CAP TODAY
The one publication most important to your job!

LIS niche modules flourish amid IT consolidation

captodayonline.com/lis-niche-modules-flourish-amid-consolidation/

11/20/2017

Anne Paxton

November 2017—"There's an app for that" was a common, if flippant, catch phrase to suggest that a software solution had already been devised for just about every need (at least until 2010, when Apple trademarked the catch phrase).

In the laboratory industry today, you are likely to hear more references to software's "functionality," but the concept is the same. While debate continues over whether best-of-breed products or comprehensive information technology systems should rule the laboratory, health care IT companies have developed a profusion of modules or ancillary applications—sometimes packaged with an LIS, sometimes sold separately—to fill software gaps.

"Many specialized niche vendors today are coming to laboratories and saying, 'We're offering major functionality, and we can integrate with your LIS, and we're a better bet as a third party in working with your LIS vendor,'" says pathology informatics expert Bruce A. Friedman, MD, emeritus professor of pathology at the University of Michigan.

In league with fellow informatics specialists, Dr. Friedman helped develop in 2013 an LIS toolkit called LISFAT (LIS functionality assessment tool) for the Association for Pathology Informatics that listed 850 functions laboratories should consider when comparing information systems. "These niche vendors have had a long history in the LIS world. If classic LIS vendors may not want to provide a certain category of functionality, then niche vendors jump into that market." LISFAT can be used to evaluate classic LISs with broad functionality or specialized modules like blood bank systems.

The expansion of modules taking place now is different from the patterns seen even five years ago, says Andrew R. Splitz, cofounder and CEO of S&P Consultants in Braintree, Mass. Splitz was part of the Association for Pathology Informatics team that developed the LIS toolkit.

Splitz's company works with almost all the major LIS vendors—SCC Soft Computer, Epic, Cerner, Sunquest, Orchard, and to some extent Meditech—to help laboratory clients implement and manage their LISs. More and more clients, Splitz says, are coming to S&P seeking help with strategic planning due to one main driving point: Epic's LIS, Beaker. "The client has a Soft or Sunquest or Cerner maintenance agreement coming up or a version upgrade that will represent a significant expense," he says. CIOs and lab directors consult with S&P to evaluate the advantages between an upgrade or moving to Beaker.

After looking at what the laboratory needs, what it has, and what it wants to happen in the next five or 10 years, Splitz asks what technology the lab is planning for. “Then we back into what modules they have.” Five years ago, Splitz explains, “everyone had general lab, microbiology, anatomic pathology, and blood bank. They’re all independent modules, even though you sometimes bought a suite of these four modules. You might choose best of breed, but hospitals usually had these four.

Splitz

“Recently, in addition to vendors coming out with these niche applications, Cerner and Epic have also been pouring money into different modules. They’re continuing to go head-to-head in the modules.”

Epic has devoted much time and money over the past two years to a molecular module because that was what everyone was asking for, Splitz says. “And we’ve been seeing a big push by Cerner on Millennium Helix, its molecular module,” including a recent revamp of Helix slated for release soon.

Advanced barcoding is another niche module that Cerner has developed, and Splitz expects digital pathology to come out down the line. “Cerner has to show they’re competitive,” he says.

Splitz forecasts that Epic (2016 revenues: $2.6 billion) and Cerner (2016 revenues: $4.8 billion) will be the two big remaining EHR systems in 10 years as laboratory systems consolidate. Other EHR companies include Allscripts, which is large (2016 revenues: $1.6 billion) but doesn’t have an LIS, and Meditech (2016 revenues: $432 million), which retains many smaller hospitals as clients. But now, Splitz says, Cerner and Epic are going after those hospitals.

Cerner is motivated to keep pace with Epic in developing modules to meet the IT needs of its clients, he believes, because laboratories will tend to stay with the modules they have. In addition, when big institutions buy new hospitals, the hospitals consolidate their software, moving to the EHR or LIS the buyers already use. “We see a lot of people moving away from LISs like Sunquest’s because their hospital has been bought and is moving to a Beaker or a Cerner,” Splitz says.

LISs sold by Soft Computer, Sunquest, and Cerner are packaged as a set of the four basic modules (AP, microbiology, blood bank, and gen lab). But other modules are available. “They all now have a quality control module. They were once included in the package but they are kind of fractionated out now and sold separately. It’s another way to make money,” Splitz says.

Cerner is installing a new infection control module to be used throughout the hospital, not just in the laboratory space, he adds. “So you are starting to get these niche modules that you could say are being pulled out of what used to be part of the basic LIS, and they’re selling them now as independent systems. Let’s say you were operating a Sunquest system in the lab but you had a Cerner EHR. Well, now you can buy the Cerner infection control module, which would integrate with the Sunquest but also work with the Cerner EHR.”

