Test utilization: a united front against waste

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July 2013—When it comes to laboratory test orders, the connection between bloodletting and financially draining an institution is more than metaphorical. But a wide range of techniques can help stem test overutilization, clinical laboratory experts have found; you don't have to drive a stake through a vampire's heart to stanch the flow.

It took only a simple intervention to slash daily phlebotomy charges at one tertiary care hospital. In their 2011 article, "Surgical vampires and rising health care expenditure" (*Arch Surg.* 2011:146[5]:524–527), Elizabeth A. Stuebing, MD, and Thomas Miner, MD, report on how they reduced the cost of daily phlebotomy by announcing each week to surgical house staff and attending physicians the dollar amount charged to nonintensive care unit patients for laboratory services.

After 11 weeks, the charges for daily phlebotomy had dropped from \$147.73 to \$108.11 per patient per day.

It was a classic study, not only demonstrating that knowledge is power, but also that process improvement begins by the mere act of monitoring the process. In business, the maxim is known as the Hawthorne effect, says A. Neil Crowson, MD, chief of staff at St. John Medical Center and president of Pathology Laboratory Associates, Tulsa, Okla.



Dr. Crowson

At his institution, the for-profit core laboratory has taken these principles and applied them for a basic purpose: avoiding the misclassification of patients with normal test results as abnormal. St. John's Regional Medical Laboratory is one of a few labs in the U.S. with an enterprise knowledge warehouse, Dr. Crowson says.

"This is a vast granular database, created since 1998, with more than 2 million unique patients and over 350 million lab tests that can be correlated on these patients with ICD-9 codes."

In the old days, Dr. Crowson explains, people would take only 100 presumably normal people and use them as the reference range for a test such as liver function. "But with the enterprise knowledge warehouse data, when we do normal reference ranges, we have up to 100,000 patients by decade for each of the analytes we study."

The laboratory develops these more precise reference ranges for every analyte it runs. "When we look, we find, for example, that roughly a third of transaminases reported as abnormal in men age 20 to 50 are, in fact, normal."

"The benefit is, if you run your reference ranges properly, you don't misidentify normal people as abnormal and then embark on an investigation that might lead, for example, to an unnecessary liver biopsy and potentially to an adverse patient outcome."

Using the large database allows the laboratory to add refinements in setting reference ranges. "Each ethnic group has minor variances in lab results and we can create separate data universes. African-Americans, for example, have lower white cell counts and that's normal. But you need to have a database that can identify huge numbers of people for these things to become significant."

The laboratory also uses data to tailor the pop-up blockers that appear during computerized physician order entry,

Dr. Crowson says. "In flagging test orders that might be duplicates, the time period varies depending on the type of test. If it's a trauma patient, you might order a CBC every three hours, but if it's a patient coming for a breast biopsy, for example, you might only need to know you've ordered one in the last week."

With the relational database, current lab data for each patient can be related to the lab tests that person has had for the last 12 years. "For molecular testing, that's significant data, because you rarely want to do that test a second time in the setting of solid organ malignancies. Leukemias and lymphomas, in contrast, can show an altered genotype over time."

The other category under scrutiny is tests that should not be ordered in the hospital, Dr. Crowson says. "For example, if a patient comes in with a stroke, many of their coagulation parameters are abnormal because of the clot, so what you want to do is manage the neurological injury, get them anticoagulated according to national stroke guidelines [St. John is a nationally recognized stroke center], and then do an investigation of coagulation abnormalities two to four weeks later on an outpatient basis."

At that point, the tests will have meaning because they won't be conducted after an acute thrombotic event. "If the patient has a hereditary abnormality such as factor V Leiden, there's no reason to do that test when they're in the hospital because it may not influence short-term patient management. We can do the test after they're out."

It's all part of operating in a DRG environment, because when the hospital gets paid a set charge by disease, event, and type, "the more tests you order, the more you erode the hospital's profitability." St. John itself is a Catholic, not-for-profit institution, Dr. Crowson points out. "In 2010, we did \$60 million worth of indigent care. But it doesn't matter whether you're a for-profit or not-for-profit facility; you have to be efficient. If we lose \$20 million, we have to close our doors. 'No margin, no mission,' as the saying goes."

