Finding and fixing large-scale laboratory errors

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Anne Ford

December 2013—Quality systems and quality management plans can be as solid as a laboratory can make them and still lab errors will occur. And as laboratories become more automated and test volumes grow, the potential for large-scale errors grows too.

“Laboratory errors are a fact of laboratory life,” and in medical care, large-scale errors are unique to the clinical laboratory, says Nikola A. Baumann, PhD, D(ABCC), co-director of the central clinical laboratory and director of central processing at Mayo Clinic.

Dr. Santrach, left, and Dr. Baumann at Mayo, where one physician’s inquiry about a chloride result that didn’t add up led to an investigation into potential large-scale error. “Taking clinician inquiries seriously is important,” Dr. Baumann says.

“A physician might actually touch 10 or 20 patients a day,” Dr. Baumann says. “In our laboratory, we touch 10,000 patients a day. The causes [of errors] might be calibration instability, instrument problems, assay interferences, variations in reagent quality, or preanalytic variables. Any of those can contribute to a large-scale testing error. And there are often anywhere from a few to hundreds of patient results affected before the error is identified.” To close the loop, she adds, the clinical impact of these errors is often difficult to assess.

At this year’s AACC annual meeting and in recent interviews with CAP TODAY, Dr. Baumann and Paula J. Santrach, MD, associate dean for the Mayo Office of Value Creation and a consultant in the Division of Transfusion Medicine, talked about the importance of having a response and recovery plan for errors of this type and outlined the steps laboratories should consider taking upon discovering errors.

To emphasize the potential frequency of large-scale errors that can occur even in laboratories with very low error rates and robust error detection and quality control plans, Dr. Baumann shared numbers from Mayo's central clinical laboratory: During one year, the laboratory issued more than 5.5 million billable test results and experienced 2,053 "events" (defined as an error or failure of a planned action to be completed as intended), of which 693 required revision of results, and of which 15 affected more than 20 patients. "These testing errors may occur over time spans of anywhere from one hour to days to several years," Dr. Baumann says. "And the same large-scale error never seems to happen twice." It is important to ensure that the lab's capability to detect errors is continuously optimized.

Several types of situations can lead to the uncovering of large-scale testing errors—for example, the receipt of manufacturer product bulletins. "We often receive manufacturer notices, and they might say something like, 'Electrolyte results prior to the new protocol or the new formulation may be erroneous,'" Dr. Baumann says. "And then the lab is left wondering how do we deal with that? What kind of retrospective result or chart review do we do? How do we communicate that to our clinicians?'"

"You're left with almost nothing to guide you," she says. "Manufacturers do what is required to notify users of their products, but it's difficult for a laboratory to try to troubleshoot, for example, possible erratic calcium results over a three-month span. There's almost no way for the laboratory to identify which patients may have been affected." Fortunately, well-designed quality control plans that incorporate both quality control and patient data often enable laboratories to detect these issues long before the assay manufacturer communicates the problem.

"We often identify an assay issue in the lab, and we notify vendors and provide data, but the burden of proof that a problem exists lies on the laboratory. Most manufacturers are quite responsive, but it takes time, and in the interim you're on your own, trying to determine a response and recovery plan—and, in the back of your mind, knowing that other laboratories are using these same methods and probably having these same problems and may be unaware of it."

By way of illustration, Drs. Baumann and Santrach discussed an example from their own institution. "We had a patient who presented with what appeared to be very severe hyperchloridemia, but the other electrolyte results weren't consistent with the chloride," Dr. Baumann says. "Because of the questionable result, analysis was repeated and the same result was obtained."

"A resident dealing with this patient," she continues, "contacted me with questions about the method used to measure chloride and possible interferences." To make things more complicated, "This patient was seen first in the emergency department and then admitted. The stat lab results were very high, but samples were also sent to the central laboratory, and those chloride results were normal, indicating discrepancies between two different analyzers." The two laboratories quickly identified that the root cause was a medication interference that affected only the stat laboratory analyzer. But identifying the cause was only the first step.

