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Assessment of Pre-Analytical Error on Blood Specimens Referred for CD4 and Haematology Tests in Central Oromiya, Ethiopia

Mulat Woldie Wondimagegn[1, *], Walelegn Worku Yallew[2], Takele Teklu Anijajo[3]

[1]Department of Public Health, Faculty of Health Sciences, Mekelle University, Mekelle, Ethiopia

[2]Departments of Environmental and Occupational Health and Safety, Institute of Public Health, University of Gondar, Gondar, Ethiopia

[3]Departments of Immunology and Molecular Biology, Collage of Medicine and Health Sciences, University of Gondar, Gondar, Ethiopia

Email address:

mwold1979@gmail.com (M. W. Wondimagegn), walelegnw@gmail.com (W. W. Yallew), takeleteklu@yahoo.com (T. T. Anijajo)

[*]Corresponding author

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Abstract: Although, Ethiopia is working to improve the qualities of laboratory services, errors are still prevailing. These errors are classified as pre-analytical, analytical and post-analytical. Studies that focus on prevalence and factors that influence the pattern of laboratory error remain very scarce in Ethiopia. This study aimed to assess the extent of pre-analytical error and factors contributing to this error among blood specimens referred for CD4 and Haematology tests. We conducted a quantitative study triangulated by qualitative technique in three laboratories in Central Oromiya; Ethiopia. For quantitative study, a total of 754 randomly selected blood specimens and its accompanying laboratory request forms were reviewed using a structured checklist. Data was analysed using SPSS version 20 software. P value of less than 0.05 was considered as statistically significant. For qualitative part thematic content analysis of the interviews was performed using Open Code software version 3.4 and three different categories were emerged. The magnitude of pre-analytical error among 754 blood specimens and its accompanying laboratory request forms was 314 (41.6%) with 95% CI of (38.3-45.2). Blood specimen collected using syringe and needle methods and specimens collected in under 15 years old patients were prevalent for pre-analytical error; with ORs (95% CIs) of 4.948 (1.993-12.285) and 6.973 (4.032-12.060) respectively. In-depth interview indicated that Knowledge, Process failure and lack of patient centeredness were factors accounted for pre-analytical error. Alongside of the efforts to control laboratory error, this study highlighted complexity of pre-analytical error control efforts. Co-operation with clinicians and personnel outside the laboratory, process automation, computerized test requesting, procedure for specimen collection and training are of vital importance to make progress on pre-analytical testing process.

Keywords: Error at Pre-analytical Phase, Preparatory Phase, Error Before Testing

1. Introduction

The modern medical practice is increasingly dependent on reliable clinical laboratory services [1] as the laboratory results influence up to 70% of medical diagnosis [2-7]. Errors in the laboratory can results in adverse consequences for medical outcomes and patient safety [8]. These errors can arise at pre-analytical, analytical or post-analytical phases [3, 9-10].

The pre-analytical phase plays a prevailing role in decreasing the quality of testing, and increase the likelihood of diagnostic errors [11]. Error that occur at this stage often become apparent later in the analytical and post-analytical phases [2, 12-13] and accounts 46-68.2% of the laboratory errors [9-10, 14]. Due to the laboratory quality cycle, reliability cannot be achieved in a clinical laboratory through the control of accuracy in a single component of testing process alone [15-17]. Development of evidence-based performance metrics in all the testing process including the pre-analytic and post-analytic phases is a critical need of the Total Testing Process (TTP) [18-19].

Pre-analytical phase involves all process from ordering tests to preparing specimens for analysis [2, 7-8, 20-21]. The determinants of this process is factors related to the patients, the clinicians requesting the testing, phlebotomist collecting the samples, materials used for sample collection and transportation and the laboratories processing and aliquoting the samples [2, 22]. However, studies that focus on prevalence and factors that influence the pattern of laboratory error remain very scarce in Ethiopia. This study was therefore, aimed to assess the magnitude of Pre-analytical error and factors associated with this error on blood specimens and accompanying Laboratory Request Forms (LRFs) referred for CD4 and Haematology tests and recommend effective measures that would lead to significant improvements in Clinical Laboratory Quality Management System (CLQMS).

