

Calm before spring storm? Compass on COVID

GROUP'S MEMBERS CONSIDER VARIANT SIGNIFICANCE, STRATEGY

April 2021—Test volumes and positivity rates were down and vaccinations and interest in variants were up on March 2 when Compass Group laboratory leaders met with CAP TODAY publisher Bob McGonnagle for another in a series of calls about SARS-CoV-2.

Also in the discussion: antigen and serologic testing, school and sports team testing, and testing for travel. Pre-procedure testing, too: "That's a new struggle in trying to figure out how we can keep everybody happy," said Janet Durham, MD, of ACL Laboratories and president, Great Lakes Pathologists, West Allis, Wis.

With McGonnagle and Dr. Durham were Judith Lyzak, MD, MBA, Alverno; Modena Henderson, MHA, MT(ASCP), Atrium Health; Dan Ingemansen, Sanford; James Crawford, MD, PhD, Northwell; Michael Quigley, MD, Scripps; Walter Henricks, MD, Cleveland Clinic; Sterling Bennett, MD, MS, Intermountain; Tony Bull, AdventHealth; Clark Day, Indiana University Health; Steven Carroll, MD, PhD, Medical University of South Carolina; Mike Black, MBA, MT(ASCP), DLM, Avera; Lauren Anthony, MD, Allina; Diana Kremitske, MS, MHA, MT(ASCP), Geisinger; and Stan Schofield, MaineHealth.

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's what they shared in March.

The first thing I will ask for is a reaction to the title for today's conversation: "COVID's March Anniversary—No Longer a Wolf but Not Yet a Lamb." How apt is that title at this time?

Judy Lyzak, MD, MBA, VP of medical affairs, Alverno Laboratories, Indiana and Illinois: The decline in positivity rates, hospitalizations, and deaths is encouraging. And yet a note of caution and a bit of prudence would be wise given the warnings we're hearing from the CDC director about the plateau in the decline, the small bump they have seen, and the worrying circulating variants.

In my organization we are concerned about a surge in April and spring break. That age group has not been vaccinated nor are they eligible to be vaccinated.



Dr. Lyzak

What's going on now in your lab, Judy, as regards testing and positivity rates?

Dr. Lyzak (Alverno): We have capacity to do 4,000 to 5,000 tests a day and our volume now is about 1,300 a day. We've been fortunate to see a decline in the positivity rate, and we separate our preprocedure asymptomatic population from our symptomatic population. Our symptomatic population on average across our 26 hospitals is down to about seven percent to a high of 10 percent, which is great compared with what we saw in the fall and winter. Our asymptomatic rate on March 1 was 0.5 percent. There was a collective shout of joy from all of our ID physicians.



Henderson

Modena Henderson, how do you see the current environment in your laboratories across Atrium Health?

Modena Henderson, MHA, MT(ASCP), VP of laboratory services, Atrium Health, Charlotte, NC: Thankfully, we're seeing a decrease in test volumes and in positivity rates across the communities we are privileged to serve. At this time we're optimistic that the more than 250,000 doses of the vaccine we have administered at our many vaccination events are having a great impact, and we continue to monitor for a possible surge in the March-April time frame because of the variants.

Dan Ingemansen, have your positivity rates and test demand continued to fall?

Dan Ingemansen, senior director, laboratory, Sanford Health, Sioux Falls, SD: Our positivity rate across our system has decreased. We're running about 11 percent now. We've continued to see volumes sharply decrease since Thanksgiving, but they remain at about 1,000 tests a day in our health system.

Jim Crawford, are you getting a lot of demand for variant testing, and are you seeking answers to do that?

