Original Article

Preanalytical phase management: identification and control of nonconformities in the sampling room of a clinical laboratory in Tunisia

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Abstract: In the total analytical process of clinical specimens, there are many possible preanalytical sources of error. The objective of this work was to evaluate the overall level of conformity of the internal preanalytical phase according to ISO 15189: 2012 and the guideline of laboratories practice in the laboratory of clinical biochemistry of Charles Nicolle hospital, Tunis. In order to identify and understand the failures in the preanalytical process, we have established an internal audit methodology to verify the accordance of different process with the requirements of the quality management systems. The nonconformities noted by the internal audit were mostly related to the execution of sampling, the medical prescription and the transmission of laboratory samples. To improve and ensure quality we have used quality tools, implemented corrective actions and re-evaluated the frequency of nonconformities to verify the effectiveness of the actions implemented. The total number of nonconformities was reduced by 52% after the application of quality tools. The results of the corrective action investigation showed a highly significant difference (P=0,004) of the percentage of nonconformities before and after corrective actions. The application of an internal audit methodology was a promising method to contribute to the enhancement of patient safety and produce valuable benefits for the entire healthcare system. However, the actions put in place remain insufficient on some nonconformities. Thus, the laboratory must ensure human and financial mobilization and full commitment and cooperation of the entire laboratory staff.

Keywords: Quality improvement; preanalytical phase; internal audit; Medical laboratories

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Introduction

Quality control is crucial to a clinical laboratory for providing the reliability and accuracy of test results in order to ensure the best possible patient care. Quality management concepts can be put into place to more effectively implement total quality management (1). To achieve a satisfactory degree of analytical quality, the laboratory of clinical biochemistry of Charles Nicolle Hospital was engaged in Picture Archiving & Communications System (PACS) Project supported by the European Union.

In a clinical laboratory, assuring quality of the analytical

procedures alone does not guarantee precision and accuracy of analyses and reliability of the results (2). The preanalytical phase is much more vulnerable to uncertainties and accidents, which can substantially influence patient care (3). This phase enrolls all the procedures before the start of laboratory testing. It includes requesting test, specimen collection, and handling and distribution of samples to multiple work stations (4).

In this study, we evaluated the types and frequency of preanalytical non-conformities found in our laboratory. This evaluation was carried out in the form of internal audit. Afterward, we implemented corrective actions and re-evaluated the frequency of nonconformities to verify the effectiveness of the actions implemented.

Methods

Procedure of data collection/internal audit methodology

We have established an internal audit methodology. First, we identified the activities and processes of the analytical process and focused on the internal preanalytical procedures, from patient preparation to laboratory analyses. Second, we prepared a nonconformities grid which contained criteria for acceptance/rejection of primary samples and the cause of the non-conformities. Practice of laboratory professionals was strictly monitored for 1 month. Auditors were independent and had a whole knowledge of biological standards.

To fully understand the origin of the flaws found in the preanalytical process, we used a designed questionnaire addressed to laboratory professionals.

Control of nonconformities/corrective action

In order to act on different dysfunctional found in the internal audit and to improve and ensure quality we have used quality tools, implemented corrective actions and re-evaluated the rates of the frequency of nonconformities to verify the effectiveness of the actions implemented.

All nonconformities are documented then investigated and resolved. Among quality tools, we chose brainstorming and diagram of Ishikawa as a management method.

Statistical study

We performed a descriptive analysis of the errors in preanalytical phase. The sums of nonconformities were calculated. Their relative frequencies comparing to the total specimens were presented as percentage. The differences between relative frequencies of nonconformities observed before and after corrective actions were tested by khi-deux test using EXCEL 2007. The statistical significance level accepted in this study was set at P value equal to 0.05.

Results

Types and frequency of preanalytical nonconformities

During the study period, among a total of 6,449 specimens, 498 findings were confirmed as preanalytical mistakes; with a relative frequency of 7.7%. We identified and classified all nonconformities found in various preanalytical procedures (*Table 1*). We noted some positive aspects in the laboratory such as the disposition of an enriched documentary system (procedures, instructions, and recommendations). Some of the weak points found were misidentification of responsibilities and a lack of collaboration in the face of work overload.

This could be a source of error because if a specific task is not assigned to a professional from the laboratory, each will think that it is the colleague's task.

As shown in *Table 1*, we identified 498 cases of nonconformities in the internal preanalytical phase. The most frequent nonconformities were related to the execution of sampling with a rate of 69.5% (n=346) followed by nonconformities related to the medical prescription with a rate of 24.1% (n=120) and finally nonconformities related to sample transportation with a rate of 10% (n=50). The questionnaire of the laboratory staff reveals that 6/10 have never received any training regarding the preanalytical phase, 4/10 have no idea about the meaning of nonconformity and 5/10 think that the more frequent nonconformity was unsuitable sample (*Table 2*). It should be noted that despite of the low number of participant, the questionnaire shows that the high rate of nonconformities is probably due to poor education and self-improvement program.

