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Pregledni članak

MEDICAL ERRORS: PRE-ANALYTICAL ISSUE IN PATIENT SAFETY

MEDICINSKE GREŠKE: PRE-ANALITIČKA FAZA I BEZBEDNOST PACIJENTA

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Summary: The last few decades have seen a significant decrease in the rates of analytical errors in clinical laboratories, while a growing body of evidence demonstrates that the pre- and post-analytical steps of the total testing process (TTP) are more error-prone than the analytical phase. In particular, most errors are identified in pre-pre-analytic steps outside the walls of the laboratory, and beyond its control. However, in a patient-centred approach to the delivery of health care services, there is the need to investigate, in the total testing process, any possible defect that may have a negative impact on the patient, irrespective of which step is involved and whether the error depends on a laboratory professional (e.g. calibration or testing error) or a non-laboratory operator (e.g. inappropriate test request, error in patient identification and/or blood collection). In the pre-analytic phase, the frequency of patient/specimens misidentification and the presence of possible causes of specimen rejection (haemolysis, clotting, insufficient volume, etc.) represent a valuable risk for patient safety. Preventing errors in the pre-analytical steps requires both technological developments (wristband, barcodes, pre-analytical workstations) and closer relationships with the clinical world to achieve an effective team-working cooperation. The most important lesson we have learned, therefore, is that laboratory errors and injuries to patients can be prevented by redesigning systems that render it difficult for all caregivers and in all steps of the total testing process to make mistakes.

Keywords: errors in laboratory medicine, patient safety, total testing cycle, quality indicators, patient identification, sentinel events

Kratak sadržaj: U poslednjih nekoliko decenija značajno je smanjena stopa analitičkih grešaka u kliničkim laboratorijama, dok sve veći broj dokaza pokazuje da su pre- i post-analitički koraci u ukupnom postupku testiranja (TTP) podložniji greškama od analitičke faze. Preciznije, većina grešaka je otkrivena u pre-preanalitičkim koracima, izvan laboratorije i van njene kontrole. Međutim, u okviru pristupa pružanju zdravstvenih usluga orijentisanog na pacijenta postoji potreba da se istraži, u ukupnom postupku testiranja, svaki potencijalni nedostatak koji može negativno uticati na pacijenta, nezavisno od toga o kom se koraku radi i da li greška zavisi od laboratorije (npr. kalibracija ili greška u testiranju) ili nelaboratorijskog osoblja (npr. neodgovarajući zahtev za test, greška u identifikaciji pacijenta i/ili uzimanju krvi). U pre-analitičkoj fazi učestalost pogrešne identifikacije pacijenta/uzorka i prisustvo potencijalnih razloga za odbijanje uzorka (hemoliza, zgrušavanje, nedovoljna zapremina itd.) predstavljaju važan rizik za bezbednost pacijenta. Sprečavanje grešaka u pre-analitičkim koracima zahteva kako tehnološki razvoj (narukvice, barkodovi, pre-analitičke radne stanice) tako i blisku saradnju u kliničkom svetu, radi postizanja efikasnog timskog rada. Najvažnija lekcija koju smo naučili je, dakle, da se laboratorijske greške i radnje štetne za pacijenta mogu sprečiti preoblikovanjem sistema koji zdravstvenim radnicima u svim koracima ukupnog postupka testiranja otežavaju pravljenje grešaka.

Ključne reči: greške u laboratorijskoj medicini, bezbednost pacijenta, ukupni ciklus testiranja, pokazatelji kvaliteta, identifikacija pacijenta, iznenadni obrt

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Introduction

Medical error and patient harm have been described and studied for well over a century. However, apart from a few isolated pioneers, the medical and nursing professions did not appear to recognize the extent and seriousness of the problem or, if they did, were not prepared to acknowledge it (1). During the

past decade, after the publication of the Institute of Medicine report, *To Err Is Human* (2), patient safety finally became the object of medical and public attention. The awareness and understanding of medical errors have expanded rapidly, with an energetic patient safety movement promoting safer health care through »systems« solutions, thanks to a major message from the IOM report: the cause of medical errors and preventable deaths was not careless or incompetent people but bad systems (3). Compared with other types of medical error, however, diagnostic errors and, in particular, errors in laboratory medicine received little attention and the reasons for this neglect are complex.

