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Quality Assurance and Calibration of Medical Devices Practices: Case Study of Government Regional Referral Hospitals in Uganda

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ABSTRACT

The accuracy of medical devices directly influences clinical decision-making and overall patient outcomes. To ensure that medical devices are accurate and safe all the time, it requires robust calibration and quality assurance practices coupled with maintenance. However, this topic is underexplored in studies regarding medical devices in Uganda. Here, we examine the calibration and quality assurance best practices in regional, national, and specialized public hospitals in Uganda. Moreover, we hypothesized that calibration and QA status directly influence medical device usage. To achieve this, we conducted quantitative and qualitative research in a cross-sectional study design in 17 regional referral hospitals, 3 national referral hospitals, and 5 specialized hospitals. A structured questionnaire was administered to 42 participants, which included biomedical engineers, technicians, and maintenance officers. It covered thematic areas of examining the existence of SOPs & QA protocols, availability of test tools, equipment downtime during calibration, calibration support, and training. The results of the study demonstrated that calibration and acceptance testing of donated equipment were performed on-demand. Nearly 43% of respondents had no SOPs and QA protocol, while 26% were unsure of it. Additionally, 20 of 42 respondents recorded the unavailability of test tools. Furthermore, about 75% of the respondents' sentiment revealed that calibration status directly affects use. This was consistent with a 71% score for a more than 1 month period on average time a medical device remains grounded as it waits for calibration. Overall, the calibration and QA practices of medical devices in public hospitals in Uganda are still in their infancy. It requires administrative, technical, and financial support. This study will become a precursor to calling for more effort, guidance, and strengthening the calibration and QA practices among biomedical engineers in Uganda.

Keywords: *Biomedical Engineers, Medical devices, calibration, quality assurance, test tools.*

1. INTRODUCTION

Medical gadgets are crucial to a healthcare system, particularly for accurate diagnosis, illness monitoring, and treatment, as well as for patient rehabilitation [1]. Clinical decision-making and overall patient outcomes are directly impacted by their operational performance. Ferda I. et al. (2026) state that this trend is substantially documented in affluent nations where patient health outcomes are consistent across demographic groupings. Because of the rigorous best practices for managing and maintaining medical devices, including quality assurance, calibration, and routine maintenance. As a result, medical devices are used extensively.

Medical gadgets are crucial to a healthcare system, particularly for accurate diagnosis, illness monitoring, and treatment, as well as for patient rehabilitation [1]. Clinical decision-making and overall patient outcomes are directly impacted by their operational performance. Ferda I. et al. (2026) state that this trend is substantially documented in affluent nations where patient health outcomes are consistent across demographic groupings. Because of the rigorous best practices for managing and maintaining medical devices, including quality assurance, calibration, and routine maintenance. As a result, medical devices are used extensively.

Muhammad K. et al. (2020) reviewed the literature on Nigerian medical imaging quality assurance. The results showed that inconsistent calibrations and quality assurance caused disparities in image quality and clinical judgements. The impact of medical device quality assurance and calibration on the use of medical devices, however, was not specifically addressed in the study. The confidence in medical device calibration knowledge and skills among healthcare professionals (HCP) in Ghana was investigated in a comparable cross-sectional study by Benjamin A. et al. (2025). According to the authors, clinical engineers and technicians were more confident than other HCP. Additionally, trained HCPs reported feeling more confident than their untrained counterparts.

However, the authors did not clearly examine the best practices and impact of medical device quality assurance and calibrations on its use.

There is a research gap in identifying the best practices in medical device quality assurance and calibration practices specific to sub-Saharan Africa, despite the fact that several studies have taken advantage of the difficulties, skilled capacity gap, and factors affecting maintenance, quality assurance, and calibration of medical devices in sub-Saharan Africa. We evaluated the best practices in medical device calibration and quality assurance across Uganda's regional referral hospitals in order to close this gap. Additionally, we assessed how quality control and calibrations affected the use of medical devices. Here, we postulated that, in addition to maintenance, calibration and quality assurance procedures have a direct impact on the use of medical devices.

In fact, we saw uncalibrated or subpar quality assurance and calibration procedures as quiet, deadly murderers that are overlooked throughout the medical device lifetime. It's also critical to keep in mind that issues with medical equipment are directly linked to poor patient outcomes [2].

