To reduce UTIs, one lab takes a long, wide look

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June 2013—Lance Peterson, MD, wasn't expecting to be surprised. But the numbers were dramatic enough to startle even him.

Dr. Peterson, an epidemiologist and director of microbiology and infectious diseases research at NorthShore University HealthSystem, in Chicago's northern suburbs, was looking at figures from the interim analysis of a study he and his colleagues were doing to review presumed urinary tract infections at the four-hospital system. Were they truly UTIs? Or was the laboratory reporting urine culture results in a way that led physicians to treat UTIs that weren't clinically significant, adding to inappropriate use of antibiotics?

Laboratories in general had been constructing their own Maginot Line of sorts over the years, using culture counts of more than 1,000 or 10,000 colony-forming units per milliliter in reporting diagnostic culture of a urine specimen. That didn't sit right with Dr. Peterson. Like the famed line in France, the lower thresholds may have seemed like a good idea at one time, but were kaput as a one-size-fits-all reporting strategy.

Several years ago, Dr. Peterson says he spoke with Calvin Kunin, MD, whom Dr. Peterson calls the "grandfather" of urine cultures. He told Dr. Kunin of his suspicions that his lab was overreporting UTIs by using the 1,000 and 10,000 CFU/mL thresholds for inpatients. Dr. Kunin, he says, concurred, saying the thresholds should never drop that low for hospitalized patients. "That gave me a very, very senior person to confirm what I thought we might find" when NorthShore undertook its study, Dr. Peterson says.

Even with that imprimatur, however, Dr. Peterson was impressed by the dramatic change when the threshold shifted to 100,000 CFU/mL. The rate of appropriate detection went up some 73-fold.

When he spoke to his statistician on the project about the interim results, he asked how much longer to continue the study. At this point, the researchers had looked at about 170 cases. "He told us, 'There's no point in going any further. It's just spending more time, and you aren't going to be able to make the statistics any better,' " recalls Dr. Peterson. The study, which eventually looked at 185 cases total, was published last year (Kwon JH, et al. *Am J Clin Pathol.* 2012;137:778–784).

There was, for Dr. Peterson, one more surprise. Despite the dramatic results, it took a significant amount of time to address the problem once it had been confirmed. Dr. Peterson sounds like a homeowner embarking on a minor—supposedly—renovation project. "It's not unheard of for me to think we can get it done quicker," he says. Looking through past messages and interventions, however, Dr. Peterson says he was reminded that he and his colleagues had begun their efforts to lower UTIs 10 years earlier. "I underestimate the time things will take."

On March 19, NorthShore changed how urine cultures are ordered and results interpreted. Again, the results have been dramatic. Neither legerdemain nor a balancing of the metaphorical ledgers have been involved, though among the steps the lab took, one can be seen, partially, as a type of accounting change. "What we're doing, in a sense, is changing the threshold so we have fewer false-positives," Dr. Peterson says.

Data from the first month were remarkable. In the five intensive care units at the four hospitals, there was only one urinary tract infection. "Absolutely amazing," says Dr. Peterson. "Normally it would be in the eight to 10 range."

In that period, says Dr. Peterson, there were about 8,000 urine cultures total, of which some 1,700 were inpatient specimens. Of those, a little more than 300 were inpatients who were hospitalized more than two days; 80 of them were affected by the new reporting. When the charts of those patients were reviewed, none of them had a UTI by clinical symptoms. "They did *not* get antibiotics, and they did fine," Dr. Peterson says.

While these results are not statistically significant, the new approach should help the hospitals meet the system's

goal of reducing nosocomial UTIs, an infection that, not coincidentally, is now both publicly reportable in Illinois and nonreimbursed by the CMS.