2. Materials and Methods

This was a quantitative study triangulated by qualitative technique conducted from May to June 2014 in OPHL, Fiche and Saint Lukas hospital laboratories in central Oromiya; Ethiopia. For quantitative aspect of the study, pretested checklist was used with observation of blood specimens and accompanying laboratory request Forms (LRF). 754 samples, 374 from OPHL, 190, from Fiche and 190 from Saint Lukas hospital laboratories) were collected using simple random sampling strategy. The sample size in each laboratory was determined according to the proportion of the blood specimens referred to each laboratory since April 2013 to March 2014. Data collectors were trained and data quality was checked by principal investigator in all the data collection period and correction were made immediately through practical demonstration and telephone consultations. A purposive sampling method was used for qualitative aspect of the study. The principal investigator and a trained research assistant (RA) performed a one-to-one in-depth interview using a semi-structured guide in places convenient for the participants. The interview guide was developed in English and translated into Amharic (native language of study participants). The principal investigator and research assistant (RA) were guided by participant response to probe the emergent themes. Interviews were continued until all categories well defined and saturated after interviewing 10 participants. In addition, to hand written notes during the interview, interviews were tape-recorded which were later transcribed and translated into English. The main issues addressed by in-depth interview were the health system and individual (provider) factors that affect the pre-analytical process.

2.1. Definitions of Pre-analytical Error

Error on analytical requests information and blood specimens.

2.2. Definition of Error on Analytical Request Information

LRF presented to the laboratory in the absence of either of unique patient identifier, name of person legally authorized to request examinations, examination requested, clinical information relevant to the patient, gender, age of the patient, referring facility name and date test requested.

2.3. Definition of Error on Blood Specimen

Was defined as the blood specimens received to the laboratory either with wrong/no information on its container, insufficient volume of blood, inappropriate quality, inappropriate container, or wrong specimen types.

2.4. Data Processing and Analysis

For quantitative study, data were analyzed using SPSS version 20. Association between selected factors and pre-analytical laboratory error on blood specimens and LRFs were estimated by computing Odd Ratios (ORs) and their 95% confidence Intervals (95% CI) from logistic regression model. The model fit was checked by hosemer and Lemeshow test. 0.25 were the maximum limit to transform from bivariate to multivariate analysis. The criterion for significance was set at $p< 0.05$. Thematic content analysis was applied for qualitative aspect of the study. Tape-recorded in-depth interviews were firstly transcribed in to Amharic and then translated to English. Codes were then developed based on the original terms used by participants using Open code 3.4. Tentative categories and sub-categories were created from the clustered codes, and subsequently main themes emerged based on the patterns and relationship between the categories.

2.5. Ethical Considerations

Approval to conduct the study was obtained from Institutional Review Board (IRB) of Addis continental Institute of Public Health (ACIPH) and Mekele University (MU). Notifications were made to OPHL, Fiche and Saint Lukas hospitals and Clinicians and laboratory professionals about the purpose of the study to get permission from the Organizations and the participant health care providers.

3. Results

3.1. Findings from Quantitative Study

In this study, the magnitude of pre-analytical error among 754 blood specimens and its accompanying laboratory request forms was 314 (41.6%) with 95% CI of (38.3-45.2). Of which, laboratory request forms and blood specimens were accounted for 228 (30.2%) and 66 (8.8%) errors separately and together 20 (2.6%); with 95% CI of (26.8-33.6), (6.8-10.9) and (1.5-3.8) respectively. For a better understanding, this study is presented by categorizing as error on laboratory request information and blood specimens.

3.1.1. Error on Laboratory Request Forms Information

The magnitude of pre-analytical error associated with LRFs was 248 (32.9%) with 95% CI (29.6-36.3%). Out of all the required information's on LRFs, only the referring health

facility names, date test requested, unique patient identifier and the investigation requested were present on all 754 LRFs. The name of the clinician ordering the test, the clinical details and ages of the patient were not provided on 170 (22.5%), 135 (17.9%) and 16 (2.1%) of LRFs respectively. While patient's gender was present on 744 (98.7%) of LRFs (Table-1).

Table 1. *Types and frequency of errors linked with LRF in Central Oromiya, 2014 Ethiopia.*

variables	Frequency	Percentage %
LRF information overall	248	32.9
Requesting clinicians name	170	22.5
Patient clinical data	135	17.9
Patient Age	16	2.1
Patient sex	10	1.3

From all, 76 (10.1%) of the LRFs presented to the laboratory were overlooked at least two of the required information's. The proportion of error among LRFs referred from health centres (73.4%) were higher compared to hospitals (26.6%).

