Errors in Laboratory Medicine

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Background: **The problem of medical errors has recently received a great deal of attention, which will probably increase. In this minireview, we focus on this issue in the fields of laboratory medicine and blood transfusion.**

Methods: **We conducted several MEDLINE queries and searched the literature by hand. Searches were limited to the last 8 years to identify results that were not biased by obsolete technology. In addition, data on the frequency and type of preanalytical errors in our institution were collected.**

Results: **Our search revealed large heterogeneity in study designs and quality on this topic as well as relatively few available data and the lack of a shared definition of "laboratory error" (also referred to as "blunder", "mistake", "problem", or "defect"). Despite these limitations, there was considerable concordance on the distribution of errors throughout the laboratory working process: most occurred in the pre- or postanalytical phases, whereas a minority (13–32% according to the studies) occurred in the analytical portion. The reported frequency of errors was related to how they were identified: when a careful process analysis was performed, substantially more errors were discovered than when studies relied on complaints or report of near accidents.**

Conclusions: **The large heterogeneity of literature on laboratory errors together with the prevalence of evidence that most errors occur in the preanalytical phase suggest the implementation of a more rigorous methodology for error detection and classification and the adoption of proper technologies for error reduction.**

Clinical audits should be used as a tool to detect errors caused by organizational problems outside the laboratory.
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Measuring and improving laboratory-related patient outcomes require methods that relate the total quality of laboratory information to more effective patient management, including diagnosis, treatment of disease, clinical monitoring, and disease prevention. The improvement in analytical quality, documented through proficiency testing, should guarantee that the actual performances of clinical laboratories are suitable for improving a patient's health. Furthermore, increased attention to patients' needs is demonstrated by efforts to improve the quality of the entire service provided, e.g., reduction of the turnaround time (TAT). However, improvement of laboratory performance does not automatically indicate a reduction in the number of errors, both analytical and organizational. Even certification or accreditation processes focus attention more on the general performance of the laboratory than on events such as errors that, by their very nature, are considered exceptional. Moreover, the lack of a universally accepted definition of error and above all of "allowable error rate", reduces the possibility of evaluating the impact of laboratory error on patient outcomes.

Although there is abundant scientific literature dealing with increased laboratory quality (mainly analytical), the literature on errors in laboratory medicine is scarce. One reason for this, in addition to the insufficient attention paid to the problem, is the practical difficulty in reporting and measuring the number of errors.

In fact, there are several limitations in the study designs of reports dealing with the frequency and types of mistakes in the clinical laboratory.

The first limitation is that most of the studies focus simply on analytical errors, which represent only a percentage of the errors in the total testing process, which includes all pre-, intra-, and postanalytical phases. Other studies are based on methodologies, such as the split-specimen design, that are insensitive to total testing process problems that can occur before specimens are collected and after results are obtained by the analytical process *(1, 2)*.

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The second limitation is that it is possible, even probable, that the most frequent preanalytical errors are represented by an inappropriate choice of laboratory tests or panel of tests and that most postanalytical errors derive from inappropriate interpretation and utilization of laboratory results. Although large differences in laboratory test requests and utilization between hospitals, even within the same country, have been described recently (3), a systematic review of laboratory clinical audits has demonstrated that many studies identifying inappropriate laboratory use are based on implicit or explicit criteria not meeting methodologic standards (4).

Regarding the postanalytical phase, only a few studies are available that demonstrate the inappropriate utilization of or response to laboratory results. It has recently been demonstrated that the introduction of new technologic facilities (online connection between laboratory and wards) without proper organization can worsen, rather than improve the communications between laboratories and clinicians (5). The lack of immediate notification and/or clinical utilization of a critical value can have an effect on outcome as negative as a wrong result. As pointed out by Lundberg in an outstanding editorial in *JAMA* (6), proper interpretation and action must be accomplished before the laboratory test loops are actually completed.

The third limitation is that, apart from a reluctance in reporting their own errors, it is extremely difficult for laboratories to identify all errors because many errors will neither produce detectable abnormal results nor raise questions for the user. Although their observations were not based on actual data, Goldschmidt and Lent (7) estimated that up to 75% of errors produce results still within the reference intervals, that ~12.5% produce wrong results that are so absurd that they are not considered clinically, and that the remaining 12.5% of laboratory errors may have an effect on patient health.

