Hematology panel: bridging gaps, staffing, Lab 2.0

October 2019—*Automation, the workforce shortage, manual review rates, and Laboratory 2.0 were some of what came up in CAP TODAY's latest gathering of hematology experts for a roundtable on what's new, pressing, and in play. CAP TODAY publisher Bob McGonnagle convened a panel in August consisting of Cordelia Sever, MD, of TriCore Reference Laboratories; Olga Pozdnyakova, MD, PhD, of Brigham and Women's Hospital; Danette Godfrey and Simon Shorter of Sysmex; and Matt Rhyner, PhD, MBA, and Rachel Burnside, PhD, MBA, of Beckman Coulter. What they said follows.*

Access the 2019 hematology analyzer interactive product guide here.

Danette, what are Sysmex's latest initiatives and how have customers responded?

Danette Godfrey, director of IVD product marketing, Sysmex: We added a new module to our hematology automation lines to bring even greater differentiation than our existing platform. At the low end of the market we made substantial changes for the point-of-care market with scalable solutions in the area of the XW-100 and changes to the instrument and the markets we serve.

Godfrey

We're pleased with what we're hearing well into the launch of our XN-20, to deliver next level flagging, with the new white precursor channel based on similar technology that our customers have grown to love. Being able to offer more differentiation to precursor cells is certainly helping our markets, which find value in highly sensitive and specific flagging of abnormal white blood cells, automatic reflex testing, and the information technologists need to reduce manual slide review rates. At the low end of the market we see an expansion of the understanding of the positioning of the XW and the markets we serve there. We have made advances there in how we communicate this to our customers and to what extent our customers find value in the solution.

Matt, what, if anything, has changed in the last year from your perspective and from the perspective of Beckman Coulter?

*Matt Rhyner, PhD, MBA, senior director of product management and global marketing for hematology, Beckman Coulter: W*e've had two FDA clearances this year—one for our low-volume analyzer, the DxH 520, and the other for our Early Sepsis Indicator. Both have really added clinical value. Early Sepsis Indicator has a tremendous amount of value, but when we have worked with customers, we have had to help them bridge their own gaps between emergency doctors as well as the laboratory, and that's been an interesting journey.

Rachel Burnside, PhD, MBA, senior manager of global marketing for hematology, Beckman Coulter: It's just an aspect of bringing on a new assay. People are interested in what the Early Sepsis Indicator brings to the table, but they need education on what it is, what it's measuring, and how it can impact their workflow.

We're also anticipating the imminent launch of the DxH 690T, which is a tabletop analyzer for mid-volume laboratories that will have, as does the DxH 900, the capability for Early Sepsis Indicator.

Dr. Pozdnyakova, is there anything you would like to raise at the outset?

Olga Pozdnyakova, MD, PhD, associate pathologist, Brigham and Women's Hospital; associate professor, Harvard Medical School; and medical director, B&W Harbor Medical Physician Diagnostics Lab: I would like to comment on

bridging gaps. We use Sysmex hematology analyzers in all labs across Partners. These are modern, sophisticated analyzers that allow us to measure a lot of clinical parameters and advanced clinical parameters. I would like to mention immature platelet fraction and immature reticulocyte fraction parameters, which we are currently validating and planning to report. However, there is a great need to educate our clinicians on what to do with these parameters. Due to a lack of familiarity with these new parameters, clinicians may not find them useful and will not order them, creating a big gap between advanced laboratory technologies and their implementation into clinical practice.

You have dozens if not hundreds of clinicians and other people within your system who need to understand new assays and need to know how to handle the information you provide. Are rules-based applications within instruments and IT systems helpful there? Do you need to do in-service and visits and newsletters? How do you communicate information about the new features and benefits you can provide out of hematology instrumentation?