3.1.2. Error on Blood Specimens

The overall magnitude of pre-analytical error among 754 blood specimens presented for CD4 and haematology tests was 11.4% with 95% CI of (9.2-13.8). Inappropriate quality of the blood specimens drawn was the most common cause for unsuitable specimen 38 (5%) followed by insufficient volume of blood 34 (4.5%), mislabelling (wrong information) 10 (1.3%), and unlabelled specimens 4 (0.5%) (Table-2).

Table 2. *Types and frequency of errors linked with blood specimens referred to three laboratories in Central Oromiya, 2014 Ethiopia.*

Variables	Frequency	Percentage %
Blood specimen characteristics	86	11.4
Inappropriate quality	38	5.0
Insufficient volume of specimen	34	4.5
Mislabeled specimen	10	1.3
Unlabeled specimen	4	0.5

We compared some of the key characteristics of 754 blood specimens included in the analysis with those of 86 blood specimens with error and found little difference in gender (9.7% and 12.2% were men and women respectively). In the present study factors associated with pre-analytical error on blood specimens were using syringe and needle methods for specimen collection and specimens collected in under 15 years old patients; with ORs (95% CIs) of 4.948 (1.993-12.285) and 6.973 (4.032-12.060) respectively. In this study there were no significant associations between pre-analytical error connected to blood specimens and gender, specimen referring health facilities, blood specimen transportation methods and qualifications of specimen collector (Table-3).

Table 3. *Association between selected factors and pre-analytical error on blood specimens, Central oromiya, 2014, Ethiopia.*

Variables	Pre-analytical error on blood specimens		COR (95%CI)	AOR (95%CI)	P value
	With error, 314 (41.6%)	No error, 440 (58.4%)			
Gender					
Men	26 (9.7%)	241 (90.3%)	1:00		
Women	58 (12.2%)	419 (87.8%)	1.283 (0.787-2.092)	0.318	
Age group					
> 15 years	45 (7.1%)	586 (92.9%)	1:00	1:00	
< 15 years	41 (38.3%)	66 (61.7%)	8.090 (4.937-13.255)	6.973 (4.032-12.060)	<0.001
Blood specimen referring health facility					
Hospital	16 (4.8%)	314 (95.3%)	1:00	1:00	
Health centre	70 (16.5%)	354 (83.5%)	3.881 (2.208-6.821)	1.099 (0.369-3.270)	0..866
Specimen collection methods used					
Vacuum closed tube	16 (4.1%)	375 (95.9%)	1:00	1:00	
Syringe &needle method	70 (19.3%)	293 (80.7%)	5.599 (3.185-9.844)	4.948 (1.993-12.285)	0.001
Specimen transport methods used					
Triple packaging	23 (8.3%)	253 (91.7%)	1:00	1:00	
Test tube rack only	63 (13.2%)	415 (86.8%)	0.599 (0.362-0.990)	0.869 (0.395-1.913)	0.728
Qualification of sample transporter/collector					
Degree holder	13 (4.7%)	265 (95.3)	1:00	1:00	
Diploma holder	72 (17.3%)	345 (82.7%)	4.542 (2.302-7.845)	1.098 (0.339-3.557)	0.876

3.2. Findings from the Qualitative Study

3.2.1. Characteristics of the Study Population

A total of 10 health professionals were successfully interviewed, of which Five (5) were Laboratory professionals, Five (5) were Nurses and Health officers. The average years of work experience of the study participants were 8.7 years (ranging 4-12 years). Three main themes were developed from the interview findings and the findings are:

3.2.2. Theme One: Knowledge on Pre-analytical Error

The majority of the participants described pre-analytical error as error; before specimen collection, during collection and after collection. The main reasons, given by participants for error in the pre-analytical phase of laboratory testing were lack of clinicians understanding of information's on LRFs for patient identification and laboratory result interpretations, lack of knowledge of laboratory professionals on venous blood collection and blood specimen handling procedures

and involvement of different health professionals in the process including the patient and the facility managements.

"The pre-analytical testing starts from test selection and ends in sample processing. The individuals involved here are clinicians, patients and phlebotomist/laboratory professionals. You don't know where and by whom the error is occurred and that is difficult to manage" (laboratory professional).

