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Evaluation of the pre-analytical phase in the central laboratory at Mohammed VI University Hospital of Oujda

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Abstract

In addition to using the most up-to-date analytical technique, a thorough preparation phase must come first in order for the biological examination results to be reliable. The pre-analytical phase is this important step. We decided to conduct a prospective and descriptive study within central Laboratory department of the Mohammed VI University Hospital of Oujda with the goal of evaluating the pre-analytical phase in order to take action on the primary causes of pre-analytical nonconformity. In the course of observing 310 samples, we found 214 instances of pre-analytical nonconformities, of which 62 had to do with the prescription sheet, 62 with patient preparation, 31 with equipment preparation, 37 with the sampling procedure, 22 with waste management. Following the identification of these nonconformities in the hospital services under review, a multitude of corrective and preventive measures were taken in order to meet the standards of International Standard ISO15189 and to ensure the best possible patient care. Indeed, these key initiatives include audits, ongoing education, staff awareness and support.

Keywords: Biochemistry laboratory; Pre-analytical phase; Nonconformities; Blood samples

1. Introduction

Medical biology is a complicated, multidisciplinary field of study. Results of analyses produced by laboratories are frequently used for clinical or public health purposes. For the best possible care of the patients, it emerges that the quality of laboratory examinations is essential.

Quality is defined as the ability of a product, a process, or a service to satisfy the explicit and implicit needs of the user. It can be described as the accuracy and reliability of the findings of analyses in the field of medical biology[1].

The accuracy of the results of the biological examination depends on more than just the technique of analysis being carried out according to established norms; a suitable preparation must come before the analytical phase. This crucial step is referred to it as the pre-analytical phase.

The pre-analytical phase that is the focus of our study is divided into two steps, one taking place outside of the laboratory and the other within, and can be the source of numerous nonconformities (NC).

All steps that occur outside of the lab are grouped together as the external pre-analytical phase: The biologist has no control over the medical prescription, the drawing of the blood sample, the identification, the preservation and its

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transfer to the lab. In fact, research has shown that the percentage of errors related to the pre-analytical process ranges from 48 to 68% [2] and that more than half of these errors are attributable to the external pre-analytical phase [3].

2. Material and methods

This is a prospective, descriptive, observational and quantitative study over a period of 6 months from November 23, 2021 to May 25,2022, it included the observation of 310 samples in order to evaluate the pre-analytical phase and particularly at the sampling stage at the central laboratory of Mohammed VI University Hospital of Oujda. This study targets the observation of samples taken by any sampler practicing in the central laboratory and excludes patients who refrain from sampling. All statistics were done using Microsoft's Excel version 2016.

3. Results

3.1. Overall pre-analytical NC

During the course of the study, 310 samples were observed, collected from the central laboratory sample boxes, 214 non-conformities were found.

3.2. Distribution of the different types of NC

The most recorded non-conformities (NC) were those related to the prescription form and patient preparation, which each represented 29% (62 NC), followed by NC related to the sampling process 17% (37 NC), then NC related to material preparation 14% (31 NC), as well as NC related to waste management 10% (22 NC), while no NC related to sample transfer was detected. (Table 1).

Table 1 Distribution of the different types of NCs

		NC	Percentage
1.	NC related to the prescription form	62	29%
2.	NC related to patient preparation	62	29%
3.	Nc related to material preparation	31	14%
4.	NC relating to the sampling process	37	17%
5.	NC related to waste management	22	10%
6.	NC related to sample transfer	0	0%
TOTAL		214	100%

3.2.1. NC related to the prescription sheet

No sample will be taken until a prescription form containing all the biological examinations to be performed has been received(figure1).

The surname, first name, age and gender of the patients sampled, as well as the clinical and therapeutic information were noted by the prescribers on all the prescription forms. No identification errors were reported at this level.

The name, first name, stamp and signature of the prescriber were mentioned on all the prescription forms.

