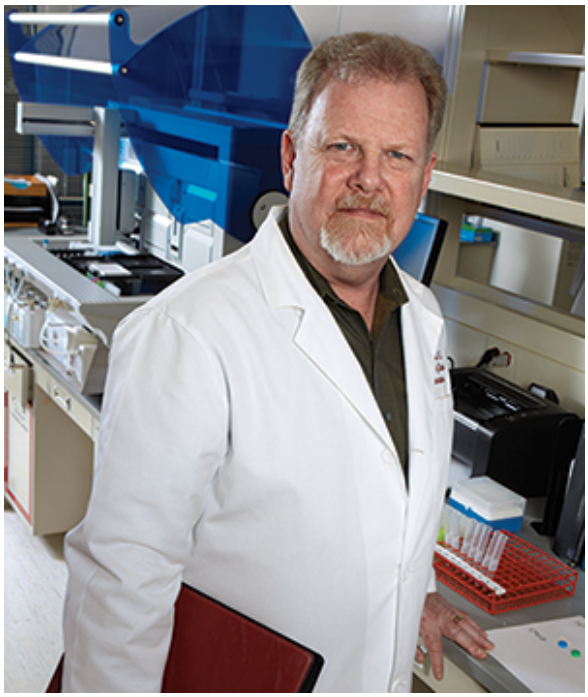
How POC testing is pushing the envelope

Anne Paxton

April 2014—It can be hard to remember a time when GPS was not available in cars, the Web didn't exist, and only eight diagnostic tests were classified as waived and able to be performed at the point of care. But after CLIA's enactment in 1988, those were some basic realities of location and speed.

Today, whether for blood gas and electrolytes, glucose, coagulation, cardiac markers, drugs of abuse, food pathogens, hemoglobin, or infectious diseases, hundreds of tests once considered too complex for point of care are routinely performed outside the laboratory. But some of the nation's experts in point-of-care testing say that developments on the near horizon could make previous advances in POC testing look tame.



"With point-of-care testing, I think we'll be amazed by what happens in five years," says Dr. Timothy Hamill. "And we'll be stupefied at what we'll be able to do in 10 years."

"A number of tests are on the cusp of being available at point of care, from the realm of infectious disease biomarkers, all the way up to PCR and molecular testing right at the bedside," says Timothy R. Hamill, MD, vice chair of the CAP Point-of-Care Testing Committee. Wearable biosensors and lab tests on a chip are no longer just the stuff of science fiction, says Dr. Hamill, who is director of clinical laboratories at the University of California, San Francisco. "It's amazing technology and it's going to bring a real revolution."

"Ten years ago, people would have said, yeah, maybe when we're flying around in spaceships that'll happen. But it's here. And where it will go will be really interesting to see."

It's not only technology that's pushing POC testing in new directions. Research findings, new regulatory scrutiny, and economic and business imperatives are powering point-of-care testing to carve out a new niche within the health care system. In conversations with CAP TODAY, pathologists and others all agree that it will continue to

diversify and mushroom. From differing perspectives, they report on how government and industry initiatives are combining with research and clinical practice to steer POC testing into its next era.

“We’ve got competing pressure points on POC testing,” Dr. Hamill says. “One is a desire to get a quick, reliable answer immediately so a provider can make a treatment decision on a patient. Second, that laboratory test is probably more expensive than what we can do in the clinical lab. Everyone’s looking at cost containment these days, so the cost of testing in the inpatient arena is being scrutinized. In the outpatient setting, the question is: Can we get reimbursed for a POC test? And is a lack of reimbursement sufficient to say we shouldn’t use it?”

“Third, there is the ever increasing level of regulatory scrutiny on POC testing, particularly when it comes to provider-performed tests. It used to be the doctor could run any kind of test. Now pretty much everything has regulations wrapped around it—competency evaluations are an example. I think it is appropriate, but all of this weighs against the potential benefits of having rapid POC testing at the bedside.”

