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Factors Affecting Medicines Quality in Public Sector Health Supply Chains In Uganda: A Case of National Medical Stores

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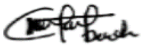

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LIST OF ACRONYMS

ADR	Adverse Drug Reaction
DV	Dependent Variable
GMP	Good Manufacturing Practices
GoU	Government of Uganda
GPHF	Global Pharma Health Fund
HC	Health Center
LMIC	Low and Middle Income Countries
MoH	Ministry of Health
MOMHSM	Management of medicines and Health Supplies Manual
NDA	National Drug Authority
NMS	National Medical Stores
NPSSP	National Pharmaceutical Sector Strategic Plan
PFP	Private for Profit
PNFP	Private Not for Profit
SPSS	Statistical Package for Social Scientists
SSFFC	Substandard/ Spurious/ Falsely-Labelled/ Falsified/ Counterfeit
SF	Substandard/ Falsified
UNMHCP	Uganda National Minimum Health Care Package
WHO	World Health Organization
WTO	World Trade Organization

ABSTRACT

This study sought to analyze the factors affecting quality of medicines in Public Sector Health Supply Chains in Uganda taking a case of National Medical Stores (NMS). In particular, the focus was the effect of procurement management, storage of medicines and pharmaceutical quality assurance on the quality of medicines. The study used perception data collected from a sample of 85 respondents from NMS and Key Informant Interviews with NMS key heads of department. Results were summarized at three levels of analysis, namely; univariate using frequencies and percentages, bivariate analysis using Pearson's correlation coefficient and multivariate analysis using multiple linear regression. Objectives of this study were answered with results from the multiple linear regression model. Perception data was used because NMS does not have a quality control laboratory for testing quality of medicines

Findings from the descriptive analysis indicated that respondents agree that procurement management (mean score=4.08), storage of medicines (mean score=4.2), and pharmaceutical quality assurance (mean score=4.0), have a relationship on the quality of medicines distributed to health facilities at NMS.

The study revealed that there is a statistically significant positive relationship between procurement management (p-value=0.049) and quality of medicines at NMS with attributes such as medicine specifications, procurement system on evaluating procurement samples, tender evaluation process and sourcing based on capability to supply good quality medicines as being key in driving this positive effect. Also the study further revealed a positive statistically significant effect of pharmaceutical quality assurance (p-value=0.037) on quality of medicines with attributes such as quality assurance manual, inspection of all incoming shipments, and expiry of medicines being key in driving the this positive effect. However, findings revealed that storage of medicines (p-value>0.05) was not significant at influencing the quality of medicines.

The study recommends that: NMS should establish a quality control laboratory for testing the quality of medicines before distributing them to health facilities as this will help in avoiding recall and rejection of medicines in health facilities due to quality standards, NMS should maintain robust procurement systems such that areas such as evaluation of procurement samples, tender evaluation process and sourcing based on capability to supply good quality medicines are well managed to reduce on the risk of

compromising quality during procurement of medicines. Finally, NMS should maintain the good storage practices especially temperature monitoring, humidity and dust in the warehouse as there were revealed as key areas under storage which do affect quality of medicines.

CHAPTER 1: INTRODUCTION

1.1 Introduction

The significance of medicine quality in a functional health supply chain and health care system is no longer a subject for debate. Medicines are of vital importance in any health system(1) with access to quality assured medicines being one of the basic rights to health(2). This is a key requirement for the universal minimum health coverage policy in countries like Uganda. In reality however, many health systems are still grappling with poor quality medical products partly because of ineffective supply chain management systems. There is therefore a need to analyze the factors determining medicines quality in public sector health supply chains. This study assessed the factors affecting quality of medicines in Public health supply chains in Uganda, taking a case of the National Medical Stores. In the study, medicines quality was the dependent variable (DV) and procurement management, storage of medicines as well as pharmaceutical quality assurance constituted the independent variables. This chapter presented the background to the study, problem statement, purpose of the study, objectives, significance and limitations of the study.

1.2 Background to the study

Health commodities are an indispensable component of health systems useful in the prevention, diagnosis and treatment of disease and in alleviating disability and functional deficiency(1). Pharmaceutical supply chain systems are the means through which lifesaving health commodities are delivered to the people that need them(3). Health care supply chain logistics refers to the process involved in the movement of medicines and medical supplies from source of manufacture to the service delivery points where patients can have access to them (8). Supply chain management is the set of activities involved in moving a product (in this case medicines, diagnostics and other health supplies) and its associated services from the ultimate supplier to the ultimate consumer (2).

Healthcare supply chain logistics cycle includes selection, quantification (or forecasting), procurement, inventory management, storage, and distribution. A well-defined Logistics Management Information System (LMIS) provide linkages between these components. All of these functions must work together to ensure that supply can meet demand (2).

In low and middle income countries (LMICs), the main public sector supply model includes a public or parastatal entity responsible for procurement and distribution of health supplies to public sector outlets. This entity is often called a central medical stores (CMS) (3) as is the case in the Ugandan setting. The share of medicines distributed through the public sector for sub-Saharan Africa was estimated at 33.2% in 1990. These figures vary greatly from country to country, ranging from 16% in Senegal to 50% in Zimbabwe. More recent estimates vary from 70 to 90% in Malawi, to 15% in Mali and 10% in Ghana(4).

However, pharmaceutical supply chain systems are complex and often have several intermediaries which poses a challenge with regard to medicines quality(3). The supply chain if well implemented ensures availability of quality medicine/ product at the right time, minimizing inventory wastage, maximizing patient care, coordination in all departments minimizing human error/ medication errors. Strong national medicines registration and quality assurance system is also required to ensure quality of available medicines (3).

As pharmaceutical supply chains become more global, the risk of fraud, substitution and counterfeiting increases. Substandard and falsified medicines burden health systems by diverting resources to ineffective or harmful therapies, causing medical complications and prolonging illnesses. Therefore, consumers are demanding more transparency and safety adherence as these issues arise(5).

Substandard/counterfeit antimicrobial drugs are a growing global problem affecting most commonly antimicrobials (beta-lactams) and antimalarials (chloroquine and artemisinin derivatives) which are sometimes found to have a reduced amount of the active drug(6). Counterfeit antimicrobial drugs may cause increased mortality and morbidity and pose a danger to patients. The growing menace of poor quality and falsified drugs therefore constitutes a major hazard, compromising healthcare and patient outcomes(7), therefore it was necessary to analyze the effects of the factors affecting medicines quality in public sector health supply chains in Uganda.

According to the World Health Organization (WHO) (2017), an estimated 1 in 10 medical products in low- and middle-income countries is substandard or falsified with a 10.5% failure rate for analyzed medicine samples. The number of deaths reported by

WHO due to childhood pneumonia as caused by SF antibiotics was a record breaking 72,430-169, 271. Malaria in sub-Saharan Africa was also reported as responsible for up to 116,000 deaths at a cost of US $ 38.5 million to the affected economies(8).Great efforts have been made to combat this very important public health issue of poor quality medicines through international, national and local initiatives (6).

On the global scale, WHO established a medicines prequalification program in the past decade to ensure that low-cost generic medicines are quality-assured and can be procured safely since they were fast becoming increasingly available, especially for treatment of HIV/AIDS(Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome) (9).

Given the fact that low-cost pharmaceutical products of assured quality have the greatest potential for maximizing the impact of pharmaceutical procurement(10), the WHO prequalification undertook several interventions to assure the quality of these medicines. This includes the assessment of active pharmaceutical ingredients and finished pharmaceutical products. In addition, quality control laboratories and manufacturing sites are also assessed based on stringent, internationally-agreed requirements to ensure safety, quality and performance. WHO also endeavours to work together with manufacturers and regulators to develop and regulate medicines of assured quality in compliance with Good Manufacturing Practice(9).

In Uganda's context, the government put in place the National Medicines Policy and National Pharmaceutical Sector Strategic Plan (2015) which were intended to align with the health sector's goal of accelerating progress towards Universal Health Coverage with essential health commodities and related services needed for promotion of a healthy and productive life. This is in order to ensure access to good quality, safe and efficacious, affordable essential medicines and health supplies for the Ugandan population(11).

Whereas the national drugs regulatory authority is responsible for the safety of a country's drug supply, the challenges of weak national regulatory agencies may undermine efforts to achieving access to quality medicines in a health system. These include limited batch testing to supplement in-country testing, limited quality control laboratory testing capacity and lack of accreditation as well as limited

pharmacovigilance (3). WHO estimates that about one-third of the world's population lack access to essential medicines and diagnostics(12). In the poorest parts of Africa and Asia, this proportion increases to 50 percent (11). It is important to note that poor quality medicines affect not only national, regional and global endeavours to improve access to effective healthcare but also increases pressure on limited financial resources, contribute to drug resistance and consequently increases morbidity and mortality rates(12).

Quality Assurance of pharmaceuticals has become a major public health challenge because diseases know no borders. In order to combat the effects of diseases, countries need medicines that are manufactured to the same standards of safety and effectiveness so that they can be relied on everywhere(13). As international demand for medicines grows, substandard/ spurious/ falsely-labelled/ falsified/ counterfeit (SSFFC) medical products have been found in both developing and developed countries. Such products are at best ineffective, resulting in growth of drug resistance and prolonged or ineffective treatment for patients, and at worst they are dangerous, putting lives at risk even resulting in death. Medicines that are ineffective or harmful not only damage lives but also waste public resources(13).

According to WHO, medicines quality refers to when a medicinal products is suitable for its intended use in terms of its efficacy versus safety (health risks); or the conformity to specifications like identity, strength, purity and other characteristics such as tablet hardness, disintegration and dissolution properties for solid dosage forms; and sterility for parenterals(14). It is therefore imperative for pharmaceutical supply chain operations to put conditions in place that ensure medicines quality. In this study, supply chain management is conceived in terms of procurement management, storage of medicines and Pharmaceutical Quality assurance, and how these relate to the quality of medicines in the public health supply chain in Uganda. The next sections of this report present the enduring problem of medicines quality.

1.3 Problem statement

The quality of medicine in the Ugandan health supply chain system faces substantial challenges. Reports according to National Drug Authority indicate that out of 301 adverse drug reaction (ADR) cases received in 2016/17, 73% were serious ADR cases. The notable reasons were product quality problems or defects and therapeutic

failures(15). In the financial year 2017 to 2018, the National Drug Authority (NDA) reported failure rates of 7.3% for medicines, 25% for gloves and 42.3% for condoms(16).

However, in 2018 to 2019, 25% of the total products recalled had quality problems namely, discoloration, failure of drug quality tests and failure to meet drug specifications. For example, diclofenac injection and calcium tablets were reported to have changed colour on storage. Besides, 60% of products recalled were due to failure of manufacturer's compliance with Good Manufacturing Practice(17). In addition, health facilities continue to face acute unexplained shortages of essential medicines, delayed deliveries, expiry of essential medicines, and accumulation of unwanted and expired medicines, mainly as a result of poor quality medications entering the health supply chain system(18).

