One year later, life in labs remains a juggling act

March 2021—*Tackling staff shortages, urging vaccination, answering questions about serology testing, and raising questions about variants were some of what Compass Group members were doing when they spoke on Feb. 2 about COVID-19.*

"Staffing has continued to be a challenge, the greatest of which is phlebotomy staffing," said Darlene Cloutier, MSM, MT(ASCP), HP, director of laboratory operations at Baystate Health, Springfield, Mass.

"Our biggest pain point is laboratory technologists," said Tony Bull, executive director, AdventHealth, Orlando, Fla.

CAP TODAY publisher Bob McGonnagle led the roundtable. With him and Cloutier and Bull were Terrence Dolan, MD, Regional Medical Laboratory; James Crawford, MD, PhD, Northwell; Jennifer Laudadio, MD, University of Arkansas for Medical Sciences; Stan Schofield, MaineHealth; Sterling Bennett, MD, MS, Intermountain; Heather Dawson and Lauren Anthony, MD, Allina (post-roundtable, Dawson is with Philips Healthcare); Johan Otter, DPT, and Michael Quigley, MD, Scripps; Joseph Baker and Peter Dysert, MD, Baylor Scott & White; Linda Mirkes, MBA, MT(ASCP), Atrium; Judy Lyzak, MD, MBA, Alverno; and John Waugh, MS, MT(ASCP), Henry Ford.

The Compass Group is an organization of not-for-profit IDN system lab leaders who collaborate to identify and share best practices and strategies. Here is what they had to say last month.

Terry Dolan, can you fill us in on what's going on at Regional Medical Laboratory?
Terrence Dolan, MD, president of Regional Medical Laboratory, Tulsa, Okla.: We're seeing the positivity rate drop. It was running in the mid-20s—though we weren't sampling the whole population—and now it's in the mid-teens, and the antibody levels that were nonexistent in the spring are now running over 40 percent positive. We're seeing fewer patients in the hospital in this area.

The variants haven't hit here, although we're not looking for them ourselves, and it is a concern. But we seem to be turning the corner, and all the health systems in this region are experiencing the same.

How is the supply chain?
Dr. Dolan (RML): Our volume of tests is down but still significant, and our supply chains are holding up well. We have multiple platforms—that was our strategy.

Cloutier

Darlene Cloutier, do you have equally good news to share with us from western Massachusetts?
Darlene Cloutier, MSM, MT(ASCP), HP, director of laboratory operations, Baystate Health, Springfield, Mass.: We are feeling the same cautiously optimistic relief. Our goal has been to sustain or increase our test volume capability and capacity, and gradually we've been able to do that.

Antibody testing is becoming a conversation among our providers—identifying COVID exposure versus vaccine response and what tests are good for each.

Staffing has continued to be a challenge, the greatest of which is phlebotomy staffing. We have sign-on bonuses in place, travelers in place. We've created different models of support for the team. We're trying to launch a training program partnered with local phlebotomy certification programs to help us identify external candidates and create a pool of applicants to support this staffing. That's been a big focus, particularly the inpatient side of phlebotomy.

Do you have retired phlebotomists who might be returning to help out?
Darlene Cloutier (Baystate): It's possible. We see that in our technical staff—they retire and then we ask them if they want to come back as per diem, and many of them will.

Jim Crawford, tell us what's going on at Northwell.
James Crawford, MD, PhD, professor and chair, Department of Pathology and Laboratory Medicine, and senior VP of laboratory services, Northwell Health, New York: Our testing continues to go up and up. We're now receiving upward of 14,000 test samples per day. We load balance between doing it in-house and sending out to, in particular, one lab in Manhattan, and we keep that and other commercial labs on a short leash as regards turnaround time.

