Analysis of Laboratory Critical Value Reporting at a Large Academic Medical Center

Anand S. Dighe, MD, PhD,[1] Arjun Rao, MBBS, MBA,[2] Amanda B. Coakley, RN, PhD,[3] and Kent B. Lewandrowski, MD[1]

Key Words: Informatics; Clinical pathology; Clinical chemistry; Management; Administration; Hematology; Patient safety; Critical value reporting

DOI: 10.1309/R53XVC2U5CH6TNG8

Abstract

Reporting of laboratory critical values has become an issue of national attention as illustrated by recent guidelines described in the National Patient Safety Goals of the Joint Commission on Accreditation of Healthcare Organizations. Herein, we report the results of an analysis of 37,503 consecutive laboratory critical values at our institution, a large urban academic medical center. We evaluated critical value reporting by test, laboratory specialty, patient type, clinical care area, time of day, and critical value limits. Factors leading to delays in critical value reporting are identified, and we describe approaches to improving this important operational and patient safety issue.

Critical value reporting originally was highlighted by Lundberg,[1] who defined a *critical value* as a result suggesting that the patient was in imminent danger unless appropriate therapy was initiated promptly. In the 30 years since Lundberg's observations, the concept of defining critical values and systems for reporting have been adopted widely by laboratories throughout the world.[2] In the United States, laboratory accrediting agencies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the College of American Pathologists have made critical value reporting part of the requirements for accreditation.[3,4] Consequently, critical values are used in virtually all US clinical laboratories.

The recent national focus on patient safety has brought increased attention to the issue of laboratory critical value reporting. The JCAHO has made improving the process of critical value reporting a National Patient Safety Goal for the years 2004 through 2006.[3] The JCAHO requires health care organizations to track and improve the timeliness of reporting and receipt of critical test results by the responsible licensed caregiver. Moreover, the JCAHO has defined *critical test results* as not only laboratory tests but also imaging studies, electrocardiograms, and other diagnostic studies. Therefore, the process of critical value reporting is of interest across the health care organization.

Critical value reporting parameters may be considered an important laboratory outcome measurement because they reflect clinical effectiveness, patient safety, and operational efficiency. For the critical value reporting process to be effective, the organization must understand and address the variables involved in the process. This information is not readily available in the literature. Most reports have analyzed

only a few analytes for short periods or have reviewed a small number of critical values in a number of different institutions.[5-7] In the present study, we analyzed 12 months of critical value data and more than 37,000 individual critical results to understand the scope of critical value reporting and identify opportunities for process improvement.

Materials and Methods

Setting

The Massachusetts General Hospital, Boston, is an 898-bed tertiary care academic medical center. All major medical and surgical specialties are supported by the hospital, along with pediatric and obstetric services and extensive primary care and specialty outpatient practices extending into the greater Boston community. The clinical laboratories include chemistry-hematology (core laboratory), microbiology, blood transfusion services, and various specialty laboratories (immunology, diabetes, health center laboratories, neurochemistry). In 2004, the laboratories performed 14 million reportable tests, of which 52% were for inpatients, 41% for outpatients, and 7% for emergency department (ED) patients. Critical values reported from October 1, 2003, to September 30, 2004, were examined. Testing performed in the chemistry, hematology, and outpatient health center laboratories (chemistry and hematology) was included in our critical value analysis. Microbiology critical values were not included in the present study because our microbiology laboratory uses a different documentation process for critical values.

Critical Callback Procedures

Table 1 shows the critical callback list for chemistry and hematology that was in use at our institution at the time of the study. The laboratory uses a module in our laboratory information system (LIS) that automatically flags each test result requiring critical callback and organizes it in an application that aids in the documentation of the phone call placed to the patient's location (for inpatient and ED patients) or the ordering clinician's location (for outpatients). Laboratory staff (technologists in the chemistry laboratory and clinical laboratory assistants in the hematology laboratory) regularly monitor the LIS callback application and perform critical callbacks.

Data Collection and Analysis

All data were obtained from reports generated from the LIS (Misys Healthcare Systems, Tucson, AZ). The data were exported to Microsoft Access/Excel (Microsoft, Redmond, WA) for analysis.

