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Management of preanalytical nonconformities in the biochemistry laboratory

H. Chemsi [1, α], N. Kamal [1]

[1] Biochemistry Laboratory, Ibn Rochd University Hospital of Casablanca,
Faculty of Medicine and Pharmacy, Casablanca, University Hassan II, Casablanca, Morocco

[α] Corresponding author : **Dr H. Chemsi**, E-mail: *chemsi.h2@gmail.com*

Abstract

Introduction : The preanalytical phase is a crucial step in the analytical process. The control of nonconformities during this phase is a requirement of ISO 15189 Version 2012. The objective of our study was to detect nonconformities in order to improve the quality of biochemical examinations.

Materials and Methods : This is a study of the preanalytical phase carried out in the biochemistry laboratory for a period of one year. The study included all samples from clinical and external services, and excluded samples for which the nonconformities were corrected. Noncompliant analysis requests were noted in a register and entered into excel for analysis.

Results : 1923 nonconformities were listed in total. 1088 (56%) concerned the prescription sheet, 750 (38.5%) concerned the sample and 103 (5.5%) secondary to a routing error. Regarding the prescription sheet, 455 (41%) were linked to the absence of the prescriber's stamp, 217 (20%) due to an identity mismatch between the prescription sheet and the tube, 134 (12%) due to the absence of the entry number, 107 (10%) linked to the absence of a service statement, 100 (9%) linked to the mismatch of identity of the identity number and 28 (3%) due to the absence of identity ... Regarding the sample, the nonconformities linked to the absence of identification of the sampling tube were 400 (54%), noncompliant sampling tube 208 (28%), delay of routing of the sampling tube 57 (8%), insufficient quantity of sampling 26 (4%), absence of tube 18 (2%) ... The month which records the greatest number of nonconformities was the month March 258 (13.42%). 61% of the nonconformities identified during this month concerned the prescription sheet.

Conclusion : In view of the results of our study, proposals can be made, namely the provision of a manual of parameters and sampling, the continuous training of medical personnel and the improvement of communication between the laboratory and clinical services.

Keywords: accreditation, nonconformities, preanalysis, quality, sampling

Introduction

The carrying out of biological examinations occupies an important place in the daily activity of the services. It optimizes the diagnostic and therapeutic management of patients. The reliability and quality of the results of the biological examination does not only depend on an analytical technique but also on compliance with the preanalytical phase. Controlling nonconformities is a requirement of standard EN ISO 15189 Version 2012. Any medical biology laboratory must implement an appropriate policy and procedure in order to use these indicators as part of the dynamic of continuous improvement of the quality. The objective of our study is to detect nonconformities (NC) in order to improve the quality of biochemical examinations, to propose corrective actions in order to reduce the number of nonconformities and to sensitize

medical and paramedical staff on the importance of the phase preanalytical according to preventive actions.

Materials and Methods

This is a prospective internal study concerning the preanalytical phase in medical biochemical analyzes. The study took place at the Biochemistry Laboratory and is carried out over a period of approximately one year. The study took into account all the samples that come from clinical and external services (hospital service, consultation services and reception center for samples processing prescription sheets coming externally). The inclusion criteria for this study included the different types of nonconformities revealed within the laboratory; the exclusion criteria excluded samples for which the nonconformity was resolved. The variables recorded are: date of receipt of the sample, requesting service, nonconformities concerning the prescription sheet, non-conformities concerning the sample taken, examinations requested. Requests for nonconforming analysis detected at the time of receipt of requests for examinations were noted in a register and then the data was entered into Excel. The samples received and the prescription sheets were checked and verified. After sorting and assessing the conformity of requests and direct debits. The departments concerned have been contacted. Untreated nonconformities were recorded in a register and software with a number assigned to them.

Results

Overall representation of identified preanalytical nonconformities

During the period of our study, 1923 nonconformities were identified. The latter are classified according to the type of nonconformities concerning the prescription sheet, nonconformities concerning the sample and those linked to the service. They are shown in Table I and expressed as a percentage in Figure 1, 2.

