Karen Dalton-Beninato

Critical Value Notifications Are Never Welcome News

Quality Consultant for Oregon Medical Laboratories Vivian Benfield, MT(ASCP)SBB, describes a memorable case: "Our client service rep called the doctor at home and he didn't believe the results. He doubted the lab and said, 'That's impossible.' So we repeated the [test, obtained the same] results and called him a second time. He was still upset at being called and didn't believe it. When he called the patient at home, the patient answered the phone and then dropped the phone out of his hand." The patient was unconscious. Fortunately, the doctor arrived in time and a life was saved.

"That's the exception," Benfield adds. "More often than not, we're annoying people who already are aware of the values." Therein lies the rub.

Defining Critical Values

Critical values are "A laboratory result which represents a pathophysiologic state at such variance with normal as to be life-threatening unless some action is taken in a very short time and in which the state may not be readily detectable or highly suspected by the clinical physician,"[1] as defined by G.D. Lundberg in 1972.

Although simple enough in definition, putting it into practice is a complicated matter. Some of the challenges in critical values implementation and notification are that some doctors will accept calls only during specified windows of time, determining how much effort is enough to protect the laboratory in questions of liability, complying with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), and assessing whether one list of critical values is enough or if there should be specialized lists with more strictly set limits—for results in the intensive-care unit, for example.

Critical Values and Clinicians

Laboratories' frustration can stem from exhausting all avenues of reaching the treating clinician and still not being sure whether documentation is adequate to prove that sufficient effort has been made. According to CLIA, "the laboratory must develop and follow written procedures for reporting imminent life-threatening laboratory results or panic values. In addition, the laboratory must immediately alert the individual or entity requesting the test or the individual responsible for utilizing the test results when any test result indicates an imminent life-threatening condition."

As far as who liability falls on in a life-threatening situation, endocrinologist Morton Field, MD, Beverly Hills, CA, says, "If I were a malpractice attorney I would say to the doctor, 'You should have been able to tell that the potassium was going to be very, very high,' and [the attorney is] going to get a couple of experts on the stand to say, 'Yes, you would be able to tell.' But the reality is that you can't."

"So many, if not most, critical values that are reported after or beyond 4 hours [since] the time the blood was drawn are probably not critical values," Field says. "And the doctors say don't bother me because they've handled the immediate situation [already], and at 4 AM they're not going to call a patient's home and say, 'Hey, are you still alive?' It's a meaningless exercise. It just wakes a doctor up and annoys him."

The key for any critical value as far as I am concerned is to document the attempts.

—Robert Footlik, MS, MT(ASCP)

However, Robert Footlik, MS, MT(ASCP), bioanalyst with the regulatory and quality assurance branch of a California medical center, believes the laboratory must make the call in compliance with CLIA: "The key for any critical value as far as I am concerned is to document the attempts." Footlik adds that colleagues have told him of physicians who "have told the lab, 'Don't bother phoning me because I'm never going to call you back. Don't even bother paging me.'"

Physician Waivers

Some laboratories use waivers wherein the treating clinician accepts full responsibility for liability when he or she refuses to take calls with critical value results. But a question remains. Would a waiver hold up under CLIA?

Karen Nickel, PhD, DABCC, branch chief of the California Department of Health Services, Laboratory Field Services, Oakland, CA, points out that the doctor who requests a waiver, however, can then change his mind and say, "In this case, I should have been called. You should have known, and I'm going to sue you because you didn't call me."

"That's just not going to cut it," says Nickel. "In this case . . . , the doctor is asking for an exception," Nickel explains. "Maybe a critical value of potassium of 12 would be reported to every doctor but him. You know, that's expecting an awful lot. And I think if the doctor doesn't want to get that critical value in the middle of the night, then he should designate someone else to get it, but somebody has to get it."

Monitoring Responsibility of Laboratory Director

The responsibility for setting the reporting criteria falls upon the laboratory director. "A quality assurance program will assure that the critical values are being reported appropriately," Nickel says. "If they're not, then of course the laboratory has to take corrective action."

When the matter came up at the health department's advisory committee in California this past April, "there were some concerns on our advisory committee about how a laboratory can assure pre- and post-analytical conditions. 'Pre' meaning 'How is the sample going to get there?' and 'What condition is it in?' and in the 'post', 'How is it the result going to be reported?' Nickel emphasizes. "The law is quite clear …that the laboratory director is responsible, and there has to be a program set up to track it. And we're very careful about that—we check for compliance."