Medical device calibration is one component of complete maintenance from the perspective of clinical engineering. According to Kumar R. et al. (2023), medical device calibration is a systematic process that verifies and adjusts medical device measurements to a recognised standard. This procedure guarantees that medical equipment consistently deliver precise measurements and outcomes within the permitted tolerance range or at all times.

According to John G. *et al.,* (2025), a typical calibration includes the following:

1) Purpose and scope;

2) Roles and responsibilities, e.g., in-house calibration and supplier-based calibration;

3) Frequency of calibration;

4) The use of risk-based scenarios for decisions (refers to second-level document for risk management) and the impact on the DMR;

5) Required equipment and standards;

6) Limits for accuracy and precision;

7) Limits of uncertainty and calculations;

8) Preliminary examinations and operations;

9) Calibration process description;

10) Remedial action for product as linked with the nonconforming corrective action process; and

11) Documentation requirements for not only internal process, but also those of the calibration supplier.

Calibration and Quality Assurance (QA) procedures are essential to the medical device lifecycle in a hospital setting. While quality assurance methods aim to reduce errors and increase safety and performance compliance, calibration ensures that medical equipment consistently produces reliable and accurate findings. As a result, both guarantee accurate and safe medical devices.

Together with the knowledge and experience of medical professionals, the accuracy and utility of medical devices are essential for accurate diagnosis and patient treatment. Kumar R. et al. (2025) state that "proper functionality of medical devices is crucial for patients in a large number of serious medical situations." Therefore, it is crucial to carry out as thorough and independent testing of medical device capabilities as is practical in order to obtain the most reliable and accurate diagnosis and patient treatment.

The purpose of this case study is to examine the quality assurance and calibration processes for medical devices in Ugandan government regional referral hospitals. We will then evaluate how calibration and quality control affect the use of medical devices. We postulated a relationship between the calibration and quality assurance status of medical devices and their use in hospital settings.

3. MATERIALS & METHODS

Research design

We investigated medical device calibration and quality assurance best practices (set procedures) at regional referral hospitals in Uganda using both quantitative and qualitative research methods in a cross-sectional study design. There were five-point Likert scale items in the survey, ranging from strongly disagree (1) to strongly agree (5). Other questions required a yes, no, or maybe response. Finally, there were open-ended enquiries that needed succinct, exact answers.

The overall survey questionnaires were structured as follows:

1) General information which included; hospital name, hospital level, participant's primary role, and number of years in practice.

2) Calibration test tools and resources; which assessed availability of test tools such as: patient monitor simulators, defibrillator analyzers, electrical safety analyzer, etc. In this section, we also examined external support to provide calibration services as well as availability of UPS or voltage stabilizers for high-risk medical devices.

3) Calibration & quality assurance procedures. This section was a multiple-choice grid with a 5-point Likert scale. It analyzed; planned preventive maintenance frequency, calibration status, acceptance testing of donated medical devices, spare

parts availability, inventory tracking, and documentations. Here, we analyzed the calibration and quality assurance practices based on widely applied clinical engineering practices.

4) Open end questions which explored; whether donated medical devices were provided with user/service manuals, issuance of calibration stickers, availability of standard operating procedures (SOPs), participants opinions on medical device calibration status and utilization, and major challenge in ensuring medical device accuracy.

Study population.

The targeted study participants were biomedical technicians and engineers who are full-time, part time or volunteering at regional, national and specialized public hospitals in Uganda. There are 17 regional referral hospitals in Uganda scattered in the Northern, Northeastern, Eastern, Central, Southwestern and Western parts of the country. Each regional referral hospital is estimated to serve 2 million people with an average 400-bed capacity, according to Sherry R.*et al.,* (2022). The national referral (3) and specialized hospitals (5) were included because of the limited number of biomedical engineers and technicians employed in public hospitals in Uganda. On average, there are two biomedical engineers/technicians per public hospital in Uganda. The regional, national and specialized public hospitals provide medical services that are not available at district level hospitals and lower health centers.

