academicJournals

Vol. 5(1), pp. 1-10, January 2014
DOI: 10.5897/JMLD2013.0084
ISSN 2141-2618 ©2014 Academic Journals
http://www.academicjournals.org/JMLD

Journal of Medical Laboratory and Diagnosis

Full Length Research Paper

Risk analysis and management of non-conformities of the pre-analytical phase in a university testing laboratory of bacteriology

Youssef El Hani[1]*, Hafsa Lamrani Alaoui[2], Najat Mahassini[3], Leila Radi[4], Mimoun Zouhdi[2] and Abdelkarim Filali-Maltouf[1]

[1]University Mohammed V-Agdal, Faculty of Sciences of Rabat, Laboratory of Microbiology and molecular Biology. 4 Avenue Ibn Batouta, B.P. 1014 RP, 10100, Rabat, Maroc, Morocco.
[2]University Mohammed V – Souissi, Faculty of Medicine and Pharmacy, Rabat. Laboratory of Microbiology, Avenue Med Belarbi Alaoui Souissi-Rabat. BP 6203 Rabat Instituts, Rabat 10 000, Maroc, Morocco.
[3]International Quality Control Corporation (IQCC), PO Box 3719, Mount Vernon New York 10553, USA.
[4]University Mohammed V – Souissi, Faculty of Medecine and Pharmacy of Rabat. Laboratory of Anatomy and Pathological Cytology. Av. Mohamed Belarbi El Alaoui, B.P. 6203 Rabat, Maroc, Morocco.

Accepted 1 December, 2013

Due to the great deal of attention given to patient's security, it is necessary to reduce non-conformities in pre-analytical phase, so the laboratories of medical bacteriology that can ensure the quality of examination results can contribute to diagnosis and prescription of treatment and patient safety. It is important that these laboratories collect and exploit statistics of the non-conformities rates which occur during pre-analytical phase in order to implement improvement plans. This study was done in a period of 10 months in a laboratory of bacteriology in a university hospital center. It aims to control the nonconformity rates of the biological samples found, show their nature and causes and to assess their criticality. Results obtained showed that overall rate of non-conformities identified in the year 2012 were 2.5% (310 samples from 12 398). 61% of the recorded errors concerned both the identification of biological samples and patient's identity. 29% was on conveyance and 10% on the quality and quantity of samples. The setting up of the corrective and preventive actions plan was done by the application of Pareto law. The adoption of the Failure Mode, Effects and Criticality Analysis (FMECA) approach was meant for the risks analysis linked to these dysfunctions at pre-analytic phase. Anomalies of heterogeneity during this pre-analytic phase of the studied laboratory suggest the requirement of more rigorous methodology and exploitation of the projected indicators with suitable technologies to assess non-conformity and to follow quality improvements. Finally, to improve exams quality in laboratories, an organization and a quality action plan are proposed to ensure the management and control of the non-conformities occurring during the pre-analytic phase.

Key words: Non-conformities, pre-analytical phase, medical bacteriology, risks, quality improvement, management.

INTRODUCTION

Guide to the Correct Execution of Biomedical Analysis (GBEA) and ISO15189 standard impose a number of obligations to biologists during the exercise of their profession. From a regulatory point of view, these quality standards require that medical bacteriology laboratories (MBL) implement a policy and a management procedure

*Corresponding author. E-mail: youssef_qmss@hotmail.fr. Tel: (00 212) 6 61 47 67 99.

to control non-conformities according to their quality management system (GBEA, 1999; ISO 15189, 2003).

Nowadays, the importance of the awareness of errors in MBL practices and their potential negative impact on patient outcomes increase as the data analysis are directly involved in the vast majority of diagnosis and medical treatments (Forsman, 1996). GBEA defines these analyses as a set of successive steps, from sampling of the biological sample to delivery of results. The quality of pre-analytical and analytical phases and results validation determine the final quality of the overall result. In medical bacteriology, the general approach of the pre-analytical phase includes several steps, among which the sequence and coordination must be flawless. The choice of samples, methods of collection, conveyance and storage must be of high quality. Otherwise, test result may have no clinical utility (Cheminel et al., 2000; Rémic, 2010).

Several classes of non-conformities exist. Their management should be a procedure that describes the rules of registration and treatment (Rogowski and Annaix, 2010). The compliance of biological samples is always the subject of special attention for the professionals of biology. In fact, it determines the reliability of the analytical phase to be followed (Ovaguimian, 2004). This step is essential for a quality analysis, since non-compliance in the biological sample may affect results (Astion et al., 2003; Plebani and Carraro, 1997; Rousset, 2004). Recent studies show that in 32 to 75% of cases, the causes of errors of results are due to failures in this phase (Bonini et al., 2002; Hawkins, 2012; Plebani, 2010). Many laboratories have obtained very encouraging results following the introduction of a system for managing non-conformities samples under their quality approach (Rousset, 2004; Vachée and Ramon, 2004).

Like other countries and in the field of health, Morocco was involved in a quality approach towards the end of 2006 through a partnership between the Ministry of Health and the World Health Organization (WHO). They aim to mobilize the whole staff in an effort to achieve total quality. This underlines the willingness and the major concern of Ibn Sina University Hospital (CHIS), which started in November, 2007 an ambitious program for the institutionalization of quality management at the establishments under the CHIS in general and the ISO certification 9001v2008 of its biomedical analysis laboratories in particular.

