

# Laboratory Informatics: Supporting the Future Needs of Healthcare

Changes taking place in healthcare require the laboratory to expand its reach and become more involved in patient outcomes. Is your LIS capable of taking your lab into the future?

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## Healthcare’s Seismic Shift

The U.S. healthcare system is currently in the process of the most comprehensive change in decades. The Institute for Healthcare Improvement (IHI) Triple Aim concept at the center of healthcare reform calls for improvements in individual patient care experience and in overall population health, as well as reductions in per capita spending. In an effort to make these goals a reality, there are more government regulations than ever, with the Patient Protection and Affordable Care Act (PPACA) being the largest overhaul the healthcare system has experienced since the introduction of Medicare in 1965. This is not a small change, but a complete restructuring of how healthcare in the U.S. is delivered.

Laboratories that intend to thrive in this changing environment will require nimbleness and high adaptability in order to ensure longevity. Change, particularly of this magnitude, can be both demanding and stressful, yet at the same time exciting. **Laboratories, as well as all healthcare service lines, must have the most powerful and best-fit tools to successfully navigate these changes—and no single mechanism is more valuable to a laboratory than a well-outfitted LIS.**

As the volume and complexity of healthcare data continue to increase, it is evident that clinical data can provide a treasure trove of valuable insights if properly captured and analyzed. But healthcare organizations have to carefully consider what combination of software they can rely on to harness that tremendous potential. Part of this includes having a robust LIS that meets the intricate and complex needs of the laboratory, now and into the future. Is your LIS capable of meeting the future needs of healthcare?

### Factors Influencing Healthcare Change

- **Transition from volume- to value-based payments**
- **Decrease in reimbursements**
- **Growth of population health management**
- **Advances in Health Information Technology (HIT)**
- **Implementation of telemedicine and mHealth**
- **Caring for an aging, sicker population**
- **Increase in patient involvement**
- **Increase of government regulations**
- **Surge of mergers and consolidations**

Figure 1: Factors Influencing Healthcare Change

## Data Surge

The share of data generated for medical use is steadily and rapidly increasing, with a predicted fourfold increase from 2012 to 2020.<sup>1</sup> Healthcare, one of the largest producers of data, is one of the least prepared industries to handle this data deluge. Concurrently, the amount of data generated by the laboratory and handled by the LIS has increased dramatically and is expected to continue increasing at an exponential rate, particularly with advances in molecular and genetic testing and a shift toward personalized medicine. “Cancer genomics will require a different model in terms of LIS function because interplay is required between the patient data and sophisticated archival databases which we’ve never had before in the LIS world,” explains Bruce A. Friedman, MD, Emeritus Professor of Pathology at University of Michigan Medical School.

Healthcare executives indicate that gathering intelligence from their data is a top priority, yet most do not have the appropriate IT solutions in place, which translates into lost revenue and less efficient patient care. One solution is to have partnerships with IT vendors that specialize in each clinical area (e.g., laboratory, radiology,

imaging, pharmacy, etc.) and integrate data from those specialized systems into the patient's electronic chart. Advanced lab-focused software is needed to leverage clinical data to make better strategic decisions that support population health management and patient-centered care.

## LIS Development

The historical function of an LIS is to record, manage, and store data for laboratories. Traditionally, the LIS has been most adept at receiving lab orders, sending test orders to lab analyzers, tracking those orders, and recording and transmitting the results. The standard LIS has supported public health laboratory operations by managing and reporting critical data concerning infectious diseases. By the time Health Level 7 (HL7) was introduced in the late 70s/early 80s, the LIS had already become fundamental to clinical laboratory practice. Its development, in regards to functionality and security, was beginning to be influenced by governmental regulations.

Over the years, LIS growth has been greatly influenced by the need for laboratories to comply with a plethora of regulatory requirements. Although these regulations continue to increase, the future of healthcare will require a shift in focus and will bring new responsibilities to the laboratory. Not only are test menus changing and expanding, but test methodologies and workflow processes are advancing. Under pressure to reduce cost, increase efficiency, and maintain quality testing, labs are turning to automation in an effort to do more with less.

Additionally, the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs' push to provide meaningful use of certified EHR technology has encouraged providers to implement EHRs, and has had a profound impact on the functional needs of the LIS. Prior to the EHR, orders were placed in the LIS, making medical necessity flagging and ABN printing important functions for the LIS. With Meaningful Use (MU) now in effect, the majority of lab orders must be placed directly in the EHR using Computerized Physician Order Entry (CPOE), making this pre-analytical functionality less important in the LIS.

## Importance of Structured Data

The sheer, ever-growing volume of clinical data creates an increasing challenge that calls for very specific HIT solutions to manage and extract insight from that data and use it to improve the patient experience, improve the health of the population, and decrease costs—the Triple Aim goals. As the PPACA pushes healthcare organizations toward value-based reimbursement models based on measurable outcomes, the very essence of demonstrating improved outcomes and decreased costs will rely on the use of discrete, codified, structured data. Laboratories must ensure that their LIS is capable of supporting this configuration.

