Digital pathology and AI—drivers, budgets, and jobs

December 2023—*Digital pathology and AI—the push, the potential, the changing questions, the reimbursement, and the caution. All that and more came up when* CAP TODAY *publisher Bob McGonnagle on Oct. 17 led a conversation online with pathologists and industry representatives.*

M. E. (Doc) de Baca, MD, told the group that what makes pathologists unique is the wisdom derived from knowledge. "Our results are given with perspective and in context; they then lead to correct actions. I do not believe that in my lifetime, in the arena of wisdom, human physicians will be conquered by machines." The value of augmented intelligence, she added, "is proportional to the wisdom only we can provide."

More from Dr. de Baca and the others follows.

Katie Gillette, the report your consulting company released in May provided an overview of the digital pathology market from 2023 to 2028 and was the inspiration for CAP TODAY's October cover story (["Digital path's star rises from the mists"]). My perception, after reading the report and other coverage, is while we're still in low digits in terms of using digital pathology for surgical pathology primary diagnosis, the slope seems to be going almost straight up. I'm hearing more and more about people implementing it. What's your impression about where the field stands today?

Gillette

Katie Gillette, senior project leader, DeciBio Consulting: It's hard to have a clear definition of what digital pathology adoption looks like within an institution. In many institutions, digital pathology might be having one scanner sitting in a corner. In very few institutions, every slide is scanned and the workflows are fully digitized. We're seeing changes in both of those groups. Some who are nonadopters and don't have any of these tools are now becoming more familiar with the companies and technologies and thinking about how their practices could adopt them. Some groups that have the scanner in the corner are starting to think, Can I use this to support tumor boards? Can I use it to look at the harder cases? The transition from that to a fully digitized workflow is hard and requires champions across the lab and institution, but the right conversations are being had.

Leading academic medical centers and comprehensive cancer centers are increasingly interested in offering best-in-class pathology tools, including digital pathology hardware and the algorithms, and being involved in the development of those tools. We're continuing to hear excitement from oncologists and it's been great to see that increasing over the past six months.

Mike Quick, as the incoming president of the Digital Pathology Association, tell us what your impression is about the rate of adoption now.

Quick

Michael Quick, president-elect, Digital Pathology Association, and vice president, research and development and innovation, Hologic: Perceptions about how quickly digital pathology is being adopted can vary widely. For example, if you were to attend the upcoming Pathology Visions meeting and talk with members of the DPA, you could conclude that digital pathology and the use of AI is largely fully adopted. There are a lot of champions who are moving the field forward, excited about the technology, and transitioning that into clinical practice. However, attending more general pathology meetings you might see that it's still early days. We are exploring ways to harness and extend the excitement and enthusiasm evident at Pathology Visions and in the DPA community more broadly.

I have been working on the membership committee of the DPA for the past several years, and the association has grown tremendously—we recently surpassed 4,000 members, and attendance at Pathology Visions is expected to be the largest yet. This level of involvement is outstanding and reflects the growing interest in the field.

Eric Glassy, what's your perspective on the rate of adoption? I note, in passing, that Alverno has gone with a completely digital workflow. Also, Keith Kaplan, one of the longtime leaders in the field, wrote a few brief notes on the first 100 days of using digital pathology for primary diagnosis (tissuepathology.com).

Eric Glassy, MD, medical director, Affiliated Pathologists Medical Group, Rancho Dominguez, Calif.: The drivers have shifted. Initially pathologists were pushing it, saying they need it for tumor board, education, research. Remote sign-out was a big boost that helped people understand the value of digital pathology. Slow adopters thought, This isn't as bad as I thought it would be; I can modify my workflow to accommodate it. Many of us thought AI would push it, and that's helped a bit.

The push now is the shortage of pathologists. Providence health system in California, Alaska, Montana, New Mexico, Oregon, and Washington has a number of smaller hospitals and there are not enough pathologists for the workload. So the next wave of adoption, or at least interest on the part of those who write the checks, is around the shortage of pathologists and trying to fill those needs, particularly in rural hospitals.

