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All for one—unifying CP and AP data



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When Henry Heyl filed the first U.S. patent for a stapler in 1877, the idea of data integration was pretty much limited to fastening two pieces of paper together—but at least people could easily grasp the concept.

Infinitely more complex today, the integration of computer-managed clinical laboratory data has become far more difficult to comprehend—especially when it comes to integrating clinical pathology and anatomic pathology information. Bruce Friedman, MD, emeritus professor of pathology at the University of Michigan Medical School, says he has no trouble lecturing on the topic of integration, because he’s spent most of his career trying to understand the term. Pawan Singh, product manager at Sunquest Information Systems, refers to the Buddhist parable of three blind men who, after one touches a tusk, one an ear, and one a trunk, make wildly different surmises about elephants. “Integration is a big elephant, and everyone is touching it from different sides,” he says.

Is there such a thing as “true” integration of CP and AP data? Is integration compatible with information systems that are “best of breed”? Is integration even necessary or desirable? Are there alternatives to integration that might be better at meeting the needs of pathologists, clinicians, and patients? And will we still be talking about integration in 10 years? LIS vendors and specialists in pathology informatics have a variety of perspectives on these questions, but most agree that integration is shaping up as a major preoccupation of this decade.

Because of the evolution of anatomic and clinical pathology and their differing procedures, CP and AP data have traditionally been kept in their own information “silos”—with numbers, values, graphs, and charts for CP, and primarily text, qualitative interpretations, and images for AP. But as the volume of data balloons, the need to make sense of it all is starting to crumble the silo walls. “What both doctors and patients want is somebody to look at their specific disease in a holistic fashion,” says Michael Becich, MD, PhD, professor and chair, Department of Biomedical Informatics, University of Pittsburgh School of Medicine. “The problem is that CP and AP labs are so differentiated. What they get back are a bunch of disconnected pieces of information that very frequently, in the management of the patient, aren’t put into the context of treating that specific disease.”

“In the past, if you were an anatomic pathologist, all you had to do was look at a glass slide, speak into a microphone, get the transcriptionist report, and you were done. That was it,” says John David Nolen, MD, PhD, director of laboratory strategy for Cerner Corp. “Now practice has changed to where you’re having to integrate clinical lab data, molecular data, radiology data—the list goes on and

on—into a report for the clinician and the patient. We’ve moved past the days where clinicians can expect to keep up with the myriad tests and range of results; we just need to be able to tell them what the diagnosis is. They need to get that integrated report that they can quickly digest, that synthesizes all the testing data across all spectrums.”

But shipping a PDF file of a result back and forth is not going to do the trick, he says. “We have to get past that point,” Dr. Nolen emphasizes. “People in lab medicine understand the fact you’re not just posting a result. Data has to go elsewhere, to clinicians’ eyeballs, so they can convey it to patients face to face. You have to make your data as portable as possible. That means you’re not just putting it into a slick PDF; it has to go live inside the EMR in a form that you can look at and understand.”

Because a lot of pathologists are saying they want to get their molecular data when signing out an AP report, Cerner’s Millennium PathNet plans to offer that capability, Dr. Nolen says. “Today, we are able to pull data in from our molecular solution Helix, and you can predefine a template to bring that data across. That’s our first foray into that type of integration, and we’re working on making a more flexible type of integrated report builder, where you can make a template and then style it the way you want it. That appliance, that report builder will preserve the extremely significant feature of the electronic control of documents.”

Staging of the report will be needed, he says. Even though results will be integrated, “the bone marrow comes in and has to be fixed; then the flow will come out before you sign out the bone marrow. Then maybe cytogenetics will come later. But the clinicians want to start taking that information as soon as possible, so they can start ruling things out. It’s a report that’s going to change over time as new things are added to it. So you can see how complicated this can get. To give our clients the toolset to easily build these reports and not triple their workload at the same time is the significant challenge we’re working on right now.”

If true integration is defined as a single common database, there are only a few vendors that have or are planning to have a common database for CP and AP information, says Hal Weiner, president of Weiner Consulting Services, Florence, Ore., who does strategic planning for information systems in health care delivery networks. Orchard Software, having integrated AP and CP data in its Orchard Pathology system, believes it is the only vendor that houses both types of data in a common database. The company’s reasoning, says vice president for sales and marketing Curt Johnson, is simple. “There are more and more cross-overs between anatomic and clinical pathology, and a lot of that is being caused by molecular. We believe there is really not going to be a clinical, an anatomic, and molecular laboratory much longer. You’re just going to have a laboratory. And all those silos are going to go away.”