The fourth limitation is that new pathophysiologic insights and the development of highly specific and sensitive laboratory tests have changed the relationship between laboratory information and the gold standards. This is the case for myocardial damage in acute coronary syndromes, in which the measurement of cardiac troponins is the method of choice for detecting small myocardial injuries. The same is true for molecular analyses to evaluate disease susceptibility. In this and other clinical situations where it is difficult or impossible to compare laboratory results to gold standards, possible errors should be identified by evaluating the relationship between laboratory information and medical outcomes.

In contrast to the above-described situation, which was derived essentially from the scientific literature, "errors in medicine", including laboratory mistakes and problems at blood banks, are frequently cited by the mass media even if the attention is especially driven by errors in other healthcare sectors (e.g., drugs or surgery). In many of these reports, it is suggested that the reported errors are only the tip of the iceberg and that the consequences on patient outcome are likely to be worse than described. For this reason, we reviewed the scientific literature on errors in laboratory medicine and blood banks.

For laboratory medicine, we searched the MEDLINE database from January 1994 to June 2001 by crossing several headings: "laboratories, diagnostic services"; "chemistry, clinical"; "diagnostic errors"; and "medical errors". All articles with the words "blunders OR problems OR errors OR mistakes AND laboratory" in the title were also selected. Additional hand searching was performed, starting with the references of the selected papers. Finally, only articles reporting information on the total testing process (including the preanalytical, analytical, and postanalytical phases, not just one of them) in which data were obtained by direct collection (not just by questionnaires) were chosen and are compared in Table 1.

For blood banks, we searched the MEDLINE database from January 1992 to June 2001 by crossing several headings: blood transfusion/st (standards); blood group, incompatibility/co (complications); blood transfusion/ae (adverse effects); quality of health care; quality control quality assurance; health care/sn (statistics & numerical data); quality assurance, health care/og (organization & administration); quality assurance, health care/st (standards); safety; medication errors; and patient identification systems/st (standards). Starting from these results, we performed additional hand searching and selection. The results are presented in Table 2 and represent only those studies including more than three hospitals or a data collection period longer than 1 year. Only the most recent literature was analyzed because advances in laboratory informatics, automation, and analytical quality would make comparison to older studies nearly impossible (see also Table 3).

The most relevant features of the studies involving laboratory errors are summarized in Table 1: (*a*) data collection period; (*b*) number of tests considered; (*c*) number of patients involved; (*d*) total number of errors and their relative frequencies; (*e*) distribution of errors in the preanalytical, analytical, and postanalytical phases; (*f*) errors caused by patient misidentification; and (*g*) effect of errors on patient outcome. The findings confirm that there is a very limited number of studies on this topic and that those that exist are very heterogeneous. These studies used different data collection approaches [process analysis (*8*), audit and questionnaires (*9*), and collection of complaints (*7*)], the time span for data collection ranged from 3 months to 10 years, and the laboratory sectors examined were very different. Another obstacle to comparing these studies or reaching general conclusions is that in some reports, the errors are indexed to patients, whereas in others they are indexed to tests performed. Data have been partially re-elaborated to calculate frequencies, to divide them into the phases of the working process, and to harmonize the categories of relevance of the effect on patient outcome. It is evident from the data

Table 1. Review of the literature on laboratory errors.

