

Stand-alone Laboratory Information Systems Versus Laboratory Modules Incorporated in the Electronic Health Record

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• The increasing availability of laboratory information management modules within enterprise electronic health record solutions has resulted in some institutional administrators deciding which laboratory information system will be used to manage workflow within the laboratory, often with minimal input from the pathologists. This article aims to educate pathologists on many of the issues and implications this change may have on laboratory operations, positioning them to better evaluate and represent the needs of the laboratory during this decision-making process. The experiences of the authors, many of their colleagues, and published observations relevant to this debate are summarized. There are multiple dimensions of the interdependency between the pathology laboratory and its information system that must be factored into the decision. Functionality is important, but management authority and gap-ownership are also significant elements to consider. Thus, the pathologist must maintain an active role in the decision-making process to ensure the success of the laboratory.

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The Medicare and Medicaid Electronic Health Care Record (EHR) Incentive Program (also known as *Meaningful Use*) has driven a marked expansion of EHR use in health care organizations.^{1–4} The expansion is

occurring in a setting of cost constraints, a challenging economic climate, and the frequent consolidation of health care facilities into systems or alliances. These forces align to affect decision-making processes regarding laboratory information system (LIS) selection and oversight, potentially posing challenges to the ability of the laboratory director to ensure that the laboratory and its LIS meet the operational and clinical needs of the organization.

The laboratory information system directly manages the workflow within a clinical laboratory.^{5,6} Although the obvious “output” of an LIS is a test result or report on a patient specimen, be it paper or electronic, the LIS also coordinates and underpins the day-to-day laboratory activities associated with generating that report. Those activities include test-order receipt and management, asset tracking (eg, specimens, tissue blocks), task segmentation and distribution, status monitoring, and a number of quality assurance and other regulatory requirements that are unique to the operation of a clinical laboratory. Instrument interfacing and support for laboratory automation technologies have also become important elements of the modern LIS. The LIS is so fundamental to the operation of the laboratory and so specialized for that purpose that it has usually been selected, purchased, and controlled directly by laboratory staff.^{7,8} Because of fundamentally different workflows and data models, laboratories commonly have separate LISs for the anatomic pathology laboratory and the clinical laboratory, each specialized for the unique operational needs of those laboratories.⁶ In addition, laboratories may implement LISs that are necessary to support the operations of laboratories with specialized needs, such as blood banks and cytogenetics laboratories.⁵

As described in the first article of this series,⁹ the prevalence of EHRs is increasing which, in turn, is changing the dynamics of LIS selection and control within health care organizations. As organizations look to purchase and implement EHRs, laboratories may find themselves facing pressure from hospital or health-system executive leadership to replace their current LIS or LISs with one from the same vendor as the EHR, current or planned. This article discusses the important implications and potential threats for laboratories and pathologists in this evolving landscape.

EVOLUTION OF THE LIS AND EHR

The LIS and EHR have different lineages. Laboratories were at the forefront of the use of computers for clinical

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Table 1. Purported Benefits of Using a Laboratory Information System Module Available From an Electronic Health Record System Vendor

- “One-stop shopping”—dealing with a single vendor
- Significant cost savings on purchase price (may be “included” in overall purchase)
- Simplified solution deployment
- Consolidated and potentially reduced maintenance costs
- Single installed system—single vendor responsible for all elements of system operation
- Promise of “seamless integration”—reduced or eliminated need for interfaces
- Increased ability to standardize laboratory practices across different hospitals within the health system

patient-care purposes, largely because of the intensive data management required by their work. The LISs have been common in clinical laboratories since the 1970s. During the past several decades, laboratories and pathologists have developed substantial expertise in the use of this form of health information technology, and LISs have become increasingly sophisticated to meet the needs of increasingly sophisticated laboratories. The LIS (for anatomic and/or clinical pathology) has typically been a distinct system (or systems) that the laboratory selected, installed, and managed,^{7,8} and, in many instances, LIS implementation predated the arrival of the EHR at the institution. In contrast to LISs, the use of EHRs evolved from hospital information systems, which, in turn, started largely as patient management and financial systems.⁷ The EHR must meet the diverse needs of multiple, and often operationally distinct, clinical services for documentation, patient management, billing, and regulatory compliance, among other functions.¹⁰ A hospital or health system purchases an EHR and chooses an EHR vendor based on enterprise-level considerations, financial issues, and (hopefully) input from multiple, diverse stakeholders. An institution-level information technology (IT) unit implements and supports the EHR.