Categories	Type of nonconformities	Effective (%)
Preanalytical nonconformities relating to the prescription	A. Absence of doctor's stamp	455 (23,1%)
	B. Identity mismatch between prescription sheet and tube	217 (11,3%)
	C. No entry number	134 (6,97%)
	D. Requesting service not mentioned	107 (5,6%)
	E. Mismatch entry number between prescription sheet and tube	100 (5,2%)
	F. Lack of identity on the prescription sheet	28 (1,5%)
	G. Two prescription sheets with the same entry number	21 (1,1%)
	H. Lack of prescription sheet	13 (0,7%)
	I. Nonconforming prescription sheet (Nonconformity not specified)	8 (0,4%)
	J. Parameters not specified	5 (0,26%)
Preanalytical nonconformities relating to the sample	I. Unidentified collection tube	400 (20,8%)
	II. Noncompliant collection tube	208 (10,82%)
	III. Routing delay	57 (2,96%)
	IV. Insufficient sample quantity to carry out the sample	26 (1,35%)
	V. No tube	18 (0,94%)
	VI. Broken tube	11 (0,75%)
	VII. Hemolyzed sample	7 (0,36%)
	VIII. Soiled sample	6 (0,31%)
	IX. Empty collection tube	4 (0,21%)
	X. Icteric sampling	1 (0,05%)
	XI. Noncompliant debit	1 (0,05%)
	XII. Sampling tube for analysis of ammonium arriving without ice	1 (0,05%)
Routing error	**a**	103 (5,12%)
Others	**b**	2 (0,1%)

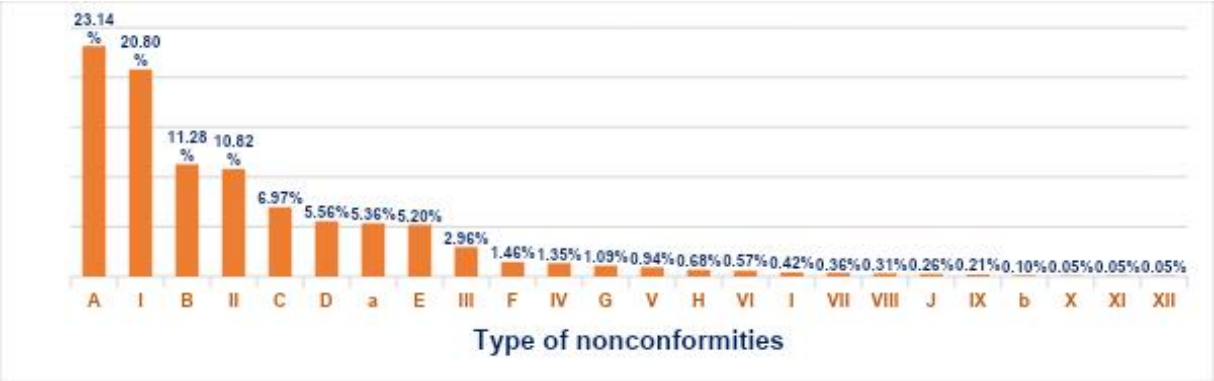

Fig 1. Percentage of preanalyticals nonconformities

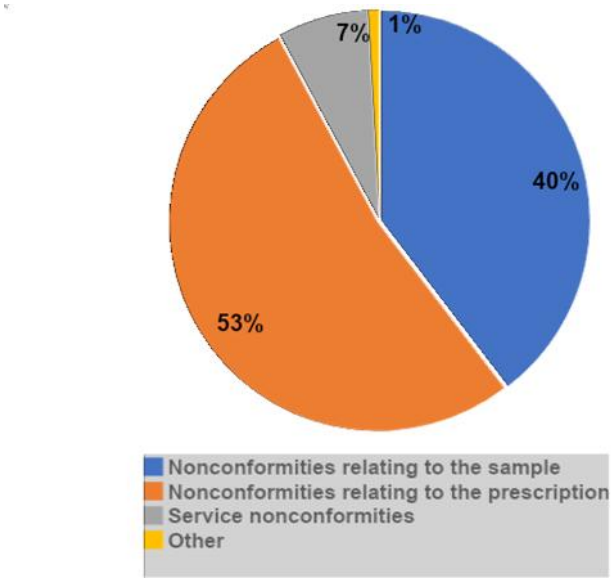

Fig 2. Distribution of preanalyticals nonconformities

The absence of the doctor's stamp represents the highest proportion of non-conformities, with 455 cases (23.1%), followed by the absence of identification of the tube nearly 400 cases (20.8%). The collection tube is noncompliant in 208 cases (10.8%). As for the entry number, it is missing in 134 cases (7%). The service is not mentioned in 107 prescriptions sheets (5.6%). 100 cases of discrepancy in the entry number between the prescription sheet and the tube are noted (5.2%). The delivery delay concerns 57 samples (3%) and the reagent rupture concerns 50 samples (2.6%). The absence of identity and requested parameter not available at the laboratory each concerns 28 samples (1.5%). The quantity of the sample to be analyzed was not sufficient to carry out the parameter assay in 26 cases (1.4%). 2 prescriptions sheets with the same entry number are read 21 times (1.1%). The absence of the tube or the prescription sheet concerns 18 and 13 cases of noncompliance respectively (0.9 and 0.7%).

