

Ensuring Blood Grouping, Cross Matching, and Appropriate Storage and Delivery in Compliance with Quality Standards during Preparation and Delivery of the EQC Materials to the Participating Laboratories in Nairobi City County, Kenya

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Abstract: ***Background:** Ensuring high - quality laboratory services is crucial for accurate diagnoses and patient care. It is therefore paramount that high standards be maintained in the conducting of tests as results forthcoming from the tests will be used for diagnosis purposes. External Quality Control (EQC) is therefore essential for the relative assessment of quality among laboratories in the bid to identify dispersion from a set mean and general accuracy and reliability in the conducting of tests and test outcomes. The status pertaining to External Quality Control in Nairobi city County is such that few institutions are engaged because of the high cost. **Methods:** Z - score analysis was used to analyze data obtained from the participating laboratories. Data presentation was done using graphs, tables and pie - charts where applicable. **Results:** Distributions to the Nairobi City County hospitals of samples per nine months was nine cycles, one cycle per month. Each of the nine cycles was independent. **Conclusion:** In conclusion, locally prepared EQC materials attracted many clinical laboratories. Regular external quality assessment programs are essential for ensuring the accuracy and reliability of laboratory test results, especially in Nairobi, where inadequate laboratory testing is prevalent. The development of stable and reliable external quality control materials is critical for the success of EQA programs. The goal of the research is to raise standards for laboratory care in Nairobi County. This will be done by finding out if quality results are generated from our laboratories and if not, mentoring the laboratories that did not perform well in the EQC testing will be considered. This study suggests that laboratories employ external quality control material and measure their results using variance comparison to do this.*

Keywords: Dispersions, Accuracy, Internal and External Quality Control, Dependability

1. Introduction

The apparent need for effective medical procedures in laboratories necessitates an exposition into the quality standards currently employed in ensuring accurate, reliable and consistent output of findings from medical laboratories (Marshall *et al.*, 2020). This apparent need for effective medical procedures in laboratories necessitates an exposition into the quality standards currently employed in ensuring accurate, reliable and consistent output of findings from medical laboratories (Marshall *et al.*, 2020). Quality is an important aspect in ensuring accurate and reliable test results are obtained. Wrong results can lead to fatal outcomes and this is especially true in hematology and biochemistry laboratories. Consequences such as unwarranted therapeutic interventions, wrong diagnosis, increased costs and even death can be attributed to inaccurate laboratory results (Donohue *et al.*, 2021). In order to compare a laboratory's performance to that of others, external quality control programs periodically send samples with unidentified results to participating laboratories. When a laboratory gets a sample of this type, it analyzes it and provides the findings within a predetermined time frame for comparison with findings from other laboratories taking part in the survey – the objective being to achieve precision and accuracy relative to other laboratories under assessment.

The estimated value's accuracy is how closely it resembles the value that is generally accepted to be true. precision is

the reproducibility of a result, whether it is accurate or not. (Wang *et al.*, 2023). Improper standards or reagents, faulty instrument calibration, or bad technique all contribute to inaccuracy and/or imprecision. Quality is an important aspect in ensuring accurate and reliable test results are obtained. Wrong results can lead to fatal outcomes and this is especially true in hematology and biochemistry laboratories. Confirmation of clinical impression expressed by an individual seeking medical attention in the health institution is ultimately achieved through the tests results generated from clinical laboratories. Clinical laboratories at all levels and irrespective of size continue to generate test results which are used to determine the prevalence of diseases that affect a certain population within a geographical region. Clinical laboratories need a system that tries to regulate the quality of data (results) generated in order to reduce the likelihood of inefficient operations. This system, which is an integral part of good laboratory practice, is referred to as quality assurance system (Heinz - Taheny, 2022). A quality assurance system is a set of constituents which includes plans, procedures and policies that together provide a base for clinical laboratory efforts to achieve quality goals (Montgomery, 2020). Every person and any activity that takes place in the clinical laboratory is incorporated, through a set of stipulations, in the quality assurance system. A solid quality assurance system is anchored to several essential elements; these essential elements include – commitment, facilities and resources, technical competence, quality assurance procedures and

