

IT in a pandemic year, now and what's ahead: interfaces, analytics, telepathology—seven weigh in

November 2020—*Information technology from a COVID-19 perspective. What has been the impact on IT, and what change is yet to come?*

That is what seven people who met virtually on Sept. 10 talked about with CAP TODAY publisher Bob McGonnagle. They are James Harrison, MD, PhD, of the University of Virginia; J. Mark Tuthill, MD, of Henry Ford; Stephen Hewitt, MD, PhD, of the National Cancer Institute; Bob Dowd of NovoPath; Michelle Del Guercio of Sunquest; Curt Johnson of Orchard; and Brian Gunderson of Roche.

You will see here, in the conversation that follows, where their focus is as the crisis continues.

CAP TODAY's laboratory information systems product guide begins on page 62.

James Harrison, how has your IT support been since the COVID crisis began?

James H. Harrison Jr., MD, PhD, associate professor and director of clinical laboratory informatics, Department of Pathology, University of Virginia School of Medicine: The crisis has focused our attention, so the scope of our activities has been less broad than it might normally be. If you looked over the past six months, people in the lab would raise supply chain issues for lab tests as more of an issue than IT, which is unusual. Our support has been good; we haven't noticed deficits.

Brian Gunderson, how has the IT environment within Roche and how have your customers been affected by COVID-19?

Brian Gunderson, international business leader, software, Roche Diagnostics: It's all things COVID, and it has pointed out a few things, especially in the molecular area. As we've been deploying our large-volume analyzers, it has shined a light on the need for the connectivity, for the IT component, and maybe where molecular was lagging behind in the past. We're also starting to see that it's driving more rapidly the digital adoption that is necessary in health care and in IT, and I think it will have an impact on provider consolidation too. We've seen this trend of consolidation for a few years, but that is going to pick up over the next three to five years.

Curt Johnson, we're hearing reports about data reporting demands that have stressed laboratory IT operations. Have you had that experience with your customers at Orchard?

Curt Johnson, chief operating officer, Orchard Software: Yes, we have. We've had a lot of inquiries, and the demands on our clients made by the CDC or the state departments of health change periodically, as they dial in on exactly what information they need for the benefit of the country. The integration needs vary, and they change as they go. We work closely with our clients and offer professional services to assist them with those requirements.

Clients deal with a couple of obstacles. One is the changing criteria for the information that's needed, and then the people requiring that information have different connectivity capabilities for how they can receive the data. Some of those state departments of health would like to have it in an interface using the 2.5.1 ELR interface method. Others can't accept that yet and are looking for CSV files, with specific information in specific spots. So we're working with each of the clients to meet these needs individually through our professional services team and to make sure we're doing everything we can to support the client base, getting the information to the right people in a timely fashion.



Dr. Tuthill

Mark Tuthill, what is it like to be the head of pathology informatics in the middle of a pandemic crisis?

J. Mark Tuthill, MD, division head of pathology informatics, Henry Ford Health System, Detroit: Busy. We've been inundated with not only analytic report requests but also interface projects for new technology that we have been standing up for novel lab testing methods that include new test orders and results. This work is not only the LIS. Since we are integrated with our EMR for orders and results, we have to work with additional teams to build out all of that for the EMR as well. This includes development to help cohort our patients as well as gather the required information for reporting to comply with national reporting requirements. Most of this has been accomplished through a combination of ask-on-order-entry questions and basic LIS information such as patient location and admission category—ER, inpatient, outpatient, et cetera. This data is used to manage our pipeline and route samples to different testing platforms with different turnaround times, sensitivities, et cetera.

