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Evaluation of the Medical Laboratory Equipment Standardization and Harmonization Program on Availability of Reagents and Controls at Council Hospitals

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Abstract: This study evaluated the effectiveness of the Medical Laboratory Equipment Standardization and Harmonization Program on the availability of reagents and controls at council hospitals in Arusha, Tanzania. Specifically, the study assessed the stakeholders' participation in the program based on their knowledge and accessibility of the program guidelines, the availability of standardized laboratory equipment at the council hospital laboratories also assessed changes in the availability of the reagents and controls for the standardized equipment at the council hospitals' laboratories. Purposive sampling and Simple random sampling were used to obtain the sample size for the study. The study randomly sampled 64 respondents from district hospitals where 5 District Medical Officers, 19 Laboratory Assistants, 3 Laboratory Scientists, 2 Medical Officer In charge, and 28 Laboratory Technologists were enrolled, also staff from the council health management team (CHMT) whereas 7 District Laboratory Technologist were also enrolled in the study. Quantitative data were collected using Questionnaire tools. Analysis of data was done using SPSS software to obtain descriptive information between different variables. Study findings revealed that there was inadequate knowledge among key stakeholders implementing the program as 51.5% Low; 43.75% moderate; and 4.6% High levels of knowledge. Stakeholder's accessibility to the program Guideline was 15.60%, Council Hospital Accessibility to Standardized Laboratory Equipment was 90.60%, Accessibility and Affordability of Laboratory Reagents and Controls was 79.70%, and thus an overall increase in the availability of Laboratory Reagents and Controls at the Council Hospitals was 65.60%. The study further revealed that the standardization program had a positive impact on the availability of reagents and control at Council hospitals as participants revealed an increase in the availability of reagents in their laboratories, but for more improvement of the program, it recommended that dissemination of the Standardization Guideline to all key stakeholders as well as engaging them in the implementation so as to improve ownership and efficiency of the program. The study also recommends to the government to make policies and regulations that are in line with the standardized program as well as ensure standardization program reaches all health facilities, including private and faith-based organizations with the aim of improving overall laboratory services across the country.

Keywords: Evaluation, Standardization and Harmonization, Laboratory Equipment, Analyzer and Reagents and Controls

1. Introduction

1.1. Background to the Research Problem

Laboratory testing is an integral part of modern medicine as it impacts patient management regarding screening, early diagnosis, prognosis, appropriate treatment, and monitoring. Assessing the quality of medical laboratories has become increasingly important not only for pressures to reduce costs but also for the evidence of testing-related diagnostic errors. It has been demonstrated that performance and outcome measures improve the quality of patient care. [10]

The standard of medical equipment directly affects the value of healthcare services in different areas from diagnosis to cure and post-cure. The resource challenge often forces the developing world to depend on the medical equipment donated by donor countries from developed or emerging economies. Although, the donation of equipment has

significantly helped developing countries to improve services in the healthcare sector, sometimes, usually quality issues come in and adversely affect the goal of the whole process. The quality assurance and maintenance of the standards are linked to the efficiency of the procurement procedures, which in public sector organizations, must check adherence to the applicable regulatory framework [17].

Laboratory equipment includes instruments or analyzers that are used in a laboratory to prepare samples, examine specimens, or conduct tests. These machines may vary in size and complexity. Examples are Hematology and Chemistry analyzers, centrifuges, microscopes, and CD4 machines. The equipment available in laboratories must match the test menu at the level of the health system. [14] Most laboratories are short of modern operational equipment and/or properly trained staff and a consistent reagent supply chain from suppliers, and many laboratories had insufficient physical facilities, among other key laboratory essentials needs. The outcomes of the assessment formed the basis for the evaluation of the national health laboratory policy guidelines and the introduction of the national laboratory operational plans in support of HIV/AIDS care and treatment to harmonize tests and standardize laboratory equipment at the different tiers of the laboratory facilities. [9].

Too high variability amongst health laboratory equipment and reagents in the health facilities complicates the procurement process and equipment repair and maintenance. Thus, recent efforts have been focusing on harmonization and standardization of the minimum amount of laboratory supplies, tests, and equipment that are needed at each tier of the laboratory system. In addition, awareness is growing of the requirement for national laboratory strategic plans to specify the lists of laboratory commodities and equipment to be used in each country. [7].

The study by Zomboko [7] shows that as much as 96% of medical laboratory equipment in Tanzania was donated and about 40% of medical equipment was out of service. These facts have clear repercussions for health outcomes in these countries with the patients suffering from lack of correct diagnostic or satisfactory treatment. Large amounts of unused donated equipment in storage put a marked strain on facilities' funds. The medical system in Tanzania too, relies heavily on the equipment which are acquired via donated projects from partners. These equipment are usually used second-hand but are technically suitable for the intended purpose. [17]

Improving the national health laboratory networks in Tanzania is critical to attaining the United Nations Millennium Development Goals. Despite strong commitment from the international community to fight major infectious diseases, weak laboratory infrastructure remains a huge rate-limiting step. Some major challenges facing laboratory systems in resource-poor settings include dilapidated infrastructure; lack of human capacity, laboratory policies, and strategic plans; and limited synergies between clinical and research laboratories. Together, these factors compromise the quality of test results and impact patient management. With increased funding, the target of laboratory strengthening efforts in resource-poor countries should be the integration of laboratory services across major diseases to leverage resources with respect to physical infrastructure; types of assays; supply chain management of reagents and equipment; and maintenance of equipment [1].

Key points of discussion during the consideration of the integrated laboratory strategy should consider the following: (1) the physical infrastructure needed at each level for the laboratory to provide a safe and efficient work environment in which the physical space matches the equipment needed for laboratory assays, (2) the assays to be performed and the required throughput, (3) the supply chain of equipment and reagents to prevent stock depletion, and (4) the provision of routine equipment maintenance. Key to this opportunity is defining the expected assay throughput and matching the instrument specifications to the number of assays to be performed. This aspect is often overlooked, with other issues becoming the key areas of discussion. [1].

Budgetary implications like high costs are involved in procuring and operating equipment; therefore, the process of selecting equipment must be comprehensive, consultative, and transparent. Equipment is often procured by donor agencies and implementing partners; however, the machine will generally outlive funding cycles, and the operational cost of running equipment (e g. maintenance, servicing, etc.) will be borne by the host Ministry of Health (MOH). Therefore, donors and partners and the MOH should work together to ensure the commitment of all parties to supporting the established equipment standards. [16] The research, Efficiency of health laboratories in delivery of HIV laboratory and supportive services in the few Tanzania districts, showed that Investigative and supporting services for HIV were provided in most of the health Centers and hospitals while few dispensaries were offering the services. Because of challenges such as shortage of staff, service of equipment, and participation in Quality Assurance programs, the NHLS should be improved so as to ensure enough human resources, implementation of Quality Assurance, and sustainable preventive and repair maintenance services of equipment. [6]

