

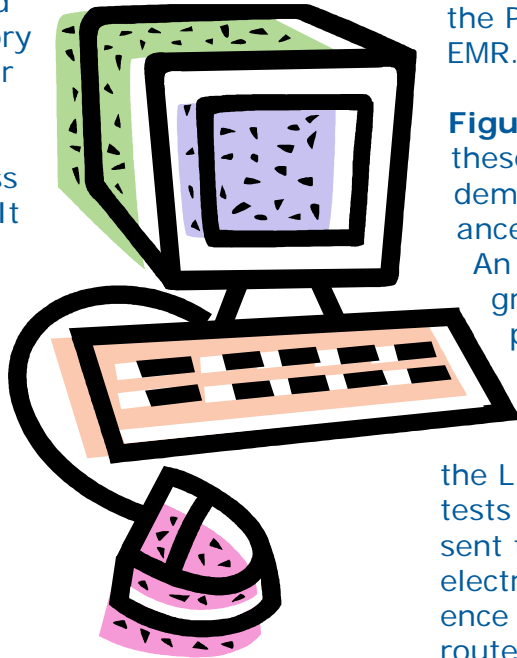
## ■ Purchasing a Laboratory Information System -- Now What??

*By Ginger Wooster, MBA, MT(ASCP), Applications Specialist, Orchard Software*

You and your facility have decided it's time to dig out from under all the paper and go electronic. Are you excited about the opportunity to streamline your laboratory workflow or would you rather have a root canal? Feeling a little overwhelmed? Where do you start? What do you need? The good news is that you are not alone. Many have gone down this path before and are happy to share some insights on what to do and what to avoid.

### What exactly is an LIS?

You know how the lab functions in a paper world but perhaps are not quite sure what to expect when you automate by adding the LIS. A laboratory information system (LIS) is software that manages the laboratory work flow. It sends order information to the analyzers and receives result information back so you can evaluate the results and produce a concise and easy to read report for your physicians. The LIS also provides tools to ensure (and document) regulatory compliance and your quality indicators. It allows your lab to function as paperless as you want to be. It can stand alone or work in conjunction with the other systems at your facility.



### Integration is Key

The first order of business is to identify your other information systems and understand how they will all fit together. Most practices have a practice management system (PMS) that handles scheduling, patient demographic information, and billing. Perhaps your physicians are now looking at or have recently added an electronic medical record (EMR) to replace the paper chart. You have a relationship with a reference lab; they may have installed a computer in your lab to help you order tests and receive results. Now you are adding the LIS to manage the laboratory workflow. How do all these systems work together so the right result gets to the right patient's file in the EMR or paper chart?

Information flows between systems via an interface. There are 2 main types of interfaces used in the lab. The first is ASTM, a standard developed by the American Society for Testing and Materials, which is used by the instrument manufacturers to transfer information from the analyzer to and from another system such as the LIS. The second interface is HL7 (Health Language 7) which standardizes how information moves from one system, such as the PMS, to another, such as the LIS or the EMR.

**Figure 1** shows a simple example of how these systems come together. The patient demographic information (name, DOB, insurance, etc) is sent from the PMS to the LIS.

An alternative would be to send the demographic information to the EMR. Physicians place the lab orders in the EMR. The order information is sent from the EMR to the LIS (if the demographics are sent to the EMR, they will then be passed on to the LIS with the order). The LIS knows which tests are done in-house and which need to be sent to the reference lab. Send out testing is electronically routed from the LIS to the reference lab. In-house testing is electronically routed to the analyzers. Results from the analyzers and the reference lab will be sent electronically to the LIS. Upon approval, results are sent electronically to the EMR and the billing information flows to the PMS.