Doc de Baca, the early years of digital pathology were plagued by concerns around FDA regulation, but pathologist anxiety was also a drag on the field. There was concern about pathologists losing their jobs to digital pathology, with visions of digital pathology enabling a handful of centers or even pathologists to take a dominant amount of the work. That anxiety seems to be going away. Do you agree with that? And can you talk about the latest anxiety—that AI is now the big threat to job security?

Dr. de Baca

M. E. (Doc) de Baca, MD, vice president for medical affairs, Sysmex America; founder of MDPath; and hematopathologist, Pacific Pathology Partners, Seattle: With the entry of digital pathology we were concerned about regulations and pathologists losing jobs; now with AI, here we are, talking about regulations and pathologists losing jobs. If we had a Gaussian curve of technology implementations, our buckets would be: one, the "bleeding edge" group—the early adopters of technologies; two, the "kind of early" adopters; three, the "we have to get on this train because it's already out of the station" folks; and finally, four, the "never going to join"-ers. Take that Gaussian curve and think about where it was 20 years ago. Now shift it further left, because the people we call Luddites today would have been on the bleeding edge then—they have more computing power in their cell phones than took us to the moon. Current society is extremely amenable to the idea of technology permeating our lives,

resulting in a significant reduction in the activation energy needed to bring highly sophisticated digital or computational solutions into every space of medicine.

People have to make decisions about spending money, that's a big deal, but it is currently offset by the insufficient numbers of people in our workforce. Additionally, the ONC [Office of the National Coordinator for Health Information Technology] and FDA are asking for data; they want information for pre- and post-market surveillance of instruments, drugs, and diagnostic tests. It's become clearer that with data interoperability—if we could share our data—our patients would be better for it. While pathologists continue to fret about jobs, they're starting to notice that adapting to the new technologies makes them more, rather than less, appealing in the market.

We still have regulations to think about. Pathology has the CLIA environment that people in other specialties don't have to deal with. My anxiety is that pathologists aren't blowing our own horns loudly enough: We're the physicians who understand how tests and data work and how they work together. We can see where data are adequate or inadequate in a way other specialties are not as well equipped to do. If people start using our data for algorithms without involving us, their algorithms have the potential to be less safe than they would if we were invited to or forceful about being included in those conversations. I'm hesitant to say I'm pro-regulation, but I support doing everything we can to ensure our patients' safety, even if it means added CLIA-like regulations for AI models originating outside the lab.

Dr. Glassy (Affiliated Pathologists): Pathology is a job, an occupation, but it's made up of a bunch of smaller tasks. AI is very good at the small tasks but terrible at jobs. It doesn't have a way of putting it all together like the pathologist needs to do. So if your job is to find acid-fast bacteria, you are going to be out of a job. If your job is to diagnose a lymph node with a constellation of features that are critical to the patient's treatment, you are not out of a job. I look forward to AI making those repetitive tasks easier, helping with business management and QA and QC, finding mitoses, et cetera, but I don't see a threat for the job itself.

Mike Quick, talk about how Pap test screening affected the job market for cytopathologists and cytotechnologists. We know technologies like this disrupt and change the standard patterns of employment. Give us a little history and then project how that history might replay itself, or not, in the field of digital pathology for surgical pathology.

Michael Quick (president-elect, DPA): We've seen ups and downs in the cytology workforce and it's been significantly impacted by changes in guidelines. Technology has come alongside and supported the wave of those transitions and been the driver behind where these tools help laboratories offer the work in a way they hadn't previously. With each new technology there can always be fear that it will replace jobs, but that's not been the case in cytology. There's currently a significant shortage relative to the need for trained cytologists as well as pathologists. The roles of the cytologist and pathologist in the laboratory are evolving. It's not just looking through a microscope and doing the same repetitive task. The amount of information practitioners have to take in, the combinations of additional IHC stains, molecular testing, genetic profiles—much more data is being used to make a diagnosis. The only way that will be possible is to bring in tools that make the more repetitive tasks easier to do.

