

# SETLabs Briefings

September 2008



BUSINESS INNOVATION through TECHNOLOGY

## TECHNOLOGY FOR ■ BETTER HEALTHCARE ■ DELIVERY



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# Improve Care Delivery with Technology

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In the previous issue of SETLabs Briefings, we had put together papers that dealt with the theme of compliance, collaboration and transformation. Through this issue we continue the journey of providing much deeper insights into the way healthcare organizations can integrate technology to provide better care delivery solutions.

A recent report published in The New England Journal of Medicine points at two contradictory findings. One, doctors using EHRs have indicated that the timeliness and quality of care have improved multifold and two, only one in five doctors have moved from traditional care delivery to using EHRs. While the first finding is reason enough to migrate to EHRs, the second indicates at the economics of care delivery. Only large organizations can withstand lesser incomes and doubling costs incurred during transition from paper to computer records. Single doctor practices will have to see far fewer patients during the transition and hence are wary of migrating to electronic care delivery.

The question thus is: should pecuniary considerations hold back a transition that is more likely to benefit a larger stakeholding group of the healthcare community? Obviously, no! Governments should take steps to incentivize doctors to move from paper to electronic patient records. The US government's recent announcement of a \$150 million Medicare project to help over 1200 small practices make the conversion is a commendable step in that direction.

In the last issue we had contended that given the dynamic changes in the healthcare and life sciences industry sub-optimal firms are more likely to shut down if they do not jump on to the transformation bandwagon by adopting the latest technologies. In this issue, we have navigated through a welter of technologies in picking the most pertinent ones for your consideration.

We have an interesting paper that advocates the need to move towards a web-based tele-radiology marketplace, alongside papers that discuss the importance and role played by technologies like Semantic Web, Service-Oriented Architecture, SPARQL and Semantic EII in delivering quality patient care.

This collection gains its richness from the interesting experiential insights shared by Sanjeev Arora MD, Director of Project ECHO, University of New Mexico Health Sciences Center. In his conversation Dr. Arora discusses the importance of interoperable healthcare systems and the role played by ECHO in delivering holistic patient care solutions.

Better healthcare decision making is crucial to delivering timely and quality patient care. We have put together four papers focused on this idea. One of them explores the extraction of knowledge from unstructured healthcare data through effective information mining techniques while another advocates the need to adopt an integrated process framework to mitigate compliance, cost effectiveness and quality related challenges.

We have an insightful paper that traces two generations of drug discovery models and proposes a third 'connected, shared services' model that the authors believe will help facilitate innovation and improve decision making. In yet another paper, the authors assert the need to give healthcare facility layout planning a serious thought and suggest the adoption of a BPM tool which they feel will enable quality decision making.

I wish you enjoy reading our Healthcare industry specials!



Praveen B. Malla PhD  
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Editor

**Insight:** Towards a Web-based Teleradiology Marketplace*By Ashish Sureka PhD and Sivaram Thangam*

Teleradiology is the most sought after form of telemedicine in the healthcare sector. In order to bridge the gap between the demand and supply of trained radiologists, the authors suggest the adoption of a web-based e-marketplace.

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**Trend:** Semantic Web: Elixir for Drug Discovery and Development*By Ipsita Nanda*

Given the volume of data that is generated across an R&D value chain in Healthcare, real time intelligence becomes a distant dream to be realized. In a quest for a plausible solution, the author analyzes the effectiveness of the Semantic Web approach.

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**Opinion:** SOA: A Beacon for Future in Healthcare*By Anirban Ghosal and Rakesh Mishra*

A continuous flux characterizes the healthcare industry, given the rapid changes in the regulatory requirements and thus in the IT systems. SOA can prove to be a boon to the industry with its agile and interoperable platform, catering to the concerns around ever-changing standardizations, feel the authors.

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**Viewpoint:** Role of SPARQL and Semantic EII in Patient Record Harmonization*By Deepti Parachuri and Bijoy Majumdar*

Electronic Medical Records are imperative to high quality patient care. The use of ontology to define meta-model system proves effectual in harmonizing health records, where the changes in standards and data can be taken care of without affecting the core system. The authors here present data modeling using semantic technologies like RDF and show the data retrieval process using SPARQL.

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**Third Angle:** Interoperable Healthcare Systems and their Practical Applicability

Sanjeev Arora MD, Director- Project ECHO, University of New Mexico Health Sciences Center, in an interview with Praveen Soti MD, analyzes the effectiveness of interoperable healthcare systems and suggests that projects like ECHO are much required, as they consider care from a holistic point of view and while they develop IT support, they also train support healthcare staff to work as local teams and cater to basic as well as chronic medical events.

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**Perspective:** Information Mining in a Collaborative Healthcare Environment*By Harikrishna Rai, Pranav P Mirajkar, Sai Deepak and Sivaram Thangam*

A huge amount of knowledge remains unexplored in unstructured data like reports and images. The authors feel that mining these will provide much effective inference for better healthcare decision making. The paper discusses the benefits and challenges of data mining in the healthcare sector.

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**Framework:** IT Applications for Healthcare: Leverage Processes for High Quality*By Ravishankar N*

Cost effective IT solutions are the need of the hour. IT divisions in healthcare sector need to do a balancing act of managing rising costs, while not compromising on essentials like compliance, data security and quality. The author suggests some models and processes towards software application development to address the growing concerns.

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**Practitioner's Perspective:** Connect and Bolster Pharma R&D Model*By Mandar Ghatnekar PhD, Anirban Ghosh and Kamal Biswas*

Drug discovery sits at the core of the pharma industry. The paper traces the early models of drug discovery and suggests that a connected pharma R&D model and Activity analysis model are effective means to next generation drug discovery.

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**Spotlight:** Algorithmic Approach to Intelligent Healthcare Facilities Planning using BPM and Simulation*By Raamakrishnan M and Rakesh Mishra*

The authors suggest an intelligent tool that will leverage the capabilities of BPM tool while concurrently utilizing the qualitative decision making capabilities of a knowledge based system. In their opinion, this will prove to be cost effective for healthcare facilities in the long run, while providing increased satisfaction in the healthcare chain.

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**View from the Trenches:** Leverage Technology to Deliver Better Healthcare*By Mark Brownlee*

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*“Disruptive innovation called Knowledge Network is a key component of the ECHO model. Under this model, specialists are given access to technology to share their knowledge about best practice protocols, using case-based learning approach to co-manage patients with primary caregivers in rural communities and federally qualified health centers in cities.”*

**Sanjeev Arora MD**

Director - Project ECHO

Executive Vice Chairman - Dept. of Medicine

University of New Mexico Health Services Center

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*“A web-based teleradiology marketplace not only shortens the gap between the demand and supply interpretations but also improves patient care because of faster and easier access to medical specialists.”*

**Ashish Sureka PhD**

Senior Research Associate

Information Management Group, SETLabs

Infosys Technologies Limited

# Towards a Web-based Teleradiology Marketplace

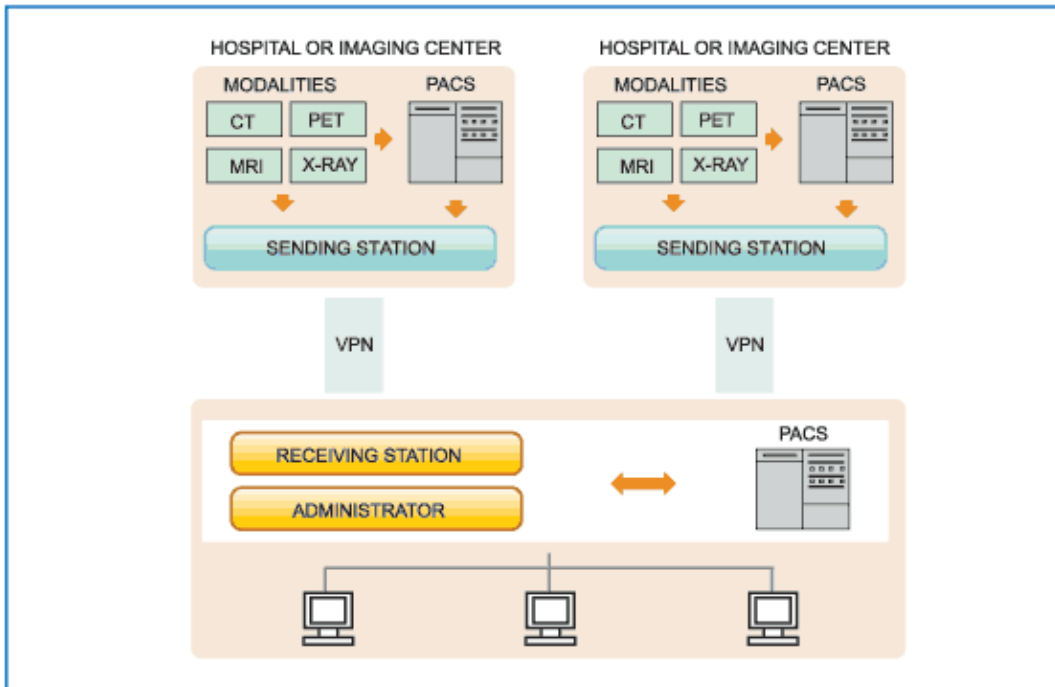
By Ashish Sureka PhD and Sivaram Thangam

*Improve patient care and resource utilization  
using a web-based teleradiology marketplace*

Medical imaging interpretation via teleradiology is an area that has gained a lot of significance in recent times. Teleradiology allows diagnostic imaging centers to leverage modern computer networking technology and advances in the field of medical software to transfer patient medical images to radiologists working from a remote location for image interpretations and consultations. The primary business driver for teleradiology is the wide gap between the radiology demand of hospitals and the supply of trained on-site radiologists at the hospital to cater to that demand. The amount of radiological study that needs to be interpreted exceeds the capacity of in-house or on-site radiologists. Hence, hospitals are increasingly looking at teleradiology as a solution to the problem of in-house manpower shortage. The annual rate of growth in the number of radiologists is around 1.5% to 2% whereas the annual rate of growth in the number of radiology images that need to be interpreted is around 6% to 12% [1]. Teleradiology has resulted in improved patient care and better

utilization of resources and is currently the most common form of telemedicine. There has been an influx of several teleradiology service providers and companies in recent times providing quality nighthawk as well as day radiology services, including weekend coverage. Through teleradiology, hospitals are now able to better manage demand and are also able to access subspecialty expertise that used to be a major challenge before teleradiology came into existence. As a result of technological advancements, difference in time zones and the cost benefits of knowledge process outsourcing, many teleradiology companies in developing countries like India, China, Vietnam and Philippines have started providing complete radiology diagnostic support to hospitals in United States and Europe [2].

There are two parties involved in a teleradiology business as illustrated in Figure 1 overleaf. One of the parties is a consumer and the other a supplier or service provider. Hospitals and diagnostic imaging centers are the consumers or buyers, whereas teleradiology



**Figure 1:** A Typical Teleradiology Setup between Imaging Centers and Teleradiology Facilities **Source:** Infosys Research

companies are the sellers, suppliers or service providers. In majority of the present teleradiology scenarios, the suppliers form alliances and connect to the consumers through an “off-line” or “non-dynamic” mechanism. A Virtual Private Network (VPN) or a dedicated network connection is established between the two parties for transferring images. As shown in Figure 1, the images acquired from various modalities such as CT, PET, MRI and X-RAY are transferred to the teleradiology facility directly through a sending station or stored into an image database and then transferred from the image database. A receiving station at the teleradiology facility routes the images to the appropriate radiologist for image interpretation. However, there are certain limitations in the way teleradiology business is presently conducted.

We list some gaps in the current teleradiology setup and describe a new business paradigm shift in radiology. This new business paradigm is that of *Teleradiology Marketplace*. Professional service e-marketplaces like [www.elance.com](http://www.elance.com) are becoming popular because they provide consumers a flexible workforce and a wide coverage of service providers or professionals thereby resulting in increased efficiency and better utilization of resources. E-marketplace in the teleradiology industry is in a nascent stage. A teleradiology marketplace provides a platform where diagnostic imaging centers can leverage radiologist expertise in a much efficient manner. We predict that teleradiology marketplace will gain a lot of traction in future as it results in dramatic productivity

improvement, improved healthcare outcome and improved collaboration of the stakeholders involved. However, setting up a teleradiology marketplace introduces its own set of technical and non-technical challenges. We discuss challenges in making teleradiologists' marketplace a reality and propose solutions to overcome the challenges. Also, we do an analysis of companies having a business model in-line with the concept of a teleradiology marketplace. The questions that we address in this paper are—Can e-marketplaces be extended to the teleradiology domain? What are the challenges associated with it and what are the solutions to those challenges? Which companies have made progress in making teleradiology marketplace successful?

### GAPS IN THE CURRENT TELERADIOLOGY BUSINESSES MODEL

In this section, we list some limitations of the existing teleradiology setup from the perspective of both the communities - radiologists and imaging centers.

Limitations for radiologists and teleradiology service providers are:

- *Upfront collaboration with imaging centers and teleradiology providers is needed for providing their valuable service.* With the current business model, there is no common platform for radiologists to provide their service when they can spare time as it needs a business tie-up that is usually a long term commitment. This results in under-utilization of available resources that makes the technologists think beyond the current business model. In the current setup, it is not possible for imaging centers to share cases post a requirement and get service

from any radiologist around the world without an upfront tie-up.

- *Need for hardware and software infrastructure to work off the business hours from anywhere.* Typically a radiologist's workstation should have Picture Archiving and Communications System (PACS) diagnostic viewer and the Radiology Information System (RIS) application installed with a dedicated connectivity for the diagnosis. The absence of all this restricts the ease and mobility of the radiologists thereby dampening the opportunity to expand their service.
- *Limited delivery of services and lack of wide reach-ability.* Since radiologists are tied-up with the imaging centers and hospitals, their chance of providing service across geographic boundaries is restricted. This demands the need of having community portal that can be utilized by radiologists to expand their business and improve their reach.
- *Lack of community based platform to communicate and collaborate with fellow radiologists and imaging centers about the latest trends and interesting cases.* When a radiologist comes across an interesting rare case, there is no means to share the case with other radiologists worldwide and leverage the knowledge pool of radiology community.

Limitations for imaging centers, hospitals and referring physician office are:

- *Need for upfront collaboration and thus small scale physician offices, hospitals and*

*imaging centers are unable to afford the service of radiologists. This creates a gap in the reach of state-of-the-art diagnosing technologies in the rural areas that further diminishes patient care in the country.*

- *Interpretation options are limited.* Radiology department has sub-specialties like neurology, cardiology, etc., that need sub-specialist radiologists for better diagnosis. As it is very difficult to find all the sub-specialists in a single teleradiology center, this becomes a grey area.
- *Lack of opportunity to grow their business without any capital investment.* Setting up a PACS, installing it and sharing the images with teleradiologists needs upfront investment that smaller hospitals or physicians might find unaffordable.

#### TELERADIOLOGY MARKET-PLACE

E-marketplace for radiology industry is a relatively unexplored area. E-marketplaces are now common in the professional service industry. Websites like Elance.com for buying and selling services online or Ebay.com for buying and selling products online are quite popular as they provide a win-win situation for both the consumer as well as the seller. Such marketplaces provide both the consumers as well as the sellers' community a much wider coverage. They have shown to increase efficiency and better utilization of resources. We feel that teleradiology industry can also benefit by having such an e-marketplace where hospitals can search for radiologists anytime and anywhere in an on-demand manner. Such a marketplace can provide a platform to connect radiologists or teleradiology solution providers with hospitals

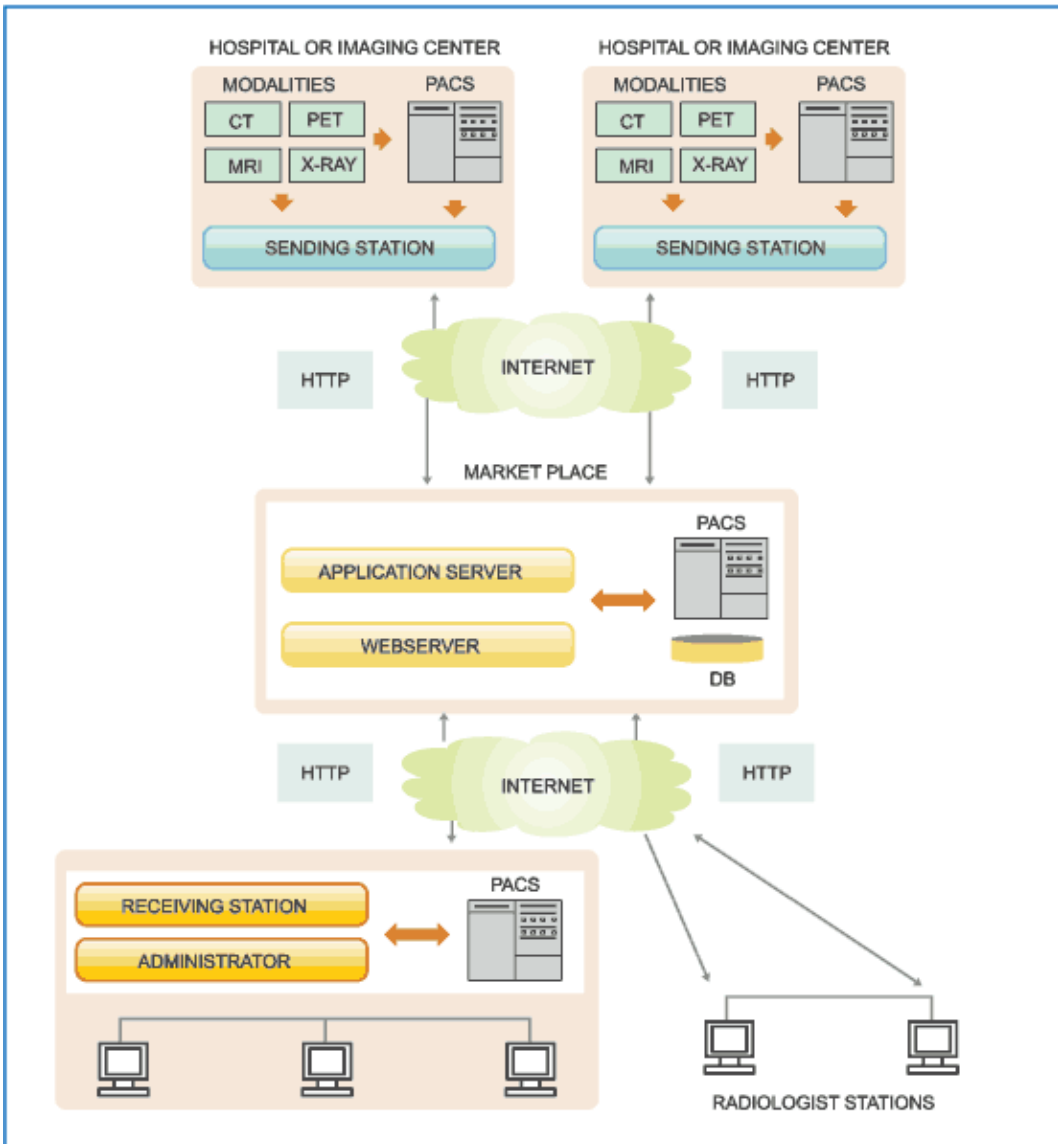
and imaging centers. A facility that helps connect providers with consumers in an efficient manner can be very useful. Figure 2 illustrates an e-marketplace to connect imaging facilities with an extensive community of radiologists, so that teleradiology solution providers of all sizes in every part of the world can be easily found and searched through a website. A teleradiology marketplace also eliminates the need for a partnership with just one or two off-site practitioners as the negotiation and contract for the provision of the teleradiology service happens online as and when the demand is generated.

Figure 2 shows a typical teleradiology marketplace setup where imaging centers can search for radiologists online and transfer images through a secured connection. Imaging centers and radiologists can search each other, based on parameters such as availability, specialty, license and insurance to operate in a region, qualifications and feedback. The benefits of having such a marketplace are efficient utilization of manpower and improved patient care due to easier access of specialists.

#### CHALLENGES AND SOLUTIONS IN TELERADIOLOGISTS' MARKETPLACE

A lot of technical and non-technical challenges need to be countered and solutions provided for, to ensure a widespread adoption of teleradiology market place. Listed below are some challenges and ways to mitigate them through the setting up of a proper system in place.

**Legal Issues and Medical Liability:** Business aspects of teleradiology have gone beyond the reach of legal boundaries. Current practice of teleradiology is making use of radiologists from remote countries for the job of interpretation.



**Figure 2:** A Typical Web-based Teleradiology Marketplace Setup *Source: Infosys Research*

Several legal issues have been associated with this which poses a major hurdle for a successful teleradiology marketplace. Each country or state has its own regulations and licensing for practicing radiology. Current law requires a tele-radiologist to have the license of the geographic location for which he or she

is serving and the license of the location from which he or she is interpreting.

When doing the interpretation across geographic boundaries, in case of any malpractices, there is no defined jurisdiction or governing rule to define the law of a country the case will be dealt

with [3]. Typically all the parties involved need to have an international medical insurance coverage. Getting such a medical insurance with international coverage for malpractices is also a major challenge [4]. In current teleradiology practice, the referring physician or patient facing hospital must take the responsibility for any such malpractices in interpretation. But the referring physician can deal with the teleradiology provider as there will be a well defined contract with clauses for malpractices [5]. When it comes to teleradiology marketplace, as and when the upfront contract and collaboration are eliminated, this way of dealing with medical liability does not hold good anymore. This calls for the medical community to come

Insurance Portability and Accountability Act (HIPAA) [7] have been formulated to ensure strict confidentiality of patient's data. The amount of privacy information preserved must not affect the quality of the diagnosis.

Privacy preserving has been a major research area and there have been various techniques available for concealing patient identification information from the radiology images or reports before they have been made available to the radiologist. The simplest of them would be masking or shuffling the patient's demographic data that could not give away the identity of the patient. An efficient system is one that employs such a technique to preserve patient's privacy.

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*International medico-legal restrictions, privacy protection and workload balance are a few roadblocks in the emerging teleradiology marketplace*

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up with an international commission like joint commission in US for standard-setting and governing these international medical practices [6]. When such a provision is made available, radiologists can register and get their credentials approved and in this manner a viable way can be found for dealing with medical liability.

