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Voluntary Electronic Reporting of Laboratory Errors: An Analysis of 37 532 Laboratory Event Reports From 30 Health Care Organizations

Laura K. Snydman, MD,[1] Beth Harubin, MS,[1] Sanjaya Kumar, MD, MSc,[2] Jack Chen, BM, BS,[2] Robert E. Lopez, MS,[1] and Deeb N. Salem, MD[1]

Abstract

Laboratory testing is essential for diagnosis, evaluation, and management. The objective was to describe the type of laboratory events reported in hospitals using a voluntary electronic error reporting system (e-ERS) via a cross-sectional analysis of reported laboratory events from 30 health organizations throughout the United States (January 1, 2000, to December 31, 2005). A total of 37 532 laboratory-related events were reported, accounting for 14.1% of all reported quality events. Preanalytic laboratory events were the most common (81.1%); the top 3 were specimen not labeled (18.7%), specimen mislabeled (16.3%), and improper collection (13.2%). A small number (0.08%) of laboratory events caused permanent harm or death; 8% caused temporary harm. Most laboratory events (55%) did not cause harm. Laboratory errors constitute 1 of 7 quality events. Laboratory errors often are caused by events that precede specimen arrival in the lab and should be preventable with a better labeling processes and education. Most laboratory errors do not lead to patient harm.

Keywords

laboratory errors, laboratory events, medical errors, quality events

Over the past decade patients have become health care consumers, with expectations of privacy, efficiency, convenience, and information. In addition, patients expect the health care system to be error free. Patient safety has become a quality measure, and health organizations are responding.[1]

The Institute of Medicine (IOM) defines a medical error as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim."[2p1] Since the IOM released the 1999 report, *To Err Is Human: Building a Safer Health System*, which discussed preventable medical errors and the importance of developing safer systems of care, the topic of medical errors has become commonplace.[2] In 2001, the IOM released its follow-up report, *Crossing the Quality Chasm*, which provided a rationale and a framework for the redesign of the US health care system.[3] To move this initiative forward, we must have data on the types of errors occurring.

Laboratory medicine is a critical aspect of a patient's hospitalization and is essential for diagnosis, evaluation, and management. It is estimated that clinical laboratories contribute to nearly 23% of all reported errors.[4] Laboratory (ie, blood bank, chemistry, hematology, microbiology, specimen receiving/processing area) errors may cause patients avoidable physical, emotional, and mental discomfort as well as costing time and money. A study at Valley Hospital in Ridgewood, New Jersey, found that 255 steps were needed to obtain laboratory data on a patient from the time a physician writes the order through storage of the sample. Analysis of these steps found that 63 of the 255 steps were a potential source of error.[5]

The College of American Pathologists (CAP) has been monitoring errors in pathology and laboratory medicine since its inception in 1946, long before the 1999 IOM

[1]Tufts Medical Center, Boston, MA
[2]Quantros Inc, Milpitas, CA

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Corresponding Author:
Deeb N. Salem, MD, Department of Medicine, Tufts Medical Center, 800 Washington St, Box 079, Boston, MA 02111
Email: dsalem@tuftsmedicalcenter.org

report. In 1989, the CAP Q-Probes program was initiated, followed by the Q-Tracks program in 1998. There are more than 130 interlaboratory studies to date, and both programs have provided valuable information on error rates.[6] It has been well documented that most laboratory errors result from a process that occurs prior to the specimen arriving in the laboratory.[7-9] To decrease laboratory errors, we must first understand their epidemiology, occurrence, and timing. Only then will we be able to examine the process behind these errors and effect clinical change. This article presents the results of an analysis of 37 532 laboratory-related errors from 30 health care organizations and provides a rich resource for hospitals, laboratory administrators, health care researchers, and others who wish to study, understand, and prevent laboratory errors and improve patient care.