A more comprehensive strategy for controlling utilization would help many clinical laboratories, says Michael Hallworth, MA, MSc, a clinical chemist and laboratory director at Royal Shrewsbury Hospital in Shropshire, England. "We're all tack-ling overutilization in a few selected areas, but very few of us are controlling it consistently across laboratory medicine. In the UK, we're sitting on a lot of data on overutilization which we aren't making the best use of. So it's about putting together a package of measures that everybody should use."

The new molecular tests are particularly relevant to reducing utilization, he notes. "People don't tend to understand what they're for and they do tend to be very expensive tests you have to send out. Some of the low-hanging fruit for cost savings are things like endocrine testing and tumor markers. But it's important to remember there are other savings to be had. Hundreds of thousands, or millions, of very cheap tests still cost a lot of money, right across the spectrum of tests."



Dr. Hallworth

While he has found retrospective approaches powerful educational tools, the most effective way to save money has been talking to clinicians prospectively about the ways tests are used. "Clearing up any misapprehensions they may have about what tests can and can't do, getting the right tests done at the right intervals, and following any local agreements or national guidelines—those are the things that stick best."

The Pathology Harmony Group in the UK is an initiative the government funds to minimize the variation among hospitals in a range of areas—very simple things, like 'Do we all use the same reference range for potassium?' If the lab community cannot agree on what's normal and what's not normal, how is the physician supposed to work with that?" Professional bodies such as the UK Association for Clinical Biochemistry and Laboratory Medicine have

recommended national minimum retesting intervals (www.acb.org.uk/CPS/CPSNews.asp).

Dr. Hallworth finds especially promising what a few labs in the U.S. are doing. "Instead of asking physicians to guess which coagulation tests they actually want, the approach is to say, 'Tell me what your problem is, then the laboratory will address it through the right test. All you do is indicate the clinical problem on a request form.'"

"There aren't many places where it's happening, but we do use that approach for thyroid function testing. We have a box on the form that essentially says 'tell me what's wrong,' and we will decide based on the clinical presentation what tests to provide."

This would be a new role for the pathologist and it's one that is in an evolutionary stage at this point, Dr. Hallworth says. But he notes that in the U.S. physicians "order" tests, while in the UK they "request" them.



Dr. Levy

"There is a cultural difference in there that's quite important. Treating the laboratory as a black box is not a particularly good model, and as lab testing becomes more complex and sophisticated, it's becoming an unsustainable model. No physician can understand all the complexities of lab testing, and there's a real role for workers in the lab, who do understand, to say which tests should be requested."

One doesn't find similar problems in radiology, he notes. "A physician would have no qualms at all in calling a radiologist and saying 'what do I need to do, how do I interpret this, and what does this mean?' But they seem to think that we in the lab community can't help them so much."

One of the problems Dr. Hallworth encounters in the UK occurs when physicians screen for rare causes of abnormal metabolic function. "Wilson's disease is one condition; it's an inborn error of metabolism, if you have a teenager and they have an abnormal liver function test, that needs to be in the forefront of your mind. But if someone is 85, then Wilson's disease is vanishingly unlikely. For someone in their 50s we would offer testing, but not include it in our first-line panel."

Another common mistake relates to confusion over test names—in the U.S. there are at least 18 different names for vitamin D-related tests, for example, 25-hydroxy and 1,25. "That's not rocket science. If we can at least call the same things the same names, we can reduce physician confusion."

He hopes that the focus on laboratory utilization will grow stronger and clearer. "Rather belatedly, it's become a hot topic in the U.S. and Europe as we try to practice medicine in a much more cost-controlled environment. But people are also realizing that controlling utilization is about preventing overdiagnosis and overmedicalization as well."

At the University of Rochester (NY) Medical Center, where Paul C. Levy, MD, chairs the Department of Medicine, the initial efforts to improve test utilization got underway in 2009 and were centered on reference laboratory tests.

"There were concerns in the area of reference lab testing that medical necessity was not being met," Dr. Levy says. "This was an especially important problem because with some of the more expensive tests that were being ordered, we may not be fully reimbursed, and ultimately our institution was having to cover these costs."

