Clutter-free POC testing nearing reality

Road-testing a connectivity solution

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Cover Story

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More than half a century into the Information Age, it comes as a surprise to many people that only a small fraction of point-of-care test results are downloaded electronically to hospital computers, and only about half of POC test results make it into the information systems at all, whether entered by hand or by computer.

Historically, "the minute testing escaped the laboratory, it could not be tracked," says Emery Stephans, president of Enterprise Analysis Corp., Stamford, Conn. As long as POC testing was one percent of the total volume, nobody cared. But it's no longer a minor problem. "POC testing is growing at 12 percent to 16 percent per year, now one in four tests is POC, and in 10 years it may be 40 percent of tests, measured in dollar terms."

The main obstacle to tracking POC test results: lack of connectivity, or bidirectional communication between POC devices and the laboratory or hospital information system. "Portable, handheld, even larger transportable whole-blood analyzers generally do not exchange adequate patient demographics, test results, and performance data with computerized systems," says Gerald J. Kost, MD, PhD, director of the Point-of-Care Testing Center for Teaching and Research, University of California at Davis.

Where results are communicated, it occurs under proprietary protocols that vary from vendor to vendor—and often requires countertops full of terminals, cables, and docking stations to cover all the different POC devices. "Most manufacturers have data management systems, but all have inherent limitations, and they are device-specific," sums up James Nichols, PhD, medical director of clinical chemistry at Baystate Health System, Springfield, Mass.

It was told in the story of the Tower of Babel: Without a common language, communication won't happen. And Brueghel's Tower of Babel was the image Dirk Boecker, MD, PhD, principal scientist with Agilent Laboratories, chose for the Connectivity Industry Consortium when it was launched Oct. 20, 1999. Formed by vendors and users, the CIC was designed to jump-start the often painfully slow process of adopting a common standard. In a short 15 months, it was scheduled to develop a draft connectivity standard that the established standard-setting organizations could finalize.

That schedule was met, the draft—including a three-part connectivity proposal—was published in February, and the standard awaits review and balloting by CIC members. Once the standard is ratified with at least 66 percent of the vote, the CIC will automatically sunset, and the proposals will be transferred to three standards development organizations—NCCLS, HL7, and IEEE—that will publish and continue to develop them.
The plan is to complete the standard approval process by July. When the standard is widely adopted, "the point-of-care world will have changed almost 180 degrees, because you'll be able to connect devices from different vendors to one piece of software," says Christopher Fetters, of Medical Automation Systems Inc., who serves as CIC vice president, secretary. "I think the end product will have enormous impact," agrees Frederick Kiechle, MD, PhD, director of clinical laboratories at William Beaumont Hospital, Royal Oak, Mich.

**Millions of dollars, of course, are at stake.** As diagnostics companies continue to see most testing shift to the point of care, continuous investment in new device concepts and technologies is mandatory. The market for POC testing products is expected to grow from $450 million to $950 million by 2005. But in some ways POC testing is still a low-tech endeavor.

"In many ways, POC testing is very amateurish and slow. It's about where banking was 20 or 30 years ago," before ATMs and other electronic devices moved banks beyond slips of paper, says Stephans, whose company develops marketing strategies for diagnostics companies. But POC testing is under great pressure to perform better for the same reasons, he believes. Like banks, which have to close the books by quitting time, hospitals have an end-of-day clock.

"They don't have to post a balance to the Federal Reserve, it's true. But at discharge they have to have a complete collection of data that goes with that person. And until hospitals can assure that POC results are recorded electronically, more or less when they're obtained, they are always going to be behind the clock."

A connectivity standard had become urgent, not only because POC testing has been growing three to four times faster than core laboratory testing, but also because compliance has taken such a starring role. "A couple of years ago you saw a nurse managing glucose data maybe part time," Fetters says. "Now the regulatory needs have become so strong that hospitals are assigning medical technologists to manage QC for dozens of instruments and thousands of users." But going around with a laptop and downloading instruments once a month, or more frequently if a high-volume unit is involved, is cumbersome. "That's not quality time, that's menial labor time, or a waste of time."