A number of new requirements under Stage 2 of MU impact labs, both directly and indirectly. For providers moving into this stage, at least 30% of lab orders must be entered into the EHR through CPOE, and 55% of orders must be received electronically in a structured data format. Hospitals and physicians are measured by quality metrics that rely on structured lab data. For example, physicians will report the number of patients with controlled diabetes using hemoglobin A1c results.



The future of healthcare will be built on data—data to support population health management and analytics to improve outcomes. To effectively promote the interoperability necessary to share the laboratory's data and include the ability to fully and effectively mine data to promote better conclusions, laboratories need to review their information system (IS) capabilities carefully and make sure they are equipped for future needs. Being able to recognize patterns in clinical data that can be used to inform decision-making and monitor and promote proper test utilization can increase the laboratory's efficiency and value and save healthcare dollars. In order to accomplish these goals, the laboratory's information system must be capable of handling data in a structured format and readily support standardized languages (e.g., LOINC, SNOMED, and ICD-9/10).

### **When is the Right Time to Make a Change?**

Evaluate your current IT solutions and determine if they are meeting your needs now and for the future. The revamping of the healthcare system creates huge opportunities. The fundamental change in the U.S. from fee-for-service (FFS) to value-based reimbursements will impact every laboratory in one way or another. Laboratories that embrace this change and proactively get systems in place that can fortify their organization's overarching goals will have an advantage. If your laboratory has an outdated legacy LIS, this may be the right time to think about whether you need to update your system to meet the changing environment. With the transition to a value-based system, cost-effective solutions become imperative. Consider the changes taking place in your facility now and going forward, and evaluate how well your current lab system meets your needs and goals for the next three to five years. Given the enormity of these changes, time spent carefully considering your lab's future IT requirements is likely a wise endeavor.

In the midst of healthcare reform, this is an opportune time to heighten your lab's productivity and efficiency. This may require more suitable information system tools with advanced configurability to meet the forthcoming needs of the laboratory industry. Advances in technology, changes in our healthcare delivery system, and the need for useful business analytics make an antiquated system that is "band-aided" with middleware insufficient to face the needs of the laboratory market going forward.

### **Change Brings Challenges: Reasons to Change...or Not**

Laboratories play a vital role in supporting positive patient outcomes by providing rapid, accurate diagnostic information. Having a highly configurable, flexible, and scalable LIS with specialized offerings that sustain the laboratory's role in the future of healthcare provides the extra advantage and security that laboratories can rely on in order to thrive and prosper going forward.

According to Dennis Winsten, founder of Dennis Winsten & Associates, Inc., a healthcare systems consultant group that specializes in clinical information systems, the number one reason to replace an LIS in a hospital setting in today's market is because of pressure from the C-suite to go to a single integrated system. Incentives may differ for smaller, non-hospital laboratories. "Smaller labs realize they need to change their LIS because it's outdated and the vendor is not the best business partner to move forward with," adds Jim Sundberg, President and CIO for LabMetrics.

Andrew Splitz, President and CEO of S&P Consultants, Inc., describes incentives to move forward in LIS replacement as “triggers.” “Triggers are issues that require healthcare institutions to discuss modifying or changing their LIS; and also important are significant barriers that institutions may have to change,” he explains.

### Triggers

One of the most common triggers that may open up the discussion of whether to replace an LIS occurs when a current system requires a version upgrade, either for a scheduled update or in order to meet MU2/3 criteria. “Version upgrades for the larger LIS vendors can cost upwards of \$500,000 to \$1 million. This brings up a big red flag that the current lab system will continuously need to be upgraded and at a very high cost, so it opens the discussion with the CIO of the possibilities of reducing that cost,” explains Splitz.

Another possible trigger is when a lab system is missing a needed function. “If the vendor that you have currently does not have the module or functionality that you need, that becomes a trigger for a discussion for change,” says Splitz.

### Barriers

The most glaring barrier to LIS replacement is the expense. Splitz explains, “Currently, among the large vendors, it costs a single institution with 300 to 400 beds around three to four million dollars to put in a new lab system.” Add the fact that it may take as long as 12 to 24 months to completely install a new system and you have a couple of significant barriers to overcome.

If you combine these two barriers with a push from the CIO to go with an enterprise-wide lab product, the lab’s opinion may not even be taken into account. According to Splitz, often the CIO’s perspective is this: “We can use the enterprise-wide lab system (which is not bad) because the license charge was included in the cost of the EHR and we’ve already paid that, so it will cost between 1.2 and 1.4 million dollars to convert to the enterprise-wide lab solution versus spending three to four million to put in a new lab system.”

Splitz adds, “Most often, these discussions and strategic planning sessions take place in the C-suite and not in the lab. We are talking about millions of dollars and the institutional strategies to move forward, and basically the pathologist or lab director is not coming up with a good business case to negate going with the enterprise-wide solution because of lacking functionality. If that case is not presented, then the CIO is going to make the decision from a financial standpoint rather than a functionality standpoint.”

