A Qualitative study on HL7 Adoption in Indian Scenario

A Dissertation Proposal for

Post Graduate Diploma in Health and Hospital Management and specialization in Healthcare Information Technology

By

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PG/10/043

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Date

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A dissertation submitted in partial fulfillment of the requirements

For the award of

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Acknowledgement

I owe my deep sense of gratitude to **Mr. Manas De**, Chief Manager, my mentor, for giving me an opportunity to learn various aspects of HL7 standard and its implementation in Indian Scenario.

My special thanks to **Mr Lingaraj Ray**, Chief Consultant, for his guidance, support, interest, involvement and encouragement. He left no stone unturned in updating me about the subject.

I also thank Dr. Anandhi Ramachandran for her guidance throughout the dissertation period.

My sincere gratitude to Mr Lakhwinder Singh, Director, International Institute of Health Management Research, New Delhi, who always has been a source of motivation and inspiration.

CERTIFICATE OF APPROVAL

The following dissertation titled "A **Qualitative study on HL7 adoption in Indian scenario**" is hereby approved as a certified study in management carried out and presented in a manner satisfactory to warrant its acceptance as a prerequisite for the award of Post- Graduate Diploma in Health and Hospital Management for which it has been submitted. It is Understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation .

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Prof. J. Bhattacharya	
Prof. (Dr.) T. MUTHULAKSHMAL	
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CERTIFICATE FROM DISSERTATION ADVISORY COMMITTEE

This is to certify that Ms Shruti Sengupta, a participant of the Post- Graduate Diploma in Health and Hospital Management has worked under our guidance and supervision. He/She is submitting this dissertation titled "Adoption of HL7 in Indian Scenario" in partial fulfillment of the requirements for the award of the Post- Graduate Diploma in Health and Hospital Management.

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Internship Completion Certificate

This is to certify that **Ms. Shruti Sengupta** has undergone training at our Organization from **24th February, 2012** to **27th April, 2012.**

She was involved in the project titled "**A Qualitative Study on the Adoption HL7 in India**"

During her stay at Siemens, we found her to be committed. Her performance as well as conduct was appreciable.

We wish her all the very best in her future endeavors.

for Siemens Information Systems Ltd.

Parijat Sengupta
Asst. Manager
Human Resources

Abstract

A QUALITATIVE STUDY OF HL7 ADOPTION IN INDIA

BY

Shruti Sengupta

HL7 is a standard concerned with the exchange of messages between two or more computers in the health care organizations. It is also concerned with the interoperability within the healthcare enterprise related to exchange, integration, sharing and retrieval of electronic health information.

HL7 (Health Level 7) Standard: An ANSI standard for healthcare specific data exchange between computer applications.

HL7 Messages are used to transfer electronic data between disparate healthcare systems. Each HL7 message sends information about a particular event such as a patient admission.

HL7 is widely used in USA but it has limited use in Indian Hospitals.

This study aims to study the various data exchange processes in USA and in Indian Context, the data integration, data interoperability, role of HL7 in data integration, challenges of HL7 interface, privacy issues during the data integration process and to suggest ways of implementing HL7 in Indian hospitals in order to have a standard, secure and fast data flow across the healthcare organization. Also, the future role of HL7 in each and every department's workflow in a typical hospital is being shown by various usecases.

A futuristic model of HL7 that can be implemented in India is also shown here which help in the process of electronic data exchange making healthcare data integration more easy, convenient, reliable, time savvy, accurate

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Acronyms / Abbreviations / Key words

- HL7 Health Level 7
- ANSI American National Standards Institute
- HITECH Health Information technology for Economic and Clinical Health
- MML Medical Markup Language
- RIM Reference Information Model
- CDA Clinical Document Architecture
- CCOW Clinical Context Object Workshop
- HIPAA Health Information Portability and Accountability Act
- XML Extended Markup Language
- DICOM Digital Imaging and Communications in Medicine
- HTTP Hyper Text Transfer Protocol
- FTP File Transfer Protocol
- RHIO Regional Health Information Organization
- LOINC Logical Observation Identifiers Names and Codes
- SNOMED-CT Systematized Nomenclature of Medicine- Clinical Terms
- ICD International Classification of Diseases
- EDIFACT Electronic Data Interchange For Administration, Commerce and Transport
- EDI Electronic Data Interchange
- VPN Virtual Private Network
- DLP Data Loss Prevention
- EHR Electronic Health Records

Part I - Internship Report

1.1 Organizational Profile

Siemens was founded in Berlin by Werner von Siemens in 1847. As an extraordinary inventor, engineer and entrepreneur, Werner von Siemens made the world's first pointer telegraph and electric dynamo, inventions that helped put the spin in the industrial revolution. He was the man behind one of the most fascinating success stories of all time - by turning a humble little workshop into one of the world's largest enterprises.
Siemens is today a technology giant in more than 190 countries, employing some 440,000 people worldwide. Siemens' work in the fields of energy, industry, communications, information, transportation, healthcare, components and lighting have become essential parts of everyday life.

Siemens in India
The Siemens Group in India has emerged as a leading inventor, innovator and implementer of leading-edge technology enabled solutions operating in the core business segments of Industry, Energy and Healthcare. The Group's business is represented by various companies that span across these various segments.

Siemens brings to India state-of-the-art technology that adds value to customers through a combination of multiple high-end technologies for complete solutions. The Group has the competence and capability to integrate all products, systems and services. It caters to Industry needs across market segments by undertaking complete projects such as Hospitals, Airports and Industrial units.

Siemens Healthcare

Siemens Healthcare (formerly Siemens Medical Solutions, formerly Siemens Medical Systems, internally within Siemens known as "Med") is a supplier to the healthcare industry, and is headquartered in Erlangen, Germany.

Siemens contribution to healthcare sector-

- Accessories and OEM equipment
- Healthcare education
- Healthcare services
- Infrastructure services
- Therapy systems
- Hearing instruments
- Laboratory diagnosis
- Medical Imaging

Siemens helps to deliver more efficient patient care with innovative information technology (IT) solutions as follows-

- *Ambulatory and Home Health*- Siemens and **NextGen Healthcare** are transforming the exchange of data, connecting acute and ambulatory environments. This collaboration combines Siemens expertise in enterprise IT systems with NextGen's leadership in ambulatory EMR and practice management software. Together, they enable interoperability and workflow across the continuum of care.
  Interoperability and management of patient records—Transforming healthcare by connecting acute and ambulatory care records, through interoperability between our IT solutions, helping providers and executives improve the management and delivery of healthcare services.

- *Clinicals*- Siemens is committed to delivering a group of proven solutions that provide INVISION® customers with the tools they need to pursue clinical excellence, sound financial management, and operational efficiency. With **INVISION Clinicals**, Siemens provides ongoing solution enhancements based on customer insights, emerging technologies and changes in regulatory requirements. INVISION solutions work together to support communications, workflow, and efficiency across the enterprise. Various software are being made for **Bed management, Enterprise Access Directory, Medication Reconcilation, PDA Clinical Assistant, Clinical Notification Inbox, Lifetime clinical record, patientcare documentation**

- *Departmentals*- Siemens combines proven departmental and clinical solutions to provide an enterprisewide healthcare information environment. This environment connects clinicians, administrators, and processes, simplifying workflow, and providing access to a unified patient record. It makes information available when and where needed, helping providers reduce the errors and miscommunications that can occur when departmental applications remain "siloed." Various softwares by Siemens in this field are- **Soarian Cardiology(For Cardiology), Siemens syngo Suite(For radiology), Novius Lab System(For laboratory), Critical Care, Pharmacy**

- *Revenue Cycle Management*- No matter what the size of your organization, Siemens **Revenue Cycle Management** solutions can help you maximize business throughput, streamline processes, and manage budgets. Covering every aspect of your business—from revenue cycle optimization to increased operational efficiencies to improved employee satisfaction—Siemens solutions help you measure and control costs while driving quality patient care.

- *Business Intelligence*- Siemens created **Decision Support Solutions** (DSS) to collect enterprisewide data and transform it into business intelligence. This integrated data warehouse provides easy access to key performance indicators measured against defined standards, and provides interactive, analytical views for the entire healthcare management team. With DSS, Siemens helps you make informed decisions about budgets, processes, personnel, quality data, equipment, payer relationships and more.

- *Connectivity- Integration Engine*- For over 20 years, healthcare providers have successfully achieved systems interoperability using**Siemens OPENLink™,** an

application-independent interface engine. It provides innovative, user-friendly tools that empower users to quickly build interfaces enabling the exchange of complex information.

- Enable the EHR through systems interoperability – Siemens OPENLink bridges clinical, lab, Imaging, financial, administration, and other systems that require online data.

- Reduce redundant manual data entry – Siemens OPENLink seamlessly transfers data between systems that utilize different communication standards and protocols.

- Helps providers meet HIPAA regulations – Siemens OPENLink provides the security tools needed to help hospitals comply with HIPAA rules and guidelines.

- Based on industry standard**s** – Siemens OPENLink is based on web-based, health system and research standards, including HL7, X12, XML, and DICOM.

- Siemens helps healthcare providers streamline the patient vitals collection process with **Soarian®Device Connect.** This innovative solution electronically collects information directly from vital signs monitors and then sends the data to the clinical repository for access from practically anywhere in the enterprise. Soarian Device Connect improve provider data collection efficiency, Make patient data available more quickly –Support increased provider productivity, Minimize the opportunity for human error.

  - *Healthcare Information Solutions*- Siemens provides comprehensive solutions for hospitals of every size with a broad portfolio of Healthcare Information Solutions. Siemens recognizes the importance of CCHIT Certification and is proud that **INVISION®**, **Soarian®** and **MedSeries4®** have received inpatient certification. Siemens customers regularly receive recognition for patient safety, quality, and outstanding performance.

  - Thought Leadership and Industry Initiatives
  - Consulting and IT services
  - Point of care

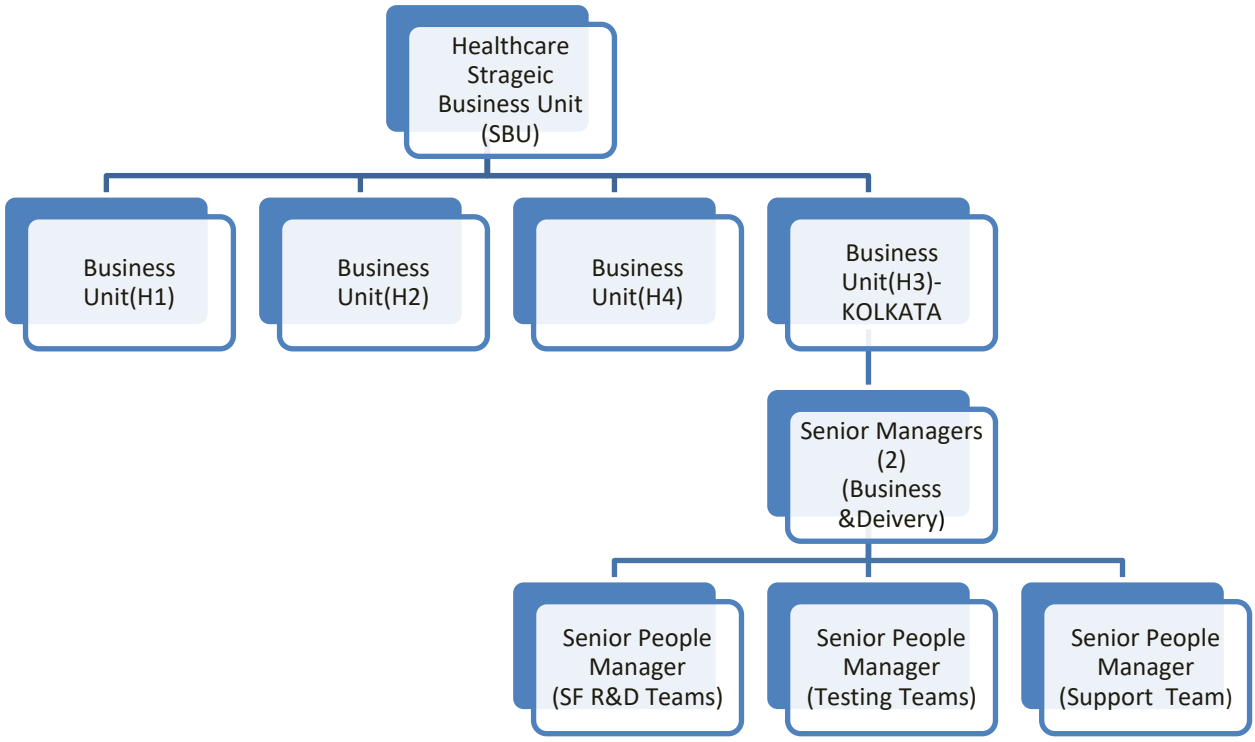


Figure Organizational Hierarchy(Healthcare division in Kolkata)

1.2 Area of Engagement

The area of engagement during internship was the HL7 project. I was mainly associated with the literature review of HL7(its features, standard protocols etc), requirement analysis of HL7, communicating with the clinical and financial people on the requirement specifications, proposing a simpler yet efficient model of HL7 for Indian Healthcare Industry.

