Slashing send-out costs with lab formularies

Anne Paxton

July 2014—A glance at most hospital laboratory spreadsheets makes it clear: Where laboratories could reduce high-cost reference testing for inpatients and unreimbursed send-out testing for outpatients, the savings would be striking. But voluntary education programs geared to improving test ordering practices are known to have their limits. Could a mild form of, well, coercion be helpful?

Enter the test formulary. Modeled after drug formularies in pharmacy, it's a utilization device that, like a brigade of virtual accountants with sharp pencils, can laser in on possibly unnecessary or mistaken test orders and pare their numbers without detracting from patient care.

Test formularies are winning some laboratories surprising leverage over costs because of one valuable trait. "They make it easy for clinicians to order the right tests, and hard for them to order the wrong tests," says Casey Leavitt, director of consultative services for reference laboratory ARUP Laboratories.

Still relatively rare, test formularies aren't a new idea. But they are gaining traction at large academic centers and drawing interest from smaller hospitals as well, says Brian Jackson, MD, ARUP Laboratories vice president and chief medical informatics officer.

Dr. Jackson

ARUP Laboratories' involvement in test utilization management goes back at least 15 years, says Dr. Jackson, an associate professor of pathology at the University of Utah. ARUP started offering advice on test formularies more recently when the need for a systematic program became evident. "We have long provided our clients and labs with rich information regarding utilization, but we realized a couple of years ago that what they should do with that information is not necessarily intuitive."

Now, through its utilization management consulting program, the company offers a road map for implementing a lab formulary, and many ARUP clients want to sign on. "Demand has just skyrocketed," Leavitt says. The larger organizations that have IT resources tend to be first to line up, but "we're getting more and more interest from smaller community hospitals wanting to set up a program as well."

A majority of labs are focusing on inpatient testing to start because that's where they can realize cost savings, she says. "When reimbursement models change on the outpatient side and become more value-based, then a formulary will help. Hospitals will have a good handle on how to make it work on the outpatient side because they'll have the governance structure in place, the formulary, and the metrics that will let them be successful." For outpatient testing, she adds, ARUP also offers utilization analytics, but in a fee-for-service environment, formularies are more difficult to implement.

Methods for setting up a test formulary differ and depend on the culture at individual clients' facilities, ARUP has found. Most clients go with criteria-based test tiering, Leavitt says. "If a test really only needs to be ordered by a small group of transplant specialists, then it can be restricted in that way. Some hospitals will take some tests totally off the ordering menu. Others will develop a process by which the physician has to justify the test order."

Or sometimes the solution is as simple as providing an additional description around the test, she points out. “Vitamin D is an excellent example. You can say that the 25-hydroxy vitamin D test is intended for routine vitamin D deficiency screening, and just explain the difference between that and the more esoteric vitamin D 1,25-dihydroxy test.”

For any given test that is being misused, Dr. Jackson says, the laboratory needs to ask questions. “Is it a process problem? Is it a miscommunication problem? Do the doctors mean to order that test or are they perhaps getting it wrong because the order process is problematic?” It sometimes turns out that the protocols are the problem. “You may actually know the appropriate use of the test, but the institution is driving an obsolete protocol that hasn’t been updated. Part of the formulary committee’s job is to look at those standard protocols and panels and reflex process.”

Where doctors can define their own preference lists and convenience order sets, that can be a real problem, he adds, and laboratories may want to consider not allowing them to set up their own convenience sets. Departments, too, can be guilty of setting up lists that are too broad. “Some departments have clearly very thoughtful order sets and others come up with kitchen sinks based on past practice.” A central formulary committee overseeing these protocols can make a huge difference, he says.

Information technology departments can play a crucial role in developing an effective lab test formulary. “One of the simplest ways is by looking at the tests that are available on the CPOE [computerized physician order entry],” Dr. Jackson says. “The traditional IT department perspective is that every test on the menu gets billed in CPOE. But in some circumstances it may make sense to not actually have it findable in CPOE and require them to order it under ‘Miscellaneous.’ When they search for vitamin D and only find the commonly used one, that simplifies their life.”

