

Full Length Research Paper

Quality analysis of the preanalytical phase of laboratory tests: Case of the civil hospital (Tetouan–Morocco)

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Several studies report that between 60 to 85% of laboratory errors are produced during the preanalytical phase. The objective of this study was to identify the factors at the origin of nonconformities during this phase at the Civil Hospital of Tetouan. A mixed preanalytical descriptive study realized between April and May 2014 was based on a questionnaire, an observation grid, focus groups and semi-structured interviews. The quality of preanalytical phase determines the quality and reliability of laboratory results. Indeed, 30% of the prescriptions of biologic tests are drafted by nurses and not doctors this is in the absence of an updated list of exams. The samples are taken at 84.6% by unqualified personnel and 98% without any guide or manual. For the traceability aspect, the name of the sampler is never placed on the sheet of examination, age, sex of the patient; time and nature of the sample are often not mentioned in the label vials of samples. The factors causing nonconformities laboratory tests at the civil hospital may have an impact on the quality of care. They result from a major defect of coordination between the laboratory and the services and the weak competence of the staff involved in this process.

Key words: Nonconformities, quality, biological sample, preanalytical phase, hospital laboratory.

INTRODUCTION

Care services provided by health facilities are increasingly put under scrutiny by instances that require that the public has the right to quality services (Lereutre et al., 1999). Medical biology occupies a place increasingly important (Erikson et al., 1974). However, the reliability of laboratory results depends on adequate preparation

which must precede the analytical phase (Togni et al., 2002).

According to the French standard ISO 15189 (2007, version), the preanalytical phase represents a series of steps chronologically starting by the requirement of the analysis and by the clinician (Saadouni, 2011). In another

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study, the management of biological samples is a sequence of activities and therefore process inseparable from each other. It begins with the realization of the levy at the care unit following a medical prescription, the delivery of the biological and sample to the laboratory (Séguéla et al., 1999; Alonso et al., 2016).

The French regulations through ISO 15189 (2007 version), the Order of 26 November 1999 on the proper execution of medical biology analyzes (ISO, 2012) and the decree of 24 April 2002 on the approval of the regulation on good practice of the transport of samples, products and samples derived from human blood (AMS, 2010). Indeed, laboratory tests are carried on samples taken from patients in good conditions. The process that follows between prescription and analysis is called preanalytical phase (ARF1, ARF2, 2002).

Several studies showed that preanalytical phase is an important step that conditions the quality of laboratory tests and the results obtained after analysis (Wiwanitkit, 2001). Regarding the fallen mistakes of the preanalytical phase on the quality of examinations, a study realized by Murat in a French hospital showed that the elements of the nonconformity of the preanalytical phase could invalidate the result product in the next phase said analytical (Murat, 2003). This researcher concluded that these errors will have several possible consequences for the patient such as mistake of the diagnostic, medical care and treatment. Nonconformity is high according to the literature. Indeed, it is estimated at 25% of the annual budget of the sampling equipment. Some authors report that nonconformities of samples can result in damage to the analyzers which amplify the extra cost due to maintenance work (Bustin, 2005).

In Morocco, previous studies have confirmed these errors. For example, the laboratory has identified 1048 nonconformities on 19503 biological samples that is a proportion of 5.37%. The most frequent nonconformities are related to the leaves of exams request with a rate of 60% (627 samples), followed by nonconformity associated with the routing conditions with a rate of 19% (196 samples) then nonconformities related to the removal of identification concerning 4% (47 samples), and finally the nonconformities related to the collection with a rate of 17% (178 samples) (Duchassaing, 1999; El Hani et al., 2014).

This study received ethics approval from the Committee on Human Experimentation of Moroccan Medical University and the National School of Public Health. Written informed consent concerning conduct of the survey was obtained from each participant. We protected the privacy of individuals in processing personal data and maintained confidentiality of individual records and accounts.

The study aim is to sustain the improvement of the quality of the preanalytical phase of laboratory tests and thus contribute to improving the quality of medical care for patients at the Civil Hospital in Tetouan city (Morocco).