In such a puzzling situation, what's a laboratory to do? Turn to a checklist—a step-by-step list of how to proceed once a potentially large-scale error has been discovered. "The checklist really is designed to be a checklist," Dr. Santrach says. "It [each checklist item] may apply, it may not apply, but at least the tool is there to make you systematically think your way through the process." That said, the process "isn't totally sequential," she says. "You're going to be jumping around and doing things at various times depending on what you know. One of the things that's important to realize is that when you first

discover an error, you may not totally understand the nature of the error and what the root cause is, so you have to do the best you can until you finally get to what you really understand is the error."

The first three things a laboratory typically wants to ask after discovering an error: What's the nature of the error? Do we know what caused the error? And how long has it been occurring? After answering those questions to the best of its ability, the laboratory should then turn immediately to preventing additional errors. "You want to take the stance of, 'Do I have to stop the line?'" Dr. Santrach says. "I really don't want to have any other errors that could potentially impact a patient." To that end, the laboratory should aim to correct the root cause of the error immediately.

However, Dr. Santrach says, it's relatively rare to be able to do that at this point in the process. Thus the laboratory should consider ceasing testing, performing duplicate testing, performing testing on a backup system, testing using a different validated method, or testing at a different site or facility.
In the example from Mayo, the nature of the error was elucidated after a discussion with clinicians, review of the patient record, testing of additional samples spiked with the drug, and review of the literature. The manufacturer's package insert said there was not significant interference in samples containing the drug, so the laboratory also communicated its findings to the manufacturer. However, the lab was unable to correct the root cause of the error, Dr. Baumann says, "because the interference is electrode- and analyzer-specific." The laboratory was able to characterize the interference and continue providing test results "because we do have a testing system that is interference-free." The laboratory thus felt comfortable releasing the normal chloride results. As a safety net, the laboratory sent elevated chloride results or electrolyte panels with low or negative anion gaps to the central laboratory for confirmation.

On to step three: the actual event investigation. In this step, Dr. Santrach says, the goal is to ask: "What is the scope of the testing error? How many patients will be affected, and how many reports?" Consider, too, the clinical significance of the error. "Really get into the mind of your providers and clinicians," she urges. "What kind of clinical decisions would they make based on these results? Would they [the decisions] be erroneous? What would potentially be the impact? How serious is that impact to a single patient?"

In the Mayo Clinic case, Dr. Baumann says, "We know it's analyzer-specific and we know it is an interference from a common over-the-counter medication. We have to think about the prevalence of this medication being administered to hospitalized patients, and what concentration is needed to cause this interference. At this point, we speculated that the worst case would be that many patients may be affected, and yet we didn't yet know the concentration threshold for the interference."

As for the clinical significance and possible patient impact of the error, the laboratory directors held discussions with clinicians, who agreed that "chloride is really only one parameter of the electrolyte panel and it is not interpreted as a stand-alone test," Dr. Baumann says. "One of the hallmarks of this interference was a low or, more often, a negative anion gap, which is physiologically improbable, so we have a red flag that we can use to help us identify the interference and trigger sending the specimen for testing on the alternative platform." The lab, however, continued to characterize the interference, assess the patient risk, and put both short-term and longer-term solutions in place.

Now on to corrective action. As Dr. Santrach points out, it's vital to know the institutional policy for addressing these kinds of errors. "You want to make sure you're following what your organization

expects. And think outside of the lab—particularly [think about] risk management, if you have such a group." She urges laboratories to consider how remedial action might differ from population to population: inpatients, outpatients, reference laboratory clients, outreach testing clients. "You may have to customize what you're doing for each group," she points out.

The next question, then: Who really needs to be notified of the error and how, and who should do the notifying? "Most importantly, it is probably the providers who need to know," Dr. Santrach says, "and you might do that as a global thing in a circumstance like this. But in other circumstances, you can't do it globally, and you have to do it individually." Ultimately, there may be a question of whether the patient needs to be notified. Don't assume you are done when you've let the provider know, she says.

"The other question is: Should re-testing be offered? If you do re-testing, who will pay for it? What are going to be the logistics? How will patients know they can do that? How will they come in? Who will draw them? Are they all local? Are they from far away? Then finally, what is the time frame for this to be done? Again, the clinical impact is going to dictate that time period."

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Six steps to investigating error

Early fact gathering

- What is nature of error?
- Do we know what caused the error?
- Do we know its duration?