The specter of unwanted publicity, coupled with financial strictures, brought a renewed burst of energy to longstanding laboratory efforts to rein in nosocomial UTIs. In fact, that helped launch the aforementioned study, says Tom Thomson, PhD, director of the microbiology laboratory and division head of clinical pathology. The lab wanted to know how many there were, and what types of patients they occurred in. The conclusion from this project was clear: Half of the so-called nosocomial UTIs that the system would soon be penalized for were not nosocomial UTIs. They weren't infections at all. Instead, says Dr. Thomson, they were contaminated urines or samples from patients who had asymptomatic bacteriuria. These cases were not associated with symptoms, "and in almost every case would not be treated."

Getting hospital leaders to make the project a priority was fairly easy. No one wanted the nosocomial UTI rate to be reported as double the actual rate. "The administration said, 'This is not going to happen,' " Dr. Thomson recalls.

After getting administrative support, the lab met with other key players, pitching the proposal and asking for feedback. "And then running for cover," Dr. Thomson says with a laugh. "It takes time, persistence, and a lot of friends calling in favors."

The laboratory had its own problems to tackle, including the logistics of figuring out when organisms in urine should be identified and reported. It redid its urine test codes to differentiate the types of urine samples and patients. When physicians place an order for a urine test, they now choose from several types of culture, including:

- culture, bacterial, urine—inpatient (non-straight cath)
- culture, bacterial, urine—outpatient or Emergency Department (nonstraight cath)
- culture, bacterial, urine—straight cath or bladder aspirate.

Urologists have their own urine culture test code as well, which enables them to order the testing needed for cystoscopy and other invasive procedures.

Dr. Thomson sums up the laboratory changes in two parts. First, the lab is taking information that's been there all along, but packaging it differently, so to speak, by redoing the urine codes to help the lab more easily apply standard criteria. The second step was to create a new category of patient—inpatient with a possible urinary tract infection—and apply a new count.

In a related step, Dr. Thomson says, the lab also did away with the highly popular—among clinicians, anyway—reflex urine test. When a physician ordered the test, the lab would do a urinalysis. If the result was normal, no culture was performed. If the result was positive, the urine would be reflexed to microbiology for a culture setup.

The lab wasn't a fan of this. Most labs aren't, Dr. Thomson says. "But they're sort of forced into it by their clinical colleagues," who consider it a cost-effective way to identify UTIs.

"In truth, it's not," says Dr. Thomson. "It misses many positives."

So the lab asked clinicians why they defended the reflex test so ardently. The clinicians replied: *We're screening for urinary tract infections.* "So we showed them the literature, which indicated their beloved approach actually missed 15 percent of UTIs," says Dr. Thomson. The clinicians countered with, *We want it to screen patients before they go to surgery, to see if they have asymptomatic bacteriuria.* The lab responded with additional evidence, showing the test missed 50 percent of those patients. The screening, furthermore, is no longer required for many surgeries, Dr. Thomson says. "And the downside of treating them is that they're going to get *C. diff* disease."

After plenty of discussion, the plan moved forward. For Dr. Thomson, there's an obvious lesson to be learned from this thrust and parry. "You can't take your opinion and make it a new requirement. You've got to take your opinion, round off the corners, support it with medical and scientific evidence."

It can take time, however, for behavior to catch up to new evidence.

"It's embarrassing," says Dr. Thomson. "I've been doing this a long time. We've been trying to get people to wash their hands, and we've been trying to get people to screen for *Staph aureus*—many things." Not until the CMS imposed its financial and public reporting penalty were the problems solved. "They were fixed in two years. Embarrassing, but that's what happened."

The 100,000 CFU/mL has its roots in clinical research done in the 1950s, says Dr. Thomson. "The good news was the 100,000 figure was a really useful term and differentiated people who were infected from those who were not infected, who had disease from those who did not have disease," he says.

"The bad news is the research was done on one type of patient: those with pyelonephritis," he continues. Most of the patients sampled now don't have that disease; rather, they tend to have prostatitis or bladder infection, he says. "We've learned over the decades since the 1950s that 100,000 does not pertain to every single patient who has a urinary tract infection."