## Triggers

- **Version upgrade**
- **Meaningful Use**
- **Needed functionality**

Figure 2.1: Triggers

## Barriers

- **Expense**
- **Implementation time**

Figure 2.2: Barriers

Hal Weiner, of Weiner Consulting Services, LLC, points out that the second most common reason for LIS replacement in today’s healthcare market is the growing number of vendors that are sunsetting their products. Winsten and Weiner agree that there are several external and internal factors that may drive a laboratory to look at replacing its LIS (see Figure 3). “It’s a hard sell to justify a multi-million dollar expenditure. It’s not easy to convince your administration, particularly in a hospital setting, that you need to replace your LIS,” says Winsten.

“Many of the LIS replacements we are seeing have been to a large extent to the protest of the lab. If you’re going to convince hospital administration to replace your LIS, you have to be able to say, ‘I can’t meet our business needs with our current system and here’s why,’” Winsten adds.

### Factors to Consider in Making a Decision

Thoughtfully and thoroughly review your current LIS functionality, as well as the relationship you have developed with the vendor. Think about your current needs and your plans for the future. In what ways do you anticipate your lab will change in response to healthcare reform and other regulatory interventions? Is there functionality missing from your current system that would allow your lab to improve its productivity?

**If you agree that healthcare is changing and you want to be prepared rather than left wondering what happened, now is the time to carefully review your strategic plan and forge a path that ensures future success.** Laboratory data and its integration into the patient’s clinical picture is a vital component of the new model, so it is important to ensure you have the best IT system in place to deliver coordinated patient care. Review the pros and cons of LIS replacement and determine if your laboratory’s future needs will be supported by the systems you have in place.

### Advances in Laboratory Technology

New, more complex testing, and the need to make results available to clinicians faster, continues to shape laboratory dynamics and LIS growth. Furthermore, changes in the laboratory market are happening at a rapid pace. In addition to test menu changes and volume shifts, advances in molecular and genetic testing are occurring quickly, encouraged by legislation. The shift to a value-based system brings to light the need for integration and business analytics. Laboratory professionals and pathologists are finding new opportunities to be involved in best test selection, development of testing cascades, and reporting of value-added test interpretations. Your LIS

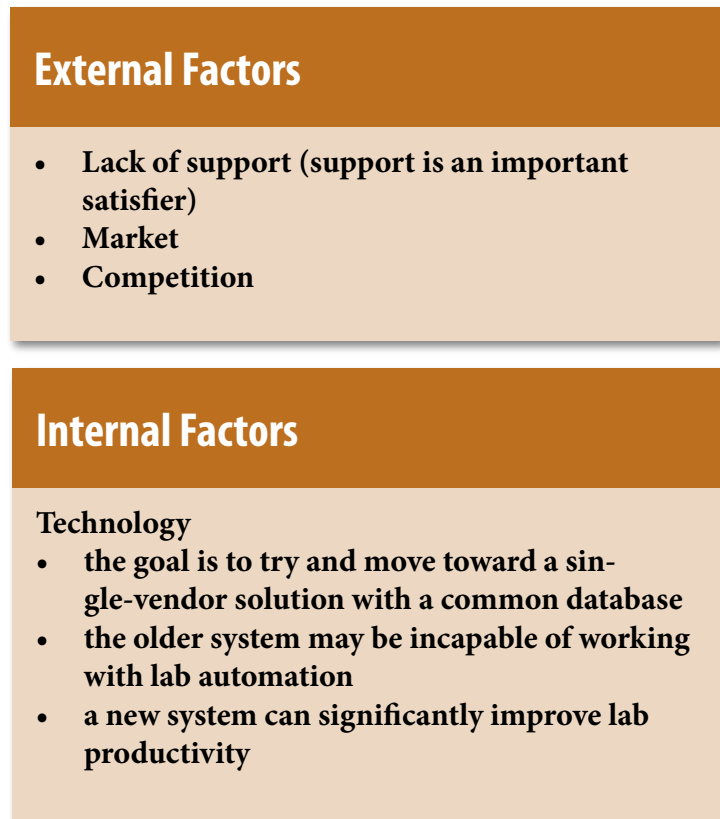


Figure 3: External & Internal Factors



should be capable of supporting these initiatives that allow laboratorians to expand their role and increase their lab's efficiency.

Because molecular advances have been made so quickly and are of such a diverse, often unique nature, the LIS market has struggled to keep up in this area of development. Few vendors currently have strong offerings. "Large hospitals are getting involved in molecular, and currently there is no strong molecular IS solution that meets the lab's needs. Labs are often handling molecular manually and without instrument interfaces, which is a major problem because in molecular genetics the data is what you need," says Splitz.

Dr. Friedman sees laboratories in a chasm between what was and what will be. He explains, "I view this as the golden era of diagnostics in the lab and radiology—a time when functionality of an LIS is absolutely critical, most importantly in molecular and genomics, and particularly for cancer genomics, and there's a void in the market in terms of these very sophisticated modules."