The exact time of collection and the identity of the collector were not indicated in 31 samples which amounts to 10% of the prescription forms.
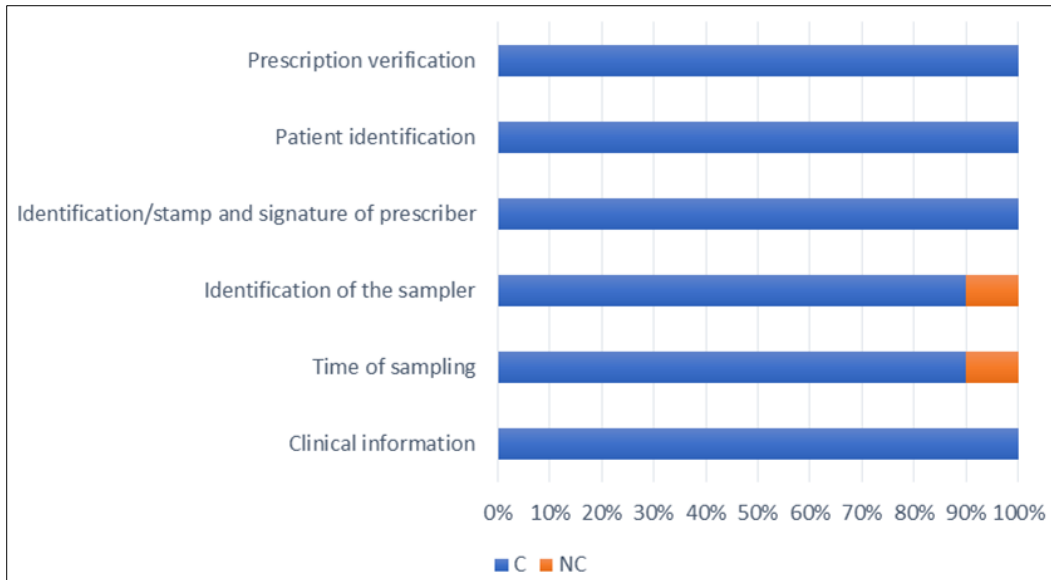
Figure 1 Nc relating to the prescription form in the central laboratory

3.2.2. NC related to patient preparation:

Concerning the NC relating to patient preparation (figure 2), the most observed were those relating to the non-respect of the rest time granted to the patients before the sampling act and the NC relating to the verification of the nature and the last medication taken, which represented each 6% (19 NCs each), followed by the NC relating to the verification of the duration of fasting 5.8%% (18 NC) and the NC relating to patient information 2% (6 NC).

No samples were taken without the free and informed consent of the patient.
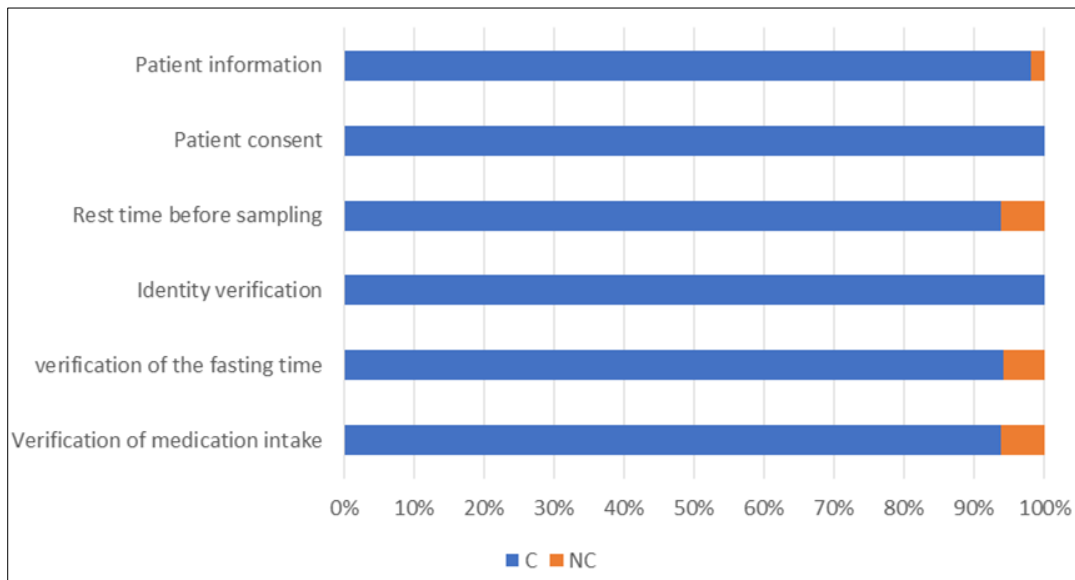
Identity was checked for all patients' samples.

