Talking tests, instruments, and what's best where

June 2019—*Analyzers, menus, test distribution, and middleware were the topics of a roundtable led in April by CAP TODAY publisher Bob McGonnagle. Samuel McCash, MD, Frederick Kiechle, MD, PhD, Christina Reita of Roche, and Mimi Dang of Tosoh talked IT, turnaround time, and what challenges stand out. Here is what they told us. Click to view CAP TODAY's guide to chemistry and immunoassay analyzers for the POC and low-volume markets.*

Dr. McCash, tell us about your practice at Memorial Sloan Kettering and what now is top of mind for you.

Samuel McCash, MD, director of 53rd Street Clinical Laboratory, Department of Laboratory Medicine, Memorial Sloan Kettering Cancer Center: I am director of three outpatient laboratories and assistant director at our main laboratory. We want to make sure our precision and sensitivity are similar across our outpatient labs and main campus, keeping results comparable regardless of which site runs the tests. Also, results have to be sufficiently accurate for chemotherapy-related calculations.

Christina Reita, we associate with the large chemistry manufacturers like Roche the idea that you have members of a family and, in particular, models within that family that are suitable for all kinds of labs and their applications, all running on one system. Can you tell us about the evolution of that at Roche and how important an initiative it has been to have one model in many capacities?

Christina Reita, vice president, centralized diagnostics, Roche Diagnostics: Laboratories are consolidating into ever growing integrated health networks. Their diagnostic purchasing decisions are increasingly made by committees, so they face the challenge of when and what testing to centralize versus decentralize. This is an area we have focused on largely through our commitment to research and development.

We were pioneers in modular systems and continue to offer the only integrated, standardized solution. This means that no matter the platform or the reagents, we have the same package insert claims, the same sensitivities, specificities, and measuring ranges that laboratories expect so that when the cancer patient, to use Dr. McCash's example, who was at the main facility is then tested for creatinine levels at an outpatient facility, the results are standardized.

As I see it, there are two key benefits to having this kind of installation. First, technical personnel are trained so they can easily go anywhere within a system and operate the test. The second is the importance of establishing a systemwide reference range. Dr. Kiechle, can you speak about the importance of one standard reference range across a system?

Frederick Kiechle, MD, PhD, consultant, clinical pathology, Cooper City, Fla.: What's important has been addressed, and that is to find instrumentation manufactured by the same company that has the same methodology, the same issues, no matter which machine you're putting the test on—high, medium, or low volume.

Dr. Kiechle

Also important in deciding what kind of equipment to place at large, medium, or small institutions is turnaround time. It depends on how far away the centralized lab is from the smaller institutions. The longer the transportation time, the more tests you're going to have to do at the smaller site. The quicker the transportation time, the smaller the number of tests. If the institutions are close enough, say across the street from each other, that will affect how

to split menus and instrument decisions.

There's also the concept of sharing expertise. It is popular in Canada but doesn't work as well in the United States. Here it makes more sense to look at the question of turnaround time, and then beyond that, what is clinically needed in that particular smaller institution that is not necessarily requiring a fast turnaround time but is essential to moving patients around. For example, TSH may not be considered a decisive lab test for most hospitals. However, in an emergency department with an elderly population, TSH is the primary test. It might turn a patient into an inpatient or an outpatient.

Mimi Dang, what is top of mind for your current customers and those who are making inquiries of you for your instrumentation, particularly in immunoassay? Do you see some shifting? What's the latest in terms of what you're hearing from customers and what you're trying to develop within your R&D structure?

Mimi Dang, associate product manager, Tosoh Bioscience: With our customers it is about having similarity across all the instruments. Tosoh offers a solution for all testing volumes, and because we use the same reagents across the platforms, it offers the standardization.

Dang

Customers want a wide range of immunoassays with minimal waste. For esoteric assays they want the flexibility of single use tests to optimize their reagents.

They want an analyzer or reagent that takes away the errors that can happen in immunoassays, for example reconstituting reagents and worrying about stability, calibration, and interferences. Tosoh R&D is working on the next generation of immunoassay reagents and analyzers to meet these needs.

Most of our customers are looking for not only the high- and medium-volume analyzers but also the smaller ones, where it can be intraoperative, so if they do need stat testing, it can occur on the floor.

While we talk about the need for a family and similarity across systems, we also have a kind of best-of-breed question that seems to come up when we talk about certain analyzers. For example, I know laboratories where they like immunoassay system A for nutrition and anemia markers, system B for cancer biomarkers, and system C for general immunoassay tests.

