Sin of omissions: When tests fly under the radar

Kevin B. O'Reilly

“There are known knowns; there are things that we know that we know,” then-defense secretary Donald Rumsfeld famously said in response to a question at a 2002 news briefing.

“We also know there are known unknowns....” he added. “But there are also instances in which we know things that we don’t know we don’t know.”

Rumsfeld—the principal subject of a new documentary, “The Unknown Known,” by Oscar-winning director Peter Landesman—was addressing the case for war against Iraq. But when it comes to the case for improving the use of laboratory testing, the “known knowns” is fairly clear. Overutilization is widely understood as a problem that plagues American medicine, with lab testing no exception to the rule.

But there also is a “known unknown”—the world of test utilization—the extent of underuse, its effect on care, and how to deal with it. How often do clinicians fail to order the tests that would improve diagnosis, prognosis, or management? And how can pathologists and their colleagues in the laboratory take action to improve test ordering if they lack the complete patient picture that would allow them to help clinicians spot the instances in which ordering more tests is the right answer?

Dr. Oscar Arnaout, MD, PhD, directs the core laboratory at Massachusetts General Hospital, where efforts to tackle overuse are well known. He succinctly states the problem many labs face in detecting and addressing underuse.

“You’re looking for something that’s not there,” he says. Barbara A. Zehnbauer, PhD, chief of the Laboratory Research and Evaluation Branch in the Centers for Disease Control and Prevention’s Division of Laboratory Programs, Standards, and Services.

“It’s like the old saying, ‘If you don’t get this letter, tell me and I’ll send you another one.’ It’s hard for labs to know what’s not being done. It’s a big hurdle,” she says.

From the lab’s perspective, unnecessary use of testing is simpler to spot and act upon, says Ronald B. Schultman, MD, chief of diagnostics at the Southern Arizona Veterans Affairs Health Care System in Tucson and associate professor of pathology, University of Arizona College of Medicine.

“It’s easier to look at duplicate testing, too-frequent testing, that sort of thing,” he says. “It’s harder to look at underutilization because in many cases you have to do more clinical assessment. It’s easy to say that if you order two glycohemoglobins back to back over a two-day period, that’s pretty obviously unnecessary, and it’s a systems issue. It’s another thing to look at an abnormal test that was not appropriately followed up on—that’s more difficult to do.”

Despite the impediments that belie the work of making underuse a “known known,” it appears that fitful progress is being made in the effort to better appreciate the dynamics of lab underutilization. For example, a recently published meta-analysis of a decade and a half’s worth of research on laboratory utilization by Ramy Arnaout, MD, DPhil, associate medical director and director of sendout testing at Israel Deaconess Medical Center in Boston, and his colleagues reveals that underuse of tests may happen twice as often as overuse.

And there are promising strategies that could help tackle underuse, often drawing on health information technology tools similar to those that have helped health care systems rein in unnecessary tests. Meanwhile, much of the movement to so-called value-based health care is geared toward improving the use of lab testing in chronic disease diagnosis and management. Another piece of the puzzle, experts say, is to improve collaboration among pathologists and ordering clinicians so that physicians view the lab as a full partner in patient care. That includes proper test selection.

“You really have to reach out to physicians to find out what the patterns of ordering are, and how they associate various tests with their ability to make medical decisions,” Dr. Zehnbauer says.

What is known about the underuse of laboratory testing? Dr. Arnaout and his colleagues have attempted to provide a comprehensive answer. They analyzed studies conducted between 1997 and 2012 that examined 40 of the 50 most commonly used laboratory tests, evaluating 1.6 million tests ordered. To be included in the meta-analysis, a study had to specify valid criteria for the appropriateness of lab testing and explicitly reference previous literature or published guidelines used to develop those criteria. The meta-analysis, published Nov. 15, 2013 in PLOS ONE, included 38 studies that examined overuse, eight that looked at underuse, and four that investigated both (doi:10.1371/journal. pone.007962).

