ORGANIZATIONAL PRACTICES INFLUENCING AVAILABILITY OF ESSENTIAL MEDICINES AT HOSPITALS IN NAIROBI COUNTY

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DECLARATION

This study is my original	work and has not been presen	nted for award of a degree in this or any
other University. All reso	urces contained herein have b	been duly acknowledged.
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DEDICATION

This project is dedicated to my parents, and my sister Lillian for their endless love, support and encouragement throughout my study period.

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ABBREVIATIONS/ACRONYMNS

ACT Artemisinin Combination Therapy

AIDS Acquired Immune Deficiency Syndrome

ART Anti-Retroviral Therapy

EML Essential Medicines List

HAI Health Action International

HIV Human Immunodeficiency Virus

ICT Information Communication Technology

KEMSA Kenya Medical Supplies Agency

LMICs Low and Middle Income Countries

MDG Millennium Development Goal

NCDs Non-Communicable Diseases

SARAM Service Availability and Readiness Assessment Mapping

SDG Sustainable Development Goals

UN United Nations

WHO World Health Organization

DEFINITION OF OPERATIONAL TERMS

Availability

The association between the category and quantity of medicines or pharmaceutical services needed, and the category and quantity of medicines or pharmaceutical services provided.

Access

Access is defined as having medicines continuously available at health facilities in acceptable quantities, appropriate dosage and with assured quality for consumption by the population when needed.

Essential (basic) medicines

Essential medicines are those that address the priority health care needs of the population. They are intended to be easily accessible and affordable.

Essential Medicines List (EDL)

A list of most efficacious and affordable medicines prioritized as treatment choices for health care needs of majority population. The list ensures consistent and uninterrupted supply of effective medicines in a health care system.

Financing

The act of raising or providing funds, allocating the funds based on budget estimates and payment for purchase of medicines.

Forecasting

The process of approximating future consumption needs/demand of medicines based on past consumption, service provision reports, morbidity and/or demographic data or assumptions.

Inventory control

Inventory control is a function of inventory management concerned with issuance and use of commodities and application of information generated for stock management.

Lead time

The time interval needed to complete the procurement cycle. It entails the time between stock ordering and stock reception and availability for use.

Organizational practices

Refer to procedures, techniques, processes, or rules used in an organization or a profession; a set of which are considered as standard.

Pharmaceutical Management Information System (PMIS)

Refers to all activities related to data collection, processing and presentation of information that helps staff at all levels of a country's health system make evidence-based decisions to manage pharmaceutical services.

Procurement

Activities and processes involved in acquisition of goods and services. Procurement involves selection, quantification, supplier selection, purchase and distribution of goods and services.

Public hospital

Herein also referred to as 'organization'. Refers to a hospital owned by the government and receives government funding. Such facilities provide medical care free of charge or at subsidized rates, the cost of which is covered by the funding the hospital receives.

Quality

Quality reflects the extent to which a healthcare service or product produces a desired outcome to its intended consumers. It includes aspects such as effectiveness, efficiency, equity and safety.

Quantification

Quantification, a function of procurement process, refers to approximation of quantities of commodities needed based on available funds.

Safety stock

Herein also referred to as buffer stock. Refers to an amount of stock that is kept in reserve, calculated as the average amount required to cover a lead time period to prevent stock-outs arising from abrupt supply or demand fluctuations.

Supply chain

This refers to institutions, individuals, technology, processes, and information that are involved in transfer of pharmaceutical commodities from manufacturers to customers.

ABSTRACT

Background

Sub-optimal access to affordable essential medicines in developing countries is mainly attributable to poor availability of these medicines, mainly in the public health sector. Easy access to prescribed medicines is routinely cited by healthcare consumers as the most important measure of quality of care, the absence of which contributes significantly to the under-utilization of public health services. This study determined the organizational practices that influence supply and hence availability of essential medicines at public hospitals in Nairobi County.

Methods

A cross-sectional survey was conducted in three County referral hospitals in Nairobi City. Hospitals were selected purposively based on a multi-level variation approach. Consenting staff in pharmacy and procurement departments were recruited for participation. Information on availability of essential medicines, procurement, inventory management and management of pharmaceutical information was collected using structured interviewer- administered questionnaires and abstraction tools. Univariate data analysis was done using Microsoft Excel ® 2010 and STATA®14. Bivariate analysis for statistical correlation was also undertaken.