James Crawford, MD, PhD, professor and chair, Department of Pathology and Laboratory Medicine, and senior VP of laboratory services, Northwell Health, New York: Demand is an interesting word because demand suggests it's coming from the providers. I've spent a good portion of the past month trying to understand what the New York State region and New York City approach and strategies are for variant testing. And my brief version after countless conversations is that New York City is working with New York City Health & Hospitals for coordination and—through the NYC Economic Development Corporation—with the Manhattan-based Pandemic Response Lab, PRL, to provide public health data for detecting variants. In turn, the state public health laboratory, the Wadsworth Center, has achieved its target of 600 genomes sequenced per week based on hospital and other laboratories around the state sending them samples with Ct counts of less than 30. The sampling the state does is on the basis of geographic diversity using zip codes as a guide.

The remainder of variant testing in New York State is through the university community, which is providing key regional information because a lot of variants are identified by such university-based laboratories as Columbia and Cornell. But what I'm going to pressure test in the 4 PM meeting of the New York State SARS-CoV-2 Testing Consortium, which I moderate, is the question: Is it true that the university-based variant testing is funded either by repurposed or other extramural funding from NIH and/or commitments from institutional funding?

Every time I've asked the question so far, the answer is yes, the university is funding it themselves or repurposing other research funding. Yet I can't help but conclude from publicly available information that a substantial portion of the information we are getting regionally as well as nationally is from university labs.

So the question I remain with, four weeks from our last conversation, is how does this roll up to a national strategy? Is it true that every state is taking its own approach? California with UCSD, Michigan with Michigan State and the University of Michigan, New York with the Wadsworth Center laboratory, New York City with PRL, and the university labs are operating independently but staying in touch through the reporting systems for their state? And how many other 47 different versions do we have of variant reporting partially subsumed by the CDC's feeding of samples to LabCorp?

This is reminiscent of what we were going through a year ago when we didn't have a good broad-based strategy for the labs. Mike Quigley, what do you think about this variant situation as it relates to Scripps?

Michael Quigley, MD, medical director, Scripps Health core laboratory, San Diego: I agree completely about the lack of a federal, central strategy for variant testing. So basically it's the same story as a year ago. It's unfortunate, but it's something we have to live with and have to figure out locally. In San Diego, the county is working with health care systems and sequencing partners. The goal for the region is to test 20 percent of the positives for variants; overall they are running about 17 percent now.

Walter Henricks, MD, vice chair, Pathology and Laboratory Medicine Institute, and laboratory director, Cleveland Clinic: Our state health department is aiming to partner with us, with The Ohio State University, and with two other labs to obtain sequencing information. And we have done some sequencing at Cleveland Clinic on a research basis and we're looking to expand that out, for public health purposes, not for patient reporting.

To my knowledge, no one is reporting for clinical decision-making, nor have we had significant demand for variant sequencing for clinical decision-making. We've received questions about whether our nonsequencing tests will detect cases with the variant, and they do. We've also been asked, can you tell us if a given patient has the variant? The answer is not at this time.



Dr. Henricks

Do you, like others, lament the fact that there doesn't seem to be a national coordinated strategy on the variant testing?

Dr. Henricks (Cleveland Clinic): If we knew it was tied to an immediate patient care need, I'd be more concerned. We do need tests, and variant testing is important for public health and research purposes. I don't know that a national strategy by itself is going to put tests that can identify the variants quickly into clinical labs in a way that is relevant for patient care decisions. There are other reasons a national testing strategy would be helpful, as have been described.

Sterling Bennett, let's hear from you on this topic.

Sterling Bennett, MD, MS, medical director, Intermountain Healthcare central laboratory, Salt Lake City: Things are better here, and the Intermountain experience is the same as that of the others. With variant testing we're seeing the same pattern we've seen with many other things COVID-related: We wouldn't know yet what to do with the results even if we had them.

Our state has told us that it has a shortage of pipette tips for its sequencing methods and it has turned around a lot fewer genomes than we anticipated. We know there is a variety of variants in the state, but we don't have any real sense of frequency. With the rates falling, we're uncertain about the significance.

So within your system, the infectious disease physicians and other clinicians are not yet a source of demand for test results on patients for the SARS-CoV-2 variants?

Dr. Bennett (Intermountain): They would love to see testing for variants, but they're not beating down our doors and demanding that we have the testing available. They're not going to bat with our system executives saying we must have high-throughput sequencing capabilities so we know what's going on in terms of variants. We're not seeing that level of demand, but there is interest.

