

Available online at [GSC Online Press Directory](https://www.gsonlinepress.com/)

GSC Biological and Pharmaceutical Sciences

e-ISSN: 2581-3250, CODEN (USA): GBPSC2

Journal homepage: <https://www.gsonlinepress.com/journals/gscbps>

(RESEARCH ARTICLE)



## High preanalytical non-compliance and samples rejection rate in clinical biochemistry laboratory are decreased by nurse staff training in phlebotomy and sample handling

Modibo Coulibaly<sup>1,\*</sup>, Abdelaye Keita<sup>2</sup>, Moussa Diawara<sup>1</sup>, Valentin Sagara<sup>1</sup>, Brehima Traoré<sup>3</sup>, Oumar Guindo<sup>3</sup>, Bakary Maiga<sup>4</sup>, and Amagana Dolo<sup>4</sup>

<sup>1</sup> Centre National de Recherche Scientifique et Technologique, Hôpital Sominé DOLO de Mopti, Department of Biomedical Laboratory, Mopti, Mali.

<sup>2</sup> Institut National de Santé Publique, Department of Biomedical Laboratory and Research, Bamako, Mali.

<sup>3</sup> Centre National de Recherche Scientifique et Technologique, Hôpital Sominé DOLO de Mopti, Department of Public Health, Mopti, Mali.

<sup>4</sup> Université des Sciences Techniques et Technologiques, Faculty of Pharmacy, Bamako, Mali.

Publication history: Received on 01 December 2020; revised on 09 December 2020; accepted on 11 December 2020

Article DOI: <https://doi.org/10.30574/gscbps.2020.13.3.0400>

### Abstract

**Background:** Preanalytical phase of biomedical analysis remains an important source of diagnostic errors that deserves special attention. This study aims to evaluate the training in phlebotomy and sample handling impact on the preanalytical non-compliances.

**Material and Methods:** we performed a prospective study before and after staff training in phlebotomy and sample handling by systematically recording all clinical samples non-compliances. First, we assessed and describe the non-compliance baseline rate from January to December 2017 in the clinical biochemistry laboratory of Hôpital Sominé DOLO de Mopti. After two sessions of one week staff training in January 2018, we performed the same study from January to December 2018. We compared the proportions of non-compliances between the two assessments. Data were collected on the case report forms, captured in Excel and analyzed by R software for (Mac) OS X version 4.0.3. Pearson Ch2 or Fisher exact tests were used for the comparison of proportions. The statistical significance was set at  $p < 5\%$ .

**Results:** a total of 27,810 venous blood samples were received during the study period; 48% was for biochemistry, 41% for immuno-serology, 9% for blood cell count and 2% for coagulation tests. There were 3,826 instances of preanalytical non-compliances (13.76%) identified that led to sample rejection. Out of the 11 types of non-compliances investigated, 5 (45.4%) accounted for nearly 91% of the problems: insufficient sample volume (28.9%), hemolyzed samples (20.5%), inappropriate collection time (17.8%), sample clot (12.9%), and inappropriate sample collection tube (10.8%). We observed a significant difference in rates of non-compliance between inpatients and outpatients samples (44.4% vs 7.3%;  $p < 0.001$ ). The proportion of non-compliance have significantly decreased after the two training sessions of hospital staff in phlebotomy and sample handling 3,826/27,810 (13.8%) vs 3,009/32,476 (9.3%);  $p < 0.001$ .

**Conclusion:** we report a significantly higher rate of non-compliance in inpatients. Hospital staff training in phlebotomy and sample handling reduce the proportion of preanalytical non-compliance and thereby improve patient management and safety.