### Acceptance of Cloud Technology

The healthcare industry is admittedly at least a decade "behind the times" in terms of IT progression, and is justifiably hypersensitive to security concerns, yet is beginning to embrace the benefits of cloud computing. Cloud computing involves offering hosted services via the Internet. Advances in virtualization and improved access to high-speed Internet have accelerated the growth of cloud computing.<sup>2</sup> We are quickly seeing improvements in data security in terms of resiliency and privacy, and cloud computing can offer fast innovation often at lower costs. Because of economies of scale, cloud service providers are able to build large redundant data centers that place a higher emphasis on backup, data resiliency, and uptime for lower costs.<sup>3</sup>

Dr. Friedman feels that the next generation of LISs can and should be hosted in the cloud for a variety of technical and strategic reasons. "With the deluge of data brought into play by advanced genetic testing, cloud hosted services may decrease the cost of processing and storage, and improve interoperability," he says. "Cloud access can be a big factor as we move forward from an informatics perspective and from a precision medicine perspective," adds Sundberg. What role will cloud technology play in the future of healthcare? Will laboratories of the future need to turn to cloud storage for the expansive amount of data that needs to be stored for molecular and genetic testing?

### POC Testing Growth

As healthcare reform encourages a more proactive and patient-interactive stance, point-of-care testing (POCT) can offer substantial benefits because of its ready availability and quicker turnaround time, potentially reducing ER visits and hospital admissions. As accountable care organizations and integrated delivery networks (IDNs) continue to develop, more testing will be performed outside of the core lab, in ambulatory settings and POC locations. It will become extremely important to coordinate this testing and ensure that all healthcare workers on the care team throughout the network have access to the data in order to make timely, optimal care decisions. And it will be important that these POC test results are captured by the EHR for quicker diagnosis and treatment, for billing, and so that data from POC testing can be included in analytics needed for risk stratification and population health statistics.



“POCT has always lagged in terms of IT support, but is becoming more sophisticated. POCT suffers from being decentralized, often performed by non-laboratory personnel, and historically has been more expensive,” explains Dr. Friedman. “We are entering an era where it will be much more common, and with more sophisticated technology, costs will go down. Clinicians appreciate the turnaround time and continue to put pressure to implement POCT, and pathologists are beginning to realize that the lab needs to take responsibility and make sure POCT is properly integrated training-wise, quality-wise, and from a billing perspective,” he adds.

### Consolidation & Interoperability

One of the most significant industry trends is hospital consolidation to create larger systems with broader service reach and economies of scale that can withstand the myriad economic and regulatory pressures. Weiner calls this trend the “being acquired syndrome,” where smaller healthcare facilities are merged into larger IDNs, sometimes resulting in five or six LISs being replaced with one vendor’s products. This movement makes information system interoperability even more important than before. In order for the vast amount of clinical data in the laboratory to be successfully incorporated into analytics for risk stratification and population health management, your LIS must be integrated into the IS network of your facility. The future requires advanced interoperability—getting laboratory data in the right form into the right system quickly and accurately becomes key to a laboratory’s success.

### The Need for Outreach Growth

Additionally, declining inpatient visits are compelling laboratories to expand outreach services, creating the need for connections to physician EHRs, nursing homes, clinics, and pharmacies. This creates a demand for full robust outreach operability that includes courier management, customer relationship management, supply and inventory tracking, and services marketing. According to Winsten, it can be difficult to find an LIS solution with integrated outreach capabilities. “Very few vendors have the whole outreach capability in an integrated way, rather than as an add-on service,” he says. “Over the next few years, we expect reference lab work to become more important as large healthcare facilities support multiple mergers and acquisitions,” says Dr. John D. Halamka, MD, CIO at Beth Israel Deaconess Medical Center.

### Regulatory Compliance

New rules, regulations, laws, and amendments that impact the laboratory are being created quicker than ever. The Protecting Access to Medicare Act of 2014 (PAMA) recommends reductions in lab reimbursements every year for the next six years, and also slipped in a year’s delay for the implementation of ICD-10, for which many labs were diligently preparing. There is a Clinical Laboratory Improvement Amendments (CLIA)/HIPAA amendment that allows patients direct access to their lab results, MU dates are being amended, labs are excluded from the Safe Harbor Stark Law exception, and the FDA is preparing to monitor laboratory-developed tests. The list continues to grow; it is enough to make your head spin. **The rapid rate of change makes it imperative that laboratories be poised for transition, and a must-have is an agile LIS that can evolve as quickly and efficiently as the laboratory evolves.**

### Patient Safety Concerns

Ensuring that your IT systems and their interaction between internal tables and with other systems do not create gaps in data that can lead to patient safety concerns is of utmost importance. Does your current system have gaps in it that may jeopardize patient safety and/or generate litigation?

### Patient Focus & Involvement

Looking forward, laboratory management's view must extend beyond the lab's inner circle and encompass the entire patient episode with an awareness of how the timeliness, accuracy, and cost of a patient's lab work impacts their episode of care and final outcome. Patients need lab work all the way from delivery of diagnosis and treatment plan to follow-up and disease monitoring. Our new healthcare paradigm puts the patient at the center of its focus.