Sector of the laboratory	Lapworth and Teal (10) Clinical chemistry	Goldschmidt and Lent (7) Whole laboratory	Nutting et al. (36) Primary care	Plebani and Carraro (8) Stat laboratory	Stahl et al. (37) Whole laboratory	Hofgärtner and Tait (9)	
						Molecular genetic tests onsite survey (2 laboratories)	Molecular genetic tests questionnaire (101 sent, 42 respondents)
Data collection period	1 year	6 years	6 months	3 months	3 years	10 years	1 year
No. of tests	~997 000	ND[a]	ND	40 490	676 564[b]	4234	88 394
No. of patients	~249 000	ND	160 714	ND	ND	ND	ND
No. of errors	120	133	180	189	4135[b]	16	293
Frequency	0.05% of patients		0.11% of patients	0.47% of test results	0.61%[b] of test results	0.38% of test results	0.33% of test results
Preanalytical phase	31.6%	53%	55.6%	68.2%	75%[b]	44%	60%
Analytical phase	31.6%	23%	13.3% overall (4.4% if referral laboratory; 40% if POCT)	13.3%	16%[b]	31%	19%
Postanalytical phase	30.8%	24%	30%	18.5%	9%[b]	12.5%	15%
Multiple phases	6%					12.5%	6%
Identification errors	41 (34%)	77 (58%)	ND	5 (2,6%)	ND	ND	ND
Impact on patient outcome	ND						
None		43%		74%			63.4%
Mild		23% (delays)	13%	19.6% (further investigations)		25%	20%
Moderate		26% (potential damage)	13%	6.4% (inappropriate therapy modification)		50%	10.2%
Severe		8% (erroneous medical interventions)				25%	6.4%
Very severe		None					

[a] ND, not defined; POCT, point-of-care testing.
[b] Mean values of the 3 years.

Table 2. Review of transfusion errors.

Transfusion-related studies

	Renner et al. (38)	McClelland and Phillips (39)	Linden and Kaplan (40)	Shulman et al. (32)
Data collection period	4 weeks	2 years	22 months	6-month pilot study followed by 2-year main experience
Sample description	712 hospitals (US)	245 hospitals (UK)	285 regulated facilities (US)	2000-bed hospital (US)
Number of observations	Patient wristbands checked on 2 463 727 occasions	ND	1 784 641 red cell transfusions	35 000 transfusions/year
Results and patient outcome	67 289 errors (2.7%)	Total incidents, 111 (1/29 000 transfusions); deaths, 6 (1/550 000 transfusions); morbidity, 12 (1/275 000 transfusions); no adverse effect, 93 (1/36 000 transfusions)	Total errors during the study period, 104; ABO-incompatible transfusions, 54 (1/33 000); ABO-compatible errors (estimated), 96 (1/19 000)	ABO-incompatible transfusion, 1/6000 transfused patients
Types/causes/ sources of error	Absent wristband, 49.5%; multiple wristbands, 18.3%; incomplete data, 17.5%; partly erroneous data, 8.6%; illegible data, 5.7%; wrong wristband, 0.5%	Wrong blood tube, 23; laboratory errors, 6; transfused wrong blood, 82	Outside blood bank, 61 (45 patient misidentification); in blood bank and outside, 18; in blood bank, 25	Major cause of errors, misidentification

shown that the collection method has a very strong influence on both the prevalence and the error types. For example, when data collection was based on complaints (7) or on more or less fortuitous finding of blunders (10), the errors reported were mainly attributable to misidentification, and their number was very low: 133 errors in 6 years (7) or 0.05% (10). On the other hand, when a careful review of the whole working process was performed (8), the number of errors increased substantially (189 in 3 months, 0.47% of the test results). In this last report (8), misidentification errors represented only 2.6% of all errors, but their absolute frequency was more than double that reported by Lapworth and Teal (10). The heterogeneity of the literature is even more obvious in Table 3, where only the frequencies of errors from these and older studies are reported.

One common finding in this review of data on laboratory errors is that even when different study designs, patient numbers, and discovery techniques were used, the distribution of errors across the different phases of the entire testing process was very similar. This comes through despite the large differences in actual error frequencies. In particular, all available studies demonstrated that a large percentage of laboratory errors occur in the pre- and postanalytical phases, with fewer mistakes occurring during the analytical step. Indirect evidence of the importance of the preanalytical phase stems from the

