

Dissertation Training
at
ATTUNE TECHNOLOGIES

The Ideal Laboratory Information System

by
Retika Lohani
Enroll No. Pg/13/054
Under the guidance of
Ms. Kirti Udayai

Post Graduate Diploma in Hospital Management

2013-15



International Institute of Health Management Research
New Delhi

The certificate is awarded to

Name Retika Lohani

In recognition of having successfully completed her
Internship in the department of
Marketing and Sales

and has successfully completed her Project on
Ideal Laboratory Information System

Date 30-May-15

Organization Attune Technologies

He/She comes across as a committed, sincere & diligent person who has
a strong drive & zeal for learning

We wish him/her all the best for future endeavors



Training & Development

Head-Human Resources

TO WHOMSOEVER IT MAY CONCERN

"This is to certify that Retika Lohani student of Post Graduate Diploma in Hospital and Health Management (PGDHM) from International Institute of Health Management Research, New Delhi has undergone internship training at Attune Technologies from 3-Feb-15 to 3-May-15. The Candidate has successfully carried out the study designated to him during internship training and his approach to the study has been sincere, scientific and analytical. The Internship is in fulfillment of the course requirements.

I wish her all success in all her future endeavors.



Dr. A.K. Agarwal
Dean Academics and
Student Affairs
IIHMR, New Delhi



Ms. Kirti Udayai
Assistant Dean
IIHMR, New Delhi

Certificate Of Approval

The following dissertation titled "**The Ideal Laboratory Information System**" At "**Attune Technologies**" is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **Post Graduate Diploma in 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.

Name

DR ASHOK K AGARWAL
Dr A.K. KHOKHAR


Signature


Agarwal
Khokhar

Certificate from Dissertation Advisory Committee

This is to certify that **Dr. Retika Lohani (PT)** a graduate student of the **Post- Graduate Diploma in Hospital Management** has worked under our guidance and supervision. She is submitting this dissertation titled "**The Ideal Laboratory Information System**" At "**Attune Technologies**" in partial fulfillment of the requirements for the award of the **Post- Graduate Diploma in Hospital Management**.

This dissertation has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other dissertation, monograph, report or book.


Ms. Kirti Udayai
Assistant Dean
IIHMR, New Delhi


Mr. Prashant Vijay Dalvi
Regional Manager
Attune Technologies

INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH,
NEW DELHI

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled "**The Ideal Laboratory Information System**" and submitted by Retika Lohani Enrollment No. PG/13/054 under the supervision of Ms. Kirti Udayai for award of Postgraduate Diploma in Hospital Management of the Institute carried out during the period from 3-Feb-15 to 3-May-15 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.


Signature

TABLE OF CONTENTS

S. No	CONTENT	PAGE No
	Acknowledgment	Xi
	Abstract	xii-xiii
	Introduction	1-4
	Acronyms	5
	Background	6-8
	Problem statement	9
	Scope of study	10
	Review of Literature	11-20
	Methodology	21
	Data analysis	22-24
	Result	235
	Discussion	26-27
	conclusion	28
	Limitation	29
	Recommendation	30
	References	31-32

ACKNOWLEDGEMENT

Words can never be enough to express my sincere thanks to **ATTUNE Technologies Pvt. Ltd.** and especially **Mr. Prashant Vijay Dalvi** my reporting officer for his continuous guidance and support.

I convey my gratitude to **Mr. Partha Sarthy, Head Sales and Marketing of ATTUNE Technologies Pvt. Ltd.** who gave me the opportunity to be a part of this Project. I express my greatest thanks to **Ms Vasuki , my senior in ATTUNE Technologies** for her support and guidance to make this project possible.

I also express my thanks to my IIHMR mentor **Ms. Kirti Udayai** without whom this project would have been a distant reality. I would also thank **Dr. L.P.Singh** and **Dr.A.K Agrawal** .I pay my sincere offering to the almighty without whose grace I would not be able to add a new dimension to my life.

In the end, I am thankful from the core of my heart to my beloved parents and my husband **Mr. Vivek Joshi** who supported me throughout the course of study. Last but not the least; I am thankful to all the colleagues for their help and cooperation.

Retika Lohani

Hospital administration

2013-15

Roll No: PG/13/054

EXECUTIVE SUMMARY

A significant aspect of health care reform has been the encouragement of the use of health information technology (HIT), which includes institutional use of electronic health records (EHR) by doctors and healthcare facilities such as hospitals. This has resulted in clinical laboratories needing better, more effective laboratory information systems (LIS) that can streamline workflow, integrate multiple laboratory specialties, including non-clinical laboratory components, and have the flexibility to grow with the technology for both the LIS and laboratory testing⁸.

A laboratory information system, or LIS, is a software program that provides all the basic functionality needed for a clinical laboratory, whether that laboratory is hospital-based or a standalone commercial laboratory facility. Various components of the LIS will handle patient check-in, order entry, results entry, physician and patient demographics, specimen processing, and have some level of reporting ability^{1,2}.

Laboratory information systems (LIS) are critical components of the operation of clinical laboratories. However, the functionalities of LIS have lagged significantly behind the capacities of current hardware and software technologies, while the complexity of the information produced by clinical laboratories has been increasing over time and will soon undergo rapid expansion with the use of new, high-throughput and high-dimensionality laboratory tests. In the broadest sense, LIS are essential to manage the flow of information between health care providers, patients, and laboratories and should be designed to optimize not only laboratory operations but also personalized clinical care¹.

The basic components, however, are too basic for most modern clinical laboratories, which usually have more complex requirements: the ability to interface with the institution's electronic medical record(EMR) and to interface with the laboratory's instrumentation, which allows patient results to be directly entered into the database and then into the EMR; Web-based order entry/result inquiry; and workload balancing.

The LIS often has non-clinical functionality such as workflow monitoring and billing services. A modern medium to large clinical diagnostic laboratory is made up of numerous specialized laboratory units – microbiology, chemistry, hematology, anatomic pathology, etc. – which all have unique needs and workflows. This presents challenges for LIS's, which can be handled through modular systems that utilize a single database, are flexible and scalable, and can be customized for each laboratory unit or institution's needs. Many laboratories also require customize non-clinical applications like billing and client connectivity⁸.

