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Short paper
Kratki rad

MISIDENTIFICATION AND OTHER PREANALYTICAL ERRORS

POGREŠNA IDENTIFIKACIJA I OSTALE PREANALITIČKE GREŠKE

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Summary: The largest number of laboratory errors occur in the preanalytical phase and are mainly due to educational and organizational reasons. The experience of our institution, as well as the results of an Italian interlaboratory effort to detect and reduce errors/risk of errors in laboratory medicine will be illustrated.

Keywords: errors in laboratory medicine, preanalytical phase, misidentification

Kratak sadržaj: Najveći broj laboratorijskih grešaka događa se u preanalitičkoj fazi uglavnom iz razloga koji se tiču obrazovanja i organizacije. Biće predstavljeno iskustvo naše ustanove, kao i rezultati zajedničkih napora italijanskih laboratorija da se otkriju i umanje greške ili rizik od grešaka u laboratorijskoj medicini.

Ključne reči: greške u laboratorijskoj medicini, preanalitička faza, pogrešna identifikacija

Introduction

After the publication of some recent (1) and less recent (2) documents, the concern about errors in Medicine is growing, expressed both in the scientific literature and in mass media. As far as laboratory medicine is concerned, errors occur mainly in the preanalytical phase (3–5). Also, in our institution there is much evidence of the preanalytical phase being the most critical one in this respect (*Figures 1–5, Table I and II*).

The question is: why so many errors occur in the preanalytical phase? Apart from the difficulty in exactly defining the preanalytical phase (this phase certainly includes also the prescription of laboratory tests and

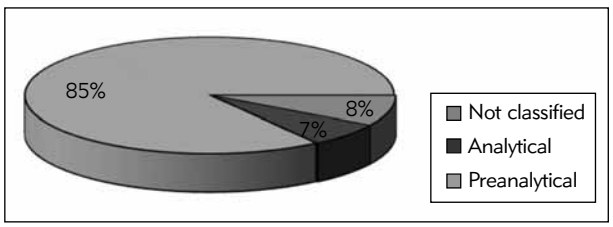

Figure 1 Recall of outpatients in the Department of Laboratory Medicine in 2006, Istituto San Raffaele, Milano. The incidence of the preanalytical phase.

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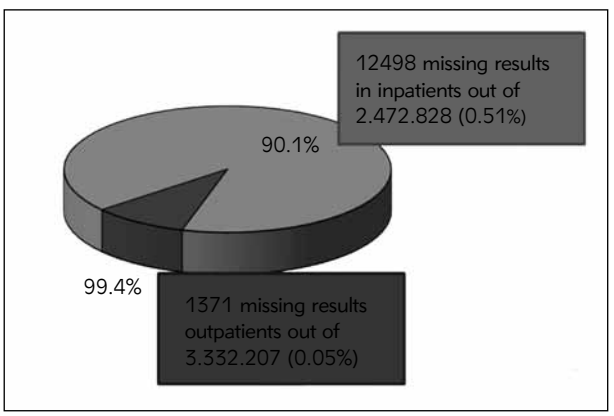

Figure 2 Distribution of Preanalytical Errors in in-and out patients in 2006. Istituto San Raffaele.

Table I Type of preanalytical errors in in-and outpatients in 2006, Istituto San Raffaele.

Preanalytical Error	Inpatients	Outpatients
Hemolyzed sample	7403	268
Insufficient sample	2367	413
Wrong tube	1178	465
Clotted sample	623	96
Test already performed	279	5
Patient misidentification	160	19
Empty tube	148	36
Tube not signed	88	0
Sample not in ice	93	19
Broken tube	34	14
Open tube	37	23
Test not booked	11	0

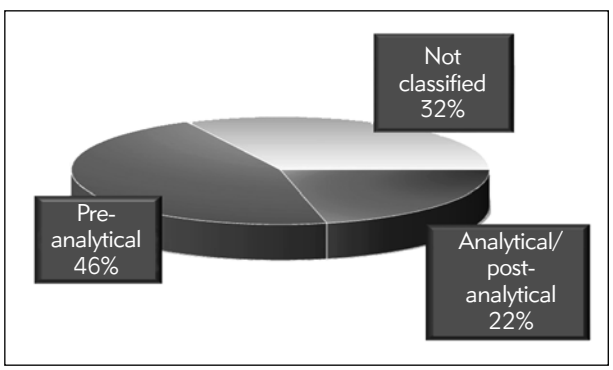

Figure 3 Recall of outpatients in the Department of Laboratory Medicine in 2007, Istituto San Raffaele, Milano. The incidence of the preanalytical phase.