**Privacy of Patient's Data:** When the study is available onboard for interpretation, the privacy of the patient's data needs to be preserved. Preserving patient's privacy is a legal need and the regulations such as Health

**Workload Issues:** To encash time, radiologists who are online may over-commit in most cases which may severely affect the quality of the case on hand. There must be a facility in system to keep track of the workload of available radiologists and balance it amongst them. For individual radiologists, once the job is assigned, the system can mask their identities disallowing them from taking any more cases till they deliver the case on hand. An analogy is of online airline ticket booking. As soon as the ticket is booked by a passenger, the ticket becomes unavailable and so the same seat

cannot be booked by any other passenger. The system should access the credentials like head-count, sub-specialty, etc., and allocate work accordingly.

**Gap between the Referring Physician and the Radiologists:** As the barrier of geographic location is cut-off, there is an amplified chance that when diagnosing the cases, the radiologist might lose interest in the patient. Also in case of emergency or interesting rare cases, radiologist's communication with referring physician is vital. This can be made easy by providing facilities like video chatting, email and messaging between the engaged radiologist and the physician.

there is a chance that she might lose the patient care focus. System in place should make sure to allow access only to radiologists who have a valid educational profile and credentials to assure the quality. Also, it is appropriate to have feedback and rating mechanism to evaluate the efficiency of the radiologists.

**Licensing for Radiologists:** Licensure poses yet another challenge to the radiologists' market-place. Each country/state has its own regulations and licensing for practicing radiology. A teleradiologist should have the license of the geographic location for which she is serving and the license of the location from which she is interpreting. As we approach the issue with the existing way,

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*Challenges need to be dealt and viable solutions must be figured out before the wide scale adoption of web-based e-Marketplace*

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**Secure and Faster Image Access:** As we go web-savvy, the security and the need for faster image access could pose a major challenge for information sharing between the stakeholders. Need for faster image access could be alleviated by providing online PACS access and viewing facility, in which the image will be processed on the server side and the results will be displayed on the radiologist's side. Security for data transacted through public network can be increased by opting for secured protocols and encryption techniques.

**Quality of Patient Care:** When the individual radiologist is interpreting the scans remotely,

the system must be able to handle this issue by taking account of the license credentials of radiologists and the geographic location of the referring physician/imaging center. Radiologists need to obtain proper certifications for providing their services such as a certification from the American Board of Radiology for reading scans originating from USA.

**Tracking of Job/On-time Delivery:** Once the job/case is assigned to a radiologist, it is mandatory that she delivers the reports within the committed time. As there is no business

collaboration between the radiologist and the imaging center/referring physician, there is a possibility that the time of delivery could get compromised. As with usual e-marketplace, the radiologist can be entitled for the payment only when the result report is delivered on time. This type of action is inappropriate as the delay in giving back the result report may cost the life of a patient. These can be minimized by tracking the work profiles or previous job histories of radiologists and taking appropriate action on them by denying the usage of the marketplace. The slip in on-time delivery is potentially riskier and makes this e-marketplace more suitable for providing secondary opinions at least at the initial stages of the usage.

## COMPARISON OF SIMILAR BUSINESS MODEL IN THE MARKET

Teleradiology is slowly but gradually being enveloped by a paradigm shift in the way radiology is being practiced. Making best use of the digital revolution and the latest technology, this new radiology business model is more likely to yield better benefits to the stakeholders. Industry community has started venturing towards this model in the recent times but they are at a nascent stage. Neurotsar's Virtual Radiology Community [8,9], AG Mednet [10] and RadExpert Opinion [11] are the market players whose business model is inline with the radiology marketplace.

Table 1 is a high-level snapshot (as of mid 2007) on these market players with the key features of teleradiology marketplace.

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*A web-based e-Marketplace enables an innovative platform among the physicians and radiologists and irons out major concerns about the shortage of radiologists*

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**Availability of Radiologists on Board:** Non-availability of radiologists can be minimized by backing up the system initially with teleradiology service providers who can be online around the clock. By creating more awareness among the imaging centers and hospitals, there is an increased chance to make the referring physicians start using the marketplace. Also, the system must be backed up by an online community where the physicians and the radiologists share their thoughts and knowledge and also connect them to the radiologists' market-place.

## CONCLUSION

Teleradiology industry can benefit significantly by having a web-based e-marketplace enabling efficient collaboration between hospitals and imaging centers with the radiologist community. The primary benefit of a web-based teleradiology marketplace is improved patient care because of faster and easier access to medical specialists. Also, such a marketplace provides a platform to shorten the gap between the demand and supply of radiology interpretations. Teleradiology marketplace is a relatively unexplored area

Providers in the Current Market Space			
	AG Network	Neurostar's VRN	RadExpert Opinion
Typical Features of Teleradiology Marketplace			
Web-based Connectivity	No [dedicated lines]	Yes	Yes
Online Image Viewing	No	Yes	Yes
Community Based Workforce	Yes	Yes	No
Elimination of Upfront Collaboration	Yes	Yes	Yes
Elimination of IT Administration	No	Yes	Yes
Centralized Image Archival	No	Yes	Yes
Single Platform and Worklist	No	Yes	No
Pay-per-study	Unknown	Yes	Yes
Automatic Routing of Studies To Radiologists	No	Yes	Yes
Option to Choose Radiologists	Unknown	Yes	No
Control Over the Assigned Job by the Referring Physician / Imaging Center	Yes	Yes	Yes
Control Over Turn-around Times	Unknown	Yes	Yes
Storage & Routing Of Reports	No	Yes	Yes
Assurance that the Job Will Be Taken Up by Radiologists	Unknown	No	Yes
Feedback Mechanism & Rating of Radiologists	No	No	NA
Technology	Unknown	Proprietary	Internally uses Neurostar's solution
Web URLs:	<a href="http://www.agmednet.com">http://www.agmednet.com</a> <a href="https://www.neurostarsolutions.com">https://www.neurostarsolutions.com</a> <a href="https://www.virtualradiologycommunity.com">https://www.virtualradiologycommunity.com</a> <a href="http://www.radexpertopinion.com">http://www.radexpertopinion.com</a>		

**Table 1:** Comparison of Features of Companies in the Teleradiology Marketplace  
**Source:** Infosys Analysis

and recently some companies have started venturing into this space. However, there are certain technical and non-technical challenges that need to be addressed before teleradiology marketplace enjoys widespread adoption.

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# Semantic Web: Elixir for Drug Discovery and Development

By Ipsita Nanda

*Semantic web powered knowledge discovery will lead the way for the next generation knowledge management strategies for leading global LSOs*

Knowledge discovery and real time intelligence using data across the R&D value chain finds its place only as an item on the wish list of the top CIOs today. With the cost of discovery and development of a new molecule, now estimated at around US\$1.4 billion, leading Life Sciences Organizations (LSOs) are under increasing pressure to improve efficiency and economics of drug development [1]. The gestation period of more than 10 years - intrinsic in bringing a new drug to market - further increases business risks.

Earlier, the answer to the quest for reducing time to market and increasing efficiency lay in the use of technology. Equipments like High Throughput Screening (HTS) promised higher efficiencies and hence helped reduce the time taken to generate a hit. The use of such technology increased in the lab only to generate new challenges for the researcher. The data generated needed to be managed and analyzed efficiently; the reason why sophisticated data analytics systems find their place in leading R&D labs today. Given the volume of data generated these days, producing

real time information over layers of disparate data spread across geography and formats is a proverbial 'needle in the haystack' situation. For the researcher, to be able to intuitively derive intelligence from real time data using sophisticated decision analytics, effective and seamless data integration is required at the back end.

The solution may be in the form of Semantic Web (SW). This approach provides new capabilities for data integration, not just for the R&D lab, but also across the enterprise. A researcher can now take decisions based on not just the scientific data, but also be able to factor in regulatory, IP and legal elements, while deciding on a go-no-go status.

This paper outlines the effectiveness of semantic data integration in drug discovery and development landscape and evaluates various aspects of such a vision.

## CHALLENGES FACED BY THE RESEARCHER

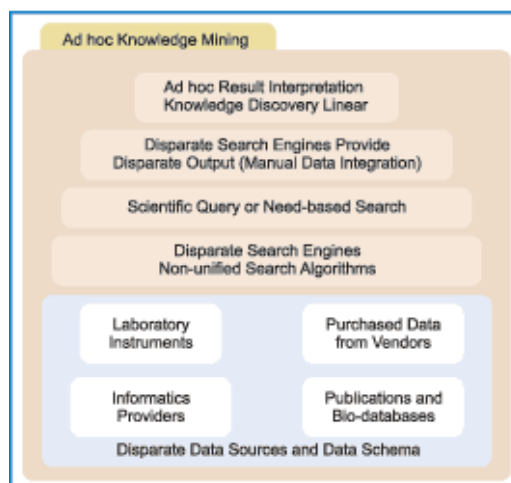
The recent scientific advances and most notably the "Omics" revolution have turned the

traditional linear flow of information through the discovery value chain into a dynamic and iterative loop. Also, the processes are tightly coupled with the feedback of different pieces of information generated at every step. The key to effectively manage such a dynamic situation depends heavily upon the integration, analysis and dissemination of critical real time information to enable actionable knowledge. This is no easy task considering the terabytes of disparate data from incompatible databases, possibly spread across multiple departments, systems and formats. Some of the key challenges faced by discovery led LSOs today in effectively driving knowledge discovery are:

**Time Factor:** Time is spent in searching for the relevant data on disparate data sources. For instance, Google and Pubmed are external and impervious to enterprise search agents. Also, some enterprise tools require search/ query expertise. More often, expertise of trained software professionals result in higher cost implications.

**Information Complexity and Non-indexed Data:** There are now more than a thousand different biological data repositories available; far too many for practitioners to remember or navigate through different interfaces to get to the data of interest. Data is also available in different formats as experiments are performed across the organizations and geographies. In some cases, though experiments are designed for specific projects, results often apply to other projects. But these results are often inaccessible as they are typically stored locally and not globally.

**Inconsistent Ontology:** Biological entities in different repositories may not be similar due to the difference in methods of data generation or in the use of terms for defining concepts.



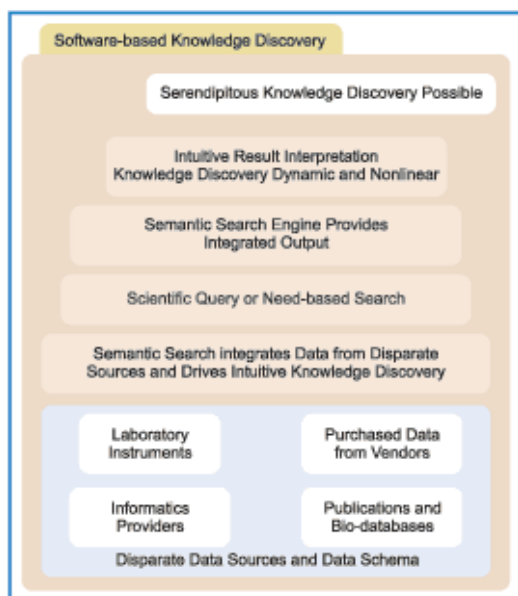
**Figure 1:** Manual Data Integration  
**Source:** Infosys Research

## SEMANTIC WEB AS THE SOLUTION

The three challenges described above is aptly addressed by SW through the use of Web Ontology Language and a RDF framework which form the core of SW technology. Semantic Web components are:

**Resource Description Framework (RDF):** The RDF metadata model is based upon the idea of making statements about Web resources in the form of subject-predicate-object expressions, called *triples* in RDF terminology. The subject denotes the resource and the predicate denotes traits or aspects of the resource and expresses a relationship between the subject and the object. A Uniform Resource Identifier (URI) can be then assigned to a triple. This results in an open standard for sharing data [2].

**Web Ontology Language (OWL):** It is a family of knowledge representation languages for authoring ontologies to provide a common way to process the content of web information. It uses a novel model intended to provide compatibility with RDF Schema. Therefore OWL is both syntax for



**Figure 2:** Data Integration with Semantic Web  
**Source:** Infosys Research

describing and exchanging ontologies and has a formally defined semantics that gives the meaning (based on domain knowledge) [3].

### BUSINESS DRIVERS FOR IMPLEMENTING SOFTWARE

The critical business driver and the core benefit

derived from implementing SW is the ability to take key business decisions. Decisions such as, market potential of a drug candidate, competitor analysis or adverse events are fairly business critical and if taken in the light of pertinent information, would enable the LSOs to not only mitigate risk of failure, but also enable key go/no-go decisions. Having said that, the following are the business drivers for the large LSOs:

**Critical:** 1. Market analysis, 2. Competitor analysis, 3. Exploratory decision making, 4. Clinical & pre-clinical study design, 5. Molecular candidate screening, 6. Drug candidate selection

**Good to Have:** 1. Team learning, 2. Intuitive Knowledge creation & sharing, 3. Organizational learning and serendipity

**Wish List:** 1. Predictive modeling, 2. Intuitive knowledge discovery, 3. Formulating Novel targets through AI systems.

### CORE BENEFITS AND BUSINESS IMPACT ANALYSIS

The following table analyses the core benefits offered by SW technology in light of the key business drivers for large LSOs:

Core benefits	Business Impact		
		Cost Saving	KM Impact
1. Flexible Data storage and management <ul style="list-style-type: none"> <li>• Semantic data management is flexible</li> <li>• Data searches are fast and intuitive owing to the use of "triples"</li> <li>• Single version of truth</li> <li>• Cleansed and validated data</li> </ul>	Reduces Time-to-market for new molecule.	Reduces cost incurred in data cleansing operations and incremental costs on re-programming and other time-consuming approaches for searching data.	Augments KM objectives by retaining one version of truth by real time updates of the data.
2. Apposite and Reusable <ul style="list-style-type: none"> <li>• Use of proper semantics and ontology renders relevant result output</li> <li>• Data is referenced across platforms and applications</li> <li>• Analytics becomes easy and data can be viewed from different vantage-points</li> </ul>	Reduces discovery time significantly by enabling business decisions earlier on in the development lifecycle.	Significant cost saving when the time to search the data is reduced considerably and scientist's productivity is enhanced. Significant and demonstrable ROI.	High impact as information sharing is possible.
3. Format of data storage is open to interoperability <ul style="list-style-type: none"> <li>• Integration of legacy database possible</li> <li>• Data loss minimized</li> </ul>			

**Table 1:** Business Benefits

**Source:** Infosys Research


## JUSTIFYING SEMANTIC WEB THROUGH ROI

The decision to implement SW would be justified considering the potential ROI of such a system to be both implicit and tacit. To understand the ROI considerations for SW we have to judge it against possible savings as compared to the current cost of data integration. Replacing stand-alone systems would be costly that in turn deters organizations to take strong steps in this direction. In addition, productivity costs are also to be considered that includes the large amount of time researchers spend on managing data to fit existing systems. Also, rigid systems of this age result in gaps in data storage, retrieval and end up sacrificing productive time. All of this would eventually result in decisions that are misaligned with the real facts and can end up increasing the business risks manifolds.

## CONCLUSION

In a hyper competitive pharma landscape, large LSOs have started to comprehend the benefits of analytical drug discovery and development. An environment tuned to knowledge led discovery and analytical decision making would be critical today for achieving shorter time to market and reducing overall cost incurred during the early stages of the drug development. Semantic web can be the answer to this particular need. The key steps to achieving SW-based R&D efforts require LS organizations to mitigate the challenges faced on all the three fronts--people, processes and technology.

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# SOA: A Beacon for Future in Healthcare

By Anirban Ghosal and Rakesh Mishra

*SOA enables healthcare organizations deliver better services to the social ecosystem at large*

IT in healthcare has evolved immensely over the past few decades. During this process of evolution, systems were developed in isolation with limited focus on interoperability. With the growth of organizations, the integration between these systems has become a key challenge given that its stakeholders viz., doctors, hospitals, insurance companies, patients and regulatory requirements keep changing regularly. The challenges of integration of IT in healthcare, thus, are highly complex.

With the emergence of EAI, integration between these systems is simplified to a certain extent. However, the industry is seeking for better flexibility, scalability and interoperability in order to provide better service. On assessment of the current scenario, it is felt that SOA in healthcare enables its participating systems to be more interoperable and flexible in order to deliver better services to the social ecosystem at large.

## KEY INTEGRATION CHALLENGES

In order to realize the value of SOA in healthcare, the first step is to understand the key integration challenges.

**Standard Messaging Requirements:** Healthcare messaging is the communication of health related data between various information systems within the health sector; for instance, between a hospital database and the practice management system of a general practitioner. The ability of healthcare domain IT applications to distribute and share healthcare data, lowers costs to patients and increases the effectiveness and efficiency of care.

Standards like Health Level 7 (HL7), Integrating Healthcare Enterprise (IHE), AS 5023 Supply Chain Messaging Standards, etc., protocols provide the much needed interoperability amongst health care systems and enable easy sharing of data. Thus an increased support to a range of message formats becomes inevitable.

**Business Process Integration of Distributed Communication:** Clinical and administrative processes will depend on a combination of local, regional and national systems. Business process management and composite application technology can provide the much needed control

of these end-to-end processes across departments and also at a national level.

**Single View of Patient:** A single view of patient is at the center of many new regional and national initiatives as also some emerging initiatives such as customer self service across multiple channels. A key requirement of the initiatives is that patient information, once captured, should be available for use across all potential care processes. This is a challenging task as the patient information is stored differently in each IT system and the patient identifier conventions used are often different.

**Data Sharing Requirements to External Enterprise:** With healthcare emerging as a vital marketplace, the need to present data to external

responsible for any slippage.

A major challenge thus is standardized information sharing amongst stakeholders within the healthcare system. SOA by virtue of being an enabler of interoperability offers a panacea to this problem. Today, more and more healthcare organizations are increasingly considering adopting SOA as their fundamental architecture for integration, to overcome these challenges.

Health Level 7 (HL7) is the American National Standard Institute's (ANSI) approved group that develops the standard for health care. So SOA adoption in health care should include the standards already developed for HL7 to leverage and maximize the benefits of the standardization effort already done by HL7.

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*SOA being an enabler of interoperability offers a panacea to the problem of standardization in healthcare systems*

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partners, customers or government agencies has become very important. Exposing the data and services to share the data as well as the services with the outside world, requires B2B integration software to manage communication, security and business processes.

**Regulation and Security Requirements:** Each country has its own health care regulation. A regulation such as Health Insurance Portability and Accountability Act (HIPAA) 1996 emphasizes the need for standard security and business processes. Such regulations impose penalties on non-compliance and hold senior management

Apart from the standardization, one major challenge that today's healthcare industry along with other industries is facing, is to leverage key technology advancements to make IT eco-system more business efficiency focused. The biggest hurdle in this mission is the ability of the organization to effectively morph its processes and practices.

Service-orientation, the key vision of SOA, is largely about the transformation of IT designing approach from application-centric view to business service centric view.

SOA adoption in Healthcare should also provide standardization in business-IT alignment by defining standardized business services in

Service	Description	HL7 Relation
Decision Support Service (DSS)	A decision support service (DSS) receives patient data to support effective clinical decision support capability	A DSS could be used to support many of the Clinical Decision Support functions specified in the EHR functional model
Common Terminology Service (CTS)	CTS define the functional requirements of a set of service interfaces to allow the representation, access, and maintenance of terminology content either locally, or across a federation of service nodes	Common Terminology Services 2 (CTS 2) Specification is to expand on the original functionality developed in HL7's Common Terminology Service (CTS) Specification.
Entity Identification Service (EIS)	EIS is a set of service specification for lookup and management of different entities like patients, individual providers, institutional providers and medical devices	This service functional specification is intended to be included in HL7 standards.
Record Locator and Access Service (RLAS)	Record Locator and Access Services (RLAS) are means by which the multiple healthcare participants can share information for the benefit of the patient's health outcomes as well as their individual business goals. Allows the service client to locate and retrieve records for a patient across systems	This service functional specification is intended to be included in HL7 standards.
Patient Record Update Service (PRUS)	Allows the service client to update a patient's record	This service functional specification is intended to be included in HL7 standards.
EHR Action Brokering Service (EABS)	EABS service provide the means through which various actions can be performed within an electronic health record	This service functional specification is intended to be included in HL7 standards.

**Table 1:** Health Care Services

*Source: Infosys Research*

healthcare derived from the standard business processes.

**SOA ADOPTION IN HEALTHCARE – SERVICE IDENTIFICATION**

While adopting SOA strategy for healthcare with the standards defined in the HL7, a mapping of the services and the standards defined in HL7 is essential to leverage the work that has already been carried out.

Web service has been the leading standard for SOA. In HL7, web services profiles are properly defined. The HL7 web service profile enables HL7 messages to be transported using SOAP.

However it does not provide a solution to the key benefit of SOA – business-IT alignment. It

is a kind of messaging that uses some of the web service protocols. The methodology is focused on message development.

This shortcoming of HL7 leads to a new approach, namely Healthcare Services Specification Project (HSSP).

**SOA and HL7 –HSSP Framework:** The Healthcare Services Specification Project (HSSP) is a joint endeavor between Health Level Seven (HL7) and the Object Management Group (OMG). The HSSP was chartered at the January 2005 HL7 meeting under the Electronic Health Records Technical Committee (TC), and the project was subsequently validated by the Board of Directors of both the organizations.

The purpose of this project is to promote and create standards, by defining an SOA for Healthcare deriving the services from the end-to-end health care business processes. The aim is to provide a means for organizations to define and implement business services in a consistent, interoperable fashion.

This is the first realistic step to fulfill the ultimate goal of SOA i.e., business-IT alignment. HSSP defined services are derived from the standard health care business process that enable standardization in business processes and services. The functional specifications of these services are intended to be included as HL7 standard.

Key functional and technical specifications of health care services defined by HSSP and their relationship with HL7 standards are shown in Table 1 overleaf.

### SOA ADOPTION IN HEALTH CARE – SERVICE REALIZATION

As the standard services are being identified, questions arise on how these services will be realized.

*The key question is, how does it benefit if we have vendors, system integrators and healthcare organizations creating and adhering to common set of services in order to promote standards?*

The interaction between these participants changes constantly. So interoperability is a necessity in this ever changing world. Each participant needs to provide a common set of business functionality in order to maximize interoperability. A common set of industry standard business services thus becomes critical for all these participants to adhere to.

SOA is not revolutionary but evolutionary. Even though HSSP provides the industry standard service definitions, healthcare organizations must leverage existing software implementation apart from adopting HSSP. However, the ultimate goal should be to realize the services as standardized in HSSP and subsequently in HL7.