Footlik believes that some clinical laboratories use waivers out of frustration so that physicians aren't angered. "It's particularly difficult in the commercial arena where a clinical laboratory can't afford to lose clients, and it might lose a client over this issue where [the physician will] look for a lab that won't bother him or her with critical values. But can they really expect clinical laboratories to accept a waiver to a regulation that's the law?"

According to Benfield, her laboratory has had physicians sign waivers in the past but does not advertise the option. An Internet query helped the Oregon laboratory sort out issues such as waivers on critical values notifications. The laboratory also updated its critical values process with input from community physicians, pathologists, and laboratory personnel.

Microbiology—Critical Values

Test	Critical Value
Acid-fast bacillus smear or culture	Positive
Bacterial antigen screen	Positive
Blood culture	Positive
Cerebrospinal fluid culture	Positive
Sterile body fluid Gram stain	Positive
Stool culture	Initial isolate of *Salmonella*, *Shigella*, *Campylobacter*, or *Yersinia*

This table is based on consensus limits derived from the College of American Pathologists (CAP) Q-Probes Study (Steindel SJ, Heard NV. *Critical Values: Q-Probes 92-04.* Northfield, IL: College of American Pathologists;1992). This list is not intended to be interpreted as a standard of good laboratory practice. Each laboratory should modify the enumerated tests, the critical values, or both to meet the needs of the patients it serves.

From Emancipator K. Critical values: ASCP Practice Parameter. *Am J Clin Pathol.* 1997;108:247-253.

The laboratory currently has 2 critical values lists. "One we call 24 hours a day, 7 days a week on hospital inpatients and nursing home patients, and we call outpatients during the day hours," Benfield says. "Then we have a list with more extreme criticals where we call outpatients between the hours of midnight and 9 AM. So they have to be more extreme to interrupt somebody at home at night, basically. We already had that in place, but we still have complaints, of course."

Physicians sometimes complain that, "for their particular patient it's not really a critical value because [the patient] always runs this way," Benfield adds.

In complying with CLIA, it is crucial that the laboratory director has such a protocol in place, determined by the laboratory or hospital administrator. A critical value documentation system within the laboratory can prove that personnel attempted to notify clinicians of results.

Chemistry—Critical Values

Test	Critical Values	
	Conventional	SI
Arterial pH	<7.2 or >7.6	<7.2 or >7.6
Arterial pCO_2	<20 or >70 mm Hg	<2.7 or >9.3 kPa
Arterial pO_2	<40 mm Hg	<5.3 kPa
Bilirubin, neonatal	>15.0 mg/dL	>256.5 µmol/L
Calcium, total	<6.0 or >13.0 mg/dL	<1.5 or >3.25 mmol/L
Carbon dioxide	<10 or >40 mEq/L	<10 or >40 mmol/L
Creatinine	>5.0 mg/dL	>442 µmol/L
Glucose	<40 or >450 mg/dL	<2.20 or >24.75 mmol/L
Magnesium	<1.0 or >4.7 mg/dL	<0.41 or >1.91 mmol/L
Phosphorus	<1.0 mg/dL	<0.32 mmol/L
Potassium	<2.8 or >6.2 mEq/L	<2.8 or >6.2 mmol/L
Sodium	<120 or >160 mEq/L	<120 or >160 mmol/L
Urea nitrogen	>80 mg/dL	>28.6 mmol/L

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Written Documentation Policy

The best solution can be a written policy, showing what should be done when the results are within the critical range. When a jury decides on matters of medical malpractice liability, following comprehensive critical values policies can help show the paper trail of a laboratory's efforts to reach a treating clinician. This can help the laboratory director rest assured that proper protocol has been followed in all instances in a timely manner.

Benfield describes her laboratory information system, "We have a call documentation field and so we do document who we spoke to, what we told them, time of day, and that kind of thing, and the way our computer system is designed, we cannot release that result until that call has been made. In other words, the field pops up when you come to a critical result, and you cannot release the result until you have documented the call."

When a physician specifically asks not to be called again on a matter such as a patient tolerating very low potassium levels during hemodialysis, the question becomes whether the physician's request is good enough to protect the laboratory from liability.