When turnaround time balloons at one of these labs, your sample is already there, and the real pinch point is the pre-procedure scheduled testing where patients show up the morning of and their PCR results are not back. So we are getting into an erratic routine of 5 AM phone calls where the PCR test is not back, and we have to re-swab and run the repeat test in the hospital on a cartridge before the patient can undergo the procedure. The root cause is that our clinicians are interpreting five days as three days as 48 hours, which turns out to be 30 hours. So there's a lot of education of our medical staff as to how to pull this off. And the concept of, "Well, my patient is more important than other people; surely you can make it stat" currently exceeds our robust daily in-house capacity.

As regards workforce, we're running about 130 percent of where we were prior to COVID, of which the last 30 to 35 percent is COVID testing, and yet we don't have additional staff. So, yes, people are feeling tired. That's one of our fundamental load-balancing activities—to make sure we take care of our staff.

The medical science of serology is interesting though not yet clear, but even if it's not clear, our clinicians are still ordering about 2,800 to 3,000 antibody tests per day. I asked them, "What are you learning?" They say, "We're seeing the footprints of disease." Our serologic positivity rate has crept up from a steady 17 or 18 percent over the summer to mid-30 percent now.

The question of the hour, the question of today, which we are discussing at the state level, is viral sequencing. We at Northwell are stirring the pot because we need to be making decisions, not necessarily to test for medical practice, but about what we as a laboratory community should be doing to support public health.


Dr. Crawford

What is your own view on that? What will you tell your colleagues in the state?
Dr. Crawford (Northwell): We formed a New York State SARS-CoV-2 Testing Consortium, which consists of the laboratory leadership of 12 major academic medical centers in the state, and we have punched our way through any number of paper bags over the course of the last 11 months. The current paper bag is SARS-CoV-2 genome sequencing.

There are a variety of versions of the sequencing issue. The first is if it is just surveillance, samples are de-identified. But for tracer purposes, sequence information on identified patients has to go back to the source department of health, especially if the goal is to contain outbreaks of variants. There is ample evidence now that the U.K. variant B.1.1.7 is already present in New York State. So the real hobgoblin is what if one of the other variants that escapes monoclonal antibodies and vaccination enters our region? Will we identify it at the time of entry or are we going to be chasing it after it is already spreading? And all you have to do is look at the data from South Africa to have concern. The question I pushed in a state call is, what are the criteria for a successful regional

strategy? Is it surveillance and tracer only? Is it sequencing in a clinically licensed lab where you can return the information for the purposes of patient care? Because if you were going to do monoclonal antibodies for a variant that may or may not be resistant, the turnaround time from a clinically licensed laboratory is critical.

Lastly, what is the relationship of sequencing, where you're looking for any and all mutational variations, to multiplex PCR, where you have, basically, these are the ones we're looking for, whether it's in the *S* gene or somewhere else? Should you feed off sequence surveillance to do clinically licensed PCR testing, including looking for specific mutations, or *S* dropout on a multiplex PCR test? Should you have a more clinically oriented sweep of the population? At this moment in time, these are unanswered questions.

How much thinking and preparation can and should we do as a laboratory community with public health authorities to anticipate what could quickly be upon us? The CDC has contracted with LabCorp, Quest, and Illumina for expanded genome sequencing. Public departments of health around the country are being instructed to send samples to those three companies. The turnaround time supports surveillance but may not support tracer intervention. So the question I am asking at the state level is, how do we take care of our region, and what does that translate into?

Would you say the COVID situation as a matter of public health is improving in New York as you see it, or is it holding steady?
Dr. Crawford (Northwell): The lid is still on the pressure cooker; the second surge is plateauing. The positivity rates are dropping a bit, as are hospitalization rates. As long as a new variant of concern doesn't enter the area, there is cautious optimism that we may be able to see things through.

Jennifer Laudadio, your state is not nearly as big or complex as New York, but tell us what's happening in Arkansas at UAMS.
Jennifer Laudadio, MD, professor and chair, Department of Pathology, University of Arkansas for Medical Sciences College of Medicine: Last week we were feeling hopeful as our inpatient numbers started to decline, and then over the weekend they went back up and we now have as many inpatients. We're at our highest level, exceeding where we were right after the holidays. So we continue to struggle with that and the nursing shortages that go with it. On the laboratory side, we are adequately staffed other than at quarantine times.

