records is very weak (Teich et al. 2002). There are several other facts which further strengthen the requirement for interoperable healthcare systems, such as: (i) there is a large number of cases where institutions have split or merged, and existing data are physically distributed; (ii) there are several 'mobile' individuals who frequently use medical facilities in different states or even countries; and (iii) the aged population contribute significantly to overall healthcare costs and very often have limited mobility. This increases the requirement of access to healthcare records from a previous residence or transmittal of medical data to remote facilities for diagnosis rather than to move the patients themselves.

The challenges inherent in transforming disparate islands of data into an archipelago of integrated information have been highlighted by Gupta (1988) and others (Reddy, 1994; Arellano, 1998; Arts, 2002). The constituent systems differ in terms of data types, data definitions, data structures, data hierarchies, data categorizations, and underlying assumptions that are not expressly denoted in the concerned information systems. Imagine that you receive an electronic medical record of a new patient. The weight of the person as shown in the corresponding database field is 75. If you are a medical professional in the US, your immediate reaction is that the person is extremely underweight, based on the assumption that weight is specified in pounds, whereas it is actually in kilograms. The US is among the handful of countries that still use the traditional British system for most measurements; the other counties in this category are in Africa. Britain moved to the metric system a few decades ago. Ironically, the healthcare arena is the only one where the metric system has been adopted in the US for measurement of mass and volume. However, many other types of differences continue to remain in terms of underlying assumptions of data types and other parameters; such assumptions are not revealed by looking at the data alone.

The above example highlights that healthcare data must often be converted from one form into another to facilitate communication, either at the source or at the destination. The process of conversion of data, manually or by computer, involves significant costs and is prone to the loss of information (Barthell, 2004; Shapiro, 2006). Since many healthcare applications require access to each others data, and neither the source nor the destination is willing to do the required conversions, the only possible solution is to transform the data en route from the source to the destination.

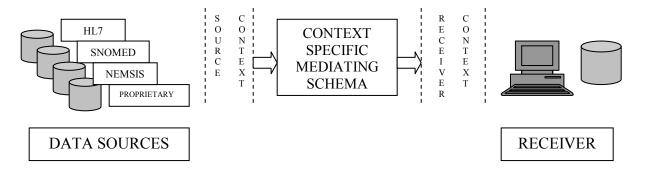
The format and other details related to the data at the source are maintained in the source schema. The target schema contains the same types of underlying information for the destination. As the number of potential sources and potential targets increase, the number of likely transformations increases in a non-linear fashion. Haas et al. (1997), Milo and Zohar (1998), Abiteboul et al. (2002), and Shaker et al. (2002) advocated the use of middleware and the use of one common schema that incorporates data elements from multiple client schemas. The complexity of this common schema increases with the number of sources and targets, thereby restricting the use of this approach in large, diverse healthcare applications.

Wiederhold and Genesereth (1997) highlighted the fact that a single mediating schema in a large domain such as healthcare is not feasible and advocated that that the implementation of domain-specific data standards and mediators across heterogeneous medical information systems results in a cost decrease for mediating the transfer of data. Despite these findings, there is minimal

standardization in the creation of healthcare information systems in the United States and in many other countries. This means, for example, that if there are "m" ambulance systems and "n" Emergency Department systems that could potentially need the medical data from any of the "m" ambulance systems, one could be dealing with as many as "m multiplied by n" transformations of data. Given the complexity of dealing with such a large number of possibilities, the process of data transformation is clumsy, time-consuming, and costly (Gupta, 1998).

One approach to address the above problem of non-linearity is to create a mediating schema as the framework for reconciling heterogeneous information systems within and across hospitals and other healthcare facilities. Using the approach described in several papers, including Reddy and Gupta (1995), the number of necessary transformations can be reduced from "m x n" to "m + n". This requires that the mediating schema contain a core set of context-specific patient care related information and a comprehensive methodology for specifying the ontology (vocabulary) of the relevant healthcare domain. The lattice based context interchange approach, described by Reddy and Gupta (1995), allows evolutions of the semantics of data in the source or target schemas to be managed in a more effective manner as compared to traditional approaches. Differences in ontology always exist in large information systems (Wiederhold and Genesereth, 1997). Within a single hospital, each healthcare unit may collect, store, and process its own set of data, based on its own specialty and needs. The application of the mediating schema approach requires the careful study of the different ontologies, and the formulation of rules to transform data from a particular ontology to another.

Sarnikar et al (2007) describe the problems and challenges involved in creating a mediating schema that would transfer data between the heterogeneous databases of a particular pre-hospital and ED system in the Boston area, and in extending the prototype system to cater to the idiosyncrasies of additional medical systems (see Figure 2). Based on the assessment of the size and complexity of the source and destination databases, as well as the associated data dictionaries, it was concluded that the mappings between single data elements needed to be done manually. This was based on the realization that the available software approaches to automate the mapping process between databases were frequently unreliable and required human intervention to analyze and to make corrections to the mappings generated. The manual creation of mappings could, however, lead to a set of development rules that could facilitate the creation of additional schemas in the future.



# Figure 2: The use of the mediation approach to reduce the effort involving in integration data from heterogeneous information systems (Adapted from Sarnikar et. al. 2007).

These tasks involved extensive consultation between members of the development team and experts from several concerned medical specialties, especially for "analysis of what information most succinctly and completely composed the patient care record across the source and target hospital information systems." The analysis of the data elements involved acquiring deep understanding of the meaning of each element in the source schema and its corresponding element in the target schema, as well as the associated differences in cardinality.

Sarnikar et al (2007) presented a performance analysis of the above system in terms of information loss during the automated data translation process, relative to the coverage (amount of fields populated in the target schema using information from the source schema). Due to the presence of certain type conflicts and missing-data conflicts, a small amount of information was lost (< 15%) in the presence of significant coverage values (> 80%). Further, this was eliminated through the use of appropriate converters and filters.