Dr. McCash, do you adopt that philosophy at Memorial, whereby you have some analyzers that are very dedicated because they may be best for a certain subset of tests, irrespective of the need to standardize across the system on large mainframes?

Dr. McCash: Yes, we do have a variety of analyzers for immunoassays, particularly when looking at tumor markers, hormones, that sort of thing. They were selected because of certain parameters—analytical sensitivity, for example. How low can they go, how low can they measure and still be accurate, because some of our clinicians want to have a number to look at, but it is also research related.

However, that can change over time, and other factors come into play, such as turnaround time. They want to know right away with some chemotherapies if the patient is at toxic levels or if they're below the therapeutic window so they can act on it immediately. Even though there may be tests that have higher sensitivities or specificities, we may prefer a system that is faster.

We're also always looking at where we can consolidate. To meet desired turnaround times we try to move manual and more specialized tests to the automated instruments our technologists are already familiar with. We willingly look at any test we can move to one of our more automated systems that allows us to run the tests 24 hours a day.

Dr. Kiechle, I'm hearing a desire to standardize on the fewest systems that get the work done reliably and at the clinical quality levels that are demanded, not only within the lab but also by the clinicians who are using the results. But based on what Dr. McCash says, is there still a need to evaluate individual systems and their individual assays and performance characteristics in order to get the optimum testing situation established in a laboratory?

Dr. Kiechle: I worked with two large hospital integrated systems, and the usual issues that come up are for those tests that are more esoteric, those ordered less frequently. They come stat; you have to sit down and think about what is this machine and its tests and are they available 24/7, and often that's not the case. For example, if you're doing immunosuppressive drugs in a special chemistry lab, and that lab is open only for about a shift and a half and the rest of the 24-hour period is not covered, and someone comes in and has a need for a stat drug level to assess transplant rejection issues.

You want to have your best machines for these esoteric tests located in your centralized lab and have a rapid way to get those specimens to that central location. If you have to decentralize that process, you have to be careful that the technology, the training, is spread equally across the system so everyone is functioning at the same level.

Immunoassay used to be a method, but now it's becoming a place, and once it does, it's difficult to move it and decentralize it. Molecular tests are a place and soon they will be decentralized to the point where you will hardly recognize it. It's something we need to watch out for as we plan.

Then there's the issue of having selected a main chemistry system—and guess what? It does troponin I. But there's no high-sensitivity troponin I available, and my cardiologist is saying, "I want this Roche troponin I assay I'm hearing about, and I want it now." You have to make a decision about whether to buy a small Roche device to handle that issue or a more medium-size immunoassay instrument.

Another issue is the PTH assay, which is often performed intraoperatively. This is an assay for which there was technology at one time that you put on a cart and rolled into the operating area. In the large hospital system I worked in, we did not have it on a cart. We had the OR test done manually in the central lab where we did the most rapid testing we had available on our automated equipment. There are challenges to each alternative.

Human chorionic gonadotropin is another; it needs to be done on women suspected of having ectopic pregnancies. Do not waste your time on a urine test and call it a rapid turnaround time test with a sensitivity that is much less than the central laboratory test.

Beware that kind of rationalized criticism, because now physicians are expecting a serum test to be the same sensitivity throughout their universe of experience, which is one high-sensitivity assay. Now you introduce one with intermediate sensitivity and they don't know how to use it. And they shouldn't use it. You use a urine test for that, and not the serum test.

There are pitfalls along the way of trying to find the right fit for the right test, the right time, the right location.

It's clear this is an enormous area that requires a lot of experience and analysis, and even a lot of working out exactly how your test menu will be set up with what analyzers in which places, and even which methods, as Dr. Kiechle mentions. What do you do at Tosoh to help laboratories with these decisions?

Mimi Dang: Our team is made up of different technical groups. These teams work with the customer to identify what's the best workflow. Because Tosoh has different models of analyzers, we can customize the solution based on the needs of the laboratory. Our analyzers use the same reagents across platforms, which allows for the standardization of the tests, whether it's in the core lab, ER, surgical suite, or a satellite lab. This is what is

appealing to our customers.

We also train the customers on the clinical utility of the tests and the current trends in the market, whether it is interferences in the immunoassays or standardization of assays.

How does Roche help a laboratory work through these questions around analyzers, test distribution, menu, and critical assays?