Data exchange between the LIS and the EHR occur via electronic interfaces, most commonly based on the health level 7 protocol.⁶ Admission, discharge, and transfer information, consisting largely of patient demographic data, is sent from the EHR to the LIS to minimize errors in the entry of patient information. Test results flow back from the LIS to the EHR. As EHRs have developed the capability to support computerized provider order entry, orders for laboratory tests can be entered directly into the EHR and be sent to the LIS.

Increasingly, EHR software and LIS software can be acquired from a single vendor. Some EHR vendors have long included LISs in their product portfolios, even building on their success in the laboratory domain to expand their scope to enterprise-wide offerings. For others, the LIS is an entirely new product, developed as a “module” within an established EHR.

The Promise of a Single Vendor for the EHR and LIS

The philosophic conflict between deploying a department-specific LIS versus an LIS provided by the institution’s EHR vendor (single-solution LIS) is not new and represents another instance of the long-standing value debate of “stand-alone” (also known as *best-of-breed*) versus “enterprise-wide integrated” information system solutions.^{11–13} Indeed, this debate is not unique to pathology and occurs in

other medical disciplines where frequent interactions with an information system are part of the daily service-line workflow such as radiology.¹⁴ In the enterprise-wide approach, a single vendor provides clinical information system functionality for the entire institution; in the best-of-breed approach, each department, section, or functional unit within the institution selects a vendor and software package that it believes best meets its particular needs. In the latter case, establishing and maintaining data exchange among systems becomes a shared responsibility between the departments and the institution. The task of setting up and maintaining the many, often complex, interfaces needed to achieve that interconnectivity is far from trivial,¹⁵ so there must be real benefits to the department-specific (or best-of-breed) approach if health care organizations choose to pursue that course. The combination of numerous factors unique to individual institutions, including real and perceived needs, history and culture, personalities, management structures, and politics, ultimately determines the mix of enterprise and department-specific information solutions in a particular health care setting.

Integration offered by a single-vendor solution for the LIS and EHR appeals strongly to hospital and health-system administrations and is driving purchase decisions. Another driver is the belief that long-term cost savings will be achieved by consolidating products to those provided by a single vendor. In a recent KLAS (KLAS Enterprises, Orem, Utah) survey, 74% of the health care organizations interviewed believed that an LIS that was part of an enterprise-wide solution was preferable.¹⁶ In the same survey, 90% of those planning a new LIS purchase planned to install an LIS from their EHR vendor. Another recent industry report¹⁷ showed that 19% of hospitals were planning to replace their LIS, and the most important LIS attribute that would be sought was integration with their current EHR.

Unfortunately, administrators who decide to purchase an LIS from their EHR vendor may do so without consulting pathologists or even other physicians. It might seem unlikely that this sort of decision could be made without input from pathologists and/or the laboratory; however, in the 2011 College of American Pathologists practice characteristics survey of its members, one-half of the pathologist respondents indicated that they had no involvement in the selection of the LIS used in their laboratory.¹⁸ Fewer than one-quarter indicated that they had a role in the actual purchasing decision.

The advantages often claimed for the single-vendor solution are summarized in Table 1. They include the belief that working with a single vendor will simplify many aspects of the selection, installation, and maintenance process. There is also the promise that an integrated LIS component will eliminate the overhead of LIS-EHR interfaces. Experience has indicated that single-solution vendors may offer to “throw in” the LIS at, ostensibly, drastically reduced prices. In addition, as hospitals consolidate into health systems, there may be the perception that the single-solution EHR and LIS can simply be “dropped-in” at a sister hospital, standardizing information management practices and minimizing information technology challenges.

