AP LIS panel: complexity, middleware, reports, AI

February 2020—*Middleware, transmitting and consuming reports, and artificial intelligence are just some of what AP LIS roundtable panelists talked about in December with* CAP TODAY *publisher Bob McGonnagle. Members of the panel were pathologists Monica de Baca, MD, and Jeffrey Prichard, DO, Rick Callahan of NovoPath, David Liberman, MD, of Computer Trust, and Chad Meyers of Sunquest. Here is what they said. (Access the interactive anatomic pathology computer systems product guide here.)*

Anatomic pathology systems have changed over the past 20 years, and I'm wondering how much they are beginning to morph into something that is a basic LIS that happens to be structuring the anatomic pathology reports, the instrumentation, protocols, and interfaces. Rick, what is your view on this evolution?

Callahan

Rick Callahan, vice president of sales and marketing, NovoPath: Over the past 10 to 15 years, there has been substantial change. In the '90s it was unique to put images into reports and to create a report that was fairly fluid. Now images are accepted as status quo. Reports are customized for individual facilities and even for individual doctors. In the early days people focused purely on anatomic pathology—generating information for histology and cytology. Now when we refer to AP, it's the broad spectrum, from histology and cytology to hematopathology, cytogenetics, and molecular, in terms of functionality and specialty cases and tests. Over the years we've evolved to looking at more CRM and business analysis tools to be added into a basic platform for anatomic pathology. It was basically an on-site server solution in the past, though they're still widely thought of in university and medical facilities, and now we're moving more to a cloud acceptance solution too.

Dr. de Baca, can you comment on Rick's piece of history? It seems to be in sync with what most of us have observed.

Monica de Baca, MD, founder of MDPath LLC and hematopathologist, Pacific Pathology Partners: What Rick said is astute. A lot of the LISs started out with many of the more accounting functions and then moved into the medical aspects of their functionality. As the technologies have advanced, so too have the specific capabilities of the AP LIS. I was heartened to hear Rick speak about the reporting capability, since reports are the primary product of the pathologist. One of the opportunities I still see in AP LISs is creating integrated reports and offering the possibility for different readers to see specific items they're interested in in that report. Still, the complexity of the AP LISs has had to increase dramatically in the past 20 years as pathology itself has become more complex. By and large, the AP LIS community has done a great job in trying to keep up with our needs.

Dr. Liberman, how do you see this evolution and the increased complexity of AP systems?

David Liberman, MD, president, Computer Trust Corp.: As a physician by training, I see the top goals that we've always had, and have no less today, as reducing disease, promoting health, and delivering a report that clearly and accurately communicates the diagnosis, and that's the key element we're producing in the lab.

Twenty years ago we saw basic automation of the report—in a character-based, monochrome way of trying to deliver the content. About 10 years ago client service demands became more sophisticated. The clients wanted to be able to do better for their patients who needed and demanded more. EMRs were coming in and there was tighter integration. Images improved communication. But what we've seen more recently is a PDF of the report that can do special things to call attention not only in images but in color content of abnormalities.

Our lab clients have seen downward reimbursement pressure; they have to do more with less, and there is increasing lab competition. It's a tougher barrier to entry, especially for smaller labs, and we're looking at a landscape of larger and multisite customers. The needs today are stronger than they were 10 years ago and certainly 20 years ago.

Meyers

Chad, tell us from Sunquest's point of view what you're seeing in the environment for the anatomic pathology practice through Sunquest anatomic pathology systems.

Chad Meyers, vice president of product management and strategy, Sunquest Information Systems: One of the things that might sum up that history point is that the level of complexity the labs are managing day to day has continued to expand, and that's where the LIS played its critical role, in becoming the backbone of the laboratory, interfacing with the EMR and electronic owners as clients acquire other hospital practices and their footprint grows and gets more complex. Clients may have the same EMR but multiple instances of it, or they may have different EMR vendors they're trying to connect with electronic orders, so that raises the need for the LIS provider to be able to integrate across the diverse topology of an individual client. It may be from an orders and reports perspective, but it may also come into play with specimen tracking or billing or even imaging systems across the different labs performing work. The LIS has continued to help handle that multi-vendor complexity and allow labs to innovate on the workflows but manage the spectrum of orders and incoming specimens. There's a lot of complexity to handle while making sure it's not visible to the physician.

Dr. Prichard, when people talk about complexity of an operation, you're top of mind because you have a complex operation at Geisinger and seem to have organized it magnificently. Tell us about the role that anatomic pathology systems have played in the evolution of the anatomic pathology operation and the informatics at Geisinger.

