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Professional paper

DESIGN OF A FUTURE LABORATORY INFORMATION SYSTEM (LIS) IN A CLINICAL LABORATORY

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Summary: This study presents an overview of the architectural infrastructure in which existing laboratory information systems can be made to interoperate with additional modules, offering a range of advanced clinical laboratory functionalities in the Department of Clinical Laboratory (DCL), Hospital »Aleksandrovska«. The infrastructure is based on an open distributed computing platform, and its specification is described using the open distributed processing reference model. The design and specification of a framework for the interoperability of existing systems and new advanced services are described, and consequently, the paper concentrates on the issue of integration. Laboratory Automation is essential to releasing laboratory technicians from simple routine work, allowing them to use their time for more skilled tasks. Further improvement, however, should be possible through a more consistent user interface, better integration into the laboratory workflow, and interfaces that allow the LIS to query instruments regarding their internal operating status.

Key words: laboratory information system, network, interoperability, interface, plug-and-play, RS-232C, environment

Introduction

Major forces are now reshaping all businesses on a global basis, including the healthcare and clinical laboratory industries. One of the major forces at work is information technology (IT), which now provides the opportunity to create a new economic and business model for the clinical laboratory industry based on the creation of an integrated vertical meta-network, referred to here as the »total laboratory solution« (TLS). At the most basic level, such a network would include a hospital-based laboratory, a reference laboratory, a laboratory information system/application service provider/laboratory portal vendor, an *in vitro* diagnostic manufacturer, and a pharmaceutical/biotechnology manufacturer. It is suggested that each of these participants would add value to the network, primarily in its area of core competency. Subvariants of such a network have evolved over recent years, but a TLS comprising all or most of these participants does not exist at this time (1). Although the TLS, enabled by IT and closely akin to the various e-businesses that are now taking shape, offers many advantages, from a theoretical perspective, over the current laboratory business model, its success will depend largely on (a) market forces, (b) how the collaborative networks are organized and managed, and (c) whether the network can offer healthcare organizations higher quality testing services at lower cost. If the concept is successful, new demands will be placed on hospital-based laboratory professionals to shift the range of professional services that they offer toward clinical consulting, integration of laboratory information from multiple sources, and laboratory information management. These information management and integration tasks can only increase in complexity in the future, as new genomic and proteomics testing modalities are developed and come on-line in clinical laboratories (2).

The function of the laboratory is to provide information for physicians. This information is usually in the room where data derived from the analysis of patient samples are stored. This information transfer requires that the data be integrated with the patient's entire database. To perform the information transfer rapidly and efficiently, a computer-based information system, called a laboratory information system, is needed.

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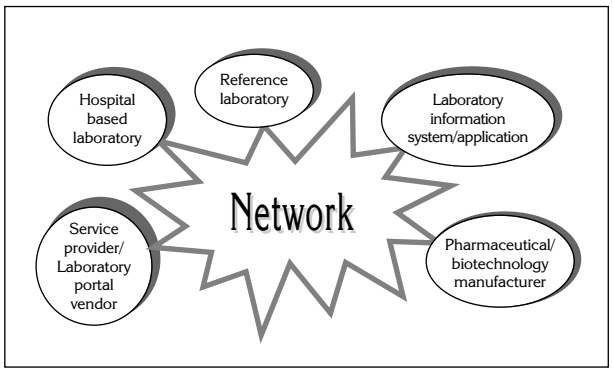

Figure 1 The most basic level of such a network

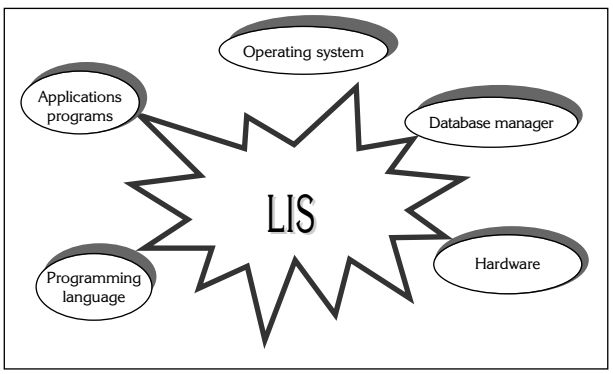

Figure 2 The technology chain builds upon products and systems developed

The laboratory information system can be defined as one or more applications software packages, along with the associated operating system software and the hardware needed to run computer programs that support the operational and management needs of a clinical laboratory. Because the spectrum of services required can significantly differ from one laboratory to another, both the software and the hardware can significantly vary. Most successful information systems structure routine tasks and assist in the integration of diversified processes (3). As a secondary benefit, the LIS provides management data and imposes management controls. An LIS, therefore, must be closely tuned to the operating needs of each laboratory and its organization. The computer can be a powerful tool for improving both productivity and quality, unlike an automated instrument which primarily affects the technologists operating it. The LIS directly influences almost everyone within the laboratory, and many users outside the laboratory.