Results

The proportion of medicines dispensed in full to patients at the three hospitals was 42.22 %, 48.88% and 46.66% (Mean-46%; SD-0.2%) respectively. The median availability and stock-out duration for a cluster of five tracer medicines was 75.34% (Range: 0-98%) and 90 days respectively. Almost half of all orders were not exclusive to EMLs or formulary lists. The order frequency was significantly associated with supply lead times (p=0.036). Prescribers, suppliers and end-users were not involved in quantification of medicines. Lead time for hospital based orders was shorter (1-14 days) compared to purchases by the county government (2-3 months). Procurement was principally done in an open and competitive manner though direct purchases were done as well. Insufficient and delayed funding was significantly associated with delays in the procurement process (p=0.033). Refresher training of front-line staff on procurement

procedures was uncommon. Management of inventory and pharmaceutical information were predominantly done manually.

Conclusion

County referral hospitals failed to provide all prescribed medicines to a majority of its clients due to stock-shortages. One or more commodities were lacking in stock at any given time. For a cluster of five essential medicines; the median availability was marginally low whereas the stock-out duration was significantly high. Varied pharmaceutical procurement practices were established many of which were suboptimal compared to the WHO recommended practices.

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CHAPTER ONE

Essential medicines refer to medicines that address the priority health care needs of the population based on public health relevance, evidence on efficacy and safety and cost-effectiveness (WHO, 2015). Hospitals and other dispensing entities must ensure that such medicines are made available at all times, in adequate amounts, in the appropriate dosage forms and with assured quality. In this chapter, background information of the study, concept of essential medicines list and availability of medicines are discussed.

1.1 Background of the study

Availability of essential medicines in healthcare facilities, particularly hospitals, is vital in promotion of curative health of the population and in ensuring healthcare outcomes and goals are met. This requires effective financing, procurement and inventory management systems; supported by timely and accurate pharmaceutical information for evidence-based decision making.

The Kenya National Pharmaceutical Policy's (KNPP) stated goal is provision to all Kenyans of efficient, effective pharmaceutical services that are sustainable, equitable, accessible and affordable with safe, efficacious and quality essential medicines, which are appropriately used (MoMs, 2008). This national goal resonates with the United Nation's Sustainable Development Goal (SDG) 3, Target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all. The attainment of this SDG target would also contribute to the attainment of other targets under this goal mainly: improve maternal, neonatal and child health, combat both communicable and non-communicable diseases including TB, HIV/AIDS and malaria (UN, 2015)

There have been improvements in Kenya's pharmaceutical industry in recent years; however frequent medicines stock outs are common in Kenya's public health sector (UNIDO, 2010). Poor availability of medicines at facility level has been attributed to inappropriate selection, poor distribution, inadequate funding and irrational use. (Mwathi, 2014). Additionally conclusive local and regional data on sustainable access to affordable essential medicines are lacking. (UN, 2015)

1.2 Essential medicines List (EML)

The WHO recommends the essential medicines list as a list of minimum medicine needs for the basic health-care system. Such medicines are the most potent and cost-effective with a favourable safety profile.

EMLs facilitate equal access to medicines across different countries. The WHO, Universal Declaration of Human Rights (United Nations, 2015) and the Millennium Development Goals' targets (United Nations, 2008), highly advocate for world-wide enactment and periodic updates of national EMLs to ensure acceptable availability of essential medicines, especially in low and middle income economies. EMLs exist in 134 countries, where 94% use them for prioritisation of procurement of medicines in public sector for the poor (van den Ham R, 2011) However, the existence of EML does not directly translate to availability of prioritised medicines in health care facilities.

The Kenya Essential Medicines List 2010 and associated clinical guidelines were developed to replace the Kenya National Drug List 2003 and Clinical Guidelines 2002 (MoMS & MoPHS, 2010). Together, they comprised important pillars in the elaboration of the Kenya Essential Package for Health (KEPH) and the National Health Sector Strategic Plan (NHSSP II: 2005-2010). The EML and treatment guidelines are published to guide and standardize healthcare delivery. They are regularly reviewed to promote evidence based practice, and to enhance cost-effectiveness in healthcare.