ACRONYMS

EHR – Electronic Health Records

EHRIS - Electronic Health Record Information System

HIS – Hospital Information System

HIPPA – Health Information Protection & Portability Act

HL7 – Health Level 7

ICT – Information Communication Technology

IT – Information Technology

OPD - Out Patient Department

QMS - Queuing Management System

SDLC – Software Development Life Cycle

SRM -Supplier Relationship Management

EDI- Electronic Data Interchange

MM -Materials Management

ORGANIZATION

About the Organization

ATTUNE Technologies is an India based organization with its HQ based in Chennai, Tamil Nadu and Singapore. The CEO of the organization is Mr. Arvind Kumar. The organization came into existence in November 2008. It is one of the pioneers in Cloud Based LIS, ATTUNE TECHNOLOGIES offers next generation Healthcare IT products to the market with primary focus on delivering business benefits to its customers. Technology platform & architecture can serve a Single Centre as well as a National Healthcare Network. They have more than **3 MILLION PATIENT RECORDS** on cloud. They are backed by premier investors from **Singapore** and **US**.

Their unique solutions run in METROPOLIS, SERUM, MEDALL Precision and many more eminent labs. Customers are in **Singapore, India, Philippines, Indonesia, Kenya, Sri Lanka & Malaysia**. They constantly keep innovating new solutions for the entire healthcare value chain. They now are having 200+ employees working with them since their origin¹¹.

Products of Attune:

- **Attune Health Kernel** is a complete state of the art, secure & web-based solution for hospitals that integrates all the departments and branches that are geographically separated. All the hospitals/branches needs are low-end PC's and Internet connectivity with rest of the IT infrastructure and software taken care by us.
- **Attune Lab Kernel** is an advanced and contemporary software that combines all the collection centers, branches and partner networks into a single platform to facilitate easy functioning.
- **Attune Clinic Kernel** is a complete state of the art, secure & web-based solution for clinics and Clinic chains that integrates all its departments and branches that are geographically separated. All the clinics/branches needs are low-end PC's and Internet connectivity with rest of the IT infrastructure and software taken care

Modules in Attune LIS¹¹:

- ◆ Sample registration and
- ◆ Billing
- ◆ Pre- Analytic-al sample tracking
- ◆ Sample accession and chain of custody
- ◆ Analytic-al work flow & decision support system
- ◆ Report Publishing & Dispatch system
- ◆ Client Management
- ◆ Lab purchase, inventory & consumption tracking
- ◆ Lab interfacing & interoperability
- ◆ Attune Lab kernel Extensions

Vision¹¹ - To manage world's health information

Values¹¹ - To provide innovative solutions to business problems by appropriate usage of technology

Work culture at Attune¹¹:

Work culture at Attune includes the trio factor:

- Entrepreneur
- Team work
- Positive contribution

Entrepreneur¹¹- Culture and Innovation: We actively foster Entrepreneurship and Innovation across the organization. In this era of Knowledge Economy, we strongly believe that the most valuable asset of an organization is its human talent. By promoting Informed Risk taking, we provide the ability to tap the combined potential of individual team members to add more value to our customers. For us, encouraging Innovation involves fostering a culture of applying un-conventional ideas to solve everyday business problems of our Customers. By challenging ourselves and practicing a vibrant and informal work culture, we ensure constant flow of ideas and suggestions across the organization.

Team work¹¹ - One of the critical success factors of our business model is the ability of our project teams to deliver effective solutions to our Customers. This requires seamless co-ordination and transfer of knowledge among various specialized teams. Ability to work in cross-functional teams is a key pre-requisite for any member coming on board. Our Recruitment, Retention, Reward & Recognition Policies are aligned to foster and encourage team work across all levels of the organization.

Positive contribution - The organization promotes a culture where everyone is free to challenge the ideas of any other person in the organization. Every employee is expected to positively challenge the issues and come out with alternatives and in the end, the valid propositions are accepted based on objective discussions. Once a decision has been arrived at, the team goes ahead implementing it without postponing any further

Position and Description

Designation:- Business Development Manager

Job Purpose and outline

Business development includes a number of techniques designed to grow an economic enterprise. Such techniques include assessments of marketing opportunities and target markets, intelligence gathering on customers and competitors, generating leads for possible sales, follow-up sales activity, formal proposal writing and business model design. Business development involves evaluating a business and then realizing its full potential, using such tools as marketing, sales, information management and customer service.

Key Facets of job includes-

- ◆ Partner with sales staff to identify accounts that have growth potential

- ◆ Interact with executives in the customer organization to learn about the customer's business and to strategize about growth plans

- ◆ Coordinate all aspects of on-site, customer events(eg. Attune resources, customer availability , agenda, travel plans)

- ◆ Analyze and monitor the performance of the customer base to identify areas of opportunity and to pre-empt customer issue

- ◆ Manage own territory and sales target

- ◆ Support the marketing team in delivering appropriate marketing campaigns to the local customers

- ◆ Interact with product manager to learn about new products, new vendors, and vendor promotions

- ◆ Introduce vendors into accounts to help position specific products.

INTRODUCTION

OBJECTIVE

General objective

To improve the clinical care by intelligent management of laboratory information system.

Specific Objective

- ◆ To recommend suggestions
- ◆ To help in optimizing the operation of clinical laboratories

Our current information society makes extensive use of information system and technology . In the field of health care, information technology has been applied as long as computers have existed, and many types of information technology applications have been developed. However, there still exists a potential for growth of information technology in health care. Bangemann report foresees that application of information technology will result in saving the health care costs in better service accessibility in more effective and efficient service delivery and in better support for elderly and home care. In fact, health information system are even seen as an essential prerequisite for rational and efficient decision making in health care². In Finland, the Ministry for Social Affairs and health produced a strategic plan on how to better utilize information technology and system in social services and health care. The visions driving this plan focus on the implementation of cost effective, custom oriented seamless care processes, networking of service production and delivery, and improvement of the well being of service providers, patients, clients and citizens¹.