Despite efforts to ensure safety, efficacy and quality of medicines in Uganda, there is continuing circulation of poor-quality medicines in public sector health supply chains. These medicines are deliberately falsified and may contain incorrect or no amount of active ingredients at all, substandard or degraded over time(19,18) . If this enduring problem is not addressed, there may be dire consequences. At present, the plausible factors affecting quality and the effects of said factors on the quality of medicines in the public health commodity supply chain are not well-established and this study proposed to fill this gap.

1.4 Purpose of the study

The purpose of the study was to examine the factors affecting quality of medicines in public sector health supply chains in Uganda taking a case of National Medical Stores.

1.5 Specific Objectives

The specific objectives of the study were;

i. To determine the effect of procurement management on the quality of medicines in National Medical Stores, Uganda.
ii. To ascertain the effect of storage of medicines practices on the quality of medicines in National Medical Stores, Uganda.

iii. To establish the effect of pharmaceutical quality assurance practices on the quality of medicines in National Medical Stores, Uganda.

1.6 Research Questions

The key research questions were;

i. What is the effect of procurement management on the quality of medicines at National Medical Stores, Uganda?
ii. What is the effect of storage practices on the quality of medicines at National Medical Stores, Uganda?
iii. What is the extent to which pharmaceutical quality assurance practices affects the quality of medicines at National Medical Stores, Uganda?

1.7 Significance of the study

This study provided evidence about the effect of the main factors influencing the quality of medicines i.e. procurement, storage of medicines practices as well as pharmaceutical quality assurance, which will inform planning and decision making in NMS.

This study was intended to shed light on how to improve medicines quality and generate information necessary for policy makers on matters regarding the best practical ways to strengthen procurement, storage of medicines, pharmaceutical quality assurance and the quality of medicines in the health sector in Uganda.

This study has also provided a basis for further research especially for studies that will opt for large samples to include the private sector, for example, the Joint Medical Stores (JMS) and all levels of health facilities at higher and lower local governments. It is therefore intended to help fill the existing gaps in the research about how procurement, storage of medicines as well as pharmaceutical quality assurance, affect the quality of medicines at NMS Uganda.

1.8 Delimitations

The study was conducted in one Government entity by only examining the factors affecting the quality of medicines, namely, procurement, storage of medicines and pharmaceutical quality assurance.

1.9 Limitations

The study was conducted in NMS only which is a public sector entity. Though the study examined the factors influencing the quality of medicine in NMS, it didn't conduct laboratory quality tests due to logistical and time constraints.

1.10 Operational definitions:

In the context of this study, the following operational definitions were adopted.

Quality of medicines: refers to when a medicinal products is suitable for its intended use in terms of its efficacy versus safety (health risks); or the conformity to specifications like identity, strength, purity and other characteristics such as tablet hardness, disintegration and dissolution properties for solid dosage forms; and sterility for parenterals(14)

Procurement: refers to the process of identification, sourcing, access & management of the external resources that an organization may need to fulfill its strategic objectives(20)

Storage of medicines: the process of safe keeping products in such a way that ensures the maintenance of physical integrity, safety and packaging of these products until they are dispensed to end users/ clients(21)

Pharmaceutical Quality Assurance: refers to a process that ensures that pharmaceutical products in a health commodity supply chain are of the quality required for their intended use.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter presented the literature review using a structured approach based on the study themes and according to the objectives. The review of literature involved conceptualisation and theorisation of study constructs in relation to dependent variables. Empirical results of previous studies are also presented to identify the gaps to be filled by this study.

2.2 Supply Chain and Quality of medicine

Globally, since the establishment of the World Health Organization (WHO) the quality of medicines has been a concern. Any health service in the world can be said to be evidently compromised if there is no assurance that the medicines provided are relevant to priority health needs and that they meet acceptable standards of quality, safety and efficacy(2). The proliferation of substandard medicines globally has become a serious public health concern, for instance in Pakistan, a study on an epidemic of *Plasmodium falciparum* Malaria revealed that the anti-malarial drugs used routinely in patient treatment, and which were widely in circulation were substandard. The substandard drugs were procured centrally in response to shortages and subsequently distributed through local government organizations in the country. The author also suggested that the substandard drug inevitably contributed to disease transmission and this was undoubtedly a factor contributing to the malaria epidemic(22).

The scenario is even worse in sub Saharan African countries which suffer weak systems of governance and regulation(23). Across a number of studies, it has been reported that 4-92% of anti-malarials tested in the developing world are poor quality. This represents an enormous risk to the population in the developing world subjected to the use of these medicines. These include more severe and prolonged illness, additional costs to individuals who already depend on meagre resources, with potentially a loss of confidence in treatments(19).

Despite all the strategies implemented by the Uganda Ministry of Health policy-wise, as well as the national drugs regulatory authority, which is responsible for the safety

of the country's drug supply, anecdotal evidence shows that counterfeit and substandard medicines are still prevalent in the Ugandan market(17, 24).

Evidence shows that the use of falsified and substandard drugs can have several adverse consequences; including mass poisoning(23) , treatment failure in acute, chronic and infectious diseases(23,25); and encouraged drug resistance thereby threatening today's and future populations(26). Use of falsified and substandard medicines in unsuspecting health systems presents social and economic consequences such as wastage of already limited financial resources in terms of raising drug costs to patients and the health system. Drug resistance also reduces the useful life cycle of a drug and society must bear direct and indirect costs of new drug development (27)(28). A compromised drug supply causes stakeholders to lose confidence in medicine, health care providers and national regulatory agencies (27).

2.3 Medicine supply chain in Ugandan Context

The overarching health goal for Government of Uganda, through Ministry of Health, is to ensure access to affordable good quality medicines for the people of Uganda. Despite the progress made, a lot still remains to be done to improve access to quality essential medicines and pharmaceutical services in Uganda as outlined in the priority areas of the NPSSP III(29,23).

The supply and management of drugs is a continuous cycle. The drug management cycle includes the selection of drugs, quantification of drug needs, procurement, storage and distribution(30). At the central level, the Quantification and Procurement Planning Unit (QPPU) in the Ministry of Health coordinates supply planning with all relevant partners, monitors stock levels at the national warehouses, leads quantification and undertakes gap analyses. NMS complements the MoH by procuring and distributing medicines to public health facilities using a pull system for Health Centre IVs and hospitals; and a kit (standing order) system for all HC II and HC III (29).

In the case of Uganda, evidence suggests that medicine quality problems still persist such as the reported medicines discoloration, failure of drug quality tests/ failure to meet drug specifications, which reasons are responsible for the recall of 25% of total recalled products in the past one year(19) Quality of medicines remains a challenge at

health facility level as evidenced by the numerous reported ADRs which are attributed to defective product used in treatment of patients(15).

2.4 Reviewing Factors affecting quality of medicines

There are several overlapping factors that encourage the proliferation of falsified and substandard medicines. These include failure to adhere to good manufacturing practices, poor quality-control processes, the high demand and erratic supply of drugs, weak regulatory systems, and uneven awareness about falsified and substandard drugs(27). Even though poor-quality drugs are often both falsified and substandard, other potentiating factors may encourage both kinds of problems. The factors of interest that are under review in this chapter included procurement management, storage of medicine and pharmaceutical quality assurance practices.

2.4.1 Procurement Management and Quality of Medicines

Procurement is the process of acquiring goods at the best possible total cost of ownership, in the right quality and quantity, at the right time, in the right place and from the right source for the direct benefit or use of corporations or governments (31).

Pharmaceutical procurement is a complex process which involves many steps, agencies, ministries and manufacturers. Existing government policies, rules and regulations for procurement as well as institutional structures are frequently inadequate and sometimes hinder overall efficiency in responding to the modern pharmaceutical market(33) and yet procurement of pharmaceutical drugs plays a crucial role in management of health(31).

The procurement of drugs starts off with the selection of drugs based on the national essential drugs list. This is followed by quantification which is necessary to avoid wastage through over-stocking or stock outs of pharmaceuticals. Procurements executed through competitive tenders aim to provide quality drugs at the lowest possible cost when needed. The procurement system must be in compliance with the requirements of both local government procurement regulations(32) and the international Procurement Agreement of the World Trade Organization(30).

As a substantial part of the health budget in many countries is used to purchase pharmaceutical products, procurement of drugs is obviously a crucial function.

Various types of tender mechanisms are in place including direct procurement which are used in conjunction with prequalification procedures. Public procurement agencies in the health sector favor restricted tenders to which only prequalified suppliers are invited in order to ensure product quality(32).

For there to be continuity of flow of drugs, the procurement procedure is essential and objectives should be considered in the procurement of pharmaceutical drugs. Studies, have asserted that the main factors which affect the procurement of drugs are inadequate funding resulting in delay in paying the suppliers and poor quantification(31).

Transparency must be maintained throughout the procurement cycle by following formal written procedures, basing decisions on explicit criteria to award contracts. Also information specifying the best evaluated supplier and price for each product, should be made available to all bidders. It is important that tenders are thoroughly evaluated involving competent persons with technical knowledge of pharmaceutical products and their manufacture(34).

As is often the case, the determining factor for awarding a tender is price(32). However, quality must be a more important consideration due to the fact that substandard products give rise to health hazards as well as financial losses to the procurement agency. While products of assured quality may be priced higher, they may be cheaper in the long run. Drugs are not ordinary commodities and should therefore be treated as such - purchase of cheaper pharmaceuticals without quality assurance invariably results in losses as follows: expiration of stocks soon after delivery because of too short shelf-life; substandard drugs and health hazards(34).

A recent research study suggested that some of the components of WHO Model Quality Assurance System for Procurement agencies (MQAS) are not consistently applied by major procurement agencies, particularly supplier accreditation and re-assessment. This creates a significant threat to quality of medical products (35). In Tanzania and South Africa, the focus on improving quality is through procurement policy by restricting national tenders to suppliers with registered products are registered in the respective country(36).

Across a number of studies, it has been demonstrated that 4-92% of antimalarials tested are poor quality. This represents a massive risk to the population subjected to the use of these medicines in the form of more severe and prolonged illness, additional costs to individuals who already have very little money, and lack of confidence in treatments(19).

The circulation of poor-quality medicines persists despite efforts to combat the supply of poor-quality medicines such as developing guidelines for the procurement of medicines, and programs to educate consumers about the risks of poor-quality medicines, development of new technologies to quickly identify poor-quality medicines in the field, and incentivizing retailers to identify and report falsified medicines (19).

Procurement related factors contributing to poor-quality medicines include absence of good operational principles of pharmaceutical procurement, limited technical capability of staff, inappropriate selection, lack of timely, accurate and accessible information and poor budgeting and financing which negatively affects health service delivery (32).

2.4.2 Storage and Quality of Medicines

Storage and handling has also been known to affect quality of medicines therefore it is important that formal structures are set up to identify and report perceived quality concerns(37). Correct storage of drugs is crucial to avoid deterioration and waste and also involves performing drugs quality assurance activities in order to monitor and improve the drug management cycle (38).

In a study on quality of medicines in Southern Togo, it was reported that inappropriate storage conditions may have been an important cause of substandard quality medicines(39). Boyer (2018), in an access to medicines analysis also notes that stakeholders in health supply chains have an important role in improving local manufacturing capacity. There was also need to strengthen supply chain capacity in low and middle income countries through engaging in activities to build capacity in these areas. In this way companies are able to reduce risks of manufacturing substandard and falsified medicines which would then enter the supply chain and compromise medicine quality during storage (40).