However, there can be both short-term and long-term consequences to this approach, and such consequences may not surface until long after the selection decision has been made. Pathologists must be prepared to educate hospital administration of the potential risks to operational efficiency

Table 2. Key Points for Pathologists as Advocates for Laboratory Information System (LIS) to Have Specialized Functionality to Meet Patient Care and Laboratory Needs

- Numerous and diverse specialized LIS capabilities are necessary to support modern pathology and laboratory services (eg, point-of-care testing, molecular testing, digital imaging)
- Switching costs of changing an LIS must be considered in cost equations
- Accurate comparison of price/features is necessary (“apples to apples”)
- Certain areas of the laboratory have domain-specific LIS requirements (eg, blood-bank)
- The need for LIS interfaces to other systems will not disappear (eg, reference laboratories, public health reporting, tumor registries, among others)
- Revenue-providing laboratory outreach activities require client-centric LIS functions (eg, customized interfaces or automated faxing, client specific fee schedules, specimen tracking)
- Laboratory requires high-level vendor responsiveness on LIS-specific issues.
- Adoption of new testing technology often requires an LIS vendor to make modifications that allow interfacing and integrating ever-changing equipment

and patient care (Table 2). Vendor selection is often made based on desirable functionality in a few “important” areas, with a less-thorough investigation of the capabilities of other modules. Even though the LIS software may be included “free” as part of the purchase, implementation is typically not free. Switching costs to change an LIS are high. There can be substantial short-term costs associated with installing a suboptimal LIS in a laboratory and hidden long-term costs associated with diminished operational efficiency in the laboratory.

It may also be necessary to point out to hospital IT groups and administrations that the EHR vendor’s claim of “no more interfaces” with an integrated LIS module is not entirely accurate. There will clearly be an ongoing need to maintain additional system-to-system interfaces to address tests sent out, blood bank information systems (which require a US Food and Drug Administration–approved information system and is, therefore, often not included in either integrated or stand-alone LISs), point-of-care instruments, genetics and molecular testing, and tumor registries. In addition, laboratories have analytic instruments that require interfacing, either directly or via middleware, which can provide important functionality. Although instrument interfaces are different than LIS-EHR interfaces, they still require software licensing, configuration, testing, validation, monitoring, maintenance, and upgrades, and this is not a one-time activity. As new laboratory testing equipment becomes available, new interfaces will be needed, and the vendor of the LIS (whether stand-alone or an integrated EHR module) will have to be prepared to accommodate any system changes needed to allow the laboratory to take advantage of new technology.

THREE DIMENSIONS OF THE LABORATORY—LIS INTERDEPENDENCY

The level of integration of laboratory information (orders, results, and other related data) between the LIS and the EHR remains an important determinant in how effectively the laboratory fulfills its mission of providing crucial

information to patient care providers. Unquestionably, a department-specific approach to information system deployment and management within a health care system creates a need to develop and support systems integration via multiple interfaces.¹⁹ Nevertheless, many successful health care systems have taken that approach.

The relationship between pathologists/laboratories and their LIS is fundamentally different than the relationship between many EHR users and the EHR and that may, in part, explain the persistence of department-specific LISs in an increasingly enterprise-focused environment. Most clinical services use an EHR primarily for clinical documentation, placing provider orders, and receiving/reviewing results of tests, studies, and consultations. Although many individuals outside the laboratory may perceive the LIS as simply a “black-box” into which orders are sent and from which results emerge, the LIS is actually a highly complex collection of software that is mission critical to the operation of the laboratory and thus to the care of patients. More than being simply a vehicle for documenting the clinical work that has been done, the LIS informs, orchestrates, and manages the actual performance of the work.^{5,6,20} The laboratory’s effectiveness in meeting patient care needs is tightly coupled with an LIS that optimally addresses laboratory workflow, staff activities, and institutional expectations.