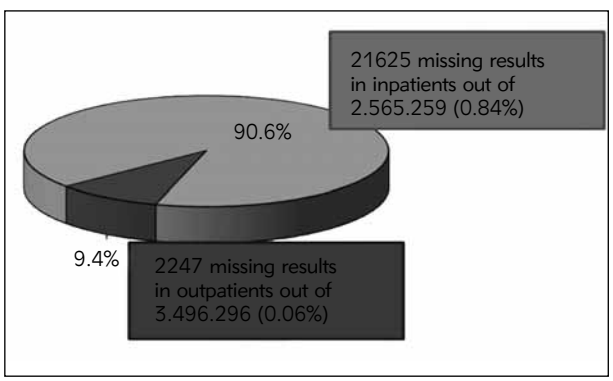

Figure 4 Distribution of preanalytical errors in in-and out patients in 2007, Istituto San Raffaele.

appropriateness in their selection, but this very relevant issue will not be included in the present lecture), we must consider that the preanalytical phase is largely performed outside the clinical laboratory and very often out of any control from the clinical laboratory. In fact the

Table II Type of preanalytical errors in in-and outpatients in 2007, Istituto San Raffaele.

Preanalytical Error	Inpatients	Outpatients
Hemolyzed sample	1480	66
Insufficient sample	1771	147
Clotted sample	615	130
Test already performed	4	0
Patient misidentification	40	5
Empty tube	83	26
Tube not signed	68	1
Sample not in ice	182	9
Broken tube	64	54
Control Sample	64	54
Not arrived	16104	994
Inadequate sample	764	173
Other	94	16

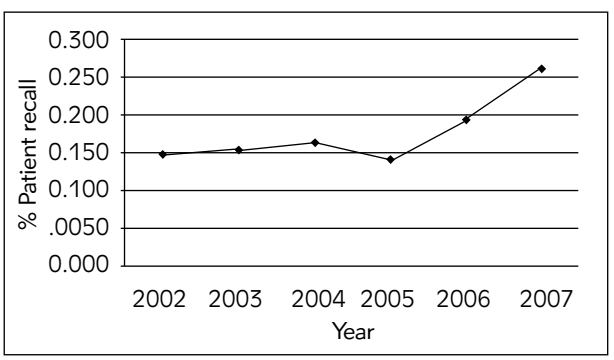

Figure 5 Six-year trend in recalling outpatients in the Department of Laboratory Medicine, Istituto San Raffaele, Milano. The increase in 2006 and 2007 is likely due to the great increase in the activity of our laboratory as Lab Service (=samples received from other Labs all around our country).

personnel in charge of the preanalytical phase, usually included in the staff of wards, does not report to the clinical laboratory direction. In many cases this personnel is not specifically trained in the clinical laboratory problems and very often not too much concerned about the errors in health care settings, and even less about the risk of errors in the preanalytical phase in the area of laboratory medicine. Only in a limited number of well organized institutions these activities are performed by well trained nurses; in very few cases, at least in Europe, there is a team of phlebotomists, depending on the clinical laboratory, in charge of the blood drawing and many laboratory preanalytical activities; in institutions these activities are performed by less trained personnel and sometimes also by students!

