

Powering down on excessive test use

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William Check, PhD

February 2014—Utility companies can generate electricity in many ways—fossil fuel, nuclear reaction, solar panel, wind turbine. Which power source is preferable depends on the circumstances and the work that needs to be done. Generating optimal laboratory utilization is much the same. Providing an efficient and effective combination of tests for diagnosing hematologic neoplasms requires a different approach from achieving appropriate repeat ordering of chemistry tests in ICU patients. Delivering only the necessary blood components to cardiovascular surgery patients may take different tactics from curbing orders of expensive molecular genetic send-out tests.



**Dr.
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Pathologists today face all of these challenges and more. Fortunately, they have a variety of methods to power their utilization objectives. Over the past 10 years pathologists at Massachusetts General Hospital have developed a broad repertoire of tools in their utilization program, says Kent B. Lewandrowski, MD, associate chief of pathology and director of pathology laboratories and molecular medicine, one of the leaders of this program since its inception. Among their tools, says Dr. Lewandrowski, professor of pathology at Harvard Medical School, are clinical education, practice standards, laboratory review (gatekeeper functions), physician profiling, ordering frequency limits, order-entry pop-ups, a test menu formulary, and, occasionally, a ban on a test.

At Mayo Clinic the laboratory and pathology practice committee works from much the same toolbox. In particular, Curtis A. Hanson, MD, professor of laboratory medicine and pathology, who leads the Mayo utilization effort, puts emphasis on a variety of steps that can be invoked to establish a utilization review process: develop medical criteria for sending out high-cost tests, avoid repeating tests unnecessarily, and set up a laboratory review process using algorithms and guidelines for selected tests.

To some extent, profligate testing practices can be laid at the door of the laboratories, Dr. Hanson says. “We have encouraged the notion that a clinician will get any test they want, anytime, instead of helping them to sequence tests, to do the most likely test first,” he says. “Labs don’t provide guidance on how to order the appropriate assays in various diseases. And if laboratories don’t have an appropriate review and ordering process in place, clinicians have no choice but to order excess testing.”

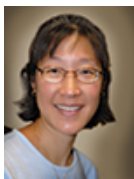


Dr. Hanson

The job of laboratories, he says, is to move clinicians from asking “Do you do this test?” to “Can you help me solve this clinical problem?”

Making this transition requires that there be trust and confidence between clinicians and laboratorians, says hematopathologist Annette S. Kim, MD, PhD, assistant professor of pathology at Vanderbilt University Medical Center, who represents a team of clinicians and pathologists (led by Mary Zutter, MD, assistant vice chancellor for integrative diagnostics, and Adam Seegmiller, MD, PhD, director of hematopathology) that carried out a successful intervention to improve ordering of hematopathology tests.

Pathologists can’t simply demand that internists and surgeons change their ordering patterns, any more than utilities can get consumers to use electricity and gas in a more environmentally aware way by simply showing them the data and telling them to change. To get users to employ pathology services more judiciously, pathologists must change clinicians’ attitudes. And that requires a formal, committed, long-term interdisciplinary effort.



Dr. Kim

At Vanderbilt the hematopathology campaign took the form of a joint committee, termed diagnostic management team, to devise evidence-based standard ordering protocols. At the University of Washington, where a similar effort is underway, it will be a bit different, Daniel Sabath, MD, PhD, told CAP TODAY. “We are being asked more to come up with testing algorithms and clinicians will give their blessing,” says Dr. Sabath, head of the hematology division in the Department of Laboratory Medicine. “They will not be as involved in the initial stages of the process. The tricky part,” Dr. Sabath says, “is this: If the lab is going to be ordering tests, we need to make sure we don’t give the appearance of self-referral, which could raise compliance issues.”

In the effort to change ordering practices, experts agree clinician education is a relatively weak intervention. Truly changing behavior requires forcing functions, such as clinician profiling, or report cards, which create peer pressure. “One of the most decisive things in changing clinician behavior is peer review and approval and peer data,” Dr. Hanson says. “As physicians we didn’t get where we are by being willing to be at the bottom.” For example, peer pressure has been highly effective in Mayo’s campaign to get cardiovascular surgeons to improve their use of blood products.



Dr. Sabath

At MGH, report cards and peer review were used to curb orders of expensive pediatric genetic send-outs, says Anand Dighe, MD, PhD, associate pathologist and director of the core laboratory. “Forcing functions work,” agrees Dr. Dighe, associate professor of pathology at Harvard Medical School.