**Keywords:** Preanalytical phase; Sample non-compliances; Staff training in phlebotomy

\* Corresponding author: Dr. Modibo Coulibaly

Centre National de Recherche Scientifique et Technologique, Hôpital Sominé DOLO de Mopti, Department of Biomedical Laboratory, Po/Box : 139, Mopti, Mali. Phone : +22379319145, Email : [modibocoulibaly@yahoo.com](mailto:modibocoulibaly@yahoo.com)

---

## 1. Background

Advances in biomedical technologies, particular automation and the development of bidirectional laboratory information systems have made outstanding improvements in the quality of the analytical and postanalytical phases of testing [1]. However, the preanalytical phase of biomedical analysis remains an important source of diagnostic errors that deserves special attention [2-3]. Preanalytical sample non-compliances taints the quality and validity of biomedical analysis results. Moreover, preanalytical errors could be harmful to patient outcome when they are not detected. Non-compliance in the preanalytical phase is responsible for 60 to 70% of laboratory errors. In addition, about one-fifth of preanalytical errors could lead to inappropriate clinical decisions, treatments, untimely re-testing, and economic losses [4]. The International Organization for Standardization (ISO) 15189 version 2012, in its chapter on the technical requirements for the accreditation of medical biology laboratories, attaches particular importance to the preanalytical phase [5]. The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Laboratory Errors and Patient Safety project working group recommends the identification and systematic recording of preanalytical quality indicators for the improvement of test quality and patient safety [6]. The purpose of this work was to assess the impact of staff training in phlebotomy on preanalytical non-compliance in order to focus interventions to improve patient care and safety.

---

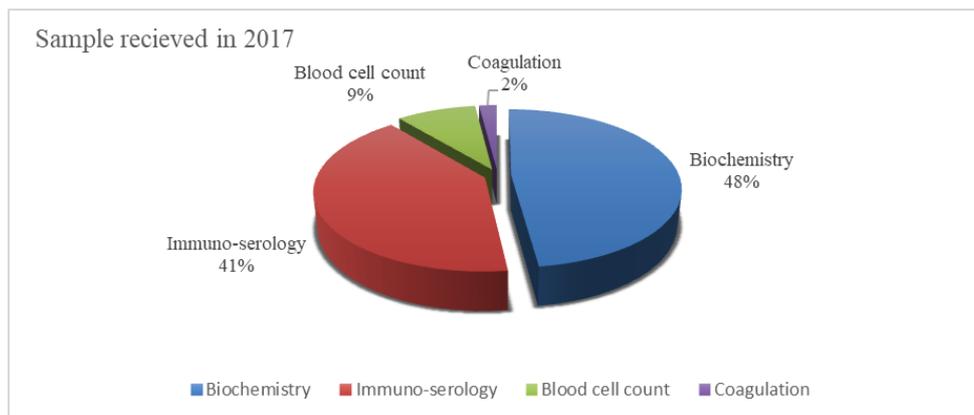
## 2. Material and Methods

We performed a prospective study by systematically recording all clinical samples non-compliance from January to December 2017 to assess causes of samples non-compliances and their proportions in the preanalytical phase in our clinical biochemistry laboratory. Inpatient specimens were collected by clinical department nurse staff, while outpatient blood samples were collected on site by laboratory staff, or referred from other health facilities in the city. After two sessions of one week staff training in January 2018, we performed the same study by systematically recording the preanalytical non-compliances from January to December 2018. The study was first validated by the scientific committee and submitted for approval to the ethics committee of the Hôpital Sominé DOLO de Mopti. Patient's rights were respected, particular their anonymity was preserved so that no data could be linked to a patient. This study involved venous blood samples for biochemistry, blood cell count, immuno-serology and coagulation. Specimen non-compliance with requirements was checked by our quality assurance manager according to a checklist designed for this purpose. Issues recorded include inappropriate sampling time, hemolysis, inappropriate tube, insufficient volume, sample clot (for blood count or coagulation testing), inappropriate transport delay, inappropriate transport temperature, sample damaged or lost during transport, inappropriate ratio of anticoagulant/sample (for coagulation testing), wrong test requested, and unlabeled sample. Data was recorded in the case report forms, captured in Microsoft Excel and analyzed by using R software for Mac OS X version 4.0.3. Pearson  $\chi^2$  or Fisher exact tests were used for the comparison of proportions with  $p$ -value  $\leq 0.05$  as the threshold of statistical significance.