results of several recent studies. In the College of American Pathologists Q-Probe study (11) performed in 660 institutions, a total of 5514 of 114 934 outpatients requisitions (4.8%) were associated with at least one type of order entry error. In 1658 (1.4%) of the requisitions, one or more tests on the requisition were not ordered in the laboratory computer, whereas in 1221 cases (1.1%) at least one test was ordered in the computer that had not appeared on the requisition. A total of 2130 requisitions (1.9%) contained one or more physician name discrepancies between the requisition and the laboratory computer entry, Finally, in 943 requisitions (0.8%), an incorrect test priority was entered for at least one of the requested tests. In an Australian survey on transcription and analytical errors, the transcription error rate was up to 39%, the most frequent types of errors being associated with misidentification of the requested tests, the requesting doctor, and/or the patient. The laboratory with the worst performance had errors in 46% of requests, but even the three best-performing laboratories achieved an error-free reporting of only ≥85%, with only one achieving 95% (12). Another indirect indicator of the importance of preanalytical processes stems from studies that have demonstrated that the evaluation of specimen adequacy is a critical preanalytical factor affecting test result accuracy and usefulness (13).

Shown in Table 4 are the errors, relative only to the

Table 2. Continued.

Transfusion-related studies

Taswell et al. (41)	Baele et al. (22)	Linden (42)	Williamson et al. (43)	Linden et al. (44)
10 years (1982–1992)	15 months	5 years (New York State Department of Health); 1 year FDA[a]	2 years (1996–1997) (1996–1998)	10 years (1990–1999)
1 hospital (US)	3 teaching hospitals (Belgium)	ND (US)	1996–1997: 94 hospitals; 1997–1998: 276 hospitals (UK)	256 transfusion services (US)
ND	808 patients of 1448 undergoing surgery were transfused with 3485 units of RBC or FFP	ND	3 400 000 red cell transfusions	9 000 000 transfusions
Overall error rate, 20–30/ 10 000 procedures; identification, 2.2/10 000; performance, 15.5/ 10 000; transcription, 7.9/10 000; storage and retrieval 2.7/10 000	Incidence of errors, 165 (1/21 transfusions)	Deaths from ABO-incompatible transfusion, 1/1 700 000 units in New York State; 1/1 300 000 units in US, (FDA)	Errors, 191 (1/18 000); deaths 9 (1/199); major morbidity, 42 (1/199); minor or no morbidity, 136 (1/ 199); death attributable to underlying condition, 12 (1/199)	
Identification errors, 1–3/ 10 000 procedures; performance, 15–17/ 10 000; transcription, 5–11/10 000	165 errors/3485 transfusions (misidentification, 7; misrecordings, 61; mislabelings, 6; failure to document transfusions, 83; other, 8)			Administration to the wrong recipient, 38%; phlebotomy errors, 13%; blood bank errors, 29%; multiple errors, 15%; others, 5%

[a] FDA, Food and Drug Administration; ND, not defined; RBC, red blood cells; FFP, fresh frozen plasma.

preanalytical phase, detected in the San Raffaele Hospital Laboratory in 1 year. All the preanalytical problems that prevented us from reporting a result were automatically collected and divided by in- and outpatients. The data indicate the number of missing test results attributable to a specific type of preanalytical problem, not the number of problematic samples (e.g., a single hemolyzed tube could have caused the absence of 20 or more results). The difference between in- and outpatients is noteworthy: there were a total of 15 503 errors in 2 583 850 test results (0.60%) for inpatients vs 792 errors in 2 032 133 tests results (0.039%) for outpatients. There are multiple reasons for this difference: (*a*) direct control of sample drawing for the outpatients vs blood drawing performed by ward personnel, who have a high degree of turnover and lower skill, and (*b*) the higher complexity of the

Table 3. Error rates in clinical laboratories.

One identified error every	
33–50 events	McSwiney and Woodrow (45)
50–100 events	Souverijn et al. (46)
330 events	Chambers et al. (47)
1000 events	Boone (48)
8300 laboratory results or 2000 patients	Lapworth and Teal (10)
900 patients	Nutting et al. (36)
214 laboratory results	Plebani and Carraro (8)
164 laboratory reports	Stahl et al. (37)
283 laboratory results	Hofgartner and Tait (9)

Table 4. Types of preanalytical errors registered during the year 2000 at the Laboratory of San Raffaele Hospital.