Table 1
Massachusetts General Hospital Critical Value List

Test	Critical Values
Chemistry (blood gas)	
Bilirubin, total, 0-3 mo old, mg/dL (μmol/L)	>20 (>342)
Calcium, ionized, mg/dL (mmol/L)	<3.20 or >6.16 (<0.8 or >1.54)
Hemoglobin, g/dL (g/L)	<6.5 (<65)
pCO_2, mm Hg	<20 or >75
pH	<7.10 or >7.59
pO_2, mm Hg	<40
Chemistry (main laboratory)	
Calcium, mg/dL (mmol/L)	<6.5 or >14.0 (<1.63 or >3.53)
Carbon dioxide, total, mEq/L (mmol/L)	<11 (<11)
Glucose, CSF, mg/dL (mmol/L)	<40 (<2.2)
Glucose, plasma, mg/dL (mmol/L)	<45 or >500 (<2.5 or >27.8)
Magnesium, mEq/L (mmol/L)	<1.0 or >4.9 (<0.50 or >2.45)
Osmolality, plasma or serum, mOsm/kg H_2O (mmol/kg H_2O)	<250 or >335 (<250 or >335)
Phosphorus, mg/dL (mmol/L)	<1.1 (<0.36)
Potassium, mEq/L (mmol/L)	<2.8 or >6.0 (<2.8 or >6.0)
Sodium, mEq/L (mmol/L)	<120 or >160 (<120 or >160)
Hematology	
All hematocrit values, %	>56% (>0.56)
δ values	Various δ checks for platelet and hematocrit values
Differential	Presence of blasts on initial smear
Initial hematocrit, %	<20 (<0.20)
Initial platelet count, × 10^3/μL (× 10^9/L)	<50 or >999 (<50 or >999)
Initial WBC count, /μL (× 10^9/L)	<2,000 or >50,000 (<2.0 or >50.0)
Partial thromboplastin time, s	>100
Prothrombin time, s	>30

CSF, cerebrospinal fluid.

DOI: 10.1309/R53XVC2U5CH6TNG8

Results

Critical Value Reporting

During the period of the study (12 months), the chemistry and hematology laboratories reported 37,503 critical values. During the same period, these laboratories reported more than 14 million test results. Therefore, tests with critical values represented approximately 0.25% of the total test results reported. Examination of only the tests potentially eligible for callback (5.1 million tests) demonstrated that 0.74% of these tests were in the critical range (37,503/5.1 million). The majority of critical callbacks (68.6%) resulted from testing performed in the chemistry laboratory **Table 2**. The hematology laboratory accounted for 31.4% of critical callbacks. The analytes most commonly called back were potassium (7,955 results; 21.2% of critical results) and partial thromboplastin time (5,467 [14.6%]) **Table 3**. These critical callbacks correspond to 1.8% of all potassium levels (7,955/439,104) and 3.0% of all partial thromboplastin times (5,467/183,768) performed.

Analysis of call volumes vs time **Figure 1** showed that inpatient critical value call volumes were high throughout the 24-hour day, with a range of 830 calls from 12:00 to 1:00 AM to 1,570 calls from 10:00 to 11:00 AM. Outpatient critical value calls were prominent from 9:00 AM until 11:00 PM, dropping off to near zero during the late night and early morning. ED critical value calls were highest during the day, but all times of day had a significant number of calls. As expected, these call volumes correlate with outpatient, inpatient, and ED specimen throughput (data not shown).

Table 2
Critical Values by Laboratory

Laboratory	No. (%) of Critical Test Results
Chemistry	25,733 (68.6)
Hematology	11,770 (31.4)
Total	37,503 (100)

Inpatient Critical Callbacks

Results for inpatients (which account for 52% of all tests) constituted 74.0% of critical callbacks; for ED patients (7% of all tests), 9.1%; and for outpatients (41% of all tests), 16.9%. Thus, on a per test basis, inpatient tests were 3.5 times more likely to result in a critical callback than outpatient tests. As shown in **Table 4**, the intensive care units (ICUs; medical, surgical, cardiac, neonatal, transplant, burn, neurosurgical, and pediatric) were frequent locations for inpatient critical callbacks, together accounting for 50.1% of all critical callbacks, despite representing only 14.1% of the total inpatient population (127/898 beds). The number of critical values per year per bed was 109.5 for ICU beds and 18.0 for non-ICU beds.