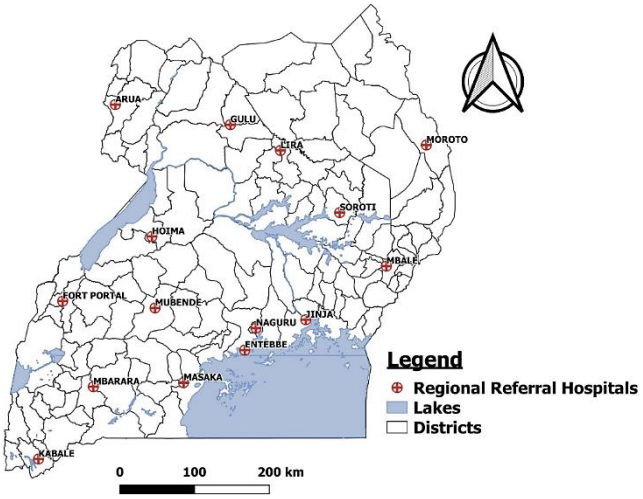


Figure 1: Location of regional referral hospitals in Uganda. Adopted from Sherry. R. et al., (2022).

Inclusion criteria.

The study participants must meet the criteria as follows:

a) The study targeted all engineering and technical cadres who are primarily responsible for the planning, acquisition, maintenance, management and disposal of medical devices in the respective public hospital.

b) The study participant must be a full-time, part-time, contract-based or a volunteer employed at a public regional, national or specialized hospital in Uganda.

c) The study participant must voluntarily agree to verbally consent to the study.

d) The study participant must have worked in the respective hospital for more than 6 months, which is a recommended probation period.

Exclusion criteria.

The exclusion criteria for the study were set as follows:

a) The participant is not directly responsible for planning, acquisition,

maintenance, management and disposal of medical devices in the respective public hospital.

b) The participant is not an employee at public regional, national or specialized hospital in Uganda.

c) The participant withdrew his or her consent at any time of the study.

d) The participant has not completed more than 6 months' probation period in the respective public hospital.

Data analysis.

The study collected data through administering a structured questionnaire to the study participants. The questionnaire was designed in google forms and pretested prior to publishing the link to the selected target participants. Furthermore, participants were limited to only one response to minimize data duplication. In an event of any digital challenges, a paper-based copy of the questionnaire was issued to the respective study participant. Responses to the questionnaire were verified for completeness and duplication for onward analysis. The collected dataset was migrated to Spreadsheet, 2016 for analysis. In some sections, the 5-point Liker scale responses were converted to numerical figures for quantitative analysis.

Privacy and confidentially.

An informed consent was obtained from the participants. The participants were debriefed on the study objectives and their right to withdraw from the study at any time without any penalty. Furthermore, the participant's personal information such as: names, age, gender, phone number, marital status, date of birth, ethnicity, and email address were not collected. This was to mitigate identification of study participants. The data collected were securely stored in passworded computer with a cloud back up option.

4. RESULTS & DISCUSSION

General information.

With the exception of the Ministry of Health, district/general hospitals, smaller health facilities, and private hospitals, regional, national, and specialised public hospitals in Uganda employ an average of fifty biomedical engineers and technicians. Of these, 42 people responded. Regional, national, and speciality public hospitals were where the responders were dispersed. The majority of responders (21, or 50%) were from regional referral hospitals. Nearly 59.5% of the respondents are biomedical engineers, and their years of experience ranged from 1 to 19.

42 Total respondents	**50%** Regional Referral Hospital	**33%** Specialized Hospital
Appx. **6yrs** Median years in practice	Appx. **60%** Biomedical Engineers	**17%** National Referral Hospital

Figure 2: Shows different hospital level in the study.