So, there has been a lot of work in the LIS and with the EMR. Ultimately, it comes down to getting the data out timely and accurately. Fortunately, we are on one LIS and one EMR across our entire health enterprise, and our interface to the state department of health has been in place for four or five years. We were easily able to add the required COVID reporting elements into our interface, so by March 16 we were sending all the requested COVID data the state needed. Over time, we have added additional elements as requested to comply with changes mandated by the CDC or Health and Human Services. For the most part, we were able to add additional HL7 segments. Occasionally, we have had to go back to the LIS vendor to have them run a stored procedure to generate data we were not getting. To sum it up, between the LIS maintenance, instrument interfaces, the EMR configuration and coordination, managing ask-on-order-entry questions, and directing samples by cohorting process, we have been incredibly busy.

This underscored to us that our efforts to create an efficient, highly integrated, up-to-date laboratory information system has stood us in good stead. This has allowed us to be extremely nimble and to deliver information to leadership that would not have otherwise been available from the EMR.



Dowd

Bob Dowd, tell me about some of the challenges that COVID may be presenting to NovoPath's clients and how you've responded.

Bob Dowd, VP of strategic accounts, NovoPath: NovoPath started off as predominantly an AP software provider, but over the years we've added other modalities. We can handle clinical pathology, microbiology, cytogenetics, therapeutic drug monitoring. We added all of that because of the diverse nature of our clients.

A client would rather have one system for all data, one set of data interfaces. So as we continue to develop, we integrate all of that. With more molecular COVID testing, we can accommodate that. And one of our strengths is our data management capabilities through our interface engines, our instrument interfaces. So we can integrate clinical and AP reports and give clients clinical only reports, AP reports, combined, all results for a patient on the same day.

We created a special COVID repository that each client can have that will track the patients who have been tested—negative, positive, recovered. It's a special add-on for clients.

Michelle Del Guercio, if you'd like to comment on the current state of affairs for your customers and LIS initiatives, please do. In addition, I'd like to have you comment on the multiple platforms labs are adopting, in part in response to supply chain difficulties. This means extra work on interfaces and reporting at Sunquest. Am I right?

Michelle Del Guercio, VP of marketing, Sunquest Information Systems: That's correct, and I agree with what the others have said about the complexities, the many moving parts that laboratory organizations have, and how they are turning to technology to help support that.

The reporting has continued to fluctuate. There are other federal and state reporting requirements, and as that all shifts, the nimbleness that Dr. Tuthill mentioned is extremely important. And we have found it helpful to talk to our customers in a town hall call, to which our customers can dial in for assistance or product availability updates or to provide us with feedback.

There were also the issues related to the patient locations that were added—tents in parking lots, for example. The technology had to be able to help support where that patient is, where that report goes, and getting the information into the EHR.

As our customers stand up additional tests, they often need new instrument interfaces to manage the workflow. We've introduced rapid deployment options of our solutions to help customers start and scale their testing—from order capture, test performance, and results delivery—to help them manage connectivity, capacity, and volume demands.



Johnson

Curt Johnson, in April or so we heard about some people from laboratories sitting at home, from the surgical pathology area of the lab, for example. Now I'm hearing from laboratories that they can't get enough personnel. Are your customers now under strain to get the work produced?

Curt Johnson (Orchard): They can be, and your information is correct. We have a diverse client base at Orchard—physician offices, hospitals, independent reference labs, and public health. In April we did see a test volume drop in our physician office customers, when the patients stopped coming in for routine visits. Our anatomic pathology volumes decreased as well. Our hospital volumes stayed fairly even. But our reference lab business started to pick up right away and has been exploding ever since. And for our department of health clients, both receiving data and testing, one effective COVID-19 testing strategy that many labs are employing is to use multiple platforms. The more platforms they have to bring in, the more integration is needed from us. One of our reference labs is now managing 20,000 accessions a day and another one is testing more than 12,000 a day, and it's 98 percent COVID-19.

Our physician office business has picked up since the summer. All of our business is starting to pick up, but predominantly we're dealing with COVID-19, helping get analyzers online, getting the integrations and the HL7 2.5.1 interfaces in place.

The CEO of another health care information company, who is not directly in the LIS business, said to me today that lab data has become the universal language of health care. It's interesting because for the first time in a long time, the laboratory and laboratory information are in the spotlight in a way that shows how valuable they are.

