Enabling 'the magic' in hematology—eyes on what labs need

October 2022—New and better solutions for the hematology laboratory. That was at the center of a Sept. 2 virtual roundtable, led by CAP TODAY publisher Bob McGonnagle. With him were Jonathan Galeotti, MD, of the University of North Carolina School of Medicine, and representatives of Sysmex America, Siemens Healthineers, Beckman Coulter, and CellaVision.

"It's a new era in terms of what can happen in hematological data," said Fernando Chaves, MD, global head of hematology, Siemens Healthineers.

CAP TODAY's guide to hematology analyzers begins here.



Dr. Chaves

The predominant themes of these roundtables in the past few years has been the ease of the workflow in hematology and in eliminating unnecessary manual differentials—we'd like to pull percentages way down. The other concern that feeds into this is the labor shortage in laboratories. Fernando Chaves, do those themes still preoccupy you and your customers at Siemens, or is there something new in the mix?

Fernando Chaves, MD, global head of hematology, Siemens Healthineers: One out of three hematology tubes that comes through the laboratories is a burden on our customers, so it's critical that we address workflow efficiency, operational excellence. And it's not only labor shortage but also knowledge shortage. The analyzers have to be not only efficient and operational but also easy to use, with minimal training—so the technologist who is running the chemistry/immunoassay night shift also finds it easy to operate the system.

That's why integration into all core disciplines—when you have a single system offering the same IT environment, same interface, for hematology, chemistry, immunoassay—is a major value to customers. It can be problematic if we have technologists who are using one environment, one interface, one middleware for chemistry and immunoassay and then have to learn something new only for hematology. It's a major opportunity for improvement in industry.

Linda Garlaus, what is your perspective on current developments in the world of hematology?



Garlaus

Linda Garlaus, MT(ASCP), senior manager of product management, Beckman Coulter: We continually talk to our customers, and we hear the same challenges Dr. Chaves mentioned—workflow, staffing, and experience. So we continue to focus on addressing those challenges and making sure we have workflow integration that will go beyond what we have today as well as look for novel technologies. Customers want to further reduce blood smear

reviews; the technologies on the market today are great, but there are opportunities for improvement.

Ken Childs, it seems that your offering at CellaVision may be more important now than ever in a world of knowledge shortage, as Dr. Chaves said, as well as staffing shortage.

Ken Childs, MBA, director, Americas, CellaVision: What Dr. Chaves said is true and something we've been trying to address in the hematology process for the past few years. The workflow options available today and the interfaces are terrific, but if that CBC analysis is rejected or flagged by a cell counter, it needs to be reviewed, and that's where the difficulty is for the hematology laboratory in many cases.

CellaVision started years ago addressing the manual process, which also addresses the knowledge shortage. Not only is it a labor saver, but it addresses the need to have standardization in hematology, which has been lacking since the beginning. By using digital morphology, you're able to standardize the process, provide a better result, and share that resource across many areas, such as having a core lab with a specialist in hematology who can review slides from a clinic or another laboratory within the system. Digital technology has become more the standard, and during COVID there's been an even greater need because we've had so many people out and many not returning to work. We're seeing an acceleration in the desire to use remote review capability with the slide review.

Jonathan Galeotti, how does what you've heard relate to your daily work at the University of North Carolina?

Jonathan Galeotti, MD, clinical assistant professor, Department of Pathology and Laboratory Medicine, Division of Hematopathology, University of North Carolina School of Medicine: We're struggling to manage the staffing shortage. Even when you get people in, you still have to train them, which takes time. Having a uniform system across the health system helps because we have many people balancing between different sites.

CellaVision has been a helpful tool during the pandemic because many people are working remotely or offsite or unable to come into work. It has been helpful for us as an academic center to try to help the laboratory do its manual reviews, to support the core laboratory.

The staffing shortage extends to the world of working pathologists, and we hear that hematopathologists are in the greatest demand.

Dr. Galeotti (UNC School of Medicine): I tell our trainees that there's a shortage of hematopathologists, particularly with experience. It is a good time to go into hematopathology.