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problem - solving mechanisms. A lack of appropriate quality assessment programs, as reported by Guiñón *et al.*, 2021 in a study conducted across 292 laboratories in 47 counties, results in subpar laboratory reporting; results from the study indicated that only 61% of results were accurate and reliable. During an EQA survey, samples are submitted from one laboratory or management body to many cooperating labs so that the concentration of analytes may be determined (Simundic *et al.*, 2020). The samples should replicate the clinical samples that are typically measured. The participating laboratories are expected to conduct the measurements similarly to how they would with patient samples even though they are not aware of the analyte concentration in a particular sample (Serdar *et al.*, 2021). Following completion of the measurements, the samples' results are sent back to the EQA organizing body for review of conformity to the anticipated outcomes. The organizing group or body then prepares a report with the results from a laboratory as the report, including the methods that have been used by the laboratory for measurement, the target values that each analyte is expected to return, and then an evaluation is made on whether the results received from a laboratory had attained the required expectation. The reports may as well include an evaluation of the performance of the various measurement procedures used by the participating laboratories.

2. Materials and Method

Distributions to the Nairobi County hospitals of samples per year was nine samples, nine times at one months interval.

The samples were analyzed using routine laboratory methods, including complete blood count, blood grouping and compatibility testing.

2.1 Study design and site.

Purposeful sampling was used to select the laboratories while random sampling was used for the laboratory practitioners.

The area of study is Nairobi city County, Kenya which has 17 subcounties both rural and urban and each subcounty has 5 wards. Therefore, I selected 7 or 8 facilities from each subcounty considering the wards and they made up the sample size.

The main study site was Mama Lucy Kibaki Hospital, Nairobi, Kenya at the Haematology and Blood Transfusion section from where all samples were prepared. A Level - 5 facility, it is found in Nairobi's bustling Embakasi District. Eleven kilometers east of the city center, near the crossroads of Kangundo Road and Kayole Spine Road, is where Umoja - 11 and Komarock Estates can be found. The area is mainly residential and has numerous informal settlements. Nairobi city county is approximately 698 square kilometers in area and has a population of approximately 5, 119, 000. This was an ideal site due to its locality. The study population could readily be available during the study period.

2.2 Study Population

All laboratories within Nairobi city County, Kenya. According to the Kenya Medical Laboratory Technicians Technologists Board (2019) there are currently 201 medical laboratories registered with active licenses; these laboratories formed the population of 132 medical laboratories in the study.

2.3 Sample size determination

Sample size formula (Cochran, W. G.1977).

$$n_0 = \frac{Z^2 \times p(1-p)}{e^2}$$

Population size, denoted by N, is 201.

p= population reliability (or frequency calculated for a sample of size n), with p=0.5 assumed for all populations.

e = error, with 95% confidence set at a margin of 5% For a significance level of 0.05. The value of z is 1.96.

$$n_0 = \frac{Z^2 \times p(1-p)}{e^2} = 384.1568$$

The sample size is above the 5% precision required from the population size. Hence I used the Cochran correction formula. (Cochran, W. G. 1977).

$$n_1 = \frac{n_0}{(1+n_0)}$$

$$1 + n_0 = 2.911243781$$

$$= \frac{384.1568}{2.911243781}$$

$$= 131.957345 \text{ hence } 132 \text{ respondents}$$

2.4 Data collection

The research relied mostly on two methods of data collection: questionnaires and hematological test results. Questionnaires were structured to include both open and closed ended questions aimed at establishing the current state with regard to utilization of quality control programs and materials and the self - reported benefits, if any. The Questionnaires were administered to the laboratory in charge. Subsequently, quality control materials were distributed to laboratories that opted into the EQC programs after which hematology tests results were collected from the respective laboratories forming both the treatment and reference groups of the study; this data constituted the quantitative data to be used in inferential analysis in testing EQA. For the laboratories that opted to the use of quality material, requisite publications were created and distributed after which, following and adjustment period, samples were administered to assess the assessment on EQA outcomes.

2.5 Data management, Analysis and Presentation.

All data collected for the study was entered and was confidential by use of study numbers only known to me. The data was deposited in a central repository with a private password and kept confidential for the duration of the study. All data was written onto spreadsheets as necessary in preparation for analysis in accordance with the research objectives.