Most LISs depend on the joining of technologies provided by two or more vendors. Each vendor in the technology chain builds upon products and systems developed by other vendors. At the highest level in this chain are software called applications programs. This is the end product that is recognized by most users. These consist of software development tools, such as the database manager, the programming language or languages, and the operating system. Finally, a vendor provides the hardware, or the computer that executes the software. Because of the close relationship between the hardware and the operating system, they are frequently provided by a single vendor. Use of more than one vendor allows the user to dissociate applications software changes from changes in the hardware (4).

LIS functions

Over the last several years, LISs available in the marketplace have become increasingly standardized. Most systems contain modules supporting many tasks, such as specimen collection, order entry, manual results entry, results reporting, and interfaces to automated instrumentation and computers. **Preanalytical** – *test ordering, phlebotomy* (*labels, collection times*), *specimen tracking;* **analytical** – *manual work list, instrument work list, manual result entry, quality control;* **postanalytical** – *electronic results inquiry, historical patient archiving, result correction* (*Figure 3*) (5).

Additional modules usually included are those providing management reports and other *ad hoc* reports. LISs for hospitals support phlebotomy by providing blood drawing lists, the ability to print labels, and other essential organizing duties; systems for independent laboratories usually include specimen tracking and financial and billing functions (6). Typically one such module supports clinical laboratory functions for high-volume testing areas that provide numeric answers, as in hematology and chemistry. Larger institutions may use two or more LIS vendors to meet their needs. In such cases, one vendor may provide a system to meet the needs of general laboratory functions, whereas another vendor provides support for one or more additional areas. The following sections cover features of an LIS that supports the sample analysis process in the general laboratory areas.

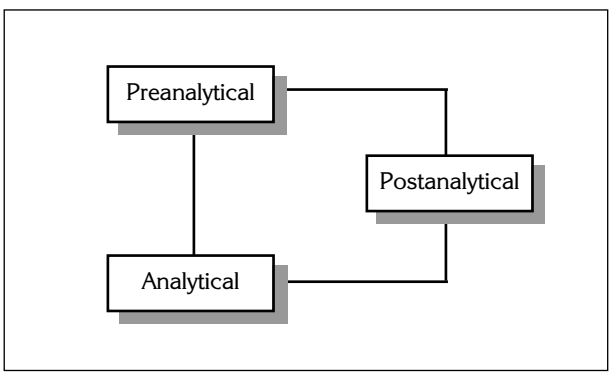

Figure 3 Information function of input process, output and control

Laboratory Information System (LIS) shall enable new modular functionalities to be incorporated in a 'plug-and-play' fashion. The synthesis of the main user needs and requirements implies that the future IT solutions: (a) must be highly flexible and maximally customizable by the users (b) are based on the concept of open systems, both technically and functionally, which enables modular functionalities from different vendors to co-operate forming a global LIS functionality; (c) are future viable and able to incorporate already installed IT functionalities; (d) support management of failure prevention, repair, success, and change (7).

Historical overview

During the 1960s, the US and analytical instruments were difficult to interface. The analog output of spectrophotometers and the binary (digital) input of computers were major economic and technological barriers. The few computers served the management and reporting needs of the laboratory and were often justified by the capture of lost charges, and less often by reduced clerical work when producing patient cumulative reports. Manual result entry was accepted because high-volume analyzers were rare and manual analytical procedures allowed time for data entry.

By late 1960s, continuous-flow analyzers from Technicon and hematology counters from Coulter greatly increased the analytic capabilities of clinical laboratories, and data handling became a formidable obstacle to use of the US. An interface between the analyzers was the logical solution to the data-entry problem. To interface, a potentiometer (variable resistor) was mechanically connected to the chart recorder. As the graph recorder needle moved, the potentiometer's change in value was measured through an analog-to-digital convector connected to the computer. This mechanical coupling allowed inaccurate recordings, and the A/D convector required expensive hardware. The signals sent to the ticket printer were diverted to a custom hardware device that allowed the computer to read the signals. Interfacing was considerably easier and less expensive because neither the A/D converter nor a peak-finding program were needed (8).

