Critical Values
ASCP Practice Parameter
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Appropriate use of critical values improves patient outcome by ensuring that physicians are promptly notified of immediate life-threatening conditions. Conversely, overuse squanders resources and actually may impair patient outcome. A generic critical values list derived from interlaboratory surveys is an excellent starting point, but every laboratory must customize its list to meet the needs of the organization that it serves. Category-specific and once-per-period critical values can limit superfluous reporting, but they make the critical values list more complicated. Strict semantic interpretation of critical limits is appropriate. The best ways to report critical values are by telephone and by alphanumeric pager. When required, repeat analysis should precede critical value reporting. Laboratories should avoid reporting invalid results (due to poor specimen integrity, for example) as critical values. An institutional committee initially should approve, and periodically should review and revise, the critical values policy. (Key words: Critical values; Panic values; Alert values; Critical limits; Alert limits; Good laboratory practice; CLIA) Am J Clin Pathol 1997;108:247-253.

The concept of critical values was introduced by Lundberg in 1972 and incorporated into accepted standards of good laboratory practice shortly thereafter. The Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) state:

§493.1109(f) 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.

Despite its long-standing tenure and its widespread application, the concept of critical values has received little attention in the indexed medical literature. This document provides guidelines for developing a critical values list and for reporting critical values.

A critical value is “a pathophysiological state at such variance with normal as to be life-threatening unless something is done promptly and for which some corrective action could be taken.” When properly implemented, the reporting of critical values promotes the prompt initiation of potentially lifesaving therapy, thereby improving patient outcome. A poorly implemented critical values protocol, however, may impair patient care by squandering human resources.
THE CRITICAL VALUES LIST

The diversity among the critical values lists in use by various laboratories is quite remarkable.6 Apparently, this diversity stems from the need for each individual institution to use a critical values list that is tailored to its own specific mission. Therefore, attempting to implement a uniform list in all laboratories would be counterproductive. In fact, for precisely this reason, the College of American Pathologists (CAP) Q-Probes Committee abandoned its original intent to establish (by consensus) a national standard critical values list.6 The use of individualized critical values lists clearly benefits patient care.

A generic critical values list, however, does have its purpose. It can be used as a starting point for the development of a customized list or as a reference point for reviewing an existing list. Table 1 is offered