Owing to the complexity of inpatient care, critical test results may not directly reach the responsible caregiver but

Table 3
Critical Values by Test

Test	Critical Test Results	Percentage of All Critical Test Results*	Yearly Test Volume	Percentage of Test Volume With a Critical Result
Potassium	7,955	21.2	439,104	1.8
Partial thromboplastin time	5,467	14.6	183,768	3.0
Platelet count	3,104	8.3	490,068	0.6
Glucose	2,891	7.7	505,452	0.6
pCO_2 (blood gas)	2,346	6.3	140,832	1.7
pO_2	1,892	5.0	136,104	1.4
Total CO_2 (chemistry)	1,862	5.0	365,004	0.5
Prothrombin time	1,788	4.8	218,100	0.8
Toxicology/TDM drug levels	1,544	4.1	14,280	10.8
Osmolality	1,436	3.8	31,620	4.5
Total calcium	1,325	3.5	338,580	0.4
Hematocrit	1,270	3.4	495,156	0.3
pH	920	2.5	138,936	0.7
Phosphorus	914	2.4	207,840	0.4
Sodium	912	2.4	512,520	0.2
Ionized calcium	698	1.9	90,264	0.8
Magnesium	648	1.7	215,544	0.3
Glucose, CSF	171	0.5	2,796	6.1
Hemoglobin (blood gas)	169	0.5	73,608	0.2
WBC count	151	0.4	496,260	0.03
Total bilirubin (neonates)	40	0.1	9,500	0.4
Total	37,503	100.1	5,105,336	—

CSF, cerebrospinal fluid; TDM, therapeutic drug monitoring.
* Does not total 100.0% because of rounding.

DOI: 10.1309/R53XVC2U5CH6TNG8

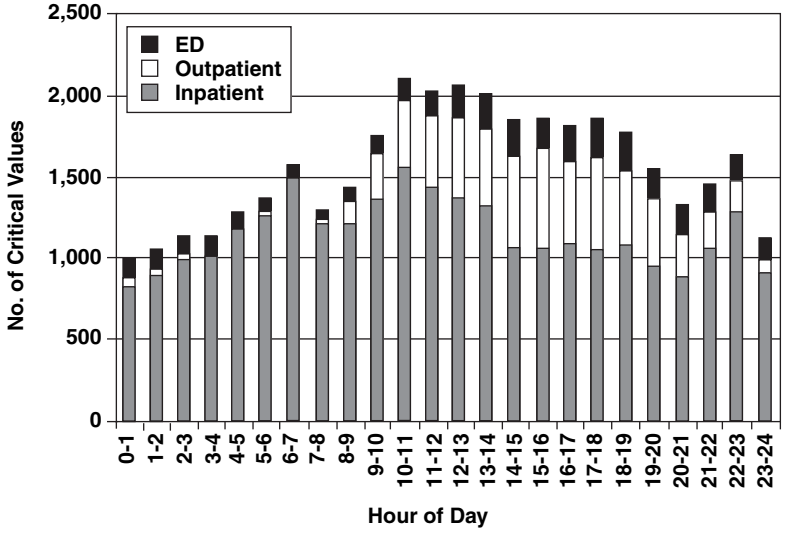

Figure 1 Critical values vs time of day. Distribution of critical value calls vs time (24-h clock) for the emergency department (ED), outpatients, and inpatients.

rather may be communicated to the caregiver via an operations associate (OA; clerical staff members who perform clinical support functions). We therefore wanted to examine the communication process from the OA to the responsible caregiver (physician or nurse). To examine the timeliness of reporting, we created a logbook that each inpatient floor maintained to monitor critical values. The OA documents in the logbook the time the call was received from the laboratory, patient identifiers, the test result, and the time the critical result information was communicated to the responsible caregiver. Critical results communicated directly to the licensed caregiver (without involving the OA) were not documented in the logbook because this information is already captured in the LIS callback application. We examined the logbooks for 29 inpatient care units for 1 month. During this period, 1,477 critical values were documented in the logbook. The mean on-floor communication time (OA to responsible caregiver) was 1.8 minutes (median, 1.0 minute). Increased communication times were observed on non-ICU floors compared with ICUs (ICU mean, 0.5 minute; non-ICU settings mean, 2.0 minutes; $P = .010$). This was likely due to the greater availability of caregivers in the ICU setting.