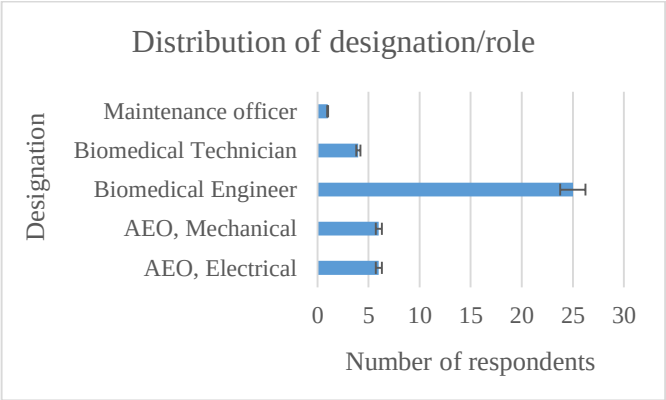


Figure 3: Shows different cadres or profession primarily responsible

for medical devices. Where AEO means Assistant Engineering officer

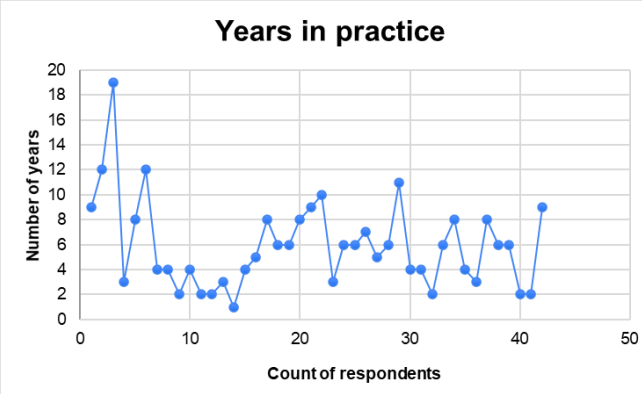


Figure 4: Shows distribution of years in practice among the count of respondents.

Test equipment and resources

The availability of test tools (simulators and analysers), such as electrical safety analysers, patient monitor simulators, and infusion pump analysers, is examined in this section. According to relevant standards, these test instruments are used to confirm that medical equipment are accurate within a permissible tolerance range.

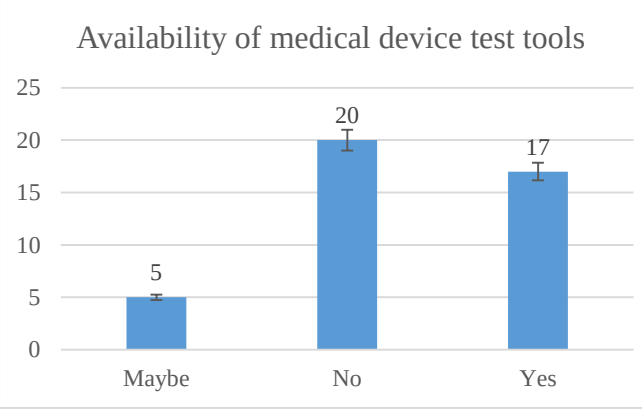


Figure 5: Availability of test tools.

The majority of responders (28.6%, n = 12) indicated the availability of gas flow analysers, followed by patient monitor simulators (23.8%, n = 10). The least accessible test tools among the 42 respondents were the ultra-sound phantom scoring (2.4%, n=1), water quality tester, and defibrillator analyser. For primary calibration help, hospitals without test equipment mostly relied on other institutions. Private outsourcing accounted for the majority (42.9%).

Additionally, about 26% of the respondents said that even the internal biomedical staff did not offer any external calibration support. Only 19% of respondents, however, said they were capable of internally calibrating medical equipment. According to 73.8% of respondents, all high-risk equipment was connected to a dedicated UPS in addition to the calibration services. This method simplifies quality assurance procedures by lowering errors brought on by unpredictable power supply.

Calibration and quality assurance.

In order to reduce the recurrence of errors and/or faults, we examined important calibration and quality assurance practices in this section, including calibration frequency, a risk-based approach to planned preventive maintenance, the implementation of a standard operating procedure for calibration, and incident reporting tools. It was found that, in contrast to planned preventive maintenance, which was primarily performed quarterly, calibration and acceptance testing of donated equipment was primarily conducted on-demand.

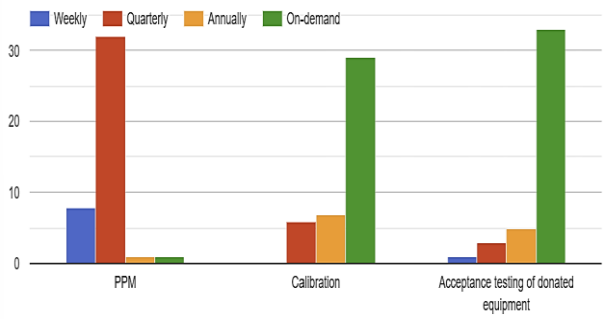


Figure 3: Planned preventive maintenance, calibration and acceptance testing frequency.

