Managing Information in Today's Laboratories

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Information management is the collection of information from one or more sources and the management and dissemination of this information that evolves into a collective information solution that is worth more than the sum of all its parts.

Informatics across Industries

Informatics is the art of using information technology (IT) to properly manage information. Informatics is ubiquitous in all of today's industries. The vibrant finance industry has the largest IT-spend in any industry. It is also has the most cutting edge technology available finding the best ways to make a faster and fatter buck. Why is this the case? For any financial transaction, the most important things to consider are the time it take for a transaction to occur, the accuracy of the transaction and the type of financial model. With the correct model, it is just but a race to see which financial company can make the most profitable and accurate transactions within a limited span of time. Financial companies can access a wealth of data and use complex algorithms to automate the buying and selling of equities in a matter of seconds. If people treasure one thing more than their lives, it has to be their money, and in all financial companies, errors are unacceptable - money is treated extremely important, all the way to the last decimal point.

The energy industry on the other hand uses informatics to manage multiple complex machineries to harness raw power (i.e. oil and gas.) Informatics is used in all these areas to manage critical safety limits to protect both the instrument operators as well as the customer. In the example of an electric power station, informatics is used to monitor safety limits through sensors and forewarn operators in the event of any potential hazard. Operators entrust their safety and lives on the use of informatics daily.

The telecommunication/media industries use informatics in a different way. They use the wealth of customer data that they have and they create models to identify specific customer behavioral patterns. Mining the data in an appropriate manner can help companies understand past trends but more importantly predict trends and the customer's future usage patterns enabling them to more successfully cross-sell and up-sell to the appropriate customer.

In all these three industries we have seen very different ways of how informatics could be used. We have seen how companies make use of informatics to automate fast and voluminous trading, maintain safety standards, provide appropriate warning indicators as well as help predict instrumentation usage and understand customer trending. How can informatics then be used in a laboratory? Some readers might immediately see the correlation between their laboratory goals and some of the goals that informatics can help achieve.

- A quicker and more consistent turn-around time (TAT) through automation
- Reduction in human errors
- Improved patient and operator safety
- Improved patient management through historical trending
- Better adherence to regulation standards/bodies

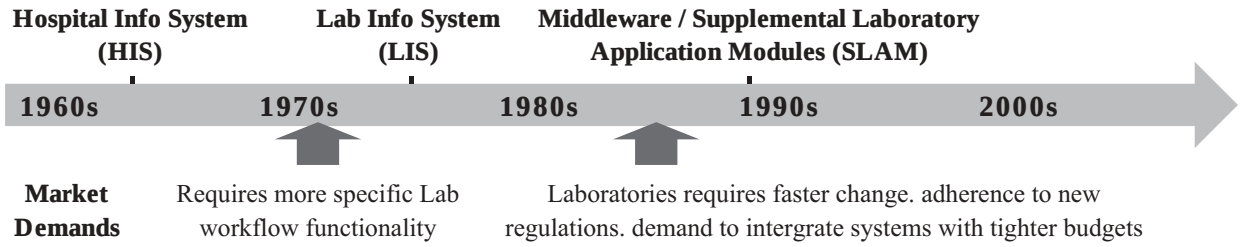

Figure 1. Development of laboratory informatics.

Here are but a few goals that informatics can help achieve, however, before we get into more detail, let us take a look at how laboratory informatics has developed over the years (Fig. 1).

Laboratory Informatics

It all began in the mid-1960s where hospitals were required to maintain records of their patients. This need gave birth to the hospital information system (HIS) as it is today and it focuses mainly on patient accounting (billing and finance), patient management (admission, transfer, discharge etc.) and other hospital aspects. However, the HIS ran on antiquated mainframe systems and had poor and unreliable functionality. There was a long maintenance period and it was not sufficiently specific to the needs of a laboratory or the radiology department.