We're exploring Thermo Fisher's primers for some of the mutations and trying to get that in and at least take a look to see if it provides useful information to us about the number of variants. The reason we're looking at a PCR option is that we don't think we're going to get the timeliness or the number of sequencing tests done by the state that we wish we could.



Bull

Tony Bull, what is your situation in Florida?

Tony Bull, executive director, AdventHealth, Orlando, Fla.: We're seeing an easing of demand for testing and an easing of the number of hospitalizations. We're proceeding cautiously in light of the variants in Florida and spring break visitors.

We're sharing samples with some manufacturers to help make sure tests are accurate for variants. We're also working with the Florida Department of Health and providing them with specimens. There's a focus with the state on patients who are PCR positive 14 days after a second vaccine. We hope to understand if these are variants or patients for whom the vaccine was not effective.

Clark Day, what's going on at Indianapolis, particularly with regard to variant testing?

Clark Day, VP of system laboratory services, Indiana University Health: We were asked to incorporate variant testing into the positives we might detect in the course of testing for the NCAA tournament of 68 teams. We are partnering with a separate entity to perform testing for variants on any positives we might detect over the course of the tournament.

Our weekly testing volume has been down lately by as much as 20 to 30 percent. The capacity we gained is allowing us to perform the testing for this national tournament without affecting care for our own patients.



Dr. Carroll

Steven Carroll, what's going on in South Carolina?

Steven Carroll, MD, PhD, chair, Department of Pathology and Laboratory Medicine, Medical University of South Carolina: We're seeing declines in viral infection rates and testing. We started sequencing genomes; so far we've identified only the South African variant, but it's something we're devoting resources to because of the public health implications. We've been working in partnership with our public health lab and reporting the data to them because there is worry that we're going to have some of the more rapidly spreading variants put the brakes on our decline.

There is also discussion, and it's come up several times, about whether we need to look at wastewater out of some communities as a means of monitoring. We have not gone there yet; we've been mainly looking at individual genomes.

We have individuals who have been vaccinated but still become infected with COVID, so we're sequencing their variants to see if known mutations or new mutations might be accounting for why the vaccine was not effective in them.

Do you think this could be a looming problem?

Dr. Carroll (MUSC): It's something we're worried about and that's why we're taking a closer look at those individuals. The Johnson & Johnson vaccine has a lesser effectiveness than the other vaccines, so it is something

we're going to pay attention to. We don't have solid data to say that's the case yet, but we have those cases collected and are starting to take a look. There could be other explanations.



Black

Mike Black, what's your experience?

Mike Black, MBA, MT(ASCP), DLM, assistant VP, laboratory services, and laboratory service line administrator, Avera Health, Sioux Falls, SD: We have seen decreases in percent positivity and test ordering, which has increased our testing abilities by PCR. We are monitoring the variants and continue to send random positives to the South Dakota health lab for confirmatory variant testing.

Our vaccination statistics are good, and the turnout for vaccinations in South Dakota has been good, too. Is that what you're seeing, Dan?

Dan Ingemansen (Sanford): Yes. Our mutual state of South Dakota is predominantly served by two health systems, and we have connections to all of the rural communities and a responsibility to provide those vaccinations. Having two large health systems that are rural explains why we are where we are with vaccinations. Would you agree, Mike?

Mike Black (Avera): Absolutely. Our health systems work closely and that has been part of the success as we've moved forward in South Dakota. It's a good relationship.

Lauren Anthony, what can you tell us?

Lauren Anthony, MD, system laboratory medical director, Allina Health, Minneapolis: The incidence in our asymptomatic population is below one percent, and even in our symptomatic population it's low. On average everything is below five percent. There have been infections post-vaccine.

We have had queries about variants. The ICU physicians were seeing a spike in mortality and were concerned if they were dealing with a variant. The state worked with them. The state is sequencing about 10 percent of positives.