Majority of the respondents implement quarterly planned preventive maintenance

following a risk-based approach as described by J. Tobey Clark. *et al.,* (2009). Regarding standard operating procedures and QA protocols, the highest percentage of respondents (43%) do not have SOPs and QA protocols in place. Only 31% of the respondents have SOPs and QA protocols while the remaining 26% are unsure of SOPs and QA protocols. Conversely, a significant representation of 81% of the respondents have a formal incident reporting system for medical device malfunction or near misses.

From the perspective of capacity building, 28.6% of the respondents received training in calibration and or quality assurance practices. In addition, 69% of the respondent acknowledged no dedicated budget for calibration and quality assurance services or tools. Furthermore, most of the respondents disagree on availability of sufficient spare parts for medical devices in stock.

In general, the results from this portion of calibrating capacity and quality assurance showed deficiencies in almost every component. Many facilities lacked regular operating procedures, qualified personnel, a dedicated budget, and adequate calibration tools. There is a systemic resource gap since only 16.7% of facilities have a specific budget, and 71.4% of medical devices are grounded for more than a month as they wait to be calibrated.

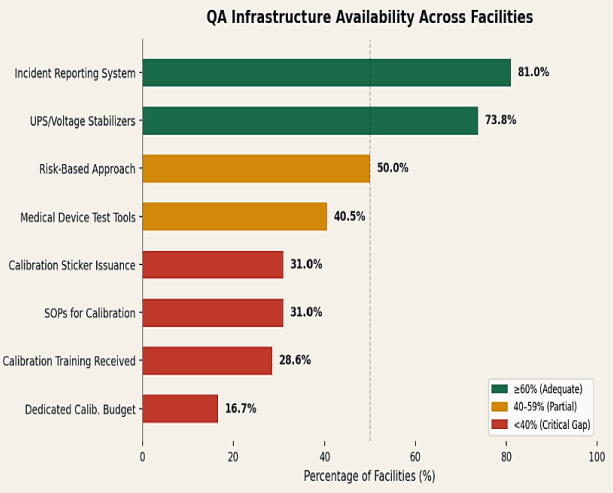


Figure 4: Quality Assurance infrastructure availability.

Most of the hospitals use Excel sheet for medical device tracking.

Impact on medical device utilization

This was a subjective response on how calibration and quality assurance practices can directly affect medical device utilization. Particularly, respondents provided feedback on an average time a medical device remains grounded as it waits for calibration. Furthermore, participants rated on a scale of 1 – 5 with 5 stars being the highest, the effect of calibration and quality assurance on medical device utilization.

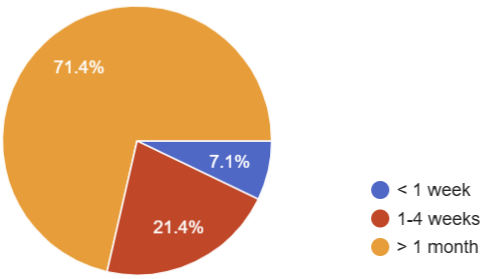


Figure 5: Average time medical devices remains grounded as it waits for calibration.

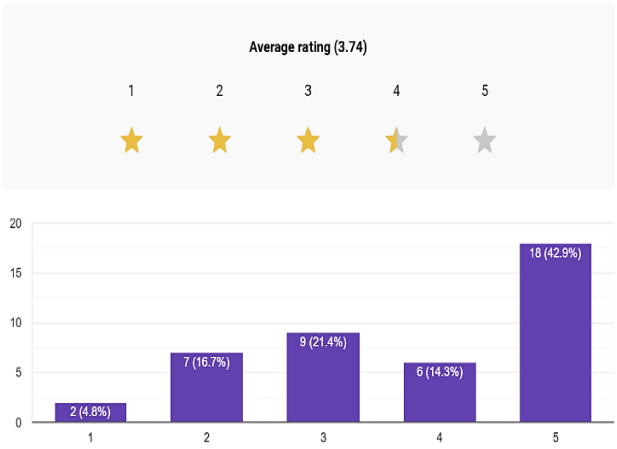


Figure 6: Sentiment rating on effects of calibration & QA activities on medical device utilization.

