Broadening the productivity spectrum with middleware

Anne Paxton

March 2016—As James Beck, MT(ASCP), remembers it, middleware was introduced at his institution about the same time that the nursing department decided connectivity should be the province of the laboratory.

When the concept of docking and interfacing glucose testing devices came on the scene around the turn of the millennium, that was a turning point, says Beck, who is point-of-care testing coordinator for the University of Pittsburgh Medical Center–St. Margaret, which uses the Telcor middleware solution QML. "What had previously been a nursing-run program turned into a lab-run program just because of their unfamiliarity with the electronics and connectivity issues. Our nursing department, at least, felt, okay, this is the end of line for us—you take it on."

At that point, middleware was considered revolutionary in its ability just to handle getting point-of-care data to the laboratory information system, never mind to the hospital information system. But between its beginnings a couple of decades ago and today, middleware has charted a more multidimensional role. It is increasingly being called upon as an agile and resourceful productivity manager, software vendors and users say.

It was about 2006–2007 that middleware's role started to evolve from connectivity to more "productivity opportunities," Maureen Marentette recalls. Middleware vendor Data Innovations (DI), where Marentette is director of North American sales, started in 1989 with the interfacing of instruments to the LIS as its focus. Now, products like DI's Instrument Manager take the information that instruments provide plus what the LIS provides, and "they combine those two pieces to provide powerful management of results at a completely different level."

With drivers available from more than 1,000 different instruments in anatomic pathology, molecular, microbiology, immunoassay, and more, DI has vastly multiplied the number of parameters it can manage, Marentette says. "We've got over 473 data fields that we can use to create very specific rules that are patient- and physician-specific as well as specimen-specific."

For example, if an instrument is giving a bilirubin result, depending on the hospital, it might be a result on a newborn, a 10-year-old child, or an adult. "Whereas most LISs only handle reference ranges in years, using a middleware product you're able to drill down to a reference range based on number of hours old, because that parameter can be significant for a newborn from a diagnostic perspective."

Some LIS companies still use DI for their interface engine for point-to-point interfaces from each new instrument a hospital purchases into their LIS. But when a laboratory purchases Instrument Manager, Marentette notes, "if you switch from, say, a Beckman to a Sysmex hematology instrument, you can simply repurpose the connection you had for the first instrument and move it over to the new one, then just do the editing needed to recognize the codes that are unique to each instrument. It's really just a tweaking rather than having to recreate the entire interface. So we've evolved from connectivity to being able to help labs with productivity and optimizing their workflow."

These capabilities become particularly important for laboratories dealing with staffing constraints. Some Instrument Manager clients, for example, have 95 percent autoverification of their core chemistry lab results, she says, so those tests go straight into the LIS once released, and then into the HIS for interpretation by the physician. Many labs are still using LIS autoverification protocols only about 40 percent of the time but could be doing much more, Marentette believes. "People kind of look at it over the short term. There is change management that goes into moving into a middleware product initially. It's a cost thing, and there's a knowledge piece, and it takes time to implement and get people to understand how much better off they would be with middleware."

Focused specialization is what Sysmex's middleware product WAM (Work Area Management) offers for

hematology labs, says Anne Tate, MT(ASCP), IT/automation group manager at Sysmex America. "We concentrate on managing everything around the lavender top." As a best-of-breed solution, WAM provides hematology-specific rules honed over the past 10 years and now used by more than 300 hematology labs serving 1,100 hospital sites, Tate says.

Sixty percent of Sysmex WAM clients are large integrated health networks, many of which use Sysmex instruments such as the DI-60 and its slidemaker/stainers and sorters, as well as Bio-Rad and Cellavision instruments. "We have instrument lines with one or two instruments on them, up to large systems with two automation lines. So we support both complex and the high-end markets."

Multisite capability is one of WAM's key features. "It's a server-based system, so whatever results you have on site A, you'll be able to see them on site B. So you can get delta checking and previous results and be able to correlate data from one site to another, but also apply the same standard rules. Doctors and other professionals are assured predictability in how the results are looked at and managed between sites," Tate says.

She considers middleware as the "production floor" of the lab. "We manage all the results coming out of the instruments, applying rules and logic to either autovalidate to the LIS, or hold up results to do something further such as rerun, reflex, review, or maybe move to another Work Area Manager."