First of all, this certification demands the compliance with regulatory requirements, namely the Moroccan GBEA, a quality referential, the application of which meets the regulatory requirement related to Guide to the Correct Execution of Biomedical Analysis (Order of the ministry of health N° 2598-10 of 27th Ramadan, 7th September, 2010). The program of quality management was proposed to CHIS Medico-Technical Services and Departments of Rabat, on one hand, by an institution circular of the Quality Management Program (Circular No. 34/07) and by a circular requiring managerial compliance to GBEA requirements, on the other hand (Circular CHI, 2007).

The implementation of GBEA requirements facilitates the mastery of most pre, per and post analytical adverse events. GBEA specifies particularly, in Chapter III (2.1 and 2.2) compliance monitoring to be carried out regarding the collection and identification of biological samples before performing the analyses requested. While 9001v2008 ISO standard requires, in Chapter 8.3, the establishment of a procedure to detect, record and process non-conformities.

This study is a normative and regulatory assessment of non-conformities of medical bacteriology laboratory of CHIS. It is based on a systemic approach that would lead to the establishment of a reliable action plan for controlling errors in the pre-analytical phase. To achieve our goal, we have to implement development methods and appropriate deployment such as the identification of non-conformities and analyzing causes successively, assessment (FMECA process), prioritization, drafting and implementation of the Quality improvement plan (PAMQ).

MATERIALS AND METHODS

Presentation of the studied medical bacteriology laboratory of Ibn Sina Hospital

The study targeted a University Laboratory of Microbiology that serves 10 university hospitals under Ibn Sina Hospital of Rabat (CHIS) that joined a quality management program of the Moroccan Ministry of Health. This laboratory receives requests and biological samples from care hospitals and hospitalization institutions such as: Ibn Sina Hospital (ISH), Children's Hospital of Rabat (HER), Laboratories and Outpatient Clinics (EXT), ERRAZI Hospital (HEY) of Sale, Rabat Hospital of Specialties (HSR), Souissi Maternity Hospital, EL AYACHI Hospital in Sale (HAS), MOULAY YOUSSEF Hospital (HMY) of Rabat, National Institute of Oncology (INO), and National Center for Reproductive Health (NCRP). For the medical staff, it is composed of a manager who is a professor of higher education, four biological physicists, one assistant professor and internal residents. The para-medical staff consists of five engineers, 12 technicians, a head nurse, three versatile nurses and six service agents. The laboratory has two controllers. It provides analytical activities involving: Medical bacteriology, bacterial serology and the control of the hospital and food hygiene.

In 2009, the laboratory was committed to a quality approach that aimed for ISO 9001 certification in short-term and long-term accreditation. In 2011, quality cell service of bacteriology has developed a self-report diagnosis about application of Moroccan GBEA.

The different steps of the approach

During 2012, in the space of 10 months, we collected information on non-conformities identified and treated samples. The goal was to have a qualitative and quantitative identification of all non-conformities identified by well-defined criteria (Table 1). Indeed, their management was essential for corrective actions to optimize the terms of the pre-analytical phase and thus improve the quality of service provided by the laboratory (McPherson and Dalton, 2011). The methodology adopted in the studied bacteriology laboratory is as follows: when a malfunction is found, a datasheet of non-conformities is completed. An example of a plug of non-

Table 1. Criteria of non-compliant samples.

Type of Non-conformities	Criteria for identifying non-conformities
Identification	Sample unidentified Unconformity Identification sample / plug No sample Absence of plug Unidentified Service
Quality and quantity of sample	Volume: insufficient volume Container: Defective sample Container: Nature of inadequate container (choice of tube) Container: Non-compliance with health and safety rules in force
Routing	Incorrect conditions of conveyance Delay in receiving Laboratory error (incorrect destination)
Prescription	Prescribing identification Date and time limitation Absence of clinical information

Identity of the patient:
Date : time:
Service: prescriber:
sampler:

Nature of sampling: ☐ Blood ☐ Urine ☐ Stools ☐ Puncture
☐ Pus ☐ Others ☐ specified

Analysis requested:

Nature of non-conformity

Container according to the analysis ☐ insufficient volume ☐ Absence or vacuum tube ☐ uneven ☐ Non compliance with health and safety rules

Identification ☐ Lack of identity ☐ Identity mismatch ☐ Illegible or multiple identities ou absent ☐ Others (o specify) :

Request sheet ☐ Not ☐ Absente ☐ Clinical information

Routing conditions:
- Non-compliance of Carriage Conditions :
☐ temperature ☐ Time out ☐ Routing error

Actions taken
- Cancellation by the laboratory (clinical service is accused of non-conformity).
☐ Sampling {and / or request sheet} returned to the clinic service.
- Review effected subject below:
☐ Recherche de compléments d'information effectuée par le personnel du laboratoire. ☐Search for additional information made by the laboratory staff.
☐ Correction delayed by the sampler of a defect or lack of identification.

Visa identity of the speaker:

Figure 1. Example of a plug of non-compliance samples

conformities nominal by patient is shown in Figure 1. One or several immediate corrective actions are implemented by the person who finds the malfunction. If the laboratory cannot meet the contract with reference to the client, this latter is informed of the proposed adjustments. Every month, a summary of synthetic results of non-conformities are well presented to have the number and nature of

each type of non-conformities relative to the total number of applications. A root cause analysis is then engaged with an assessment of the importance of failure modes and criticality of services to be engaged in the improvement of quality and identification (HAS, 2012).

The determination of the criticality index needs to prioritize non-conformities. It is calculated as the product of the scores assigned to the frequency with the severity and the probability of detection of the anomaly (Metais, 2004; ISO 15189, 2009). Thereafter, preventive actions are proposed for application to prevent the recurrence of certain anomalies. Finally, the head of quality assurance monitors non-conformities and verifies that the corrective and preventive actions are effective in order to close the plug (ANAES, 2000).

