New starts: rapid-molecular pullback, fentanyl screen

January 2023—*Respiratory viruses were up in most states when Compass Group members met online Dec. 6 with* CAP TODAY *publisher Bob McGonnagle, and some were looking to centralize their now decentralized rapid molecular testing. At least one system had already done so.*

In California, a new law requires fentanyl screening be included in drug screens in all general acute-care hospital lab settings. What lab leaders had to say about that and about digital pathology, remote sign-out, and the No Surprises Act.

Day

Clark Day, with respiratory virus rates so high, what's going on at IU Health?
Clark Day, VP of system laboratory services, Indiana University Health: If you look at a three-month moving average, our total RSV, flu, and COVID is down versus the past two-year periods over September, October, and November. But flu is two-and-a-half times what it was this time last year, RSV is almost two times what it was this time last year, and COVID is down about 60 percent. So it is a shift from COVID to flu in particular.

To ensure we continue to offer the best care for our patients while balancing good financial stewardship, we are moving to test only symptomatic patients with local rapid PCR assays in our region facilities. We'll make some exceptions for hospital settings in which double-occupancy rooms are the only boarding option or where patients are high risk or require time-sensitive treatment. All other routine PCR-based testing will be routed to our central pathology laboratory to be performed on our fully automated high-throughput platforms.

Is anyone else contemplating a similar move?
Jennifer Laudadio, MD, professor and chair, Department of Pathology, University of Arkansas for Medical Sciences College of Medicine: We've already centralized at UAMS. It was partly due to continued inability to get supplies for some of our regional campus sites. And we had to make a substantial commitment to one of the vendors in our central lab and wanted to be able to continue to fulfill that contract. With test volumes decreasing, we needed that centralized volume.

Dwayne Breining, has recentralizing molecular infectious testing been brought up within the Northwell system?
Dwayne Breining, MD, executive director, Northwell Health Laboratories, New York: We're looking at it constantly but haven't pulled the trigger because we're fearing another wave. It's crowded here and we've seen an uptick from around Thanksgiving of around 30 percent with COVID. In New York State the flu curve is vertical now, and we anticipate being in this for probably two months. We're looking to continue doing a lot of testing and focusing on figuring out a way to decant our emergency rooms when they get overcrowded from people who need just testing. We have plans to do a pseudo-drive-through or a walkthrough—go around the corner if you need just a test and then wait for your results at home.

Carino

Winnie Carino at Scripps, what do you have to share from Southern California?
Winnie Carino, MA, CLS, MLS(ASCP), director of laboratory services, Scripps Health, San Diego: We're seeing an increasing number of flu and COVID cases, also some RSV. We previously had RSV centralized in our core lab, but we're decentralizing it again.

The state of California passed a law [Senate Bill 864] effective January 1 that for every drug screen we perform, we have to include fentanyl screening in all general acute-care hospital laboratory settings. Currently our rapid drug screen does not include fentanyl, so we're running fentanyl on our chemistry analyzer. We added the screening test using a Sekisui reagent. It's an FDA-approved third-party reagent and we ran it on our chemistry platform, the Vitros 5600, but you can use it on other platforms as well. Whenever the screening is positive, we reflex a confirmatory test by liquid chromatography-tandem mass spectrometry sent to a reference lab. Since we're just a few miles from the southern border, our rate of positivity is high and there are a lot of overdoses in the area. I went as far as reaching out to the vendor of our MedTox screen test kit; they have the panel that includes fentanyl but it's not FDA approved in the United States. The product is available in Canada but not here. I tried to follow up and escalate the urgency of getting the product approved in the United States but haven't had any luck. Hard to believe with the fentanyl crisis in the United States nationwide that no one has come up with a rapid screen yet that includes fentanyl.

Dhobie Wong, do you have insight on this fentanyl requirement?
Dhobie Wong, MBA, MLS(ASCP), CLS, VP of laboratory services, Sutter Health, Sacramento, Calif.: Our approach is to add the fentanyl to our urine drug screen, which is run on our chemistry analyzers. We're in the process of implementing that.

Do you have to do a lot of validation to put it on the urine drug screen?
Dhobie Wong (Sutter Health): Yes. It's a work in progress, and there's the information systems component, as with any new test implementation.