More and more customers are demanding middleware when they purchase automation, Tate points out, and middleware is increasingly becoming an essential part of the lab. "We've always been important. But the LIS really depends on us to manage these combinations and multiple sites because that's where our expertise is."

Tate believes LISs have to concentrate on other issues. "LIS vendors really can't know everything about vendors' automation and all the changes and parts that go with it. LISs are concentrating their dollars on interfacing more with the EMR and medical necessity and other modules, but they depend on us for decision logic to process results for small to large automation."

Keeping track of operator competency is another WAM capability. "With our management reports, you can search by user and track almost everything users are doing on the system, with competency based on whatever your criteria are."

What Sysmex customers most like about the WAM middleware is "they don't have to look at every result. It automates the process so they are assured that all the logic they would have done manually is being done consistently without a verification."

At Dartmouth-Hitchcock Medical Center in Lebanon, NH, which includes a main hospital, several clinics, and a network of regional lab partners, Sysmex's WAM is what allowed the laboratory to bring on the clinics and increase its volume in 2009, says Dorothy Martin, MT(ASCP), hematology supervisor.
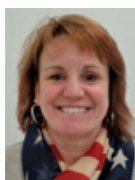
Martin

"Originally we were sending many tests out to a reference lab because we could not handle the volume, but Sysmex allowed us to expand and then bring on the regional partners. This is helping us to drive cost out of the system for our patients." Her lab also has middleware for urinalysis and is exploring use of middleware in coagulation testing as a 2017 goal.

The facility started with the Sysmex WAM 3.0, which communicates to Dartmouth-Hitchcock's Cerner LIS and its

Epic HIS. After upgrading to WAM 5.0 in November 2015, "we've increased our autovalidation to 87.5 percent, so that's another 2.5 percent that we can autovalidate. Not only that, but we decreased our manual differential rate. Before, it was a little over four percent, then we brought it down to two percent. Because those manual diffs take longer, that's less tech time we're spending at the scope."

The 5.0 version also offers manager reports. "Before, in order to know my autoverification rate, I had to use my Cerner system and pull a number of different reports and export that data into Excel spreadsheets. Now, with a click of a button or two, I can mine all of that data out of my WAM system. We can create reports based on rules, based on our turnaround time, based on technologist. So it's great. It's quite amazing."

Martin works with database coordinator Kari Agan who does the "rules building" and integration work with Cerner. "We actually work with Sysmex to create our rules so they do exactly what we want. We want them customized to be based on critical values in our facility." For example, "I have different platforms in the main lab than we have in the smaller facilities. I have rules for our hematology-oncology population that are different than rules we would have for a patient who comes in for their primary care visit. WAM allows us that flexibility."

The WAM has been a key contributor to Dartmouth-Hitchcock's reputation as an innovator, Martin believes. "We've been on this Lean Six Sigma journey for a number of years, and I think that middleware and automation have helped us get to those Lean processes." The distance among the Lebanon, Nashua, and Manchester laboratories has been a non-issue. "All the labs, even though they are as much as 70 miles apart, are tied into the same middleware on the same server and perform the same way. There's no issue with networking at long distances and it's done through the Dartmouth-Hitchcock secure network, so all the patient data is protected."

With the standardization the middleware has allowed among the technologists, and the growth of the network and technical staff that it has facilitated, "we are really proud of how much Sysmex has helped us improve the processes in our lab," Martin says.

Kerstin Halverson, point-of-care coordinator for Children's Hospitals and Clinics of Minnesota, uses Telcor's QML Data Management and Connectivity Solution to interface five instruments and seven manual device types for the roughly 120,000 POC tests per year, encompassing glucose, hemoglobin, rapid strep, pregnancy, blood gases, and urine dipsticks. "We have Sunquest as our LIS and Cerner as our HIS, and everything point of care flows through Telcor from either a device or via Telcor's offshoot product called WebMRE for manual result entry."

She handles most every issue involving the connection between point of care, middleware, and the LIS. "I'm the point person when we have to upgrade servers or add devices. I work pretty specifically with the vendors to make sure everything gets established and connected properly." Over the years, her lab has gone from having only glucoses and blood gases interfaced to having five device types interfaced, and manual testing is electronically entered now too.