Point-of-care testing supervisors have a name for the technology they use to get their POC testing devices to communicate with the hospital information system. "It's called 'sneaker-netting,' because you have to do a lot of walking," says Jesse Olvera, POC testing supervisor at Valley Baptist Medical Center, Harlingen, Tex. A 480-bed hospital, Valley Baptist is negotiating with three vendors for a partial connectivity solution—glucose meters that, when placed in a little holster on the wall, will automatically transmit results to the LIS.

Hospitals have become somewhat resigned to a clutter of cables and terminals to handle POC test results. "We couldn't find a single hospital in the U.S. that had this problem nailed," says Jeff Perry, a project scientist at Agilent Technologies, Palo Alto, Calif., and current CIC vice president and chief technical officer. "They're all tearing their hair out." At Massachusetts General Hospital, he recounts, the emergency room asked the central laboratory to assemble a list of 10 POC tests that could be done, and it found to get these 10 tests it would have to buy devices from four vendors, and to manage the data it would need four different PCs in the ER for download.

For the Point-of-Care Testing Division of the American Association for Clinical Chemistry, the biggest topic of conversation at meetings and on the listserv for some time has been the proliferation of proprietary solutions to connectivity, reports Suzanne Cross, CIC president and director of sales and marketing for LifeScan Inc. She describes the CIC as a "virtual" organization, because its members are individuals from
well over 50 industry and customer institutions.

Manufacturers had also begun to realize that it was in their own interest to get past proprietary answers. One of the original premises of the CIC, in fact, was "If we don't do this right, we'll be restricting our own market from being able to grow," Fetters says.

Stephans, who chairs the Industrial Liaison Committee of the AACCPOC division, has the numbers that bear this out. "We found from surveys that with the dollars and people they had to dedicate to connectivity, it was a very difficult proposition even for the majors in the industry."

The CIC borrowed elements of its structure and organization from previous standardization efforts, one of which was the Andover Working Group. Organized by Agilent Technologies progenitor Hewlett Packard, the Andover industry-driven consortium developed data-exchange standards to make hospital computer systems interoperable. Once the standards were complete, the Andover group sunset and handed the standards over to chartered standards development organizations. Likewise, the CIC set a 12- to 15-month sunset date. "We didn't want anybody to structure a lifetime job out of setting a standard," says Stephans. "Perfection was not the issue. Speed was."

"What they wanted to do with this consortium was get us together in real quick 'tiger team' format, to go in and slam out a standard as quickly as possible, hopefully as maturely as possible," agrees MAS' Fetters. The CIC hopes that vendors are looking at the draft standard and planning to build to it in the next year, and that users will specify the standard in their requests for proposals. Arguably, it's an 80 percent solution to the problem of proliferating data management, he admits. "But at least we're not letting the industry get another three years down the road in developing solutions at cross purposes."

The consortium is unique in bringing together all the POC testing vendors. Abbott, LifeScan, Roche Diagnostics, Medical Automation Systems, and Bayer are core members with equal voting rights, while manufacturers from other sectors, including coagulation, hematology, and blood gas, are also centrally involved. But the CIC also wanted to make sure users played a large part from the beginning. "We were very concerned that this would not be just the vendors shoving a solution down users' throats," Fetters emphasizes. Thus, under the CIC's structure, a committee composed solely of users, chaired by Baystate's Dr. Nichols, has veto power over what the industry adopts.

Fetters believes the standard will work because most of the companies are tired of worrying about data management. "These vendors spend an inordinate amount of time putting together R & D teams to reinvent the wheel on every product release, to figure out the connectivity, what the data stream looks like, what the connectors look like. We've taken that off the table, so if they adhere to the CIC standard they won't have to think about it. They'll only have to build to spec."

"Manufacturers have technical expertise, they know devices, and they're experts in POC testing, but they're not experts in data management," notes Dr. Nichols. "They have to contract with young computer engineers graduating out of college and getting snapped up by Microsoft."

The standard-setting process had to be industry-driven to keep it grounded in the possibility of commercial reality, says Perry. "But it had to be customer-focused—not a solution to just help the vendors engineer products a little cheaper." Agilent's interest in promoting standardization stems from its position as a supplier of diagnostic devices and bedside patient information systems. "As an information system vendor, we need to connect to many other vendors' instruments, and as an instrument supplier we need
to connect to a variety of other information systems. Standardization is the only sane approach." Agilent's Dr. Boecker, a member of CIC's board of directors, secured his company's support and participation in the consortium by getting the approval of Agilent CEO Ned Barnholt.