1.3 Availability of essential medicines

The WHO in its medium-term strategic plan recommended 80% availability of medicines in all sectors (WHO, 2011). However, studies in subsequent years have shown poor availability of medicines in low and middle income countries (LMICs). Availability of 15 essential medicines in 36 developing countries was undertaken (Cameron A E. M.-D., 2009). Generic medicines were sub-optimally present in both the public and private sectors (median availability 38% and 64%, respectively). However, significant differences were noted in public and private sectors. A health facility survey on essential medicines in Kenya's public, faith based and private sectors established that; a majority of essential medicines for common ailments at primary care level were available and fairly affordable to citizens. However, stock outs for medicines including

essential medicines for priority health needs were significantly reported at hospital levels (MoMs & MoPHS, 2009). This was attributable to a number of factors including: irrational prescription, inadequate storage infrastructure, and an acute shortage of qualified pharmaceutical staff to manage medicines supply, dispensing and use.

Availability of essential medicines is routinely cited by healthcare consumers as the most important measure of quality of care, the absence of which contributes significantly to the underutilization of public health services. The Kenya Service Availability and Readiness Assessment Mapping (SARAM) 2013 established generally availability of health commodities for primary care services in most health facilities. The mean availability of general tracer medicines in Nairobi County was 34% (national mean=49%). Notably and of concern were essential medicines for Non-Communicable Diseases, maternal health services and child health which were generally not available. The report recommended the need to prioritise financial resources by aligning quantification of the health products at health facilities with disease burden, and decentralization of procurement to lower levels to increase coverage and access to services. It also recommended the need to operationalize an information management system for pharmaceutical supplies to improve efficiency (MoH, 2013)

This study determined organizational practices that influence the availability of essential medicines at Public Hospitals. The results are expected to influence effective operational management of the pharmaceutical system particularly the procurement and inventory management units at County referral facilities. Managers will be able to better plan and monitor activities related to procurement and inventory management of essential medicines; critical steps in enhancing availability and hence clinical care outcomes.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter introduces studies that have been undertaken on essential drugs including those on: variability in the availability, management of the procurement system, financial sustainability for essential medicines, capacity of supply chains and pharmaceutical information systems. Variability in the availability of essential medicines exists across geographical regions, therapeutic groups of medicines, sampling criteria, and number of medicines studied. These and other context specific factors have made generalization of such results impossible. The studies involve surveys of medicines at various levels of healthcare using the WHO/HAI Medicine Price Methodology framework (HAI/WHO, 2008).

2.2 Variability in availability of essential medicines

The WHO recommended at least 80% availability of medicines across health systems. Nevertheless, studies have reported sub-optimal availability in developing Countries. For instance, a study in 36 LMICs on availability of 15 medicines in the public and private sectors established that overall generic medicines were not adequately available in both the public and private sectors with median availability of 38% and 64%, respectively (Cameron A E. M.-D., 2009).

Similarly, systematic analysis of WHO/HAI surveys on drug price and availability established differences in the availability of medicines for chronic and acute diseases in the public and private sectors of developing countries for originator and generic brands of medicines. In the public sector, the mean availability of generic medicines was low for both baskets (acute conditions=53.5% and for chronic conditions=36%). In the private sector, the mean availability of generics in each basket was higher than in the public sector (66.2% for generics for acute conditions and 54.7% for generics for chronic conditions), but it was still low (Cameron A R. I.-T., 2011). Inadequate funding for medicines; inaccurate need forecasting at facility level and weak procurement and inventory management systems were identified as factors for the suboptimal availability.

A few studies have however reported favourable medicines' situation. For instance a study in 36 public health facilities in Sudan established that averagely 82% of the basic medicines were

available in the facilities whereas 85% of the medicines prescribed by the clinician were dispensed to the patients. Adherence by prescribers to standard treatment guidelines in management of uncomplicated diarrhea and diarrhea was found to be 45% and 64%, respectively (Cheraghali, 2009). A similar study in Burkina Faso measured the availability, affordability and management of essential medicines in public hospitals. The average rate of availability of 50 basic medications was 77.69% (Saouadogo H, 2011).

None of the above surveys concentrated solely on essential medicines. A few studies have however explored the availability of medicines included in national EMLs.

The availability, cost and inclusion of children's medicines in essential medicines lists and standard treatment guidelines were assessed in 14 countries of the WHO African Region. It was found that the availability of key essential medicines for children was poor. District hospitals had marginally better availability (range: 10–80%) than teaching hospitals, while primary health care clinics generally had poorer availability (range: 18–48%) (Jane Robertson, 2009). Poor availability was associated with low understanding of the demand patterns and supply systems for medicines in the countries studied.