There are some complex wet cancers that become the preoccupation of many hematopathologists. How is that work, and the importance of that work, coupling with the usual analysis through the blood counting machines, the digital image analysis, et cetera? In other words, those two are distinct and yet one imagines that manufacturers are trying to do better diagnostics with their analyzers to help you get on your diagnostic journey. Is that correct?

Dr. Galeotti (UNC School of Medicine): Yes. They are two different things, and the core hematology lab is used for all our patients in the health system. There's an overlap with what we're doing, and automated hematology is critical to how we monitor our patients with hematologic malignancies. They're interconnected, and we're all in tune with our analyzers and the challenges that can come up with certain types of cancers or therapies.

Fernando, Siemens has new instrumentation in hematology that it's looking to bring to the market. Will considerations like this go into the design of that instrumentation?

Dr. Chaves (Siemens Healthineers): Yes. There is a natural tendency to connect hematology with hematological cancers.

Digitalizing health care is one of our promises to customers. We have a vision in which the value of hematology for clinical care can be revolutionized, because the CBC is one test that is affordable and ordered for pretty much any clinician encounter a patient will have.

Many times a clinician is not suspecting a specific disease and they order the CBC. There are dozens of parameters

in one test, and until now we did not have the capability to analyze those parameters. We know clinicians are looking at only a few parameters. But with artificial intelligence algorithms, it is possible to pull together the different parameters and get information from it. There are flags for diseases that have nothing to do with the blood—infectious diseases, malaria, sepsis.

With the new technology that exists, we have a full field of research ahead of us and innovation in which information from the CBC will be used to alert clinicians to many diseases beyond hematological cancers. That's the opportunity we have in the hematology industry, and nothing makes our job as exciting as having this in our future.

Jennifer Starks, most of us who look into the field of hematology believe there's a lot more information to be extracted from blood samples. What is Sysmex doing to make that a clinical reality?



Starks

Jennifer Starks, MT(ASCP), group manager, hematology portfolio, IVD product marketing, Sysmex America: What Dr. Chaves said about artificial intelligence marrying with the CBC result is on the horizon. We will be able to tease out some of that hidden information by using artificial intelligence to perhaps see a trend, where you start to see a patient become sick over time and you can trigger an alert.

Linda, we have to bear in mind that physicians' comprehension of what new laboratory results may mean for their patients sometimes falls short. I would think there's an element here in which this further analysis and the use of algorithms and AI is going to mean vendors and the hematopathology department reaching out to the clinician. It's no longer going to be enough to send a result and expect the clinician to know what to do with it. As you plan at Beckman Coulter, is that also top of mind?

Linda Garlaus (Beckman Coulter): Yes, and a good example of that is what we've done recently with our novel MDW [monocyte distribution width] biomarker. We went into emergency departments to listen to clinicians to understand the challenges they have with sepsis and how we could help them get information so they can diagnose patients with sepsis, or at increased risk of sepsis, earlier. Historically our primary customers typically are the laboratory and the pathologist, but we know we have to reach the end users to ensure we understand their pain points and get their feedback firsthand, so when we roll out the solution it's meeting their needs.

Using common screening approaches that clinicians use today, for example in the emergency room, together with our biomarkers creates powerful decision support solutions, allowing clinicians to be able to react more efficiently.

We're excited, too, because we're partnering with Massachusetts General Hospital and the U.S. Department of Health and Human Services to further advance the information for diagnosing sepsis using MDW in the pediatric population.

Jonathan, some people are concerned about the EHR being able to adequately present laboratory results to the clinician. How do you find your reporting of hematology results to be in the EHRs you have experience with?

Dr. Galeotti (UNC School of Medicine): As it is now, our CBC result is a discrete result, it's reported into the LIS, it's straightforward. If we start adding interpretive components, that requires more review and a more thoughtful approach to how you report the results and to whom you're reporting them. But it comes with the benefit of being able to provide additional information from tests we're already running, which is efficient and useful.

There are multiple ways to view data in the EHR. Depending on how you look at the data, all the information may not be apparent to you. So you worry that certain people will look in certain places and not see all the relevant information. In a discrete result review, you might see just the lab value and you might not see the interpretive component.