Standards are slippery things in this business, says Stephans. As valuable as they are, their slow development often makes them obsolete by the time they are adopted. It was a struggle, he adds, but "we tried to do something that will be good for four years to give time for NCCLS to catch up." For example, right now everything uses wires, but a POC instrument with an infrared communication device will soon be able to send data over a wireless "short path" with no connection, no dialing, and no manual protocols. "We had to make provisions so that oncoming new technology doesn't blow away the standards' usefulness." Conversely, LifeScan's Cross notes that the CIC standard will be somewhat "retrofittable," so that existing systems could be made compliant through another piece of software.

The CIC standard will alter the competitive landscape to some degree, because, though there are many POC testing device makers, 95 percent of POC testing is done on instruments made by one of the top four vendors. The standard will be a boon to smaller diagnostic testing companies, most experts agree. "We saw the CIC as an 'enabler' for them," says Perry. "Most of them focus on the diagnostic assay part—not information management. When we talk to them, they say they can do one standard interface, but not six or seven."

An "open" standard, one that is available to any entrant, unlocks all kinds of doors, says Robin Felder, PhD, professor of pathology and director of the Medical Automation Research Center at the University of Virginia Health Sciences Center. "I think the CIC will completely revolutionize the point-of-care industry, because some companies are still trying to hang on to a proprietary standard."

He points to Bluetooth, the connectivity tool for portable electronics like Palm Pilots and laptops, as a good example of a successful connectivity standard. When the same process is completed for POC testing, the devices will be able to be connected instantly to the hospital information network, so data handling will no longer be the differentiator in the POC market. Success will be measured by the quality and specificity of the diagnostic test and simplicity of the user interface.

The problems of manual entry of results are legion. At Methodist Hospital of Indiana, where Catherine Cox, MD, formerly worked as a pathologist, there were numerous complaints that manually recorded point-of-care test results were not available for inquiry in the LIS. "If clinicians couldn't find the test result, they would just repeat the test. They couldn't wait, especially on a critical patient," says Dr. Cox, now director of medical affairs at Thermo BioStar, a medical device firm in Boulder, Colo.

Nurses at St. Louis University Hospital in Missouri also have to double-record POC test results. "I would say we probably lose 30 percent of our charges because the nurses are so busy they fail to do one or the other," estimates administrative director Bette Stanley. With 312 beds in the hospital, it takes 1.4 full-time equivalents to do data entry on POC testing, including daily pick-up of the log sheets.

Teresa McDonough, MT(ASCP), CLS (NCA), POC testing coordinator for Mercy Medical Center, Des Moines, Iowa, says one goal of her program is to lessen the paperwork for nurses, who have to record POC test results twice-first on logsheets and then on the nursing notes for the patient. Both the controls and the patient results for Mercy's new glucose meters are downloaded directly to a computer in McDonough's office, which is also interfaced to the laboratory computer so results are printed on patients' charts. "This connectivity also has the capability to include other POC tests, and that's what we're looking at in the future, to get rid of some of the manual logs.
We're working on computerizing everything," she says.

Cathy Bartholomew says Baystate Medical Center, where she is POC testing coordinator, chose a glucose meter vendor because of the instrument's connectivity features. "We're able to capture virtually any glucose results and have them available on the patient's permanent record and bill for them," she says. But about 20 to 25 percent of the hospital's POC testing is still entered manually into the hospital information system.

When it comes to urine dipsticks, or tests for pregnancy or occult blood, the communication gap is even greater. "Non-instrumented connectivity is nonexistent," says Kent Lewandrowski, MD, associate director of laboratories at Massachusetts General Hospital, Boston. "For instrumented tests, connectivity is an option provided you stick with one vendor, or you have an adequate supply of geeks to do the connectivity solution internally."

"For a lot of tests it [connectivity] isn't happening," Dr. Lewandrowski says. It could happen technically, he points out, noting that a sophisticated, well-off institution with enough money and programmers could theoretically hook up all of its POC testing instruments. But he compares POC instruments to telephones, which customers expect to just plug in the wall without having to climb poles and string wires.