Dr. Pozdnyakova (Brigham and Women's): The rules we use are created mostly for our clinicians and sometimes with their help. This is one of the ways to accomplish that. We do have a general broadcast to communicate changes and new features, which I do not find helpful because we see several each day. I find the best way is face-to-face communication and doing in-service and going to physicians' offices or to their departments and explaining why we do what we do and how new technologies and instruments' features can help them provide even better patient care.

Dr. Sever, would you like to comment?

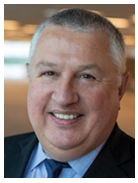
Cordelia Sever, MD, VP and director of clinical pathology, Pathology Associates of Albuquerque; co-medical director of the clinical laboratory, hematology, TriCore Reference Laboratories; and medical director of the laboratory, Presbyterian Hospital: I am observing two major trends in our system. One is the migration of testing to the point of care, especially for the emergency department. In our system, they are overtaxed. They have too many patients and need to get them through the door, and many new models are popping up now. In that scenario we need machines that are robust and can be operated as moderately complex instruments. It's important to be able to hardwire lockouts and be able to interface with POC software that can manage a lot of the QC, and there are new solutions out there.

The other trend is what Dr. Pozdnyakova said: We are using more and more of the new parameters—immature platelet fractions and reticulocytes—so we are getting more sophisticated. I agree with Dr. Pozdnyakova that sending out paper or email notifications is rather ineffective. It has to be targeted presentations to clinicians and customer broadcast in the outpatient area. It's slowly getting traction. For example, we find the immature retic fraction very useful as a screen for iron deficiency. So we are using numerous things to decrease other testing and expedite diagnoses at the point of care.

Matt, this reminds me of comments you made in a similar roundtable discussion last year, which is that the market is tending to go in two directions—a barbell scenario—in which we're seeing a lot of interest at the point of care, as Dr. Sever mentioned, and a lot of interest in huge efficiency in core labs. How is that trend developing?

Dr. Rhyner (Beckman Coulter): One thing that's clear is that 10 years from now the market will be very different. There have been a lot of entrants on the low end of the market in terms of the physician office lab or POC space, as well as more and more acquisition of hospital labs by companies like Quest and LabCorp that are driving a different sort of pressure in those ultra-high-volume spaces.

The cost drivers are huge for both ends of the market and that's probably what we're seeing, as well as the lack of trained staff to operate these devices. There is enormous cost and efficiency pressure, and it's pushing the market in those two directions. I've only seen that trend intensify in the past year.



Shorter

Will that create a certain strain within the system, because we're talking about the need for education at both ends of that spectrum? It often falls on a labor force that's increasingly stressed and strained and sending out in many places. It's a burden that seems to be landing on laboratory staff of all types.

Simon Shorter, senior director of IVD product marketing, Sysmex: We'd broadly agree with Matt about that sort of barbell direction, and cost and efficiency and the age of the workforce are always concerns. So one of the areas that Sysmex has been focusing on is how we can reduce the burden for laboratory scientists by way of a new product we're launching called BeyondCare Quality Monitor, where we perform calibration verification in a different way.

We used to go on site and perform calibration verification, and in the next version we did this remotely, where the customer would run the product but we do everything else. Now with this new product, we are capturing the data from daily QC runs conducted by the customer and effectively performing continuous calibration verification every day. That's one example where we are trying to find technological solutions to this and trying to begin to enter this space of digital transformation.

The workforce shortage seems to be becoming more acute. Dr. Pozdnyakova, how do you see your labor situation, particularly in reference to the hematology section?

Dr. Pozdnyakova

Dr. Pozdnyakova (Brigham and Women's): I could not agree more. We are short-staffed and have a hard time retaining people. It's a problem across the country. And it affects all areas of hematology labs, and manual review of smears in particular. The best way to approach the problem is to become more efficient. One of the efficiencies we see with hematology analyzers is a more accurate flagging leading to more accurate identifying of the smears that require manual review. Currently our manual review rate of the smears hovers around 15 to 18 percent, and I think that's pretty much true for many large academic institutions of similar size.