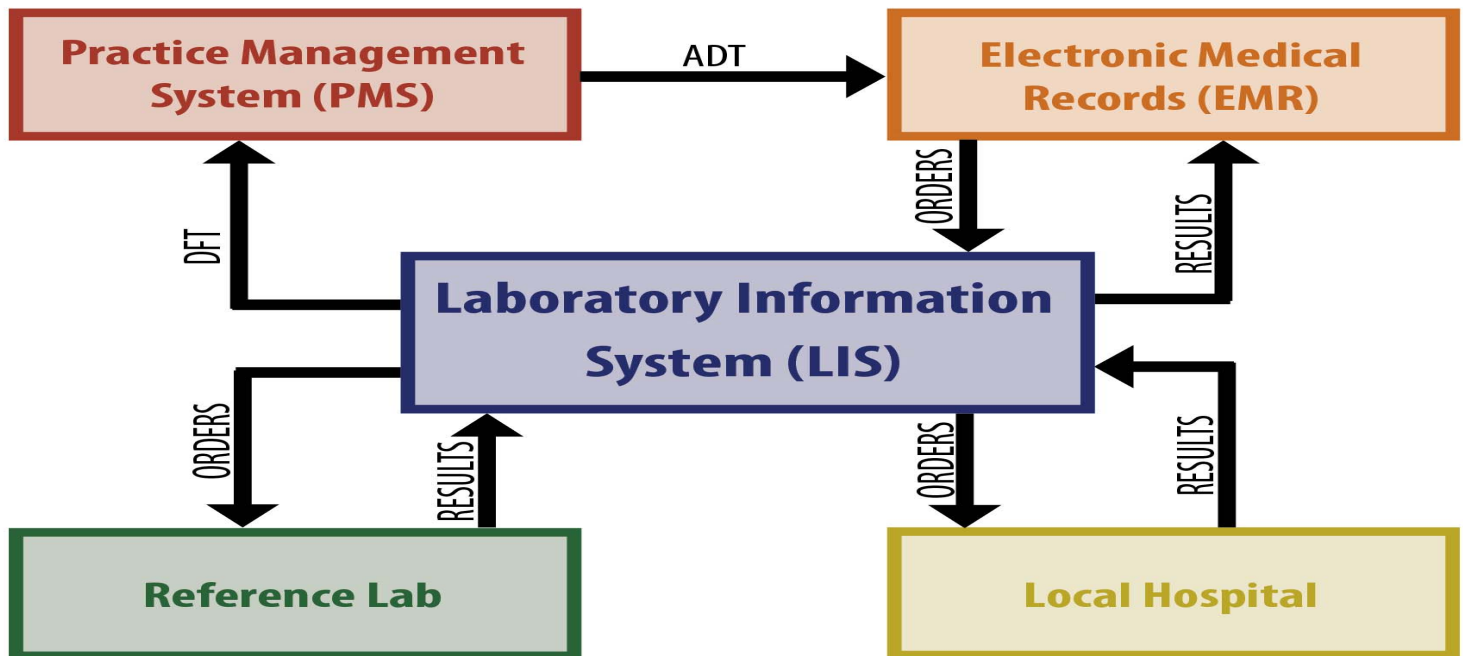


Figure 1

Your facility may decide to delay adding the EMR. Information will then flow as above except the orders will come to you on paper (superbill) and the LIS will generate a consolidated paper report for the patient's chart.

### Preventing Information Overload

Often, in the POL setting, an LIS enters the picture with the purchase of a new analyzer. The instrument vendor (or distributor) may include a lab system as part of the analyzer purchase. On the surface, this looks like a good deal, and it may be, but before you commit, consider that nothing is free, so the LIS costs are folded into the purchase somewhere. With this in mind, you might as well compare this LIS to others to be sure the LIS being offered is the best fit for your lab. "Our instrument came with an LIS," states Angie James, lab supervisor of Millard Henry Clinic. "QC was a nightmare. It took 6 hours to print and we couldn't run the analyzer while it was printing QC."

If you have never used an LIS or seen one in action, it might be beneficial to you to seek out a neighboring physician office lab already using an LIS. You might even want to check out a few of the LIS vendors' websites. This will help you begin to understand how the LIS will potentially affect your facility.

Next, do a little self examination. What do you want to accomplish with your LIS? What is important to you and your facility? Take a good look at your workflow, and decide what workflow issues you want to improve. "Make a list of your expectations, keeping in mind your pocketbook and your employees' comfort level with computers," suggests Libby Knollmeyer, consultant/owner of Laboratory Management Resources. Think about how your physicians will place orders. How does your EMR handle orders, especially future orders? Where does medical necessity checking take place? Who is responsible for obtaining the ABN forms when appropriate? Adding an electronic system is a great opportunity to rethink your workflow. Automating a bad workflow does not add efficiency. Taking time for due diligence up front will save you a lot of time later in the process.

Once you have a good idea of your needs, you can begin to narrow the field of possible vendors. Not all lab systems will be a good fit for your facility, so narrow the search to those that serve the POL community and that have the features that are important to you. At this point, price should not be the main concern. Focus on gathering information to find the LIS that best fits your needs and workflow.

Kristin Wilems, lab manager at Coastal Bend Women's Center cautions, "Look for the LIS that will grow with your practice. You may not need all the features at the beginning, but you will someday." David George, lab manager of Pochontas Medical Clinic agrees, "Don't jump on the lowest price. Take your time and make sure you get a system that integrates well, is easy to use, and you are getting value for your money."

Use the Internet to search for "laboratory information systems" and visit the LIS vendor websites. You might also review the annual LIS survey in the November issue of *CAP Today*. Talk to other labs in your area for recommendations, and ask your PMS and EMR vendors which lab systems they recommend. Likewise, talk to your instrument vendors and reference lab(s) to see which LISs they have easily interfaced with in the past. During this process, you should uncover a few LIS vendor names and narrow the list to the top two or three.

### See the Software in Action

Contact the selected vendors for more information. They will all be happy to send you their brochures that spotlight the best features. This is good, but you must see the software in action. Do not rely on the demo disk that might come in the mail. No two laboratories are alike, and you need to see how the software handles *your* workflow. Ideally, it is best to schedule all the demonstrations as close together as possible so everything is fresh in your mind about each system as you compare.