Representation of preanalytical nonconformities concerning the prescription sheet

We collected 1088 cases of nonconformities which are related to the prescription sheet, 56.13% out of a total of 1923 nonconformities. Their proportions are reported in Figure 3. 41% of the nonconformities concerning the sheet are linked to the absence of the prescriber's stamp. 20% of them relate to a mismatch of identity between the prescription sheet and the tube. 12% of nonconformities in the prescription sheet are due to the absence of the entry number and in 10% of cases, the service is not mentioned. The identity number mismatch is at the origin of 9% of the nonconformities linked to the prescription sheet. Lack of identity represents 3% of noncompliant prescription sheets. The rest represents 5% of nonconformities.

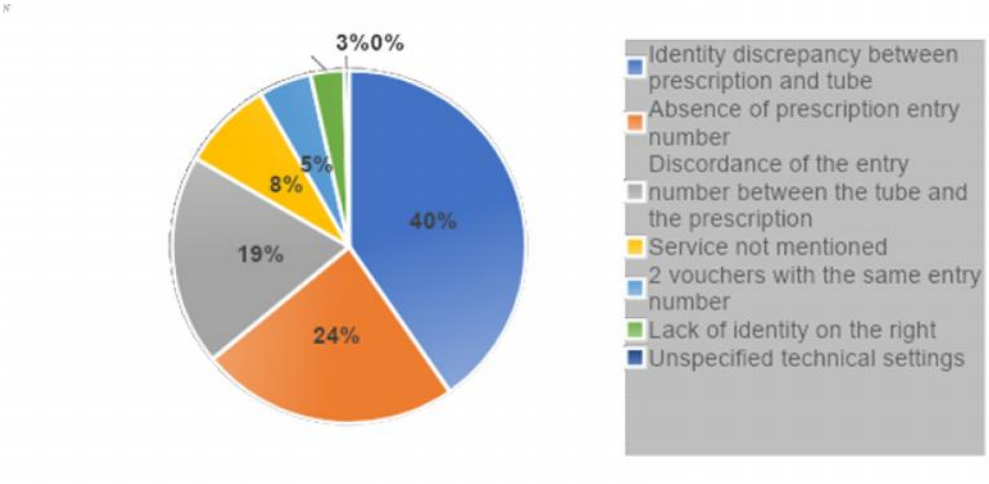

Fig 3. Distribution of preanalytical nonconformities relating to the prescription sheet

Representation of preanalytical nonconformities concerning the sample

Regarding nonconformities related to the sample, we recorded 740 cases (38.47%). Their distribution is shown in Figure 4. More than half of the nonconformities in the sample (54%) are due to a lack of identification of the sampling tube. The second noncompliance of the sample is represented by the noncompliant collection tube (28%). 8% concerns a delay in the routing of the sampling tube, then comes the insufficient quantity to carry out the analysis with 4% of the non-conformities linked to the sample.

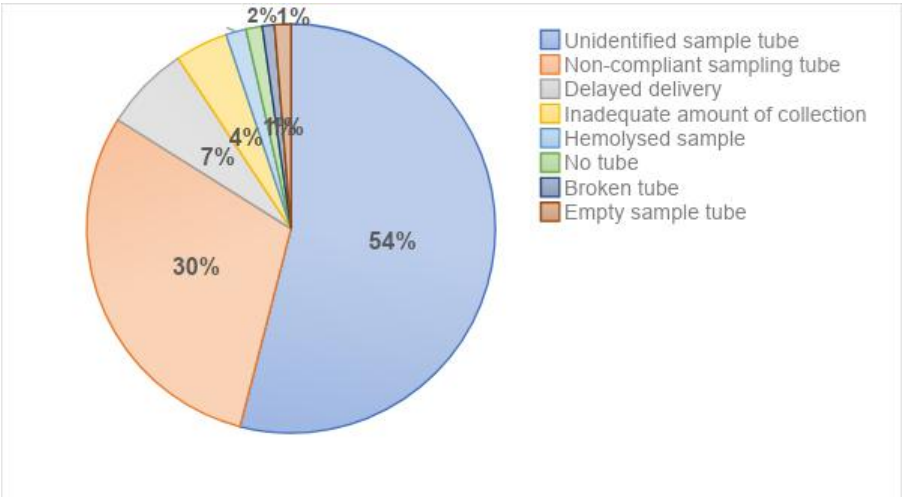

Fig 4. Distribution of pre-analytical nonconformities relating to the sample

Distribution of nonconformities by month

The service receives an average of 160 noncompliances per month. Figure 5 gives a percentage breakdown of the nonconformities according to the month during which they were recorded. The month of March 2019 registers the highest number of nonconformities 13,42% of the total of nonconformities recorded (258 cases) followed by the month of July 2018.