In line with this, patients are expected to become more involved and diligent about their own personal healthcare decisions. The lab must be forward-thinking and realize how this may influence its testing menu, volumes, and testing locations. And consider the role that patient self-monitoring apps play. The prediction for the future involves an increase in the use of healthcare mobile apps, or mobile health (mHealth). Mobile health apps offer an easy way to involve patients in their care plan and can play a significant role in patient care. The worldwide mHealth market is rapidly growing and is predicted to exceed \$1 billion by 2017.<sup>4</sup>

We are now seeing lab-on-a-chip technology, such as the mChip microfluidic card that can perform 10 ELISA assays in less than 15 minutes and allow results to transmit into a patient's EHR.<sup>5</sup> Telcare has a smart-phone app (see Figure 4) that automatically receives and tracks your blood glucose data. How will this new technology play into the lab's future? Is your LIS technology advanced enough and versatile enough for this new paradigm of patient involvement?

### Clinical Data Analytics

Changes to our healthcare system demand that we find a way to provide better patient care and simultaneously spend less money. This challenge shines a light on the need for laboratories to focus on greater productivity, maximum efficiency, and useful data analytics that can guide future business decisions. Analytics will be the key to survival in the new payment models. Laboratory analytics can provide management data that can boost lab productivity, and your laboratory information solution needs to be able to provide detailed laboratory analytics to assess and improve laboratory efficiency. This includes analytics for turnaround time, physician utilization, staffing workload, auto validation percentages, and quality measures, such as tracking rates of blood culture contamination, hemolysis, QNS, and cancellations. These solutions must be rapid in order to proactively address problems head-on and develop time-efficient solutions.



Figure 4: Source - [www.telcare.com](http://www.telcare.com)

“The key to lab analytics is to determine what the lab needs from a data standpoint that is different from what the organization needs and can derive analytically from the EHR. Lab analytic data is essential for labs to determine if they are running in a cost-effective, optimized way, both from a resource standpoint and from a reagent and contracting standpoint,” says Splitz. Dr. Friedman expounds, “Labs are getting squeezed to operate better, cheaper, and faster, and advanced laboratory analytic tools can enable lab management to get a better handle on overall lab operation, particularly if laboratory management utilizes the analytic software to its full advantage.”

### LIS Vendor as a Strategic Long-term Partner

The lab-LIS vendor relationship is a long-term one. Therefore, when a laboratory chooses an LIS, it chooses a long-term business partner. Now more than ever before, your LIS vendor must be able to rapidly adapt to the changing needs of the laboratory and the healthcare market. Your LIS vendor needs to be a good fit for your organizational needs and must be positioned for growth and agility.

Consider the relationship you currently have with your LIS vendor, and their reputation for follow-up and support. Is your LIS vendor’s mission and vision aligned with your organization’s? Take into account the company’s longevity and its stability going forward. What are the future prospects for the company? Is your vendor adding new accounts or are they maintaining status-quo with their install-base? How long can they maintain that scenario?

Winsten says, “We are finding that functionality and features between vendors are becoming less important. What becomes more significant is the vendor’s reputation for service and support and a strong implementation. In addition, critically important is the expertise of the vendor’s sales team in terms of being able to relate to the client. For example, for a multi-million dollar system, it surprises me when we see sales representatives show up with little knowledge of the clients—that they do not take the time to understand the client’s hot buttons and then customize the software demonstration to target what the client is really interested in.”

### Implementation Challenges

Replacing any IT system presents myriad challenges, particularly when patient care is involved and there is potential workflow disruption. A system as intricate and involved as an LIS is not simple to replace. Patient data has to be transferred, tables and dictionaries have to be defined, interfaces have to be set up, and training has to take place. And often, laboratory staff who are comfortable with the current system are reluctant to change. “I think everyone underestimates just how disruptive it will be to transition to a new system, so there’s an incentive not to replace your system,” says Winsten.

In Splitz’s experience, “None of the vendors seem to give their clients an adequate estimate of the resources they need to fully implement the system. Also, another implementation problem occurs when vendors perform a generic or vanilla setup. Labs get handed a generically-built lab system created by staff with no lab experience, and then they go live and realize that after a \$4 million investment, there are no bells, no whistles, and the optimization isn’t there for their site; it’s for a generic lab site. We see this happen over and over again.” Dr. Friedman agrees, saying, “Facilities often underestimate implementation. Some vendors are stronger than others at implementation and labs may need to augment what the vendor provides, including



ramping up internally for installation to try and prevent having to go back and buy additional install support from the vendor.” Weiner’s advice is to look into the history of the vendor’s installations: “Does the vendor that I am considering have a proven track record for implementation that is smooth, or will they completely turn my lab into a disaster area for the next 18 months?”