We have achieved vaccination of about 75 percent of our laboratory. The remaining individuals are either waiting because they are being asked to wait 90 days from testing positive or they are just going to decline, but we're at a pretty good number for the lab overall.

What's the demand for antibody testing?
Dr. Laudadio (UAMS): Almost zero. We announced to the health system that we have it, and we've gotten inquiries about what the utility is. We tell them we don't know that there is any, and so people aren't using it outside of the convalescent plasma setting.

Stan Schofield, have you had an easy time getting vaccinations to laboratory staff who need it?
Stan Schofield, president, NorDx, and senior VP, MaineHealth: We were in the first group to be vaccinated, and about 68 percent of the staff have been vaccinated. Every day I send out a message to the staff and the managers to get vaccinated: It's important for your health, your safety, your coworkers, your patients. We have groups that are reluctant. They've been working from home; they're not considered high risk in what they're doing now. They've been a little slow to take up the vaccination.

I fully believe the variants are here and I've been instructing my staff to gear up for another surge in late March, early April, to stockpile reagents and pipette tips. Part of the message is if the variants are here, you want to be vaccinated.

Jim is right about sequencing. The government has been slow. They've tried to figure out what it means. It's expensive. Now we're being instructed to start sending positive samples to the CDC, or asked what the sampling methodology is, what the demographics are, what's going on. It's a poorly organized situation for the variant by

the federal government, and the states are clueless. To me that means what we're doing is Groundhog Day from a year ago: Nobody knows what they're doing, nobody knows who's in charge, and at the end of the day we're going to get the same results and it's not going to be pretty. Based on my Groundhog theoreticals, I think in late March we're going to have the U.K. B.1.1.7 surge at the least. South Africa is still a wild card, and that's the one I would be most worried about, but it's been pretty contained there.

I don't know that the vaccination rollout has been adequate to defer or deflect that.

What is your experience with demand for antibody tests so far at NorDx?
Stan Schofield (MaineHealth): Slim to none. We're still testing 4,000 patients a day on PCR and we're getting five to six, maybe 10, antibody test requests a day. We think antibody testing in the spring on a quantified antibody will probably be in demand after the vaccines are out, as part of the immunological status of patients going forward, and we're prepared. But at the moment it's a non-event.

Tony Bull, tell us about the COVID life in Orlando.
Tony Bull, executive director, AdventHealth, Orlando, Fla.: Our biggest pain point is laboratory technologists, and that's been a limiting factor in COVID testing. We are bringing in a group of people from overseas to help us.

We're not doing much antibody testing yet. We're still waiting for that to be discovered. Florida is seeing the U.K. variant more than anywhere else, but we are seeing an easing in our positivity and hospitalizations.

For rapid testing, we're limited by what we can get, like everyone else. Our pain point now, too, is media. We started doing all our own testing, so we no longer had send-out labs to provide us with media. We make our own and we've outstripped our capacity.

What is the vaccination rate for laboratory staff?
Tony Bull (AdventHealth): All lab employees have had the opportunity and we're around 80 percent vaccinated.


Dr. Bennett

Sterling Bennett, please tell us about Salt Lake City.
Sterling Bennett, MD, MS, medical director, Intermountain Healthcare central laboratory, Salt Lake City: We saw a surge in cases after Christmas, but since that time our number of tests and number of positives have dropped to October levels. Our positivity rate on a seven-day moving average is now under 15 percent; it was pushing 30 percent at the first of the year. We know the U.K. variant is in Utah. Our state lab is doing sequencing on a limited number of samples. We provided a sample from a case in December that turned out to be the U.K. variant. There are now three documented cases in the state. Whether it's lurking out there and going to come roaring up soon is unknown. Wouldn't surprise us.

Do you share Stan's prediction that we're going to see a resurgence due to the variant taking root?
Dr. Bennett (Intermountain): There's a high likelihood of that.

