Assessment of Pre-Analytical Quality Indicators and the Associated Errors in Clinical Laboratory Testing at Kombewa Sub County Hospital, Kenya. A descriptive study.

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ABSTRACT

Laboratory quality Indicators focus on the performance of analytical processes; however pre-analytical phase is vulnerable to the risk of error hence their consistent identification is crucial. This study identified pre-analytical quality indicators and their associated errors in laboratory testing in Kombewa Sub-County Hospital. The study evaluated 385 blood draws performed by care givers stratified proportionate to size. Univariate Pearson Chi-Square test was used to test for relationship between the variables. p value of <0.05 was considered significant. The 53% of errors resulted from lack of clinical history and 38% due to incomplete requisition forms. There was significant relationship between; source of error and profession ($p<0.05$), cadre and occurrence of clotted sample ($X^2=5.28$, df= 2, =0.017) and intravenous fluid contamination ($X^2=11.276$, df= 2, =0.004). Sample integrity varied depending on experience and carder. Regular related continuous education, auditing of preanalytical quality indicators and Laboratory-Clinical interphase should be cultivated to improve pre-analytical outcomes.

Key terms: Clinical Laboratory, Quality Indicator, Pre-Analytical Phase, Quality

1. INTRODUCTION

Clinical laboratories are an integral part in the health care system and the results of analytical testing have a strong impact in medical care and management of patients globally (1). Medical laboratory services account for 60–70% of the most important decisions on; admission, discharge, and medication (2). The World Health Organization (WHO) advices on Systems strengthening by improving quality of public health laboratories in developing countries to achieve ISO 15189 standards. This is through the World Health Organization Africa Regional Office (WHO-AFRO) Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) (3). Drawback have been realized to this noble requirement due to pre-analytical errors that are encountered and are carried over to analytical phase. This process enables laboratories to develop and document their ability to detect, identify, and promptly report all non-conformities of significance that may be present in the Total Testing Process that affect quality realization. Majority of laboratory errors occur in the pre-analytical phase of the total laboratory testing process (4). Pre-analytical errors can occur at the time of patient assessment, test order entry, request completion, patient identification, specimen collection, specimen transport, or specimen receipt in the laboratory(5). Other causes include ordering tests on the wrong patient, ordering the wrong test (Unintelligible), patient misidentification, use of incorrect sample collection container, or wrong labeling of containers. pre-analytical errors predominated in the laboratory, ranging from 31.6% to 75%(6) .Quality indicators (QIs) measure the extent to which set criteria are achieved and provide a quantitative basis for achieving improvement in care and laboratory services(7). Generally, most errors fall outside the analytical phase, where the pre- and post-analytical steps have been found to be most vulnerable to the risk of error, however, minimal attention to extra- laboratory factors and related QIs prevent clinical laboratories from effectively improving total quality and reducing errors. There is need for establishment of these pre-analytical QIs, associated errors and rates occurrence as this will be an important means in Laboratory Quality Improvement and realization of significantly reduced errors in pre-analytical phase. The pre-analytical phase is defined as the steps starting in chronological order, from the clinician's request and including the examination requisition (including medical history), patient preparation, primary sample collection, and transportation to and within the testing laboratory, and ending when the analytical examination procedure begins (8). The establishment of Quality indicators (QIs) in accreditation programs for medical laboratories is a fundamental step in providing sound evidence for quality in the TTP(9). QIs are equally important in ensuring targeted continuous improvement activities aiming at reducing the risk of errors in clinical practice are undertaken. Currently, pre-analytical errors account for up to 70% of all mistakes made in laboratory diagnostics, most of which arise from problems in patient preparation, sample collection, transportation, and preparation for analysis and storage (9)

2. METHODOLOGY

2.1 Study Design.

This study adopted descriptive study design; Questionnaires were administered to medical staff performing phlebotomy and Checklists were used to evaluate through observation the Quality aspects of Pre-analytical Phase.

2.2 Study Site.

This study was undertaken at Kombewa Sub-County Hospital (KSCH) in Seme Sub-County located in Kisumu County.

2.3 Study Population.

Comprised of Nursing Officers, Clinical Officers and Laboratory staffs working in Kombewa sub county hospital.

2.4 Sampling Technique.

Staffs were purposively sampled while stratified random sampling technique was used to achieve desired number of blood draws subjected to the quality checklist. The population was stratified equally amongst the different carders.