Despite that there was a well-established national health laboratory system (NHLS) in place, coordination of HIV laboratory services was found to be weak. Forty-six respondents were interviewed. In most laboratories, guidelines for HIV diagnosis were available but healthcare providers were not aware of their availability. Utilization of the guidelines for HIV diagnosis was higher at the national level than at the lower levels. The low level of awareness and utilization of guidelines was associated with inadequate training and supervision. There was a shortage of human resources, mostly affecting the primary healthcare level of the system and this was associated with inequity in employment and training opportunities. Laboratories in public health facilities were better staffed and had more qualified personnel than private-owned laboratories. [6]

The unsatisfactory laboratory services, the multitude of partners, and the demand for a functional, consistent

responsive service by the HIV / AIDS care and treatment program required a review of the national health laboratory standard guidelines to harmonize tests, provide direction on equipment placement to avoid a multitude of diverse equipment and to ensure equitable distribution of laboratory personnel and services and conformity to the National Guidelines for the HIV/AIDS Care and Treatment of in Tanzania which determine the tests and frequency of orders for diagnosis, staging, and follow-up of patients on care and treatment. [9]

From the findings of the studies discussed above the problem of availability of reagents and controls for laboratory equipment seems to be correlated to several factors such as the lack of modern and standardized laboratory equipment stated by Massambu and Mwangi, [9], a large amount of unused donated equipment stated by Zomboko, [17] as well as untimely equipment maintenance services stated by Ishengoma, [2], Thus this study will assess the standardization and harmonization program of equipment used in laboratories which will reduce the vast amount of equipment available in our country (harmonization) as well as provide procurement guideline of the quality/standard of equipment required (standardization) at each laboratory tier/level.

Arusha Region is one of the regions with a high population in Tanzania, due to that council hospitals serve a large population that requires quality laboratory services. Thus, the study will be able to reach different population settings, from highly populated Arusha City, Meru, and Arusha DC center to less populated Councils such as Ngorongoro, Longido, Karatu, and Monduli District Councils.

1.2. Statement of the Problem

The study intends to assess the effectiveness of the Standardization and Harmonization program for Laboratory equipment at Council hospitals, in increasing availability of reagents and controls. Most laboratories at council hospitals have different types, sizes, capacities, and qualities of laboratory equipment which makes it hard for the National Medical Store Department to supply reagents and controls for testing. This usually results in inconsistent availability of laboratory reagents at council hospitals and thus leads to the absence of testing services during stockout times. Since the Standardization and Harmonization program is new to Tanzania settings, the guideline was developed in 2018 and implementation had then begun by distributing standardized equipment to different key stakeholders.

According to Massambu and Mwangi, [9] laboratories do not have modern operational equipment and/or properly trained personnel and a consistent reagent supply chain, and also many laboratories lacked physical facilities, among other important laboratory elements. Also, according to Zomboko [17], 96% of medical equipment in Tanzania is donated and about 40% of medical equipment is out of service. Thus, procurement of reagents and controls becomes a very challenging task for health facilities, leading to poor availability of Laboratory Reagents and Controls to operate the available equipment.

This study will fill the knowledge gap concerning how effective the standardization program has been towards improving reagents availability at councils' hospital laboratories as well as other issues affecting the implantation of the program.

1.3. Objectives of the Study

1.3.1. General Objective

The general objective of the study was to evaluate the effectiveness of laboratory equipment standardization and harmonization program in ensuring the availability of reagents and controls at Arusha council hospital laboratories.

1.3.2. Specific Objectives

1. To assess stakeholders' participation in the program based on their knowledge and accessibility of the standardization and harmonization guidelines.
2. To assess the availability of standardized and harmonized laboratory equipment at the council hospital laboratories.
3. To assess changes in the availability of the reagents and controls of the standardized equipment at the council hospitals' laboratories.

1.3.3. Research Questions

1. Do stakeholders participate in the program based on their knowledge concerning the program?
2. Are standardized and harmonized laboratory equipment available at Arusha district council hospital laboratories?
3. Are there changes in the availability of the reagents and controls of the standardized equipment at the Arusha council hospitals' laboratories?

1.4. Significance of the Study

The findings of the study are expected to fill the gap of knowledge by assessing the effectiveness and success of the Laboratory Equipment Standardization and Harmonization program as well as specifically assess the knowledge and understanding of key laboratory stakeholders towards the program. District Hospitals in Tanzania are the first-hand referral point for different challenging disease cases from primary health facilities (Health Centre and Dispensaries), thus a well-established laboratory testing system is most needed in such hospitals so as to properly diagnose and treat different disease conditions.

The findings from District Hospitals Laboratories will show the achievements of the program as well as provide lessons learned from the challenges observed during its implementation and thus provide recommendations for future improvement. The study will be informative to stakeholders at all levels from facilities up to the ministry level in Tanzania on their efforts to improve laboratory diagnosis services, the medical store department as well as private organizations which work hand in hand with the government. Standardization will also contribute to the global efforts

which are the Sustainable development goals whereas the third goal elaborates on Good Health and Well-being, thus ensuring the proper provision of health services including diagnostics services is very key.

2. Literature Review

2.1. Standardization Theory

Standardization can be defined as the act of setting standard requirements for different factors concerning a given subject. Standards can be established for the product, methods, process, raw material, time, or working environment. It uses standard equipment, methods, and processes in order to maximize the output keeping in mind the quality standards. [13]

While Harmonization is defined as "a process of coordinating host country governments and stakeholders in the procurement and placement of laboratory products within a defined tiered laboratory network" [16]

Several types of equipment, with varying levels of complexity, will be relevant during the standardization process. Basic lab equipment such as water baths, timers, and centrifuges do not usually pose a big problem because they do not require (a) extensive training for proper use, (b) specialized reagents, (c) consumables to operate, or (d) significant service and maintenance. The more complex analyzers are typically the main focus of the standardization exercise: They pose a number of special considerations because they are expected to produce very accurate results that are critical to patient management; they also require regular service and maintenance to keep them functioning at a scientifically acceptable level and to produce clinically useful information. The support needed to keep the equipment functional after it has been purchased is one very critical consideration. The provision of reagents, calibration, and quality control (QC) materials is another important factor that should be weighed carefully when selecting appropriate equipment. [14]

The final selection of complex analyzers will be brand-specific because each brand of equipment usually has unique or brand-specific reagents and other commodities (as they are often closed systems) that must be used with that equipment. Therefore, it is extremely important that all rationale and discussions that lead to the decision are well-documented. The development of a transparent and accountable process for selecting equipment and documenting that process will ensure that all stakeholders can have confidence that the process is equitable and leads to the best possible outcome for the laboratory services in the country. Laboratory personnel, biomedical engineers, equipment technicians, and procurement experts should work closely to ensure the selection of the most suitable equipment. [14]

Standardization is an essential intervention; it is a prerequisite to designing, implementing, and strengthening laboratory logistics systems. Standardization streamlines and reduces the range of commodities that must be procured and distributed from a central place, thereby increasing the effectiveness of the system to deliver the high-quality commodities needed to provide testing services. However, the benefits of standardization reach far beyond just reducing the complexity of the supply chain; standardization yields benefit for the overall management of laboratory services across the country and for the programmatic and clinical aspects of laboratory services. Standardization almost always leads to improvements in both efficiency and effectiveness, because it is the basis for developing standard procedures and processes for operating the overall program or system. [14]