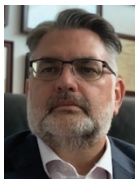

Dr. Datta

Milt Datta, what do you have to share on the issue of fentanyl?
Milton Datta, MD, chair of pathology, Abbott Northwestern Hospital, Allina Health, Minneapolis: Lauren Anthony [MD, system laboratory medical director], who is in our group, looked at fentanyl testing with Hennepin County Medical Center, which does our rapid toxicology screens. Because fentanyl is so potent, the testing cannot get a reliable and accurate read on it. There were no rapid tests available as of June, when we did our study.

We're cautious from a legal side, in particular for maternal screening with fentanyl because of false-positive results with testing. There is a legal case in which a false-positive result led to a patient becoming upset regarding how she perceived the medical staff treated her. So we're treading carefully with the fentanyl testing question.

Stan Schofield, would you like to comment on fentanyl?
Stan Schofield, president, NorDx, and senior VP, MaineHealth: We test for fentanyl, but we do it with mass spectrometry. There's nothing else; there's not a good immunoassay that we know of, though I haven't shopped this in the past year. We do not screen for fentanyl on presurgical or emergency cases unless medically suspected or there's a history, and it has to be a physician request. It's not in our normal screening panel for toxicology primary drugs of abuse because it's hard to do and it's expensive using mass spec. Mass spec technology is

easy—getting the sample, setting it up, doing a run. Having people at a dedicated machine is what's expensive.



Dr. Breining

Dwayne, what are your strategies around fentanyl testing?
Dr. Breining (Northwell): It's similar to what other people have reported. We looked for a point-of-care test option a few months ago and didn't find anything. The potency of fentanyl is so high that the levels you have to detect are tiny. The reference toxicology labs we use seem to be doing a prescreen immunoassay. I don't know what platform it is, and they're probably doing 100 percent backup on liquid chromatography-mass spectrometry to get the detection levels. We'd love to implement fentanyl testing systemwide in all our rapid-response labs but we haven't found an option yet. It's clearly the right thing to do medically.

In New York, virtually weekly there's a fatal overdose from someone who didn't think they were taking fentanyl. It has become a major problem in the street drug world because the ready availability of cheap fentanyl has flooded the illicit market. It's being used to enhance and cut every substance sold on the underground.

Frank Beylo, where is your laboratory on this? And to be clear, this requirement is in California but it may become national?
Frank Beylo, BS, MT(ASCP), director, operations and technology, Inova Health Systems, Falls Church, Va.: We're working on validation of fentanyl with our Abbott Alinity series. Yes, I would assume it may become national.

Pete Dysert, what is top of mind for you at Baylor Scott & White?
Peter Dysert, MD, chief, Department of Pathology, Baylor Scott & White Health, Dallas: We've validated our digital imaging platform at Baylor University Medical Center. So we're looking forward to seeing, largely in the beginning, efficiencies around our conference obligations. My department does more than 400 multidisciplinary conferences a year, at which pathology either presents slides or reviews reports and comments on findings. Currently we're taking pictures and using PowerPoint to present those things, and we're hopeful, with a digital imaging platform, we'll have a workflow that'll be more efficient for residents and staff. We're also looking at moving to Epic Beaker and hopeful that integration will not further erode surgical pathologists' productivity and efficiency and will improve our current-state workflows.

Are you planning to use the new CPT category three digital pathology codes?
Dr. Dysert (Baylor Scott & White): My administrative colleagues are looking at the ability to apply those billing codes to our practice.

Dr. Sossaman

Greg Sossaman, where does the ability to do remote pathology sign-outs stand?
Gregory Sossaman, MD, system chairman and service line leader, pathology and laboratory medicine, Ochsner Health, New Orleans: It is still permissible according to the Centers for Medicare and Medicaid Services. I was involved in the Clinical Laboratory Improvement Advisory Committee and it has been in favor of extending that and

making it permanent through CLIA. CLIAC is able to make recommendations to the federal agencies, and it came up at the last CLIAC meeting. So the recommendation will be for it to become a changed part of CLIA going forward. Those things can take a while to wind through the system.