Methods

Reporting System

The event reporting system is a secure, Web-based program available on any hospital computer that is linked to the network; it was previously described by Milch et al.[10] After logging onto the electronic error reporting system (e-ERS), the hospital employee enters the details of the event when prompted for certain information. Information requested includes the date and time the event occurred, location of the event, type of event, and impact of the event. When the completed report is submitted, an event number is generated. Although reports are not anonymous, the events are peer-review protected at each health care organization. Access to event reports is limited to specified health care personnel, who are notified by e-mail that an event has been entered and who can then review and respond to the event. Data entry using this e-ERS requires approximately 10 minutes for each event.[11]

Institutions

We evaluated all reported laboratory events from 30 health care organizations throughout the United States that voluntarily implemented a commercially available, Web-based e-ERS (DrQuality; Quantros, Inc, Milpitas, CA) as a component of quality improvement efforts. A health care organization consisted of an individual hospital or a hospital system. The types of institutions implementing this e-ERS were described in a previous paper.[11]

Report Definitions

Category of event. One of the authors (LKS) classified each laboratory event into 1 of 3 areas: preanalytic, analytic, and postanalytic. The preanalytic phase begins when the test is ordered by the physician and ends when the sample is ready for analysis. The analytic phase begins when the specimen is prepared for testing and ends when the test result is interpreted in the laboratory and verified as ready to report. The postanalytic phase begins when the test results are released to the clinician and ends when the clinician interprets the results and makes diagnostic and therapeutic decisions accordingly.[7]

Level of impact (LOI). Each event report was categorized into a LOI. Persons reporting the event determined the level of harm. The classification system is as follows: (0) unknown; (1) safety/environment (unsafe practices and/or conditions in the institution); (2) near miss (error/event corrected or averted before it reached the patient); (3) no harm—no increased monitoring; (4) no harm—increased monitoring; (5) temporary harm—no treatment; (6) temporary harm—minor treatment; (7) temporary harm—major treatment (temporary or reversible effect on patient); (8) permanent harm; (9) near death; or (10) death. For the purposes of this study, we differentiated between events that did not cause harm (LOI 3 and 4), events that caused temporary harm (LOI 5, 6, and 7), and events that caused permanent harm, near death, or death (LOI 8, 9, and 10). Figure 1 illustrates the classification system. DrQuality's LOI Index is very similar to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index. Although the NCC MERP index may be seen as the industry standard, we decided not to use the NCC MERP index because it was created for use in medication error reporting, not laboratory error reporting. In addition, we agree with Henriksen et al[8p176] that the taxonomy is not yet standardized and that "it is seldom possible to map terminologies of the different classification systems to each other because of differences in granularity (eg, the NCC MERP Taxonomy of Medication Errors has a very detailed classification of product labeling issues as a cause of error that is not matched by the codes in DoctorQuality Inc's Risk Prevention and Management system) or asymmetries in classification (ie, assigning terms under different categories in different terminologies)."

Data Analysis

All laboratory-related events that occurred from January 1, 2000 through December 31, 2005 were analyzed. All completed reports were placed in a single database for this analysis. Hospitals were de-identified to study investigators. Data received for each report included position of employee reporter, category of event, and impact level on the patient. The data were analyzed and results interpreted by 1 author (LKS), who does not have ties to commercial companies associated with medical events reporting systems. The commercial entity from which the