The first LIMS solution appeared in the 1970s and the first commercial solution was launched in 1982.¹

Two types of LIMS are currently on the market:

- Commercial (license based solutions)
- Open Source (free access solutions designed by web communities)

LIMS have multiple uses in quality control/quality assurance (QA/QC), manufacturing, R&D laboratories, workflow and data tracking support. Compared to ELN, LIMS is highly configurable and scalable (well adapted for research in genomic and genetic laboratories for example) with a flexible architecture and smart data exchange interfaces.

1.1 What is a **LIMS**?

The modern laboratory exists in an environment that produces a large amount of data. With the advent of new technologies, both the quality and quantity of information is increasing exponentially. This increase of data can cause significant problems and methods are needed to manage it. One such method used is a LIMS². A LIMS provides a way of automating part of the laboratory system. In a traditional laboratory 75% of the total cost comes

from manpower. Removing the need for some human interaction can significantly reduce overheads. The primary function of most laboratories is to provide validated information under some sort of time constraint and then based on that information, allow customers to make decisions¹². Nowadays, traditional record keeping solutions are simply not up to the task. A LIMS can be of great importance in integrating laboratory operations with the laboratory itself. One of the most important aims of a LIMS is the integration of many different subprocesses, bringing together and consolidating the efforts of potentially many individuals and consequently speeding up the whole process. LIMS can save considerable amounts of time and dramatically improve the level of data access for all stakeholders of any given project. This is where a LIMS can become extremely beneficial. The sooner the user is notified of a problem, the sooner that problem can be fixed and the less the solution will cost^{12,8}. The ideal LIMS should help provide the documentation to ensure that a laboratory and all of its operations exist in compliance. LIMS have been used for over 20 years and the technology has been considerably evolved during this time. This paper will document the current state of the LIMS technology and attempt to identify some of the pitfalls of the current technology.

1.2 Benefits of a **LIMS**

A LIMS provides benefits for many of the users of a laboratory. However, a LIMS does represent an expense that must be considered. This expense will almost certainly have to be justified by a level of higher management. The following is a brief outline of several of the main benefits identified and realized from current users of LIMS.

- ◆ Information can be obtained with the click of a button rather than having to dig through files.
- ◆ Years of data can be kept easily without the need for traditional archiving.
- ◆ The improvement of business efficiency
- ◆ Improvement of data quality (all the instruments are integrated).
- ◆ Automated log-in, tracking and management.
- ◆ Automated customer reports (Turnaround Time, Work Load).
- ◆ Automated Integration of Hand-held LIMS devices.
- ◆ Automated Quality Control.
- ◆ Daily Quality Reports.
- ◆ Easily accessible data via the web.

Historically the LIMS, LIS, and Process Development Execution System (PDES) have all performed similar functions. Historically the term "LIMS" has tended to be used to reference informatics systems targeted for environmental, research, or commercial analysis such as pharmaceutical or petrochemical work. "LIS" has tended to be used to reference laboratory informatics systems in the forensics and clinical markets, which often required special case management tools. The term "PDES" has generally applied to a wider scope, including, for example, virtual manufacturing techniques, while not necessarily integrating with laboratory equipment

PURPOSE OF THE STUDY

Laboratory services are an essential and fundamental part of all health systems. Reliable and timely laboratory tests are at the center of the efficient treatment of patients. Moreover, prevention and management of infectious and noncommunicable diseases requires accurate laboratory diagnostic information. Many therapeutic decisions rely heavily on data from health laboratories and, at the time of disease outbreaks or other public health events, laboratories are at the very heart of the public health investigation and response mechanisms. Today's world cannot afford unreliable laboratory results, wasting precious time, precious samples, and too often, precious lives⁵.

Laboratories offer their services to many clients: patients, physicians, or public health programme for evidence based decisions. Many medical hospital, public health, and academic laboratories -- be they public or private -- contribute through their diagnostic activities to health care and public health improvement. In addition, animal health, food safety, and environmental health laboratories' services contribute to health care and public health security. Therefore, many public health programme are conducting laboratory assessments for different purposes and objectives^(1,3).

This document offers guidance to assess laboratory organization and the individual laboratory system. It describes a general process for assessing laboratories and provides questionnaires to help assessing the individual laboratories. The document and its questionnaires can be used as such or after an adaptation to meet local requirements or specificities and better fit the assessment context. The sample of the document is any individual employed in laboratory organization. This document does not intend to replace the current laboratory information system used by the various organization but to assess the requirements or needs of the laboratory organization about the laboratory information system which will help the health care It companies to meet the local requirements of there client

SCOPE OF THE STUDY

A LIMS provides benefits for many of the users of a laboratory, information can be obtained with the click of a button rather than having to dig through files. Years of data can be kept easily without the need for traditional archiving. The improvement of business efficiency⁵.

Patient can be registered easily and details are maintained for long time.

Sample transferring receiving made easy.

Processing sample is the most time consuming process, interfacing and manual processing will be easy using LIMS. Results are gone under four levels for rechecking which will ensure accurate result and quality. Immediate report via mail will help patient for diagnosis of disease⁸

REVIEW OF LITERATURE

Health information system and market growth

Healthcare information system is an extensive integrated system which captures, stores, manages and transmits information related to the health of individuals or the activities of organizations that work within the healthcare sector. Globally, increase in aging population is playing a major role in increasing the demand of healthcare information system. Older people have less regenerative abilities and are more prone to disease, syndrome and sickness. As a result, healthcare information system market is expected to grow at a CAGR of about 7.1% during 2013 – 2019⁵.

Some of the key driving factors for the healthcare information system market are:-

- ◆ Aging population
- ◆ Rising healthcare cost
- ◆ Rising government initiatives
- ◆ Rising need for integrated healthcare system
- ◆ And rising investments by healthcare IT players.

However, the market faces some restraints such as lack of experienced professionals, high maintenance & service expenses and interoperability issues. North America has the largest healthcare information system market and Asia is the fastest growing healthcare information system market. Some of the fastest growing markets for healthcare information system are China, India, Japan and the U.S. Adoption of wireless and cloud computing is constantly on the rise, which is resulting in reduction in operational costs. For instance, the number of patients who used home health monitoring systems was about 2.8 million in the world in 2012. The growth rate for home health systems is projected to increase to 26.9% in the near future. Similarly, About 5.7 million patients are expected to be monitored with a wireless medical device by 2015⁵.

