Selection and Implementation of New Information Systems

Keith J. Kaplan, MD[a,*], Luigi K.F. Rao, MD, MS[b]

KEYWORDS

• Laboratory information system • Implementation • Selection • Workflow

ABSTRACT

The single most important element to consider when evaluating clinical information systems for a practice is workflow. Workflow can be broadly defined as an orchestrated and repeatable pattern of business activity enabled by the systematic organization of resources into processes that transform materials, provide services, or process information.

OVERVIEW: SELECTION

BACKGROUND AND CONCEPTS

Do I really need a new system? How do I go about that process? Do I want to replace what I have? Is what I have good enough, so that all I need to do is surround it with additional capabilities?

How do you go about finding out which candidates are the correct systems for you? Do you want to go best of breed, or do you want to have a single vendor?

Regardless of your current practice—its members, partners, hospitals, and laboratories that comprise your practice—these questions are almost always the same.

Workflow can be broadly defined as an orchestrated and repeatable pattern of business activity enabled by the systematic organization of resources into processes that transform materials, provide services, or process information.[1]

The single most important element to consider when evaluating clinical information systems for your practice is workflow.[2] You want your anatomic pathology (AP) laboratory information system (LIS) to fit your existing workflows or improve them but not redesign them to meet the requirements of the LIS. Software can be modified to meet your physical and virtual needs much easier than the converse. Many people make the mistake of evaluating the features of the software and all that they can and perhaps initially cannot do as areas for improvement and lose sight of how any of them fit into existing operations and desired workflows. Although many of the particular functions of the software may change or be modified as you customize the features, the particular workflows of your laboratory, perhaps on its third or fourth LIS system, are unlikely to change as often. Workflows within laboratories, ideally, are designed over time with particular goals or deliverables in mind and exist and persist to meet those goals after years of refinements. Although they may not seem ideal to an outsider, they may be completely practical and functional in an established laboratory to meet its specific needs with its patients, providers, technical staff, partner laboratories and/or hospitals, vendors, clients, and customers. An information system without your workflow in mind will not achieve the overall goals of any implementation—increased efficiency, increased productivity, and cost savings with measurable return on investment (ROI).

Practical matters, such as accessioning, gross processing, histology processing, workload assignment, case distribution, additional test ordering, case resulting, and result delivery, may seem like routine, mundane, basic requirements of any AP LIS; however, you may find particular vendors' thoughts on laboratory workflow may not fit yours. They may not appreciate assigning

Dr K.J. Kaplan is the Publisher for www.tissuepathology.com.
[a] PO Box 473431, Charlotte, NC 28247, USA; [b] Department of Pathology, Walter Reed National Military Medical Center, 8901 Rockville Pike, Bethesda, MD 20889, USA
* Corresponding author.
E-mail address: keithjkaplanmd@gmail.com

Surgical Pathology 8 (2015) 239–253
http://dx.doi.org/10.1016/j.path.2015.02.009

certain cases to certain pathologists perhaps at the time of accessioning based on client requirements rather than at case assembly as many laboratories have historically done. Conversely, you may not want cases assigned at accessioning but perhaps the following day when slides are cut and stained, the daily schedule is known, and the volume of cases, blocks, slides, and staffing are up to the minute.

Without getting too far ahead in the overall evaluation process, the most practical way to do this is to process a week's worth of specimens through a mock installation in tandem with your soon-to-be legacy system and see how one compares with the other, focusing not on "how" the system may necessarily perform a certain task but asking "why" does the system behave in this fashion. What rules, logic, recent enhancements/upgrades, or potential opportunities or issues upstream or downstream from that process may be affected for the next user in the process? For example, what may look like a nice shortcut or feature at accessioning may look attractive; if it creates potential for error at grossing, embedding, or with the immunohistochemistry stainer interface, you need to address the pain points early in the process to ensure workflow requirements are met for all users.

With that said, it cannot be assumed that a prospective LIS does something in a manner that is different from how you currently handle a portion of your workflow or that the new LIS, or at least that part of it, is inferior to your current system. Commercially available systems often represent an aggregate of workflow solutions that have been validated by current customers with enhancements provided in the form of upgrades to the current versioning of the application. Thus, much as new information is learned when conducting peer reviews of other laboratories and often new workflows are implemented based on experience elsewhere, the proposed solution in terms of a new LIS may offer some functionality that would be an improvement to your existing workflow but perhaps unable to perform due to current system limitations and workarounds put in place many years ago that have become routine workflow without anyone able to recall, "Why it is we do it this way?" other than the tried and true explanation, "That is the way we have always done it."

Vendors may make claims that their system supports your particular workflow or portion thereof that is of concern while perhaps not having done so before but would be willing to provide that specification as a customization to their existing system. In general, instead of implementing their current solution in your laboratory for a week, as previously discussed, to detail what level of customization to their source code is required to meet an important detail of your workflow, which is impractical, speak with current customers or references provided by the LIS vendor. Ideally you may know of or be provided a list of clients who use the software currently that are similar in scope and volume to your laboratory.