### TABLE 1. GENERIC CRITICAL VALUES LIST*

<table>
<thead>
<tr>
<th>Chemistry Tests**</th>
<th>Critical Values (Conventional units)</th>
<th>Critical Values (SI units)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial pH</td>
<td>&lt; 7.2 or &gt; 7.6</td>
<td>&lt; 7.2 or &gt; 7.6</td>
</tr>
<tr>
<td>Arterial pCO₂</td>
<td>&lt; 20 or &gt; 70 mm Hg</td>
<td>&lt; 2.7 or &gt; 9.3 kPa</td>
</tr>
<tr>
<td>Arterial PO₂</td>
<td>&lt; 40 mm Hg</td>
<td>&lt; 5.3 kPa</td>
</tr>
<tr>
<td>Bilirubin, neonatal</td>
<td>&gt; 15.0 mg/dL</td>
<td>&gt; 256.5 umol/L</td>
</tr>
<tr>
<td>Calcium, total</td>
<td>&lt; 6.0 or &gt; 13.0 mg/dL</td>
<td>&lt; 1.5 or &gt; 3.25 mmol/L</td>
</tr>
<tr>
<td>Carbon dioxide</td>
<td>&lt; 10 or &gt; 40 mEq/L</td>
<td>&lt; 10 or &gt; 40 mmol/L</td>
</tr>
<tr>
<td>Creatinine</td>
<td>&gt; 5.0 mg/dL</td>
<td>&gt; 442 umol/L</td>
</tr>
<tr>
<td>Glucose</td>
<td>&lt; 40 or &gt; 450 mg/dL</td>
<td>&lt; 2.20 or &gt; 24.75 mmol/L</td>
</tr>
<tr>
<td>Magnesium</td>
<td>&lt; 1.0 or &gt; 4.7 mg/dL</td>
<td>&lt; 0.41 or &gt; 1.91 mmol/L</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>&lt; 1.0 mg/dL</td>
<td>&lt; 0.32 mmol/L</td>
</tr>
<tr>
<td>Potassium</td>
<td>&lt; 2.8 or &gt; 6.2 mEq/L</td>
<td>&lt; 2.8 or &gt; 6.2 mmol/L</td>
</tr>
<tr>
<td>Sodium</td>
<td>&lt; 120 or &gt; 160 mEq/L</td>
<td>&lt; 120 or &gt; 160 mmol/L</td>
</tr>
<tr>
<td>Urea nitrogen</td>
<td>&gt; 80 mg/dL</td>
<td>&gt; 28.6 mmol/L</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hematology Tests†</th>
<th>Critical Values (Conventional units)</th>
<th>Critical Values (SI units)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activated partial thromboplastin time</td>
<td>&gt; 78 s</td>
<td>&gt; 78 s</td>
</tr>
<tr>
<td>Fibrinogen</td>
<td>&lt; 100 mg/dL</td>
<td>&lt; 1.00 µmol/L</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>&lt; 7.0 or &gt; 20.0 g/dL</td>
<td>&lt; 70 or &gt; 200 g/L</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>&lt; 20 or &gt; 60 %</td>
<td>&lt; 0.20 or &gt; 0.60</td>
</tr>
<tr>
<td>Platelet count</td>
<td>&lt; 40 or &gt; 999 x10^3/µL</td>
<td>&lt; 40 or &gt; 999 x10^9/L</td>
</tr>
<tr>
<td>Prothrombin time</td>
<td>&gt; 30 s</td>
<td>&gt; 30 s</td>
</tr>
<tr>
<td>WBC</td>
<td>&lt; 2.0 or &gt; 30.0 x10^9/µL</td>
<td>&lt; 2.0 or &gt; 30.0 x10^9/L</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Microbiology Tests‡</th>
<th>Critical Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood culture</td>
<td>Positive</td>
</tr>
<tr>
<td>Cerebrospinal fluid culture</td>
<td>Positive</td>
</tr>
<tr>
<td>Acid-fast bacillus smear or culture</td>
<td>Positive</td>
</tr>
<tr>
<td>Sterile body fluid Gram's stain</td>
<td>Positive</td>
</tr>
<tr>
<td>Stool culture</td>
<td>Initial isolate of Salmonella, Shigella, Campylobacter, or Yersinia organisms</td>
</tr>
<tr>
<td>Bacterial antigen screen</td>
<td>Positive</td>
</tr>
</tbody>
</table>

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*This table is based on consensus limits derived from the College of American Pathologists (CAP) Q-Probes Study. 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.

†The numerical value of each limit is the median of the corresponding values that are used by CAP Q-Probes survey participants; a limit is omitted from the table if analogous limits are not used in at least 200 of the 623 participating laboratories.

‡Results that were considered to be critical values by at least one third of the CAP Q-Probes survey participants are included.

§Smears or cultures that are positive acid-fast bacillus (AFB) are handled as critical values primarily for epidemiologic reasons; the patient must be isolated immediately. Because the patient does not suffer from a condition that is immediately life-threatening, positive AFB smears and culture are not critical values in the strictest sense.
as a generic critical values list, with the caveat that this list does not possess any special attributes. Table 1 is based on the CAP Q-Probes survey. Note: this survey is chosen only because it is more recent than that conducted by Kost. It is emphasized that Table 1 is not to be construed as a standard of laboratory practice.

Published consensus surveys provide additional and invaluable information for customizing or revising a critical values list. For each critical limit, the surveys give the range of values that are reported by the participants. These ranges offer guidance when the numerical value of a critical limit requires adjustment. The surveys also provide data for analytes that are included on critical values lists infrequently (i.e., analytes that are included on the lists of only a small fraction of the survey participants). These data are useful when one of these analytes is added to a particular laboratory’s list. Two original articles provide consensus data relevant to the general medical population. A third original article provides data relevant to the pediatric population. These same data also have been published in secondary trade journal articles.