The graphs below show the respondents perceived impact of quality assurance and calibration on medical device utilization.

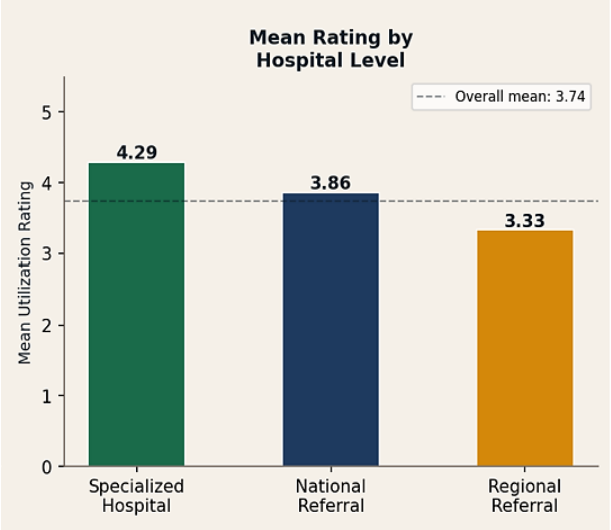


Figure 7: mean rating by hospital level

Role	n	Mean Rating
Biomedical Technician	4	4.25
Biomedical Engineer	25	4.16
AEO, Electrical	6	3.17
Maintenance Officer	1	3.00
AEO, Mechanical	6	2.33

Figure 8: Mean utilization rating by role

The correlation between medical device utilization impact rating and quality assurance and calibration practices were analyzed. The Spearman rank correlations were computed. Ordinal variables encoded as: Yes =2, Maybe = 1, No = 0.

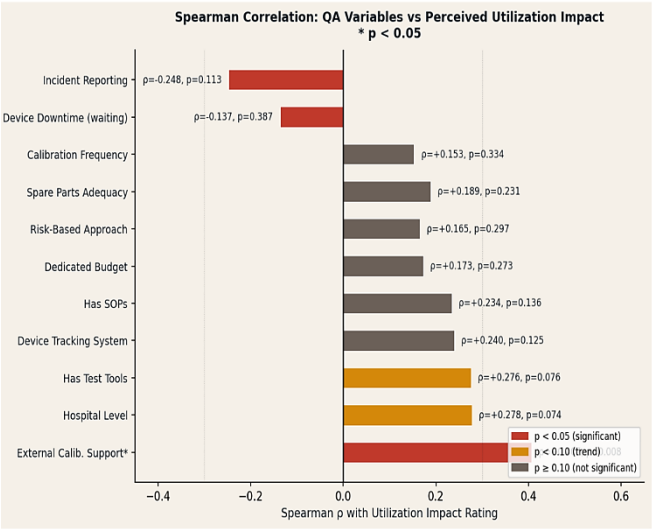


Figure 9: Spearman correlation on QA variables Vs perceived utilization impact.

The external calibration support was the highest significant correlation of utilization (rho = 0.407, p=0.008). Hospitals with in-house support perceived greater utilization impact than those relying on private outsourcing or receiving no support.

In addition, calibration budget was the strongest structural predictor of device downtime. Hospitals with a budget: 14.3% grounded more than 1 month. Hospitals without: 82.8% grounded more than 1 month. Chi-square = 14.342, df = 4, p=0.006