2.2. Empirical Review of Literature

2.2.1. Supply of Laboratory Commodities (Reagents and Controls)

Public medical laboratories often form a tiered network of testing facilities operating under common principles and procedures with a rational distribution of testing capacity. The networks may include government-run and private units that are commonly integrated with hospitals and clinics. Typical networks consist of 3 to 5 levels or tiers, depending on whether testing is conducted in health center facilities and whether the network includes reference laboratories. Laboratory networks require a degree of central management and direction setting through national laboratory policies and regulatory oversight and coordination of operational functions such as procurement, quality assurance, and logistics to ensure more efficient operation and collective benefits across all laboratories. The establishment of policies and guidelines on the standardization of test menus, service delivery, and technology across the network promotes more efficient and cost-effective operation and management of the network, and the policies and guidelines are implemented through strategic and operational plans for laboratory strengthening that define the priorities, timelines, and resources needed. The first step toward standardization in laboratory networks is the establishment of common test menus within each level of the healthcare hierarchy. These menus should be harmonized between different levels and based on the minimum package of healthcare services, and tests required locally. [4]

For health laboratory commodities, a full supply and a non-full supply are not always as straightforward as with the other health commodities. Laboratory supply chains manage a lot (if not standardized) of commodities, are generally underfunded, development partners are not generally coordinated in their supporting activities, and thus sometimes they don't meet all commodity requirements. While everyone strives for a situation where commodities are in full supply, unlike other products (eg. ARVs, contraceptives), laboratory commodities as a special group are not presently in full supply. However, in some instances, some laboratory commodities are in full supply (eg. CD4 reagents or HIV rapid tests) because they are supported by a particular specific donor or program. Moreover, it may be true that a health facility, such as an institutional hospital, may have enough funds to have all laboratory commodities in full

supply. The full supply of some commodities and no other significant implications where multiple commodities have to be available simultaneously in order to perform a particular test. If only one commodity is missing, it may hinder the performance of certain tests. Lastly, full supply and non-full supply are changing categories for laboratories, meaning that commodities might be available in full supply for a year and disappear in the next one, and therefore systems must be stable enough to accommodate the changing environment. [14]

2.2.2. Laboratory Management Information System (LMIS)

LMIS is a system that helps personnel involved in the management of health commodities in the timely documentation, collection, and management of the information necessary to support sound and objective decision-making in managing the supply chain of the commodities, so as to ensure an uninterrupted supply of commodities and to identify any problems in the supply pipeline. It provides the data required to maintain an inventory control system, such as quantity at hand at the service delivery point, quantity received and quantity used within a reporting period, number of people that were served per the period, and the quantity of the commodity required to bring it to the accepted level (maximum level) per time in the reporting period. To achieve this, forms and documentation are used to move items from one point to another within the health facility and to other facilities, track usage, maintain records, and produce reports on the logistics system. The data collected through LMIS helps the facility to determine if the stock available at the facility is enough to serve its patients or whether to make an emergency order to the supplying facility or not before the order interval when there will be a comparison of stocks available to established maximum stock level and order the quantity needed to bring stock levels to maximum. [13]

The Supply Chain Management System (SCMS), which is the higher level in the supply chain, uses the LMIS data to track consumption in the facilities to identify whether there is overstock of commodities and therefore redistribute them to prevent wastages, identify exceptionally high levels of product expiry and then initiate action to prevent this situation from recurring or determine the quantity to issue to the facility to bring it up to established maximum stock or under stock and therefore redistribute from neighboring health facilities. The data is also used for the determination of national-level consumption and for planning, budgeting, and quantification for the procurement of commodities. A failure in any of the levels of the system could result in a stockout of health commodities and therefore inability to attend to patients who visit such facilities for their healthcare needs. [13]

2.2.3. Equipment Ownership

Equipment ownership is an important consideration and standardization provides an opportune time to implement the appropriate ownership strategy. There are three different types of ownership to consider:

1. Purchase
2. Lease/Placement
3. Reagent Bundle
4. Reagent Rental

The recommended type of ownership for laboratory analyzer equipment is reagent rental. This is for a number of reasons including minimum initial capital expenditure; less dependence on resource-constrained biomedical engineers and technicians; minimized risk of being caught with outdated technologies; improved quality of service and support from the supplier. It should be clearly stated in the tender specification that all-in costs are provided, these include insurance, controls, calibrators, and any other expenses that may be encountered.

In Tanzania, the majority of analyzer equipment has been purchased. Therefore, it is recommended that reagent bundle service contracts are negotiated. This will assist in ensuring planned equipment maintenance and limit reagent stock-outs. It is recommended that most ancillary equipment is purchased, and suppliers will typically only offer this option. It is important to also include, where relevant, a maintenance service plan when purchasing ancillary equipment. Consideration should be put on using local biomedical engineers for servicing ancillary equipment. Therefore, equipment installation and on-site training should be included in the tendering process; and local biomedical engineers should be involved during installation and on-site training. [12]

Another equipment ownership mode that has been adopted by most district and regional hospitals is equipment placement. Equipment placement is an equipment ownership mode where the vendor owns the equipment and is responsible for maintenance of it, rather than equipment procurement where the purchaser owns the equipment and is directly responsible for its maintenance and repair, thus should be preferred for, especially for very expensive, highly sophisticated equipment. This method of procurement has advantages since it does not require an initial investment, has a lower price per test, is easy to adapt to technology, and has equipment management to be handled by the supplier, which includes maintenance of the equipment. With the testing of many samples and the fact that this option is packed together with reagent procurement, this scheme would be adventurous to most health facilities. [9]

2.3. Research Gap

Few researchers have studied laboratory equipment standardization and harmonization, especially in Tanzania, Massambu and Mwangi, [9] foreshadowed the Tanzania experience in Clinical Laboratory Testing Harmonization and Equipment Standardization at Different Levels of a Tiered Health Laboratory System where they addressed problems such as vast donated equipment and reagents procurement challenge thus suggested harmonization of tests conducted in the laboratory and standardizing equipment laboratory at different tiers of the laboratory system.

Thus, the study furthermore evaluated the current program

in areas such as the knowledge of key laboratory stakeholders, the availability of standardized and harmonized equipment as well as the accessibility of the reagent and controls after the standardization program.

2.4. Conceptual Framework

The study is conceptualized within the context of the Laboratory Commodities Supply Chain where the Laboratory Equipment standardization and harmonization program will reduce the vast number of machines available in the country, so as to enable smooth procurement and supply of reagents and controls to district health facilities.

The conceptual framework is theorized as a model identifying the concept under evaluation and the associations between the dependent variable and the independent variables of the study. According to Kothari [8], a research variable is an idea, which can take on qualities of quantitative or quantitative values. Thus, this presentation of the variables and ideas will direct the researcher in this research so that to aggregate data/evidence for addressing the study objectives. This conceptual framework explains the relationship and interrelationship between the variables in the study to be evaluated (these are independent variables) and also explains how the independent variables cause affect to the dependent variable.

