The rush to deliver integrated reporting in pathology

February 2022—Oracle's purchase of Cerner, cloud computing, and integrated reporting were up for discussion when CAP TODAY publisher Bob McGonnagle convened a virtual roundtable Jan. 6 on anatomic pathology computer systems. Hematopathologist Monica E. de Baca, MD, said on the call she was encouraged by what she heard about integrated reporting from the AP LIS vendor reps on the call. But she said: "We should also be thinking about what is next; we don't want to be talking about things 10 years after they were needed."

She and seven others answered McGonnagle's questions, among them: Are the resources in pathology adequate to make progress toward and enable the necessary IT outcomes?

Joining Dr. de Baca and McGonnagle were Aaron Auerbach, MD, Joint Pathology Center; Suren Avunjian, LigoLab; Curt Johnson, Orchard; Nick Trentadue, Epic; Joe Nollar, Xifin; and Ed Youssef and Dayna Carlin, NovoPath.

CAP TODAY's guide to AP computer systems begins <u>here</u>.

What is your reaction, Nick Trentadue, to the news of Oracle taking over Cerner?

Nick Trentadue, product manager, Beaker, Epic: It was expected. Cerner had been propping up the balance sheet, making business decisions. It was Cerner's goal to sell the company, whether it was to Oracle, Amazon, Microsoft, Facebook, one of the big tech players.

Monica de Baca, what's your reaction?

Monica E. de Baca, MD, founder of MDPath and hematopathologist, Pacific Pathology Partners, Seattle: Oracle was trying to get into the space and Cerner was trying to sell. What that means for those of us in pathology will be determined as we go forward.

Joe Nollar, perhaps this will clarify Cerner's role in anatomic pathology and open opportunity for vendors.

Joe Nollar, associate VP, product development, Xifin: The acquisition gives Cerner the opportunity to modernize using Oracle's new investment, and they need to. If they're going to remain relevant in our space, that's the next step for them. It's a great marriage because Cerner's assets and the health care data are valuable. That's exactly what Oracle was looking for.

Suren Avunjian, what's your reaction to this news?

Suren Avunjian, founder and CEO, LigoLab: Overall, the news was great for the industry and good for vendors. It will accelerate more of the information systems going to the cloud, which will be good for customers. It's a good combination.

Aaron Auerbach, do you have a reaction to Oracle's acquisition of Cerner and what it might mean for the AP space?

Aaron Auerbach, MD, senior pathologist in hematopathology, Joint Pathology Center, Silver Spring, Md.: My first thought is how the existing Cerner products will be affected. Parts of the government have been shifting to CoPathPlus and this acquisition may have big consequences for us.

Curt Johnson, let's hear from you.

Curt Johnson, chief commercial officer, Orchard Software: It could be exciting for the industry. It's always a positive when new technology is moving in the direction the industry needs to go to benefit our clients, such as moving to the cloud.

I am not sure, with the size of Cerner, if laboratory is its main focus anymore, let alone anatomic pathology. In the big picture, if you're sitting in the corporate strategic room at Cerner, how often does anatomic pathology come up and where are they going with it? We'll have to wait and see. Overall, anything moving to the cloud, any new technology investment coming in, should benefit their clients as long as it's done with a customer focus.



Nollar

Is there now unanimity of opinion that cloud-based solutions are indisputably the future for laboratory and AP LIS computing? Joe, do you think that's a settled issue?

Joe Nollar (Xifin): We believe it is the future and have for the past 20 years. We built all our products as web-based products from our inception. We believe it's the fastest way to deliver new product to our customers and keep them on the latest and most updated platforms month to month and keep their costs under control.

Ed Youssef and Dayna Carlin, you have a lot of movement into the cloud at NovoPath, including new versioning. Ed, can you outline what this new release will be like?

Ed Youssef, VP of operations, NovoPath: We've been working on our cloud platform for a few years; it has already been live at a few clients. Our official launch of the platform is January 2022, so we're excited to present the market with a fully web solution that is completely cloud—based on cloud architecture and technologies. The new platform addresses all the aspects used in the lab, including all the workflows; it's a flexible system, able to adapt to the environment for our clients. We're looking at it as a new market player that can shift the market toward the cloud.

Anatomic pathology computer systems product guide

We have done a lot of reporting on the disruption of cybersecurity in health care and particularly in laboratories. Monica, does the cloud offer more security in your mind?