Laboratory information system and the market growth

Laboratory information system is a complex information system designed for data and information management related to industrial and medical-related laboratories including clinical and analytical laboratories. Laboratory information system allows users to obtain, store, manage, retrieve and record laboratory data. Laboratory information system provides information that helps in the diagnosis, prevention, management and treatment of disease, as well as being an indicator for individual and population health. There is no standard laboratory information system designed due to the fact that client laboratories are highly diverse and have different requirements. Therefore, a laboratory information system is developed, customized and configured according to the needs of a laboratory. Globally, improvement in healthcare services is playing a major role in increasing the demand of laboratory information system. As a result, this market is expected to grow at a CAGR of about 7.7% during 2013 – 2019. Improvement in healthcare services in different parts of the world is increasing the global laboratory information systems market^{4,5}.

Rising cases of fatal diseases and their diagnostic and treatment needs are some of the major factors driving the demand for laboratory information systems in the region. Also, its public funded structure is acting as a significant driver for the North American market for laboratory information systems. In addition to increasing disease incidences, government initiatives to promote the use of laboratory information systems have resulted in Europe becoming the fastest growing laboratory information system market. Clinical diagnostics laboratory information system has the largest market share on the basis of its applications and is expected to grow at a CAGR of about 8.9% during 2013 – 2019. On the basis of its mode of delivery, the market can be classified into web based technology, on-premise technology and cloud based technology market for laboratory information systems⁵.

Above mentioned theory indicates the importance of LIS in laboratories and how a lis can improve the efficiency and quality of a laboratory management, it indicates the increasing market growth of health information technology and how Asia is fastest growing industry for health information technology.

LIMS/LIS

In 1982 the first generation of LIMS was introduced in the form of a single centralized minicomputer, which offered laboratories the first opportunity to utilize automated reporting tools. As the interest in these early LIMS grew, industry leaders like Gerst Gibbon of the Federal Energy Technology Centre in Pittsburgh began planting the seeds through LIMS-related conferences. By 1988 the second-generation commercial offerings were tapping into relational databases to expand LIMS into more application-specific territory, and International LIMS Conferences were in full swing. As personal computers became more powerful and prominent, a third generation of LIMS emerged in the early 1990s. These new LIMS took advantage of the developing client/server architecture, allowing laboratories to implement better data processing and exchanges⁵.

By 1995 the client/server tools had developed to the point of allowing processing of data anywhere on the network. Web-enabled LIMS were introduced the following year, enabling researchers to extend operations outside the confines of the laboratory. From 1996 to 2002 additional functionality was included in LIMS, from wireless networking capabilities and georeferencing of samples, to the adoption of XML standards and the development of Internet purchasing⁵. As of 2012, some LIMS have added additional characteristics that continue to shape how a LIMS is defined. Examples include the addition of clinical functionality, electronic laboratory notebook (ELN) functionality, as well as a rise in the software as a service (SaaS) distribution model⁴.

A Laboratory Information Management System (LIMS), sometimes referred to as a Laboratory Information System (LIS) or Laboratory Management System (LMS), is a software-based laboratory and information management system that offers a set of key features that support a modern laboratory's operations. Those key features include — but are not limited to — workflow and data tracking support, flexible architecture, and smart data exchange interfaces, which fully "support its use in regulated environments."¹ The features and uses of a LIMS have evolved over the years from simple sample tracking to an enterprise resource planning tool that manages multiple aspects of laboratory informatics²

INNOVATION IN LIS

Modern clinical laboratories are purveyors of information, in the form of laboratory results, which may be numbers, text, graphs, or other images, together with interpretative data, to assist health care providers in delivering optimal patient care. The complexity of the information produced by clinical laboratories has been increasing over time, and with the advent of large-scale analytic techniques, such as micro arrays and next-generation sequencing, the amount of data produced will rapidly grow by several orders of magnitude. Advanced developments in data management and bio informatics will need to be incorporated into LIS for these large data sets to become clinically useful. In addition, the ability to query large cross-sectional laboratory databases (data mining) is increasingly used to improve the quality and efficiency of health care delivery. These two tendencies mandate an ever-expanding capacity and processing need for LIS and supporting hardware. Increasingly, the focus of efforts to improve the quality of laboratory operations is shifting from the analytic phase, which currently presents few problems, particularly for those tests performed by highly automated instruments, to pre analytic and post analytic aspects of laboratory testing. Advanced LIS and associated database and expert systems will be critical to the goal of improving the quality of the extra-analytic aspects of laboratory testing, including the implementation of paradigm-shifting innovative approaches⁷

Comparison between Sepulveda, Young's model of ideal LIS and Ripples model

Sepulveda and Young have outlined the requirements for the Ideal Laboratory Information System (Sepulveda and Young 2012). The challenge they see for the laboratory information System (LIS) is not only to optimize handling of high-throughout and high-dimensionality tests within the laboratory, but to optimize how the laboratory tests contribute to personalized patient care.

They outline the features required for this ideal information system, shown below in Figure 1.