2.4.1. Dependent Variable

A dependent variable is a variable that is the result of the program, the one that is being assessed as an outcome of the study. The independent variables, also known as the effector or predictor variables, are factors that show differences in the dependent variable. In this study Dependent variable was the Availability of Reagents and Controls at health facilities, which is influenced by different factors that were accessed as the independent variable.

2.4.2. Independent Variable

From this study, several independent variables were accessed such as Demographic characteristics of participants such as participant working Position, Facility, and their respective District.

Variables such as the Availability of standardized Equipment whereby a cross-section survey was conducted to determine if district hospitals have received the standardized equipment.

Stakeholders' sensitization (knowledge) to the program whereby the general understanding of the program was measured as well as their accessibility to the standardization guidelines.

Availability of Reagents and control at the Council Hospitals was assessed compared to previous availability before implementation of the program.

3. Research Methodology

3.1. Study Area

The study was carried out in the Arusha region in Tanzania, whereby the region has a total of Seven councils with Seven council Hospitals and other private hospitals with similar capacities. In total, the region has 313 dispensaries, 60 health centers, and 19 hospitals. The region also has about 407 Laboratory health workers from both private and Government health facilities, 118 (29%) working at government laboratories while 289 (71%) are laboratory health workers working at private health facilities.

The study was conducted in the Arusha Region which is one of the regions with a high population in Tanzania, and thus most Council hospitals serve a large population that also require quality laboratory services. Thus, the study will be able to reach different population settings, from highly populated Arusha City, Meru DC, and Arusha DC center to less populated Councils such as Ngorongoro DC, Longido DC, Karatu DC, and Monduli DC.

3.2. Study Design

The study design employed in this study was cross-sectional research design whereas adequate and enough amount of data will be collected from the study participant. The study design allowed study variables to be assessed at a single point in time and is one of the well suitable designs for descriptive studies Also, according to Kothari [8] a good design will ensure that the information collected is consistent with the study objectives, and data are collected and analyzed by accurate and economical procedures of research. The study design was also appropriate due to the fact that it is quick, cost-effective, and can better show relationships between the variables of the study. [8]

3.3. Research Philosophy

A research philosophy is a belief about the way in which data about a phenomenon should be gathered, analyzed, and used. The term epistemology (what is known to be true) as opposed to doxology (what is believed to be true) encompasses the various philosophies of research approach. The purpose of science, then, is the process of transforming things believed into things known: doxa to episteme. Two major research philosophies have been identified in the Western tradition of science, namely positivist (sometimes called scientific) and interpretivism (also known as ant-positivist). [3]

The study data was collected from study respondents at council hospital laboratories as primary data from the source and analyzed to obtain the required information. Response from the study participant was representative as it was considered as a situation for other regions and councils across the country.

3.4. Study Population

The study involved several stakeholders across Arusha Region, which were District Medical Officers, District Laboratory Technologists, and Laboratory health workers from all seven District Hospitals. The study also involved administrative members from the council medical officer as

they are important in the implementation of the program. As stated in the SMLEG [12] governance structures are a critical aspect of standardization, and it is important that all relevant stakeholders are included in the appropriate structures. These stakeholders include clinical experts, development partners (DPs), implementing partners (IPs), procurement and legislative bodies.

3.5. Sampling Framework

3.5.1. Sampling

The general rule for the appropriate selection of the sample is that its findings are able to reflect almost similar characteristics that are obtained in case the whole universe is surveyed. According to Kothari, [8] the sample size of the study should not be extremely large or too small to represent the population under study. The sample size was drawn from a study population.

3.5.2. Purposive Sampling Method (Non-Probability Sampling)

Purposive sampling was considered desirable when the universe happens to be small and a known characteristic of it is to be studied intensively. Also, there were conditions under which sample designs other than random sampling may be considered better for reasons like convenience and low costs. The sample design to be used must be decided by the researcher taking into consideration the nature of the inquiry and other related factors. [8]

Deliberate sampling is also known as purposive or non-probability sampling. This sampling method involves the purposive or deliberate selection of particular units of the universe for constituting a sample that represents the universe. When population elements are selected for inclusion in the sample based on ease of access, it can be called convenience sampling. [8] A purposive approach is well compatible with small-scale studies as well as in-depth studies.

The study deliberately used a non-probability sampling method because the Standardization and Harmonization program is rather a new intervention and have not yet been implemented at all levels of Health facilities as the program rollout still continues to lower health facilities such as the Health Centre and Dispensaries across the country. Thus, council hospitals were deliberately sampled to represent the rest of the health facilities as they have already been supplied and trained on how to operate the standardized equipment. Councils and Regional referral hospitals were among the first health facilities to start implementing the standardization program in their settings.

3.5.3. Sampling Unit

The general rule for suitable selection of the sample is that its findings are able to reproduce almost similar characteristics that are obtained in case the whole universe is studied. According to Kothari, [8] The sampling unit will be drawn from a study population of Laboratory stakeholders from Districts Hospitals and CHMT officials across the Arusha Region. Stakeholders consulted will include CHMTs and Laboratory Personnel from District Hospitals.

Harmonization and standardization proposed substantial reductions in instrument diversity, ranging from a 17% reduction in Country Diversities in existing CD4 instruments to a high of 88% for the Country Health facility's chemistry testing instruments. As mentioned, and demonstrated chemistry and hematology account for the most diagnostic instrument diversity, hence have the largest potential for instrument reduction. [17]

Thus, this study focused on assessing the effectiveness of the Standardization and harmonization program on the availability of Chemistry and Hematology reagents and controls at council Hospital laboratories.

3.5.4. Sample Size

The sample size is a representative subgroup of the population understudy you are interested in from the total population. The most preferred sample size is one which attains the experience, representative, dependability, and flexibility requirements. Purposive judgmental sampling was preferred to select participants who have enough information about the phenomenon under study [17]

Council hospitals were purposively sampled to be enrolled in the study. As all the council hospitals in the Arusha region were involved in the study as well as their respective Council Laboratory Technologist and Council Medical Officers.

Participants were selected by random sampling methods where a total around 636 of key laboratory stakeholders in the Arusha Region was sampled. According to Kothari [8], a sample size of about 10 percent of a population under study can often give reliable representative data. Thus, taking 10% of 636 which was the population understudy, the sample size included a total of 64 respondents.

3.6. Data Collection Methods

Since the study design used a cross-sectional study design and collected quantitative data from the population, the study used the Interview method to get data from respondents. Structured Quantitative Questionnaire tools were deployed in data collection and analysis, this method falls under the category of quantitative research, also known as closed questionnaire they are positivist research methods. In such questionnaires, there is a low level of involvement of the person who is conducting the questionnaire and a high level of involvement of the person who is answering the questionnaire. A structured questionnaire, on the other hand, is one in which the questions asked are precisely decided in advance. When used as an interviewing method, the questions are asked exactly as they are written, in the same sequence, using the same style, for all interviews. Nonetheless, the structured questionnaire can sometimes be left a bit open for the interviewer to amend to suit a specific context.

The questions were designed for literate respondents; therefore, English and Swahili language were used. The researcher used this method because it has several merits such as less cost and expenditure, the possibility of covering

a large area, greater reliability and validity of information, and free from external influence, enabling the study to collect and analyze applicable information according to the study objectives and uniformity from one measurement to another. Also, the researcher used open-ended questions to key informants where respondents had the flexibility to provide answers.

