Solving problems, restricting orders: Compass on COVID

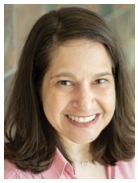
December 2020—*The Compass Group reconvenes to share the latest on SARS-CoV-2 testing—this time on Oct. 6 and again by Zoom. What they said about supplies, labor, and flu follows. Serology testing too: "It's the one test we have loads of and the one test they don't use a lot of," said Heather Dawson of Allina Health in Minneapolis.*

CAP TODAY publisher Bob McGonnagle led the roundtable. With Dawson were Walter Henricks, MD, of Cleveland Clinic; Jennifer Laudadio, MD, of the University of Arkansas for Medical Sciences; Joseph Baker of Baylor Scott & White; Judy Lyzak, MD, MBA, of Alverno; Susan Fuhrman, MD, of OhioHealth; Dan Ingemansen and Rochelle Odenbrett, MT(ASCP), MBA, of Sanford Health; Janet Durham, MD, of ACL Laboratories; Diana Kremitske, MS, MHA, MT(ASCP), of Geisinger; Darlene Cloutier, MSM, MT(ASCP), HP, of Baystate; Stan Schofield of NorDx; Clark Day of Indiana University Health; Tylis Chang, MD, of Northwell; and John Waugh, MS, MT(ASCP), of 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.

Wally Henricks, what is the current state of play and what's uppermost in your minds in the labs at Cleveland Clinic?
Walter Henricks, MD, medical director, Center for Pathology Informatics, Cleveland Clinic: We've ramped up capacity, we diversified our platform, we deployed Cepheid in our regional hospitals. We are not doing any antigen testing or serology testing. We are testing pre-procedure whether the patient is symptomatic or not, and we're testing all patients who are symptomatic. We're supporting community efforts with community fairs and through some of the state's pop-up testing.

What is your supply of the Cepheid tests like? I've heard from people who are finding it difficult to get all the Cepheid tests they want.
Dr. Henricks (Cleveland Clinic): Yes, we would put ourselves in that category. Our allocation fluctuates and at times it's constrained to the point that we have placed restrictions on what can be ordered.



Dr. Laudadio

Jennifer Laudadio, do you have the same supply chain problems others have experienced?
Jennifer Laudadio, MD, professor and chair, Department of Pathology, University of Arkansas for Medical Sciences College of Medicine: We don't have a problem with instruments, but we are having a hard time getting cartridges for those instruments. We have a Cepheid platform, and we're also using GenMark and the Roche 6800. None of those are being used to the capacity they could be. So we're making up the difference with a laboratory-developed test, using the CDC primers and probes, and we haven't had problems getting supplies for that.

The challenge continues to be viral transport media; we are making our own and also using sterile saline collection tubes. We had a challenge with pipette tips but not specifically COVID. It was a Roche pipette tip issue for our 4800, on which we run our CT/NGs, which used to be our highest-volume testing in the lab before COVID. Now we're having to send out 1,000 CT/NGs every month in addition to the COVID tests.

What is your lab labor situation now in Little Rock?
Dr. Laudadio (UAMS): We are sending out some of our low-volume, more complex molecular tests so that our

technologists can be dedicated to COVID testing. We brought back someone who was retired, and we have someone who used to be 50 percent now working 100 percent time. We've also created four new positions in our molecular lab.

Joe Baker, what is your situation like?

Baker

Joseph Baker, VP of laboratory, Baylor Scott & White Health, Dallas: It's no different than what everyone else is experiencing. We have a plethora of equipment in our system—Roche, Hologic, Applied BioCode, others—because we can't rely on any one vendor to meet all our testing needs. We have Cepheid and BioFire at many of our community hospitals for the pre-procedure and emergency work. We are doing antigen testing in some of our clinics. We are also using ID Now for the emergency discharges across the system. And we have a few sites that are using Luminex.