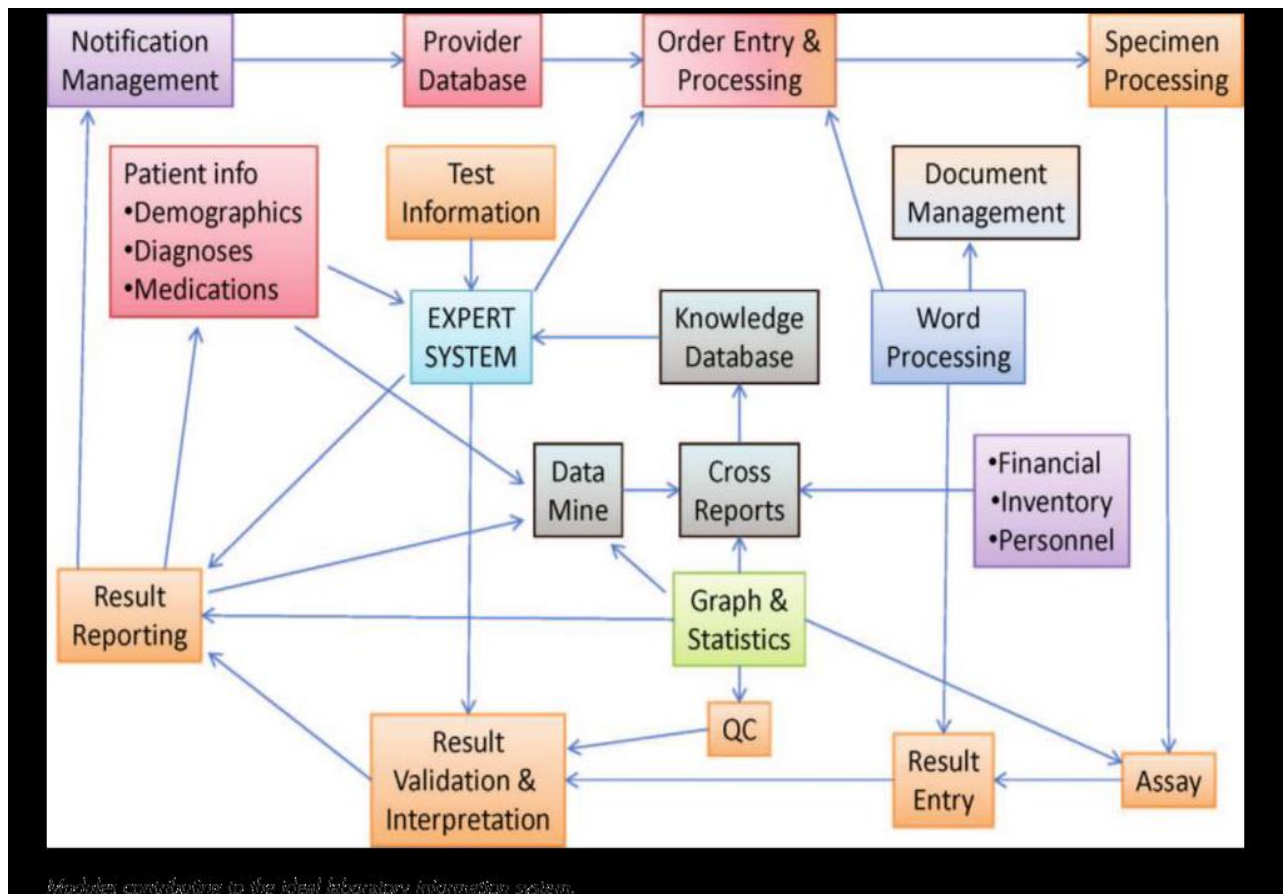


Fig 1. The components of the ideal laboratory system taken from Sepulveda and Young (2012)

The ideal laboratory information system can largely be achieved now, by supplementing a current LIS with Ripple Down. Figure 2 shows Sepulveda and Young's diagram again, but boxes shaded in blue for all the tasks where Ripple Down contributes and the data that Ripple Down can use and Sepulveda and Young believe should be used in the ideal Laboratory Information System. Ripple Down knowledge builder module has been added to the figure, because the central feature of Ripple Down is that the knowledge base is entirely under control of the pathologist or other senior laboratory staff, who can very easily change and add rules without reference to the IT department.

Order Entry and Specimen Processing

Conventional LIS all have modules for order entry, but at most provide some minimal check that the order is appropriate. The Ripple Down Data Entry Auditor enables the Data Entry Manager to write rules to ensure that tests ordered comply with health rebate and insurance guidelines; that the tests are appropriate given previous tests and other information about the patient either current or from their history, that billing information is correct, that the referring and copy doctor details are correct etc. Customers using the Ripple Down Data Entry Auditor make significant savings by ensuring inappropriate tests are not ordered, and contribute to patient care by helping to ensure optimal tests have been ordered and that reports are delivered to the correct doctors³.

Ripple Down users can also include rules for reflexive testing depending on results so far, slide-making decisions, and other workflow in the laboratory, improving both efficiency and patient care¹.

Result Validation and Interpretation

A major role for Ripple Down is in providing interpretative comments for laboratory results. Rather than a simple piece of canned text, the pathologist can write rules that take into account all the information that is available in the LIS: previous results and whatever clinical notes or other information is available. This allows very patient specific and useful advice to be provided. Providing high quality advice does impact on medical care. For example a laboratory using Ripple Down to provide information about lipid results showed a consequent decline in patient's low-density lipoprotein levels³.

The particular advantage of Ripple Down is that rules can be written very rapidly and easily taking on average only two minutes for a pathologist to write a rule and revalidate the knowledge base. This means highly specific rules can be written to produce the reports the pathologist believes are most useful for the clinicians and patients that use that particular laboratory service¹.

Validation

Ripple Down includes a Validate module where the pathologist or other senior staff will accept or reject the comment produced by Ripple Down for a report. If the comment is rejected, the case can then be referred to the Knowledge Builder to add another rule if appropriate. Statistics are also provided in the Validate on how often a particular comment is changed, so when the pathologist has sufficient confidence in a comment being made reliably, they can choose to have reports with this type of comment auto-validated – sent directly to the referring clinician without manual checking. Some reports might rapidly be set to 100% auto-validation, while reports for some other patterns of results might never be auto-validated¹.

Pathologists can also choose to auto-validate some fraction of the results for a particular pattern, so they can still carry out some checking on reports that are being auto-validated. Across 7.5 million reports from 185 knowledge bases in 12 laboratories using Ripple Down the auto-validation level was 85%¹.

Ripple Down auto-validation also provides auto-verification of laboratory results in the conventional sense of limit checks, delta checks and biological validation, i.e. checking whether a result for a patient is plausible given the results for other tests, past results, clinical information about the patient and so on. In writing a rule to provide a very precise comment, the pathologist is also identifying a particular pattern of results as being plausible with respect to that comment. That is, in providing clinical advice for a set of results the pathologist is implicitly carrying out limit checks, delta checks and biological validation. Pathologists can also write rules which identify cases which specifically require manual validation. The auto-validation achieved with Ripple Down across a wide range of different domain areas of 85% is extremely high. It is also a by-product of generating interpretative reports, rather than using two different technologies for interpretative reports and validation¹.

