NEWSMAKER INTERVIEW

Healthcare's Transformation Now Bringing Changes to Lab Industry

"Today, patients want to get diagnosis and treatment faster with fewer visits to the doctor's office. They want speedier and more comprehensive delivery of clinical services, be it laboratory tests, imaging, or other procedures."

—Ralph Taylor, **President, Sysmex America, Inc.**

CEO Summary: To bring testing closer to patients, clinical laboratories will need to offer sophisticated point-of-care systems for two reasons. First, that's what patients want, and second, a shortage of applicants for lab tech jobs will force labs to use more senior staff to process abnormal test results, leaving lower-level staff to manage normal results. Abnormal results will be produced in the central laboratory, and normal results will be produced closer to patients. Therefore, hospital labs will become almost like referral labs for abnormal specimens while normal testing will migrate to near-patient settings. To make these changes, labs will need to work with companies developing automated systems that reduce staff hands-on time.

Since passage of the Affordable Care Act of 2010, almost every aspect of healthcare in the United States has changed significantly. Changes certainly are occurring in the clinical laboratory sector, and many lab directors expect Congress and the Trump administration will make still more changes.

To get an idea of how those changes have affected labs and to analyze how clinical labs can prepare for what's ahead in the coming years, The Dark Report interviewed Ralph Taylor, Chief Executive Officer of **Sysmex America** in Lincolnshire, Ill. Sysmex America serves clinical labs in North and South America with automated hematology and urinalysis analyzers and middleware information systems.

Taylor joined Sysmex as an Executive Vice President in 2007, and in March, Sysmex named Taylor CEO. He is responsible for management and strategy and continues to lead operations in Latin America while also growing the flow cytometry business.

In the interview, Taylor focused on three general themes:

1. How Sysmex views the way the healthcare system is transforming in the United States.
2. How Sysmex's executives believe clinical laboratories will respond to healthcare's transformation by changing how they are organized and deliver test results to physicians and patients.
3. How Sysmex and other companies serving labs are developing technologies, products, and services that will help medical labs meet the changing needs of hospitals, physicians, and payers.

EDITOR: Let's start with the changes happening to healthcare. What are the primary drivers of change that you see here in the United States, and, more broadly, across the globe?

TAYLOR: We are watching the trend in which healthcare is moving closer to the patient. Today, for example, patients seek fewer encounters with the healthcare system. They want to receive diagnosis and treatment faster with fewer visits to the doctor's office. They want faster and more comprehensive delivery of clinical services, be it laboratory tests, imaging, or other procedures.

EDITOR: Is this trend something younger generations, such as Generation X and the Millennials, are pushing?

TAYLOR: In part, yes. We see this trend happening among all patients. But it is particularly true with Millennials. This generation is more educated about healthcare. Compared with older generations, Millennials are savvier in how they select healthcare providers and in how they acquire the care they need.

EDITOR: What does this mean for providers?

TAYLOR: For providers, a greater proportion of their patients are now well-informed. They show up having researched their health conditions. They know the type of care and treatment they want.

EDITOR: How are physicians and hospitals responding to these informed patients?

TAYLOR: For informed patients, we see innovative providers adopting a consumer-based approach to delivering care. They recognize that growing numbers of patients now go on the Internet to rate healthcare providers on such factors as convenience, wait times, and the quality of care they receive.

EDITOR: How can medical technologists, pathologists, and other lab professionals respond to these consumers?

TAYLOR: When you see such changes occurring at the macro level, then we as lab professionals need to focus on how we can meet those demands by doing our jobs more efficiently. That means we need to deliver test results faster and provide more information about what those test results mean.

EDITOR: Do you see connections between this consumer-based emphasis and how payment models are changing as Medicare and private payers move away from fee-for-service and to payment arrangements that reward providers on patient outcomes and satisfaction?

Ralph Taylor

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TAYLOR: Yes, absolutely, there is a connection. Consumers are searching for service efficiencies in healthcare—just as they do when buying other products. They want more information about the care they receive. In particular, they want information about what forms of treatment are best. Providers need to respond to those demands for information.