### True Costs & the Need for Cost-effectiveness

With renewed focus on cost savings, laboratories can no longer afford inefficiencies or be unaware of “hidden” costs. Beyond the initial cost of an LIS, consider carefully the amount of money spent on annual support and upgrades. Any IS solution requires support, upgrades, interfaces, and requests for modification in order to stay up-to-date and maximize efficiency. With the need for a laser-focus on cost savings, laboratories cannot afford to spend 250,000 to millions of dollars for support year after year, and hundreds of thousands of dollars for each software upgrade. That just doesn’t make sense anymore. If the cost of upgrading your system comes close to the cost of buying a new system, and that cost will be repeated every few years, this creates another opportunity for the laboratory to have a voice in recommending a system that better supports its workflow needs and meets its budgetary requirements.

Some laboratories delay important software upgrades because of the cost, putting them even further behind the technology curve. Your LIS must be a cost-effective integration system, and upgrades cannot be so cost-prohibitive that they are avoided. **Overall, the future will demand a very efficient, less expensive system with the lowest possible operating costs.**

Make sure you understand the true costs of LIS ownership. What are the future charges for service and support? Are there additional charges for upgrades? Evaluate the long-term costs and return on investment (ROI) of your LIS. As new payment models, such as bundled payments, replace FFS models, ROI will be measured in ways that we may not even have a clear grasp of today. In our current FFS system, think of all the steps that waste both money and time. **We are no longer in a situation where we can be unaware of the full costs involved in operating the systems we have in place.**

### **Necessary LIS Components**

The laboratory industry is very dynamic, which makes it crucial that you partner with an LIS vendor who can quickly and accurately respond to changes in regulatory requirements, modification needs of its client base, and new instrumentation, interface, or other technological advances. Figure 5 outlines several features to consider if replacing your LIS.

### Best-of-Breed vs. All-inclusive

In the journey to determine the best LIS fit for an organization, laboratories are often encouraged by upper management to consider the enterprise-wide

### LIS “Must-haves”

- **Support flexible testing capacity and timeliness of reporting results**
- **Access to complete patient history**
- **Real-time business analytics for laboratory managers and directors**
- **Deliver reportable disease information to public health departments**
- **Ability to incorporate POCT results**
- **Complete specimen tracking and inventory management**

Figure 5: LIS “Must-haves”



LIS component that comes “included” with the EHR package. As EHR adoption continues to expand and health-care organizations strive for interoperability, implementation of enterprise-wide solutions (EWS) can override consideration of other LIS systems that are considered best-of-breed (BoB).<sup>6</sup> A BoB LIS is defined as a stand-alone system that offers optimum functionality as compared to equivalent competing systems.

From a lab viewpoint, the EWS is often not a solution at all, but a forced endeavor in which it had little vote. According to Winsten, “The number one reason to replace an LIS within a hospital these days is because of C-suite pressure to go to a single integrated system, often to a large extent being protested by the lab.” Weiner adds, “One of the issues that has a lot of pathologists up in arms is the fact that the strategy of some EHR vendors is to set up organizations that drive vendor-wide systems and this often leaves the lab without a seat at the table. Some of those implementations are the ones that have the lab up in arms asking for a BoB system because their needs are no longer being taken into consideration.”

He continues, “However, those vendors who encourage all departments to have active roles in defining how the EHR is established and how it interacts with other ancillary systems are successful and have satisfied clients.” Winsten explains, “This has to do with customer relationships where the integrated system does not have the lab actively involved and this tactic can come back to bite them. There’s a fairly strong pre-conceived negativism within labs about some of the integrated systems, so even if the issue of lagging functionality is improved upon over time, unless they deal with the emotional aspect of it and the participatory aspect of it, there’s still a problem.”

Despite all this, functionality of the EWS is slowly improving. Dr. Friedman explains, “About a year ago, we could perform a functional gap analysis and demonstrate that the EWS lab system would not be as good as other LIS products, but recently, clients know that the EWS will function sufficiently for the core labs. The problem occurs when you get into specialties because clients know that functionality will be lacking or non-existent, requiring a hybrid solution, so they have to consider the cost for that. What is it really going to cost us to put in an EWS versus keeping what we have and upgrading?”

With a large number of systems that need integration, it is easy to understand the lure of a single-source system. However, with the improvements in interoperability standards making it just as easy to connect the better system, why settle for the lesser technology? **In our new healthcare model where we must connect systems and share data, it makes no sense to limit your capabilities by using the immature lab software that most all-inclusive choices offer.** “It will take even the largest EWS years to have a comprehensive, full-featured lab system, so this opens an opportunity for a BoB system built on today’s technology, given that most LISs are based on very old architectures with horrible customer service,” adds Dr. Halamka.

### LIS-Functionality Assessment Toolkit

In an effort to support the laboratory’s best interests, the Association for Pathology Informatics (API) developed an LIS Functionality Assessment Toolkit (LIS-FAT) to enable laboratories to more succinctly convey to their C-suite the complexity of lab IT needs. The toolkit’s Appendix I is an 850-item list of each LIS

function.<sup>7</sup> Laboratories in the process of LIS selection can use the list to grade each line item by its weight of importance. The toolkit includes a white paper explaining the rationale behind the toolkit and how to use it, as well as two other appendices: possible scenarios for managing on-site vendor demos and suggestions for developing a total-cost-of-ownership (TCO) worksheet.<sup>8,9</sup>

Splitz says the LIS-FAT is a work in progress and that labs should be aware that even though a vendor may be able to answer yes to a specific function, there will be variations in the complexity of function. “It could take one vendor 10 clicks to perform a function, whereas another vendor may be able to perform that same function in one click, so it’s somewhat subjective in that regard,” he explains.