References are an economical source of valuable information, whether their experience has been overall positive or negative with the application. Most speak openly about a company, product, implementation, validation, testing, production, and ongoing service, support, and upgrades. Here you can uncover issues related to the performance of the company, the application, installation, or post go-live issues that another laboratory has experienced. Be prepared with a list of questions that address their experience today with a particular vendor and application. You may not need this list if you have a talkative reference, but it will help organize an important part of your due diligence in this process. Address workflow and any current or previous issues they had or uncovered that may be an issue for your operation. Also address any customizations that were or were not supported to address those concerns. Customization is a complex process that involves both the laboratory and the vendor to complete successfully. Hearing from another laboratory that it was or was not a pleasant experience may go a long way in your decision making. Be sure to address what resources they had internally to work with the vendor and what resource the vendor supplied to the project and balance those with your resources, or lack thereof, if you have the skills, support, and time to work with the vendor on developing.

SELECTION

Armed with a basic concept of how to approach system requirements within your laboratory's environment and workflow considerations and a decision made to explore and potentially select a new AP LIS, consider a request for information or request for proposal (RFI/RFP) from vendors to respond to for potential selection. Many companies, such as the College of American Pathologists and KLAS, regularly provide lists of commercially available LIS systems and ratings, respectively, to begin to research companies and products. Although much of the information is self-reported, both sources of information provide a common starting point for many to begin your own research.

A common starting point is to submit an RFI/RFP to vendors you think may be suitable based on install base, size and scope of clients, interface experience, previous experience, and customer feedback. This initial filter is important only in terms of considering how many companies you would like to potentially demonstrate their system for you, site visits to attend, and reference calls to make initially. You may want to choose from a wide range of small and large companies with any AP experience or limit the range. This commitment likely is long-term one for your laboratory, so be sure to address whether a particular product has been in use for several years at multiple locations and the likelihood it will continue to be so for years to come. What are the mission and vision for a company and its applications? Do they align with your core business model and practices?

The RFI/RFP may go a long way in terms of vendors selected for the next phase or eliminated from consideration based on their responses.

A couple of sample, high-level RFI/RFP approaches are provided in different forms to consider using as a road map for your own organization based on its specific needs and requirements. Some of these may not apply or be a short- or long-term consideration. At this phase, it may not hurt to ask about a company's thoughts on a particular specification should that need become necessary in a few months to years, perhaps during the time an implementation may be started or is finishing. The laboratory business is constantly changing and information technology (IT) needs to be fluid to respond to those changes and paramount to these are AP LIS performance issues even if they do seem like a "nice to have" but not a "must have" today.

Sample Request for Information or Request for Proposal #1

Technical environment

Hardware Describe the required hardware configuration, including descriptions of central processing unit(s), networking hardware, back-up devices, and uninterruptible power supply.

Describe the ability of the proposed system to support fail-safe data storage (redundancy, mirrored, and so forth).

Describe the requirements of system cabling for communication to the server and to the existing network.

Does the system employ 32-bit architecture?

What are the warranty periods provided for hardware?

Please outline service and maintenance costs for the system as proposed.

In an outreach environment, describe the connectivity of the proposed system.

Software Describe the operating systems under which the proposed system will operate (UNIX, DOS, Windows, Windows NT, and so forth).

Name and describe the database management program utilized by the system.

What programming language(s) was used to develop the system?

Describe the file purging/archiving methodology used by the proposed system.

List cost of license agreements, renewal, and upgrades.

Describe the length of time a software version is supported.

Please describe your system's database reporting tools.

Describe the security system used by the proposed system.

Describe your proposed disaster recovery plan to safeguard source code and ensure that the proposed system is recoverable in the event of a disaster at the headquarters of your facility.

Describe your proposed disaster recovery plan to ensure that data are safe and secure in the event of a disaster.

Network and interface issues Have you interfaced your LIS with other clinical information systems? (Provide names of interfaced systems.)

Describe the network topology of your outreach solution in conjunction with your LIS solution.

Describe the network topology of your outreach solution in conjunction with another vendor's LIS solution.

Can your outreach solution be a stand-alone application utilizing a different LIS?

Have you interfaced your outreach solution with other information systems (ie, the outreach solution needs to be able to accept orders from and send results to information systems that do not reside on the same local area network [LAN] or wide area network [WAN] as the laboratory)?

Does the proposed system comply with Health Level Seven International interface standards for importing and exporting data to and from other systems?

Have you interfaced your LIS with reference laboratories? (Provide names of interface reference laboratories.) Describe the interface functionality.
Does your LIS have the capability to provide a direct link to off-site locations for order entry and result retrieval? Describe this capability in detail.
What communication protocols are supported?
What speeds of network lines are required for proposed LIS to function on WAN?
What network infrastructure is needed to operate a true outreach operation (ie, the laboratory needs to accept orders from and send results to a nursing home that is not within the same LAN or WAN as the laboratory)?