Critical Value Turnaround Time

The "in-laboratory" turnaround time for each critical value was determined to assess the timeliness of critical value reporting. For the 37,503 critical values, the mean time from the value entering the critical callback queue to the time when the critical value information was conveyed to the patient location or ordering clinician was 22 minutes, and the median time was 9 minutes (data not shown). Delays in critical value reporting correlated with testing performed on outpatients and testing ordered on requisitions lacking the name of the ordering clinician or the ordering location. Tests performed in settings where there is continuous technologist presence (eg, blood gases) were called back faster than tests performed in other areas. This information was useful as we began to implement measures to improve critical value reporting in all areas of the laboratory.

Table 4
Critical Values by Site

Location	No. (%) of Critical Test Results	No. of Beds	Critical Values per Year per Bed
Inpatient	27,744 (74.0)		
ICU	13,901 (50.1)	127	109.5
Non-ICU	13,843 (49.9)	771	18.0
Total	27,744 (100.0)	898	30.9
Outpatient	6,330 (16.9)	—	—
ED	3,429 (9.1)	—	—
Total	37,503 (100.0)	—	—

ED, emergency department; ICU, intensive care unit.

DOI: 10.1309/R53XVC2U5CH6TNG8

Examination of Critical Value Limits

To better understand our present upper and lower value limits for critical callbacks (eg, the limits for potassium of <2.8 and >6.0 mEq/L [<2.8 and >6.0 mmol/L]), we plotted the number of critical callbacks for each analyte vs the result value. This enabled us to examine the potential effect that changing the limits of critical callback would have on call volumes. Representative graphs of the critical value calls for potassium and glucose are shown in **Figure 2**. This information was used in conjunction with published literature and consultation with clinicians to propose changes to the critical callback policies to reduce the number of critical callbacks. For example, changing the lower limit callback value for glucose from less than 60 mg/dL (<3.3 mmol/L) to less than 45 mg/dL (<2.5 mmol/L) has resulted in 2,136 fewer calls per year (an overall reduction of 5.7% of all callbacks) **Figure 3**.

Discussion

In this report, we provide a comprehensive view of the critical value reporting process in a large academic medical