## LIS Selection Process with Consultant

- **Current state review**
- **Gap analysis**
- **LIS toolkit (what does client need/want?)**
- **Vendors respond to LIS toolkit**
- **Clients review and rate vendors**
- **Consultant documents vendor responses and client needs**
- **Client votes on which vendors to demo**
- **Have demos (ask for specific functionality to demonstrate features that match client needs)**
- **Client reference visits**
- **Client votes**

Figure 6: S&P Consultants Process for LIS Selection

### Lab Consultant Services

The significance of the decision to replace your LIS, the long-term partnership that you need to consider with your LIS vendor, and the amount of money involved make this one of the most important choices a laboratory can make. “Pressure from the C-suite because of the large financial investment—that’s a barrier that can be hard for the lab to penetrate,” says Sundberg. The magnitude of the decision to replace your LIS along with the stress of implementation push many labs to seek outside help from laboratory consultants. “Consultants are not only able to provide a direct benefit to the lab, but we can provide tremendous benefit in educating the C-suite and administration, and consequently they have much more accurate data to make better-informed decisions,” explains Sundberg.

It can be a difficult undertaking to get your administration to understand the complex needs of the lab from an IT standpoint. A consultant who understands these needs and is familiar with the process and the current issues can bring everyone up to speed on the industry and on the available products; this can be the framework for a good dialogue between the lab and administration. “One of the consultant’s goals is to create a valid interaction between the lab, the C-suite, and IT—to create a multi-disciplinary team that consists of department heads that form a collaborative committee,” adds Sundberg.

Consultants can help with the implementation process to optimize the installed system. Figure 6 outlines some of the steps taken with S&P Consultants to walk through the process of selecting an LIS, starting with an evaluation of the lab’s current state combined with a gap analysis. A similarly guided process is provided by Weiner and Winsten that includes workflow analysis and vendor contract amendment and negotiation. The consultants ask questions to determine workload and functionality requirements to get a clear picture of what the lab needs and to move forward through the decision-making process from there.

### Can One System Do It All?

Consensus among experts in the field is that currently there is no system that meets all the needs of the laboratory. The idea, however, is to get the best system for your specific needs with the least amount of IT tools. “Fragmentation of the lab itself can create the need for a plethora of different IT products for blood bank, blood donor, pathology, outreach, HLA, etc.,” explains Dr. Friedman.

Sundberg adds, “There’s a misconception about what going with a ‘big box’ integrated system is going to accomplish—that it’s going to eliminate having to use additional products in the lab. We’re not there yet. Labs will continue to have separate products and will continue to need those products to talk, so go into the process with that understanding. If you currently have four or five products, you want to minimize, collapse, consolidate... ideally to one, but in reality, probably two or more if you have a blood donor program or transplant center.” Dr. Friedman agrees, “There is this assumption that one system or multi-modules from a particular vendor can support all healthcare IT needs. I think this is a pipe dream that’s incorrect and that in three to five years there will be disillusionment and the EHR will be viewed as what it is designed to be—which is essentially an electronic copy of the paper record, and you will have specialized systems in the areas of cardiology, lab, and radiology.”

Dr. Halamka comments in his blog that the concept of BoB is being abandoned by the healthcare industry because “such a strategy is unworkable in an era when everyone needs access to everything for care coordination, population health, and patient/family engagement.” He replaces the concept of BoB with the term “Best of Suite,” which he defines as “the smallest number of applications or modules that meet the need for business integration.”<sup>10</sup> Dr. Halamka is referring to IT systems across the entire healthcare organization, but the concept can be applied to the laboratory. Laboratories are complex and each is unique, offering every specialty from pathology with slide imaging to molecular and genetics testing. This complexity requires advanced decision support rules technology, lab analytics, and data warehousing. Figure 7 lists several problems with a current LIS that may indicate it is time for system replacement.

### Consider replacing your LIS if your current system....

- **is outdated, cumbersome, or unreliable; thus difficult to support**
- **when customer service does not meet your needs or expectations**
- **lacks adaptability or functionality vital to your operation**
- **is difficult to integrate with other systems**
- **includes exorbitant upgrade costs**
- **is based on regulatory requirements for interoperability**
- **when your workflow requires a new platform that is not supported**

Figure 7: Considerations for LIS Replacement

“EWS lab solutions are not yet competitive in the marketplace, so hospitals have to choose an alternative lab software supplier. They will seek the fewest number of vendors, ideally one lab vendor. The only exception is they may require different systems for the general lab versus specialized lab departments, such as cytogenetics/genomics. Ideally, however, one lab vendor is desirable,” says Dr. Halamka. **Look for a system that meets your specific needs and is poised to continue to do so as your lab evolves and grows to meet your clinician and patient needs.**

### Prepare for a Different Future

As healthcare continues to make major shifts, appropriate use of laboratory testing becomes even more essential for achieving safe, effective, and efficient care for patients. It becomes crucial to make sure the right test is ordered at the right time, leading to the right diagnosis and treatment. Although laboratory costs account for only about 3% of healthcare dollars, the data produced by the lab and the timeliness with which it can be reported can have a profound impact on the other 97% of healthcare spending. By getting a prompt, accurate diagnosis, downstream costs can be significantly decreased.