In our November issue is a roundtable on artificial intelligence. In the discussion, Ajit Singh of Artiman and Stanford made an important point that no AI can work unless the greatest experts in the field to which it's applied are in the trenches working with the algorithms and the machine learning. He did that to suggest there's a pairing of expertise with machine learning that is indissoluble. Mike Rivers, can you comment on that?

Rivers

Michael Rivers, vice president and lifecycle leader of digital pathology, Roche Tissue Diagnostics: We've been talking about pathologists and AI as if it's a conflicting relationship, but it's a complementary, mutually beneficial one. AI is only as good as the ground truth it's given, and that comes from the pathologists, from the stains that are prepared, et cetera. The AI tools contemplated now will bring new insights to pathologists to aid in the diagnosis and treatment path for that patient and will impact our lives in an exciting way.

We still need a pathologist who's taken the Hippocratic oath and has the judgment to drive the diagnostic decision for the patient. But we are going to see more and more of these tools come into practice. It's still more about potential than reality; there are very few available for clinical use, but that will change dramatically in the next several years, and those who embrace it will do extremely well.

Lisa-Jean Clifford, what are your thoughts on digital pathology adoption?
Lisa-Jean Clifford, chief operating officer and chief strategy officer, Gestalt Diagnostics: Using the technology as we have, coming out of the pandemic, to work virtually and have roundtables in settings such as this, has helped with adoption and access to different types of technologies as well as with the comfort with and acclimation to them. We have clients who are using digital platforms to onboard new pathologists and to manage their credentials. There are ways to think outside the box in how the technologies can be applied to benefit an organization.

You engage with many people in the field, from veterans to people who are getting started, and many look to you and Gestalt as an entry point and as someone to talk to as they contemplate this. What is uppermost in their minds, and how has that changed in the past year?

Clifford

Lisa-Jean Clifford (Gestalt): Depending on the organization and its size, goals, and objectives, the questions vary widely. The smaller and midsize organizations have fear of missing out. But they're also concerned because they have the tightest financial constraints and are trying to understand the differences in the hardware, scanners, and the technologies and platforms. Digital pathology providers vary greatly in what they provide—the components, whether they are an all-encompassing platform, whether they are a glorified viewer that makes it easier to adopt digital in small bites.

The questions and approaches have changed in the past 12 to 18 months. It is no longer, Should we do this? Is this something we want to spend time on? Should we find the budget for this? It has shifted to, How do we do this? When do we do it? What will our approach be? How do we justify the budget?

Katie Gillette, is this in sync with what you've heard in your research? How do people approach their budgeting in the tight financial environment we're living in?
Katie Gillette (DeciBio): The budgeting is still tough. A lot of laboratories are working on figuring out what financial equation makes sense for digital pathology, depending on the type of lab and its priorities. A large reference lab can take advantage of the economies of scale whereas in a small community hospital, the biggest value is in remote consultations or as a solution to the pathologist shortage. Within academic centers, the financial aspect isn't necessarily the first consideration; it's more about the research opportunities that adoption of these tools enables.

It's not a simple equation because direct reimbursement is not in place. It's not: Do test A, get reimbursed for test A, we make money. Labs have to ask, Am I retaining pathologists whom I would otherwise be losing, so am I saving money there? Am I saving time per slide, even if it's small, and does it make sense in the long run? Am I able to

insource cases that I would otherwise not be able to do because I can look at things from a wider geographic area, and that could be revenue-generating for me?

Dr. de Baca (Sysmex): The CAP and American Medical Association have successfully added more than 30 category three CPT codes for digital pathology and are now working on AI codes. I hope CAP TODAY readers speak to people in their information systems service and facilitate implementation of category three CPT codes in their systems. This is the way that CMS gathers the data that informs the need for reimbursement for a certain new service. CMS doesn't run to us with money; category three codes offer the only official way for us to let CMS know, Here's what we are doing, and how much, and this is valuable work and we need to be reimbursed for it.