1.3 Reflective Learning

As the concept of HL7 is quite new in Indian context, there are not many research and developments in this field especially in India. So, this study helped me to-

- Have an in depth knowledge of Health level 7 (HL7), its application, areas where it is used, knowledge of US and Indian healthcare delivery process etc.
- Compare data exchange process of India with western countries(e.g USA).
- Study hospital workflows in detail and propose where HL7 can be used to improve data transfer within hospitals.
- Do requirement gathering, make usecases, identify key stakeholders, identify interface/HL7 challenges.
- Propose a simpler version of HL7 for Indian Scenario.

Part II – Dissertation Report

Dissertation on "Adoption of HL7 in Indian Scenario"

Part A- Dissertation Overview

1.0 Introduction

Data Exchange is the establishment of a pathway, based on common data standards, to facilitate the incorporation of interoperable, clinically useful remote monitoring information into EHRs and PHRs to support clinical decision-making and management of patients with chronic conditions.

In USA, the healthcare delivery mechanism involves a lot of different stakeholders like Care Coordinators, Clinical support staff, decision support tool providers, health researchers, Regional Health Information Organizations(RHIO) unlike in India where only a few stakeholders is involved in the healthcare delivery process. Hence, the data exchange standards adopted in USA will be quite different from that in India.

As USA spends approximately 16% of GDP in healthcare, the healthcare delivery process and the use of IT in imparting patient care is very advanced and efficient in USA. The active role of TPA and the government sponsored healthcare is common in USA. Out of pocket expenses are minimal and the healthcare data is seamlessly exchanged between authorized agencies for accurate, timely, convenient care to all patients. For the smooth running of the healthcare indiustry, well defined standards are used like HL7, DiCom, LOINC, SNOMED, ICD-10 etc.

But in India, the healthcare is a state subject but is largely managed by the private sector. There are no proper data exchange mechanisms among different healthcare entities, low penetration of IT in patientcare, lack of interconnectivity standards, outdated technology used, high cost in private hospitals, lack of treatment in government hospitals and so on.

There is an increasing demand for healthcare centers, hospitals and healthcare physicians to receive/send critical data, healthcare reports and other important information on a constant basis. Although information is generally stored in a non-standard format, for information to get transmitted, it must be changed from one format to another format. The HL7 standard is a protocol that has been developed to address the problem of data exchange between different systems.

So, a data exchange standard which is well implemented in the USA has to be modified in order to be implemented in Indian Scenario.

2.0 Vision

To modify the HL7 standard used in USA in accordance with the needs of Indian Healthcare in order to provide accurate, timely, relevant information to physicians and other healthcare entities for rendering better care to patients.

3.0 Need for the Study

There is a huge difference between healthcare delivery in western countries and healthcare in India. Out of all the standards, HL7 is most relevant for the data flow between healthcare entities. So the HL7 standard for data exchange should be modified and made simpler so that it suits the needs and demands' of the Indian healthcare industry.

4.0 Scope of the study

This customization of HL7 standard for Indian scenario can be used in future in order to provide standard data flow mechanisms and this simpler version would be easier to implement for the healthcare institions.

5.0 General Objective

To enumerate ways of adapting HL7 in Indian healthcare context.

6.0 Specific Objectives

1) To study the healthcare process in USA
2) To study the Indian healthcare process
3) To study how information exchanges takes place
4) To compare the healthcare process between USA and India
5) To study the workflow of hospitals and to predict the areas where HL7 can be used for data exchange.
6) To devise a simpler version of HL7

7.0 Assumptions

It is assumed that all the HL7 specifications are being met in making a futuristic HL7 model and HL7 is being used in a rudiment stage in India.

8.0 Work plan

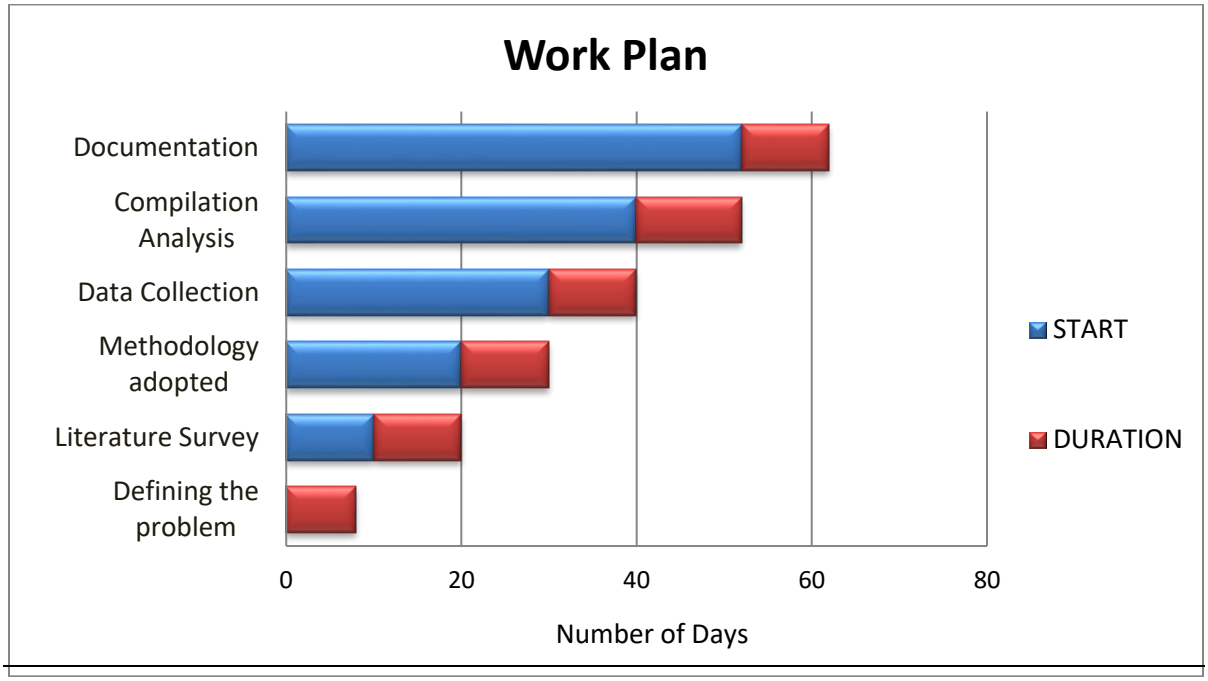


FIGURE 2- WORK PLAN

9.0 Limitations

As it is a purely qualitative study and the concept of HL7 is quite new in India, there is limited quantitative data available on HL7. Also the study aims to propose a future implemented model of HL7 in India, so there is lack of practical problems which might be faced by the systems after implementation

Part B – Project Overview

1.0 Review of Literature

1) *Realization of Real-Time Clinical Data Integration Using Advanced Database Technology*

Sooyoung Yoo,[1] Boyoung Kim,[1] Heekyong Park,[1] Jinwook Choi,[1] and Jonghoon Chun[2]

With the recent movement toward shared clinical data in health care, a number of models, methods, and evaluative strategies have been developed. Data integration, especially in the medical environment, is the most important issue that must be considered. HL7 (Health Level 7) has been proposed as a standard for electronic data exchange in medical environment [3], to understand data communication and system interoperability among the various systems

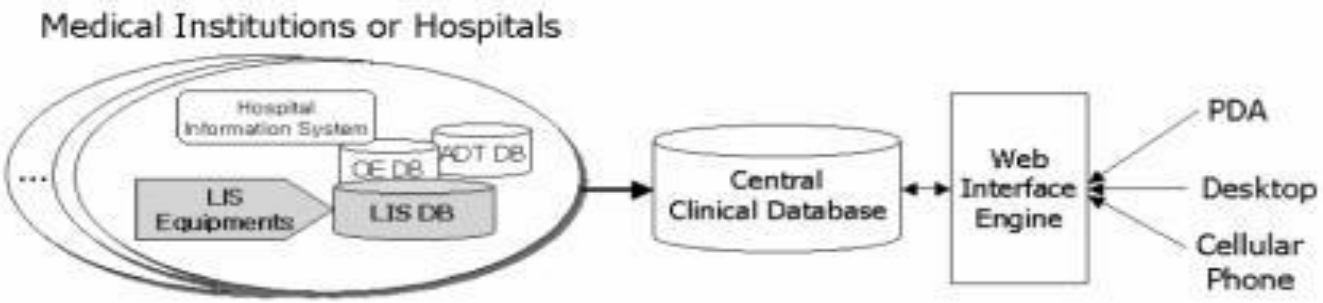


Figure 3- Data Exchange using Interface Engine

The HL7 Message Server (HMS) is an interface at each medical institution and the HL7 Message Archiver (HMA) as an interface for the central clinical database. These two interfaces communicate with each other by HL7 messages, currently version 2.3.1 messages, on the TCP/IP network. Also, to minimize the database communication overheads and the amount of data to be transmitted to the HMS, the LIS database usually sends only small-sized data sets including several key identifiers, to the HMS whenever interesting transactions occur. The HMS queries again to obtain complete data needed for fulfilling the HL7 messages if necessary.

2) *Use of HL7 to integrate a HIS-subsystem: limits and possibilities.*

***Flaig M*, *Graeber S*, *Sybrecht GW*.**

Modern computer-based hospital information systems are mostly distributed with several heterogeneous subsystems connected together by specialized communication services. The common standard to integrate subsystems is HL7. By the example of subsystem integration for a pulmonary function test lab, we discuss the possibilities of HL7, the limits we encountered and how we overcame these.