The majority of the participants except one Health officer thought that the qualities of laboratory request form information's provided and the specimens received to the laboratory are the determinants for the reliability of laboratory tests. The quality of the laboratory testing is also increasingly dependent on the qualities of specimens received, the testing machineries and the competency of the laboratory professionals.

"The quality of the laboratory tests can be affected by the qualities of laboratory request form information's provided and the qualities of blood specimen received to the laboratory" (laboratory professional).

3.2.3. Theme Two: Breakdown or Failure on Process

The main reasons, for pre-analytical error as reported by the participants were lack of a procedure for ordering, preparing and applying of this process. Laboratories and primary care practices have a responsibility to develop comprehensive processes designed to allow accurate and complete follow-up beginning in the pre-analytic phase and ending in the post-analytic phase. The health care practices that had no written protocols or procedures for test selection, patient preparation and blood specimen management steps were associated with laboratory errors and a frequent contributor to patient harm. The impact of laboratory procedures and utilization by health care team was quoted by two laboratory professional in different way as follow.

"There is no procedure in our laboratory. I didn't get training on sample collection. I simply prepare patients, and collect blood samples and transport to the testing laboratory with the knowledge I had from university".

"Well, here there is a set procedure and the degree to which the clinicians and the laboratory technologists use the procedure is, I think, variable".

The interviews indicated that, blood specimens collected in one laboratory and transported to other laboratory for CD4 &haematology testing. Practices that used more than one laboratory, and forced to have more than one process, are much more likely to experience pre-analytical and post-analytical errors in testing. The end result of process failure is clinical decision without necessary laboratory information.

'The more steps involved in a process, the more likely there will be an errors" (laboratory professional). '

All participants reported that in the current practice the patient to the health care provider ration couldn't be proportional and mostly errors arise due to workload and hasty conditions. Furthermore, Laboratory professionals forced to travel long distance to transport the specimens from their facility to the testing laboratory. Most of the time the transportation cost is covered by specimen transporters and it was not reimbursed. The effect of financial problem and workload on the qualities of laboratory procedure and health care practice was quoted as follow by two participants.

"My salary is not enough for me during the current living cost burden. Beside this I am forced to transport the sample from here to the testing laboratory. Imagine the transportation cost to and from here is 50 birr and the cost is covered by me. So how I get to fully responsible for the tasks I am supposed to do? Beside this I didn't ever get training after I left the university" (laboratory professional)

"The patient daily volume and the manpower ratio are not proportional in our laboratory so error is unavoidable" (laboratory professional).

3.2.4. Theme Three: Patient Centeredness

We found that the main reasons for pre-analytical error in laboratory testing process was health provider's lack of patient participation on decision making process. As our ultimate customers, patients play an important role in the laboratory testing process. Patients are effective alleviator of near-miss events and should be more actively involved in the process. Majority of Participants noted that they didn't tell the patients about the types of laboratory examinations requested, procedures used for specimen collection and the activities before and during specimen collection process. The effect of patient involvement was quoted as follow by one Health Officer.

"Patient care managements are the process which involves health care providers and management teams including the patient. So coordination between health care providers, management teams and the patients and patient health education program is helpful to minimize errors and improve the laboratory testing qualities".

Most of the participants reported that majority of pre-analytical errors occur before specimen collection due to negligent attitude of clinicians about filling the laboratory requisition slips and problem on patient preparation prior to sampling. As evidenced by the participants' financial interests of the health care providers, training, and poor working environment and conflict of interest between health care providers were the main factors for lack of patient centeredness. Patients have the potential to be effective mitigators, as they have a different lens on events and can see things that are often missed by health care providers.

"It is the patient history and physical examination, which helps for proper test selection. So we should involve the patients and get their consent before starting any procedure" (Health Officer)

"You know we don't have frequent training. The salary that we have paid is not enough with the current living cost burden. If you come and see here there are individuals who get money other than their salary but some others like me don't have any other than monthly salary. So how I get motivated and become keen to the work I am assigned?"

4. Discussion

Though, this result is by far better than the study in Taiwan [23], the finding tells us that the pre-analytical phase is the important source of error in the laboratory testing process. This can give an impression that emphasis is not given to preparatory activities to the laboratory testing process.

