State of External Quality Control Program Subscription Among Laboratories and Strategy for External Quality Control Material in Nairobi County, Kenya

Stanley King'e Waithaka [1], Damaris Akatsa Katsutsu [1,2*], and Kennedy Muna Kuria[3]

[1] Department of Medical Laboratory Sciences Mount Kenya University, Kenya
[2] Department of Medical Laboratory Sciences Jomo Kenyatta University of Agriculture and Technology, Kenya
[3] Department of Medical Laboratory Sciences Murang'a University of Technology, Kenya

Abstract

Background: The quality of service provided by any laboratory is a matter of seminal importance to the populace serviced by the laboratory in question. 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 allows for relative assessment of quality among laboratories in the bid to identify dispersions from a set mean and general accuracy and reliability in the conducting of tests and test outcomes. The status quo pertaining to External Quality Control (EQC) in Nairobi County is such that few institutions are engaged in endeavor and a lack of enforcement of legislation on quality control results substandard service.

Methods: A mixed methods research design with questionnaire and Purposeful sampling was used to select the laboratories. Among the 201 facilities targeted in Nairobi county 132 availed responses to the study prompts. Structured Questionnaires 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, were administered to the laboratory in charge in the 132 facilities. After filling the questionnaires, they were sent back to the researcher for analysis.

Results: All laboratories involved in the study employed the use of internal control measures hence 100% IQC was reported for the sample. The vast majority of the laboratories did not engage in EQC (90.152%). The distribution of EQC outcomes in the Nairobi laboratory reveals varying levels of representation across different categories. The majority of the samples fall into Level 4, accounting for 96(~73%) of the dataset. Level 3 included 30(23%) Health facilities of the dataset. Level 5 accounted for 5(4%). Private facilities accounted for approximately 38% of the EQC participation. Public facilities represented approximately 61% of the EQC participation. Mission facilities accounted for approximately 1%.

Conclusion: The production and availability of locally prepared external quality control material have succeeded to attract the participation of many clinical laboratories both big and small. These participating clinical laboratories were either public, private, or mission. The current study established that most clinical laboratories are unable to participate in external quality control programmes due to the high cost of participation charged by the external agents.

Keywords: External quality control, Internal quality control assessment, Dispersions, Accuracy, Analysis.
* Corresponding author: dkatsutsu@yahoo.com

1. Introduction

Quality assurance is essential, in haematology, to ensuring that laboratory tests are carried out reliably, (Lewis, S., 2017). The various aspects of quality assurance include internal quality control, external quality assessment, standardization of methods and proficiency surveillance (Lewis, S., 2017). External quality control is a way to compare the performance of a laboratory with reference to others; to this end, programs periodically provide samples of unknown results to participating laboratories. When a laboratory receives such a sample, it analyses and returns the results within a specified period of time for comparison with the results obtained from other laboratories participating in the survey – the objective being to achieve precision and accuracy relative to other laboratories under assessment. Quality assurance programmes play an integral part in clinical laboratories of developed countries, and they have not been accorded the same degree of importance in the laboratories of developing countries. In Kenya, several organizations namely Randox International Quality Assessment Scheme (RIQAS), Human Quality assessment Scheme (HUQAS), Kenya Accreditation Services (KENAS), East African Regional Quality Assessment Scheme (EAREQAS) and External Quality Assessment Scheme (EQAS), among others, regularly organize EQAS in haematology including haemoglobin estimation. Despite the existence of the EQAS programmes in Kenya, laboratory participation is still very low and optional (Amukele *et a*l., 2012).

In order to avoid the risks of inefficiency in laboratory procedures, it is necessary to introduce a system which aims to control the quality of data (results) produced in the clinical laboratory. This system, which is an integral part of good laboratory practice, is referred to as quality assurance system (McClathcey, K. D., 2002). 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 (McClathcey, K. D., 2002). 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 problem-solving mechanisms. The study was conducted to establish the state of

external quality control program subscription among clinical laboratories in Nairobi County, Kenya

2. Materials and methods

2.1 Study design and site.

A mixed methods research design was adopted with questionnaire used in collecting data from laboratory tests used as quantitative data in the main inferential analysis procedures. The study was both an observational and descriptive study using a cross sectional design. Purposeful sampling was used to select the laboratories

The main data collection tool employed in the study was questionnaires which 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. Questionnaires administered 'on site' by the researcher were used to establish the type of diagnostic services provided by the study health facilities, the tests performed by the laboratories, the methods used.

The main study site was Mama Lucy Kibaki Hospital, Nairobi, Kenya at the haematology and blood transfusion section from where all samples (EQA samples) were prepared before dispatching to various participating laboratories.

2.2 Study Population

The population under study were all laboratories within Nairobi County, Kenya. According to the Kenya Accreditation Service (2019) there are currently 201 registered laboratories with active licenses; these laboratories form the population of the study.