Several dimensions of the laboratory-LIS relationship factor into successful laboratory operations and are areas in which potential threats lie if the influence of the laboratory or pathologist in the LIS selection and management is compromised. Three distinct, but intimately related, dimensions need to be considered: functionality, management, and gap ownership. Assessment of those dimensions requires not only an evaluation of the vendor and its product but also an evaluation of the institutional IT support structures that would be necessary if that vendor’s solution were to be chosen. Department-specific and enterprise-wide single-solution approaches will score differently in those dimensions in different environments. The best decision for a particular institution depends heavily on how effectively each solution supports each of those dimensions of the laboratory-LIS relationship.

LIS Functionality

The debate between department-specific and single-solution LISs in a particular health care organization often centers on the functionality available in the products. *At a minimum, the LIS must have all the specialized functionality necessary to meet the laboratory’s patient care mission, to preserve patient safety, and to support efficient operations.* Laboratories are complex environments, supporting a variety of both common and specialized workflows, and it is a daunting task for any LIS to meet those needs. The existing LIS options available have had varying degrees of success in providing needed functionality, and none fully meets the needs of all laboratories.^{21–26} Surveys of health care providers knowledgeable about LISs have shown that nearly 70% feel there is no “best” LIS.¹⁶ As a result, many large laboratories have found it necessary to deploy multiple systems within the laboratory to support the heterogeneous operations that constitute a typical hospital laboratory.^{22–26} Because of the mission-critical role of laboratory services and LISs, an institution considering replacing its current LIS will be best served by careful consultation with pathologists and analysis of the implications of functionality gaps. For their part, pathologists must educate decision makers who

Table 3. Specialized Capabilities of Laboratory Information Systems Required to Support Laboratory Operations

- Test order receipt and management
- Task segmentation and distribution
- Test and specimen status monitoring and reporting
- Autoverification and complex rules-based processing
- Asset tracking (specimens, blocks, slides, aliquot containers)
- Instrument and middleware interfaces
- Quality control and quality assurance
- Regulatory compliance (eg, Clinical Laboratory Improvement Amendments of 1988, Health Insurance Portability and Accountability Act)
- Patient safety measures
- Specimen-centric data modules, including cross-patient sample batching and analysis
- Tracking of reagent lots and analytic equipment used
- Control samples and standards management
- Support for laboratory outreach activities
- Management of molecular testing protocols
- Digital image management
- Flexible result reporting options
- Laboratory-specific billing functions

may not comprehend the complexity of laboratory processes and information management needs.

Assessment of LIS functionality can be divided into 2 separate discussions: (1) existing functionality, and (2) the ability to rapidly incorporate new functionalities.

The major capability categories that LISs must have to support sophisticated work processes in clinical laboratories are summarized in Table 3. Many of the more-mature LISs (both stand-alone and integrated) have, during their life span, incorporated advanced features that promote clinical care and patient safety, including such things as accommodating common exceptions to the standard laboratory workflow; duplicate patient handling; outreach support; support for multisite laboratories; flexible and sophisticated, rule-based instrument interface and middleware-configuration options; advanced specimen tracking and routing capabilities; laboratory automation technologies; quality-assurance functions; and regulatory reporting, among others. Although newer LISs have had an opportunity to learn from the more-mature products, they typically still have functionality gaps because they have not yet had the time and experience-of-use to develop the breadth and depth of functionality needed by a modern laboratory. “Experience-of-use” is an important driver in the maturation process: shortcomings in the software operations are identified by users, brought to the attention of the vendor, and then (ideally) addressed in new releases of the software. Maturation of the LIS product typically occurs faster with stand-alone LISs than it does with LIS modules within EHRs because (1) there is generally greater direct interaction between the laboratory and the developers, (2) needs of the users within the laboratory are not diluted at the institution by the needs of the other departments using the EHR, and (3) the resources and focus of the developers are not diluted in meeting the needs of many diverse users. As a result, the functionality currently available in newly developed LIS modules within EHRs tends to be less than that in either a mature stand-alone LIS or an LIS module in an EHR that was developed from/around a mature LIS.