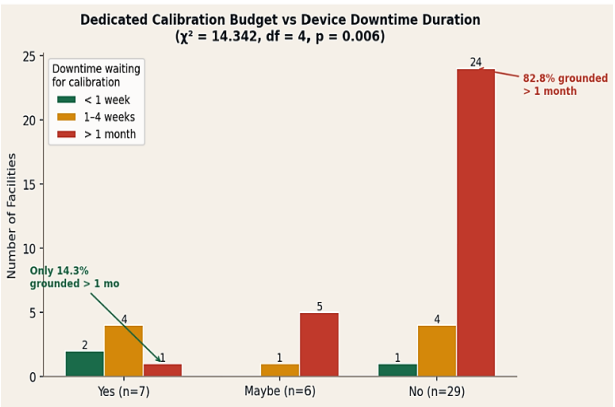
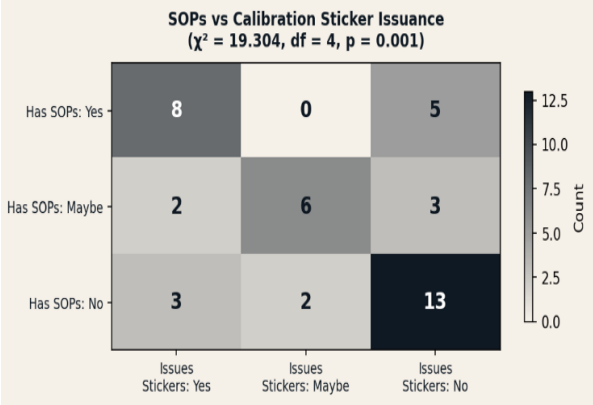


Figure 10: Budget vs medical device downtime duration

Furthermore, the presence of SOPs was strongly associated with calibration sticker issuance indicating that documented procedures drive observable compliance behaviours.



Lastly, the dual burden of inadequate spare parts (71.4%) and poorly documented donated medical equipment creates a compounding effect where hospitals cannot perform calibration even when willing, and cannot calibrate to appropriate standards without service manuals and test tools. Only 21.4% agree or strongly agreed that donated medical devices arrive with technical or service manuals.

Overall, the study hypothesis that medical equipment use in Ugandan hospitals is impacted by quality assurance and calibration procedures was rated as moderate. The direction of each link is consistent with the study hypothesis, even though only one predictor (external calibration support) met traditional significance standards at this sample size. The chi-square associations between the budget and downtime (p=0.0006) and SOPs and stickers (p=0.001) are strong. Strong respondent unanimity is shown in the mean utilisation impact rating of 3.74/5, with 42.9% choosing the highest grade.

The 'Uganda context'

The purpose of this section's open-ended, structured questions was to pinpoint the main issues and potential areas for development with medical equipment calibration and quality assurance procedures in Uganda's public hospitals. First, we investigated whether service manuals and calibration status stickers are included with donated medical equipment. While 28.6% of respondents disagreed that donated equipment lacked repair manuals, nearly 33% of respondents were unsure. Calibration stickers were not provided for any tested or calibrated medical devices, according to half of the respondents.

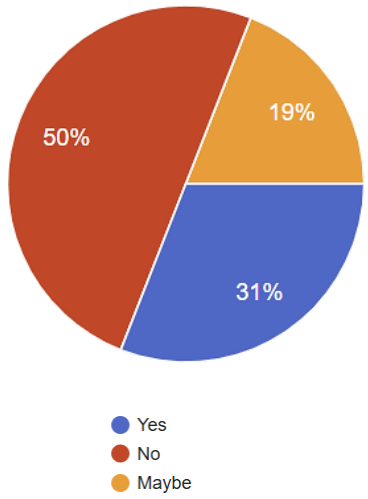


Figure 11: shows issuance of calibration stickers

Secondly, the respondents provided numerous challenges associated with calibration and quality assurance practices in public hospitals in Uganda. These included the following:

a) Limited or no funding at all for calibration services, especially when the medical device is required to be shipped outside or bring in a technical expert from oversea.

b) Limited or no test tools to verify the accuracy of medical devices to determine whether calibration is required.

c) Insufficient administrative support for technical capacity building and training on calibration and quality assurance practices.

d) Most medical devices are supplied without technical or service manuals for references on how to calibrate the model-specific medical device.

e) Unclear regulatory pathways and regulatory overlap among government agencies and technical working groups such as: National Drug Authority (NDA), Uganda National Bureau of Standards (UNBS), National Advisory Committee on Medical Devices (NACME).

f) No national reference accredited calibration laboratory, except for selected laboratory equipment like biosafety cabinets.

Lastly, the respondents pinpointed changes that could improve the medical device calibration and quality assurance practices in public hospitals in Uganda. These included: administrative support to trained specialised biomedical engineers on calibrations, adoption of computerize maintenance management systems (CMMS) that is comprehensive to the entire equipment lifecycle, procurement of test tools and dedicated budget line for calibration and quality assurance activities.