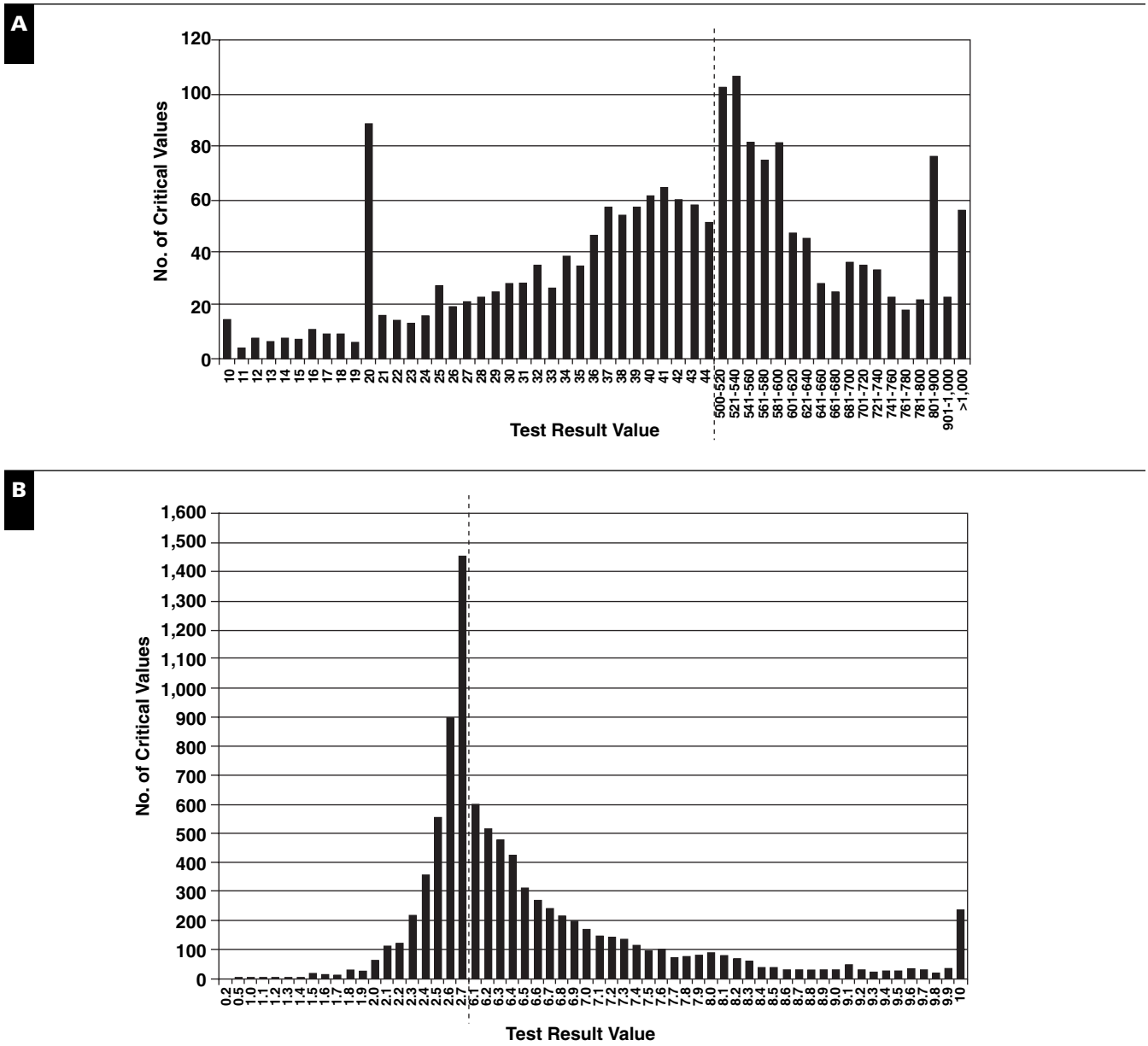

Figure 2 Critical value limit analysis for glucose and potassium. The number of critical value callbacks for glucose (**A**) and potassium (**B**) are plotted vs the test result value. The dotted line indicates the critical value limits for each test (glucose, <45 or >500 mg/dL [<2.5 or >27.8 mmol/L]; potassium, <2.8 or >6.0 mEq/L [<2.8 or >6.0 mmol/L]).

DOI: 10.1309/R53XVC2U5CH6TNG8

center. We provide details regarding the scope, volume, timing, and operational aspects of critical value reporting. Many of these parameters should be applicable to a variety of settings. This analysis provides a context for comparison and process improvement.

Increasing workload in the clinical laboratory makes it important to achieve efficient use of laboratory resources to maximize clinical benefits. Expansion of critical callback lists to include testing that does not meet the criterion of the "imminent danger" standard may dilute the urgency of a critical value call and lead to unnecessary interruptions for clinicians. For example, critical value calls for high creatinine levels will not be of clinical value for patients receiving dialysis and in many situations in which the high creatinine value is an expected finding. In addition, there are many clinical settings (chemotherapy, malignancy) in which the "critical" test result is expected and reporting of this value may not contribute to improved patient care. By applying this logic to other scenarios, we have not adopted critical callbacks for positive cardiac markers (creatine kinase-MB and troponin T). The marginal clinical usefulness vs the marginal resource cost should be considered carefully when the tests and cutoff limits for critical value reporting are determined. National standards have been published concerning critical value ranges.[8,9] These standards provide a benchmark against which the laboratory can compare and adjust its critical values list accordingly.