MATERIALS AND METHODS

The study adopted a mixed descriptive study. The complementarity between quantitative and qualitative methods has generated a variety of sources of information and to cross the obtained results (Lafamme, 2007). The quantitative approach requests structured measurement instruments and analysis using appropriate statistical tools (Poisson, 1983). We undertook a cross-sectional study that allowed us to describe and explore the determinants of nonconformities preanalytical phase. The qualitative method is an inductive approach, explored the phenomenon studied, these processes and the people who participated by this method. It has not targeted the generalization of results (Congarda et al., 2012). We conducted two focus group and semi-structured interviews (Shortell et al., 1998). The target study population corresponds to all personal (n=154) including 64 doctors, 74 nurses, 2 medical assistants and 5 laboratory technicians, 5 service agents and 4 officials.

Statistical analysis

Quantitative data were treated by absolute and relative frequencies, and mean and standard deviation for quantitative variables. Indeed, the software used was Epi-Info Version 3.5.1.

RESULTS

Quantitative data

On the 138 questionnaires distributed, 104 were collected with a rate of participation of 75.4%. Indeed, for male 21.2% (42) of respondents were for doctors and 59.6% (62) for nursing. While for female, 40.4% (42) of the respondents were for doctors and 100% for nursing (62).

The age of 41.3% (43) of questionnaire respondents is between 40 and 49 years. Then, that between 30 and 39 years is about 28.8% (30). While those over 50 years are of the order of 26.9% (28), finally, those between 20 and 29 do not exceed 2.9% (3). However, the seniority 30.8% (32) is more than 20 years, while the percentage of those with 1 to 5 years, 5 to 10 years, 10 to 15 years and 15 to 20 years are respectively about 10.6 (11), 20.2 (21) and 19.2% (20), respectively (Table 1).

Moreover, 70% of personal participating in the study reported that the prescription is made by the doctor. But, 30% estimated that it was transcribed by the nurse. This requirement is made on the basis of a list of tests available for 51.9% of surveyed nursing staff. However, 98% of this part believes that this list is not updated regularly. For 48.1% of them, there is not a list of available examinations and this list is not displayed in the treatment room for 64% or it is not passed by the laboratory for 36%. The results of these elements noted in list of the prescription of biological examinations are shown in Figure 1. Moreover, 86.5% of respondents (nurses) say that it is the nurses who are responsible for biological samples (Table 2).

Concerning the labeling of containers containing the biological sample at the sampling time and at the bedside,

Table 1. Characteristics of participants at survey.

Characteristics			ni*	fi** (%)	Fi*** (%)
Profile	Doctor	Male	22	21.2	21.2
		Female	20	19.2	40.4
	Nurse	Male	20	19.2	59.6
		Female	42	40.4	100
Age (year)	20-29		3	2.9	2.9
	30-39		30	28.8	31.7
	40-49		43	41.3	73.1
	> 50		28	26.9	100.0
Seniority (year)	1-5		11	10.6	10.6
	5-10		21	20.2	30.8
	10-15		20	19.2	50,0
	15-20		20	19.2	69.2
	> 20		32	30.8	100.0

*ni: number of participants, **fi: effectif, ***Fi: cumulatif effectif.

