Handling a reagent recall, step by strenuous step

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February 2014—Recalling a reagent is about more than just removing a product from laboratory shelves. It's about retracting test results and thus affecting diagnoses and treatment plans. It's about questioning patient outcomes and revisiting past decisions.

Dr. Harbour

"So much of what laboratories do is central to making a diagnosis and determining treatment," says John Harbour, MD, regional medical director of HealthPartners Laboratories, medical director of the Bon Secours St. Mary's Hospital Laboratory, and president of Monument Pathologists Inc., Richmond, Va.

Consequently, a recall can challenge a patient's trust in his physician, a physician's trust in her laboratory, and a laboratory's trust in its vendors. It's a major event. And unfortunately, Dr. Harbour says, the number of these events has increased dramatically in recent years.

A structured approach to reagent recalls can help save time, and sanity, by streamlining the laboratory's response and restoring confidence in the laboratory test reporting process.

If practice makes perfect, Dr. Harbour's laboratory has had ample opportunity to be so. "Unfortunately, our 'practice' is real life," he says. "We've had enough recalls that we're starting to get the process down rote."

Almost anything can be recalled, he says: single reagents, calibrator materials, computer programs that support electronic reporting. Depending on the nature of the recall, the impact on patient care can range from barely perceptible to pervasive.

"If it's a reagent glitch, it could result in a test result being too high, too low, negative when it should be positive, or positive when it should be negative." Similarly, a programming error could prevent the report from getting to the clinician, or could send an incomplete report to the clinician. "If the physician didn't know to look for part two or part three of the report, they might just go with the information on the first part," he says. As a result, recalls can affect thousands of patients over a period of several years, or a few patients over the course of a week.

Generally, tests that are urgently needed—complete blood counts, chemistry tests, for example—aren't often recalled, Dr. Harbour notes. "It's the more esoteric tests, immunology, chemistry, drug levels, and so forth, that tend to be affected."

When that happens, a laboratory can likely use another reagent or instrument to complete the test. Alternatively, patient samples can be redirected to another laboratory nearby. "Bon Secours uses a certain vendor for our chemistry analyzer, for example," Dr. Harbour explains. "If we have a problem, we can send patient samples to the University of Virginia Medical Center or the local hospital, which use different vendors and wouldn't be affected by the recall. We do have a natural backup in that sense."

But in the most unfortunate of circumstances, a wide-reaching recall could affect a staple product or platform used by multiple labs in town. That calls for a plan C. "If a routine test like coagulation got recalled, that would be hard

because everybody in town is using the same thing and many labs purchase enough coag reagents to last an entire year," Dr. Harbour notes. In that case, a relationship with a referral lab would be key.

A successful response to a recall, Dr. Harbour says, largely depends on having a plan in place ahead of time—and on establishing a well-defined response team, usually led by the laboratory director. "It's never a good idea to create a procedure to deal with a problem as the problem occurs. That's one thing. The second thing is to ensure that you identify the types of expertise you need."

A few years ago, Dr. Harbour's laboratory was notified that a certain test reagent may or may not be affected by the presence of an antibody, and it was unpredictable whether the antibody might cause the test result to go up or down. "So here we were in a situation of telling physicians, 'If you had a result on your patient with this reagent, during this two-and-a-half-year window, the results may or may not be correct. The test result might be high, it might be low, we don't have a way of knowing.' The vendor just didn't have enough information with enough patients in variable settings to be able to tell me clearly what to expect." In the end, Dr. Harbour established a relationship with a referral laboratory that could retest patients affected by the recall.

In that event, as with any recall, the first step is to stop using the reagent, Dr. Harbour says. "To do that, you need a bench-level staff member who knows where the reagents are stored, which ones are next in line to be used, and which lots are affected. You need someone who can say, 'Gee, are we even using this reagent anymore? Did we use it in the past? Or have we not started using it?'"

Assuming the reagent is still in stock, the second step is to immediately communicate with all laboratory staff that the reagent has been recalled and should not be used.
And then the investigation begins. "You don't know how significant the recall will be to the patient until you dive into it a bit," Dr. Harbour says. "So you want to start the investigation as soon as possible and make sure you have the right people at the table."

Within 24 hours, the response team should complete a quick preliminary assessment of the manpower needed to respond to the recall, as well as the number of patients affected.

The magnitude of patient impact is gauged by an important team member: the data miner. This person should be trained to quickly access the laboratory's electronic or manual medical records system to identify the affected patients and their physicians during a specified date range.