Figure 2 NC relating to patient preparation at the central laboratory

3.2.3. NC related to equipment preparation

The required equipment for sampling had already been prepared by every sampler, yet 10% of them didn't check the expiration date(figure3).
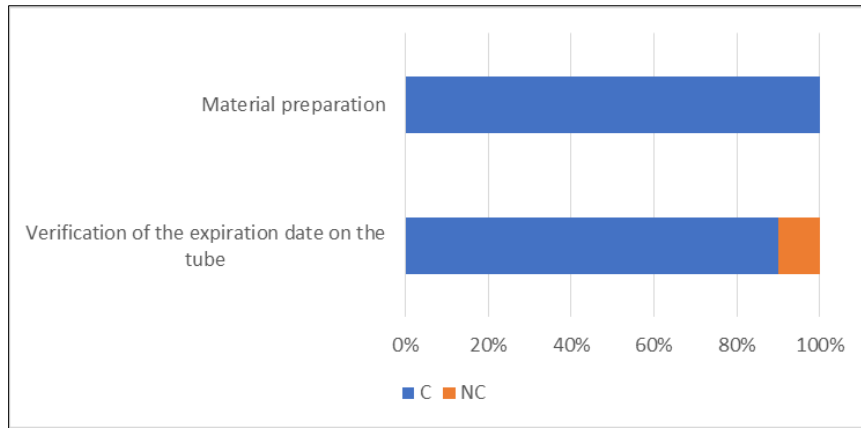
Figure 3 NC relating to the preparation of materials at the Central Laboratory

3.2.4. NC related to the sampling process

The most recorded NCs 7% (22 NCs) were related to inadequate tube homogenization followed by NCs related to hand hygiene 2.9% (9 NCs).

Prolonged tourniquet use time and failure to follow the order of tube filling each accounted for arround 1% of samples.