Christina Reita: Laboratories do face challenging decisions about when to centralize or decentralize some of their diagnostic testing. Our strategy positions us to provide value to our customers by consulting with them on when and how to do that. We have our Roche Healthcare Consulting service, which is made up of workflow consultants who can look at testing across the sites and help determine which testing makes sense to do at which site.

We also have invested in emerging IT solutions that can help laboratories and the health systems they are a part of. For example, Viewics delivers end-to-end health care analytics and provides insights to empower labs with the data required to improve operational and financial outcomes across the health care system.

We talk a lot about IT in our roundtables on instrumentation. First, the interface from the instrument to the LIS; we have a lot of middleware that's important there. But then, importantly, reporting of the instrument result into the EMR. Dr. McCash, what has been your recent experience? I know you have an interest in the IT side of the clinical laboratory. Tell me about the challenges there, particularly as they affect instrumentation.

Dr. McCash

Dr. McCash: In terms of laboratory information systems, one of the issues is there aren't many choices. There's probably a handful of laboratory information systems out there that can handle large volumes in a testing laboratory. And these systems don't necessarily push the boundaries of being able to do what you want them to do, to report how you'd like them to report. Part of that is because of the lack of competition. If laboratories want certain functionalities, they could put pressure on the laboratory information system companies, but that doesn't always work. So to get the desired functionality, laboratories have to rely heavily on middleware and other systems from other companies.

A lot of what goes into what you want to bring in-house will depend on what the middleware can do and how it interfaces with laboratory information systems, maybe even with EMRs. That brings up the additional challenge of laboratories handling multiple systems for things like autoverification rules, quality control, critical value alerts, repeat testing, and reflex testing. There is also a challenge in organizing all of the data dispersed among the systems so that the laboratory can use it efficiently, with clinical results distributed appropriately to clinicians and patients.

On a scale of one to 10, with 10 being hugely satisfied and one being not at all satisfied, how would you rate your ability to put clinical lab results from chemistry and immunoassay into the EMR that your clinicians depend on?

Dr. McCash: There are always pros and cons, and I would say what we're doing now is adequate. It is not ideal, especially since we do not have control of the EMR. We in the laboratory are trying to bridge that gap a bit more by communicating with the people who are in charge of the EMR to see what they can do for us. And we're doing better in getting that communication and that teamwork going forward. There's also a lot of effort in making sure

we all communicate about these different systems that are in place. For instance, when we were bringing in our laboratory information system, we had talked to people who are in charge of the EMR, and we all had to come together to discuss our needs, what had to happen, and then come to a conclusion about which system to go with. And that relationship has been going well.

Christina, it's well known that Roche has an enormous number of installs at some of the biggest core labs with high volumes serving large integrated delivery networks. Geisinger comes to mind. I'm sure those of you in centralized diagnostics live almost daily with some kind of IT issue.

Can you give me a sense of how that plays out and some highlights, if you will, of what kinds of problems customers need you to help solve, even though their real problems might be with an IT vendor?

Christina Reita: We have placements in large and small laboratories. Both the complexity and the resources of the IT systems that a site has will vary.

Our Roche Healthcare Consulting team works from a workflow perspective, and we have a strong IT consulting team that helps our customers as they operate in this new normal, where digital is critical to not just the laboratory but to the health care delivery system overall.

We have middleware solutions to help our customers solve some of their challenges, whether it's basic connectivity all the way to sophisticated dashboards, because these labs are sitting on a mountain of data and expected to leverage that data to provide valuable insights.

We also move beyond middleware into our new digital suite, Cobas Infinity laboratory solution, which is designed to help our customers manage their sample and data flow across centralized and decentralized sites. We've got a workflow engine that helps determine the fastest route for every sample. It can negotiate changes—for example, when an emergency sample comes in. It's a comprehensive workflow management tool designed to help the smallest laboratories to the largest with their biggest challenges.

Our diagnostics optimization solutions through our Viewics platform help customers solve the problem of what's the right test to use at which time and whether all clinicians are leveraging the tests in the same way.

So while customers have a variety of information technology challenges, we look at these as opportunities to help them solve some of their most critical problems.

Mimi, tell us about the IT system challenge as you see it from your perch at Tosoh.

Mimi Dang: It is what's been discussed thus far—everyone is trying to centralize their information to be able to distribute it to multiple channels. The LIS-LIMS providers are not always able to accomplish that in ways that are customizable to each laboratory's needs.