Organizations implementing a SOA framework thus will have means to fully realize the benefits of SOA using HL7 V3 semantics in a consistent, standardized way for:

- Easy integration, both within and across enterprises (e.g., for sharing patient data, evaluating and paying claims, referrals)
- Enabling more business agility, e.g., the ability to quickly create new applications and processes and ways of doing business
- Facilitating faster and cheaper integration between systems through use of standards-based automated development tooling.

### SOA ADOPTION IN HEALTH CARE – SERVICE ORIENTATION GOVERNANCE

To adopt SOA in an organization a strong governance mechanism needs to be in place for various phases in the service orientation. Organizations should focus on certain key elements while defining governance process.

**SOA Centric Architecture Framework:** Define and agree on a enterprise architecture blueprint that ensures SOA benefits being realized and interoperability maximized (at least meeting minimum interoperability levels defined by HL7).

Based on the architectural blueprints, define an SOA framework/approach that leverages existing IT standards to enable services

to be consistently identified, described and used in healthcare environments. This should provide a consistent technical context for HSSP OMG RFP submissions and also include a “generic” SOA approach that is not tied to a specific technology.

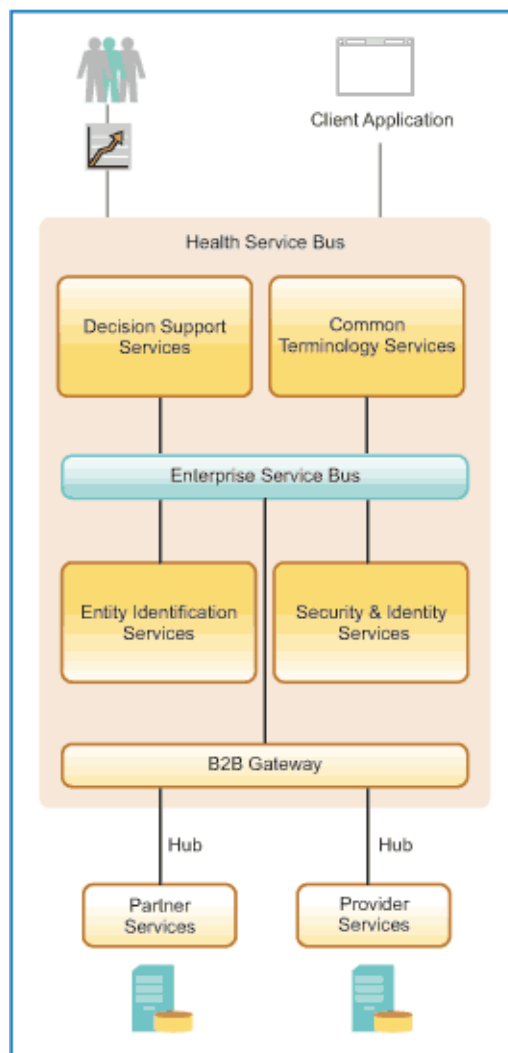
**Service Delivery Methodology:** Define extensions to the HSSP SDF methodology for creating service definitions and implementations, including approaches to conformance and profiling where appropriate. This should offer a consistent way to define and implement services for HL7 V3 (and other healthcare as appropriate) content.

**Migration from HL7:** Define a mapping of current HL7 artifacts to the SOA framework. This should provide at least rules for deriving or transforming from SOA elements (contract or headers) to (at least) mandatory HL7 Wrapper items. This will include identification of those elements that should be left to other protocol and technology standards and any constraints that should be imposed on those elements.

### HEALTH SERVICES BUS - A SOLUTION FOR HEALTHCARE SOA

The concept of a *health service bus* will provide a solution to some of the issues. Figure 1 shows how a common service bus might act as a broker or integrator for multiple backend services. Presently, each user connects to a single URL and a single set of credentials provides identity identification. But if concerted efforts are made in providing a secure and reliable connection point for all kinds of users then the gateway or hub takes over all responsibility in helping the user connect to the appropriate backend service.

Architecturally, any authorized client



**Figure 1:** Context and External Interactions of Health Service

**Source:** Infosys Research

can access the services provided by the *health services bus*. These can be websites and portals servicing their own end-users; applications running on enterprise systems or any external systems that request services from the hub through B2B Hub. The services exposed by the health service bus are typically consumed by various clients.

Typical categories of clients for the hub include:

- **Portals:** Portals are used internally by the front end users, partners or external parties. Portals will perform required authentication of the user and provide the authorized information to the client.
- **Provider and Consumer Applications:** Internal systems within the enterprise will consume the service to provide required business operation.
- **Partner Systems (through B2B Hub):** Partner or government systems will

With the implementation of standard services and the interoperability through industry standards, *health service bus* solution helps in realizing the needed service orientation.

#### ACHIEVING SOA BENEFITS

A technical solution cannot solely deliver all the benefits of SOA to an enterprise. To achieve and maximize the benefits of SOA, a healthcare enterprise needs to focus on some key aspects other than the technical solution. Enterprises must concentrate on the following to maximize the benefit in SOA realization.

**Business:** Services should be defined top-down based on business processes. It maximizes

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*Health services bus solution provides cross-platform interoperability that helps in realizing the needed service orientation, thus easing client interactions*

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connect to the health service bus through a B2B gateway. The gateway will perform the required authentication and authorization for information exchange.

All these interactions will be through HSSP published service, based on industry standards. This will provide the necessary openness, compatibility with a wide range of commercial products and cross-platform interoperability.

Client interactions with the *health services bus* provides interoperability between heterogeneous applications deployed on various platforms.

alignment and agility to adapt to business needs. Services must not be defined based on messages since messages do not align functionally most often. Use of simple, dynamic/ad-hoc intermediary capability within SOA is key to this adaptability and flexibility. Constraints and complexity need to be minimized.

**Development Tools:** Standard service modeling tool is cheaper and easier for organizations to incorporate services into the enterprise. These are increasingly configured to work with domain independent OASIS, WS-I standards etc. Enterprises should not handle different content in different ways.

**Infrastructure:** Standards based infrastructure for security, policy definition and run-time evaluation, reliable messaging, etc., should be defined to deal with all content in a consistent manner for time and cost efficiencies, and ease.

## CONCLUSION

To maximize the benefits of SOA, it is essential to have an industry-wide service identification that improves standardization and interoperability. Organizations should leverage the framework defined by HSSP for their SOA strategy. Leading vendors and system integrators are coming up with SOA based healthcare solutions. Apart from leveraging the service defined by HSSP and the solutions provided by the technology vendors and system integrators, healthcare

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*Healthcare organizations should define their own  
SOA strategies for quality delivery of healthcare services  
to the larger ecosystem*


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organizations need to define their own SOA strategy and appropriate benefits through better and quality delivery of healthcare services to the larger ecosystem.

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# Role of SPARQL and Semantic EII in Patient Record Harmonization

By Deepti Parachuri and Bijoy Majumdar

*Data Convergence as against Data Transformation  
can help deliver effective interoperability*

Advances in information technology have led healthcare organizations adopt healthcare information systems to establish efficient and high quality patient care and thereby provide accurate and comprehensive EMR (Electronic Medical Records) of the patient's health. On the flip side, most of the systems adopted were proprietary and catered to only one unit or to the hospital owning the software. There has been a lot of interoperability issues with existing floating standards like HL7 (Health Level Seven), CCR, openEHR, EHRcom etc., that are in existence for electronically handling medical records of the patients. Interoperability issues have surfaced due to the need to converge or correlate information from patient's clinical history for further treatment. In general, a patient's information is available in different sections and in different forms. Hence there is a mandate in the medical world for harmonization of patient's records from various departments to produce a consolidated report. Various transformation technologies that convert information from one standard to a specific destination standard or

form are available to tackle these interoperability issues. However, the overhead of transformation in the exchange and discrepancies involved has given rise to ontology that provides a uniform definition of a patient record system structure.

Some of the current works in semantic interoperability in the healthcare domain are projects like COCOON, ARTEMIS etc., that introduce mediators to handle communication between different standards.

The major motivation here is to organize data of patient records in a well defined manner thereby enabling the machines to understand, interact and retrieve the content with greater ease. The point to drive home is to use ontology to define the healthcare meta-model system for harmonizing the patient clinical records. Any additional standard or patient data structure can be aligned to the semantics with no change in the core system execution. Here, we present modeling of the data using semantic technologies like **RDF** and **OWL** at the data level and also show the process of retrieving data using **SPARQL**. Ontology, the underlying technology for semantic

web helps model information effectively by adding metadata [6]. Many ontology modeling editors are available viz., Protégé, OilEd and webOnto. We demonstrate the modeling and retrieval of patient record data using Protégé.

### NEED FOR RECORD HARMONISATION

The collaboration and harmonization of patient records can help in improving care outcomes and lowering costs. Benefits resulting from the harmonization of patient records are numerous and substantial. Integrating data can assist medical practitioners in making correct and quick assessments and also administer proper treatment. Annotating findings and interpretations formally eases sharing of information with other medical practitioners. Proper integration of knowledge enables reusability of knowledge by several applications across business. The aim of record harmonization is to integrate all discrete information and present rich, correct and accurate information to the medical practitioners.

### EXISTING HEALTHCARE STANDARDS

Hundreds of healthcare standards have been established, yet no significant solution for system integration has come up [1]. Existing systems primarily aim at addressing the electronic interchange of data and have a very narrow scope of use. They are not built on common industry standards, making it impossible for integration with other standards. In the following section we describe three prominent healthcare standards used by many medical systems:

**HL7:** A group of healthcare computer systems in 1987 started developing the HL7 protocol to create common language that allows healthcare applications to share clinical data with each other [2]. HL7, along with the object management group ([www.omg.org](http://www.omg.org)) in 2005, came up with Healthcare

Services Specification Project (HSSP) to provide communication between healthcare systems.

**ARTEMIS:** Artemis is a semantic web service-based peer-to-peer (P2P) infrastructure for the interoperability of medical Information systems. Artemis project is one of the first initiatives to use web services in the healthcare domain. Artemis web service architecture does not propose globally agreed ontologies, rather healthcare institutes reconcile their semantic differences through a mediator component [1]. The mediator component uses ontologies based on prominent healthcare standards as references to facilitate semantic mediation among involved institutes.

**COCOON:** COCOON aims at building knowledge driven and dynamically adaptive networked communities within European healthcare systems, for supporting healthcare professionals in reducing risk management in their daily practices [3]. As proposed in WSMO, COCOON uses Goal-Goal mediators (ggMediators) to overcome interoperability problems that may appear when provider and requestor entities cannot reach an agreement in defining goals and web services descriptions using same ontologies.

The above mentioned systems are mainly aimed at developing system interfaces rather than data integration. However, unless the underlying structure of healthcare data system is defined in a common and unified way, integration will remain ineffective. The Metadata Company proposed a data modeling methodology for healthcare systems [4]. According to them, any level of healthcare systems integration requires a development and use of common data model. Their data model is used in Metadata's medication management system known as Meta-Med. Here,

we propose the use of a W3C standard data modeling language RDF for data representation and SPARQL for retrieving the stored data.

### SEMANTIC WEB FOR HEALTHCARE

Semantic is a solution for finding meaningful information and integrating with related information [5]. Ontology is the key technology behind semantic web for making information more meaningful, by adding more knowledge. Rules are the next development area in semantic web to specify declarative knowledge constraints and to enforce policy. The idea of the semantic web is to refine the existing web incrementally by inserting machine-readable *semantic* tags into web documents or other data-streams. These tags are supposed to provide more information regarding the concepts within the data and their relationships to each other. Since the information regarding relationship between the data is present, it is faster and flexible to retrieve data. And also no transformation/mediation is required as data is present in a unified and common way. The following are the challenges of the usage of semantic web for harmonization of patient records:

- Heterogeneous Data Integration by virtue of uniform standard encompassing, different formats in the medical industry and avoiding transformation
- Expressing well-defined and rich models of biological systems supporting all models of medical records
- Annotating findings and interpretations formally and sharing with other medical practitioners so that they can infer the data with their respective tools equipped with semantic understanding

- Applying logic to infer additional insights and to propose/capture new hypotheses.

We use semantic technologies like RDF, OWL and SPARQL to meet the above challenges. RDF is used for heterogeneous data integration, OWL is used to provide relation between the data and provide the interpretable capability and SPARQL for semantic based search. In the section following, we describe each of these technologies in detail.

**Resource Description Framework (RDF) for Data Modeling:** RDF is a W3C standard for the common data format. RDF provides the technology for expressing meaning of terms and concepts in a form that computers can readily process. RDF creates graphs of nodes and arcs to represent simple statements. Every statement in RDF is represented as triple (Subject-Object-Predicate). In the example “the document Record#20 belongs to Jack” *subject* is Record# 20 and *predicate* is Belongs to. Every resource has a URI attached to it. Ontologies are used to label the RDF tagged elements [6].

Ontology is a formal, explicit specification of a shared conceptualization. It is the basic building block of semantic web. The RDF data as a triple record can be stored in traditional RDBMS systems. Hence, there is no requirement of additional persistence system for storing RDF.

**Web Ontology Language(OWL):** OWL is based on RDF with additional capabilities. By using the W3C’s Web Ontology Language (OWL), equivalences between predicates makes it easier to combine databases without revising one database to have the same schema as the other. For example, if *patient\_number* and *patient\_id* are defined as equivalent, a search on patients with

```

Consider a definition
Every patient name should be given a unique patient id.

OWL specification is

<rdfs:Class rdf:ID="Patient id">
<rdfs:subClassOf>
<owl:Restriction>
  <owl:onProperty>
    <owl:ObjectProperty rdf:ID="is given">
      <rdfs:range rdf:resource="patient id"/>
    </owl:ObjectProperty>
  </owl:onProperty>
  <owl:cardinality rdf:datatype="xsd:integer">1</owl:cardinality>
</owl:Restriction>
</rdfs:subClassOf>
</rdfs:Class>

  This says that a patient should be given one unique patient id.
  Now supposing that a patient is given a patient number instead of patient id:

<Patient id rdf:ID="HUMINS">
<Patient id rdf:resource="Patient number"/>
</Locus>

In general, traditional databases would raise a constraint
violation that patient name should be assigned a patient id.
But OWL interprets that both patient id and patient number are the same.

```

Figure 1: Example to Show the Interpretable Capability of OWL

Source: Infosys Research

*patient\_number* value of 101 will also get the details written under *patient\_id* value 101. This feature of RDF is an attractive approach towards aggregating distributed data not controlled by a central authority. If we can define ontology to manage data, then RDF triples are the best way to track entries into the ontology. RDF is for modeling the data whereas OWL is for processing the content. Figure 1 shows a simple example to depict the interpretation capability of OWL.

**SPARQL:** A W3C specified query language for RDF works for any data source that can be mapped onto RDF [7]. SPARQL is a data-oriented query language, i.e., it only queries the information held in the models and there is no inference in the query language itself. SPARQL is a syntactically-SQL-like language for querying RDF graphs via pattern matching. The

language's features include basic conjunctive patterns, value filters, optional patterns and pattern disjunction. It has strong support for querying semi-structured and ragged data, i.e., data with an unpredictable and unreliable structure. Variables may occur in the predicate position to query unknown relationships and the **OPTIONAL** keyword provides support for querying relationships that may or may not occur in the data.

#### ADVANTAGES OF RDF/SPARQL OVER TRADITIONAL FORMATS

Table 1 depicts few advantages of using semantic languages for data integration over relational databases and XML data formats. The two major business benefits of using a semantic data model (RDF/SPARQL) are the promise of tremendously improved search capabilities and in the long term provide improved systems interoperability,

RDBMS/SQL	XML /Xquery	RDF /SPARQL
Efficient and correct transactions	Transaction across organizational boundaries	Flexible information sharing
Metadata is embedded in application or database schema	XML wraps the metadata about the transaction around the data thereby increasing size	Enables semantics as well as the syntax to be embedded in documents making it machine readable

Table 1: Advantages of Using Semantic Languages

Source: Infosys Research

potentially enabling machines interoperability and potentially enabling machines to reach new levels of automation.

CASE STUDY

The case study used here is to depict the part of information flow in a healthcare organization. Figure 2 shows the process flow across various departments and systems. Applications that need to merge or synchronize with other existing applications in different domains require to comply with the semantic platform in order to have a robust and agile information system.

The purpose of this exercise is to manage the interoperability of information communicated across doctors distributed by geography or medical practices. Healthcare businesses with discrete applications are carried out in discrete departments. At times when the business applications are outsourced, it becomes difficult to synergize with other applications in the system. To add to the problem, doctors contracted by the hospital who are accustomed to other standards, will find it difficult to understand the health reports of the hospital. The scenario mandates an interoperability mechanism in place to minimize the total cost

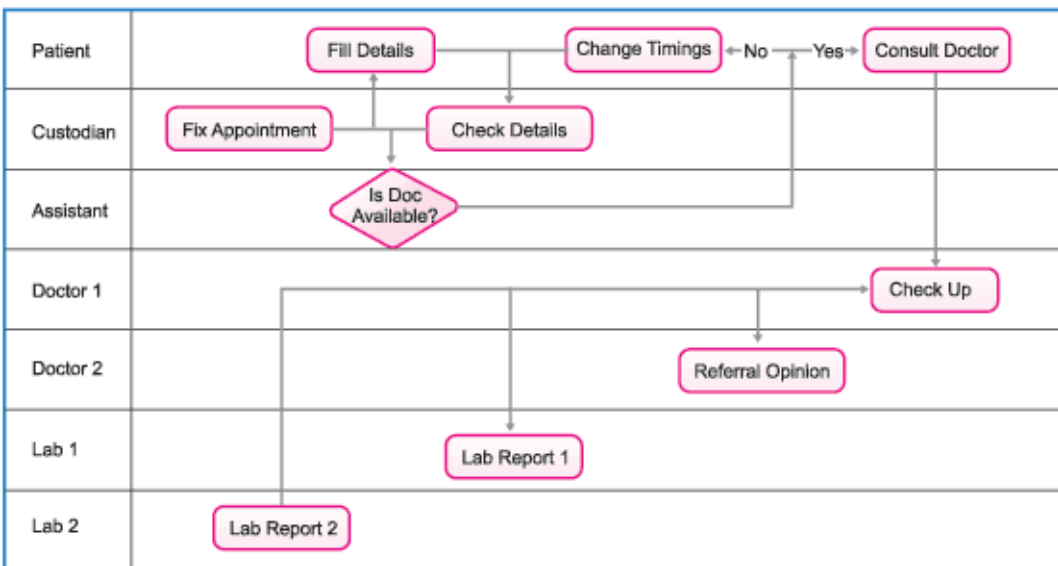


Figure 2: Part of Flow Diagram of Healthcare Information System

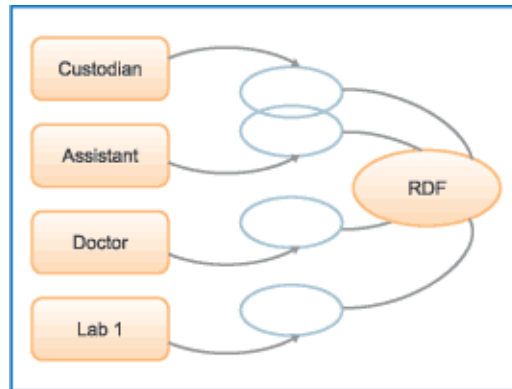
Source: Infosys Research

of operation and as also maneuver a smooth execution of the sophisticated health system process. Here, we present a case study on healthcare information system to provide a deeper insight for designing of ontologies to achieve harmonization of patient records. Interoperability issues creep up exactly when the doctors need to correlate information from the patient’s clinical history for further treatment. A patient’s information is spread over many departments and hence necessitating the need for *harmonization* of patient’s records from various departments to produce a consolidated report.

### Enterprise Data Integration: RDF

Healthcare information system consists of many processes like, custodian keeping track of patient records, fixing an appointment with doctor, checking with assistant for doctor’s availability, referral to another doctor, information from different lab reports, etc. Different departments need to share data but the lack of an interoperable, integrated solution prevents this. Even if one healthcare department wants to cooperate with other healthcare departments to exchange data across applications, the need for compliance to emerging standards and government regulations arises. Another scenario where the need for standard data format arises is when there is a merger or acquisition where the disparate software infrastructure and underlying content and functions of two healthcare institutes need to be integrated. Figure 3 shows domain ontology stored in RDF format and provides mappings between various processes.

Different data providers use different ways to structure their data. They use different identifiers to reference the same entities and there is acronym collision between the data sets. Even data can be presented in different formats



**Figure 3:** Data integration within a Healthcare Information System

*Source:* Infosys Research

namely file formats, XML schemas and relational models. RDF comes out as a better solution to overcome these problems. For example, *patient id* and *patient number* are alias names and refer to the same thing. RDF data format makes it easier to store the alias names and retrieves the data from both the processes if the query is “Get all details of patient with patient ID: 10”. SPARQL is used to query the RDF data model. Figure 4 shows a simple SPARQL query that returns details of patient with patient ID 10.

We have used RDF for data modeling and OWL for creation of ontologies. SPARQL is used as query language.

Figure 5 shows snapshot of Protégé editor used for data modeling and design of ontologies.