Quick answers on possible infectious diseases are a chronic need, but there are always tradeoffs to take into account. For instance, a POC test for methicillin-resistant Staphylococcus aureus is in the regulatory pipeline and will be a significant step forward in identifying infections with these organisms, but Dr. Hamill does not believe it would change the way patients are screened for MRSA carriage. “Although potentially quicker, the cost will likely be an issue,” he says, and the MRSA culture his hospital can do in the clinical lab probably has a fast enough turnaround already.

“Other things like rapid tests for viral pathogens and/or diagnosing ventilator-associated pneumonia may be viewed as more important to clinicians than screening for MRSA carriers. Similarly, in the case of a patient with possible sepsis, being able to do a quick test to find out if it looks like gram-positive or gram-negative bacteria would let clinicians start an empiric therapy right away while they’re waiting for a test to be done in the lab on a MALDI-TOF or one of the other newer bacterial identification systems.”

More POC testing that helps reduce antimicrobial resistance would be a boon, Dr. Hamill believes. With the right POC device, “You could test at the bedside, find out the nature of the causative bacteria, and perhaps learn something about its susceptibility patterns based on the test result. Then you would know how to structure your antibiotic therapy right from the get-go, and not expose it to that heavyweight drug that we really need to reserve for that organism that’s really resistant.” Such a device isn’t available at the point of care yet, but with MALDI-TOF mass spectrometry in the central laboratory, answers that used to take 24 to 36 hours can now get out in a few hours, helping hospitals with antibiotic stewardship.

Molecular testing at the point of care is promising, Dr. Hamill says, but it will take some time. “I think when the FDA approves molecular tests at point of care, they will initially be either moderate or high complexity, and at least from the institutions I’ve reviewed as a CAP inspector, no one is going to do high-complexity tests at point of care. For example, here in California, because of our regulations regarding who can perform high-complexity testing, if I tried to roll out a POC test that only licensed clinical laboratory scientists or physicians could perform, it would be very hard. Certainly in inpatient care and probably the physician office, it’s eventually going to happen, but I don’t know when.”

Also likely in time, he says: Glucose, sodium, serum chemistry, and chloride testing will be done by biosensor or new POC technology, and samples for such testing will no longer be sent to the clinical lab. That means the laboratory will be moving on to testing more esoteric biomolecules, hormones, drugs, and other analytes that still aren’t available as a POC-type test, Dr. Hamill predicts. “With point-of-care testing, I think we’ll be amazed by what happens in five years. And we’ll be stupefied at what we’ll be able to do in 10 years.”

One factor that has kept POC testing on the leading edge technologically is that it has drawn major investment from the Pentagon through DARPA, the Defense Advanced Research Projects Agency, which is funding companies like Ceres Nanosciences, Tasso, and Biomatrica to work on biospecimen collection and preservation.

Tasso, for example, has a DARPA grant to develop a wearable blood draw device that collects a 200-µL blood draw with a microfluidic platform, while Ceres has invented Nanotrap technology to better capture low-abundance protein biomarkers and protect them from degradation.

Under a contract with DARPA's Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT): Diagnostics on Demand program, Biomatrica is developing technology to solve biostability problems. DARPA describes ADEPT as seeking to "provide Soldiers, Sailors, Airmen, and Marines actionable information about their health, on demand, by developing…diagnostics that can be carried on-person and self-administered, coupled with formats suitable for preservation of self-collected biospecimens for later expanded testing."

Dr. Wattendorf

"We are funding both chemistries that you add to a specimen to preserve it without culturing, and materials that blood would bind to or be absorbed in to protect it from degradation," says Lt Col Daniel Wattendorf, MD, program manager at DARPA. "On top of that, we have two strategies: one where you draw a specimen into the preservation device for immediate analyses, and the second where samples may be archived for future analyses." The specimen preservation formats for immediate analyses allow the sample to be shipped to the lab and used directly in instruments in the reference lab with few changes. Processes similar to a filter paper card are useful in archival settings such as newborn screening, he explains.