Advances in digital electronics during the 1970s transformed analytic instrumentation and computers. The mechanical sampling and analysis systems were replaced by servo systems controlled by inexpensive integrated circuits. Many vendors also started to incorporate inexpensive A/D converters to monitor analytic processes and digital signals. Because digital computers and instruments used similar electronic components, hardware compatibility improved substantially.

Communications between a computer and external input/output devices often used teletypewriter terminals. During the 1960s, the RS-232C standard was established by the Electronics Industry Association to resolve incompatibilities for this interconnection. Instrument manufacturers picked up this standard for reporting because printers used RS-232C. Most computers also had RS-232C inputs, and LIS vendors conveniently connected the instrument printer output with the data input on the computer. Some instruments introduced in the early 1970s, such as Beckman Astra, even had RS-232C inputs designed for interfacing with an LIS. Although RS-232C eliminated the need for custom hardware, instrument companies treated interfaces as an optional, or worse, as a proprietary feature. Users often had difficulty determining if an instrument supported an LIS interface. Sales personnel had trouble ordering interfaces and did not understand interface requirements. Some instrument vendors refused to give LIS vendors interface specifications, because most LIS vendors were small and had little leverage. Users had to help obtain specifications, or LIS vendors determined characteristics through trial and error. This lack of cooperation added cost and introduced delays in developing interfaces (8).

Through the 1980s, interface complexity increased significantly along with instrument capabilities. Instrument and LIS vendors started sharing interface information, often during instrument development, so that working interfaces would be available when instruments were released. With the availability of inexpensive microprocessors and semiconductors, most instruments incorporated internal A/D convectors and computer. Interfacing was considerably easier and less expensive because neither the A/D converter nor a peak-finding program was needed.

The EI 394-91 standard specifies the next higher level, the data format between the instrument and its LIS host. Finally, the E 1466-92 provides guides for using bar codes in labeling specimens so that they can be read in automated instruments. The EI 394-91 standard follows the protocol outlined in the EI 238-94 standard for exchanging patient information between computer systems, and this is a formal subset of the HL-7 standard for information interchange in the healthcare environment. The verbosity of the protocol creates problems for high-speed and high-volume analyzers in communicating over a limited bandwidth RS-232C interface. Furthermore, the standards do not define the interaction in sufficient detail to prevent problems with instrument integration. For example, the bar-code standard can result in two different instruments having incompatible labeling requirements. Bar codes consist of series of small parallel lines of varying width that are used to represent a number of letters and numbers and that are readable by automated equipment. There are no public software validation suites that allow testing for standards compliance. The patient number, patient demographics, time/date, and test are written in human readable form (10).

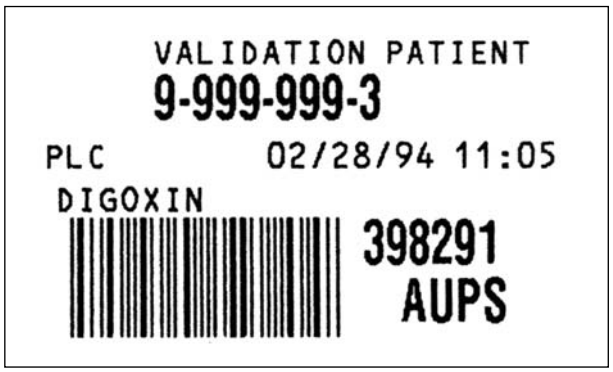

Figure 4 Bar-coded specimen label.
The six-digit specimen number (398291) is bar-coded

Analytical instrument interface

Automated instruments perform most testing in clinical laboratories. Interfacing between an instrument and the LIS requires compatibility of software and hardware, but, once accomplished, greatly improves productivity and decreases errors. The LIS and the instruments must be linked by a compatible physical connection. Most clinical laboratory instruments expect the physical data interface to adhere to the Electronic Industries Association RS-232C standard. Interface software must be available on the LIS to allow it to receive data from and transmit data to instrument. Although the physical connection between instruments and the LIS requires minimal adaptation, considerable software differences exist among automated instruments even with software standards. Since current standards are not satisfactory, most instrument manufacturers provide LIS vendors with instrument-interface specifications before they are introduced into the marketplace to allow time for interface software (9).