URMC chose to develop a formulary for laboratory tests, a tiered system similar to the pharmacy formulary model. "Our efforts were not driven only by cost but by matching a provider's training and understanding of a clinical area with certain diagnostic tests."

For each subspecialty area—allergy, dermatology, GI, and so on—a group of five or six experts on a committee would assign each test on the menu to three tiers. This three-tiered, layered approach has had a big impact on the hospital's physician ordering profile, he says.

Tier 1 tests are those that any generally primary care or community-based internists should have open access to order, while tier 2 tests are available only to specialists. For tier 2, many of which are genetic and tend to be more expensive, "We wanted to have the additional training and education of a subspecialist to drive those test orders, rather than just have the Wild West with an open menu."

Most important is tier 3: tests that the expert panels did not see a need to offer to the patient population upon this review. "You need an exceptional case with an exceptional justification to obtain a level 3 test."

"There are so many new tests coming on the market right now, some that haven't necessarily been proven in the clinical arena to be medically useful. For example, if I came across a new blood marker for asthma or pulmonary fibrosis, and I wanted our institution to place it on the formulary, our expert subcommittees would actually review the data, much as a pharmacy and therapeutics committee would review a new drug for clinical benefit versus risks, and so on."

"It isn't that the tier 3 tests are excluded permanently from our formulary, but I'd describe it as putting them up higher on the shelf. You need to take more steps to have the test approved before we would draw a specimen."

How controversial have the tier assignments been? "Nobody got a black eye over it," Dr. Levy says. "But there were some heated discussions about test X or test Y." For example, with inflammatory bowel profile, "there's controversy about the utility of these tests in managing patients with abdominal pain or other GI symptoms. The committee thought the IBD panel should be tier 3, meaning it's available but you'd really have to build a case to get approval for it."

"I don't think the company that performed these tests was happy with our approach. I was told they tried to lobby our GI physicians to ask us to reverse our decision. But we have proceeded."

The institution chose not to go down the path of putting dollar signs for approximate prices in its electronic ordering system. "There has been discussion about that to help create an environment of cost consciousness among our providers, but we have not yet done it."

But, Dr. Levy explains, "Our tiered formulary system was largely driven by the effort to marry the tests themselves, their utility in clinical patient management, and the ordering provider. It wasn't a financial model where we drew a line saying any test over \$1,000 is going to get different scrutiny. What we did is line up all the reference lab tests and say 'Let's get our specialists to think about these.'"

An added advantage of the formulary approach is that it can help protect an institution from becoming the go-to site for reference tests that other hospitals may wish to dodge because of the expense. "You may be caught in a position of processing blood and reporting results of patients with little or no contact with your health system, and that could potentially have a really negative effect on your bottom line."

"With reference lab testing, the way the reimbursement models work, we become the payer of last resort," Dr. Levy says. "I doubt that Rochester is the only place where this is happening. With a formulary of tests and criteria as to who can order them, you avoid the potential problem that could arise if you don't have a laboratory test management system and a nearby health system does."

With so much pressure on high value care, the formulary approach fits the value metric nicely, Dr. Levy believes. "We are trying to be absolutely certain we do not bend the quality curve. We are only trying to bend the cost curve."

With or without the Affordable Care Act, says Kent Lewandrowski, MD, associate chief of pathology and director of laboratories and molecular medicine at Massachusetts General Hospital, insurers have been pushing for more risk

sharing, and physicians are becoming financially accountable for the cost of care.

"Hospitals have long had a motivation to consider utilization management because of DRGs, but now clinicians are being incorporated into the loop of accountability where their potential income could be impacted. And they understand the problem much more quickly. The younger clinicians especially are really grabbing hold of utilization management, saying this is an area where they can make an impact beyond being a clinician.

"We used to take the approach of finding a target of opportunity, basically finding the clinicians and trying to take one foxhole at a time," Dr. Lewandrowski says. Now, however, the laboratory is achieving a more pervasive impact by using informatics.



D r . Lewandrowski

With the computerized physician order entry system and middleware designed by pathologist Anand Dighe, MD, PhD, director of the hospital's core laboratory, "we not only have a better grasp of who is ordering what tests and why, but we also interact with the physician at the time of ordering the test."