Al has the potential to be powerful in this setting, but I envision growing pains. Integration with LISs has been challenging for other tests that require interpretive components, and it requires a person to review it and make sure the language is appropriate and the information is relevant. I worry it will add work for the pathologist or laboratory staff to interpret these downstream results and put them into the LIS in a way that makes sense. There are a lot of hypotheticals, so I would be interested to see how it would work.

Ken, do you find, at places where CellaVision systems are installed, there are clinicians who are interested in looking at these images as part of the reporting and understanding of the pathology results?



Childs

Ken Childs (CellaVision): Yes, we have seen that, and people are becoming more comfortable looking at a screen to view what they typically looked at under the microscope. But having access to that information was not easy in the past.

Artificial intelligence networks are trained by looking at millions of different cells. Al brings a consistency to the differential that you can't get even by asking dozens of technologists to do the same differential, and it applies that standardization upfront. It still requires the operator to review the information and make a proper diagnosis or recommendation. Having better information provided to you by using artificial intelligence has been critical and game-changing in standardizing differentials in hematology.

Jennifer, do you think we are at the beginning of these algorithms being useful to us?

Jennifer Starks (Sysmex): I hope so. I think physicians will be looking to diagnostics for more interpretive information to be able to figure out what's going on with their patient.

Fernando, can you comment on the autoverification element in hematology reporting and instrumentation?

Dr. Chaves (Siemens Healthineers): It's a critical aspect. Given the challenges with the shortage in labor and expertise and the need for standardization and consistency in results and to drive down manual differentials, there is no question that autoverification is a key aspect of any successful solution in hematology.

Linda, the importance of refining reference ranges for patient populations is a first step to get to useful autoverification and artificial intelligence. Are you thinking about dealing with the mass of data to help refine reference ranges in hematology?

Linda Garlaus (Beckman Coulter): Yes. We would like to use data mining to gather data fairly easily versus having to do specific studies.

The other component of autoverification is trying to mimic what the laboratory is doing as part of its operating procedure. What's critical for them? What is their action point? It's not the same across different laboratories.

Jonathan, will the increasing subspecialization in pathology play into improved autoverification and understanding of reference ranges? Where are you in your practice in terms of special reference

ranges for the population you serve?

Dr. Galeotti (UNC School of Medicine): Yes, I hope subspecialization will mean improved autoverification and understanding of reference ranges.

How to appropriately define our reference ranges is something we deal with and think about often. People do it in different ways. A lot of factors go into it. It's critical to know what is normal and what is abnormal. You can't do one without the other. It's important to us in the lab to have good reference ranges we believe in and have evidence to support.

Fernando, are vendors increasingly taking on some of that data mining and refinement as part of their offering?

Dr. Chaves (Siemens Healthineers): We are taking the steps to prepare for that. You need to have solutions that are digitally integrated across networks, with similar interfaces. At the stage where we are in the industry, it is critical for us to set up the platforms that will enable all of this magic to happen.

When it comes to reference ranges, it's as Dr. Galeotti said—you can only know what is abnormal once you know what is normal, and knowing what is normal changes depending on your population. So we need to create platforms that will enable the AI algorithms, the digital work that is coming. It will be a tremendous value if the background noise of the data can be recognized and eliminated.

It's a new era in terms of what can happen in hematological data, and we are moving in that direction, as is the rest of the world—all industries are using artificial intelligence now. We in the industry need to keep that in mind so that we create platforms that enable this innovation.

Jennifer, how is Sysmex reacting to the issues we've raised today, and what is your focus in research and development and in educating clinicians?

Jennifer Starks (Sysmex): We've been focusing recently on software solutions. The history of hematology and the laboratory in general was: We buy an analyzer, it has the software loaded on that operates that analyzer, and then we use the brains of the pathologists and technologists to interpret the data.

We're starting to see more emphasis on having software that can interpret the data as well as tease out information. The challenge becomes leading the laboratory toward identifying the value to be gained by investing in software solutions that can provide much more help and enhancement to the data they're currently producing with their hematology analyzers.

