Leveraging urinalysis for value-based health care

Anne Paxton

November 2015—Tim Skelton, MD, PhD, knows a fair amount about how to enhance the clinical value of urinalysis. It's a subject that, as medical director of the core laboratory and laboratory informatics at Lahey Hospital and Medical Center in Burlington, Mass., he's been focused on for the past three years. But he didn't exactly set out to become an expert in that particular area. He was mainly trying to figure out why his laboratory was experiencing repeated urinalysis quality assurance failures.

In a presentation at this year's American Association for Clinical Chemistry annual meeting, Dr. Skelton related his frustration in trying to meet the clinical tolerances in testing for protein, glucose, occult blood, and ketones. "We got new analyzers in, we retrained technologists, we tried to change our procedures, we told them not to put certain specimens on. And none of those things helped." Added to that, the leukocyte esterase, nitrates, and occult blood tests done by dipstick frequently gave false-negative results. "The current method [of urinalysis] does not meet the performance characteristics required for good patient care" was the conclusion of a June 2012–January 2014 QA project at Lahey Health System.

As an example of the type of quality assurance problems that were cropping up, in July 2013 the laboratory performed split patient sample comparisons across different instruments: the main dipstick reader in the main hospital, a small backup dipstick reader, and a separate hospital's medium-sized dipstick reader. "We had three techs at different hospitals do a manual interpretation and tried to compare them, and what we found was a huge variation. The same specimen could come in at 15, trace, or negative for ketones, depending on which tech was reading it. Proteins could vary from greater than 300 mg/dL to 30–100 mg/dL." Clinically, those results require very different actions, he notes. "So we needed to change the system."

At the time, the laboratory reflexed to a microscopic analysis only when a chemistry was positive. "We realized that wasn't adequate. It wasn't possible to get what we needed clinically from the urine dipstick; based on the evidence, you needed a microscopic analysis on every urine specimen."

Dr. Skelton

Lucky timing was part of what led to the cure, Dr. Skelton says. In response to the quality concerns, his laboratory was doing a lot of research on efficient urine analyzer instruments just at the moment that a number of mergers were occurring in his health care system. So standardization across Lahey Health System was a leading priority, and rules and order sets were being built to convert to a systemwide electronic medical record.

At the same time, the task of migrating all workflow processes to the middleware or to the EMR and away from the LIS was overburdening the medical technologists, while faster turnaround to the emergency room was badly needed. So increased automation began looking like a must. "I would have to say a lot of things converged to make us surge ahead with the solution," says Dr. Skelton in an interview with CAP TODAY.

With promising new urine analyzers coming on the market, the laboratory decided to make the switch from manual microscopic methodology to integrated flow cytometry and chemical analysis on all specimens. A validated dipstick

reader with color correction was available from U.S. Arkray, and Sysmex had developed the UF 1000i automated urine particle analyzer, which is the flow cytometry side. “They got together and merged the two instruments into one integrated urine analyzer, and that allowed walkaway automation.”

This combination gave the laboratory the solution it needed, and it went live with the automated flow cytometry method about a year ago. “The two things that solved the problem for us were to get an analyzer with color correction, so we could correct for the colored specimen, and to do the microscopic particle analysis on every specimen. So even if the dipstick was incorrect, we would find the elements in the urine that were clinically important.” Together, the walkaway automation and color correction allow for effective information technology workflow integration and autoverification for improved turnaround times and patient flow through the emergency department, Dr. Skelton says.

One of the major benefits of flow cytometry is that it gives users precise quantification of white cells, red cells, and bacteria. It can be reliably autoverified without morphologic confirmation or sedimentation, he notes. After training the technologists to put all colored specimens on the analyzer so long as they were translucent and not turbid, his laboratory is now able to let the software autoverify everything, without using any human visual color interpretation. “The color correction now allows us to get much more precise with our semiquantitative protein analysis.” As a result, “We moved from five grades on the dipstick analyzer to 11 grades on the integrated analyzer with color correction.”

Middleware rules make it easier to adopt the flow cytometry for urinalysis, Dr. Skelton says. “The middleware can interpret the instrument error codes and provide logic to guide workflow and clinical interpretation. Using the middleware, you can manipulate the data that is coming off the flow cytometer just the way that it’s coming off the instrument into a format that’s more easily interpreted by an EMR.” The traditional LIS, by contrast, tried to do it all, he explains. “But with the new EMR, you need the middleware to do the kind of data manipulation the LIS used to do. The middleware lets you interpret the complex data and translate it down to something simple, like a review flag sent to the EMR.”