3.7. Data Processing and Analysis

Computers are ideally suited for data analysis concerning large research projects. Researchers are essentially concerned with the huge storage of data, their faster retrieval when required, and the processing of data with the aid of various techniques. In all these operations, computers are of great help. Their use, apart from expediting the research work, has reduced human drudgery and added to the quality of research activity. [8]

Data analysis refers to the computation of certain measures along with searching for patterns of relationship that exist among data groups. Data collected were revised, coded, and sorted by the as to ensure accuracy, precision, and completeness.

Quantitative data analysis methods were used to analyze the data in the study. This was to collect, model, and transform collected data in order to show the important information, show conclusions, and support decision-making in the study. Thus, Quantitative data collected from study participants were summarized, cleaned, coded, sorted, and then analyzed using the IBM SPSS Statistics Data Analysis tool. Descriptive analysis was conducted to obtain tables, graphs, and analysis chats for results interpretation.

4. Results and Discussion

4.1. Effectiveness of the S&H Program on the Availability of Reagents and Controls at DH Laboratories

The profits of standardization include better prioritization of resources in the laboratory settings for capacity development and more effective supply chain management through bulk price reductions for reagents, controls, and instrument repair. Procurement protocols, including specification, prequalification, and contract conciliation, need to go together with the standardization guidelines for maximum profit. Standardization guidelines should be followed irrespective of whether procurement of laboratory commodities is centralized or decentralized or whether is done by national institutions or development partners. [4]

The study intended to assess the effectiveness of the S&H program on the availability of Reagents at Council Hospitals, thus through the Laboratory program, all district hospitals that had received standardized equipment were able to acquire reagents and controls from the Medical Store Department. Study respondents from the visited Laboratories and other stakeholders from Council's offices were interviewed to assess the effectiveness of the program and elaborate on whether there has been a stable availability of Laboratory reagents and controls.

Thus, from the study, it was observed that 65.60% (42) of respondents from district hospitals reported having an overall increase in the availability of Reagents and Controls. While 34% of respondents from district hospitals reported no increase in the availability of the Reagents and Controls was observed compared to previous unstandardized laboratory equipment.

Table 1. *A Table showing the Percentage Increase in Availability of Reagents and Controls at District Hospitals Laboratories.*

		Increase in_Availability_of Chemistry and Hematology_Reagents and Controls		
		Yes	**No**	**Total**
Councils	Arusha Cc	7	0	7
	Arusha Dc	9	0	9
	Karatu	1	9	10
	Longido	1	7	8
	Meru	13	0	13
	Monduli	11	0	11
	Ngorongoro	0	6	6
		42	22	64
TOTAL		100.0%	100.0%	100.0%
		65.6%	34.4%	100.0%

The foregoing research findings showed that the majority of respondents had experienced an increase in the availability of Reagents and Controls in their Hospital Laboratories after receiving standardized laboratory equipment. Reagent and Controls availability at these hospitals was not 100% as needed to ensure the provision of diagnostic services to clients.

Meru and Monduli District Councils reported the highest increase in the availability of Reagents and Controls as respondents reported, while Arusha City and Arusha District Council had an average increase of reagents and controls, lastly, Ngorongoro did not report any changes in reagents and controls availability because it did not receive the standardized equipment.

Through having standardized equipment, the District Hospitals laboratory in the Arusha region experienced an improvement in the availability of reagents as shown in Table 1. and thus, laboratories have been able to ensure uninterrupted provision of laboratory services.

4.2. Knowledge of Stakeholders Concerning the Laboratory Equipment S&H program

From the study, it was observed that 51.5% (33) had low knowledge concerning the program, 43.8% (28) had average knowledge and only 4.6% (3) had high knowledge concerning the program. The low knowledge concerning the S&H program contributed to the overall low performance of the program, as stakeholders especially the implementors at facilities did not have enough understanding of the program. Thus, it is a special chance to address a wider variety of laboratory training requirements. Basically, addressing the absolute number of laboratory personnel without dealing with career development and continued education opportunities will not result in the development of a stable professionalism of key personnel. Moreover, ensuring that skilled laboratory staff has access to up-to-date, well-

functioning laboratory equipment is vital. [1]

Stakeholders' knowledge concerning any program directly affects its implementation, thus standardization of laboratory equipment programs would have been more effective if all key stakeholders would understand and played their parts during implementation. All key stakeholders from health care workers (laboratory and clinicians), Medical officer-in-charge, Council, Regional and National authorities; Facility level ensure business operation of the equipment, where they ensure that profit is generated during the use of the equipment.

Table 2. *Showing Participant Knowledge Levels Concerning Laboratory Standardization and Harmonization Program.*

District * Knowledge Cross tabulation				
Councils	**Knowledge**			**Total**
	HIGH	**AVERAGE**	**LOW**	
Arusha Cc	0	4	3	7
Arusha Dc	1	3	5	9
Karatu	0	6	4	10
Longido	2	2	4	8
Meru	0	6	7	13
Monduli	0	3	8	11
Ngorongoro	0	4	2	6
Total (%)	3 (4.6%)	28 (43.8%)	33 (51.6%)	64

Data showed respondents from Arusha DC and Longido had High knowledge concerning the Standardization and Harmonization program, this is because the council officials were involved during different stages of planning and designing of the program. Otherwise, the majority of stakeholders have very low knowledge concerning laboratory standardization and harmonization program.

4.3. Stakeholders' Access to the S&H Guideline

The lack of adequately trained personnel is often the most significant rate-limiting step in providing quality laboratory services and clinical services in resource-limited settings. [8] Given that 84% of key stakeholders interviewed had never had access to the S&H guideline, it also signifies that stakeholders have never had training concerning the guideline implementation.

In order to accommodate principles and requirements for standardization, laboratory policies should be updated. Thus, these policies should be broadly followed by all laboratories. For laboratory networks to profit from the principles of standardization, policies are needed to direct test distribution, technology differences, and procurement. However, laboratory standardization policies and prequalification procedures do not always exist or may need to be updated. [5] From the study respondent, it was observed that only 15.6% (10) had access to the guideline of laboratory standardization and harmonization while 84.4 % (54) had never had access to the guideline neither hardcopy nor electronic (Softcopy).