Application of quality tools and management of nonconformities detected by the internal audit.

Processes for conducting corrective action investigations including root cause analysis and action plans (brainstorming and diagram of Ishikawa) have been effectively implemented.

In order to reduce the preanalytical mistakes originated in the sampling room, a regular feedback system to the

Table 1 Influence of corrective actions on frequency of nonconformities

Activities	Defect found	Primary investigation		Re-evaluation after the application of quality tools	
		Number	Frequency	Number	Frequency
Medical prescription and analysis request	Univocal identification of the patient is absent, wrong or incomplete	21	4.2	14	5.8
	Date and/or physician's signature are missed	19	3.8	4	1.7
	Analysis request are illegible or missed	13	2.6	2	0.8
	Clinical information for certain specific examinations are missed	20	4.0	6	2.5
	Time of sampling for some specific tests is absent	47	9.4	21	8.8
Executing of sampling	Wrong identification of the patient	59	11.8	64	26.7
	Unqualified or absent staff	33	6.6	15	6.3
	Fasting condition not respected	60	12.0	32	10.3
	Tourniquet kept for a long time	11	2.2	2	0.8
	Order of filling of the sampling tubes not respected	40	8.0	12	5.0
	Inappropriate quantity of specimen	54	10.8	20	8.3
	Inappropriate agitation of sample tube	32	6.4	5	2.1
	Badly closed tubes	18	3.6	7	2.9
	Inappropriate container used for discharge of needles	39	7.8	15	6.3
Transportation conditions	Inappropriate sample transportation	50	10.0	21	8.8
Total		498	100.0	240	100.0

Table 2 Response of laboratory professionals to the questionnaire

Question	Response	Number	Frequency
Education regarding preanalytical phase	Yes	4	40
	No	6	60
The meaning of nonconformity	Respect the normal conditions	3	30
	Presence of the same name on the sampling and the prescription	4	40
	No ideas	4	40
The most frequent non-conformity in laboratory	Nonconformity of prescription	2	20
	Unsuitable sample	6	50
	Transportation conditions not respected	2	40

clinicians and personnel outside the laboratory was set.

This included distribution of written protocols for proper specimen collection and handling, as well as periodical auditing of preanalytical mistakes (*Table 3*).

The total number of nonconformities was reduced by 52% after the application of quality tools (*Table 1*). The results of the corrective action investigation show a highly significant difference (P=0.005) in the percentage of non-conformities before and after corrective actions. However, some malfunction remains frequent such as misidentification of patients.

Discussion

The sampling room activities (collection, handling and processing of specimens) present the greatest potential for errors and flaws.

The mean workload is 210 samples per day. However it may increase by 27% (288/day) in specific occasion (the start of weeks, after long holidays).

In those occasions like holidays, the staff is fewer and the number of patients is more important. Thus, the workload affects the frequency of errors and non-conformity which are related mainly to the lack of repartition of responsibilities and the low attentiveness due to the pressure of workload, especially in sampling room.

Blood specimen management from patient preparation to laboratory analyses, is an important tool to reduce laboratory errors, improve productivity and allow proper treatment of the patient. Unfortunately, preanalytical problems may generate wrong test results, contribute to inappropriate treatment and dissatisfaction with healthcare services (5). Internal audit addresses some of the limitations and gaps in existing quality methodologies through providing a systematic examination of the implementation of quality systems and processes. Assurance of the reliability of preanalytical activities, is essential to avoid specimen rejection, reduce financial loss and release of misleading results, which may adversely affect patient outcomes (5,6).

Recently, several authors (1,2) have demonstrated that most of the nonconformities were related to sample collection and its transportation. Most errors within the preanalytical phase involved in specimen collection leading to an unacceptable number of unsuitable specimens are due to *in vitro* hemolysis, incorrect patient identification, clotted specimens and insufficient sample volume (4,7). Hemolysis has been reported as the most frequent cause of specimen rejection (3). The presence of *in vitro* hemolysis is due to excessive shaking, delay in separation of blood cells, inadequate clotting, low transportation temperature or excessive centrifugation speed (8). Therefore, correct organization and management of both personnel and preanalytical procedures are important.