Sundberg predicts, “In the long-term, the lab will become a critical cost center because it becomes crucial in healthcare to get the correct diagnosis to maximize healthcare efficiency on the back end.” Clinical decisions are made based on laboratory data; therefore, it is important to have an adaptable, scalable LIS to support laboratorians in their efforts to make improvements to our healthcare system. Laboratories cannot operate at maximum efficiency and productivity and find ways to reduce overall healthcare costs without the tools and technology made available within a powerful LIS.

Inefficiencies in test utilization and lack of follow-up on lab results must be eliminated in order to achieve the cost savings and efficiency required by the new performance-based business models, and your LIS should have the functionality to support laboratory efforts that guide these initiatives. **A highly versatile and capable LIS will be essential to further the collective healthcare goal of using technology to care for populations based on their disease-specific needs in a proactive and patient-interactive manner.** Laboratory leaders need to be thinking about where the lab fits in the big picture of a value-based healthcare system and carefully consider their LIS capabilities. Do you have an LIS that can aptly support the needs of your healthcare organization and the patients you serve?

### Where will Healthcare’s Seismic Shift Leave You?

As diagnostics moves toward the use of genomics and personalized medicine, and we traverse down new pathways, laboratories will need a strong, extremely agile informatics partner able to adapt as testing patterns shift and workflow enhancements take place. Diagnostics will continue to move to the forefront, making a need for the LIS and the EHR to work in tandem to monitor population health dynamics. These software capabilities must be able to continually advance and become more sophisticated to support more standardized, data-driven, best practice models.



Our healthcare system is revamping to become more patient-centric and more efficient, using IT tools to help achieve this. What this means for the lab is that no longer can laboratory professionals work quietly within the walls of the lab. The future will require laboratorians and pathologists to find ways to use diagnostic testing to impact the total patient episode of care. Focus will not only be on performing accurate tests, but on finding better tests methodologies and opportunities to improve the overall health of patients and the population in general. The lab will be required to expand its reach and will need the necessary IT tools to support this shift in culture.

Healthcare's seismic shift is not only in reimbursements, but in the intricacies of how healthcare is being practiced. This shift includes a change in the way lab tests are utilized. If you currently have an old LIS that was built on yesterday's reasoning, technology, and healthcare infrastructure, consider carefully if it still meets your needs today and going forward. Newer LISs are being designed and developed with the current healthcare market in mind and with current technology, which is vastly different from what was available even a decade ago. **In order to meet the needs of a fast-changing market, your laboratory and its supporting LIS must be in a position to handle the future direction of healthcare.**

The future for labs is exciting. Laboratorians are looking to have a greater impact on patient outcomes by influencing proper test utilization, testing algorithms, and test interpretation, and by providing valuable analytical reports with the desired clinical data to support organizational goals. Healthcare's evolutionary trajectory points to the value of collaborative efforts and integrated technology with colleagues in pharmacy, radiology, and finance departments. Do you have an LIS that can support this endeavor? To answer healthcare's call for Triple Aim goals, having the right LIS is crucial. Laboratory software, now and in the future, must have the functionality to allow the laboratory to be a part of the clinical decision support system for providers—enabling laboratorians to meet their full potential.

### Featured Consultants

[Dennis Winsten & Associates](#)

[www.dwinsten.com](http://www.dwinsten.com)

[S&P Consultants](#)

[www.spconinc.com](http://www.spconinc.com)

[LabMetrics](#)

[www.labmetrics.com](http://www.labmetrics.com)

[Weiner Consulting Services, LLC](#)

[www.weinerconsulting.com](http://www.weinerconsulting.com)

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## About the Author

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## About Orchard Software

Orchard Software, headquartered in Carmel, Indiana, and founded in 1993, is a leader in the laboratory information systems industry. Orchard installed its first Laboratory Information System in Indianapolis, Indiana, in 1993. Since that first installation, more than 1,400 laboratories across the country have partnered with Orchard Software—including all types and sizes of multi-site and multi-specialty clinics and physician office laboratories, hospitals, regional reference labs, fertility clinics, veterinary labs, university student health services, and public health organizations. Orchard offers a variety of lab system solutions to handle each laboratory's unique testing, workflow, and business situation. For more than twenty years, laboratories across the country have turned to Orchard to help them improve efficiency, reduce errors, and enhance integration.

For more information about Orchard Software or to provide feedback regarding this white paper, email [news@orchardsoft.com](mailto:news@orchardsoft.com) or call us at (800) 856-1948.



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