We have problems getting universal transport media. We're using the saline tubes for the vast majority of our collections at this time. But that's worrisome when we get into fall with flu testing. We're using a ticket to test paper form in many of our hospital sites to prioritize what platforms the testing is performed on. We have Roche Liats at many of our sites, but we're waiting for the combo test to get approval.

We currently have 83 openings within our system, and about 40 of those are MT and MLT positions.

Judy Lyzak, has the supply chain improved for you? Are you able to allocate tests and select patients for testing any better than in past months? Or is it still hectic every day?

Judy Lyzak, MD, MBA, VP of medical affairs, Alverno Laboratories, Indiana and Illinois: I don't know if it's any less hectic, but we're much more used to it. The supply chain for ID Now kits is slightly better. That was one of our pain points. We had put in orders for a certain number of kits and we were getting a fraction of that week after week. We had to work with our clinicians at all of our hospitals to continually remind them what the criteria were to use that method. But we got through it and the supply has evened out in the past couple of weeks, which is critical for us because we just released our flu-COVID testing algorithm. And it's very heavy for the EDs, irrespective of admission or not, on using ID Now testing to make decisions about what is the possible etiology of respiratory symptoms.

Susan Fuhrman, how are things in Columbus?

Susan Fuhrman, MD, president, CORPath, Department of Pathology and Laboratories, OhioHealth Riverside Methodist Hospital, Columbus: We are in a similar situation. We had real issues with supplies of our Abbott ID Now reagent. It was dreadfully nip and tuck, and we went into several weekends with barely enough reagent for predicted needs and all kinds of backup plans in case we ran out before the next shipment. The situation appears to have settled out.

In the meantime, we're implementing the combo flu-COVID Liat tests at many of our sites, and we're waiting for the Cepheid combo test to be FDA approved. We're going to do the combo tests on our symptomatic influenza-like illness patients, which allows us to use only one swab on these patients in our emergency rooms at most of our sites. We're going to test patients with two swabs—a flu and a COVID, using the Abbott ID Now—in the emergency rooms at our larger hospitals because of larger reagent allocations of the ID Now kits. So everyone who's symptomatic with ILI is going to get a COVID and a flu test. The algorithm for this is complicated because it depends on the site where the patient is being seen. The Liat and Cepheid require specimens in viral transport

media, and the Abbott ID Now is a dry swab, so we need to have the computer system to indicate the correct swab to collect for the order.

We're going to roll out the Abbott ID Now to all of our urgent cares to be performed on site. We couldn't do that until we knew we reliably had Abbott ID Now reagent. The urgent cares were flip-flopping—using dry nasal swabs on the Abbott until we ran low on Abbott reagent, then we had to switch them to viral transport media and do PCR. Then we had issues with the pipette tip shortages for our PCR assays and had to switch them back to the dry swabs. It's pretty much a nightmare.

What is your labor situation now?
Dr. Fuhrman (OhioHealth): We're constrained by reliable supply availability, particularly with the Abbott ID Now reagents. The ID Now used for any kind of high-volume situation requires a lot of labor, which is also in short supply.

To meet these demands, we're implementing Thermo Fisher QuantStudios in a brand-new molecular lab with automated liquid handlers and processing equipment. That's a big labor savings because we can automate some of the higher-volume testing that we're doing manually now on the Abbott ID Now. Since the Abbott ID Now can only do one specimen at a time, this constrains the total number of tests that can be performed by each tech using this testing platform in a high-volume location.

Dan Ingemansen, what's going on in South Dakota? You had a low rate and now you're almost leading the league tables.
Dan Ingemansen, senior director, laboratory, Sanford Health, Sioux Falls, SD: South Dakota has had the fewest restrictions of all the states. But just as the other Compass Group members have done, we started early and we diversified. We now have five different methods, and supplies are limited but have yet to run out. We divide our testing pathway into two categories, rapid and batch testing. For rapid testing, we, like others, are receiving Cepheid cartridges, and we are focusing those supplies to our hospitals for our inpatients and emergency patients only. Anything coming from an outpatient setting going through the hospital is not being routed to a Cepheid; we have had to supplement some of our Cepheid usage with the DiaSorin instruments. But it's not a great rapid solution because it's a 90-minute test. On the batched side, Sanford Laboratories does not have a Hologic Panther or a Roche 6800/8800. We started with a single Abbott m2000 that is exhausted—we were running it 24/7. In addition, we added a PerkinElmer solution, including a Chemagic 360 extractor, and several Applied Biosystems 7500 thermocyclers.