Dr. de Baca (MDPath): Theoretically yes; however, there are also many regulatory issues that remain unclear in terms of data transmission, which makes a definitive yes or no outright almost impossible. From a computational point of view, if data are split up and shared in many places, it's more difficult to pirate complete documentation of any one topic/patient, which is definitely more secure. HIPAA guidelines speak more to a paper-based world than to a digital world. Trying to thread the needle of what our regulatory environment requires of us and what our ever-evolving digital possibilities grant us is, to use two metaphors in one sentence, a dance that we're trying to figure out the steps to.



Avunjian

Some people in labs are saying, given the staffing problems and the cybersecurity needs, that budgets will be devoted to these two big problems. Suren, do you have a feeling about cloud- versus web-based solutions?

Suren Avunjian (LigoLab): There's still relevance to hosted solutions, especially with larger laboratory organizations that do high-throughput testing, to having the data close to them. Typically this is how we deploy to laboratories that have daily volumes of a few thousand and up with a lot of instrumentation. You don't want to have the cloud lag between your instruments and the data needed in real time. We deploy local appliances where the rest of the software and the application layer live in the cloud and the instrument communication happens locally. This is our hybrid deployment strategy. Larger organizations typically have their own server environment, and if they want, we give them the flexibility to have the data closer to them. For smaller customers, cloud is a no-brainer.

There is higher-level security compliance that could be done via the cloud, just because cloud hosting is becoming more of a commodity. The hosting vendors themselves have invested a lot in the security layer; however, LIS vendors also have to go through SOC [service organization control] 2 type one and type two security compliance just so we can have our internal security practices in place. Those two things together will improve security and mitigate risk for laboratories.

We partner with a vendor that helps laboratories with security because that's not a service we provide. This company helps with ransomware and provides insurance against it.

Suren comments on two issues. One, the anatomic pathology laboratory is a complex place compared with what it was 20 years ago. There's a lot of instrumentation and middleware, all of which need to be handled in some kind of sync, and security is always an issue. At the same time, we see a trend toward the consolidation of work in anatomic pathology. I realize there are areas where smaller startup AP labs are getting traction, but by and large would you agree with me, Curt, that we're seeing more consolidation of pathology activities and groups?

Curt Johnson (Orchard): From an anatomic pathology point of view, we are continuing to see consolidation. COVID testing has been such a catalyst for molecular technologies that these technologies are going to continue to explode and we will see growth that we haven't seen in past decades. That change will affect anatomic pathology as well.

Moving into the future we're going to see a combination of instrumentation in the anatomic pathology laboratory designed to work with digital pathology, the pathologists, and molecular testing. That's going to be the next big change that takes place and moves cancer diagnostics further along. A lot of the testing we're doing now will be immensely more accurate, and diagnoses will be faster.

The move to the cloud is going to be important, and you will have to have a way to integrate localized instrumentation. You will need the flexibility of a system that can be all-inclusive. You have to be looking to the future—what will it look like five, 10 years from now in terms of cybersecurity, the cloud, and personnel? You have to be able to make best judgments on where the market is going, have opportunities for each of those, and how you're going to address them.

Aaron, as you look at it from the perspective of the Joint Pathology Center, this is a pretty tall order in terms of what needs to be in place for you to optimize your work and efficiency. Does this ring true with you as you think about the future of computing?

Dr. Auerbach (Joint Pathology Center): Absolutely. We're looking at cloud-based solutions, but being part of the government, cybersecurity is our primary concern. With our IT-based platforms, we focus on the highest level of security.

Within the AP LIS world, as we traditionally know it, there is a lot of buildout of AP systems. In CAP TODAY product guides we have AP companies in the LIS guide and LIS companies in the AP guide. There's been a blurring to some degree.

Dayna, if you were to envision what a pathology department will look like in five years, has it integrated clinical, molecular, and anatomic pathology, along with the other bells and whistles, like digital pathology, all under one system? Or is there still a lot of division?

Dayna Carlin (NovoPath): I think pathology labs are going to consolidate, make it easier for themselves. Having one

platform that does it all would have benefits from a maintenance standpoint, for example. I foresee labs consolidating their IT footprint and having one vendor or one system in place. That would also help with the security of going to the cloud. Instead of having your IT team focus on workarounds and looking at the different infrastructures, you'd shift them from infrastructure to security.

Nick, what are your impressions about this notion of an integration of the work of pathology and of the various subspecialty areas?

Nick Trentadue (Epic): When Beaker launched in 2006 it was clinical pathology only. Anatomic pathology came in 2009. We've never had different systems, so it's always built as one on top of that integrated patient record. As we offer more features, it's on our one integrated lab product. Whether it's molecular, whether it's a COVID test, or cytology, an autopsy, a basic chemistry test—it's all done in one system.