Misidentification is certainly a major risk in the preanalytical phase, but many other important and very critical aspects of the preanalytical phase must

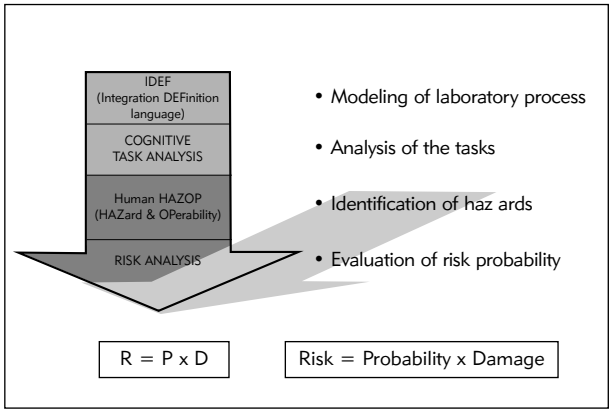

Figure 6 Measurement of risk through a proactive risk analysis method.

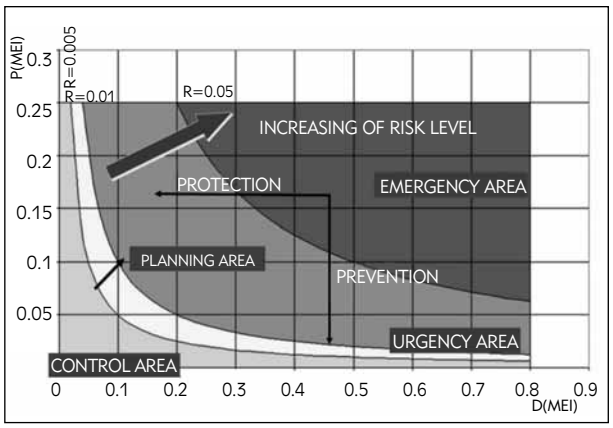

Figure 7 Iso-risk curves for graphic representation of the severity of risk.

be taken into consideration as, for example, the sometimes unreasonable and extremely high amount of blood drawn (6).

Mislabelling of laboratory samples is essentially one aspect of misidentification of patients and certainly derives from the poor attention to the risk of errors linked to a non-proper identification of patients in any medical procedure (7).

Even if the introduction of automation has certainly reduced the risk of mixing up laboratory specimens as described in rather old documents (8), the preanalytical phase largely relies on manuality and, as such, is very subject to various errors: for example,

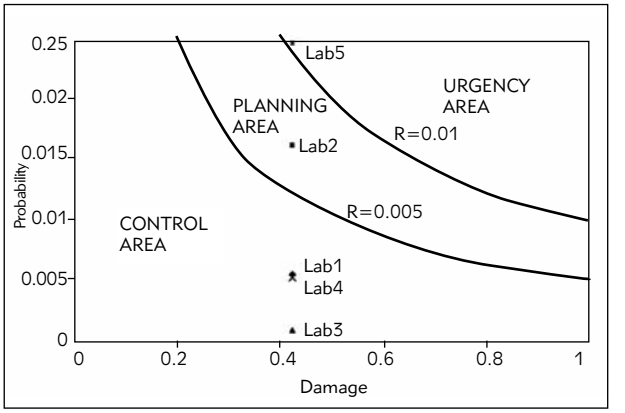

Figure 8 Results of an interlaboratory experiment in Italy using the risk analysis method.

the impossibility to reduce the minimum error rate in transcriptions below a level of 3% in an environment free of stress and distraction is well demonstrated! (9). An incorrect use of technologies per se very appropriate for reduction of errors, as the wrist band for patient identification, can also result in a great number of errors (10).

The impact of laboratory errors and especially preanalytical errors on patient outcome is considered to be severe or very severe in 12.5% of errors (11). In some very critical areas, like blood bank, errors can often result in severe injuries to the patients (7) and also in their death (12).

A cultural and educational approach is certainly the most important one in facing the problem of preanalytical errors in an efficient way. In the area of mislabelling of laboratory samples, the laboratory profession has unfortunately been so far rather reluctant in applying some internationally approved guidelines for a fail safe patient/sample identification (13).

A major effort has been recently spent also in order to identify the risk of errors rather early, that is before they result in damage to patient. In this respect the process and risk analysis (*Figures 6 and 7*) seems a method very appropriate and well applicable in interlaboratory experiences for comparison of these errors (14) (*Figure 8*).

A common effort of the professional/scientific community is needed in order to face this problem.

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