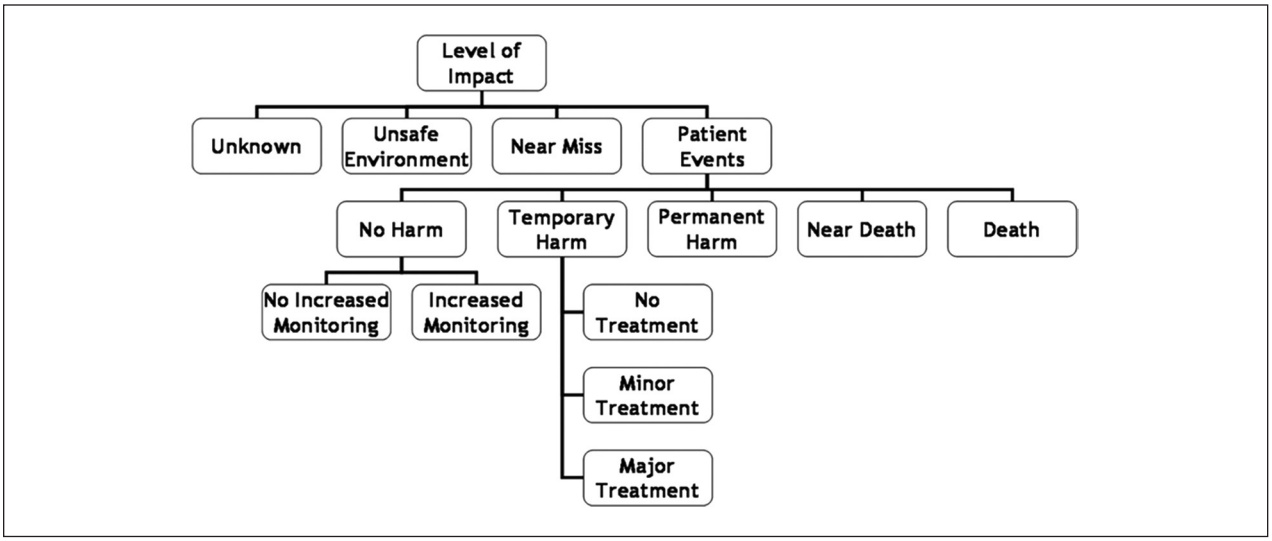

Figure 1. Diagram of classification of impact level

data were obtained was not involved at any level in data analysis or interpretation of results and did not provide financial support for the study.

Results

A total of 266 224 event reports from 30 health care organizations were evaluated for the period from January 1, 2000 through December 31, 2005; 14.1% were laboratory-related events (37 532). In all, 15 of 30 health care organizations reported 98.8% of all laboratory-related events. These 15 hospitals ranged in size from 25 to 973 beds and contributed 164 to 6285 laboratory-related reports (median 1632). These 15 organizations were located in 13 geographically dispersed states and consisted of 51 hospitals. In all, 8 of these organizations were part of hospital systems comprising several facilities; 10 of the 15 organizations were inpatient facilities, and 5 had both inpatient and outpatient facilities. There are 2 reasons why 50% of the health care organizations contributed the majority of the data: (1) these organizations were more rigorous in reporting errors and (2) the e-ERS had been in use at these organizations for a longer period of time and, therefore, staff were more familiar with the program.

Reporters

The person who reported the laboratory event specified his or her job title. Reporters were grouped into "laboratory technologist," "administrator," "nurse," "physician," or "other." The laboratory technologist group included any reporter who used the terms *technician, laboratory*, or *phlebotomist* in their title but excluded imaging technicians and dialysis technicians. The administrator group included any reporter who used the term *administrator, director, manager, supervisor*, or *coordinator* in their title but excluded case managers and clinical care coordinators. The nurse group included any reporter who used the term *nurse* in their title but excluded nursing assistants. The physician group included any reporter who used the term *physician, attending, house staff, resident*, or *fellow* in their title but excluded physician assistants. The remaining reporters were classified as "other" and included a variety of employees (ie, administrative assistants, clinical care coordinators, medical assistants, pharmacy staff, physician assistants, quality management staff).

Of all laboratory-related reports, laboratory technologists reported 38.8%, administrators reported 28.8%, nurses reported 9.9%, and physicians reported 0.8%.

Event Classification

Laboratory errors were separated into 3 components: preanalytic, analytic, and postanalytic. Preanalytic errors accounted for 81.1% of all laboratory errors; analytic and postanalytic errors accounted for 6% and 5.2% of all laboratory errors, respectively; 7.7% of laboratory errors could not be classified. The top 3 preanalytic errors were specimen not labeled, specimen mislabeled, and improper collection. The top 3 postanalytic errors were delayed report, critical results not reported, and misinterpreted results (Table 1).

