# Mistakes in a stat laboratory: Types and frequency

**Article** *in* Clinical Chemistry · September 1997

DOI: 10.1093/clinchem/43.8.1348 · Source: PubMed



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*Clinical Chemistry* 43:8
1348–1351 (1997)

Laboratory Management

# Mistakes in a stat laboratory: types and frequency

Mario Plebani* and Paolo Carraro

**Application of Total Quality Management concepts to laboratory testing requires that the total process, including preanalytical and postanalytical phases, be managed so as to reduce or, ideally, eliminate all defects within the process itself. Indeed a "mistake" can be defined as any defect during the entire testing process, from ordering tests to reporting results. We evaluated the frequency and types of mistakes found in the "stat" section of the Department of Laboratory Medicine of the University-Hospital of Padova by monitoring four different departments (internal medicine, nephrology, surgery, and intensive care unit) for 3 months. Among a total of 40 490 analyses, we identified 189 laboratory mistakes, a relative frequency of 0.47%. The distribution of mistakes was: preanalytical 68.2%, analytical 13.3%, and postanalytical 18.5%. Most of the laboratory mistakes (74%) did not affect patients' outcome. However, in 37 patients (19%), laboratory mistakes were associated with further inappropriate investigations, thus resulting in an unjustifiable increase in costs. Moreover, in 12 patients (6.4%) laboratory mistakes were associated with inappropriate care or inappropriate modification of therapy. The promotion of quality control and continuous improvement of the total testing process, including pre- and postanalytical phases, seems to be a prerequisite for an effective laboratory service.**

INDEXING TERMS: total quality management • emergency medicine • clinical audit

Quality and accountability are the focus of current concern in laboratory medicine. Mounting evidence indicates that reliability cannot be achieved in a clinical laboratory through the mere promotion of accuracy in the analytical phase of the testing process. Laboratorians have long realized the importance of monitoring all steps in laboratory testing to detect and correct defects. However, most of their attention has been directed toward detecting and correcting defects in the analytical portion of the testing process, such that analytical mistakes now account for <10% of all mistakes. Ross and Boone found that mistakes made in laboratory testing were distributed as follows: preanalytical 46%, analytical 7%, and postanalytical 47% *[1]*. Similar data were obtained by Bachner et al. in a CAP Q-probe study on blood bank quality-assurance practice *[2]* and, more recently, by Boone et al. in a survey on transfusional medicine *[3]*.

The application of Total Quality Management to laboratory testing requires that the total process, including preanalytical and postanalytical phases, be managed so as to reduce or, ideally, eliminate all defects within the process. Reports in the literature disagree as to the frequency of mistakes in the clinical laboratory. The error ratio is often stated as 1:1000, but other studies show a frequency of 1:100 *[4]*. As observed by Goldschmidt and Lent *[5]*, to a certain event the difference depends on the fact that ~75% of any test results within the clinical laboratory are, in general, normal and any interchange will be unnoticed and have no effect on the thinking process of physicians or on the well-being of patients. Of the remaining 25% of mistakes, half are so absurd that they are recognized by the requester as useless information, and are therefore not taken into account in any medical decisionmaking. However, the remaining 12.5%, i.e., 1:800 to 1:8000, may cause an erroneous medical decision.

The aim of this study was to evaluate the frequency and types of mistakes in our laboratory so as to identify the most critical steps in the analytical testing process and to plan a corrective strategy. We defined a "mistake" as any defect during the entire testing process, from ordering tests to reporting results, that influenced in any way the quality of the laboratory service.

To overcome some previously described limitations and to ascertain the number and type of medically recognized mistakes, we designed a prospective study, selecting the following: (*a*) the emergency department of the laboratory, in which the percentage of results in the reference interval is only ~50%, and an immediate clinical evaluation of results is presumed to occur; (*b*) a highly

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Presented in part at the 2nd European Meeting on the Preanalytical Phase in Laboratory Sciences, Oxford, UK, July 5–7, 1996.
Received November 21, 1996; revised March 27, 1997; accepted April 1, 1997.

accurate intralaboratory medical validation of data, taking into account all potential mistakes that cannot usually be detected; and (*c*) four cooperating departments, in which the physicians and nurses were willing to make an appraisal of laboratory findings, paying maximal critical attention.

We excluded all mistakes identified by routine quality-assurance procedures and amended before the final reporting of results, because they did not lead to giving erroneous information to clinicians.