"For the two-and-a-half-year window we had a few years ago, we really relied on the electronic system, and we were able to mine that data fairly effectively. But if you're in a manual system and faced the same sort of recall, that would be more difficult." Some hospitals limit data mining to the evening hours, when the extensive mining won't slow down the whole system and interfere with patient care.

Risk management personnel—often nurses—should be brought on board early in the process. They often work with a hospital attorney, Dr. Harbour says. "People in risk management think differently than people in laboratories. Whereas I want to tell everyone everything as quickly as possible and make sure no one is hurt, risk management is trained to look at it the other way around: How can we take care of the patient, but also deal with the risk?"

An effective team should also include subject-matter experts who can read the vendor's description of the recall and gauge the potential patient impact. "If the recall would cause you to see a five percent change [in a test result], is that a clinically important difference?" In particular, clinicians and pathologists can often lend a greater appreciation for the implications of a certain type of recall. "If this is a cardiac marker, for instance, does it really matter? Physicians order these tests all the time, and they can give you very quick insight into how impactful a minor variation might be." In many cases, expert feedback determines the pace of the response team.

Finally, he says, clerical support is key. "You'll need to figure out how you would handle an eight-patient recall versus a 15,000-patient recall. There are very different logistics involved. I mean, just think about that. Fifteen

thousand letters," he says.

Companies overseeing the recall sometimes, though not always, reimburse laboratories for the cost of replacing recalled lots with new material. Sometimes companies defray the laboratory's cost of mailing letters to clinicians. But recalls can be potent time wasters, and there's not often a way to reimburse for lost productivity.

In the wake of recent recalls, Dr. Harbour says, he has signed thousands of letters—one letter to the physician of each patient affected by the recall. He wasn't reimbursed for his time, or his lab manager's time, or for the subject-matter experts who assessed the patient impact. "I can sign letters pretty fast. I'm not one to put a streak as my signature, but you just sit down and you work your way through a pile for a half hour. And then you go to the next pile." It takes a while, he says, but he'd rather invest energy in the process than risk implying to clinicians that the recall isn't a big deal. "I want them to know that I looked at this carefully."

Physicians are then tasked with the cumbersome chore of examining individual patient records to determine if a skewed test result might have affected past care, whether it might affect ongoing care, and whether the patient should be notified. Because most clinical practices are already pressed for time, laboratories field the same question from physicians time and again: "What do you think I should do?"

Unfortunately, labs can rarely provide a straightforward answer, Dr. Harbour says. In years past, his laboratory has offered to collect new patient samples and retest, depending on which reagent was recalled. But without access to patient records, laboratories are not often in a position to recommend an across-the-board statement on how clinicians should proceed.

"The physicians are the ones who need to review the medical records and decide whether or not a minor or moderate or major test variation would have changed the course of therapy or whether it could change the patient's current therapy today," Dr. Harbour says. "Some patients will have recovered totally and the test result may no longer be meaningful. And so [the clinician] may choose not to say anything, and just put the letter in the file."

The process tends to proceed most smoothly when there is ample trust between physicians and laboratories. "The physician you're talking to has to trust your laboratory, whether you become aware of a problem you caused or whether you're notified of a problem by a vendor—that you'll be in touch with physicians as soon as possible, convey the significance of the problem, and help them get the patient redrawn if needed."

But even when such trust exists, tempers can flare. "There are times when physicians will get upset and feel that the extra work is being dumped on them, when in reality it was dumped on the laboratory and maybe even on the vendor," Dr. Harbour says, recalling a time when a physician was notified about 85 patients who might have been affected by a recall. "They said basically, 'This is a huge amount of work! How can I do all my current patient work and do this, all because of somebody else's problem? I don't have the staff, the FTEs, to be able to pull all these charts and review them. You need to do that.' I understood their frustration, and I said, 'I understand where you're coming from. Let's try to find a way to work our way through this. What can I do to help you? But I can't do it for you.'"

Fortunately, lab tests aren't the only deciding factor in patient diagnosis and treatment, Dr. Harbour acknowledges. "It's the history, it's the physical, it's the physician's understanding of all the different parameters going on with a given patient. A single test is not the only thing you're hanging your hat on."

Nevertheless, recalls present an easy target for laying blame. "When samples get mixed up, or are borderline interpreted, people might be likely to think about suing," Dr. Harbour says. And that's when a strong recall response plan can make all the difference.n
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