"I don't want to have to worry about whether cardiac is going to talk to coagulation and glucose," Dr. Lewandrowski says. "I'm a doctor. I want the company to solve that for me." A hospital may have POC instruments from Biosite, Abbott, and Bayer all hooked up to an LIS, he says. "But I'd love to see whether it's really plug-and-play—or are they going to make me climb poles?"

He sees people at companies that have invested heavily in their own connectivity solutions viewing the CIC with mixed emotions. "It's a theme we've seen played out all across the country over centuries, and with technology it's played out more frequently. Whoever has the best chip, or the best operating system, or the best wireless technology—once you are the standard, then you've got the whole thing."

While he applauds the goals of the CIC, Dr. Lewandrowski has doubts the reality will live up to the hype. "Consortia sound so wonderful. But do they mean just the port on the back of the instrument will be the same, or will I get true plug-and-play connectivity?"

Enormously complex new Medicare regulations have aggravated the problems posed by the onslaught of new technology. "There is so much going on with APCs [ambulatory patient classifications] and all the compliance requirements," says Stanley at St. Louis University Hospital. For her, installing the Medical Automation Systems RALS-G system within the next few months will mean retraining 600 nurses along with the other staff who do bedside testing, but she has other worries.

"You have to have in the outpatient documentation that the physician ordered that fingerstick glucose," but that doesn't always happen. For example, radiopharmaceuticals injected in patients undergoing PET scans depend on glucose levels, so the protocol was always to do the glucose. "But nowhere in the chart did the doctor write it down, so Medicare doesn't want to pay because there's no order," she says. "All of these issues have to be ironed out."

Medical Automation Systems announced in January that its RALS-Plus data management system, slated for launch this spring, will interface initially with all of Roche Diagnostics' glucose devices and Roche's AVL Opti for blood gas. But more interfaces with other vendors' devices will be released throughout the next year, and MAS intends the system eventually to become vendor neutral and able to interface with
all manufacturers' POC devices and applications.

MAS has been centrally involved in POC data management for six years. The company grew out of licensed technology developed at the University of Virginia, technology which in its first form took blood gas instruments, interfaced them to an LIS, and had the core laboratory sign off on the results. Roche later contracted with MAS to devise a similar system for glucose testing. That solution, now called RALS-G, is installed in more than 200 institutions, where it has been successful, Fetters says.

"People were spending all their time trying to manage their data, processing a lot of paper, and they said this solved so many of their problems," he notes. "They said, now fix all the other analytes for us too." That was what led MAS to announce a vendor-neutral approach once its co-marketing agreement with Roche expired in January. Dr. Nichols does not believe the adoption of a connectivity standard will make RALS obsolete; in fact it will become more valuable because the standards will assist people in linking other devices to the RALS system. "As it is now, if customers want a new device they have to wait until MAS comes up with the interface. If all devices come out with the same standard, and they have a CIC-compliant interface or port, then you just plug them in and you're ready to go."

Johns Hopkins was fortunate to have computer engineers and software designers in house, who were able to develop a data management system for the institution that allowed communication of all the raw POC test data, says Dr. Nichols, who worked at Johns Hopkins until recently. Hopkins is interested in marketing its system, but has found that many manufacturers, wary of disclosing proprietary secrets, are unwilling to give out the communication protocols for their devices—even to customers. "Everyone is so worried about giving a competitive edge to another vendor," Dr. Nichols says. "We could take the instruments apart and figure out the protocols, but we prefer to partner with the manufacturers."

**Dr. Nichols does not believe POC testing is actually replacing central laboratory testing.** "Although you'd think there would be a one-to-one shift [a test normally done in the core lab is done instead at the bedside], in many ways POC testing is an additional service, not a replacement. You end up with the operator getting the result rapidly, then saying 'I don't believe it,' then repeating the test, drawing a sample and sending it to the lab anyway." Data management, he says, if it really linked POC testing and core lab testing in real time, would prevent a lot of that extra testing.

In June, Dr. Lewandrowski says, he will launch a new journal called *Point of Care: The Journal of Near Patient Testing and Technology*, and he agrees POC testing is an intriguing opportunity. But he is cautious about growth predictions in the industry. "Ten years ago all the consultants said commercial laboratories would annihilate hospitals, and it didn't happen. Five years ago, they said hospitals would annihilate commercial laboratories. It didn't happen. Now it's the POC growth market. But how come these companies are barely profitable? The laboratory market, like the NASDAQ, has inherent uncertainty and defies reliable predictions."