Another researcher who assessed the quality of anti-malarial medicines in five counties in Liberia, observed that 19% of collected samples failed as a result of poor manufacturing practice while 79% failed due to poor storage of medicines and unregistered medicines(41).

Similarly, in the Ugandan scenario, the drug regulatory body, NDA asserts that risks from medicines arise due to several reasons including how these medicines are stored(42).

2.4.3 Pharmaceutical Quality Assurance and Quality of Medicines

The purpose of quality assurance in pharmaceutical supply chain system is to help ensure that each medicine reaching a patient is safe, effective, and of acceptable quality. A comprehensive quality assurance program includes both technical and managerial activities, spanning the entire supply process from pharmaceutical selection to patient use(43) for the purpose of monitoring and improving the drug management cycle(38).

One study reviewed literature on antimalarial drug quality studies in Africa and their findings indicated that in order to ensure that populations in the continent have access to antimalarial drugs that are safe, of the highest quality standards and that retain their integrity throughout the supply chain, there is an urgent need to strengthen pharmaceutical management systems such as post-marketing surveillance and the broader health systems in Africa including the adequate enforcement of existing legislation and enactment of new ones if necessary, and provision of the necessary resources for drug quality assurance(44).

In a study analyzing the quality assurance systems of pharmaceutical distributors, findings suggested that public and humanitarian distributors supplying LMICs do not consistently apply stringent criteria for selecting and evaluating products. Local private distributors were generally weak in their storage practices. It is urgent to strengthen the capacities of the national regulatory authorities to assure the quality of medicines provided by distributors(45).

A study on the global challenge of falsified medicines and detection of harmful fakes in developing countries using Global Pharma Health Fund (GPHF)-minilabs noted

that owing to the widespread danger of falsified medicines, quality control in supply chain systems of developing countries has acquired new dimensions to date. Unless adherence to good pharmaceutical manufacture, distribution and trading practice is achieved, a greater number of samples have to be tested in order to maintain an appropriate assurance of drug quality. However challenges like the absence of the means for effective drug quality control or if available and fully in place, full testing is expensive, hardly accessible or time consuming illustrate this as a capacity gap on drug quality testing in LMICs(46).

In many LMICs, pharmaceutical distributors play a key role de facto in defining the quality of available medicines. Therefore, the absence of a robust pharmaceutical quality assurance as prescribed by the WHO Model Quality Assurance System (MQAS)- which sets QA standards for procurement agencies/ distributors(10) or low compliance to MQAS indicates a risk that poor quality medicines are supplied (45,44).

2.5 Summary of literature review

Overall, literature review has showed that there are critical factors which affect medicine quality. Such dominant factors include insufficient regulatory capacity in susceptible countries, inadequate funding to perform regulatory functions, poor coordination between regulatory authorities, and inefficient import/export control systems , uncoordinated presence of heterogeneous actors, weakness of the national regulatory authorities and complexity of supply chains(47).

However, much as an expansive body of literature describes various factors, there was inadequate empirical focus on understanding how procurement management, storage of medicines and pharmaceutical quality assurance affect the quality of medicines in the health supply chain context of Uganda. This study therefore isolated those factors in NMS and analyzed how they affect quality of medicines in Uganda.

2.6 Conceptual framework

Factors (IV)

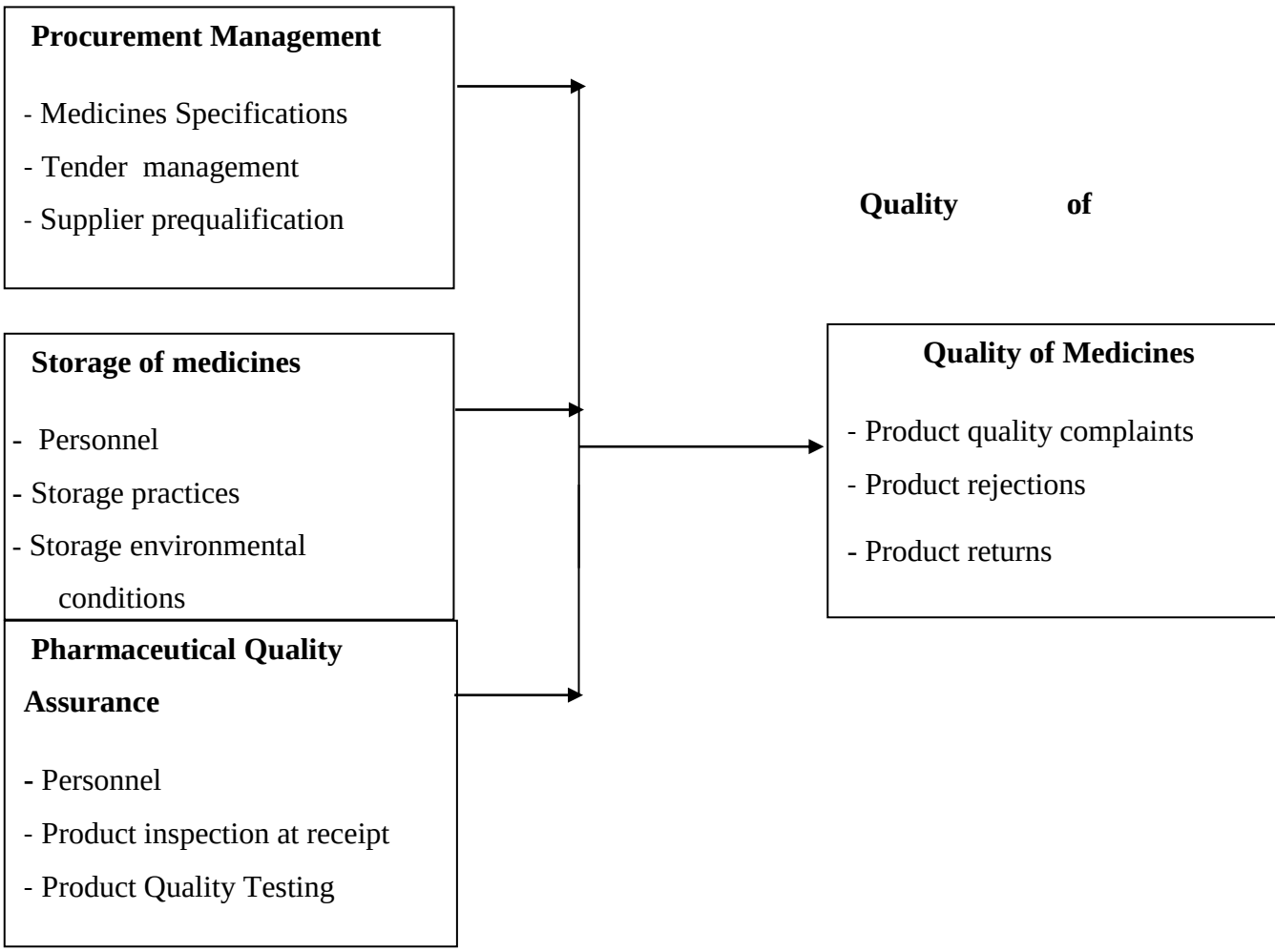

Figure 1: Conceptual Framework illustrating hypothesized association of factors affecting Medicines quality in in public health supply chains in Uganda

Source: Adapted from WHO Model Quality Assurance Systems for procurement Agencies(43)

CHAPTER 3: METHODOLOGY

3.1 Introduction

This chapter highlights methods that were used in the study. These include; the research design, study population, sample size and selection, sampling techniques, data collection methods, data collection instruments, procedure of data collection, reliability and validity of instruments, data analysis and measurement of variables.

3.2 Research Design

The study used a cross-sectional design which was preferred in order to enable a onetime investigation of the study problem at one point in time. This helped significantly in obtaining useful data in a relatively short period and cheaply as little time was available (48).

This study applied both qualitative and quantitative research approaches. Whereas the quantitative approach included using a questionnaire survey, the qualitative approach involved in-depth interviews (49). This mixed-methods methodology involved collection of both quantitative and qualitative data which helped in triangulation of data findings.

A questionnaire was administered to each selected participant and this information triangulated with findings from the qualitative methods. This involved face to face key informant interviews to provide deeper insights into these findings. (50).

3.3 Location of the Study

The study was conducted in National Medical Stores of Uganda which was set up by government with a mandate to procure, store and distribute essential medicines and medical supplies to public health facilities across the country (51). This is done through a chain supply management policy that ensures maintenance of agreed minimum and maximum stocks at all levels, effective service delivery points, direct delivery to health facilities and effective intra-health facility supply and distribution. NMS is headquartered in Entebbe Municipality in Wakiso district in Central Uganda.

3.4 Study Population

The study population was generated from NMS as the case in point. NMS has seven (7) departments, that is, General Manager (MIS Section), Human Resource & Administration, Secretary to the Board (Risk Management Section), Internal Audit, Procurement, Stores and Operations, and Quality Assurance & Control (52). The population of the study is 159 respondents all of whom are staff of NMS (refer to table 3.1). The staff provided both survey data and detailed information about performance of NMS by revealing what is going on in the key function departments in terms of health facilities medicines product quality related complaints and how these are remedied.

3.5 Sample size and selection

The sample size achieved was 90 respondents all of whom are staff of NMS because this is the sole public entity mandated to Procure, Store and Distribute essential medicines and medical supplies to health facilities in Uganda(51). This was a relatively smaller sample size (66% response rate) compared to the target of 137 owing to factors such as limited time for the study as well as other respondents refusing to participate in the study because of their tight schedule especially in the stores and operations department where daily work depends on targets set by their supervisors. The sample size was determined based on the sample size selection table according to Krejcie and Morgan(53) (Appendix A). The study also adopted simple random sampling as a sampling strategy wherein respondents are selected within their categories/ strata each of which is internally homogeneous(54). The different categories represent the different hierarchies of staff in NMS under which the respondents fall. Simple random sampling ensured that all people in particular categories are given equal chances of selection(54).

Purposive sampling was used in selecting the NMS Top management officials like the General Manager, Head of Procurement who offered a wealth of information regarding the area under research. The sample for the top management staff was determined purposively (non-probability method) and these provided in depth information and knowledge of the phenomenon of (55).

Table 1: Population, Target Sample Size and Achieved Sample Size

Category	***Population***	***Sample size***	***Achieved Sample Size***	***Sampling technique***
NMS Top Management	8	8	5	Purposive sampling
NMS Procurement Department	15	14	12	Stratified sampling
Stores and Operations Department	100	80	40	Stratified sampling
Quality Assurance Department	5	5	4	Stratified sampling
Sales and Marketing Department	25	24	23	Stratified sampling
Internal Audit department	6	6	6	Stratified sampling
Total	**159**	137	90	

Source NMS, 2016

3.6 Demographic characteristics of respondents

The study collected demographic information on respondents relating to gender, age characteristics, education background, and length of service in NMS which findings are presented below.