Our assessment on LRF information showed that only the referring facility name, patient identification number, date test requested and the investigation requested were appeared on all the LRFs assessed. This is better compared to similar studies in India and Ghana [24-25]. This was not surprising since it was very likely that the request would have been turned down if the required test was not stated and the specimen referring facility name/patient location was absent.

On the contrary, the patient's demographic data such as age and gender were not affirmed on 2.1% and 1.3% LRFs respectively, this is lower than figures of 25.6% and 32.7% individually obtained from study in Ghana [25]. Age and gender are vital in identifying and sorting out both the subject and specimens where specimens from different subjects have similar names. To accurately interpret test results, it is also necessary to know gender-specific and/or age-stratified reference intervals since the values for many analytes vary with developmental stage or age [26]. On the other hand, clinical information's and requesting clinicians name were not provided on 17.9% and 22.5% of the LRFs sampled in this study. This is better compared to the study conducted in Ghana [25]. Absence of clinical information or ambiguous information leads to extraneous and unnecessary additional tests. In addition, where interpretative comments are made on laboratory results, inadequate clinical information may lead to misleading and potentially harmful comments. Panic results can be rapidly conveyed back to the requesting clinician if the requesting clinicians name and contact telephone number is present on the request forms presented to the laboratory.

From all LRFs included in this study, those requests brought from the Health Centers (73.4%) are lower than from hospitals (26.6%) in terms of completeness of the required information's, where usually nurses and Health Officers requested CD4 and haematology tests, many of whom might not aware of the importance of LRF information's for patient identification and result interpretations.

Our assessment on blood specimens reveals that only the specimen type, and containers used for specimen collections are comparable with the requirements [2, 27] and it is better than the previous study [16-17]. In the present study, the most common cause for pre-analytical error on blood specimens are poor qualities of blood specimens (5%), followed by insufficient volume (4.5%), wrong patient information on the specimen container (1.3%) and unlabelled specimen containers (0.5%). This is lower than figures from previous study [17]. These may be caused by, excessive workload; improper mixing of specimens just after collection, anticoagulants used, specimen collection methods and phlebotomy techniques used. In this study, we have found that the independent predictors of pre-analytical error are using syringes and needle methods for blood specimen collection, age and lack of training on specimen collection. This is because, the specimen collection techniques and methods were not appropriate, veins from under 15 years old patients were not visible as of adult patients and the specimens collected from Health centres, where many of sample collectors might not get training on venous blood collection. Venous blood collection procedure is the source of numerous types of errors [28] in the pre-analytical phase of laboratory testing process. Appropriate specimen collection methods, correct blood specimen collection and handling procedures and frequent quality monitoring and training is important.

Knowledge and failure in process, also contribute to pre-laboratory examination error, as has been described in a study [18]. In our present study, failure in decision making, lack of procedural manual, supply and laboratory designs are the most common factors associated with pre-laboratory examination error. Training on phlebotomy techniques and factors that contribute for pre-laboratory examination error, standardizing work-which includes identifying who is responsible for each step of a task, procedure for laboratory medicine and proper laboratory designs facilitate work flow and error minimization in the laboratory testing process.

Lack of patient centeredness, is one of the key issues found to be associated with pre-analytical laboratory error in our study. The main reasons for lack of patient centeredness as evidenced in this study, are financial interest of the health care providers is not well operated by the government and there is also conflict of interest between health care providers. Training was also the reason for poor motivation of the health care providers. So besides to the monetary and training, motivating the health professionals may encourage them to be responsible and keen to the works assigned.

5. Conclusions

In conclusion, alongside of the efforts to control laboratory error, this study highlighted a complexity of pre-analytical error control efforts in central oromiya health institutions. Co-operation with clinicians and personnel outside the laboratory, process automation, computerized test requesting, procedure for specimen collection and training are of vital importance to make progress on pre-analytical testing process.

List of Abbreviations

ACIPH; Addis continental institute of Public Health, CD4; Cluster of differentiation marker 4, CI; Confidence interval, CLQMS; Clinical Laboratory Quality Management System, IRB; Institutional Review Board, LRF; Laboratory Request

Form, MU; Mekele University, OPHL; Oromiya Public Health Laboratory, OR; Odd Ratio, RA; research assistant, TTP; Total Testing Process, WHO-AFRO; World Health Organization –Regional Office for African accreditation scheme.

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