"If we could customize our computer system by doctor, that would be ideal, so we would have a set of critical values per doctor," Benfield says. "But that's a ways down the road yet. I don't think anyone's got something like that in place."

Hospital laboratories working together with the hospital's physicians and quality assurance and risk management personnel can establish guidelines that work for all concerned.

According to Nickel, "The law holds the laboratory director responsible, so if he or she thinks the oncology results should have to be more critically reported, [he or she has] to state that in [his or her] policy and procedures and then the laboratory is compelled to follow that." For example, Nickel says that, "when we go into inspection, we ask, 'What is your policy and procedure for reporting oncology reports?, and then [ask to] show [that this has been done] according to the policy procedure." If it has not, Nickel says, then we request they show quality assurance and make sure that if they goofed this 1 time, they're not going to goof it again.

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—Karen Nickel, PhD, DABCC

The medical technologist or medical laboratory technician has an obligation to be compliant. Footlik points out that "Certainly in today's day and age if you are participating in federally funded programs such as Medicare and Medicaid, it is a condition of participation that the clinical laboratory is in compliance with CLIA in order to participate in these programs."

But when the specimens collected Friday night are analyzed at 2:00 in the morning, will the doctor take the call in the event of critical values?

Therein lies the conundrum. What is a timely notification?

"What they often say is, what can I do about it right now," comments Benfield.

Field describes a critical value as, "a blood test is out in which if the result is really true it presents a clear and present danger to the patient. A potassium that is markedly elevated, a blood sugar that is very, very low. They are normally, under CLIA, supposed to report it to physicians immediately. But here's the problem, for instance I draw a blood test in my office at 2 o'clock in the afternoon. The laboratory picks it up at 5 or 6 because I don't suspect a critical value. They don't run it until midnight or 1 o'clock only because in routine lab runs, the runs start at 12 or 1 o'clock in the morning because they wait until everything is picked up from the whole day's run and run them all at one time. So it comes off the machine at 3 o'clock. Now, is it a critical value at 3 o'clock? Well, it was a critical value at 2 o'clock when it was drawn. But because it is now 12 hours later, is it still a critical value?"

Probably not, Field maintains, "because by that time either the patient is dead or it has become obvious that it is a spurious result."

Nickel shares 1 physician's perspective encountered during a recent advisory committee meeting. "When he gets a call at 3 in the morning it really makes him angry, and he thinks it's because the laboratory doesn't have time or efficiency to run it in the day and get the result back to him. They have to run it and night and that's why they're calling him in the middle of the night." Nickel is aware, however, that often samples are picked up at the end of the day, with results not available until very late. "And what are you going to do? You've got to report them. And which of the doctor's staff represents a high enough [position on the] chain of command to take the call when he or she will not?"

Benfield agrees that human contact is of utmost importance. "We've got a policy of speaking to a person. We don't leave messages on answering machines. We do page doctors, and sometimes they don't answer their pages, but we're pretty persistent in calling them at home or calling their answering service and having the answering service reach them [and] have them call back to us.

Footlik adds that when complying with CLIA, "…the laboratory is not only trying to fulfill this requirement, but feels a moral obligation to report a life-threatening result in the meantime.

Hematology—Critical Values

Test	Critical Values	
	Conventional	SI
aPTT	>78 s	>78 s
Fibrinogen	<100 mg/dL	<1.00 µmol/L
Hemoglobin	<7.0 or >20.0 g/dL	<70 or >200 g/L
Hematocrit	<20% or >60%	<0.20 or >0.60
Platelet count	<40 or >999 $\times 10^3$/µL	<40 or >999 $\times 10^9$/L
Prothrombin time	>30 s	>30 s
WBC count	<2.0 or >30.0 $\times 10^3$/µL	<2.0 or >30.0 $\times 10^9$/L

aPTT, activated partial thromboplastin time.

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Because the alternative is, what if there is harm or fatality that results from not doing that? [If this is the case], then you [would] hear from the physician, 'Why didn't you notify me?'"

Field has the luxury of a laboratory in his office and gives the following scenario. "A patient comes at 2 o'clock, I get a blood sugar report at 2:15. The blood sugar is 50; it's reported to me right there. I treat it right then and there."