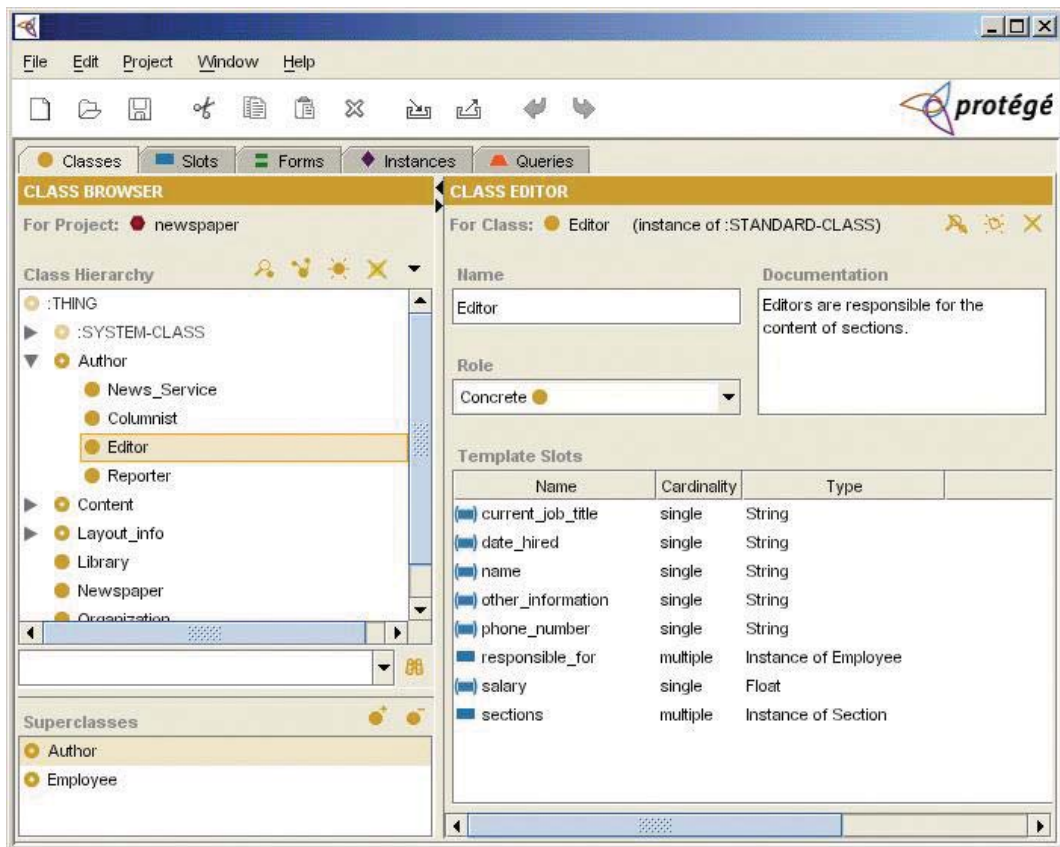
```

PREFIX abc: <http://patientinfo.com
/patientOntology#>
SELECT ?patientinfo
WHERE {
  ?x abc:getpatientinfo ?patientdetails ;
  abc:withpatientid ?y.
  ?y abc:patientid abc:10;

```

**Figure 4:** Simple SPARQL Query Returns Details of Patient with Patient ID 10

*Source:* Infosys Research



**Figure 5:** Snapshot of Protégé Editor for Modeling of Data using RDF and Storing Data using MYSQL Database **Source:** <http://protege.stanford.edu/overview/pf-screenshots.html>

We have used protégé for modeling and MYSQL and sesame to store the data.


### CONCLUSION

Harmonization of patient records can be achieved by adopting a standard way of modeling data like RDF. Rather than using interfaces/mediators for data integration, underlying structure of healthcare data system should be defined in a common and unified way to make harmonization of records effective. Healthcare systems are bound to expand both horizontally and vertically and with the usage of RDF data modeling, expansion can be accomplished easily and also, collaboration

between disparate healthcare systems can be achieved seamlessly.

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# Interoperable Healthcare Systems and their Practical Applicability

*Sanjeev Arora MD, Director-Project ECHO and Executive Vice Chairman -Department of Medicine, University of New Mexico Health Services Center, shares his vision on the effectiveness of interoperability in healthcare systems, in a discussion with Praveen Soti MD, Senior Engagement Manager, Healthcare Practice, Infosys Technologies Ltd.*

**Praveen: Healthcare Information Technology is in the spotlight now more than ever before, with a lot of industry debate happening about its practical applicability. President Bush has called for the adoption of Electronic Health Records (EHRs) by 2014 and the Office of the National Coordinator for Health Information Technology (ONCHIT) has called for clinical and other administrative data interoperability. As a clinical leader at one of the country's leading academic medical centers, how do you see these initiatives to rewire American medicine making an impact on your organization?**

**Dr. Arora:** The first question is whether electronic health records improve the quality of care and make the healthcare system safer and more efficient for the average American. The answer to these questions is a definite yes. An interoperable healthcare system much like a financial system would work very well. Interoperability in financial systems enables me to go to another country like Vietnam, and use my credit card to get information on my personal finances and do financial transactions. If the same kind of interoperability was to be implemented for electronic health records, it

would be advantageous for the patient, as it would reduce medical errors, resulting in better safety and quality of care.

I think the key challenges of electronic health records are essentially posed by the current model of healthcare in the United States. Healthcare here uses the small business model. Private practices usually have just one to three doctors on an average. The predominant reimbursement system used is the *fee-for-services* model. Physicians essentially get paid for what they do in the short term, rather than for optimizing long-term outcomes of diseases like Diabetes or Hepatitis C. This reimbursement mechanism prevents the doctor or his practice staff from putting a lot of time and effort into prevention, patient education and chronic disease management. Electronic health records haven't been successful because it takes more physician's time to populate an electronic health record than to write a brief note on a paper chart. Doctors face enormous time pressures as in a practice, patients are scheduled every 20 minutes. Adding on another task of populating and maintaining an electronic health record without any additional revenue reduces the efficiency of their practices and has the potential to decrease income.

As the largest payor of healthcare services in the United States, the federal government has a compelling interest to enhance the safety and efficacy of healthcare. I believe an effective way to enhance adoption of electronic health records is to have a federal mandate towards the use of electronic health records for interoperability. There should be some incentives for physicians, hospitals, HMOs and pharmacies to adopt these new standards.

This is a difficult task, but I am optimistic. As far as our own organization, University of New Mexico Health Sciences Center is concerned, we spend more than 15 million dollars a year on IT systems, mostly on purchase and maintenance of clinical information systems and electronic health records. Although it is difficult to demonstrate a major return on investment in the short term, over time this investment should yield huge benefits.

Without this information healthcare providers are prone to repeat the mistakes of the past.

**Praveen: What are your observations on Regional Health Information Organizations (RHIOs)? Do you agree that RHIOs today lack a tangible and sustainable business model?**

**Dr. Arora:** Although the RHIO partners understand the quality benefits of such exchanges, there is inadequate funding for this activity. Provider organizations need incentives to engage in the work of creating interoperability between the various systems.

One approach is for the federal government to provide tax or other incentives for organizations to standardize around best practices.

Patient records need to be accessible by the patient and her physician from anywhere in

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*To encourage standardization of best practices, federal government should either mandate or offer incentives towards adoption of electronic health records*

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At present our IT systems are unable to communicate with the electronic records of other health systems or physician offices. This leads to duplication of tests when patients come to the University for Healthcare. Carrying photocopies of paper records from one organization to another is inefficient and often incomplete. Patients are often unaware of what is the most relevant information to transfer. Besides the cost and time involved, there is also an issue of safety since patients are not medically aware enough to provide complete information about their condition and the drug interactions that may have occurred during admission to other hospitals.

the world regardless of the healthcare institution that created them. A good analogy would be a bank check, where some of the digits in the check number represent the bank and conveys other banks how to route new information to the home bank. This concept of routing could be used in patient records to support interoperability.

**Praveen: In your opinion, what are some of the most important challenges facing US Hospitals and how can they be addressed in the light of Project ECHO Care Delivery model?**

**Dr. Arora:** There are two levels of care within the US healthcare system. There is very good

access to care for patients with health insurance. However 20% of patients between the age of 18 and 64 do not have any health insurance. These patients have a hard time accessing specialty care. The uninsured typically get primary care in community health centers or federally qualified health centers. These are supported by the federal government but do not provide any means for specialty care. Project ECHO can help bring access to specialty care for these uninsured patients. Even patients with health insurance that live in rural and underserved areas and have chronic complex diseases such as Hepatitis C or mental health disorders, face difficulties in accessing the specialty treatment they need. The ECHO model addresses this problem by giving physicians --who specialize in treating complex and chronic conditions like HCV--access to technology,

Network. In a one-to-many knowledge network, the expertise of a single specialist is shared with several primary healthcare providers, each of whom sees numerous patients. The flow of information in a Knowledge Network is bi-directional – the specialist and community-based primary care providers gain invaluable feedback and case-based experience through weekly consultations.

Telemedicine and internet connections enable specialists in the program to co-manage patients with complex diseases using best practice protocols, case-based knowledge networks and learning loops. Learning loops are case-based educational experiences in which community providers learn through three main routes:

- (i) Longitudinal co-management of patients with specialists

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*Primary care should be reachable to people irrespective of their health insurance coverage. Training teams of support caregivers in rural areas can be of great help in this regard*

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enabling them to share knowledge about best practice protocols, using a case-based learning approach to co-manage patients with primary caregivers in rural communities and federally qualified health centers in cities. Empowering primary caregivers at rural clinics has several long term benefits. Rural physicians gain expertise, earn required continuing education credits and are encouraged to remain in remote communities by having one of their highest priority needs answered – an opportunity to continue learning and to interact with professional colleagues.

The key component of the ECHO model is a disruptive innovation called a Knowledge

- (ii) Other primary care providers on the network via shared case-management decision making

- (iii) Short presentations on relevant topics, such as vaccination for hepatitis A and B and diagnosis of depression.

These learning loops create deep domain knowledge about the area in question—here HCV – among rural providers, enabling them to provide the highest quality treatment for their patients. Systematic monitoring of treatment outcomes is an integral aspect of the project.

We believe this methodology can be adopted for other complex and chronic conditions in a wide variety of underserved areas to improve disease outcomes. The primary beneficiaries of this innovation are patients in such areas.

In addition to enhancing access to care, Project ECHO helps manage patients with chronic diseases more effectively. If a patient weighs 240 pounds and suffers from diabetes, high cholesterol and hypertension, he will need team-based longitudinal care to impact these diseases. That means professionals like dieticians; exercise physiologists and diabetes educators need to assist the physician towards caring the patients. Complex medical conditions require teams for effective treatment. For example, a cardiologist will need a team to manage and treat a patient's congestive heart failure. The team would be required to monitor the patient's sodium intake, monitor body weight regularly and make adjustments to doses of diuretics. In rural areas doctors do not have access to these supporting teams and therefore care suffers. Project ECHO knowledge networks can assist in training of these supporting providers so that complex patients can be cared for by local teams.

We have realized that there are two kinds of diseases that can benefit from Project ECHO. The first kind would be diseases like HIV or Hepatitis C, where the primary care doctor does not have the knowledge to treat the patients and we can help them via our knowledge networks. Then there are other diseases like diabetes, hypertension, obesity or smoking cessation, where the primary care doctor has the requisite expertise but is ineffective because of the lack of a trained team to manage the patients. At Project ECHO we train ancillary providers to be part of the team. We empower nurses, medical assistants and community health workers through knowledge networks to become part of the disease management team.

This serves as a force multiplier for best practice implementation. We can multiply the capacity of a physician by training other professionals who get paid significantly less than the doctor, but with the help of a knowledge network can provide the same protocol driven care. Once the doctor has prescribed the medicine and the protocol is in effect, these trained workers can execute the protocol effectively. Over time of course, the learning loop kicks in and these support providers become experts in their areas.

**Praveen: In short, is it about building remote capacity and capability as a team?**

**Dr. Arora:** Yes, it is about team-based capacity. In most diseases it is team-based capacity that delivers outcomes.

**Praveen: Can you please share your perspective of the role of Information Technology in Healthcare and specifically how it has complemented Project ECHO's success?**

**Dr. Arora:** In collaboration with Infosys Technologies we have developed a web-based patient management tool in which we have incorporated best practice protocols. This tool called iHealth will allow patients and providers anywhere anytime access to medical information on the web. In the future we plan to incorporate patient safety tools like alerts to healthcare providers. We plan to provide this tool at no cost to providers who care for underserved populations.

We also extensively use audio and video conferencing and emails to operate our knowledge networks.

I believe IT will be playing a vital role in the care of underserved patients. IT will:

- a) Connect people at low cost around the world so that they can talk, share and learn from each other – that's what I will

call conferencing capacity , and

- b) Share data using the web like we are doing with iHealth.

Project ECHO sits at the interface of this conferencing and data sharing capacity.

There are many other things we are trying to accomplish with Project ECHO. The initiative we are taking on right now involves training large numbers of ancillary providers to become diabetes educators. By using information technology like video conferencing and webinars, we are significantly lowering the cost of these trainings.

Other things we are looking into are fellowships for rural primary care doctors while

Infosys as a partner. First, we felt Infosys was an industry leader and was a company thinking ahead of times. Although there are many good IT companies, we felt Infosys has shown leadership and been an innovator that has led the evolution of the entire Indian IT industry. It was encouraging to see that the company had received many industry awards for best-in-class performance. Most importantly, Infosys has demonstrated a social conscience in giving back to society. I saw that the company leaders were devoting time and effort to advance public causes.

During our engagement I found that Infosys had robust processes and spent a lot of time listening to our needs. Infosys constantly

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*Real time access through internet and audio and video conferencing and safety tools like medical alerts can help patients and providers stay connected and therefore avert many medical exigencies*

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they live in their home towns. Usually these providers need to move to a large city for one year to complete these fellowships. Our plan would be to use IT to connect the providers to these Universities so that they can get their fellowships while continuing to serve in the rural areas and be able to study while they work. So we are developing ECHO as a training and development tool.


**Praveen: What are some of the key reasons to select Infosys as a partner for such a Strategic Initiative and what key benefits have you seen with this collaboration?**

**Dr. Arora:** There were several reasons to select

kept us in the loop and updated us on how the work was progressing.

**Praveen: Infosys' partnership with UNM on Project ECHO has been quite successful. The project has won many awards and will surely get even more recognition going forward. What do you think are the factors that have made this partnership successful?**

**Dr. Arora:** I think that our partnership is successful because Infosys has demonstrated an understanding of our mission and worked hard to create a software program that meets the needs of underserved populations.

*Sanjeev Arora, MD, is the Director of Project ECHO. Arora is Professor of Medicine and Executive Vice-Chair, Department of Internal Medicine at University of New Mexico Health Sciences Center. He has been involved in management of viral hepatitis for over 15 years and has led the development and implementation of the Hepatitis C Disease Management Program at UNMHSC. Arora developed the Extension for Community Healthcare Outcomes (ECHO) model as a platform for service delivery, education and research. In his spare time, he enjoys playing golf.* 

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# Information Mining in a Collaborative Healthcare Environment

By Harikrishna Rai, Pranav P Mirajkar, Sai Deepak and Sivaram Thangam

*Transformation in information distilling process by coalescing federated health data is the key to combined knowledge discovery and decision making*

With the introduction of digital technology in healthcare industry, there has been a tremendous increase in the amount of data generated. These include images, endoscopic videos, doctor's reports, lab reports, bills, etc. Typically, in a healthcare center, the amount of data generated per year is of the order of several terabytes [1]. To manage such huge volumes of data, healthcare industry has many data management systems like Hospital Information System (HIS), Radiology Information System (RIS) and Picture Archiving & Communication System (PACS). These systems provide authorized access to patient data and facilitate information management tasks such as storing, accessing, organizing, viewing and printing.

These systems are intended just to facilitate workflows in healthcare centers. This creates an opportunity for data mining solutions to analyze, mine and summarize these data from different perspectives for useful inference. For

example, while interpreting radiology image of a patient, similar cases from the archive can be found and the linked reports can be mined to get some useful insights to help diagnose better.

To cater to the growing needs of such a data mining solution in healthcare environment, there has been an increased awareness in the market. Few vendors have emerged recently to meet the challenges. Their solutions have targeted very specific departments like radiology and laboratory or simple data analytics, making use of structured data and not utilizing the unstructured data, like reports and images. Also, most of the systems work in a closed network of the owning hospital, without having access to the health information present in other healthcare units. The vast amount of relevant information present in these healthcare centers that could have provided another dimension to knowledge obtained is not exploited.

In healthcare industry there is a huge

scope for an effective data mining solution that can help derive implicit knowledge out of ubiquitous structured and unstructured data sources, aiming towards better patient care.

Governing regulations in healthcare industry and demand for high quality services have led to the development of storage and communication standards to be followed by hospitals, radiology centers and pathological labs. But these guidelines do not focus on collaborative efforts to bring together varied health information sources. This gives rise to information deficiency for deriving useful inference in data mining solutions. Collaboration between healthcare units will provide a data mining system with complete information to derive more trustworthy knowledge. Data mining solutions need to focus more on non-operational data like patient data, medical reports and images. A huge amount of knowledge remains unexplored in unstructured data like reports and images. Mining these would provide much effective inference for better healthcare decision making.

Therefore the focus of a collaborative healthcare data mining solution should be:

- Providing sufficient information through collaboration for better decision making
- Mining non-operational data like medical reports, images and patient data
- Knowledge management for high competency and quality decision making
- Complementing experts' knowledge with existing information for improved analysis.

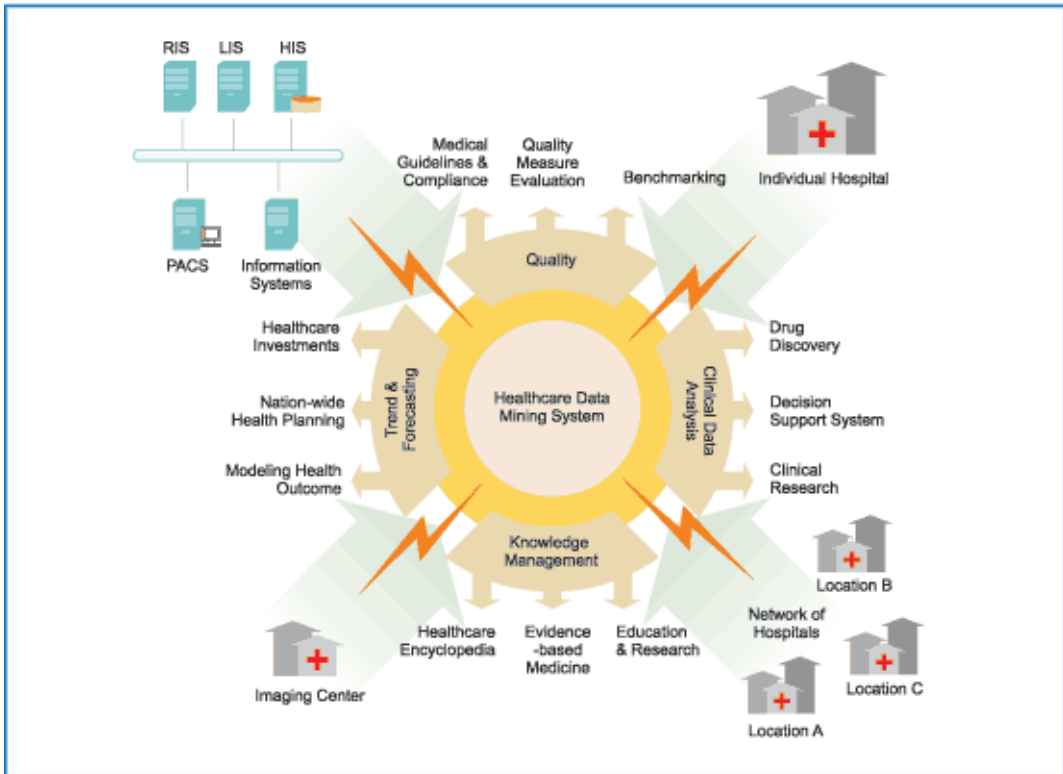
## TOWARDS EFFECTIVE HEALTHCARE DATA MINING

Initiatives like Integrating the Healthcare Enterprise (IHE) have been taken to connect the departments within the hospital, among

the hospitals and all health centers across the nation. There has been an increased awareness among the healthcare personnel about the potential use of the knowledge that has not been accessed. Taking the current scenario to a further level by connecting all the health information sources across the state or even the nation by making appropriate collaborations, we can step into the next level of information usage in healthcare. Assuming that all the health information across the nation is connected, there are a plenty of opportunities to make use of the staggered data that drastically change the healthcare delivery system. A well-built data mining system must make use of both the structured and unstructured data from the connected environment.

Such a well-built system can have many aspects of usage. Figure 1 shows a healthcare data mining system connected to all the health information sources like hospitals, imaging centers and PACS with few aspects and their end applications listed. For instance, pharmaceutical research has potentially huge scope for such a data mining tool in a connected environment. This would make the drug discovery faster and more effective as the location-wise disease specific information is on hand very easily.

When we scale down the same idea to the hospital level, there still remains a huge scope for such a data mining tool. With all the information sources within the hospital being connected, useful inference can be derived out of operational, clinical and financial data. Table 1 depicts few aspects of usage and its end-applications in a connected hospital environment. A typical usage will be case based diagnosis, where the radiologist can diagnose a very rare case by making use of the data mining tool that helps find similar cases with the diagnosis information attached.



**Figure 1:** Data Mining System in a Collaborative Healthcare Environment

Source: Infosys Research

**BUSINESS SCOPE AND ANALYSIS**

Conventionally, healthcare providers use healthcare data deliberately, to manage operations. To remain competitive, renowned organizations use data strategically – to expand business, enhance organizational revenues,

to reduce healthcare delivery time and costs. Mining operational data in hospitals provides lot of inference in the form of statistical graphs, reports and tables. Healthcare executives in network hospitals can get answers for several business questions like “Which hospital had largest

Healthcare Data Mining System Hospital Level		
Clinical Data	Finance Data	Operational Data
<ul style="list-style-type: none"> <li>● Evidence Based Medicine</li> <li>● Education &amp; Research</li> <li>● Case Based Diagnosis</li> <li>● Quality Of Healthcare Delivery</li> </ul>	<ul style="list-style-type: none"> <li>● Budget Allocation</li> <li>● Throughput Analysis</li> <li>● Investment &amp; Growth Planning</li> <li>● Cost Effective Analysis</li> </ul>	<ul style="list-style-type: none"> <li>● Utilization Management</li> <li>● Staff productivity monitoring</li> <li>● Quality of service</li> <li>● Administrative planning</li> </ul>

**Table 1:** Healthcare Data Mining in Hospital View

Source: Infosys Analysis

*change in revenue compared to the same quarter last year?" or "Did we have enough stock of medicine and accessories to treat breast cancer?" Similarly, mining clinical data in networked hospitals can answer varied questions of clinical researchers like "What was the percentage of patients who had coronary blockage with diabetic and high BP problems in Boston?" or "How many patients had tumor in brain and what was the medication given to them and how did they react for different dosages?" – where this refers to a reference medical image belonging to the clinical case in hand and having particular visual pattern. These kind of clinical data mining business cases call for integration of different databases like PACS, RIS and Laboratory Information System (LIS) to arrive at clinical decisions as discussed in the earlier section.*

Business drivers for this kind of integrated data mining solutions are:

- **Medication Errors:** In 1999, Institute of Medicine (IOM) did a survey in US. According to the survey report, between 44,000 and 98,000 deaths each year may result from medical errors in hospitals. And more than 7,000 deaths each year are related to medications in US [2]. This gives a clear indication of strong need for Computer Assisted Diagnosis (CAD) systems to overcome errors introduced by manual diagnosis and medication process. CAD systems complement existing manual diagnosis process.
- **Unexplored Archives:** Majority of patient data in hospitals and radiology departments are in the form of images. The number of images stored in archives increases exponentially. There is a strong need for a mechanism to

manage such archives for effective navigation and organization and means to explore hidden patterns and key clinical and administrative insights from such unexplored archives. Governing regulations like Health Insurance Portability and Accountability Act (HIPAA, 1996) are imposing healthcare providers to invest more on the storage and data management solutions. They recommend robust healthcare record management, clinical data retention and quick retrieval.