3) *Health Level 7: Barriers and solutions to full data integration in the Dutch healthcare sector*

Rens Ariëns

The Health Level 7 standard is a very popular communication standard that is frequently used in the Dutch healthcare sector. Although about every hospital uses the standard internally, there seems to be almost no communication between healthcare organizations, especially when they are in a different healthcare layer.
The amount of different versions of HL7 does not seem to be of any problem for internal communication [IRB07], because HL7 version 2 is backwards compatible. As circa 95% of all HL7 messages is still based on version 2 this does not give any problems within organizations [SD07] [IRB07]. From the interview with the MST hospital it seems that the main problems regarding internal communication within healthcare organizations lay in the fact that suppliers of the necessary software do not support the latest subversion of HL7 version 2 [IRB07].
Currently there is almost no HL7 communication between healthcare organizations. Some hospitals have set up an interface with an important partner due to the financial advantages this creates [IRB07]. One of the most important kinds of external communication has not been implemented much, communication between primary care and secondary care . The main cause is the different standards these layers use [IRS07].Within the primary layer EDIFACT is the most known standard.
The lack on external communication between healthcare organizations is not primary caused by the technique used, but is more a problem of interests and investments in older standards and software. Even if external communication provides surplus value, it needs to be cheap and easy to use. If it costs a lot of work for the clinicians they will not use it as much as they should do.

4) *HL7 ontology and mobile agents for interoperability in heterogeneous medical information systems*

B. Orgun, J. Vu
Department of Computing, Macquarie University, Sydney NSW 2109, Australia and Health Data Operation Centre, South Western Sydney Area Health Services, Liverpool NSW 1871, Australia

Received 5 April 2005; accepted 5 April 2005

Modern medical information management is a knowledge intensive activity requiring a high degree of interoperability across various health management entities. Ontology-based multi-agent systems provide a framework for interactions in a distributed medical systems environment without the limitations of a more traditional client server approach.
The costs involved with maintaining different software from different vendors and maintaining their interfaces with each other is phenomenal.
A solution to this problem involves the use of a centralised warehouse of all patient information (for instance, Western Sydney Area Health Services uses Customer Hub—a large database which contains the demographic information on all the patients in the area and their area wide

unique identifier).. Moreover, with various new technologies (WAP, MMS) being available now, there has also been a change in the type (home care, in-patient services, etc.) and degree of accessibility (patient, clinician, etc.) to health care, advice and information.There is a pressing need for usable interfaces and easily accessed, integrable information sets.
Ramesh et al. [12] proposed a multi-agent system with a UMLS [20] based ontology to provide access to patient information across multiple databases. Lanzola et al. [10] proposed a network of agent communities working co-operatively to improve the healthcare delivery process as a follow up of related work in patient management [9].

eMAGS—an intelligent HL7 ontology-based multi-agent system for heterogeneous medical systems

The system provides translations between local data and the HL7 format through the use of a rule based, semi-automated approach that has the flexibility to withstand changes in the HL7 standard itself. The eMAGS architecture (see Fig. 1) consists of numerous agent servers, each serving a database application that is part of the eMAGS network; an agent broker and an ontology server. Any health care database application subscribing to the eMAGS network can function as a source or a sink for an HL7- based message carried by an HL7 agent

5) Coordinating shared care using electronic data interchange.

Branger P, van't Hooft A, van der Wouden HC. Source: Department of General Practice, Erasmus University, Rotterdam, The Netherlands.

Shared care is the situation in which physicians jointly treat the same patient.. Optimal communication is considered to be a vital aspect of shared care, both from medical and cost-effectiveness points of view. One recent technology is Electronic Data Interchange (EDI), defined as "the replacement of paper documents by standard electronic messages conveyed from one computer to another without manual intervention".

Therefore, a new message, called MEDEUR, was developed, that is designed for integrated patient data exchange between computer-based patient records. The message can contain both administrative and medical data and can be used for transmission of a complete medical record, or sections of it.

Work has been done on a project in which general practitioners and specialists use their own electronic medical record system for storing data of jointly treated patients. In addition, the participating physicians use the MEDEUR message standard in communicating about these patients. The use of EDI enables physicians to transmit patient data electronically to another physician's computer system. The receiving physician can store the data automatically in his electronic medical record without having to re-type the data.

6) An infrastructure for Integrated Electronic Health Record services: the role of XML (Extensible Markup Language).

Katehakis DG, Sfakianakis S, Tsiknakis M, Orphanoudakis SC. Center of Medical Informatics and Health Telematics Applications (CMI-HTA), Institute of Computer Science (ICS), Foundation for Research and Technology, Heraklion, Crete, Greece.

The sharing of information resources is generally accepted as the key to substantial improvements in productivity and better quality of care. In addition, due to the greater mobility of the population, national and international healthcare networks are increasingly used to facilitate the sharing of healthcare-related information among the various actors of the field. In the context of HYGEIAnet, the regional health telematics network of Crete, an Integrated Electronic Health Record environment has been developed to provide integrated access to online clinical information, accessible throughout the island.

The Integrated Electronic Health Record environment developed in HYGEIAnet provides the basis for consistent and authenticated access to primary information over the Internet in order to support decision-making. Primary information is always kept at the place where it has been produced, and is maintained by the most appropriate clinical information system, contrasting traditional store and forward techniques, or centralized clinical data repositories.

Since documents are much more easily accessible rather than data inside a database, Extensible Markup Language has the potential of becoming a very cheap technology provided, of course, that the underlying Healthcare Information Infrastructure exists. XML can be introduced incrementally and its implementation is completely transparent to the end user.

7) Privacy Challenges and Solutions for Medical Data Sharing

By Aris Gkoulalas-Divanis and Grigorios Loukides

Various types of data, including demographics, clinical, and genomic information, are increasingly collected and stored in Electronic Medical Record (EMR) systems and biomedical research repositories. Such data have been traditionally used in automating the workflow of healthcare, but were recently recognized as an invaluable source for performing large-scale and low-cost biological, medical, and healthcare analysis and decision making. This article deals with Medical data representation, storage, and management, the use of person-specific medical data in applications, existing policies governing medical data sharing: HIPAA and the NIH GWAS policy, Privacy fiascoes and threats related to sharing medical data, Challenges in medical data privacy, Anonymizing clinical information, protecting patient's genomic and location information, removing identifying information from unstructured data.

8) Electronic Health Record Systems and Intent to Apply for Meaningful Use Incentives Among Office-based Physician Practices: United States, 2001–2011. Chun-Ju Hsiao, Ph.D.; Esther Hing, M.P.H.; Thomas C. Socey; and Bill Cai, M.A.Sci.

The 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act authorized incentive payments through Medicare and Medicaid to increase physician adoption of electronic health record (EHR) systems (1,2). Eligible Medicare and Medicaid physicians may receive incentive payments over 5 years if they demonstrate 15 Stage 1 Core Set objectives and 5 of 10 Menu Set objectives, using certified EHR systems

In 2011, 57% of office-based physicians used electronic medical record/electronic health record (EMR/EHR) systems, with use by state ranging from 40% in Louisiana to 84% in North Dakota. In 2011, 52% of physicians reported intending to apply for the Medicare or Medicaid EHR incentive payments, a 26% increase from 2010. In 2010, interest among physicians in applying for meaningful use incentive payments was similar to the national average (41%) across most states.

9) ***Design and development of an international clinical data exchange system: the international layer function of the Dolphin Project***

Jing-song Li, Tian-shu Zhou, Jian Chu, Kenji Araki, Hiroyuki Yoshihara
Professor Jing-song Li, Healthcare Informatics Engineering Research Center, Zhejiang University, No 38 Zheda Rd, Hangzhou 310027, China;

At present, most clinical data are exchanged between organizations within a regional system. However, people traveling abroad may need to visit a hospital, which would make international exchange of clinical data very useful. An international layer system named Global Dolphin was constructed with several key services, sharing patients' health information between countries using a medical markup language (MML). The system was piloted with 39 test patients. The three regions above have records for 966 000 unique patients, which are available through Global Dolphin. Data exchanged successfully from Japan to China for the 39 study patients include 1001 MML files and 152 images. The MML files contained 197 free text-type paragraphs that needed human translation.

The pilot test in Global Dolphin demonstrates that patient information can be shared across countries through international health data exchange. To achieve cross-border sharing of clinical data, some key issues had to be addressed: establishment of a super directory service across countries; data transformation; and unique one—language translation. Privacy protection was also taken into account. The system is now ready for live use.

The project demonstrates a means of achieving worldwide accessibility of medical data, by which the integrity and continuity of patients' health information can be maintained.

10) ***Use of a health information exchange system in the emergency care of children***

Joshua R Vest[1*], 'Jon (Sean) Jasperson[2], Hongwei Zhao[3], Larry D Gamm[4] and Robert L Ohsfeldt[4]

Children may benefit greatly in terms of safety and care coordination from the information sharing promised by health information exchange (HIE). First, HIE has the ability to better support the care and detection of vaccine preventable conditions by incorporating immunization histories and linking to both local public health agencies and schools [4,6,7]. Second, minors constitute a substantial proportion of emergency department (ED) visits in the US,[8] with infants having the highest rates of ED visits [9].

Users accessed the system for 8.7% of encounters. Increasing patient comorbidity was associated with a 5% higher odds of basic usage and 15% higher odds for novel usage. The odds of basic system usage were lower in the face of time constraints and for patients who had not been to that location in the previous 12 months.

HIE systems may be a source to fulfill users' information needs about complex patients. However, time constraints may be a barrier to usage. In addition, results suggest HIE is more likely to be useful to pediatric patients visiting ED repeatedly. This study helps fill an existing

gap in the study of technological applications in the care of children and improves knowledge about how HIE systems are utilized.

2.0 Methodology

The methodology involved analysis of secondary data sources from different international journals, medical databases, international publications etc.

I have used the following types of literature in order to carry out a literature survey-

- ☐ Original Investigations-4
- ☐ International Publications-4
- ☐ Monographs-1
- ☐ Articles-1

I found them by using various Databases, Journals like the PubMed database, Centers for disease control and prevention, Journal of the American Medical Informatics Association, Biomed Central etc.

The keywords used for search were Electronic Data Interchange, Data Privacy and Security, healthcare process in USA, Health Information Exchange, Use of HL7, Clinical Data Integration which produced a number of results, which after filtering out and removing irrelevant results reduced to a limited number of appropriate results in accordance to my subject matter. These results were further skimmed down on the basis of advanced search options.

I have identified four themes/basis for identifying standard good literatures-

- ✦ Assessing the quality of published work-. The most trustworthy conclusions are those reached in double-blind randomized controlled trials with a representative sample of sufficient size to detect the smallest worthwhile effect. The weakest are the case studies. This is the reason why international publications, original investigations are used
- ✦ Interpreting effects- the effects- a thorogh explanation of the terms, effects, statistical significance of the effects, impact of the study on population etc has been done in order to make the literature worthwhile to study.
- ✦ Points of grammar and style- The article/publication should be grammatically correct and should be presented in a simple language with clearly written sentences. It should be easy to understand and comprehend the inner meaning of the survey
- ✦ Few remarks about tables and figures- A good article is one which has lots of facts, figures, bar graphs, pie charts, line graphs for the better understanding of the results of the investigation. Diagrammatic representations like line diagram, workflows, sequential analysis makes the article interesting to read and analyse its contents.

3.0 What is HL7?

HL7 is a standard concerned with the exchange of messages between two or more computers in the health care organizations. It is also concerned with the interoperability within the healthcare enterprise related to exchange, integration, sharing and retrieval of electronic health information.

HL7 (Health Level 7) Standard: An ANSI standard for healthcare specific data exchange between computer applications. The name comes from "Health Level 7", which refers to the top layer (Level 7) of the Open Systems Interconnection (OSI) layer protocol for the health environment. The HL7 standard is the most widely used messaging standard in the healthcare industry around the world.

The seventh layer of OSI Model supports functions such as security checks, participant identification, availability checks, exchange mechanism, negotiations and data exchange structuring.

HL7 Messages are used to transfer electronic data between disparate healthcare systems. Each HL7 message sends information about a particular event such as a patient admission.