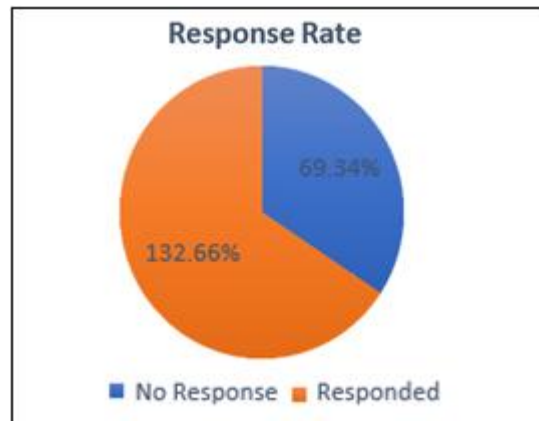
The acquired data were input into Excel, cleansed, and statistically analyzed using SPSS version. The findings were analyzed using one - way analysis of variance (ANOVA). Data presentation are in graphs, tables and pie - charts where applicable.

2.6 Ethical Considerations

In light of the potentially sensitive nature of the information gathered throughout the course of the investigation, all research instruments were first presented to the Mount Kenya University Ethics board for approval. Research authorization was sought from National Commission for Science, Technology and Information (NACOSTI), Mama Lucy Kibaki hospital, Nairobi Health Department ethical review boards were contacted for approval of the study. Since KMLTTB oversaw the research project, a cover letter to all of the accredited labs in the country was requested. No tests proceeded except after approval by all pertinent review boards. Consequently, the study's data was shielded from public view and kept secret at all times. No unauthorized persons were allowed to gain access to the data collected from the various laboratories and all data collection tools included explicit mention of study participation was entirely optional. The EQC material was blinded for objectivity. The laboratory manager was aware of EQC material while the technologist was not aware and was given to run together with the patient’s samples.

3. Results

Of the 201 registered laboratories with current licensing, 132 availed responses to the study prompts thus placing the response rate at 66 percent. Out of a total of 201 targeted laboratories, 132 laboratories (approximately 66%) underwent EQC (External Quality Control) testing, while 60 laboratories (approximately 30%) did not undergo EQC testing. Despite this important fact as far as delivery of quality laboratories services is concerned, not all clinical laboratories are able to fulfil this important requirement. Out of 201 number of registered clinical laboratories, 132 agreed to join the current study whilst 69 refused to join the current study despite the fact that joining was completely free.



In order to establish the current status of clinical laboratories having an ongoing external quality control programme, 132 clinical laboratories were recruited in the current study. 119 clinical laboratories revealed that they have never been involved in any external quality control programme. All laboratories involved in the study employed the use of internal control measures hence 100% IQC was reported for the sample. Many laboratories did not engage in EQC (90.152%) thereby indicating, at the whole, that quality assurance provisions were limited to the internal practices of laboratories with minimal effort to cross - reference practices against those of other laboratories. This finding is of pertinence to the first objective of the study state of subscription of EQC.