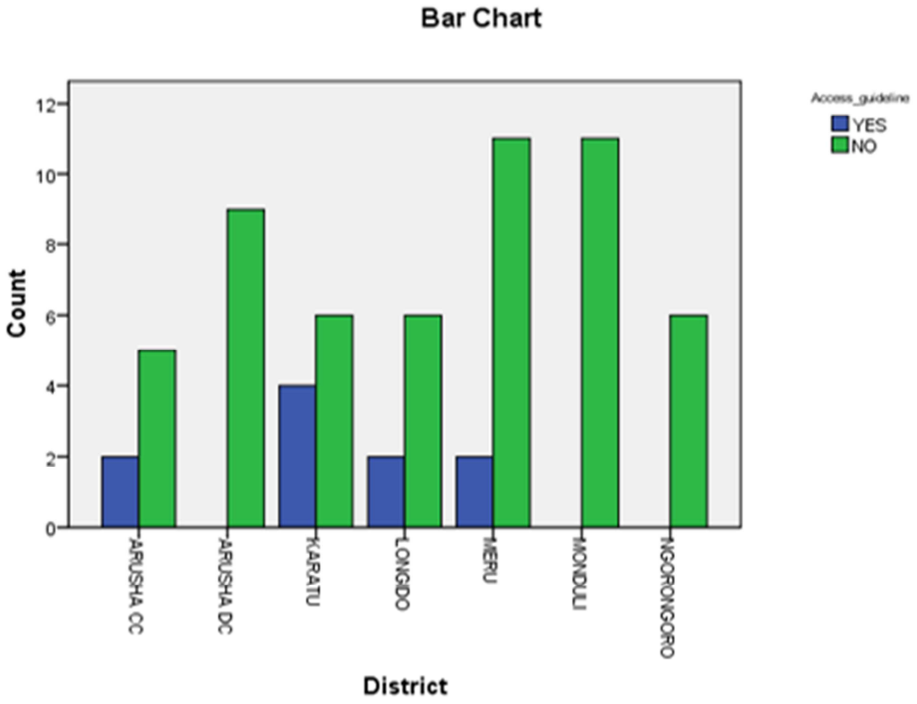

Figure 1. *A Bar Graph showing Stakeholders' Access to S&H Guideline from all Seven Arusha Districts.*

As observed that most of the key stakeholders did not have access to the S&H Guideline which also contributes to low knowledge concerning the program itself, as stated by Justman et al [7] in resource-limited countries such as Tanzania we can't depend on online dissemination of documents thus, we must conduct training and print hard copies for easy accessibility by all stakeholders and having a common understanding.

The study revealed that only a few respondents from Arusha CC, Karatu DC, Meru DC, and Longido DC had access to the guideline of Lab. Standardization and Harmonization program. Otherwise, the majority of the respondent did not have access to the guideline. (Neither hardcopy nor softcopy). For effective

implementation of the S&H program, MoH must ensure the availability of the guideline across all responsible stakeholders.

4.4. Accessibility of Standardized Equipment at Council Hospitals

The standardization and Harmonization program of laboratory equipment introduced a mode to acquire a piece of equipment which is the Equipment placement model, where the facility receives equipment without any initial payment, then the facility will procure reagents and controls from the same supplier (MSD) with small additional payments to cover for the equipment price. Thus, it was expected that all district hospitals have access to standardized laboratory equipment and the availability of equipment to be 100%.

From the study respondent, it was observed that 90.60% (58) of the respondent from district hospitals reported having received standardized medical laboratory equipment. Thus, most of the district hospitals had standardized equipment. While 9.4% (6) of the study respondent from the district hospital reported having not received the standardized medical laboratory equipment, this was observed at Wasso Council Designated Hospital (Ngorongoro DC) which is not owned by the government.

Table 3. *A Table Showing Percentage of District Hospitals that received standardized Laboratory Equipment.*

		Access to Hematology and Chemistry Equipment		
		YES	**NO**	**Total**
	Arusha Cc	7	0	7
	Arusha Dc	9	0	9
	Karatu	10	0	10
Councils	Longido	8	0	8
	Meru	13	0	13
	Monduli	11	0	11
	Ngorongoro	0	6	6
		58	6	64
TOTAL		100.0%	100.0%	100.0%
		90.6%	9.4%	100.0%

Note: Wasso District Designated Hospital being a Faith Based Organization has not been part of the current Standardization Program in Tanzania, thus it is one of the areas which can be improved for future implementation of the program.

4.5. Accessibility of Standardized Equipment Reagents and Controls

According to Tanzania regulations, all government-owned health facilities should procure health commodities from the Medical Store Department (MSD). Thus, it is expected that reagents and controls for the standardized equipment to be available and accessible so that facilities can able to acquire them. From the study respondent, it was observed that 79.7% (51) had access to the reagents and controls from MSD while 20.3% (13) did not have access to the reagents and controls.

The advantage of standardization has included reduced service contracts by using economies of scale, and procurement prices for equipment, and reagents hence, maintainable cost-effective laboratory services and implementable quality assurance and inter-comparability of laboratory results between laboratories. It has been best to also standardize training modules for equipment installation, and also training of standard operational procedures. [9]

The S&H program in Tanzania has adopted the best means of equipment ownership model which is Equipment Placement, whereby the facility does not require any initial cost to acquire equipment, and instead, the procurement cost will be added gradually to the Reagents and Controls costs.

Table 4. *A Table showing the Percentage Increase in Accessibility of Reagents and Controls for the Standardized Equipment.*

Percentage Accessibility of Haematology and Chemistry Reagents & Controls for the Standardized Equipment from MSD.				
		Accessibility of Haematology and Chemistry_Reagents_& Controls		
		YES	**NO**	**Total**
	Arusha Cc	7	0	7
	Arusha Dc	9	0	9
	Karatu	10	0	10
Council	Longido	1	7	8
	Meru	13	0	13
	Monduli	11	0	11
	Ngorongoro	0	6	6
		51	13	64
TOTAL		100.0%	100.0%	100.0%
		79.7%	20.3%	100.0%

Increased accessibility of the Hematology and Clinical Chemistry reagents and controls from MSD was contributed by many factors, one of them being MSD having the ability to stock a large consignment of the same equipment reagents and controls. Another factor is the direct transportation of controls from manufacturers direct to the laboratories by their

own vendors has greatly improved its easy accessibility across district hospitals.

4.6. Effect of the Program on the Affordability of Reagents and Controls

From the study respondent, it was observed that 79.7% (51) reported that prices of reagents and controls from MSD were obtained at reasonable and affordable prices. While 23.3% (13) stated that the prices for Reagents and controls from MSD were not affordable for the hospitals to procure and operate with profit for the sustainability of laboratory services.

Table 5. *A Table Showing Percentage of Affordability of Reagents and Controls for the Standardized Equipment.*

		Affordability Haematology and Chemistry_Reagents_& Controls		
		YES	**NO**	**Total**
Councils	Arusha Cc	7	0	7
	Arusha Dc	9	0	9
	Karatu	10	0	10
	Longido	1	7	8
	Meru	13	0	13
	Monduli	11	0	11
	Ngorongoro	0	6	6
		51	13	64
TOTAL		100.0%	100.0%	100.0%
		79.7%	20.3%	100.0%

Increasing healthcare services has also increased the need for affordable and stale laboratory diagnostics services in areas resource-limited areas. Many areas are responding by improving the standards of their public laboratories and advancing technology to deliver a high coverage area of service. This extension carries the chance of more and more diversity of an already very highly diverse technology and thus testing platform overall, making it harder to oversight laboratory networks in all levels of the healthcare system. To control this situation, countries are suggested to make policies, regulations, and guidelines that standardize technology, test menus, commodities, and platforms across all levels of laboratories. The advantages of standardization may include balanced utilization of resources for capacity building and even more robust supply chain management through volume-based charge reductions for reagents, controls, and equipment service. Procurement process such as specification, prequalification, and contract conciliation, needs to go together with the standardization regulations for maximum advantage. Standardization should be followed in spite of whether procurement is centralized or decentralized or carried out by national institutions or non-governmental development partners. [10]

Prices affordability is one of the crucial factors that may predict the accessibility of reagents. In order to ensure easy accessibility of the reagents and controls from MSD prices for reagents and controls needed to be at affordable prices. Most of the study respondents reported that the Reagents and controls were fairly sold from MSD considering the equipment was acquired by the DH through the method of placement (which required no initial payment to get a piece of equipment).