Stand-alone LISs have data models tailored specifically to manage laboratory data and operations, and those models differ fundamentally from those of EHRs. Aspects of that

difference are instructive in the evaluation of LIS functionality. Electronic health records are built to focus on patient encounters—encounters are attached to patients, and everything else is attached to encounters. That makes sense from the standpoint of hospital operations, billing needs, and the regulations that health care systems face. Rarely does one access any data within an EHR without first starting with a patient. The data model for a laboratory system, however, is quite different. The central entity of an LIS database is the specimen. Although specimens are always attached to patients, specimens can have, or be split into, multiple components (as described in the third article of this series¹⁵), and it is the type of specimen and the analysis being performed that drives the workflow in the laboratory, not the patient from whom the specimen was obtained. Electronic health records are not fundamentally designed to handle cross-patient batching, and sample control results cannot be associated with any specific patient encounter. Also, many of the types of laboratory workflow data and process controls that are crucial to laboratory operations and to assuring the accuracy of the test results, have little direct value to patient management or to most of the users of an EHR, for example, quality-control results, tracking of which analyzer was used to perform a test, identification of the technologist entering results, among others.

Hospital-based laboratories that maintain outreach, reference laboratory, and/or consultation practices have additional LIS functionality needs.^{5,6,27–29} Outreach and reference-laboratory activities, in which a laboratory performs testing for entities that are not part of the organization, can benefit the laboratory and the health system, not only by increasing revenue to the organization but also by increasing test volumes to a level that justify and support esoteric testing, development of a wider test menu, and subspecialty expertise. The catchment area of a laboratory can far exceed that of a single health care system because specimens can easily travel longer distances than patients typically will. As a result, the LIS is often expected to meet the specimen handling needs of a larger geographic area than the reach of the EHR.

To support outreach programs, LISs require more-complex client-centric and patient-identification functionality. Because specimens arrive from outside the organization, no patient identifier or encounter to which an outreach specimen can be linked will exist within the local EHR. *Client-centricity* refers to the need to organize information around client-specific identifiers that are defined and maintained in the LIS. Importantly, and more so in the EHR era, setting up and maintaining LIS interfaces with client site EHRs has (or will) become an essential part of the business mission of many laboratories.³⁰ Some of the most important client-centric LIS functions needed to support a successful outreach program include client definition parameters (eg, client name, identification number, contact information, fax number, etc), client-specific report formats, and the ability to support client-specific fee schedules and billing practices. Duplicate patient handling also becomes crucial to managing patients who receive care from multiple locations.

To aid in the critical dimension of LIS functionality assessment, the Association for Pathology Informatics has recently developed and released an LIS Functionality Assessment Toolkit.³¹ The toolkit consists of 4 components: an introductory report that guides the use of the toolkit, a list of approximately 850 weighted functionality statements,

scripted scenarios to guide vendors during demonstrations, and guidelines for determining the total cost of ownership rather than simply the purchase price for the solution.

However, the functionality gap between the more-mature LISs (be they stand-alone solutions or LIS modules available with EHRs) and those with less experience-of-use is closing, and as a result, this dimension as a discriminating factor is decreasing. As vendors commit more resources to developing and enhancing their LIS offerings, driven largely by requests/demands from their user base, nearly comparable levels of functionality are likely to be achieved in the future.

Equally important as the current (or near future) functionality of the LIS is the ability and level of commitment of the vendor to rapidly adapt the LIS to meet changing needs. Laboratory testing is one of the most rapidly changing fields in health care, driven by new technologies and an increasing understanding of disease mechanisms. Maintaining the strength of a laboratory and the health system it serves requires the ability to adopt and integrate new testing, and that requires an LIS vendor that can grow and adapt its system quickly in response to the changing environment.³² Remaining current is not only a priority among vendors of stand-alone LISs, it is a main focus of competition among vendors, and that competition drives advancement. Freidman et al³³ presented objective and subjective criteria in differentiating between marketing-driven and technology-driven vendors for medical information systems and described the importance of alignment between the strategic goals and objectives of a client and its information system vendor. Much of the drive today within hospitals and health systems to purchase or enhance an EHR system is focused on keeping up with federal meaningful-use requirements. As such, vendor focus is on meeting that need. For vendors offering enterprise-wide solutions, enhancing LIS modules beyond the rudimentary functionality required to meet meaningful-use requirements is typically not a priority and is often not a priority of the group or groups within the health care institution charged with management and oversight of the EHR. That difference in priorities can compromise the ability of the laboratory to remain current with changing needs and new technology.

