‘Doing more for less and with less’: Turning to IT

February 2023—*As this year’s guide to anatomic pathology computer systems was taking shape,* CAP TODAY *publisher Bob McGonnagle met online with representatives of five companies and with John Sinard, MD, PhD, of Yale University School of Medicine. They talked about the cloud, CPT codes, training of pathology informaticians, and artificial intelligence, for which the time frame in pathology is far longer than it’s been portrayed, in Dr. Sinard’s view.*

“It will start to impact the careers of some of our trainees, but it’s probably a 10- to 20-year time frame before it plays a major role,” he said.

The view of Joe Nollar of Xifin: “Speculation that AI will someday replace pathologists is completely overblown,” though it will help to triage cases and mitigate risk.

Their full conversation, which took place Dec. 20, 2022, follows.

Last year we talked about Oracle’s acquisition of Cerner, which led to a discussion about the cloud, its advantages, and how it seems to have entered into a prominent point of desire for customers and vendors alike. Joe Nollar, what has changed in the past year? Have you seen this deepening? And have you seen evidence from the Oracle-Cerner combination that’s of importance to the anatomic pathology marketplace?

Joe Nollar, associate vice president of product development, Xifin: The merger is an opportunity for Cerner to leverage Oracle assets to a great benefit. But it’s a long process to bring the entities together in a meaningful way, so we haven’t fully seen its impact. What I’ve seen pick up steam is people on older platforms migrating to cloud-based solutions from traditional, locally hosted environments. There’s a lot of activity in the AP sector moving from traditional on-premises systems to the cloud.

Chad Meyers, can you comment on where the Oracle-Cerner combination and the cloud stand a year later?

Chad Meyers, MBA, vice president/service line manager, global anatomic, molecular, and digital pathology solutions, Clinisys: To Joe’s point, it’s going to take time, and Cerner still has a large focus on the EHR versus the laboratory information systems space where Cerner started. They’re working to bring those two companies together, especially with their Veterans Affairs contracts and others.

We’re seeing more health systems’ chief information officers looking at their overall cloud strategy, doing five-year planning, and in some cases working with third-party partners like Accenture to plan how to move their IT assets to the cloud, including the EHR and other systems. The Cerner-Oracle deal combined with Epic’s release of Hyperdrive, a Web-based client that can better
support a cloud-hosted version of Epic, is a catalyst for them to look at their overall footprint and say, If I can move my EHR to the cloud, I should plan to move the rest of my ancillary systems to the cloud.

John Sinard, what do you make of the movement to the cloud and the future of Cerner, which you’ve had a bird’s-eye view of for a long time?

John Sinard, MD, PhD, professor of pathology and of ophthalmology and visual science; vice chair and director of clinical operations, pathology; and medical director, pathology informatics, Yale University School of Medicine: Many health care organizations are still uneasy with the cloud. There’s a greater emphasis on security, and the larger, more conservative institutions have been reluctant to put their data there. For the places that are moving into digital whole slide imaging, there are huge storage needs for the volume of data. Institutions are finding that the cloud is a cheaper solution than bringing the storage in-house. It’s starting to get a lot of places, including my own institution, to look more seriously at cloud-based solutions, initially for storage and then potentially for applications. Trusting a cloud solution for applications will still take effort for some institutions that recognize the importance of uptime and the risks to their missions of downtime.

Suren Avunjian, give us your opinion about what's going on a year after the big move to the cloud and Oracle's acquisition of Cerner.

Suren Avunjian, founder and chief executive officer, LigoLab Information Systems: I agree it will take them time to fully shift to the cloud. I also agree with John—the larger laboratories we work with like to have the data close to them. Smaller organizations are more apt to have their data in the cloud because there is a significant up-front capital expenditure to build out a data center or server room and hire IT professionals to manage it. That would not make sense for smaller laboratories. The cloud solution breaks this cost down to a small monthly fee that is easier to absorb. Larger organizations continue to ask for an environment that's deployed within their internal cloud. We need to provide the flexibility of both options.

McKinney

Keith McKinney, what are your thoughts?