3.6.1 Gender of respondents

The gender characteristics of respondents showed that the biggest percentage of respondents (67.1%) are males while the females are only 32.9%are presented in the figure 1 below

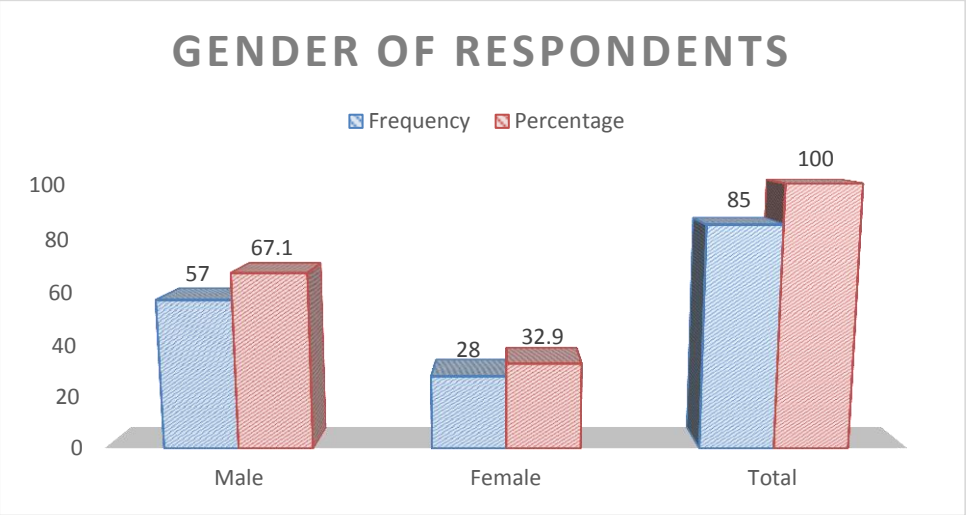

Figure 1: Gender of Respondents ***Source: Primary data***

3.6.2 Distribution of age of Respondents

Respondents were asked to indicate their age bracket and the age categories were then constructed on intervals of 10 years. Figure 2 below shows the distribution of age categories to which respondents belong with majority (68.2%) of employees aged between 20-29 years. This was followed by the age category of 30– 39 years (28.2%), 2.4% were aged 40- 49 years and only 1.2% were aged 50 years and above. Findings indicate that majority of respondents (68.2%) were at least 30 years of age, they were mature enough to understand and appreciate study.

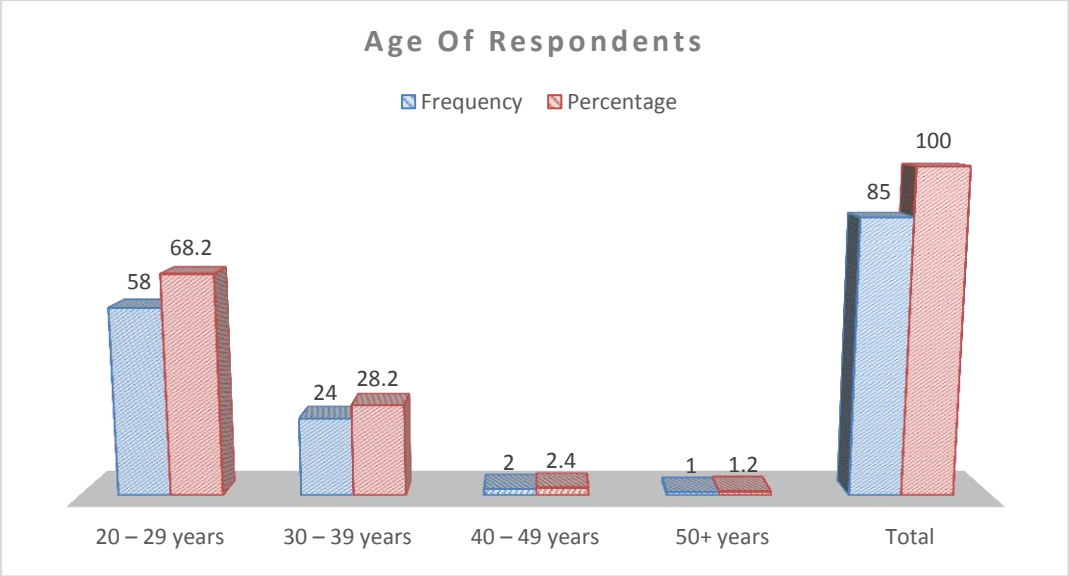

Figure 2: Age of respondents ***Source: Primary data***

3.6.3 Education background of respondents

Respondents were asked to indicate the level of education they have attained to-date. For this study, these were categorized as Post graduate, Graduate (Bachelors' degree holder) and Diploma. The categories were drawn as above with Diploma as the minimum level of education because the entity does not employ any one below Diploma level except casual workers who were not part of the study population.

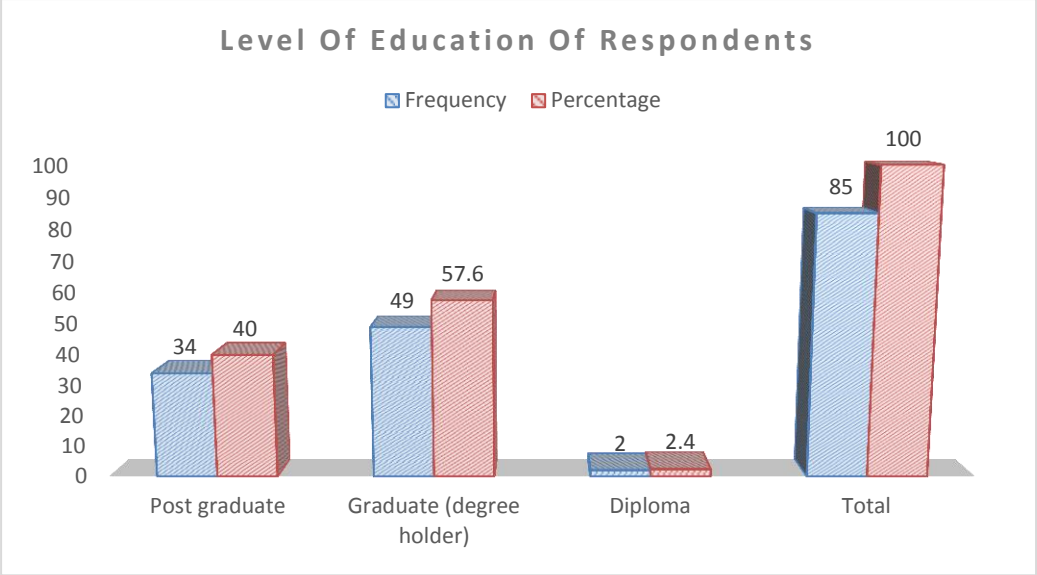

Figure 3: Level of education of respondents ***Source: Primary data***

Figure 3 above revealed that nearly 6 in every 10 NMS employees (57.6%) were graduates with only bachelor's degrees followed by those with post graduate qualifications (40.1%) while diploma holders accounted for only 2.4% amongst NMS employees interviewed. Basing on the above findings where all the respondents had a tertiary level certificate, the study was conducted on people who had enough cognitive capacity to tell what is required in the study, which implies that with regards to factors affecting quality of medicines, such people had enough capacity to understand what is taking place in NMS.

3.6.4 Length of Employee Service in NMS

Respondents were asked the number of years they had spent as employees at NMS. Results are presented in figure 4 below.

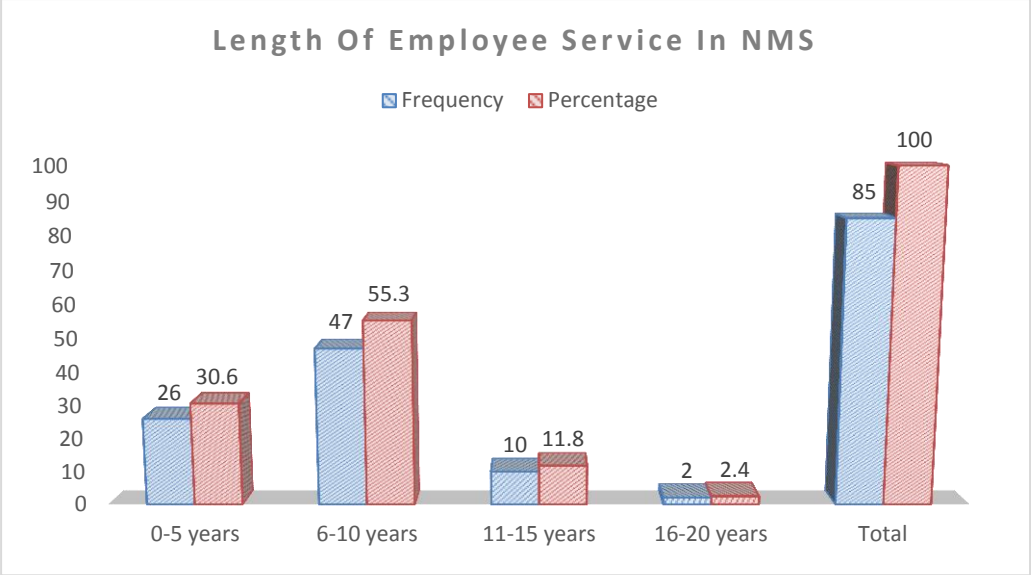

Figure 4: Length of Employee service in NMS ***Source: Primary data***

Figure 4 above indicates that majority (30.6%) of the current NMS employees interviewed had spent less than 5 years in the organization followed by 55.3% who had spent 6-10 years in NMS. Nearly 12% had spent 11-15 years and 2.4% had spent 16-20 years in the organization. No one amongst those interviewed had spent over 20 years in the organization

3.7 Data collection Methods and instruments

Both primary and secondary data was used. Three data collection instruments were used in collecting data. These include; a self-administered questionnaire, interview guide and document review checklist.

3.7.1 Self-administered Questionnaire

Quantitative data was collected using a self-administered questionnaire. A self-administered questionnaire was selected because it enables collection of data from a large number of respondents in a short time. In addition, a self-administered questionnaire gives the respondent more time to understand the meaning of the question, and retrieve and compose an answer, which improves the quality of answers. The questionnaire was simple, short, and structured enabling the respondents to fill it more easily(56). The questionnaire had two sections i.e. section (A) on background characteristics containing nominal questions and section (B) containing questions on the independent and dependent variables.

3.7.2 Interview Guide

Qualitative data was collected using an interview guide on a few respondents to explore their perspectives on the subject matter under inquiry. The interview guide helps to collect data that is exploratory in nature-by gathering more detailed information(57). The interview guide had open ended questions requiring detailed views from the respondents.

3.8 Quality Control of Instruments

3.8.1 Reliability

Reliability essentially looks for internal consistency within the instrument. When an instrument is reliable, it yields consistent responses because it is interpreted well. If the desired variable is not measured reliably, the information obtained would not be correct and therefore not be reliable. The questionnaire was pre-test on a sample of ten (10) respondents. Pre-test data from the pilot was entered in the Statistical Package for Social Sciences (SPSS version 22.0) and a Cronbach alpha coefficient test of reliability was calculated using the formula below;

Equation 1: Cronbach alpha coefficient test of reliability

$$\alpha = \frac{K}{K-1}\left(1 - \frac{\sum_{i=1}^{K}\sigma_{Y_i}^2}{\sigma_X^2}\right)$$

where σ_X^2 is the variance of the observed total item scores, and $\sigma_{Y_i}^2$ is the variance of component *i* for the pilot sample. The overall reliability was 0.827. Items which had a low Cronbach alpha value (<0.7) were rephrased for consistency and these that completely failed to achieve 0.7 were dropped. Only constructs whose items attained a reliability of more than 0.70 were retained. This is because a reliability of 0.70 or higher indicates internal consistency.

