AP-LIS vendors on AI, practice complexity, the cloud

February 2019—Practice consolidation and complexity, Web-based and cloud computing, and artificial intelligence. That and more is what writer Valerie Neff Newitt asked six AP-LIS companies about recently. Here is what they had to say.

The profiles of their AP information systems are in the <u>Anatomic pathology computer systems product guide</u>, along with those of 16 other companies.

How is the increasing complexity of technologies, instruments, reporting requirements, etc., in anatomic pathology changing the marketplace? And how do you prioritize software and system development in such an environment?

Curt Johnson, chief operating officer, Orchard Software: Increasing complexity, new technologies and instruments, new reporting requirements and documentation are all standard business within labs. We look at such developments in a three-phased approach. First, what do we have to do now for our clients to make the versions they already have better? What new features and tools can we add? Are there new modules we can provide to clients to keep them up to date, move them forward, and benefit them? Next we consider a mid-term solution: What do we need for the next install in the next 18 to 24 months? What new instrumentation is coming out? What will new reports look like? What new interfaces will be required? Where will digital pathology fall? Finally, we take a long-term look: What will laboratory needs look like 36 months from now? Where is pathology going? Where will artificial intelligence be? Where will genetics and molecular testing be? What new tools will be out there? What will we need in terms of voice recognition? We are developing those tools right now so that we are ahead of the curve. We evaluate quarterly what percentage of our development time is to be spent on current, mid-term, and long-term concerns to make sure our resources are dedicated properly, in alignment with our clients' goals and our goals.

Joseph Nollar, associate vice president of clinical product development, Xifin: Pathology is becoming a profession where physical geographic location is diminishing in importance. With the albeit slow acceptance and adoption of digital pathology and shared revenue programs such as technical component and professional component splits, it is imperative to have lab systems that are accessible anywhere and can be integrated with digital pathology systems. Xifin's philosophy is to leverage open application programming interfaces [APIs] and build tool sets where all possible laboratory testing can be configured and performed, whether clinical, AP, molecular, or genomics. APIs allow us to provide single sign-on to digital pathology platforms so that a pathologist can launch directly to an image viewer from a case of interest. Our tool sets allow labs to have control over their test menus, link that test to defined workflows, or configure their own workflow process around the type of testing performed, design or configure screens that capture the data required for each test, and configure the final report.

We provide labs with the option to combine many different lab testing specialties in a single cloud-based platform. Having that flexibility gives laboratories the power to create new revenue streams, grow quickly, and adapt to the markets they wish to serve. We use an outside-in approach where we evaluate market demands and the latest emerging technologies to develop our product roadmap. We prioritize using an objective scoring method; development items with the highest scores are developed first.

Wally Soufi, chief executive officer, NovoPath: I would add government regulations and reimbursement practices to the list of items that are increasing complexity in AP labs. We have found, over 25-plus years in the AP marketplace, that listening to our clients and anticipating their needs is one of the best practices we engage in that enables us to exceed clients' expectations. Ultimately, our clients are our best compass when it comes to prioritizing new modules, features, and enhancements.

Chad Meyers, vice president, product management and strategy, Sunquest Information Systems: Effective and transparent communication with our customers leads to clear prioritization of the critical issues they deal with daily. We know we have to support high-quality, cost-effective lab testing while also reducing waste. Future development is not enough if it is not being done in a thoughtful and specific manner to support evolving customer

requirements, and having a rigorous and honest prioritization process is critical to controlling scope and eliminating redundancy of function.

There are so many exciting developments that are having an impact on the AP lab space—EMR interfaces and their evolving standards, multidisciplinary reporting that crosses organizational divides, and digital pathology, just to name a few. All of these help the customer to be more successful and sustainable during the marketplace's evolution. We must stay focused on the critical problems our software needs to solve and on our customers' long-term objectives as they evolve.

Nick Trentadue, product manager, Beaker Laboratory, Epic Systems: Technology in the lab space is always evolving, including the software that runs it. We work with our customers to identify what technologies are the most promising and drive our development to support them. In the past it was voice recognition, real-time Health Level-7 messages to stainers—now we are in the digital age where slides are moving into the cloud and image analysis and algorithms are driving care and where to focus attention.

Rodney Schmidt, MD, PhD, pathologist consultant, Cortex Medical Management Systems: Complexity in AP might be divided into three areas. Inbound complexity relates to client complexity, locations, ordering mechanisms, and interfaces. Internal complexity includes instrument interfaces, integration of results from different sources into coherent reports, partnership or inclusion of advanced testing modalities, and synoptic reporting. Outbound complexity mirrors inbound complexity but focuses more on how to get results to where they're needed. The underlying theme is discrete data. All data need to be in discrete form so they can be efficiently manipulated, stored, and reported by computer systems. In many cases, this may require re-architecting the LIS database and adding new functionality. AP vendors have to be attuned to the market and willing to make changes.

