Point-of-Care Testing: Past, Present and Future

Interview: Frederick L. Kiechle, MD, PhD
Medical Director, Clinical Pathology
Memorial Healthcare System
Hollywood, Florida

Please describe the evolution of point-of-care testing. How has it changed over the last 10 years?

Dr. Kiechle: I like to think of the evolution of point-of-care testing in 3 phases. First were the early applications, the underground phase, where urinalysis, fecal occult blood, gastric occult blood and perhaps other tests were being performed at nursing stations either by a nurse, a nurse's aide, a resident or even physicians.

The advantage obviously was a rapid result. The disadvantage was frequently inadequate training, and there were instances when gastric occult blood developer was used for fecal occult blood and vice-versa because no one actually told anybody that that wasn't an appropriate thing to do.

There were often no protocols or action plans for a positive result, so often the results were obtained and not placed in the patient record or acted upon. In many cases the results were written on the back of a hand, a paper towel or simply forgotten.

In the late 80s, diabetologists and the ADA changed the process of monitoring a diabetic patient. They discontinued using dipstick urine glucose testing and replaced it with a finger stick whole blood method for monitoring at home, allowing the patients to use a sliding scale of insulin based on the results they obtained.

This revolutionized and markedly improved the care of diabetic patients. However, diabetic patients who were then hospitalized noticed that the turnaround time from the central laboratory for a glucose measurement that they could obtain by sticking their finger at home, took anywhere from 30 minutes to 2 hours from the central laboratory.

Patients complained to their physicians, and they began to wonder why glucose meters couldn't be available at the nursing stations to provide more rapid turnaround time. This led manufacturers providing glucose meters to sell them directly to the nurses and nursing management, with limited laboratory involvement.

The laboratory was sort of resistant, but as time evolved, there was a clear need for standardization. Glucose, in fact, was the test that led the way in organizing hospital-based point-of-care testing. Guidelines were developed primarily for monitoring finger stick glucose in the hospital. It was in 1994 that the NCCLS, now called CLSI – Clinical Laboratory Standards Institute, published their guidelines called ancillary (bedside) blood glucose testing (C30-A2) in acute and chronic care facilities. These guidelines have been revised recently.

That publication really provided a paradigm for developing standards and guidelines around future point-of-care programs. Key elements included the recommendation for a point-of-care testing committee organized at the hospital to approve new programs, new devices, or to approve the expansion of an already existing program. They also suggested that there be a single device used for

a particular test being done at the bedside, standard operating procedures, QC and QA programs, and annual recertification of the testers.

Then, probably the third major influence on point-of-care testing was CLIA-88, approved in 1992, which provided a framework for the laboratory to move in and begin to develop rules and procedures and guidelines for training and monitoring the activity of these underground, unregulated programs.

Based on the strength of the government's new guidelines, many hospitals were able to embrace point-of-care testing that had been in existence for years without any standardization in procedures, any quality control or any education.

The equipment itself has improved from generation to generation. Some of the early complaints about glucose in particular were that the accuracy and precision were very poor compared to the central laboratory method, and also, of course, more expensive.

The real advantage and the driving force behind point-of-care testing, which all point-of-care testing committees need to understand, is the improvement in patient outcome or in patient clinical decision-making that springs from the use of point-of-care testing. If the protocol says we're going to change the insulin drip every hour and the glucose from the central laboratory comes at its best turnaround time, every hour-and-10-minutes, the value of that glucose is totally useless to the team taking care of the patient. The result is needed much earlier.

It's clear that if the central laboratory can't solve the problem and point-of-care is available and the equipment is reliable -- that is, has high accuracy and precision -- it really becomes a very difficult argument to say, "We're not going to do this."

Now, you might ask, "How has point-of-care testing changed over the last 10 years?" I think the major changes that we've seen are more acceptance of point-of-care testing by the laboratory professionals, including pathologists, and enormous interest in organizing programs that reduce patient errors. Laboratories are set up to have a high level of competency training throughout the program's existence, and are interested in finding ways to monitor and improve quality control throughout the program.

I think one of the biggest and probably the most important last frontiers that exists out there is connectivity -- being able to link the results from the point-of-care testing activity through an interface, either wireless or hardwired, directly to the laboratory computing system and therefore to the hospital information system so that the glucose values and all of the other point-of-care tests can be included in the permanent patient record and available for review as soon as the test has been completed and validated.

From your perspective what are the critical success factors for point-of-care testing?

Dr. Kiechle: I like to talk about critical success factors for point-of-care testing based on what I call the 5 golden rules. I think the first thing is that you need to establish a point-of-care testing committee in the hospital, empowered to make all decisions related to the expansion of existing programs or the initiation of any new program.