"The Department of Defense is interested in these technologies because it has more than 9 million beneficiaries, with most of our practice either on home soil or in clinics throughout the world," Dr. Wattendorf says. "We care about emerging threats, such as an influenza pandemic, as well as engineered threats, such as someone engineering a biological organism in a purposeful way to cause harm, and antimicrobial resistance. These are all major challenges to DOD and national security. We think that existing infectious diseases that are highly transmissible need rapid testing performed as locally as possible. But we want to ensure that when they're performed, wherever they are globally, they are performed within the health care infrastructure."

The traditional concept has been that the battlefield is a proving ground for what later often become domestic uses. But DOD's strategy with POC testing is in some ways the reverse of that. "We want to develop diagnostic systems that work for unmet needs in the U.S. health care system; otherwise they will not be adopted and used when there is an engineered threat," Dr. Wattendorf says. "If we do not have PCR systems in doctors' offices, how are we ever going to be able to perform a local test for a new threat that develops? We need to get these platforms out and used in more distributed ways before we can think about assays for new threats on the horizon."

The major challenge is showing the utility of a diagnostic test performed in a distributed place—meaning outside the clinical lab, in a home or office—where the test is linked back to the reference lab. "What we need is the 'killer app' for that. For most of the diagnostics industry, it's not within their business model to sell instruments to the doctors' office. We're trying out a model where the reference lab would lease these devices to doctors' offices, and if the doctor orders a respiratory pathogen panel, the test then gets sent with CPT codes into the laboratory system. The device would still be part of the reference lab; it just won't be located within the brick and mortar of the reference lab."

This DOD strategy could aptly be called a hybrid between POC and central lab testing. "To me, POC testing means a standalone test where the result is often outside of a qualified lab setting and doesn't really enter into the laboratory information management system." But when instruments are in different settings, Dr. Wattendorf points

out, “you have no way of tracking the analytics of the device and its performance in a continuous fashion.” The DOD has in mind not just connectivity of results but also quality assurance of the instruments that can perform complex testing, including high-performance molecular diagnostics, he says.

“We’d like a future diagnostics business where a centralized lab performs most tests. But when turnaround time is a necessity for clinical action—for example, to test a respiratory pathogen for an infectious disease—you want the ability to perform that test as locally as possible. We are hoping that many tests, for everything from serology to proteomic assays to molecular diagnostics, could be performed this way if you are able to assure the quality of the test.”

Surprisingly, there has been almost no research on the question of patient satisfaction with POC testing. Do patients find POC testing as convenient as their clinicians do? That is one of the questions that interests Kent B. Lewandrowski, MD, associate chief of pathology and director of laboratory and molecular medicine at Massachusetts General Hospital, who undertook a twofold study of POC testing in a physician practice to find out.

The study involved implementing POC testing for HbA1c, a lipid panel, and a comprehensive metabolic panel in a primary care practice. “We wanted to determine the impact on patient satisfaction and also on practice efficiency,” says Dr. Lewandrowski, who is a professor of pathology at Harvard Medical School. “We chose those tests because they are the most commonly ordered ones, and we gave the patients an anonymous questionnaire inquiring about their satisfaction on a scale of bad/horrible to lovely/wonderful.”

“Suffice it to say that the scores were extremely high: ‘It was great to review results with my doctor at the time of the office visit,’ ‘It’s very convenient,’ ‘It makes the whole experience much more enjoyable and positive.’ The study also found that the number of letters and phone calls as well as the total number of tests ordered and the number of re-visits fell. So there was strong improvement in practice outcomes,” Dr. Lewandrowski says.

For the next phase of the study, the researchers will test the same model with different practices to see whether they can generalize their findings. “This has not been extensively studied in the past.” In fact, he says, “There are essentially no studies of efficiency outcomes in primary care.”