Result Reporting

Ripple Down can be used not only to provide interpretative comments for the referring clinician, but can be used to control the formatting of the report, so very high quality pdf reports can be produced where results are organized, tabulated and highlighted making very clear the key issues that require consideration. Results can also be accompanied by graphs indicating trends over time, or the position of a result with respect to its normal range. Report formats can be highly customized, i.e. not just for the clinical domain but according to the referring doctor's preferences. Reports can also be sent out multiple languages, with some laboratories send out reports in one of three different languages depending on the recipient¹.

Ripple Down can also be used to produce a personalized letter about a patient. For example for bone mineral density a report might refer to the patients clinical history, previous results, fractures, height and weight changes, medications, calcium intake and so on. Another type of comprehensive report is a cardiac risk assessment after hospitalization for a myocardial infarct to help guide post-hospitalization rehabilitation and health care. This has been used successfully to reduce the likelihood of an early repeat hospitalization, which is not funded under US Medicare rules. In providing highly specific advice Ripple Down can also be used to integrate information via grid or cloud access from multiple source, going beyond the requirements for the "ideal" laboratory information system⁷.

Notification Management

Ripple Down can also be used to manage the way laboratory results are provided to clinicians. For example Ripple Down has been used to generate real-time alerts for possible cardiac events where no adverse events were missed and false positive alerts were drastically reduced⁴.

Rules can be written to instigate reflex testing based on current results. Experts can also write rules to flag that certain patterns of results, perhaps limited to certain referring clinicians, should result in a phone call.

Data Mining, Cross-Sectional Reports, Graphs and Statistics

Since Ripple Down classifies patient results into whatever fine (or coarse)-grained patterns a pathologist wishes to use, it can be very easily used for data mining. It is far easier to write a rule to retrieve a complex pattern of results than to write a data base query. For example one could write rules to retrieve all patients who had an abnormal pattern of results, and distinguish those who were on relevant medication or not according to the clinical notes available. Such discrimination could be used for example to identify referring clinicians with seemingly different treatment patterns for the same type of patients. Ripple Down can output such data in spreadsheet format for further manipulation and display, or automatically forward such results to a public health registry⁵.

Ripple Down also provides various dashboards to monitor laboratory performance. For example the auditor dashboard provides feedback, including graphs, on errors in data entry, and can be used to assist individual staff with personalized training programs¹.

Result Entry

Although not normally required in Chemical Pathology, where results entry is either on-line or is a simple manual procedure, there is also a Ripple Down Smart Forms module. The Smart Forms provides a result entry environment for more complex manual result entry. It dynamically guides the process of entering data depending on the data already entered or previously available. Smart Forms is again controlled by rules to suit the particular requirements of that laboratory for data entry. As with all Ripple Down applications, end users can very rapidly and simply enter the rules.

METHODOLOGY

- ◆ Study area:- Delhi NCR
- ◆ Type of study:- Cross sectional descriptive study.
- ◆ Study period:- Two months 1st April to 31st May.
- ◆ Study population:- Ten NABL accredited labs of Delhi NCR.
- ◆ Data Collection:- Observational check list, on field interviews.
- ◆ Sampling:- Random sampling is done.

Inclusion criteria

- ◆ The labs with NABL accreditation were included
- ◆ The labs which are using LIS from last three years or more were only included.

Exclusion Criteria

- ◆ Labs which are not NABL accredited were excluded from the study
- ◆ The labs which are not using LIS or using it from less than three years were also excluded from the study

Variables

- ◆ User friendly
- ◆ Satisfaction level
- ◆ Using cloud based software.
- ◆ How efficient is the management of data

DATA ANALYSIS

LMIS OBSERVED

Organization name

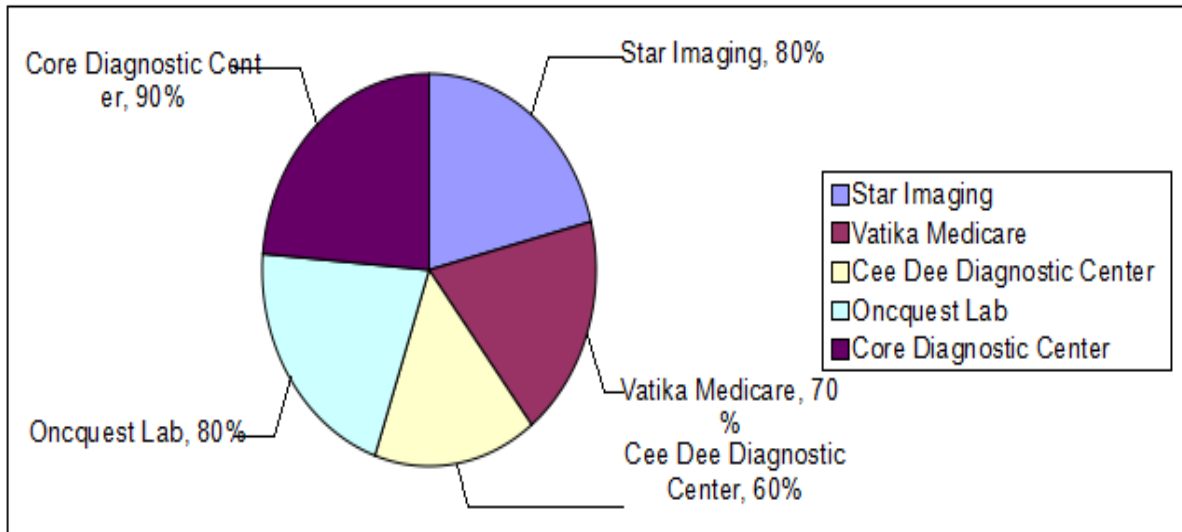
Software used by the organization

◆ Star imaging	Bizzysoft
◆ Vatika Medicare	Vishal
◆ Oncquest	Akhil
◆ Cee Dee	Labmate
◆ Core	Attune

1.