We've known the value, and now the rest of the country is coming to see that because of the COVID-19 crisis. I think we will see laboratory testing stay at the forefront even as the crisis passes and COVID-19 becomes another mainstream test.

Brian Gunderson, I am sure you're hearing some of the same things about renewed prominence and appreciation for laboratories. Is that right?

Brian Gunderson (Roche): Yes, it is. We've had a lot of interactions that we have never had before as a company,

with governments, with CEOs of health systems across the world. Typically in the laboratory you fly a bit under the radar, but in the last six to nine months it's been anything but that.

Roche began to speak a lot about the digitization of health care and diagnostics and it became a prominent theme in its communications two or three years ago. I am assuming you're glad you emphasized that direction at Roche and continue to implement solutions in that direction. Can you tell me more about that?

Brian Gunderson (Roche): A few years ago we started to put a focus on what we call digital diagnostics and driving that forward. As laboratorians we've done a great job of understanding the sample flow, the automation of the laboratory from instruments through large track systems, and now we're moving into this area of understanding the data flow that parallels that sample flow.

The investment we put into that is paying dividends today. It's allowed us to quickly develop new dashboards and new reports specific to COVID, and it has allowed us to get instruments up and running faster than we ever had to do in the past. I expect that this is going to leapfrog us into the future when it comes to digitization of the laboratory.

Michelle Del Guercio, Sunquest is not a barebones LIS product. You have a lot of arrows in your quiver, so to speak, at Sunquest. Can you talk about how that diverse portfolio is helping you and your clients during the pandemic?

Michelle Del Guercio (Sunquest): The suite of solutions that Sunquest provides very much supports that value of laboratories as they look to support the strategic initiatives of their health care organizations, and that has lifted the laboratory out of the basement. If you think about disease management and population health and COVID, the laboratory is in all of that, and the ancillary components of the Sunquest offering are helping to drive some of it, specifically with the orders and results management, the integrated reports, the connectivity with instrumentation, and extending through to the molecular laboratory. It has helped drive our customers forward quickly and efficiently as they deal with this new paradigm.

Stephen Hewitt, how has the pandemic affected your world, particularly as it regards IT, at the National Cancer Institute?

Stephen Hewitt, MD, PhD, CAPT U.S. Public Health Service, head of the Experimental Pathology Laboratory, Laboratory of Pathology, Center for Cancer Research, National Cancer Institute: The pandemic has had an enormous impact on my group and all the technologies I work with. It put the surgical pathologist off on the side and inactive, and we turned down our in-house services to just bare minimum because we did not have specimens coming through in our in-house service. Our consultative services continue at full steam, and one direct impact on us was the request to digitize slides for our pathologists to review in consultation for the consult material that was coming in the door.

We have a number of older pathologists for whom it isn't safe to be out, and we were able to digitize and support them to perform telepathology, and they were delighted.

What you see when you go to telepathology is that there's such a distinct learning curve that sometimes the simpler and older systems that they're comfortable with are a better environment for this because you don't have the time to bring them up to speed with learning sessions and everything else. We were working with limited staff, so we were doing this on a shoestring.

On the other side of the coin, NIH has performed 21 COVID autopsies. As an experimental pathologist, I was one of two attending pathologists for those autopsies. We built an immediate biobank, so I already have 1,500 COVID tissue samples in my laboratory as a part of our ongoing pathology research. And we're already bringing up assays and doing correlative studies to understand COVID.

And because I have been involved in digital pathology, on or about March 17 I said to the other pathologist who was going to do the COVID cases with me, Do you think we should stand up a digital pathology repository for COVID autopsies? He said yes, and three weeks later we launched a COVID team with about four cases that we had

obtained in consultation from COVID autopsies. As I sit here in early September, six months later, we have in process more than 101 autopsies that we're presenting to our community in digital format, so pathologists across the United States and the world can understand the pathology they're going to encounter [[COVID19pathology.nih.gov](https://www.covid19pathology.nih.gov)].