We are a tertiary care center so we have a lot of sick people, and many with hematologic malignancies, and that also drives the increase in the manual review rate. If we rely on our hematology analyzers more, if we validate them and know they truly do not miss what we don't want them to miss, and they flag what needs to be flagged and do a manual review on those smears, that would help us tremendously.

Another efficiency is the use of CellaVision. We've had it in the lab for a little under a year, and it's been a great, positive change in the operation of the lab. It is a more efficient way of reviewing peripheral blood smears, and we have seen a tremendous improvement in the turnaround time of the smear review and in the quality of work and quality of life of the technologists in the hematology lab. Our labs work very closely with Dana-Farber hematologist-oncologists, and they also recognize the utility and benefits of using the CellaVision system and its

positive impact on patient care.

The way to deal with the labor shortage is to be smart and creative in how to become more efficient with what we have.

Dr. Sever, you're in a similar situation because you have one foot in Presbyterian Hospital but you're the co-medical director of the clinical lab in hematology at TriCore Reference Laboratories, which also is serving an enormous group of clinicians and patients. What is your current rate of manual review? Dr. Pozdnyakova said her lab's is 15 to 18 percent. Is that in sync with what you're seeing in Albuquerque?

Dr. Sever (TriCore): We have actually pushed it down even lower. In our core lab it's about 12 percent, and at our hospitals it's around 15 percent, with a high concentration of abnormal smears. We have addressed some of this with delta checking and looking at counts horizontally and not repeating differentials with the certain flags. Our clinicians are very good too at not ordering too many differentials. We have a high monitoring mode for just CBC, so we have the same problem in keeping our technologists well trained. We have distilled it to the highly abnormal smears.

Interestingly, in our hospital situation, we decided it takes more time to QC the CellaVision and maintain it, and we still have to look at manual diffs, especially in oncology, where low counts don't work with CellaVision. So we don't have that system in our high-complexity oncology environment. But in the core lab it makes sense. We have a much higher number of near normal with just a little bit of left shift or not, and those are still running with the CellaVision. So it's targeted to the populations, and that works for us.

I appreciate that nuance on the usefulness of the CellaVision depending on the site and patient population served. Danette, can you comment on what we've just heard from two sophisticated laboratories with excellent medical direction? How do the rates of manual review strike you in the wider context? Does this sound like something you wish many other laboratories could achieve, and if so, would realize even greater efficiency from their hematology automation?

Danette Godfrey (Sysmex): I would have to agree. And it's refreshing to hear the close alignment with the solutions that are coming to market today, and to hear the new value laboratories are able to achieve through integrated technology solutions. I also have an appreciation for the need to provide more efficiency solutions, whether that's through image analysis, middleware, or through digital solutions in general. We mentioned the BeyondCare Quality Monitor to help laboratories manage quality through modernized innovations. Providing solutions to laboratories to be able to address these staffing challenges is something that struck me as critically important to our customers and also remains a focus of Sysmex. Sysmex is now providing quality and operational data to laboratories through new dashboards and digital solutions to manage productivity of their teams and their solutions, instruments, and analyzers.

Matt and Rachel, please comment on what you've heard from Dr. Sever and Dr. Pozdnyakova with reference to what they have achieved in terms of manual review rates and the other points they raised.

Dr. Rhyner

Dr. Rhyner (Beckman Coulter): Those are good rates. We think about the manual review as a function of three different parameters. One is the patient populations, oncology centers, for example, where I'd expect a

significantly higher manual review. Pediatric hospitals, also much higher. Then there is what would be termed the rate due to instrumentation or flagging due to instrumentation, and coefficients of variation. Then there would be consideration for the rate that is taking care of the second reflex on a lot of instruments. We're proud of having a high first-pass yield. While we have some cancer centers that are in the 30 to 40 percent range, we've seen labs, especially outside the United States, where they have maybe more aggressive decision rules, in the single digits in terms of review rates. We have one webinar regarding our partner in New Zealand where it's about 3.8 percent.