Sometime in the mid-1970s, the laboratory information system (LIS) was created to work more specifically around laboratory workflow. This involved patient accounting and management but also managed results entry and reporting to the physician. This was perfect for the laboratories because it catered to their needs but were highly customized and specialized to each individual laboratory. Effort was placed on this customization and not on continued R&D to how laboratories could better use informatics. The focus on aging technology prevented laboratories from using better available technology that other industries were slowly beginning to enjoy. Aging technology brought about increased costs of maintenance and functionality modifications. With the coming of the mid 80s, laboratories required to change faster, adhere to multiple new regulations, and the ever increasing demand to integrate systems with tighter budgets.

The late 1980s till present and the healthcare industry is seeing a shift in paradigm. Middleware and/or supplemental laboratory application modules (SLAMs) are more conducive to laboratories that want faster continual growth. They provide a cheaper, lightweight and faster option for laboratories to quickly realize benefits. These software packages come with the latest technology and a much easier user interface. They also provide options for automating processes and even customization that is so user-friendly that even the laboratory staff themselves can modify! These packages usually do not provide the core functions of the LIS/HIS such as billing, patient and physician demographic management, but provided more focus on the automation of common laboratory processes. Informatics has developed differently and also at a different pace in the laboratory arena. While other industries have been busy developing and optimizing the use of informatics, laboratories were focused on improving their existing LIS setup.

Laboratory Options

Laboratory informatics is focused on improving the laboratory's performance, results consistency and accuracy, governance, management and support process. Depending on location around the globe, laboratories are facing different pressures in different markets. Laboratories in the US are facing increased labor-shortage and rising labor costs. Laboratories in Asia are being squeezed to provide better services, standardization through accreditations, reduced budgets and in some parts of Asia, reduced laboratory floor space. In order to bring these costs down and efficiencies up, laboratories have several options to help streamline and automate their laboratories (Fig.2).

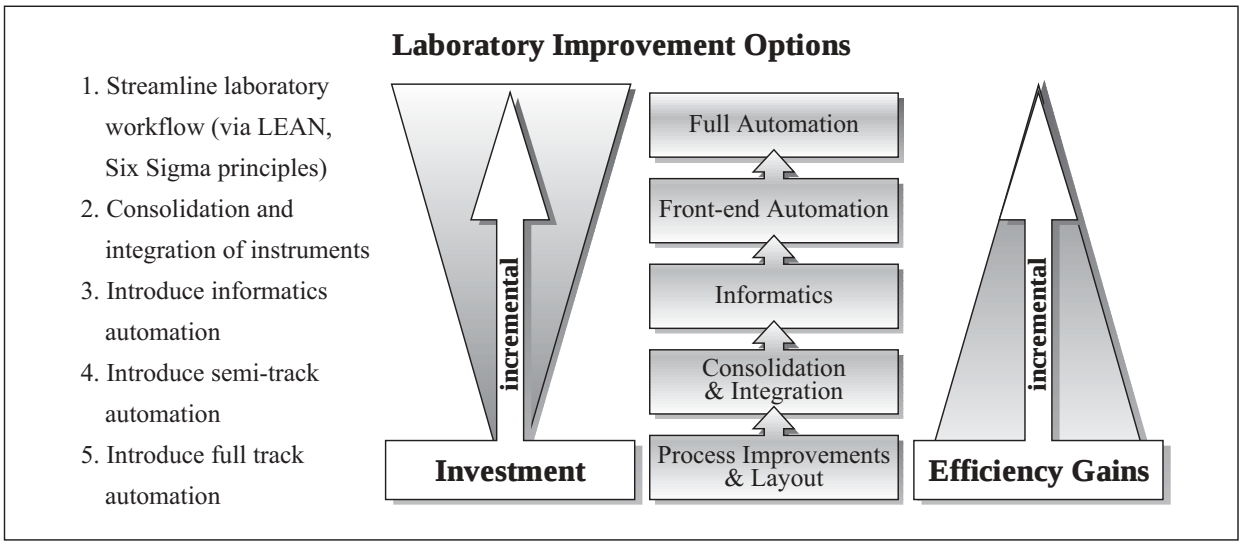

Figure 2. Laboratory improvement options

However, with every type of investment, there is a non-linear efficiency gain the laboratory can achieve. Finding this balance of investment and efficiency gain is crucial for each laboratory before making any decision. If it is possible to spend 100% of the laboratory budget for a "top-of-the-line" automation system to attain a 50 minute TAT goal, OR to spend 60% of the budget for an improved workflow, consolidated analyzers with effective informatics to attain a 55 minute TAT goal, which is a better choice? Laboratories have to be able to balance the investment costs and benefits of these options in order to be competitive and keep up with today's soaring demands.