2.3 Sample size determination

The Sample size was determined using Cochran, W.G.1977 formula

$$z\text{^}2 * p(1-p)/\ (1+\ ((z\text{^}2 * p(1-p)/e\text{^}2\ N))$$

Where

N = size of population (201)

p = population reliability (or frequency estimated for a sample of size n), where p is 0.5 which is taken for all population

e = margin of error considered as 5% for 95% confidence level

z = value for the selected alpha level (at 0.05 level of significance), Z is 1.96

$z\text{^}2 * p(1-p)$= 384.1568

$1+\ ((\left(z^2 * \frac{p(1-p)}{e^2 N}\right) = 2.911243781$

384.16/ 2.911243781 = 131.957345 hence 132 respondents.

2.4 Data collection

Two aspects of research quality were assessed in the study – validity and reliability. Kothari, C. R. (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, the researcher conducted a pretest of the study questionnaire at Kajiado 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 changes made to the study tool. With regard to the reliability of the research tool, the researcher ensured that all collected data were subjected to documented and standardized procedures to both ensure equal treatment and trackability of the methodology path. Whereas applicable, in the use of Likert scales, Cronbach's alpha was computed to assess the reliability of the scales; a score of 0.8 was used as the cut-off value (Kothari, C. R.,2004).

The structured questionnaires which included 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, were administered to the laboratory in-charge in the 132 facilities. After filling the questionnaires, they sent the questionnaires back to the researcher for analysis.

2.5 Data management, Analysis and Presentation.

The questionnaires were analyzed by use of descriptive analysis. Data presentation are in graphs, tables and pie-charts where applicable.

2.6 Ethical Considerations

The study was ethically reviewed by Mount Kenya University ethics review board focusing on human research and permissions sought from Nairobi Health Department ethical review boards, Mama Lucy Kibaki hospital, National blood transfusion laboratories and all other hospitals involved in the study. The permit was accorded by the national board in charge of research in Kenya the National Council for Science Technology and Innovation (NACOSTI). The study was conducted under the auspice of Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) hence an introduction letter targeting all registered laboratories was sought from the organization. All data collected for the study were anonymized and treated as confidential throughout the running of the project.

3. Results

3.1 Response Rate

Of the 201 facilities, 132 availed responses to the study prompts thus placing the response rate at 66 percent. According to Baruch and Holton Cruz, R C. et al 2019, there is marked apathy in responding to academic research with most studies reporting average response rates of 52.7%. The current study thus presented a higher-than-average response rate hence justifying analysis of the collected data in keeping with the study objectives.

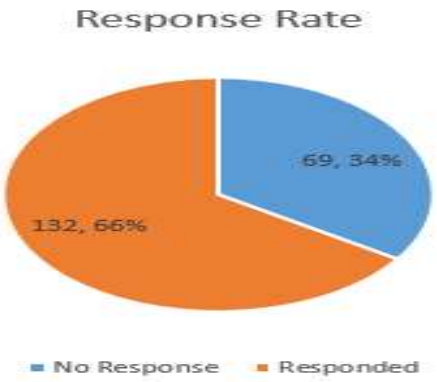

Figure 1: Response Rate of the participating laboratories

3.2 Subscription to external quality control

Prior to running of hematological tests, the respondents were required to provide information on their use of quality control standards (internal and external). All laboratories involved in the study employed the use of internal control measures hence 100% internal quality control (IQC) was reported for the sample. The vast majority of the laboratories did not engage in external quality control (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 objective of the study – state of subscription of EQC (figure 2).

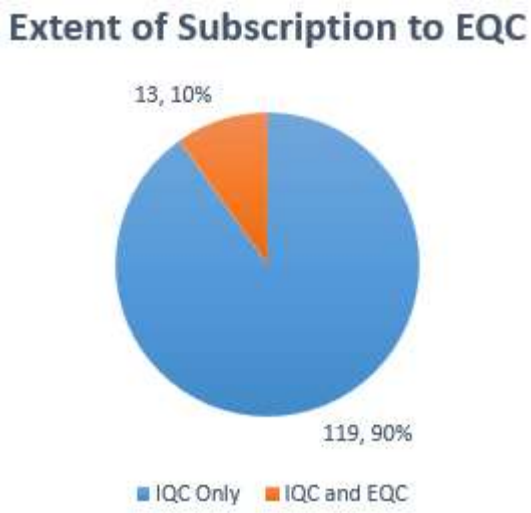

Figure 2. Extent of subscription to EQC by the participating laboratories

3.3 Distribution of laboratory performing EQC by level

The distribution of EQC outcomes in the Nairobi laboratory reveals varying levels of representation across different categories. The majority of the samples fall into Level 4, accounting for 96(73%) of the dataset. Level 4 represents the most prevalent category and suggests a satisfactory level of quality control compliance. Level 3 included 30(23%) Health facility of the dataset. This indicates a substantial representation of health facilities meeting the criteria or thresholds for Level 3. Level 5 accounted for 5(4%), it still represents a subset of Health facilities that meet specific criteria beyond Level 4.