- **Know the Business Trend:** Policy planners in healthcare institutions can analyze their clinical and pharmaceutical data to know the trends in diseases and which drugs are sold more and why, and design a business strategy accordingly. It also helps to measure and analyze how well the hospital is providing services. This information is really a value addition to drug discovery initiatives. By mining clinical data, healthcare organizations can identify disease in premature stages and design an early warning system for patients about possible threats and also plan a counter measure to face such encounters.
- **Health Insurance Sector:** Success of insurance companies relies on how smartly and effectively they use the available claim and healthcare data. Advances in clinical data mining and analytics domain will enable health insurance firms to make larger investments in predictive modeling technologies to identify patients who will be benefited from care management programs and reduce fraudulent claims and identify medical malpractices.

- **Patient Safety and Healthcare Quality:** Successfully addressing patient safety requires effective prediction and detection of disease events in advance. With the available clinical data at hospitals, detecting events automatically is of great help in patient safety. Predictive clinical data analysis helps in identifying high-risk patients before costly medical events occur. Key healthcare quality focus is towards optimizing clinical processes in terms of medical and administrative quality, as well as cost-benefit ratio. Major issues in medical quality management are the quality of data, standards, plans and treatments. These qualities can be evaluated with different indices. Analysis of data collected from various sources

base. Knowledge gained by analyzing the clinical data can assist in both diagnosis and treatment planning. Another anticipated area is health universities and clinical research centers for creating centralized repository of clinical knowledge base for conducting extensive research and study. To enable such systematic approach to manage and exploit the massive amounts of potentially valuable data, it requires collaborative efforts from all stakeholders ranging from healthcare providers, to industries and government agencies.

#### CHALLENGES FOR DATA MINING IN COLLABORATIVE ENVIRONMENT

Collaboration for improved inference not only provides many advantages but also faces

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*A synergy between the stakeholders ranging from healthcare providers to industries and government agencies is required to exploit potentially valuable data*

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across hospital is the key to successful quality measure. Extracting patterns from large data archives and using them to produce new knowledge is demanding for quality analysts and decision makers in the health sector. Potential for quality of healthcare improvement lies with novel clinical data mining technology used by healthcare institutions.

- **Knowledge Management:** Clinical decision support systems rely on the best evidences available in the knowledge

challenges due to varied data, platforms, regulations, conventions and privacy issues. Here we discuss the relevant issues and suggest some possible ways to mitigate the challenges.

- **Distinguishing Good Evidence from Bad Evidence-based Medicine:** This heavily depends on relevant information stored in medical databases. The information thus returned has to be consistent, valid, relevant and suggestive. This is difficult due to information explosion in a collaborative environment and asks

for intelligently distinguishing evidences to be shown to the user for second opinion. This will require systematic review of relevant information through intelligent data mining techniques [3]. Only a systematically reviewed data should be considered for inference. This calls for application of domain specific rules to rank relevance for structured data and text tagging and annotation rules for unstructured medical reports and image mining techniques for image databases. Data from various sources has to be collected in such a way that it ensures both quality and relevance.

- **Data Inconsistency:** It is one of the primary issues in data mining in an

from multiple vendors. Standards like Health Level 7 (HL7) and Digital Imaging and Communication in Medicine (DICOM) address the communication and interoperability issues between information sources within the hospital. Initiatives like IHE have emerged to address data sharing issues across the healthcare enterprises. These standards come to our rescue in cases of interoperability issues [5, 6].

- **Variation in Presenting Information:** This issue can be a hurdle in analyzing unstructured medical reports. Variability of medical words or terms occur due to the difference in clinical practices across regions that in turn makes meaningful data

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*Multiple data platforms, data relevance, security concerns and unstructured data are major pain points in effective data mining*

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integrated environment. It is often the case that more than enough data is available for consumption and that crucial data is lost in the data jungle. Data can be old, missing, some structured and other unstructured, illegible or much more than necessary [4]. Extraction, transformation and loading of inconsistent data have been a potential problem in data warehousing and many tools and frameworks have been developed to address this problem.

- **Interoperability Issues:** These arise due to multiple platforms and technologies

mining of these reports more difficult. This can be addressed by building a domain specific lexicon/dictionary [7, 8] that can be used for text tagging, annotation or similar data mining techniques for text mining. Rule based techniques using a lexicon is a popular method for solving the problem of variability in representation of words in data mining.

- **Legal issues on Sharing of Data (Privacy, Security and Confidentiality):** Legal issues in data sharing over network can be in--privacy, security and confidentiality

of information. These concerns in data sharing are not new [9, 10] and have been addressed in similar scenarios like Telemedicine [11] and Teleradiology [12]. The Health Insurance Portability and Accountability Act (HIPAA, 1996) also provides guidelines on, provision of health benefits, delivery and payment of healthcare services and the security and confidentiality of individually identifiable and protected health information. Failure to comply with any of these standards, leads to penalties and other legal actions. An important aspect of collaborative scenario is the common understanding and awareness of these issues between the parties involved. Then these policies can be implemented at system level in order to achieve a level of transparency in the actual day-to-day operations.

- **Regulations:** Healthcare regulations vary in different regions and understanding of similar regulations might also differ with regions and culture. Common understanding of regulations and agreement on all methods of operation in a networked environment is crucial for this system to work without any hassles.


## CONCLUSION

Healthcare industry can be immensely benefited by mining patient's data that is generated on a day-to-day basis in healthcare units. This model could achieve more success when all the health information sources are connected. To address the modern healthcare demands, we draw the attention of healthcare providers to invest on clinical data mining researches in integrated environment that results in improved healthcare delivery. Sharing health information in this way

is essential to opening new dimensions in clinical data mining. Collaboration between healthcare providers will not only lead to innovation in knowledge discovery techniques but also enhance quality of patient care. In this way cutting edge tools and solutions for knowledge discovery on rapidly growing healthcare databases for pattern discovery can be realized. This will also help in extracting information in compact and abstract form to periodically analyze current business trends by applying intelligent data mining techniques.

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# IT Applications for Healthcare: Leverage Processes for High Quality

By Ravishankar N

*An integrated process framework derived from industry models can help address compliance, cost effectiveness and quality challenges*

Healthcare systems make effective use of IT applications to deliver affordable, quality healthcare to the human community. Worldwide, the total IT spend of healthcare organizations is predicted to be around US\$ 94 billion by 2011 [1]. IT applications significantly impact the outcome of a variety of healthcare systems, ranging from a hospital management system to core pharmaceutical research and drug development systems. IT divisions of healthcare organizations face challenges related to compliance, cost effectiveness and quality. Thus, besides delivering the required functionality at affordable cost, the IT applications have to deliver on three key parameters:

- **Performance:** Transaction volume handling ability, response time, etc.
- **Security and Privacy:** Prevention of loss and unauthorized access to critical data.
- **Compliance:** Ability to enforce the controls required by statutory regulations.

Though these parameters could be considered within the broader context of *quality*, each parameter represents a key dimension in the success of a healthcare IT application that satisfies the core functional requirements. Increasingly, with stringent regulations and compliance expectations, the requirements related to the above key parameters are being considered as seriously as the basic functional requirements of a given healthcare system.

## CURRENT CHALLENGES

Today IT divisions of healthcare organizations face challenges in delivering cost effective IT solutions doing full justice to the three key parameters listed above. Many statutory regulations impact the IT solutions. While some of these regulations indirectly relate to IT systems, some directly ask for certain elements to be part of IT systems. Some examples are:

- SOX 404 that specifies IT controls to

- minimize financial risks
- FDA 21 CFR Part 11 – electronic records, electronic signatures
- FDA 21 CFR Part 820 – Quality System Regulation

Healthcare IT organizations' applications have to build the necessary controls in their organization and the necessary checks and control features in their products, to satisfy the applicable sections of each of these stipulations.

Security vulnerabilities such as hacking and theft of private data pose a threat to the success of the IT applications and diminish confidence levels of users as well as service providers. These vulnerabilities exist in both paper and electronic records. According to the Los Angeles Times, roughly 150 people for e.g., doctors, nurses, technicians, billing clerks, etc., have access to parts of a patient's records during a hospitalization and about 600,000 payers, providers and other entities that handle providers' billing data have some access to the records too [2]. To thrive in such a scenario, IT organizations have to constantly attempt to build more and more checks and controls to ensure that their products are robust enough to prevent loss, as well as spot and report unauthorized access to private data.

Large integrated databases, data mining, extraction, analysis and accurate reporting of clinical data are some examples of today's requirement in the healthcare field. In 2005, the National Health Service (NHS) in the United Kingdom began an Electronic Health Records system. The goal of the NHS is to have 60,000,000 patients with a centralized electronic health record by 2010. The plan involves a gradual roll-out, providing general practitioners in England, access to the National Program for IT (NPfIT) [3]. That is just an example of the size and processing speed

requirements of a Healthcare IT system. To cater to such a large volume of patient data and to retrieve, process and report data at acceptable speeds to doctors and researchers, the IT applications must inherently provide built-in design elements and software features supported by fast and reliable hardware components.

### PROCESSES AND MODELS THAT CAN HELP

The success of a Healthcare IT application is largely influenced by the processes used to conceive, design and develop it. Given the 'mission-critical' nature of majority of healthcare systems it is of utmost importance that the processes used to create them are geared towards assuring near zero-defect quality. A set of structured processes leveraging industry best practices and process models can help an IT organization build the IT applications, to cater to the demanding requirements for success. Healthcare IT organizations have acknowledged the need for standards and processes. According to a Gartner survey, 'Implementing Quality Standards' is among the top 5 IT priorities for healthcare organizations [4].

The processes for engineering the software for healthcare applications could be structured in different stages:

- Requirements Elicitation
- Design
- Coding (Development)
- Validation
- Common to these core software engineering processes will be the steps for managing changes to requirements and the associated configuration/version management procedures
- Along with the overarching project management procedures, to support and verify the above activities, two other

Stage	Aspects to be Considered
Requirements Elicitation	<ul style="list-style-type: none"> <li>• Unambiguous, implementable requirements</li> <li>• Documentation and traceability of requirements</li> <li>• Review and sign-off of requirements from the healthcare service providers</li> <li>• Performance, data retrieval, processing and display/reporting</li> </ul>
Design	<ul style="list-style-type: none"> <li>• Information availability and confidentiality</li> <li>• Interoperability with multiple external hardware/systems</li> <li>• Interfaces to legacy systems</li> <li>• XML/EDI data exchangeability</li> </ul>
Development	<ul style="list-style-type: none"> <li>• Customizable rule engine to deal with geo-specific stipulations</li> <li>• Code modularization and flexibility to take care of frequently changing healthcare regulations</li> <li>• Data encryption/decryption</li> <li>• Security features</li> </ul>
Validation	<ul style="list-style-type: none"> <li>• Review of code and design components</li> <li>• Manual and automated testing</li> <li>• Regression testing to unearth unintended changes to code</li> </ul>
Configuration Management	<ul style="list-style-type: none"> <li>• Version control</li> <li>• Naming convention</li> <li>• Traceability and change management</li> <li>• Release procedures, documentation</li> <li>• Integrated patient record and case history database to feed government and other research organizations on birth, death and statistics of diseases prevalent in different geo locations</li> </ul>
Audits	<ul style="list-style-type: none"> <li>• Security audits</li> <li>• Quality audits</li> </ul>
Knowledge Management	<ul style="list-style-type: none"> <li>• Taxonomy and classification of case references</li> </ul>

**Table 1:** Stages to Address Specific Needs of a Healthcare IT system **Source:** Infosys Research

process sets would also be required:

1. Audit/ Assessment Processes
2. Knowledge Management Processes

The above stages could be used to address specific needs of a healthcare IT system. Some examples are given in Table 1.

### LIFECYCLE STAGE OF A TYPICAL SOFTWARE PROJECT

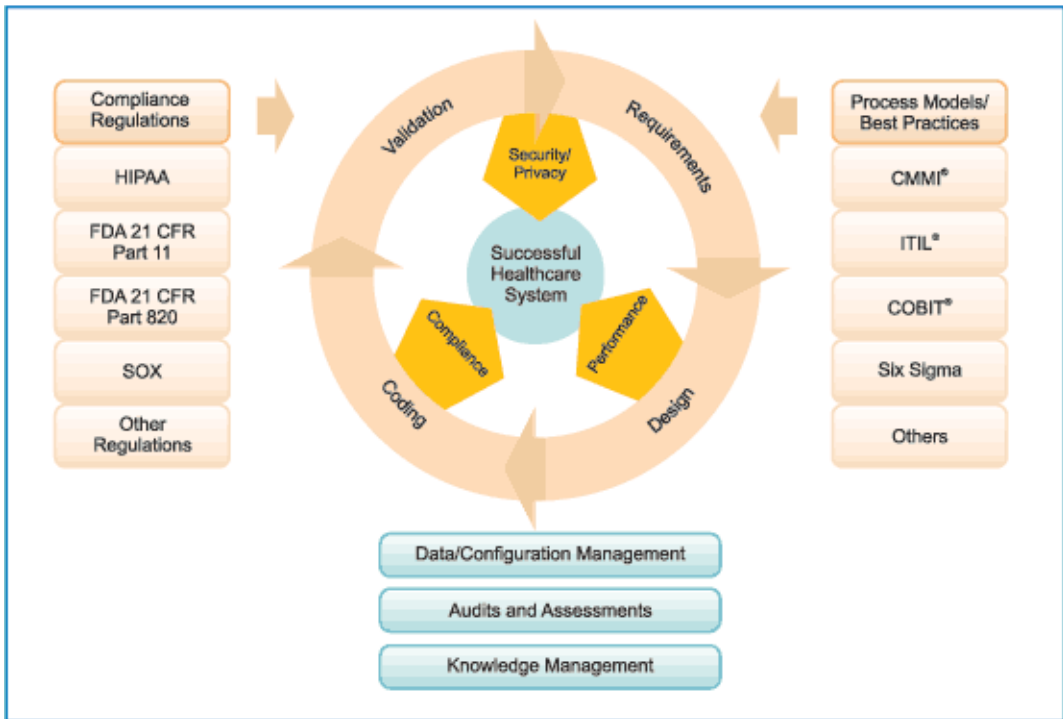
A typical software application development project goes through the following software engineering lifecycle stages:

1. Requirements elicitation and analysis
2. Design
3. Development (Coding)
4. Validation (Testing)

To plan and execute these stages the project needs an overarching project management focus. Along with the activities specific to each of the software engineering stages, the success of the project is strongly influenced by support activities such as configuration management, quality assurance, reviews and audits and knowledge management.

Figure 1 overleaf shows how the compliance stipulations, lifecycle stages and the process models are inter-related.

With the compliance stipulations such as HIPAA, FDA 21 CFR and SOX on one side and the key dimensions of success at the core, the execution of the activities in the above lifecycle activities and the quality of the corresponding deliverables will determine the success of the project and the overall quality of the final product.



**Figure 1:** Compliance Regulations, Software Engineering Stages and Supporting Industry Models *Source: Infosys Research*

This is where an IT organization can leverage process models effectively in order to deliver quality healthcare IT solutions. As can be seen in the above diagram, the models provide

the necessary support by offering best practices, methodologies, controls and audit guidelines, thereby positively influencing the software engineering lifecycle stages.

SW Engineering Areas	Degree of relationship			
	CMMI®	COBIT®	ITIL®	Six Sigma
Requirements elicitation	**	*	*	*
Design	**	**	**	**
Coding	**	**		*
Validation	**	**	*	*
Configuration management	**	*	**	*
Audits	**	**	*	*
Knowledge Management	*	*		*

\*\* Strong Relationship \* Moderate Relationship Blank-Weak/no relationship

**Table 2:** Industry Models Relate to Specific Areas of Software Engineering Lifecycle

*Source: Infosys Research*

	Performance	Compliance	Security
<b>CMMI®</b>	<ul style="list-style-type: none"> <li>Requirements Definition</li> <li>Technical Solution</li> <li>Product Integration</li> <li>Verification, Validation</li> <li>Decision Analysis &amp; Resolution</li> </ul>	<ul style="list-style-type: none"> <li>Configuration Management</li> <li>Process and Product QA</li> <li>Requirements Definition</li> <li>Technical Solution</li> <li>Product Integration</li> <li>Verification, Validation</li> </ul>	<ul style="list-style-type: none"> <li>Configuration Management</li> <li>Requirements Definition</li> <li>Technical Solution</li> <li>Product Integration</li> <li>Verification, Validation</li> </ul>
<b>COBIT®</b>	<ul style="list-style-type: none"> <li>Performance and Capacity Plan</li> <li>Requirements</li> <li>Define &amp; Manage Service Levels</li> <li>Manage Operations</li> <li>Acquire and implement technology infrastructure</li> <li>Install and accredit solutions and changes</li> </ul>	<ul style="list-style-type: none"> <li>One of the 7 core information criteria for COBIT</li> <li>More specifically, Monitor and Evaluate Domain - ME3</li> <li>Ensure Compliance with external requirements – laws, regulations and contractual requirements</li> </ul>	<ul style="list-style-type: none"> <li>3 of the 7 core information criteria Information Security Confidentiality, Integrity and Availability</li> <li>DS5 – Ensure Systems Security AI 2&amp;3 –</li> <li>Acquire and Maintain Technology and Application Infrastructure</li> </ul>
<b>ITIL®</b>	<ul style="list-style-type: none"> <li>Capacity Management</li> <li>Availability Management</li> <li>Service Level Management</li> <li>Incident Management</li> <li>Problem Management</li> <li>Change Management</li> </ul>	<ul style="list-style-type: none"> <li>Change Management</li> <li>Configuration Management</li> <li>Service Level Management</li> <li>Release Management</li> </ul>	<ul style="list-style-type: none"> <li>Configuration Management</li> <li>Change Management</li> <li>Service Level Agreements</li> <li>Availability Management</li> <li>IT Service Continuity Management</li> </ul>
<b>Six Sigma</b>	<ul style="list-style-type: none"> <li>House Of Quality</li> <li>Process Capability Analysis</li> <li>Benchmarking</li> <li>Hypothesis Test</li> <li>Design of Experiments</li> <li>Failure Mode &amp; Effects Analysis</li> </ul>	<ul style="list-style-type: none"> <li>Gage Repeatability and Reproducibility</li> <li>SPC/Control Plan</li> </ul>	<ul style="list-style-type: none"> <li>Failure Mode and Effects Analysis</li> </ul>

**Table 3: Success Dimensions addressed by different Models** *Source: Infosys Research*

Though the industry models have their own core objectives, they relate to specific areas of the software engineering lifecycle as shown in Table 2.

### MODEL COMPONENTS AND SUCCESS DIMENSIONS

With a plethora of models, controls and best practices available, it is challenging for an IT organization to figure out which ones would best suit them. Having identified the models, it

is important to map the elements of these models to the success dimensions of performance, compliance and security. Such a mapping leads to a superset of elements from each model addressing success criteria in one way or the other. Table 3 depicts this superset of model elements.

As can be seen in Table 3, there are overlaps in the way the models correspond to these dimensions. For example, the success dimension of Security is addressed by Configuration

Management element of CMMI® as well as ITIL®, though with differences in coverage and implementation focus. Similarly, managing service level agreements is addressed by Define & Manage service levels and service level management components of COBIT® and ITIL® respectively. Overlaps such as these pose challenges to a healthcare IT organization in deciding on the right components from each model, to address the generic and specific requirements of IT applications. Thus, to avoid duplication of effort in implementing the overlapping practices and to keep off from the trap of process proliferation, it is imperative that the IT organization identifies the most relevant ones from the above set of process elements.

The following section proposes a framework that would help in making the right choices and integrating the applicable elements in alignment with the objectives of the IT organization.

### THE PROCESS FRAMEWORK

A framework, enabling achievement of quality and the success dimensions, should provide a structure and discipline for software engineering using the industry best practices. At the same time it should provide the necessary flexibility to include new practices and tailor the existing processes and procedures to cater to the updates in compliance regulations from time to time. Further, with rapid technological advances, the framework should be scalable to exploit these advancements and cater to the changing needs of the user community in terms of performance and data security.

The integrated framework depicts a collection of specific components chosen from the superset of applicable elements from the industry models [Fig. 2]. It accelerates the 'Discover' and 'Define' stages in determining the best-fit practices leveraging on these models.

As seen in the integrated framework (Fig.2), the chosen elements from the models revolve around the software engineering lifecycle activities. Let us consider each lifecycle stage and discuss how the model components address the activities of that stage.

**Requirements Elicitation and Analysis:** This is an upstream stage in the software engineering lifecycle and entails interaction with the appropriate stakeholders to gather their business requirements, analysis and prioritization of the requirements and creation of specifications that would be fed to the next stage of the lifecycle. This is a critical stage of the lifecycle and the cost of fixing a requirements related defect in production could be 110 times more than the cost of correcting it during requirements definition [5]. In the framework shown (Fig. 2) the specific components from the different models are proposed to capture functional and non-functional (performance, security, compliance, etc.) requirements in a structured manner and to trace the requirements and changes to the requirements, to the subsequent stages of the development lifecycle.

