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Management of Preanalytical Noncompliances in the Biochemistry Laboratory

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Abstract :- Introduction The preanalytical phase is a crucial step in the analytical process at the Laboratory of Biochemistry. The control of nonconformities during this phase is a requirement of the Standard EN ISO 15189 Version 2012. This control is considered one of the most reliable performance indicators. The objective of our study was to detect the percentage of annuals differents nonconformities in order to improve the quality of reception and results of biochemical examinations.
Materials and Methods This is a cross-sectional, prospective study of the preanalytical phase in biochemical analyzes carried out in the Biochemistry Laboratory during a period from 01/01/2020 to 31/12/2020. The study included all types of samples requested by clinical services and excluded samples and prescriptions that did not meet the criteria for good prescription and for which they were the subject of nonconformities. Analysis requests are processed at the reception level, nonconformities will be noted in a register and entered into the computer system for analysis.
Results A total of 1,533 nonconformities were identified. 728 (47%) related to the prescription sheet, 796 (52%) related to the sample and 9 (1%) related to a delivery error or delay. Regarding the prescription sheet, the identity mismatch between the collection tube and the prescription represented the highest proportion with 313 (20%), followed by the absence of the doctor's stamp on the prescription with 235 (15 %), the absence of the patient's entry number with 110 (7%), a nonconformity of the same entry number in two patients with the same name 44 (3%) and finally the absence of the sheet prescription with 26 (2%). Regarding the nonconformities relating to the sample, the highest proportion was that of the absence of the identity on the collection tube with 457 (29%), followed by the nonconformity of the collection tube with 216 (14%), the absence of the sample to be treated recorded 55 (4%), the insufficient quantity with 42 (3%) and finally the broken tube which was of the order of 26 (2%). Regarding routing issues, it was rated 9 (1%).
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 the clinical services.

Keywords:- *Nonconformity, Preanalysis, Prescription, Samples.*

I. INTRODUCTION

Medical biology, exactly biochemistry, occupies an increasingly important place in the healthcare system. The reliability and quality of the results of the biological examination do not depend only on an analytical technique but also on preanalyticals compliances. The preanalytical phase includes all the steps from the initial contact by the patients and / or the samplers outside the laboratory to the biological validation and transmission of results. The control of nonconformities (NC) is a requirement of the standard EN ISO 15189 Version 2012. Any medical biology laboratory must implement an adapted policy and procedure in order to exploit these indicators within the framework of the dynamics of continuous quality improvement. The objective of our study is to identify the nonconformities in order to improve the quality of the biochemicals examinations, to propose corrective actions in order to reduce them and to sensitize the medical and paramedical staffs on the importance of the preanalytical phase according to preventive actions to improve the quality of biochemical examinations.

II. MATERIALS AND METHODS

This is a prospective internal study concerning nonconformities in the preanalytical phase in biochemical analyzes. It took place at the Biochemistry Laboratory of the Ibn Rochd CHU in Casablanca, for a period of one year from 01/01/2020 to 12/31/2020. The study took into account all samples from clinical inpatient services, consultation services and the sample reception center processing requests for external examinations. The study included the different types of samples received within the laboratory. The exclusion criteria for this study were samples for which the preanalytical nonconformities were resolved through immediate corrective action. The variables taken into account in this study are : date of receipt of the samples, requesting clinical service, types of nonconformities concerning the prescription form, types of nonconformities

concerning the sample taken, examinations requested. Sampling takes place outside the laboratory. The labeling of the tubes must be carried out during the sample, mentioning the identity and the patient's entry number, which must be strictly identical to those entered in the prescription form. The transport of samples accompanied by their prescription sheets must be carried out as quickly as possible at room temperature, using containers provided for this purpose in accordance with packaging and labeling standards. The collection and analysis of data from noncompliant requests detected at the time of receipt of the prescription and the sample are recorded in a register, then the data are entered into the computer system for statistical analysis of the data by the SPSS V.20 software at the risk of 5%.