"Over the decades, we've learned that some populations have symptomatic urinary tract infections at lower colony counts," Dr. Peterson says. "What microbiology laboratories have tended to do is then use those lower cutoffs for everybody," rather than focusing on what level is most appropriate for individual populations. Historically, the lower colony counts were found to have evolved from sexually active young women, who can have symptomatic UTIs, Dr. Peterson says.

The 1950s have had a lasting influence, and not just in antique malls. Over the years, action became habit—and habits are hard to break even when the motivation is strong. With UTIs, such motivation has been lacking.

UTIs, it's safe to say, have been a sleepy topic. They lack a ripped-from-the-headlines vibration—this is not a new cancer breakthrough. In fact, talk has, generally speaking, been nonexistent. "I don't remember being at a symposium on how to diagnose a urinary tract infection for probably two or three decades," Dr. Peterson says.

Physicians who think they already know about UTIs also tend to treat them, which has given rise to excess antibiotic use, says Dr. Peterson. Physicians find it difficult to *not* treat something once the laboratory reports a positive result. It's like ignoring the "ping" of a text. And while he's pleased that physicians are paying attention to lab results, responses based on reason, rather than reflex, are to everyone's advantage.

Using reason helped the laboratory propel its proposal through the system. When physicians and nurses saw the new approach would improve patient care, they bought into it. Nevertheless, transformation came slowly.

Dr. Thomson likens it to changing the direction of a large ocean liner. "There's a tremendous amount of work and education that goes into something as simple as this." Coming up with the original data was the easy part. As activists of every stripe continually learn, however, having a good idea is never enough.

The larger issue is changing a behavior that's been allowed to persist, undisturbed, for years. In many cases, the lab is working with clinicians who've been ordering urine cultures for decades. All of a sudden (or so it seems to the clinicians) the test code is labeled differently, forcing physicians to choose among several options where formerly there was one. "And in a busy day, nobody wants to stop and relearn that," Dr. Thomson concedes.

It's not that the choices themselves were tricky, he says. It was the fact of having to make one at all. As Dr. Thomson characterizes it, physicians respond by saying, in their heads, if not directly to the lab, "I've been ordering urines forever. Why do I need to do this differently? Someone's just trying to complicate my life."

In the laboratory, changing the test codes brought its own challenge: how to organize the workbenches efficiently.

One of the most difficult steps, according to Dr. Thomson, was to accurately define an inpatient.

Per National Healthcare Safety Network/CDC criteria, an inpatient urinary tract infection is one that occurs in someone who's been in the hospital for more than two days. "So in our mind, an inpatient is not a patient who's been in the hospital for two days or less," Dr. Thomson says, which lends a surreal note to the conversation as well as imposing a technical challenge. "Somehow, when we look at that at the bench, we need to identify inpatients as two days or less, or more than two days." It's not an easy thing to do, given that the lab receives hundreds of urine specimens every day. Says Dr. Peterson: "We actually went through all the screens that are available to the medical technologists and technicians." Fortunately, one screen contained admission information. Making the inpatient/outpatient distinction adds under an hour's worth of work per day to the process, according to Dr. Thomson, who suggests the time may fall even further as the added identification steps become routine.

Another challenge was to *not* miss patients who have bona fide UTIs whose cultures showed less than 100,000 CFU/mL, which was now being called negative.

This didn't appear to be a problem during the six-month study. But to be safe, Dr. Peterson is provided with a list of all patients in for two days or more and to whom higher interpretive criteria have been applied; he then reviews each patient's chart to make sure an infection (based on additional criteria set up by the Infectious Disease Department) hasn't been missed. The additional quality check will last for a full year to make sure there are no adverse consequences to the new practice.

Urologists had their own needs, since they required cultures for surgical procedures. "We'd sort of forgotten about these kinds of urines," Dr. Thomson admits. Reminded of them, the lab developed the aforementioned special test code for urologists. That, says Dr. Thomson, was another lesson for the lab: Ask for ideas, then use the good ones.