2.5 Sample Size Determination.

385 Blood draws was calculated based on *W.G Cochran's* (1977) formula ($n = Z^2pq/d^2$)

2.6 Inclusion and Exclusion criteria

2.6.1 Inclusion

1. Blood draw procedures within the Laboratory Phlebotomy area performed by Laboratory staff.
2. Blood draws procedures within the wards performed by the by Nurses, Clinical officers, or Laboratory staff.
3. All staff involved in clinical laboratory sample collection.

2.6.2 Exclusion

1. Emergency Phlebotomy procedures
2. Clinical Samples transported from external sites to the laboratory

2.7 Data Collection and management .

2.7.1 Data collection

The Questionnaires were administered to all the staff involved in clinical laboratory sample collection. The data was obtained from the participants using structured checklists. This was administered carefully by observation during venous sampling procedures as carried out by the different participants. Questionnaires were administered to all the staff involved in clinical Laboratory sample collection.

2.7.2 Data Analysis.

Data was entered into excel spreadsheets, cleaned and analysis was done using SPSS version 20.0 and by graph Pad prism 5. Pearson's Chi-square, a non-parametric method was used to determine the level of significance at $p < 0.05$ which was considered significant.

2.8 Ethical considerations.

Permission was sought from the Masinde Muliro University of Science and Technology Independent Review and Ethics Committee (IREC) and The Kombewa Sub-County Hospital Management Board.

3. RESULTS

3.1 Demographic profiles of respondents

The respondent population was mostly composed of Nurses at 57%, the least were Laboratory staff at 18% and Clinical Officers composed 25% of the respondents (Table 1).

3.2 Pre-Analytical Errors identification and frequency of Occurrence

These were classified into two different categories; The Pre-pre-analytical errors (These are errors that occur outside the control of the lab) and the Pre-Analytical errors

3.3 Pre-pre-analytical Qis.

The pre-pre-analytical errors were identified using the request form filled by the Clinical Officer, the gaps and errors were then identified. 53% of respondents' request forms lacked clinical question followed by requests without full details of the client at 38% (Figure1)

3.4 Assessment of Pre-Analytical QIs.

The laboratory staff had low propensity in committing pre-analytical errors as compared to their counterparts. The Nursing officers performed poorly in technical and procedural quality indicators such as improper sample labeling and patient identification by use of unique numbers leading. The Clinical Officers however had issues in employing the correct order of draw during sampling and proper vein-puncture technique. A Pearson Chi-Square test of independence ($p<0.05$) showed that there is a significant relationship between source of error and profession. (Table 2)

3.5 Occurrence of pre-analytical errors.

The occurrence of pre-analytical errors was assessed in two different categories; there were errors associated with experience of the staff collecting the samples regardless of their profession and errors attributable to applicability of SOP. The experience Cohort of 5-9 was prone to pre-analytical errors than other cohorts. It was realized that 70% of the study population were not allowed by SOPs to collect clinical laboratory samples. Out of the population proficient, 53.8% of the respondents were Laboratory, only 30.8% and 15.4% of Nurses and Clinicians respectively were proficient by sampling SOPs (Table 5)

3.6 Evaluation of CME Trainings by Profession.

Inadequate continuous medical education led to many cases of re-drawal requests. Those who attended CME more often did not have re-drawal requests as opposed to those who never attended CME who were responsible for most of the sample re-drawal request. However, the Pearson Chi-Square test of independence ($X^2=13.518$, $df=3$, $p=0.333$) showed that no significant relationship between attending continuous medical medication and proficiency in preventing re-draws. (Table 4)

3.7 Influence of the Pre-analytical errors on sample integrity.

Majority of the samples (77%) were accepted whereas the rejected numbers were largely due to short draws at 7% followed by clotted samples; the least errors were due to Wrong patient preparation. A Pearson Chi-Square test showed that there was significant relationship between profession and occurrence of clotted sample ($X^2=5.28$, df= 2, =0.017) and intravenous fluid contamination ($X^2=11.276$, df= 2, =0.004) respectively (Table 5)

4. DISCUSSION

Like in most hospitals, most of the care givers were Nurses at 57%, whereas the least were Laboratory staff at 18% and Clinical Officers composed 25% of the respondents. This is confirming that the Nurses composes a critical proportion of care givers involved in sample collection and any intervention in reducing the error burden must critically include this population.