The quality tools used

Non-conformities often belong to lack of information, training, non-compliance procedures or a flaw in the organization and operation of the laboratory. To prioritize non-conformities and to identify priorities and relevance of corrective and preventive actions to be undertaken, it proved very useful to use simple tools of analysis and decision support such as Pareto chart (Cattan et al., 2008; Clément, 2006), Ishikawa diagram (Ishikawa and Loftus,1990; Bertrand, 2001) and A Failure Mode, Effects and Criticality Analysis (FMECA) method (Archier, 2004). This latter, advised by High Health Authority (HAS) especially in the evaluations of professional practices and is a strategic axis of the CHIS and meets our expectations. In this perspective, a laboratory committee named Co-LAB was created for the development and validation of grid, rating scales as well as actual risk analysis. We used Pareto chart to identify potential causes. The Ishikawa diagram has allowed us to analyze the causes and group them as a family. As for the FMECA method, it allowed us to assess the criticality index (CI) of non-conformities according to their frequency, severity and detectability:

CI = Frequency (F). Gravity (G). Detectability (D)

RESULTS

Identification and measurement of non-conformities studied

The overall rate of non-conformities identified in the year 2012 was 2.5% (310 from 12,398 samples). Since 2009, when the rate of non-conformities was 8%, we observed a significant decrease in 2012. 61% of the recorded errors concerned both the identification of biological samples and patient's identity. 29% was on conveyance and 10% on the quality and quantity of samples (Figure 2). Among the causes of non-conformities relating to identification problems, it should be mainly noted that lack of identification of the sample was 29% and sometimes the discrepancy between the demand form and sample was 14% (Figure 3). Non-conformities due to conveyance errors carries a rate of 26% and a rate of 3% for the period of transport. The laboratory receives 10% of biological samples with a discrepancy or lack of labeling and 10% with abnormal sample container (bad choice or defective tube). By studying the rate of non-compliance of the requirement, we find that it is equal to 1%.

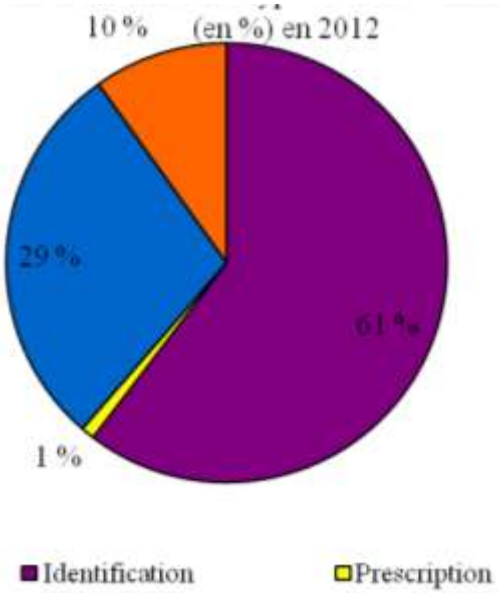

Figure 2. Pie chart showing different types of non-comformities in LBM-CHIS.

Root cause analysis and prioritization of the studied non-conformities

We conducted research on potential non-conformities according to Pareto law which states that 80% of non-conformities come from 20% of causes. After ranking frequencies of the possible causes of non-conformities that result in decreasing order of importance and computing their percentages and accumulation, we have plotted the Pareto diagram considering types of non-conformities recorded (Figure 4), hospitals (Figure 5) and type of sampling (Figure 6) to quickly view the priorities of action to be taken. The results show that 72 to 86% of cases of errors result from the total absence of identification of biological samples, errors of destination laboratory and identification of discrepancy between the request form and the sample. After application of the same Pareto law on these types of non-conformities, according to their distribution facility, it appears that 80% of these non-conformities identified are related to samples received from the HIS and HER with a respective distribution of 60.84 and 19.09% (Figure 5). Thus, most of the non-conformities found at this institution are due to lack of identification of the sample (58 at the HIS for 89 non-compliant samples) and the discrepancy between the application form and the sample (34 at the HIS for 44 non-compliant samples at 10 hospitals).

In order to guide our actions, we sought to better understand the relationship between the rate of non-conformities and types of sampling (Chan Tche Hiong, 2012) (Figure 6). Results indicate that 74 to 85% of non-conformities are induced by tests of blood type, urine culture (urine cytology examination) and sputum (Figure 6). Meanwhile, monthly meetings of managers and

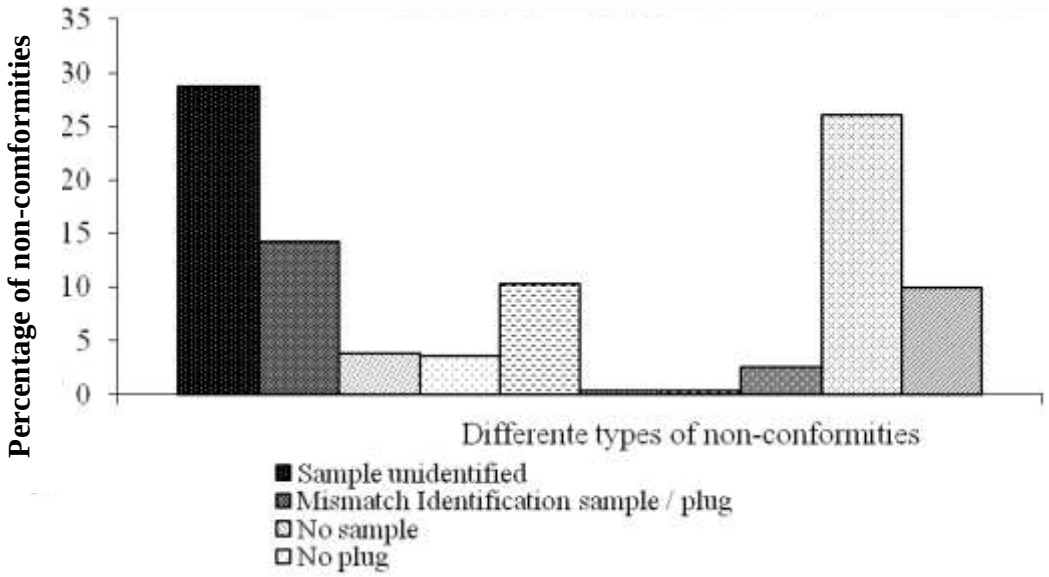

Figure 3. Distribution of different types of non-comformities.