EDITOR: Can these changes be seen in the health systems and hospitals where many lab professionals work?

TAYLOR: We do see this, particularly as payers evolve in how they reimburse hospitals. For example, we see some hospitals competing in terms of the way they provide services. More intense competition will drive improvements in efficiency throughout the healthcare system.

EDITOR: Given what you've said about how health systems need to have a more consumer-focused approach to care, do you foresee health systems, hospitals, physicians, and even insurers taking different approaches to meet this demand for consumer-facing care?

TAYLOR: We believe hospitals and insurers will soon be able to publish data on the results they've produced from pay-for-performance programs. As that happens, physicians and hospitals will become much more cognizant of how they're measured and how their performance compares with that of other physicians and hospitals.

EDITOR: Will this published data give better-performing providers a competitive advantage?

TAYLOR: All evidence to date says, yes, that will be true. With access to patient outcomes data and satisfaction scores, most patients will be able to select among the top performers and avoid poor performers.

EDITOR: What type of patients will use this information to shop for a hospital, a physician, or a lab?

TAYLOR: Only the more informed patients will bother to seek out that information. They will research all providers who deliver their care. That research will include each provider's background and prior experience. By contrast, the everyday healthcare consumer will not do that even though such information will be more readily available.

EDITOR: Can providers use outcomes data and patient satisfaction scores to their advantage?

TAYLOR: That is happening already. Many hospitals and insurers use existing

rankings and similar information in their marketing materials. In the future, more such marketing will be used to drive patients toward better-performing providers.

EDITOR: Now that we've covered that first theme about what changes are occurring, let's go one level deeper. Given the changes you've described in healthcare, will these changes affect how labs organize themselves to deliver testing services?

TAYLOR: My answer is consistent with the major changes we just discussed for the healthcare system at large. As providers shift their focus to patient-centric healthcare—delivered as close to the patient as possible—so also will clinical laboratory testing services move closer to patients.

EDITOR: Do you have examples that are already in the marketplace?

TAYLOR: Today, you can see health systems and hospitals trying to accommodate patients' schedules rather than requiring patients to show up according to the hospital's or the lab's schedule. Another example is how some clinical labs are establishing patient service centers in retail settings, including pharmacies and grocery stores.

EDITOR: THE DARK REPORT has written about this trend. Last year, **Laboratory Corporation of America** and **Quest Diagnostics** announced agreements with national grocery and pharmacy chains to put PSCs into retail stores.

TAYLOR: That strategy makes sense because it's patient friendly. It's time-consuming for patients to drive to the local hospital, find a parking place, and then get to the PSC in the hospital or the nearby physicians' office building. Conversely, it's much more convenient for patients to go from where they live to a grocery store or pharmacy to have their lab specimens collected. We expect that kind of accessibility will increase across the marketplace.

EDITOR: Is "faster and more convenient" a trend in lab test turnaround times, and, if so, are Sysmex's lab clients moving in this direction?

TAYLOR: That answer is a definite yes! We already have some labs making test results available to patients within the same day or—in some cases—by the next morning. Along with a faster TAT in reporting lab results, as appropriate, those results will include more commentary and guidance from labs about what those results mean. Many physicians already find this added value helps improve their medical practice productivity.

EDITOR: Given that you see early signs of labs shortening test turnaround times and adding clinically-useful commentary in lab test reports, how is this trend consistent with moving more lab testing closer to the patient? What is the future for core laboratory facilities versus point-of-care and near-patient testing?

TAYLOR: Sysmex strongly believes that core laboratories will continue to anchor lab testing services in the communities they serve. What will change is the type of lab testing that makes up the largest volume of specimens tested in core labs.

EDITOR: Would you explain that?

TAYLOR: Core laboratories have something unique and irreplaceable. This is where the expert knowledge of lab medicine resides in a community or region. In core labs, you have experienced clinical pathologists, chemists, and laboratory scientists working in close collaboration with each other and with referring physicians. The core lab of the future will be the center of sophisticated diagnostic expertise and capabilities.