As labs consolidate and as we go more into diagnostic management teams or do more on an integrated disease level, having all the data on top of the clinical data has proved to be beneficial for pathologists who do hematopathology reports or complex oncology cases, where they can bring outside testing from a specialty lab into their tissue-based reports or a tumor report and have all that data in one platform. It has also been a benefit to academic medical center groups.

Joe, tell me your thoughts about this.

Joe Nollar (Xifin): Having a single integrated platform for CP, AP, and molecular is where the market is going. The ability of our systems to provide that is important, because when the pathologist is looking at, say, heme path, they're doing comprehensive bone marrow morphologies and looking at several testing modalities including clinical, FISH, flow, cytogenetics, and molecular. The pathologist needs to be able to easily view and assess these results.

Ultimately they need to create comprehensive summary reports that take all those diagnostics and communicate them in a consolidated, cohesive way to the treating oncologist. It's about having a system that breaks down those silos and provides consolidated reporting.



Dr. de Baca

Monica, can you comment on this pursuit of the holy grail? The other side of this coin is kind of a bestof-breed tissue system, and the integration of a lot of pathology information has been a headache almost as long as I've been in the field.

Dr. de Baca (MDPath): Integrated reporting has been my main goal since joining pathology. I was a patient-facing physician before, so in the beginning of my career I was reading those reports. To Joe Nollar's point, the real goal is for the person who is treating a patient to get a report that tells them everything they need to know. Pathologists have been trying to do that for the past 20 years in an ever-increasingly complex series of systems required to inform all the new testing modalities we have.

In a past roundtable, the conversations revolved around things we were aspiring to; now it's good to hear that the vendors are aligned with those needs. It's uplifting to think that perhaps by the time I retire, we'll be at a place we envisioned at the beginning.

The things we are discussing today as up-and-coming are what we need right now. I'm glad vendors are already considering these things. We should also be thinking about what is next; we don't want to be talking about things 10 years after they were needed. We must think proactively: How are things changing? Are these systems

considering how AI and machine learning products are going to be included? Are we talking about the transparency of those products—how product methods will be shared, how patients will be affected, how patient safety will be assured?

Important in making these things happen are interoperability and data standards. Data standards are not sexy—we can talk about the cloud, cybersecurity, but underlying it all is interoperability. If cybersecurity is the house, interoperability and standards are the bricks, and bricks aren't sexy. But without those bricks your house might fall.

We need to continue to lead in the conversation about the need for interoperability and, more specifically, making sure the standards are supported and built out so we can create interoperable systems that will allow complex reporting systems—LISs and EHRs—to maximize what's possible.



Youssef

Dayna and Ed, tell me how you're poised with your new release to address some of the issues around data standards, interoperability, and making it easier on pathologists to get the work accomplished.

Ed Youssef (NovoPath): AP labs have been redefined to include a lot more than AP-specific testing. And vendors are consolidating, through mergers, acquisitions, or partnerships, and with that comes the interoperability. The problem is, how do we interface with other systems? How do we make use of strong partnerships with other vendors that provide the components, whether it's AI or machine learning, that might be needed for the future?

One of the components in NovoPath 360 is an interface engine that is responsible for communicating and making connections with third-party systems and external systems that the lab can work on—for example, a specialty lab that has third-party applications they need to integrate with NovoPath. Or if a lab has external systems and partners that are specialized in a certain solution they're providing to the lab, we can come together to quickly and easily hook up the two systems. With that, we provide the lab not only the best of breed in the AP system or an LIS, but also a best of breed of partners that can come together and provide a comprehensive solution to the client.



Carlin

Dayna, would you like to add to that?

Dayna Carlin (NovoPath): We spent a lot of time with our existing clients looking at how we can make it easier for them to use the system. The pathologists and lab managers we talked to said to reduce clicks, reduce clicks, reduce clicks. And that's what we've done. We've redesigned the interface to the system and made it easier to order stains, add images, and release reports within a second, one click. We've also made it easier to train. With the staffing shortages, clients are asking: How do we make it easy to bring people onboard without having to go through a 100-page document? It should be intuitive enough that the user can jump on, understand where they need to go, and complete their work. And we've done that.

Suren, are you hearing the same from your clients and potential clients about minimizing clicks and

time on task at a keyboard?

Suren Avunjian (LigoLab): Absolutely. Our entire development philosophy revolves around streamlining and adding market differentiation for our partner laboratories. It's important to consider the pathologist and every other role that interacts with the platform. Throughout the years we have invested a lot of time and effort into making these interactions as intuitive and fast as possible.

Everything can be programmed with keyboard shortcuts, which translates to voice dictation. With all the different voice dictation systems, you can fully control the software just by sitting back and using a microphone. We've extended the system to where there is zero need for some pathologists to click.