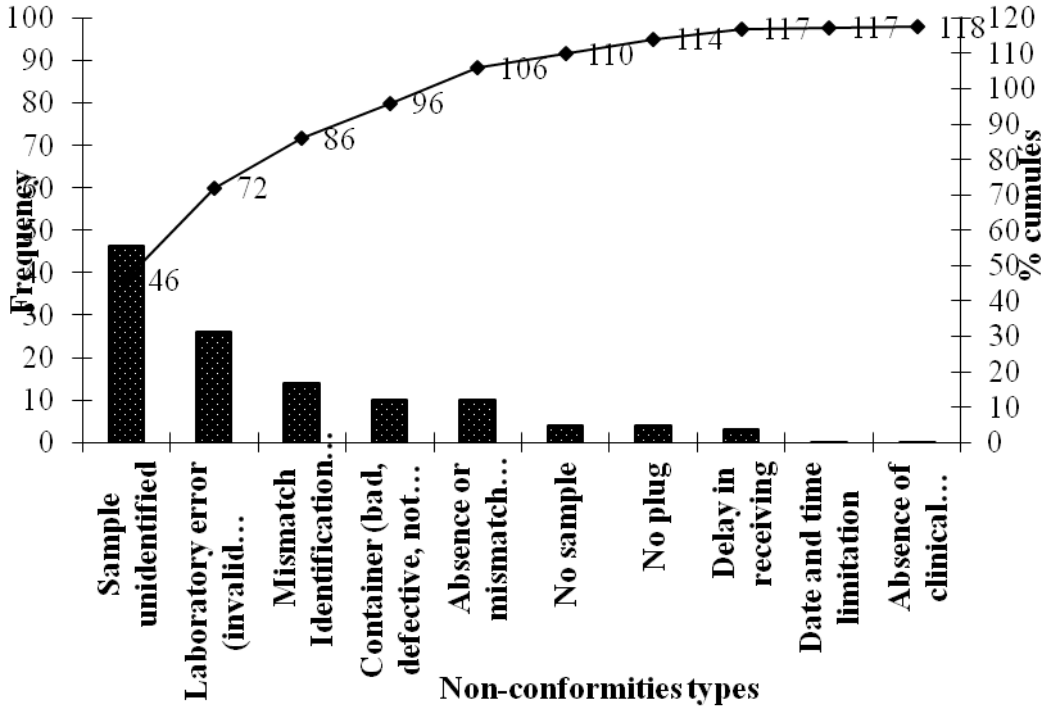

Figure 4. The Pareto diagram considering types of non-conformities recorded

nurses' staff allowed the initiation of a global reflection and discussion on the identification of causes from Ishikawa diagram (Azzabi, 2010) (Figure 7). A manual and reminder are developed by a working group to guide prescribers and samplers in achieving different bacteriological samples to perform analyses under optimal conditions. These documents will be distributed to guide care services and be made available on the intranet of the CHIS.

FMECA analysis process of non-conformities studied

The analysis of non-conformities recorded and the

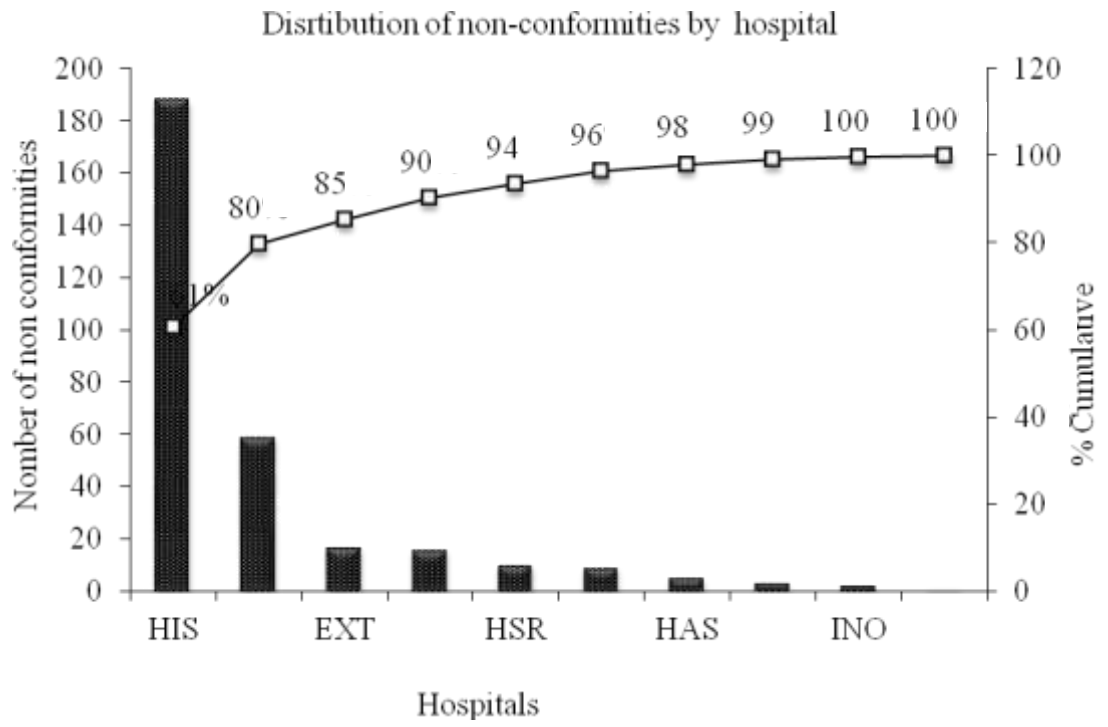

Figure 5. The Pareto of non-conformities by hospitals.