Our most recent investment has been two Abbott Alinitys, and we've had good luck getting the supplies to keep those analyzers humming at 600 to 800 tests per day.

Despite the diversification, we still can't keep up with the demands.

Heather Dawson, are you seeing greater clarity on or understanding of the usefulness of the serology tests?
Heather Dawson, VP of laboratory services, Allina Health, Minneapolis: We haven't spent a lot of time on the serology. It is up and running with limited usage. The clinical team on the ambulatory side put together the indications for when it would be appropriate and they adhere to their own guidelines, and we see very little of it. It's the one test we have loads of and the one test they don't use a lot of. What's different since our last call [on Sept. 1] is we now have equipment coming: We're standing up T2 Biosystems in all of our smaller community hospitals and bringing in Seegene to the central laboratory.

What is your labor situation at Allina?
Heather Dawson (Allina): It's as tight as everybody else's. A lot of people working a lot of overtime. We have about 40 openings across the system now between the ambulatory division and some of our smaller hospitals. We have a batch of students starting soon and we hope to hire them as soon as they graduate.

Janet Durham, what is your experience at ACL?

Janet Durham, MD, medical director, Wisconsin operations, ACL Laboratories, and president, Great Lakes Pathologists, West Allis, Wis.: It's similar to that of the others. Diversification is how we're staying up on the testing requirements. We have a lot of instruments for which we don't have enough reagent. We're using Hologic Panthers and Cepheid in the hospitals and ED, and we started antigen testing at urgent care facilities. Now we have some send-out tests also. But the biggest recent change is that we started pooling in the low-prevalence population on the Hologic Panthers, and that has helped the reagent shortage problem. It's been a cost savings.

Diana Kremitske, I assume your experience at Geisinger is similar, but is there a new wrinkle you can share with the group?

Kremitske

Diana Kremitske, MS, MHA, MT(ASCP), VP, Diagnostic Medicine Institute, Geisinger, Danville, Pa.: Geisinger has been involved in a regional health collaborative, which is an effort by the commonwealth to support the pandemic response in skilled-nursing facilities. Under our purview are now 229 long-term–care facilities, from skilled-nursing to assisted-living facilities to personal care homes, all of which have different degrees of required medical leadership. That has rallied the team on how we get orders, ensuring results are transmitted in a timely manner, and how authorizations are obtained to do employee testing. Our organization has been involved in many facets of the pandemic response at these facilities, including not only that work and testing but also PPE training and understanding the facility layout.

It's funded by a grant from the CARES Act that extends from July through December. The commonwealth is speaking to us and other health care facilities involved in the collaborative about the plan for support when the grant awards end.

On supplies we've been challenged using a multiplatform strategy to help mitigate these issues. We are using the Hologic Panther for its high-throughput capability and then our supplies changed to about 25 percent of what we had been getting. So we had to work with our surgical teams to see how they could rationalize better pre-procedure testing utilization, carefully considering the rate of positivity observed in the presurgical testing population so we would have the capacity for the nursing homes, other symptomatic testing, and specific requests for surveillance testing in the community.

Darlene Cloutier, how do things stand in western Massachusetts?
Darlene Cloutier, MSM, MT(ASCP), HP, director of laboratory operations, Baystate Health, Springfield, Mass.: We have three different platforms running now, one of which is Cepheid for which we are beginning to see an expanded allocation of reagent, which is great. Just this morning we had only 18 tests left in the lab before a shipment arrived, and those 18 remained only because we had backed off rapid testing earlier when we knew we were going to run out.