LIS Management and Oversight

The integral role of the LIS in supporting laboratory operations demands a high level of physician oversight and laboratory-focused management of the LIS. The rapidly growing field of pathology informatics is a testament to the increasing recognition on the part of larger health care systems and academic medical centers of the crucial role proper laboratory technology management plays in advancing patient care.⁶

What options exist within the health care institution for management of the selected LIS solution? Although management of the LIS is actually a continuous spectrum, it is useful to consider 3 typical support models along that spectrum, as described below. Regardless of the LIS support model in effect, however, *under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the laboratory medical director remains ultimately responsible for laboratory operations, including proper communication of test results, irrespective of the system(s) in use, and even if some of those functions have been delegated to others.*¹⁵

Model 1.—Information technology staff is within the laboratory and reports to a pathologist who manages the

LIS; that staff interacts directly with the LIS or EMR vendor relating to laboratory and LIS issues.

Model 2.—All information systems are managed by central, institutional IT, but a distinct unit within that structure is dedicated to supporting the laboratory and the LIS; pathology has some oversight authority of that unit; the central LIS support unit advocates for laboratory issues within the central IT structure; and when LIS projects are prioritized high enough, the LIS support unit works directly with the LIS or EMR vendor.

Model 3.—Central institutional IT staff manages the LIS and other hospital systems; pathology may submit support requests, including LIS-feature requests; all requests from all departments are prioritized centrally before communication to the vendor; and all vendor interactions occur through central, institutional IT.

In smaller pathology laboratories, model 1 may not be a viable option, and in that setting, pathologists have often, voluntarily or involuntarily, ceded control of the LIS to institutional IT units. Although this is unfortunate for the field of pathology in general, it is an understandable solution for laboratories that provide basic services for their local clinicians and that lack the IT resources or expertise to effectively manage their own LISs.

In larger and more-complex laboratories, however, direct involvement by pathologists in the oversight and management of the LIS can be crucial to a successful operation. An IT team with expertise in laboratory operations can provide more-efficient, cost-effective support for an LIS.^{34,35} A laboratory-oriented support team will best know how to adjust the optional features and settings of the LIS to maximize the synchronization between the LIS and the workflow in the laboratory. Such tailoring promotes ongoing efficient operations and enables adaptation to the evolving repertoire of clinical testing in a modern laboratory. For those instances in which modifications to the LIS are needed, a close relationship between the pathologists and the LIS vendor is important in maintaining a nimble and adaptable information management system. In this setting, management models 1 and 2, in which there is LIS support personnel with laboratory-domain expertise who are dedicated to laboratory issues, are greatly advantageous to the laboratory. Those models are typically easier to achieve at institutions where the LIS is acquired from a different vendor than the provider of the EHR. Even with model 2, the LIS support unit within central IT is likely to have some freedom to work independently with the LIS vendor.

Model 3 is the most common at institutions with single-vendor, integrated LIS modules, and it can be decidedly more of a threat to the laboratory and to efficient and effective laboratory support of patient care. Because of its broad scope of oversight and diverse stakeholder population and priorities, central institutional IT may (1) lack sufficient domain expertise to meet the laboratory's specific needs related to the LIS and possibly to laboratory information management in the enterprise, and (2) deprioritize laboratory requests and needs in favor of needs perceived to be more "institution-wide" or to other politically powerful groups.