---

## 3. Results

A total of 27,810 venous blood samples were received in laboratory, of which 48% was for biochemistry, 41% for immuno-serology, 9% for blood cell count and 2% for coagulation (Figure 1). There were 18,390 (66.1%) samples from outpatients and 5,371 (19.3%) inpatient samples. A total of 3,826 preanalytical non-compliances (13.8% of samples received) led to sample rejection. Out of the 11 non-compliances studied, 5 (45.4%) accounted for near 91.0% of the preanalytical problems (Figure 2). These were: insufficient sample volume (28.9%), hemolyzed samples (20.5%), inappropriate sampling time (17.8%), sample clot (12.9%) (in coagulation and hematology samples), and inappropriate tube type for testing requested (10.8%). We observed a significant difference in non-compliance rates between inpatients and outpatients (44.4% vs. 7.3%;  $p < 0.001$ ). Non-compliance with sampling times, insufficient sample volume, hemolyzed samples, sample clot in the EDTA and citrate tubes and collection in an inappropriate tube were significantly more frequent with inpatients samples (Table 1). In contrast, non-compliance with delivery times and temperature during transport was significantly more frequent in outpatients. We found no difference between inpatient and outpatient samples for damaged or lost specimens, anticoagulant /sample ratio errors, incorrect analyte recording, and unidentified samples. The proportion of non-compliance have significantly decreased after the two training sessions 3,826/27,810 (13.8%) vs 3,009/32476 (9.3%);  $p < 0.001$ . However, training did not have a reducing effect on sample damaged or lost during transport, inappropriate transport delay, and inappropriate transport temperature. In contrast, the other non-compliances have significantly decreased after the two training sessions (Table 3).



**Figure 1** Proportion of sample according to laboratory section.

**Table 1** Comparison of non-compliance proportions between inpatients and outpatients.

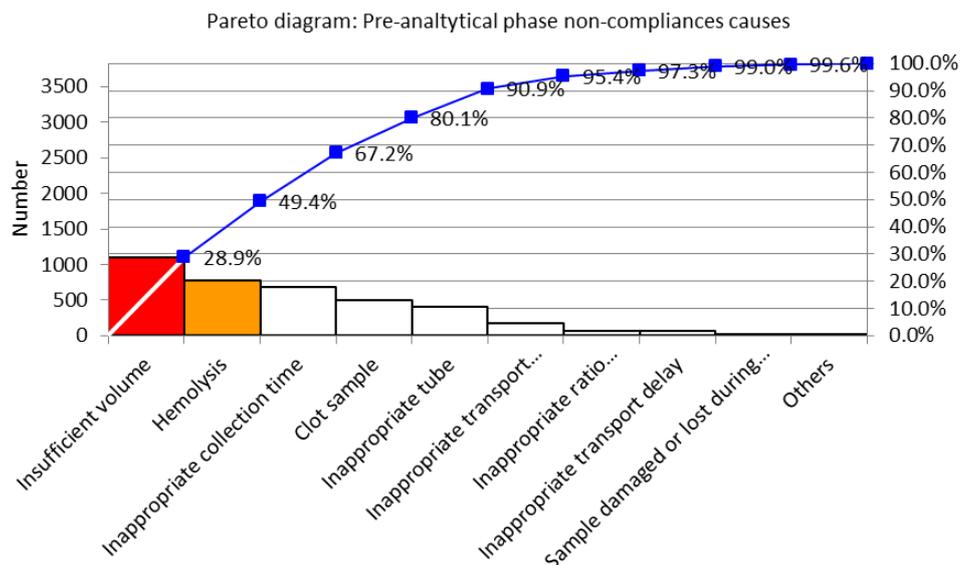
Non-compliances	Number	Inpatients N= 5,371	Outpatients N = 18,390	p*
Inappropriate collection time	681	392 (57.6%)	289 (42.4%)	< 0.001
Sample damaged or lost during transport	25	8 (32.0%)	17 (68.0%)	0.81
Inappropriate transport delay	64	7(10.9%)	57(89.1%)	0.02
Inappropriate transport temperature	175	27(15.4%)	148(84.6%)	0.01
Inappropriate tube	412	129(31.3%)	283(68.7%)	< 0.001
Insufficient volume	1,107	965(87.2%)	142(12.8%)	< 0.001
Hemolysis	784	527(67.2%)	257(32.8%)	< 0.001
Clot sample	492	309(62.8%)	183(37.2%)	< 0.001
Inappropriate ratio anticoagulant/Sample	72	14(19.4%)	58(80.6%)	< 0.31
Others	14	8(57.1%)	6(42.9%)	0.5*
Total rejection rate	---	2,386(44.4%)	1,440(7.3%)	< 0.001

\*Fisher's exact test.