Halverson

Children's Hospitals and Clinics, with its 2,200 credentialed operators, was the first of Telcor's customers to go live with an e-learning interface between Telcor and the hospital's e-learning software, PeopleSoft. "As a piece of this interface, tracking attendance at the annual competency fair that all staff must attend is now done electronically. This allows us to monitor point-of-care testing competency efficiently in one spot," Halverson says.

This project required considerable lead time. "It was not something we switched on one day. It was probably a

three-and-a-half-year project with Telcor to get all my POC courses in a table and then on a daily basis, using PeopleSoft, have that information be updated with all the additions, deletions, department changes, course passing and failing, and so on." The whole process is now automatic, Halverson says, which is useful for dealing with so many operators over 11 different device types.

In her previous job, more than 13 years ago, "we did not have any middleware," she notes. "At that time, we had glucometers connected through fax machines, not on the hospital's network. But results weren't electronically transferred to charts yet; the nurses would just see results on the device and chart them. There was still a lot of discussion about whether to bill for point of care back then, so some institutions probably did not worry about interfacing and getting things electronically recorded the way things have evolved now." These days, "IT is one of my major focuses. I can't do point of care without it."

In her work as POC coordinator, competency takes a huge chunk of her time—for example, keeping records of diplomas for anyone who is doing moderately complex testing. She says Telcor is working on a way to store those records centrally in its database. "After competency, I would say I spend the most time making sure we're meeting all the regulations on a daily basis, and by that I mean monitoring QC, making sure the instrumentation is up and functioning properly, and troubleshooting issues."

A change she has greatly appreciated was moving the Telcor software from a single PC at her desk to a server. "I had two different campuses to travel between, and as much as I try to clone myself, I can't. So having it moved to a server and having access to the server if I'm somewhere else has been a huge jump forward. I can do troubleshooting pretty much anywhere I need to go now."

Halverson likens POC to a spiderweb with middleware at the center. "For me, the Telcor middleware ends up being the center of the web to help pull everything into one place where I can manage it. It passes everything along to the LIS, then eventually to the HIS, but it helps cut down on a lot of potential problems by locking people out who aren't trained and keeping the interfaces up. It's a one-stop shop."

Today, some POC devices have their own data-management systems and others don't, but Telcor is able to interface with them either way, says UPMC's James Beck. "I can't say that Telcor makes those systems obsolete. But from my perspective, the fewer systems I need to get into, the easier it is to do what I need to do. Which is basically oversee what's going on in the system, make sure quality checks are being done, and make sure data is moving through the system and getting to the end users. The fewer systems there are for that data, the more likely the data is going to end up on the chart so that clinical decisions can be made on it."

Most devices, he has found, are interfaceable through Telcor, which is installed in about 1,900 U.S. and Canadian hospitals. UPMC uses Abbott's Precision Xceed Pro for glucose, and has seen unprecedented growth in the number of tests it conducts using Abbott i-Stat in the past nine months. The connectivity issues have been for the most part already resolved—"we have just been adding a lot more tests to the menu."

Beck

Siemens' Clinitek automatically uploads standard urinalysis dipstick and urine hCG testing results to Telcor and in turn to the EMR, Beck says. "So a person who is multitasking does not have to stay there. They can load up a device and walk away and know that the result is going to automatically upload." Similarly, Accriva's Hemochron Signature Elite is used for activated clotting time, and Avoximeter 1000E, another Accriva device, is used for co-

oximetry testing and cardiac catheterization labs. Both also connect to Telcor.

The ABL blood gas analyzers, Beck says, are considered by many to be laboratory instruments, not point-of-care devices, because they are tabletops. But "this is another example of Telcor flexibility, because before, many of the instruments were being run by respiratory therapists and they had a hard time internalizing how to use that lab interface. They didn't get enough repeat experience with it, the way a lab person would, and the standard lab interface was really failing them. They could not seem to get the hang of it as far as the flow of data."

Beck approached Telcor about taking over the interface, and the company appointed a dedicated analyst to work it out. "Then our next hurdle was actually to convince the LIS folks to allow us to do it. I said, 'I can make life so much easier for these respiratory therapists if we can send the information through a middleware system like Telcor as opposed to a standard lab interface, which is full of rules and things to remember. I can cut 20-plus steps and mouse clicks and verifications out of their process.' So it took a lot of convincing but finally they said, okay, go ahead and try it. And that actually got us a patient safety award for our facility improvement process. It was copied at other hospitals within our health system because they had the same dilemmas and we had a proven model that worked."