He hopes to expand this inquiry to include other panels as they become available at point of care. “At some point, when there are CLIA-waived complete blood counts and they come in a convenient POC format, we might add those.” That’s not such a far-fetched idea, Dr. Lewandrowski notes, because waivers have been the trend. “Probably one sentinel event was a year or two ago when the Food and Drug Administration approved an over-the-counter salivary HIV test that is also CLIA waived for use in practices. The saliva tests are being used in settings where HIV is commonly encountered, such as EDs, STD clinics, ID clinics, and so on. So you’d have to say, if the FDA is okay with that, they’re probably going to be okay with a lot more. Because other tests are not as controversial as HIV.”

There are many companies working on molecular POC testing, and Dr. Lewandrowski predicts that molecular diagnostics for microbiological applications will be the first to take off. “It’s an ideal test for point of care because traditional methods take so long. And it will take off in hospital settings for MRSA and C. difficile where we need rapid identification of infected patients, and also in clinics where they need viral load monitoring of patients with HIV or HCV to make decisions concerning treatment.”

Another advantage of fast molecular microbiology is managing beds, he says. “If it takes 24 hours for the lab to turn the test result around, you’re having to manage your beds based on a lack of knowledge. You can’t put an influenza patient in with a patient who doesn’t have flu, so it makes it very difficult.”

He sees a strong trend toward increased POC testing across the board. “We are getting more and more requests for it, and a lot of that is being driven by the need for the hospital to improve its capacity utilization and efficiency, which can be problematic as we’re getting pushed to get more patients through the system.”

POC testing has proved its worth in process improvement at MGH, Dr. Lewandrowski says, because it can efficiently provide help with one of the key concepts of Lean: queue management. He explains how queues had become a problem for the radiology department at MGH because of a chronically missing laboratory test.

"If you are going in for a CT scan or MRI with gadolinium, you have to have had a creatinine within the past 30 days, because patients with poor kidney function get contrast-induced kidney injury and gadolinium-associated nephrogenic systemic sclerosis. But at our hospital, about 400 to 500 times a month, the patient shows up for the scan and no creatinine is available."

"Then the radiologists have a choice: Do the scan without contrast, which is suboptimal, or cancel the scan and reschedule and send the patient to the lab, which is really suboptimal. And when you are managing a multi-million dollar MRI or CT scanner and you have hundreds of canceled scans, you can imagine the economics and efficiency for that unit." Almost all hospitals have this problem, he adds, and it's a nightmare to manage.

But by putting a POC creatinine test right in the radiology area, if the patient shows up and there's no creatinine, hospital staff can perform the test on the spot, Dr. Lewandrowski says. "It's a key Lean concept to take non-value-added work out of the system. And point-of-care testing is something that, when implemented selectively, allows you to do this. You don't want to implement it indiscriminately because it's more expensive than the central laboratory, and it can be difficult to manage in terms of regulatory compliance and QC."

"So it's really a 'smart bomb' you can use, instead of saturation bombing. You want to hit the target, and usually that target is a queue in the operation of the system. People often don't think about it, but there's a science to managing queues, and POC testing allows you to manage queues better. When it's implemented properly and thoughtfully, point of care is very good at impacting operational efficiency."

Still, Dr. Lewandrowski cautions, POC testing presents myriad pitfalls. "We do not want to implement point-of-care testing just for the sake of implementing point of care. It's a tool that can be used along with the central laboratory and the reference laboratory. But with POC testing, maintaining operator competence is a problem, ensuring performance of QC and PT is a problem, some of the analytic technologies are not robust, and specimen acquisition is prone to contamination."

"Then there are technical things like whether the reagents need to be refrigerated, and whether the system can detect if the reagents are expired. So there are plenty of problems with point-of-care quality. We have to increase POC testing predominantly to affect queues in the medical delivery system, where it can allow the clinical operation to process more efficiently."

Despite POC testing's limitations, does he foresee it being the predominant form of testing in the future? "I think for the common laboratory tests, probably within 10 years you'll have a handheld device that will be able to do a menu of 40 or 50 tests using single-use or multi-use cartridges. The majority of common chemistries and hematologies could, in theory, be done at point of care on the spot in the hospital or physician office."