Communication by telephone, especially when performed by technologists, is a costly practice in terms of the resources required to complete the phone calls and document the process. For this reason, it is helpful to try to reduce the number of phone calls by careful review of the critical values list. In addition to determining which tests are to be included in the critical values list, another important strategy is to examine the consequences of changing the boundaries for critical value reporting. These boundaries must be defined in consultation with clinicians. Small changes in critical value reporting parameters may result in the addition or loss of thousands of phone calls for the laboratory staff.

Outpatient critical values present unique challenges in timely reporting to clinicians. One of the strongest correlates of delayed reporting of critical values was the specimen being obtained from an outpatient. Outpatient critical values are challenging to communicate to the responsible clinician because there often are different approaches in various practices for determining patient coverage. Unlike inpatients, there is no fixed patient location that can be phoned.

Another factor we identified as causing delays for outpatients was illegible or missing ordering provider information. As a result of this analysis, we have changed our medical policy to explicitly state that all requisitions must have an ordering provider and an ordering location printed on the requisition. We are in the process of communicating this to our caregivers. We also have instituted daily exception reports of critical values called back in times that exceed our threshold limit of acceptability (30 minutes). These reports are distributed to the laboratories and are being used to understand and remedy the root causes of delays in critical results reporting. We have noted that recent improvements in the critical value communication times have coincided with increased awareness of critical value monitoring. We presently are working with our outpatient practices to improve communication between the laboratories and the outpatient care centers.

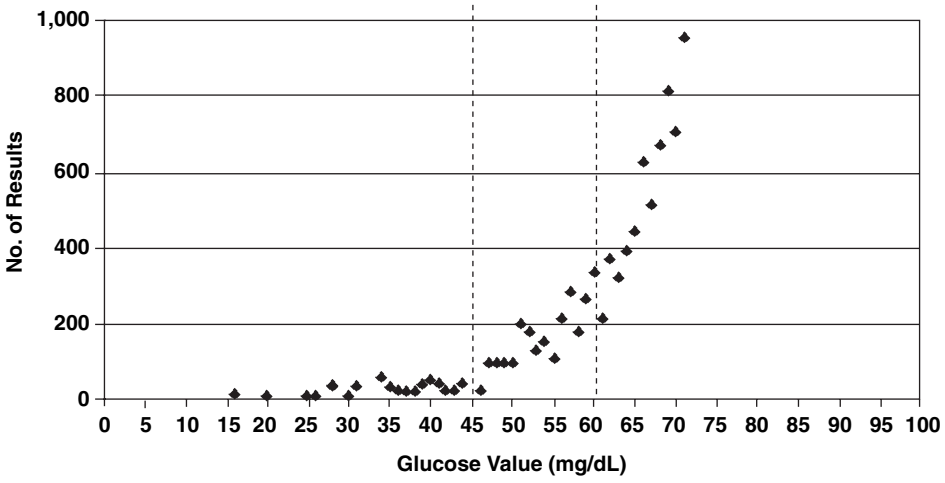

Figure 3 Glucose test results and critical value limits. Glucose values are plotted vs the number of results with that value for a 12-month period. The dotted lines indicate the 2,136 results falling between the previous critical value limit (<60 mg/dL [<3.3 mmol/L]) and the current critical value limit (<45 mg/dL [<2.5 mmol/L]). To convert conventional values (mg/dL) to Système International units (mmol/L), multiply by 0.0551.

DOI: 10.1309/R53XVC2U5CH6TNG8

Another contributor to delays in outpatient critical value reporting is the heterogeneity of the outpatient population, with specimens arriving from health centers, clinics, urgent care centers, dialysis centers, and physicians' offices. Each of these areas is likely to have a different call schedule, answering service, and cross-coverage procedure, making reliable communication with the responsible licensed caregiver challenging. The nature of outpatient specimen transport and processing often results in outpatient test results being generated in the evening when the outpatient clinic or physician's office is closed. The laboratory must have a mechanism to determine on-call coverage and work with outpatient practices to improve the communication processes.