There has been a pendulum swing since Meditech first came out with a fully integrated LIS and automated record system some 20 years ago, Splitz says. “Meditech was the first one that came out, and it had all clinical areas, billing, scheduling, patient records, etc., all fully integrated. Then the pendulum started to swing back to best of breed, with the idea that Cerner has a lab system, Soft has a lab system, Sunquest has a lab system, and they’re much better than the Meditech system.”

All those vendors that were LIS vendors—Soft, Sunquest, and Cerner—came out with radiology modules and pharmacy modules that were best-of-breed systems or best within their departments or clinical specialties, Splitz recalls. “Then Soft and Sunquest stopped doing those modules and just returned to laboratory. Cerner, however, continued to build out until it was a full EHR. And now Cerner’s ambulatory product is almost as good as Epic’s product.”

On the Epic side, he says, “They’ve come a long way in the last five years. They have an ambulatory system, an inpatient EHR, and now they’ve got a Beaker LIS that’s considered part of an integrated system but is also getting to the point of being best of breed. So now, instead of having a mediocre system that does everything—the way Meditech did 20 years ago, that barely could provide functionality of all the different modules—now you’ve got an integrated system that is really best of breed in many areas. The Epic and Cerner systems are good in all the disciplines required in the patient care module.”

Given these trend lines, Splitz predicts that Meditech will continue to keep a portion of the small hospital business but with drastically reduced numbers, while Allscripts will likely be pushed out of the market. “I don’t see Allscripts as having a niche anywhere in the market that they’re safe in. They will lose market share over time until they don’t have enough to remain viable.”

Still, there always remains the chance of a disruptive change in the health care IT market, Splitz points out. “Both Epic and Cerner are not using the cloud. They do not want to create a cloud-based system that everyone can utilize and not have to have implementation costs, because they both make a lot of money on implementation costs. So I don’t see them changing that. But, one wonders—could something disrupt the normal strategic plan for these companies? Does Athenahealth, for example, come out with a system that’s good enough both in the ambulatory space and in hospital-based medicine? That is in the cloud? That is drastically cheaper?” Any of these scenarios could happen, in his view.

But a persistent issue remains: the C-suite’s lack of familiarity with the functionalities laboratories need, whether in an integrated system or in modules.

“I believe the functionality in these LIS systems has been drastically undervalued,” Splitz says. “CIOs and CFOs really don’t understand what their LIS functionality delivers. Except in the big institutions, CIOs—who only came into being 10 or 15 years ago—don’t understand the modules that are under them.” What they are thinking is: “‘If I can move to Beaker, I only have to pay one vendor. I only have to have my LIS staff be within my IT department,’” Splitz says. “That’s a big barrier to remove, for a lab trying to say, ‘No, I need to stay on this lab system because its functionality is better than the EHR’s lab system.’”

There is some question as to whether the best-of-breed strategy for “ancillary” applications like lab and radiology might give way to a “good enough” enterprisewide solution covering all bases, Dr. Friedman says.

“The executives in the C-suite favor enterprisewide solutions even if they might result in some decreased functionality for labs,” he notes. Admittedly, “There’s going to be a lot of inertia with hospitals happily running Cerner LIS, or Soft LIS, or Sunquest LIS.” But he agrees that Epic has not been static in its Beaker development despite its dominance for EHRs: “Epic has spent a lot of development in the last five years on increasing the functionality of Beaker, and the penalties are not as great as they used to be for going with an Epic LIS module instead of a standalone LIS.”

Penetration of Beaker is growing slowly but inexorably, he says. “Epic is very happy for the use of Beaker to grow organically, and that’s always been their strategy—to look for a gradual transition. They never make outlandish claims for Beaker because it’s not necessary for sales.”

Although all Epic software is developed and written by Epic, Dr. Friedman notes, “the software modules were written at different times and have variations so that the integration is not always as graceful as one would assume” given that all are produced by the same vendor. “The degree of integration—that is to say the sharing of data across all modules—is not always perfect. And an interfaced LIS from a different vendor is not necessarily inferior to Beaker.”

“Some people are saying that the best strategy for LIS vendors competing with Epic’s Beaker is to pursue functionality that Epic doesn’t have or may not develop,” Dr. Friedman says. He envisions clinical lab operational

analytics as a module that may develop separately from the LIS. “We have had automated rules for decades that can flag redundant testing or unnecessary testing. The new analytics frontier will be the prediction of future diseases based on minor variations of routine testing based on deep learning and big data studies.”

He cites a September announcement by Mayo Clinic that, in collaboration with National Decision Support Company, it is deploying a real-time clinical decision support system based on rules firing on the EHR side rather than on the LIS side, with immediate feedback to the test-ordering physician.