Clearly, the membership of that committee will vary depending on what the topic is. There must be an administrator involved because clearly point-of-care testing does cost more than central laboratory testing. You need to have pathology involved and you need to decide whether nursing or the laboratory is going to run the program. Both work quite well if you have motivated individuals.

The second rule is one device only per point-of-care test. Standardize them throughout your multiple hospital system. Do not allow variability. It will just create chaos.

Number 3, you must have a good QC/QA plan in place throughout your institution or institutions. You have to have buy-in from the nonlaboratory testers. On our application form for expanding or starting a new point-of-care program, we always ask the question, "Why can't the central laboratory perform this function?"

You need a nurse manager or someone responsible to sign off that the users understand that there are particular activities that are required for the program to remain in good standing. You have to perform quality control, competency exams have to be done, and annual reauthorizations of users, otherwise the device will be removed.

The fourth rule is to ensure that there's adequate time for training. One-on-one training is absolutely important and that's why you need an adequate number of point-of-care coordinators to train all users.

You also need to develop a method for same-day -- as close as possible -- feedback when errors occur. That implies that program managers are able to interact with the program and review some of the deficiencies.

Lastly, I think in this day and age it's really important to have connectivity. You just cannot run a large program with multiple tests, with a multitude of different devices at many different sites effectively. It becomes physically impossible for a point-of-care coordinator to go to all these places and review paper records and be able to make any sense out of what's going on.

Connectivity allows you to keep track of your users, such as how many times the users do quality control. You can then use the quality control activity as a competency monitor and if you choose to, annual recertification.

I think those 5 general rules need to be in place to ensure critical success. Always remember, anything you implement is not cast in stone, and probably will need to be changed as time progresses and methodologies improve. If you have those in place you probably have a program with a high degree of chance for success.

Are there any data published that demonstrate that point-of-care testing actually achieves an improvement in patient outcomes?

Dr. Kiechle: Intuitively, we believe that's true. If we can get the results sooner and implement a therapeutic maneuver sooner, then one would believe the patient's outcome would be improved.

In some instances that's true, and in some instances, it's more complicated than that. Let's take the chest pain area in the emergency room where it has been recommended by some that cardiac markers at the patient's bedside are extremely important.

I would say, "I don't think so." Most cardiologists are interested in getting those markers drawn and usually performed in the central laboratory as a baseline. They're more interested in the EKG, the patient's history, and based on those findings have that patient in angiography getting an angioplasty done before the first set of numbers even come back.

Drug overdose information in some cases is very valuable if there is, in fact, an antidote that can be given to reverse the effects. Often these antidotes are given anyway before you even know what the drug is. So again, there is some debate about whether that has value or not.

Probably the best studied use of point-of-care testing that definitely demonstrates a fabulous outcome is in tight glycemic control, and the first published or at least the first widely read was the study by Van den Berghe and colleagues in the New England Journal of Medicine.1 In this study, surgical intensive care patients were studied either on an insulin drip where the glucose range was tightly controlled between 80 mg/dL and 110 mg/dL, and for the noninsulin drip regular patients were given insulin as needed, and the glucose value was attempted to be kept less than 200 mg/dL. Both morbidity and mortality were reduced in the tight glycemic control group. That has encouraged studies in a variety of different clinical settings, including, of course, the medical ICU.

The question is should we expand tight glycemic control to patients with high glucoses throughout the hospital, no matter where they're located? Currently in most hospitals, when the patient leaves the surgical ICU they go to a step-down unit where now anything < 200 mg/dL is fine. You're no longer trying to maintain that very tight 80 mg/dL to 110 mg/dL range but what should that range be? With such an inexpensive tool, a therapeutic intervention -- that is insulin drip -- you're able to provide extreme improvements in morbidity and mortality. It argues that eventually this will, in fact, become the clinical practice paradigm and anybody not practicing in this manner, I predict, will have problems when they have their Joint Commission inspection.

How widespread do you think tight glycemic control is in the ICUs and what is the key limitation to more widespread use?

Dr. Kiechle: Well, my impression is that it's growing rapidly throughout the surgical ICUs and slowly making inroads in the medical ICU. Actually Dr. Van den Berghe published a paper in the New England Journal of Medicine2 last year on that subject. It demonstrated you had to be in the ICU for > 3 days before you could see an improvement. The fear of people running the program, which of course are nurses, is that they will somehow create a larger number of hypoglycemic events. That, in fact, just isn't the case. But it is one of the fears and phobias you have to get past during the initial training to get one of these programs going.

But if you're looking for a place where outcomes have been well demonstrated in the literature, that's the place.

There is another great example of several studies that were published using the i-STAT in the emergency room. Probably one of the better organized ones was published from Washington University in Clinical Chemistry several years ago.3 They looked at emergency room patients and their disposition. They compared not using the i-STAT for about 3 months, and then they introduced the i-STAT analyzing for Na, K , Cl, glucose, and blood urea nitrogen, and made those test results available to the emergency room physician before they were available from the central laboratory.