In most LISs, Johnson says, there’s a fundamental flaw: In the reports that are provided, “you can’t see the HPVs with the Pap smears, you can’t see the PSAs with the biopsies, and you can’t see the CBCs with the bone marrows.” For example, a high percentage of laboratories have an HPV instrument sitting in the clinical lab, and it interfaces to the LIS, which doesn’t communicate to the AP system. “That causes the pathologist to have an ASC-US Pap test result and the HPV pathology result on separate reports. When we designed our system, we wanted to eliminate that. So rules can be set up to automatically reflex an ASC-US result to an HPV. Then the results are integrated into one report.” (See “Unified AP/LIS—one system, with one database,” page 58.)

Orchard, which now has 30 live installations of its Orchard Pathology system with integrated AP and CP, and another 12 to 15 lined up to launch this year, had its

roots in products for physician office labs. “It took a while for people to understand where we are in AP,” Johnson says. The biggest issue the company had to resolve in developing its common database was the AP data structure. “In today’s world you must have structured data from the AP side, something that’s new. In the past, systems were designed to help pathologists with very elaborate high-quality reports—but they were just sophisticated word processors. We had to make sure our design accommodated synoptic reporting.”

Johnson admits that at the design phase of the system, because clients are creating structured data, “there are more mouse clicks potentially required on the front end.” But once this setup is completed, the savings come on the back end, he says, because the reports can be scheduled and produced hands-free, saving pathologists hundreds of hours.

Weiner agrees that Orchard Pathology is integrated into a single database. It’s something Cerner with its new Millennium product also claims to offer, he adds, though Cerner is also marketing CoPath separately, “so it depends on the system they’re talking about.” However, he contends that as of yet, no vendor has a fully integrated solution that takes care of molecular imaging, all the handling of the assays, and the massive amounts of data relating to genomics and cytogenetics. Vendors like Soft and Cerner have standalone products to handle that, but no one has a single solution that does it all.

Such “true” integration may not, in fact, be the most worthwhile goal anyway, he suggests. “Look what’s happening between CP and AP. Traditionally, CP systems are based on discrete data elements while AP systems are based on blocks of text. But that distinction is starting to blur, because AP is moving to synoptic reporting, and that includes the creation of discrete data components as well as textual reporting. In addition, molecular diagnostics has added the need to store massive amounts of data, and pathology systems are not designed to handle all of that.” Labs need to start re-evaluating how their LISs have to deal with these more complex data, he says.

Over the years, many of the solutions being called “integrated” were developed separately at different companies; they were not developed by a vendor as a single integrated solution but came in through acquisitions and were interfaced through coding, Weiner points out. The distinction between integration and interfacing is one that vendors agree on for practical purposes, he notes, but for marketing purposes it sometimes gets lost.

The new approaches to creating diagnostic tests are causing a rethink of the architecture of these systems, in his view. He foresees systems like the one on Epic’s drawing boards as becoming the standard. “They plan a total solution for the total institution that will include radiology, pharmacy—everything. And that would be bypassing the LIS replacement systems.” That’s where the market is moving, he says, and while one or two vendors have the lead in the development cycle, it’s hard to say which company will be first to achieve a total solution.

For the time being, there are still sharp differences in the level of sophistication of pathology informatics at different institutions. One of Weiner’s clients, for example, is a large teaching institution with five or six hospitals. “They have thousands of workstations and you can go to any one and have the entire medical record of any patient online, including lab, x-ray, and everything else. The response time is instantaneous because vendors have figured out how to structure the databases for these large transactional volumes that are required—just as the banking system has.”

“You don’t have to wait five minutes to get money out of an ATM, but I still know

of lab systems out there where a 30- to 45-second response time is not uncommon. Try taking that kind of data structure and add billions of data points that are required to store all this genetic data, and a response time of hours would not be surprising.”

Dr. Becich believes Orchard’s AP/CP LIS may work well in group practices or smaller labs, “but unfortunately, for whatever reason, it doesn’t look like their system will scale up into large, complex networked environments.” At his system, “we have 23 hospitals and four core laboratories doing millions of tests per day rather than a few dozen,” and he doesn’t see an immediate solution for integrating AP/CP databases in such large networks. He thinks Sunquest and Cerner have real opportunities to accomplish this feat, because they have best-of-breed CP LISs and very good AP systems. “The systems are both very good alone, but how do you get the data from those together and delivered in a disease-specific report to the clinicians we serve? We just can’t do that yet.”