“Finding from the study that has received the most attention is that 20.6 percent of tests are ordered unnecessarily. What has drawn less notice is the underuse rate of 44.6 percent, meaning clinicians fail to order the appropriate test nearly half the time.”

The table below, “8 instances in which lab tests are underutilized,” includes leading examples of missed testing opportunities that researchers consider therapecutic drug monitoring, suspected venous thromboembolism, and hemoglobin A1c testing. Dr. Dighe agrees that lab underuse is a widespread problem. He often sees poor use of lipid panels or LDL cholesterol testing in patients with cardiac risk factors, as well as inadequate INR monitoring of patients taking warfarin. But he says it is hard to determine the magnitude of underuse given the small number of studies included in the PLOS ONE meta-analysis.

“There haven’t been that many papers on underutilization,” he says. “Generalizing those findings across billions and billions of lab tests each year—you have to do that cautiously.”

Dr. Arnaout agrees that circumstances are warming, yet contends that his team’s work demonstrates the severity of lab underuse.

“It is hard to say that underutilization is so sure twice as prevalent as overutilization,” he adds. “This is not a find; this is a finding. This is for real.”

Other research seems to support Dr. Arnaout’s claim. A landmark study that examined the medical records of 6,712 randomly sampled American adults in 13 large metro areas found that they received just 54.9 percent of recommended care across 439 quality indicators (McGlynn EA, et al. N Engl J Med. 2003;348[26]:2635–2645). Many of those indicators involved proper use of lab testing or radiography and showed scores between 50 and 60 percent for screening, diagnosis, treatment, or followup.

That research helped awaken policymakers to the problem of underuse. Now, many pay-for-performance programs, quality reporting programs, and other initiatives carried out by private and public payers focus on reducing underutilization.

There are other signs that underuse persists—for example, a 2013 CAP Q-Probes study, “Frequency Monitoring of Outpatient Laboratory Testing.” In this study, 49 participating labs submitted 1,915 cases involving patients with diabetes who had at least three FbG tests during the previous three years. While the glycated hemoglobin of these patients was monitored properly, the Q-Probes found that 73 percent did not get urine protein testing in line with guidelines, while 21 percent did not have the appropriate LDL tests.

Meanwhile, the inherent limitation of studies on —continued on 62
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Lab test underuse is that they’re based on clinical encounters that don’t consider in the denominator those without access to specific health care services, says Shahram Shahangian, PhD, a supervisory health scientist who works at the CDC with Dr. Zehnbauer.

“For laboratory health screening, for example, population-based studies by the CDC show inadequate use of laboratory tests for screening of colorectal cancer, chlamydial infection, and cervical cancer,” he says. Increasing the uptake of appropriate lab tests, he adds, may entail identifying and lowering the patient-specific barriers.

For their part, physicians admit to challenges when ordering lab tests, as reported in a survey sponsored by the CDC’s Clinical Laboratory Integration into Healthcare Collaborative, led by Julie R. Taylor, PhD (Hickner J, et al. J Am Board Fam Med. 2014; 27[2]:268–274). Nearly 1,800 primary care physicians told researchers they felt uncertainty about lab orders 14.7 percent of the time. One in five respondents said the different test names laboratories use were extremely problematic, while the same share complained that tests were not available except in a panel. Despite the frequency of test-related uncertainty, only 35 percent of doctors said asking a lab professional was useful, and just six percent said they did so at least once a week.

The biggest lab-ordering challenge, primary care doctors said, related to costs. More than half said uncertainty about patients’ share of costs was extremely problematic.

Questions about health plan limits on testing or mandated use of a specific lab test, and lack of comparative cost information, also posed big problems, the study said.

Better understanding of the complete cost picture of lab testing is critical to reducing underuse, Dr. Arnaout says.