Industries and applications that are still at an evolutionary stage are frequently characterized by the existence of no standards or by the existence of too many standards, none of which carry broad acceptance. In the case of the healthcare arena, multiple standards currently exist, including HL7, EDIFACT, X12, ASTM, NCPDP, DICOM and XDT (Dudeck, 1998). Further, as a reviewer of this paper pointed out, the need for the transmission of medical data may be acute, sub-acute or delayed. The electronic transmission of acute data (pre-hospital to emergency department) usually occurs in the case of healthcare providers who can use a common data set for their medical records. Sub-acute transmission could apply in situations involving hospitals and providers who use similar data elements, but not necessarily a similar platform. Delayed transmission, such as transmission of data across a national boundary, will need a standardized health care language, but not common data elements or platforms.

Based on the above discussion, we find that the use of cutting edge computer and communications technology alone cannot accomplish the goal. Instead, large amounts of computational power and human expertise are needed to create the bridges across legacy healthcare information systems at this stage. Hospitals and other healthcare facilities in the US have traditionally used medical and information technology personnel in the US to undertake initial efforts in this area. Unfortunately, a vast majority of work remains to be done, and this cannot be accomplished, in terms of both time and costs, by the personnel available in the US. As such, one needs to explore non-conventional solutions that involve the use of resources from abroad.

Until the eighties and the nineties, large US companies belonging to other sectors of the economy focused on doing all of their information technology work in the US (Gupta et al. 2007). This was the traditional model, and the concerned management and technical personnel were satisfied with the pace of progress. Options for doing such work abroad, or by persons recruited from abroad for temporary work in the US, were frequently discarded on the basis that:

(i) only the persons currently associated with the work were familiar with the intricacies involved, thereby implying that such peculiarities were too complex or too confidential to be shared with others;

(ii) organizational procedures or governmental regulations did not permit data and process information to be transmitted abroad or shown to foreign nationals;

(iii) the concerned work was too important for the success of the company and the option of saving costs on this particular application was miniscule in comparison; and

(iv) the work could not be performed by persons working in Asia because the difference in time zones made it impossible for them to interact with domain experts in the US.

The above situation was dramatically altered by the Y2K dilemma. Management and technical personnel could no longer plead for 6 more months to complete a project. The date, December 31, 1999, was a very hard deadline, and the conversion of information systems had to be completed by then: no exceptions, indeed. This inflexible scenario forced the companies to become flexible. They permitted parts of the conversion work to be done abroad, as well as to employ persons with foreign qualifications and experience. The conversion from national currencies to the common currency, euro, had a similar impact in Europe. The unqualified success in both cases forced companies to depart from their arrogance in maintaining status quo.

A similar compelling need currently exists in the case of management of healthcare records. Conventional database systems are clumsy, costly, and time consuming. The integration of information in such systems, as well as the gradual incorporation of newer concepts, requires the healthcare industry to seriously consider the use of the hybrid model, involving the use of human resources in the US, human resources abroad, and state-of-the-art information technology. The success of the banking industry, the insurance industry, and several other industries too relies heavily on ensuring the privacy and the security of data belonging to their customers. Yes, glitches do happen from time-to-time. In 2004, information on 20 million credit card holders was compromised at a credit card processing facility in Tucson, Arizona. This particular facility was subsequently acquired by another company. But this unauthorized disclosure was not used as the basis to cease this type of application altogether. Instead, it should serve as the motivator for human experts, both in the US and abroad, to develop more robust applications that can be used by more industries.

## 4. Remote Diagnosis

Remote diagnosis is both an outsourcing and an insourcing phenomenon. For many years, medical records and medical images from patients and healthcare practitioners in Latin American countries, as well as from other countries in the world, have been reviewed by doctors at Massachusetts General Hospital in Boston and by a number of other leading hospitals in the US. The Arizona Telemedicine Program (ATP) is a pioneer in terms of medical professionals located in Tucson, Arizona, providing expert advice to patients located elsewhere in the state, in neighboring states, and in other countries. ATP provides teleradiology, telepathology, and teleoncology services to patients in hospitals, in prisons, and in other settings (Weinstein et al. 2007). A significant number of the patients, who seek remote diagnostic advice, are from Navajo Nation and from other Native American nations in Arizona and neighboring states of the US.

On the outsourcing side, medical personnel in other countries are looking at medical records of patients in the US. The specialty that has witnessed the most attention is teleradiology (Pollack 2003). Teleradiology involves the electronic transmission of radiological images, such as X-rays, computed tomograms, and magnetic resonance images, across geographical locations via telephone lines, satellite connections, and wide area networks. It enables a single radiologist to serve multiple hospitals concurrently, even ones in other continents. Further, it enables the image to be interpreted by an alert physician working a day shift rather than a radiologist who has been up all night (Weinger & Ancoli-Israel, 2002; Firth-Cozens and Cording, 2004).

Telemedicine is the delivery of healthcare services in situations where the physician and the patient are not at the same geographic location; it is a broad term and includes teleradiology, telepathology, and teleoncology. Telepathology involves the use of video microscopy at the patient's location and a pathologist's workstation at the physician's location. Teleoncology refers to the use of remote technology to address different aspects of cancer care.

For the purposes of studying "Remote Diagnosis", we will focus primarily on teleradiology for four reasons. First, the area of teleradiology has attracted wide attention in the media; see, for example (Pollack 2003) Second, this paper focuses on outsourcing rather than insourcing, and the other specialties are characterized more by insourcing than by outsourcing. Third, within outsourcing, we are focusing on offshoring issues and are looking at applications that transcend national boundaries, not just local or state boundaries. Fourth, the teleradiology scenario allows an objective assessment of the potential risks and opportunities for individual radiologists in the US, as well as for the broader medical community in the US.