Availability of commonly prescribed medicines (antibiotics, analgesics, antihypertensive, emergency drugs and pediatric formulations) in Kenya's public hospitals remains sub-optimal with frequent stock outs reported. A study on public hospitals in Nakuru County established that a majority of the essential medicines were stocked out averagely for a period of one month for 3 classes of the drugs. Most out of stock days were reported for; analgesics (91%), antibiotics (75%) and anti-diabetic drugs (56%). Identifiable factors for the unavailability included: inadequate funding by national government, irrational selection of medicines and disregard of EMLs by procurement staff, extended lead times and irrational medicine use by prescribers (Mwathi, 2014). A related pharmaceutical survey across facilities revealed higher stock out rates in Kenya's rural than urban facilities (87% of rural health facilities experienced at least one stock out occurrence 3 months prior to the study). Kenya had the highest antimalarial stock out rate compared to Ghana and Uganda (7% of facilities compared to 2% in Ghana). Amoxicillin stock out was equally highest in Kenya(21% compared to Ghana's 5%). The study also established a significant association between having a laboratory and reduced essential medicines stock outs, owing to rational treatment of confirmed cases only (Masters, 2014).

2.3 Management of the procurement system

Pharmaceutical procurement is a complex and multi-phasic process routinely involving many actors. The main goals of an effective procurement process include: purchase of the most cost effective medicines of acceptable quality, the selection of reliable suppliers, availability of effective distribution systems for timely deliveries, and minimization of overall costs. Procurement is guided by national and institutional laws, protocols, and structures that collectively may impede or facilitate the overall process (WHO, 1999). In Kenya the process is guided by the Public Procurement and Disposal Act (2006) (Kenya Law Reports, 2010). Successful hospital procurement is a collaborative process, involving staff with skills in purchasing, finance, management, clinical and nursing specialties, pharmacy, quality control, and even the end user: the patient. Procurement ensures timely and effective delivery of medicines to patients as ensuring hospital, clinical, and pharmacy goals are met. In defining the role of a pharmacist in procurement, Karr (Karr, 2004) underscores the need for additional knowledge and skills in planning, management and law besides pharmacy. Other pharmaceutical tasks identified in related global surveys in hospital settings include purchasing and being involved in formulary decisions. However the surveys reported severe shortage of pharmacists in Kenya's public and private sectors that deter effective service delivery (FIP, 2009)

2.3.1 Selection and quantification of medicines

Procurement of pharmaceutical supplies ought to be guided by drug selection. The selection and quantification team identifies the drugs to be purchased through evidence-based decision making. The process of drug selection is also routinely facilitated by the availability of a national essential medicines list (MoMS & MoPHS, 2010) or more-specific drug formulary lists. Selection and quantification are principally undertaken by pharmacists. However there is emerging need to ensure procurement matches demand by harmonization of medicine quantification with prescribing habits and preferences of consumers. This can be achieved through the involvement of prescribers in selection and quantification, and by use of surveys of consumer tastes and preferences to determine suitable dosage forms (Josephine, 2010).

Quantification of medicines is usually based on consumption patterns; however, morbidity patterns are used as well. Recommended by W.H.O as the most precise method, consumption based approach requires complete, accurate and properly adjusted data sources. However the

method does not address suitability of past consumption patterns, which may or may not match public health priorities and needs. Morbidly based approach is most complex and time consuming and is chiefly dependent on availability of valid morbidity data (MSH, 2012).

2.3.2 Financing for medicines

Successful procurement is tied on availability on adequate financial resources. Drug-financing may involve: government financing, pre-payment through insurance, donor financing, and out of pocket expenditure. In Kenya, 69.4% of household health-related out of pocket purchases were expended on outpatient care (WHO, 2011). According to the 2009/10 Kenya National Health Accounts, 3% of total health expenditure was spent on pharmaceuticals. When hospitals fail to procure enough medicines, patients either forfeit treatment altogether or buy medicines from private chemists at higher prices. (Mecca, 2014) demonstrated a change in stock out rate at Webuye district hospital (falling from 21.75% in 2010/11 to 19.47% in 2012/13) after introduction of the national health insurance scheme. This resulted from higher allocation for the 'user fees' and increase in actual expenditure on essential medicines.

2.3.3 Inventory management

The increase in healthcare costs has necessitated a rise in demand for quality care amongst health service providers. By increasing the efficiency of supply chain, healthcare cost savings could be realised (Kim, 2004). The American Production and Inventory Control Society (APICS) (Cox, 1998) defines inventory management as the branch of business management concerned with planning and controlling inventories.