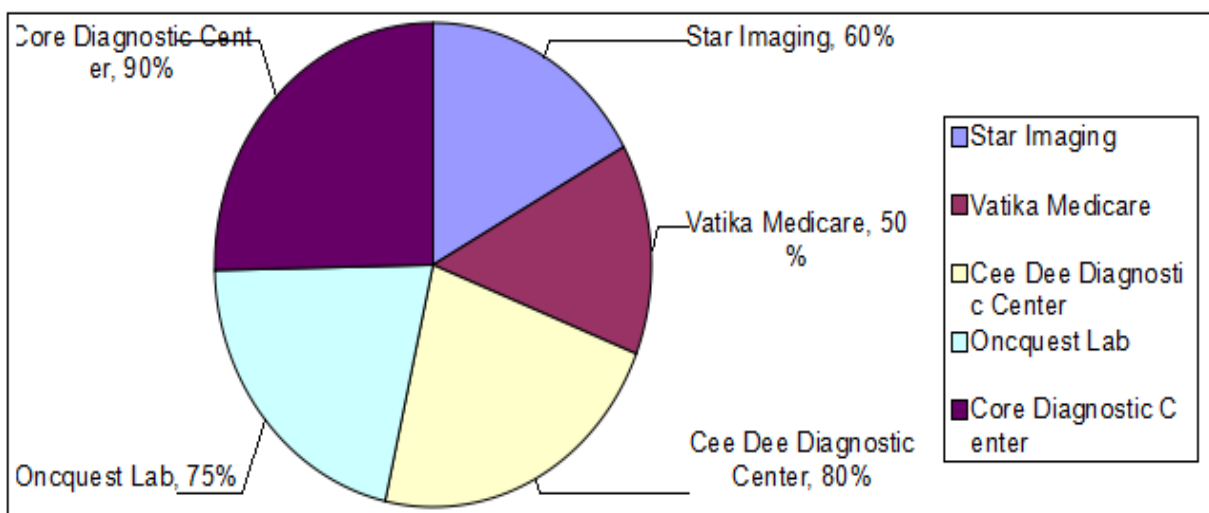
- 1) The figure shows the level of user friendly LIMS in different Labs

USER FRIENDLY



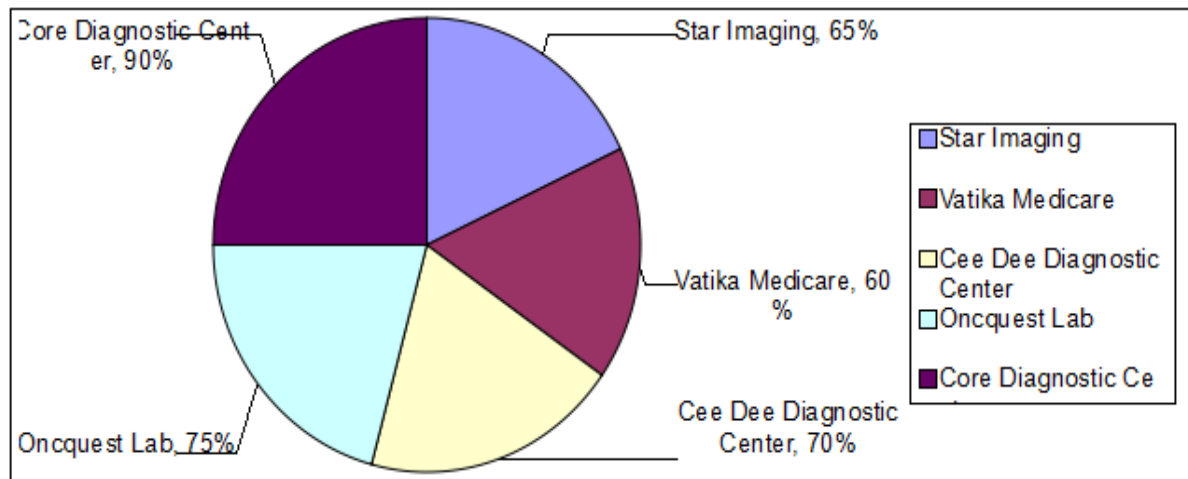
- 2) The Figure shows the satisfaction level of the users for there LIMS

SATISFACTION LEVEL



- 3) The Figure shows the level of data management by the LIMS

LEVEL OF DATA MANAGEMENT



- 4) Cloud based software is used by only one lab that is Core Diagnostic center using Attune technology software

RESULT

From this comparative analysis, the following result was analyses

- ◆ Except Attune no other software is cloud based
- ◆ Attune has the highest data management skills
- ◆ Attune provides the most user friendly LIMS and the satisfaction rate of client is highest there.

Benefits of using Cloud

Cloud based LIMSs typically use the Software as a Service (SaaS) model, wherein applications are hosted by the LIMS service provider and made available to clients i.e. labs over the Internet. Adopting a cloud based LIMS has the following benefits

- ◆ Since the software application is already installed and configured, on boarding clients is faster, resulting in reduced time to benefit.
- ◆ Lower costs of operation as pricing is differential and maintenance costs are mostly handled by the LIMS provider.
- ◆ Up gradation of software is hassle free.
- ◆ Patient data can be easily integrated with PMRs and EHRs to ensure that there is only one record per patient.

DISCUSSION

In an increasingly competitive economic environment for health care services, clinical diagnostic laboratories are looking at tools that can improve their efficiency and increase their profits. Of primary interest are sophisticated laboratory information systems (LIS) that can interact with the facility or institution's electronic medical record (EMR) system and/or electronic health record (EHR). Although the LIS concept is not new, advances in technology have made them more sophisticated than ever, offering clinical and non-clinical applications, Web-based connectivity, customize configurations and rule-writing, scalability, and modular units that can offer data handling for the most cutting-edge laboratory techniques and testing⁸.

Every clinical laboratory is unique, as are the needs of each laboratory's LIS. A number of different technological approaches have been developed to meet the varied needs of the heterogeneous nature of the clinical laboratory industry, including fully integrated LIS's, middleware solutions, and Software as a Service (SaaS) solutions⁹.

Advantages of SAAS

- ◆ The primary advantage of an SaaS LIS is low cost and no fuss. A laboratory, especially a smaller physicians office laboratory, only needs to load relatively inexpensive software on their POL computers that allows them access to the SaaS provider's servers via the Internet. They then have whatever level of functionality the provider offers. In other words, SaaS-based LIS systems offer full functionality to even the smallest of laboratories⁹.
- ◆ In addition, any upgrades and configuration issues are handled by the vendor/host.
- ◆ SaaS-based LIS solutions also support multiple clients and users, while requiring minimal resources. It is scalable, so if the laboratory grows or merges with another facility, very little change in terms of the laboratory is necessary⁹.