Informatics also works. In the MGH program, informatics provides online decision support and computer dashboards for test ordering and reporting. Dr. Dighe calls provider order entry “a key leverage point” for improving ordering practices and preventing ordering errors. At the other end of the process, informatics can

provide enhanced interpretive results reporting.

Dr. Dighe's team used an advanced informatics program, Supervised Machine Learning, to achieve highly accurate identification of spurious glucose values. Techniques such as these can be adapted for routine results reporting, he says, and can provide more information to the clinician by putting the test results in the context of other related results.

When it comes to controlling the overall utilization process, pathologists at MGH and Mayo agree that pathologists should be in the forefront. Pathology involvement begins, Dr. Dighe says, as soon as the hospital decides to purchase a new electronic medical record system. "Many decisions about that system will dramatically affect the pathology department, such as how results look, how order-entry screens appear, and what information they present to clinicians. If pathology doesn't have a seat at the table two years before things start to roll out, it will already be too late."

Reducing cost is one of the main drivers of the increased attention paid to utilization. Payers continue to squeeze fee-for-service, which means payments will decline and labs can't depend on volume increases to pay for services, Dr. Hanson says. He cites oncology, with its expensive biological therapies and companion molecular diagnostics, as an example. Some observers predict that the Centers for Medicare and Medicaid Services may implement bundled payments for some aspects of oncology by 2015 or 2016.

In an example closer to the laboratory, data from the University Healthcare Consortium show a wide variation in the number of laboratory tests per inpatient discharge. "Most of the hospitals at the lower end have a utilization plan in place," Dr. Hanson says.

At Vanderbilt, all of these factors came together a few years ago in hematopathology and led to a successful utilization program. "There was an explosion of possible tests that can be run," Dr. Kim told CAP TODAY. "The most rapid growth was in identification of new molecular aberrations that are diagnostically, prognostically, and therapeutically important." Clinicians were pressed to keep up with these tests and their uses and under pressure to see more patients. "It was difficult for busy clinicians to keep track of all molecular aberrations on all of their patients," she says. As a result, they often ordered a huge number of tests and received a huge number of results over a period of one to two weeks.

That is why hematopathologists now determine which tests to order. With sophisticated IT tools, the pathologists at Vanderbilt have more information. Crucially, the hematopathologist knows histologically what is going on in the marrow. "That helps us narrow down the number of tests that need to be ordered," Dr. Kim says. In a collaborative manner, clinicians and pathologists set up a hematopathology diagnostic management team, with the motto, "The right test for the right patient at the right time." Pathology's goals were to keep track of all tests, especially repeats, and to put results in context. In addition, the pathologist was able to put together all the results coming out over time in the lab and send a single, comprehensive interpretation to the doctor.

A team of hematologists and hematopathologists (led by Dr. Zutter, with Dr. Seegmiller, Dr. Kim, and Claudio Mosse, MD, PhD) devised a system of evidence-based guidelines and algorithm-based reflex test ordering, known as standard operating protocols. Protocols are specific to disease and stage of therapy and applied only after a pathologist views the aspirate and biopsy. Where evidence was not available in the literature, they used a "community standard of practice" approach, erring on the side of overtesting at the outset. A test is ordered at followup only if it was positive at diagnosis and is sensitive enough to detect minimal residual disease.

To use the SOPs, the pathologist needs the patient history, as well as the history of disease and treatment. "We got complete buy-in from clinicians," Dr. Kim says. "We told them we needed clinical history, and they were committed to providing it."

SOPs are Disease and Stage-Specific

Disease	Diagnosis	Staging	Follow-up (Overt Disease)		Follow-up (No Overt Disease)		Post-SCT
			Persistent Disease	Relapse	New Patient	Routine (MRD)	
1. AML							
2. MDS							
3. BM Failure							
4. MPN							
5. B-ALL							
6. T-ALL							
7. Lymphoma							
8. Myeloma							

A2: AML - Diagnosis

- Flow Cytometry
- Cytogenetic
 - Karyotype
 - MDS FISH Panel
 - AML FISH Panel
- Molecular
 - FLT3
 - NPM1
 - CEBPA
 - c-Kit

Standard operating protocol, Vanderbilt University Medical Center (Courtesy Annette Kim, MD, PhD)

"Informatics support was fantastic," she continues. The IT group at Vanderbilt created a hematopathology testing form that can be filled out by a nurse practitioner, which requires only a couple of minutes to click on the boxes. IT also created a dashboard that shows what tests were ordered and their status, and the patient flow sheet, which provides, in a single screen shot, the longitudinal history of the patient's test results. In addition, the group developed tools to autopopulate comprehensive reports with discrete elements from primary reports.