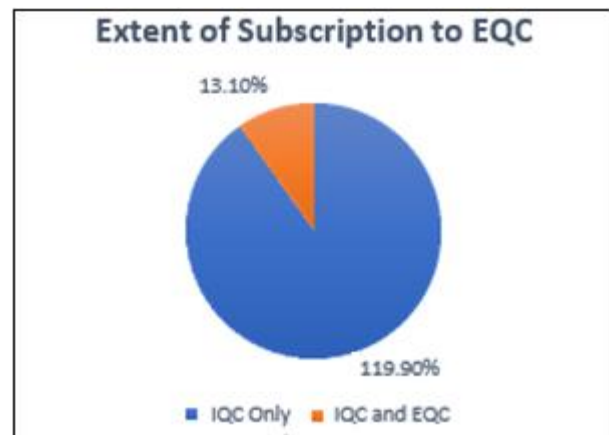


Figure 2: Extent of subscription to EQC

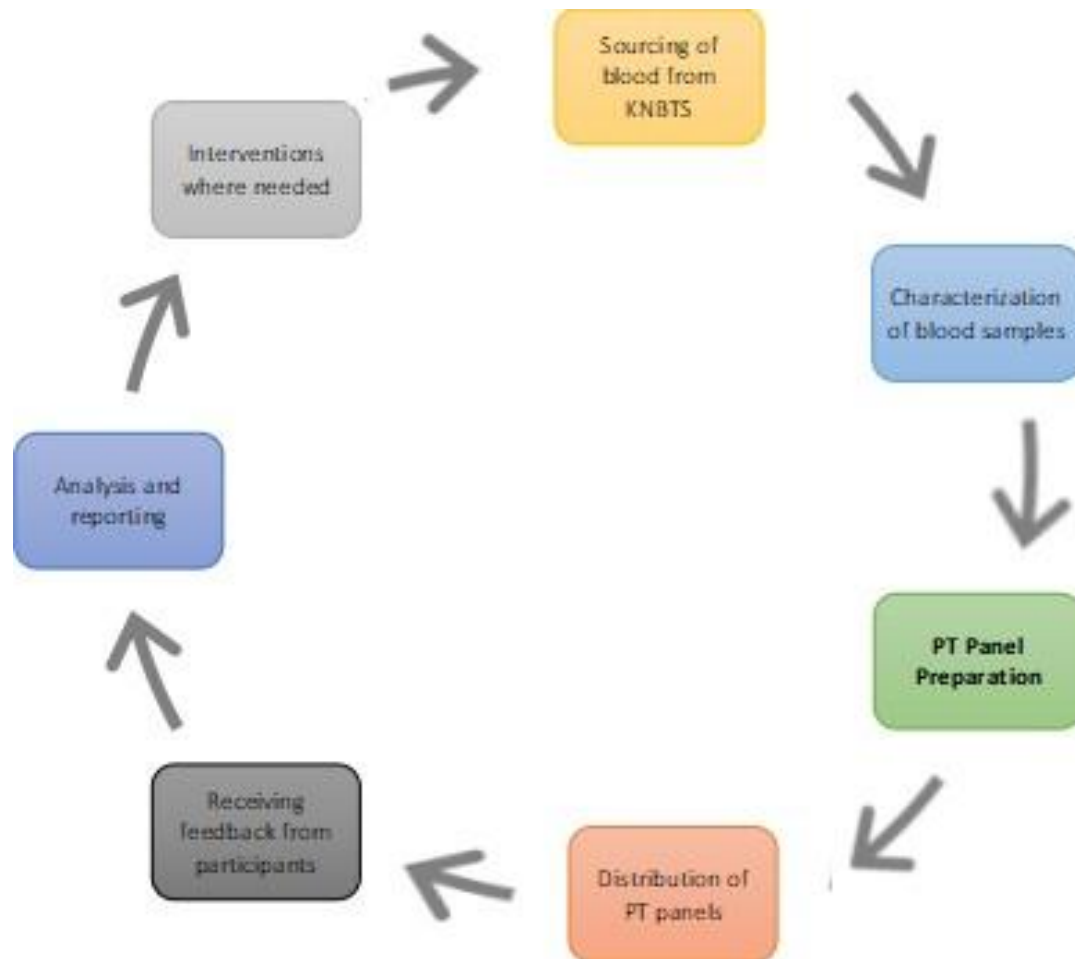


Figure 3: Preparation and transportation the EQC materials to the participating laboratories.

Blood was sourced from the Kenya National Blood Transfusion Services, whereby characterization of the samples was performed and transported to Mama Lucy hospital. The prepared EQC Samples from Mama Lucy Kibaki hospital were transported to various Nairobi county facilities in cool boxes or cardboard boxes with cool packs prepared, along with instructions to maintain the specimens at 4°C immediately after receiving and processing them as early as possible and send the results within five days.

Distributions to the Nairobi City County hospitals of samples per nine months was nine cycles, one cycle per month. Each of the nine cycles was independent. Each cycle was a new sample that had been just prepared. What informed the preparation of the nine cycles was:

- Consistent of results.
- Accuracy and Precision
- Aspect of data saturation. That is a point at which new data no longer provides additional insights.
- To minimize potential variation of results.
- Limited resources that I could only perform nine cycles.

It is worth to note that all the parameters were analyzed from the same external quality control material and using the same equipment either automated or manual. The other aspect of commonality was that all the parameters had to be calibrated before the analysis. With this understanding, it was expected that all the participating clinical laboratories to

produce similar results for the specific haematological parameters.

3.1 Preparation of blood products at Mama Lucy Hospital laboratory.

The blood specimen in the plain vacutainers were centrifuged using MSLZ19 centrifuge at 2000 rpm to obtain serum. The serum obtained was first used for screening of the following TTI's; Human Immunodeficiency Virus (HIV), Hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV) by The Enzyme Linked Immunosorbent Assay (ELISA) method and syphilis by Rapid plasma regain test (RPR), in order to transfuse non - infected blood to the patients. Only those specimens which tested negative for the TTI screening were used in the study. Six drops of blood from each EDTA vacutainer were used for blood grouping as indicated in Table 1. Six tubes were labeled as follows Anti - A, Anti - B, Anti - D, A - cells, B - cells and O - cells. One volume of antiserum was added into the respective tube labeled Anti - A, Anti - B, Anti - D Subsequently, one volume of 4% known cells suspension of each to respective tubes labeled A - cells, B - cells and O - cells. One volume of 4% test cells suspension was put in tubes with antiserum. One volume of test serum was then added in each of the tubes with 4% known cells suspension. The contents were mixed in each tube and span at 1000RPM for one minute. Tube contents were examined both macroscopically and microscopically for agglutination or haemolysis.