	No. of missing results	
Type of error	Inpatients	Outpatients
Hemolyzed sample	8494	256
Insufficient sample	3256	102
Incorrect sample	1824	289
Clotted sample	792	80
Incorrect identification	287	2
Lack of signature (blood group)	266	
Empty tube	238	8
Lack or wrong compilation of the accompanying module	120	
Sample not on ice	75	6
Tube broken in the centrifuge	57	36
Test not reserved	31	
Urine not acidified	24	
Open container	20	13
Module without signature	14	
Urine volume not indicated	5	
Total	15 503	792

examinations performed and multiple blood drawings for the inpatients.

Guidelines for collecting samples and for evaluating submitted specimens are therefore essential because acceptance of improper specimens for analysis may lead to erroneous information that could affect patient care, but only by monitoring on a regular basis the rejected specimens and identifying factors associated with the rejection can we avoid errors and promote continuous quality improvement of laboratory service (14). Moreover, an increasing body of evidence demonstrates the importance of the postanalytical phase for monitoring and improving the TAT (15), for improving the appropriateness of reference intervals (16), and for allowing more objective validation and interpretation of data by use of expert systems (17, 18). Recently, there has been growing interest in implementing and disseminating guidelines for the provision of interpretative comments on laboratory reports (19). To avoid possible errors, this critical activity requires that the laboratory personnel receive adequate training; moreover, there is the need for quality assurance in providing interpretative comments and for auditing this activity (20).

We also paid attention to the area of blood banking. This field is strictly related to laboratory medicine and has very similar working methodologies, which are always being subjected to a very high degree of control because of the high degree of related risk. A report from the College of American Pathologists in collaboration with the CDC Outcomes Working Group (21) describes error stratification in the working process for clinical laboratories similar to the one reported in Table 1. Of >88 000 defects, 41% were observed in the preanalytical phase of testing, 55% in the postanalytical phase, and only 4% in the analytical phase (21).

Table 2 summarizes a selection of the published reports on errors in transfusion medicine, taking into consideration the effect of the error on the patient. In this case, the essential elements have been extracted: duration of data collection; frequency of misidentification errors; and effect of the error on the patient's health. Once again the heterogeneity of the results of the different studies is noteworthy; particularly evident is the very high number of risks of error (4.7% of the transfusions) reported by Baele et al. (22). Point 3 below presents a tentative explanation for this fact.

The heterogeneity of the reported data, in addition to underlining the total lack of a benchmark, the lack of a definition of "maximum allowable error rate", and the lack of a classification of errors, puts in evidence some aspects of critical relevance:

1) There is a need for better definition of laboratory errors and their causes. In fact, we can agree that laboratory errors may be defined as "any defect from ordering tests to reporting results and appropriately interpreting and reacting on these", but because our aim was to identify the most critical steps in the total testing process and to set up a plan for a corrective strategy, we made a distinction between (a) errors exclusively inside the laboratory (analytical errors, but also an undue increase in TAT or a sample mismatch during the analysis) and (b) laboratory errors caused by organizational problems outside the laboratory (e.g., sample-patient mismatch during the blood withdrawal performed by nonlaboratory personnel).

For errors within the laboratory, an increasing body of evidence demonstrates that the analytical error rate has improved significantly over time (23); it is affected by the training and qualification of testing personnel (24, 25) and by the correct adoption of rules for defining the allowable errors in internal quality-control practice (26). Moreover, the effectiveness of external quality assessment schemes and proficiency testing programs has been widely demonstrated, not only in identifying analytical errors, but also in detecting their possible sources, thus allowing laboratories to prevent further errors (27).

For laboratory errors caused by organizational problems outside the laboratory, these causes are often related to other frequent errors in healthcare and require similar corrective actions aimed at improving the organization of the ward. Typical examples of these errors are mistakes in patient identification for blood drawing or drug administration and transcription of data to the patient chart. Therefore, as stated by David Blumenthal, "the quantitatively largest reductions in laboratory error are likely to result from interdepartmental cooperation designed to improve the quality of specimen collection and data dissemination" (28). The role of the clinical audit in detecting this type of error and in improving clinical performance is being increasingly recognized; laboratories need to monitor adverse incidents, to learn how to minimize risk by studying them, and to establish procedures to prevent them (29).