SYSTEM IMPLEMENTATION AND TECHNICAL SUPPORT

Describe and attach your typical implementation plan. Describe the length of time your engineer will be on site during implementation and the exact scope of the work he/she will perform.
Describe the experience and qualifications of your installation team.
What kind of client communication and implementation planning is done prior to the installation?
Describe the training provided. Include a training outline.
Where is your technical support center located?
What are the methods for contacting technical support?
What are your hours of operation for technical support?
Describe the qualifications of your technical support staff.
Describe the organization and structure of your technical support services.
What percentage of your total employees is responsible for direct client support?
Describe the ongoing system support provided by the vendor.
Are software upgrades provided as part of the software support contract?
Describe your software upgrade process.
Are there "hot fixes" or "updates" between versions? Do these updates cost extra?
How often are new versions released?
How are customer requests for enhancements and customizations handled?
How many separate modifications were included in the last release?
How many separate modifications included in the last release requested by current users?
Describe the qualifications of your product development department.
What percentage of your total employees is responsible for product development?
Do you have a formal users' group?
Describe the company's policy regarding source code.

SYSTEM PROPOSAL

Provide a system proposal that includes

- Detailed listing of hardware provided
- Detailed listing of software provided
- Description of training provided, including location and time commitment
- Description and cost of ongoing support
- Cost of proposed system

Sample Request for Information or Request for Proposal #2

List of functional requirements

Assign one of the following availability codes to each item:

A—Feature is available off the shelf.
N—Feature is not available.
C—Feature is available with additional cost and custom programming.

- Detailed responses to and descriptions of each checklist item mentioned are required.
- Elaborate on any items that differentiate you from other vendors.
- Failure to complete or respond to all checklist items may result in dismissal of your RFI/RFP submission. If you do not have the functionality mentioned, please respond accordingly with "not available," "in development" or "in testing" or if you would propose doing so at additional cost and customization following the appropriate code (C).

Technical requirements
Describe hardware requirements (see previous example questions).
Describe software requirements (see previous example questions).
Describe network and interface issues (see previous example questions).

Interfacing

Provide operational interfaces for the following applications:

- Hospital information system (HIS)
- Reference laboratory
- Electronic medical record (EMR)
- Billing system
- Practice management system
- Demographics system
- Pathology module/software
- Microbiology module/software
- Radiology module/software
- Other information system(s)

Provide additional interfaces for multiple systems

Provide all interfaces as an integral part of the application requiring no additional third-party software to implement or maintain the interface.

Provide technical support for all active interfaces.

Provide operational interfaces for the following applications (please provide a functional description of each interface available):

HIS

Reference laboratory

EMR

LIS

Billing system

Practice management system

Demographics system

Pathology module/software

Microbiology module/software

Radiology module/software

Other information system

Provide additional interfaces for multiple systems.

Provide all interfaces as an integral part of the application requiring no additional third-party software to implement or maintain the interface.

Provide technical support for all active interfaces.

Security and auditing

Provide a multilevel security system that is separate from the LIS to ensure the confidentiality of patient-related information and to control access to outreach functions and features.

Restrict access to specific areas of the application based on system function to be performed.

Provide practice level security ensuring that associates of one practice cannot gain access to the patient records of another practice.

Allow password protection at different levels (system administrator, phlebotomy, nursing, provider, and so forth).

Allow a user of proper security clearance to modify the database parameters once the system is live, without requiring programming knowledge.

Restrict access to configuration tables, profile indexes, and so forth to designated personnel via security controls.

Maintain an automated system log of user sign-on activity.

Maintain an audit trail for system entries, including user code, date, and time of each system transaction.

Provide multilevel password security down to options within menus.

Provide a multilevel security system that is separate from the LIS to ensure the confidentiality of patient-related information and to control access to outreach functions and features.

Restrict access to specific areas of the application based on system function to be performed.

Provide practice level security ensuring that associates of one practice cannot gain access to the patient records of another practice.

Allow password protection at different levels (system administrator, phlebotomy, nursing, provider, and so forth).

Allow a user of proper security clearance to modify the database parameters once the system is live, without requiring programming knowledge.

Restrict access to configuration tables, profile indexes, and so forth to designated personnel via security controls.

Maintain an automated system log of user sign-on activity.

Maintain an audit trail for system entries including user code, date, and time of each system transaction.

Provide multilevel password security down to options within menus.