Katie Gillette (DeciBio): The Digital Pathology Association hosted a webinar earlier this year on this topic, looking at how category three codes are being adopted. There's still work to be done on the billing side to make sure the category three codes that exist now are being used so their tracking purpose can be realized. Otherwise they are shouting into the abyss.

Years ago a friend of mine put together a huge proposition for total lab automation in the clinical laboratory and ran it up the flagpole to the financial people in the hospital. They shot it down, saying, "This is much too expensive, being that nobody is reimbursing you just because you can get the work out faster or more efficiently." Yet less than a year later they went back to him and said, "Where is that plan to give us total automation in the clinical laboratory? We're overwhelmed with volume now and can't exist unless we put it in, and the sooner the better." This reminds me of the digital pathology conundrum now. Eric Glassy, does it remind you of that?

Dr. Glassy

Dr. Glassy (Affiliated Pathologists): It does. People who rejected it are now coming back and saying, "How do you help us implement?" The CAP can help, the DPA webinars are great, and attending the DPA meeting is a wonderful way to get indoctrinated and educated about the values of digital pathology, once you get the green light from administration. But there has to be caution about adoption. People need to better understand validation. They understand chemistry validation needs but may not understand anatomic pathology validation needs, and our professional organizations can provide educational opportunities.

Lisa-Jean Clifford, UPMC just brought in more computational pathology expertise, as has IU School of Medicine. Do you expect to see an ever-increasing influx of those types of experts as part of the pathology department?

Lisa-Jean Clifford (Gestalt): Yes, and having the pathologist involved in the process is fundamental to ensure patient safety and the correct application and adoption of the technologies. Part of my role at the Association for Pathology Informatics is making sure that industry and medicine mix as a whole. Having people who can bridge that gap and provide meaningful, accurate information while technologies are developed and tested is fundamental.

Mike Quick, let me ask you about the AI applications that will be and have been approved by the FDA. I often think of the liability element. I can imagine a lawyer in a medical liability case saying to someone on the stand, "Doctor, were you not aware there's an FDA-approved AI algorithm that can back you up and support your diagnosis? And did you use that or have it available?" It would seem to be a slam dunk for adoption. Give us your thoughts about that line of argument.

Michael Quick (president-elect, DPA): We've lived through this for the past 20 years with the adoption of

automated technology in cervical cancer, one of the most litigious areas in medicine. There's still an understanding that it's not the AI or the pathologist but a combination of the two that gives us the best diagnosis. But it's still early days regarding regulatory-cleared AI algorithms. The FDA has cleared nearly 600 AI devices in medicine but only one algorithm in digital pathology to date. I expect we'll see that accelerate but there is a gap now that people are aware of, and it's leaving laboratories in a difficult position of wanting to implement these new technologies, get experience with them, and be involved in developing and validating them, but not knowing what the regulatory environment is going to look like, whether it will be superseded by an FDA-cleared application in the future. Having the FDA, industry, laboratories, and practitioners working together will move this forward.

Mike Rivers, what is your impression about the speed of approvals through the FDA? And is the FDA equipped to properly examine these submissions?
Michael Rivers (Roche): A lot of work has been done behind the scenes and in preparation for what I think will be an acceleration in approvals in the coming months and years. The FDA, with its guidance documents and engagement with manufacturers, is signaling an interest in this area, a desire to move forward but in a careful, safe way. And that's appropriate; there are a lot of unknowns about this technology. We talk a lot about explainable AI. It's important for the agency and for pathologists to be able to understand how AI is determining the decisions it's making, and whether the pathologist can agree with that and sign their name on it.