But then the question will still be the costs of POC testing versus the benefits, Dr. Lewandrowski points out. "If the cartridges are twice what the tests cost in the central laboratory, the hospital will lose millions. We will need to get the economies of scale to approach the cost of the central lab to make this kind of point-of-care testing a winning proposition."

Sheldon Campbell, MD, PhD, director of laboratories for the Veterans Affairs Connecticut Healthcare System, has found that POC testing sometimes doesn't get ordered because there's a path of least resistance heading in a different direction. His second law of POC testing (No. 1 to come later) holds that "No POC test is easier than checking one more box on the laboratory order form." As a corollary, he says, inpatient POC tests are only useful if the time for transport to the lab for that single analyte significantly and negatively impacts care, or the test is performed on an easily obtained sample, such as fingerstick blood, more frequently than routine blood draws are obtained.

Dr. Campbell,/b >

An experience five years ago showed Dr. Campbell's second law at work, when the VA in Connecticut made plans to do rapid HIV testing in primary care. "We got the tests in, got trained up, and had a full pile of clinicians ready to perform rapid HIV tests, and in the next four months they did exactly one test."

"Nobody was doing it because these patients were being seen in an environment where followup was not that big a challenge, and it was not easier than checking off one more box on the lab order form and getting the results 20 minutes later with the other results you need anyway." So while rapid HIV tests have made a substantial difference in diagnosing certain patient populations, "in our health care system they are not particularly useful."

That's one reason why he thinks the magical Star Trek tricorder, a science-fiction POC instrument that could theoretically replace the laboratory, is 50 years away or more. "There's no good intermediate stage between doing one key analyte at point of care and doing everything the laboratory does."

He points, too, to the constant QC struggle. Thus, his first law of POC testing: "Nobody ever went into nursing because they wanted to do lab tests." "People do QC because they have to, not because they understand it or are dedicated to doing it," he says.

When molecular tests are approved for performance at POC, Dr. Campbell says, the typical POC testing problems will be compounded because of the interferences. "Molecular tests are going to have to have internal extraction controls, and many tests can be inhibited by things like blood and excess DNA in the sample. So the internal controls to look at those things are going to be important."

"Molecular tests are also particularly prone to contamination. If there are lots of patients walking through with the flu, they can be dropping droplets on surfaces, or the collection device, or the port of the instrument can cross-contaminate specimen A with specimen B. I think the current generation of molecular tests has a better handle on that, but it's something you have to think about with waste disposal and getting rid of cartridges after the test is done."

Bringing POC tests online involves a tricky metric of cost-effectiveness, Dr. Campbell points out. "The savings don't come on the testing side; they come on the care side. And it's really hard to know how much it's worth to get one lab result 20 minutes sooner. Quantifying those savings is one of my challenges."

He expects dramatic changes as the FDA starts to expand its authorization of waived tests. "But nothing happens as fast as you think it will." Antibiotic susceptibility tests will be the very last to be available at POC, he predicts. "They are really, really complicated. At some point we'll be able to do antibiotic susceptibility by sequencing bacterial genomes, but that's quite a ways off. Maintaining a sequence database for HIV testing, with a couple dozen drugs and two main genes, is a small industry; it's about three orders of magnitude harder for bacterial susceptibility testing, with some 50 to 100 antibiotic drugs and thousands of genes."

National differences in economies, health care systems, and social environment will play a huge role in the future of POC testing, Dr. Campbell believes. For the developed world, it's a question of choosing between fast and faster on many tests. But where POC testing will really make a difference is in the developing world, where lab order forms, nurses, refrigeration, power, and lights can be in scarce supply.

There, Dr. Campbell's laws are less relevant and POC diagnostics are desperately needed, he says. "It's one thing

to have a central lab where you can pick up a test today and review it tomorrow. But where you have to put a sample on a truck that goes 50 miles over bad roads and you get the results next week, that's where POC diagnostics will be extraordinarily important."

In the regulatory arena, two recent developments indicate that the key federal agencies are planning more flexibility for some point-of-care devices in the area of quality control, but a lot less flexibility for the POC workhorse, the glucose meter.