EDITOR: Given that core labs will continue as the medical community's most sophisticated testing resource, what type of testing will be dispersed within the community and done closer to the patient than is currently done?

TAYLOR: As mentioned earlier, the trend is to serve patients in convenient settings, so that routine screening and

common tests will be pushed outside the core lab, meaning to point-of-care and near-patient settings.

EDITOR: Is this trend why specimen collection will shift into retail stores and similar settings?

TAYLOR: Yes, particularly for routine screening and other common tests, more specimens will be collected in such convenient settings as **CVS' Minute Clinics** and in PSCs in supermarkets and other retail stores. Quest, LabCorp, and other large lab companies are moving draw stations into pharmacies, such as **Walgreens**. If these pharmacies had the equipment to do the testing there, then they would do so. That's the next logical step in the evolution of moving care closer to patients.

EDITOR: Our readers will note your statement that lab tests in retail pharmacies is a next logical step in the move to bring lab tests closer to patients. What other disruptive trends do you see coming?

TAYLOR: How about the news that **CVS Health** will acquire **Aetna**? That creates the opportunity for CVS to establish an integrated health delivery system that includes the health insurer and can provide care in 9,600 CVS pharmacies nationwide.

EDITOR: What would you say about the trend of consolidation in the hospital sector and the way integrated health systems are establishing large spheres of influence? The **Aurora** and **Advocate** combination in Milwaukee and Chicago and **Northwell Health** in New York are examples of such big health systems. From your perspective, how do these big health systems change the landscape for clinical laboratories?

TAYLOR: There are two important ways that these systems affect labs. First, these systems have learned to adapt to the crisis that most other labs face because all labs have an aging population in the workplace and need to hire and retain skilled staff while facing a shortage of applicants to fill those lab-tech positions. One consequence of this crisis is that the labs in larger health systems are supplementing those workers with less-skilled staff who then run most of the analyzers and other lab systems.

EDITOR: What is the second way large health systems affect labs?

TAYLOR: The second way large health systems affect labs is that they are separating normal results from what we might call abnormal results. Normal lab test results will be produced closer to patients. However, abnormal results will be produced in the core laboratory.

EDITOR: By that, do you mean lab tests for generally-healthy patients will move closer to the point of care? And tests for patients with complex conditions or difficult-to-diagnose diseases, will be referred to core labs?

TAYLOR: Yes. Sysmex believes that specialized laboratory staff will handle the abnormal test results, meaning the skilled staff will be assigned to those samples. When that happens, the hospital lab will become almost like a referral lab for abnormal specimens within its community. Meanwhile, normal testing will migrate to near-patient settings.

EDITOR: This is consistent with your earlier prediction that core laboratories will be an essential resource in their service areas because they have the sophisticated expertise and experience to perform complex testing and to help physicians with difficult-to-diagnose patients. How will IVD manufacturers support this development?

TAYLOR: While these changes are happening, Sysmex and other IVD manufacturers will respond by developing automation for laboratories specifically designed to remove the hands-on time for each sample.

EDITOR: What areas of lab workflow will be the most difficult to automate in this way?

TAYLOR: Even with new automated systems that reduce staff hands-on time, the fact is that much testing must still go through accessioning, the one part of clinical labs where hands-on processes are still required. In their struggle to address this problem, labs and companies serving labs do not yet have an answer.

EDITOR: Now that we've connected how patients will drive change and how hospitals and health systems are responding to those changes, are there other transformative forces that will cause labs to operate differently over the next three to five years?

TAYLOR: Yes. Probably the most significant of these other transformative forces is the new Medicare 2018 Clinical Laboratory Fee Schedule. It substantially lowers the prices for many key lab tests and this will negatively change lab finances.

EDITOR: Many expect the Medicare fee cuts will cause some labs to shrink or close, but will there be other consequences from these price cuts?