Order entry
Allow multiple tests ordering for a single patient using a common demographic record.
Allow laboratory orders to be entered from any computer on or off the local network.
Allow the laboratory to develop and customize orderable items.
Allow simple test ordering: single header linked to a single test result field (eg, glucose).
Allow compound test ordering: single header linked to multiple test result fields (eg, complete blood cell count [CBC], lipid panel, and comprehensive metabolic panel).
Allow the user to order tests by entering test codes and/or by selecting from a test menu.
Automatically alerts users to previously ordered laboratory work.
Allow at the time of ordering a request that patient laboratory results be sent to more than one provider.
Allow the cancellation of orders for patients who do not show for appointment.
Provide medical necessity validation based on laboratory-defined valid diagnosis codes for each applicable test.
Allow the generation of Medicare-compliant Advanced Beneficiary Notice forms when test ordering fails medical necessity validation.
Allow entry of 4 diagnosis codes for each ordered test.
Provide automatic testing destination routing as specified in payor's contract.
Provide automatic label printing as orders are entered.
Allow laboratory-defined label configuration.
Describe the bar code formats your outreach solution accepts and prints.
Provide the specific sample requirements or sample tube types at the time of order entry.
Store diagnosis codes in registration function.
Support retrieval of patient records by partial (eg, first few letters of) patient last name.
Support sample storage and retrieval modules for the purpose of drug testing, add-on testing, and so forth.
Process orders for profiles that include multiple tests (eg, cardiac enzyme profile).
Allow a miscellaneous test code so previously undefined tests can be ordered and charged.
Ability to correct a field on a screen without having to re-enter entire order transaction.
Allow splitting one ordered test into more than one request (eg, group tests, pre-operative, and coagulation screen).
Automatically check for and warn of duplicate single test orders with profile orders.
Support cancellation of tests—logging accession number, test code, patient name, reason, date, time, and tech ID.
Provide simple method to order additional test requests on sample already received and processed in laboratory.
Allow cancellation of an order without canceling prior results.
Provide flexible, customizable sample ID formats.
Print sample collection labels for timed and routine collections.
Allow for multiple labels per test to print.
Print instructions/comments (eg, do not collect from right arm) on sample labels.
Print aliquot labels when more than one test is drawn in the same collection tube.

Provide that uncollected samples continue to appear on subsequent lists until canceled or collected.

Provide for easy free text entry of information, such as critical result notification, sample rejection, or culture sites.

Provide for intelligent prompting for accessioning (eg, when a wound culture is ordered, the system prompts the user for site/location).

Provide easy access to sample requirements for laboratory users.

Provide intelligent sample labeling—groups samples in chemistry together and prints on labels, while hematology tests print on separate label and microbiology prints separately. Allows for making the number of labels customizable for each test.

Provide intuitive user interface—easy to locate screens for accessioning, reporting queries, and so forth.

Provide for an easy, systematic, and logical method of adding, editing, or deleting tests in the test code dictionary.

When looking up a patient in the system, tests performed on that patient and test results are made available without additional steps.

Allow outreach clients to customize their own order entry screens to fit their practice's needs.

Allow outreach clients to customize colors and logos of the system for their practice only.

Result reporting

Provide ability to auto deliver results by the following methods:

Web delivered (ie, provider logs in to a Web site to retrieve results)

E-mail

Fax

Print

Electronic interface to client information system (EMR, HIS, medical practice management software, and so forth)

Accept images, graphics, and linked documents from a host LIS via interface to display on reports.

Provide ability to designate HTML or PDF format of reports.

Maintain patient result history indefinitely.

Provide ability to purge results after a specific amount of time if desired.

Provide ability to graph historical results on a report.

Provide scheduler for automatic result delivery.

Allow redelivery of results.

Automatically maintain a record of reports delivered by each reporting modality (fax, printer, and e-mail, and so forth). Provide easy access to these results at any time.

Allow patient test to be incomplete for at least 8 weeks in the system.

Print daily detailed master log of all work performed in laboratory for audit purposes.

Display abnormal or critical results uniquely from other results.

Allow for cumulative result reporting. Please explain.

Describe the procedure for correcting test results that have been resulted. After correcting, are the corrections able to be altered?

Print list of received but untested samples due to insufficient quantity.

Allow for a comment to be placed on the sample accordingly.

Includes features that allow batch reporting.

Allow features for customizable patient report formats.

Display patient results in an easy to view format for all patients of a provider or location.

Provide ability to batch print and batch acknowledge receipt of results.

Provide the date/time reported on reports transmitted by fax, laser printer, and e-mail.

Provide a permanent log of all test results that have been edited.

Workstations work independently of each other. Multiple functions can occur simultaneously without one party having to exit the system.

Provide flexible reporting formats.

Provide the ability to access all patients of a particular client by name, date, or date range.

Allow look-up of patient and patient results by client number.

Rules-based logic

Ability for rules-based logic where laboratory personnel can define criteria in "if-then" statements.

Ability for rules program to evaluate all rule entries for tests, not just the first one, so that complex or "cascading" rules may easily be designed, where several rules can be invoked based on one scenario.

Provide rules-based report routing.

Provide the ability to create rules to assist in decision support.

Must have ability to flag results based on criteria other than standard reference ranges to include testing location, drawing location, ordering provider, patient age, and priority of order.

Charge rule capability.

Provide ability to customize order entry rules.

Allow rules to be enabled by practice (ie, one practice has certain rules enabled and another practice does not).

Sample status and tracking

Provide the ability to track patient samples throughout the testing process.