The lab spent plenty of time talking about when to order a urine culture. It's not unusual for ICU patients with a fever to get a culture repeatedly until the fever disappears. There's no need for that, says Dr. Peterson. Instead, it may be more appropriate to do a urine culture at the outset, to make sure the fever isn't related to an infection in the urine, and then desist from daily cultures.

Nurses, too, are obviously important, since they collect the specimens. Those that aren't collected appropriately will be filled with pathogens. "If you take an 80-year-old patient, and put a cup on the table, and say, 'The next time you urinate, could you please do it in this cup?'—it's always contaminated," Dr. Thomson says. The lab has yet to identify foolproof collection methods. In elderly and pediatric patients, nursing personnel need to be more instructive, or even help with collection, Dr. Thomson says.

Once a specimen is collected, it needs to be labeled properly. Is it a mid-stream urine? A catheter urine? Is it from a Foley catheter? Those are now key descriptors for urine specimens and in some cases are different from what were used before.

The nurse leaders are under pressures of their own to make sure they handle specimens correctly, Dr. Thomson notes, by being "graded" on the number of Foley catheters that remain in patients longer than the system's rules dictate. Leaving Foley catheters in may ease the demands on nurses, but can increase the chances of a nosocomial UTI. "Since we're being financially penalized now, medical centers are watching that more carefully, too," Dr. Thomson says. "I hate to admit it, but that's what's happening."

One of the biggest efforts was changing the electronic records. That meant putting in a request for service to the IT Department. "And the IT people have a stack of requests six feet tall," Dr. Thomson says. To get a request to the top of that pile requires lobbying decisionmakers. In this case, as noted, the administration hopped onboard quickly. Then, after working through various iterations, there was the matter of handling the "million phone calls" the day the new system went live, says Dr. Thomson.

It's too early to assess the impact of this approach. Dr. Thomson says he hopes other data will appear in the literature, and that other institutions will do their own studies. At the very least, he says, he hopes the changes at

NorthShore will inspire colleagues at other laboratories to make a similar effort to stop reflex urine testing. "It's something many, many people want to do, but they get so much pushback that they haven't done it," he says.

In the meantime, NorthShore is looking to alter its approach to *Clostridium difficile* testing. Moving from primarily enzyme immunoassay to primarily PCR testing doubled the sensitivity of *C. diff* testing, Dr. Peterson says. A very sensitive test will pick up colonization as well as infection. So how do labs enhance the preanalytical specificity, so to speak, to the colonized patients who are testing as positive? "In a sense, that's what we're doing—fixing the preanalytical sensitivity, but we're doing it in the laboratory rather than through screening tests or screening questions," he says.

Last October NorthShore began interviewing every inpatient at its hospitals. After collecting information for 12 months, Dr. Peterson says, the lab hopes to have preanalytical ways of deciding who should be tested for *C. difficile*.

It's not because he's anticipating another swing of the CMS cudgel. "It's just our infection control program," says Dr. Peterson. "And it [C. diff] is a big issue nationally as well as here in Chicago."

For all the work, Dr. Peterson says the premise of these efforts is, at heart, simple. Looking for an analogy, he compares it to screening done on respiratory secretions, when the lab rejects specimens that lack sufficient neutrophils in the Gram stain of the sputum and contain too many epithelial cells. It's a matter, he says, of making sure the lab has good specimens and is using the right reporting criteria.

Maybe art offers a better analogy. Art, after all, makes us see things differently. And that's what Dr. Peterson, Dr. Thomson, and their colleagues are doing. "It's like all of a sudden you see that your test has a lot of false-positives," Dr. Peterson says. "And you realize if you change the threshold for reporting, you improve your specificity." It may have taken decades of looking at things the same way before the new view dawned, but at NorthShore, it's been a transforming experience.

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