We have two other platforms: Roche 6800 and Hologic Panther. The most consistent supply chain has been from Roche. We use the Panther to back up our 6800.

In terms of staffing, we've done a lot of cross-training. Everyone has been terrific, but burnout is setting in.

Stan Schofield, manufacturers said that if they have to crank up flu tests in manufacturing, they won't be able to meet both the COVID demand and the flu demand. Can you speak to that?
Stan Schofield, president, NorDx, and senior VP, MaineHealth: We at NorDx are working on a lab-developed flu-COVID assay. All the big manufacturers I've talked to are going to a combo multiplex. It will be hard to get single

flu, single COVID molecular assays after the next 30 days. We started buying flu Liat kits in June in anticipation of difficulty, and they stopped manufacturing those in early August. The shipment of Liat cartridges that arrived today are a combo, and for 11 hospitals I get 200 cartridges a week.

Everybody is worried about flu. The ambulatory settings are trying to figure out how we're going to do a flu combo with COVID. We tell them there's no antigen test that we support that will work that way. We've had false-negatives with it. So everything we're doing as of about November 1 will be an automatic flu-COVID combination. Rarely will you be able to get a single flu. Until we run out of the flu cartridges, we might be able to do it, and when we do the combo LDT we will still have single flu LDT, but it won't be the high rapid priority that a combo with COVID requires for a patient who's symptomatic.

As far as instrumentation, we went with open channel and it seems to have been our savior because we're a low priority state and we're doing 1,896 tests today. Getting 200 from Roche a day with the 6800 wouldn't cut it. So our LDT has been our destiny and it's hard to source, but we've stabilized on our supply chain. We're stockpiling—every conference room and spare cubicle in the administrator area has supplies stacked in it. We've been going outside normal channels—buying directly from Europe, from South Korea. But it's not anywhere near normal ease of use or ease of business. It's all stressful, it's all out of the box. But it has served us well.

Clark Day, how are things similar or different at IU Health? And do you have any experience with serology testing?

Day

Clark Day, VP of system laboratory services, Indiana University Health: It is similar for us, but we're doing fine. We are launching pooling today—our first experience with it. A little trepidation on the pathology side but we're doing it for our pre-procedural patients only—about 1,800 patients a week.

We too are preparing for flu season with a lot of unknowns. We're protecting our Roche supply of the PCR-based tests by telling them we want to stay on the single PCR test, not their combo kit. We will launch the combo on Cepheid when it's available. We also have the Liats regionally in our regional hospitals for combo testing.

We are launching antigen testing, too, on a Sofia platform. We're going to launch that initially for asymptomatic patients before admission to a double-occupancy room as well as our team members who have incurred a high-risk exposure. We will also test our phlebotomy team members who are going into skilled-nursing facilities, for sequential or repeated testing.

There was a sense of urgency for serology testing in late summer. I was tasked with building as much capacity as possible for it. We were telling Beckman we may need 30,000, 50,000 tests a day. When we launched we struggled to get to five ordered tests a day. Nobody is ordering it. We're not using it, and it's off of my radar now.

Has anyone had a different experience with serology testing?

Dr. Lyzak (Alverno): We've had interest from a niche area in our organization, behavioral health, where we've struggled with how to deal with patients in our EDs who suffer from psychotic breaks. We've had patients who are psychotic and COVID positive—a horrible combination of circumstances. We're going to combine our ID Now capabilities with an IgM assay, which we will have on our Beckman Access in the hospital. If either one of those methods is positive, they're going to be considered COVID positive. That seems to be the most readily identifiable and somewhat niche indication for that particular test. The IgG otherwise is, as was said, kind of ho-hum—volumes aren't large. But we may see it pick up with more talk of reinfection.