Through the S&H program of Laboratory equipment, the Medical Store Department MSD has been able to buy reagents and control prices directly from Manufacturers at a high volume-based price, thus has been able to reduce selling prices for the reagents and controls for equipment under the S&H program.

5. Conclusion

5.1. Summary of Findings

With the limited human resources in the healthcare systems, for scaling up a number of testing scopes at different facility levels, it became necessary to increase the number of laboratory personnel to oversee the implementation of laboratory standardization and harmonization. Recently several authors have demonstrated that harmonization of laboratory activities is a critical step in developing stable laboratory services.

Also, Knowledge of laboratory standardization and harmonization program observed that 51.5% had low knowledge of laboratory standardization and harmonization program. Low knowledge of stakeholders concerning the program was mainly contributed by the Standardization and Harmonization Guideline have not yet been disseminated to the Regional and District Authorities to increase their understanding of the program. The guideline is well known to stakeholders at the ministry level, the Ministry of Health, PORALG, MSD, and other stakeholders who were involved in the development of the guideline.

The study found that only 15.6% has access to the standardization and harmonization guideline neither softcopy nor hardcopy guideline, in order to accomplish the target objectives of this initiative we need all involved stakeholders to have access to the guideline for standardization and harmonization and apply its guidance in the procurement of laboratory equipment. With limited access to printed hardcopy guidelines, an effort should be made for stakeholders to access softcopy from the Ministry of Health website.

The study revealed that 90.6% of district hospitals received standardized medical laboratory equipment, while 9.4% had not received standardized laboratory equipment,

analysis showed that one privately owned hospital operating as a District designated hospital had not received standardized laboratory equipment. Many Districts in Tanzania are using private or FBO's own Hospitals as District Designated Hospitals, thus not involving these Hospitals in this intervention is a gap that needs to be filled. As long as they provide services to the community. Laboratory Equipment owned by these facilities needs to be in harmony with the rest of the equipment in the country to make easy the supply chain of reagents and controls, maintenance services, and operational tasks for technologists.

Harmonized laboratory tests and standardized laboratory equipment have improved the management of public and private sectors and thus developed partner contributions in the country and improved the making of planned preventive maintenance as well as needed maintenance and the management of service contracts and the formation of a well-organized, cost-effective, and responsive service and maintenance of laboratory infrastructure. [9]

In most of the hospitals, 79.7% reported that prices of reagents and controls from MSD were obtained at reasonable and affordable prices. As Massambu [10] recommended, If government needs to scale up laboratory testing services, it is necessary for the government to install standardized equipment, and ensure the supply of health commodities and maintenance services to ensure the stable provision of testing services without interruption.

The Standardization of laboratory diagnostics requires the development of uniform test menus suitable for the health service provision at different tiers and the choice of the best technology platforms, including equipment, reagents, controls, and consumables for each laboratory testing parameter at each tier. Implementation of standardization in laboratory systems will improve access to all required diagnostics equipment and management of tests and the efficiency of procurement and, subsequently, the excellence of testing which affects patient care. Standardization will reduce the unnecessary variety of technology and testing equipment and, through this consolidation, offers a number of profits as in terms of cost reduction and ease of management in laboratory systems. The improvement of regulations regarding test menus by service provision levels and the procurement of laboratory diagnostic equipment and their commodities is the key step in the process of standardization and a vital requirement for refining the supply chain of laboratory commodities. Such regulations will provide the environment needed to lower reagent and consumable prices and well-organized and more cost-effective post-sales services from laboratory suppliers. [17]

5.2. Conclusion of the Study

The study has shown that a standardization and harmonization program is a policy intervention that enables the adoption of standardized laboratory equipment according to facilities levels thus enabling a good public health approach to managing laboratory services because it allows the organization of testing services to be more stable and thus ensuring the community can access quality laboratory services with the resources available.

5.2.1. Stakeholders' Participation as Per Guideline Availability, and Accessibility

From the study, it was observed that there was low involvement of stakeholders in the implementation of the program, as most participants had low knowledge concerning the program. Since the program assessed the accessibility of the standardization guideline by the participant, most participants had not yet seen the standardization guideline.

5.2.2. Availability of Standardized Laboratory Equipment at the Facilities

From the study, it was observed that standardized laboratory equipment had been distributed to all council facilities, the supplier for the equipment had successfully distributed laboratory equipment, had trained Laboratory personnel on how to use the equipment, and provided the startup reagents kits. It was observed there was no involvement of private or faith-based health facilities. Involvement of private or faith-based health facilities may be very important as some councils they didn't have a government councils' hospital thus they use a Faith based hospital as a Council designated Hospital, so their involvement in the laboratory equipment standardization will improve diagnostics services in their health facilities.

5.2.3. Availability of the Reagents and Controls at the Facilities

Availability of reagents and controls for standardized equipment at council hospitals had increased, as this was contributed by the accessibility of the reagents and controls from suppliers was also very high as well as the affordability of the reagents and controls from the supplier was at a reasonable price for hospital laboratory to procure. Recent efforts have therefore focused on harmonization and standardization of the minimum package of supplies, tests, and equipment needed at each level of the laboratory network. In addition, recognition is growing of the need for national laboratory strategic plans to specify lists of commodities and equipment to be used in each country. [7]

It has shown improvements in both efficiency and effectiveness of the entire level of the health system. In addition to having significant supply chain benefits, standardization also will have clinical benefits in the management of patients at District Hospitals as well as cost-effectiveness in the management of laboratory services.

5.3. Recommendations

From the areas assessed in the study, different conclusions were made and thus different recommendations are suggested to further improve the standardization and harmonization program for laboratory equipment,

5.3.1. Stakeholders' Participation as Per Guideline Availability, and Accessibility

All stakeholders should be on board with the intervention,

guideline needs to be disseminated to all responsible stakeholders for a common understanding of the intervention as well as good practice. Ministry of Health through, the Pharmaceutical Services Unit (PSU) should ensure that all reagents and controls for standardized equipment are accessible in the electronic logistics management information system (eLMIS) for facilities to order and report consumption and stock status.

Laboratory systems need a higher-level management and direction setting through the national laboratory policies and guidelines and regulatory eye and coordination of all operations functions affecting the program such as procurement, quality management, and commodity logistics to ensure a more well-organized performance and collaborative advantages across all levels of laboratories. The establishment of policies regulations and guidelines on the standardization of testing parameters, service provision, and quality technology across the levels promotes more competent and cost-effective operation and organization of laboratory systems, and thus policies, regulations, and guidelines will be implemented through strategic plans and operational plans for laboratory establishment that defines the significances, timeframes, and resources required. [10]

S&H Program must be collaborative and should be implemented in association with all key stakeholders such as MSD, TMDA, PORALG, and MoH across all directorates. Programs (NACP, NMCP, NTLP, etc) should accommodate the standardized list of equipment so as to plan for reagents and consumable procurement, and follow-up usage.