A lot of it gets down to the decision rules, their comfort, the patient population, how the instrumentation is performing, and leveraging the technology. What it comes down to is manual touches. We do have a flow cytometry product outside the U.S. that also dramatically reduces these reviews. So, I can see a future where there are single-digit-style reviews in a broader segment of the population, and in which the cost and staffing pressures are going to force us into that range.

We recently launched the DxA 5000 this year, which is our next-generation total lab automation solution, currently pending FDA clearance, that integrates seamlessly with our DxH hematology platform. That's another way in which you can reduce the rate: have an entire lab fully automated with integrated middleware. The DxA 5000 works with our middleware and total lab automation for what we refer to as multidiscipline reflex. This could be where follow-on sepsis care bundles with tests like lactate or procalcitonin. It could be run after an initial flag. Beckman Coulter is looking at the total lab perspective with hematology being a major piece of that.

You would reflex from a hematology result back to a tube to put on the chemistry analyzer for an add-on or a follow-up?

Dr. Rhyner (Beckman Coulter): Yes, you get one draw and we refer to it as multidiscipline reflex. It works with our DxOne Clinical Informatics Platform.

It seems to be in everyone's interest to optimize the efficiency of the instrumentation and then the laboratory site—the instrumentation in combination with the professionals who staff that laboratory. Rachel, would you like to add anything?

Dr. Burnside

Dr. Burnside (Beckman Coulter): I would agree with Matt with respect to what drives manual reviews. I see this not just as something related to individual institutions but across the country with respect to technical staff aging and there not being enough workforce. This is not unique to core labs. I was in a cytogenetics laboratory for many years as a director and we experienced the same thing. It's just high-complexity testing as opposed to moderate-complexity testing.

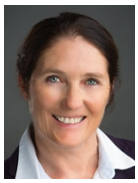
This is industrywide across health care. So, I think you're going to see more focus in the future on development of technologies that reduce the manual burden on people, and that would include a reduction in the need for making a slide and/or improvement in image analysis where cells can be analyzed in real time or on a slide without human intervention. This is the way of the future. We're not there yet, but it's exciting to participate.

In some ways this is a race between the technology advancing fast enough to keep pace with an accelerating labor shortage. Dr. Pozdnyakova, is that how you see this?

Dr. Pozdnyakova (Brigham and Women's): I don't know. I do not want to see or continue to see the reduction of medical professionals in the laboratory. We could use more people but maybe redeploy them to different tasks. I

would hate to see all the labs being replaced by an automated process that does everything from start to finish. There is a lot of value in what we do. In addition to patient care, there is a lot of interaction between providers and technologists, between pathologists and technologists. We have to be more efficient, given the shortage, and use lab professionals in other areas and train them to do other things.

Dr. Sever, at TriCore you have been part of the Santa Fe Project that's sometimes now called Clinical Lab 2.0. TriCore is a founding member, and Sysmex has been highly interested and involved in it. Many in the industry, in labs and in companies, are looking at this. Can you talk about how improvements in the operation of the hematology laboratory can lead to a greater appreciation of the laboratory endeavor and to some assurance for those who work in laboratories and service laboratories that the future is bright for them?



Dr. Sever

Dr. Sever (TriCore): It's a comprehensive approach to everything, more or less. And again, for me, it's important to realize what patient populations you serve and incorporate values across different disciplines into actionable clinical data.

We are taking baby steps in hematology; in other areas we already have some 2.0 running. One of our initiatives was offering an anemia screen for outpatients. The intent is to have patients come only once to the lab draw site and diagnose two-thirds of anemias in the outpatient setting. You can order a CBC with reticulocyte count, reticulocyte hemoglobin content and immature retic fraction, which has all the information to diagnose uncomplicated iron deficiency. We are rolling that out to leverage some of the new capabilities.