Provide identification (ID) of the individual who ordered the test, collected the sample, and released the test results, including the date and time of these occurrences so that this information is accessible throughout the process.

Support user-defined priorities.

Support a way to identify the phlebotomist (doctor, nurse, and so forth) in system for samples not drawn by laboratory personnel.

Include data for tracing order (dates, times, tech ID, and results) from order entry to final reporting in master log.

Provide index to master log by accession number.

Provide customizable sample storage tracking, including ID of freezers, refrigerators, and so forth.

Allow sample storage/retrieval by use of a barcode scanner (ie, the requisition is scanned into the system and the system tells the laboratory where the sample is stored in the laboratory).

Management and administration
Provide ability to create completion reports by date.
Provide ability to create billing summary reports by date.
Provide ability to create reports of failed medical necessity checks.
Provide ability to create canceled test reports that include test name and reason for cancellation.
Provide for a customizable overdue report that would indicate tests, such as urine cultures, that become overdue at 4 days while blood cultures become overdue at 7 days and CBC overdue at 4 hours.
Provide ability to create turnaround time reports by date.
Provide a summary report for test usage over a user-definable period of time.
Provide physician utilization report (eg, number of tests requested by a physician).
Provide ability to print a list of draws that need to be performed.

Patient records
Provide ability to easily generate historical patient reports.
Allow patient database search based on
Patient name
Patient account number
Patient Social Security number
Allow the user to search previous patient results for specific tests and easily view historical results of that test.
Allow the user to graph patient results by test to identify possible trends.
Allow historical results for multiple tests to be graphed on one normalized graph.
Describe how the system handles storage of old results. Is archiving/purging necessary?
Allow the user to review specific patient's results without paging through the entire list of patient results.

Data mining
Provide user-friendly report generator with graphic user interface as an integral part of the outreach application.
Provide ability to create reports from any computer.
Provide ability to create a billing report.
Provide ability to create a report showing all tests completed during a date range.
Provide ability to create a report for order exceptions.
Provide ability to generate patient lists (with certain demographic data) that meet specific result criteria for public health reporting.
Provide ability to create reports on standing or recurring orders.
Provide ability to write queries using logic in great detail within the application.
Support the use of commercially available tools for report generation.
Provide ability to save commonly performed searches.
Provide ability to schedule automatic, unattended runs of data reports.
Provide ability to create reports to mine patient data for specific practices within the application.
Provide online help screens to assist novice users in all applications.

After responses to the RFI/RFP (**Table 1**) customized from the options and others, you may want to include for your laboratory get cost quotations for the system according to your requirements. Be sure to look at initial implementation costs as well as costs for the following 1-, 3-, and 5-year periods for total cost of ownership with ongoing support and maintenance as well as depreciation on the hardware for the total cost of the system to gain a full measure of ROI. Again, at this point, telephone reference checks are an economical way to talk with your peers about the system you are considering.[3]

Once you have narrowed down the possible list of candidate systems to choose from, it is time for vendor demonstrations. Demonstrations are extremely important. If you are going to have 2 or 3 vendors come in, have them come in at the same time or as close to it possible. You have an opportunity to go from one vendor to the other,

Table 1
Sample request for information or request for proposal #3

Enterprise Features	Required/Desired Optional	Score
Multisite capability?		
Sign-out via Web interface? (No need for VPN, Citrix, or terminal server?)		
Clinical pathology system included		
Build our own interfaces to clients, EMRs, instruments, etc., without vendor fees or involvement?		
Subtotal		
Scalability		
Can system accommodate current volumes?		
Can system accommodate 100% increase to current volumes?		
Database supports mirroring/replication failover?		
Experience configuring and supporting mirrored/replicated environments?		
Subtotal		
System set-up and accession		
Build our own part types?		
Field to store office chart number?		
Mini vs maxi accessioning capability?		
Custom data entry screens by site? Specimen type?		
Enter both AP and clinical data?		
Configurable workflows?		
Custom report generation without vendor assistance?		
Subtotal		
Histology production		
Dynamic notification of special stain and recut orders? E-mail notification?		
Automated logs? Print on defined schedule?		
Subtotal		
Outreach tools		
Interface to practice management systems?		
Result interfaces for common EMRs and hospital systems?		
Autofax/fax on demand?		
Fax chutes by location, client, physician?		
Real-time numeric and graphic client data tracking volume, etc.?		
Custom client productivity reports?		
Subtotal		
Interface capabilities		
Interfaces to Aperio?		
Interfaces to stainer(s)?		
Interfaces to slide and cassette printers?		
Support for scanned supporting documentation (Reqs, Ins, send-out reports, etc.?)		
Import slide images remotely via Citrix or terminal server?		
Subtotal		
Paperless solutions		

(*continued on next page*)

Table 1
(continued)