An interfaced instrument must link each specimen to its specific test request. Many modern instruments link the specimen through its bar-coded specimen number on the specimen label. The most common information download to an instrument from the LIS are the tests that have been required for the specimen. The communication and interactions between the host LIS computer and the instrument can be complex. Adding to this complexity is the requirement of some instruments for an immediate response from the LIS upon reading the bar-coded specimen number. The order in which the LIS processes specimen for a specified instrument is called a work list.

Interface protocols

RS-232C does not specify the format of the data being interchanged, which is analogous to a person who specifies an alphabet but ignores the vocabulary and grammar. Specifying and understanding this format becomes more important. Data formats generally fall into three groups: (1) instruments that use an ASTM or ASTM-like format, (2) instruments that send output in a printerlike format, and (3) instruments that use a proprietary format. Most instruments introduced within the last 5 years follow an ASTM-like format. A few older or semiautomated instruments have interfaces that mimic a printer output, such as some blood gas analyzers. Majority of the third group are high-volume analyzers that cannot use the ASTM format because of the large volume of data that must be transmitted. In addition to the format of the data interchange, the interaction between the LIS and the instrument must also be specified, although standards have not defined this area. Most LIS and instrument vendors divide the protocols into unidirectional and bidirectional. Neither LIS nor instrument have any way of determining if an error has occurred. This protocol is used on most instruments. LIS determines if it received the data correctly by comparing a computation sent by the instrument in the message with its own computation. The instrument retransmits the data until it receives an ACK. The LIS response to the instrument is usually limited to either an ACK or an NAK. Unidirectional interfaces work well when the analyzer always performs the same tests on every sample. Most hematology instruments are unidirectional (10).

Bidirectional protocols require substantial interaction between the instrument and the LIS. In such an interface, the LIS downloads to the instrument a specimen identifier or a tray-and-cup position with a specific list of tests to be performed. The instrument stores the information until it reads a bar-coded specimen with a matching identifier or, if bar codes are not used, until the specified tray-and-cup position is reached. When a match occurs, the instrument performs the specified analyses and transmits results back to the LIS. Bidirectional interfaces are required when an analyzer must perform different analyses on each sample. Most larger chemistry analyzers have bidirectional interfaces (10, 11).

Conclusion

Our experience suggests that this approach may well be the way forward for the high performance but user-friendly laboratory systems of the future.

LIS approaches the utilization management (UM) and considers how developments in information technology (IT) may affect the latter. We feel there is a distinct possibility for implementation of UM in real time, and we propose this as a new paradigm whose realization has implications for choice of IT and for how clinical laboratories operate in the future.

Changes in the healthcare and laboratory environment require greater efficiency and increased automation. To support both, changes are needed in the integration of instruments into the overall laboratory operation.

In the last 30 years, improved integration has resulted from the introduction of better instrument interfaces. Considering differences in instrument functionality, evolving analytic methods, and changing computer technology, a truly integrated and plug-and-play instrument LIS interface will be unlikely. Many changes, however, are still needed to support functions such as computer review and release of results and a robotic automated laboratory. Some of these changes may yield new regulations; others may require large capitalization and major redesign. Most design changes, however, can be implemented through a better understanding of laboratory needs.

NACRT BUDUĆEG LABORATORIJSKOG INFORMACIONOG SISTEMA (LIS) U KLINIČKOJ LABORATORIJI

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Kratak sadržaj: Ova studija predstavlja pregled arhitektonske infrastrukture u okviru koje se postojeći laboratorijski informacioni sistemi mogu povezivati s dodatnim modulima, što obezbeđuje brojne pogodnosti u radu kliničke laboratorije bolnice »Aleksandrovska«. Infrastruktura sa zasniva na otvorenoj distribuiranoj računarskoj platformi, a njena specifikacija opisuje se pomoću otvorenog distribuiranog modela za obradu podataka. Dati su nacrt i specifikacije mogućeg okvira za interoperabilnost postojećih sistema i novih, unapređenih servisa, a studija se potom usredsređuje na pitanje integracije. Automatizacija u laboratorijama je neophodna da bi se laboratorijski tehničari oslobodili rutinskog posla a dobijeno vreme iskoristili za komplikovanije zadatke. Dalji napredak, međutim, biće omogućen stvaranjem doslednijeg korisničkog interfejsa, boljom integracijom u rad laboratorije i interfejsima koji će LIS-ovima omogućiti da ispituju instrumente kroz njihov interni operativni status.

Ključne reči: laboratorijski informacioni sistem, mreža, interoperabilnost, interfejs, »plug-and-play«, RS-232C, sredina

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