2) It is important to classify laboratory errors by relating them to their real or potential effects on patient outcomes, allowing definition of the relevance of the error itself. A hemolyzed sample is probably less problematic than sample mismatching or a TAT that is too long in a critical situation. However, abnormal hemolysis that prevents sample analysis can lead to a request for a new sample, which prolongs the TAT and could potentially be very harmful for critical patients. Moreover, it would be advisable to define the acceptable error rate to give medical laboratories a realistic goal for quality improvement initiatives.

3) A standard for laboratory error detection and reporting needs to be defined, and an accurate analysis of the risk of errors in the clinical laboratory needs to be performed. In the previously mentioned report, Baele et al. (22) demonstrated the existence of 1 error for every 21 transfusions (4.7%), whereas in other reports, the mean error frequency is ~1 error for every 6000–

12 000. This enormous error risk is attributable to the methodology of process analysis adopted by the authors, who reviewed all the transfusions in three University Hospitals in the Brussels area. To our knowledge, this is the only case of systematic analysis of the transfusion process at the bedside, and it shows the very high risk for strictly controlled events such as blood transfusions. The enormous difference in sensitivity of an error detection method based on complaints or fortuitous detection (very low sensitivity) and one based on systematic analysis of all the steps needed to complete the medical act (very high sensitivity) thus is extremely evident. Introducing process analysis in laboratories to identify the error risk related to different procedures is quite advisable (e.g., risk of sample mismatching during blood drawing or during the analytical process).

4) It is important to define ways to decrease laboratory errors and to possibly avoid completely those with a real or potentially significant negative effect on a patient's health. It is impossible in medicine, as in any other human activity, to completely eliminate errors, but it is possible to reduce them. It is advisable to adopt techniques for error prevention and evaluation, perhaps taking them from some industrial sector such as the aviation industry, and searching for systems with error rates in the 1–2 ppm range. To reach the goal of error reduction, it is necessary to go outside the laboratory and to reorganize the activity of the wards. This can be done with appropriate educational programs and by introduction of automation technology and robotics. These solutions are also likely to contribute to error reductions in other aspects of patient care, such as drug administration, as we demonstrated in other studies (30, 31). Errors attributable to sample or patient misidentification have been recognized as a significantly severe source of problems that will worsen the quality of healthcare in all developed countries unless appropriate remedial actions are taken (32–34). On this topic, the European Countries within the CEN (Commission Europeenne de Normalization), the European standardization body, recently unanimously approved a document (34) for correct patient identification regardless of the medical act. In Italy, a document on patient safety, including standards on correct patient identification, has been issued and is currently being implemented.

5) An appropriate error detection program and adequate measures for error reduction that quantify the effects of these measures and evaluate whether the reduction can be considered satisfactory are critical. A reduction in the number of errors is a valid and sensitive indicator of the efficacy of the corrective actions only for less-severe errors (errors with little or no effect on patient health, such as an empty tube or a hemolyzed sample). The important errors, those dangerous for patient health (e.g., patient mismatch during blood drawing, drug administration, or transfusion), appear to be, at least in the reviewed literature, rare events (none of the authors reports very severe consequences). Therefore, relying on their reduction to judge the efficacy of the adopted measures might not be sufficiently sensitive. In these cases, the only effective criterion is the demonstration, via process analysis, of an adequate reduction of the error risk. The introduction and use of auto-controlled and noncircumventable systems for patient identification can help in the reduction of errors (31, 33, 34).

6) Another fundamental step is to create a culture in which the existence of risk is acknowledged and injury prevention is recognized as everyone's responsibility. As stated Leape et al. (35), the transforming insight for medicine (and for laboratory medicine) from human factor research is that errors are rarely attributable to personal failings, inadequacies, and carelessness and that naming, blaming, shaming, and punishing have not worked in addressing and decreasing errors. On the contrary, the new look has focused research on how people, individually, as groups, and as organizations, make safety. This needs training, education, and culture.

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