The buzz around Web-based and cloud computing continues to grow. How do these developments affect your customers and your planning?

Johnson (Orchard): The health care industry had to get over a hump to believe in cyber security and feel confident that data was safe in the cloud. It is becoming proven that data is extremely safe in the cloud and that hosted systems and cloud computing are potentially much more cost-effective and efficient systems, as opposed to organizations having their own data centers. Believing that health care will continue to move toward more cloud computing and hosted systems, Orchard has already progressed in that direction with mid-term and long-term development. We cover the spectrum of options, from on-premise-based systems to hosted systems and full-blown cloud-based computing systems. Our goal is to understand clients' needs today, their goals, and where they believe their IT resources will be in 36 months, and then to match them with the best solution going forward.

Nollar (Xifin): As the industry shifts toward a value-based model, more laboratories are making a strategic decision to invest in cloud-based solutions instead of traditional on-premise solutions, drawn in part by the lower cost of entry and operational costs and the reduced maintenance responsibilities. As a result, we are seeing that data security and redundancy are more critical than ever. Our customer data is hosted at the nation's only Tier V Platinum data center built on high-availability architectures, accessible from anywhere with an Internet connection. Xifin ensures clients will always be using the latest version of our software, without ever having to deal with maintenance or costly, time-consuming software updates. Beyond the reduced IT overhead, a cloud-based computing environment also facilitates rapid deployments of new sites and physician collaboration activities and it benefits revenue-sharing initiatives such as TC-PC splits through native workflow and remote accessibility.

Soufi (NovoPath): The infrastructure may be changing but the functional aspects of what labs do daily will not change dramatically. Some NovoPath customers have adopted cloud computing already while others have not. NovoPath will remain open to using various technologies while focusing on better overall user experience.

Meyers (Sunquest): We account for technical developments in several ways. For example, acquisitions lead to larger footprints, which are more easily served and maintained with Web and cloud computing. We know customers will need to share data between sites for unique testing reporting, such as genetic variants, which requires real-time access to the cloud. Consolidation may be having an impact on where pathologists are providing

their professional services, requiring them to provide interpretations remotely. And above all, all of this data must be constantly and consistently protected and secured. All of these dynamics mean we have to take into account not only these new future-use cases but also where such activities will be performed. Sunquest must be prepared to manage all of the data a customer needs to support future testing, as well as support the data they may need to share across the organization. This is an exciting yet complex evolution process that we evaluate constantly in order to set our customers up for long-term IT management.

Trentadue (Epic): We see cloud computing as a big advantage for organizations, primarily in the form of infrastructure cost savings and enabling more accurate machine learning models. We have developed our cloud-based AI platform called Cognitive Computing, which leverages Microsoft Azure to offload data processing from production, increases accuracy of predictive models over time, and leverages more data sources to build a more comprehensive view of the patient.

Dr. Schmidt (Cortex): The underlying driver is customers needing functionality but wanting to minimize the costs of obtaining it, such as data center and IT administration costs. We are implementing technologies for customers to move in this direction when they choose to do so.

How is artificial intelligence affecting anatomic pathology labs and their future plans?

Johnson (Orchard): AI is being talked about a lot right now; it has potential. But it's still far enough off that it is not affecting plans today. We believe the first area in which AI will make the biggest impact is in augmenting pathologists' diagnoses. Computers will be able to take in more information than a pathologist can, particularly when it comes to difficult, specialized, one-off, uncommon cases. The other place AI will make a big difference is in workflow efficiency. Having the ability to augment rules-based technology standards with artificial intelligence ramps up efficiencies and the workflow in the lab to a whole new level. But it's still a few years away.

Nollar (Xifin): Artificial intelligence in the world of pathology, in some respects, has been around for a long time. Whole slide imaging and image analysis technologies have been available but have seen limited adoption because of inability to gain FDA approval for primary diagnosis. The recent progress digital pathology providers have made should change the marketplace rapidly. Integrating digital pathology AI into existing workflows should allow pathologists to screen out negative cases and focus their time on critical cases. Xifin has been involved in integrating digital pathology and image analysis solutions since the early days of Chromavision, Aperio, and Biolmagene and continues to integrate the latest digital pathology solutions into its LIS workflow for review and reporting. Beyond AP, AI is poised to play a major role in clinical decision support, bioinformatics, and big data analysis solutions across many other testing modalities, including molecular diagnostics and genomics.