TAYLOR: Those lower rates will drive labs to look for more efficiencies. And, when calculating a lab's total cost of testing, the manufacturer's costs may be one of the smallest components of total costs. Therefore, labs will need to drive efficiencies into the cost of each test. That will force them to be creative in rethinking current testing models. One obvious way to drive down testing costs is to reduce labor costs. Even though some staff are not highly paid, their salaries are a major element driving the cost of each test.

EDITOR: Now that we've covered the first two themes, we can address the third theme: How will Sysmex and other companies develop the products and services that labs will need in a transformed marketplace?

TAYLOR: I will repeat one theme central to our strategic thinking about healthcare and the lab testing marketplace. Sysmex and all companies serving clinical labs will need to look at how they can develop analyzers to move testing closer to the patient. For Sysmex, the XW-100 was the first entry in this new world of CLIA-waived CBC testing.

EDITOR: You surprised many IVD executives with the FDA clearance to sell a CLIA-waived hematology analyzer that can do routine CBCs in near-patient settings, including physician offices.

TAYLOR: That may be true. But your readers should understand the more significant aspect of FDA's clearance. Sysmex had to work in close communication with the FDA to develop a path to develop a CLIA-waived system for what is a CBC with three-part differential. The next step would be to develop a five-part differential with a CLIA-waived status. If we can do that, we would obviously be providing more useful information to clinicians and patients from a hematology perspective.

EDITOR: What other clinical lab tests do you want to develop for use in CLIA-waived systems?

TAYLOR: Sysmex intends to expand its portfolio of testing that is CLIA-waived. To accomplish that, we are exploring whether it is possible to create a CLIA-waived suite of analyzers and instruments that functions as a near-patient lab. For example, we are trying to determine if we can add the most commonly-requested immunohistochemistry tests.

EDITOR: That is an ambitious goal.

TAYLOR: Yes, it is, but it's not immediately achievable. If we can do all that, however, we would provide a greater form of intelligence to assist doctors who need diagnostic test results. What I'm describing is a type of mini-CLIA-waived lab suite. That's an area we are assessing and the CLIA-waived XW-100 is the first step in that direction.

EDITOR: Will this CLIA-waived suite of analyzers and instruments be developed in stages?

TAYLOR: Certainly, yes. We knew we could develop the first CLIA-waived CBC with three-part differential. But it was still a challenge to make that a reality. Now our task is to create a suite of products in the CLIA-waived space. The next step for us is to provide more relevant parameters to our XW-100 so it can handle abnormal testing. Another development challenge is to help laboratories manage those samples in specific ways that require the minimum amount of staff work. As we do that, we will help clinical labs reduce the amount of lab-staff intervention that is needed from laboratory technicians.

EDITOR: Do you have a guiding vision for all of these future analyzers and tests?

TAYLOR: My vision for the future is that one day the lab technician will not be someone who stands in front of a hematology, immunochemistry, or other analyzer. Instead, the future lab tech will sit at a terminal reviewing and acting on data coming from many different analyzers. The lab tech of the future will not be touching tubes and loading analyzers.

EDITOR: Are you hoping, therefore, to bring an end to the current era where highly-trained clinical laboratory scientists spend their time managing analyzers or a section of an automated line?

TAYLOR: Definitely. Our vision is that the lab systems of the future will be operated and managed by lab staff that have much less training than is true today. These new staff members basically will be machine minders. That is not the best term, but it describes what they will do.

EDITOR: In your view, will the highly-skilled clinical laboratory scientists continue to be essential to every laboratory because they will spend their time ensuring the quality of lab test results? If so, will they be the source of added value for labs in the future, meaning these clinical pathologists, chemists, and other lab scientists will collaborate with providers to help them make faster, more accurate diagnoses?

TAYLOR: Yes. Lesser-skilled staff will handle specimens, load and unload machines, and do similar tasks. The qualified lab staff will do all of the interpretive work, authorizations, and sample validation.

EDITOR: Does that mean lab professionals should expect to see Sysmex and other IVD manufacturers offer analyzers, instruments, and automated solutions designed to reduce hands-on labor?