Curt, you have an interesting customer base. You have very large laboratories, smaller laboratories, pathology groups, and pathology groups embedded in health systems. Are you hearing from your customers and potential customers the same things you're hearing from your colleagues here?

Curt Johnson (Orchard): We are, and one of the things Dr. de Baca brought up was that when we talk about interoperability and standards, the standards never seem to be in front of where the market is going. They seem to be where we were five years ago, which can make it difficult if you're trying to come up with a standard to use for interoperability. We're still talking LOINC codes, object reporting, HL7 2.3. We need to move on. We need to move to application programming interfaces and determine the best way to integrate with digital pathology. What is needed in the document and in the transfer of information, and what is needed for the doctor's use and the pathologist's use? If we wait for people to bring us a standard, it's too late because it's archaic and out of date.

The future of integration and interoperability involves moving toward APIs that we understand, and then we set the standard for what these things are going to look like in conjunction with the pathology community. You will see over the next couple of years a shift from HL7 integration to APIs, and that conversion to APIs will open the door for better interoperability and should assist us in meeting a lot of the pathologists' needs.

Joe, comment on this, because there is a kind of a paradox here. Monica is right, no one loves standards. But do you think APIs may offer a more universal solution, as Curt suggested?

Joe Nollar (Xifin): Absolutely. It is about having APIs and making it easy—providing the toolsets to our customers to easily access, extract, and share the data. APIs are an easy way to do that. APIs allow them not only to access the data but also to do their own interfacing if they have an IT team that can support it. It's a great option for our customers.

We have a standard XML output so that we can provide an easy way to populate third-party data warehouses and provide that dataset to our customers. But it's the APIs our customers gravitate to. They want to write their own interfaces. They want to get an easy standard output and be able to select which output they want—will it be an HL7, an XML, or JSON [JavaScript Object Notation], or whatever they require. It's having the flexibility within those APIs to be able to provide that data and those web hooks. It's a great way to go.

Monica, give us a general definition of an API and then talk about standards.

Dr. de Baca (MDPath): APIs are functions or procedures that allow applications to access features in other places.

I don't think that shifting the words from standards to API is a move out of the current Venn diagram. I think there is a union there because data standards are still needed for the data that cross an API, and agreeing that we're going to do things with APIs is also a kind of standard. Data standards are generally documented agreements on how data is going to be managed, represented, formatted, defined, structured, tagged, transmitted, et cetera. I see APIs as part of a continuum of this series of circles in the Venn diagram and not something completely outside it.

Ed, can I go to an Apple store or a Best Buy to buy an API? That is, is there an API flavor that is NovoPath, Xifin, or Epic, and as a result we still have a pileup at the intersection needing a data standard?

Ed Youssef (NovoPath): We all have APIs, they all look a lot different from one another, and it takes a considerable amount of time for us to connect the systems. It is an effort that will need to be led by some of the members on

this team here today. There may continue to be a dependency on HL7 standards, so there could be a reliance on that as we build the API, at least in the message structure.

Once the move on the cloud is stronger and more companies and customers are living on the cloud, you will probably start to see more of us leaning toward sharing and exchanging our APIs and partnering to create that standard.

Nick, would you like to make a comment?

Nick Trentadue (Epic): We have probably tens of thousands of APIs, and we're trying to be transparent. Any customer or vendor can go to open.Epic.com, and all of our public APIs are there. I agree with Monica that standards have to be part of it. A pretty standard API is: get patient sex. Is that sex assigned at birth, is that legal sex, is that sex the person identifies with? It sounds easy but it's not.

Where we have the cross-section of standards and APIs as more technology or groups want to do one, two, or six things—there are tons of APIs out there—but if you don't intersect them with standards, our customers or the lab community will be spinning their heads trying to piece together these different applications with these APIs that might not be grabbing the same thing.

Joe, do we have adequate resources in the world of pathology to enable and make progress toward these important goals? Or is pathology underfunded?

Joe Nollar (Xifin): It is probably underfunded, though this past year has seen a great level of investment in new technologies. We're seeing more AP labs expanding into molecular testing, a lot of it initiated by COVID.

We've seen investments in digital pathology and we're doing more digital pathology integrations than ever before. This past year we've seen a huge uptick in artificial intelligence algorithms being applied to digital pathology platforms. It's exciting to see that level of investment. To Dr. de Baca's point about investing in the future and trying to be ahead of the industry, that is where the market is going—support of digital pathology and artificial intelligence and giving pathologists the toolsets they need to be successful for the future.