**Table 2** Comparison of non-compliance proportion between adult and enfant samples.

Sample	Adult N = 17,965	Enfant (0-15 years) N = 9,845	p*
Normal samples	16,177 (90.0%)	7,807 (79.3%)	< 0.001
Non-compliance samples	1,788 (10.0%)	2,038 (20.7%)	< 0.001

\*Pearson's Chi-squared test with Yates' continuity correction



**Figure 2** Pareto diagram of preanalytical phase non-compliances causes.

**Table 3** Comparison of non-compliances proportions before and after training of staff in phlebotomy.

Non-compliances	Before training N = 27,810	After training N = 32,476	p*
Inappropriate collection time	681(2.4%)	435 (1.3%)	< 0.001
Sample damaged or lost during transport	25 (0.09%)	18 (0.05%)	0.15
Inappropriate transport delay	64 (0.2%)	62 (0.2%)	0.33
Inappropriate transport temperature	175 (0.6%)	167 (0.5%)	0.07
Inappropriate tube	412 ( 1.5%)	418 (1.3%)	0.05
Insufficient volume	1,107 (4.0%)	975 (3.0%)	< 0.001
Hemolysis	784 (2.8%)	554 (1.7%)	< 0.001
Clot sample	492 (1.8%)	321 (1.0%)	< 0.001
Inappropriate ratio anticoagulant/Sample	72 (0.2%)	37 (0.1%)	< 0.001
Others	14 (0.01%)	22 (0.07%)	0.48
Total rejection rate	3,826 (13.8%)	3,009 (9.3%)	< 0.001

\*Pearson's Chi-squared test with Yates' continuity correction.

#### 4. Discussion

Limitations of this study include lack of evaluation of test request form, patient's preparedness for tests, and microbiology specimens, which also constitute important preanalytical quality indicators as described by ISO 15189:2012 [5] and Laura Sciacovelli and *al* [6]. Also we did not assess the baseline of nurse knowledge's in phlebotomy and samples handling before and after training sessions. Nevertheless, systematic recording of samples non-compliances yielded interesting results in clinical biochemistry laboratory. The proportion of the outpatients sample in our study is comparable to that obtained by Ambachew S and *al* in 2018 who reported 70.1% and 29.8% respectively for outpatients and inpatients sample [7]. The rate of samples non-compliance in our study (13.8%) was very high compared to those observed by Ma Jesús Alsina and *al* in 2008 [8] (0.699%), Guimaraes AC and *al* in 2012 [9] (0.57%),