The demonstration should be tailored to address your specific workflow issues. Don't just ask "can the software do this or that?" The answer will always be "yes." Instead, insist that the vendor show you how you will use the features at your facility. Ask about software upgrades. How often and are there additional charges? Is support included or extra? What happens if you want to make changes in the system? Is there a charge to get the NCD information into the system? What administrative reports are available, and how easy is it to create them? How does the system handle normal ranges and critical values? How does the system address quality control and regula-

tory documentation? How will training be done, and how much training is included? Who builds the database? How easy is it to add to or modify the database? What validation documentation is provided? "Pay attention to the screens during the demo. They should be uncluttered and easy to understand," suggests Miguel Bran, lab director of NeuroMedical Center Hospital. "Also look at how easy it is to perform repetitive tasks, such as Order Entry." Be sure to take notes during the demo to jog your memory of what you liked or didn't.

Be sure to ask the vendors for references, and also ask for a list of clients where they have replaced one of the other LIS vendors on your list. Talking to these clients will give you insight that is not found in the brochure. And don't just ask about the software. Be sure to ask about the training and system support. Knollmeyer suggests, "Ask them how responsive the LIS vendor is to their needs. Call the vendor's tech support and see how long it takes to talk to a live person, and don't forget to verify the technical support hours for your time zone."

### Apples to Oranges: Comparing the Quotes

After the demonstrations, each vendor will submit a quote based on the configuration they feel best fits your needs. Do not rely on a quote from a vendor who has not seen your lab, as it may not contain everything you need. Unfortunately, there is no standard quote format, so don't just look at the bottom line. Review the detail line by line, and be sure you are comparing apples to apples. Be sure to understand what is included, because some of the features you discussed may have been left out to meet your budget expectations. For those who don't thoroughly clarify, there can be some unfortunate surprises upon installation.

For example, how much time is allocated to the installation? Is it enough? Is training included? Is it all on-site during the installation or is a portion completed off-site? Understand that part of the installation and training time must also be spent connecting and validating the instrument interfaces. Be sure you have enough time to install and train on the system properly.



Be sure to know what interfaces are included. Are all instrument interfaces listed and included? What about the interfaces between the PMS, the EMR, and your reference laboratories? The quote should include the LIS vendor's cost of each interface, but realize that there may be costs from your reference laboratory and the other systems' vendors. Contact your EMR, PMS, and reference laboratory to see what their charges will be.

And finally, don't forget to know the on-going cost of support. Are major upgrades included, or are they an additional cost. Not all LIS vendors include upgrades as part of their support contracts. These long term costs of the system should be considered along with the initial purchase price.

### Installation and Training

Ask about the installation process and the training included. Most vendors will be on site to install the software and validate that it is working properly. Be sure the vendor is also on-site when you go live to help. Depending on the complexity of the installation, this may take more than one week. Some LIS vendors train you while on-site while other vendors offer off-site training too. Knollmeyer recommends, "If at all possible, take advantage of this opportunity. Given cost constraints and staffing levels, this may not be feasible, but understand it is difficult to complete training in a working environment because no matter how hard you plan, there will be interruptions that need attention." Knollmeyer continues, "If you are inadequately trained, you will not get to use the system like you want." Wilems concurs, "We had to forego off-site training to keep our costs down, so I had to learn a lot on my own. I know I missed out." To get the most of your LIS investment, the more trained you are on your system, the better you can put it to work for you and maximize productivity in your lab.

### Beyond the Installation

Your relationship with the LIS vendor does not end here. An LIS is a long-term investment' so be sure to pick the system that can grow with you. Budget to replace the hardware every three to five years, but if you have chosen the right LIS vendor, you should never

need to replace the software. Most LIS vendors regularly add new features and make them available as upgrades. In addition to new features, ongoing service and support is key to a successful relationship. Take advantage of the vendor's customer user groups and any advanced training that may be offered. Get to know your vendor contacts. This is the start of a long and mutually beneficial relationship.

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## CLIA Deficiency #1



Confusion about the difference between "waived" and non-regulated tests is the probable cause for the Number One CLIA deficiency cited in 2007.

The cited regulation is 493.1236(c)(1) in the CLIA Interpretative Guidelines. This regulation specifies that for all tests not listed in subpart I (i.e. "non-regulated") a laboratory must verify the accuracy of the test or procedure twice annually.

This means that while "waived" tests do not require proficiency testing, "non-regulated" analytes **DO** require some form of accuracy verification. This verification may be accomplished through several options.

1. Enroll in an accredited PT program. This is the simplest way to meet the requirements. By simply adding these analytes to your PT menu and reviewing the results, you will meet this requirement easily.
2. Perform split-sample testing. In this scenario, the lab selects random patient samples, performs testing as normal, and also sends a portion of the sample to a reference lab. The results of both tests are compared. The results should match within an established range, or testing is suspended.

Whichever approach you choose, be sure to document your verification of accuracy to avoid being among the 6% of labs cited for this deficiency.