Diana Kremitske, Geisinger is a huge system. Is the COVID news there good news?

Diana Kremitske, MS, MHA, MT(ASCP), VP, Diagnostic Medicine Institute, Geisinger, Danville, Pa.: Our story is similar to everybody else's story. In addition, we're not doing any sequencing for variant testing but we have been asked what's causing individuals to become sick post-vaccine. Our microbiologist experts are going to be discussing with our infectious disease experts what the game plan is in those circumstances.

I'd like to turn the conversation a bit to, what's the next chapter to support our communities? College and university athletic teams in our surrounding areas are requesting help with their surveillance testing. We are exploring how to provide not only the on-site immediate testing for officials who show up for games but also for the sports team. We're having conversations about how to help a minor league team in the area with testing, though nothing is settled yet. We're fortunate because our organization has the medical contract with some of these organizations.

We've also been asked to provide CLIA directorship for one of their student health centers that is providing COVID testing. This is for a small, local private community college, just to get our toes in the water to see how it goes. We're early on in that process and I'd be more than happy to report back.



Ingemansen

Labs are looking at a new line of business as schools and leagues reopen. It sounds like an important opportunity to serve your communities. Is anyone else getting involved with the local sports scene regarding the need for testing?

Dan Ingemansen (Sanford): We were contacted early and we developed mobile laboratory trucks and have three different units that have been following the PGA Tour, the Korn Ferry Tour, which is developmental, and the PGA Tour Champions. This weekend we'll be in Atlanta testing for the NBA All-Star Game.

It's been interesting, but it's like having a whole other service line. It takes another mindset and skill set. And it takes one dedicated person just to work through all the regulatory hurdles because we're testing in different states with different regulations. We've had to have on-site inspections before we could start testing.

Tony Bull (AdventHealth): We did PCR testing at the Daytona Speedway Rolex 24 race. It was difficult because all the drivers were from other countries so there was a language barrier. To fly into Amsterdam, they also had to have an antigen test that had to be done no more than four hours before their flight departed. We had tested them at the Speedway and then we have a storefront testing site at the Orlando airport. Those same patients showed up a day or two later to be tested again in order to get on their flight. That was an eye-opener.



Kremitske

Would anyone like to comment on how antigen testing is being used or will be used?

Diana Kremitske (Geisinger): We are going to institute antigen testing for travel purposes and make this service accessible to the community. We're going to pilot test it in a couple of easily accessible outpatient phlebotomy sites. So these will be mid-turbinate swab, self-collected. It's not going to be a point-of-care test; those specimens will come to the laboratory for testing.

Dr. Crawford (Northwell): The Department of HHS has put out an RFI for expanding the national testing capacity to 25 million per month for the purposes of opening up K-8 schools. And they're being agnostic in their messaging so far about whether it's PCR or antigen based. That's a story worth paying attention to. HHS is asking for four regional coordinating hubs that will work with up to 40 regional laboratories, including university laboratories. I think the expectation is that it will be the big box labs that do something. But the question is, who's going to be coordinator and devote their life to K-8, which is not something that is in our current job descriptions, and then who is going to provide the actual testing? HHS is saying: Use the existing leveraged capacity, with the expectation that it's not going to hurt the supply chain, which is an interesting way of thinking about it. This federal discussion is something we should keep our eye on, including the fact that the February 17 HHS press release said this \$650 million program for K-8 school testing is just a down payment on further COVID testing funding.

With regard to travel, my understanding now is you need to have a PCR test result before you step into the airplane gate. Maybe not, but I do wonder if antigen testing is going to pass muster for air travel.

It reminds me of what we talked about in prior calls: Why is there no pathologist on these important

national committees and panels that are determining such things?

Dr. Crawford (Northwell): An answer I've gotten is that these committees are civic servants only, not public/private. The private is only advisory.

Any additional comments on antigen testing?

Janet Durham, MD, medical director, Wisconsin operations, ACL Laboratories, and president, Great Lakes Pathologists, West Allis, Wis.: We have been using the antigen testing at our urgent care centers because of the EUA for the patients having to be symptomatic; that's the location where we've had success with those.