No NC were detected concerning the choice of the venipuncture site, the use of the tourniquet, the distance of the tourniquet placement, the disinfection of the puncture site, the respect of the drying time, the correspondence between the biological examinations and the types of collection tubes, the filling level of the tubes, the duration of the collection, the identification and the position of the tubes(figure 4).
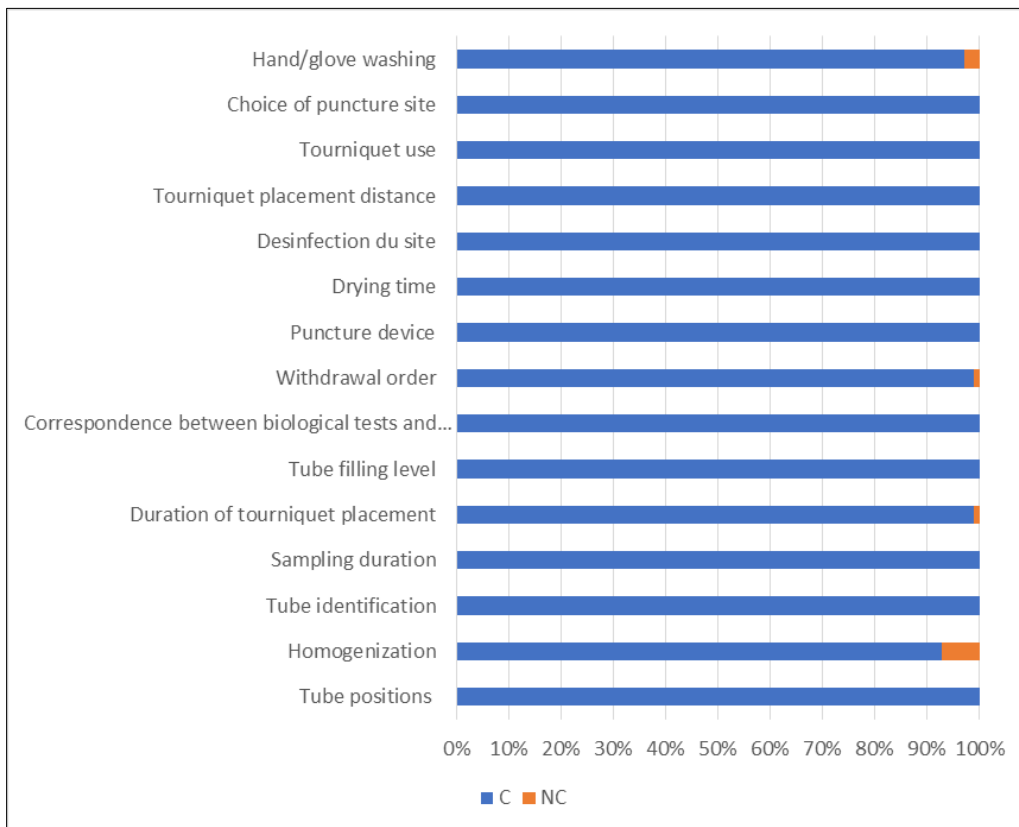

Figure 4 NC relating to the sampling process at the central laboratory

3.2.5. NC related to waste management

The most frequent NCs were those related to the disposal of the needle which amounts to 7% of the samples (22 NCs), although the container was always available, while no NCs related to hygiene and safety conditions were observed (figure 5).
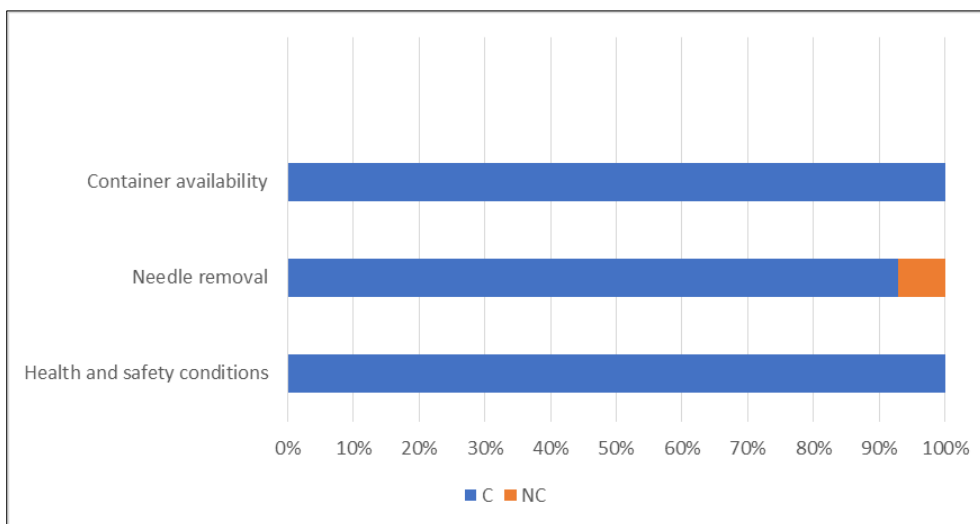

Figure 5 NC relating to waste management at the Central Laboratory

3.2.6. NC related to sample transfer

No NCs related to sample transfer were detected.