- ◆ An additional advantage is because the SaaS LIS is already networked, it's a fairly straightforward extension to connect physicians offices and reference laboratory clients to the network⁹.
- ◆ SaaS-based LIS solutions simplify instrument connectivity through reduced custom interface costs and manage data flow between a large number of laboratory instruments and the corresponding data. Most importantly, SaaS-based LIS solutions help integrate otherwise standalone instruments directly to an EHR, EMR,

practice management or other host system using industry-standard interface protocols⁹.

Concerns

There are not many fully functional, true SaaS laboratory information system vendors operating at the moment, although there certainly would seem to be a lot of interest in that direction, and cloud-based computing in general is trending toward the SaaS model. Within the healthcare industry, there are some concerns regarding SaaS in general, and SaaS LIS specifically⁹.

Downtime

All IT systems require maintenance and upgrades. LIS's are no different, no matter what type they are. Many in-house LIS's depend on in-house IT staff, or commonly in smaller laboratories, a (hopefully) tech-savvy employee to handle the system for maintenance and problem solving. In a web based server you don't have to depend on in house IT staff to resolve the issues as they will be looked after online by the service provider⁹.

CONCLUSION

Laboratory test results are a vital part of a patient's health record and provide health care professionals with data to support decision-making and case management at the point of care. Implementation of laboratory information systems will reduce duplication of tests and help accelerate diagnosis and appropriate care. By ensuring results are correctly linked to patients, safety will be enhanced and health care providers will have a more complete and accurate medical profile to assess patient need. Laboratories need to be supported by an information system that can provide quality and timely information to¹⁰:

- (1) support appropriate patient information
- (2) support laboratory management
- (3) on a broader scale, contribute to disease surveillance, prevention and control.

Thus, the information processes for a laboratory information system and manual documentation—from data collection, transmission, processing and analysis including an early warning system—are designed to meet these three functions. Establishing standards to manage data and to facilitate exchange of information across the laboratory network is of prime importance. In some countries, electronic solutions may be appropriate. To support laboratory management, the laboratory information system needs to be designed to accurately log patients' information and examination results, to track the use of reagents, to facilitate inventory management, to assist in quality assurance, and to meet accreditation requirements. Oftentimes, the laboratory information system must interface with instruments and other information systems such as hospital information systems. Health services in charge of epidemiological surveillance should be able to access data to maintain subnational and national epidemiological database. At all times, individual patient confidentiality should not be compromised¹.

Recommendations

Specific suggestions for improving the function of LIS are listed under the following sections⁶:

- 1) Data Curation
- 2) Capturing each work station
- 3) Information security
- 4) Quality management
- 5) Home collection for samples
- 6) Notification Management
- 7) Method Validation

LIMITATION

- ◆ The study is limited to a specific geographic location.
- ◆ Time to conduct the study is very less for the analysis of the outcome.
- ◆ The sample size taken can also be increased in future researches

REFERENCES

1. Auto-validation with Ripple Down (2013).. Pacific Knowledge Systems white paper, <http://www.pks.com.au/technology/white-papers>.
2. Balis, U. J. (2012). Introducing the World of Encoded Data for Predictive Laboratory Medicine Results: Thiopurine Metabolite Testing as an Exemplar. Pathology Informatics Pittsburgh, <http://www.pathinformatics.pitt.edu/2012schedule/fullschedule> (pdf available).
3. Bell, D. A., R. Bender, A. J. Hooper, J. McMahon, G. Edwards, F. M. van Bockxmeer, G. F. Watts and J. R. Burnett (2013). "Impact of interpretative commenting on lipid profiles in people at high risk of familial hypercholesterolaemia." Clinica Chimica Acta. 422, 21-25.
4. Compton, P., L. Peters, T. Lavers and Y.-S. Kim (2011). Experience with long-term knowledge acquisition. Proceedings of the sixth International Conference on Knowledge Capture, KCAP 2011. Banff, Alberta, Canada, ACM: 49-56.
5. Crowgey, F., K. Phalor, E. Zabaleta, J. Burgess and M. Patterson (2010). Using Artificial Intelligence Software as a Clinical Decision Support Tool for Laboratory Results: First Increased Troponin - I Alert Project. Pathology Informatics (Session #3 - DIAGNOSTIC INTERPRETATION), <http://www.pathinformatics.pitt.edu/schedule/fullschedule> (see powerpoint presentation).
6. Sepulveda, J. L. and D. S. Young (2012). "The Ideal Laboratory Information System." Archives of Pathology & Laboratory Medicine.
7. Zabaleta, E., J. Burgess, K. Truax and M. Patterson (2012). How Can Laboratories Help Their Hospital Decrease Readmission Rates for Heart Failure Patients? Pathology Informatics, Pittsburgh, <http://www.pathinformatics.pitt.edu/node/982>.
8. Gerald Choder Vice President of Sales and Marketing, Laboratory Information

Systems (LIS) in the 21st Century: The Challenges and the Promises

9. Mark Terry :-Transferring Laboratory Data Into The Electronic Medical Record: Technological Options For Data Migration In The Laboratory Information System
10. Asia Pacific Strategy for Strengthening Health Laboratory Services (2010-2015) by W.H.O
11. Attune technologies brochures and materials & website
12. Laboratory asses-ment tool by W.H.O
13. Ben Tagger:- An Introduction and Guide to Successfully Implementing a LIMS (Laboratory Information Management System)
14. Decision support system from health informatics perspective:- University of Tampere 2000
15. Dullabh P and Moiduddin A. Electronic Exchange of Clinical Laboratory Information: Issues and Opportunities <http://aspe.hhs.gov/sp/reports/2009/informationissues/report.pdf> (Last accessed June 24, 2011).
16. Winston D. Molecular, Genetic Data and the LIS. ADVANCE for Administrators of the Laboratory. April 2008.
17. Vendors bank on new billing system features. CAP Today. May2008.
18. Stonecipher R. Time to Replace your LIMS? Laboratory Informatics. Scientific Computing.