Keith McKinney, vice president of sales, Orchard Software: Our client base is rapidly accepting the move to the cloud. One factor is the shortage of hardware—some clients are due for hardware upgrades and can't get the needed hardware. It's driving people to the cloud to keep their systems secure and maintained to minimize situations related to hardware failures. We're also seeing large and small clients move to the cloud because of the risks of their systems being hacked and the associated liabilities.

Is this also reflective of shortages around IT and other staff who need to service these systems?

Keith McKinney (Orchard): In health care organizations, yes. People are even contracting our support department for more services because their ability to staff and take care of their information systems is limited at this time.

Ed Youssef, NovoPath has a big initiative to put a version on the cloud, but is there also an economic squeeze that is leading people to think the cloud is a great solution for a stressed health care system?

Ed Youssef, chief strategy officer, NovoPath: Yes. We're seeing a huge shift toward the cloud especially in the last couple of years. For the larger organizations, maintaining on-premises environments is more expensive than maintaining a cloud environment. While smaller labs may be able to utilize the minimum required hardware on-premises that is less costly than the cloud in the short run, in the long run a cloud-based solution offers scalable, cost-effective, and secure options.

Nollar

Joe, what's your assessment of the overall health of anatomic and molecular laboratories as we move past COVID? Is the customer base, current and potential, optimistic? Pessimistic? We know there's still a reimbursement struggle.

Joe Nollar (Xifin): Our lab volume index report indicates volumes are up in the AP space, probably a result of people deferring care during the pandemic. There is huge interest now in upgrading systems, in particular the AP systems that specialize in hematopathology, IHC, FISH, flow cytometry, cytogenetics, molecular testing. We are also seeing consolidation in the laboratory space as a result of greater efficiencies that can be gained when smaller practices

merge. I'm sure that is a consequence of the reimbursement constrictions.

There is greater interest in doing TC/PC [technical component/professional component] splits—laboratories looking to split the technical and professional work and collaborate with other pathology or physician office practices to do revenue-sharing programs to increase their revenue.

Chad, do you agree with Joe? I thought the TC/PC split was in the rearview mirror, but it seems to be an increasingly important topic that's getting a second life.
Chad Meyers (Clinisys): I do agree, and there are a couple of factors behind it. With precision medicine and molecular and genetics testing, we see labs trying to optimize what they do in-house versus externally—based on volumes and whether they can justify the equipment investments or integration—and looking at whether they want to do the professional or technical component or both, depending on the test. With the new CPT codes for consultations with oncologists and patients and the encouragement from digital pathology and its new CPT codes, labs are asking us to help optimize their business models and tie that in with specialization, as precision medicine is requiring pathologists to spend quite a bit of time staying current in a specific tissue type, whether it's breast or lung or prostate. We're seeing more specialization that can lead to a TC/PC split.

What's exciting about the cloud is that it frees up administrative LIS analysts and system administrators from focusing on infrastructure so they can help implement new capabilities for precision medicine and digital pathology—that's a win-win. There's concern there won't be a need for the staff after going to the cloud, but in my opinion it frees them up to do valuable things that we need to do to progress as an industry.


Dr. Sinard

John, can you comment on the shortage of pathologists and the drive to subspecialize, particularly as they affect the systems that everyone will need in anatomic pathology?
Dr. Sinard (Yale): The drive to subspecialization is real, particularly at the larger academic centers, and it's probably irreversible. It doesn't work at smaller institutions, so there will always be a mix of the two. At larger institutions, it's almost expected and demanded by the clinical teams. That, in combination with the shortage of pathologists, which is driving the need for greater efficiency, requires people to look at information systems as solutions—what can we do with this information system to improve our efficiency and meet the needs of a given subspecialty?

In contrast, a lot of institutions are now dealing with changes in funds flow, and there's a push toward centralized funds flow models. With that change, there is a shift in the decision-making power about what the correct IT solutions are to help with efficiency. Unfortunately, it seems the further the decision-making authority gets from the lab, the less they realize the importance of a system designed for anatomic pathology, rather than a CP system into which AP specimens have simply been stuffed.

Joe, can you speak to that?
Joe Nollar (Xifin): In the academic medical centers we've been in discussions with, the power is shifting back to the pathologists, who are dealing with CP systems they're forced into and who don't have AP systems that support their subspecialties in the way they need them to. What John said resonates with the interest we are seeing in systems built for AP and AP sub-
specialties.