The growth in teleradiology is being driven by four major forces. First, there is a significant shortage of radiologists, because of a significant number of radiologists retiring from practice and training programs not keeping pace with growing demand (Sunshine et al., 2004; Bhargavan et al., 2002). Second, the aging population and the advent of newer imaging technologies are leading to annual increases in imaging volumes; for example, a 13% increase in the utilization of radiological imaging was observed among Medicare beneficiaries (Maitino et al., 2003). Third, the increased use of imaging technologies in trauma situations has led to a corresponding need for round-the-clock radiological services in hospital emergency rooms (Spigos, Freedy and Mueller, 1996). Fourth, changing regulations and guidelines have contributed to the need; as an example, the Health Care Financing Administration (HCFA) requires that overnight coverage be provided by certified radiologists, rather than by residents or trainees in order to be billable (Federal Regulation 60: 63124).

Typically, the radiology group outsources its night calls to a teleradiology provider and pays the latter for preparing the preliminary report. The insurer is billed for the final report that is prepared by the radiology group the following morning. The service delivery model depicted in Figure 3 includes mechanisms for communications, workflow, and payments.

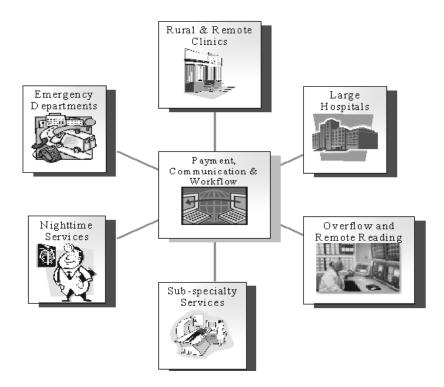


Figure 3. A Service Delivery Model for Teleradiology (Adapted from Kalyanpur et. al., 2007)

Teleradiology offers several advantages: (i) a single professional can support multiple hospitals concurrently via teleradiology links to a central reading facility (often the radiologist's home); (ii) remote locations with radiological scanning, but no on-site radiologist, can be supported leading to improved patient care (Franken et al., 1995; Lee et al., 1998); (iii) the productivity of the radiologist can be enhanced by bringing the images to the radiologist, rather than vice versa, thereby eliminating commuting time and delays; (iv) the work can be optimally assigned among multiple radiologists in large hospitals; (v) greater availability of subspecialty consultations resulting in better patient care (Kangarloo et al., 2000; Franken et al., 1997; Sickles et al., 2002); (vi) residents (junior doctors) covering night shifts in academic hospitals can use teleradiological services to ensure correct diagnosis and to seek confirmation; and (vii) the increasing disparity in the patient-to-radiologist ratio, especially during off-peak hours, can be effectively addressed by off-shoring teleradiology services.

The increasing availability of technologies that replace invasive screening procedures (virtual colonoscopy replacing actual colonoscopy) means enormous increases in patient volume. Further, defensive medicine increasingly employs tests to guard against missing even the most unlikely diagnosis. The use of head CT in the ED under circumstances when the chance of an abnormal reading is extremely small is one example. It remains commonplace to get a head CT done if the patient has expected meningitis before doing a lumbar puncture, even though the literature indicates this is typically unnecessary. While this example of defensive medicine is not gratifying to mention, it represents the current reality. It also provides another reason why the workload in the radiology department has increased, and will continue to increase further.

Teleradiology providers must conform to the guidelines of the Health Insurance Portability & Accountability Act (HIPAA) and are required to implement adequate privacy and security practices as Protected Health Information (PHI) and Electronic Protected Health Information (EPHI) are transmitted over public networks on a regular basis. HIPAA requires that "covered entities execute contracts that consist of specific provisions for protection, use and disclosure of health information" (Hilger, 2004). The Privacy Rule deals with all forms of patients' protected health information that is in electronic form, including EPHI that is created, received, maintained or transmitted. The security rule does not prescribe any specific technologies; being technology neutral, it allows the HIPAA covered entities to choose solutions based on their specific requirements. Technical safeguard standards include stringent guidelines for Access Control, Audit Controls, Data Integrity, Person or Entity Authentication, and Transmission Security.

The biggest hurdle to the rapid deployment of teleradiology services is the credentialing process. The US requires state-wide licensing requirements and board certifications; as such, a teleradiologist based in Australia must be registered to practice in all the relevant states in the US, in order to look at radiological images from hospitals in these states, as well as pay appropriate fees to these states on an annual basis. Canada does certification at the national level for radiologists. And in Europe, some of the members of the European Union allow still greater flexibility. The current U. S. regulatory and credentialing structure was designed for a physical presence of medical professionals, and needs to be adapted for the evolving technologies and procedures. Recently, some states have modified credentialing laws to allow out-of-state radiologists to perform remote diagnosis. Further, several federal and military healthcare organizations in the US have licensure laws that enable them to render services independent of state and national boundaries. However, such privileges have not been extended to the private sector.

Other obstacles to the growth of teleradiology are: (i) limited availability of reliable internet connections, especially in remote locations; (ii) limited availability of trained technicians; (iii) traditional billing and reimbursement procedures that vary by country and state, such as Medicare not paying for services rendered from abroad; (iv) variations by nations and states, as well as underlying ambiguity, in medical malpractice liability laws Gantt (1999); (iv) and the need for incorporating new encryption methods while transmitting image data (Cao et al., 2003).

Other related aspects of radiology have been discussed by several researchers (Bradley 2004, Graschew et al. 2006, Hayward 2000, Jacobson and Selvin 2000, Kalyanpur et al. 2003, Kalyanpur et al. 2004, Levy and Yu 2006, Maitino et al. 2003, Mun et al. 2005, Takahashi 2006, Weinger and Ancoli-Israel 2002).