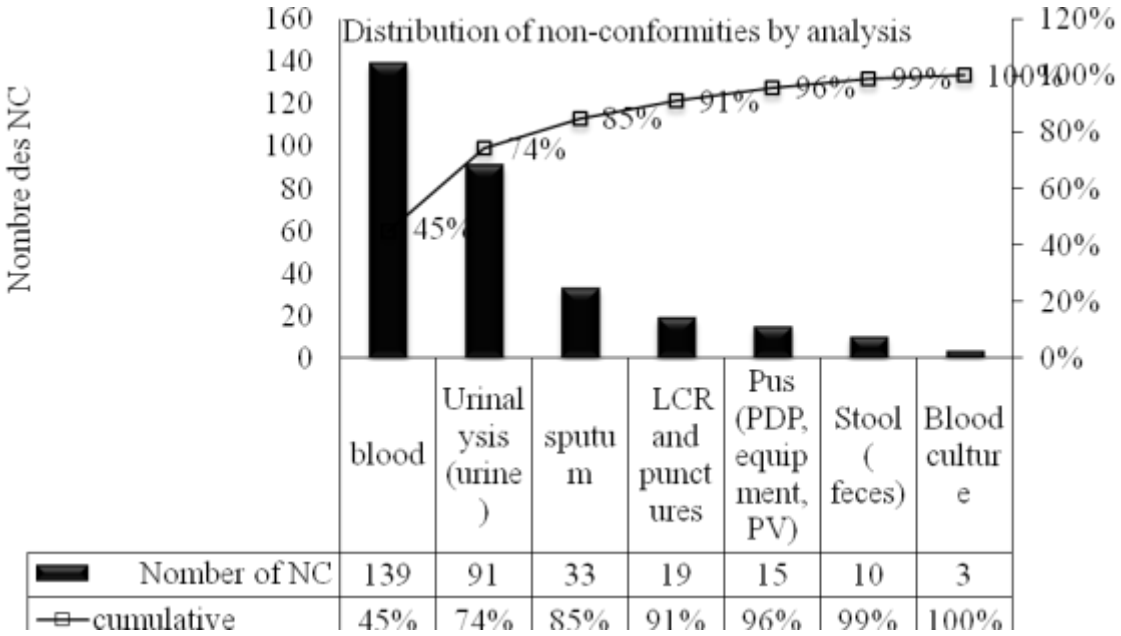

Figure 6. The relationship between the rate of non-conformities and types of sampling.

evaluation of their criticality was made by adopting the FMECA method as analysis approach of risks related to the pre-analytical phase. Thus, we have established rating scales of frequency, severity and detectability of the reported non-conformities (Tables 1 to 4). Thereafter, a gate of criticality was made to perform a classification of the deficiencies found and define corrective and preventive shares to begin according to criticality index (Table 5). The results highlight three critical failures with the highest criticality index (CI). This is due to the wrong