Discussions

This study explored medical device calibration and quality assurance best practices in Uganda's public hospitals. From the estimated total of 50 biomedical engineers and technicians in regional, national and specialized hospitals, we received responses from 42 personnel. This demonstrates the keen interest regarding the topic. Biomedical engineers formed the largest respondents also suggest a growing workforce and absorption into public hospitals. Initially, the role of medical device maintenance and management were held by technicians, many of whom were diploma holders with background in electrical or mechanical engineering.

Respondents greatly acknowledged the importance of medical device test tools with majority recognizing the different kinds of test tools and its application. The initial small number of respondents providing in-house calibration and quality assurance support to their respective hospitals could be attributed to a JICA project in collaboration with ministry of health, health infrastructure division (MoH-HID). The project was themed '*Improvement of health services through health infrastructure management (II): testing and calibration equipment/tools.*' In 2021, the project procured assorted medical device test tools and trained selected personnel in performance and safety testing of medical devices. Further study needs to evaluate the outcome of the project, especially in capacity building, training and instilling calibration and QA practices.

The highest number of respondents provided uninterruptable power supply for critical equipment demonstrating the importance in ensuring calibration accuracy. For instance, unstable power can reset calibration parameters in medical devices. Specifically, any power fluctuation during CT scanner QA and calibration can result into faulty reference data. Hence, making the equipment unreliable even after immediate QA and calibration. Thus, this leads to calibration inaccuracy and quality assurance protocols.

Interestingly, calibration activities and acceptance testing of donated equipment were mainly performed on-demand. This could be attributed to lack of test tools in many public hospitals, and untrained personnel. In addition, it also suggests that the biomedical engineers are extremely reluctant in performing calibration

and QA activities albeit availability of test tools. In principle, as a norm of best practices, medical devices must be tested for accuracy after every maintenance. However, this crucial practice is not yet adopted by many biomedical engineers at public hospital, which is consistent with the result observed in figure 6 under calibration and quality assurance frequency.

Subsequently, majority of the respondents had no SOPs and QA protocols in place. This exacerbates the reluctances from the biomedical engineers towards calibration and QA practices, especially those with the resources and tools. Limited or no SOPs is understandable in hospitals without any calibration resources and or support. However, this does not exempt developing a QA protocol for medical devices. These protocols may include: incoming medical device inspection, acceptance testing, inventory and documentation management, incident management, and among others.

Despite the limited effort to develop a comprehensive QA protocol for medical device covering its lifecycle, there is mushrooming interest in developing components like incident reporting tool. This was evident from the 81% score of respondents with medical device incident reporting system for malfunction and near misses in place. Perhaps, there is a growing effort that needs more refresher training, dedicated budget and resources to empower the biomedical engineers.

Besides calibration and QA best practices, this study subjectively examined medical device calibration status & QA activities to its utilization. Moreover 71.4% of the respondents indicated that medical devices remained grounded for more than 1 month as it waits calibration. Therefore, this simply means the medical device remains unavailable for use during that time, hence, directly affecting its utilization. Furthermore, respondents provided an average sentiment rating of 3.74 on a scale of 1 – 5; with 5 being the highest stars. The above average sentiment rating demonstrates that calibration & QA activities potentially affect medical device utilization. However, this study was limited in scope to further evaluate this hypothesis. This study simply pinpointed that there is likely relationship between calibration status and utilization of medical devices. Another study may be required to objectively provide insights rather than relying on subjective responses.

5. CONCLUSION

The study revealed that calibration and QA best practices are still in infancy with limited test tools available in public hospitals in Uganda. Additionally, majority of medical devices remains out of services for more than one month awaiting calibration. This was hindered by numerous challenges from administrative, technical and financial will. There is need for more emphasis to the biomedical engineers to test medical device after every maintenance, at incoming inspection and acceptance testing, especially for donated equipment. Moreover, the biomedical engineers need to start developing QA protocols for entire equipment lifecycle. This may require less finances compared to procurement of test tools. Lastly, the government through ministry of health needs to recruit more biomedical engineers to reduce the workload. Furthermore, provide specialty technical training for biomedical engineers other than recruitment of maintenance generalist.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest in relation to this work.

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