Over time, the concept of using both onshore and offshore radiologists will grow in terms of overall numbers of radiological images analyzed, as well as in terms of the breadth of the cases studied. Further, we expect the trends in both insourcing and outsourcing to continue. Parts of some medical diagnostic and allied applications will be performed abroad because of lower costs, quicker response, and load balancing. Conversely, more patients from abroad will seek professional advice from medical experts in the US. Overall, it appears appropriate to gradually lift barriers that currently impede outsourcing and insourcing activities; most of these barriers are in the former category.

### 5. Monitoring and Enhancement of Safety

Timely information on adverse drug effects can save lives and reduce healthcare costs. Previous studies show that more than two million adverse drug reactions occur yearly and are responsible for an estimated 100,000 deaths (Lazarou, Pomeranz and Corey, 1998; Gurwitz, Field, Avorn, et al., 2000; Fontanarosa, 2004). Some systems exist for identifying drugs with serious adverse effects, but they have had limited success (Kopec, 2003; Ray, 2006). Between 1997 and 2005, the MedWatch system in the US identified 15 drugs with toxic side-effects, taking an average of 5.9 years for the identification phase and the subsequent drug withdrawal phase. In general, after the introduction of a drug into the market, the process of eliciting and analyzing information from patients is weak, especially when problems arise during extended use of the drug (US Department of Health and Human Services1999, Brewer and Colditz 1999; Okie, 2005). The problem with Vioxx, for example, was only uncovered during controlled clinical trials (Bombardier, Laine, Reicin, et al 2000). And there is still no system, either in existence or under discussion, for addressing this need at a global level.

In order to address these issues, the Institute of Medicine (2006) presented a report on "The Future of Drug Safety" and made the following recommendations: (i) Increase FDA's authority to ensure sponsor compliance with standards and regulatory requirements, especially those related to packaging and distribution: (ii) Establish separate performance goals for safety, in addition to existing goals for speed of approval: (iii) Ensure proper communication of the drugs approval/testing status to consumers and medical practitioners through effective package indicators and advertisements; and (iv) Improve the facilities, available resources, and organization structure of the FDA

Towards these goals, a prototype Community Pharmacy Safety Network (CPSN) was developed. Pertinent raw data are spread over the computer systems of multiple organizations including: 1) the one who performed the original drug development work; 2) the one that produced the drug; 3) the one that conducted the clinical trials; 4) the FDA in the US and equivalent government agencies in other countries; and 5) one that prescribed the medication. In addition, pharmacies contain information on the buyer of the drug, on what date, and in how much quantity. The problems involved in integrating these types of information from diverse sources were discussed, in a different context, in Section 3; additional details are available in recent papers by Kalyanpur et al (2005), Corcho and Gomez-Perez (2005), and Cristani and Cuel (2005). The problems become even more complex in the present case because of the need to access information from multiple countries and cultures.

The prototype system, including the key modules, is depicted in Figure 4. Detailed information on the system architecture and allied issues are available in (Gupta et al. 2007A, Gupta et al. 2007B). With proper infrastructure and incentives, pharmacists and pharmacy technicians would be designated agents for collecting raw information on the patient's medication history, including the adverse reactions experienced by the patient.

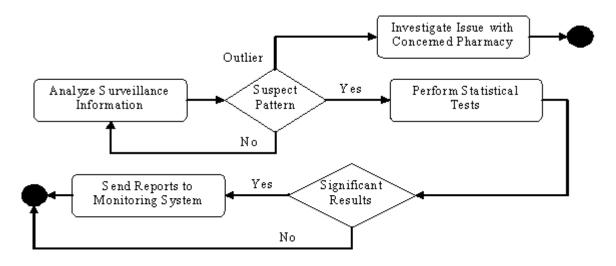


Figure 4: Surveillance Process for Medical Drugs (Adapted from Gupta et al., 2007)

Development of the prototype system revealed several issues and opportunities. First, some drugs are given as samples by physicians to patients and significant effort would be involved in incorporating such information into the overall system. Second, individual patients buy drugs from multiple pharmacies; in view of the current guidelines for privacy of patient records, it is very difficult to link records concerning the same patient from different pharmacies. Third, the procedures differ very significantly across countries. Fourth, analysis of the information requires the use of sophisticated data mining technology, with the help of (human) domain experts and (human) data mining experts. Such experts are already pressed for time in the US; they are expensive too. It therefore seems appropriate to explore if this type of work could be done abroad. For example, one could envisage the creation of a global center of excellence for this particular field in Mexico, close to the US border, so that one could benefit from the less expensive rates in Mexico in conjunction with the feasibility of experts from the US visiting such a center on a frequent basis.

Gopal (2007) and her associates have employed an entirely different approach to assimilate information from patients, especially related to the side effects of alternative medicines. Their approach focuses on the mining of information from chat groups and other online repositories of information voluntarily provided by the patients, such as message boards, blogs, and list serves. They utilize proprietary search and aggregation techniques to distill raw data into structured information that answers critical questions. Their approach, again, utilizes a combination of computer power and human expertise.

## 6. Dissemination of the Latest Healthcare Information

The ideas presented in this section are currently geared more towards medical education and medical research, rather than the provision of improved patient care. The current version of the prototype system enables users to search for current and previous literature, how-to articles and other educational items. In the future, the enhanced website will assist healthcare providers by providing immediate lookups for symptoms and diagnosis. This would not only aid practitioners by giving them access to the latest medication data available, but also reduce treatment times. Further,

based in part on a suggestion from a reviewer of this paper, access to a human expert will be provided for the purpose of providing additional advice and support on specific cases.