Impact on Patients and Patient Care

Analysis of the consequences of a laboratory error (Figure 2) revealed that approximately 0.08% (30/37 532)

Table 1. The Most Common Reported Events Within Each Category

Category of Event	Description of Lab Error	Percentage of Total Lab Errors (No.)
Preanalytic (n = 30 431)	Specimen not labeled	18.7 (7003)
	Specimen mislabeled	16.3 (6132)
	Improper collection of specimen	13.2 (4964)
	Delay in test/ treatment	6.6 (2463)
	Specimen label incomplete	4.7 (1760)
	Incorrect patient ID used	4.4 (1655)
	Clotted specimen	4.1 (1546)
	Quantity not sufficient	2.9 (1101)
	Specimen-requisition mismatch	2.9 (1088)
	Specimen lost/not received	2.2 (821)
Analytic (n = 2264)	Test not performed as ordered	5.1 (1927)
	Incorrect test performed	0.9 (337)
Postanalytic (n = 1946)	Delayed reporting of critical results to clinician	3 (1129)
	Critical results not reported	0.9 (328)
	Misread/ Misinterpreted results	0.7 (265)
	Incorrect results reported	0.5 (183)
	Incorrect reading of test result	0.1 (32)

of laboratory events caused permanent harm, near death, or death (Table 2). Nearly 8% (3002/37 532) of laboratory events caused temporary harm, and 55% (20 602/37 532) did not cause harm to the patient. The LOI was not reported for 9.9% (3712/37 532) of events; 14.4% (5403/37 532) of events were related to safety/environment (unsafe practices and/or conditions in the institution), and 12.7% (4783/37 532) were considered "near misses" (averted before reaching the patient).

In Table 2, we see that a χ^2 value of 311.33, with 6 degrees of freedom, results in a P value <2.2e−16. The P value of Pearson's χ^2 test remains close to zero regardless of how the counts are redistributed. This indicates that the distribution of the occurrences between LOI and type of error are dependent on each other.

Discussion

The monitoring of medical errors and adverse events has become a focus for health care organizations. To detect, track, and evaluate adverse events and errors, many organizations have implemented voluntary electronic reporting systems. This study provides data regarding the makeup and severity of laboratory errors from 30 health care organizations that use a voluntary e-ERS.

Our study presents several important findings. First, laboratory errors are a common cause of voluntarily reported quality events. The majority of laboratory errors are caused by events that precede specimen arrival at the lab and thus should be preventable with better labeling and education. A number of other studies of laboratory errors have found preanalytic errors to be the most common error type detected.[7,9,11] The preanalytic error rates we report in this study are similar to the rates reported in CAP Q-Probes studies. Howanitz[6] reported that 6.5% of blood specimens were from incorrectly identified hospitalized patients, which is similar to the 4.4% in our study (Table 1). Valenstein et al[12] further classified identification errors into errors that were detected before results were released (85.5%) and errors that were detected postverification (14.5%) using Q-Probes data of 6705 identification errors from 120 institutions. Their results also showed that 55.5% of identification errors were from errors in primary specimen labeling, compared with 39.7% in our study (Table 1).[12] By better understanding the profile of laboratory errors, specific interventions can be designed to improve patient safety. For example, a study at Children's Hospital and Regional Medical Center (CHRMC) in Seattle, Washington, found that 61% of preanalytic errors were specimen-labeling errors. As a result, CHRMC implemented an awareness campaign and was able to reduce specimen labeling errors by 41%.[13]

Second, more than one third of reporters of laboratory events are laboratory technologists. This finding is not surprising given that laboratory technologists are trained in the routine use of daily quality control.[14] Administrators report more than a quarter of laboratory events. The large percentage of administrators reporting laboratory events may reflect this group's increased awareness of the importance of reporting adverse events. Administrators also may have more of a vested interest in the success of the health care organization, which relies on the ability of the organization to identify errors and then institute standardized procedures to prevent mistakes. Although nurses report nearly half of all medical errors, they report only 10% of laboratory errors.[10] This difference could result from the increased number of reports submitted by laboratory technologists and administrators. It has been well documented that physicians rarely report medical errors,