In a recent review (4), Plebani has summarized the main reasons for this neglect, as shown in *Table I*.

Table I Errors in laboratory medicine: reasons for neglect.

1. Heterogeneous and ambiguous definition of the term »laboratory errors«;
2. Difficulties in discovering and identifying all types of errors in the total testing process (TTP);
3. Complexity of TTP and need for cooperation and integration between different health care providers;
4. Poor perception by physicians and laboratory professionals of the harmfulness of errors in laboratory medicine;
5. Laboratory professionals reluctant to report and disclose data on types of errors and their frequency;
6. Increasing use of complementary/alternative testing options (e.g. point-of-care, near-patient, and self-monitoring).

Errors in laboratory medicine: the pre-analytical phase

While the frequency of laboratory errors varies greatly, depending on the study design and TTP steps investigated, a series of papers published between 1989 and 2007 drew the attention of laboratory professionals to the pre-, and post-analytical phases, which currently appear to be more vulnerable to errors than the analytical phase. Our group published two papers, in 1997 and 2007 (5, 6), using one study design that allowed us to investigate most TTP steps in the same clinical context; it also used the same menu of tests (stat laboratory). A significant, although not dramatic, decrease in the error rates was observed in 2007, but the distribution remained very similar.

The pre-analytic phase had the highest error rate, the most frequent problems arising from mistakes in tube filling, inappropriate containers, and requesting procedures. Identification errors were noted for three patients and 14 related tests (875 ppm) in the latter study, but were significantly fewer than those observed in the former study for specimens collected from the infusion route.

Other studies confirmed these data, underlining the need to improve not only the analytical quality, which remains the »core« of laboratory activity, but the pre-, and post-analytical steps (7–11).

While the concept of brain-to-brain loop was developed by Lundberg in 1981 (12, 13), laboratory professionals were not concerned enough about the initial and final TTP steps, namely the appropriateness of test requesting, patient and specimen identification and, respectively, the physician's reaction to the laboratory report, and the interpretation and utilization of laboratory results. However, on exploring the beginning and the end of the loop, it emerges that currently these steps, performed neither in the clinical laboratory nor, at least in part, under the control of laboratory personnel, are more error-prone than others (14–16). In particular, errors in test ordering were found to be common both in primary care as well as in the emergency departments (15–20). Recent data on errors in the pre-pre-analytical phase underline that failures to order appropriate diagnostic tests, including laboratory tests, accounted for 55% of observed breakdowns in missed and delayed diagnosis in the ambulatory setting (15–18), and 58% of errors in the emergency department (19). In the final steps of the loop, the incorrect interpretation of diagnostic or laboratory tests was found to be responsible for a high percentage of errors in the ambulatory setting as well as in emergency departments (16–19). This, in turn, led to the introduction of the concept of *»pre-pre-analytical phase«* that means the initial steps of the TTP that usually are not performed in the clinical laboratory, neither are under the control of laboratory professionals. However, from the patient point of view, and for assuring patient safety, a consensus has been achieved to include any mistake and failure in all steps of the TTP in the definition of laboratory error (21, 22).

Starting from the beginning of the TTP, misidentification represents a major problem in the pre-analytical phase. According to Lippi et al. (23), prevailing causes of misidentification in laboratory diagnostics are: a) physician ordering laboratory tests on the wrong patient; b) incorrect or incomplete entry of patient's data in the Laboratory Information System (LIS); c) collection of specimens from the wrong patient; d) inappropriate labelling of the specimens; d) lost identification (label) on the specimens; incorrect entry of patient's results in the database of the LIS. Automated systems for patient identification (wristband, barcodes, radio frequency identification, pre-analytical workstations) provide the foundation for error prevention and improvement in patient safety, but strict adherence to available guidelines and recommendations for specimen collection is mandatory for assuring safety in pre-analytical steps (24–27).