To evaluate the impact of this effort, Dr. Zutter and colleagues asked what a successful diagnostic management team, or DMT, would look like. They came up with four criteria: empowered, efficient, effective, and evolving, all of which they measured (Seegmiller AC, et al. *Am J Clin Pathol.* 2013;140:643-650).

Clinicians felt empowered, as judged by the high positive agreement rates (80 percent to 90 percent) of 22 responding clinicians to such statements as:

- I am aware of the option to order a bone marrow testing panel.
- I trust the pathologists to order appropriate tests for my patients.
- I trust the SOPs to help the pathologists choose the right tests at the right time for my patients.

Clinicians also said the DMT was efficient—it saved them time.

Efficacy was shown by a 69 percent decrease in unnecessary test ordering at 12 months after DMT implementation. Standard protocols also prevented omission of useful tests and increased the rate of positive test results by 75 percent.

As a Rapid Learning System, the DMT is evolving through feedback from the outcome of each case. "We are now on iteration three," Dr. Kim says. "Based on our results, we have already made multiple modifications to the SOPs."

They're also moving into other areas. Utilization work in the Vanderbilt laboratories first centered on coagulation, under Michael Laposata, MD, PhD, who started the process at MGH. "We were able to achieve a lot rapidly, based on his lead," Dr. Kim says. Microbiology and blood bank have implemented a version of the DMT concept that she calls "DMT lite." Now in the design phase is a DMT for breast cancer. "This requires integration of radiology, so it is logistically a bit more challenging," Dr. Kim says.

The Vanderbilt group also estimated cost savings to payers, based on a total decrease in tests of 15 percent. Savings approximated \$442 per marrow, for an annual savings at Vanderbilt of \$500,000 to \$1 million. In some ways, this translated into savings to the medical center too. The DMT program also freed up laboratory time to bring on additional clinically important testing. It saved clinicians time so they could see more patients.

"In some cases we were doing fewer tests. As we go to more complicated reimbursement models, that may be a good thing financially," Dr. Kim says.

Dr. Hanson agrees. "You have to look at the savings for the overall health care network." Look at the emerging payment models, he says. "We know that under ACOs we will be getting fewer dollars per patient. So we have to reduce our cost structure. We can't expect to be reimbursed for every test the way we have always been.

"I'm familiar with the argument that since lab tests only account for a few percent of overall health care costs, don't be stressed about test utilization," Dr. Hanson continues. "But I see labs being able to take a leadership role in driving down overall costs within a health system. We touch all clinicians by dealing with utilization in the laboratory." It sets a goal, he says, and puts processes in place that can then be used throughout the health care system.

One of Mayo's first utilization efforts was hematopathology (see "Lab teams up to curb unneeded testing," CAP TODAY, December 2012). More recently they applied many of the same principles to optimizing use of blood products, with James R. Stubbs, MD, chair of the Division of Transfusion Medicine, leading the effort.

"In the latter part of 2008, we were charged with decreasing the cost of cardiovascular surgery while maintaining the same high standard of care," Dr. Stubbs says. "One area where we could save money and potentially enhance patient care was blood product use." The cost of transfusing cardiac surgery patients had increased 47 percent between 2006 and 2008 while the number of cardiovascular patients rose only five percent. "We were going in the wrong direction," Dr. Stubbs says.

A "champion" emerged, anesthesiologist Mark Ereth, MD, who developed a program of blood management in cardiovascular surgery patients initially based on a study in which he participated at Mayo years earlier (Nuttall GA, et al. Anesthesiology. 2001;94: 773-781). Dr. Ereth and his colleagues had developed an algorithm based on coagulation tests routinely obtained in cardiopulmonary bypass (CPB) patients. When they applied the algorithm intraoperatively to half of a group of 92 cardiovascular surgery patients with abnormal bleeding after CPB, they found a statistically significant decrease in the amount of fresh frozen plasma and platelets transfused compared with usual practice. Patients in the algorithm group also had less bleeding in the ICU and a decrease in mediastinal exploration. "So it was all good," Dr. Stubbs says.

When the utilization effort in cardiovascular surgery blood product use was initiated, the intraoperative algorithm was brought into play. In addition, an algorithm was developed for postoperative care. At that point, Dr. Stubbs says, "There was a push to make people aware of the algorithms and to empower all providers involved to use the algorithms for decision support in cardiac surgery patients."