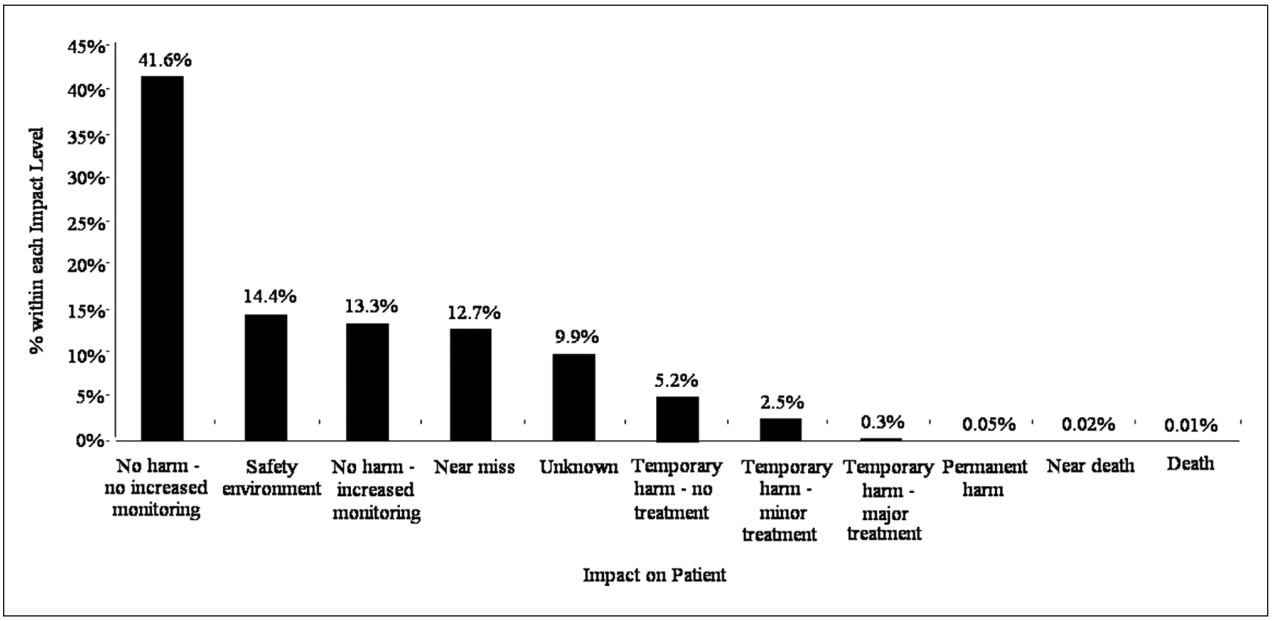

Figure 2. Level of impact of laboratory error

Table 2. The Type of Laboratory Error by Level of Impact (LOI)[a]

Level of Impact	Preanalytic	Analytic	Postanalytic	Other
Did not cause harm: LOI 3 and 4 (n = 20 599)	82.6% (17 015)	6.4% (1309)	4.1% (838)	7% (1437)
Temporary harm: LOI 5, 6, and 7 (n = 3002)	73.6% (2208)	10% (300)	9% (269)	7.5% (225)
Permanent harm: LOI 8, 9, and 10 (n = 30)	43.3% (13)	10% (3)	43.3% (13)	3.3% (1)

[a]Pearson's χ^2 test = 311.3285; *df* = 6; *P* value < 2.2e-16.

and laboratory errors are no exception.[10] Prior studies have hypothesized the reasons why physicians contribute only 1% to 2% of event reports: Physicians have less education regarding the importance of reporting medical errors, they feel personally responsible for harm caused to a patient, they fear repercussions from the patient or institution, or they may not want to implicate a colleague.[10,15] However, there is another reason why physicians constitute the smallest group when it comes to reporting laboratory errors. The methods used to detect laboratory errors generally bypass physicians. Preanalytic errors are the most common, and these types of errors are generally recognized by laboratory technologists and never reach the clinician.