Blood collection remains an error-prone phase of the TTP and opportunities for reducing errors and quality improvement include reliable procedures for sample collection and quality criteria for specimen

acceptance (28). In particular, efforts have been done for evaluating the quality of specimen (28). The most common reasons for unsuitable blood specimens are hemolysis and clotting. Insufficient volume and clotting specimens are the most common causes for rejection of inpatient samples, whereas the prevalence of inappropriate containers is particularly high for outpatient specimens (29). Hemolysis is a rather frequent occurrence and accounts for nearby 60% of rejected specimens (30, 31) and the detection of hemolysis should be improved by introducing automated systems, commonly known as the hemolysis index (32, 33).

Finally, the current trend toward the consolidation of clinical laboratories into megastructures and the increased distance of these structures from clinicians and patients may result in pre-analytical errors, and in some cases, over-prescription due to the possible lack of efficient communication between the laboratory and clinicians. The more distant the site for blood drawing, the higher the risk of pre-analytical errors.

Impact of errors in laboratory medicine

Only a small proportion of laboratory errors results in actual patient harm and adverse events thanks to the several barriers and defensive layers present between the release of laboratory information, the decision-making process and, ultimately, the action on the patient. Data reported in the literature on the impact of laboratory errors on patient care, however, underline that about 25–30% of laboratory errors may have some effects on patient care, while about 6–10% translate into adverse events or risk of adverse events (5, 6, 7, 21).

In the studies published by our group, errors translated in undue admission to critical care units, inappropriate transfusions, modifications in heparin and digoxin therapies. The incidence of effects on the patient's journey, for instance, for further inappropriate investigations of both laboratory and imaging examinations and more invasive testing and consultations, is much higher and, although not necessarily harmful, creates discomfort and incurs higher costs for both patients and the health care system, among others (5, 6). From a risk management viewpoint, the great majority of laboratory errors with little direct impact on patient care provide important learning opportunities. In fact, any error, regardless of its apparent triviality, might indicate weaknesses in policies and procedures that may not lead to adverse events in their particular context, but might cause the patient harm in slightly different circumstances.

Processes to reduce pre-analytical errors in laboratory medicine

In the last few years, in addition to efforts aiming to reduce analytic errors and improve analytic quality, important achievements have been made in addressing errors in laboratory medicine. Thanks to the introduction of pre-analytic workstations, a significant reduction has been achieved in pre-analytic errors due to procedures performed in the laboratory such as specimen preparation through centrifugation, aliquoting, pipetting, and sorting (24, 34). The increasing interest shown in developing guidelines and standard operating procedures for patient identification, blood collection, sample handling, and specimen acceptance or rejection will surely translate into higher quality standards (25–38). However, further efforts are needed to translate these initiatives into clinical practice.

The Working Group on »Laboratory Errors and Patient Safety« (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has undertaken a project named »Model of quality indicators« based on the identification of valuable and consensually accepted quality indicators in all steps of the testing process. Briefly, 25 quality indicators were selected after discussing and analyzing the proposal made by 26 clinical laboratories enrolled in the Working Group: 16 for the pre-analytic, 3 for the analytic and 6 for the post-analytic phase. Currently, participant laboratories may introduce the data collected in their own institution on each and all quality indicators in a specifically developed website (www3.centroricercabiomedica.it) (35).

Conclusions

In the last two decades significant advances have been achieved in the comprehension and reduction of errors in medicine. In laboratory medicine, the first lesson we have learned is that the unique framework for identifying and reducing error is TTP, including initial steps such as patient identification and appropriateness in test requesting, and final steps, such as communication and interpretation of test results.

Process analysis, the recording/documentation of all procedures and processes according to quality standards, particularly the ISO 15189: 2007 (36) which has been specifically developed for medical laboratories, are key tools for changing and improving upon every-day clinical practice. The accurate analysis and control of all procedures and processes included in the testing process, particularly if effective tools such as FMEA and HAZOP techniques are adopted, may significantly reduce weaknesses and vulnerable steps, thus maximising patient safety (37–39).

Conflict of interest statement

The authors stated that there are no conflicts of interest regarding the publication of this article.

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