James Crawford, MD, PhD, professor and chair, Department of Pathology and Laboratory Medicine, and senior VP, laboratory services, Northwell Health, New York: This was a formal CLIAC recommendation at the most recent meeting [November 2022], which, in essence, sketched out recommendations for the framework of the parent laboratory being the regulatory and compliance host for remote sign-out. My hope is that, with the relaxation in effect, perhaps we'll have a bit of a honeymoon as this navigates along, as opposed to trying to change something that hasn't yet occurred.

Lee Bridges, what's top of mind for you at Bon Secours?
C. Lee Bridges, MD, regional medical director, Bon Secours Mercy Health, Richmond, Va.: I've heard from several pathology groups around the country that the No Surprises Act has had devastating effects on their practices. I wanted to find out if others are experiencing something similar.

Greg, do you have experience with the No Surprises Act?
Dr. Sossaman (Ochsner): No, there is not an out-of-network issue for us at Ochsner. I would suspect this would be problematic for some of our pathology colleagues who are in smaller group practices and who still may have some of those contracts with insurers, not through the larger health system or institution. I haven't talked to anybody who's had this issue.

Dr. Bridges (Bon Secours): I know of one group out of state that happened to go out of network prior to the No Surprises Act being enacted, and they ended up in an untenable situation. I anticipate payers will start to renegotiate or cancel contracts because it's to their advantage to have practices not be in network with them now. That's a concern I have. It has not directly affected our pathology group—we have 11 pathologists in our practice—but I can see some of the payers potentially initiating this, which could pose significant problems.

Farmer

I think it's largely true that most insurers are seeking to make their networks ever more narrow and then have greater control over how they deal with the few that are left in the narrow networks. Is that a reasonable statement of fact?
Dr. Bridges (Bon Secours): It seems that way to me.

Autumn Farmer, MHA, chief laboratory officer, Bon Secours Mercy Health, Cincinnati: It gives them a huge leverage chip because the pathology group never has the opportunity to present to the patient, and say, This is what your out of pocket will be. And the health system doesn't know. We don't necessarily have that information to share with the patient. So you're essentially in violation if you go out of network.

Dr. Bridges

It's also my understanding that it's difficult for a pathology group to make a good-faith estimate of what the cost would be to the patient of the work they're being asked to do.
Dr. Bridges (Bon Secours): Yes, and the challenge is with arbitration. For my colleague who is going through this now, the arbitrators are so overwhelmed there's no good, efficient way to go through that process.

Stan, do you have contracted pathologists within MaineHealth?
Stan Schofield (NorDx): Yes, but we're not having a problem with the No Surprises Act. We have a lot of pathologists but it's a contained network within the state. They do work for other organizations but it doesn't impact us. They're a separate corporation and it's a supergroup—anesthesia, radiology, and pathology together—and they provide additional services in surrounding hospitals and states. We don't have a problem because we don't do the professional billing, and the technical billing is well spelled out. We haven't had blowback or pushback on billing transparency.

Dwayne, what is the position on masking in your laboratory now?
Dr. Breining (Northwell): At Northwell it's no longer required as long as you're in a nonpatient-care area. However, walking through the lab today, I see around 75 percent of our people are still wearing masks.

Pete, what is the current policy at Baylor?
Dr. Dysert (Baylor Scott & White): It's in line with regulatory—relaxing and encouraging it to be worn.

John Waugh, I'll ask you for the last word. What is your holiday forecast for what's ahead?
John Waugh, MS, MLS(ASCP), system VP, pathology and laboratory medicine, Henry Ford Health System, Detroit: Health care systems, as we all know, are still facing strong financial headwinds, and there's a lot of budget remediation going on. That has occupied a lot of my and others' time during this month.

I like that our staff get an opportunity to get away and spend time with their families. Some are visiting families far away, on the other side of the world. It's gratifying to see those things, and a lot of moms are going to smile.

I'm telling our staff: We recruit the best people every day, and we titrate the limited amount of capital we have because it will have to last us until we get to the other shore. There will be another side to the valley and things will be better there, but it's going be a long walk up and down. There are no small jobs left in health care, only big ones, so focus on the mission-critical things—length of stay and the legal and regulatory issues that help our organizations and add value.