Table 1: Forward and Reverse Grouping

Blood Donors	Anti - A	Anti - B	Anti - D	A - cells	B - cells	O - cells	Blood group
Donor 001	+	-	+	-	+	-	A+Ve
Donor 002	-	+	+	+	-	-	B+Ve
Donor 003	+	+	+	-	-	-	AB+Ve
Donor 004	-	-	+	+	+	-	O+Ve

Crossmatch Procedure

A cross - match is a test done to find compatible blood for a recipient. It detects antibodies in the patients or donor's serum that will destroy the donors or patients' cells. There are a number of steps taken before a transfusion to ensure the right kind of blood is given to the patient and to identify any abnormal antibodies in the recipient's serum that might compromise the survival of the donor's red cells. The importance of cross - match is: To detect irregular antibodies in the recipient serum that are directed against the donor's cells (major cross - match), to detect donors' irregular antibodies in the serum against recipients red cells (minor cross - match), to detect errors in ABO grouping and to detect errors in labeling, recording or identifying donors or recipients' samples.

3.2 Preparation of quality control materials

3.2.1 Blood Specimen

Quality control material were prepared from grouped and Pooled blood, to avoid agglutination due to incompatibility, collected from healthy blood donors recruited from blood donor centre of National public Health laboratories, Kenya National blood Transfusion Centre (KNBTS) or healthy Kenyan individuals recruited from colleges/ universities/ churches/ mosques within Nairobi County.

3.2.2 External Quality Control Materials

Preparation of Preserved Blood

Thirty volunteers of the same ABO blood type were recruited and their blood taken in either CPD (Sodium citrate, Citric acid, Sodium dihydrogen phosphate, dextrose) or ACD (Sodium citrate, citric acid, dextrose) blood bags (Lewis 1998). Whole blood components collected from anonymous donors via a national blood transfusion service is a sustainable supply of raw material, but it must be authorized by the transfusion services, as stated by Barbara De La Salle, 2017. Red blood cells (RBCs) and hemoglobin content (Hb) may be preserved by CPD anticoagulant for at least 21 days, according to research by Pulliam et al., 2021. Unless utilized immediately after venesection, the material is unsuitable for automated white cell differential because the characteristics of the cells gradually degrade with the same storage errors found in EDTA. However, the total number of white blood cells or leucocytes remains constant for many days. This instability extends to platelets as well.

Compatibility testing is performed on all the 30 pints of each cycle. Cross match was prepared on the Pints pairing two by two. Sample from one pint being used as the donors blood while sample from the alternate pint being used as the patients serum, therefore performing 15 cross matches from the 30 pints.

From the 15 compatible cross matches, the paired samples were mixed and cross matched with the alternate pair, ending up with 4 other cross matches being performed.

From the 4 compatible cross matches, the paired samples were mixed and cross matched with the alternate pair, ending up with 2 other cross matches being performed.

From the 2 compatible cross matches, the paired samples were mixed and cross matched with the alternate pair, ending up with 1 other cross match being performed.