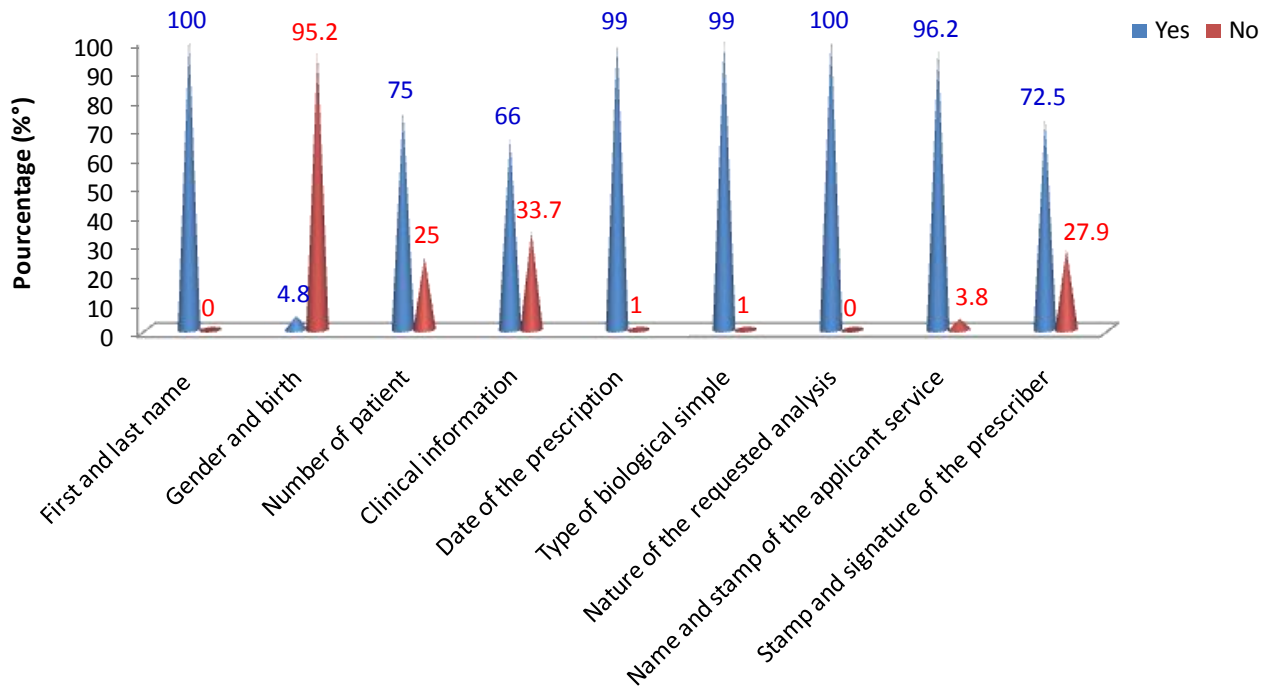


Figure 1. Results of the questionnaire on the elements noted in a prescription paper.

the distribution of responses of the surveyed staff is as follows: 91.4% (95) always estimates do the labeling, 6.7% (7) often estimates do it, 1.9% (2) estimate rarely do it (Figure 2). Caregivers surveyed believe that it is the agents (100%) who are responsible for the delivery of biological samples in the laboratory (Table 3).

For, the validated procedures specifying the conditions

for manipulation biological samples between the time of harvest and the time of receipt at the laboratory: 100% staff report that there is no validated procedure to put their provisions specifying any need for manipulation particular between sampling time and the time of receipt by the laboratory (transport requirements, refrigeration, delivery time).

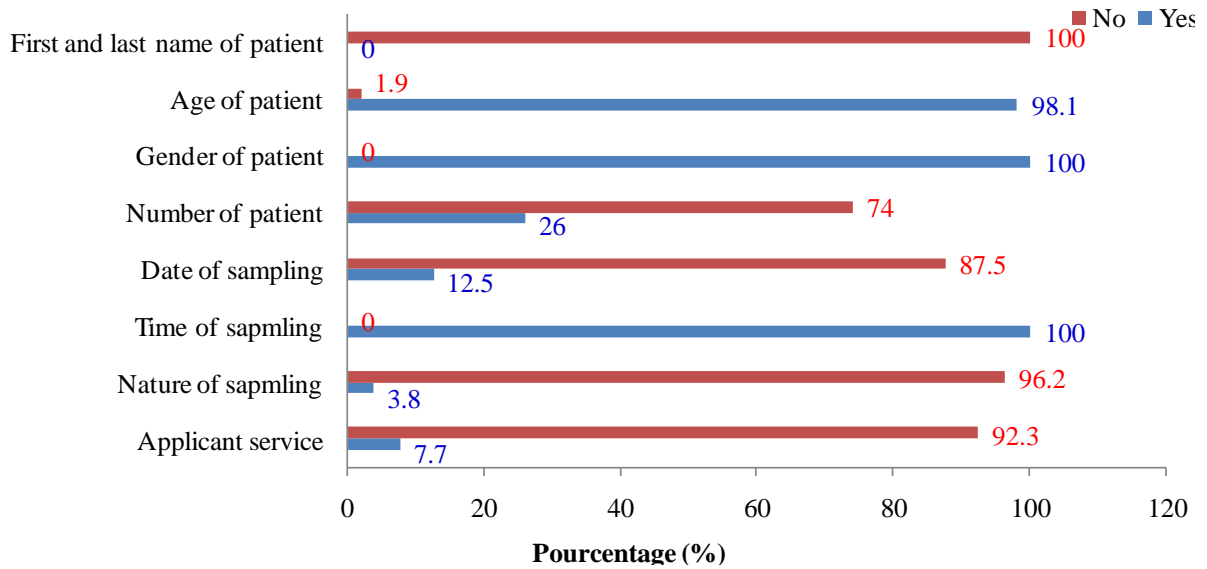


Figure 2. Results of the questionnaire on the elements noted in a container containing the biological sample.