Both algorithms were piloted for three months in summer 2009, and outcomes were compared with the same period in 2008. "Use of the intraoperative and postoperative algorithms reduced red blood cell transfusions by 47 percent and transfusions of plasma, platelets, and cryoprecipitate by 57 percent," Dr. Stubbs says. During that period the total cost of transfusions dropped by \$2 million, for a calculated savings of \$7.37 for every dollar invested in the project. Further, all outcome parameters, such as use of blood products and acute kidney injury in association with cardiovascular surgery, were improved with the use of the algorithms.



Dr. Stubbs

With Mayo's approval, the algorithms were put in place and support measures were developed. Now, Dr. Stubbs says, "A more sophisticated order-entry system allows people at the head of the bed to know pertinent lab test values associated with the algorithms and whether they are significant." They also developed a dashboard that visually alerts practitioners when test results reach an algorithm-based decision point and transfusion therapy needs to be considered. For instance, when the platelet count reaches a level specified as a transfusion trigger on one of the algorithms, a visual marker alerts the practitioner to the prospect of administering a platelet transfusion. A different "product not indicated" visual marker is displayed when there is no laboratory evidence to support the transfusion of a specific blood component.

"We developed processes that make it easy to do the right thing and hard to do the wrong thing," Dr. Stubbs says.

"On top of that, using data-mining techniques, we developed a near real-time feedback mechanism for reporting to practitioners on blood utilization," Dr. Stubbs says. Using evidence-based rules, actual intraoperative transfusion decisions are compared with the algorithm's recommendations and a report is generated that is available for prescribing physicians to review on computers shortly after each case. The report provides feedback to practitioners on how well they adhered to the algorithms, and this information is also made available to hospital leadership.

Cardiovascular anesthesiologists and surgeons meet regularly to review compiled data on their individual performance in blood product use. "I have not attended these sessions," Dr. Stubbs says, "but I've been told that the cardiac anesthesiologists and surgeons have embraced the program and use the feedback and peer comparison data" to achieve consistent application of best transfusion practices for their patients.

Blood product use has continued to drop, particularly plasma, platelets, and RBCs, for a total estimated savings of at least \$28 million in transfusion-related costs since the inception of the program. "And our patient outcomes in cardiovascular surgery are as good as or better than before implementation of blood management," Dr. Stubbs says, adding that this process is applicable to any discipline that uses transfusion therapy.

They will now turn their attention to transfusion practices in hematology, focusing initially on the autologous stem cell transplant population. In this effort, too, they have identified a champion, hematologist Dennis Gastineau, MD.

A utilization program in the MGH blood bank, managed by the directors of the Blood Transfusion Service, targets both high-volume, lower-unit-price components (RBCs, FFP, platelets) and lower-volume, high-unit-price components (factor rVIIa, intravenous immunoglobulin, factor IX). Blood products consume about 70 percent of the blood bank budget, Dr. Lewandrowski says.

To improve the decision to transfuse, all units released from the blood bank trigger a computerized algorithm and physician review. If the order doesn't meet pre-established criteria, the blood transfusion director sends an e-mail to the ordering physician to promote education about transfusion guidelines.

Eliminating routine monthly use of intravenous immunoglobulin in bone marrow transplantation saved \$1 million, and an evidence-based approach to eliminate IV-Ig in toxic epidermal necrolysis saved half a million dollars. Using a gatekeeper function reduced factor rVIIa use by 95 percent, saving more than \$600,000 annually.

In a redesign of cardiac surgery at MGH, a multidisciplinary team reviewed improved blood use as one of the goals. Benchmarking against Brigham and Women's Hospital and other institutions showed a much greater use of some blood products at MGH. In particular, MGH surgeons used a considerable amount of factor IX, while none was used

at the other hospitals. “We were the only hospital in our system using prothrombin concentrate,” Dr. Lewandrowski says. “The team said, Let’s stop doing it.” Once this decision was made, factor IX use dropped drastically, from \$150,000 annually in 2008 to less than \$10,000 in 2011.

Administrators have always been interested in utilization management and have wanted pathologists to participate, Dr. Lewandrowski says. Clinicians used to feel it was intrusive. But things have changed dramatically in the past decade, he says. With clinicians under greater scrutiny and pressure to cut expenditures and unnecessary testing, “The vast majority of physicians understand this is an issue we have to deal with.”

Dr. Hanson agrees: “What I have seen is a huge change in the mindset of clinicians over the last few years, and a willingness to discuss and implement utilization guidelines. This is a wonderful opportunity for the clinical laboratory to step up to the plate.”□□

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William Check is a writer in Ft. Lauderdale, Fla.