Middleware Components

Middleware options are plentiful; however, most of the options fall into four main components and are as follows: (Fig. 3)

Connectivity

Connecting new instruments always seem to bring up cost and time issues between LIS vendors and lab managers. By this time, there should be some standard language in which communications between the instruments and the LIS should be understood. Because middleware sits between the instrument and the LIS, it is able to solve this problem by directly interfacing with the instrument and translating it into the language the LIS most commonly understands (HL7 or ASTM.) Middleware enjoys the ability to have the interfaces written once and used everywhere else that setup is required. Connectivity options also include the ability to support image transfers (i.e. hematology instruments), the ability to connect to multiple different physical locations, and even have monitoring/diagnostic tools to troubleshoot or fine-tune the connection.

The better middleware packages have a proven list of connected instruments that scale across multiple vendors and different laboratory departments, so that if and when the laboratory scales, the middleware can scale alongside.

Data Management

The storage/collection of data in a usable fashion is an important requirement for retrospective analysis, real-time analysis, or even predicting and trending patient(s) outcome. Similar to the telecommunications/media industry, it is easy to trend and perform delta checks on a patient. At the same time, trending can be performed on instruments too showing laboratory managers the utilization rates of each instrument and even each assay with respect to the time of day. Another middleware capability is to inventory the physical archival/storage of a patient(s) and provide easy sample recovery location functionality and/or time-based sample destruction lists.

Better middleware packages are able to offer customizable reporting options where users can get direct ODBC access to the middleware's database. Such an option provides the

Middleware Components	*Description*
Connectivity	Software options that connect the middleware to the instruments and to the LIS
Data Management	Enhanced functionality in the management of sample and results data
Expert Software	Application that utilizes decision logic and serves as a decision support system to automate and seek human intervention only when necessary
Reliability & Assurance	Concurrent user, remote access and back-up solutions in the event of LIS or primary database failure.

Figure 3. Middleware options.

user with enhanced flexibility to mine the data to their liking.

Expert Software

Computers are used for their logic, speed and accuracy. By defining a computer's logic with the normal result ranges for a sodium test, it can alert the laboratory staff when a sodium test result is normal or abnormal. Similar to how financial systems buy or sell based upon price ranges, expert software in middleware can be used to embed sample test reference ranges (based on age, sex etc.) and perform automatic verification, re-runs, add-ons, reflexes etc. With today's available customer variables and logic available in the middleware, there is almost no limit to how complex these algorithms can be written.

Better middleware packages offer the ability to allow users to create "rules" that cover across multiple instruments, including QC allowing laboratories to save time from manually verifying 80% of results and allowing the staff to focus on the abnormal results.

Reliability & Assurance

Laboratories are only operational when test(s) can be conducted. In the event of a power failure or computer malfunction, it is necessary to have a backup. Such reliability options are crucial as important patient information is stored and would be meaningless if it was destroyed, corrupted or lost. Can one be assured of the safekeeping of the data, either during the event of an equipment failure or unauthorized access? Does the product adhere to specific regulatory bodies i.e. CAP? Are there any audit trail tools that can help you identify individuals that made changes throughout the verification process? These options are available in some middleware packages, but not all. They are all of critical importance and should be considered seriously. Many of these functionalities also help laboratories attain their adherence to standards much faster.

Conclusion

With the growing array of patient information and diagnostic results along with the sea of biomedical literature published annually, health professionals must combine their factual, conceptual and procedural knowledge in order to accurately diagnose and treat patients. Laboratories understand that change is inevitable, but more importantly need to be aware of what options are available and weigh the investment costs versus benefits before making a decision. It is not always the case that laboratories with newer flashier toys win. It is the proper optimization of workflow process and instrumentation with informatics that is driving and enabling the other laboratories in becoming one step ahead of the competition.