“It’s like the old saying, ‘A stitch in time saves nine,’” he says. “Lab tests account for five cents on the health care dollar, but they guide at least 30 percent of downstream medical decisions. While we usually know how much a test itself costs, we don’t usually know what its downstream cost-effectiveness is. As a result, we don’t know the cost of not doing a test. Instead of thinking about tests in isolation, we ought to be thinking about them as a lever for moving downstream cost-effectiveness in a positive direction.

“But we can only do that if testing and downstream outcomes are linked together, which is not yet the case at most institutions,” Dr. Arnaout adds. “I want to know—when I order a CBC on a 50-year-old male coming into my hospital coughing up green sputum with a fever of 103—what’s the cost of my ordering that test relative to the cost of not ordering that test, for example, extra days in the hospital, summed over all such patients coming in.”

That kind of real-time cost data may be available someday, but for now the most widely used approach to improving appropriate use of tests involves EHR-system–enabled reminders, registries, and checklists. That is the method likeliest to enable better meeting of quality targets in primary care, says Bruce Bagley, MD, president and CEO of TransforMed, a subsidiary of the American Academy of Family Physicians that helps primary care practices transition to the patient-centered medical home model of care.

The majority of lab testing underuse can be blamed on the frailty of human memory, Dr. Bagley says.

“For the most part, it’s because we’re trying to remember instead of having systems to help us get it done reliably,” he says.

“When it comes to the systematic care of chronic illness, we need to be using a registry or a checklist so you know what’s been done and what’s required for evidence-based medicine. So, having a system that helps you remember that every time will keep you doing it and ordering the appropriate test.”

Laboratorians have a key role to play in enabling such IT systems, says Dr. Shahangian of the CDC.

“Where the lab professionals can best come into the equation is to impact the electronic means of providing information to —continued on 64
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The clinicians, in terms of electronic reminders or providing customized assistance and help in terms of encouraging appropriate lab utilization, by promoting tests that are indicated and discouraging tests that are contraindicated,” Dr. Shahangian says.

Implementing such informatics fixes can be easier said than done. That has given rise to a collaborative website called The Can (http://thecan.apth.com), a working group project of the CAP’s Diagnostic Intelligence and Health Information Technology Committee. At this article’s deadline, nine organizations were participating, and contributors had composed 22 rules, many of which target potential underuse. To wit: “With ACE-I/ARB, monitor potassium one week after beginning or changing the dose. These drugs may cause hyperkalemia.”

The plan is to develop a coded scheme for the rules, says Ronald George Hauser III, MD, a resident in laboratory medicine at Yale-New Haven Hospital. He and Dr. Arnaout co-chair the CAP’s DIHIT working group.

“The idea is to get everyone using the same language and sharing information using these codes,” Dr. Hauser says. “This takes the domain expertise from pathologists or other physicians and takes that information to this coded scheme and then that scheme can be used by hospitals that want to implement the rule. We’re still working on how to do that.”

Yet clinical decision support systems have their limits when it comes to optimizing test use, the CDC’s Dr. Zehnbauer says.

“Even CPOE or the pop-up box, if you will, just serves as a reminder of something the physician already knows,” she says. “It will not teach you something you don’t know, and it’s not a replacement for professional consultation.”

Making such collaboration easier and more beneficial to ordering physicians is part of the idea behind a long-running program at Vanderbilt University Medical Center. The underlying problem is that ordering physicians need help from experts in clinical pathology, says Michael Laposata, MD, PhD, the Edward and Nancy Fody professor of pathology at Vanderbilt University School of Medicine. He will take over as pathology chair at the University of Texas Medical Branch at Galveston in July.

“We don’t educate our medical students much in laboratory test selection and interpretation,” Dr. Laposata says. “It’s odd. We teach the anatomic part. But the day you graduate, there’s a pathologist who looks at all those slides for you and writes a report. For clinical lab medicine, we still ask you to pick the tests and still say you have to interpret the test results.

“The biggest problem,” he says, “is that doctors are really taught so little about how to order the right tests that they don’t know when they’ve made a mistake.” An example of the “unknown unknown.”