Effective inventory management ensures determination of precise order quantities without subjecting the organization to unnecessary costs associated with overstock or under stock. Many challenges have been reported in handling hospital pharmacy including: influence by strong institutional and regulatory laws, operational limitations in demand forecasting due to variable consumption patterns and inaccurate data sources and the need to maintain adequate safety stock to cope with uncertainty demand, which results in high inventory holding costs.

In a study by (Bunde, 2007) on essential medicines supply chain, poor availability of reports to perform forecasting, quantification and procurement planning in Kenya was identified as a major challenge. Consequently patients experience treatment discontinuations and complications due to recurrent stock-outs (Pasquet, 2010). Related findings were reported by (Oballah, 2015).

Additionally, adequately trained staffs are an essential resource in ensuring proper inventory management. A study by (Waako, 2009) established that trainings on HIV/AIDS mainly emphasized clinical management with few programs having included pharmaceutical supply management in their training. This contributed significantly to the competence gap amongst staff in management of supplies. These findings were replicated in the service availability and readiness assessment report where only 8 staffs in Nairobi County had undergone short term training on procurement/supply management in the year preceding their study (MoH, 2013)

2.3.4 Management of pharmaceutical information

Staff at all levels of care relevant, need timely and accurate information to make rational decisions regarding planning, demand forecasting, and resource allocation for pharmaceutical services. These decisions influence the uninterrupted availability of essential medicines. However available information is often insufficient, incorrect, and untimely, which undermines its value and helpfulness (Luoma, 2010).

An assessment of the Logistics system in Kenya reported the existence of only incomplete data upon which planning and procurement for health products was being conducted (Bunde, 2007). An assessment of HIV/AIDs and malaria programs established limited use of collected data for effective decision making due to incompleteness and untimeliness (Owunna & Whitt, 2007). Additionally, private facilities had more complete medicines records than public health facilities. In a related study of anti-malarial management records Machini et.al reported 20% decline in the updating of records between 2010 and 2012, whereas completion of summary reports declined by 8.8% during the same period (Machini, 2013)

2.4 Problem statement

The quality of a public health care system is routinely evaluated by the patients, chiefly on the basis of the presence of adequate human resource for health and availability of quality essential medicines (WHO, 2004). Availability of essential medicines in healthcare facilities, particularly hospitals, is vital in promotion of curative health of the population and in ensuring healthcare outcomes and goals are met (MoMs, 2008). Essential medicines are supposed to be available in health facilities in adequate amounts, at appropriate dosage forms, assured quality and at affordable prices for use by the population. Availability is dependent on existence of a functional

pharmaceutical system that is characterized by: rational use and selection of essential medicines, sustainable financing, affordable prices and reliable health supply systems.

Nearly half of Nairobi residents are slum dwellers who principally rely on public health hospitals which are considered affordable. However, lack of availability of essential medicines in such facilities delays treatment thereby complicating outcome of diseases. This negatively affects access to health services. In Kenya health sector funding relies heavily on out -of -pocket payments due to underfunding and regressive health care contributions (Chuma and Okungu, 2011).

The public supply chain is prone to interruptions and stock-outs due to weaknesses in the distribution system and general poor performance of the supply chain. Stock-outs inevitably affect clinical outcomes since patients would miss medicines when needed (MoMs & MoPHS, 2009).

It is therefore imperative to understand practices that influence availability of essential medicines in key public hospitals, particularly: procurement practices in use, inventory management and management of pharmaceutical information.

2.5 Purpose of the study

2.5.1 Main objective

To determine organizational practices influencing availability of essential medicines at public hospitals in Nairobi County.

2.5.2 Specific objectives

- i. To assess the availability of essential medicines at public hospitals in Nairobi County.
- ii. To investigate whether recommended procurement practices of essential medicines in the public hospitals are adhered to.
- iii. To determine inventory management practices used in management of essential medicines in public hospitals.
- To determine practices used in management of pharmaceutical information at public hospitals in Nairobi County

2.6 Research question

i. How do prevailing pharmaceutical procurement practices influence availability of essential medicines at public hospitals in Nairobi County?

2.6 Conceptual Framework

Availability of essential medicines is reliant on effective interaction of the procurement and inventory management systems. These processes are cyclical in nature and mutually interdependent. Accurate and timely information has to be shared amongst all the involved stakeholders to facilitate evidence-based decision making.