3.8.2 Validity

Validity refers to the extent to which a construct (an instrument/questionnaire) measures what it claims to measure(48). Therefore, the researcher ensured content related validity of the instruments for both the self-administered questionnaire and interview guide through consultations with the researcher's supervisors. The tools were given to the content experts who ranked the questions as 1=relevant and 2=Not relevant and this information was summarized using the Content Validity Index formula below.

$$\text{Content Validity Index (CVI)} = \frac{\text{Number of items declared valid}}{\text{Total number of items}}$$

The overall findings from content expert is summarized in the table below.

Table 2: Content validity index (CVI)

Expert	**Content validity index**	
	Questionnaire	**Key Informant Interview Tool**
Expert 1	0.81	0.79
Expert 2	0.84	0.82
Overall	**0.825**	**0.805**

Source: Primary data

3.9 Data Analysis

Data was analysed using a combination of quantitative and qualitative techniques.

3.9.1 Quantitative Analysis

Data was analysed using uni-variate, bivariate and multivariate levels of analysis as follows: data analysis for quantitative data involved uni-variate level analysis involving use of frequencies, percentages and descriptive statistics, in particular, the mean. This descriptive analysis provided description of the variables.

At bivariate level, Pearson's correlation coefficient was used to establish the association/ relationship between quality of medicines and each of the independent variables. A correlation coefficient with a p-value<0.05 at 95% level of confidence

indicated a statistically significant relationship between quality of medicines and the independent variables.

At multivariate level, a regression model was used to determine the magnitude of influence of each of the independent variables on the dependent variable, specifically quality of medicines.

3.8.2 Qualitative Analysis

The analysis for qualitative data will be done out through thematic and discursive methods. The discursive method will consider detail of the text, interpreting the analysed text and attributing meaning. On the other hand, thematic analysis will ensure that clusters of text with similar meaning are presented together(58). Qualitative data will supplement quantitative data and help in providing explanations. The technique here, was content analysis. Qualitative data supplemented quantitative data and helped in providing explanations.

3.9 Ethical Considerations

The proposal was first submitted to the Ethical Review Board for approval under reference SHS REF: 2019-057 after which the researcher then obtained a letter allowing her to proceed to the field. The researcher sought permission to collect data from the General Manager of NMS. The respondents were informed about the general nature of the study. They were assured of safety of the data, preserving confidentiality, objectivity, and truthfulness before giving their informed consent to participate in the study.

CHAPTER 4: ANALYSIS PRESENTATION AND INTERPRETATION OF FINDINGS

4.1 Introduction

This chapter presents findings of the study on factors affecting quality of medicines in public sector health supply chains in Uganda, taking a case study of National Medical Stores. In particular, the chapter presents the findings on how the established factors affected the quality of medicines in public sector health supply chains in Uganda if at all.

This study was guided by three specific objectives intended to establish the effect of procurement management, storage practices and pharmaceutical quality assurance on the quality of medicines being distributed to the public sector health facilities in Uganda. Proportions at each level of the Likert scale are also presented where 5 corresponds to Strongly Agree, 4 corresponds to Agree, 3 corresponds to Neutral, 2 corresponds to Disagree and 1 corresponds to Strongly Disagree. The next sections of this chapter presents statistical findings according to each objective.

4.2 Effect of Procurement Management on Quality of Medicines at National Medical Stores Uganda

The first objective explored procurement management key areas including; Medicines specifications, National and International medicines standards, documented procedures, tender evaluation, procurement systems, performance of suppliers, prequalification of suppliers and among others.

Table 3 below provides the proportions of responses at each level of the score as well as the mean score on the indicators of procurement management.

Table 3: Procurement Management Indicator Variables (n=85)

Procurement Management	Strongly Disagree		Disagree		Not Sure		Agree		Strongly Agree		Total		Mean
	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	
NMS generally uses up-to-date medicines specifications	0	0.0	2	2.4	0	0.0	15	17.6	68	80.0	85	100.0	4.75
NMS medicine specifications generally include detailed descriptions of medicines	0	0.0	12	14.1	20	23.5	43	50.6	10	11.8	85	100.0	3.60
NMS medicine specifications include national/ international quality standards	0	0.0	2	2.4	10	11.8	47	55.3	26	30.6	85	100.0	4.14
NMS medicine specifications form an essential component of contract	0	0.0	2	2.4	0	0.0	39	45.9	44	51.8	85	100.0	4.47
There is a documented procedure for changing medicine specifications	0	0.0	6	7.1	4	4.7	45	52.9	30	35.3	85	100.0	4.16
The tender evaluation process generally considers medicine quality as one of the evaluation criteria	2	2.4	4	4.7	2	2.4	39	45.9	38	44.7	85	100.0	4.34
The procurement system generally evaluates procurement samples when using new suppliers	0	0.0	4	4.7	6	7.1	45	52.9	30	35.3	85	100.0	4.19
Performance of selected suppliers regarding quality of medicines delivered by suppliers is continuously monitored	0	0.0	2	2.4	22	25.9	41	48.2	20	23.5	85	100.0	3.93
NMS generally ensures that prospective suppliers are prequalified based on capability to supply good quality medicines	6	7.1	12	14.1	4	4.7	31	36.5	32	37.6	85	100.0	3.84
NMS Procurement system mostly uses restricted tenders to solicit bids only from suppliers that have been prequalified for medicines supply	0	0.0	4	4.7	6	7.1	21	24.7	54	63.5	85	100.0	4.47

Source: Primary data

The findings in table 3 above show that NMS generally uses up-to-date medicines specifications with a cumulative percentage of about 97.6% (mean score=4.75). Respondents generally agreed that NMS medicine specifications generally include detailed descriptions of medicines (mean score=3.6) with a cumulative percentage of over 62.4%. The study findings further revealed that NMS medicine specifications include national/ international quality standards (cumulative percentage=85.9%, mean=4.14), NMS medicine specifications form an essential component of contract (cumulative percentage=97.4%, mean=4.47).

However, some respondents were not sure whether NMS has a documented procedure for changing medicine specifications (mean score =4.16), whether the performance of selected suppliers regarding quality of medicines delivered by suppliers is continuously monitored (mean score=3.93), and whether NMS procurement system mostly uses restricted tenders to solicit bids only from suppliers that have been prequalified for medicines supply (mean score =3.84). Generally, NMS procurement management is performing well to ensure that is positivity in quality of medicines as reflected in the overall mean score of about 4.08.

Table 4: Descriptive statistics on Procurement Management

Summary Statistics	**Value**
Sum	347.14
Mean	4.08
Minimum	3.00
Maximum	4.80
Std. Deviation	0.402
Skewness	-0.54
Kurtosis	0.04

Table 7 above gives a summary statistics of procurement management.

Source: Primary data

Findings above show that the total sum of all scores on procurement management was 347. The mean score was 4.08 which indicates that majority of NMS employees agree and perceive that the key areas under procurement management have an effect on quality of medicines. The standard deviation was almost negligible (SD=0.402) which

meant that respondent's views on this aspect did not vary so much from the mean score. Results therefore indicate that NMS management is relatively performing well in terms of procurement management to ensure quality of medicines.

Interviews with key informants also confirmed the above findings. However, some of the key informants looked at other procurement management attributes, which also affect quality of medicines including; strict monitoring of suppliers after contract award especially in the later stages of product delivery to the central warehouse, the procurement principle of lowest bidder, minimized political interference, establishing systems for post distribution surveillance among others. In a verbatim by one manager, who stated that, "*It is key and important especially in a government procurement system to procure medicines from prequalified suppliers. However, some of these things are beyond us as managers, for example, if some of the items are special to some specific conditions and you can only find one supplier in the country and in such circumstances, quality may be compromised because of the urgency and need"*. This means that in the process of managing procurement of medicines, NMS has well aligned procedures which also concurred with the overall mean score from respondents. However, this may not be in totality a guarantee to all medicines procured and stored at NMS.

4.3 Effect of Storage of Medicines Practices on Quality of Medicines at National Medical Stores, Uganda

The second objective explored storage of medicines under the following key indicators; Stores and operations procedure manual, training of warehouse personnel, observing of high level hygiene, space in the warehouse, temperature monitoring humidity limits recalling of medicines among others. Table 5 below provides the proportions of responses at each level of the score as well as the mean score on all indicators of storage of medicines.

Table 5: Storage of Medicines Management Practices (n=85)

Storage of Medicines	Strongly Disagree		Disagree		Not Sure		Agree		Strongly Agree		Total		Mean
	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	
NMS has a Stores & Operations procedure Manual with established written procedures	4	4.7	0	0	6	7.1	49	57.6	26	30.6	85	100.0	4.09
Warehouse personnel generally receive training in relation to medicine storage procedures	0	0	0	0	4	4.7	51	60.0	30	35.3	85	100.0	4.31
Warehouse staff generally observe high levels of personal hygiene	0	0	0	0	8	9.4	47	55.3	30	35.3	85	100.0	4.26
Medicines are generally stored off the warehouse floor	0	0	0	0	10	11.8	39	45.9	36	42.4	85	100.0	4.31
Storage areas are always kept clean, dry and free from accumulated waste and vermin	1	1.2	1	1.2	33	38.8	30	35.3	20	23.5	85	100.0	3.81
Storage areas are maintained within acceptable temperature limits	0	0	4	4.7	4	4.7	47	55.3	30	35.3	85	100.0	4.21
Storage areas are maintained within acceptable humidity limits	0	0	0	0	14	16.5	35	41.2	36	42.4	85	100.0	4.26
The clean-up of any spillage in the warehouse generally adheres to cleaning SOPs	0	0	6	7.1	28	32.9	33	38.8	18	21.2	85	100.0	3.74
There are precautions taken to prevent unauthorized persons from entering medicines storage areas	0	0	2	2.4	8	9.4	45	52.9	30	35.3	85	100.0	4.21
Rejected or recalled medicines are	6	7.1	6	7.1	21	24.7	31	36.5	21	24.7	85	100.0	3.65

Storage of Medicines	Strongly Disagree		Disagree		Not Sure		Agree		Strongly Agree		Total		Mean
	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	
generally quarantined to prevent their use													

Source: Primary data

The study sought to find out whether NMS has a Stores & Operations procedure Manual with established written procedures. To this end, cumulatively 88.2% were in agreement with this (mean score=4.09). Most respondents (60%) agree that Warehouse personnel generally receive training in relation to medicine storage procedures and 35.3% strongly agree with this statement with an overall mean score of about 4.31. Other noticeable areas where respondents agreed that storage practices affect medicines quality under storage of medicines include; Warehouse staff generally observe high levels of personal hygiene (cumulative percentage=90.6%, mean=4.26), Medicines are generally stored off the warehouse floor (cumulative percentage=88.3%, mean=4.31) among others.