Table 2. Distribution category of the staff responsible for biological samples.

Staff	Effectif	Percentage
Doctor	8	7.7
Nurse	90	86.5
Other	06	5.8
Total	104	100

Table 3. Category of staff responsible for the delivery of biological samples to the laboratory.

Staff	Effectif	Percentage
Nurse	10	9.6
Agents	104	100
Other	06	5.8

The existence of a deadline for delivery of biological samples in the laboratory showed that 81.6% of staff estimates that there exists a deadline for delivery of biological samples to the laboratory against 18.4%. This period is: Always respected for 52.8%, often respected for 24% and rarely observed in 4.8%. However, the manual transport remains the most used in the transportation of biological samples to laboratory with 70.2% of responses (Table 4). Receipt of biological samples in the laboratory showed that the entire staff surveyed 100% estimates that this is the laboratory staff that makes the receipt of the samples at the laboratory.

Table 4. Distribution of materials used in the transport of biological samples.

Materials	Effectif	Percentage
Rack	29	27.9
Coolers	00	00
Isothermal bags	02	1.9
Other	73	70.2
Total	104	100

Table 5. Distribution of responses on the existence instant control of sampling error at the moment of receipt of biological samples.

Instant control errors	Effectif	Percentage
Always	7	6.7
Often	11	10.6
Rarely	80	76.9
Never	6	5.8
Total	104	100

Specifically, there are laboratory technicians that make the receipt with 88% (92) of them.

Therefore, existence of instant control of sampling error at the laboratory at the time of receipt of biological samples showed that the majority of surveyed staff (76.9%) considers that this control is rarely done (Table 5). Direct observations in care units found that 53.1% (17) observations have shown the absence of the name and stamp of the prescriber doctors against 72.5% for the

questionnaire. The absence in a proportion of 59.4% of good exam pertinent clinical patient information against 33.7% of the questionnaire, non-prescription in 100% of cases of gender and age of patient on the review sheet for both tools, the time sheets requests for examinations with unreadable writings and soiled with blood and the list of exams available at the hospital laboratory is not displayed in the treatment room in the majority of the service.

Observations have shown that people who perform blood sampling in the care units are especially nurses, sometimes prescribing doctors and trainees. The absence of a manual sampling in all units of hospital (100%) confirms the results of the questionnaire (98.1%), and the absence of a job description of a nurse within each unit (100%). These are nurses guard who generally perform blood sampling. The sampling protocol is not entirely respected (37.5%), the equipment used for the collection of blood samples is the syringe (100%) being the same result as the questionnaire (100%). The labeling of containers containing the biological sample is made at the time of the sampling for a large part of observations (75%) this lower the results of the questionnaire (98.1%).

The variables noted on the bottle label for the patient identification for which the sample was taken, were made at different proportions: The last/first name: 43.8%. However, for the questionnaire, the result was 100%, age and sex of the patient, time of collection, the name and surname of the sampler on the right exam: 00%. Thus confirming the results of the questionnaire (100%), the withdrawal date: 90.6% confirming the results of the questionnaire (87.5%), the nature of the required biological examination: 96.9% the same result as the survey (96.2%) and the requesting service: 68.8% significantly lower than the result recorded for the questionnaire (92.3%).

The observations revealed the following results: The category of staff responsible for the delivery and transport of samples from care units to the laboratory triage unit which consists of: service agents (93.8%), the nurse on guard, trainees, cleaners and security agents (6.3%) and the delivery time for unity triage is often observed: 87.5%; except for hot services for example the emergency. These results are consistent with the results of the questionnaire.

Qualitative data

This study aims to improve the quality of laboratory tests especially during the preanalytical phase and as highlighted all managers shared responsibility between the administration and the laboratory. Interviewees have declared that there is a problem concerning information time care units of nonconformities encountered. According to them, the nonconformities declaration is made according to the normal process, prolonging the patient's

stay. All the interviewed officials say: the need to introduce a new material to make withdrawals instead of syringes and equipment of adequate material care units in the transport of biological samples and staff training on techniques and equipment samples. Interviews confirmed some results revealed in the quantitative section as the absence of an updated list of available laboratory examinations in care units. In terms of nonconformities management of biological samples, the majority of staff did not undergo training on the subject of management. Nonconformities sought are often linked to the discrepancy between the prescription sheet and the sampling tube, the name and surname of the patient, the sample volume and blood-anticoagulant ratio, hemolysis and non-conformity the tube. All of the interviewed service agents said the head nurse, the nurse on guard or the doctor, ask them to transport biological samples every day between 9am and 11am. The transport is done either in a cardboard box or a plastic rack. This confirms the results reported in the quantitative section. This deadline is not respected for urgent cases. For the respect of transport procedures, all agents indicated they have never heard of their existence.