Rochelle Odenbrett, MT(ASCP), MBA, senior executive director of laboratories, Sanford Health, Sioux Falls, SD: A research branch of our health care organization launched a study using antibody testing on health care workers. We're testing 3,000 to 4,000 of our front-line staff and we're redrawing them every 30 to 60 days. So we do get a good number of antibody tests coming into our reference laboratory daily, primarily for that study.

Tylis Chang, what is the current state of play at Northwell?
Tylis Chang, MD, CMIO and vice chair of pathology and laboratory medicine, Northwell Health: We are up to 11 validated different platforms across our core lab and our hospitals. The primary platform is Hologic but we also have Roche and Abbott. The supply chain has been an enormous challenge. We've spent a lot of time educating our C-suite about the fact that the PPE supply chain seems to have improved while on our side it's been the challenge everyone else is experiencing. GenMark has been our most reliable supplier at the hospital level.

We're using our Abbott ID Nows in a focused way because of the supply chain issue. We're using them in two major scenarios. The biggest scenario is our partner in the urgent care space for low clinical suspicion cases. We did a correlation. We used Hologic as our primary screening platform and we pooled 20 positives out of our core lab, which we know are primarily asymptomatic outpatient screenings. And we were thrilled to discover that 19 of the 20 correlated. We feared that in that patient population the correlation would be much worse.

We brought serology testing up early when we were uncertain about the supply chain. Seven different assays, none of them lateral flow. We were gratified when we first validated it. The validation I initially did was on employees or patients who were not hospitalized. The clinical sensitivity in PCR-positive validated individuals was blended around 94 percent. Some assays are a little better, some a little worse. But there appears to be a robust five percent who were seronegative.

We went back to revisit the employees who were positive initially, again by a mix of platforms. Not only is there a drop in seropositivity, which we expected, but also there's a difference among the vendors. What appeared to be good beforehand isn't now, though the data are preliminary.

John Waugh, do you expect the serology testing to pay off sometime next year as a potential solution to some of the testing dilemmas we face?
John Waugh, MS, MT(ASCP), system VP, pathology and laboratory medicine, Henry Ford Health System, Detroit: You're asking me to be a fortuneteller. We're doing a few hundred a day. It's lackluster in my view. It will take time to see whether that bears fruit or not.

Regarding flu, we've asked our clinicians to hold tight on flu testing because we do not have flu in our community now, to avoid burning through flu testing supplies and burning up our staff.

We are expecting antigen testing to come our way in about mid-November. We think it could be helpful for screening populations of people where there are outbreaks—schools, universities, sports teams.

We got our chair of pediatrics to buy off on respiratory syncytial virus testing only for children under age five. We realize there are going to be elderly individuals from time to time, so we will go back to antigen testing for RSV and a PCR test with Cepheid.

Would anyone like to comment on Henry Ford's approach of discouraging clinicians from ordering flu tests until flu has arrived?
Dr. Fuhrman (OhioHealth): We just struggled with this. We're working on the combo tests and we have the Liat and Cepheid, which isn't yet approved. We have no flu in our community, and we decided we needed to give ourselves time to make sure our algorithms were appropriate for symptomatic patients. We normally would turn flu on between September 15 and October 1. We've decided we would not even make it available until November at the earliest. We're going to watch the prevalence of flu in the community as we do that. Our clinical colleagues are okay with this. We have had a few random requests for flu-only testing, which is odd because these patients present with the same symptoms as COVID. So I've been challenging our clinicians on the rationale for that.

For inpatients, we are using the BioFire respiratory panel, so we will find flu if there's flu in the community.

Heather Dawson (Allina): We took out flu antigen testing this year and it's been an unpopular move. We also made flu PCR difficult to order. We've had some supportive ambulatory clinicians who are basically saying, "Please treat empirically, that's what the guidelines say." Frankly, it doesn't matter if it's flu; you're going to do COVID and care for the patients. Yes, it matters in certain cases, and where it matters we put those indications in an order and, if you meet the criteria, you can have one. We'll look at utilization and report back to the group.