Heather Dawson, I hope you're going to tell us that there's a silver lining in that you haven't been struggling with flu in Minneapolis at a time when you would have been.
Heather Dawson, VP of laboratory services, Allina Health, Minneapolis (now with Philips): No, we are not struggling with the flu. We've had so little of it that we had to check to make sure we were right.

Our positivity rate and testing volumes continue to drop. We've had a lot of antibody conversations but not a significant increase in testing. Dr. [Lauren] Anthony [system lab medical director] did a fantastic job helping our clinicians understand the different test types and the clinical utility or not of such an endeavor.

We're about 60 percent vaccinated in the lab. We take a hit every time day two rolls around with a number of people who are out because the immune response can be intense.

Lauren Anthony, MD, system laboratory medical director, Allina Health, Minneapolis: Yes, we've been trying to educate our physicians about monitoring for vaccine response. There is no recommendation at this point, and no value of titer. So we are navigating that and trying to educate physicians on the difference between antibodies to the nucleocapsid and the spike protein. We perform the nucleocapsid protein antibody assay on Architect. The spike assay we would send out, and we deliberately chose a test with qualitative reporting because we don't want to get into semiquantitative numbers. Numerical results aren't actionable at this point and would just create confusion if we decided to bring different spike antibody tests in-house. There are multiple add-on studies to the vaccine trials in progress to define titers that would have clinical decision points after vaccination. But at this point we're just trying to manage that.

Dr. Anthony

There's not a large demand for antibody testing, but there were tons of questions, and we needed to get the education out there about when to order which test and what would be the appropriate indications. We've leveraged our electronic medical record system to give them just-in-time education when they order a test. They're getting pop-ups and alerts and having to answer order questions, and it's deserved in this situation so we have clinical support to have all those interruptive alerts.

My biggest frustration is that in the media there is no distinction between testing people who are in a high-risk situation who could have an adverse outcome if they have undiagnosed COVID versus surveillance testing for people who just want to know or are planning to travel and aren't going into a super high-risk situation like a surgery. There's confusion about what the purpose is of the testing or who it's appropriate for, and the various risk stratifications for the levels of testing—the least sensitive tests for the lowest-risk situations and the most sensitive tests for the highest-risk situations. We're in a hospital where people with COVID and people with vulnerable conditions and people at high risk of bad outcomes are gathering. And we have to protect the integrity of the health care system, and it's important to have the best test when they enter our environment. Now we have the capacity to say they must have those tests at Allina so we can be sure of their status when they enter our hospitals.

Dr. Otter

Johan Otter, can you comment on how things are going at Scripps?

Johan Otter, DPT, assistant VP, Scripps Health, San Diego: It's been interesting being as close to the border as we are. One of our hospitals, in the South Bay area, until about 10 days ago was still running a more than 30 percent

positivity rate. Our ICUs last week were at 118 percent, and you wonder how that's possible. It's because we open other beds and get them temporary licenses as ICUs.

From a testing perspective, we report twice a week and we can see what's going to happen next. When we see a high outpatient positivity rate come through, we know it's going to hit the hospitals the next week, and then the ICUs. But in the last week and a half we dropped. We're down at seven percent overall now. Our outpatient is way down. We send about 120 positive samples for sequencing to the Scripps Research Institute weekly. From our side, we've not seen variants yet, but we have them in San Diego. We've had a couple of people who tested positive after both vaccine shots, and that makes the providers think it's the variant. We have to do a lot of education daily that you can still get COVID even after full vaccination.

What has it been like trying to get lab staff vaccinated?
Dr. Otter (Scripps): We couldn't line up fast enough. I don't know of even one employee who has refused the vaccine at this point.

Joe Baker, let's hear from you.
Joseph Baker, VP of laboratory, Baylor Scott & White Health, Dallas: As a system we're at about 60 percent having been vaccinated, with about 82 percent of our physicians having been vaccinated.

Our main problem as a system is on the staffing side. We're struggling to find staffing—phlebotomists and technologists. We've had to use agency staffing for the first time on the phlebotomy side. We're looking into market assessments for MTs, MLTs, and phlebotomists.