The National strategic and operational plan for laboratory services strengthening and national laboratory resources allocations needs to include standardized test protocols and equipment distributed when planning and allocating budgeting for the repairs of laboratories infrastructure and systems, procurement of new equipment and laboratory commodities, the employment and training of new and experienced staff, and the formation of the logistics system and the stable laboratory sample referral systems in the way to make standardization reach all tiers of the laboratory networks [10].

Ministry of Health continuously updates the National Health Laboratory Service Supplies List (NHLSSL) to accommodate the changes in the field of laboratory testing and the whole standardized medical equipment program intervention. For the newly introduced laboratory equipment at all levels of laboratories, there is a need for a uniform list that will inform suppliers of the current country's needs of laboratory equipment and reagents in the respective facilities.

Ministry of Health should ensure that reagents and controls for standardized equipment follow the recommended path as stated in the SMLEG, that due to the short shelf life of controls usually less than Six (6) months. Controls should be transported directly from the manufacturer/supplier to the facilities as per the agreed supply plan. Furthermore, there is a need to have a unique supply chain system for laboratory commodities different from the current system where laboratory commodities are treated the same as Medicine. Laboratory commodities usually have a shorter shelf life as compared to medicines thus modification can be made especially by having supply deports/ vendors at the same areas where respective equipment is located so as to shorten the supply chain and eventually cost of transportation.

5.3.2. Availability of Standardized Laboratory Equipment at the Facilities

Suppliers of standardized equipment for public facilities should follow up on the performance of the equipment for future adjustment and improvement of the program intervention. There must always be room for improvement so that facilities can always have the latest technology and better-quality equipment.

All acquired laboratory commodities and their sellers should be subject to a pre and routine performance assessment and post-market observation to make sure that the equipment qualifies for inclusion in the standardized commodity lists. The quality or Operational problems should be dealt with quickly to give room for the replacement of equipment or product if needed. Standardization must not confine the introduction of other technologies and platforms in the market. New and better technologies must always have the opportunity to the laboratory supplies market, and the formation of a monopoly supply system must be avoided at all costs. Standardization regulations need to be controlled by suitable and flexible instructive procedures that would give room for other platforms to be speedily, justly and clearly reviewed on a frequent basis and for changes to be made to the collection of equipment allowed for use, when suitable. [10]

Harmonization of laboratory equipment at all facility levels should be a long-term process, thus transition from old equipment to newly standardized ones should take place gradually; as it may require time; resources; adoption, as well as leadership and commitment from the Ministry level down to the health facilities.

Standardization and harmonization are cooperative interventions that should be conducted by national and international organizations as well as non-governmental institutions. These efforts may require long-term plans and commitments of technical, political, and financial resources.

The government must generate policies and guidelines modifications to facilitate changes made by the S&H program so as to allow effective implementation of the program. As the current public procurement act may pose a challenge to the direct procurement of equipment from manufacturers so as to have a single source of reagents and controls from one manufacturer/supplier.

One other challenge faced is the Public Procurement Act as it requires the use of an open competitive tendering system that uses a generic specification for the item procured. After harmonization, equipment for which has only 1 manufacturer, agent, or supplier. The Public Procurement Act, therefore, may block the principles behind the harmonization of laboratory equipment, as it may forbid the choosing of a certain brand, trade, or specific names procurement during

the selection of equipment, reagents, or controls, this allows suppliers to quote for any equipment or reagents that adhere to the generic specifications of the advertised tender, but that may not fit what is needed for procurement. Thus, most donated equipment was different from the standardized equipment due to this reason. [9]

Due to changing environmental factors subsequently, the modified versions of the Public Procurement Act were introduced in 2004 and again in 2005. However, despite the many changes and alignments throughout these procurement Acts, the issue of donated medical equipment procurement has not been addressed separately. In addition to the procedural and technical requirements of the procurement, there are a number of other related factors that affect the procurement and use of donated equipment. [17]

As for Laboratory policies and regulations, they must be reviewed and updated to include policies and guidelines for standardization programs. These policies should be strictly followed by all laboratory stakeholders in the network, as well as the government institutions and non-governmental institutions involved in laboratory network strengthening and procurement. The policies and regulations must ensure a high degree of openness, accountability, and flexibility in the choice of technologies and equipment. [10]

Laboratories should enroll the tests undertaken by the standardized equipment into an accreditation quality management plan so as to enhance equipment utilization and adherence to standard operating procedures. This will be of benefit to the client as well as the laboratory as good management of the equipment will ensure its longest survival and good functionality. As stated by Russel [15] Once staff have received training and the management structure for QMS has been established, laboratories were able to put in place systems for monitoring and improving quality. Implementation was generally a stepwise process based on 'plan, do, act, and check' cycles characteristic of improvement planning for the laboratories.

5.3.3. Availability of the Reagents and Controls at the Facilities

Suppliers to ensure a full supply of reagents and controls for the standardized equipment as well as provide on-time maintenance services whenever they are needed by the facilities. Considering the large market available in the country as the same equipment has been distributed countrywide, MSD must take advantage of the market available.

As Standardization can help increase the efficiency of procurement and supply chain systems of s laboratory networks and assist in ensuring that the correct testing materials are all times available when needed. Networks that implement common test menus, technology platforms, and supplies across all levels of laboratories and can aggregate testing numbers across these laboratories to more easily negotiate bulk reductions for reagents, controls, consumables, and related laboratory commodities than if the volumes are divided amongst a bigger range of dealers. By controlling the number of orders transactions and/or increasing the expectedness and forecasting correctness of orders, the procurement process becomes even more effective. [10]

Suppliers to speed up the process of installation and training to facilities receiving the standardized equipment as some hospitals reported Chemistry machines were delivered but were not yet installed. When most facilities receive the S&H equipment the greater market for MSD to sell the reagents and controls and get maximum profit.

For laboratory systems to profit from standardization, policies, and regulations are needed to guide laboratory test distribution, technology choices, and procurement processes. However, laboratory standardization policies and the prequalification process does not always exist or may be required to be reviewed and updated. [10]

MSD as a supplier of the standardized equipment should conduct timely planned preventive maintenance (PPM) and repair services so that downtime for broken equipment will be very low as all cases reported will get the repair services needed as soon as possible. Delays in repairing equipment will affect its working time and thus cause the expiry of reagents or controls at a particular health facility.

As most facilities have received standardized equipment, laboratories should develop a business model/plan for laboratory services provided to ensure profit gain from the services provided as well as the sustainability of services. Modal like block payment should not be used to pay for laboratory tests unless it can cover the test prices as required.

All health facilities laboratories should adhere to timely reporting of equipment functionality using proper channels, the use of Laboratory Equipment Management (LEM) platform in the eLMIS should be well utilized to report the functionality of machines as well as reagents and control consumer data. These data are necessary for future planning and decision-making across different levels of governance.

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