The module, CareSelect Lab, will offer extensive clinical guidance on all testing, direct interaction with the test guidelines in the provider’s normal EHR workflow, and benchmarking and analytics tools that make it possible to compare ordering patterns, gaps in care, and overall test use.

Another potential module category might be business or operational analytics, allowing a report to the laboratory director that, for example, “This particular instrument is a bottleneck, or your turnaround time is slower on the second shift; you might want to move more employees there,” Dr. Friedman says.

His preference would be for laboratory-specific rules like these to be deployed on the LIS rather than the EHR, since the EHR has a far broader database. But he believes that Epic has enough control over vendors, like Mayo’s partner NDSC, that it can push for having this clinical decision support system on the EHR side. “Software vendors on the EHR side become part of the Epic ecosystem,” he says.

A third option relating to the location of lab rules (in addition to the EHR and LIS), and the most decentralized, would be to have the lab rules deployed as middleware—between lab analytic instruments and the LIS—which is generally supplied by the instrument manufacturers. “Those rules would fire only in relationship to lab test results coming from their own analyzers, so there’s a limited scope for them.”

To respond to the improvements that are occurring with Epic’s Beaker, Dr. Friedman says, “it’s incumbent on the LIS vendors like Sunquest and Soft to keep improving the functionality of their systems to compete. They may not have the kind of R&D capital that Epic does, but Sunquest is owned by Roper, and Roper is a very large, profitable company, so Sunquest’s strategy will depend on what its priorities are, how much R&D capital is being provided to them, and what areas they choose to invest in—perhaps in precision medicine and genomics over analytics.”

Along those lines, Sunquest has announced a new genomics, cloud-based product called Mitogen. It is described as a LIMS rather than an LIS and can be used by standalone genomics reference labs. (The name “LIMS” provides a clue to its heritage—the term was historically assigned to “industrial” lab systems as opposed to hospital lab systems, Dr. Friedman notes.)

Epic’s response to the emergence of LISs with greater functionality and standalone lab software modules has been indifference, Dr. Friedman says. “Epic is so huge at this point, and it has such a quasi-monopoly on EHRs, if a hospital demands new lab functionality x, y, or z, Epic responds, ‘You’ll get it when we develop it.’” Once Beaker is installed at an Epic shop, it can exercise control over other lab software modules, he says, “so Epic has total client control in that situation.”

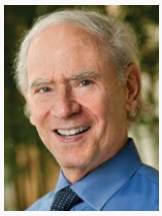
Epic has been able to place golden handcuffs on the hospital as to its overarching strategy, and the hospital may not fully understand the implications, he says. “Most hospitals have a set of goals and strategy, and you can’t pursue any modern goals of a hospital without a sophisticated IT system. So if you essentially say Epic provides all our IT, then you are ceding a huge part of your agenda and goals to Epic.”

But contracting with specialized vendors might be unavoidable. A hospital that buys a Sunquest LIS is going to have microbiology and blood bank included as standard modules on its best-of-breed system. Beaker does not include blood bank, so a niche vendor would be necessary for Beaker users that need blood bank. “Epic has been promising the development of a blood bank module for Beaker but has not delivered on this promise thus far,” Dr. Friedman says, “perhaps because of the high level of regulatory oversight over blood banking systems.”

More important for IT in the diagnostics world, he believes, is the future role of the decision support and clinical analytics software. In three to five years, he says, predictive diagnostics will be widespread.

The diagnosis of “predisease,” the detection of diseases of the future for patients, will be commonplace, Dr. Friedman predicts. “This is analogous to the diagnosis today of metabolic disorder, a precursor of diabetes. The laboratory database will be critical to this trend and all predictive analytics, so its control is going to be very strategic as we move deeply into the analysis of big data and predictive analytics.” It’s not clear at this time which vendors will be able to commercialize predictive analytic tools for the LIS database: “We may need to turn to data scientists from academic institutions or Silicon Valley firms,” he says.

Hospital data, wherever it is stored, will need to be normalized—put into a format where it can be analyzed by analytics software. “This anticipates the greater use of these databases for a better understanding of clinical flows and processes or the necessary financial studies to reduce the cost of care,” Dr. Friedman says. Sophisticated analytics also requires natural language processing so that textual entries in the clinical records can be studied. “All of this will require sophisticated population health software. This may be developed by LIS vendors, EHR vendors, or new entrants into this market, which is a lucrative one because health care is such a major industry.”



Dr. Friedman

Other developments with consumers as customers can’t be ignored, he says. These include “wearables,” home lab testing devices, and the transformation of retail drug stores as health centers with walk-in clinics, phlebotomy services for national reference labs, and even point-of-care testing. Lab testing performed outside of hospitals will require integration into the various hospital databases. “The increasing deployment of telemedicine services will also pose a challenge to pathologists,” Dr. Friedman says, “because patients will no longer be a ‘captive audience’ of hospital phlebotomy services and hospital-based lab testing.”