However, the study further revealed that most respondents remained neutral on rejected or recalled medicines being generally quarantined to prevent their use (mean score=3.65).

Generally, all scores tend towards a mean score of 4 (agree) which indicates that NMS management is performing well across nearly all indicators of storage of medicines, which would otherwise, affect quality of medicines.

Table 6 below gives a summary statistics of storage of medicines.

Table 6: Descriptive statistics on Storage of Medicines (n=85)

Summary Statistic	Value
Sum	355.9
Mean	4.2
Minimum	2.6
Maximum	5.0
Std. Deviation	0.5
Skewness	-0.7
Kurtosis	0.5

Source: Primary data

Findings above show that the total sum of all scores on customer service management was 355.9 and the mean response was 4.2 which indicated that majority of NMS employees agree that there is an effect of storage practices on the quality of medicines. The standard deviation was almost negligible (SD=0.5) and this means that there was a small variation in the responses on storage of medicines. Results therefore indicate that NMS management is relatively performing well in storage management of medicines to positively influence quality of medicines.

Qualitative information on the other hand also explored other storage attributes which should be looked at so as to ensure quality of medicines during storage namely; Quality measures too should also focus on temperature and humidity monitoring and dust protection. The key information reiterates that, "*If quality is medicines chemical integrity being preserved in the condition that meets NDA, WHO and NMS standards, then storage does have a bearing. Extreme temperatures may compromise the chemistry of the medicines and so would humidity". Another key informant believes that storage of medicines affect quality of medicines through poor labeling, lack of use of First Expiry First Out principle, batching among others*".

Generally, 90% of the responses on the effect of storage of medicines on quality of medicines including key informants, highlighted temperature monitoring and humidity as the other major thematic area of storage practices which affect quality of medicines.

4.4 Effect of Pharmaceutical Quality assurance on Quality of Medicines at National Medical Stores, Uganda

The third objective explored pharmaceutical quality assurance of medicines under the following key indicators; Quality assurance manual, inspection of all incoming shipments, expiry of medicines, quality control medicines, quality documentation verification complaints management and documentation of medicines recalled from health facilities.

Table 7 below provides the proportions of responses at each level of the score as well as the mean score on all indicators of Pharmaceutical Quality Assurance.

Table 7: Pharmaceutical Quality assurance of Medicines (n=85)

Quality Assurance of Medicines	Strongly Disagree		Disagree		Not Sure		Agree		Strongly Agree		Total		Mean
	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	
NMS has a Quality Assurance Manual with documented written procedures	0	0.0	0	0.0	6	7.1	29	34.1	50	58.8	85	100	4.52
QA staff generally inspect all incoming medicine shipments on receipt to verify that they meet the specifications	0	0.0	0	0.0	6	7.1	35	41.2	44	51.8	85	100	4.45
Medicines that are found not to meet required specifications are rejected	0	0.0	0	0.0	10	11.8	43	50.6	32	37.6	85	100	4.26
Expired medicines are generally destroyed to prevent unauthorized use	0	0.0	4	4.7	8	9.4	29	34.1	44	51.8	85	100	4.33
NMS generally performs quality control testing of suspicious medicines received	14	16.5	14	16.5	24	28.2	25	29.4	8	9.4	85	100	2.99
NMS has access to quality control lab with equipment to test samples of delivered medicines/ suspect medicine medicines	22	25.9	16	18.8	29	34.1	12	14.1	6	7.1	85	100	2.58
Medicine quality documentation verification such as certificates of analysis is generally done	0	0.0	6	7.1	15	17.6	32	37.6	32	37.6	85	100	4.06
NMS has a complaints monitoring system for reporting customer medicine quality complaints	0	0.0	2	2.4	14	16.5	45	52.9	24	28.2	85	100	4.07
NMS customer reported complaints are generally carefully assessed, investigated and appropriate corrective action taken	0	0.0	4	4.7	8	9.4	47	55.3	26	30.6	85	100	4.12
There is a documented procedure for medicines recall from health facilities in case of defective medicines	4	4.7	6	7.1	16	18.8	41	48.2	18	21.2	85	100	3.74

Source: Primary data

The study sought to find out whether NMS has a Quality Assurance Manual with documented written procedures. 92.9% cumulatively agreed with this statement (mean score=4.52). Respondents also agreed that quality assurance staff generally

inspect all incoming medicine shipments on receipt to verify that they meet the specifications (cumulatively percentage=93.0%, mean score=4.5) and that Medicines that are found not to meet required specifications are rejected (cumulatively percentage=88.2%, mean score=4.26). Also, respondents agreed that NMS customer reported complaints are generally carefully assessed, investigated and appropriate corrective action taken (cumulatively percentage=85.9%, mean score=4.12). On whether NMS has access to quality control lab with equipment to test samples of delivered medicines/ suspect medicines and NMS generally performs quality control testing of suspicious medicines received. Respondents disagreed on this with mean scores of 2.99 and 2.55 respectively.

Table 8 below gives a summary statistics of pharmaceutical quality assurance.

Table 8: Descriptive statistics on Pharmaceutical Quality Assurance (n=85)

Summary Statistic	**Value**
Sum	341.1
Mean	4.0
Minimum	3.0
Maximum	5.0
Std. Deviation	0.51
Skewness	-0.04
Kurtosis	-0.72

Source: Primary data

Findings above show that the total sum of all scores on Pharmaceutical Quality Assurance was 341.1. The mean response was 4.0 which indicates that majority of NMS employees agree that there is existence of effective Pharmaceutical Quality Assurance at NMS. The standard deviation was almost negligible (SD=0.51) and this means that there was a small variation in the responses on Pharmaceutical Quality Assurance. Results therefore indicate that NMS management is performing well in terms of pharmaceutical quality assurance which positively lead to quality of medicines being distributed to health facilities.

Almost all key informants also emphasized the effect of quality assurance on the quality of medicines with some suggesting that NMS should do quality control on every product so as to ensure quality of medicines. One of the key informants states that, "*Quality assurance ensures that all medicines are tested on each batch number*

being brought into the stores of NMS, any batch that does not match the specifications is rejected and with such an approach the best quality is accepted in the stores."

Quality of Medicines

Finally the study also explored employee perception about Quality of medicine. The study investigated areas such as procurement of good quality medicines, complaints on the quality of medicines, product rejections at facility level and recalling of medicines due to quality issues.

Table 9 below provides the proportions of responses at each level of the score as well as the mean score on all indicators of quality of medicines.

Table 9: Quality of Medicines (n=85)

Quality Medicines	Strongly Disagree		Disagree		Not Sure		Agree		Strongly Agree		Total		Mean
	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	
NMS procures medicines which are of good quality	0	0.0	2	2.4	18	21.2	41	48.2	24	28.2	85	100.0	4.02
NMS views quality as very important to its customers	0	0.0			14	16.5	35	41.2	36	42.4	85	100.0	4.26
NMS often receives complaints from customers about poor quality medicines	2	2.4	22	25.9	24	28.2	23	27.1	14	16.5	85	100.0	3.29
Medicines delivered to health facilities from NMS are often rejected due to poor quality	12	14.1	35	41.2	22	25.9	12	14.1	4	4.7	85	100.0	2.54
Delivered medicines are often	7	8.2	38	44.7	18	21.2	16	18.8	6	7.1	85	100.0	2.72

Quality Medicines	Strongly Disagree		Disagree		Not Sure		Agree		Strongly Agree		Total		Mean
	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	
recalled from health facilities due to quality problems													

Source: Primary data

Findings above show that whereas respondents agree that NMS procures medicines which are of good quality (cumulatively percentage=76.4%, mean score=4.02) and that NMS views quality as very important to its customers (cumulatively percentage=83.6%, mean score=4.26), they also disagreed that NMS often receives complaints from customers about poor quality medicines, Medicines delivered to health facilities from NMS are often rejected due to poor quality and also that delivered medicines are often recalled from health facilities due to quality problems.

Table 10: Descriptive statistics on Quality of Medicines (n=85)

Summary Statistic	Value
Sum	286.2
Mean	3.4
Minimum	2.6
Maximum	5.0
Std. Deviation	0.58
Skewness	1.3
Kurtosis	0.7

Source: Primary data

Findings above shows that the total sum of all scores on customer demand was 286.2. The mean response was 3.4 which indicated that majority of respondents were not sure and therefore remained neutral about the quality of medicines at NMS. The standard deviation was almost negligible (SD=0.58) and this means that there was a small variation in the responses on customer service management from the me.an score. Results therefore indicate that NMS management must work hard to improve on the quality of medicines in the warehouse.

4.5 Statistics

4.5.1 Effect of Independent Variables on Quality of Medicines

The study also sought to understand the statistical association of procurement management, storage of medicines, and pharmaceutical quality assurance on quality of medicines at NMS. A bivariate analysis was used to establish the correlation coefficient and the strength of this association. Results are summarized in table 11 below

Table 11: Bivariate Relationship between Independent Variables and Quality of Medicines (n=85)

		Storage of Medicines	Pharmaceutical Quality Assurance	Procurement Management	**Quality of Medicines**
Storage of medicines	Pearson Correlation	***1.000***	***0.714****	***0.667****	***0.196***
	Sig. (2-tailed)		0.000	0.000	0.073
Pharmaceutical Quality Assurance	Pearson Correlation	***0.714****	***1.000***	***0.692****	***0.232****
	Sig. (2-tailed)	0		0.000	0.032
Procurement management	Pearson Correlation	***0.667****	***0.692****	***1.000***	***0.228****
	Sig. (2-tailed)	0.000	0.000		0.036
Quality of medicines	Pearson Correlation	***0.196***	***0.232****	***0.228****	***1.000***
	Sig. (2-tailed)	0.073	0.032	0.036	
**. Correlation is significant at the 0.01 level (2-tailed).					
*. Correlation is significant at the 0.05 level (2-tailed).					

Findings above shows that procurement management (r=0.228, p-value=0.036) and Pharmaceutical quality assurance of medicines (r=0.232, p-value=0.032) have a statistically significant positive relationship with quality of medicines. This therefore, means that any positive improvements in procurement management and pharmaceutical quality assurance of medicines will induce better quality of medicines. The study further revealed that storage of medicines has a slight relationship on quality of medicines (r=0.196, p-value=0.073, >0.05), but this relationship is not statistically significant at 95% level of confidence and therefore, therefore there may be need to maintain storage conditions at NMS warehouse, but any improvements made may not much affect quality of medicines.

4.5.2 Effect of Procurement Management, Storage of Medicines and Pharmaceutical Quality Assurance on Quality of Medicines at NMS

Correlation analysis was run as exploratory analysis before further analysis in regression models so as to avoid spurious results under regression coefficients. Results from a multiple regression model are presented in table 12 below.