We're losing staff to agencies; they're going out to do traveling so they can get better hours, better pay, whatever it may be. Some folks are just leaving the profession. Some are retiring probably a little sooner than planned. We're investigating if we need to look at retention bonuses in key sites.

Retention bonuses have been used by many of the Compass Group members in the past few years. We have a fundamental shortage that the pandemic is exacerbating.
Joe Baker (Baylor Scott & White): It is. We worry about the health of our team because without them, nothing else functions. Team members are getting burned out and there's only so much we can do to recognize them and try to lessen the stress, but we're ever mindful of that.

On the testing side, we're averaging about 2,500 tests a day for our system. Five weeks ago, our positivity rate was about 28 percent, and now we're at about 15 and a half percent.


Dr. Dysert

What is the antibody test demand like?
Peter Dysert, MD, chief, Department of Pathology, Baylor Scott & White Health: Not much test demand, but we have a lot of interest in using it in some of what we'll call our strategic patient populations, our transplant and cancer patients, to study their response to vaccine, to develop clinical protocols that line up with those particular patients as we follow them after they're vaccinated. We're in the process of finalizing research protocols mainly in that domain. We have a lab-developed antibody test that has nucleocapsid; it also has total spike S1, S2, and RBD. We're proposing to follow those vaccinated immunocompromised patients. That's where the major interest is now. On the clinical side, there isn't much demand for antibody testing.

We're sending about 20 samples a day out of our facility, randomly chosen, to our state lab for sequencing, for

surveillance purposes. We've had a couple of specific requests for patients who clinically look like they might have become reinfected, or we had a test result called into question.

We have two assays in-house that have the spike antibody in them—one is an LDT using Thermo Fisher and the other is the BioFire assay. So we have the ability, like some of you, to look for a spike dropout as an indirect assessment for those variants. We've been retesting the questionable samples on our Thermo Fisher LDT.

A question for the group: Are your organizations considering, or do you think they will consider, vaccination status as a deferral for requiring RT-PCR as part of preprocedural testing, and, second, vaccination status allowing the organization to get back to face-to-face meetings?

Stan Schofield (MaineHealth): Face-to-face meetings are still not allowed even with vaccination, and there is no procedural exclusion of PCR testing because you've been vaccinated. So there is no immunity passport today based on COVID vaccination.

Dr. Dysert (Baylor Scott & White): We're in the same position.

We would also like to figure out a way to get a version of the South African variant that we could add to that multi-target assay and just follow the individual vaccine response relative to what we can quantitate or semiquantitate. The target we have now was built against the original and dominant strain of COVID. We're interested in following a group of individual patients to see, given the same vaccine, if their relative coverage of the South African variant is the same or significantly different. Does anybody know a vendor that could provide such a target?

Stan Schofield (MaineHealth): The sources and availability of information from South Africa are limited. The country is shut down and almost incapable of functioning because of this. It's going to be a while before we get any real scientific and commercial exchange, to start building these kinds of products. I don't think anybody has it except maybe the World Health Organization and a couple of other highly esoteric groups at the moment. The CDC probably has it, but I don't know that they're going to share it.

Dr. Quigley

If no one else has a different answer to Peter's question, I'll move on and ask Mike Quigley at Scripps to comment on any of our topics today.

Michael Quigley, MD, medical director, Scripps Health core laboratory, San Diego: My comment is related to the variants. The populations most of interest are likely to be those that have developed COVID after vaccination, those who have reinfections, and the chronically infected, and those are the ones to watch for the new variants. Do you do searches of your EMRs to try to identify those patients? Is there a plan or program in your public health system to look at those?

Dr. Crawford (Northwell): The current New York State Department of Health approach is for hospital-based laboratories around the state to send positive PCR samples of Ct counts less than 30, and that's not too far off from the CDC's request to send positive samples with Ct counts less than 28.