Enterprise Features	Required/Desired Optional	Score
Ability to scan documents in?		
Bar coding?		
RFID?		
Launch case automatically on screen with gross description/ preliminary transcription, attached scan of req, prompted by slide bar code/RFID detection?		
Subtotal		
Transcription productivity		
Quick text templates?		
Medical spell check?		
Synoptic reports (CAP-approved cancer reporting)?		
Means to designate cancer registry reports?		
WYSIWYG throughout report generation?		
Subtotal		
Sign-out		
Ability to easily navigate from module to module without need to exit one or the other?		
Do quick searches?		
Check on history?		
Ability to know if a pathologist has referred the case to another pathologist?		
Transmit e-mail to pathologist that case is transcribed (for rush or other critical cases)?		
One-click sign out? (Cases automatically move to the next in line after sign out.)		
Subtotal		
Vendor qualifications		
Other software products that could be integrated with these products are available.		
Active user group exists for each product.		
User group influences release of the product (eg, controls x% of enhancements to the product).		
Reference sites provided for each product		
Published evaluations of software provided		
Proof of success in similar organization provided		
Willing to demonstrate products: at customer site; at vendor site		
Proposed contract provided		
Sample plans provided (eg, implementation, training)		
Software license agreements provided (eg, software maintenance, support)		
Subtotal		
Warranty/support		
Documentation updated for any fixes		
Procedures for vendor-initiated fixes provided		
On-site expertise available at no or low cost		

(*continued on next page*)

Table 1
(continued)

Enterprise Features	Required/Desired Optional	Score
Customer can modify software without impacting warranty or support		
Updates, enhancements, and new releases covered under maintenance agreements		
Failure to install an update, enhancement, or new release impacts the warranty/support/maintenance after		
30 d or Less		
31–60 d		
61–90 d		
91+ d		
Warranty/support/maintenance is provided for modifications specifically requested by the customer.		
Subtotal		
Total score		

Abbreviations: Reqs, requisitions; RFID, radio frequency identification; VPN, virtual private network; WYSIWYG, what you see is what you get.

see something at the first vendor, then go to the second vendor and see if that vendor has it as well. Also, if you spread demonstrations out over time, people are going to forget what they saw. Be sure to include as many shareholders/stakeholders in the process as possible. This is a critical time for someone in accessioning or billing or for a pathologist to question something seen, or more importantly not seen, or that the company was not able to address clearly, to raise concerns about workflow functionality.

Understand your vendor's business strategy. Where are they going? What market are they after? If you are a midsize reference laboratory, for example, and the vendor's primary target market is large academic teaching hospitals, you need to consider the consequences. Also, what do you need to do to install and keep the system running? If you cannot have a medical technologist who is fairly up on IT components and can write the expert rules, and you have to hire 3 programmers to do that, that is something you have to understand.

This visit is also important for understanding the basic architecture of the system and what operating system the system runs on, which are important in the context of other laboratory software applications for functionality as well as those of any corporate partners, hospitals, or clients.

Be cognizant of site visit(s) and users' opinions of the system from due diligence through contracting, implementation, validation, testing, go-live, post–go-live support, and maintenance/upgrades since go-live. Be sure that knowledgeable IT, technical, and professional personnel are available to discuss the pros and cons with you openly. The vendor should not be present at these discussions to allow the client to be completely transparent with their opinions about the company and product. Make a concerted effort to follow specimens from collection to sign-out to see all components of the system. If billing or result interfaces are required or desired, be sure to inquire what systems their LIS interfaces with and their experiences. A site with multiple users/customers who express serious doubts about the company and/or product may be a red flag. Although no system can be everything to everyone, a current user who expresses nothing but frustration with the company and/or the product and regrets either implementing a solution or migrating from a previous solution needs to be addressed in your due diligence. It may be that a customer's expectations were not met based on functionality that did not exist or it may be that a customer was misled by the vendor, as discussed previously. This needs to be sorted out.

Although vendors have different strengths and weaknesses, the aggregate—the area under the end of the curve in integral calculus—for most of the leading vendors is about the same. What is different is how we/they do certain things.[3]

It is also worthwhile to make the time and necessary budget to visit a vendor's headquarters during this process and meet with leadership and see how the customer service center operates

and what the corporate culture is like. Now is the time to know if it has a full-functional 24/7 help desk within the headquarters or whether it outsources that service and how that is managed. One question we like to ask at the headquarter visit of the chief executive officer or chief operating officer is, "What are 3 items you are working on now?" or "What 3 major functionalities do you see on the short-term horizon of importance to clinical laboratories?" Meet the people who are going to be installing and supporting your system. You are going to be business associates and colleagues for potentially the next 7 to 10 years.

Scenarios to provide each vendor may be helpful so that you can compare how one system does a specific function to another. For example, have 10 to 15 scenarios for them to demonstrate, such as assigning specific cases to specific pathologists based on client requests, processing reflex testing, preordering special stain requests, and running a report for client services on volumes of orders/tests received as a month-to-month comparison for business analytics. Ensure that the demonstrations and site visits are the current version and not "mocked up" with functionality that does not exist in a production environment or a database that is unrealistic for clinical use with missing patient identifiers or generic specimen sources, types, or procedures. Try to have the team get some hands-on exposure, to the extent possible, during demonstrations and perhaps on the site visit(s) interact with the system enough to get a flavor of working with the system. You and your laboratory will be seeing this wallpaper on their computer screens for some time.