Medical information has been maintained in books, journals, and specialty magazines. Now, a growing number of people turn to the internet to retrieve healthcare related information, and they do so from a variety of sources, most of which are run by commercial entities. The next area of growth will be sites that focus on specific fields of medicine, contain data culled from scholarly publications, and are operated by eminent specialists in the field. One such site is being developed for the field of gastrointestinal motility; it builds upon the concept of existing healthcare information sites with the intention of serving the diverse needs of lay people, medical students, and experts in the area. The site, called Gastrointestinal Motility Online, leverages the strengths of online textbooks, which have a high degree of organization, in conjunction with the strengths of journal collections, which are more comprehensive, to produce a knowledge base that can be easily updated, is comprehensive, and can provide accurate and high quality information to users. In addition to implementing existing web technologies such as wiki and Amazon-style commenting options, Gastrointestinal Motility Online uses automatic methods to collect information from various heterogeneous data sources to create coherent, cogent, and current information for the diverse base of users.

Gastrointestinal motility is a very small part of the vast field of Medicine. Books such as Harrison's Principles of Internal Medicine serve as the main source of information in the field of medicine including gastrointestinal motility (Kasper, Fauci, Longo, Braunwald, Hauser, and Jameson 2005). Most of these books now also have electronic versions. More recently, electronic texts sites such as Wiki, eMed, WebMD (http://www.webmd.com/) and UpToDate (http://www.uptodate.com/) have evolved and are rapidly gaining popularity. Because these works are designed to provide a broad overview of the field of medicine, they only provide a very superficial treatment to a topic such as gastrointestinal motility. More detailed information about gastrointestinal motility disorders may be found in medical journals. Many journals that were previously in paper format now come out both in paper and electronic formats. Searchable electronic archives, such as PubMed (http://www.pubmedcentral.nih.gov/), now place a plethora of information into the hands of researchers and physicians. However, such searches are very time consuming and inconvenient. Sites like AccessMedicine (http://www.accessmedicine.com/) serve as search engines that attempt place the most suitable information on a medical topic in a user's hand.

As shown in Figure 5, Gastrointestinal Motility Online is a hybrid between standard textbooks and review articles. It seeks to centralize the information and to present the information in a scalable manner that is customized to the user's information requirements. The user base includes: lay persons, patients, medical students, biomedical scientists, physiologists, pathologists, pharmacologists, biomedical students, researchers, pharmaceutical personnel, house staff, specialty fellows, internists, surgeons, and gastroenterologists.

Online Textbook -Well organized -Well edited -Updated infrequently -Specific audience -Not as comprehensive Journal Collections -Loose organization -Limited editing -Frequent updates -Comprehensive -Limited search features

Hybrid - GI Motility Online -Comprehensive -Well organized -Frequent updates -Well edited -Intelligent features, such as knowledge searching, differential diagnosis

# Figure 5: Gastrointestinal Motility Online is a Hybrid of Online Textbooks and Journals

Creation of the gastrointestinal motility knowledge repository started with calls to key gastrointestinal experts inviting them to submit a chapter, in electronic form, for inclusion in this knowledge repository. The titles and themes of these chapters were determined through discussions involving the concerned authors and the editors for this project (Dr. Goyal and Dr. Shaker). The inputs from the contributing authors were reviewed by the editors and by others. Under the aegis of an unrestricted grant from Novartis Corporation, the two editors worked closely with the staff of Nature Publishing Group on a number of tasks that ultimately led to the creation of the following website:

#### http://gimotilityonline.com

This site may serve as a model for user driven, scalable, and interactive medical information at a single site for other specific medical topics. These sites can then be interlinked to cover the broad field of medicine. Since, GI Motility Online is a hybrid that includes textbook type material as well as authoritative up-to-date reviews and also contains interactive features, it posses many new problems and opportunities. Currently, all updates must be initiated manually. Automated content generation or extraction from other publications is not feasible, due to the stringent need to maintain relevance and quality. This applies to addition of new material, editing of existing material, and deletion of parts of existing material as new test results become available.

In the next part of the endeavor, the goal is to enable machine-assisted updating of the material in the gastrointestinal knowledge repository. Given the large number of articles published weekly and the difficulty in ascertaining relevance and quality, a number of automated tools will be used to optimize the updating process. One technique that will assist in the maintenance and updating of the site is presented in (Sarnikar, Zhao, Gupta, 2005). This method selects articles ranked by relevance using a combination of both rule-based and content based methods, using the following principles:

- 1. Profiles are modeled in the form of rules.
- 2. The purpose of the rule based profile is used to identify sub-set of documents of interest to a user.
- 3. Each role has a set of predefined rules associated with it.
- 4. Rules specify knowledge sources to access (for example, nursing journals for Nurses).
- 5. Rules can specify knowledge depth and knowledge breadth.
- 6. Rules can specify semantic types of primary importance to roles.

Profiles are used in the gastrointestinal motility context to separate information into categories; for example, new clinical findings versus basic science. Articles could be assigned a category and a weight, given categorization rules based on Unified Medical Language System (UMLS) synonym lists and the categories sign or symptom, diagnostic procedure, therapeutic or preventive procedure and disease or syndrome semantic types. These tools can form the basis for an RSS XML news feed or to efficiently assemble relevant articles for use by the editors or website administrators. While these tools will aid the editor, there is no replacement for the role of humans in selecting and classifying information.

Ontologies and semantic networks are necessary prerequisites to the development of and classification of information repositories. Ontologies serve many purposes including: to reuse and share domain knowledge; establish classification schemes and structure; and make assumptions explicit. They also allow analysis of information and complement the stricter terminology that is used in straightforward text searches, with or without synonyms. Examples of ontologies in use today include the National Library of Medicine's Medical Subject Heading (MeSH), disease specific terminologies such as National Cancer Institute's PDQ vocabulary, drug terminologies such as the National Drug Data File, and medical sociality vocabularies such as the Classification of Nursing Diagnoses and the Current Dental Terminology. In Gastrointestinal Motility Online, the ontological hierarchy will be used to make distinctions between parts of the gastro-intestinal tract and the different sections of the stomach and the esophagus (Kumar, 2005).