The medical director of the laboratory is primarily responsible for customizing the critical values list. The director must consider the needs of any special programs (e.g., cardiac surgery, bone marrow transplant, or high-risk obstetrics) that are supported by the laboratory. It is essential to consult with members of the medical staff through informal discussions or through a formally recognized committee (that can be ad hoc) within the organization. Usually, special programs require greater use of critical values (more narrow noncritical ranges for a given analyte or additional critical analytes). The director must adjust the critical values list to balance medical needs with the pragmatics of notification.

To control the utilization of critical value reporting is legitimate and necessary. Lundberg warns that critical values might lose their impact if reported excessively; thus he emphasizes that the critical values list in use at his institution was “deliberately limited to a crucial small variety of tests with undeniably critical limits.” Kost notes that “critical limit tests have expanded vastly since their inception” and that “inappropriate use of critical limits may penalize the [physician] with an untimely information overload.” Therefore, he suggests using his critical values consensus survey for “resource allocation” and including “only tests truly critical for acute treatment of patients” on the critical values list. The CAP Q-Probes report comments that many of the critical values listed by survey participants do not meet Lundberg’s original definition. It suggests that the use of critical value notification for all toxic therapeutic drug levels (digoxin > 2.5 µg/L or theophylline > 20 mg/L, for example) is probably excessive and makes note of the substantial labor impact of critical value notifications (on average, it takes approximately 6 minutes to report a critical value for a hospital inpatient, 14 minutes for an outpatient).

Category-specific critical values—those considered to be critical for only a subset of the general patient population—make it possible to curtail critical value reporting while simultaneously fulfilling the needs of a particular group of patients. Neonatal bilirubin is a common example. Unfortunately, category-specific limits makes the critical values list more complicated. Furthermore, the laboratory staff must be able to access accurate patient demographic information immediately and easily. At a minimum, the laboratory information system should display the relevant information along with the test result at the time of verification. Despite their widespread use, most laboratories should use category-specific critical limits sparingly.

Once-per-period critical values—those considered to be critical only the first time they occur within a specified time—also make it possible to curtail critical value reporting. For example, a laboratory may classify a positive blood culture as a once-per-24-hour critical value. This would imply that it is necessary to handle only the first positive blood culture (within a 24-hour period) as a critical value. After the cause of the patient’s sepsis is known, subsequent positive blood cultures are expected. However, a positive blood culture obtained more than 24 hours after the first, or one that contains a new isolate (e.g., gram-positive cocci in addition to gram-negative bacilli), is also a critical value; it may indicate the need to change antibiotic therapy. Once-per-period critical values are appropriate for only a few analytes. Furthermore, this entity makes the critical values list much more complicated. Thus, the use of once-per-period critical values is relatively uncommon.

THE CRITICAL VALUE NOTIFICATION

The critical value notification process begins with the recognition of a test result as critical. This facet is generally straightforward, but two situations often confuse the laboratory staff and deserve some clarification. First, critical values should be identified by strictly semantic interpretation of the critical limits (e.g., using Table 1, a glucose result of 451 mg/dL is a critical value, but a result of 450 mg/dL is not). Second, a critical value should be reported only if the
condition of the sample is satisfactory (e.g., free of gross lipemia and hemolysis) for routine reporting of that same result. These instructions should be included in the critical value policy. In addition, the laboratory staff should be instructed and reassured that this response is correct and appropriate.

The reporting of unverified critical values is inadvisable. No laboratory result, including a critical value, should be reported unless its validity has been established. Therefore, reanalysis, if required by laboratory protocol, should precede critical value notification. In addition, to assuage staff anxiety, the critical values policy should provide realistic guidelines for the expected time frame to initiate and complete a critical values notification. The time frame will vary greatly among institutions. Some authors recommend that the critical value notification be initiated as soon as possible. Generally, the technologist verifying the result reports the critical value directly to the physician. (Note: if standard orders authorize a licensed nonphysician health care professional, such as a physician's assistant or registered nurse, to initiate potentially lifesaving therapy, then contacting this individual is virtually equivalent to contacting the physician.) Frequently, circumstances prevent the technologist from contacting the physician immediately. To expedite notification, the policy may permit other persons to receive critical value reports from the laboratory—with the understanding that these persons will relay this information to the physician as soon as possible. Generally, professional staff (e.g., physicians' assistants and nurses) relay critical values more reliably than non-professionals (e.g., receptionists, secretaries, and answering service operators).