Folks who are part of the due diligence process need to record and share their thoughts at every stage of the process in the event it is later discovered that part of the RFI/RFP, responses, demonstration, or site visit was incomplete, and that they need to go back to and ensure the specification or functionality was discussed as to whether the system has the capability or not and how it is currently used in a similar clinical environment, if at all.

When multiple vendors are on site at the same time, you have a chance to revisit these vendors, confirm things, and fill in the gaps. If you see a demonstration of one component from one vendor and 2 hours later see the same demonstration from another vendor and see something they are doing that is totally different, go back and ask the first vendor, "Show me how you could do that same function."[3]

Lastly, make a decision and stick to it. You are entering into a long-term relationship most likely, so time is required to make the right decision but the decision-making process should not take longer than it will to implement and validate the system for use, in general. Begin the process of contracting with 4 major principles in mind[3]:

1. The worst time to negotiate a contract is during contract negotiations. You have lost leverage if you have told the vendor they are your choice over all the others.
2. There are standard contracts that are presented. These are a good baseline but the final version may not resemble the original boilerplate version you were initially presented. Often there is good infrastructure there with which to work that you can build on.
3. The contract has to cover the entire system. If you are acquiring hardware, software, implementation services, support, database training, user training, and more, the contract should cover it all.
4. The contract has to be fair and protect the interests of both parties. Without going into an exhaustive review of types of contracts and stipulations within contracts, the reader should recognize legal counsel should be sought for assistance in contract matters of this complexity.

Have a negotiation team prior to contracting. If you want the first year of on-site support to be included beginning at go-live, be sure to include this in negotiations or better yet within the RFI/RFP as a requirement. This is important (discussed later). The vendor may agree to include support but it may affect the price inclusive at implementation rather than an optional line item in the contract. Both sides need to be flexible and not adversarial. Again, the intent is a long-term relationship that requires the terms of the relationship are clearly delineated on the front end. Being treated poorly before you are a client during this process may present some additional information as to whether you want to associate your business with theirs.

A contract checklist should include, but may not be limited to, the following items[3]:

1. System specifications
2. Operational characteristics, including performance criteria, reliability and availability criteria, and backup and recovery
3. Acceptance testing criteria. Make installment payments for capital expenses and implementation based on milestones the vendor has to achieve to be remunerated. For example, you may want to propose 20% of purchase price due at signing, 20% due at database configuration, 15% due at validation, 15%

due at testing, 10% due at go-live, and 20% due at 60 or 90 days post–go-live to resolve any bugs that are identified.
4. Terms and conditions of the license. How much are additional licenses and how few can be purchased at 1 time?
5. Payment terms (discussed previously)
6. Source code availability and user programming provisions and constraints. If the vendor goes out of business, you have the right to find some fallback procedure, whether it is access to source code or the ability to hire a third party to maintain the system for you.
7. Warranties
8. Inclusion of RFI/RFP responses. It is important that they respond to the RFI/RFP in a manner that reflects they meet a particular requirement that was demonstrated and that the production version satisfies the response and demonstration.
9. Confidentiality of data
10. Provisions for additional locations
11. Rights to future applications
12. Manuals and other documentation
13. Legal conditions and remedies. Consult an attorney.

If all goes right, you will have selected the best system to meet your needs within your workflows, to add efficiencies, productivity, and data mining capabilities for both clinical and operational business considerations with a measurable ROI. And in 7 to 10 years' time you may want to do it all over again!

SYSTEM IMPLEMENTATION

Now that the critical aspects of selection of a new information system are covered, focus shifts to implementing this designated system. Although your institution-specific considerations will drive many of the significant decisions surrounding whether to use your chosen vendor's standard functionality or configure for your own environment, the general principles highlighted cover many possible scenarios. And although the discussion remains focused on AP, the overarching themes of the criticality of workflow considerations, a team-centric approach, and multiple iterations of testing remain the same in meeting the needs of implementing a clinical pathology or digital imaging system (among other potential applications).

It would be remiss to not mention the implications of the widespread adoption of electronic health records on the LIS arena,[4] particularly as EHR vendors begin to encroach into space that historically was the lone domain of LIS companies. These developments have often compelled LIS managers and their teams to take on a more involved role, and such involvement needs to be considered because personnel time commitments and expectations rapidly change in this type of scenario. Such considerations are particularly worth dedicating thought and time to if your practice and associated IT support are small in size and/or perhaps larger with more resources and personnel but geographically spread across a large swath of area. Should your technical group be limited in either number, time, and/or adaptability, utilizing a contractor, either wrapped within the original contract with your vendor or as a third-party consultant, may be worthwhile, especially if it offers expertise and seasoned experience as a broker for both sides (of course not losing sight of this temporary but not insignificant expense). Regardless of which approach is taken, a project manager ultimately responsible for the implementation's success should be designated to guide the team through the overall process to completion.