**Design:** With requirements gathered and documented, the next stage in the lifecycle is Design. In this stage, foundation is laid to give shape to the requirements. This foundation could include a high level architecture, functional design, data models, technical design and detailed program specifications. A weak design could produce error-prone modules that could result in up to 50% of the defects [6]. Thus to make this foundation strong, flexible, scalable and unambiguous, the proposed framework recommends components from the industry models. These components would enable the development team in the following:

Model	Requirements	Design	Development	Validation
CMMI®	Level – 2 Requirements Management	Level -2 Configuration Management	Level - 2 Configuration Management	Level - 2 Configuration Management
	Level – 3 Requirements Definition	Process and Product QA Level – 3 Technical Solution Product Integration	Process and Product QA Level – 3 Technical Solution Product Integration Verification Validation	Process & Product QA Level – 3 Product Integration Verification Validation
COBIT®	AI3 – Acquire and implement technology infrastructure AI7 – Install and accredit solutions and changes DS5 – Ensure Systems Security AI 2&3 – Acquire and Maintain Technology and Application Infrastructure ME3 – Ensure Compliance with external requirements – laws, regulations and contractual requirements			
ITIL®	Change Management Service Level Agreements	Performance Management	Change Management Release Management	
Six Sigma	House Of Quality	Process Capability Analysis Benchmarking Hypothesis Test Design of Experiments Failure Mode and Effects Analysis	Process Capability Analysis Failure Mode and Effects Analysis Hypothesis Test	Failure Mode & Effects Analysis Gage Repeatability & Reproducibility SPC/Control Plan
	Management Commitment	Project Management	IT Org Level Audits/Assessments	People Enablement

Figure 2: Integrated Framework

Source: Infosys Research

- Define an enterprise architecture and lay down the design principles at the IT organization level
- Consider alternative architectures / designs and evaluate them against defined hypotheses and select one that would best suit the requirements
- Consider risk factors and possibilities of failure and provide for building alternatives, self diagnostics and failure handling features
- Provide for high performance, security and flexibility in the final product.

**Development (Coding):** This is the stage that actually gives shape to the requirements and builds the product. Adherence to the development standards, constantly tracing the software components to the design elements and the requirements and unit testing are key to the success of this stage. In the proposed framework, elements from industry models are chosen in order to ensure that the built software components meet the requirements, adhere to the quality standards, are traceable to the design components and test cases, and are managed

through sound configuration management procedures.

The elements proposed in the framework enable the IT organization to measure productivity of the development team, using size measures such as *lines of code* or *function points* and continuously improve team capability and hence the final quality of their deliverables.

**Validation (Testing):** Placed towards the end of the lifecycle before moving the application to production, this stage owns the responsibility to ensure that nothing defective escapes into a production scenario. The components suggested in the framework address different types of testing, including Integration Testing, System Testing and Regression Testing when the software undergoes changes. Before releasing the software to the field, it has to go through Acceptance Testing to give confidence to the user that the delivered software indeed performs what is expected of it. This type of testing is addressed by the validation process area of CMMI®.

As can be inferred from the above sequence of events, the software passes through different stages – from the developers desk through different testing areas to the user acceptance stage and finally to the field. To ensure the integrity of the software, versions and security, a robust configuration management process and a well-structured release process should be in place. These two aspects are addressed by configuration management process area of CMMI® and release management process of ITIL®.

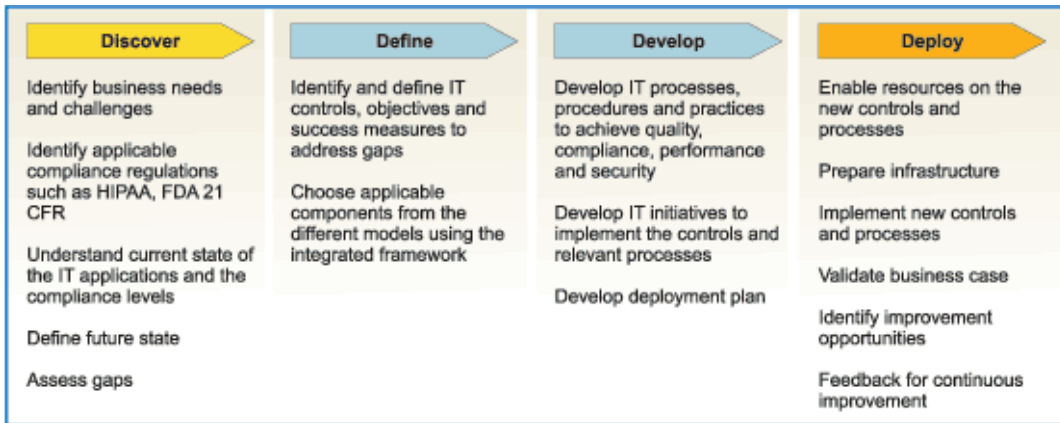
With the overarching project management process, the software engineering activities are surrounded by knowledge management and audit/assessment activities that the IT organization has to identify and define at the

organization level. All the models mentioned in the framework provide recommendations for these support activities as well. For example, the project planning and project monitoring and control process areas of CMMI® Level 2 provide inputs on the best practices to plan and manage a project. Similarly the ‘Ensure Compliance with External Requirements’ (ME3) process of Monitor and Evaluate domain of COBIT® provides the necessary guidelines to ensure compliance with statutory and regulatory requirements.

### IMPLEMENTATION APPROACH

The framework discussed in the previous section indicates the applicable elements of the industry models, to efficiently execute the different software development lifecycle stages in order to achieve quality, performance, security and compliance requirements. A healthcare IT organization has to carefully tailor the above framework in its specific business context. Choosing and implementing controls and best practices from the above framework requires a structured approach, taking into consideration the organization’s business objectives, expectation of the leadership and stakeholder needs. The following four-stage approach provides an implementation methodology [Fig. 3].

**Discover:** During the first stage in this methodology, an as-is study of the healthcare IT organization is conducted to understand the business context, challenges, future vision, objectives and targets. Based on the business an objective, management vision, applicable regulatory requirements and a to-be state is defined in consultation with the key stakeholders. Then the existing software development processes and practices are also



**Figure 3:** Implementation Methodology

*Source: Infosys Research*

studied in detail to identify gaps against the to-be state.

**Define:** In this stage, using the gaps identified in the previous stage, the IT objectives and targets are refined. The applicable IT controls are identified and defined in alignment with the objectives. Parameters for measuring success are also determined at this stage. Based on these, the appropriate components of the framework are selected to meet success criteria and achieve business objectives.

**Develop:** Detailed processes for the IT organizations are defined using the selected components of the framework. Along with processes the corresponding implementation aids such as templates, checklists and guidelines are also developed at this stage. Involvement of practitioners such as project managers, architects, designers and developers is key during the development of the processes and aids. Towards the end of this stage a plan is created to train and deploy the processes in the IT organization. If a need for piloting the processes in a small group is identified, suitable pilot plans are also created at this stage.

**Deploy:** This is the actual process implementation stage where the defined processes are implemented. As a precursor to implementation, the management’s mandate and support are communicated to the project teams, the necessary infrastructure is set up and people are empowered to implement the processes. After implementation at the organization level the benefits are validated against the success measures defined at the Define stage.

As with any change initiative, feedback is actively sought and continuous improvements are carried out recursively using the above stages.

### APPLYING THE FRAMEWORK - AN ILLUSTRATION

The following scenarios illustrate how the framework can be applied to typical scenarios in the healthcare software area. These scenarios focus on one of the success parameters - compliance - and consider the compliance requirements of SOX, FDA 21 CFR Part 11 and FDA 21 CFR Part 820.

Tables 4, 5 and 6 illustrate how components of the framework can be used to address each of these compliance requirements.

**Scenario 1:** In this scenario a set of controls from SOX are considered, though not in any specific sequence.

Requirement	Model Used	Implementation Guidance
A control should exist to ensure that problems and incidents are appropriately resolved.	ITIL <sup>®</sup> : Service Support.	Incident Management: Define and deploy the processes to resolve an incident and reduce its impact.  Problem Management: Define and deploy a problem management process to reduce the number and severity of incidents and problems on the business, and report it in documentation to be available for the first-line and second line of the help desk. The proactive process identifies and resolves problems before incidents occur.
A control should exist to ensure that relevant technical and end-user system documentation is updated after significant modifications/ upgrades are made to systems.	CMMI <sup>®</sup> Maturity Level 2 Process Area Requirements Management.  CMMI <sup>®</sup> Maturity Level 3 Process Area Technical Solution.	Maintain requirements traceability from a requirement to its derived requirements and allocation to functions, interfaces, objects, people, processes, and work products.  Develop and maintain Product Support documentation. Review the requirements, design, product, and test results to ensure that issues affecting the installation, operation, and maintenance documentation are identified and resolved.
High-risk system settings and logical security settings are maintained to ensure adequate system and logical security.	3 of the 7 core information criteria for COBIT <sup>®</sup> address Information Security Confidentiality, Integrity and Availability.	DS5 Ensure Systems Security AI 2&3 Acquire and Maintain Technology and Application Infrastructure.

**Table 4:** Applying the Framework to SOX

**Source:** Infosys Research

**Scenario 2:** In this scenario a set of controls from FDA 21 CFR Part 11 are considered, though not in any specific sequence.

Requirement	Model Used	Implementation Guidance
A clear description of the product functionality or service supplied should be available.	CMMI <sup>®</sup> Maturity Level 3 Process Area Requirements Development.	Establish and maintain product and product component requirements, that are based on the customer requirements.
Tests should be traceable to requirement or design.	CMMI <sup>®</sup> Maturity Level 2 Process Area Requirements Management.	Maintain bidirectional traceability among the requirements and work products.
The architectural layout or description should be clear and available for review.	ITIL <sup>®</sup> ICT Infrastructure Management.	ICT Design and Planning provides a framework and approach for the Strategic and Technical Design and Planning of ICT infrastructures. It includes the necessary combination of business (and overall IS) strategy, with technical design and architecture.
An internal audit program should be in place.	COBIT <sup>®</sup> One of the 7 core information criteria for COBIT <sup>®</sup> .	Monitor and Evaluate Domain - ME3 Ensure Compliance with external requirements laws, regulations and contractual requirements.
An appropriate Quality Manual or SOP should be in place.	COBIT <sup>®</sup> Planning and Organization Control objective.	On a more specific level the Planning and Organization Control objective PO8: Manage Quality defines that Quality needs to be one of the Control Objectives right from planning stage. Within this CO PO8.1: Quality Management System mandates the need for a QMS in place. Related control objectives are PO4: Define IT Processes, Organization and relationships and PO4.7 Responsibility for IT Quality Assurance and AI2.8 Software Quality Assurance.
Communication of personal information with third parties is conducted via a secure medium that ensures the confidentiality and integrity of the information.	3 of the 7 core information criteria for COBIT <sup>®</sup> address Information Security Confidentiality, Integrity and Availability.	DS5 Ensure Systems Security AI 2&3 Acquire and Maintain Technology and Application Infrastructure.

**Table 5:** Applying the Framework to FDA 21 CFR Part 11

**Source:** Infosys Research

**Scenario 3:** In this scenario a set of controls from FDA 21 CFR Part 820 are considered. Though these controls are closely associated with the design, manufacturing and testing of healthcare devices, the software aspects of the design and development process are considered in identifying how the model components can be leveraged seamlessly.

Requirement	Model Used	Implementation guidance
Sub Part C Sec 820.30 Design Control: Procedures for Design and Development Planning, Design Input, Output, Review, Verification and Validation should be established.	CMMI® Level 3 Process Area Technical Solution.	Evaluate and select design alternatives that satisfy the requirements.  Develop detailed designs for the selected alternative including the information needed to manufacture, code, or otherwise implement the design as a product or product component. Implement the designs as a product or product component.  Additionally, the Generic Practices support planning and review of the design activities.
Sub Part D Sec 820.40 Document Controls : Procedures to control all documents should be established and maintained.	CMMI® Level 2 Process Area Configuration Management.	The specific practices listed below address this requirement. <ul style="list-style-type: none"> <li>• Identify Configuration Items</li> <li>• Establish a Configuration Management System</li> <li>• Create or Release Baselines</li> <li>• Track Change Requests</li> <li>• Control Configuration Items</li> <li>• Establish Configuration Management Records</li> <li>• Perform Configuration Audits</li> </ul>
Sub Part N Sec 820.200 Servicing: Procedures for servicing and verification should be established and maintained.	ITIL® Process areas: Service Level Management, Incident Management and Problem Management.	Service Level Management to set up and monitor service levels around solution / application performance availability, downtime etc.  Incident Management to manage incidents related to system performance  Problem Management to manage problems resulting from system performance


**Table 6:** Applying the Framework to FDA 21 CFR Part 820 *Source: Infosys Research*

## CONCLUSION

With the growing challenges of cost competitiveness and meeting regulatory requirements, a healthcare IT organization has to instill confidence in the management and the business user community, that the software applications are not vulnerable to security threats and data leakage but are rather compliant to statutory requirements and would indeed perform at expected quality levels. To ensure these, the IT organization has to embark on a structured way to define, design and develop the software applications. While

there are many industry models providing best practices to deliver quality software applications, adopting a single model would not address all the specific requirements of quality, performance, compliance and security. Therefore it is imperative that healthcare IT organizations leverage on the best of these process models and methodologies and use an integrated framework such as the one suggested in this paper for process improvement, leading to software applications that are secure, compliant and of superior quality.

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# Connect and Bolster Pharma R&D Model

By Mandar Ghatnekar PhD, Anirban Ghosh and Kamal Biswas

*Shared services model can help R&D organizations leverage a global talent pool at a much rapid pace*

The healthcare industry is poised at a critical point where it may collapse under its high-cost structure, if the steep rise in drug development cost continues. Pharmaceutical companies have transformed drug discovery and development processes from the empirical chemistry-based discovery to next generation rational drug design, but are yet to master the techniques that can leverage the ever burgeoning biological knowledge to ensure speedier delivery. This transformation has always been looking for stronger organizational support to manage operations to deliver better results.

Pharmaceutical R&D organizations are in a continuous state of evolution to meet the paradigm shift in the drug discovery process. The evolution of these organizational structures has moved from the functional organization, e.g., target identification, target validation, to being disease-area focused. The former comes with organizational units that excel in specific

scientific disciplines, but lacks in special focus around diseases. However, the therapeutic-area aligned organizations lead to redundancies in creating multiple silos, carrying out similar functions independently. This paper describes how the big pharma R&D organizations can utilize the best of both worlds and create a connected model in R&D to bolster their success. The proposed organization structure relies on clearly segregating specialized activities from repeatable tasks to build a shared services model that can leverage a global talent pool while retaining focus on the therapeutic area (TA). We also present an example of an analytical model which applied to core drug discovery process can help companies identify research functions that can fold into a shared service, based on complexity of task, step inter-dependency, timeliness and mobility of constituents. Thus the next generation of R&D organization will be a logically fragmented structure with TA focused units being driven

by functional centers of excellences that are globally distributed shared services for various TAs.

### GROWTH MODEL

In the early part of the 20th century, the alliance between chemistry and pharmacology worked wonders for the pharmaceutical industry leading to the present day, where the top ten Pharma companies have nearly 50% of the worldwide market share. Advances in the emerging fields of genomics, proteomics and integrative biology have brought in a paradigm shift in the understanding and treatment of diseases. Better understanding of drug mechanism is not only helping pharma companies, but also promising a better overall healthcare management. Regulatory authorities all over the world have done well to leverage this knowledge to raise standards for drug approval. End users have gained knowledge on the drug mechanism better than ever before and are now making informed decisions. However, despite a steady increase in spending on R&D, the pharmaceutical industry has seen record failures of drugs under development and an overall decline in the number of new drug approvals. Drug discovery has become so complex that it can neither be contained within the confines of the pharmaceutical industry, nor is it easily amenable to “industrialization” that brings significant improvement in throughput of R&D organizations.

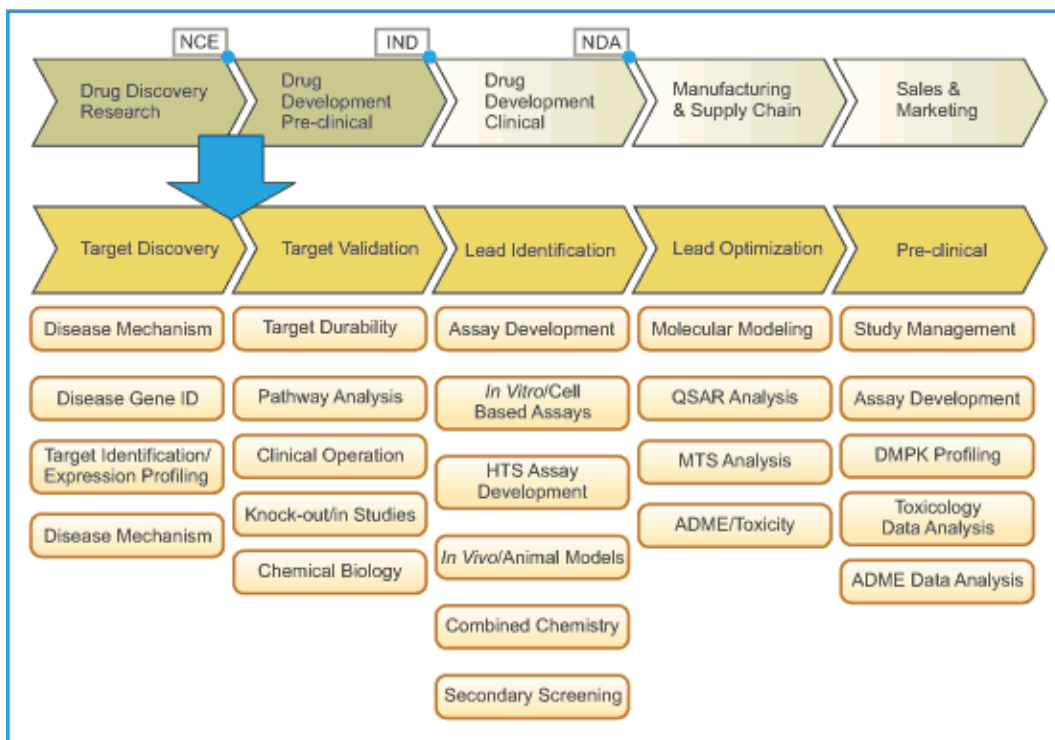
With the changes in drug discovery processes, the industry has made several attempts in the past to align the R&D organization to cope with various nuances in these different drug discovery models. While these changes are made for better results, it has never seen absolute success. This brings in the hybrid model in an organization for pharmaceutical companies

that will promote innovation and enhance productivity while containing costs.

### OLD WORLD DISCOVERIES: TRIAL AND ERROR

Pharmaceutical companies have traditionally relied heavily on the fields of chemistry and pharmacology that laid the foundations of drug research in the 19th century and the early part of the 20th century. A series of medicinal compounds were derived from coal-tar, largely due to the advances in chemistry and pharmacology based on the scientific theories proposed. Other serendipitous discoveries like Penicillin led to the hunt for medicinally active compounds from natural resources like microorganisms and plants. Drug research was still largely restricted to the fields of chemistry and pharmacology and was carried out in pharmacies or in pharmaceutical divisions of chemical or dye companies.

During the first half of the 20th century drug research was shaped and enriched by several new technologies, all of which left their imprint on drug discoveries and therapies. After the discovery of penicillin and other antibiotics, many drug companies established departments of microbiology and fermentation units that added to their technological scope. There were only a few large companies that did not participate in the search for new antibiotics. Some companies, for example, Merck, Sandoz and Takeda used their microbiological capabilities to find drugs that exerted other pharmacological or chemotherapeutic properties (e.g., Ivermectin against tropical filariasis, Lovastatin against hypercholesterolemia, Cyclosporin A as immuno-suppressant). The modus operandi for research was trial and error and although much of the action mechanism of these drugs were not known, pharmaceutical companies achieved great success in the wake of these discoveries.



**Figure 1:** Pharmaceutical Drug Discovery Process for Rational Drug Design **Source:** Infosys Research

### BIOCHEMISTRY CHANGED THE PARADIGM: RATIONAL DRUG DISCOVERY

Biochemistry influenced drug research in many ways. The dominant concepts introduced by biochemistry were those of enzymes and receptors, that were empirically found to be good drug targets. The description and characterization of enzymes and biosynthetic pathways led to the discovery of sulphanilamide and a series of sulfa drugs ranging in pharmacological activity from antibiotics and hypo-glycemics to diuretics and anti-hypertensive agents.

Chemistry, pharmacology, microbiology and biochemistry helped shape the course of drug discovery and brought it to a level where new drugs are no longer generated solely by the imagination of chemists but result from a

dialogue between biologists and chemists. This dialogue, centered on biochemical mechanisms of action, stems from the understanding of biological structure and function and gives rise to the creation of novel chemical structures. Molecular biology has exerted a profound influence on drug discovery, allowing the concept of genetic information to be dealt with, in very concrete biochemical and chemical terms. This philosophy has led to the establishment of the modern pharmaceutical R&D organizations based on the principle of 'rational drug design' [Fig.1].

### FIRST GENERATION MODERN DRUG DISCOVERY ORGANIZATION

Advances in understanding of disease mechanism have presented a large number of

protein molecules that have been targeted for new drug discovery. Pharmaceutical companies adapted to rational drug design by organizing their R&D efforts along specific research processes like:

- **Target Identification:** Understanding disease mechanism and identifying biochemical pathways involved in disease etiology and target proteins for drug discovery.
- **Target Validation:** Determine that a target protein is critically involved in the disease process and validate the 'druggability' of a target protein by determining specificity and selectivity of the target.
- **Lead Identification (Exploratory Screening):** Synthesis and screening of potential drug candidates that can modulate the action of a validated target.
- **Lead Optimization:** Optimize the molecules or compounds that demonstrate the potential to be transformed into drugs (proof-of-principle), retaining only a small number of them for the next stages.
- **Pre-clinical Testing:** Demonstrate the safety of the drug for humans and to prove that the therapeutic advantages of the compound greatly outweighs any associated undesirable side-effects by conducting in-vitro and in-vivo studies.
- **Clinical Development:** Systematic studies in human patients aimed at

determining the safety and effectiveness of new or unproven therapies.

- **Formulation Development:** Develop a drug delivery form that will be administered to clinical study participants and patients.
- **Process Development:** Develop and scale-up processes for large-scale manufacturing of the new drug and its formulation.

## SECOND GENERATION OF R&D ORGANIZATION: TA ALIGNED

For the past 15-20 years, our understanding of the molecular basis of drug actions, as well as disease and biological processes, has burgeoned, which has resulted in a considerable increase in the number of potential targets that can be pursued by the pharmaceutical industry for disease treatment. However, instead of seeing a steep rise in the number of new molecules entering clinical development, the industry has experienced a steady decline. The cause of this decline is unlikely to be an increasing inability of companies to move drugs through development as during this period most companies have been able to improve the efficiency of their screening and lead optimization and development processes even further. A more probable explanation is that the industry has been unable to take advantage of this new biological knowledge in terms of transforming the information into drug projects, an explanation supported by the tendency of many companies to pursue the same non-proprietary targets [1].