"There's more pressure to manage these devices than there was three years ago," points out Agilent's Perry, citing both increasing use and realization of the value of POC testing as two interacting forces. With a growing number of studies showing that quick turnaround on results actually decreases costs in the long run, more devices are sold. However, these instruments can't be operated by just anybody; they have to be managed as part of the clinical process in the hospital, so they need data management systems.

Consolidation has also highlighted the need for improved data management, Dr. Nichols says. Before, POC testing may have been performed haphazardly in some clinics under their own whims. But now that so many have been rolled under large
health care networks' umbrellas, regulators see their practices as part of the larger institution's. "That drives even more the need to be able to collect that data in one location and manage it centrally," he notes.

How frequently do nurses and other operators perform a POC test, read the result, and not log it at all? "I would say it's common," Dr. Nichols says. The percentage probably varies according to the test, the site, and other variables. "Some sites are really good because they're billing very conscientiously; others are not so good because they're not billing and don't have good follow-through." He questions the value of results that go unrecorded. "You may generate a value and act based on that, but if you don't have good documentation, it's worthless; it was meaningless to do the test in the first place, because if it was ever questioned or came into a court of law, what would you do?"

Recent publicity about the prevention of medical errors has fueled the quest for connectivity. "We'll never know how many errors are truly important until we get systems connected so we can objectively test vendors' and others' claims of accuracy and precision," says Dr. Kost.

But the timetable to solve the connectivity problem won't be nearly as short as the one that set up the CIC. "The trick with all of these standard-setting efforts," says Perry, "is that you come up with a wonderful standard, but the reality is that devices are replaced every two to five years, so there will still be legacy devices out there in five years even if we only had CIC-compliant devices tomorrow."

Dr. Felder, who predicts a rapid demise for proprietary connectivity solutions, says LISs exemplify their inherent problems. "LIS vendors, a large proportion of them, are still selling legacy systems, with computer architecture based on old software systems. Those that offer newer client-server architecture are outselling all the other companies, while the legacy systems are trying to hang on to their installed customer base." That base is eroding, but the multi-million dollar investment in an LIS is not easily abandoned.

Hospitals outside the U.S. have not embraced POC testing so rapidly. "Many of the issues are the same in Europe, but the timeline in many countries looks like the U.S. three years ago," Perry says. The Netherlands is advanced in the use of POC and home testing, but other countries are just starting to get there. They are just now making the transition from seeing most devices bought by doctors, to seeing most devices bought by hospitals, he says.

Nevertheless, the CIC is starting a European initiative as well as one for Asia before it is set to expire. "Our vision was to eliminate competition on the level of connectivity, and if you're still competing on that as a global company, you have not neutralized the problem," Cross points out.

As for wireless transmission, which is already well established in other industries, Dr. Kost says a few ordering systems and a selected few of the LISs have some component of wireless modality, but the manufacturers really don't consider connecting to POC testing as a big piece of the action. Nevertheless, while the CIC standards won't say all POC testing needs to go wireless, "The future is wireless," he maintains. "A couple of vendors have already specified wireless for glucose testing within the next year and a half."

Down the line, it will be the Internet that provides connectivity for all diagnostic testing, Dr. Felder believes. "Ultimately, every electronic device will have an IP address and be able to connect directly to the Web."

But, he adds, "I'm always disappointed by how far ahead the technology is from human acceptance. The problem is that everything in medicine is done by committee and by
various departments that don't communicate. Until medicine focuses on the common good for the entire hospital, they will still have this big delay in accepting technology."

In the meantime, the CIC will be celebrating its accomplishment in laying the groundwork for what Dr. Kost calls POC testing's "millennium challenge": connectivity for all. Says Stephans: "My last role with the CIC will be to throw a formal recognition affair at July's AACC meeting in Chicago for all the CIC people who made special contributions to this project." As they listen to chamber music and drink champagne, he predicts, they will all be toasting something that has never happened before, the feat of getting the POC diagnostics industry and users together in one organization with a single purpose.

Anne Paxton is a freelance writer in Seattle. For more information on POC testing, visit the Web site of the Point-of-Care Testing Center for Teaching and Research, University of California at Davis: www.poctctr.ucdavis.edu.