## Materials and Methods

The Department of Laboratory Medicine of the University-Hospital of Padua is a large laboratory service providing tests for clinical chemistry, hematology, coagulation, and immunology. The laboratory serves a hospital with 2900 beds and highly specialized care units, including organ transplantation.

The Stat Service, which is a part of the Laboratory Department, performs $1.4 \times 10^6$ tests per year with individual spaces, instruments, and staff. Clinical chemistry analyses are performed with Ektachem 950 (Johnson & Johnson Clinical Diagnostics, Milan, Italy) and Synchron CX7 analyzers (Beckman Analyticals, Milan, Italy); hematology is performed with one Coulter STKS and one H3 analyzer (Bayer Divisione Diagnostici, Milan, Italy); coagulation with an ACL 3000 (IL, Milan, Italy); toxicology and drugs with an ACA star (Dade Diagnostics, Milan, Italy) and an Abbott Diagnostics (Rome, Italy) TDx.

Each of these instruments is connected to the laboratory information system, <5% of the results being manually entered into the computer. The laboratory information system allows results to be directly communicated to the care units.

Four different departments (internal medicine, nephrology, surgery, and the intensive care unit) were selected for this study, and all stat laboratory data for these departments were strictly monitored for 3 months. The brevity of the observation period was a prerequisite for the study design, the physicians and the nurses of the four departments involved being asked to pay maximal critical attention to all test results. These personnel were provided with a special notebook in which any "suspect" result was recorded, together with all pertinent clinical information. In addition, every day, a laboratory physician visited the care units to discuss and review any suspect laboratory results. If data were considered clinically questionable, the original request was checked and the specimen was inspected and retested, sometimes with different methods and instruments; finally, a search was made for possible interferents. We considered analytical laboratory mistakes to be all data that exceeded proposed and interim European quality specifications for imprecision and inaccuracy. In particular, *imprecision* is "less than one-half of the average within-subject biological variation or less than the state of the art achieved by the best 0.20 fractile of laboratories"; *inaccuracy* is "less than one quarter of the group (within- plus between-subject) biological variation or less than one-sixteenth of the reference interval, when these data do not exist, or less than twice the ideal imprecision, if the ideal imprecision of the above specifications are too demanding" *[6]*. Likewise, we considered as laboratory mistakes all results exceeding by >3 SD the internally defined mean turnaround time. The statistical significance of differences between relative frequencies of mistakes observed in the departments considered was calculated by using the Confidence Interval (CI) Analysis microcomputer program *[7]*.

## Results

Among a total of 40 490 analyses, clinicians notified us of 359 questionable findings, 189 of which were confirmed as laboratory mistakes; this was a relative frequency of 0.47%. In the department of internal medicine, the frequency of mistakes found was relatively higher (Table 1); by Confidence Interval (CI) Analysis this difference was statistically significant ($P < 0.05$) compared with the frequency from the surgery and intensive care departments. The distribution of mistakes (Table 2) was: preanalytical 68.2%, analytical 13.3%, and postanalytical 18.5%. In the preanalytical phase in particular, the most common faults (Table 3) depended on inaccurate procedures for sample collection, including blood drawing from an infusive line, resulting in sample dilution, and utilization of an inappropriate container. Three specimens for determination of activated partial thrombin time were collected in tubes with heparin as the anticoagulant instead of sodium

**Table 1. Laboratory mistakes in stat testing.**

| | Samples | Tests[a] | Mistakes | |
|---|---|---|---|---|
| Department | No. | | | Frequency, % (95% CI) |
| Intensive care | 1 115 | 14 646 | 58 | 0.39 (0.294–0.493) |
| Surgery | 1 785 | 7 704 | 32 | 0.42 (0.322–0.523) |
| Medicine | 1 895 | 8 803 | 54 | 0.61[b] (0.507–0.706) |
| Nephrology | 1 660 | 9 337 | 45 | 0.48 (0.379–0.582) |
| Total | 6 455 | 40 490 | 189 | 0.47 (0.369–0.572) |

[a] The number of tests is greater than the number of samples because more than one test was performed on a sample.

[b] Statistically different ($P < 0.05$) from that for surgery and intensive care departments.