Table 92: The Effect of Procurement Management, Pharmaceutical Quality Assurance and Storage of Medicines on Quality of Medicines at NMS

Model Summary						
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate		
1	.250[a]	0.063	0.04	0.57285		
a. Predictors: (Constant), Procurement management, Pharmaceutical Quality Assurance						
Coefficients						
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	1.948	.641		3.038	.003
	Pharmaceutical Quality Assurance	.163	.169	.143	.965	.037
	Procurement management	.188	.215	.129	.873	.049
a. Dependent Variable: Quality of medicines						

Findings in the regression model summarized in table 12 above indicate that the independent variables jointly explained only 4% of the variance in quality of medicines (Adjusted R Square= 0.04) and hence almost 96% of the variation in the dependent variable is explained by error. When all explanatory variables are equal to zero the average performance of NMS on quality of medicines is 1.948. Any unit increase in Pharmaceutical Quality Assurance increases quality of medicines by 0.163 and this relationship is statistically significant at 95% level of confidence (P-value=0.037). Any unit increase in procurement management increase the quality of medicines by 0.188 and this relationship is statistically significant at 95% level of confidence (P-value=0.049). The results generally imply that firstly, there are some other factors which affect quality of medicines which were not captured in this study and that is the reason for the low adjusted R-squared. Secondly, in order to improve quality of medicines considering the variables which were covered in the study, NMS has to improve on Pharmaceutical Quality Assurance and procurement management as these are key at influencing quality of medicines.

CHAPTER 5: DISCUSSION OF THE FINDINGS

5.1 Introduction

This chapter presents the discussion of the findings on the factors affecting quality of medicines at NMS.

5.2 Procurement management and quality of medicines

The study findings revealed that procurement management has a positive significant relationship on quality of medicines in public sector health supply chains in Uganda. This finding concurs with other scholars who had earlier asserted that the procurement practices in Tanzania and South Africa were the focus on improving quality i.e. through procurement policy by restricting national tenders to suppliers with registered products in the respective countries (36).

Factors contributing to poor-quality medicines include absence of good operational principles of pharmaceutical procurement, limited technical capability of staff, inappropriate selection, lack of timely, accurate and accessible information and poor budgeting and financing which negatively affects health service delivery (32). In this study, the above factors were implied in areas such as use of up-to-date medicines specifications, following national and international quality standards, tender evaluation process generally considering medicine quality as one of the evaluation criteria, and prequalification based on capability to supply good quality medicines, and were significantly highlighted in this study as factors, which if managed well, may lead to good quality of medicines. The other areas of procurement management which were not unearthed by this research but has been explained in others researches as one of the elements which affect quality of medicines is weak regulatory oversight, insufficient human/financial resources, weak negotiating power, and lack of institutional commitment to quality (37).

Generally, NMS has procurement management systems in place to induce quality as revealed in the indicators of procurement management, these should just be improved to contribute considerably to the development of more robust evaluation techniques at NMS for monitoring of quality of medicines right from procurement through the entire supply chain.

5.3 Storage of medicines and the quality of medicines.

The study findings revealed that storage of medicines has a no effect on quality of medicines in public sector health supply chains in Uganda. This finding, however, contradicts other researches which have been conducted on storage of medicines and its impact on their quality. In a study on quality of medicines in Southern Togo, findings revealed that inappropriate storage conditions may have been an important cause of substandard quality medicines(59). Another researcher who assessed the quality of anti-malarial medicines in five counties in Liberia, observed that 79% of collected samples failed due to poor storage of medicines and unregistered medicines(41).

This observation suggests that there may still be storage challenges at NMS which may need to be addressed so that quality of medicines is enhanced.

5.4 Pharmaceutical quality assurance and quality of medicines

The study findings revealed that pharmaceutical quality assurance has a positive significant relationship on quality of medicines in public sector health supply chains in Uganda. This resonates with other scholars who found that strengthening the quality assurance systems of pharmaceutical distributors supplying LMICs was important in assuring the quality of medicines supplied(43). The finding also concurs with Amin et al. (2007) to the extent that high quality standards and strengthening quality assurance systems such as post marketing surveillance are important in ensuring that medicines retain their integrity throughout the supply chain(44).

Therefore findings suggest that improvements in areas of pharmaceutical quality assurance will improve on the quality of medicines in the public sector health supply chain in Uganda.

CHAPTER 6: SUMMARY, CONCLUSION AND RECOMMENDATIONS

6.1 Introduction

The study investigated the effect of procurement management, storage of medicines and pharmaceutical quality assurance on quality of medicines, taking a case of National Medical Stores. This chapter presents the summary of the findings, draws conclusions and recommendations.

6.2 Summary

6.2.1 Procurement management and quality of medicines

The study established a positive significant relationship between procurement management and quality of medicines in public sector health supply chains in Uganda. The finding implies that improving procurement management will reciprocate in ensuring good quality of medicines in public sector health supply chains in Uganda.

6.2.2 Storage of Medicines and quality of medicines

The study established that storage of medicines had no significant effect on quality of medicines in public sector health supply chains in Uganda. The finding implies that there may not be any effect of improving storage practices on further enhancing the quality of medicines in public sector health supply chains in Uganda.

6.2.3 Pharmaceutical Quality Assurance and quality of medicines

The study established a positive significant relationship between pharmaceutical Quality Assurance and quality of medicines in Uganda. The finding implies that improving pharmaceutical quality assurance practices will enhance quality of medicines in public sector health supply chains Uganda.

6.3 Conclusions

This study set out to examine factors affecting quality of medicines at NMS, Uganda. Based on results and discussion with the null hypothesis that the predictor variables do not have an effect on quality of medicines at NMS, the following conclusions were made:

The study revealed that there is a statistically significant positive relationship between procurement management and quality of medicines at NMS with attributes such as medicine specifications forming an essential component of contract, procurement system generally evaluating procurement samples when using new suppliers, tender evaluation process and sourcing based on capability to supply good quality medicines being key in driving this positive effect. Also the study further revealed a positive statistically significant effect of pharmaceutical quality assurance on quality of medicines with factors such as quality assurance manual, inspection of all incoming shipments, and expiry of medicines being key in driving the this positive effect. The study further revealed that storage of medicines was not significant at influencing the quality of medicines at NMS.

6.4 Recommendations

In view of the findings, the researcher recommends the following:
NMS should establish a quality control laboratory for testing the quality of medicines before distributing them to health facilities as this will help in avoiding recall and rejection of medicines in health facilities due to quality standards.

NMS should maintain robust procurement systems such that areas such as evaluation of procurement samples, tender evaluation process and sourcing based on capability to supply good quality medicines are well managed to reduce on the risk of compromising quality during procurement of medicines

NMS may need to improve on any remaining challenges facing storage practices especially temperature monitoring, humidity and dust in the warehouse as were revealed as some of the key areas under storage which do affect quality of medicines.

6.5 Areas for further research

The researcher suggests the following areas for further research:

- This study should be replicated in other parallel agencies serving Private Not for Profit (PNFPs) and Private for Profit (PFPS) health facilities such as Joint Medical Stores and Medical Access Uganda Limited (MAUL). With adequate funding it may be carried out as a comparative study between government run agencies and competing agencies in the private sector

- Future studies with adequate funding should also extend the coverage of this research to also evaluate quality of medicines at service delivery points especially on the perception of receiving quality medicines.
- Future studies should also carry out pharmaceutical quality testing against pharmacopoeial testing standards to analyze medicines samples obtained from the selected study site in order to investigate medicines quality.

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Appendix 1: Table for Determining Sample Size from a Given Population

N	*S*	*N*	*S*	*N*	*S*
10	10	220	140	1200	291
15	14	230	144	1300	297
20	19	240	148	1400	302
25	24	250	152	1500	306
30	28	260	155	1600	310
35	32	270	159	1700	313
40	36	280	162	1800	317
45	40	290	165	1900	320
50	44	300	169	2000	322
55	48	320	175	2200	327
60	52	340	181	2400	331
65	56	360	186	2600	335
70	59	380	191	2800	338
75	63	400	198	3000	341
80	66	420	201	3500	346
85	70	440	205	4000	351
90	73	460	210	4500	354
95	76	480	214	5000	357
100	80	500	217	6000	361
110	86	550	226	7000	364
120	92	600	234	8000	367
130	97	650	242	9000	368
140	103	700	248	10000	370
150	108	750	254	15000	375
160	113	800	260	20000	377
170	118	850	265	30000	379
180	123	900	269	40000	380
190	127	950	274	50000	381
200	132	1000	278	75000	382
210	136	1100	285	100000	384

Note: N = population size

S = sample size Source: Krejcie and Morgan (1970).

Appendix 2: Self-Administered Questionnaire

SELF ADMINISTERED QUESTIONNAIRE

Dear respondent,

My name is Sheilah C. Nabukeera, a Masters student at University of Rwanda. I will be conducting a study to establish the factors affecting quality of medicines in public health supply chains in Uganda. The major aim of this study is to secure the quality of medicines within the health commodity supply chain. You are one of the respondents selected to participate in this study. I assure you that the responses you give will not in any way be used against you and guarantee that all information provided is purely for academic purposes, and will be handled with utmost confidentiality.

Thanking you for your cooperation & time.

Signed: Sheilah Catherine Nabukeera

Student of University of Rwanda

SECTION A: BACKGROUND INFORMATION (Please tick in the box with the most suitable answer)

1. Gender of the respondent.
    1) Male ☐
    2) Female ☐
2. Age of the respondent
    1) 20 – 29 years ☐
    2) 30 – 39 years ☐
    3) 40 – 49 years ☐
    4) 50 years and above ☐
3. What is your level of education?
    1) Post graduate (Masters, PhD, etc.) ☐
    2) Bachelor's Degree ☐
    3) Diploma ☐
    4) Certificate (secondary education) ☐
    5) Other ☐
4. I belong to this department of NMS.
    1) Procurement and Disposal ☐
    2) Stores and operations ☐

3) Client services ☐

4) Quality Assurance & Quality Control ☐

5) Internal Audit ☐

5. I have worked in NMS for these number of years.

i) 0-5 years ☐

ii) 6-10 years ☐

iii) 11-15 years ☐

iv) 16-20 years ☐

v) Over 20 years ☐

SECTION B: DETERMINANTS OF MEDICINES QUALITY AT NATIONAL MEDICAL STORES

1. On a scale of 1-5, Select the extent to which you agree with the following statements

Scale	**1**	**2**	**3**	**4**	**5**
Response	**Strongly Disagree**	**Disagree**	**Not sure**	**Agree**	**Strongly Agree**

Procurement Management **Tick the appropriate box**

Statement		Strongly disagree	Disagree	Not Sure	Agree	Strongly agree
1	NMS generally uses up-to-date medicines specifications					
2	NMS medicine specifications generally include detailed descriptions of medicines					
3	NMS medicine specifications include national/ international quality standards					
4	NMS medicine specifications form an essential component of contract					
5	There is a documented procedure for changing medicine specifications					
6	The tender evaluation process generally considers medicine quality as one of the evaluation criteria					
7	The procurement system generally evaluates					

	procurement samples when using new suppliers					
8	Performance of selected suppliers regarding quality of medicines delivered by suppliers is continuously monitored					
9	NMS generally ensures that prospective suppliers are prequalified based on capability to supply good quality medicines					
10	NMS Procurement system mostly uses restricted tenders to solicit bids only from suppliers that have been prequalified for medicines supply					

In your opinion, how does procurement management affect the quality of medicines in NMS?.....