Dr. Nichols

At the Centers for Medicare and Medicaid Services, new guidelines for Individualized Quality Control Plans (IQCP) promise to ease some of the burden of QC without compromising it. "When CLIA developed, there were really no POC tests beside glucose meters and pregnancy tests, and there's been an explosion of POC tests since CLIA," says James H. Nichols, PhD, medical director of clinical chemistry and professor of pathology, microbiology, and immunology at Vanderbilt University School of Medicine.

"Originally, all manufacturers recommended you run daily QC, but with newer point of care, the tests have built-in QC processes," Dr. Nichols explains. "So how do you balance the right amount of external liquid QC with the built-in QC? If you have a test you run only once a day, you might consume three cartridges for every patient you are testing, and for an expensive test like fetal fibronectin at $100 per test, that becomes very expensive."

Since 2000, lab directors have had latitude to set their own equivalent, more economical alternatives. But now the CMS IQCP will add new options. "It will allow laboratory directors to dictate the frequency and how QC is going to be run across all the POC devices in their lab. It no longer dictates once a week QC for some tests, but allows you to set frequency based on your risk assessments. So it helps us really find the correct balance, to conduct QC on the key things that could go wrong." The IQCP was formally adopted this January, starting a two-year education period before it becomes mandatory in January 2016.

Far more controversial is new proposed guidance from the FDA on hospital use of glucose meters. Released in January for a 90-day comment period, the proposal would drastically change current standards by making all glucose meters coming onto the market moderate complexity under CLIA, instead of waived. That means an increased education level for operators to perform the tests plus additional requirements in proficiency testing, training, quality assurance, and other areas.

The FDA's move stems not from the technology but from complaints the agency has received, Dr. Nichols explains. One high-profile case involving a maltose interference led the FDA to send out warnings. Interferences such as oxygen and hematocrit have been known to affect glucose results, he says. The meters' long-entrenched use for intensive insulin management in ICU patients has also been a factor in the FDA's proposal, because the meters have never been tested for insulin protocols.

New York state has already incorporated the FDA proposal into its own regulations and sent a letter warning against off-label uses of glucose meters such as for screening of patients at health fairs. So even before the FDA makes a final decision, the proposal is having a significant effect on POC testing.

"Everyone nationwide at this point is holding their breath and waiting to see what the final guidance will be like," Dr. Nichols says. "Speaking for myself, I fully understand why the FDA is looking at this, and I agree there are definitely some patients where fingerstick glucose is inappropriate." Although some major manufacturers like LifeScan had already exited the hospital glucose meter market, he does not believe the FDA action will mean less

POC glucose testing, because the test has become indispensable to managing patients' glucose levels.

As much convenience as point-of-care testing has to offer, it also entails more expense and more complex management in the hospital setting than tests on automated central laboratory platforms, says Gyorgy Abel, MD, PhD, medical director of clinical chemistry, molecular diagnostics, immunology, and POC testing at Lahey Hospital & Medical Center. Lahey Health is a system of community hospitals and physician groups in northeastern Massachusetts and southern New Hampshire anchored by the 320-bed Lahey Hospital & Medical Center in Burlington, Mass.

Dr. Abel

"In the hospital setting, the main advantage of POC testing would be speed—but that's not always significantly better," Dr. Abel notes. "If the core laboratory and the stat laboratory are set up correctly, and you have a pneumatic tube system from the ER or OR, then sometimes you see the advantages of POC tests kind of melting away."

He supports the use of good economic and observational models and clinical trials to measure the cost-effectiveness of POC testing. For example, researchers could take the outcome of a particular disease that makes use of POC testing versus a hospital-lab–based test and find if there are differences in life expectancy or quality-adjusted life years. "These are quite complicated analyses which have not been thoroughly done."

Over the years, there has been a strong perception that POC testing quality was inferior to central lab testing. "And there were very significant differences between central lab and POC INR and HbA1c," Dr. Abel says. "But now, with the use of microfluidics, micro-electronics, and nanotechnology, we see less and less difference in the actual analytical performance of POC when compared to central lab testing." With INR, for example, since his hospital switched to a different POC system, the reproducibility has improved substantially.