Two technologies are increasingly important in this practice. One is next-generation sequencing and

the other is liquid biopsy, and both will present big informatics challenges to users. Ed, do you agree?
Ed Youssef (NovoPath): Absolutely. We're noticing an increase in demand for those and a need to bring in results and make sense of it all. We're noticing an increase in demand for collaborations with NovoPath and third-party systems that do the analysis on this amount of data.

Suren, you have spoken in the past about the importance of a robust set of application programming interfaces in this new complex world; a lot of systems and elaborate instrument systems need to speak to one another. Are you seeing this need for integrated practice and reporting, getting the data in one place?
Suren Avunjian (LigoLab): Yes. There's been an uptick in the past two years of prospects and current customers asking for open APIs [application programming interfaces], not just results reporting via HL7 but throughout the workflow, at different trigger points to have different integration capabilities. It's a trend that will continue to grow because we can't build every possible system. We have to integrate with data providers, interpreting systems, risk stratification engines, and so on, to bring it under one roof. As was said earlier, trying to stuff different types of results into one CP-based system doesn't work. We have to model the reality of each specific discipline—AP, CP, genomics—all have to be separately built. What we've done, foundationally, is connect all those departments within the LIS as one—one order entry system, one reporting system. But to model each department, you need a system that can fit all the discrete elements of the department within the platform.

Keith, it strikes me that it's not easy as a vendor to explain to a potential client the different things they will need. In other words, do we have a situation in which the customers might be naive about what will soon be demanded, and as a vendor you have to say, "This is all good, doctor, but let's look at A, B, and C and figure out how we can solve those problems because they're here and you'll be feeling them soon, if you're not already"?
Keith McKinney (Orchard): Yes. Pathologists are required to do more for less and with less, so our job is to create and maximize efficiencies. Pathologists count clicks. Every click is time, and time is money. Volumes are going up and they have to more efficiently manage the workload in their labs. The cloud allows them to be mobile, so you have to consult with them on the advantages of cloud computing and of plugging in analytics tools to monitor and gain efficiencies in their workflows so they can make more rapid changes to better benefit their business financially.

One of our clients said their caseload is going up 100,000 in the next 12 months. They're relying on us not only to provide tools but also for consulting services.

John, you are training pathologists and pathology informaticians. What are you doing at Yale to prepare pathologists for this new world we're discussing?
Dr. Sinard (Yale): There are three facets to this that conflict with one another. One is that trainees are focused on the next step. They don't want to look too far into the future if it's not going to be on the boards. On the other hand, we try to mentor them to understand that the world in which they practice and will spend most of their career will be a little different from the world in which they're training and give them the skills to recognize and adapt to those differences.

We are trying to introduce informatics training into the curriculum. It has two components. One is didactic, and I question the value of giving these lectures because I don't know how much the trainees walk away understanding. More important is integrating these solutions into trainees' day-to-day practice—using barcode scanners and whole slide imaging, accessing the EHRs routinely as part of their workup of cases. That's when you start to have a better impact on their training for the future—you build workstations for them that are fully enhanced with these various capabilities.

The third pillar is the attitude of the trainees coming in, which varies significantly. More frequently the focus is on, "The institution is here to teach and train me, not use me to do the work." There's a conflict between doing the work and is it an educational activity? Trainees want more control over their own education. It has filtered down into medical schools, where students have a large say in the curriculum, and has continued into residency. Those

three pillars are conflicting with one another to some degree, but we do what we can to make them work together.

A lot of us are excited about digital pathology seemingly maturing and becoming an ever-greater reality and about machine learning and artificial intelligence. There must be young men and women who want to go into pathology because it all seems so exciting. You have a lot of people who want to be surgical pathologists. Do you have a few who come with an informatics aspiration from the get-go?
Dr. Sinard (Yale): There are a few, and usually the first step for them is to do a level set and a reality check. There's a lot of hype about what AI and machine learning will be able to do. A lot of the basis for the hype is true, but the time frame being portrayed is exaggerated. It will start to impact the careers of some of our trainees, but it's probably a 10- to 20-year time frame before it plays a major role. There's no reality to the thought that we won't need pathologists in five years because computers will be doing everything. There are so many issues associated with the clinical use of machine learning and AI that have yet to be tackled and resolved that I don't anticipate it will be a routine part of the remainder of my career.