We've been developing these technologies and talking about them. Now we're deploying them to help our community.

Just as Roche and Sunquest prepared years ago to be well prepared for this, to some degree, so too are the people implementing digital pathology. And it's nice to note that the autopsy gets renewed respect whenever something new and unknown enters the sphere of illness, health, and death.

Bob Dowd, you've just heard considerable discussion about anatomic pathology. My first question is not to necessarily talk about autopsy but just to clarify: Most of NovoPath's surgical pathology customers are now back running at about normal capacity, correct?

Bob Dowd (NovoPath): That is correct. The business has picked up and we have gone to the digital age, where we're doing a lot of digital reporting, whole slide imaging. And some pathologists who normally would go to multiple sites are now staying in one site and getting the work distributed and the whole slide image sent to them.

We're getting a lot more inquiries from our existing clients about what else they can do to further automate their own systems by using our workflow enhancements or new modules with added functionality. They've found differences with staffing changes—not all furloughed employees have returned, for example—and want to know what they can do to enhance workflow. So there has been interest in our workflow solutions.

We've also received inquiries from potential new clients about demos for those digital and workflow capabilities. We're starting to see now that people have realized this is more of the atmosphere and environment we're going to have to deal with, so they're questioning how it can be accommodated more efficiently. They need to have a much more efficient workflow.

Mark Tuthill, Henry Ford has been a longtime leader and enthusiast for digital pathology. Did the relaxation of CLIA during the pandemic, allowing surgical pathologists to do remote sign-outs, have a big effect this year on the operations at Henry Ford?

Dr. Tuthill (Henry Ford): Not really, but it has given us incentives and opportunities to continue to expand what we have been doing. We're at the beginning of our digital pathology journey for whole slide imaging in terms of primary diagnosis. We mainly use whole slide imaging for frozen sections, clinical conference, and so on, and all of that is in place. Digital pathology was used more extensively and we had fewer concerns about CLIA compliance, but again, we are not doing primary diagnosis.

We did make extensive use of our digital pathology tools to integrate pathology sign-outs between residents and pathologists virtually. We're already doing a lot of virtual microscopy, screen sharing, et cetera, and that went on steroids from the pathologists' offices and homes to the resident room. So we were making more use of what I would say is digital pathology 1.0, live dynamic camera viewing through screen sharing technology, as opposed to whole slide imaging. But whole slide imaging was used to move around our diagnostic controls for immunohistochemistry, which is just part of how we work now.

Dr. Hewitt (NCI): We have had much the same experience. We put cameras on every pathologist's microscope, and we were able to move our resident education online effectively. The one place we virtualized everything was molecular pathology, and suddenly much of what had been on paper and in in-person meetings, where we would have the team review all the cases together in one room, we completely moved virtual. A number of our staff haven't been on the campus in more than six months, and it's had no negative impact on performance and being able to do our molecular pathology. In some ways this experience is going to take some technologies and move them much more virtual and much faster.



Dr. Harrison

James Harrison, what is the experience of your surgical pathologist colleagues in Virginia? Did the relaxation on sign-out have a positive impact?

Dr. Harrison (University of Virginia): All the surgical pathology sign-out is still being done on site. We're in a situation similar to what Mark described at Henry Ford. We have a whole slide imager that's used for research but that's not been integrated into the clinical workflow. So we're not doing routine imaging with sign-out from home.

On the clinical lab side, we do serum protein electrophoresis with gels, and we were looking at capillary electrophoresis when COVID hit. We haven't brought those instruments in yet, although it is planned. I am part of that clinical service and we sign out gels on site. We decided not to go to remote sign-out of gels because we found literature suggesting that unless you have purpose-built equipment, scanning and displaying gels on commodity hardware reduces sensitivity. Our hemoglobin electrophoresis is already capillary, and those tracings can be reviewed on any display.