An HL7 message consists of one or more **segments**. Each segment consists of one or more **composites**, also known as **fields.**

HL7 messages are in human-readable (ASCII) format, though they may require some effort to interpret.
Each HL7 message consists of one or more segments. A carriage return character (**\r**, which is 0D in hexadecimal) separates one segment from another. Each segment is displayed on a different line of text. (As seen in the sample HL7 message below)
Each HL7 segment consists of one or more composites (also known as fields). A pipe **(|)** character is used to separate one composite from another.
If a composite contains other composites, these sub-composites (or sub-fields) are normally separated by ^ characters.

SAMPLE HL7 MESSAGE

```
MSH|^~\&|EPIC|EPICADT|SMS|SMSADT|199912271408|CHARRIS|ADT^A04|1817457|D|2.5
|
PID||0493575^^^2^ID 1|454721||DOE^JOHN^^^^|DOE^JOHN^^^^|19480203|M||B|254
MYSTREET AVE^^MYTOWN^OH^44123^USA||          (216)123-
4567     |||M|NON|400003403~1129086|
NK1||ROE^MARIE^^^^|SPO||          (216)123-4567     ||EC|||||||||||||||||||||||
PV1||O|168 ~219~C~PMA^^^^^^^^^^||||277^ALLEN MYLASTNAME^BONNIE^^^^|||||||||
||2688684|||||||||||||||||||||||199912271408||||||002376853
```

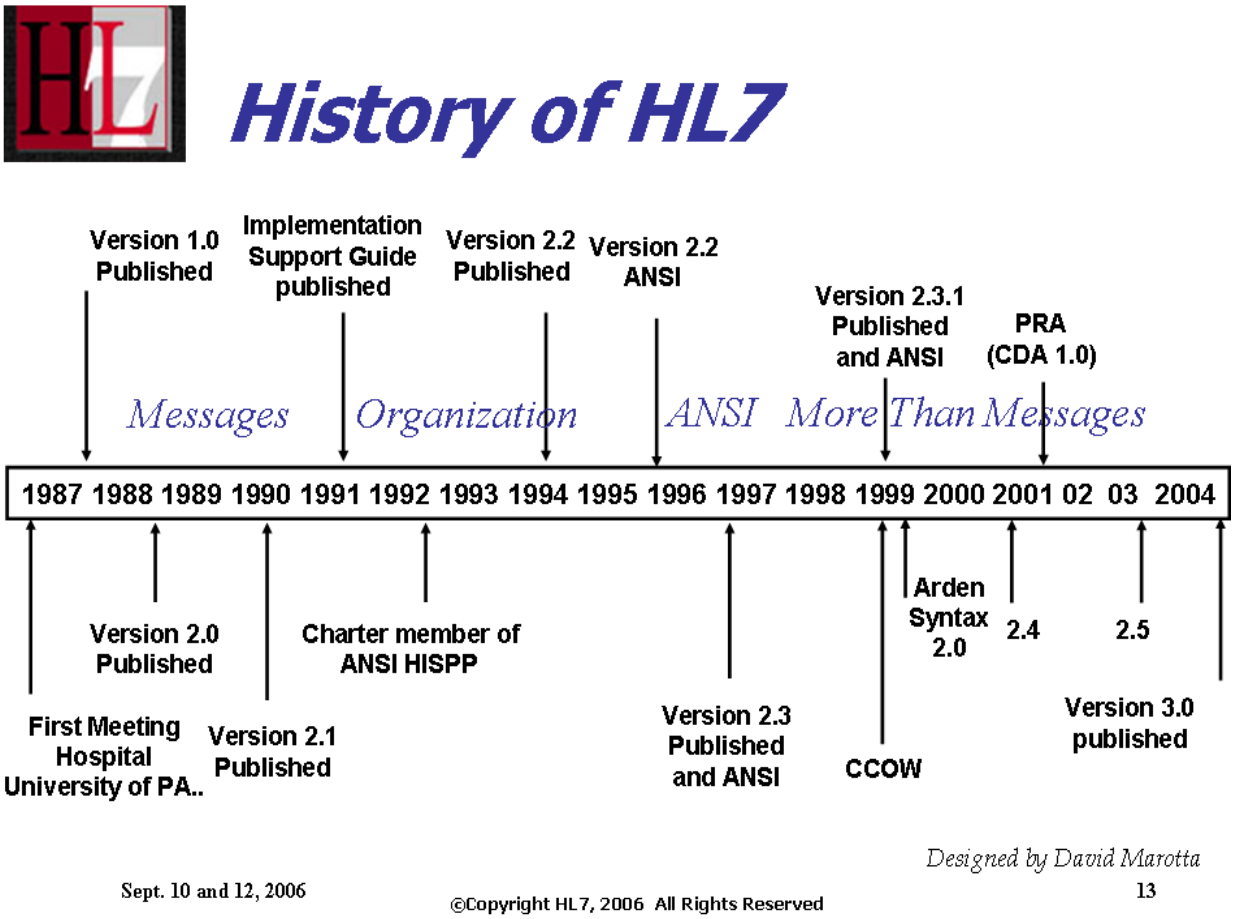


Figure 4 – History of HL7

Areas where HL7 is used

HL7 is applied in Government hospitals, insurance companies, concerned associations, entrepreneurs and developers.

3.1 HL7 ORGANISATION

It is an international community of healthcare subject experts and information scientists collaborating to create standards for the exchange, management and integration of electronic healthcare information. HL7 promotes the use of such standards within and among healthcare

organizations to increase the effectiveness and efficiency of healthcare delivery for the benefit of all.

HL7 develops Conceptual Standards (i.e Hl7 RIM), Document Standards (i.e HL7 CDA), Application Standards(i.e HL7 CCOW) and Messaging Standards(i.e HL7 v2.x and v3.0).

What HL7 doesn't cover?
It doesn't specify how messages will be delivered between the applications and other network protocols such as TCP/IP or FTP file transfers will be used to deliver messages.
HL7 doesn't describe what is done to a message after it has been received as this is the domain of the individual applications.

3.2 Introduction to HL7 Standards

HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services, and are recognized as the most commonly used in the world.

HL7 standards are grouped into reference categories:

- **Section 1: Primary Standards** - Primary standards are considered the most popular standards integral for system integrations, inter-operability and compliance. Our most frequently used and in-demand standards are in this category.

- **Section 2: Foundational Standards** - Foundational standards define the fundamental tools and building blocks used to build the standards, and the technology infrastructure that implementers of HL7 standards must manage.

- **Section 3: Clinical and Administrative Domains** - Messaging and document standards for clinical specialties and groups are found in this section. These standards are usually implemented once primary standards for the organization are in place.

- **Section 4: EHR Profiles** - These standards provide functional models and profiles that enable the constructs for management of electronic health records.

- **Section 5: Implementation Guides** - This section is for implementation guides and/or support documents created to be used in conjunction with an existing standard. All documents in this section serve as supplemental material for a parent standard.

- **Section 6: Rules and References** - Technical specifications, programming structures and guidelines for software and standards development.

- **Section 7: Education & Awareness** - Find HL7's Draft Standards for Trial Use (DSTUs) and current projects here, as well as helpful resources and tools to further supplement understanding and adoption of HL7 standards.

3.3 HL7 Versions

There have been few versions of HL7 but the most recent version is version 3.0. The HL7 version 2 standard has the aim to support hospital workflows. It was originally created in 1987. The HL7 version 3 standard has the aim to support all hospital workflows. As opposed to version 2, v3 standard, is based on a formal methodology(the HDF) and object oriented principles.
The HL7 version 3 addresses the interfaces among various healthcare IT systems that send or receive patient admissions/registration, discharge/transfer(ADT), data , queries, resource, patient scheduling, orders, results, clinical observation, billing, master file updation information, medical information, medical records, scheduling, patient referral, patient care, clinical laboratory automation, application management, personnel management messages.

Version 2.x XML(XML Encoding of HL7 message)

3.4 Need for HL7 Standard

In the past four decades, healthcare institutions and hospitals in particular, have begun to automate aspects of their information management. Initially, such efforts were focused towards reducing paper processing, improving cash flows, improving decision making. In later years, a distinct focus on streamlining and improving clinical and ancillary services has evolved including bedside and patient side systems. Today, growing numbers of hospitals have installed computer systems to manage a wide range of their information needs- admission, discharge, transfer, clinical laboratories, radiology, billing and accounts receivable etc. often these applications used for specific areas have been developed by different vendors or occasionally by in-house groups with each product having highly specific information format.
As hospitals have gradually expanded information management operations, an urgent need to share critical data among the systems has emerged. The need for extensive site-specific interface work could be greatly reduced if a standard for network interfaces for healthcare environments were available and accepted by both users and vendors.
It is proposed that HL7 can act as a superstructure in this environment to facilitate a common specification.

There is an increasing demand for healthcare centers, hospitals and healthcare physicians to receive/send critical data, healthcare reports and other important information on a constant basis. Although information is generally stored in a non-standard format, for information to get transmitted, it must be changed from one format to another format. This difficulty has brought about the need for a method to address this format conversion of information. The HL7 standard is a protocol that has been developed to address the problem of data exchange between different systems

Why HL7 is different from other standards?

While other standards focus on the needs of a particular healthcare department, HL7 focuses on the interface necessities of the whole healthcare organization. Another reason why HL7 stands out from the rest, is because HL7 creates continuously protocols. HL7 addresses the needs of the already incorporated department and hospital systems that use high-end technology. Health level 7 focuses on meeting the immediate requirements of each of its membership constituencies, consultants, vendors and users.

3.5 Goals of the HL7 standard

HL7's purpose is to facilitate communication in healthcare settings

Primary goal- provide standards for the exchange of data among healthcare computer applications that eliminate or substantially reduce the custom interface programming and program maintenance that may otherwise be required. Immediate transfer of single transactions should be supported along with file transfers of multiple transactions.The standard must support evolutionary growth as new requirements are recognized. This includes support of the process of introducing extensions and new releases into existing operational environments.

The specific goals of HL7 can be listed as follows-

- Develop coherent, extendible standards that permit structured, encoded health care information of the type required to support patient care, to be exchanged between computer applications while preserving meaning.
- Develop a formal methodology to support the creation of HL7 standards from the HL7 Reference Information Model (RIM).
- Educate the healthcare industry, policy makers, and the general public concerning the benefits of healthcare information standardization generally and HL7 standards specifically.
- Promote the use of HL7 standards world-wide through the creation of HL7 International Affiliate organizations, which participate in developing HL7 standards and which localize HL7 standards as required.
- Stimulate, encourage and facilitate domain experts from healthcare industry stakeholder organizations to participate in HL7 to develop healthcare information standards in their area of expertise.
- Collaborate with other standards development organizations and national and international sanctioning bodies (e.g. ANSI and ISO), in both the healthcare and information infrastructure domains to promote the use of supportive and compatible standards.
- Collaborate with healthcare information technology users to ensure that HL7 standards meet real-world requirements, and that appropriate standards development efforts are initiated by HL7 to meet emergent requirements.

- Develop system functional models to help guide the industry on the essential requirements for electronic health record and personal health record systems.

3.6 Clinical Document Architecture(CDA)

CDA is the part of HL7 standard and makes documents human readable and machine processable by using XML. CDA is used in EHR, discharge summaries and progress notes.

Clinical Document Architecture. A CDA document is comprised of a header, referred to as the "CDA Header", and a body, which at CDA Level One is referred to as the "CDA Level One Body". The CDA Header identifies and classifies the document and provides information on authentication, the encounter, the patient, and the provider. The body contains the clinical report. The CDA Level One Body is comprised of nested containers. There are four types of containers: sections, paragraphs, lists and tables. Containers have contents and optional captions. Contents include plain text, links, and multimedia. Both the header and the body use the data types defined in the HL7 RIM.