In assessing the effect of the LIS architecture on the oversight and management dimension of the LIS-vendor relationship, the laboratory needs to remain focused on what it would like to achieve and work to establish a support model that accomplishes that goal. Ideally, the laboratory should have the authority to make decisions

Table 4. Distribution of Laboratory Related Activities Between Laboratory Information Systems (LIS) and Electronic Health Record (EHR) Systems

LIS-Centered Activities	EHR-Centered Activities
<ul style="list-style-type: none"> • Laboratory operations/workflow • Instrument interfaces • Outreach client interfaces • Support for molecular/genetic testing • Digital pathology 	<ul style="list-style-type: none"> • Result display formats • Integrating data from multiple laboratories and at-home testing • Decision support at order entry • Patient portals

about the LIS configuration without needing to seek approval from institutional IT units. Laboratories need to have a mechanism to ensure appropriate prioritization of their requests. For example, if the laboratory has purchased new equipment to take advantage of new technology, will there be a significant delay in leveraging the benefits of the equipment while awaiting the IT resources needed to set up and validate a needed interface? For laboratories with an outreach mission, the reporting and interfacing functionality of the LIS needs to adapt rapidly to meet the needs and demands of new clients. Responding to those issues, although a priority for the laboratory, may not be a priority for hospital IT or for the vendor, and that can have not only clinical implications for laboratory clients but also negative financial effects for the laboratory and institution.²⁷ The laboratory should be able to work directly with the vendor to clearly communicate the laboratory's needs and to develop a plan to address those needs. Even where a single-vendor solution has been chosen, that vendor is likely to have a subset of its support structure dedicated to the LIS module, and that LIS group should be able to work directly with the pathology IT units (management model 1) or with specialty-specific support units within the health care institution's central IT (management model 2).

Gap Ownership: Meeting Unmet Needs

One final dimension of the laboratory-LIS interaction is the gap-ownership philosophy of an institution regarding its LIS. Because even the most-advanced LIS cannot be built, in advance, to support needs that have only recently developed in a cutting-edge laboratory, there will always be gaps between newly emerging needs and the capabilities of the LIS. Gap ownership is a natural extension of management and stems from the sense of responsibility that comes with oversight of the LIS. Gap ownership is about who assumes ownership of those gaps, seeking out ways to bridge them and formally integrating the information management needs of the new technology into laboratory operations.

Gap ownership descends, in part, from the LIS oversight models described above and can be highly dependent on the personalities of the IT leadership at the laboratory and institutional levels. Together, they create an institutional philosophy that has long-term implications for the reputation of the institution. At one end of the spectrum, institutions may be very open to bringing in new software solutions and stitching them together to close functional gaps. Bridging gaps requires innovation, through partnership with the LIS vendor, by incorporating third-party software products (eg, middleware), or through independent custom-software development.^{35,36} This ingenuity in the laboratory can help build the national and international reputation of a health care system as a leader in patient

care.³⁷ There are numerous examples of how leading medical centers have advanced patient care via software innovation in the laboratory.^{25,38-46} At the other end of the spectrum, institutions may resist solutions not provided by their primary or single-solution vendor. In such settings, custom-software development is discouraged or sometimes, frankly, prohibited unless it is done in collaboration with the vendor. In those environments, there is the risk that functional gaps in the LIS will be viewed by the laboratory as "not my problem," especially if the choice of the LIS was made at the institutional level and/or without input from the laboratory. The result can be unmet laboratory needs and missed opportunities for innovation in patient care.

Of course, there is a lot of distance between the 2 ends of the spectrum mentioned here, and most institutions fall somewhere in between. Nevertheless, this often-overlooked dimension of institutional culture is certainly affected by information-management decisions and should be considered when an institution is weighing its options for LIS selection and for LIS oversight and management. Pathologists, with their responsibilities as laboratory directors, should be aware of these dynamics and risks.