“How I define integration might be different from the way you define integration,” says George L. Rugg, senior vice president for laboratory information systems with Elekta Software, Sunnyvale, Calif. He admits that, because of the nature of Elekta’s laboratory product offerings, his bias is to focus on a best-of-breed solution rather than an integrated systems approach. His definition of a truly integrated lab system is one with a common database with a common application set that can handle the needs of clinical and anatomic pathology.

But, he asks, is it necessary to have true integration across the laboratory services spectrum? “I think what’s important is to develop applications that give providers easy access to information necessary to perform their jobs, but I am not convinced there is a clinical benefit to a fully integrated solution over one with good interfaces. Can it be done? Sure. But I just don’t think it’s necessary,” he says.

Rugg is not suggesting it’s not important for anatomic pathologists to see clinical data. Rather, he is suggesting there are alternatives to completely integrated systems that are just as effective. “For example, if a pathologist examining liver tissue wants to see the latest liver function test results or other select CP test results, he or she should be able to do that. PowerPath and other systems allow this type of ‘tissue context’ filtering, and it has nothing to do with systems integration. It has everything to do with data integration and presenting case data in a more meaningful manner.”

A potential downside of an integrated approach is that not every company that has a good CP solution has an equally good AP solution, or vice versa, Rugg points out. “And I don’t think every company that sells hospital information systems has the best AP or CP products. There are varying degrees of capabilities among different vendors, and if you buy based on CP features, you may be sacrificing functionality for the people in the AP department.” That, he says, must be recognized as a potential outcome of the integrated approach.

On the surface, an integrated approach seems to have the lowest IT cost. “It’s easier to put price tags on vendor interfaces,” Rugg admits. “What’s not easy to do is put a price tag on lost functionality, and that may well be the outcome of the integrated approach.”

Dr. Friedman agrees that what counts is the kind of system performance the pathologist experiences, not the system architecture. “A good test of integration would be if you have, say, 40 cases queued up in surgical pathology to read, and you sit in front of the terminal and create a worklist of small biopsies first, then the bigger cases. Ideally, a truly integrated system would do queries in the background, and provide all the surgical pathology cases for each patient and any relevant

clinical pathology data. As you walk down that queue, the CP data you need is presented without your having to independently go back and find it.”

That’s what Dr. Friedman would call a “real life” example of integration. “How many keystrokes, how many mouse strokes does it take to achieve a certain task? My view of integration is the ease with which you can get through your daily work without a lot of extra keystrokes. If you can do that, to a certain extent you might not care what’s ‘under the hood’ of the LIS,” he says.

“The thing that’s most important in integration of AP or CP systems is whether the company doing it takes seriously the support of AP,” says director of informatics for the USC Department of Pathology Raymond D. Aller, MD, who is responsible for four hospitals in the USC system, including the Los Angeles County–USC Medical Center. “Usually they have CP and they want to implement AP along with it.” Synoptic reporting has made AP reporting much more “fielded,” he says. “That is, you have a lot of individual fields that get populated, as opposed to the previous model, which was mostly a block of text that was the diagnosis. So in a lot of respects, synoptic reporting is much more like CP reporting.”

He finds it interesting that Cerner has purchased a number of lab vendors over the years, sunsetted many products, and merged everything into its one Millennium platform, which includes its Millennium AP product. “But every time I go to a vendor exhibit, they bring Cerner CoPath. A subset of their users clearly prefers the capabilities in this separate database system. Fortunately, over the years Cerner has connected CoPath with Millennium at several points for orders, results, and workflow.”

Being able to see the CBCs with the bone marrow, and the HPV results with the Pap tests, is an important feature of any AP system, but it doesn’t at all require AP and CP to be running on the same database, Dr. Aller says. “It simply requires that there be a protocol whereby these key tests are automatically conveyed to the AP system or at least can be displayed in a CP window on the same workstation.” Buyers of the AP and CP systems of LabForce of America, a company that eventually went bankrupt, mistakenly assumed that getting modules from the same vendor would automatically mean integrated modules, but “they got a situation where they got no integration *or* interface—the two systems could not communicate at all,” he says. So, he cautions, “When a vendor makes the claim of being integrated, remember that that and \$2 will get you a cup of coffee. You don’t know what they mean. You have to ask specifically: Tell me what I can do with this system.”