The potential for technological solutions to improve the process of critical value reporting is evident in numerous reports.[10,11] The use of information technology to automatically communicate with the responsible provider has been demonstrated to reduce the critical value reporting time in controlled settings. For implementation of automated critical value reporting, interfaces from the LIS to technologies that facilitate bidirectional communication (such as e-mail or 2-way pagers) need to be developed. An important component in such a system is the ability of the automatic reporting system to reliably determine the identity of the responsible provider. At larger medical centers, this task can be challenging because there may be different coverage lists, tests ordered by consultants unknown to the primary caregiver, and patient transfers to different locations. An electronic reporting system potentially could create dangerous delays in communication if not properly implemented. The system needs to have an "acknowledgment" function such that the laboratory can ensure that the responsible caregiver received the result. Electronic systems also require an escalation procedure so that lack of acknowledgment of the critical result prompts an alternative approach for communication.

Development of LIS middleware with alert reporting software should permit highly nuanced approaches to critical value reporting in the near future. Rules-based logic can be applied to laboratory values to build alerts that take into account not only the result value, but also other related results, a change in the current test result from previous results (ie, delta checks), patient demographics, ordering provider, and other parameters to customize the alerting to the patient's condition and the needs of the clinical team for notification. For example, many oncology physicians do not want to be notified regarding patients with neutropenia. Similarly, there is little usefulness in notifying a diabetologist of low glucose values for patients seen in an outpatient clinic because many of these "critically low" results will be falsely low or no longer relevant. The ability to provide a physician-specific critical values list could eliminate a large number of unnecessary critical value calls. These systems, when interfaced with automated alerting systems, will have the potential to improve patient safety and provide more context-sensitive critical value reporting. At present, practical implementation of this scenario would be constrained by regulations (particularly the JCAHO National Patient Safety Goals) that require all critical results to be communicated and do not allow for more nuanced approaches.

From the Departments of [1]Pathology, [2]Medicine, and [3]Nursing, Massachusetts General Hospital, Boston.

Address reprint requests to Dr Lewandrowski: Clinical Chemistry, Bigelow Bldg, Room 510, Massachusetts General Hospital, 55 Fruit St, Boston, MA 02114.

References

1. Lundberg GD. When to panic over abnormal values. *MLO Med Lab Obs*. 1972;4:47-54.
2. Lundberg GD. Critical (panic) value notification: an established laboratory practice policy (parameter) [editorial]. *JAMA*. 1990;263:709.
3. Joint Commission on the Accreditation of Healthcare Organizations: National Patient Safety Goals. Available at: http://www.jcaho.org/accredited+organizations/patient+safety/npsg.htm. Accessed August 22, 2005.
4. Center for Medicare and Medicaid Services, Department of health and Human Services. Clinical Laboratory Improvement Amendments of 1988. 68 *Federal Register* 1047 (2003) (codified at 42 CFR §493.1291(g)).
5. Lum G. Assessment of a critical limit protocol for point-of-care glucose testing. *Am J Clin Pathol*. 1996;106:390-395.
6. Howanitz PJ, Steindel SJ, Heard NV. Laboratory critical values policies and procedures: a College of American Pathologists Q-Probes study in 623 institutions. *Arch Pathol Lab Med*. 2002;126:663-669.
7. Kuperman GJ, Boyle D, Jha A, et al. How promptly are inpatients treated for critical laboratory results? *J Am Med Inform Assoc*. 1998;5:112-119.
8. Kost GJ. Table of critical limits. *MLO Med Lab Obs*. 2004;36:6-7.
9. Burtis CA, Ashwood ER, Bruns DE. *Tietz Textbook of Clinical Chemistry and Molecular Diagnosis*. Philadelphia, PA: Saunders; 2005.
10. Bates DW, Pappius E, Kuperman GJ, et al. Using information systems to measure and improve quality. *Int J Med Inform*. 1999;53:115-124.
11. Tate KE, Gardner RM, Weaver LK. A computerized laboratory alerting system. *MD Comput*. 1990;7:296-301.

DOI: 10.1309/R53XVC2U5CH6TNG8