At Ochsner Health System in New Orleans, the laboratory moved in 2013 to Soft Computer for its LIS and the various modules required, says Greg Sossaman, MD, system chair for pathology and laboratory medicine. SoftLab is the generic LIS that includes general laboratory and microbiology, and Soft’s newest version has been used as the backbone to build the company’s molecular modules. “We’re on that now and on their blood bank system. We’re not currently on their AP system, although we plan to be.” Ochsner opted not to purchase some other Soft modules including biochemistry and cytogenetics.

Before Soft, Ochsner had had a legacy LIS for at least 20 years, even purchasing the code from the software company that originated the LIS and having in-house programmers to maintain the system. During that time the laboratory also maintained separate modules for blood bank, HLA, and AP. “Our desire was to try to bring as many things as possible under one vendor’s software,” Dr. Sossaman says.

Dr. Sossaman

Ochsner uses an Abbott track system for its chemistry along with Data Innovations’ Instrument Manager. “But we only had that for a couple of years before we implemented Soft. We’d already made the investment in Instrument Manager, so for the core lab we kept those rules. Soft gave us the ability to write autoverification for hematology and for chemistry for the rest of our hospitals.”

Adding to Ochsner’s motivation to go with Soft was the laboratory’s continuing expansion. “Part of the strategy in IT here is when we purchase or manage a new facility, they migrate to our IT systems. So we were putting our hospital information system into the new facilities and also putting in our lab systems, and it became very difficult to maintain the degree of integration we wanted when we only had internal resources.”

Now, Ochsner is using Epic for its EMR and Soft for its LIS, relying on an interface engine to handle communication between Soft and Epic. “It’s helped to have a vendor partner to be able to support all the new facilities,” Dr. Sossaman says. One reason consistency is needed is that the laboratory has complicated rules for how it ships specimens around the system and how it operates.

“After Hurricane Katrina in 2006, we bought three hospitals in the area in one year, then another the year after that and another the next year, all eventually moving to Epic and Soft.” Ochsner has seen similar adoption of its IT by some of the other hospitals in the state with which it has forged partnerships or affiliations. “We also made a deal where about half a dozen urgent care centers all migrated to our information systems this year.”

The primary use for the modules is for clinical support rather than operational support. “Ochsner is interested in analytics through Epic and its data warehouse, but has so far done less with the laboratory.” The health system adopted decision support tools over the past two years but “bolted them onto Epic” rather than make them part of the LIS, he adds. In addition, “we use Soft’s A/R system primarily for outreach clients but most of our billing for Ochsner is done through Epic.”

Dr. Sossaman believes the degree of IT customization necessary and the kind of LIS needed depend quite a bit on the individual laboratory and how it is set up. “I don’t think one LIS is able to handle everything at this point.” The same is true of the EMR: “If you look at our hospitals, we have probably every Epic module you can buy except lab, but we’re still buying a number of other subsystems—for example, for infection control.”

“I could see an independent reference lab able to have a standalone LIS where they have an Atlas-type product to connect with a lot of physician office labs.” On the other hand, “a smaller independent lab or smaller hospital might have Epic plus Beaker and work perfectly with that, versus places like ours that may need flexibility with Soft, which continues to develop new modules.” He understands the argument of many hospital executives that an enterprisewide solution for IT is preferable. “It’s more efficient, and actually that’s one reason we wanted to go with Soft—because we wanted the same degree of integration.”

One of Dr. Sossaman’s challenges is making sure laboratory data get factored into clinical analytics. “We’re very involved with Epic in looking at order sets, not just to avoid duplicate testing but also to find other ways to reduce the amount of testing, by creating care pathways for procedures like joint replacement or laryngectomy.” Mapping out all the steps in that care ensures the most efficient and best practices, he says: “We try to be part of that from the lab side and make sure laboratory data gets into the data warehouse.”

Dr. Sossaman is interested in the Mayo Clinic’s new CareSelect Lab module to provide laboratory decision support, the first such commercial product he’s heard of. “It’s very new, it’s integrating with the EMR and helping guide physicians to order the best tests from a clinical guidelines standpoint. It’s kind of ‘at the elbow’ help for them.”

As new modules like these roll out, Splitz of S&P Consultants says, many laboratories are asking the same questions: “Are we looking at best of breed? Should we be looking at integrated systems that are all the same vendor? How should they be set up? Do the modules integrate with each other?” Splitz tries to stress that “modules are very expensive and very complex to implement,” and in many cases laboratories don’t need the modules they think they need. But he believes modules will continue to reshape the competitive IT market that is offering laboratories so many choices, and so many dilemmas.

Anne Paxton is a writer and attorney in Seattle.