Meyers

Chad, as a vendor do you share that view of the timeline? Or are you more optimistic about the speed?
Chad Meyers (Clinisys): It's going to take a while. When I came into the anatomic pathology industry from the medical imaging industry in 2010, Roche had just acquired BioImagene and was ramping up promotion of digital pathology scanners. Since then there's been adoption from academic medical centers, but the smaller and mid-size labs I talk to are still trying to determine their path and how to make investments and business cases. It has promise and will be a great computer-aided approach to make pathology even more precise. But it will take time to build confidence in quality and accuracy, moving from having an individual person review to allowing diagnosis with just AI.

Joe Nollar (Xifin): I'd like to add to what John and Chad said—every time we've tried to predict when digital pathology is going to have a major impact, we're disappointed. I would agree with John's timeline, although with the FDA's approvals of artificial intelligence algorithms—Paige and Ibex—we're seeing fantastic technologies in play that will be wonderful assistants to pathologists. Speculation that AI will someday replace pathologists is completely overblown, but it will be a great asset to help triage cases, mitigate risk, and identify high-risk cases. As an LIS provider, it's critical to fully integrate digital pathology into the workflow.

We're seeing a dramatically different standard of care in many cases, particularly in oncology, between what's provided in academic centers and by large laboratories of tertiary care hospitals and by the smaller community practices. I use some of the data coming out of ASCO as an example. They made the case that oftentimes in community practice not even 50 percent of patients get the basic frontline biomarker testing that would be dictated by their condition. I assume some of this feeds into what you already said about the TC/PC split and discussions around that, correct?
Joe Nollar (Xifin): Yes. We have seen an expansion of smaller community practice services due to consolidation that creates greater economies of scale and expansion of TC/PC services. These partnerships are a great way for smaller community practices to expand their test menu. Consultations are also an important consideration, including sharing of data and images using digital pathology and artificial intelligence algorithms to assist pathologists. The core to that is having the system capability to fully integrate for consultations and test add-ons with reference labs and academic medical centers so community practices can get the support they need. LISs need to support those endeavors. Our role is to integrate the latest technologies, make the process easier, and

share and transmit data and facilitate test orders and consultations, ultimately leading to better patient outcomes.

Avunjian

Almost 95 percent of new pathologists are being trained at academic centers. If they go into a community practice, they will have expectations around an ease of technology use and an ability to consult and share important and complex data to take care of their patients. Suren, are you seeing that in your customer base?
Suren Avunjian (LigoLab): Yes, we are. Whole slide imaging technology contributes greatly to the consultation capabilities for these pathologists and the systems they work in. With the help of whole slide imaging, I'm seeing more organizations scale using TC/PC relationships. I learned recently that you don't have to prepare a slide to bill for TC; you only have to do the gross and that's technically considered a TC. With slide prep and scanning available to read remotely, it is a benefit for rural communities, pathologists who are looking for an extra consult, and organizations that have an entrepreneurial spirit to deploy this technology to help smaller practices.

There are new CPT codes for consultation in cancer cases, and CPT codes for digital pathology are being developed. Keith, it's early innings, but are you seeing interest in these and an eagerness to get in on the ground floor so when they start paying off, your customers will be ready?
Keith McKinney (Orchard): We've always seen interest in how our system can help clients with their coding processes to make sure they're keeping up with current billing guidelines and maximizing reimbursements. We're also seeing interest in the coded diagnostic aspects of how that ties together to make sure they're maximizing reimbursements for their work.

Youssef

Ed, are you seeing interest in these two new categories of CPT codes as people prepare for them?
Ed Youssef (NovoPath): Yes. We have a lot of clients who ask us what's new and what has and hasn't been approved. Being able to tell them there has been movement along those lines is helpful to them. Regulators need to look deeper into and approve more technologies and come up with better ways to compensate laboratories. It's great to have the technology, but it's a question of, can I be reimbursed for it correctly? That's a challenge for our clients—can I use the technology to help me more, or are there still regulations that don't allow me to do that without challenges?