LIS AND EHR INTERDEPENDENCE—ALLOCATION OF FUNCTIONALITY

Regardless of the type of LIS selected, the LIS and the EHR should not function as islands; close interaction between them is essential for patient care. The EHR-LIS interplay involves technical, process, and administrative aspects, many of which are discussed further in the other articles in this series.^{9,15} Pathologists should not restrict their interests or domain of oversight to the LIS. Clinical Laboratory Improvement Amendments require pathologists to maintain oversight of laboratory test ordering and result reporting, and those activities have largely migrated to the EHR. In fact, assuring that the 2 systems work together seamlessly is an important transformative role for the pathologist.⁴⁷

Table 4 lists some important laboratory-related functions and where these functions typically reside with respect to the LIS and the EHR. Laboratory operations and workflow, as well as instrument and client interfaces, are clearly in the domain of the LIS.²¹ Additionally, digital pathology and molecular/genetic testing are evolving rapidly, and because those fields are subject to the same quality standards that apply to all laboratory testing, they also belong in the domain of the LIS. Laboratory result display for clinician access, on the other hand, is an EHR activity.¹⁵ Pathologists, who have special expertise in communicating test results, should work with EHR groups within the health system to maximize the readability and interpretability of those displays. Because EHRs often serve multiple hospitals, each with its own laboratories, and patients are often seen at those multiple hospitals, integrating data from the different laboratories is more appropriately an EHR activity but optimally occurs with input from pathologists, who can best advise when results can be comingled and when they should be kept separate. There is an emerging need for integration of data from in-home testing or point-of-care testing with test results generated in hospital laboratories. Laboratory directors may be reluctant to have those results entered into their LIS because their laboratory did not generate the data, and the quality assurance associated with those results is not always clear. For best patient care,

however, there may be value to having results from those sources displayed in association with results from the hospital's laboratories. The EHRs can be configured to not only integrate that information but also track and identify accurately the various sources of the data, differentially displaying data from different sources.

The question of where best to house algorithms for decision support when placing test orders may be controversial in an organization. Although such logic already exists in some LISs, for greatest effect, the decision-support logic needs to be available in real time to the ordering provider, and the reality is that most orders are (or will be) placed using computerized provider order-entry functions within EHRs.⁴⁸ Patient portals are typically not an LIS function because patients generally want to see an integrated summary of their health care data, which includes laboratory results, radiology reports, cardiology reports, and medications and appointments, among others. However, pathologist input in ensuring that the EHR provides appropriate decision support and displays laboratory results in a readable, understandable manner represents new professional activities relevant to laboratory medicine.

SUMMARY AND CONCLUSION

The debate between stand-alone (department-specific) and integrated (single-solution) LISs is still very much alive within medical centers. Ultimately, the best decision does not rest on a matter of one database or more, or one vendor or many. The LIS software features and functionality must meet the needs of the laboratory if the laboratory is going to fulfill its patient care mission in a health care organization. Furthermore, to ensure the long-term success of the laboratory in meeting the patient care needs of the organization, matters of who directs the LIS-selection process, who has management authority of the LIS, and who assumes ownership responsibility for the ongoing operations and continuing development to meet the information management needs of the laboratory are equally, if not even more, important. Each laboratory and pathology group should determine, based on their needs, environment, and the relative importance of the issues discussed here, which LIS solution best serves their laboratory and health care system. Especially for larger laboratories and complex care environments, LIS management authority and functionality advancement are important to the laboratory's success. Crucial components of the oversight structure include the ability to make laboratory-specific configuration decisions and changes in the LIS without prior approval of institutional IT groups, direct access to the LIS vendor, an independent line of prioritization of projects, commitment from the vendor to aggressively keep the product current, and the institutional support to involve third-party products or other custom solutions. With proper cooperation among the pathologist, the laboratory, the LIS vendor, and the institutional IT groups, and with the inclusion of laboratory-informatics experts, an effective level of oversight might be achievable regardless of whether a department-specific or single-solution LIS is deployed. However, in the experience of the authors and most of their colleagues in other large laboratory environments, an appropriate oversight structure is difficult (often very difficult) to implement with an enterprise-solution model, and using an LIS from a different vendor more easily accommodates ensuring that pathology

maintains its control of the LIS. Pathologists and laboratories are strongly encouraged to advocate continually for their information management and LIS needs as decisions that affect their future are being made.

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