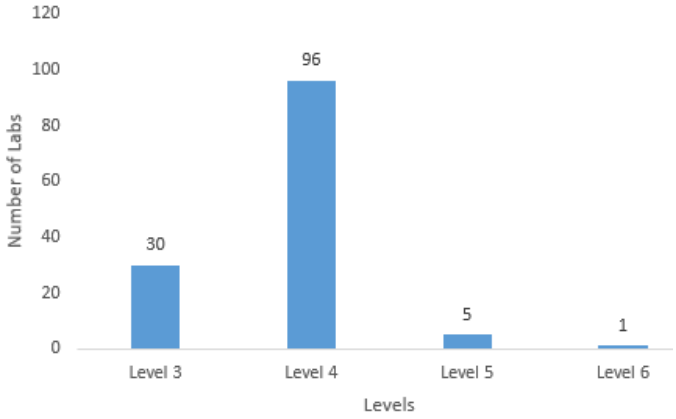

Figure 3: Distribution of laboratory performing EQC by level

3.4 Distribution of laboratory performing EQC by facility Ownership

The EQC (External Quality Control) process involved facilities from mission, Private, and Public. The distribution of EQC participation among different ownerships provides valuable insights into the commitment to quality control practices across different sectors. Private facilities accounted for 37.9% of the EQC participation. These privately-owned or operated organizations demonstrated their commitment to quality control by actively engaging in the EQC process. Their involvement emphasizes the importance placed on accurate and reliable test results within private sectors. Public facilities represented 60.6% of the EQC participation. Public facilities play a significant role in ensuring quality control standards and showcased their dedication to providing reliable testing services to the public.

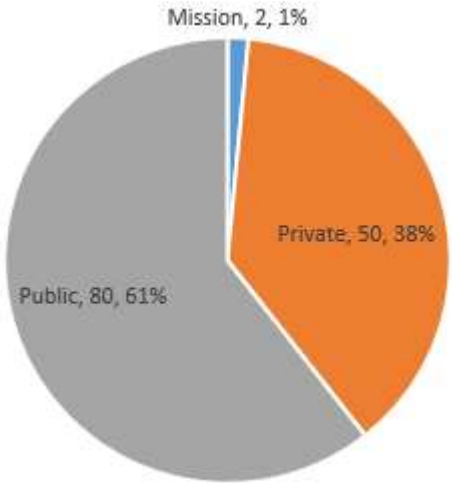

Figure 4. Distribution of laboratory performing EQC by facility Ownership

4. Discussion

External quality control is one of the components of quality assurance system and its role is to harmonize laboratory results. 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. 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. Out of 201 number of recruited 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. 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. This compares to Amukele *et a*l, 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. This compares to Amukele *et a*l, 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.

The distribution across these levels provides insights into the quality control outcomes in the Nairobi laboratory. The dominance of Level 4 indicates a significant portion of samples meeting the established quality criteria. However, the presence of other levels suggests the existence of samples with varying degrees of compliance and potential areas for improvement.

The distribution of EQC participation among Mission, Private, and Public facilities reflects a collective effort to uphold quality control in laboratory testing. The involvement of organizations from diverse sectors signifies a commitment to accuracy, reliability, and the continual improvement of testing processes. However, to gain a comprehensive understanding of the EQC outcomes and performance among different types, further analysis and specific data on the quality control results of facilities within each category would be necessary. Such information would enable a more in-depth evaluation of the effectiveness and impact of EQC practices in each sector.

Overall, the distribution of EQC outcomes across different levels in the Nairobi laboratory reflects a range of compliance and quality control performance. Further analysis and context-specific interpretation, along with a comparison to established standards, will help assess the laboratory's overall quality assurance practices and guide efforts to improve the accuracy and reliability of test results.

Conclusion and recommendations

The production and availability of locally prepared external quality control material have succeeded to attract the participation of many clinical laboratories both big and small. These participating clinical laboratories were either public, private or individual- private owned. The current study established that most clinical laboratories are unable to participate in external quality control programmes due to the high cost of participation charged by the external agents.

The finding of Reardon, D.M., *et al*, which persuitted the production of a stable easily-prepared, low cost material, met a need of the hematological laboratories. This compares to the study by Opoku-Okrah *et al.*, 2008, that established the need for external quality assessment schemes to be introduced to evaluate the performance of these laboratories and thus improve the delivery of health care in the region and in the country of Ghana as a whole. To gain a comprehensive understanding, it would be beneficial to assess these findings in relation to industry standards or benchmarks. Comparing the distribution of EQC outcomes with established guidelines can provide insights into the laboratory's performance and identify areas that require attention or enhancement.

In summary, the disparity between the number of samples undergoing EQC and those not undergoing EQC raises concerns about the reliability of the results obtained from the latter group. It is crucial for the laboratory to investigate the reasons behind this discrepancy, implement corrective measures, and reinforce a strong quality control framework to ensure accurate and reliable testing outcomes for all samples.

Conflicts of interest

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

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