III. RESULTS

- **Global representation of the preanalytical nonconformities identified**

During the period of our study, 1533 nonconformities were noted. These are classified according to the type of nonconformities concerning the prescription sheet which were 728 (47%), the nonconformities concerning the sampling tube with 805 (53%) and those related to routing error with 9 (1%). They are represented in **Table 1** and expressed as a graph in **Figure 1.** Regarding the nonconformities relating to the prescription sheet, the identity mismatch between the sample tube and the prescription represented the highest proportion with 313 (20%), followed by the absence of the doctor's stamp on the prescription with 235 (15%), the absence of the patient's entry number with 110 (7%), a nonconformity of the same number in two differents patients with 44 (3%) and finally, the absence of the prescription sheet with 26 (2%). Regarding the nonconformities relating to the samples, the highest proportion was the absence of the identity on the collection tube with 457 (29%), followed by the nonconformity of the collection tube with 216 (14%), the absence of the sample to be treated recorded 55 (4%), the insufficient quantity with 42 (3%) and finally the broken tube which was 26 (2%). Regarding routing issues, it was rated 9 (1%).

- **Representation of preanalytical nonconformities concerning the prescription sheet**

We collected 728 (47%) cases of nonconformities that are related to the prescription sheet out of a total of 1533 overall nonconformities. 43% of nonconformities concerning the prescription sheet are linked to the identity mismatch between the collection tube and the prescription. 32% are related to an absence of the doctor's stamp on the prescription. 15% of nonconformities were noted the absence of the entry number. 6% were in two patients with the same entry number. The absence of the prescription sheet noted 4%. The proportions of nonconformities linked to the prescription sheet are shown in **Figure 2**.

- **Representation of preanalytical nonconformities concerning the samples**

Regarding nonconformities related to the sample, 805 (53%) cases of nonconformities were recorded. 58% of the nonconformities concerned a lack of identity on the collection tube, 27% were noncompliant collection tubes. The absence of the tube which was around 7%. The insufficient amount and the broken tube were 5% and 3%, respectively. The distribution of preanalytical nonconformities relating to the sample is shown in **Figure 3**.

- **Breakdown of nonconformities by months**

The laboratory receives an average of 140 nonconformities per month. **Figure 4** shows a breakdown of the number of nonconformities according to the month in which they were recorded. The month of February of the year 2020 recorded the highest number of nonconformities which amounted to 340 (22%) of the total, followed by January 2020 with 199 (13%). The month with the fewest nonconformities was July with 52 (3%). The distribution of preanalytical nonconformities by quarter (**Figure 5**) showed that the first quarter of the year recorded the highest number of nonconformities received with 676 (44%).

IV. DISCUSSION

The results of improved instrument performance means that the analytical phase for automated analyzes is only 25% of the time in the process of managing sample and analysis [1]. Recent studies clearly show that the preanalyticals phases represents 57% to 75% of the total analysis time. It takes place both outside and inside the laboratory and involves a multiplicity of actors, as has been specified [2]. This preanalytical phase holds a preponderant place in the control of the quality of the analyzes [3]. The complexity of its management is obvious because of the problems of identifying samples, the number of operators involved, the multiplicity of tasks, the diversity of sampling sites and the difficulties of routing and transferring examinations. [4]. According to several studies, nearly 85% of the errors detected are produced during this phase, while only 4% come from the analytical phase and 11% from the postanalytical phase [5]. The new reform of biology, as well as the Quality standards, in particular the standard EN ISO15189 relating to the accreditation of medical biology laboratories, positions the preanalytical process as a fundamental step in controlling the quality of biological examinations. This process covers all 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, the first step of which consists in the obligation of their records by all the personnel on a medium called the nonconformities sheet and the transmission information to the biologist in charge of the laboratory [6,7]. Thus, this procedure will have to define the personnel responsible for solving the problem, the measures to be taken, the information of the clinicians when necessary, the interruption of analyzes and the retention of reports, the

corrective actions immediately taken, the recall the results of nonconforming analyzes already communicated or the identification of these nonconforming results and the documentation and recording of each nonconformance. Once the NC have been detected and processed, an analysis of the causes is carried out by quality tools, the most widely used of which is the 5M method (Ishikawa method) which allows the problem to be broken down into five axes : Method, Environment, Material, Workforce and Equipment [7].