Nick, as you look at pathology, are the resources there adequate to accomplish what we've been talking about in terms of desirable outcomes for technology and the pathology lab?

Nick Trentadue (Epic): I'm going to say yes, because hopefully the pathology groups will have to think less about it as their vendors take care of it for them. Whether you're going to offer an on-site deployment, a cloud deployment, a combination deployment, or host in a public cloud like Amazon Web Services or Microsoft Azure, the vendor you work with, whether it's Epic or NovoPath, has it figured out for you and you'll have a secure solution. You'll go through your SOC 1 or SOC 2 or all of your different security analyses—you can control what you have on site and how you access that deployment.

We spend a considerable amount of time at Epic in our hosting operation focused on cybersecurity. Customers, the pathology community, should be able to sleep better at night if they can count on their vendor—especially if they choose one that is holistic for the laboratories and they don't have a seven, eight, or nine different best-of-breed approach—to deliver it securely, assuming the customer does the things it can control on its end for secure access.

Curt, we know there has been an infusion of funds due to COVID. But are there adequate resources for all the IT needs and goals we have?

Curt Johnson (Orchard): I believe there are adequate resources out there, and as the vendors take on more of that responsibility, it benefits the overall end users and the facilities. The uniqueness of the lab is that it is still a business unit within health care. If everyone were to close their eyes, they would have different views of what a pathology lab is. Are we talking about an independent group of pathologists? A hospital? A teaching university with a large pathology and research arm? A big urology clinic that has several pathologists onboard? Depending on what you call pathology, it changes the conversation as far as resources go. But the move to the cloud, the assistance of cybersecurity by the vendors, working as partners and in cooperation with their customers, is allowing for more to be done in a faster timeline. And as I said earlier, with COVID, the molecular explosion is going to make a big difference for all customers and all of health care.

Dr. Auerbach, what's your reaction to this discussion of resources and desires?

Dr. Auerbach (Joint Pathology Center): I think your average pathologist works in a place where they have real hope that their AP solutions will do a lot of the things we talked about. They hope they'll have solutions that have digital pathology, will work more with AI products, and will do more integrative reporting. That may not always be part of a small, community hospital-based practice.

My organization is looking at resourcing at higher levels, with the hope of leading with some of these different issues. I don't know if that trickles down to the smaller practices. But pathologists are a hopeful group, so we're looking forward to these innovations in the future.

Monica, share your final thoughts on and reactions to the resources and needs we've talked about.

Dr. de Baca (MDPath): The idea that there is a gamut of possibility or need out there is a crucial comment. If I were at a major institution with a pathology department doing research in AI or in digital pathology, during the pandemic I would have been at home looking at cases, thanks to the work the CAP did to get waivers. I work at an institution that uses CoPath M. It's still functional but basic; it nicely serves the institution for which I work, but I can't do any of the complex things we've talked about today. There are other places with the intermediate functionality we've discussed. So until we bridge these gaps, then when we talk about pathology, what are we actually talking about? We're talking about a lot of different things, where some people are driving Teslas and some are trying to pound the last mile out of an old mule.

The question "Is there enough money?" also depends on which of those participating paradigms you are discussing. It will be a bigger lift for some institutions to join the 21st century because they haven't invested in pathology systems over time—the dollar delta is big. Others who have been investing in their pathology services have smaller deltas, and those shifts to up-to-date systems are small for them.

We know there are ever-increasing needs for pathology services, and we have a host of positions in the country that are unfilled. We just don't have enough pathologists. Part of that is because of the way residency programs are structured, because of visa issues and decisions about how many medical school slots to fill, and because many medical schools have not been teaching pathology as a separate discipline. Whatever the cause, pathologists need systems that allow them to increase efficiency to meet growing case loads.

I am hoping the pandemic will help people understand that although pathology is only a small part of the medical dollar, between two and three percent, without pathology and the results pathologists bring to the house of medicine, very little medical action can be taken. Perhaps people in the C-suites will realize that for what is a small investment for them—pathology is one tiny column in their big spreadsheet—the return is not just large but actually sweeping. Pathology—and the data it produces—is a good place to spend money.

As we think about interoperability and APIs and the possibility to transfer data, then the better the data, the stronger the data, the more the data, therefore the stronger the pathology departments and the better the position in which the C-suites find themselves. I'm a pathologist so that's my hammer, but I've also not been a pathologist in the past and I know that were I still a clinician I still would be pounding this hammer. It just makes logical sense. I hope others see this too.

The views expressed by Dr. Aaron Auerbach are his and do not reflect the policy of the Department of Army/Navy/Air Force, Department of Defense, or U.S. Government.