One of the keys to developing an automated system is the set of ontologies presented in the UMLS semantic network that rely upon the concepts built in the UMLS concept hierarchy. An overview of the UMLS is available at:

<u>The Unified Medical Language System: What is it and how to use it?</u> (http://www.nlm.nih.gov/research/umls/presentations/2004-medinfo\_tut.pdf) UMLS is an aggregate of over 134 source vocabularies, including the classifications from such lists as ICD-10 and DSM: IIIR-IV. It represents a hierarchy of medical phrases that can be used to classify articles and textbook entries.

The system described in (Sharma, 2005) uses techniques of Natural Language Processing (NLP) to construct a semantic understanding that goes beyond text searching. Using the ATIMED (Automated Integration of Text Documents in the Medical Domain) system, the content and order of phrases are related lexically using a concept called Word-Net. Word-Net operates on the verbs, subjects and objects of the sentences, comparing sets and subsets of subject-verb-objects collections in order to determine relatedness to a desired topic. Sharma et al. (2005) use the following two sentences as examples: Dysphagia is related to obstruction of passage of food. Since both sentences use similar objects and subjects, and use the verb "is", the sentences would be deemed similar. However, the phrase, "Dysphagia relates to obstruction of passage of food" would not result in potential match because the action verb is not similar (Sharma, 2005).

Developing a schema to accurately represent journal abstracts and determine the relevance of those abstracts is one method of exchanging contexts. Innovation in this domain allows Gastro-intestinal Motility Online to maintain updated consistent quality references without requiring an editor to read all journal articles published immediately. Knowledge-mining tools are being developed to utilize this information as it becomes available to add fast, relevant access and other utility to the information repository. Advanced technologies to aid in the conversion and integration of articles and research into the mainstream science are being integrated, and look to impact the breadth and speed of knowledge-base upgrades. These activities involve the use of medical and computer professionals, both in the US and abroad.

The base site is hosted by Nature Publishing Group. As this site was being developed, it was found that commercial tools were available to handle the production of electronic journals and static textbook efforts like AccessMedicine (http://www.accessmedicine.com/) and WebMD. Gastro-intestinal knowledge repository falls somewhere in-between these two cases; accordingly, few off-the-shelf tools and algorithms were available for immediate use. As such, a significant fraction of the necessary material had to be generated and refined, through experimentation.

An interesting addition to the above system is the addition of a "Gastrointestinal Guru", based in part on a suggestion from one of the reviewers. In specific cases where a person needs access to a human expert, the system will facilitate access to such experts who can provide support on an instantaneous basis. The situation is somewhat similar to the one we experience when we try to make a travel reservation online, experience difficulty, and feel relieved when we are able to connect to a human being, either by phone or online. However, the level of expertise and the degree of structure with respect to the desired knowledge are vastly different in the two cases. This difference is highlighted in Figure 6 (later in this paper) and its accompanying text.

# 7. Multi-Pronged Approach

While the five scenarios discussed above are drawn from different aspects of medical practice, they have several aspects in common. In all cases, the advent of new information technologies is making

a major impact on how the particular task or medical specialty is performed (Siau, 2003; Wachter, 2006). Further, in all cases, automation applies only to part of the effort. Human beings still need to be involved, though to varying degrees in the five examples considered. In some cases, a significant part of the work needs to be performed in very close proximity to the patient, whereas in others, the concept of remote tasks can be applied to a large extent. Finally, in some cases, the off-site work is medical in nature; whereas in others, it is largely non-medical in character. While similar approaches have been followed in the healthcare industry to some extent in the past, the relevance and practical importance of this model in today's scenarios is more significant. This is happening for several reasons including the following:

- The technology that is available now did not exist earlier. A growing number of previously underserved, remote locations are increasingly able to access medical services through the internet; PACS systems are improving rapidly; data and image transfer methodologies are becoming less expensive, more effective, and more error-free. This is resulting in a corresponding need for embarking on international telemedicine endeavors, instead of regional collaborations.
- There is a growing awareness of the advantages of having interoperable health information systems, especially in addressing mass casualty situations, where fast and timely diagnosis, via telemedicine, attains paramount importance.
- The increasing incidence of persons moving across national borders for work or other reasons, as well as the continued trend towards globalization, are making national boundaries lose their traditionally strong importance. As such, one needs the ability to ensure the safety of citizens when they are traveling in foreign countries and taking drugs that were prescribed for them by doctors in the US, and to support allied functions. For example, the creation of new global drug efficacy monitoring systems could enable Americans with the same ethnicity or ancestral homeland to be grouped by predictable responses to drugs based on findings by researchers in their native countries.

We consider the significance of the diverse examples, highlighted in Sections 2 thru 6 of this paper, in the following paragraphs.

In the case of mammography, a technician needs to attend to the patient in order to take the mammogram; the doctor can be off-site, either in the same country or a different one; and the computer-based data mining algorithms will be executed on an off-site basis too. This is perhaps the earliest example in healthcare where the concept of doing part of the work on-site, part off-site, with the computer providing active decision-support capability was mooted as the most accurate and the most cost-effective way.

In the case of integration of medical records in heterogeneous systems, either for emergency needs or for routine needs, computer-based techniques can be of significant help but human experts are needed at the initial stage, as well as on a continuing basis. Integration of major systems in other fields, such as logistics and manufacturing, is being increasingly done on an offshoring basis. Banks and financial institutions located in the US, Switzerland, and other countries were very reluctant in the eighties and nineties to let such work be performed abroad; by the late nineties, many of them accepted the offshoring concept, after they were satisfied that the evolving security and privacy protocols were adequate for their needs. The same is expected to occur for the

integration of heterogeneous hospital information systems; we will consider the legal and regulatory aspects later in Section 9. In addition to experts in information technology, medical personnel from multiple subspecialties will need to be involved, both onsite and offsite, in order to integrate the concerned systems based on the specific characteristics of the concerned medical institutions.