A fancier solution that requires IT help is setting up ordering privileges within the EMR or CPOE by board-certified specialty. “When clinicians go to order tests, they are only viewing tests they have rights to order. And when they seek tests that have to be ordered by a specialist, they receive information about who can order that test,” Leavitt says. Notifying physicians when a test has already been ordered can help. But it’s even better to provide them with the prior results. “That can have a huge impact on unnecessary duplicate testing.” Depending on the EMR in place, Dr. Jackson says, some ARUP clients will engineer the CPOE screens to check for prior results and display them on the spot.

Surprisingly, the predicted pushback against test formularies by clinicians hasn’t materialized, Leavitt says. “The feedback has been overwhelmingly positive. Physicians are welcoming the support and education from pathologists and laboratorians offering them greater guidance around test selection and results interpretation.” Dr. Jackson says worry about resistance has made a number of laboratory managers and pathologists he has talked with very cautious. “They’ve been worried about how it would be perceived, but in every case, the majority of clinicians accept the fact that we have to work in teams and need a wise use of resources.” In some cases, he points out, it’s the clinical side that is driving the concept—and the laboratory is having to catch up.
Laboratories can run the risk of being treated as a sort of outsourceable commodity, says Dr. Jackson, where anyone can do the test and it’s just about getting the cheapest price. “That’s a real threat, and if we redefine the laboratory’s mission from performing tests to getting the right diagnosis, that re-positions the lab to be an integral part of clinical care, which leads to a better future for the lab.”

A three-tiered test formulary on the pharmacy model has been in place at the University of Rochester Medical Center since 2009, but a process of evolution was needed to get there, says David T. Strong, the medical center’s vice chair for administration, pathology, and laboratory medicine. “We had some data on utilization, and our chair of medicine, Dr. Paul Levy, said maybe we need to get together and put some governors around all this.”

“We had a group of department chairs meet, and they agreed that they wanted to change behavior more collegially rather than through a stick or a hammer. But it turned out a top-down approach worked much better

than a peer-to-peer influence network or bottom-up approach. And what came out of that was a formulary that said some tests shouldn't be orderable, period, either because of lack of clinical utility or expense or uncertainty of the results. There are so many reasons."

For Rochester, the first target was send-out tests in the emergency department. "Those were a no-brainer, because by the time the test result came back the patients were gone," Strong says. Next, the group looked at neurology. "We have a very large outreach program here, and probably 40 percent of our outpatient work is for non-affiliated physicians in the community. And we noticed some of these very expensive tests were being ordered by community physicians with absolutely no restrictions. One particular test was $9,000 a pop and we were getting reimbursed under $600. That was kind of the poster child for what not to do."

With steps like that, the hospital saw a pretty steady decrease in all three tiers of its testing—about a 20 percent reduction within 24 to 30 months, Strong says. "But we noticed nine months or a year ago that we were slowly increasing our off-formulary testing, the very esoteric testing, largely pediatric genetics. It was 13 or 14 percent of total send-out tests and now it's 26 or 30 percent."

Part of that growth was due to an increase in the genetics faculty numbers. "There's an opportunity there for us to reduce the amount of testing using the formulary," says Bill Andrews, director of IT for pathology and laboratory medicine. "But we are an academic medical center. People come to us for answers, so it's going to be a challenge for us to work through that."

Another factor: While the volume of tier-three off-formulary genetic tests has gone down by 40 percent, Strong says, the cost per test has increased by a factor of three. "I just think it's the movement in the industry; you have these more complicated whole-genome tests—some as much as $11,000 apiece. It just moves the pile."

In Rochester's formulary, the three tiers are set up so that tier one is open to any provider to order, tier two is restricted to those with certain privileges, and tier-three tests are off-formulary. The informatics system provides pop-up messages for tier-two tests that note the test is restricted and link the user to a page where the clinician can proceed to an order if he or she is authorized. But tier-three tests are not available electronically. "We've taught our staff that tier-three tests are not orderable in our LIS. They require preapproval paperwork prior to collecting a sample," Strong says.

In April, the laboratory added a "halt and challenge" for some tests. "We display the actual test cost at the point of order, and note that this may take longer to results, and ask, 'Do you still want to order this?' And there's a yes or no box to check," Strong says. "The point is making providers aware of the potential cost to patients if insurance companies don't cover the test." It's too early to conclude that these challenges are helping. "But our medical director believes this type of information is useful, and sometimes the ordering doctors have no clue about cost."