Selection and quantification of medicines are supposed to be guided by essential medicines lists or formulary lists. All stakeholders are supposed to be engaged in such forums. Periodic reviews of quantities needed ought to be undertaken, so that supplies can be adjusted accordingly.

Procurement Selection and quantification Essential medicines list/ formulary lists Pharmaceutical Management Competitive procurement Information System (PMIS) Effective financial ■ ICT use Availability of management System inter-operability essential Written procedures Informed decision making medicines Separation of key functions Transparency **Inventory Management** Stock monitoring Continuous staff education

Figure 1: Conceptual Framework

Forecasted budgets should be reviewed accordingly based on available funds. The order frequency should be minimized through bulk purchase; this enables institutions to take advantage of economies of scale.

Supply of medicines should follow laid down contractual laws and regulations so as to reduce system complexity, promote transparency and reduce lead time. Once supplies are delivered, it

is important to have an efficient inventory management system that tracks stock movement, reduces losses and notifies the managers when to restock.

Having skilled staff at all these levels is important. Continuous education of staff should be emphasized. In order to promote effectiveness and improve efficiency automation of the systems using ICT ought to be undertaken.

2.7 Significance of the study

Availability of essential medicines is routinely cited by healthcare consumers as the most important measure of quality of care, the absence of which contributes significantly to the under-utilization of public health services. This study sought to establish availability of essential medicines and determine whether recommended procurement practices were being adhered to. It also sought to identify practices used in inventory management and management of pharmaceutical information at public hospitals.

The findings will influence effective operational management of the pharmaceutical system particularly the procurement and inventory management units. Managers will be able to better plan and monitor activities related to procurement and inventory management of essential medicines; critical steps in enhancing availability and hence health care outcomes. Ultimately quality of health care is expected to improve as is utilization of public facilities by health care clients.

CHAPTER THREE: METHODOLOGY

3.1 Introduction

This chapter details the methods of data collection, analysis and presentation that were used in this study. It focuses on the methodology and steps that were taken to enhance validity and

reliability of the data.

3.2 Study Design

A cross-sectional survey was done between 25th August and 15th September 2015 to determine organizational practices that influence availability of essential medicines at public hospitals in

Nairobi County.

3.3 Study area

The study was conducted in Nairobi County which is the Kenya's capital city. The county occupies 695.1 square kilometres and is located in the Southern central part of the country at an altitude of 1798 meters above sea level. The county's projected population in 2015 was 3,942,705 with an inter-censual growth rate of 3.8 per cent (KNBS, 2013). The County has 9 sub-counties, a national referral hospital, 16 sub-County hospitals, 9 faith-based, 32 private,

15 nursing homes, 83 health centres 30 dispensaries, and 106 clinics (NCC, 2014).

3.4 Study population

The target population were pharmaceutical and procurement staff in the sampled public hospitals.

3.6 Sampling

3.6.1 Sampling approach

Selection of hospitals and hence staff expected to participate in the study was done purposively using a multi-level maximum variation sampling strategy (Anca Vitcu, 2007).

3.6.2 Sample size

Stage 1: Sampling of health facilities

Nairobi County has eight (8) public hospitals owned by National government (3), County government (3), Prisons Department (1) and Department of Defence (1). County hospitals

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(representing 33% of all hospitals) were purposively selected for inclusion as primary study sites considering: their functional capacity as County referral facilities (Level 4) for primary care facilities and community units in Nairobi and beyond, being run as devolved units in Nairobi County (their scope of operation was thus comparable), ease of access (penetration) and existence of lean and functional procurement and pharmacy departments. This enabled easier and quicker data collection.

Stage 2: Sampling of respondents

Sample stratification was undertaken based on:

- a) The department where the staffs are based i.e. Pharmacy and Procurement.
- b) The position they hold in the department i.e. management staff, operational staff or support staff. Key informants comprised of management staff.

Pre-survey data on staff establishment in the respective hospitals was obtained; as shown in the table below:

	Hospital			Total
	CRH 1	CRH 2	CRH 3	
Pharmacy	11	11	3	25
Procurement	4	3	9	16
Total	15	14	12	41

All procurement and pharmaceutical staff on duty during the duration of the study were considered for the study. The pharmacist-in-charge and the head of procurement in each hospital were considered as key informants for being overall coordinators of respective departments. In total 33 respondents were interviewed (Response rate of 80.48%).