With two separate companies, “you as the user have to make that integration happen—cajole them into cooperating as part of a purchase order or contract.” In the cases of Orchard, Meditech, and McKesson, he believes, a single company can achieve more seamless integration than could readily be accomplished by a multi-vendor strategy.

At LA County–USC, he admits, “we have an IT setup for which the technical description is ‘complicated.’” It includes a Sunquest LIS, a Sunquest CoPath AP system (CoPath is a brand name shared by Sunquest and Cerner), Quadramed Affinity as the HIS, an Eclipsys ICU system, Quadramed Quantim document imaging system, a Fuji Synapse PACS, and at least two dozen other systems. However, asked to rate the degree of AP/CP integration at his hospital on a scale of one to 10, he gives LA County–USC a six or seven. “On one screen you can open both a CoPath window—in which you are working on a pathology case—and a Sunquest window—in which you can see the CBC results.”

With positive patient identification waiting to be addressed at the four hospitals in

the USC system, improving AP/CP integration is not Dr. Aller's burning priority. "First, what is the clinical need? I would first want to actually talk with colleagues in surgical pathology and say, what do you need? We could spend a whole bunch of money improving integration, but if it doesn't benefit practice or benefit patient care, then it's a waste of money."

"Integration is one of those words like motherhood or apple pie, and everybody thinks it's great, but sometimes it's not so great. If you have a fully integrated system and it goes down, then you have no access to data. You're dead in the water. Whereas if you are somewhat decentralized, you can use other parts of the system to retrieve data."

Second, Dr. Aller points out, integration can constrain you. "It does have the advantage that you can see things over the whole patient. But if you have to obtain your CP and AP systems from the same source, and the module you're using for AP isn't up to snuff, well that's too bad."

Some vendors question whether a single vendor could provide an integrated solution that is also considered a best-of-breed solution. Wally Soufi, president and CEO of Novovision, Princeton, NJ, maker of AP information system NovoPath, whose clients are small to large reference labs and hospital-based pathology departments, is one who is skeptical.

Sometimes clients are interested in reports of clinical lab results alongside AP findings, Soufi says. For example, they may want a chart showing PSA levels rising over time and tying that together with a prostate biopsy, or tracking of white and red blood cell counts when reporting a hematopathology case. "But there doesn't have to be a strict, permanent tie-in between the two systems to get these results. You can just import that information and have it electronically inserted into the pathology report as you would any other piece of information."

Generally, it's the treating physician who will need all the information together, not the pathologist. For NovoPath clients, the attraction is the product's flexibility to integrate with almost all hardware and software, and NovoPath's 100 percent focus on AP and nothing else. "Our clients understand that AP has its own ins and outs, its own workflows and needs. We're not distracted by multiple disciplines, and I think that's a significant benefit a best-of-breed vendor provides that an integrated vendor cannot. We understand the complexity of the discipline. And that translates into better service, better features, and lower costs."

It's true that some institutions do not want to consider anything but an integrated offering, he says. "It may be because IT has a strong influence in the facility and has concerns about integration between various vendors. These concerns, in today's environment of interoperability, are not as valid as they once were. What clients need to focus on is what makes the AP department most productive and most cost-efficient in producing the best outcome possible for the patient." A product like NovoPath offers reductions in cost, he adds, "that are very, very difficult to come by once you are tied in with a big integrated vendor. Just to upgrade a large system might cost you hundreds of thousands of dollars as the facility is committed to all the various disciplines for a significant period. You don't have issues to deal with from other functional groups within the facility or unrelated costs associated with an installation or upgrade from a best-of-breed vendor. So a best of breed is the way to go, in my opinion."

Traditionally, says Sunquest's Pawan Singh, clinical pathology has been quantitative while AP has been more interpretive and pathologist-driven. "But the molecular tests that are coming out now are starting to blur the lines by being both quantitative and interpretive." *KRAS* mutation testing is an example of such a test;

Sunquest's system allows these results to be reported and included, he says.

"Clearly there is a big need for looking at unified information," Singh says. "There are some inherent differences between CP and AP, so while you have to have integration, at the same time you need specific workflow excellence. You are talking about a seamless exchange that's giving clinicians the most relevant information and best possible cross-sectional view across time and across different departments. What users really care about is being able to flow that information."