V. CONCLUSION

The traceability of nonconformities is an essential tool in continuous improvement of the quality management system, because it allows quantification and reflection on the causes and origins of dysfunctions. It will then be possible to define the sectors of action priority. Perfection does not exist, but the challenge is to try to approach it.

Conflicts of interest

The authors declare no conflict of interest

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Tables and figures

Table 1 Global representation of the preanalyticals nonconformities identified

Categories	Type of nonconformities	Effective(%)
nonconformities concerning the prescription sheets	Identity mismatch between the tube and the prescription	313 (20%)
	Absence of the doctor's stamp	235 (15%)
	Lack of entry number	110 (7%)
	Two patients with the same entry number	44 (3%)
	Absence of the prescription sheet	26 (2%)
nonconformities concerning the samples	Lack of identity on the collection tube	457 (29%)
	Noncompliant collection tube	216 (14%)
	Absence of the collection tube	55 (4%)
	Insufficient quantity	42 (3%)
	Broken tube	26 (2%)
Autres	Routing problem	9 (1%)

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Figure 1 Percentage of global preanalyticals nonconformities

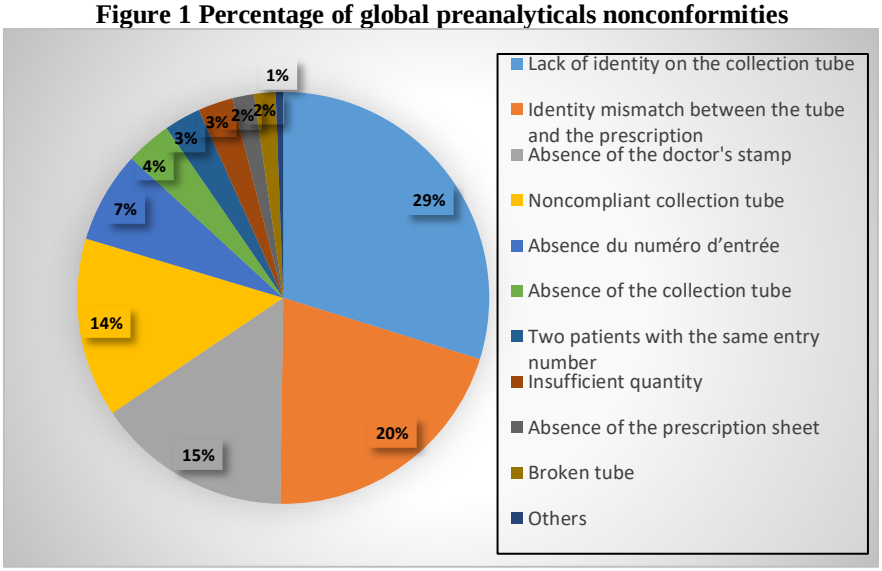

Figure 2 Breakdown of preanalyticals nonconformities relating to the prescription sheet