**Table 2. Laboratory mistakes in stat testing.**

| | Types of mistakes | | | | | |
|---|---|---|---|---|---|---|
| | Preanalytical | | Analytical | | Postanalytical | |
| Department | No. | % | No. | % | No. | % |
| Intensive care | 39 | 67 | 6 | 10 | 13 | 23 |
| Surgery | 26 | 81 | 5 | 16 | 1 | 3 |
| Medicine | 33 | 61 | 9 | 17 | 12 | 22 |
| Nephrology | 31 | 69 | 5 | 11 | 9 | 20 |
| Total | 129 | 68.2 | 25 | 13.3 | 35 | 18.5 |

**Table 3. Laboratory mistakes in stat testing.**

| | Defects found | |
|---|---|---|
| Defects detection steps | No. | Frequency, % |
| *Preanalytical* | | |
| Wrong name of patient given | 5 | 2.6 |
| Erroneous specification of hospital unit | 36 | 19.0 |
| Physician's order missed | 34 | 18.1 |
| Order misinterpreted | 6 | 3.2 |
| Inappropriate container used | 5 | 2.6 |
| Specimen collection incorrect | 4 | 2.1 |
| Specimen collected from infusion route | 39 | 20.6 |
| Subtotal | 129 | 68.2 |
| *Analytical* | | |
| Isolated malfunctioning of instrument | 5 | 2.6 |
| Lack of specificity of the method | 4 | 2.1 |
| Unacceptable performance | 16 | 8.5 |
| Subtotal | 25 | 13.3 |
| *Postanalytical* | | |
| Correction of erroneous finding overlooked | 9 | 4.8 |
| Keyboard entry error | 5 | 2.6 |
| Turnaround time exceeded | 6 | 3.2 |
| Physician not notified of problem | 15 | 7.9 |
| Subtotal | 35 | 18.5 |

citrate, and after contaminated specimens were drawn into the correct tube. Other frequent mistakes were physician's order missing and wrong identification of the department, causing a risk of delay; an erroneous diagnosis; and inappropriate treatment. Of 129 preanalytical mistakes, 84 (65%) originated in the care units; the laboratory, of course, has no control over such defects.

In the analytical phase, we identified 25 mistakes, or 13.3% of the total mistakes (Table 3). The most common mistakes were due to interference or lack of specificity of analytical methods, and to an unacceptable analytical performance. In two cases, in particular, aspecific reactions to toxicologic tests caused false-positive results for opiates and cannabinoids, and five cases involved isolated instrumental malfunctioning of the hematological analyzer. Other mistakes were an unacceptable analytical performance in terms of accuracy or reproducibility (or both), despite satisfactory evidence from internal quality control. Unacceptable performance was demonstrated by repeating the test on the same specimen after the clinician's notification and observing a failure to reproduce the original value.

In the postanalytical phase, 35 mistakes (relative frequency 18.5%) were observed (Table 3). Among other mistakes, improper data entry and excessive turnaround time were seen. In particular, a comment on interference from cold agglutinins was overlooked, resulting in an underestimation of erythrocytes, and other situations were identified in which the correction of an apparently analytically reliable result had not been noticed. In other cases, there was a lack of communication between laboratory and physicians. The distribution of mistakes showed that toxicological (relative frequency 1.38%) and hematological (0.82%) tests seem to be more affected by mistakes than were clinical chemistry tests (0.11%). Analytical and postanalytical mistakes fall totally under the responsibility of laboratory; therefore, the total percentage of mistakes for laboratory responsibility was 44.4%.

Finally, we attempted to ascertain the effect of laboratory mistakes on patients' outcome. Most of the laboratory mistakes (74%) had no significant clinical effect. In 37 patients (19%) laboratory mistakes were associated with further inappropriate investigations, thus resulting in an unjustified increase in costs. In fact, the mistakes called for repeat laboratory tests, or other more costly examinations (e.g., echography, magnetic resonance imaging). In 12 patients (6.3%), laboratory mistakes were found to be associated with inappropriate care or inappropriate modification of therapy (Table 4).

## Discussion

Only a few studies evaluate the frequency and types of laboratory mistakes in the total testing process and relate laboratory mistakes to patients' outcome. Our results appear to confirm those of Ross and Boone *[1]*, who described their experience with 336 patients, and found that in 233 patients (70%) laboratory mistakes had no effect on patient care. Seventy-eight (23%) laboratory mistakes gave rise to unnecessary procedures; however, these were not associated with increased patient risk. An additional risk of inappropriate care was observed in 25 patients (7%).