Companies are offering middleware to address the challenges that aren't able to be met through the LIMS or LIS. We have our teams and specialists for IT, where they work with customers to spec out what they need, the requirements they have with their LIS, and to be advocates to channel that conversation, if needed, especially if the laboratory doesn't have the resources to have a specialist on board to advocate for it. We also offer the middleware solution from our end for laboratories that aren't able to have a laboratory information management system within their labs or within their clinics. And we have inventory management and other solutions, through our middleware and other platforms, that would allow customers to centralize information to distribute it directly to where it needs to go.

Dr. Kiechle, what worries you the most about the next three to five years in clinical pathology? We have reimbursement pressures, staffing pressures, and pressures regarding adequate communication and understanding of the value or significance of laboratory tests on the part of busy clinicians who are taking care of patients, and not just physicians but nurse practitioners, PAs, nurses.

Dr. Kiechle: I would put on the top of the list the interface between molecular technology and anatomic and clinical staff applications. It starts with education of the physicians who are ordering these tests and education of some of the people in the laboratories. NGS is not a sodium measurement because the complexity of setting up next-gen sequencing to do tumor sequencing, for example, exceeds that of setting up a sodium as far as more bioinformatics and more understanding of complexities within the various platforms you have to choose from. Then the minute you make that decision, the next week someone else may have a solution that looks more tantalizing. But you've already just spent a couple hundred thousand dollars on something you're now working with for a while.

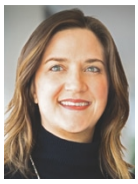
I feel the most tension in that area because the area's growing so rapidly, the information is so valuable, and the growth of immunotherapy may replace the need for that kind of technology.

Mimi, what do you have top of mind for challenges in the next three years?

Mimi Dang: The first one is, again, integrated health care—being able to help laboratories and laboratory tests transition to a digital world where connectivity is all important. With the consolidations occurring, the second challenge is being able to offer a menu that not only has some of the niche or esoteric testing but a standard menu too, to integrate all the immunoassays and chemistry onto one platform.

There's a lot of consolidation going on with the custom menu itself, but also with the laboratory, and trying to get information into one place and being able to accomplish that seamlessly is going to be a challenge for the next couple years.

Christina, can you speak to this same topic?



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Christina Reita: I agree with everything that has been said. To dive into one of those areas a little more deeply, I would say we are focused on continuing to drive those integrated solutions to help ensure that we are uniting what we're talking about from a medical value perspective. We focus on the most critical tests that are bringing the right benefits to the patient at the right time.

As you think about the fact that the decisions are being made in a more centralized way, especially in integrated health networks, sometimes that medical value piece can get pushed to the side, so we focus on thinking about how we can ensure we are providing the solutions patients need.

People make decisions around these laboratory solutions, and the solutions are going to be in their labs for the next five, seven, or 10 years because reliability of systems has gone up dramatically. As an organization, we undertake things like looking at where laboratories are focused on answering the questions such as what will be the disease burden in 2030, and how can we ensure that our development pipeline and the solutions we have today are agile enough to meet those needs.

Dr. McCash, I'm going to give you the last word. What are the points of intense concern and interest for you?

Dr. McCash: My big concern right now being in New York State is that we have a lot of buyouts. Large hospital systems are buying out physician offices, many of which have their own laboratories to run CBCs and other tests. Now that they are bought and being integrated into these larger health systems, they've come under extra regulations they have to follow—for there to be a laboratory medical director, for example.

There’s a shortage of people who can be a director, particularly in New York State, maybe in some other states as well, but then these laboratories, when they can’t find a director, cannot use the same instrumentation they were using. So they’re moving more toward point-of-care and waived testing.

However, the doctors running these offices do not entirely understand what the difference is between their old analyzers and these new waived tests. They don’t understand that the results are not going to be as precise or as accurate, the reference ranges are going to be a little different, and that they need to apply more of their clinical knowledge to these laboratory results to make the interpretation.

I fear that they don’t necessarily have all the knowledge they need to put one of these together and to run it. I’m watching this from the sidelines, to see how things go, because I’m not sure how things will turn out. Will there start to be extra regulations on waived testing? I’m not sure. Is somebody going to get hurt? I hope not. It is important for physicians to understand that waived testing tends to have a higher degree of error and that assessing the overall clinical picture is essential for making medical decisions.