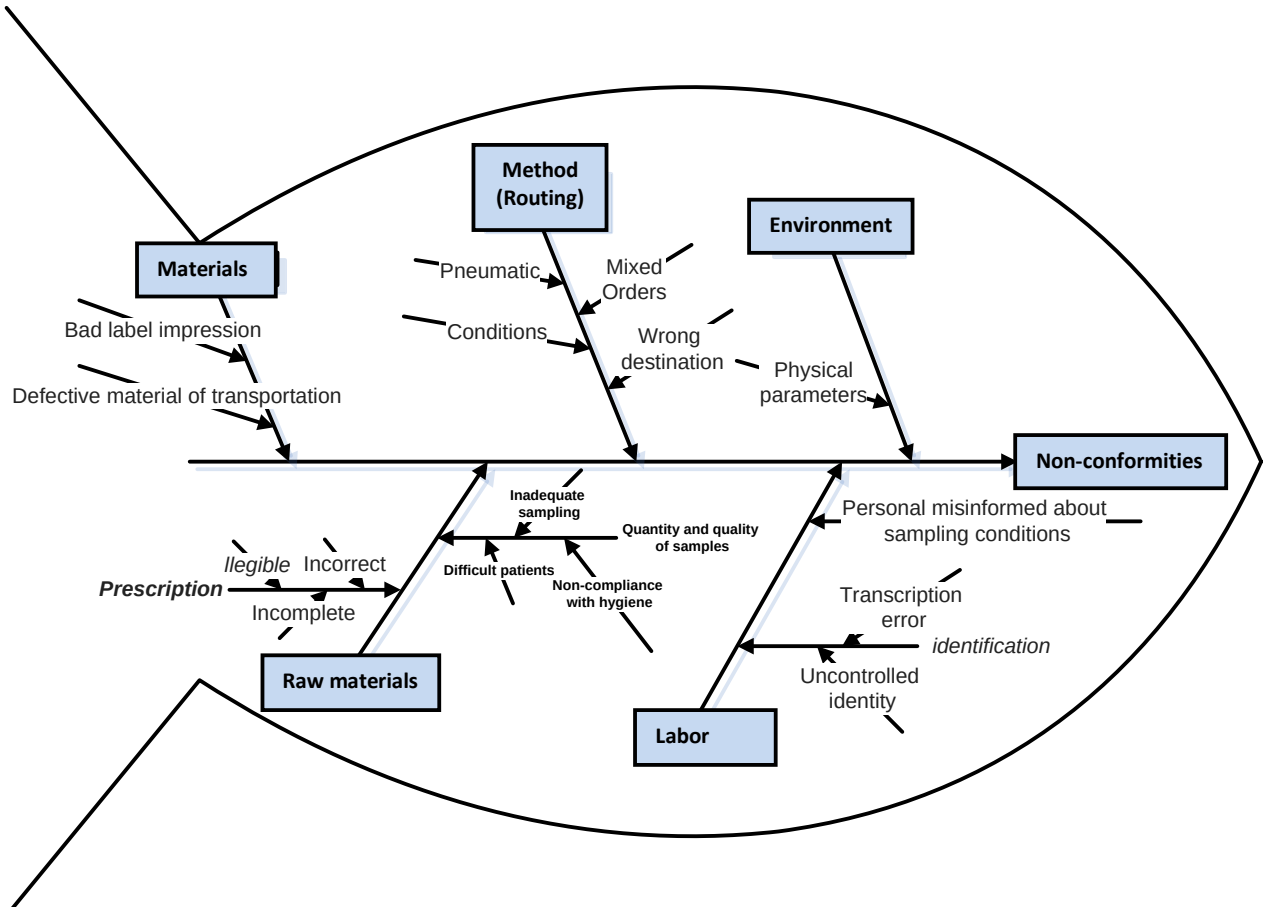

Figure 7. Ishikawa diagram demonstrating the relationship causes-effect on the conformity of the preanalytical phase.

Table 2. Frequency scale score (rating scale for frequency of failure or non-compliance.

Frequency of failure	Listing	Probability risk
Very low, exceptional or less than once per year	1	Uncommon or probable
Low frequency, 1 to 2 times per year	2	Infrequent or probable
Frequency, 3 to 12 times per year or several times per month	3	Frequent or probable
High frequency, once or more times per week	4	Very probable or highly probable

Table 3. Severity note scale (note scale for severity of failure or non-conformities).

Effect of failure severity	Listing
Absence of the effect on the patient	1
Minimal impact on the result and / or the patient or Delay rendering of the result or the patient's treatment	2
Erroneous result and / or induction of morbidity	3
Erroneous result and / or cause of death	4

Table 4. Scale score for the detectability (scoring grid for the detectability of defects or non-comformity).

Probability of not detecting the failure	Listing
Detectable by the operator but blocking communication and computing to the laboratory	1
Hardly detectable by the operator	2
Undetectable	3

Table 5. Criticality index of non-conformities studied.

Failure mode	Causes	Potential effects	F	G	D	IC
Identification	Sample unidentified	Erroneous report	4	4	3	48
	Mismatch of sample identification / plug	Erroneous report	4	4	3	48
	No sample	Not feasible analysis see refusal	3	2	2	12
	Absence of plug	No results	3	1	2	6
	Absence or labeling mismatch	Erroneous or refused analysis	4	3	2	24
Prescription	Date and time limitation	Long report or delay to support patients	2	2	1	4
Routing	Absence of clinical information	Uninterpretable results	2	2	1	4
	Delay in receiving	Biased results	3	2	1	6
	Laboratory error (invalid destination)	Erroneous or biased results	4	3	3	36
Sampling Quality and quantity	Container (Insufficient, defective, not-adequate, ...)	Baised results or not feasible	4	3	2	24

identification of biological samples and the identification of discrepancies between the tube and request form (CI = 48) and errors of destination laboratory (CI = 36).

DISCUSSION

The overall rate of non-conformities identified during this study proved that prescribers were unfamiliar with laboratory analyses in most of the time and do not apprehend more difficult pre-analytical requirements (Carolyn and Clancy, 2013). Root cause analysis and prioritization of the studied non-conformities, according to Pareto law, showed that in the case of HIS, most of errors cases are due to total absence of identification of biological samples, errors of destination laboratory, and identification of discrepancy between the request form and the sample can be explained by the magnitude of its size and the strong flow of samples sent to its laboratory (> 10,000 annual requirements). While so, when these three cases are dealt with, 72 to 86% of non-conformities will be removed (Figure 4). The geographic distance between HER and the laboratory of analysis influences significantly the type of non-conformities relating to destination errors (28 to 59 non-compliant samples at the HER) (Hinckley, 2003).

In light of the results, it is of paramount importance to reduce anomalies corresponding to the identification of biological samples due to errors destination laboratory and some others due to identifying discrepancies between the request form and sample especially for the blood type analysis, urinalysis and sputum at the less efficient institutions (HIS and HER). On the other hand, these elements highlight, first, caregivers' awareness of patient's identification and blood samples, urine and sputum collected in both hospitals cited. The rate of these types of non-conformities, especially their nature, can serve as an indicator and allow the establishment of comparative tables (monthly, yearly) (Open Motion Planning Library (OMPL), 2012).