The telephone and the alphanumeric pager (preferably a two-way pager; Table 2) are the most effective means of reporting critical values. At present, critical values are most commonly reported by telephone. Telephone reporting is optimal when the technologist contacts the physician directly: the technologist knows that the physician has received the critical value report, and the physician can readily confirm specimen integrity (e.g., absence of hemolysis and lipemia) and repeat analysis. Voice mail, electronic mail, or fax offer no assurance that the notification will reach the appropriate person in a timely fashion; they should be used exclusively when notification by telephone or alphanumeric pager fails or when other exceptional circumstances exist.

To implement telephone or pager reporting of critical values, it is imperative that the laboratory maintain an up-to-date directory of all relevant telephone and pager numbers. The directory also can include alternative telephone and pager numbers; it is not unusual to encounter busy signals when calling hospital wards, outpatient clinics, or physicians' offices. For commercial laboratories or hospital laboratories with outreach programs, the emergency telephone number(s) of each new client must be added to the directory before the laboratory accepts specimens from that client. The directory must at all times be easily accessible to all laboratory personnel. To report critical values for outpatient clients during times when clinics or offices are closed is a persistent problem. It is essential that each clinic or private physician designate appropriate persons to accept these reports during off-hours.

It is inevitable that some attempts to issue a critical value notification will fail. The critical values policy should provide the laboratory staff with explicit instructions for these situations. It is acceptable to defer notification after reasonable measures have been exhausted. It is foolish to compromise all laboratory operations by continuing futile attempts to report a critical value. However, notification should not be abandoned altogether; a delayed notification is better than none at all. Supervisory personnel should determine the root cause of an unsuccessful notification attempt and initiate corrective action. The investigation and corrective action must be documented.

The laboratory staff must document contemporaneously all critical value notifications, including unsuccessful attempts. These records must be retained for the same time period as all other patient reports. They can be in written or an electronic format. Each record must include patient identification, analyte and result, date and time of notification, identity of reporter, identity of recipient, reporting mechanism (i.e., telephone or alphanumeric pager), and, for an unsuccessful attempt, a short explanation (e.g., "no one answers phone"). The reporter and recipient must be identified by at least their first initial and complete last name or by other unique identifiers, such as computer sign-on codes. Documenting critical value notifications in the laboratory information system may be particularly convenient because it can capture most of the required information automatically.
It is necessary to report critical values only for ordered tests. A laboratory may opt to report unordered test critical values only if the turn­around times for ordered tests remain optimum. Many laboratories perform stat tests (eg, blood gases, electrolytes, and hematocrit levels) using multichannel whole-blood analyzers that do not operate in random-access mode (these analyzers lack random-access capability or are easier to operate in simultaneous mode). Generally, physicians do not order the entire test menu for every patient sample. Thus, these analyzers produce unordered test results coincidentally. If the laboratory reports unordered test critical values, its technologists must review every test result, including those produced coincidentally, and respond appropriately by repeating analyses and trouble shooting channels. This may compromise the turnaround time for ordered tests—with results that physicians want and need as quickly as possible. Arguably, laboratories with sufficient reserves should report the entire test menu on all samples. However, if laboratory resources are marginal, reporting critical values of unordered tests may actually impair patient care overall.

Method-Dependent Critical Analytes

There is a very compelling argument in favor of classifying ionized calcium as a critical analyte. Clinical assays for ionized calcium are, however, highly method-dependent. Therefore, consensus surveys express critical limits for ionized calcium relative to the midpoint of the normal reference range. This technique can be applied to other analytes, as the need arises.