The Clinical Document Architecture is based on XML, the Extensible Markup Language. Meanwhile, to represent health concepts, the CDA uses HL7's Reference Information Model, which aims to put data in a clinical or administrative context and to express how pieces of data are connected, and coding systems such as Systematized Nomenclature of Medicine -- Clinical Terms (SNOMED CT) and Logical Observation Identifiers Names and Codes (LOINC).

By setting standards for information exchange, the Clinical Document Architecture is a step toward the goal of ensuring that patient records can be created and read by any electronic medical record (EMR) or electronic health record (EHR) software system. The CDA standard does not identify a particular transport method; options include Digital Imaging and Communications in Medicine (DICOM), Multi-Purpose Internet Mail Extensions (MIME), File Transfer Protocol (FTP) and Hypertext Transfer Protocol (HTTP), as well as HL7 version 2 messages and HL7 version 3 messages.

Together with the Continuity of Care Record standard, the Clinical Document Architecture forms the basis for the Continuity of Care Document standard for patient document information exchange. Both the CCR and CCD standards meet the United States government's guidelines for the meaningful use of EHR technology.

3.7 Visual/Context Integration (CCOW)

In the context of Health informatics, **CCOW** or **Clinical Context Object Workgroup** is an HL7 standard protocol designed to enable disparate applications to synchronize in real-time, and at the user-interface level. It is vendor independent and allows applications to present information at the desktop and/or portal level in a unified way.

CCOW is the primary standard protocol in healthcare to facilitate a process called "Context Management." Context Management is the process of using particular "subjects" of interest (e.g., user, patient, clinical encounter, charge item, etc.) to 'virtually' link disparate applications so that the end-user sees them operate in a unified, cohesive way.

Context Management can be utilized for both CCOW and non-CCOW compliant applications. The CCOW standard exists to facilitate a more robust, and near "plug-and-play" interoperability across disparate applications.

CCOW is designed to communicate the name of the active user between various programs on the same machine. The user should only need to log into one application, and the other applications running on the machine will “know” who is logged in.

In order to accomplish this task, every CCOW compliant application on the machine must login to a central CCOW server called a Vault. The application sends an encrypted application passcode to verify its identity. Once the application is verified, it may change the active user (also called the “context”) on the machine. Each CCOW application also has an application “name” for which there can only be one instance. There is no correct application name (the passcode identifies which application is logging in). There may be multiple instances of the CCOW application connected to the CCOW vault from the same computer, however they must have different names. One name might be “I like HHAM”, while the other might be “I like CCOW”. The names are completely arbitrary.

After the application authenticates itself with the CCOW vault, the applications are ready to communicate the context (a.k.a. the active user)

3.8 Interoperability in Healthcare

It means the ability to communicate and exchange data accurately, effectively, securely, consistently with different information technology systems, software applications and networks in various settings and exchange data so the clinical or operational purpose and meaning of data are preserved and unaltered.

In order to achieve ehealth interoperability, legal, ethical, economic, social, medical, organizational an cultural aspects needs to be addressed.

Interoperability is the only sustainable way to help partners acting in various locations, with different expertise , perspectives, statuses and agendas, possibly cultures and languages, and using distinct information systems from different vendors, to collaborate harmoniously to deliver quality healthcare. At the very top of an ‘interoperability scale’ are three levels, each one subdivided as functional, syntactic, and semantic.

Levels of Interoperability-

- ✓ **Technical interoperability**- It ensures that systems can send and receive data successfully. It defines the degree to which the information can be successfully "transported" between systems.
  When applied to health care, some health care organizations have adopted the term "functional" as in "Functional interoperability is the ability of two or more systems to exchange information so that it is human readable by the receiver." The problem with the word "functional" is that is has so many possible meanings in health care domain. There are bodily functions, organizational functions, transmission of bits and bytes over a wire, computer software functions.

- ✓ **Semantic interoperability**- The ability for information shared by systems to be understood at the level of formally defined domain concepts so that the information is computer processable by the receiving systems. It is defined as the ability of information shared by systems to be understood… so that non-numeric data can be processed by the receiving system. Semantic interoperability is a multi-level concept with the degree of semantic interoperability dependent on the level of agreement on data content terminology and the content of archetypes and templates used by the sending and receiving systems." HL7 also defined a quality that is necessary for optimal semantic interoperability to exist. The quality-based rationale of the HL7 semantic interoperability messaging standard asserts that health information systems will communicate information in a form that will be understood in exactly the same way by both sender and recipient.

The greater the level of software-level semantic interoperability the less "human" processing is required. For some functions, this can provide relief from redundant, error-prone human data entry or analysis. However, it also creates opportunities for the intrusion of misleading information, even misguided policies, into patient care processes, if not thoughtfully and responsibly developed, tested and deployed.

- ✓ **Process interoperability**- This is defined as a social or workflow engineering which improves safety and quality in health care settings, and improves benefits realization. It deals primarily with methods for the optimal integration of computer systems into actual work settings and includes the following: • Explicit user role specification • Useful, friendly, and efficient human-machine interface • Data presentation/flow supports work setting • Engineered work design • Explicit user role specification • Proven effectiveness in actual use

One of the goals of information exchange and is defined as the ability of disparate digital entities to communicate together without human intervention. It is about connectivity and the ability to transfer, share and use data, information
and knowledge between systems. Semantic interoperability is essential for automatic computer processing which will enable the implementation of advanced clinical applications such as HER, laboratory systems and intelligent decision support systems.

HIMSS (Healthcare Information Management Systems Society) provides the following dimensions to the definition of interoperability-

- ❖ Uniform movement of healthcare data
- ❖ Uniform presentation of data
- ❖ Uniform user controls
- ❖ Uniform safeguarding data security and integrity
- ❖ Uniform protection of patient confidentiality
- ❖ Uniform assurance of a common degree of system service quality

3.9 Interface, Integration,Interoperability

Data integration – the automated aggregation and consolidation information from a variety of disparate systems and sources – across sites of care (inpatient, ambulatory, home), across domains (clinical, business, operational), and across technologies (text, video, images) – is the Heart of healthcare information technology. The call for improved data integration has come from the proliferation of advanced clinical and business systems in the inpatient and outpatient arenas, the increased use of home monitoring devices, the need to improve continuity of patient care and demands for heightened efficiency in a notoriously redundant and inefficient industry. Today, many provider organizations are grappling with how to effectively
connect disparate data– within their facilities and with business partners - to enhance value, safety and efficiency.

The integration of clinical data:

- Improves communication and information sharing among sites of care
- Offers a richer picture of the patients overall health and health history
- Can reduce redundant tests, procedures, etc.
- Reduces costs for resources (staff labor, interfaces, paper information relay)
- Provides for the timely consumption of patient data for physicians
- Provides opportunity to share databases. Fewer database entries mean fewer potential entry errors.
- Provides ability to access more data and records at a single portal.
- Installation of fewer systems — less capital and long-term maintenance costs.

Provider the ability to gather data and results for tracking evidence-based medicine.

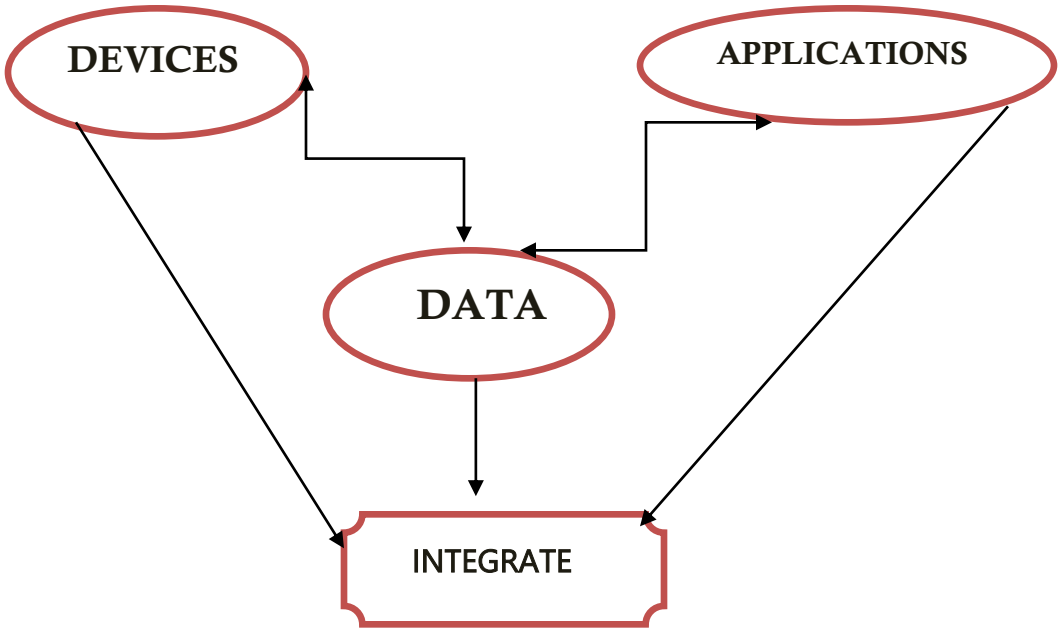


Figure 5- Data Integration

Barriers to Integration

Technical and organizational/political challenges must be overcome in data integration efforts. Some of the key technical barriers include:

- data quality and integrity, compliance with standards
- Differing uptime performance between systems (i.e., hospitals run 24 x 7 x 365 but physician practices do not and their systems may operate at differing levels of reliability)
- Lack of highly skilled technical data integration resources.

From an organizational/political side, the challenges are more subtle, but no less vexing. Integration of data from multiple systems and sources can be expensive, especially for the provider organizations which might want data integration with multiple community physicians. Depending on funding arrangements, physician groups may face similar cost concerns if they are seeking to share data with multiple hospitals and other organizations in the service area.

Interface	Integration	Interoperability
Boundary at which interaction occurs between two systems	Combination of diverse application entities into a relationship which functions as a whole	State which which exists between two application entities when, with regard to a specific task, one application entity can accept and understand data from the other and perform that task independently without any external intervention.
Data is maintained in multiple locations; thus, requiring more administration.	The data is maintained in one location.	Data flows between systems and presented in such a way that it can be understood by a user.