There has been downtime, he says, but not due to the middleware. "Recently, our centralized information support actually disconnected our Telcor server so it stopped transmission unexpectedly. It ended up getting reported by our ED where a nurse was doing a urine dip and knew it should have crossed by a certain amount of time." So temporarily, no data were moving.

But, he says, "The beauty of the computer age is that everything is basically held in a buffer so there's no data loss. Everything performed during a downtime does get captured ultimately." However, with one system processing information from 19 hospitals, catching up can take quite a while. "In fact, one of the things we requested was that they expand memory so the catch-up is quicker when there is some backlog of processing that needs to be done."

Some operators are actually physicians—typically anesthesiologists—and Beck has found there is better appreciation among physicians generally about middleware. "Definitely five or 10 years ago, they could afford to be more distant from middleware awareness, but now they are aware in making sure the data gets to the chart."

It's a good thing, too, because point of care is growing. In fact, "we're seeing explosions in point of care that are often exceeding the ability of one person to oversee." For this reason, Beck is pleased that his middleware vendor is able to keep pace with the state of technology and even stay one step ahead. Middleware capability like that has become necessary, he says.

The potential customer base for middleware is wide-ranging, says Data Innovations' Marentette. DI has diverse customers that include the Department of Defense and Department of Veterans Affairs, large academic health science centers, and reference labs. But the company is finding a market as well in smaller and midrange hospitals, which are increasingly looking at DI's productivity and quality suite modules and its "management through metrics" data mining.

Marentette

The data mining involves pulling data out of the specimen management database to conduct population or research studies. "We've now added our laboratory intelligence, which enables real-time metrics monitoring, so you can look at what's going on in your lab five minutes ago, identify issues, and drill down to what the challenge is."

On the quality assurance side, Marentette points to Instrument Manager's "moving averages" program which helps monitor how instruments are performing between quality control challenges. "If there is a problem when the moving averages go out, you can first of all stop testing and prevent those results from being released to the LIS. Therefore you have fewer edited reports. That really helps on the quality side. And using our specimen management workspace for autoverification, you can put in instructions on what to do when a particular value comes up."

Middleware's return on investment is twofold, Marentette believes. "It's not just within the lab itself, but also what it means to the rest of the hospital organization and the ability to enhance the patient experience. For example, quicker turnaround time on tests for the emergency department lets physicians make faster patient diagnostic decisions, bringing better patient experience and contributing to the overall revenue of the organization. Then, within the lab itself, if you are using the autoverification, you can redeploy your staff and take on more work by bringing on new tests or doing some of the centralized testing you maybe sent to another lab before."

Through its JResultNet software, which DI purchased from Dawning Technologies more than two years ago, the same middleware benefits are available to physician office labs, and Laboratory Production Manager is DI's parallel product in the European marketplace. DI itself was acquired in 2015 by Roper Technologies, which also owns LIS giant Sunquest Information Systems. But DI is still a standalone company, Marentette emphasizes, noting that a range of LISs (including Epic's Beaker) as well as IVD manufacturers use Instrument Manager as their connectivity and middleware solution.

Instrument Manager's usefulness also becomes apparent when hospitals or integrated delivery networks do acquisitions. "We have the ability to interface multiple LISs into the same IM database, so if a hospital acquires another hospital and wants to put things together on the same system, you can do that seamlessly through one of our interfaces. The middleware is able to keep orders and results reporting management straight between systems. So it does make consolidation much simpler and streamlined."

With the changing configuration of IT in health care, Sysmex's Anne Tate sees a changing role for middleware ahead. "WAM provides everything the LIS needs to report immediately to the EMR. In some instances, we're seeing where the WAM can go into clinics or small labs that don't have an LIS, so eventually we may have to connect the WAM directly to the EMR. We've never done it yet, but we're seeing movement in that respect." She doesn't expect it in the hospital environment. "But in standalone clinics, in nontraditional or non-hospital–supported environments, I do see it happening. We've already had requests for that."

Middleware does come with a cost, but customers understand middleware's value, Tate says. "We don't get much pushback anymore on the cost of middleware because they see the value and return on investment: They'll get vastly improved turnaround time, they can reallocate FTEs, and they get standardized results and less error."
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