Chad, can you comment on the heightened interest in new CPT codes? At the same time, it's more difficult than ever to get paid. We have difficulties with test preapproval, trouble with billing and collection. Where do you think this is going? Will there be a more vigorous, profitable practice of anatomic pathology three years from now?
Chad Meyers (Clinisys): Two things stand out. First, with these consultation codes there's been discussion with a few sites I've talked to about whether they will create a second report, one that is more patient-focused, simpler to understand. I think they're looking at how to maximize the customer experience with those consultations. Second,

we're starting to see AI converge into the billing space. We've recently done an integration with CodaMetrix at a site that is looking at applying AI to billing codes to help maximize efficiency, reimbursement, and potentially catch manual errors.

The complexity of precision medicine has made coding more challenging. A lot of labs are still figuring out how they can best use these codes and how to apply digital pathology coding and billing in the overall process. We need to make sure the systems facilitate that and automate as much as possible.

John, in this new world of CPT codes and preapprovals, are people struggling to figure out how to optimize department operations?
Dr. Sinard (Yale): We're always focused on trying to optimize department operations because of the expectation that we do more for lower pay. A key element of being able to build consultation codes is a request for the consult. At large academic centers, most of our clinicians don't feel they need to ask somebody else what test results mean; they can figure it out themselves. So there hasn't been a huge demand here.

Digital pathology codes are in their infancy. My understanding of the maturation process of a code is that one needs to demonstrate widespread use of a technology before people will start thinking about paying for it. The reason for using these category three codes is to capture information on how widespread the use of digital pathology is for primary diagnosis. It will be interesting to see that data.

Preapproval, particularly for molecular testing, is difficult for a number of reasons. One, the time frame for these preapprovals is often not consistent with the time frame needed for efficient treatment of patients. In many instances you run the test and then hope the approval comes through. The other problem pathology departments face is that reimbursement is bad for many of the molecular tests. There are a lot of companion diagnostic tests that are required for treatment with a particular drug. So we have a developing dichotomy where pathology takes the financial hit for doing the test so that other departments like oncology can get the income from providing the treatment, if the test permits. The expenses are going in one direction and the income generated is going in another. That is driving people to look at centralized funds flow models where there might be mechanisms in place to correct the disconnect between appropriate reimbursements and the testing-related expenses.

If centralized funds flow is done intelligently and appropriately, it should enhance the finances of the pathology department, yes?
Dr. Sinard (Yale): Historically that has not been the case, but it depends on how the institution deals with centralizing the funds flow. Discussions about centralizing the funds flow, particularly at this institution, have been regarding the professional component as opposed to the technical. But the technical component is where opportunities exist for correcting some of these discrepancies, and it gives institutions an opportunity to look at whole programs rather than departmental division needs.

I'll put my final question to all of you: Three years from now, will pathology departments be in better or worse financial shape than they are today?
Keith McKinney (Orchard): As we see the consolidation occurring, they won't be worse than they are. Our goal is that with the efficiencies updated software solutions bring, the cost of doing business from an LIS vendor side will be more acceptable for them and support new reimbursement guidelines. Our larger lab customers will benefit from the efficiencies brought about by new LIS solutions.

Ed Youssef (NovoPath): I'm optimistic. I think they will be in better shape, but people will need to adapt more to new technologies and a new way of doing things.

Suren Avunjian (LigoLab): I'm also optimistic that the ones that have selected the right partnerships, especially that allow them to differentiate in the marketplace, will be able to become the future laboratories and find success.

Chad Meyers (Clinisys): As for any business, those that are savvy in their strategic planning, with the cloud, digital pathology, precision medicine, will be better off. Those that operate day-to-day and don't do the strategic planning may have a harder time, given the climate.

Joe Nollar (Xifin): I agree with Chad. The key is for labs to leverage the technologies and adapt to the business environment they're in. If they can do that, they're going to be fine and they will continue to provide great service and probably be more efficient in doing so.

Dr. Sinard (Yale): Things are going to be stable. The adoption of many of these new technologies, the increased efficiency, is necessary to counteract the increasing expenses and decreasing reimbursements we're facing. Those who are not looking at ways to improve their efficiency will be hurting, and those who are aggressively looking for these opportunities will be in a better position to cover losses in other areas.