Advanced Laboratory Information System (LIS) Software

LIS software can identify critical values reliably, even if the critical values list is extremely complex. Furthermore, an LIS can be integrated with telecommunications systems that can deliver critical value notifications to alphanumeric pagers. Notifications can be routed to the appropriate physician according to call schedules. Two-way pagers provide a simple way for the physician to confirm receipt of the notification. Such systems could totally automate critical value notifications and would be perfectly reliable. As these highly sophisticated systems develop, laboratories still should maintain alternative (simple and concise) critical value lists for use during computer downtimes.

Point-of-Care Testing (POCT)

POCT is typically performed by (nonphysician) direct patient care personnel (eg, nurses). These personnel know how to contact the appropriate physician promptly and are the ones who will implement the physicians’ orders. Therefore, responses to POCT critical values tend to be very efficient. However, POCT operators must recognize critical values and react appropriately. POCT results typically are uploaded to the LIS well after the test is complete (if at all); thus, LIS software would fail to identify critical values in a timely manner.

Interval Between Sample Collection and Analysis

When samples are analyzed many hours—or even days—after collection, the clinical significance of a critical value is greatly diminished. There are no guidelines for handling critical values when the collection-to-analysis interval is prolonged. This may be an important issue to study in this era of rapid centralization of routine (non-stat) laboratory testing; off-site laboratories typically obtain results more than 12 hours after collection.

Blood Bank Critical Values

Although a particular organization may need blood bank critical values (eg, incompatible crossmatches or unexpected antibodies), the vast majority do not. None of the 623 institutions participating in the Q-Probes study include blood bank tests on their critical values lists.

ENDORsing, Disseminating, and Updating the Critical Values Policy

Approval of the completed critical values notification policy by the organization’s medical board or by another appropriate institutional committee is extremely beneficial. Such approval serves several purposes. First, review by such a committee serves as a final check that the policy is consistent with the needs of the institution. Second, recalcitrant physicians or nurses are less likely to challenge the propriety of a policy that is sanctioned by the medical board than they are to challenge the propriety of an internal laboratory policy. Finally, endorsement by the medical board may forestall later censure for the content of the policy.

Once approved, the critical values list (and possibly an abridged version of the whole policy) should be made readily available to the medical and professional staff. The best way of disseminating this information will vary among institutions. A few suggestions are
the laboratory manual, the medical staff manual, the laboratory information system, and the clinical information system.

The critical values policy must be a dynamic document. Hospitals and other health care organizations may add or delete special programs. To meet the changing needs of the organization, the critical values policy periodically must be reviewed and appropriately updated.

**SUMMARY**

Appropriate use of critical values improves patient outcome by ensuring that physicians are promptly notified of immediately life-threatening conditions.

However, overuse of critical values (noncritical ranges that are too narrow or inclusion of analytes that are not really critical) is an inappropriate use of resources and may impair patient outcome. A generic critical values list derived from interlaboratory surveys (see Table 1) is an excellent starting point for developing a critical values list for a particular laboratory. However, each critical values list must be customized to meet the needs of the health care organization that the laboratory serves. The scope of the critical values list must reflect the needs of special programs within the organization and the labor impact on the laboratory. Category-specific critical limits (eg, neonatal bilirubin) are used to meet the needs of special programs while simultaneously limiting the labor impact of critical value reporting. Superfluous reporting also can be reduced by using once-per-period critical values, but this is appropriate for only selected analytes. Category-specific and once-per-period values make the critical values list more complicated. Critical values lists should be interpreted semantically: report as critical values only those results that strictly qualify as such, not those that almost qualify. Results that are invalidated by poor specimen integrity should not be reported as critical values. Repeat analysis, when required to verify a result, should precede critical value reporting.

Critical values reports are best delivered by telephone or by alphanumeric pager. The laboratory must maintain an up-to-date list of telephone numbers, pager numbers, or both for all nursing units and physician clients. The critical values list and the accompanying policy must be written and readily available to the laboratory and medical staff. Both should be reviewed periodically and revised as indicated. The critical values list and policy should be approved by an institutional committee, such as the medical board (Fig). The major steps for developing a critical values policy are shown in the Figure.

**REFERENCES**