4. Discussion

4.1. NC relating to the prescription sheet

In relation to the prescription form, the absence of the identity of the sampler and the time of sampling was noted on 10% of all the requests examined. All these remarks and shortcomings were formalized to the competent departments of the university hospital and to the health professionals as part of a process of continuous improvement and contractual maintenance of the hospital information system.

Several studies carried out at other laboratories about the non-conformities in the pre-analytical phase have reported a high percentage of NCs related to the absence of clinical information[4].The study[5] conducted in 2022 over a period of 4 months at the virology lab of the Military Hospital of Instruction Mohammed 5 revealed that 90,95% of the prescription forms lacked clinical information.

However, no non-conformity related to clinical information was detected at the central laboratory service due to the strict application of procedures.

This is a major non conformity that cannot be overlooked as it can be a major source of misinterpretation of results and waste of reagents. In many cases, it is legitimate to know exactly the context of the prescription of a biological examination, so that the quality of the analysis is improved in terms of reliability and delay of results. This ensures a better interpretation by verifying their consistency with the various factors that may interfere [6,7].

4.2. NC related to patient preparation

In our present study, we have pointed out the lack of information given to the patient concerning the technical aspect of the sampling, the nature of the sampling and the purpose of the sampling in 2% of cases at the central laboratory. Patient information is now recognized as a real right. Consolidated by the texts, it deeply affects the relationship between the patient and the physician. Only clear, fair and appropriate information allows the patient to give informed consent to the services that the health care team will provide[8].

In our study,in 6% of samples,the healthcare provider did not grant a sufficient rest period before performing the blood sampling. According to EFLM-COLABIOCLI[9], it is recommended to allow 15 minutes of rest before sampling. The change of body position from lying down to standing and vice versa can have a significant impact on the concentration of many parameters[10]. The inconsistency of our study could be explained on the lack of samplers on one hand and on the other hand, by a lack of information and awareness of the sampler staff about the necessity of rest and its consequences on the biological tests.

In 5.8% of samples, fasting time was not considered during patient preparation, except for blood glucose. However, glucose is not the only parameter influenced by food intake, there are several other parameters that can be altered after a meal depending on the composition and the time elapsed between the meal and the sampling[11], for example: Triglycerides, Cholesterol, LDH, LDL, Phosphorus and Apo lipoproteins, all of which require a fasting period of at least 12 hours.

4.3. NC related to equipment preparation:

In 10% of cases, the sampler in the central laboratory did not check the expiration date on the blood collection tubes. The vacuum of blood collection tubes that are past their expiration date is diminished, which might cause the aspiration of less blood than anticipated and a poor blood/additive ratio. Additionally, tubes with expired expiration dates may show chemical degradation of the additive[9].

4.4. NC relating to the sampling process

According to the findings of our study, 97% of the sampling process adhere to the hygiene laws. The world health organization (WHO) reported in 2009 that routine hand antisepsis before and after the sampling act is best accomplished with hydro-alcoholic products. In addition, the WHO advises that gloves be changed systematically between patients and after each contact with blood, other body fluids, injured skin or mucous membranes; between activities with the same patient; and when hands are moved from one contaminated body site to another or to a medical device or the environment.

In our study, there were no non-conformities detected in the central laboratory regarding the choice of the venipuncture site and its sequence. The choice of the best vein and the most appropriate site to insert the needle for venipuncture is important for sample quality, patient satisfaction, avoiding nerve damage, avoiding arterial puncture, ease and speed of collection, and ultimately for a successful blood withdrawal. There is considerable evidence that the blood collection procedure can cause serious injury if it is not carried out successfully[9].