Immediate prevention of additional errors

- Can we immediately correct the root cause?
- Can we continue to provide test results?

Event investigation

- What caused the error to occur?
- What is the scope of the testing error?
- What is its clinical significance?

Remedial action for patient care

- Do reports need to be revised?
- Notification: who, how, and by whom?
- Offer retesting?
- What is urgency or time frame?

Remedial action to manage risk beyond patient care

- Are there other stakeholders?

- Are there other implications associated with the error (within and outside institution)? (Example: Do previous patient charges have to be credited?)
- What is likely to happen once providers/clients/patients know about this error?
- Does error need to be reported internally? Externally?

Long-term adequacy of corrective action

- Can this type of error occur again?
- Can its root cause affect other operations or cause other types of errors?
- Are there system issues outside the lab that need to be addressed?

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In the case of the erroneous chloride results, Mayo elected to alert its clinicians via a newsletter communication to the clinical staff. “We stated exactly what the interference was, how it was impacting results, and that there might be a delay in reporting results,” Dr. Baumann says. “We also did retrospective data review and looked for spuriously elevated chloride results in patients known to be taking the medication. For those patients, we did do targeted physician notification and approached from a risk management perspective, asking, ‘Were any decisions made based on this result that may have changed the clinical management for this patient?’”

Laboratories should think as well about the potential impact outside the lab’s walls. One of the first questions Dr. Santrach asks herself is, What is likely to happen once providers or clients or patients know about this error? “Is this going to be considered a non-event and no big deal, or is this going to generate a ton of buzz, and is it likely to get outside of the organization? Does the chief quality officer need to know? Does the quality unit need to understand what’s happened? What about risk management, and legal? Do you need to notify regulatory agencies? Do you need to notify accreditation entities?” And how about payers, Medicare/Medicaid, insurers, the FDA?

Knowledge of a particular error, Dr. Santrach notes, can quickly spread from the laboratory to the rest of the hospital and beyond. “You have to ask yourself as an organization: ‘Am I just going to react, or should I be proactive and actually disclose this as soon as I can, so that we can kind of control the message?’ The other thing is, do you need to develop contingency plans to deal with the feedback? This could involve public relations.” In one circumstance in which Mayo had erroneous test results, it disclosed the problem publicly. “We actually had a 1-800 number to call for patients who had concerns, and we had counselors available for them, and then we facilitated re-testing. Again, over-notification and over-communication is always probably the best approach,” Dr. Santrach says.

The last step of Mayo’s checklist: Assess the long-term adequacy of the corrective action. “Once you fix it, you need to be disciplined in thinking about: Can this type of error occur again, and how often, and do we have a good mechanism to detect it?” Dr. Santrach says. “We may have solved it for now, but is there a more effective preventive solution that we could put in place down the road? Another question is, ‘Could the root cause of this error impact other operations or cause other kinds of errors?’”

In dealing with the chloride errors, says Dr. Baumann, the laboratory realized the errors could indeed happen again. “We had a short-term safety net, but we needed to evaluate the effectiveness of that safety net, and we found it was quite robust.” The laboratory directors also considered whether the root

cause of the error could affect other operations or cause other errors. This provides the laboratory the opportunity to think about how it could have been more proactive. It is a good time to ”re-evaluate how we’re using our quality assurance tools in the laboratory, and make sure communication with clinicians happens continually.”

Dr. Baumann says it’s vital for laboratories to take seriously the role of physicians in detecting errors. “The case that we presented—it was all initiated based on a physician discovering a result that didn’t make sense and bringing it to the lab’s attention,” she says. “Most of the time, a physician will ask, ‘Can you repeat this test?’ Or they’ll just order a second test and see how it compares with the first. I think it is important to utilize our clinicians as error detectors, because they’re really good at it.”

The question, she says, is how laboratories react when a physician questions test results. “One must always consider that a single error may potentially be uncovering something large-scale. Taking clinician inquiries seriously is important. We can count numerous examples where it’s been a very astute clinician who has questioned a result on a particular patient and, importantly, communicated with the laboratory. We dive in and troubleshoot and investigate, but if you stop there and don’t look beyond that single inquiry, you can miss a systematic issue that affects far more than just that one patient.”
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Anne Ford is a writer in Evanston, Ill.

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