There's an interesting wrinkle to that because if your workhorse machine is the TMA Hologic Panther, it doesn't generate a Ct count. The GenMark cartridge, which is one of our two platforms for in-hospital near-patient testing, also buries its data deep inside its electronic brain. So it's only the Cepheid cartridge that spits out a Ct test, but that is at least satisfying our need to send off samples to the state. That doesn't constitute targeted populations. So in response to my question in a New York State call earlier today about what we are looking for—is surveillance

good enough?—at least for today, the goal is to identify variant entry into the state early, so it can be tracer confined.

That makes me uneasy because we proved to ourselves a year ago that the virus may already have outpaced our testing strategies. That's why John Tomaszewski [MD, University of Buffalo] and I are riffing on the possibility of hyper agile multiplex PCR to identify S dropout and/or known sequence variants. You want to design your hyper agile LDTs to have clinically licensed lab surveillance done by labs like ours, uplinking to the sequence competent public-health–oriented labs.

That's the conversation we'll be having in a state call later today—whether we could bring back to the state as a regional response a hyper agile hybrid of surveillance non-CLIA or just public health, or some combination of sequencing with clinically competent labs out in the field, targeting patients. But the corollary question is, should we be targeting cases of interest? The danger of skewing sequencing prioritization of "patients of interest"—however accurately or not—is that the public health data is then skewed. I'm not smart enough yet to get my head around that. But if there's either lab data or clinical data to identify patients of interest, for variant sequences, then there may be medical reason for obtaining sequence information. To date there is insufficient evidence for identifying SARS-CoV-2 variants on the basis of proxy patient data.

Mirkes

I'll be interested to see how this develops in the state. Linda Mirkes, would you like to comment?
Linda Mirkes, MBA, MT(ASCP), assistant VP, core laboratory and integration, Atrium Health, Charlotte, NC: Our experience is similar to that of others in that we were seeing a demand for up to 4,000 tests per day and we're down now to closer to 2,000. We're able to perform 1,500 tests per day in-house.

Our positivity rate was in the mid- to high 20s, and we're now down to around 12 percent. Staffing continues to be a challenge in Charlotte—phlebotomy staff and techs are in short supply. We're exploring bringing in resources from other countries.

Judy Lyzak, the last time we spoke you were worried about supply chain. How are things faring there?
Judy Lyzak, MD, MBA, VP of medical affairs, Alverno Laboratories, Indiana and Illinois: Things have settled down nicely. We're doing well with our ID Now kits. We have them moved out into all of our family practice network offices, and they now procure their own kits independent of the laboratory.

I am one of the vaccine ambassadors for the laboratory. It's a remarkably clinical role for a pathologist to be in. I get daily emails from lab staff with questions or concerns. It's concerning to me that there is still residual politicization of vaccination and concerns expressed around that, some of which are more reasonable, such as those of our patient-facing phlebotomists, who are also often of reproductive age. They have a lot of concerns. Misinformation circulated on social media about impact on fertility. We're trying to talk staff members through that—what are the realistic concerns about fertility, about breastfeeding. They always have an ear and we can connect them with our ID experts so that they have multiple sources of opinion, and we can help them make an informed decision. Even if they decide against vaccination temporarily, we're giving them as much information as they need to make a good decision.

John Waugh, tell me about your experience with getting adequate vaccinations for lab staff and lab staff's attitude toward getting vaccinated.
John Waugh, MS, MT(ASCP), system VP, pathology and laboratory medicine, Henry Ford Health System, Detroit:

We've had a good response to the vaccine. We had reluctance initially and had to address it organizationally.

Our testing is down substantially. We're probably under 1,500 tests per day in the past several days. And there is no draw for antibody testing at this time.

Do you think the variants will be the next big story?
John Waugh (Henry Ford): We're living in an interesting time, aren't we? Every week there's some new thing out there. I've been telling our people worry is a growth business. With the prevalence of the U.K. origin, the spike dropout in those areas, I think there's concern. And I'm not sure that people are accepting of the fact that the current testing and the current vaccines will be unaffected by these mutations. That's just my gut. They've heard a lot of things that have turned around in the last year.