In this study, we proposed an internal audit of preanalytical activities to verify that all operations comply with the requirements of the quality management system. The pilot of the internal audit revealed that some preanalytical procedures were not adequately controlled or could be improved. Several nonconformities were identified including physician's order missing, wrong identification of the patient and inappropriate sample causing a risk of delay, wrong diagnosis and inappropriate treatment. Our results are consistent with those obtained by Atay *et al.* They demonstrated that higher ratios of nonconformities were related to misidentification of the patient and blood drawing errors (6). Our investigation showed that the overload of work, the lack of awareness and training on the preanalytical phase are very often the causes of these nonconformities.

In fact, our previous investigation by Bouzid *et al.* in 2015 showed that continuous training and education are crucial to avoid errors due to wrong practices and lack of attentiveness related to the pressure of the work overload (9). In the present study we focused on spreading awareness and education and we found that the non-conformities related to the lack of training decreased dramatically. Inappropriate agitation of the blood sample, which lead to hemolysis, decreased by 67.2% after the application of corrective actions.

Hence, necessary corrective actions were taken in order to meet the requirements of standards.

We performed a comprehensive investigation and a root cause analysis using quality tools (questionnaire, brainstorming and diagram of Ishikawa). From the outcome of our investigation a corrective action plan was applied in order to reduce the preanalytical mistakes originated in the sampling room. This includes a regular feedback system to the clinicians and personnel outside the laboratory and distribution of written protocols for proper specimen collection and handling. During the intervention stage, the preanalytical errors were reanalyzed. Our action plan succeeded in reducing the frequency of nonconformities ameliorating the reliability of the results and thus the safety of patients.

These results are consistent with other studies (1,2,6) which have shown that using an action plan reduce the rejection rate of inappropriate specimen and ensure patient

Table 3 Corrective actions to the different non-conformities

Nonconformities	Corrective action
Univocal identification of the patient is absent, wrong or incomplete	✓ Discuss request form and prescription conformity with the physician of the health centers
Date and/or physician's signature are missed	✓ Distribution of detailed checklist of requested examination available to prescribers
Analysis request are illegible or missed	✓ Release of a list of clinical information needed for some specific analyzes
Clinical information for certain specific examinations are missed	✓ Setting up an appointment scheduling software to avoid work overload
Time of sampling for some specific tests is absent	✓ Disseminate guidelines recommendations for patient identification, date, time of sample collection
Unqualified or absent staff	✓ Institute a vigorous program of education and self-improvement for (staff)
	✓ Ensure the training of the samplers and a good supervision of trainees to prevent effects of adverse incidents
	✓ Distribution of written protocols for proper specimen collection and handling
Fasting condition not respected	✓ Display the fasting conditions for each analysis in several places in the sampling room
Order of filling of the sampling tubes not respected	✓ Display in each sampling box the, an awareness skit with instructions that describes the procedures for filling the sampling tubes, the closing of the blood tubes, the proper homogenization, hygiene instruction, action taken in case of accident and waste management procedure
Inappropriate quantity of specimen	✓ Train the samplers and make available to them of written protocols for proper order of filling of the tubes, specify storage times, volumes sample
Inappropriate homogenization of sample tube	
Badly closed tubes	
Inappropriate container used for discharge of needles	
Inappropriate sample transportation	✓ Monitor sample transportation conditions
	✓ Make available sampling recommendations that set the specific conditions for transport time, the storage temperature of each parameter and adequate equipment for the transport of samples

safety. In addition, an investigation on clinical laboratory errors showed that the application of training system on personnel behavior of laboratory professional showed a decrease of incidence errors (7).

However, the wrong identification of the patients increased by 55.8%. That's probably due to the presence of a new team charged with data entry of patients on the new software of the Ministry of Health.

To anticipate, identify and eliminate potential problems, all laboratory professionals need to operate together to reduce the dysfunction rate in each step of preanalytical phase (4). In our laboratory, we must develop preventive investigations and action plans to raise the awareness of all laboratory staff of the importance of the preanalytical procedures and the serious consequences that nonconformities could generate. The use of an internal audit, a self-assessment tool, along with implementation of objective and standardized systems for detecting nonconformities, can be helpful for standardizing preanalytical activities and improving the quality of laboratory diagnostics (1).

Conclusions

The preanalytical phase is a crucial step in the analytical process. It is possible to conclude that the application of an internal audit methodology is a promising mechanism to contribute to the enhancement of patient safety and produce valuable benefits for the entire healthcare system. However, the actions put in place remain insufficient on some nonconformity. For a better result, the laboratory must ensure a financial and human mobilization to eliminate the causes of these dysfunctions and to ensure that they do not reappear.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The investigation was entirely based on the use of routine analysis referred to the biochemistry laboratory of Charles Nicolle Hospital. Informed consent was obtained from all professionals of the biochemistry laboratory.

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