Interestingly, and surprisingly to some people, it turned out that the patient outcomes remained exactly the same. There was no difference whether the i-STAT was used or not.

The simplest and probably most logical explanation for this is that the laboratory frequently has very little to do with patient outcome in the emergency room. The real issues are availability of radiology, availability of a bed, availability of consultants to come in and help resolve a specific

issue before deciding to admit or not admit, and the laboratory is really not the weak link in the chain.

The other issue in the emergency room is that if you give a physician a list of values and the potassium turns out to be normal but the doctor has not had a chance to actually visit the patient or look at the patient's EKG, that number means nothing clinically. The physician needs to see the patient to collect other information before the lab values are thrust in front of him to make a final determination about what's important and what isn't.

What point-of-care testing is most appropriate in the physician's office?

Dr. Kiechle: In the physician office setting, prothrombin time, for patients who are on coumadin, and hemoglobin-A1cs for patients treating their diabetes with insulin injection or an oral agent regimen, are most appropriate. If the results are available while the patient is still in the office using a point-of-care methodology, often the treatment can be changed before the patient leaves the office, avoiding a several day turnaround from the central laboratory. I think patients enjoy the more rapid feedback.

Are there particular areas where you believe the routine laboratory tests are better than what you think can be done with a point-of-care testing device?

Dr. Kiechle: That's usually true when a new technique becomes available. I know for a fact that many of the PT testing systems are really quite difficult to use. With PT you also have to worry about INR and the ISI. Then you have to worry about if you're a hospital and you're measuring them on an outpatient basis or from physician offices and later they show up and have their PT done in a central laboratory. The data is not consistent. It's slightly confusing. So that's an issue that I think needs to be considered if a physician's office is seriously thinking about doing PTs in their office. Other than that, I think you just have to be careful.

You don't want to be the first adopter of new technology in this situation. You want to wait and be sure that it actually functions the way it's advertised to function.

From my perspective, the patients that they see and the diagnoses they have, should drive the appropriate point-of-care tests. They clearly may need to have some consultation from pathologists or medical technologists to be sure that their laboratory is set up appropriately and licensed to do waived testing (www.cms.gov).

They have to understand that it's not a black box. It does require the same kind of care and maintenance that a program within a hospital would require. There are agencies that will come and review physician office compliance, and there are organizations that will come in and inspect according to standards established for point-of-care testing.

Are there barriers to point-of-care testing?

Dr. Kiechle: Physicians adopting this type of testing need a license. They may be surprised and somewhat discouraged by the number of regulations that they have to comply with including writing a procedure manual, maintaining the device and keeping track of quality control. If they're

not familiar with how to do it or don't have someone to go to help them set it up, that maybe a giant barrier.

Reimbursement, of course, is something they're going to want to look at as well. I think for point-of-care testing, it usually works against them. If they're doing moderate complexity testing, it probably helps balance out the point-of-care testing they're doing.

What's coming in the future regarding point-of-care testing?

Dr. Kiechle: My view is that there are going to be more and more applications available at the bedside. I'm thinking about molecular point-of-care testing as a great example of that in the field of bacteriology and virology.

We need a device that can extract the DNA or the RNA, amplify it and measure it all in one box, and in a very short period of time.

That would revolutionize a lot of the issues we have: MRSA, VRE, detection of beta strep and enterovirus, for example in the emergency room. Instead of a couple of hours, a point-of-care device might provide information in minutes, speeding up the decision to admit or send the patient home.

I really believe that once this is figured out, probably within the next year or so, you're going to see an enormous increase in the number of applications available.

The next big area of advance will occur as we expand the noninvasive methodologies. Currently, there is transcutaneous bilirubinometry which is comparable to the neonatal bilirubin done in the central laboratory. It's a great screening tool when the patient comes back after the second, third or fourth day of life to have their bilirubin checked. You can use it as a screen to determine whether you really need to do a heel stick.

I think we're going to see expansions -- a great example: tight glycemic control can improve patient care in a major way. It's an extremely inventive, creative solution to reducing morbidity and mortality.

And lastly, I think the expansion of connectivity, and especially wireless connectivity, will improve our ability to get those results off paper towels and people's hands and into the patient record for treatment decisions and, of course, billing.

References

Van den Berghe G, Wouters PJ, Bouillon R, et al. Intensive insulin therapy in critically ill patients. N Engl J Med. 2001;345:1359-1367.
Van den Berghe G, Wilmer A, Hermans G, et al. Intensive insulin therapy in the medical ICU. N Engl J Med. 2006;354:449-461.
Parvin CA, Lo SF, Deuser SM, et al. Impact of point-of-care testing on patients' length of stay in a large emergency room. Clin Chem. 1996;42:711-717.www.poc.roche.com