All of our quality control sign-out and laboratory management is done remotely by online meetings. And we have a pretty good ability to access the LIS and EHR from multiple remote sites, so that has gone smoothly.

Michelle Del Guercio, I think Stephen Hewitt was hinting at something that is broadly applicable to laboratories across the country, namely that molecular may still be paper based and not necessarily as well integrated into a digital or LIS type of workflow as are the more common tests from a core lab. Have you seen at Sunquest additional interest in getting the molecular component well suited to the LIS environment, and the EMR environment for that matter?

Michelle Del Guercio (Sunquest): Yes, we have seen quite a bit of activity around molecular testing, with our LIMS for molecular diagnostics, and just dealing within the laboratory itself and with instrumentation. We developed what we'll call a rapid deployment to help support these labs that all of a sudden are saying they need a LIMS. Manual workflow was no longer working for them and they required something quick to get started so they could bring RT-PCR testing and order workflows in-house. To get them going quickly, we developed a starter package that integrates both with the external for the order entry and then internal with Data Innovations' Instrument Manager to support the instrumentation on which they're performing the tests.



Gunderson

Brian Gunderson, since you represent much of the molecular technology that needs that connectivity, can you comment on the increasing need for informatics connectivity for molecular?

Brian Gunderson (Roche): It has had a huge impact. In the past the workflows were manual. Very little IT was deployed within the molecular labs, and with COVID it's accelerated the need for the IT connectivity back into the LIS and the EMR systems.

Curt Johnson, we are all coping with COVID, so it can be hard to think about future plans and capital budgets and what may happen next year. How is the market looking for Orchard from a sales perspective as you go into next year?

Curt Johnson (Orchard): It's looking to be one of our best years. A couple of things are playing out, one of which is the laboratory getting the spotlight for testing. It depends on how far you're looking into the future. Molecular testing is becoming more mainstream. It has been rapidly deployed more clinically than it would have been in the past, and it has forced a lot of information systems to react versus being proactive. As you're reacting you must look proactively at where things are going and what the future is going to hold. Where is COVID-19 testing going to go? It's moving now into the senior living areas and nursing homes, and the government is working with those homes and equipment manufacturers to deploy point-of-care testing analyzers throughout the country. These point-of-care systems will require connectivity to rapidly communicate results. How will all of that get connected?

Point-of-care testing is going to explode, and that kind of workflow can be thought of as a different flavor of molecular. It's different than the normal laboratory information we're used to seeing, and the connectivity to those analyzers uses different interfacing specifications and has different requirements, different certifications, different types of users. It's another level of testing, and once you get into the point-of-care area, the next step is into patient homes. All of these ideas have to be in your blueprints today or you're going to be behind when those times come.

COVID-19 benefited Orchard in some ways. We were in the process of introducing our point-of-care enterprise solution and our enterprise LIS, both of which are cloud based. We had many more deployments than we probably would have had in a traditional year, so it's been a bridge for us into the future. It has taught us a lot about where we're going and it enhanced our development.

An example within COVID-19 testing in molecular is pooling of samples. It's much more than putting a few extra patients in a well. How are we going to handle the reflex testing? How are we going to identify patients? How are we going to make sure the testing gets back to the EMRs and is electronically correct? How are we going to make sure that information gets to the state department of health? All of this has to be managed proactively.

What is the school system going to look like in two years as far as testing goes? Will they have point-of-care analyzers where they can test for flu, COVID-19, and strep in the nurse's office? Who is going to want that data? How will the data be used? What kind of data is the NCI or NIH going to need? How can we benefit by capturing that data and providing it to people? All of that is on our roadmap.



Del Guercio

Michelle Del Guercio, are you hearing and feeling some of the same things at Sunquest?

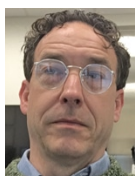
Michelle Del Guercio (Sunquest): Yes, we are. The continued growth with molecular, for example. It is becoming more mainstream, and there is more demand. We continue to focus on that within the Sunquest suite. Interoperability between systems—the pandemic may have slowed down some of the large EHR implementations. So we're helping our customers focus on interoperability within their own health systems and then external to that as they look to connect multiple EHRs and multiple LISs.