In the current versions of teleradiology, the technician can be in the US or another developed country and the radiologist can be in India or another less expensive country; in addition, there is a second radiologist in the same state (or nation) as the patient who issues and signs off on the final report. Technology is used almost entirely for transmitting the image from the developed country to the less expensive one. Over time, technology could be used to partially analyze the images, to compare the image to an earlier one involving the same part of the body of the same patient, and even to compare the image with images of the same part of the body of other patients, in order to make a diagnosis and to evaluate how the symptoms may change over time.

In the case of monitoring for adverse drug effects, the MedWatch system needs to be augmented. Some of the new tasks need to be performed by pharmacists in the US. Other tasks, such as reconciliation of duplicate records, need to be performed using inexpensive manpower, wherever available, with support from computer-based techniques. Further, individuals in the US are increasingly obtaining less expensive equivalent drugs from Canada and other countries. Such drugs must also be taken into account while designing any comprehensive system for monitoring adverse drug effects. Ultimately, this system will need to be implemented across multiple systems, as a harbinger of a global system. A growing percentage of clinical trials are now being conducted in India and other countries because of lower costs, availability of drug-naïve persons (individuals who had not taken other drugs in the past for addressing the same disease), and access to persons with different heritages. The ability to conduct these clinical trials at lower costs increases the probability that a drug company would decide to take a potential new drug from the lab to the clinical trial stage. This can also reduce delay in the launch of the new drug. However, this also implies transforming local systems for monitoring adverse drug effects into international ones. In such a case, both medical personnel and other personnel need to work from multiple countries.

In the case of dissemination of healthcare information, the initial endeavor focused on getting reputed experts from multiple countries to contribute material for inclusion in the evolving knowledge repository. The idea was to gradually support automated updates to such material on a continuing basis. So, if new results from a trusted clinical study became available, such results should be incorporated into the appropriate chapters. While part of this work can be done using computer-based techniques, the experience of the development team is that high quality and accuracy will only be accomplished if the suggested edits and updates were reviewed and approved by human experts. The use of domain experts and editorial personnel located in less expensive countries is more appealing, as it makes the overall endeavor more viable.

Scenario	Tasks by Medical	Tasks by Non-Medical	Tasks by Computer
	Personnel	Personnel	Assisted

	On- site	Off- site	On-site	Off-site	Techniques
CAD Mammography	Х	X			Х
Integration of Heterogeneous Healthcare Data Sources	Х	Х	Х	Х	Х
Teleradiology	Х	Х			Х
Monitoring of Adverse Drug Effects	Х	Х		Х	Х
Dissemination of Healthcare Information	Х	Х		Х	Х

While improvements in internet communication have made the multi-pronged approach described above possible, the lack of standardization in messaging protocols is a roadblock to the creation of a global healthcare model. We now describe how standards can be applied effectively to each of the five operational scenarios discussed, to reduce costs and improve clinical outcomes.

- 1. In the area of CAD mammography and teleradiology, the communication of radiological images and other data clearly depends on the standards used for creating, maintaining and exchanging medical images (such as PACS and DICOM).
- 2. The problem on data exchange and integration from heterogeneous data sources can be solved by the effective use of standards such as HL7. Though the current scenario does not easily allow the adoption of a single data standard among all hospital information systems nationwide; using a standard message development framework as a mediating schema could eliminate some of the problems and make the system more portable and scalable.
- 3. The area of drug monitoring and post market surveillance could also benefit from the use of standards. Using standards to create and store medication and adverse effects reports and experimental results sent from various participating agencies would create a much richer database allowing for better analysis and quicker response times.
- 4. Finally, while considering the issue of dissemination of medical information, the use of standards (not medical standards, though), for storing and displaying the information to the end users can increase the productivity and usefulness of search portals.

# 8. 24-Hour Knowledge Factory

At the end of Section 6, we discussed the scenario of seeking immediate assistance from an expert in a particular specialty; the geographic location of that specialist was totally irrelevant. The same is true of situations related to some tasks related to mammography and radiology. Finally, in the other two examples of the integration of medical information systems and the creation of global drug monitoring systems, it would be appropriate for the concerned pieces of work to proceed on a continuous basis, around the clock. In all such scenarios, the paradigm of a 24-Hour Knowledge Factory bears relevance.

The University of Arizona (U of A) has signed a three-party collaborative agreement with the Wroclaw University of Technology in Poland (WUT) and the University of Technology located in Sydney, Australia (UTS). Under the aegis of this agreement, researchers at the University of Arizona can work from 9 am to 5 pm, Arizona time. At around 5 pm, Arizona time, the research-inprogress can be transferred to fellow scientists at the University of Technology in Australia, who can work from around 9 am to 5 pm, Sydney time. At the end of the "research shift" in Sydney, the professional work can be transferred to the Wroclaw University of Technology in Poland where researchers can conduct incremental activities over the next period of approximately eight hours, and can then transfer the evolving endeavor to the first set of researchers in the US. This process is akin to the passing of a baton in a relay race with the notable difference that the baton is returned back to each participant exactly 16 hours after that participant transfers it to a colleague located on a different continent. We believe that this model will be gradually adopted by the healthcare industry, and further analysis of the historical and structural aspects will determine what subset of healthcare tasks can benefit most from the adoption of this evolving paradigm.

In general, the 24-Hour Knowledge Factory paradigm is appropriate for situations where the healthcare endeavor can be broken down into components, the underlying knowledge can be digitized, different individuals can potentially work on such components with minimal support from their peers, and the work-in-progress can be transferred at minimal cost from one collaborating center to another.