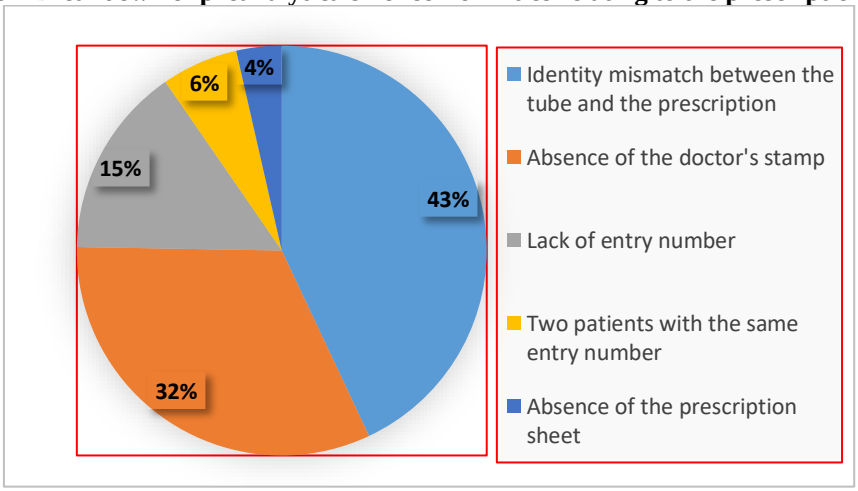

Figure 3 Distribution of preanalyticals nonconformities relating to the sample

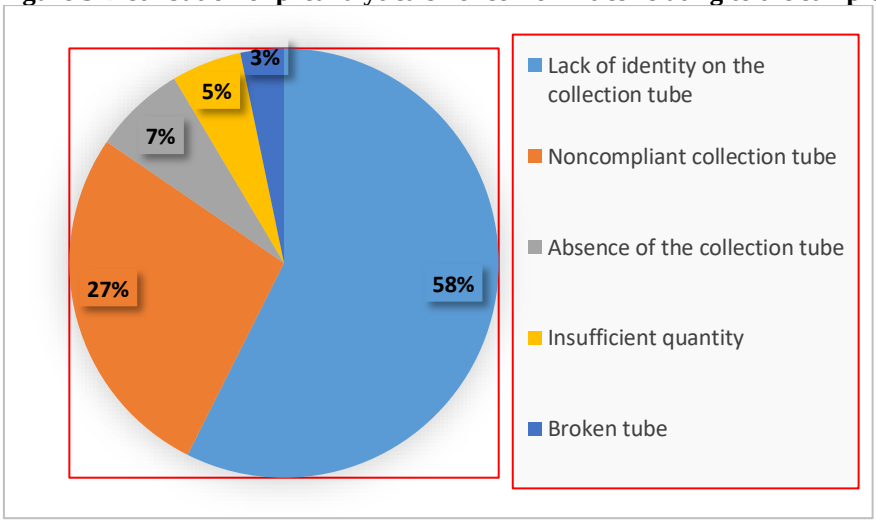

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Figure 4 Breakdown of global preanalyticals nonconformities by month

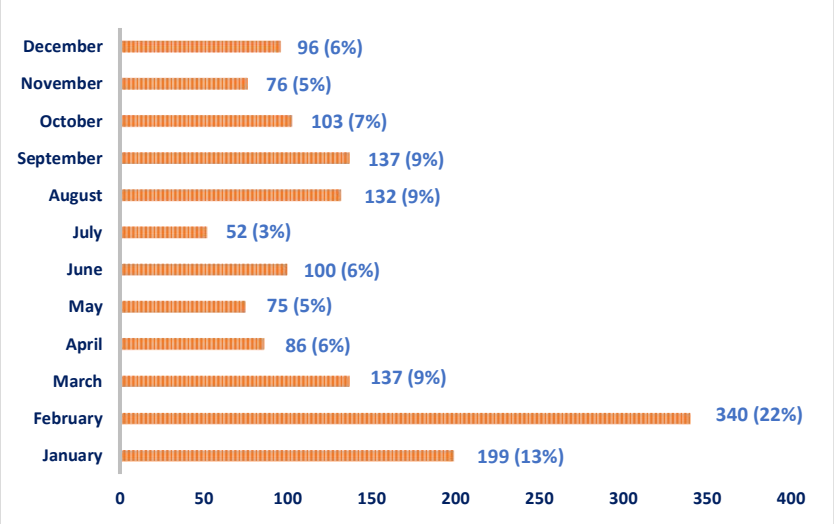

Figure 5 Breakdown of preanalyticals nonconformities by quarters