4.1 Errors associated with test requisition.

These range from Wrong test requisition, improper requisition documentation and at times intelligible. From the checklists' 53% of respondents' request forms lacked clinical question followed by requests without full details of the client at 38%, there were 7% inappropriate requisitions and 2% intelligible requisitions. The average test requisition errors agree with the findings of the study by Jones, *et al*, 1997 (10) which found out that ordering an improper diagnostic test accounted for 23% of requisition errors. These pre-preanalytical errors that occur prior to sampling of the test majorly takes place in the brain of the physician; these can cause a string of escalated errors including over-utilization of laboratory tests, economic burden to the patient and unwarranted examinations.

Proper Laboratory tests are dependent on requisition details, the clinical officers in most cases avoided the inclusion of clinical question which often comes along with patient history, this information is critical in some examinations that are diagnosed for deduction of progress or regress of different diseases/conditions.

4.2 Distribution of Sources of Pre-Analytical Errors

4.2.1 Errors in patient Identification.

It was evident from the data analyzed that the use of patient name in identification was not significant in error attribution across all carders. This means that most care givers identified their patients mostly by name. Results analysis on cross tabulation showed that the variable Identification by Name of patient did not come out significant, however, other variables which were significant at this stage were both identification by gender and unique number at $X^2 = 33.4$ and $P<0.005$ (Significant at $p <0.05$). A Pearson Chi-Square test showed that there was significant relationship between Patient identification errors and the carder of care giver. The Nurses were most affected for errors on patient identification by unique numbers followed by identification by gender; this was attributed to their long contact hours with patients making them believe to know the patients with disregard to other identification details.

4.2.2 Errors in sample Identification.

Correlational tabulation of sample identification as variables against profession indicates that improper labeling and mismatched labels was not significant as compared to unlabeled samples which were significant ($P<0.005$) The laboratory staff had low propensity in committing pre analytical errors as compared to their counterparts. The Nursing officers performed poorly in procedural quality indicators such as improper sample labeling and patient identification by use of unique numbers leading. Mislabeling of test tubes for blood transfusion pre-testing by Laboratory staff , a highly regulated task, is reported to occur in median in 1 out of 165–200 test tubes (4) .This almost compares to the findings in this study where in every 385 sample draws there are up to 4 mislabeled.

4.2.3 Pre-Analytical procedural and technical Errors.

Nursing officers performed poorly in technical quality indicators such as short draw and wrong sample type. The Clinical Officers however had issues in employing the correct order of draw during sampling and proper vein-puncture technique. A Pearson Chi-Square test of independence ($p<0.05$) showed that there is a significant relationship between source of error and profession. This included pre-analytical aspects such as volume of draws, order of draws, vein-puncture technique, Tourniquet application and improper post sampling tube mixing. Improper site preparation by the nurses appeared a major problem; this could be attributed to unawareness of possible untoward results associated with improper site preparation. Wrong order of draw also followed as a major deviation amongst the nurses followed by the Clinical officers, this could be because of genuine unawareness due to lack of enough information on phlebotomy protocols. This is also attributable to SOPs applicability which a majority of the two carders did not comply to.

4.3 Pre analytical errors' influence on the sample integrity.

Sample integrity determines whether a test will be performed or a redraw will be necessary or worse off a sample will be rejected. In all the samples drawn, 77% of the samples were accepted whereas the rejected numbers were largely due to short draws at 7% followed by clotted samples at 5%, both haemolyzed samples and wrong tube had 4% error rate. Assessment on sample integrity by profession indicates that the samples drawn by nurses were significantly at risk of most Pre-Analytical errors based on the mean frequencies followed by the clinical officers. Overally, the sample integrity depends on the whole pre-analytical process. This therefore calls for proficiency in sampling procedures which by way of documented SOPs indicate that very few of the staff involved in sample collection are proficient. Among the respondents, the laboratory staff stands out to be more suitable to collect samples by SOP compliance at 53.8%, Nurses at 30.8% while the clinical officers at 15.4%. This compliance probably explains reasons as to why different carders result to different proportions of errors. Out of the 385 procedures audited, only 48 were error free, this account for 12%. Thus the error frequency was 88%.This finding concurs with findings by Plebani *et al*,2006(9), on errors occurring during the pre-analytical phase – from the time the test is ordered by the physician until the sample is ready for analysis – can account for up to 93% of the errors currently encountered during the TTP

Uptake of CMEs related to Pre-analytical procedures also played a major role in ensuring lesser risk in pre-analytical error occurrences. The laboratory staff who had an often uptake of related CME performed better compared to their counterparts. Lack of attending continuous medical education leads to many cases of re-drawal requests. Those who attended CME more often did not have re-drawal requests as compared to those who never attended CMEs who were responsible for most of the sample re-drawal request. However, the Pearson Chi-Square test of independence ($X^2=13.518, df=3, p=0.333$) **showed** that no significant relationship between attending continuous medical medication and proficiency in preventing re-draws. This indicates that SOP adherence must be supported by regular related CMEs to augment and offer refreshers on standard operating protocols.