……

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……

……

……

……

Storage of Medicines		Strongly disagree	Disagree	Not Sure	Agree	Strongly agree
1	NMS has a Stores & Operations procedure Manual with established written procedures					
2	Warehouse personnel generally receive training in relation to medicine storage procedures					
3	Warehouse staff generally observe high levels of personal hygiene					
4	Medicines are generally stored off					

	the warehouse floor					
5	Medicines are suitably spaced to permit cleaning and inspection.					
5	Storage areas are always kept clean, dry and free from accumulated waste and vermin					
6	Storage areas are maintained within acceptable temperature limits					
7	Storage areas are maintained within acceptable humidity limits					
8	The clean-up of any spillage in the warehouse generally adheres to cleaning SOPs					
9	There are precautions taken to prevent unauthorized persons from entering medicines storage areas					
10	Rejected or recalled medicines are generally quarantined to prevent their use					

In your opinion, how does storage of medicines affect the quality of medicines in NMS?

……

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……

	Pharmaceutical Quality Assurance	Strongly disagree	Disagree	Not Sure	Agree	Strongly agree
1	NMS has a Quality Assurance Manual with documented written procedures					
2	QA staff generally inspect all incoming medicine shipments on receipt to verify that they meet the specifications					
3	Medicines that are found not to meet required specifications are rejected					
4	Expired medicines are generally destroyed to prevent unauthorized use					
5	NMS generally performs quality control testing of suspicious medicines received					
6	NMS has access to quality control lab with equipment to test samples of delivered medicines/ suspect medicine medicines					
7	Medicine quality documentation verification such as certificates of analysis is generally done					
8	NMS has a complaints monitoring system for reporting customer medicine quality complaints					
9	NMS customer reported complaints are generally carefully assessed, investigated and appropriate corrective action taken					
10	There is a documented procedure for medicines recall from health facilities in case of defective medicines					

In your opinion, how does Quality Assurance of Medicines affect the quality of medicine in NMS?

……

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……

SECTION C: QUALITY OF MEDICINES IN THE PUBLIC SECTOR SUPPLY CHAIN

Quality of Medicines		**Strongly Disagree**	**Disagree**	**Not sure**	**Agree**	**Strongly Agree**
1	NMS procures medicines which are of good quality					
2	NMS views quality as very important to its customers					
3	NMS often receives complaints from customers about poor quality medicines					
4	Medicines delivered to health facilities from NMS are often rejected due to poor quality					
5	Delivered medicines are often recalled from health facilities due to quality problems					

Appendix 3: Key Informant interview Guide

1 Would you please describe your role in NMS?

2 How is product quality achieved during pharmaceutical procurement?

3 How does NMS monitor the quality of supplies received from suppliers?

4 In your opinion, which products are prone to quality defects and why so?

5 What forms of product defects are commonly observed/ reported in NMS?

6 How are reports of non-conforming product handled in NMS?

7 What measures does NMS take while carrying out pharmaceutical quality assurance in order to ensure product quality in the NMS medicines supply chain?

8 What challenges does NMS encounter in maintaining quality of medicines during drug supply?

Appendix 4: Informed consent template

INFORMED CONSENT TEMPLATE FOR RESEARCH PARTICIPANTS AGED 18 YEARS AND ABOVE

Title of the proposed study:

Factors affecting medicines quality in National Medical Stores, Entebbe Uganda.

Study sponsor: Self-Sponsored

Background and rationale for the study:

Counterfeit or substandard (poor quality) drugs pose major threats to society; not only to the individual in terms of the health side effects experienced, but also to the public in terms of trade relations, economic implications, and the effects on global pandemics(60).

Falsified and substandard drugs increase costs to patients and health systems, they also decrease productivity. Society must bear the cost of treatment failure and increasing anti-microbial resistance, new drug development, an expense that increases as drugs become more complex. Ultimately, poor quality medicines undermine confidence in the health system and in all public institutions(60). Therefore, it necessary to establish the critical factors affecting medicines quality at National Medical Stores, Uganda.

Purpose:

The purpose of the study is to examine the factors affecting quality of medicines in National Medical Stores, Entebbe Uganda.

Procedures:

Participants will take part in key informant interviews and questionnaire surveys.

Who will participate in the study and where the study is going to be conducted from?

The study will be conducted in NMS, Uganda and the participants are as follows:

Category	**Sample size**
NMS Top Management	8
NMS Procurement Department	14
Stores and Operations Department	80
Quality Assurance Department	5
Sales and Marketing Department	24
Internal Audit department	6

Total 137

Risks/Discomforts:

Apart from engaging you for a short amount of time, you may also experience some minimal discomfort when answering some of the questions which may or may not be of a sensitive nature.

Benefits:

There are several anticipated benefits include addition to the body of knowledge regarding factors affecting the quality of medicines which will inform planning and decision making in NMS. This study may shed light on how to improve medicines quality and generate information necessary for policy makers on matters regarding the best practical ways to strengthen procurement, storage and distribution of medicines, pharmaceutical quality assurance and the quality of medicines in the health sector in Uganda. This study will also provide a basis for further research especially for studies.

Alternatives:

Please be informed that participation in the study is not mandatory.

Cost:

All possible costs encountered in the study will be met by the principal researcher.

Compensation for participation in the study:

There will be no compensation or re-imbursement for participants involved in the study because all participants are employees of National Medical Stores and will be targeted from their work stations for a short duration of time, with the authorization of the employer. The time at the place of work is therefore waived and thus no compensation/ reimbursement will be offered.

Reimbursement:

There will be no compensation or re-imbursement for participants involved in the study because all participants are employees of National Medical Stores and will be targeted from their work stations for a short duration of time, with the authorization of the employer. The time at the place of work is therefore waived and thus no compensation/ reimbursement will be offered.

Questions:

In case of any questions, concerning the research, you may call the principal investigator Sheilah Catherine Nabukeera +256772-438777

Questions about participants rights:

In case of any further questions regarding participant welfare and rights, do not hesitate to contact the following Dr. Paul Kutyabami, Chairperson of the School of Health Sciences Ethical Review Board on -+256 772404970 or +256 0200903786)

Research involving the collection of human materials/samples

Not applicable to this research.

Feedback on study findings and progress of the study

Research participants will get feedback on the findings and progress of the study through a study report that will be submitted to management, highlighting the findings and/or recommendations once the study is complete.

Statement of voluntariness:

Participation in the proposed study is voluntary and participants may join on their own free will. Participants also have a right to withdraw from the study at any time without penalty.

Approval of the research study

The study has been approved by Makerere University School of Health Sciences Research and Ethics Committee /IRB)

Confidentiality

The results of this study will be kept strictly confidential, and used only for research purposes. My identity will be concealed in as far as the law allows. My name will not appear anywhere on the coded forms with the information. Paper and computer records will be kept under lock and key and with password protection respectively.

The interviewer has discussed this information with me and offered to answer my questions. For any further questions, I may contact the Chairperson of the School of Health Sciences Research and Ethics Committee (MakSHSREC) on (+256) 772-404970 / (+256) 0200903786 / or Uganda National Council of Sciences and Technology. Tel: (+256)-041-4705500).

STATEMENT OF CONSENT

..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at any time. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name…….Signature/thumbprint of participant ……..Age..……
Date (DD/MM/YY)……

(Witness for illiterate and mentally incapacitated or physically handicapped participants should be provided below)

Name of Witness …….. Signature of Witness……
Date (DD/MM/YY)…….

Name……..Signature of Interviewer ……. Date (DD/MM/YY)……...

Appendix 5: Ethical Review Board Approval letter

MAKERERE UNIVERSITY
P.O. Box 7072 Kampala, Uganda
E-mail: healthsciences.irb@gmail.com
deanshs@chs.mak.ac.ug
Tel: 256 0200903786
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COLLEGE OF HEALTH SCIENCES
SCHOOL OF HEALTH SCIENCES
OFFICE OF THE DEAN

September 03rd, 2019

Ms. Sheila Catherine Nabukeera
University of Rwanda
Rwanda

Category of review
[X] Initial review
[ ] Continuing review
[ ] Amendment
[ ] Termination of study
[ ] SAEs

Dear Ms. Nabukeera,

Re: Approval of research protocol #SHSREC REF: 2019-057
"Factors Affecting Medicine Quality in Public Sector Health Supply Chains in Uganda: A Case study of National Medical Stores, Entebbe"

Thank you for submitting an application for ethical review of the above referenced research protocol. The committee reviewed it and granted approval for **one (1) year**, effective **September 03rd, 2019.** Approval is valid until **September 02th, 2020.**

Continuing Review
In order to continue working on this study (including data analysis) beyond the expiration date, the School of Health Sciences Research and Ethics Committee must reapprove the protocol after conducting a substantive, meaningful, continuing review.
This means that you must submit a continuing report form as a request for continuing review. To best avoid a lapse, you should submit the request six (6) to eight (8) weeks before the lapse date. Please use the forms supplied by our office.

Amendment Review
During the approval period, if you propose any change to the protocol such as its funding source, recruiting materials, or consent documents, you must seek School of Health Sciences Research and Ethics Committee approval before implementing it.
Please summarize the proposed change and the rationale for it in a letter to the School of Health Sciences Research and Ethics Committee. In addition, submit two (2) copies of an updated version of your original protocol application- one showing all proposed changes in bold or 'track changes,' and the other without bold or track changes.

Reporting
Other events which must be reported promptly in writing to the School of Health Sciences Research and Ethics Committee include:
Suspension or termination of the protocol by you or the grantor. Unexpected problems involving risk to participants or others

Adverse events, including unanticipated or anticipated but severe physical harm to participants.

Monitoring audit of research study activities
As per the Uganda National Guidelines for Research Involving Humans as Research Participants, Section 3.5, The Research and Ethics Committee has a duty to ensure that all research studies it approves are conducted in accordance with the research governance code of practice. In order to ensure compliance with scientific and ethical requirements, the School of Health Sciences Research and Ethics Committee undertakes random monitoring audits. If your research study is selected for monitoring audit, you will be given three (3) week's notice to prepare all documentation for inspection, Therefore, expect the monitoring team at your study site anytime.

It is your responsibility to inform us in the event of early termination of the research project or if you fail to complete the research project.

Documents approved for use along with the research protocol include:

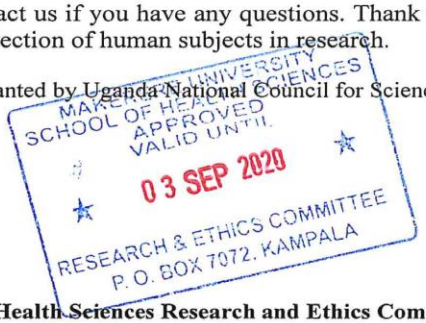
- Informed consent form for research participants (English version)
- Questionnaire (English version)
- Key informant interview guide

Note: Only stamped informed consent form and data collection forms should be used for data collection. Any data collected using unstamped forms will be considered invalid.

Do not hesitate to contact us if you have any questions. Thank you for your cooperation and commitment to the protection of human subjects in research.

Final approval is to be granted by Uganda National Council for Science and Technology.

Yours sincerely,



Dr. Paul Kutyabami
Chairperson, School of Health Sciences Research and Ethics Committee
College of Health Sciences, Makerere University