Blood from ABO - compatible donors may be pooled to make a large assay material pool, although the maintenance of homogeneity during preparation and bottling becomes a greater challenge the greater the volume of the pool, requiring specialist mixing and bottling equipment 10mls of each pint of blood was pooled in a round bottomed flask, mixing at the same time and continuously mixed for at least 20 minutes after addition of the last unit of blood. The cells from the pooled blood were treated as follows: To increase red cell count, more plasma was removed. To lower red cell count, fresh plasma was added or a solution of 5mls Ethylenediaminetetra acetic acid (K2EDTA) anticoagulant in 9g/L NACL added to the anticoagulant: saline ratio was the same as the anticoagulant: blood ratio. For WBC count, centrifuged blood's buffy coat was added. Finally, for platelet count, platelets concentrates were added. The EDTA maintains the size, integrity and appearance of cellular blood components and provides material that is commutable across different automated cell counting platforms, Bhattacharya et al., 2022. The blood was stabilized with Formaldehyde 40% and Glutaraldehyde 50%, freshly on each occasion to preserve the morphology of the blood cells for the analysis of all the parameters. After fully re - suspending and gently mixing of blood, it was transferred into a Winchester bottle to which 150µg of Penicillin and 375µg gentamycin were added in turns to serve as broad spectrum antibiotics and an antimycotic amphotericine B 3mg/L was added to ensure sterility of the blood which compared to Opuku et al, 2008, in Ghana. The blood was continuously mixed and aliquots of 2ml prepared in sterile sample vials; these were capped and sealed then labeled with the distribution numbers, date then refrigerated at 4^oC until needed. The unopened human blood vials were kept in good condition for three weeks if held at 4^oC as recommended by Mudie et al., 2021. valuation and additional recommendation for preparing whole blood control material. A study by Barbara De La Salle, 2017 indicated that the stability of whole blood for use as automated counting EQA assay material can be prolonged by chemical stabilization. Partial fixation of whole blood with aldehydes is possible for the EQA provider to undertake in - house and produces an assay material stable for several weeks. A study by Barbara De La Salle, 2017 stated that Haemoglobin concentration, Haematocrit and red blood cells can be manipulated prior to stabilization by

mixing leuco - depeleted and non leuco - depeleted blood with the addition of buffy - coat residues or platelets concentrates (Solomon, 2020). The use of blood components that would otherwise be suitable for therapeutic transfusion may represent a conflict of interest and the EQA organizers must engage the support of the national blood transfusion service to ensure sustainability of supply.

Table 2: Preparation of EQC Material

CYCLES	Bldgroup	No. of pints	Mlsdisp	Dispatch Mlsdisp
Cycle1	AB+ve	30	13	2
Cycle2	O+ve	30	13	2
Cycle3	A+ve	30	13	2
Cycle4	AB+ve	30	13	2
Cycle5	O+ve	30	13	2
Cycle6	A+ve	30	13	2
Cycle7	B+ve	30	13	2
Cycle8	O - ve	15	20	2
Cycle9	AB+ve	30	13	2

3.3 Testing for stability and homogeneity

Vials were selected at random from the dispatch lot of the produced EQC specimens, stored at 4⁰C for eight days, and assessed for stability using manual and automated counter tests using a F ratio as the statistical approach. Homogeneity was analyzed using an ANOVA, and stability was determined with a F ratio, both of which are statistical techniques. Testing of homogeneity and stability means the procedure whereby it is established that the new External quality control material will be distinguished from others whose descriptors are known, is homogeneous with respect to the recurrence of the same characteristics through out successive generations.

3.4 Dispatch of Samples

The prepared EQC Samples from Mama Lucy Kibaki hospital were transported to various Facilities in Nairobi County, Kenya, in cool boxes or cardboard boxes with cool packs prepared, with instructions to keep specimens at 4⁰C immediately upon receipt, analyze them as soon as feasible, and return the findings within five days.

3.5 Frequency of Distribution per Year

Distributions to the Nairobi County hospitals of samples per year was three samples, three times at four months interval.

3.6 Validity and reliability of the EQC samples

Two aspects of research quality were assessed in the study – validity and reliability. Kothari (2004) observes that validity indicates the extent to which an instrument measures what it is intended to measure whereas reliability involves the consistency of results achieved through a measurement. To ensure validity of findings, a pretest of the study questionnaire was conducted at Kajjado county, Kitengela to ensure comprehension of the tool by potential respondents. Findings from the pilot study conducted among 10 randomly selected laboratories from the population were used to inform the study tool. With regard to the reliability of the research tool, the research ensured that all collected data was

generated as per the documented and standardized procedure.

4. Discussion

According to Baruch and Holton (2008), there is marked apathy in responding to academic research with most studies reporting average response rates of 52.7%. The fact that 69 laboratories did not undergo EQC suggests a potential lapse in the laboratory's quality control practices. Those clinical laboratories that refused to be recruited into the current study feared that they would not be able to sustain the external quality control programme and had a myriad of other reasons ranging from capacity to managerial. The other reason could be the EQA Culture and mentality. This compares to Amukele et al, 2012, where Twenty - one laboratories, representing 54% (21 of 39) of the total, were included in the analyses in Baltimore. The current study thus presented a higher - than - average response rate hence justifying analysis of the collected data in keeping with the study objectives. Ricós, C. et. al, (2022) in their scientific paper on "External quality control in laboratory medicine. Progresses and future, expressed the need of clinical laboratories to participate in external quality control programme. All participating clinical laboratories verified that internal quality control was done and findings were within the predicted internal quality control range before analyzing the external quality control material. The analytical methods for internal quality control and the allocated means for all automated systems were quite similar.