3.10 Planning of HL7 Interface

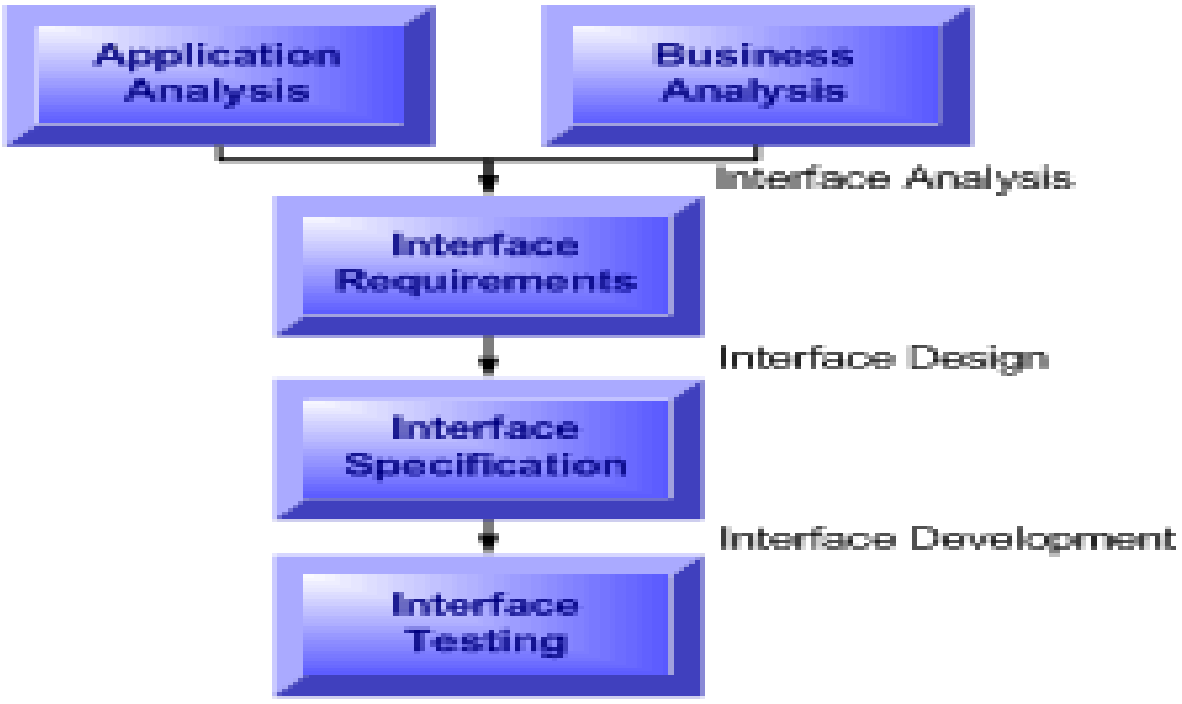


Figure 6- Planning of HI7 Interface

HL7 planning encompasses the first major activity for a typical health integration project. HL7 planning includes:

- Ø Business requirements analysis - the review of the overall project's business requirements and the role that HL7 interfacing will play in the realisation of those requirements.

  HL7 interface analysis may include:
  - Review of (and potential input to) documented business requirements
  - Participation in stakeholder reference groups used to validate and refine business requirements. These groups allow the interface analyst to better understand the objectives and business rules that apply to any required HL7 interfaces
  - Working with project business analysis to exchange ideas on how front-end functional requirements will align with HL7 interface requirements

- Ø Application analysis - The review of the applications required to be integrated (using HL7 interfaces) in order to achieve the project's business requirements.

The applications that underpin the business workflows and business requirements influence the HL7 interface analysis process. In the HL7 interface analysis process, for a set of identified applications, the application analysis will include:

- Review of the business processes practiced by the users of a particular application. For example the business processes performed by the pathology staff whose activities contribute an electronic health record.
- Review of the actual application used by a particular group of users.
- Review of existing HL7 interfaces used (or potentially available) by those identified systems.

- Ø HL7 interface requirements - Documentation of specific HL7 interface requirements identified as a result of business analysis and application analysis.

HL7 interface requirements forms the basis of the HL7 interface specification and typically includes:

- HL7 interface business requirements - based previously in business requirements analysis and application analysis).
- HL7 messages to support business business requirements (e.g. Order new pathology test, Update patient demographics)
- Data items required for each transaction and particular business rules required for a particular data item (e.g. business rules when updating a patient surname alias list

- HL7 interface specification - describes how the HL7 requirements will be realised in actual interface software components.

HL7 interface specifications describes how the interface requirements will be realised and typically includes:

- Technical description of the HL7 messages supported, the HL7 segments and HL7 fields.
- How the HL7 messages relate to the application front-end functionality, data base and code tables
- Specific technical business rules required and/or applied by the interface

∅ HL7 interface testing – It includes test planning, actual interface testing (such as HL7 interface unit testing, HL7 interface system testing and HL7 integration testing)

HL7 interface testing is linked to other project testing activities and typically includes:

- HL7 interface unit testing - typically interface specification based aiming to confirm that HL7 messages sent and/or received from each application conform to the HL7 interface specification.
- HL7 interface integration testing - testing of business scenarios to ensure that information is able to flow correctly between applications.
- HL7 interface system testing - end-to-end scenario testing focused on ensuring all relevant modules of all relevant applications are able to integrate correctly

3.11 Health Information Exchange (HIE)

It is defined as the mobilization of healthcare information electronically across organizations within a region or community. HIE provides the capability to electronically provide clinical information among disparate health care information system while maintaining the meaning of the information being exchanged.
Goal of HIE- facilitate access to and retrieval of clinical data to provide safer, more timely, efficient, effective, equitable, patient centered care.
HIE can occur in many ways. The following are examples of linking methods-

A. Federated model with shared repositories- this model uses a network of networks connected through the internet. Participants submit data to a regional repository responsible for patient identification, storage, system management, security and privacy
B. Federated model with peer to peer network- this model employs peer to peer network of participant networks connected through the internet. Participants maintain their own health information network with no centralized repositories. A national or regional entity maintains a master

patient index for HIE. Using this, participants can obtain patient data from the other individual participants network.

C. Non federated peer to peer network (co op model)- this approach uses a peer to peer network of participant network connected through the network. The network may be smaller and more community based. Participants maintain their own health information network and there is no centralized repository. All communications are direct from participant to participant.

D. Centralized database or data warehouse- a database or data warehouse may be a component or building block of other models. Storage, system management, patient identification, security and privacy are all managed at a central site. Participants submit data to and request data from this central site.

Figure 7- Health Information Exchange(HIE)

3.12 Privacy and Security for HIE

HIPAA
HIPAA is the legislation regulating confidentiality and security of patientcare data by establishing a set of federal guidelines to limit the use and disclosure of 'Protected Health Information' (PHI) to allow for necessary patient information flow between healthcare providers. HIPAA doesn't directly protect patient privacy, but rather places confidentiality based limitations on information provided to healthcare entities. HIPAA covers any form of PHI information including information electronically maintained and transferred.

The HIPAA privacy and security rules require that protected health information can be accessible t o patients , be maintained in a manner that maintains patient privacy, security and data integrity and be released in accordance with state and federal laws.

Minimum Necessary- the minimum necessary regulation under HIPAA's privacy rule requires that reasonable effort to be made to limit protected health information to the minimum necessary to accomplish the intended purpose. For routine and recurring disclosures, standard protocols must be implemented such as Continuity of Care rEcord standards. For all other disclosures, reasonable criteria must be developed for making the minimum necessary determination, and disclosures must be individually reviewed in accordance with these criteria.

Access to health information- Organizations will need to define who needs access to the information in the HIE and must ensure that there is appropriate authentication and auditing process. Patients have the right to access their health information in order to be informed consumers and to have control of their healthcare information. Due to the fact that healthcare decisions may have been based upon information from the exchange, organizations in the HIE may need to redefine their designated record set.

Identity management- the adopted exchange model should have robust patient identification capabilities. The patient identification process raises atleast two privacy concerns. First, is the correct patient is identified? If not, detailed patient information may be inappropriately disclosed about the person who was falsely identified as the patient. Second, if the correct patient is ultimately identified, does the identification process itself require disclosure of inappropriate or excessive amounts of patient demographic or health information? The search process should be designed as narrowly as possible to identify the correct patient record without exposing unnecessary information about other patients.

Quality of information- organizations exchanging health data must take responsibility for quality of data they made available to the HIE. They must establish rules addressing data definition, timeliness, accuracy, relevancy, reliability, accessibility, specificity, precision, currency and comprehensiveness.

Following are the causes of patient data loss-

- Unintentional action
- Malicious insider
- Lost or stolen computing device
- Technical systems problems
- Criminal attack

The following should be taken into consideration-

- **User/access rights**- User accounts give patients and their designated account administrators tools for granting, changing, withdrawing and auditing through activity logs, content and function specific user permissions related to viewing, updating, exchanging clinical and financial health data. Patients may select primary providers to authorize secondary providers with account access permissions, lesser than their own, as needed for consultation with specialists, referrals and transitions of care.

- **Patient consent**
- **Authorization**
- **Data security and safeguarding**

- **Digital signatures-** A digital signature or digital signature scheme is a mathematical scheme for demonstrating the authenticity of a digital message or document. A valid digital signature gives a recipient reason to believe that the message was created by a known sender, and that it was not altered in transit. Digital signatures employ a type of asymmetric cryptography. For messages sent through a nonsecure channel, a properly implemented digital signature gives the receiver reason to believe the message was sent by the claimed sender.

- **Data encryption**
- **Data protection and verification**

Security Technologies include-

- Code review tools (Example- Rietveld from Google, Code striker)
- Intrusion detection systems (Example- Snort, OSSEC HIDS)
- Physical security
- Anti-virus & anti-malware
- Firewalls (Example- Armor2net)
- Encryption
- Access control
- Data loss prevention (DLP)
- Virtual private network (VPN)
- Biometrics

3.13 Electronic Data Interchange(EDI) for healthcare

Driven by consumer demands for more efficient Healthcare services at reduced costs, President Clinton signed into law the Health Insurance Portability and Accountability Act of 1996, better known as **HIPAA**. This law gave the Department of Health the job of mandating standards Healthcare EDI. These mandated HIPAA standards are having a significant impact on the entire Healthcare industry.

The key thing to remember is that insurance companies will shoulder the majority of the burden of compliance to HIPAA as they must convert their systems to accept and implement these changes. The focus in the next few years will be on the implementation of EDI for basic Healthcare business processes which include claims transactions, remittance advices, enrolment and eligibility transactions. As compared to other industries like Financial Services, Retail and Logistics, the Healthcare industry, focused on providing service as providers, has not, as a whole, taken advantage of technology to a similar extent.

At present, the Health Care industry has worked through the process to define and implement sensible Health Care EDI standards for all flows of information in the industry for all participants. Most Health Care EDI Hubs have taken the HIPAA guidelines and implemented their own "flavour" of them to meet their business needs which are documented as "Companion Guides".

EDI Health Care Claim Transaction set (HIPAA EDI 837) is used to submit health care claim billing information, encounter information, or both. It can be sent from providers of health care services to payers, either directly or via intermediary billers and claims clearinghouses. It can also be used to transmit health care claims and billing payment information between payers with different payment responsibilities where coordination of benefits is required or between payers and regulatory agencies to monitor the rendering, billing, and/or payment of health care services within a specific health care/insurance industry segment.

For example, a state mental heath agency, may mandate all healthcare claims, Providers and health plans who trade professional (medical) health care claims electronically must use the HIPAA EDI 837 Health Care Claim: Professional standard to send in claims.. As the 837 provides the biggest benefit to all parties in the Health Care industry, it has been the focus of most implementations. It is expected to continue to be the document of choice for initial implementations.

Some of the benefits of the use of the EDI 837 Health Care Claim are:

- **Quicker Payment** - The payment floor for a clean electronic claim is 14 days versus 28 days on clean paper claims.
- **Accuracy** - Electronic billing requires claims edits, which ensures that claims are submitted with fewer billing errors. This results in a faster payment to providers.

- **Tracking Capabilities** - EDI 997 confirmation reports provide verification that your file(s) has been received. This report is available 24 hours after your file has been received

EDI Health Care Claim Payment/Advice Transaction Set - ERA (HIPAA EDI 835) can be used to make a payment, send an Explanation of Benefits (EOB) remittance advice, or make a payment and send an EOB remittance advice only from a health insurer to a health care provider either directly or via a financial institution. At present, the use of EDI in the Payment/ Payment Advice cycle in Health Care is still a uncommon document to send as the organizations in the payment cycle (Financial Institutions, Payers and Payees) place less value on this information than documents such as the Health Care Claim (HIPAA EDI 837), EDI Benefit and Enrolment (HIPAA EDI 834) and Health Care Benefit Inquiry/Response (HIPAA EDI 270, 271). That said, some of the advantages of receiving ERA instead of the paper Remittance Advice (RA) include:

- Quicker communication. The ERA is available the day claims are paid, rather than waiting for delivery of the paper Remittance Advice (RA) mailed through the Postal Service.
- The ERA can be downloaded and stored for future use.