Dr. Glassy (Affiliated Pathologists): We had labs in California that were Pap mills and patients were disadvantaged. And then Hologic came out with ThinPrep but it was more expensive and there was huge resistance from obstetricians. What helped is Hologic took the approach of getting patients involved. They advertised in *Redbook* and other magazines, and that spurred the discussion about the value of ThinPrep. That conversation with the obstetricians helped push, to some degree, the value of moving to this new technology and its commercialization.

There's an attempt now to improve pathology with AI. I've had a urologist say to me, "Did you use AI in your prostate core biopsy diagnosis? Because I have a patient who read in one of the journals that AI could really help." Here we have a patient talking to a urologist, who then says to me, "Have you put that on your report? Have you done something to help benefit the patient? Because you've got another set of artificial eyes reviewing the case." So I can see this taking off from the commercial side—patients will be using ChatGPT to review their lab data and their pathology report and get interpretations from it. Pathologists need to be prepared for that new future, which will be here in months. We're going to get inundated with this. I'd like to get Mike's take on if I'm close to the history and if he sees the parallels with what's potentially happening now.

Michael Quick (president-elect, DPA): Three things need to be in place before you involve the patient: The physician has to have access to that information and be educated about it, the technology has to be available in the laboratory, and insurance companies or payers have to say they will reimburse. We went direct to consumer, or direct to patient, wherever those three were in place. That foundation, which is what you saw in California, made pushing things forward successful.

Katie Gillette, in thinking about the field, what role can you ascribe to patients, imaginatively at least? After all, patients can make a difference, as we've seen over time.
Katie Gillette (DeciBio): The materials and conversations to date have been geared toward the pathologists and experts in this space. There's a need for the types of materials, wording, framing, and the story around it that resonate not just with pathologists but with patients, where they can see the value of this. The same is true for oncologists and specialists who, when these decisions are made at an institution level and not at an individual pathologist level, can be an important piece of it.

Cancer biomarkers are crucial steps in patient care for targeted therapy. It seems that applications in that field would become an essential part of the further development of digital and computational pathology and AI algorithms, because cancer is central to everyone's concern in this field. Lisa-Jean Clifford, do you agree with that?
Lisa-Jean Clifford (Gestalt): Absolutely. Digital pathology companies are looking at their road maps, products, and product combinations that they are bringing to market and making decisions on how they intersect. All of this

available data is valuable for a variety of reasons, such as being able to identify patients who could be a good fit for specific clinical trials. This could allow pathologists to provide guidance, as part of their report, to oncologists that a patient could be a fit for a list of current trials that apply to them. Or that based on specific biomarkers, their patient is potentially a good fit for these therapeutic drugs currently on or new to the market.

Providing that information through AI, machine learning, and a variety of available algorithms that are not diagnostic algorithms can help provide more information to the pathologist, embedding them as a core participant in the central care team for that patient.

Doc de Baca, can you comment on that?
Dr. de Baca (Sysmex): These new technologies will likely help us harness huge quantities of information more manageably. Information is facts and details; information can be transformed into knowledge. But knowledge is still only knowing. Knowledge does not do anything; it does not change behavior or treat or care for patients.

Medicine is described as a science and an art. I see an acute need to teach physicians, ergo pathologists, not only the science but also the art of medicine. What makes us unique is the wisdom we derive from the knowledge—our results are given with perspective and in context; they then lead to correct actions. I do not believe that in my lifetime, in the arena of wisdom, human physicians will be conquered by machines. The value of augmented intelligence is proportional to the wisdom only we can provide.

Physicians have been trivialized in the past 20 years. We have been reduced to “providers,” as if we were vending machines for whatever drug the TV said you need. We are not that. We are very highly trained caretakers. I *take care* of you. I care about you, I care about your disease. I know your child likes basketball, that your mother has dementia. I care that if you can’t get to my office because your spouse is ill or your car is broken, your challenge of achieving better health is a higher hurdle than if not.

Machines are not going to care. More information is good, more knowledge is good. Yet it is the soft skills of wisdom, perspective, context, and judgment that make us irreplaceable. The value of our combined scientific knowledge and our human wisdom is something we need to discuss urgently.