Jeffrey Prichard, DO, division director, anatomic pathology operations, informatics, and quality, Geisinger Health System: I've been doing this since 1998, first in Pittsburgh and then for the past almost 20 years at Geisinger. I started out in AP as a generalist signing out everything. Over time we picked up more hospitals and gained more staff, and we found a need to subspecialize, to take advantage of the subspecialty expertise we already had in the group. There was a period in which we had to go from being a generalist to being a subspecialist, and as the volumes grew—when I started there were approximately 13 of us and now we're up to 42—we didn't have enough people to fully subspecialize and staff each of the subspecialties with at least two, so that someone could go to a conference and someone else could cover the service.

We had a lot of challenge in our AP LIS in managing that transition from a generalist to a partially subspecialized group, and now we're almost completely subspecialized—we know who is available at what time to get which type of subspecialty case. Those were features we didn't have when we were trying to go through this change. We had to look at what was available off the shelf and then realized that that kind of a workload distribution tool would need to be developed. Our relationship with our AP LIS, which has been Cerner CoPathPlus, has been to take advantage of the existing features, but then add on to it the features that hadn't been developed yet in order to keep up with the growth and the complexities in our practice. So we ended up adding on almost as many as 15 pieces of software that we've had to develop to get the features to work with CoPath to support our practice.

Is it fair to say that what we often refer to as middleware has become an essential part of complex anatomic pathology operations such as yours?

Dr. Prichard (Geisinger): Yes, we needed to develop our own software to fill in the gaps to keep the efficiency and

productivity we need to maintain this type of a volume workload spread out across the state.

Dr. Liberman, there's been a lot of talk about the need for ancillary help with anatomic pathology systems. What do you at Computer Trust hear from your customers? Do some of them create their own middleware à la Dr. Prichard? Do some look to you for those solutions? If you don't provide them, do you help them find a middleware that is optimal for them?

Dr. Liberman (Computer Trust): Our main focus is what we feel we do best: deliver the core anatomic pathology system in terms of the lab function and delivering to the clients, and everything in between. In general, I think you're better off offering the customer what the customer wants to buy and let them buy the other components wherever they want. We have a number of customers that buy all of their EMR interfaces from us—we have an efficient way of delivering those—and we have many that want to use middleware. They have us develop an interface with the middleware vendor, and that company routes the traffic in and out. Our smallest customers might have a few clinical practice sites—a few GI or derm practices—and they have a single central small lab. Those will typically use us to develop the one interface with the one EMR they have.

At the other end, we have large national customers that have their own IT force managing their own internal middleware program, and they dictate how we have to interface with that and what the specs are, and then they have a formal vetting process. That probably ends up being more work from our side and more customizing than if we had interfaced to the various separate doctors' offices. But that's a process that gives them control within the lab, and they're the customer.

Chad, Sunquest is well known for having a comprehensive umbrella of offerings. How are you coping with clients who have great demands for customization and assistance in making their practices efficient?

Chad Meyers (Sunquest): Sunquest tries to meet clients where they're at and, based on their needs, to provide solutions for their next step and evolution. Whether that's implementing specimen tracking or moving toward discrete synoptic reporting or trying to manage electronic orders with the EMR and how they're collecting samples more broadly across the enterprise, we will look to leverage capabilities within the LIS or additional modules to supplement them. That may include providing capabilities beyond anatomic pathology as they expand into molecular and genetic. We've tried to have capabilities built right into the anatomic LIS and then leverage modules for other capabilities that might be shared across multiple laboratory disciplines, depending on how simple or how complex their operations may be. Sunquest knows that our customers are all at different stages based on where they started and where they've evolved to.

It's important to have a wide range of capabilities while trying to stay ahead of clients to make sure we're matching up with some of the most innovative labs and helping all of them through challenges where they're needing to provide more discrete data to cancer registries and to oncology staging applications within the EMR, as well as other needs that might be related to how they bill and manage their work and perform the day-to-day activities in the LIS. Every customer can leverage the capabilities in their current system in a greater way than they are today, especially with reimbursement cuts, to try to help them be more efficient or improve patient safety or the overall quality of the diagnostic report. All vendors need to continue to help every lab achieve its strategic plan to get to the next level.

Dr. Prichard, one of the constant themes in meetings like that of the Association for Pathology Informatics is the difficulty that many anatomic pathologists have with interfacing to their EMR—not just the mechanics of an interface to an EMR but ensuring that the physicians they're sending reports to can understand the reports, understand when amended reports come in, understand when there's still reference work that's outstanding. How do you handle some of these tricky problems at Geisinger?