The other big arena is in the oncology field where we are asked to guard utilization and we are taking on a lot of tasks that in many traditional environments are done by the oncologist—bone marrows, for example—the pathologists order everything from flow to molecular to cytogenetics. We often trigger action right away based on CBC results. We perform a lot of bone marrow procedures ourselves and order ancillary tests as appropriate. There is even a little publication from our hematopathology fellows. We are saving the system to the tune of an entire pathologist FTE by guarding these resources. And those are the most highly valued activities.

We have the same problem with replenishing our technologists. We believe they are on the frontline and it would be a disaster not to have them at night and on weekends. To get efficient, we are shifting things to moderate-complexity tasks, where we can have less-skilled personnel run these machines. Sysmex has a new machine that does five-part differentials and is moderate complexity. We are experimenting now with freestanding ERs—putting them in the ERs and having them run by the ER techs with supervising laboratory technologists and with integrating that into our entire hematology workflow. That saves a lot of technologist FTEs.

There are a lot of CBCs; it's the number one test ordered. So we have shifted an entire population out of the high-intensity, technologist-driven scenario into point-of-care, moderate complexity, with supervision by trained technologists. So those are the other approaches as a system where we can preserve our precious resource of trained hematology technologists and expand the pool of people who can run the machines.

They have to be robust machines, and there has to be software that works with the point-of-care scenario. They have to automatically prompt the operator to do the right thing and then remotely enable the supervising technologists to audit, edit, and manage this. Sysmex has a remote calibration verification system that hopefully gets approved in the budget. It's in the works. So that's another approach to preserve our resources and get more

efficient in our more difficult shifts.

Dr. Pozdnyakova, how does the laboratory demonstrate and preserve its value in the face of what we all know are enormous pressures on technology, on cost and spending, on labor? Do you see it as part of your job to make sure that the value of your service to the entire system—clinicians, patients, and others—is top of mind?

Dr. Pozdnyakova (Brigham and Women's): Yes, it's very important for us to promote our services and to educate clinicians so that they fully understand that our services are probably one of the most important contributions to the patient care.

Dr. Sever brought up important points—that we, as pathologists and as laboratorians, should be the keepers of the test ordering. This is something we're doing also, somewhat successfully, at Brigham and Women's Hospital. Deciding what tests are appropriate and inappropriate for each patient saves not only the dollars but also the valuable time of technologists and pathologists. I agree this is one of the efforts we should continue to drive and that we must continue to educate not so much clinicians in this case but laboratorians and labs themselves—how to make sure all tests ordered are appropriate in a particular clinical setting.

We are trying to be creative in how to retain our technologists and how to make do with fewer of them in the current shortage, and one way is cross-training so each technologist can efficiently work in many different lab areas. This is also one of the ways to keep laboratorians interested, because they appreciate rotating through several areas of hematology. It has paid off in our situation.

Danette, would you like to share impressions or thoughts you had as we've been through this discussion?

Danette Godfrey (Sysmex): It's inspiring to hear the feedback from our pathologists and it's something we at Sysmex hold dear to our hearts—the value of laboratory scientists. So as much as we continue to push digital solutions, automation, we can't let go of the importance of the clinical decisions and the value of the medical scientists.

The summary of my impressions is that we as manufacturers of instrumentation can do our best to provide the right hardware and software solutions for the laboratory, but our goal is to empower our clinical experts to use the efficiencies we can provide to them through automation solutions, not in an effort to replace them but to empower them and take away that busywork that can be replaced with automation so they can focus on what is important to drive clinical decisions.

Dr. Rhyner (Beckman Coulter): I can't agree more. For a long time, the laboratory has been viewed as a cost center. And part of what we hope to do is to bring labs biomarkers with real demonstrated clinical value, like our Early Sepsis Indicator, to turn the lab into something that the C-suite can see as a benefit to the entire health care network. Not just a cost center to squeeze as much as possible, but something that has real health, economic, and clinical benefits and has the potential to reduce the overall cost burden to the entire hospital operation.

So, I agree, and what we need to do is provide solutions that allow the clinical information that saves patient lives and reduces the cost of care to shine through.