EDI Benefit Enrolment and Maintenance Set (HIPAA EDI 834) can be used by employers, unions, government agencies, associations or insurance agencies to enrol members to a payer. The payer is a healthcare organization that pays claims, administers insurance or benefit or product. Examples of payers include an insurance company, health care professional (HMO), preferred provider organization (PPO), government agency (Medicaid, Medicare etc.) on any organization that may be contracted by one of these former groups. This document initially was implemented by large EDI complaint organizations (Ford, Kroger, Wal-Mart etc.) to enrol employees electronically. It is forecasted that this document will increase in popularity for sophisticated DI Hubs who wish to use it to automate the enrolment process.

EDI Health Care Eligibility/Benefit Inquiry (HIPAA EDI 270) is used to inquire about the health care benefits and eligibility associated with a subscriber or dependant under the subscriber's policy. A subscriber is a person who elects the benefits and is affiliated with the employer or the insurer. A dependent is a person who is affiliated with the subscriber such as spouse, child, etc., and therefore may be entitled to benefits. This transaction is generally initiated by medical facilities, hospitals or third party benefits management organizations to Health Care information sources (i.e., insurers, sponsors, payers, government agencies (Medicare, Medicaid).

EDI Health Care Eligibility/Benefit Response (HIPAA EDI 271) is used to respond to a request inquire about the health care benefits and eligibility associated with a subscriber or dependant. This transaction set can be used to communicate from health care information sources (i.e. - insurers, sponsors, payers, government agencies (Medicare, Medicaid) to health care information receivers (i.e. - physicians, hospitals, medical facilities) information about or changes to health care eligibility or benefits..

3.14 Process of data exchange in USA

Healthcare in USA(Department of Health and Human Services)

The healthcare system of the USA is the largest in the world in terms of funding both as percent of GDP and on per capita basis. USA spends about 16% of GDP or the government or through purchasing the insurance individually. Medicare (health insurance of elderly and disabled Americans), Medicaid(health insurance of low income people), TRICARE(Defense sector) and Veteran Aid are the major government insurance agencies through which healthcare is funded. As per WHO reports, USA is the largest spender on healthcare in the world.

The United States Department of Health and Human Services(HHS) is the department under the US government with a goal of protecting the health of all Americans and providing essential human services. The department includes 300 programs covering a wide spectrum of activities USA is a pioneer in health informatics and has led to the development of industry wide standards and guidelines for Electronic Health Records(EHR), Clinical decision support system(CDSS), health information exchange(HIE) systems, Medical terminology, Identity management, Computerised physician Order Entry(CPOE), Telehealth, m-health standards etc. the Department of HHS initiated the National Health Information Infrastructure(NHII) to develop and implement uniform standards across various e-health initiatives.

A number of U.S standard development organizations have developed clinical transaction standards for various purposes (ASTM, HL7, DICOM, IEE)and some of these like HL7 and DICOM are in widespread use in USA.
Other uses of IT in patientcare include Telehealth, Portable and handheld devices, GIS(Geographical Information system), GPS(Global Positioning System)

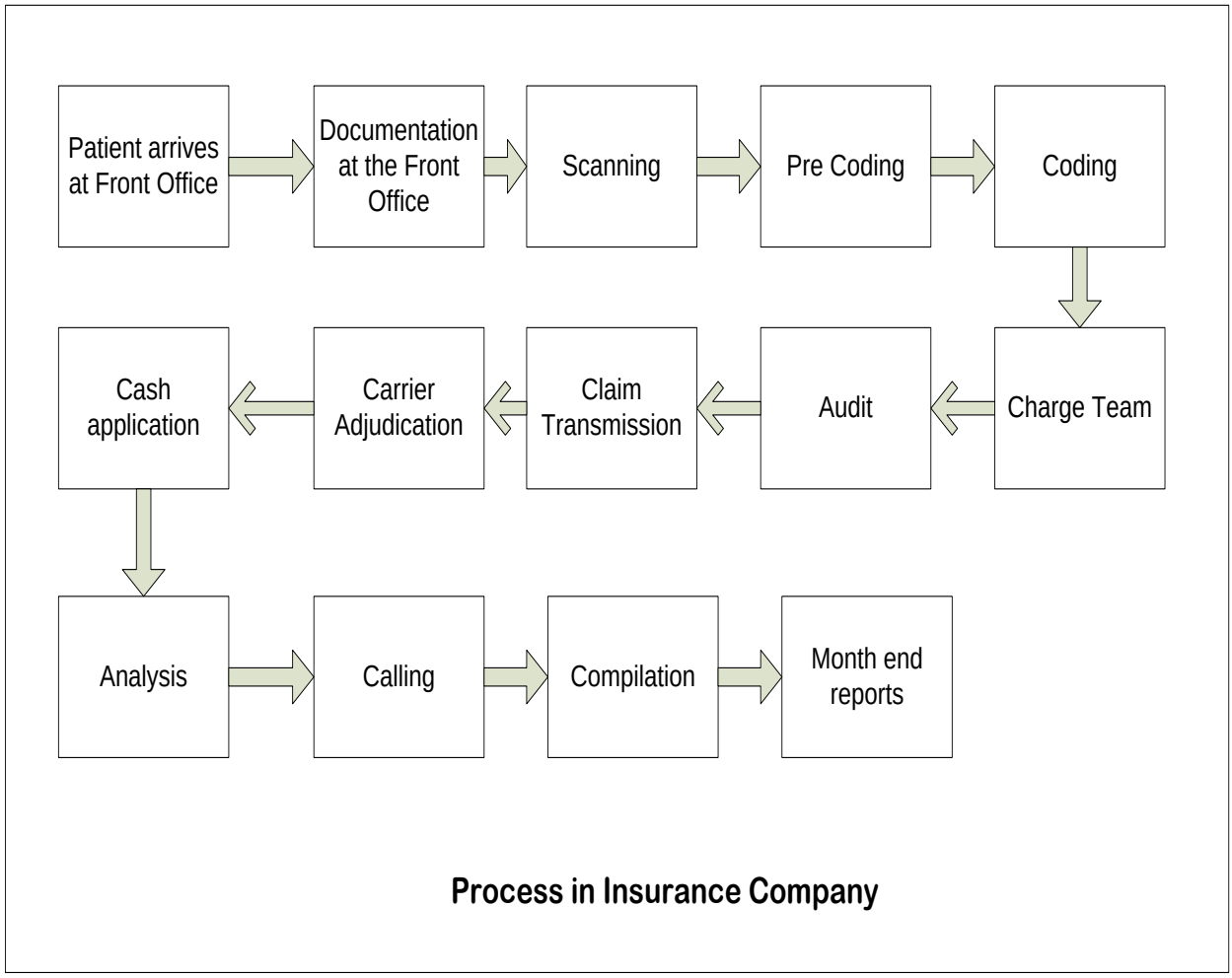


Figure 9 – Process in Insurance Company

The details of the processes followed in insurance companies particularly in USA healthcare scenario are described as-

- Front Office- A patient visits a doctor and explains his/her problem.The doctor then diagnoses the ailment and draws a chart explaining the treatment that needs to be rendered.
- Documentation at Front Desk- After the doctor completes the diagnosis, the patient hands over his insurance card copy at the Front Desk to claim for insurance. In case the card requires verification, information is obtained from the Insurance Agency.
- Scanning- Demographics, superbills/charge sheets, insurance verification data, a copy of the insurance card and any other information pertaining to the patient, are scanned and uploaded on to our secure FTP site. The team will then retrieve the files, split the images from the files and arrange them according to the

respective patient names.The files will then be sent to the appropriate departments with the control log for the number of files and pages received. Any illegible or missing documents will be identified and a mail would be sent to the Billing office for re-scanning.

- Pre-coding- Pre-Coders will enter the key-in codes for insurance companies, doctors and modifiers. Pre-coders will also add diagnosis codes and procedure codes that are not already present in the system.

- Coding- Medical Coding Team will assign the numerical codes required for CPT (Current Procedural Terminology) and the diagnosis code based on the description given by the provider.

- Charge Team- Our trained Medical Billing professionals will enter personal information about the patient from the Demographic Sheets. The Team will then check the relationship of the Diagnosis Code with the CPT. A charge will then be created according to the billing rules pertaining to specific carriers and locations. All charges will be accomplished within the turnaround time agreed with the client, which is generally 24 hours.

- Audit- The daily charge entry will be audited to check the accuracy of the entry based on carrier requirements to ascertain a clean claim.

- Claims Transmission- Claims will be filed and relevant information sent to the Transmission Department.The Operations Team will then prepare a list of claims that are transmitted electronically. Once the claims are transmitted electronically, confirmation reports will be obtained and filed after verification.Paper claims will then be printed along with attachments and dispatched to Insurance Agencies. Finally, transmission rejections will be analyzed and appropriate corrective action will be taken.

- Carrier Adjudication- The Carrier Utilization Review Department will review the processes regarding the claim for payment.The check and an Explanation of Benefits (EOB) will then be sent to the provider.

- Cash Application- The Cash Applications Team will receive the cash files (A copy of the check and EOB).The Team will then apply the payments in the billing software against the appropriate patient account.During cash application, overpayments are immediately identified and necessary refund requests are generated.The Analysts will then be informed of underpayments and denials.

- Analysis- Accounts Receivable analysts will research the claims for completeness and accuracy. The AR analysts will then set orders about making calls for the call center. The analysts will also research denied claims, rejections received from clearing houses and low payments by carriers. After this research is completed appropriate action will be taken.

- Calling- The call center executive will call the Insurance Agency and verify current status of the claim (whether it is being processed for payment or is being denied).Based on the claim status, the analyst will get the pre-requisites needed. If the claim is being processed for payment, a list of payment details will be compiled. If denied, corrective action will be initiated.
  The Call Center Team will receive work orders from the analysts. The Call Center Executive will then initiate calls to the insurance companies to establish reasons for the non-payment of the claims. All such reasons will be passed on to the Analysts for resolution.

- Compilation- . This scenario will be compiled in Excel for future use, when similar problems occur in any other specialty. This information will also be made available to anyone who needs to review past records, to identify solutions to any particular present scenario.

- Month end reports- At the end of the month, insurance companies will run procedure code usage reports and aged summary reports to asses what has been achieved for that particular month, and also to identify patterns of non payment if any.If any claim is found to be older than 60 days, immediate action will be taken. Any claims pending for clarification will be passed on to the respective account manager for remedial action

3.15 EHR Interoperability Model

EHR Interoperability enables better workflows and reduced ambiguity, and allows data transfer among EHR systems and health care stakeholders. Ultimately, an interoperable environment improves the delivery of health care by making the right data available at the right time to the right people.

Goals of EHR Interoperability Model-

- ☐ To establish a common industry reference for EHR Record interoperability..
- ☐ To establish a complementary model focused on interoperability characteristics EHR records, as companion to the HL7 EHR-S Functional Model (focused on functional characteristics of EHR Systems).
- ☐ To specify the EHR Record in context as immediate record (documentation) of the health delivery process, integral to work flow and concurrent to clinical practice.
- ☐ To build on HL7 v3 Reference Information Model, including primary classes: Act, Actor, Role, Participation…

2 types of Interoperability Model-

- ✓ EHR-S FM(Functional Model) specifies Functional Characteristics (Functions) of EHR System
- ✓ EHR IM(Interoperability Model) specifies Interoperability Characteristics of EHR Records.