Linda, what is your reaction to what you're hearing, and what is Beckman Coulter doing to address these issues?

Linda Garlaus (Beckman Coulter): Automation solutions are needed for the small and midsize laboratories; our DxA 5000 Fit is one way we are helping support the staffing challenges labs are facing today. In addition, there is a need for more help in clinical decision support, whether it's technology or putting in complex algorithms that look at the data as well as the patients' results.

Combining the knowledge of those proprietary markers with the common practices that clinicians go through in their assessment, putting them together to help with clinical decision support, is a big emphasis.

We are also focused on reducing manual steps and are looking at what technologies in the future can help. Instruments on the market today provide accurate results, but they're using conventional measurements, whether it's light scatter or fluorescence, to indirectly classify cells through correlations of identified populations. We're also thinking about what could be a cost-effective technology to address the needs to simplify workflow and provide more valuable information.

Ken, do you see within the CellaVision offering new parameters, new depth you could achieve with image analysis?

Ken Childs (CellaVision): We're always improving and adding parameters to the AI analysis. We continue to add

them as we develop the capability.

Some of the growth we'll see, I believe, is in using artificial intelligence integrated with the cell counter. There's more possibility there than just improving our hardware or adding another parameter.

The future may lie in integrated software solutions, because when you have an integrated system and workflow, you solve the labor shortage and knowledge problems. Workflow can mean a lot of things—it's not only hardware but also integrating the software and artificial intelligence into the process.

Fernando, you have a new offering on the way. What can CAP TODAY readers expect to see coming from Siemens hematology?

Dr. Chaves (Siemens Healthineers): We have the Atellica Hema portfolio, which is already available outside the United States. It is a CE-marked product. It's designed to meet key customer needs in hematology—ease of use, reliability, scalability, flexibility. Customers love how easy it is to use—few reagents, easy to load and unload reagents, walkaway startup and shutdown, few manual steps—which addresses the shortages of labor and skilled professionals.

In terms of integration, we have Atellica Data Manager, our middleware solution, in which customers can have a hematology solution under the same middleware as chemistry and immunoassay. The same technologist who is operating a chemistry system doesn't need to learn a new software or become familiar with a new environment to operate the hematology system. All of this is at the instrument level. At the solution level, the clinical content level—that's where the digital content and artificial intelligence is, and that's the platform we want to enable so clinical innovations can also become a reality.

Jonathan, can you share with these industry figures what is top of mind for you in terms of your desires in commercial hematology offerings?

Dr. Galeotti (UNC School of Medicine): Cybersecurity issues have been a hot topic in the academic world. The laboratory is a point of access to the EHR and the network, so that has come up in a lot of discussions.

The other is point-of-care testing in hematology. There's been a push from smaller clinics or specific clinics to get more bedside testing to get results faster for various patient populations.

Jennifer, can you comment on the point-of-care issue from the Sysmex perspective?

Jennifer Starks (Sysmex): Sysmex has a segment of analyzers designed to fit in the point-of-care customer segment. One is the XW-100, which is a CLIA-waived CBC analyzer. It fits easily into physician offices or small clinics that maybe don't have the ability to have a moderate-complexity analyzer.

With our partnership with CellaVision, we have the smaller CellaVision DC-1 analyzer, which can bring that level of automation to smaller facilities.

Ken, more sophisticated technologies and automation are popping up in places we've not seen before. Is that true for CellaVision's offering?

Ken Childs (CellaVision): Yes, and we introduced a new system, the DC-1 that Jennifer mentioned, in the United States last year. It can run one slide at a time and it's perfect for smaller clinics and places where you are closer to the patient and need expert consultation immediately. It is essentially identical to our larger system, but price- and size-wise it is suited to a smaller clinic or laboratory that can't afford and has no need for a high-volume system.

Jonathan, is there anything you'd like to add in closing?

Dr. Galeotti (UNC School of Medicine): I'm excited that people are thinking forward and trying to use new technology to help physicians and the laboratory staff make decisions and support us in a way that is productive and helpful. I hope we can all work together to make better solutions that help patients and the hospitals that treat them.