One challenge has been working with Medicare safeguards against overutilization via bundling of laboratory tests. “There’s this idea that if you don’t let doctors order pieces of the urinalysis like a dipstick, then you might be doing enticement or Medicare fraud,” Dr. Skelton says. Lahey fought that idea by approving the dipstick as a screening test across the organization. That means that patients should not be treated based on a dipstick result alone; the result has to be followed up with a confirmatory test. “Once we approved the dipstick as a screening test, we were able to incorporate into all our standardized order sets throughout the health system a standard definition of urinalysis as urinalysis with microscopy.”

Physicians doing order entry can choose to do a urinalysis and culture, or urinalysis with reflex to urine culture, or nurses can follow standing orders for certain urinalysis-culture combinations for defined conditions. Once this system was implemented, Lahey found the number of its total urine cultures dropped significantly. “When we switched from the LIS to the EMR, at the same time we added a reflex test that performed a urine culture only if white cells and bacteria were positive on urinalysis. A lot of doctors used to order a full urinalysis and urine culture on every patient. But a lot of those urine cultures were wastes. Seventy percent of them were coming back negative. With the urinalysis reflex criteria, our total urine culture dropped 42 percent.” Not only did that save a lot of expense, he notes, “It was also a big relief to the microbiologists, to get to do 42 percent fewer urine cultures.”

Dr. Skelton expects significant further benefits from flow cytometry. “It reduces a lot of wasted morphologic examination and downstream diagnostic workup and histories and physicals and so on.” For example, the asymptomatic microscopic hematuria screen for bladder cancer increases the clinical value of having a very precise red blood cell count near the normal range, he points out.

“The reduction of inappropriate diagnostic workups happens right away. So a lot of cystoscopies that are inappropriate won’t be done. In the longer term, what will happen is we’ll have less invasive bladder cancer in our

population. . . .We'll be able to treat bladder cancers sooner, and more patients will be cured, and we won't have to deal with all the costs of invasive bladder cancer later."

The same is true with chronic kidney disease, he says. The early detection of treatable kidney disease increases the value of sensitive protein detection and other urine tests for nephropathy. "New screening methods are making screening for proteinuria more accurate and more precise. Screening for proteinuria helps with early detection, and we hope we'll have a patient population that will get treated sooner and won't have as much advanced stage chronic kidney disease in our population."

Just having more precise and reliable test results has other important clinical effects, Dr. Skelton notes. "What happens is that doctors gain more confidence that the test is really picking up proteinuria and is not just reflecting little fluctuations related to the testing process. If you have an inaccurate test, they don't follow up on it. When doctors get used to the reliability of the test, they react accordingly in terms of their treatment. They'll recheck after three months and if the lab abnormality is still there, they will start working the patients up."

Another result of the switch to increased automation is that quality control data can now be pulled out to its own server, Dr. Skelton adds. "We have used the instrument itself to provide storage for quality control, but we found that not to be a good idea. We are planning on moving the QC to its own server—not in the instrument, not in the middleware, not in the EMR, but on a dedicated QC server. We're standardizing that approach to get all the high-volume chemistry and urinalysis QC data onto one server for all the hospitals in our system. If you standardize QC onto one server, it looks the same regardless of which method you use."

The increasingly more visible HEDIS quality metrics also play into the value equation, he points out. "We're all being measured on these now, and what they're looking for are the low-lying fruit where if you do the right screening test, you can pick up a treatable disease early. And they've identified screening for nephropathy as one of these areas, so they've started measuring how well hospitals screened diabetics for development of kidney diseases."

On the HEDIS metrics, his hospital is now at the 86th percentile in getting diabetics screened this way. "So we're not in the top 10 percent, but we're close to it. But this is becoming really important now with ACOs and health care reform, and it is going to dramatically change the role of laboratory diagnostics in a value-based health care system."

He doesn't consider what his laboratory did to increase the clinical value of urinalysis to be revolutionary. Many other hospital systems are making the same switch to flow cytometry and increased automation. "But there's a wide range of how this is done from one hospital to another. Different hospitals have pieces of it. What we've done is taken all the best practices in testing, in policy, in information technology, and put them all together into one package. It involves multiple different areas—how you design the order, how you report results, and how data is flowing across the IT platform. So we're leading the way in terms of making a really concentrated, focused effort to optimize all the different pieces."

To succeed with enhanced urinalysis, he says, the most important thing is using clinical value, not just technical tolerances, as your guide. "In the past, we've focused on trying to identify everything in the urine sediment and do everything that is technically optimum. But instead, for everything you're doing, you have to ask: Does this improve something clinically?"

This shift in thinking is part of moving to value-based health care, he adds. "You want to have the most clinical benefit with the least health care cost. It's not just reducing your laboratory budget. You're optimizing the clinical benefit to the patient and reducing the total cost to the whole system."

"You probably wouldn't do what we did if you were only concerned with the urinalysis lab budget," Dr. Skelton says. To gain the most from a shift to integrated automation in urinalysis, "You have to have a broad perspective on total health care costs in your institution—and maximum value."

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