TAYLOR: I believe that will be the case. Our strategy, and possibly the strategy of our competitors, will be on two levels. First, we will continue to drive forward with automation by working to minimize the level of manual intervention with each sample. Second, we will look at how we present lab test results—meaning the forms in which the data reside—so that we can provide greater information that allows faster and more specific data interpretation. That is the next logical evolutionary step given where we are now after developing the Sysmex XW-100.

Ralph Taylor

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EDITOR: How does your CLIA-waived system fit with this strategy?

TAYLOR: The reason we started the XW-100 project was to fulfill the unmet need for CLIA-waived testing in doctors' offices. We aim to create a type of CLIA-waived mini-lab environment to offer key immunochemistry testing and also clinical chemistry testing along with urinalysis. If we could do that, we would be moving some core laboratory testing to a CLIA-waived environment.

EDITOR: Where else might this type of testing be performed?

TAYLOR: The next logical need to fill is for the patient who is at the pharmacy waiting to get clinical lab testing done there. If we can meet that need, it would be an extension of that philosophy.

EDITOR: Now that the XW-100 is on the market, do you worry that competitors will duplicate it or make something better?

TAYLOR: Yes, absolutely. In every industry, everyone wants to produce the next better mousetrap. If you go back five or six years, we showed that the FDA was reluctant to give certification to a CLIA-waived product in hematology. Our experience is that the FDA is open to this idea if you provide the right controls in terms of the result. So, in that way, we created a pathway for how it could be done for other CLIA-waived tests.

EDITOR: Does that mean other IVD companies are expected to launch similar instrument systems?

TAYLOR: Our competitors are likely to follow that path because there are about 70,000 CLIA-waived labs in the United States. There's a lot of people eyeing the hematology part of that market because it didn't have a CLIA-waived product.

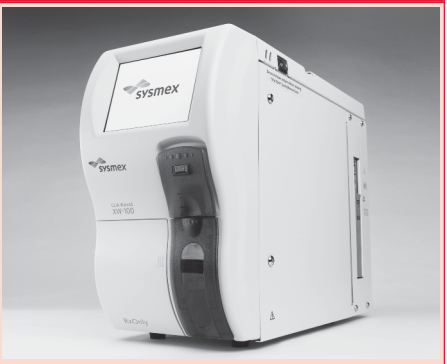
EDITOR: This has been an enlightening conversation, Ralph. Any closing thoughts?

TAYLOR: I'd like to emphasize one point, and it is that—no matter in what setting the lab sample is collected—it will be experienced, trained clinical laboratory professionals who will oversee the network of labs and sites performing those tests. As medicine becomes more complex and personalized, the need for the expertise of pathologists, clinical chemists, and clinical laboratory scientists of all disciplines will be greater than ever before. TDR

—Joseph Burns

Visit www.waivedcbctesting.com for more information."

CLIA Waiver for XW-100 Supports Fast Results



IN NOVEMBER, the FDA cleared a complete blood cell count test from Sysmex and its XW-100 Automated Hematology Analyzer.

For this analyzer, the FDA granted a CLIA waiver, allowing it to be used in non-traditional laboratory sites, such as physicians' offices, clinics, or other facilities with a CLIA Certificate of Waiver. Also, a wide range of support staff can run the analyzer, allowing for fast availability of results, the FDA said. The XW-100 is the first, automated, CLIA-waived hematology analyzer to offer an accurate, same-visit CBC with differential and a sample-to-result time of three minutes, Sysmex said.

This technology provides healthcare professionals with a report of 12 parameters in the same patient visit to assist in establishing a diagnosis and treatment plan. The XW-100 is a quantitative, automated hematology analyzer intended for *in vitro* diagnostic use to classify and enumerate the following parameters for venous whole blood: WBC, RBC, HGB, HCT, MCV, PLT, LYM%, Other WBC%, NEUT%, LYM#, Other WBC#, NEUT#.

It is not approved for use in diagnosing or monitoring patients with primary or secondary chronic hematologic diseases or disorders, oncology patients, critically ill patients, or children under the age of 2.