Lahey does have certain blood gas testing at POC in the cardiac cath lab. "There is certain testing you don't want to send to the lab, but most blood gas testing can be done there if it is placed very close to the pneumatic tube reception area and there is somebody always there waiting for the specimens," Dr. Abel says. Another example is HbA1c. Pricing can be eight to 10 times as much as comparable lab tests, and it remains a sticking point when the hospital considers taking on new POC tests. "We can perform the testing in the lab for a fraction of what the POC test costs. But that said, POC testing for HbA1c could provide immediate results, resulting in therapeutic decisions without delay and fewer patient visits."

At Lahey, clinicians have requested POC HbA1c, and the hospital is considering offering it at point of care in its satellite locations. But one procedural change in the chemistry lab has made a big difference in the hospital. "We set up a system where the patient comes in one hour before the doctor's appointment. They get their blood drawn, sit down in the doctor's office for 45 minutes, and by the time the endocrinologist sees the patient, the HbA1c result is there." The process requires extensive synchronization of laboratory work and patient appointments, Dr. Abel says, but it has answered a need by providing results to patients in the same visit.

He is eager to see POC molecular diagnostics, not necessarily in the hospital lab, which has well-developed molecular and microbiology capability, but in long-term facilities, community group practices, and other primary care settings where these tests will be useful. The cartridge-based molecular tests require only loading, placement, and pushing a start button. "I call these 'POC-type' tests. Currently they aren't true POC because they must be run with a CLIA license under the direction of a CLIA director." But some of the tests are so simple they probably will

become CLIA-waived, he predicts.

“I hope the FDA will eventually approve these molecular diagnostics, because a number of ID tests such as C. difficile and other hospital-acquired infection tests could possibly come online. But there’s a mystique about nucleic acid testing, and we know studies show that even simple POC tests are usually performed better if done by a medical technologist than by other personnel. So many things can go wrong.”

Unlike the central laboratory molecular systems, most of which require batch processing and can be run once or twice a week, the POC-type systems could take a specimen sent to the lab from the ER by pneumatic tube, and have a result in 20 minutes. “So literally in 30 minutes, you’d have a definitive answer. That can be very important if a patient has influenza or other severe respiratory infection, meningitis, or a hospital-acquired infection and you can do the test without a delay.”

Such a test would tend to cost at least twice as much as the same kind of test on a larger automated lab instrument—about $40 to $80 as opposed to about $20—“but that’s still a lot less than eight or 10 times as much, and the clinical benefit is very easy to demonstrate.”

Dr. Abel thinks that the systemic change to be wrought by health care reform under the Affordable Care Act will affect POC testing, but it’s not clear how. “These huge health systems that have been formed in the Midwest, in Pennsylvania, Texas, and recently in Massachusetts—they are everywhere I go, with new names, new logos, new branding. It’s a very big movement, and they will mean more patients remaining within the same system for the entire spectrum of care.”

“This will lead to systemwide unification and standardization of the EHRs and the LISs, and eventually the laboratory tests and procedures used on patients. I don’t have a clear vision of how this will affect POC, but I can imagine that we’ll see a lot more POC testing in home settings, on smart phones that can monitor certain key parameters, and in primary care settings.” Inside the hospital, whether the central laboratory or POC testing is more efficient in delivering results depends on the infrastructure and laboratory configuration of the particular hospital, he adds.

Weighing both the proven and speculative benefits of shifting more testing to point of care, Dr. Abel believes that evidence-based POC testing should be the goal. “By no means am I against POC testing, but I try to take a balanced view. Before we get carried away completely by enthusiasm for the exciting new technologies in POC testing, we should think it over. We need to study where exactly are the efficiencies going to be realized and the costs going to be saved. I think we will see more POC testing. But it needs to be adopted on the basis of the evidence, and often the evidence isn’t there yet.”

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