Soufi (NovoPath): There are many ways in which AI may soon be ready to augment patient care. These include scanning the EHR for previously performed test results, analyzing genetic data, ordering additional tests, suggesting treatment options, and supporting a pathologist's diagnosis with computational diagnostic information. However, in the core anatomic pathology laboratory today, AI is still considered an early-stage technology. As AI matures, NovoPath will evolve with it to meet client needs.

Meyers (Sunquest): AI may help laboratories and pathologists become more efficient and scalable, as well as more creative and data driven, to enable faster, more accurate diagnoses. Digitization of AP data could save a significant amount of time for physicians and laboratorians because using digital information is effective and timely and supports rapid analytics and image retrieval. Most important, digitization reduces the barriers between sites and facilitates consultations and referrals without boundaries. This will ensure that pathologists can have an impact on more patients. Algorithms can be used in decision support for a wide range of disease classification and may enable pathologists to spend more time on the most complex and challenging cases. Finally, AI could integrate incredibly complex, varied data from numerous sources to help pathologists make diagnoses with higher accuracy and confidence, leading to more precise, targeted treatment options for patients, all while simultaneously reducing human error.

Trentadue (Epic): AI is certainly a popular area right now and it is important to differentiate the marketing hype

from the demonstrated execution. At Epic we have incorporated AI into our software development process in two ways. First, we formed a data science team of experts in math and statistics who work to understand patterns in data to create predictive models that are ultimately embedded into the final software. Second, we have a team of software engineers who focus on the technical underpinnings of platforms as well as how to visually surface machine learning insights to users. To date, we have over 20 machine learning models available, and more than 250 customers are running at least one model in their production system.

Dr. Schmidt (Cortex): The industry seems to be in the early days of AI integration as AI capabilities are being developed. Many groups are watching carefully and readying themselves for adoption as specific AI functions mature. AP-LIS vendors need to be ready to include new features as the marketplace recognizes value. Whether this is through in-house development or through partnership with AI companies depends on the cost and complexity of including AI solutions in the AP-LIS products.

How will the trends of practice consolidation and practice complexity affect your company and the questions and needs you want to answer in the marketplace?

Johnson (Orchard): At Orchard, we listen to our clients in order to really understand their work and work environment, evaluate what changes are taking place, respond to thought leaders, and step up to become thought leaders with regard to the AP-LIS. It is only then that we can provide the best path forward for customers through this turbulent, changing time. AP-LIS vendors need to focus on labs' understanding of how data needs to be collected from a complex analyzer, and how to integrate digital pathology and all the new tools available to pathologists in a cost-effective and efficient way.

Nollar (Xifin): One of our largest growth areas has been with labs that have robust acquisition strategies and want all their labs on the same cloud-based LIS, as well as administrative functionality that enables them to "spin-up" new labs and manage all labs under a single LIS build.

We are also seeing the trend toward more complex practices reflected in an increased demand for lab information systems that perform next-generation sequencing. Many labs have developed next-generation sequencing assays for research and want to take them commercial and/or supply diagnostic testing for clinical trials. They need a system that can adapt to the requirements of the commercial marketplace and, in the case of clinical trials, can manage and report aggregate data by project. These labs are asking for flexible, configurable tool sets that can adapt to any type of testing, and they want user-configurable tools to handle their specialized and clinical trials testing.

Overall, labs recognize that the LIS is a critical, strategic component to their overall revenue growth strategies.

Soufi (NovoPath): In our experience, when laboratories are given an opportunity, they favor remaining with us. Otherwise, there is usually a transition and transfer time lag since the lab is usually one of the last departments to be consolidated. NovoPath hasn't been affected much by this trend. I would attribute this to the strength of our specialized offering and high level of service. On the positive side, we are noticing that new labs continue to form because they recognize there is a gap in the service and/or value being offered. These labs are looking at their LIS investment as a competitive advantage.

Meyers (Sunquest): The consolidation dynamic is a new reality that has an impact on the entire marketplace. It leads to more integrated pathology groups and laboratories, requiring greater IT flexibility and functionality. The spectrum of patient care interaction points continues to expand, shifting lab operation models from homogeneous ones to more heterogeneous ones. Sunquest must continue to support customers with high-quality diagnostic information to enable quality care decisions.

Trentadue (Epic): Consolidation in the health care industry as a whole has affected the laboratory as well. We see pathology practices getting larger and able to consolidate operations and create centers of excellence to drive better diagnosis and leaner processing practices. The laboratory is an integral part of the patient care team and is gaining more exposure as practices grow and specialize.

Dr. Schmidt (Cortex): The trend toward practice consolidation is continuing and there is pressure on independent pathology labs to merge or join larger enterprises. Surviving AP-LIS products will handle practice complexity—multiple labs, complex reporting requirements, efficient workflows, complex interfacing capabilities, workload and management tools, whole slide imaging integration and partnerships, and advanced molecular testing integration and partnerships. In