Results obtained with FMECA method complete those of the Pareto chart. It turns out that these three causes of non-conformities are critical (Larrose and Le Carrer, 2006). Indeed, any critical point must be a corrective or preventive action (Ridoux, 1999). From these results, it can be concluded that it is imperative to consider the major non-conformities recorded related to the identification of biological samples, errors of destination laboratory and identifying discrepancies between the request form and sample, especially for blood type analysis, urinalysis and sputum, as quality indicators to follow. Thereafter, an objective statistical analysis of these indicators reinforces the determination of timely and effective improvement actions. The measurement of these non-conformities induces a good improvement process in the studied laboratory. It motivates actors,

monitors the effectiveness of actions and measures gains. This will provide a good quality approach, which primarily targets monitoring of these indicators for improvement. The monitoring of these indicators can lead to their removal if these malfunctions are restored. Computers were mostly used in utilizing data already entered (Camara, 2002).

To enable the laboratory improve its quality management plan, it is recommended that the following priority actions are undertaken:

1. The sampler personnel of HIS and HER should be informed and reminded about the good practices of biological sample (especially blood, urine and sputum) because he is responsible to identify mistaken patient identity.
2. Caregivers should be guided to solve problems related to patients' identification and sampling or its realization (blood, urine and sputum) before recording; a telephone call center could be set up in the central reception to facilitate communication between the samplers, prescribers and bacteriology laboratory. It can be supplemented by an intranet site on biological tests. These items must be irregular information treated during meetings of COLAB on pre-analytical phase.
3. The installation or label design should be reviewed and identity control of the patient in conjunction with the SIL should be implemented. The presence and consistency of labels with the correct analysis of each patient needs to be verified.
4. To address the non-conformities related to conveyance, container should be transported in a sealed and dry plastic bag, with a separate accompanying document compartment. That is, a means of information sheet to the recipient laboratory, which also mentions every incident that can occur during sampling.
5. Notifying non-conformities reception in the SIL will lead to efficiency and will allow for computer tracking of the event in the patient's file. Thus, it would be possible not only to link the non-conformities to prescribing service, but also to know the number of samples made by the service to establish the non-conformities percentage by the latter.
6. Computer applications are important because they allow the use of multiple criteria and are refined (monthly frequency of statistical analysis, the nature of non-conformities, care service, patient etc.).

After the implementation of these actions, monitoring their performance will allow to note the quality or the projected improvement. Indeed, it is essential to organize the identitovigilance (System of surveillance and prevention of errors and risks associated with the patients' identification) as part of the risk management because the quality of the identification of the patient's biological sample is an issue of safety. An American study, conducted in 2009, proved that mistaken identity (tube and application sheet) is one of the root causes of accidents care, even if it is not specifically identified in the various investigations of medical errors (Perrin and Morin, 2009). Another study, done in five weeks in 2005, has extrapolated 160,000 serious adverse events related to misidentification of a biological sample with an error of 1/18 that had a serious side effect (Michel et al., 2005). Therefore, the Joint Commission for Accreditation of Healthcare Organizations in the United States has made the identity of the patient a first priority (National Patient Safety Goals (NPSG), 2011).

Conclusion

The concept of total quality management encompasses all the steps involved in sample processing, beginning from test ordering to the final interpretation of results by the clinicians to reduce or eliminate the errors that may arise during the various steps. In the literature, we did not find a maximum rate of "non-conformities authorized" and zero error does not exist. In our experience, an improvement was noticeable during three years (2009 to 2012).

This study is concerned with non-conformities recorded in the pre-analytical phase. To ensure accountability and accuracy of results in our laboratory, the errors of pre-analytical phase should be reduced through rigorous patients' identification and effective sample transport for more important improvement. So, the promotion of ideal practices for sample identification and sample transport procedures is a pre-requisite for the efficacy of laboratory functioning (especially blood, urine and sputum samples). Indeed, we carried out regular in-house training sessions for our technicians to familiarize them with the standard protocols for these specific sample processing. For this purpose, standard operating procedure for the different steps involved in the pre-analytical was developed. As often, information campaigns have a moderate range. So, they must be renewed and what is now left is to trigger actions that target training on specific needs of the laboratory. Such trainings have facilitated in the adoption of ideal practices by our laboratory personnel. The samples are thereby transported to our laboratory from the collection center by our staff following the basic precautions that must be adhered from sampling to transportation. A practice of keeping a record of the detected errors at all stages of the pre-analytical phase and then devising corrective strategies for their prevention can gradually free our laboratory from all such errors.

Our study has also established an effective communication between laboratory staff and those of service providers. However, this approach requires an investment of time to complete the survey (compilation of more than 140 sheets of abnormal sample per month). It also requires the involvement of all staff in the laboratory

to be exhaustive in the sampling anomalies noted. Once this work is well-organized, it would be interesting to develop it, taking into account other criteria such as the absence of identification of the sampler, of the prescriber on the request sheet. Our aim is to improve caregivers' practice during the identification of patient's biological sample and to achieve a rate below 0.3% for non-conformities. At long-term, the ultimate goal of this approach is to obtain zero anomaly of the patient's identity (tube and sheet request). We insist on the fact that the attendance of the laboratory is essential in the monitoring of non-conformities and to trigger actions. It is essential to empower all health actors (care services, laboratories). Only an awareness of the importance of non-conformities will permit the implementation of an effective prevention and the development of practical solutions to minimize errors. Although it seems unrealistic to achieve this, it is the laboratory responsibility to do everything possible to strictly stop errors at this level.

REFERENCES

Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES) (2000). Méthodes et outils des démarches Qualité pour les établissements de santé. p. 135.

Archier C (2004). Contribution à l'analyse de criticité des dispositifs médicaux : Stage SPIBH, UTC, URL : http://www.utc.fr/~farges/.

Astion ML, Shojana KG, Hamil TR, Kim S, Ng VL (2003). Classifying laboratory incident reports to identify problems that jeopardize patient safety. Am. J. Clin. Pathol. 120:18-26.