Dr. Prichard (Geisinger): In terms of getting the report to the clinician in the best way possible to help the patient the most, we've had to interface CoPath into Epic. There are limitations in how Epic can display things, at least in its current form, so we've had to take control of the format of our reports by generating them in CoPath and then passing them out into a PDF format, which is then linked into the electronic health record. That way, we can be in

control of how addendums would show up or how subsequent procedures would be tied together in that report as opposed to some of the requests we have for just text streams to go across. We interface so that it can be displayed directly in Epic. We've opted away from that because we did want to have control of the format of our reports.

Dr. de Baca

Dr. de Baca, what are your thoughts about this need to get reports into the EMR properly but also to help physicians understand the reporting and the complexity of the pathology work as it may be appearing to them in one of the many EMRs that are out there because many are in physician offices?
Dr. de Baca (MDPath and Pacific Pathology Partners): Dr. Prichard's comments refer to the status quo. The current situation in the most prevalent EMRs in the country is such that most people would agree a PDF is still the most prudent way to send in the pathology reports. It's probably not, however, the easiest way for the physician to consume that information. This is an opportunity at the level of the EHR, but unfortunately, it's not something the AP LIS vendors have a lot of control over, or the pathologists for that matter. There's a need and an opportunity to have the reporting capabilities in the EHRs evolve into something much more in keeping with what pathologists and clinicians need so that pathologists can be assured that patient-facing clinicians are seeing exactly what we need them to see and in a way that's more user-friendly.

For instance, when text streams are being shared, something could go from being "no evidence of carcinoma" to "evidence of carcinoma" because of a line shift or break. That's a real problem. So it's important to have PDFs to ensure the highest degree of patient safety.

Many physicians don't want to see the anatomic pathology report in the EMR, and I'm sure you are used to requests for a report to be sent by fax. Please talk about the importance of initiatives around that sense of comprehension.
Dr. de Baca (MDPath and Pacific Pathology Partners): I think I'm seeing a shift away from the clinician asking for a fax unless it's a smaller practice. In my experience, clinicians who have their practice in larger institutions are quite bound to their EHRs, and so that's their preference. Even with limitations in the way a report could be viewed or with a multiplicity of clicks required to get there, that's still where they are.

For people who have smaller practices and maybe less nimble EHRs or who are in such a phase of their career that they still prefer paper, then, yes, the fax is still a preference. Having faxes be the method of transmission for almost anything right now, in 2020, is an interesting place to be. It would be fun to see a statistic about who buys fax machines these days; I'd bet a large percentage of the machines are purchased by medical companies.

That's part of the point I'm trying to get at here.
Dr. de Baca (MDPath and Pacific Pathology Partners): Yes, but I'm not sure what our in-between option is. One thing we know about fax transmission is that if you have a fax machine that is a known number and you send to that, you can be pretty sure the report will arrive at the place it was intended to arrive and that the patients' health information is not shared elsewhere. If a larger practice has many clients and is trying to share things over secured email, that's always a possibility, but it's not yet the preferred way of transmitting reports.

Dr. Prichard, how do you deal with it when the clinician says, "I wish you'd just fax this to me"?
Dr. Prichard (Geisinger): We fax it to them. I'm surprised at how much faxing still goes on, and it's not something we've been able to get away from. It's the culture of some of the clinicians and their offices. But the fax does have a certain kind of security to it—that is one of the benefits that keeps it hanging on—but it would be my goal in the

future to get away from faxing if we can, especially the paper part of it because it's a degradation in the report as they print the paper out and then scan it back into their EHR. If we could have them receive things in digital format in the fax and then not have to print it but then store it into their EHR and skip that paper step, we'd be going in the right direction. I haven't been able to champion that through.

Rick, how many physician systems do you interface with at NovoPath? And do you have an observation to make about this question of faxing?

Rick Callahan (NovoPath): We have one lab that interfaces to 150 clinicians through the same EMR vendor. That could be different EMR versions, but it is the same vendor's EMR. And with that we've set up an interface engine, which the lab manages, so we'll send the information of the reports to the interface engine, and then the lab will distribute the reports to the appropriate clinician in the EMR.