PREPARATION PHASE

In the preparation phase, it is essential to ensure that you and your working environment have made any necessary upgrades to hardware (including computer workstations, servers, printers, and ports) required to take on the new information system. Along the same vein, ensuring that your bandwidth capacity can withstand the demands of the new network requirements is also of prime importance, especially in the context of your institutional security parameters.

Your data conversion and contingency plans are of paramount significance because they will cover which data are carried forward, how the data elements are moved, and by which means legacy data will be accessible while migrated to your new system. Depending on your institution's requirements, you may not feel the need for comprehensive coverage but expect to ask for total 100% conversion of prior data as your default starting point.

Before getting to day zero when you will turn on the new system for full real use, it is imperative to request and establish a testing environment in addition to your live production environment. This allows you and your team to properly go through unit and integrated testing, working through any bugs and problems that arise, in a separate arena that will not disrupt the current clinical service work utilizing the live system.

SYSTEM CONFIGURATION, IMPLEMENTATION TESTING, AND VALIDATION

After you have established dual-environment arrangements, your team's next milestone is to arrange for your system to be configured with existing laboratory instrumentation as well as software interfaces with your EHR, clinical LIS, and outreach and reference sites. Once your system has been configured, the new setup can be tested and validated. The importance of this next order of business in establishing and completing a test plan cannot be understated—it can be the sole criterion on which your project is deemed a rousing success or an utter failure. Once a test plan is in place, complete with test procedures for each function that was approved and laid out in the system design deliberations as well as any interfaces that are modified or new, the ideal testing set should involve the system's new hardware and software configurations, working within anticipated security requirements and current clinical workflows.

Prior to go-live, validation of the system and its new functionality should take place wherein the gamut of anticipated potential clinical scenarios are put together and tested for both the ordering/input component of the transaction and the results/output transmittal side of the equation. Final, end-to-end integration testing incorporating order entry, result delivery, background financial processes, and associated interface crossing with test patients and their tracer specimens is needed to ensure that all the components of the system are present and verified to be in correct working order.

TRAINING

Training involves a multitiered approached in which your team's project manager, the system manager(s), superuser(s), and designated trainer(s) are given initial instruction on the system, often at one of your selected vendor's training sites (with associated travel costs typically and presumptively built into your contract). This will allow for more extensive "train the trainer" preparation from the vendor directly and set your team leaders to become established to the point where they will be able to lead local training sessions for your end users. Be sure to inquire with the vendor about online modules or other remote training offerings that may obviate the time and financial burdens associated with training time. Whether distance training or not, be prepared to dedicate time slots for your laboratory's personnel to undergo this requisite commitment and have appropriate staffing coverage.

GO-LIVE

A few pragmatic items to mention before proceeding with your system's go-live revolve around communication and minimizing distractions. For the former, it is prudent to inform your client base (providers, outreach facilities, and the like) that you will be switching to a new system and that, although you do not anticipate any problems during the change, there may arise unforeseen hiccups during the transition. With regard to the latter, setting aside the go-live date for just your new system and avoiding any overlap with high-resource utilization periods, such as EHR installations, bringing on board new laboratory analyzers, or possible accreditation or inspection windows, is a preferred approach if such events are within your institution's control.

When the time has come to flip the switch on your new system, rest assured that you and your team's preparation and due diligence have set up for success. Granted there are postimplementation considerations surrounding issues of system maintenance or the inevitable workflow idiosyncrasy that is unique to your laboratory setting that the vendor's solution does not meet that will need to be addressed (and of course tested). But once you have reached this point, you can breathe easy—it will only be a few years before the refresh cycle comes full circle and you need to consider if and when to update your system again. Should you decide to do so, you will be better off having done it before and undoubtedly be better equipped with the lessons learned from the previous installation. We hope this article has helped you in modernizing one of the most important pieces of your laboratory's daily work.

REFERENCES

1. Anonymous. Available at: https://www.ftb.ca.gov/aboutFTB/Projects/ITSP/BPM_Glossary.pdf. Accessed June 23, 2014.
2. Sinard JH. Practical pathology informatics: demystifying informatics for the practicing anatomic pathologist. London: Springer-Verlag; 2006. p. 380.
3. Winsten D, Weiner H. Landing a new lis. Northfield: CAP Today; 2007. Available at: http://www.cap.org/apps//cap.portal?_nfpb=true%26cntvwrPtlt_actionOverride=%2Fportlets%2FcontentViewer%2Fshow%26_windowLabel=cntvwrPtlt%26cntvwrPtlt%7BactionForm.contentReference%7D=cap_today%2Ffeature_stories%2F0507NewLIS.html%26_state=maximized%26_pageLabel=cntvwr. Accessed July 15, 2014.
4. Sinard JH, Powell SZ, Karcher DS. Pathology training in informatics: evolving to meet a growing need. Arch Pathol Lab Med 2014;138(4):505–11.