Interestingly, this past week we had an increase in testing the first time since January 3; it went up 5.8 percent. But the volume of positives is going down.

The struggle now for us is in pre-procedure testing: The gastroenterologists would like to have that PCR testing rapidly, instead of in the 24- to 72-hour window prior to the procedure. It's because patients don't want to take time off from work. The scheduling for those procedures is heavy on Mondays, with some on Tuesdays, and then it plummets until the end of the week because people don't want to take those extra days off. But we don't have enough reagent to be able to do all of that rapid. We have that capacity for PCR but not rapid. So that's a new struggle in trying to figure out how we can keep everybody happy.

There has been discussion about variant testing, but our understanding is that it's not our role to do the sequencing. It's done by the state. Everyone is happy with that for now.

Where are we standing with antibody testing? It's been waiting in the wings patiently and for a long time, but is it now getting a certain updraft in your system?

Dr. Durham (ACL): We wanted to make sure when the vaccines rolled out that clinicians and everyone else understood the difference in antibody testing—that the antibody test we had available was for the nucleocapsid, not the spike, protein, so don't do that test if you're looking for vaccine purposes if the patient has antibodies. Our first line of business was to make sure everyone was aware of that. The scientists were not suggesting a check on vaccine status. But people are eager to learn that, and that is likely where we're headed. Maybe that's going to be what airlines, for example, are going to be using to check if a person is immune. We are getting ready for that so we'll be able to offer both types of testing. We are waiting for some of the vendors to get their formal approval, but we're doing validation now to be prepared.

Diana Kremitske, are you at Geisinger also preparing for an onslaught of serology testing?

Diana Kremitske (Geisinger): We are not. The serology testing has been incredibly low volume. It did not take off. Clinically we don't know what to do with that information.

Does anyone else have an opinion on or a recent experience with serology testing?

Dr. Crawford (Northwell): For the purposes of the health worker survey last spring, we stood up a capacity of 10,000 tests per day, which we consumed over a period of weeks, to go through about 50,000 Northwell health care workers. And our volume has stayed in about the 2,500 to 3,000 per day range ever since. That's a lot of testing. Our seropositivity rates, which were over the summer consistently in the 17 to 18 percent range, are now comfortably in the 31 to 33 percent range. It's a nonrandom sample because it's provider ordered. But I've asked our ambulatory leadership, what are you doing with all these tests? The answer: for patients who are more complicated. It might be those who are immunosuppressed or have cancer or autoimmune diseases, trying to get a sense of where their antibody levels might be before and after vaccination.

There's a sense that from a medical standpoint, and this is without an evidence base, at least here in our New York region, that serological data may help inform the discussion about whether a patient may be susceptible to further infection by COVID-19. Noting who becomes PCR positive 14 or more days after a vaccine in these immunocompromised patients is of high interest now. It's also a starting point for discussions about getting PCR Ct values for these complicated patients.

So the discussions are evolving without a clear evidence base to guide them, but the drumbeat of serologic test

orders remains. To me, the saving grace is that from a strategic standpoint, the NCI stood up a national consortium to explore the seroscience of COVID, and Northwell is one of the member institutions. I'm hoping over the course of the next year or three we will build the evidence base for what serologic testing means in the vaccination age.



Schofield

Stan Schofield, let's hear from you about antibody or other testing at NorDx.

Stan Schofield, president, NorDx, and senior VP, MaineHealth: There's been little interest or uptake. We've offered it since June 1 and we've had about 600 test results. We're looking into the quantification assay from Roche to see if it's going to be of value either for travel or vaccination validations. That's all that's happening at the moment.

As far as sequencing goes, the state is doing it. We're sending 100 positive random samples for the state's sequencing program, as well as post-vaccine 14-day cases. We're doing nothing other than what everyone else has reported.

Maine has a lot of summer camps, and we're contracting with them for their summer testing this year. □