In The Netherlands, the Hospitals of Tilburg house a special committee that investigates faults or near accidents (FONA). Any occasion within the hospital that might adversely affect patients' well-being must be reported to the committee, on special forms. Clinical laboratories are involved in the same procedure (external FONA complaints) and also follow a similar procedure for internal mistakes (internal FONA complaints). An arbitrary scale has been designed, ranging from no damage (score 1), minor (score 2), moderate (score 3), severe (score 4), to very severe (score 5) damage to patients' well-being. Over the last 6 years, 31 external and 102 internal FONA complaints have been filed *[5]*. Overall, only a few laboratory mistakes have led to severe clinical damage, the weighted mean for external complaints being

**Table 4. Laboratory mistakes and patients' outcome.**

| | No. | % |
|---|---|---|
| Total errors | 189 | |
| No effect | 140 | 74.0 |
| Inappropriate transfusion | 4 | 2.2 |
| Inappropriate modification of heparin infusion | 4 | 2.2 |
| Inappropriate infusion of electrolyte solution | 2 | 1.0 |
| Inappropriate modification of digoxin therapy | 2 | 1.0 |
| Further inappropriate investigations[a] | 37 | 19.6 |

[a] E.g., repeat laboratory tests, echography, magnetic resonance imaging.

2.5 and for internal complaints 1.9. However, examples of serious mistakes (score 5) have been reported, including one fetal death because of delayed reporting of HELLP syndrome (*h*emolysis, *e*levated *l*iver enzymes and *l*ow *p*latelets) and one death of a young diabetic patient attributable to erroneously low glucose test results, among others *[8]*. One should also appreciate, of course, that the laboratory has played an important role in helping to save lives by proper and timely reporting of test results.

It has been stated that 70% of faults depend on human mistakes, mainly communication problems, and only 30% are instrumental mistakes *[9]*. In the FONA study, in particular, of the total external complaints, 30 were human and only 1 was instrument-related, whereas for the internal complaints these numbers were 95 and 7, respectively (93–97% human, 1–3% instrumental). However, FONA-type complaints do not appear to be an appropriate means for revealing the real frequency and extent of laboratory mistakes, its main limitations being that it depends on the scrupulousness of clinicians in filling in the special forms, and it tends to identify only the more important clinical mistakes.

The number of mistakes identified in our study and their relative frequency are surprisingly low; this may have partly depended on some limitations of the study itself. In fact, imperfections in the detection methods mean that mistake rates are likely to be somewhat higher than observed by us. Moreover, the frequency of mistakes may differ between one facility and another, and between one time period and another. This is well demonstrated in our study by the higher frequency of mistakes observed in the department of medicine compared with the other departments. This difference is difficult to explain, especially in view of the relative frequency of mistakes observed in the different steps (pre-, post-, and intraanalytical) of laboratory work, being partly due to the different complexities of specific tests required. In spite of such variations, however, the observed mistake rates are great enough to call for some considerations concerning the sources of mistakes and the application of quality-control methods that minimize mistakes in all facilities and in each phase of the testing process.

In particular our findings confirm that, at present, the most frequent source of erroneous results in the clinical laboratory seems to be the pre- and postanalytical steps in the testing process, with fewer mistakes occurring during the actual analytical step. We did not take into account the mistakes identified and amended through the routine quality-assurance procedures designed to reduce the analytical defects. Most of the mistakes (74%) did not affect the quality of patient care. In 12 patients, however, laboratory mistakes were associated with inappropriate therapy. In another 19%, laboratory mistakes were associated with inappropriate further investigations, thus increasing costs of care. Further studies performed on a greater number of cases and using more-effective methods for detecting mistakes (e.g., Shigeo Shingo's mistake proofing) *[10]* should contribute additional information on the true frequency, nature, and sources of laboratory mistakes, thus keeping laboratory practice in pace with changes in the state-of-the-art for new technology, procedures, tests, and effective information.

If patients' interests are to be safeguarded and quality in laboratory testing promoted, there must be a departure from the conventional view of the laboratory, which focuses on the quality control of the analytical activities within the laboratory. Today, the quality system for clinical laboratories must include promotion of accuracy in the analytical phase as well as the assurance of the reliability of pre- and postanalytical activities. Our finding that a large percentage of laboratory mistakes occurs in the pre- and postanalytical phases indicates that the active monitoring of all potential defects calls for the assistance of nonlaboratory personnel, to enable the inclusion of steps outside the laboratory. Cooperation with clinicians and personnel outside the laboratory is therefore the key to improvement, and a clinical audit is an important component in the quality system for the clinical laboratory *[11, 12]*.

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