Azzabi L (2010). Contribution a l'amélioration d'un système de production: Intégration de la Méthode six Sigma et Approche Multicritère d'aide a la décision dans sidelec internationale. Thèse de doctorat en cotutelle. l'Institut des Sciences et Techniques de l'Ingénieur d'Angers. Ecole Doctorale de Sfax. p. 369.

Bertrand D (2001). Accréditation et qualité des soins hospitaliers. Adsp. 35:17.

Bonini P, Plebani M, Ceriotti F, Rubboli F (2002). Errors in laboratory medicine. Clin. Chem. 48:691-698.

Camara da Ndiaye (2002). Contribution à la gestion du Système d'Information Sanitaire de l'Hôpital Fann. Thése de doctorat soutenue publiquement à Institut Supérieur de Santé. Dakar, Sénégal. p 47.

Carolyn M, Clancy MD (2013). Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices Evidence Report/Technology Assessment. Agency for Healthcare Research and Quality. p. 211.

Cattan M, Idrissi N, Knockaert P (2008). Maîtriser les processus de l'entreprise. Edition Eyrolles. pp. 266-267.

ChanTche HM (2012). Histoplasmose pulmonaire à *Histoplasma capsulatum* A propos de quatre cas observés à Rouen. Thèse de doctorat en médecine (diplôme d'état). Faculté mixte de médecine et de pharmacie de Rouen. p. 80.

Cheminel V, Prévosto JM, Muraillat D (2000). Mise en place d'un manuel assurance qualité dans un laboratoire de biologie hospitalière. Ann. Biol. Clin. 58:228-232.

Circular N°34 de la Direction Générale du Centre Hospitalier Ibn Sina de Rabat (2007). Programme de management qualité pour les services médicaux et techniques.

Clément B (2006). Cours sur le Diagramme de Pareto. janvier.

Forsman RW (1996). Why is the laboratory an afterthought for managed care organizations? Clin. Chem. 42:813-816.

Guide de bonne exécution des analyses (GBEA) (1999). Arrêté du 26 novembre. Journal officiel du 11 décembre.

Haute Autorité de Santé (2012). Amélioration des pratiques et sécurité des soins « La sécurité des patients : Mettre en œuvre la gestion des risques associés aux soins en établissement de santé, Des concepts à la pratique ». p. 64.

Hawkins R (2012). Managing the Pre- and Post-analytical Phases of the Total Testing Process. Ann. Lab. Med. 32:5-16.

Hinckley CM (2003). Make no mistake-errors can be controlled. Qual Saf. Health Care. 12:359-365.

Ishikawa K, Loftus JH (1990). Introduction to quality control. Toky, Japan: 3A Corporation. p. 129.

ISO 15189 (2003). Laboratoires d'analyses de biologie médicale – Exigences particulières concernant la qualité et la compétence.

L'accréditation selon NF EN ISO 15189 (2009). Rev. Fr. Lab: Hors-série novembre 2.

Larrose C, Le Carrer D (2006). Traitement des non conformités en pratique quotidienne. Ann. Biol. Clin. 65:99-105.

McPherson RA, Dalton MD (2011). Henry's Clinical Diagnosis and Management by Laboratory Methods. 22nd Edition.

Metais E (2004). Analyse des modes de défaillance, de leurs effets et de leur criticité, Devinci Conseil - Stratégie et organisation industrielle - Ingénierie des produits et des process ; p. 96.

Michel P, Quenon JL, Djihoud A, Tricaud-Vialle S, de Sarasqueta AM, Domecq S (2005). Les évènements indésirables graves liés aux soins observés dans les établissements de santé : premiers résultats d'une étude nationale. Études et résultats, Drees. p. 398.

National Patient Safety Goals (NPSG) (2011). Goal 1: improve the accuracy of patient identification. Joint Commission on Accreditation of Heathcare Organizations. http://www.jointcommission.org/

OMPL (2012). Observatoire prospectif des métiers et des qualifications dans les professions libérales. Étude réalisée par le cabinet Pollen Conseil pour l'OMPL www.pollen-conseil.fr ; 16 rue jean-pierre timbaud, 75011 Paris.

Order of the ministry of health (2010). Order of the ministry of health N° 2598-10 of 27th Ramadan, 7th September. The official journal of the ministry of health N°5892 11th hija 1431 /18-11-2010; 2046-2050.

Ovaguimian O (2004). La gestion des non conformités des examens: obligation légale ou outil de coopération ? Rev. Fr. Lab. 367:80-81.

Perrin A, Morin C (2009). L'identitovigilance dans les établissements publics de santé en France: état des lieux et prospective. Ann. Biol. Clin. 67:177-189.

Plebani M, Carraro P (1997). Mistakes in a stat laboratory: types and frequency. Clin. Chem. 43:1348-1351.

Plebani M (2010). The detection and prevention of errors in laboratory medicine. Ann. Clin. Biochem. 47:101-110.

Référentiel En Microbiologie Médicale (REMIC) (2010). Par le groupe Rémic de la Société Française de Microbiologie. René Courcol. 4 éme édition.

Ridoux M, Moyen AMDEC (1999). Techniques de l'ingénieur, L'entreprise industrielle. 1:4-220.

Rogowski J, Annaix V (2010). Norme NFENISO 15189. Analyse comparative avec le GBEA et mise en place du nouveau référentiel. Ann. Biol. Clin. 68:367-377.

Rousset P (2004). Mise en place du suivi des non conformités des prélèvements : l'expérience d'un laboratoire de biochimie. Rev. Fr. Lab. 367:81-83.

Vachée A, Ramon C (2004). Extraction de données du SIL : les outils, les indicateurs qualitatifs et quantitatifs. Spectra Biologie. 23:37-39.