5. Conclusions.

1. Use of pre analytical quality indicators were directly associated to pre analytical errors; It was found out that the risk of multiple influences on sample integrity (Clotted, haemolysed, inadequate, mismatched labels or unlabeled) increased as a result of increase in non-conformances to pre-analytical QIs. It was evident from the study that the error prone carder was the nursing officers, followed by the clinical officers. This was attributable to non-applicability of phlebotomy SOPs by the two carders of care givers. A Pearson Chi-Square test showed that there was significant relationship between profession and occurrence procedural errors in pre-analytical phase. This proof is augmented by differences in relevant CME uptake by the different professions.
2. The medical staff grew in experience unknowingly and unexpectedly they become prone to technical and procedural errors. There were specific high turnout errors in proper vein-puncture technique, order of draw and proper post sampling tube mixing. This trend affected experience cohorts of 5-9 years followed by 10 and above years. This was attributable to the "comfort zone" at work that is gained with experience as the new hires toil to keep their jobs.

3. It was also observed that post collection sample integrity varied depending on experience, carder of care giver and SOPs applicability. Short draws followed by clotted samples and the wrong sampling tube were the major cases of compromised sample integrity, nurses and clinical officers were the majority contributors of these errors.
4. The capacity building through continuous medical education related to sample collection is very vital. This was because most of the laboratory staff were acquainted with knowledge on sample collection through CMEs and by SOPs. This vital aspect was adequately lacking amongst the other care givers, however, there still seemed to be an issue of needs assessment where the caregivers could make policy adjustment to let specific personnel perform sample collection except in emergency cases if this could reduce risk. There is need to be an existence of an atmosphere of co-learning and collective action amongst the carders to help realize the much-needed self-sustaining Quality standards

5.1 Recommendations

1. Progressive use and monitoring of QIs should be encouraged to promote a valuable quality system program.
2. Pre-analytical QIs should be used in laboratories to provide evidence of compliance with essential requirements of the ISO 15189 International Standard and generally for assuring quality particularly as a tool for assuring risk management and promoting patient safety.
3. The laboratory should develop extensive standard procedures on all spheres of pre-analytical sampling stages. This should be able to guide all staff performing sample collection as a mandatory policy.
4. Routine Continuing Medical education (CME) and Good Clinical Laboratory Practice (GCLP) for capacity building by all staff involved in sample collection should be made a culture
5. Quality control measures should be put to periodic monitoring through auditing of quality indicators and review of such documents to detect all non-conformities and thus initiation of corrective action as and when necessary.
6. As evidenced throughout the findings, continuous trainings related to sample collection should be intensified with increase in personnel experience. This is because of high procedural and technical error rate amongst care givers across the professional divide

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Table 1. Demographic profiles of respondents

Characteristics'		Frequency	Percentage
Age (in years)	25-30	6	15.8
	26-35	15	43.2
	36-45	12	35.0
	>46	3	7.5
Profession	Nurses	25	57
	Lab Tech	8	18
	Clinicians	11	25
Years of Experience	< 1 Year	5	10
	2 - 4 Years	10	31.1
	5 - 9 Years	17	47.5
	10 and above Years	12	11.3

Table 2: Distribution of Sources of Pre-Analytical Errors by Profession

Type of Pre-Analytical ERROR	Lab	NO	CO	Pearson Chi-Square
Patient Identification Procedures				
Not Identified by Patient Name	4	39	16	
Not Identified by Gender	22	41	12	X^2=33.40, df= 2, P<0.005*
No use of Patient Unique Number	72	214	86	X^2=33.40, df= 2, P<0.005*
Sample Identification Procedures				
Improperly Labeled	52	214	84	
Unlabeled	12	22	8	X^2=12.54, df= 2, P<0.005*
Mismatched Labels	4	16	6	
Assessment of Sample Collection Procedures				
Improper Patient Preparation	13	39	26	X^2=14.02, df= 2, P<0.005*
Short Draws	21	52	34	X^2 =14.02, df= 2, P<0.005*
Wrong sample type	2	24	13	X^2 =1.59, df= 2, p=0.451
Inappropriate container	6	32	18	X^2 =6.23, df= 2, p=0.042*
Assessment of Sampling Technique				
Wrong Site selection	8	28	12	X^2 =7.431, df= 2, p=0.024*
Improper Site Preparation	16	64	32	X^2 =19.10, df= 2, P<0.005*
Improper Tourniquette Application and time	22	12	36	X^2=33.02, df= 2, P<0.005*
Improper venipuncture Technique	14	23	42	X^2 =15.60, df= 2, P<0.005*
Wrong Order of Draw	9	65	48	X^2 =8.59, df= 2, p=0.014*
Improper tube mixing	8	22	21	X^2 =7.4, df= 2, p=0.024*