# 9. Intellectual Property and Legal Issues

The performance of medical tasks in a collaborative fashion, on a regular basis, by individuals located across state and national boundaries, raises new issues. Who owns the intellectual property such as patents on new medical or drug inventions; who can be sued for medical malpractice and under which set of laws and regulations; how the charges for medical services should be apportioned; what are the corresponding avenues for seeking reimbursements from insurance companies; and what are the mechanisms for seeking redress if and when it becomes necessary? Besides these, there are also other related social and policy-related concerns such as quality control and assurance and intensity of workflow across boundaries.

In the case of the US, the FDA plays the dominant role at the national level on issues related to drugs. However, medical professional credentialing and registration are done almost entirely at the state level. As mentioned in the section on radiology, the radiologist can render an initial opinion from outside the particular state or country, but the final opinion is still issued by another radiologist who resides within the particular state and is licensed to practice there. The use of two radiologists, though providing quicker action, increases overall costs.

In the case of patents and intellectual property, there is a common feeling among patent holders around the world that others are exploiting your work. In the US, there is a feeling that companies in foreign countries are exploiting US inventions and patents without authorization and payment of royalties. On the other side, there are people in India and China that feel the same way; there are instances of patents issued by the US patent office on items of indigenous nature that have existed for thousands of years. This is somewhat akin to the situation where different states in the US would render conflicting decisions on the same case, creating confusion. For example, until the 1970s, child custody cases were handled entirely at the state level. So in a case of divorce involving two parents residing in two different states, the first state might well give the custody of the child to the father (who resided in that state), and the second state would likely give custody of the same child to the mother (who resided in the latter state). Finally, in 1992, the Uniform Interstate Family Support Act (UIFSA) was drafted., According to this act, states have the power to reach beyond their borders for the establishment and enforcement of support orders. A similar type of action is now warranted in the healthcare domain.

Let us analyze the issue based on how laws, regulations, and norms have evolved over history. Three thousand years ago, all rules were at the village level. The village was the basis of the economy. If a person did something undesirable, the person could be ostracized from using the village well. Without water, the person could not survive. The person had to therefore, plead with his or her peers. This was one of the mechanisms, then prevalent, to enforce conformity with the norms and mores of that era. As time progressed, the size of the geographic unit increased. In England, one saw the advent of the concept of the manor, typically a collection of a dozen villages, that functioned as a unit for economic and security purposes. The manor was replaced by still larger entities in the form of principalities, which were ultimately replaced by nation states. The lawmaking and enforcement evolved too, sometimes with overlapping provisions. For example, A person residing in Tucson today may be governed by up to four sets of regulations, of the City of Tucson, Pima County, the State of Arizona, and the United States of America, respectively. (In some areas, such as intellectual property, there may be a supranational layer as well, i.e., the WTO's Trade Related Intellectual Property Agreement, which although not applied directly in the United States affects U.S. intellectual property law). Being governed by laws of the US does not imply having to go to Washington D.C. to seek redress; benches of US federal courts exist in most large and medium-sized cities in the United States.

Similarly, in the case of healthcare, the ultimate solution may be an international regulatory system that maintains offices in large cities around the world. This organization could deal with issues related to performing healthcare work across national boundaries. This could include credentialing, registration, medical malpractice, medical accounting, and reimbursement. Such an international regulatory system could be operated under the aegis of the World Health Organization (WHO).

Issues of trade and intellectual property are currently coordinated at the international level by the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO), respectively. These organizations could serve as the nucleus for establishing streamlined mechanisms that would enable better coordination of emerging types of practices, in healthcare and in other disciplines, perhaps under the aegis of the WTO's General Agreement on Trade in Services. The Agreement on Trade Related Aspects of Intellectual Property (TRIPS) is another

mechanism of IP protection. Healthcare services will increasingly transcend national boundaries as efforts are made to perform them with speed, efficiency, and in the most cost-effective manner.

## **10.** Conclusion

The traditional model of healthcare required the medical personnel to be in immediate proximity to patients being attended upon. This model will gradually be replaced, for a growing number of healthcare applications, into a three-faceted model that requires: some personnel to be on-site, other personnel to be off-site, and the use of evolving technologies to render support in a manner that is beyond the capabilities of the best medical personnel available anywhere in the world. Computers can look at millions of images of mammograms in very short periods of time to locate ones that match the key characteristics of the one currently in the clinic; such power is clearly beyond the capability of a single doctor or even groups of doctors. Off-site personnel can be located in the same state (such as physicians and surgeons of the Arizona Telemedicine program assisting doctors in clinics in Navajo Nation and in other Native American nations), in a different state or a different country. If the support is being provided from a different country, it could be in the same time-zone (to provide good overlap) or in a different time-zone (to provide complementary advice, especially advice from specialists, during night-time in the patient's country). The time difference was initially perceived to be a hindrance; today, it is considered as an asset as it enables better usage of medical and other personnel in both countries. Initially, outsourcing will be embraced using the notion of two collaborating groups that are 10-12 hours apart in terms of time of time. Gradually, the model of three collaborating centers will be embraced. The use of this 24-Hour Knowledge Factory paradigm allows three centers located in three countries to continue work on a round-theclock basis with all the tasks being performed primarily during daytime in the respective countries. New international systems have to evolve to address the intellectual property, legal, accounting, and other issues related to the various forms of outsourcing.

Medicine is geared to assist mankind as a whole. The offshoring of medical services will benefit developed countries because it can lower overall costs, provide quicker response, and facilitate load balancing. Such offshoring will be advantageous to developing nations because it can widen the range of available medical expertise and enhance the knowledge of healthcare professionals in developing countries. At the same time, one must be conscious of the fact that there is a shortage of medical professionals both in developed and developing countries, and the diversion of such resources to address the needs of foreign patients can potentially aggravate the shortage in their respective home countries. These issues will be partially resolved by market forces. Over time, we will witness more cooperative endeavors involving on-site and off-site activities in the healthcare arena.

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