DISCUSSION

Staff responses participating in the study showed that in 70% of cases, the prescription sheet biological tests is written by doctors for about 30% that it is transcribed by nurses. This percentage that is very significant of transcripts of examinations by nurses could be a source of error (Meier, 2001).

The prescription of examinations is an act reserved to persons qualified to prescribe. It must precisely define the acts which the prescriber expects results to support its clinical diagnosis (DRF, 1995; ARF3, 1999; Séguéla et al., 1999). Moroccan law requires the sampling may be effected by the prescribing doctors, biologist or by qualified personnel (Murat, 2003).

The results of questionnaires and observations showed that all blood sampling are done to the syringe while the use of the vacuum system is preferred as shown in the collection manual in medical biology published by the Ministry of Health in 2001 (Barbier, 2015). To reinforce safety conditions and minimize the risk of errors committed during the sampling, French law required that to the extent possible the samples sent to the laboratory must be associated with a medical tracking sheet containing all the information necessary to the performance analysis and the interpretation of results (ARF3, 1999).

The elements noted on the label of the container that will receive the sample for the majority of replies and comments are the first and last name and patient entry number, date of collection and the nature of the requested examinations (Morin and Perrin, 2009). It must include,

besides the identity and date of birth, declined by the patient himself as far as possible, the sex, the nature of the sample, the sampler name, date, and every time that a procedure provides, sampling time and localization (ARF1, 2002, Murat, 2003). The transportation of biological samples must be done as quickly as possible to the laboratory by taking all precautions to avoid contamination (Duchassaing, 1999).

The results of questionnaires and observations have shown that there is a specific place with a desk and chair for the reception and sample triage. Indeed, the focus group with laboratory personnel showed that non-conformities are in relation with the correlation between the biological sample and the prescription sheet, conformity labeling biological samples, and sample conformity at the reception. The results provided by the laboratory will show no value. They can result in either a therapeutic abstention in a situation where treatment would have been really necessary or inappropriate modification treatment (Séguéla et al., 1999).

ISO 15189 requires that all primary samples received at the laboratory must be registered by authorized personnel who must systematically review the prescription sheets and samples to ensure the relevance and the ability to perform analyzes (ARF1, 2002). This staff also ensures any special requests such as urgent consideration of demand. The laboratory must have a documented procedure specifying the criteria for acceptance and rejection of biological specimens (Gendt and Szymanowicz, 2010). These criteria must be defined according to the manual's recommendations biological samples. Any levy not meeting these criteria must be rejected and the fault must be traced by opening a non-compliance record (ARF1, 2002).

On acceptance of a levy does which do not meet the criteria, a waiver must specify the actions taken to correct the anomaly and the people responsible for sample acceptance. The final report signed by biologist must reveal the nature of the problem and the reservations concerning the interpretation of results (Murat, 2003). The main bias that may influence the study results are the social desirability bias and the Hawthorne effect (Contandriopoulos, 1999; Benissa, 2005; Saks and Allsop, 2010). We were able to minimize the explanation of anonymity, confidentiality and that this study will contribute to undertake improvement actions. The focus groups need an experienced facilitator to gather views from all those present and to frame the discussion (Saks and Allsop, 2010).

Conclusion

In light of these results, several actions should be undertaken to improve the quality of the preanalytical phase of laboratory tests at the Civil Hospital in Tetouan. For this, it makes sense to launch in time tenders relating to laboratory reagents and fungible to avoid stock outs in

laboratory fungible, and to establish a quality policy at the hospital structure through the revitalization of hospital quality committee, training and appointment of quality references in the various particular care units in the laboratory, and also developing a manual of biological samples and being validated to provide caregivers and sampler laboratory staff on the requirements of the preanalytical phase of laboratory tests according to ISO 15189.

Conflict of Interests

The authors have not declared any conflict of interests.

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