Crossmatching is crucial because it reveals any abnormal antibodies in the recipient serum that are targeting the donor's cells (major crossmatch), inaccuracy in ABO grouping, incorrect labeling, mis - identification of donor or recipient samples, or the presence of abnormal antibodies in the donor's serum against the recipient's red cells (minor crossmatch). The cross - match plays a crucial role in determining suitability in this thesis. If incompatible blood is pooled, reactions such agglutination and haemolysis would occur, leaving the EQC samples useless for the study. If it is not caught, the incorrect conclusions might be drawn. The care of patients is jeopardized (Turk. J. Haematol, 2022)

5. Conclusion

The study prepared the external quality control materials using whole blood from healthy blood donors. Acting as an external agent, the current study distributed external quality control to the participating clinical laboratories in nine different times hereby referred to as external quality control cycles. The external quality control materials (whole blood from recruited blood donors) differed from one cycle to another. This means that in every external quality control cycle, new set of healthy blood donors were recruited and the blood donated based on the blood group was pooled, aliquoted and then distributed to the participating clinical laboratories. In every cycle, each participating clinical laboratory analyzed haematological parameters as indicated in the test menu. Participating clinical laboratories were then required to send their haematological analytical results indicating the analytical methods used to generated the test

results. In the current study, all the participating clinical laboratories were able to fulfill their obligation by analyzing the expected haematological parameters and sending the results to the external agent for statistical analysis and report preparation. All the nine external quality control cycles that were involved in the current study produced one hundred percent success rate. Similar study carried out elsewhere also had a similar success rate. Commutable control materials are those that mimic patient samples and can be used to evaluate the performance of laboratory test methods in a way that is more representative of real-world conditions. The study found that the use of commutable control materials improved the accuracy of EQA results and reduced the likelihood of method-related errors. Another study by Vidali et al., 2021 focused on the development of a new external quality control material for hematology tests. The researchers developed a freeze-dried, whole-blood-based control material that was stable for up to 6 months and had a wide range of hematological parameters. The study demonstrated that the control material was suitable for use in EQA programs and could improve the accuracy of hematology test results. A review by Sudarshan et al., 2023 discussed the challenges in the development of external quality control materials for haematological analysis. The review highlighted the need for a reliable and stable source of reference materials, as well as the importance of appropriate sample preparation and storage. The review also discussed the potential use of commutable reference materials, which have similar properties to patient samples, in the development of external quality control materials. Another study by Bachar et al., 2021 evaluated the use of artificial intelligence (AI) in the development of external quality control materials for haematological analysis. The study used AI algorithms to create synthetic blood samples that mimicked the properties of patient samples. The synthetic samples were then used to evaluate the performance of haematological analyzers in different laboratories. The study concluded that AI-based approaches can be effective in the development of external quality control materials for haematological analysis. In a study by Pansuwan et al., 2022, the authors developed an external quality control material for the analysis of red blood cell indices. The study demonstrated that the developed material was stable and suitable for use in EQA

programs for hematology laboratories. "Development of a lyophilized whole blood external quality assessment material for hematology in Africa" by Maule, 2020.

This study aimed to develop a lyophilized whole blood external quality assessment material for hematology in Africa. I successfully developed a stable and reliable lyophilized whole blood material, which can be used for EQA programs in the region. The recommendation is that the material should be validated and distributed to participating laboratories.

6. Recommendations

External agents in charge of production and distribution of the quality control material should reduce the cost of participation so as to have more participating clinical laboratories join local external quality control programme.

Since commercial controls are so expensive, laboratory-made controls are a more practical option.

All clinical laboratories should be encouraged to participate in the local external quality control programme for reliable and accurate results. This will ensure that there is full harmonization of all the haematological results generated by the clinical laboratories in this region. Using external quality evaluation methods to measure laboratory performance would boost healthcare delivery across the city and the nation. EQA programs should be developed based on evidence-based protocols, and the results should be compared with international reference values.

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Conflicts of interest

The authors declared no conflicts of interest during and after the study.

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