Aykal G and *al* in 2016 [10] (2.35%) and Lourens A Jacobsz and *al* in 2011 [11] (1.46%). However, other high rates of non-compliance similar to those obtained in our series have been reported by Zeliha Gunnur Dikmen and *al* in 2015 [12] (13.3%) for coagulation tests. Our high rate of non-compliance suggests a very strong need of strengthen the training of our staff on phlebotomy and samples handling. The most common causes of sample rejection in our study also differed from those in other studies. Ma Jesús Alsina and *al* in 2008 [8], found that 3 non-compliances (unreceived samples, hemolyzed sample and blood clot) had caused 81.0% of preanalytical non-compliances [8]. Insufficient volume, hemolyzed sample, blood clot and inappropriate tube have been reported as the leading causes of samples non-compliances in several studies [13, 11, 9, 12, 8]. This suggests that acting on these major non-compliances would significantly reduce the rate of samples rejection while improving result turn-around time (TAT). Furthermore, this should improve effectiveness and efficiency in the management of bedridden patients, since 5.1% of repeated sampling resulted in critical results [11]. We observed a significant difference in non-compliance rates between inpatients and outpatients (44.4% vs 7.3%;  $p < 0.001$ ). This pattern was found also by Maria Salinas and *al* in 2015 [14]. However, Ana-Maria Simundic and *al* in 2010 [15] observed the inverse pattern (1.12% vs 1.36%;  $p = 0.0006$ ). It's well known that non-compliances are more likely to be occurred in pediatric department because of challenges associated with sample collection, specimen volume, hemolysis and blood clot [16]. In our study, we observed significant difference between pediatric samples non-compliances compared to adult samples non-compliances (20,7% vs 10,0%;  $p < 0.001$ ). The high rate of non-compliance among inpatients in our study could be linked to a low level of knowledge of nurse staff on phlebotomy and samples handling mainly in pediatric department as reported by Cai Q and *al* in 2018 [17]. In contrast, non-compliance with delivery times and temperature during transport was significantly more frequent in outpatients samples. This could be explained by the outsourcing of samples from other health facilities in Mopti region and the fact that those samples were collected by laboratory technologists which are well trained in phlebotomy and sample handling. To reach continuous improvement of the preanalytical process quality, we performed two sessions of training of our staff. After these training we gained a significant reduction on preanalytical non-compliance rate (13.8% vs 9.3%;  $p < 0.001$ ). Güzin Aykal and *al* in 2016 achieved a significant increase in the level of knowledge of the phlebotomist from 58.9% to 91.8% and have decreased sample non-compliance from 2.35 % to 1.56% after training their staff in preanalytical process. [10]. Fatma Demet Arslan and *al* in 2018, also achieved an increase in learners correct responses and a significant decrease in preanalytical errors (0.6% vs 0.5%;  $p < 0.05$ ) [18]. Our study shows high rate of samples rejection, their typology and where they commonly occurred. Systematic control and recording of non-compliances represent not only a monitoring tool that could be used to sharpen interventions like training of staff in phlebotomy and samples handling but also a post-training evaluation tool to measure the impact of the intervention.

---

## 5. Conclusion

The total rejection rate was 13.8%. Out of the 11 preanalytical non-compliances, 5 account for near 91% of preanalytical errors mainly from inpatients. The training of the nurse staff in phlebotomy and samples handling significantly decreased non-compliance rate 13.8% vs 9.3%;  $p < 0.001$ . Systematic recording of samples non-compliances and continue training of nurse staff could be used to monitor and assess preanalytical non-compliances for patients safety.

---

## Compliance with ethical standards

### *Acknowledgments*

We thank Dr. Robert Dufour emeritus professor of pathology at George Washington University in Washington, DC for his inputs and advices. We are grateful to all study subjects for participating in this study; the staff of Mopti hospital, French Agency for Development (AFD) for funding and logistical assistance through Expertise France.

### *Disclosure of conflict of interest*

Authors certify that there is no actual or potential conflict of interest in relation to this article. Funding for training comes from French Agency for Development through Expertise France and is free from all sources of conflict of interest.

### *Statement of informed consent*

Each participant gave fully informed written consent prior to enrollment. The protocol was reviewed and approved by Hospital committee.