Significant at p <0.05, NO: Nursing Officer, CO: Clinical Officer

Table 3: Proficiency based on SOP applicability by profession

Carder	Total Number	Number Proficient	Percentage proficiency (%)
Laboratory Staff	8	7	53.8
Nursing Officer	25	4	30.8
Clinical Officer	11	2	15.4

Table 4: Continuous Medical Education versus reason for Re-Draw

		Continuous Medical Education			Total
		Often	Annually	Never	
Reason for Re-drawal request	No re-drawal	6	4	1	**11**
	Clotted Sample	2	2	5	**9**
	short draw	3	2	4	**9**
	Haemolyzed	0	2	2	**4**
	Wrong tube	3	1	1	**5**
	Wrong labeling	0	2	1	**3**
	Wrong Patient Preparation	0	1	2	**3**
Total		**14**	**14**	**16**	**44**

X^2=13.518, df =3, p=0.333

Table 5: Sample outcome versus profession

		Lab Tech	NO	CO	Pearson Chi-Square
Outcome/ suitability of the Sample	Mismatch in Sample-anticoagulant Ratio	24	83	41	X^2=40.128, df= 2, P=0.528
	Haemolyzed Samples	8	22	14	X^2=7.43, df= 2, =0.507
	Clotted Samples	6	16	17	X^2=5.28, df= 2, =0.017*
	IV Fluid Contamination	0	24	4	X^2=11.276, df= 2, =0.004*
	Expired Supplies	12	52	21	X^2=12.54, df= 2, =0.512

***Significant at p<0.005*: NO=Nursing Officer, CO: Clinical Officer**

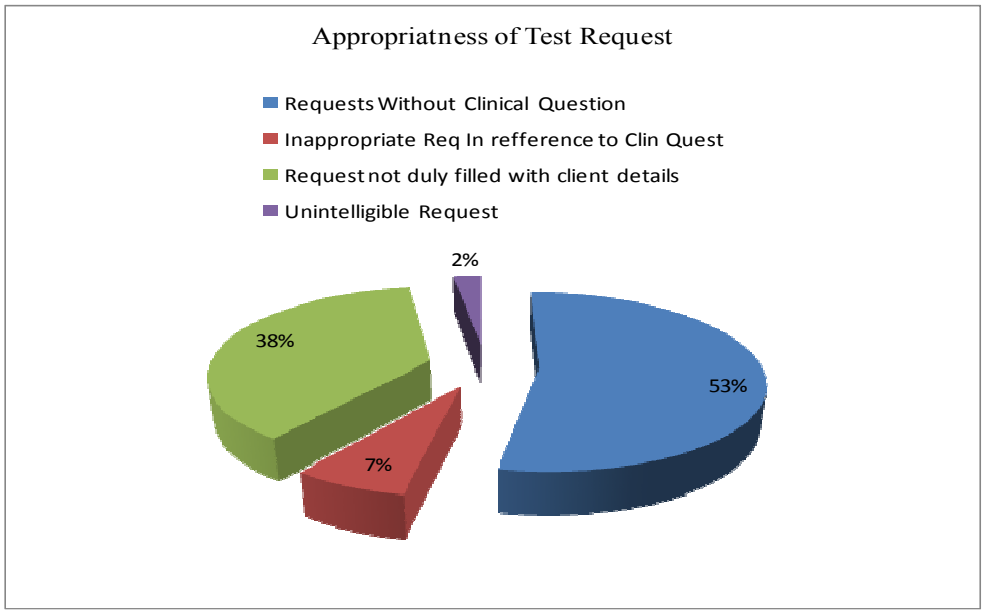

Figure 1. Pre-pre-analytical Errors associated with test requisition

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