During our study, we found that no non-conformities were detected regarding the use of *gloves as tourniquets instead of the classic tourniquet or the distance its positioning. The use of gloves as tourniquets does not have any particular influence on the quality of the specimen, as it defines all the criteria of a classical tourniquet and it should be placed approximately one hand's width (7.5 cm) above the intended puncture site and should be tight enough to stop venous blood flow but not arterial flow[9].

In the present study, 99% of the samplings did not exceed the proper duration of tourniquet use, which should be less than 1 minute. According to the study by Lippi G and Alen 2006, the application and maintenance of a tourniquet have practically no influence if the duration is less than 1 minute. Beyond that, the blood concentration of certain analytes increases due to leakage of liquids and low molecular weight compounds. Macromolecules, protein-bound compounds, lipids and cells that do not pass the capillary barrier increase their content in the blood and the contraction of the forearm muscles, which is recommended during the application of the tourniquet, increases the concentration of potassium[12], [13].

According to the results of our study, all staff at the central laboratory level use hydroalcoholic solution. According to WHO, the care providers should use a mixture of 2% Chlorhexidine Gluconate and 70° Isopropyl Alcohol, and apply it to the entire skin surface, making sure that the contact with the disinfectant lasts at least 30 seconds; or use 70° alcohol and leave it on for 30 seconds, followed by Povidone Iodine/Chlorhexidine.

100% of the blood samples taken in the Central Laboratory are collected by the Vacutainer system. The vacutainer system is currently recommended by all quality standards in medical biology for its multiple advantages, including direct filling of tubes, control of the quantity of blood to be collected according to the vacuum in the tube, avoidance of hemolysis and compliance with aseptic measures [14,15].

99% of the tubes were filled according to correct order. According to WHO guidelines, the citrate tube is first be filled after the blood culture vial if needed, then the dry tube, the heparin tube, the EDTA tube and finally the sodium fluoride and potassium oxalate tube. It is imperative to collect the contents of the collection tubes in the correct order to avoid cross-contamination by additives between tubes[16].

We observed that all the tubes taken at the Central Laboratory were sufficiently filled. The volume of the sample taken is supposed to be sufficient to ensure a better execution of the requested examination, and to allow the biologist to make a possible confirmation in case of error or doubt.

We observed that the sample tubes were pre-labelled in 100% of the cases in the central laboratory service where the identification of the samples was done next to the patient, just after the end of the sampling. The identification of the samples must be done at the time of collection at the patient's bed by the sampler himself, this allows us to avoid all errors concerning the identity of the patient[16].

Inadequate homogenization of the tubes was observed in 7% of cases. Inadequate homogenization leads to partial distribution of the anticoagulant or coagulation activator, resulting in the formation of microclots or clots, while excessive shaking of the tubes results in hemolysis of the sample[17].

4.5. NC relating to Waste Management

During the study period, there were no non-conformities related to waste management and the container was always available.

7% of collectors recapped the needles before throwing them away. This is in contradiction with the standard precautions [18].

5. Conclusion

The pre-analytical phase is the most important source of erroneous or uninterpretable results. It remains the weakest link in the sample processing chain.

Our study highlighted a certain number of pre-analytical non-conformities, including: errors related to the prescription form; non-conformities related to the preparation of the patient and the material; non-conformities related to the sampling process; non-conformities related to waste management and to the conditions of transport and storage of samples.

Following the results of this work, various actions were immediately carried out in order to improve the quality of the pre-analytical phase, such as the training and continuous awareness of all personnel involved in the pre-analytical phase, the realization of internal audits to evaluate the application the application of the requirements of the ISO 15189 standard, the distribution of technical supports including the manual and the catalog of samples and the use of adequate equipment and devices for and the use of adequate sample collection and transport equipment. Other studies and internal audits will be programmed in the short and medium term to evaluate the continuous improvement process and propose the necessary solutions to the various dysfunctions and NC observed.

Compliance with ethical standards

Disclosure of conflict of interest

The authors declare no conflict of interest.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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