At Vanderbilt, diagnostic management teams provide personalized advice to ordering clinicians on tests that might be missing or may be superfluous. Dr. Laposata says that areas such as testing for coagulation, autoimmunity, and toxicity often require a greater level of expert collaboration to ensure that the correct tests are ordered.

“If you have diabetes, your doctor will get pop-ups to make sure you get that A1c test. He will also get pop-ups to say we want to know your lipid status. So the likelihood you’re going to have those tests is reasonably high. But there are tens of thousands of other diseases for which there are no pop-ups,” Dr. Laposata says. “We’ve got to get away from this idea where lab medicine is reduced to a pop-up screen.”

The diagnostic management team model has helped Vanderbilt make strong progress in reducing over- and underutilization, Dr. Laposata says. The question is how to spread it far and wide.

“It took us 30 years to do that,” he says. “But the approach somehow has to get to the next plane and serve 300 million Americans.”

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Dr. Schifman at the Tucson VA advises that laboratory professionals use the preanalytical/analytical/postanalytical framework to shape how they think about test utilization.

In the preanalytical phase of test ordering are the mistakes in timing of lab monitoring, such as too-infrequent monitoring in diabetes care or wrong collection time for therapeutic drug monitoring, Dr. Schifman says. There are also errors of omission during this phase, such as providing a solitary blood culture, which does not provide the desired sensitivity or interpretive value for this exam. In the analytical phase, there can be mistakes such as the laboratory using a less sensitive method of testing—using only an immunounassay for detecting C. difficile, for example. In the postanalytical phase, mistakes include not properly following up on test results. An example of this would be getting a positive anti-HCV but failing to order a confirmatory test.

Dr. Schifman has found that taking steps to help physicians order the appropriate tests can yield results. “One of the things we’ve done with the middleware at our facility is to have a registry of patients with diabetes,” he says. “If a sample comes to the lab and the registry shows a patient is due to get their A1c or lipids test but there are no orders, the medical staff has given us permission to add those tests.”

Since 2009, Dr. Schifman’s laboratory has performed nearly 2,000 add-on monitoring tests for patients with diabetes.

“Labs may think they don’t have any role to play,” Dr. Schifman says. “But here’s one way that laboratories could, based on guidelines and with staff approval, interject and improve utilization.”

In another example, the Tucson VA has examined ICD-9 codes to detect patients with substance use disorders that put them at high risk for hepatitis C virus. That list was cross-referenced with patients who never received HCV serology testing. When a blood sample from one of those patients arrived at the lab, the laboratory information system would flag it after the testing that was ordered had been completed. The remaining sample was archived, and a nurse practitioner in the gastroenterology section who collaborated with the lab contacted the patient and asked for consent to run the HCV serology test on the remaining sample.

More than 90 percent of the patients agreed, and more than 100 patients were ultimately tested. Sixteen percent tested positive and were referred for appropriate followup.

“This approach doesn’t mean you detect everybody with a possible occult HCV infection, but at least you look at the high-risk patients who may not yet have been screened,” Dr. Schifman says. “This is another example where the lab could be involved, with the right algorithms and the right informatics. That’s the future with this whole business of over- and underutilization. It all involves effective use of data.”

Even though the payoff may not be as immediate as that from a successful project tackling overuse, underuse should be a focus for labs because of the outsized impact it can have on patient outcomes, Dr. Schifman says.

“And the lab does have a role—a value-added role—in addressing underutilization,” he says.

Experts say that while overuse and underuse may happen for different reasons or require slightly different responses, they also share much in common.

“They’re two sides of the same coin, and I think both are rampant,” says Dr. Dighe. “You really require the same person or program to oversee both of them. If you’re in charge of overseeing appropriate lab utilization, you should be looking at both sides of things always, and you’re looking for that sweet spot where you’re ordering the right test at the right time.”

Dr. Arnaout agrees.

“These tests give you your diagnostic or prognostic information, and they dictate a large proportion of treatment decisions,” he says. “You don’t want to underdo it or underdo it—just like Goldilocks.”

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