Most pharmaceutical companies reorganized their R&D operations along focused therapeutic areas that were organized to leverage the great amounts of information

that is getting generated in each disease-area. Within a therapeutic area, the process of target identification through development was replicated with each therapeutic area becoming a Center of Excellence for drug discovery with end-to-end capabilities [2].

It also became a common practice to divide the R&D organization into separate 'R' and 'D' units, because their strategy and requirements in terms of organization and skills are considerably different. The *Research* part of the organization is much more complex because of dealing with rapid scientific *Developments*, thus making it more amorphous; while the clinical development organization is much better controlled and organized. The increased regulatory focus in clinical development also drives the organization stabilize and reduce fluidity.

Due to the higher degree of predictability and repeatability of processes in the clinical development, a number of specialized contract research organizations have cropped up that service the pharmaceutical industry. A large portion of clinical development is thus outsourced to these clinical research organizations that afford cost advantages. On the other hand, drug discovery has remained within the confines of the pharmaceutical industry. Discovery or drug development needs a diversified and flexible industrial base. The emergence of the biotech industry as a "discovery" industry as well as the establishment of many contract research organizations show that free markets will be capable of generating the technical and analytical instruments that are needed to apply scientific advances to the solution of societal problems. This drives for better collaboration amongst various units within and outside the organization.

### THIRD GENERATION SCIENCE BASED CONNECTED MODEL

Because of its complex and tacit nature, R&D has for long been one of the least mobile activities of multinational pharmaceutical enterprises. The R&D capabilities of firms were far less globalized than their other activities, such as sales and marketing and investment in production facilities. While considering the R&D productivity crisis it is imperative that current thinking, processes and models be challenged. For example, does the current strategy to align R&D by therapeutic area need be modified or do we chart a different course? The next wave of strategic thinking needs to be around business models and structures. Additionally, the impact of globalization on these evolving models must be understood and leveraged in order to successfully take the next step forward. Focus should be on specific examples, working models, strategies and approaches to achieve increased productivity and drive down healthcare cost.

The last 10 years have seen the emerging Asian economies like China, South Korea, Taiwan, Singapore, Malaysia, India and countries like Cuba develop large pools of scientific talent and capabilities in pursuing research in biotechnology and medicinal chemistry. In response to this geographical spread of scientific development beyond traditional strongholds in USA and Western Europe, most large pharmaceutical companies have established R&D centers in these emerging markets. These countries offer the promise of low-cost drug discovery through lower infrastructure cost, lower manpower costs and easy availability of high skills. However, most of this movement has been ad hoc with pockets of drug discovery processes being moved to R&D sites in low-cost geographies.

Here we propose a model that can be

used to assess and exploit the full potential of establishing a globally distributed R&D organization. The success of this model relies on assembling the R&D organization along therapeutic areas, to ensure alignment with strategic business objectives, while establishing a shared service model that supports all the therapeutic areas seamlessly. This model can handle both the TA specialized knowledge requirement and cross TA collaboration, knowledge sharing and skills sharing. The therapeutic area (TA) research should be led by scientific disciplines such as molecular biology, microbiology, biochemistry, system biology, pharmacology, medicinal chemistry and computer modelers with specialized knowledge on the indication (disease area) and the unmet medical needs in depth. The core TA leadership teams across the R&D organization should be supported by shared services that are 'centers of excellence' in their respective scientific domain [Fig. 2].

With technology advancement in R&D operation, there are a significant number of research processes that have become routine, while some activities are very specialized that require special scientific knowledge. A thorough analysis of R&D activities could easily differentiate these gaps in operations. The specialized knowledge processes can be separated from the routine and repetitive work to drive organizational productivity through effective work breakdown and dispersion. The whole operation can become nimble through sharing skills amongst various TAs for repetitive work. In this manner, the operation becomes cost effective by eliminating redundant operations and moving selective activities away from high-cost location to low-cost operation centers. Collaboration enabled

through technology can now allow real-time review of research activities in a globally distributed environment, thus addressing some of the concerns of scientists working in geographically dispersed teams. So, there are options available to make it happen. An activity analysis model that can be applied to core R&D functions to create the third generation R&D organization based on a shared services model, is one such option.

### ACTIVITY ANALYSIS MODEL

The activity analysis model classifies steps in research into distinct categories. While some functions are identified as very critical to business, other less critical activities that are well supported by technology constitute a shared scientific service environment. The classification of functional steps in research process is attributed to – alignment with a specific disease-area, need for timeliness of execution, sample supply management and dependency with other neighboring steps. Based on input values to these parameters, one can arrive at activity analysis model, suitable for adoption for a third generation research organization.

Each of these characteristics for functional steps is scored with representative data. A 10% non-specificity to a disease research implies a score of 1, whereas 90% non-specificity implies a score of 5. An instantaneous step is given a score of 1, while a delayed timeliness is equivalent to a score of 5. A process that allows sample transfer is given a score of 1 for supply management, while a score of 5 is assigned to a step that does not involve supply management. A research function score is 1 for an inter-functional collaboration, whereas a score of 5 is assigned to an independent step. An equal weight is

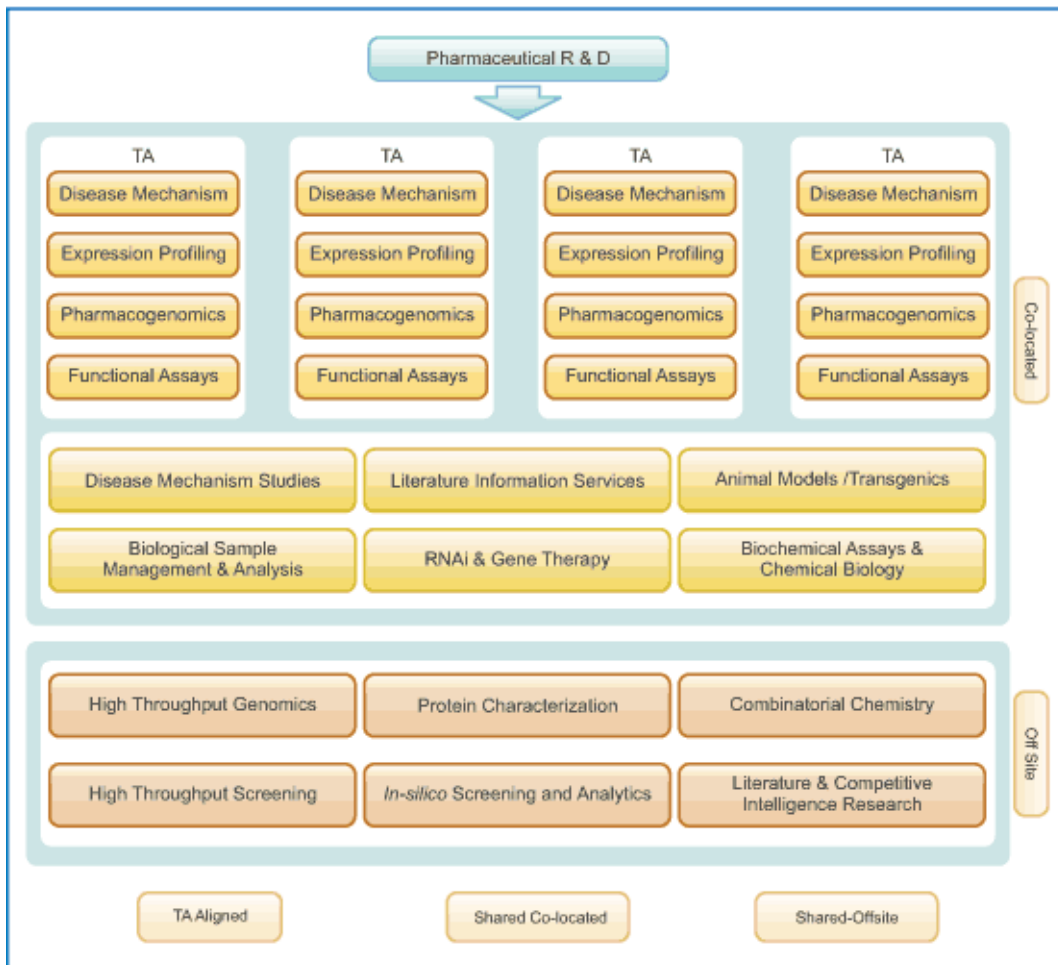


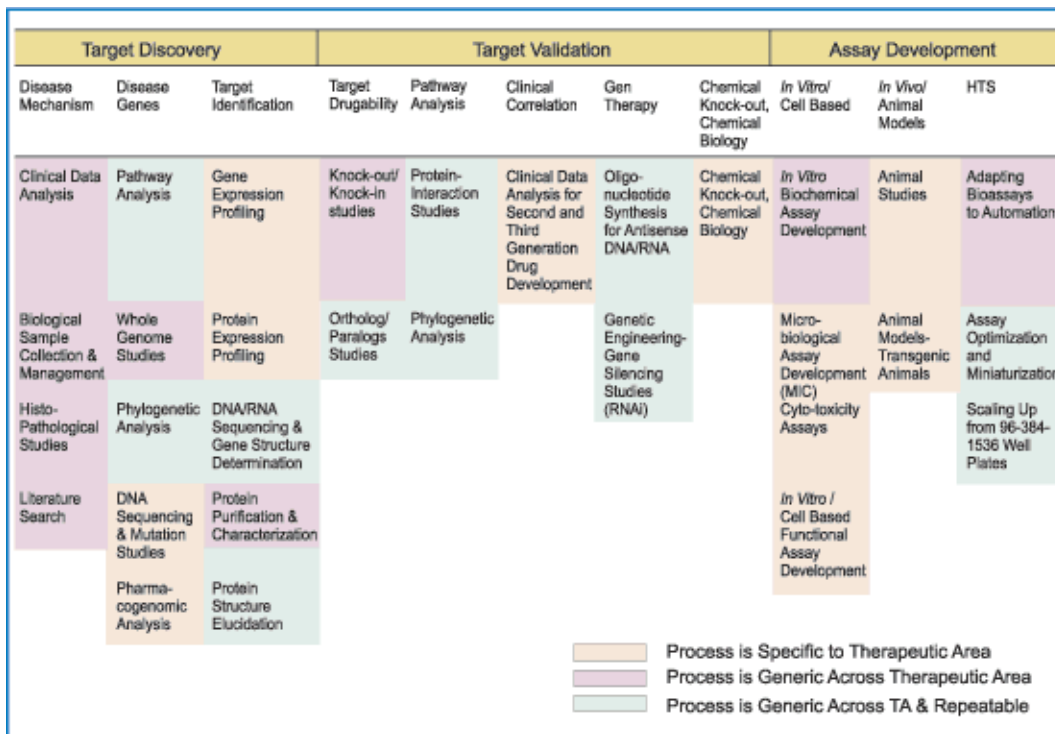
Figure 2: Third Generation of R&D Organization

Source: Infosys Research

assigned to each characteristic and rolled into a cumulative score for each research function. The scores are segregated by processes that are very niche to disease research; one that is repeated across areas of disease research and others those are well scripted steps that support multiple disease research that can be repeated by any third party support.

Figure 3 overleaf lays out a set of business research functions that are classified into domain intensive, generic and generic repeatable. It is segregated into three main

categories: 1 (Peach) – High TA-specificity indicates activities that need to be aligned and retained within the TA units; 2 (Pink)– Medium to low TA-specificity but logistically complex functions that need to be co-located with the TA units; 3 (Light Green)–Low TA-specificity and repeatable activities that can be performed in globally distributed shared environment across TA units. Figure 3 shows the outcome of an indicative analysis applied to early research phase of drug discovery process.



**Figure 3:** Distribution of Research Processes based on Specificity and Repeatability **Source:** Infosys Research

Individual characteristics associated to each research function are inter-related among themselves. For example, timeliness of a function is related with supply management, based on the representative data, with a correlation coefficient of 0.4 and covariance of 0.8. The timeliness to a research function is related to step dependency with a correlation of 0.7 and covariance of 1.3. The supply management is related to step dependency with a correlation of 0.3 and covariance of 0.3. The specificity of a research function has no correlation to step dependency.

We represent cumulative scores for each research function by boot-strapping weights associated with scores to each of the four characteristics. Table 1 shows the scores against each function by adjusting weights assigned to

the stated characteristics.

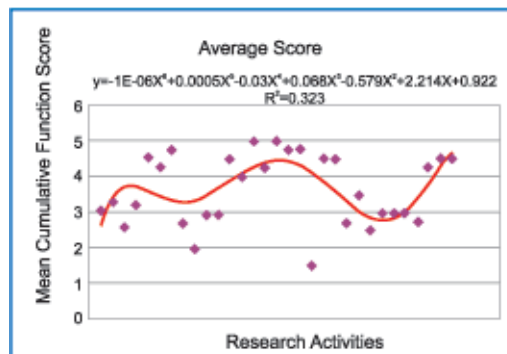
The scores are rolled up for different weight adjustments into a mean score for each function. Based on the mean value scores, we derive a best fit model. The model described here, best represents the hypothetical data presented. Figure 4 shows the best possible non-linear fit to the mean scores for each research function. We propose this optimized activity analysis model that will be a diagnostic to determine which portions of the entire research function can be part of the shared scientific services operations. The best fit function, as displayed in Figure 4, shows that a score between 0 and 2 represents that a function can be shared off-site; a score between 2 and 4 represents functions that are shared co-located; and a score of 5 represents functions that cannot be disturbed.

Functional Activities	(/25,25,25,2)	(/10,25,25,40)	(/40,25,25,10)	(/25,10,40,25)	(/33,17,33,17)	(/17,33,17,33)	(/1,49,1,49)	(/1,25,25,49)	(/10,45,15,30)	(/45,30,10,15)	(/25,1,48,25)	(/20,35,15,30)	(/6,22,28,42)	(/42,28,22,6)	Avg. Score	
Clinical Data Analysis	3	4	2	2	2	4	5	1	4	4	3	2	4	4	2	3
Biological Sample Collection and Management	3	4	3	3	3	4	5	2	4	4	3	2	4	4	3	3
Histo-pathological Studies	3	3	2	2	2	3	4	1	3	3	2	2	3	3	2	3
Literature Search	3	3	4	4	4	4	3	2	4	3	3	4	3	3	4	3
Pathway Analysis	5	5	4	5	4	5	5	4	5	5	4	5	5	4	5	5
Whole Genome Studies	4	4	4	4	4	4	5	4	4	5	4	4	5	4	4	4
Phylogenetic Analysis	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
DNA Sequencing and Mutation Studies	3	2	3	2	3	3	3	3	2	3	4	2	3	2	3	3
Pharmacogenomic Analysis	2	2	2	2	2	2	1	3	2	2	2	2	2	2	2	2
Gene Expression Profiling	3	2	4	3	3	3	2	4	2	3	4	3	3	2	4	3
Protein Expression Profiling	3	2	4	3	3	3	2	4	2	3	4	3	3	2	4	3
DNA/RNA Sequencing and Gene Structure Determination	5	5	5	4	4	5	5	4	5	5	4	5	4	5	4	4
Protein Purification & Characterization	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4

**Table 1:** Scores Associated with each Function by Adjusting Weights to the Characteristics  
**Source:** Infosys Research

These scores are rolled up from representative values for specificity to disease indication, timeliness of results, supply demands and step dependency and an optimal combination thereof. This composite function will be used to assign a function as too specific to a disease research, or non-specific enough to be reused across disease researches, or general enough to be scripted and repeated by a non-expert.

This model can serve as a rule to determine, if a given research function is indispensable to an enterprise, or to a high-cost location, or can alternatively be sourced from outside or functions from low-cost locations. The objective here is to provide a diagnostic test for distinguishing research steps that can be serviced by shared services to become more productive and cost effective.



**Figure 4:** A Non-linear Model that fit the Mean Score to Research Functions


**Source:** Infosys Research

## CONCLUSION

The connected pharmaceutical R&D model can help operations go beyond the traditional ways of delivering values and thus optimize operations globally. The activity analysis model is one diagnostic approach to determine and improve global research operations. The spectrum of operational excellence demonstrated by variety of research functions is challenged by probability of technical success, complex inter-dependent tasks and cost to operate. Validation of this model will lead to a connected and shared scientific services environment that will facilitate innovation for the best minds at a faster pace, no matter where and when.

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# Algorithmic Approach to Intelligent Healthcare Facilities Planning using BPM and Simulation

By Raamakrishnan M and Rakesh Mishra

*Holistic facilities solution can be achieved with the help of Business Process Modeling tools*

Healthcare as an industry has immense potential for utilizing Business Process Modeling (BPM) as a management practice and as a technology platform. Proper facilities planning – also known as layout planning – in any healthcare facility is paramount in eliminating process wastages. Business flows if closely studied can help in eliminating process wastages. LEAN methods – generic process management philosophy derived from the Toyota production system – can help fine-tune the process. This can be done by implementing a BPM based solution.

## CHALLENGES IN HEALTHCARE FACILITY LAYOUT PLANNING

Medical equipment manufacturers continuously collaborate with healthcare facilities in understanding their need for newer medical equipment. Advances in medical electronics and instrumentation have enabled design of multi-function equipment. This has made *providing*

*healthcare facilities* easier at many of the top hospitals across the world. Such collaboration has unintentionally created space redundancy issues in hospital layouts that broadly include, but are not limited to, the equipment used for diagnostics and treatment, patient treatment areas, clinician/ technician areas and other storage/waiting areas that the initial designers neither planned for nor anticipated. Problems arising out of a collaboration that is highly favorable to the patients and clinicians can be addressed by adopting a BPM based approach in conjunction with an algorithmic technique to solve the issue of space redundancies.

These redundancies create process inconsistencies that would increase process wastages called MUDA – meaning ‘wastage’ in Japanese – in LEAN parlance. Elimination of these wastages would directly impact the level of satisfaction that each of the economic agents in the process gets, which in turn can directly impact

profitability. In a hospital, process wastages take place in the following ways:

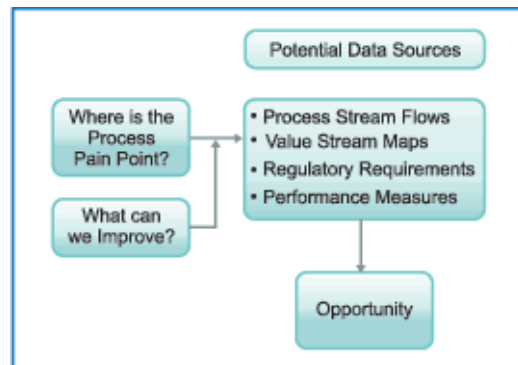
- Waiting (in queues/waiting pre and post registration)
- Moving products that may actually not be needed for performing a process
- People or equipment moving or walking more than is required to perform processing
- Over-processing.

Reducing these wastages would mean a holistic study of the process flows and mapping the value streams of the process flows. These value streams lead us to study the entire facility as a whole and see where pain-points exist in the process flow and suggest ways to resolve them. One such process would be the suggestion of changes to the layout, keeping in mind the business exigencies of a healthcare facility. This involves the study of two aspects:

- business process and
- facility layout.

An acceptable layout combined with a good process flow definition helps in eliminating process wastages to a large extent and hence these factors impact the user satisfaction levels the most. Hence the BPM exercise would be complete if it is looked at synchronously with a proper facility planning solution.

Contemporary approaches of facility planning are about fixing the flows/processes and then designing the building. In all the above situations, designing new facility should take into account learnings gathered from the existing processes and constraints. This would involve data analysis to try and remove the process pain points as shown in Figure 1.



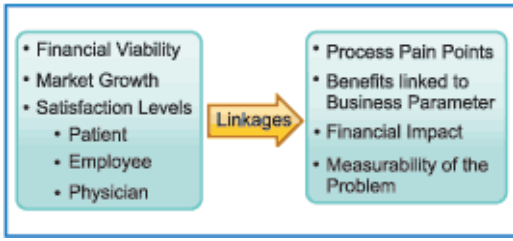
**Figure 1:** Framework for Analyzing Pain-points  
Source: Infosys Research

## ADDRESSING CHALLENGES OF LAYOUT PLANNING

A new approach to decision making and implementation of change is needed. The most important part is to realize that most performance challenges in healthcare are multi-faceted and involve multiple departments. Addressing challenges with temporary solutions like a time and motion study done on specific units do not change anything, as they do not offer a holistic optimized solution. They may at best be short term solutions and some of them may even work. But a long term approach is required that requires the right methodology, right tools and qualified people to execute it.

This can be done by the usage of process modeling techniques and simulation features, commonly available in most of the BPM tools. Based on the inferences derived from the work flow analysis an algorithmic approach to solve the layout optimization problem is suggested.

Figure 2 shows the linkages of a healthcare business model under the assumption that the present healthcare facility is financially viable and that the facility foresees good market growth for its services in the near future.



**Figure 2:** *Linkages of a Healthcare Business Model*  
**Source:** Infosys Research

Based on these two assumptions, the business process is studied and the layout is optimized such that maximum number of users gain satisfaction. We now consider the analysis of the process flows.

**PROCESS FLOW ANALYSIS BASED ON LEAN IMPLEMENTATION**

Any new layout planning mechanism study requires an in-depth understanding of the process flow and the flow of all economic activity of the process. This activity taken up by the agents – also referred to as economic agents – should be devoid of any stagnation or pain points in the process flow to enable maximum user satisfaction. In economic parlance, maximizing user satisfaction implies that the utility function that is associated with the activities of all the economic agents is maximized. Any such utility function maximization involves reducing the costs associated with the activities of the economic agents. In economic terms, costs are defined as cost vectors because of the various components –related or unrelated – associated with a cost function.

We can assign a cost vector to all economic activity that happens in a process. If we have to maximize user satisfaction, then it naturally follows that we have to minimize the cost vector associated with all activity. The least cost is what maximizes the user satisfaction. In other words: Where P= Number of units in the facility

$$\left( \sum_{i=1}^{P-1} \sum_{j=i+1}^P W_{i,j} d_{i,j} \right)$$

And dij is the distance traveled from unit ‘I’ to unit ‘j’

And W is the weight given to the distance vector.