Components of the EHR Interoperability Model

- ∅ ID (Column A)
- ∅ EHR Interoperability Assertion/Characteristic (Column B)
- ∅ Elaboration (Column C)
- ∅ Attribute Class> (Column D)
- ∅ Example (Column E):
- ∅ Use Case Example (Column F)
- ∅ Legal Record Requirement – Sample Profile (Column G)

- *End-to-End EHR Record Flow (Columns H – L)*
- Intermediary Application (e.g., interface engine) (Column K)
- Receiving EHRS/Application (Column L)
- *Key Stakeholder Assurance (Columns M – O)*
- HL7 EHR-S Functional Model Reference (Column Q)
- Normative (Column R)

WORKFLOW OF HOSPITALS (DEPARTMENT WISE)

3.17 HL7 Adoption in India

In India, there is a lack of healthcare IT standards as most of the processes are manual processes and there is no implementation of healthcare IT. So the data standards pertaining to data exchanges are also not there.

Standards like HL7 needs to be implemented for fast, rapid, error free, accurate, timely exchange of health data among different service providers.

IHL7 (Indian HL7) – A futuristic approach

Procedure Codes	Definitions
HL001	Patient Identification Number(PIN)
HL002	Patient Name(First name, middle name, last name,title,suffix)
HL003	Demographic details
HL004	Gender/Race/Ethnicity
HL005	Diagnosis/Treatment(Following ICD 10 Codes)
HL006	Date and time of admissiom
HL007	Date and time of discharge
HL008	Type of admission(Scheduled/Unscheduled/Emergency/Transfer)
HL009	Location(Ward/category/speciality, room/bed)
HL010	Payer Information(Self/Covered by insurance/employer etc)
HL011	Type of discharge(planned/Unplanned/LAMA/DAMA/Deceased)
HL012	Type of Deliveries (Normal/Caesarean/abortions etc)
HL013	Birth History(date and time of birth, name of hospital etc)
HL014	Immunizations
HL015	Investigation Results
HL016	Discharge Summary
HL017	Billing records
HL018	Current Medications
HL019	Date and time of surgery
HL020	Type of anesthesia used(none/local/general)
HL021	Allergies
HL022	Drug details(dosage, strength,preparation etc)
HL023	Types of investigation done(Lab, radiology etc)
HL024	Insurance data
HL025	Denial of Insurance

3.18 UseCase Stakeholders/Actors

Stakeholders	Contextual Descriptions
Clinicians	Healthcare providers with patient care responsibilities, including physicians, physician assistants, nurses, psychologists, pharmacists, and other licensed and credentialed personnel involved in treating patients.
Consumers	Members of the public that include patients as well as family members, and other parties who may be acting for, or in support of, a patient receiving or potentially receiving healthcare services
EHR System Suppliers	Organizations which provide EHR solutions to clinicians, patients. May include developers, providers, resellers, operators etc
Patients	Members of the public who receive healthcare services. For hospice providers, the patient and family are considered a single unit of care.
Healthcare Payors	Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations. As part of this role, they provide information on eligibility and coverage for individual consumers, as well as claims-based information on consumer medication history.
Healthcare providers	The healthcare delivery organizations like hospitals, nursing home, day care centers, standalone diagnostic center, etc which provide care to patients.
IT support staff	Persons directly involved with the maintenance, trouble shooting and upgradation of softwares installed in the healthcare organizations.

4.0 Results

After analyzing the US healthcare and the Indian Healthcare following Gap Analysis has been done in order to highlight the differences between the healthcare needs and demands of India with the Western Countries.

Gap Analysis (USA healthcare System vs. Indian healthcare System)

GAPS	USA Healthcare IT	Indian Healthcare IT
Use of HL7	Widespread Use	Limited Use
Government involvement	Direct involvement. Prevalence of Medicare(Govt Funded Insurance Payer)	Indirect Involvment through government funded hospitals
Use of health insurance	Prevalence of Medicare(Govt Funded Insurance Payer)	Less than 15% of people have health insurance(assocham.org)
Electronic Data Interchange(EDI)	Insurance payers use EDI, hence enforcing standards	Less enforcement of standards
Regulatory Environment	Defined guidelines under JCAHO	Largely Unregulated without any use of IT intervention
Quality Focus	Increasing focus on quality care(DRG, P4P,PQRI)	Not viewed as market differentiator due to lack of regulatory support
Comparative Spending	Larger IT spend(10-15% budgetary allocation)	Minimum IT spend(1-2% of revenues- Frost & Sullivan report)
Customization Issues	Little or no customization is required making the implementation successful.	High degree of customization leads to non- profitability of implementation process
Adoption of IT systems	High degree of adoption among doctors, nurses, paramedics etc	Manual systems still widely prevalent.
Data Integration	Centralized data repository with all the individual systems communicating with each other and with a centralized system	Decentralized data repository leads to poor usage of HL7 standards

5.0 Discussion

Interface/HL7 Challenges (in Indian Scenario)

- As a vast majority of hospitals in India are in the Government sector, there is very less penetration of IT in patientcare, medical records, diagnostic tests etc. Prevalence of manual systems and paper records are still there. So, until now, there has been no need of data exchange standards used for healthcare data exchange.

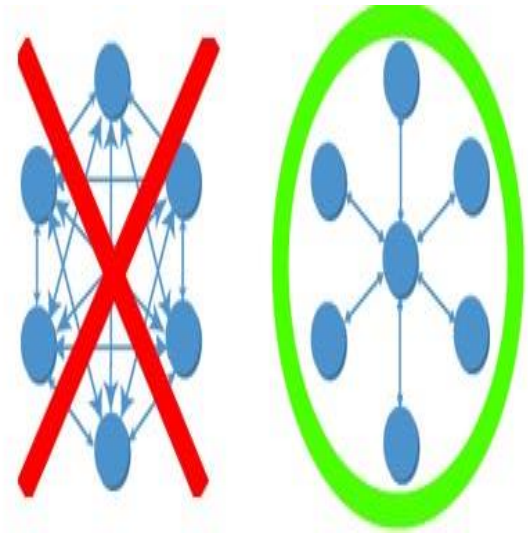
- As the messaging standards specified in HL7 are vast, complex, detailed and adapted according to US healthcare, its difficult to implement in Indian healthcare scenario.

- EMRs from one vendor don't always play nicely with EMRs from other vendors or with other hospital information management systems because they speak different languages. So integration issues are always there.

- Various healthcare organizations use different standards for exchanging healthcare data. A single nationwide health information exchange that relies on a single interoperability standard is a long way off.

- Not only the hospitals have poor data exchange standards, state and local public health agencies also have limited/no data transfer mechanisms. Data on disease surveillance, immunization records, vital statistics(MMR,IMR, CDR,CBR,TFR etc), population data are not exchanged within public health organization due to lack of standards. .

- Integration of data from multiple systems and sources can be expensive, especially for the provider organizations which might want data integration with multiple community physicians. Depending on funding arrangements, physician groups may face similar cost concerns if they are seeking to share data with multiple hospitals and other organizations in the service area. This makes adoption of HL7 standards even more difficult.



- Proliferation of point-to-point interfaces instead of using a hub-and-spoke type of model which creates confusion, problems with data integration.

- Lack of skilled and trained Health IT manpower with limited knowledge of data interoperability, data standards, HL7 etc. makes the implementation of HL7 difficult.

- The capabilities, requirements, and standards needed for consistent development, implementation, and maintenance of Clinical Decision Support have not been identified. Hence, there is limited need for having an integration interface.

- Financial incentives are not currently sufficient to promote the business practices and overall framework necessary for sustainable Healthcare IT.

- Current mechanisms do not ensure that the information transmitted is reliable, accurate, and representative of the appropriate patient. Clinicians may be reluctant to access exchanged information unless they have adequate assurance that the data is valid, accurate, and reliable.

5.1 Recommendations

- ✓ IT should be implemented in hospitals and other healthcare institutions which will automatically facilitate the need of standards for data exchange process.

- ✓ Interpreters like Gateways can be used for problems of integration of EMRs of two different vendors.

- ✓ A standard for data exchange should be implemented nationwide so that the critical healthcare data can be viewed, analyzed, retrieved from any parts of India whenever required.

- ✓ In a hospital/ healthcare organization, all individual systems should be connected to a single repository and the individual systems can speak to each other via the centralized database. This eliminates the confusion about the interoperability issues in a complex healthcare organization and creates a simple yet strong interface between various systems.

- ✓ Data validation and verification by experts should be done in order to make the quality of information transferred authentic. This can be done through Digital Signatures and the entire contact details of the concerned person should be mentioned incase any discrepancies happen.

- ✓ Appropriate funding should be made towards data interoperability and adequate training of the manpower should be done focusing on the integration issues and how to cope up with them.

- ✓ As patient data is sensitive, the data security and confidentiality should be kept in mind and care should be taken so that no data is lost or accessed by unauthorized persons in the process of data exchange. Security technologies like Data Encryption, Restricted Access etc, Biometrics should be implemented.

5.2 Conclusion

The HL7 V2 standard was created mostly by clinical interface specialists, and was designed to provide a framework in which data could be exchanged between disparate clinical systems.The V2 standard provides 80 percent of the interface framework, plus the ability to negotiate the remaining 20 percent of needs on an interface-by-interface basis.

HL7 provides a framework to support the process of mapping and exchanging disparate data. However, while the standard provides needed guidance, every provider organization and vendor takes advantage of HL7's flexibility to adapt data syntax to different clinical workflows.. As a result of the many variances and adaptations of the HL7 standard, there's no truly standard way that systems are implemented and data is handled. In response, analysts and interface engineers are forced to undertake manual, tedious work as part of implementation process — even if they're using state-of-the-art interface engines.

It should be ensured that the HL7 message is understood by healthcare vendors before and during clinical data processing. Gap analysis or conformance checking of an HL7 message is a logical process used to determine whether a message from one particular medical device or application is compatible to a standard HL7 messaging formatting.

HL7 has its own interface challenges and practical difficulties to implement in Indian Scenario. A consolidated effort to implement data exchange mechanisms, HL7, interface engines, should be made with the help and support of each stakeholder involved in the healthcare delivery process in order to make the healthcare delivery process in India at par with other western countries.

6.0 CASE STUDY

Study on work life balance and use of IT for health promotion activities among IT professionals.

Problem Background

Work–life balance is a broad concept including proper prioritizing between career and ambition on the one hand and Health, pleasure, leisure, family and spiritual development on the other. A proper balance should be maintained between the professional life at office and personal life which includes interacting with immediate family, attending to home, enjoying hobbies, having time for personal well being etc.

At the core of work life balance are two concepts- Daily Achievement and Enjoyment. Achievement defines how successful a person is in carrying out his job duties while enjoyment does not just mean happiness. It means Pride, Satisfaction, Happiness, Celebration, Love, a Sense of Well Being, in short all the Joys of Living. While most of the people working in corporate are successful in their respective careers and Achieved what they wanted to but the "enjoyment" part is missing from their life due to their high demanding jobs.

Though work pressure is present in all the industries but it is most severe in the 24x7 IT sector. Despite a high disposable income and the glamour of consumerism, employees in the information technology (IT) and IT-enabled services are not happy enough.

The long working hours, overwork, hectic work schedule, frequent official trips, tremendous pressures, deadlines at work in the IT sector have posed serious mental and physical health related issues of the employees.

The long working hours and work overload is typical of the IT industry, according to many human resources managers. Though most IT firms have a five-day week, the workload is going up. After the 2001-02 slump, companies that downsized did not always hire more people after business picked up. This means that being called to work on weekends and 14-hour working days have become synonymous with the sector.

All these factors have contributed to stress, chronic headaches, heart problems, insomnia, high blood pressure, hypertension etc.

Interpersonal relationships are also affected. Poor family relations, strained marital relations, divorces and separation are common these days.

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APPENDIX