Hal Weiner believes the concept of best of breed is fading out. "If you look at the RFPs, the vendors all check the same boxes. Maybe they interpret the questions differently, but there is pretty much no major distinction between the functionality of lab information systems today." The real problem, he suggests, is that the LIS market in CP and AP is strictly a replacement market. "The market's been pretty well saturated, so in the hospital portion of it, when departments go out to replace systems, more and more their management is saying, 'I want a single vendor for everything.'"

McKesson is one company that has invested in innovating in this area, Dr. Becich says. "They've engaged consultants to help define a technical path to do integrated reporting in the last year. I haven't seen it affect their product yet, but at least people are thinking about it." But Dr. Becich agrees that money and an over-saturated market are obstacles. "The cost of putting out something new is onerous in this very competitive environment and tough financial times for LIS companies. On the other hand, one day somebody is going to come up with a blockbuster product, and I suspect folks will scramble then."

Pathology should lead the way, in his view, by sponsoring an open-source, next-generation, integrated LIS that companies could then commercialize—similar to the way companies like Google, Yahoo, and Microsoft got behind an open code to allow social networking to proliferate. As it is, the fact that HL7 version 3 still has not been adopted as an industry standard, plus the lack of interoperability platforms within current LIS infrastructure, and the messaging framework used between pathology and other electronic reporting systems, have been barriers.

"If you don't have a standard and you don't have a kind of ontology that allows interoperability, then making complex queries about what's stored in the LIS gets very difficult," Dr. Becich points out. "It would really be great if pathologists rallied to the forefront as patient advocates and insisted that their systems integrate the information and deliver it in a disease-specific and patient-specific fashion" rather than just a slew of numbers and text. "Because we are knowledge engineers, not just data providers."

"Cloud computing" has been called a revolution that will define IT in the second decade of the 21st century. Could cloud computing, or some variation such as "software as a service" (SAAS) through which users access software on remote servers, obviate the need for integrated systems as they have traditionally been understood? In the IT world, there has been much recent discussion of zero-install cloud solutions and how, as they proliferate, they may make integration easier. Novovision's Hosted NovoPath is an example of an SAAS solution to which anatomic pathologists without in-house IT capability can subscribe.

Singh points out that housing IT systems in the back office has grown more challenging. "Hospitals didn't necessarily used to think, if you go back eight to 10 years, about bandwidth, security, and scalability. A lot got done piecemeal. But with technologies like cloud computing, rack computers, virtualization, they have the ability to scale to add more and more systems into the mix." A lot of the responsibility for this falls on the IT department, he adds. "That's partly why you

see the role of the chief information officer in the hospital elevated so much.”

Dr. Aller has already moved his personal calendar from a Palm Pilot to a cloud solution provided by Google, but in laboratory informatics, he believes cloud computing could solve some problems while creating others. “It’s the basic concept of what we called timesharing in the 1960s, and the advantage is you don’t have to buy all that hardware and software, and someone sets everything up for you. But that also means they’ve made the decisions about how you’re going to interact with the system.” The bugs are never apparent in a new piece of software, he adds, “so you have to realize you’re choosing your poison: Do I want to deal with the problems I have now, or do I want to bring on a whole different set of problems?”

But downstream integration between the AP and CP LIS and the EMR won’t even happen without the cloud, Dr. Friedman believes. “We have a problem, and that is that diagnostics is exploding. The EMR cannot accommodate all the sophisticated data we’re generating on the LIS and AP LIS. So right now if they want to see images in the EMR, they have to sign on to the pathology PACS or an enterprise image server.” Most CEOs still see cloud technology and cloud-based information as too vulnerable and want to keep their data on their local servers, he says, but the data management issue is only going to get worse. “My view is they’ll just throw up their hands, because the price of cloud storage is so much lower, and ultimately they’ll have to give in.”

IPads and other tablet computers, which basically have no storage and interact exclusively with servers in the cloud, will inevitably be part of that future scenario, he predicts. “Physicians love tablets; they’re big enough to look at x-rays and the whole field of patient data, yet they weigh only one to 1.5 pounds.” Tablets will be the viewing device of choice, Dr. Friedman says. “We have to make the data in EMRs accessible to clinicians as they’re in their cars.”

Could such a scenario nudge conventional ways of thinking about AP/CP integration to the back seat? That remains to be discovered. But, says Johnson of Orchard, it’s safe to predict “that pathology is going to continue to evolve, and the information systems of the past are going to be completely different from the systems of the future.”

Anne Paxton is a writer in Seattle.