The laboratory employed more of a "surgical intervention" with vitamin D, Strong says. "We went in and removed it from people's preference list. Then we also changed the display order so if both 25-hydroxy vitamin D and 1,25-dihydroxy vitamin D tests came up together, the true diagnostic test would come up as the first, and we put the other one into the restricted category." The laboratory has already seen a sharp drop in 1,25-dihydroxy vitamin D test orders as a result.

But the most dramatic impact of the formulary resulted from one provider and one test. It was a doctor who was ordering a particular genetic neurology test that cost $9,000 each, says Vicki VanDeWalle, process improvement and projects manager. "By having a conversation with that provider and taking that test off formulary, we instantly saved a couple hundred thousand dollars," she says. "That was one of our very first moves when we went live with our system."

In the last five years, VanDeWalle has been surprised at how well-accepted the laboratory test formulary has become. "The first couple of months were really, really rough. There was a lot to manage and a lot of unhappiness and complaints, but there was very quickly a cultural change, and people came to accept the formulary."

The key accomplishment for the medical center, Strong notes, is that its outpatient volume has gone up 10 or 15 percent but its test volume for tier-one and tier-two testing has plateaued. “Clearly, the way the trend line was going, there would have been an upward push on volume at the same time that cost per test has been rising.” He believes the formulary staved off a much bigger rise in costs.

The challenges from genetic testing, particularly in pediatrics, will continue to occupy the formulary committee, he says. But the combination of engaging the hospital’s senior leadership in the process and making the IT department a central player along with pathology has helped the formulary program succeed, he says.
Strong is now working in parallel with Dr. Jackson at ARUP to develop more decision support for clinicians. “I’d like to see more interventional support at point of order and more advisory algorithms, so we could both educate and do a little more control over ordering. And we are working with the folks at Epic to make that happen. I’ve just talked with my counterpart in imaging science in radiology, and they are working on this as well. That’s where I really think it needs to go next.”

Having a computerized order-entry system is what made a formulary possible at the University of Michigan Health System, says Jeff Warren, MD, professor of pathology. The system, known as UM-CareLink, allows basic decision support comment prompts, and starting in 2008 with the formation of the Laboratory Formulary Committee, it has helped lead to robust test use oversight and a significant reduction in laboratory expense. (In June, UMHS switched from UM-CareLink to MiChart.)

Dr. Warren

But when it first came online, the system wasn’t so decked out with features. “In order to make CareLink more palatable, because it was acknowledged that it would take increased provider time, it was kept as streamlined and bare bones as possible—and we opted not to include decision support such as drop-down boxes or pop-ups on what you should order,” Dr. Warren explains. Those kinds of enhancements have been added in recent years in the context of the formulary operation and other programs.

Concerns about expense and complexity continue to surround the order-entry system, but from a formulary perspective, “We have been happy with the progress we’ve made by focusing on very expensive send-out tests in particular,” Dr. Warren says. The formulary committee meets monthly, with its major order of business typically being the vetting of current or proposed new laboratory tests. Then the committee might decline or restrict authorization; a recent count showed that of 47 tests or panels it evaluated, it decided to not offer or restrict in 27 instances. Alternatively, the committee might choose to include pop-up messages on UM-CareLink, such as “Recommend one test X per admission” or “Test X should be ordered in consultation with neurologist.”

The most effective use of the formulary has been to reduce what the institution is paying for lab tests that are sent to Mayo, ARUP, Specialty Labs, and a variety of smaller esoteric labs. “The direct costs for tests we send out that we literally package up and send to a reference lab, or as we like to say, up the food chain, were around $7 million a year in 2008,” Dr. Warren says. That made reference testing an attractive target. “It’s more tractable. It’s more of a controllable domain, and that’s why we focused on send-out tests initially almost exclusively in our committee.”

“Every one of those really expensive tests where you improve utilization is a real savings in cost avoidance,” Dr. Warren points out. He credits the formulary’s success to use of peer-reviewed medical evidence, input by medical

content experts, excellent cooperation by the medical staff, and close oversight by the pathology department's send-out laboratory.

The formulary committee makes it a goal to respond to changes in medical practice and appeals of committee recommendations. For example, in July 2009 the committee found that utilization of vitamin D test orders was appropriate, then in October 2012 revisited that position and decided to recommend that it be ordered only in patients "at risk" of vitamin D deficiency.