In my world, faxing is not as well received or used as much as clinicians accessing a web portal and pulling their reports through the lab's web portal into their EMR. That seems to be one of the more popular means of receiving reports. The other is through the HL7 interface to the EMR. Dr. Prichard had mentioned some enterprisewide vendors being unable to receive PDFs, and there are several of them. What Geisinger has done is embed a link into the HL7 where the clinician who does have access to the EMR clicks and then pulls the report into their computer through the HL7 interface. This functionality is available in NovoPath, and it enables our clients to provide reports in a PDF format through an EMR that is unable to accept PDFs.

Regarding what Dr. de Baca said about textual transmission, we're finding that many NovoPath hospitals are moving away from textual transmission of pathology reports. If you're not aware of the ability to install a link into the HL7, then the worst possible scenario is to send the report in a textual format.

Dr. Liberman, can you comment on this question of getting reports into physicians' hands and what your experience is across the spectrum of customers?

Dr. Liberman (Computer Trust): There are two levels of question there: how and what. The question of how goes to faxing; it's secure, point-to-point. It's grainy and black and white; that's not great if you're showing images or color. If they then rescan that to load it, as Dr. Prichard said, it gets even grainier. If they can accept an EMR with a link or directly with uuencoding or 64-bit encoding of a PDF into an HL7 and then load it into theirs—clients that have EMRs that will accept such a report prefer to do it that way. We have some that don't have that, and they prefer—if it's a big enough volume client—to put a remote printer in the office and have our system send directly to that remote printer.

Now for the what. Your original question was how do you make sure you're matching up what you're communicating from the pathology lab to what the clinician needs clinically. I don't think most EMRs have adopted this, but there's one fairly widely used EMR in dermatopathology that has a suggested diagnosis feature, and that matches up with our diagnosis category. The lab customers who use that love it because it helps communicate to the client in a format they really get in terms of their clinical need.

Dr. de Baca (MDPath and Pacific Pathology Partners): We've spoken about the how and the what. It would be interesting to talk about the "wouldn't it be nice if. . . ." I used to be a clinician, and I know from experience how I as a surgical ophthalmologist read the pathology reports that came to me. It was different from the way most pathologists think a person reads the reports. If we think about cancer reporting, for example, and we think about synoptic reports, which have thankfully become the standard, we still have a host of clinician clients who are reading these reports, each one with specific interests and needs. We also have patients who are reading these reports, and then there are the insurers that are reading the reports and the people from the cancer registries, and each one of these clients consumes our reports in a different way. When our life was paper, it was necessary for all the information to be on every report. But now that most of our reports are being consumed digitally, one could foresee the moment in which, as a consumer of a specific type of report, I could choose to see specific information. For instance, if I'm the surgeon, perhaps I just want to know if the margins were clear and what the diagnosis was, and I'm not interested in seeing the gross description or the billing information. If I'm the patient, perhaps I need to see not only the report as written by the pathologist but also with natural language, if you will, or colloquial

language annotations so that I can see what was written but I can also see the comments that say “this means something to this effect” in real-life language. I’m envisioning the pathology report more as a Rubik’s cube, and every consumer of that report would be able to compose the face of the cube they need to see for their specialty or their level of specialization.

Chad Meyers (Sunquest): The future Dr. de Baca envisions is within our reach given some of the work being done by the Integrating the Healthcare Enterprise PaLM group on the diagnostic report template and FHIR [Fast Healthcare Interoperability Resources] for clinical document architecture usage. We’ve made good strides in getting some of the report body content into synoptic or discrete reporting but need to get to the point where the whole report is done that way. To be able to allow that would be powerful.

On the previous topic of faxing—the beauty of the fax is it’s a series of numbers to identify and set up a new connection, and every fax machine works the same way so there’s no testing required and no interface setup on both sides; that’s part of what makes it frictionless. And we’ve continued to try to do that on the HL7 front, but there’s still allowance for customization there. As we move toward that full report being in more of a consumable format that separates the data from the presentation, it’ll allow greater consistency in how that’s consumed across both the consumers and downstream systems.

Dr. Prichard, what would be on your wish list as you reflect on what we’ve been talking about?
Dr. Prichard (Geisinger): The next step for the AP LIS is integration with whole slide imaging and the whole slide imaging workflow and making it as efficient and easy to adopt as we can because there’s going to be resistance from some of our pathologists. That’s an obvious next step.

The one I’m facing now and trying to find a solution for has to do more with molecular testing and communicating and coordinating what is an algorithmic step-by-step if-then-else process of what test comes next and to make sure you’re moving through that algorithm efficiently, so that by the time the patient gets into the office, you have the answer to all the testing questions. Molecular testing is so complex and the guidelines are changing so often that knowing the next test you’re supposed to order has been confusing. I would like help coordinating these molecular laboratory testing algorithms.