Third, the vast majority of laboratory errors do not lead to harm and rarely cause permanent harm or death. However, 8% of laboratory errors were reported to cause temporary harm. Given that most laboratory errors are preanalytic and related to labeling errors, this statistic is unacceptable and mandates that significant effort be taken to reduce this number. Although only 0.01% of laboratory errors lead to death, this translates into 1 death for every 10 000 laboratory errors—a death that most likely could have been prevented. Bologna et al[5] found that standardization initiatives using a handheld patient identification system reduced critical errors by 83%. They also found that the intervention resulted in a 13% reduction in time spent collecting the specimen, a 55% reduction in time spent receiving the specimen, as well as decreased costs and increased financial return.[5] Howanitz et al[16] found that mean wristband error rates decreased from 7.4% to 3.05% over a 2-year period, during which time participants were continuously monitored using the CAP Q-Tracks program. Another CAP Q-Probes study evaluated the reporting of critical values and found that more than 45% of the critical values were unexpected, and immediate action was taken for more than 60%.[17] It also was found that it took 6 minutes and 12 minutes to locate an appropriate person to receive the critical value for inpatients and outpatients respectively.[17] However, almost 5% of the critical value calls were abandoned because an appropriate caregiver was not found.[17]

Fourth, most of the preanalytic lab errors resulted in errors that did not cause harm to the patient (LOI 3 and 4) or caused only temporary harm (LOI 5, 6, and 7), whereas postanalytic lab errors were more likely to cause permanent harm, near death, or death (LOI 7-10; Table 2). Knowing that postanalytic errors are most associated with the greatest harm to patients could help laboratory managers and quality improvement teams dedicate more time and resources to postanalytic procedures to best reduce the overall number of serious harmful errors.

Finally, if we extrapolate from data from our institution, we find a 0.04% (5986/15 000 000) error reporting rate when it comes to laboratory errors. Thus, the vast majority of laboratory tests are performed without incident.

There are several limitations of our study. Although the e-ERS is available on any computer connected to the hospital network, there is potential for underreporting of events; we did not attempt to identify laboratory errors by other methods. Laboratory errors may be more significantly underreported than other types of medical errors (eg, medication errors) because most laboratory errors are less likely to cause harm, and staff may be less likely to spend 10 minutes filling out the form when the error is clinically insignificant. As with any voluntary reporting system, reporting bias is a concern, and this is demonstrated by the low rate of reporting by physicians. Our second largest category of laboratory events were events that could not be classified because of limitations of the e-ERS, which gave the reporter the option of choosing "other" without requiring further specifics. Finally, results are limited by subjective designation of level of harm by reporters. This may be of increased significance when looking at laboratory errors, given that more than one third of the errors were reported by laboratory technicians who likely do not know whether patients were harmed subsequently. Although there are limitations to using an e-ERS, this type of system for reporting errors is more practical than paper forms and allows for more immediate feedback, thus improving patient care in a timely manner.

In conclusion, although laboratory errors are common, the vast majority do not lead to harm and rarely cause permanent harm or death. The majority of laboratory errors are caused by events that precede specimen arrival in the lab and thus should be preventable with better labeling and education. Monitoring of laboratory errors is imperative, so that quality management systems can be implemented to improve patient comfort and patient safety and decrease the cost of care.

Authors' Note

Data from this study were presented at the Society of General Internal Medicine New England Regional Meeting in the form of a poster presentation on March 23, 2007 (Boston, MA), and at the Society of General Internal Medicine 30th Annual Meeting in the form of an oral presentation on April 28, 2007 (Toronto, Canada). Dr Kumar is the Chief Medical Officer at Quantros Inc, which produces DrQuality, the electronic medical error and adverse event reporting system used in this study. Mr Chen is a statistician at Quantros Inc. Quantros did not provide financial support for this study and was not involved in the analysis or interpretation of results.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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