But when an outside laboratory is involved, can e-mail, faxes, and pagers expedite the reporting of critical values? They just complicate the process because it's a crutch. Nickel says, "You never know if you e-mail or fax something out whether anyone's going to see it, whether there's paper in the printer, whether the computer's turned on…and we like to have the name of the person who received it, and we like the labs to write that down and document that someone has received it, a certain name and a certain time, and then the laboratory has done the responsible thing."

Timely Notification, Then Documentation

Field's view of a timely notification is within "reasonable" limits. "If you think the potassium is high, you draw the potassium [and] call the lab to pick it up. You've still got a 2-hour wait until it gets to the laboratory and then the laboratory may or may not run it stat and you might get an answer in 3 or 4 hours. If that's the case, then yes, the critical value with a reasonable time, 4 hours, should be called to the physician. But at 3 AM to give them a result that was drawn at 3 PM, is unreasonable."

Under CLIA, does immediate notification mean 12 hours later, or is immediate notification when the blood is drawn? "The law is silent in how that's supposed to be done," Field adds.

The law is also silent on how much documentation of the attempt to reach clinicians is enough.

"I still go back to the laboratory making 2 or 3 good attempts to contact the physician," Footlik says. "I think with good documentation no one could fault the clinical laboratory…. Some things just aren't possible, no matter what it says in the rule."

So documentation is necessary. "Unfortunately, that's what the law requires. If you don't document, it's like you didn't do it. Attempted to call, attempted to call, unable to call, and then follow up in the morning. That does put a burden on the lab, doesn't it?" Nickel sympathizes.

Critical values are sometimes referred to as panic values, but most laboratories prefer the former term because notification isn't a process of panic, it's a process of attempting to comply with the letter of the law and convey a potentially life-threatening situation. l

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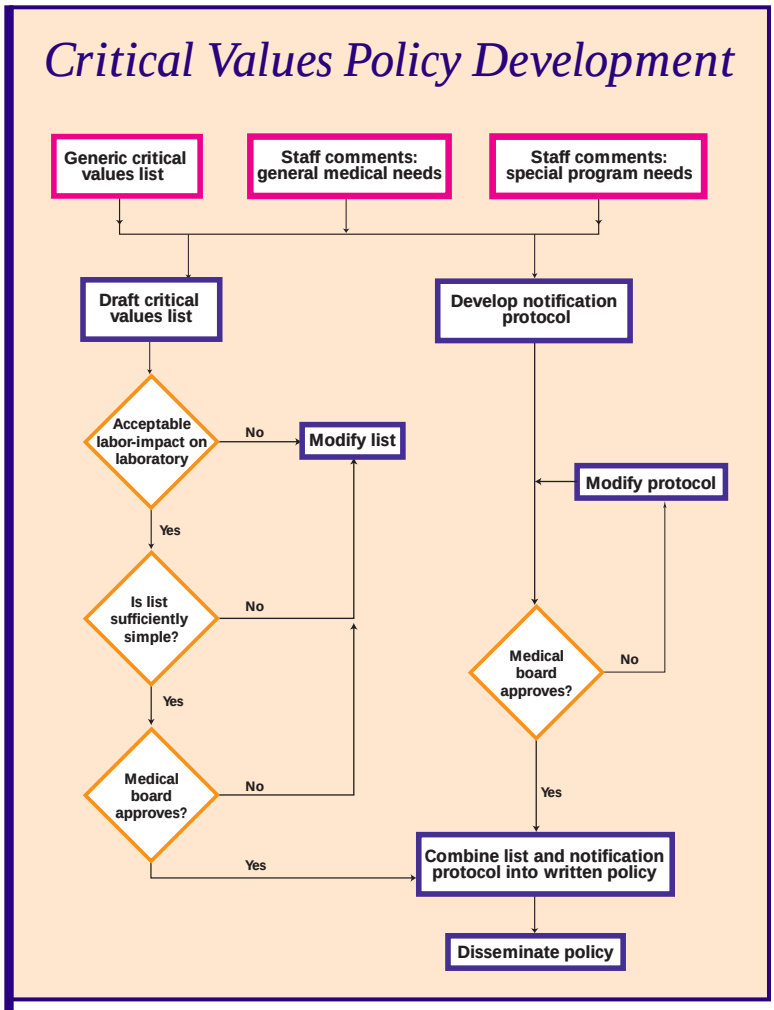

Reference

1. Lundberg GD. When to panic over abnormal values. *Med Lab Observ*. 1972;4: 47-54.