The month which registers the least nonconformities is the month of May 2019 with a percentage of 4.16%. Figure 6 shows the distribution of nonconformities recorded during the month of March 2019. 61% of the nonconformities during the month of March were related to the prescription sheet followed by the nonconformities related to the sample (36%).

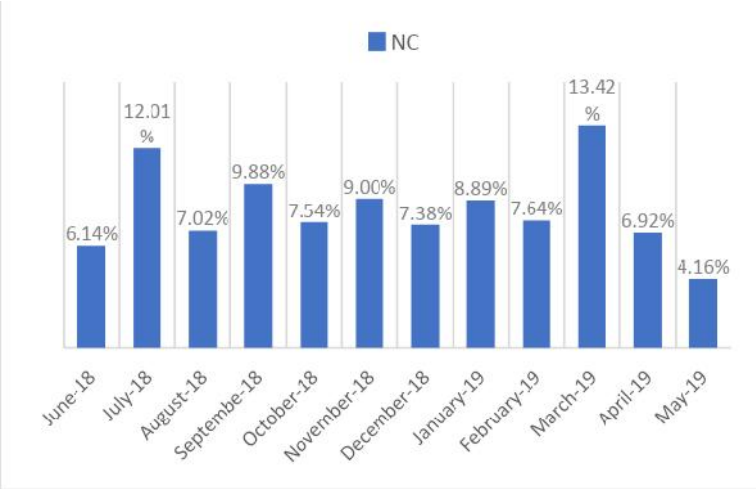

Fig 5. Repair of nonconformities by month

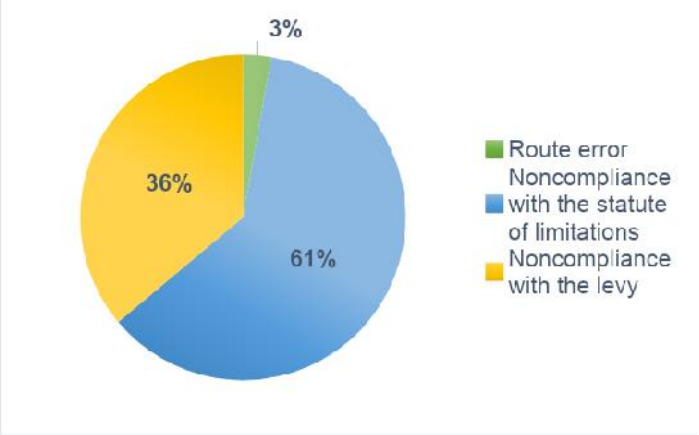

Figure 6 Distribution of nonconformities in March by type

Discussion

The result of the improved performance of the instruments means that the analytical phase for automated analyzes only takes up 25% of the time in the process of sample and analysis management [1]. Recent studies clearly show that the preanalytical phase represents 57% to 75% of the total time of the analysis. It takes place outside as well as inside the laboratory and involves a multiplicity of actors, as has been specified [1]. This phase plays a major role in controlling the quality of the analyzes [2]. The complexity of its handling is obvious because of the problems of identification of samples, the number of operators involved, the multiplicity of tasks, the diversity of sampling sites and the difficulties of routing and transferring exams [3]. According to several studies, nearly 85% of the errors detected are produced during this phase, while only 4% are in the analytical phase and 11% in the postanalytic [4]. The new biology reform, as well as the quality standards, in particular the ISO15189 standard relating to the accreditation of medical biology laboratories, positions the preanalytical process as a fundamental step in mastering the quality of biological examinations. This process covers all of the steps from the prescription of the analysis to the presentation of the sample on the analyzer. Its quality conditions the quality of the results produced. To manage the nonconformities of the preanalytical phase, the laboratory must set up a procedure whose first step consists in the obligation of their recordings by all the personnel on a support called NC sheet and the transmission of the information to the biologist responsible for the laboratory [5,6]. Thus, this procedure should define the personnel responsible for solving the problem, the measures to be taken, the information of the clinician when necessary,

the interruption of analyzes and the retention of reports, corrective actions immediately taken, recall of the results of the nonconforming analyzes already communicated or the identification of these nonconforming results and the documentation and recording of each NC. Once the NCs have been detected and processed, a cause analysis is carried out using quality tools, the most widely used of which is the 5M method (Ishikawa Method), which breaks down the problem along five axes : Method, Environment, Material, Hand of Work and Equipment [7].

Conclusion

The quality of the results delivered by a laboratory does not only depend on the analysis technique but also on compliance with the preanalytical phase. In view of the results of our study, some proposals can be made, namely the provision of a sampling manual containing the preanalytical conditions and particularities, awareness of the prescriber, continuous training of staff and improvement of internal communication and with clinical services.

Conflicts of interest

The authors declare no conflict of interest

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