We're seeing synergy between the public health world and the standard clinical world, as we see people return to universities and to work. It's the connection between the population and the patient. We will see that trend continue and a little overlap of those industries and then support them on that. We support the disease surveillance and outbreak management side, and we support the clinical pathology molecular side.

Brian Gunderson, you mentioned at the top of our discussion the increase in consolidation, particularly among providers. For those labs that are not yet consolidated and may be on older, even

legacy-type operating systems, is now a good time for them to consider what they're going to need in IT for the future?

Brian Gunderson (Roche): My advice would be that you, as a laboratory, have a digital strategy and know where you want to go with it. Laboratories have become much more visible, and traditionally we've been seen as a transactional service, but going forward, and especially pushing through COVID and going into value-based health care, it's going to be critical that you look at all of that data and holistically determine how you can provide more value to health systems. It's a challenge because understanding that digital strategy hasn't been a focus, but if we're going to survive all of the consolidations that are coming, you have to have that in place so you can react quickly, like we did through the pandemic.



Dr. Hewitt

Stephen Hewitt, what is your take on that last question? Do labs not yet in the process of getting prepared need to step up for the future?

Dr. Hewitt (NCI): Yes, they do. There is a challenge for them now and it is that many institutions are suffering an economic hit from the pandemic. The institutions that were marching down this way and had already implemented this are seeing the rewards of having been ahead on these technologies. But for institutions that had not started moving toward clouds or integration or anything else, suddenly they have less coin in their back pockets to help them get there.

Data integration is going to be critical to the future, even on the research side. I am participating in the National COVID Cohort Collaborative, known as N3C, and that's through NCATS, the National Center for Advancing Translational Sciences. N3C will make it possible to rapidly collect and analyze clinical, lab, and diagnostic data from hospitals and health care plans [[COVID.cd2h.org](https://www.cd2h.org)]. These are heavy, complex efforts that require an enormous amount of bandwidth with sophisticated IT departments. And a lot of organizations have been taking baby steps toward this. If it was not on their roadmap, it is now. Unfortunately, the economics are such that they will have to push this off two to five years, and that's concerning.

Some of the large, academic labs in metropolitan areas were surprised when they realized that many of their suburban hospitals and the labs connected with them were understaffed and didn't have adequate technology, and that accelerated the flood of testing and patients into the flagship institutions.

Dr. Hewitt (NCI): No one was prepared for the flood of testing. For pooled testing, for example, you couldn't even get a robot on the open market to pool the samples. All of a sudden we noticed how thin the infrastructure really was.

We have been obsessed with being lean, with saving money, with just-in-time inventory, and a lot has changed and may change in the future. Mark Tuthill, would you like the last word?

Dr. Tuthill (Henry Ford): One of the things we have not brought up was the need for analytics capabilities to show how the lab was performing. This was critical for our laboratory leadership and the health system at large. For example, "What's your turnaround time on your OB/GYN patients coming in in labor?" "Are you getting 100 percent of those tests back in three hours?" We were able to provide these metrics rapidly for a variety of scenarios.

Business analytics tools were critical to our success and added to the visibility of the laboratory because you just could not get that level of detail out of the EMR in real time. We could produce that information up to the minute with our LIS and the tools that we have worked to develop with our vendors in that capacity.

That was the one gap we have not talked about and it is critical. We deliver a curated report showing our throughputs, our turnaround times, our just-to-the-minute positivity rates for a variety of cohorts every day. Our chair personally curates and delivers it to the leadership of the organization. This underscores what we said earlier, that people have finally realized that the laboratory is critical to patient care and that having a hospital-based laboratory is very important for your service delivery. What a fascinating lab 2.0 opportunity, experiment, and demonstration we have all just put on. □