Two aspects need to be understood very clearly in this equation:

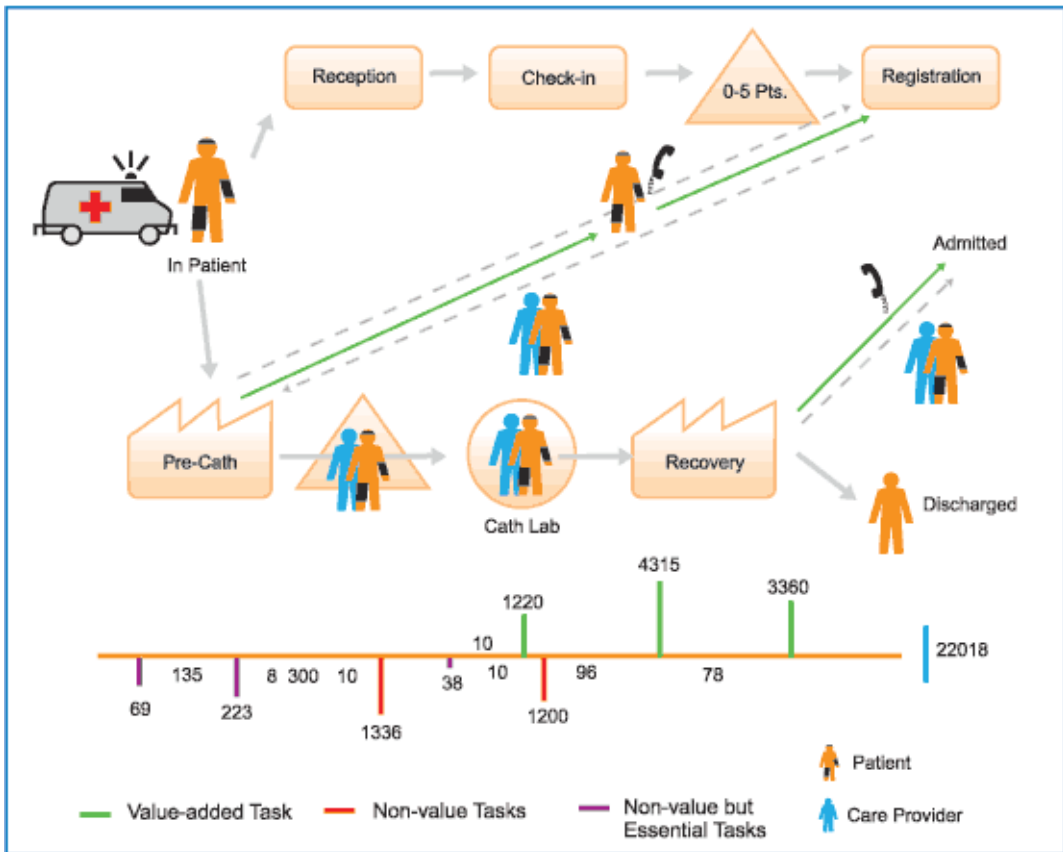
- How to determine the value of the weightage “W” that needs to be given to these units?
- How to determine the qualitative and quantitative constraints for the optimization equation?

Once these are done, we need to find out a way to solve this equation using an algorithm in a reasonable time.

Consider the process flow in Figure 3 overleaf with the associated time-stamps, to understand the basic implications of the minimization equation given. To minimize the costs, one has to make sure that the time taken at each step is minimal. This is further complicated by the fact that not all steps in the process are value creating steps. Hence one would have to do a value stream mapping of the entire process. This would split the steps into three categories:

- Value adding steps like treatment
- Non-value add steps like waiting time
- Value enabling steps like registration.

Once these steps are thus characterized, we try to decrease the time taken in performing the non-value added steps to the minimum. We should also ensure that while the value-add steps



**Figure 3:** Functional Architecture (without cross-functional dependency) **Source:** Infosys Research

are high, there is no build-up of resources in the step that would negate the value-add effect and the value-enabling steps should be carried out within the minimum possible time.

Also, this simple layout planning minimizing function is further complicated by the following parameters:

- Parameters based on design criteria
- Design issues based on process adjacencies. In a hospital not all units can be placed one next to the other. Questions of aesthetics and other health/regulatory constraints exist
- Also there exist qualitative constraints in the healthcare facility itself. The facility

may want to specialize as a high quality healthcare provider in one domain with the related domains, acting as support/subordinate unit or the units, given secondary preferences compared to the primary specialization of the facility

- Percentage mix of in-patient, out-patient, emergency patient flows and the flow of the required economic agents and material, need to be considered
- Global benchmarks established based on knowledge based reasoning.

All these factors help us in formulating the value of “W” which is a weight parameter.

**ANALYSIS OF THE MINIMIZATION FUNCTION**

Any solution for an optimization function will involve a set of constraints that act on the function. To solve the above minimization function, we may have to study the necessary constraints. Not all constraints in a real-life problem would be quantitative. Many of the constraints would also be qualitative. These include but are not restricted to architectural guidelines, regulatory aspects of healthcare facilities planning, orientation of the specific healthcare facility towards a specific specialization.

Keeping all these in mind a set of checklists have been created that will enable a quick analysis of adjacency issues and issues of whether the facility is conforming to specified regulatory and architectural guideline norms. Any BPM team

that does the study may want to work with the client team with the initial set of checklists before attempting to suggest changes to the business process. Then steps involving – modeling, validation and simulation run – follow the creation of checklists. For this, a BPM tool would enable proper process flow modeling along with the simulation of the process flows of all agents. This process is not devoid of hitches, because a healthcare facility may have many diagnostic units with patient and clinician flows moving across all units. Taking all these into account and with a proper understanding of standard flows we can arrive at an initial estimate of pain points in the process.

Figure 4 helps us to visualize the queues formed (and hence pain-points) in a specific healthcare setup. The study of these pain-points,

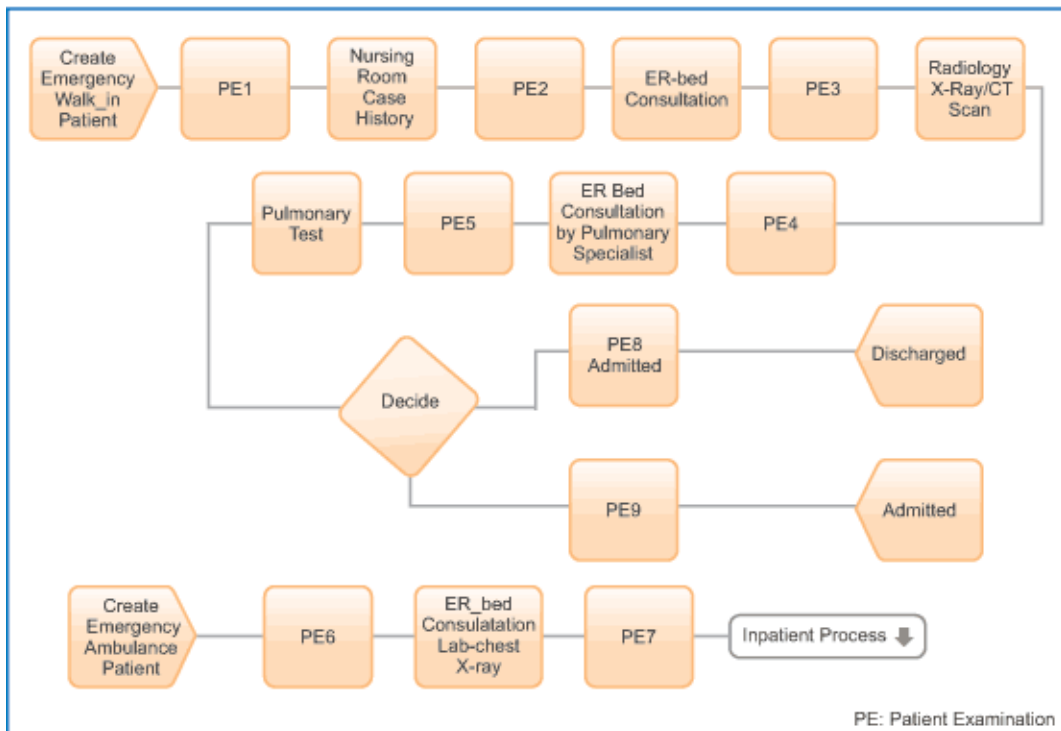
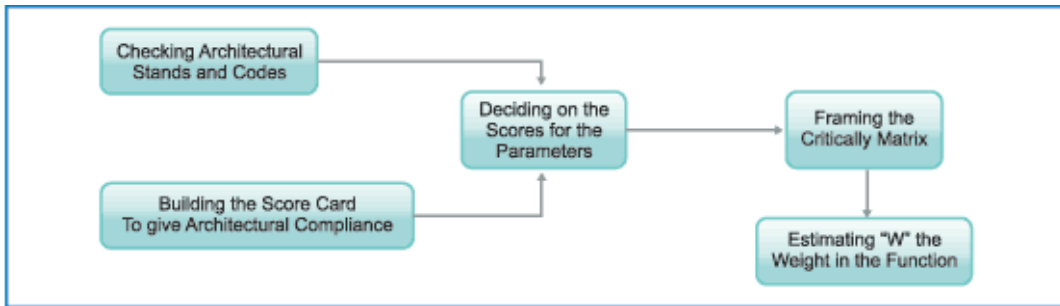


Figure 4: Simulated Pain Point Flow

Source: Infosys Research



**Figure 5:** Creating the Criticality Matrix

*Source: Infosys Research*

juxtaposed with the checklists created, helps us define a criticality matrix. This would help in determining the value of “W” in the minimizing function. The *criticality matrix* would determine the criticality of one diagnostic unit next to the other unit in consonance with the conformance values that are measured in the checklists [Fig.5]. The judgment of conformance is a subjective one and is based on individual cases, keeping in mind the nature of specialization the specific facility offers. The involvement of a business process team at this point along with the subject matter experts is highly essential.

#### OPTIMIZATION: LOGIC AND ROUTINE

Any site layout planning is evidently graphical in nature. Site boundaries, existing buildings on site, obstacles and temporary site facilities occupy space and have distinct shapes. Thus, the need to represent the relationship between all these entities in some sort of graphical format can be quite advantageous.

The current study utilizes a genetic algorithm (GA) based approach as function optimizer routine. This can be based out of the graphical information provided by the architects in their CAD based drawings. Based on the classifications provided, this approach performs a facility to site assignment based on a mathematical layout planning technique.

GAs are algorithms that encode a potential solution to a specific problem on a simple chromosome like data structure and apply recombination operators to these structures so as to improve the solution while preserving all critical information [2]. Simply put, a GA is a search technique used in computing to find exact or approximate solutions to optimization and search problems. Genetic algorithms are categorized as global search heuristics and are a particular class of evolutionary algorithms - also known as *evolutionary computation* – that use techniques inspired by evolutionary biology such as inheritance, mutation, selection and crossover (also called recombination).

One must also note that in a layout optimization for a healthcare facility, we are speaking of very large spaces wherein the possible solution space is too large to analyze in finite time. This is because of two reasons: (i) the additional information available to guide the search is absent or not sufficient, thus making conventional methods impractical and (ii) there arises an urgent need to get near-optimal solutions to use as starting points for conventional optimization methods. For illustrative purposes, consider a certain sector of a construction site with dimensions of 100 X 100 m. Also consider that no obstacles or permanent structures are present in this sector of the construction site and that four temporary

facilities (1 X 1 m) need to be assigned in the given space. Let

M be the Number of locations available for temporary facility assignment (based on a 1 m pitch / increment.)

r be the Number of temporary facilities needed to be assigned

Excluding all geometrical constraints among the temporary facilities

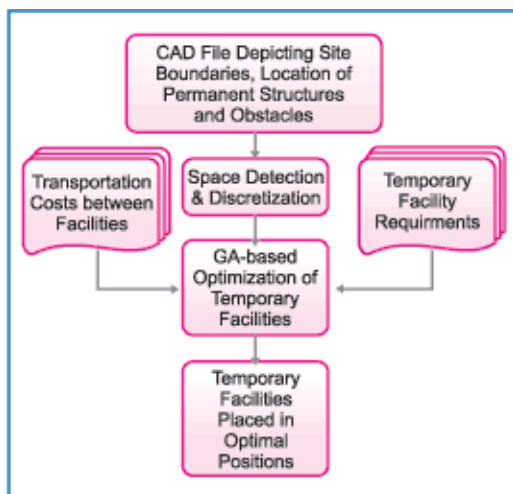
**M becomes (approximately)  $100 \times 100 = 10000$**

**Solution Space  ${}^M P_r = {}^{10000} P_4 = 1 \times 10^{16}$**

Given such a vast solution space for a simple illustration above, one can assume the vastness of the solution space for such a large facility and the computing time required for such an exercise.

Research literature points out the use of GA to such problems and the ease with which practicable solutions can be arrived at in lesser time [3, 4]. Figure 6 depicts the algorithmic approach and the flow of the algorithm in reaching the optimum solution.

### Process flow for Optimization



**Figure 6:** Flowchart for Handling the Algorithm  
 Source: Infosys Research

The algorithm helps in finding an optimum layout for the facility based on the checklists and the criticality matrices constructed. The entire simulation and flow analysis can be done using a standard BPM tool. A rule based system can also be used to do the work of flow optimization [Fig. 7 overleaf]. But we need capabilities to build an optimizer engine for the layout optimization.

Present BPM optimizers do not have this capability, but research shows methods where Microsoft VB based tools have been developed for running this optimization logic [5].

### VALUE PROPOSITION OF THE SIMULATION CAPABILITY

Simulation is used to model a process or system to understand the root cause of system behavior and performance, and optimizing such behavior. Most importantly, the optimization is done in a virtual, risk-free environment. This helps us in understanding if a change will have a positive effect on the system in question, before investing any capital. Flexibility of the simulation process makes the solution ideally suited for the healthcare industry, where different processes that deal with patients and financial objectives, involve such diversity and scope of execution. Ultimately, the goal is to solve a wide range of organizational problems with a solution that can adapt and still deliver performance.

Once the as-is process model is finalized, one needs to get all the parties who will get affected by the process change, to evaluate process improvements or changes. The BPM tool can simulate and provide results for each of the suggested process improvements. The current process and the desired process performance are discussed for potential improvement and elimination of pain-points.

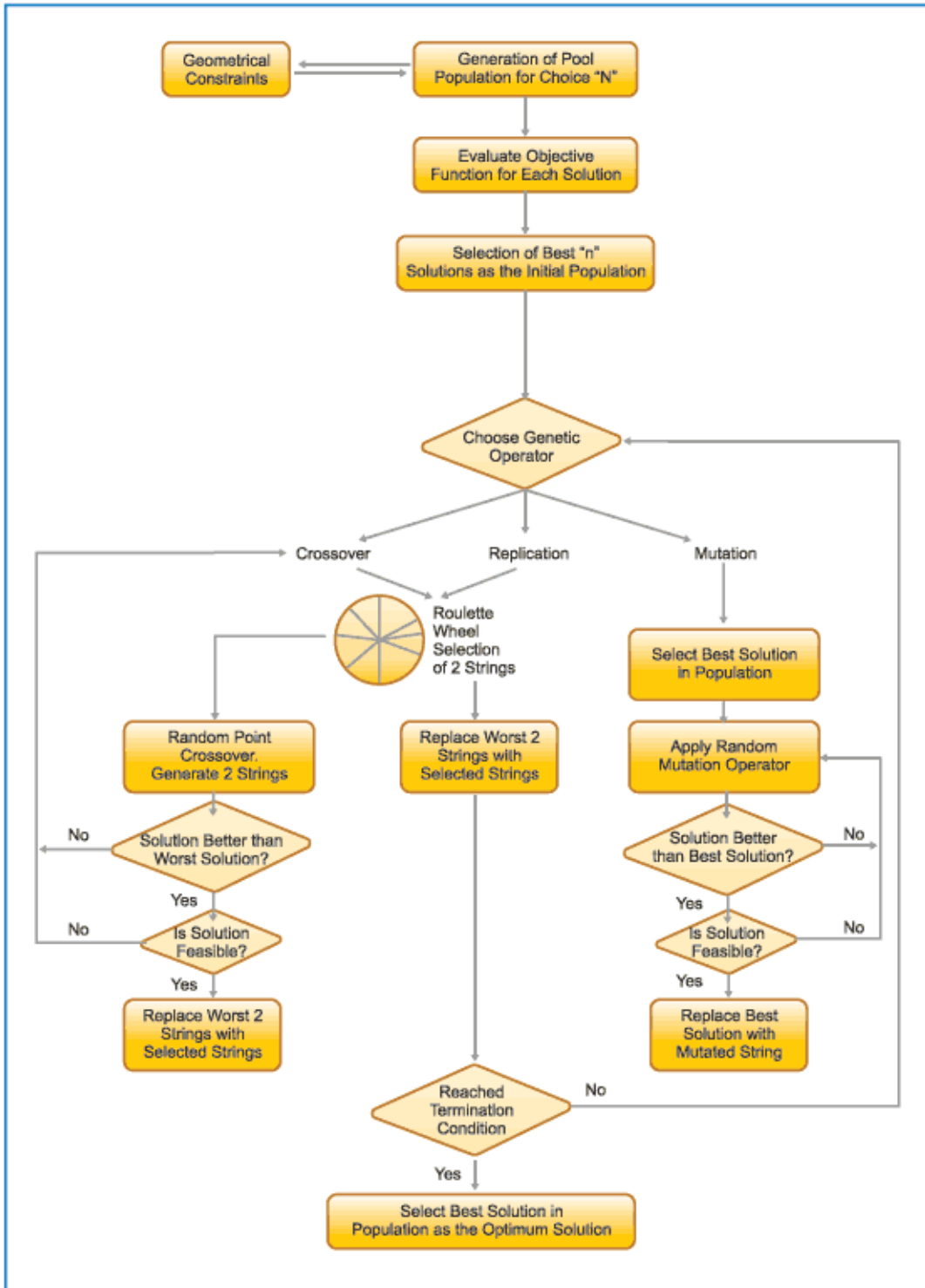


Figure 7: Optimization Flow

Source: Infosys Research

Incorporating these and the knowledge from best practice, we create the criticality matrix and then run the optimization logic to solve for the layout optimization.

### EMPOWERING RISK-FREE WHAT-IF SCENARIO ANALYSIS

The initial benefit from simulation and optimization is often a better understanding of the current process. This would include understanding the root cause of various problems and what the leverage points are, to alleviate those problems. Some of these leverage points may require additional investment; some may require training and education and some may require both. This increased understanding of the current process, while accounting for variation and flow dependencies, leads to positive changes. However, there is much more value to be realized. Virtually any “what if” can be answered with dynamic process simulation, with a degree of credibility and accuracy that most organizations have never experienced.

Just a few of the “what if” situations almost any hospital needs to consider are:

- What if I add more staff? Will it really solve the problem?
- What if I add more space or newer multi-function equipment? When will I need to expand again, given recent growth rates and projections for growth?
- What will be the impact of process changes designed to decrease turnaround time between surgeries? How much more revenue can I expect per month?
- What if I bring on a new physician group and a new specialty? How will that change the flow of my hospital or health system?

Will it create flow issues or waiting lists elsewhere?

- To what degree will more inpatient beds solve my inability to admit patients?
- To what degree will the mix of inpatient, outpatient and emergency patient flows increase the working load of the clinicians and my material resources?
- What if I altered my surgical scheduling approach? Could this help me decrease ‘denied days by payers’?

Asking “what if questions” inevitably results in quantifiable benefits such as:


- o Faster change implementation and reduced time to market
- o Higher productivity by eliminating bottlenecks
- o Increased capacity through improved resource utilization
- o Reduced operating costs and lower capital expenditures.

There are intangible benefits as well viz., greater confidence and less risk in decision making, better communication and team integration and faster buy-in to proposed changes.

### CONCLUSION

The intelligent tool that is discussed above will harness the capabilities of a BPM tool and also enable qualitative decision making capabilities of a knowledge based system. This would aid as a good tool in studying and analyzing facility layout planning and suggest ways to optimize user satisfaction. This in the long run would reduce operating costs for any healthcare facility and result in increased satisfaction of all the economic agents involved in the process viz., clinicians, doctors, patients and visitors.

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# Leverage Technology to Deliver Better Healthcare

*Meticulous evaluation of existing technologies and service options and choosing from amongst them to improve care delivery management can bring down the cost of healthcare significantly, opines the consulting editor Mark Brownlee*

**H**ealthcare is one of the most discussed topics in US, at the moment. From a political perspective, it represents a problem already getting out of proportion. In 2007, expenditure on healthcare exceeded \$2 trillion, and is expected to reach \$4.2 trillion in 2016, or 20 percent of GDP. From the perspective of healthcare consumers, premiums have been increasing, without concomitant improvement in safety or quality of care. There are many initiatives underway to tackle the problem, but one common theme amongst most of these is the use of information technology (IT) in bringing about the industry transformation.

There are several gaps in the current way of doing business that are making collaboration between the different industry stakeholders difficult and the whole system inefficient. For example, insurers want to pay for performance; but without an efficient information flow, data accuracy and reliable reporting systems at the provider's

end, linking pay and performance becomes difficult. Providers want to improve patient safety, but without interoperable systems, up-to-date data and efficient warning systems, the objective is far from being achievable. Provider organizations, in fact, have more to gain from the use of IT.

Many of the ills plaguing providers can be traced back to the heterogeneous systems they are saddled with. This heterogeneity is behind the difficulty in integrated, efficient patient and quality management and efficient management of core processes such as revenue cycle management and working capital management. However, betting the enterprise on very large HIS implementations to resolve heterogeneity is not the answer either, since there are two core problems with this approach – long implementation cycles that waste CXO's time and the unacceptably high failure rate of such programs.

Considering the current micro and macro economic factors, provider CXOs

cannot afford to ignore or wait to pursue core clinical, operational and financial improvements. They have options today that can preserve and leverage existing investments, including Enterprise Process Performance Management tools, KPO services, applying lean manufacturing concepts within and across multiple departments to eliminate waste and unlock hidden capacity. Several industry analysts have pointed out the option of more aggressively exploring innovative outsourcing options that can significantly reduce administrative expenses to free up cash to accelerate investment programs. Service Oriented Architecture (SOA) and Business Process Management (BPM) technologies and architecture do have their place in many hospital environments and CXOs owe it to themselves to understand how to leverage these. These are quick wins, when compared to the expensive yet essential goal of interoperable health records.

To sum it up, today there exist many new technology and service options for solving old, lingering problems that have led to the current state of crisis. Provider CXOs need to form an exploratory committee of their brightest technologists, who also understand your business, to do a full scan of these options and recommend how they can be used today to quickly improve patient /quality management and realize significant operational and financial improvements. This will contribute significantly in bringing down the cost of healthcare for everyone.

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