The send-out laboratory maintains an annual lab test line-item expense budget that shows the impact of the test formulary over the past six years. To calculate the impact of the formulary in a useful way, Dr. Warren says, one of the challenges was taking into account changes in overall institutional activity and clinical patient mix. So the committee employs a metric called "adjusted discharges" that hospital administrators use across the country to combine inpatient discharges with outpatients. Using that metric, the hospital has been able to show a drop in send-outs linked to use of the formulary even in the face of annual increases in adjusted discharges.

He and other committee members start with the monthly spreadsheet they get from the reference labs to decide which tests should be vetted. "We literally say, hey, we're spending $12,000 a month on test X. That might be an opportunity to reduce our expense. So I might call the microbiology lab and if they say there could be some over-ordering or questionable ordering practices, we would call the specialists in that area and ask them, 'Did you know what we're spending on this and would you mind coming to the formulary committee to explain when this test should be ordered?' And nine times out of 10, there's no hesitation at all."

At the same time, a billing and finance person in pathology administration would look at utilization of the test in detail to determine how often it is ordered, for what order sites, and by whom. "That helps us know and even predict whether the test is being ideally used or not. In the end the committee could decide that only infectious disease physicians could order the test, or that it's being well utilized, and we'll let it go."

A recent example of how the formulary works concerned leukemia patients. "We see around 70 to 90 new patients a year here with acute myelogenous leukemia, a pretty uncommon diagnosis. And there's a company that offers four genetic tests that can subdivide and prognosticate within that subpopulation of patients. But the test is very expensive and should only be used in a certain subcategory."

Oncologists at the medical center who care for these patients came to the committee and said they would like to be able to order the test, and the committee asked for literature with scientific support, and asked the clinicians to make their case at a formulary committee meeting. "And we decided that yes, this testing should be made available. But the only people who should order this test are three oncologists out of dozens that we have here."

On the other hand, the committee has found that some tests have no value. "They've become popularized because the company that developed the test is really good at marketing, and there is really no legitimate medical reason the test should be ordered," Dr. Warren says. In such a case, "we might actually delete that test from the online ordering system so you can't find it. To order it, you would have to verbally talk us into it. And that does dramatically drop the volume."

Among the high-volume, high-expense tests removed from the formulary that have had a big impact in reducing cost was a proprietary inflammatory bowel disease panel, Dr. Warren says. Myelin basic protein and a Crohn's disease prognostic test were examples of tests that the committee restricted or removed after finding they were much less needed than people realized.

In general, however, the committee makes a conscious effort to set a tone of decision support, education, and careful use of resources, rather than one of restriction. "We send out 50,000 tests a year, so we obviously can't have a discussion about every one. But if a physician wants to order a test and calls me or one of the other pathologists to discuss it, I will almost assuredly say it's fine and authorize the send-out," Dr. Warren says.

"When there is controversy over a test that's been taken off the formulary, it's usually just because a restriction

was put in and somebody basically didn't get the memo. It's usually not so much that they disagree, but they want to know how did this get changed without their having an opportunity to weigh in."

Now that the formulary committee has restricted or removed most of the easier targets, it has moved to vetting several complex algorithmic testing cascades, Dr. Warren says. "The best example is celiac disease. Basically, rather than having providers go through a half-dozen serologic tests that exist for screening for celiac disease, we have a preset where they can just order the algorithm and we'll test in a logical sequence." That was implemented about six months ago.

As medical practice has become more and more complicated, particularly with the advent of genetic testing in oncology, clinicians need better tools to support their testing decisions, he emphasizes. He is now working on developing tools to help providers better use laboratory testing.

In the meantime, Dr. Warren notes, he has gotten a couple dozen inquir-ies about how to set up a formulary since publication of his article, "Laboratory test utilization program: structure and impact in a large academic medical center" (*Am J Clin Pathol.* 2013;139:289–297). "A formulary can actually have a tangible impact on patient care, and corollary to that, a better utilization of resources. When you undertake these administrative efforts to perform better, you always have that nagging doubt you're wasting your time. But we've actually seen and quantified the impact of this formulary, and it's gratifying to know that it can work."

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Anne Paxton is a writer in Seattle.