"Any doctor trying to order a 1,25 vitamin D on an inpatient, for example, encounters a pop-up message saying that's not the preferred test to assess vitamin D status, while an attempt to order CK-MB is met with a pop-up saying CK-MB is no longer indicated; stick with troponin."

"That's basically wiped out CK-MB testing," he says.

In addition, the utilization controls are more agile than they used to be. "We have a committee that decides which tests will be flagged. But now we work out many decisions by e-mail with the clinicians—for a cardiac issue we send an e-mail to a trusted cardiologist, for vitamin D we talk with an endocrinologist."

That means speed, he says. "With e-mail, you can ask 15 specialists what they think of this idea, and get an answer from the vast majority, sometimes within minutes but certainly within a day or so."

The occasional roadblock is posed by having to go to the IT department to make changes. "They're very busy, they put things in order of priorities, and yours may not be very high. Even though you have clinical approval for something, it may take months to roll out. But Anand can go in and put a pop-up anywhere he wants in the system now within a five-minute period." Dr. Lewandrowski estimates that the system has about three dozen pop-ups at any one time.

On the other hand, pop-ups have hazards. "We don't want to flood physicians with them. Everyone hates pop-ups, so you have to use them judiciously and keep them focused. If they're highly effective in educating physicians, you can then turn them off because the culture has made the change."

A new and effective informatics tool is a search function with built-in decision support on the CPOE system, Dr. Lewandrowski says. These online laboratory handbooks provide not just a list of tests and specimen requirements, but also advice on what situations the test should be used for.

"Clinicians will always look for resources to solve their problems, and pathologists therefore have to make themselves a resource. Some clinical pathologists are known in their organizations as people who can be helpful, and others are invisible. The key is to be very much engaged with clinicians." Screening algorithms can also keep down the number of tests ordered. "I think there will always be a baseline of individual patient clinical pathology consultations of the type 'I've got this patient with X, what should I do?' OK, that's one level. But that's only about 10 percent, at most, of our utilization management activity. Clinical pathology functions more on a population level. For example, if you implement a celiac screening algorithm, you're not just impacting one particular patient and physician; you're impacting all of them."

The cost savings of utilization controls can be straightforward in some cases. "If you eliminate expensive sendout tests, you know exactly what you're saving. But it's much more difficult in the area of automated chemistry and hematology, where you're pulling tests out of a preexisting operation where the fixed costs are already covered."

"Say you eliminate albumin from a comprehensive metabolic panel. In that case, all you really save are reagent costs. But you need to have a sense of that, because your hospital administrators will always ask how much did you save. And sometimes it's not that much and other times it's hundreds of thousands of dollars."

Dr. Lewandrowski is also hoping to design a system at Massachusetts General to improve access to expert information about molecular diagnostics. "The vast majority of pathologists are not specialized in genetics, so with genetic disorders probably the best route is to have a geneticist able to provide that advice. And in some cases we could be saving thousands per test."

Molecular microbiology poses special problems, he adds. "These tests are cropping up like dandelions all over the place. Clinicians might ask, 'Why don't we do PCR for Lyme disease?' That sounds like it must be the ultimate test. But it turns out that although it has some very limited applications, it's not the optimal test and is frequently misleading." Keeping tabs on such tests is a continuing challenge, he says.

From the patient's perspective the clinical laboratory is disconnected from payment concerns—unlike pharmacy. "When we go to the doctor, we'll get whacked with a nasty copay if we don't accept a generic drug. But whether the doctor orders 50 tests or no tests, it doesn't impact us in any way." He can't say whether there will ever be a copay for the lab. "But I think probably with genetic tests in the future, it will be worthwhile to have a higher-level approval process."

For a large laboratory, getting an IT specialist on staff should be a priority, in Dr. Lewandrowski's view. "You have to start by building an informatics infrastructure to support your utilization management; otherwise you're going to be looking at raw data coming out of your system that gives very little insight into where a problem occurs."

In many organizations, the capabilities of informatics have matured, he notes. "And that's really key to an ongoing successful utilization management program."

Anne Paxton is a writer in Seattle.