I’d like a brief comment or two about artificial intelligence. It’s brooded about a great deal, and it’s become a buzzword. Dr. Liberman, what two or three things should I know or would you like to share about your view on artificial intelligence and anatomic pathology?
Dr. Liberman (Computer Trust): I’m going to use an advertising analogy. With advertising there’s the content, but you also need white space in an ad because without it people can’t read what you have to say. The LIS should largely be, in my view, the white space, and laboratorians should be able to do what they do best—accession, make and read the slides, deliver reports. The intelligence evolves as humans figure out what they need, and they need to be able to express that and codify that into the LIS, and it needs to be able to just do it. It can do it repetitively and check for a zillion exceptions at rapid speed much better than a human can focus on all these different things.

Not too long ago we saw multiple Post-its on transcriptionists’ screens. If it’s this doctor, do this; if it’s such-and-such type of case, do that—as if they’re supposed to be checking every Post-it on every case and thinking about each one. That’s hard for a human to do. Artificial intelligence should be focused on building and codifying those things.

Chad, I’d like a brief comment on artificial intelligence either from your perspective or that of Sunquest. Is it ready for prime time? Is it overhyped?
Chad Meyers (Sunquest): It’s ready for prime time, but it makes sense to test it out and validate its applications. An example the group was talking about earlier is the ordering rules and trying to implement decisions and flows. Artificial intelligence could learn the patterns there based on historical ordering and try to optimize it. If you wanted to have a standard protocol, then you might need to use that instead. There are more applications of AI if we extend it to the various types of rules that are traditionally built in LISs and other solution applications—for

example, the progress being made with image analysis and what's being done with quantitative scoring on whole slide imaging. With all of these application possibilities, we need to make sure we're proving them out as an industry and prioritizing the right use cases for our clients based on what helps them the most.

I'm excited about the possibilities, and we continue to monitor artificial intelligence progress to identify and perfect the right cases in which to apply the technology.

Dr. de Baca, what are your views on AI in pathology and pathology systems?
Dr. de Baca (MDPath and Pacific Pathology Partners): We're already experiencing and are comfortable with a lot of machine learning tools. Prognostic scoring and simple risk calculators have been used for quite a while, and artificial intelligence has also been used for a handful of years in immunohistochemistry for calculating percent positives in nuclear staining with Ki-67 or ER or PR staining, for example. There's a huge possibility for AI and clinical decision support, be that on the level of the patient-facing clinicians or as pathologists, and of course the applications with whole slide imaging abound.

One of the questions is: What are the right tools to apply? There will be a lot of people with hammers who think every possible thing a pathologist does is a nail where AI could be implemented. Another question we need to wrap our heads around is: If we have artificial intelligence algorithms that are constantly learning, how do we make sure they're adequately validated? And once initially validated, how do we continually validate them?

We're stepping into a new galaxy, if you will, of questions about the assuredness with which we are implementing some of these tools. There are scientific, computational, and ethical questions that we need to be tackling as more of these tools come to the market and as we determine which of them are algorithms that will help us save time and improve or maintain quality and won't add risk.

Rick, is AI a frequent topic of conversation among your customers and potential customers?
Rick Callahan (NovoPath): No, it's not. You asked if we are ready for prime time or if it is hype, and my own opinion is, after any necessary government approvals, we're ready for prime time, but we don't have the early acceptance or the early adopters yet that would turn it into an acceptable tool to use in a general laboratory. Once we have early adopters that have shown the benefits of computer-aided diagnosis, we'll have more of a hockey stick adoption by other labs.

Dr. Pritchard

It reminds me of the early reluctance toward digital pathology. It seems AI is tracking along the same lines, part of which is concern about professional security. Dr. Prichard, do you see the concerns about AI and those about digital pathology in the past being similar?
Dr. Prichard (Geisinger): My experience of it is pretty similar, and I think we're going to have to go through a process with AI like we did with whole slide imaging and teaching the FDA what it is they're approving. Once we got to the point where the FDA was willing to grant approvals for whole slide imaging, adoption started to pick up. We're ready for AI, but I don't think the regulatory environment is ready to take on the challenge of approving what would be actively learning systems. We're going to be restricted to having some static algorithm that they can approve, and then we'll improve on that and we'll have to submit it again. It's going to be the FDA learning how to regulate in a learning system. That's what will hold us up, much like it did whole slide imaging.n