## References

- [1] Kevin Olsen . The first 110 years of laboratory automation: technologies, applications, and the creative scientist. *Lab Autom.* Dec 2012; 17(6): 469-80.
- [2] Plebani M. Quality indicators to detect pre-analytical errors in laboratory testing. *Clin Biochem Rev.* 2012; 33: 85–88.
- [3] Plebani M, Sciacovelli L, Aita A. Harmonisation of pre-analytical quality errors. *Biochem Med.* 2014; 24: 105–113.
- [4] Giuseppe Lippi, Janne Cadamuro. Novel Opportunities for Improving the Quality of Preanalytical Phase. A Glimpse to the Future? *J Med Biochem.* 28 Oct 2017; 36(4): 293-300.
- [5] International Organization for Standardization. ISO 15189:2012: Medical laboratories: particular requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization. 2012.
- [6] Laura Sciacovelli, Giuseppe Lippi, Zorica Sumarac, Isabel Garcia Del Pino Castro, Agnes Ivanov, Vincent De Guire, Cihan Coskun. Working Group “Laboratory Errors and Patient Safety” of IFCC. Pre-analytical quality indicators in laboratory medicine: Performance of laboratories participating in the IFCC working group “Laboratory Errors and Patient Safety” project. *Clin Chim Acta.* Oct 2019; 497: 35-40.
- [7] Sintayehu Ambachew, Kasaw Adane, Abebaw Worede, Tadele Melak, Daniel Asmelash, Shewaneh Damtie, Habtamu Wondifraw. Errors in the Total Testing Process in the Clinical Chemistry Laboratory at the University of Gondar Hospital, Northwest Ethiopia. *Ethiop J Health Sci.* Mar 2018; 28(2): 235-244.
- [8] Ma Jesús Alsina, Virtudes Alvarez, Núria Barba, Sandra Bullich, Mariano Cortés, Irene Escoda, Cecília Martínez-Brú. Preanalytical quality control program - an overview of results (2001-2005 summary). *Clin Chem Lab Med.* 2008; 46(6): 849-54.
- [9] Alexandre C Guimarães, Marilei Wolfart, Maria L L Brisolara, Caroline Dani. Causes of rejection of blood samples handled in the clinical laboratory of a University Hospital in Porto Alegre. *Clin Biochem.* Jan 2012; 45(1-2): 123-6.
- [10] Güzin Aykal, Mustafa Keşaplı, Özgür Aydın, Hatice Esen, Ayşenur Yeğin, Faruk Güngör, Necat Yılmaz. Pre-Test and Post-Test Applications to Shape the Education of Phlebotomists in A Quality Management Program: An Experience in a Training Hospital. *Biochem.* Sep 2016; 35(3): 347-353.
- [11] Lourens A Jacobsz, Annalise E Zemlin, Mark J Roos, Rajiv T Erasmus. Chemistry and haematology sample rejection and clinical impact in a tertiary laboratory in Cape Town. *Clin Chem Lab Med.* Oct 2011 14; 49(12): 2047-50.
- [12] Zeliha Gunnur Dikmen, Asli Pinar, Filiz Akbiyik. Specimen rejection in laboratory medicine: Necessary for patient safety? *Biochem Med (Zagreb).* 15 Oct 2015; 25(3): 377-85.
- [13] Giuseppe Lippi, Antonella Bassi, Giorgio Brocco, Martina Montagnana, Gian Luca Salvagno, Gian Cesare Guidi. Preanalytic error tracking in a laboratory medicine department: results of a 1-year experience. *Clin Chem.* Jul 2006; 52(7): 1442-3.
- [14] Maria Salinas, Maite López-Garrigós, Emilio Flores, Ana Santo-Quiles , Mercedes Gutierrez, Javier Lugo, Rosa Lillo. Ten years of preanalytical monitoring and control: Synthetic Balanced Score Card Indicator. *Biochem Med (Zagreb).* 2015; 25(1): 49-56.
- [15] Ana-Maria Simundic, Nora Nikolac, Ines Vukasovic, Nada Vrkic. The prevalence of preanalytical errors in a Croatian ISO 15189 accredited laboratory. *lin Chem Lab Med.* Jul 2010; 48(7): 1009-14.
- [16] Cheryl M Coffin, Marilyn S Hamilton, Theodore J Pysher, Philip Bach, Edward Ashwood and al. Pediatric laboratory medicine: current challenges and future opportunities. *Am J Clin Pathol.* May 2002; 117(5): 683-90.
- [17] Cai Q, Zhou Y, Yang D. Nurses' knowledge on phlebotomy in tertiary hospitals in China: a cross-sectional multicentric survey. *Biochem Med (Zagreb).* 15 Feb 2018; 28(1): 010703.
- [18] Fatma Demet Arslan, Inanc Karakoyun, Banu Isbilen Basok, Merve Zeytinli Aksit, Esmâ Celik, Kemal Dogan, Can Duman. The Effects of Education and Training Given to Phlebotomists for Reducing Preanalytical Errors. *J Med Biochem.* 1 Apr 2018; 37(2): 172-180.