3.7 Inclusion/Exclusion criteria

The inclusion criteria were all County referral hospitals within Nairobi County with operational procurement and pharmacy departments.

The exclusion criteria were national referral hospitals and hospitals classified as 'other' such as military and prison hospitals considering their operational complexity.

Other hospital staffs besides those involved in budgeting, procurement and inventory management of essential medicines were excluded from the study.

3.8 Variables

3.8.1 Dependent Variable

Availability of Essential Medicines, as measured by the following indicators:

- a) Proportion of medicines dispensed in full.
- b) Median availability of five tracer medicines at public hospitals.

Ca	tegory of tracer commodity	No. of tracer commodities	Name of tracer commodity
i.	Essential medicines for children	1	Amoxicillin suspension 125mg/5ml
ii.	Essential medicines for children	1	Artemether/Lumefantrine(120/60 mg) 6' pack
iii.	Essential medicines for children	1	Paracetamol suspension 120mg/5ml
iv.	Maternal health	1	Ferrous salt tablets(alone or with folic acid)
v.	Non-communicable diseases	1	Nifedipine retard tablets 20mg

3.8.2 Independent variables

- a) Procurement practices: quantification, adherence to policy guidelines and written procedures, order frequency, financial management and tendering process.
- b) Pharmaceutical information system: information communication/reporting, uptake of Information Communication Technology, integration with other systems.
- c) Inventory control: stock monitoring and staff competency.

3.9 Data collection

3.9.1 Data collection tools

Data was collected using pre-tested structured questionnaires, key informant guides and observation checklists. These were adopted from UNHCR (Drug Management Manual 2006) and MSH (Managing access to Medicines and Health Technologies). Pre-testing of the questionnaires for validity was undertaken at Mutuini Sub-county hospital. The hospital was comparable to the county referral facilities for it had an established pharmaceutical department and a partially functional procurement unit. Five pharmaceutical and procurement staffs were identified for participation. Appropriate revision of the tools was done thereafter.

A data abstraction tool was used to collect quantitative data on availability of essential medicines from each hospital. Pre-coded, structured questionnaires were used to collect primary data and information on quantification, ordering, procurement and inventory management of essential

medicines. Check lists were used in validation of key observations during the study. These were incorporated in the questionnaire for easier collection of data.

3.9.2 Data collection technique

Approval of the study proposal was granted by the KNH/UON Ethics and Research Committee on 31St July 2015 vide letter Ref: KNH-ERC/A/335. The principal investigator (PI) thereafter sought relevant research authorisation from Nairobi's department of county health services and the respective hospitals (Appendix 7&8). Two Bachelor of Science Nursing (BSN) graduates who had prior experience and knowledge of the study area were recruited as research assistants to assist in data collection. They were trained by the PI on: aims and objectives of the study, data collection tools, ethical consideration and data collection skills. They also participated in pre-test and revision of the data collection tools.

Data collection was conducted between 25th August and 15th September 2015. After brief introduction by the researchers, the consent form was read out to the respondents. Only those who consented in writing (Appendix 1) were allowed to participate in the study. Interviews were conducted at the respective work desks of the respondents. The PI particularly conducted interviews for the heads of pharmacy and procurement departments being key informants. Significant observations such as availability of policy documents at hospitals were recorded on checklists that had been incorporated in the interview guide.

Abstraction of data on availability of essential medicines was done retrospectively using records found at the pharmacy stores. Copies of medicines prescriptions for patients who had sought care at the outpatient department were retrieved and documented. Stock cards (bin-cards) for a basket of five pre-determined medicines were retrieved and the number of 'out-of-stock' days for each documented. Completeness and timeliness of data were verified at end of each data collection exercise.

3.10 Data analysis

Triangulation of data sources was used to enhance validity of the findings. All questionnaires, checklists and abstraction tools were collected after each visit. These were cross checked for completeness and relevance. Quantitative data was analysed using Microsoft Excel ® 2010 and analysed using STATA®14. Univariate as well as bivariate analysis was undertaken. Correlations between key variables were tested for statistical significance using Fisher's exact

test (p=0.05). Descriptive statistics are presented as frequencies, proportions and median. Key informant interview notes were analysed by identification of recurring themes.

3.11 Ethical consideration

- a) Permission from all relevant authorities (County Health Services and Hospital Medical Superintendents) was sought before conducting the study.
 Ethical clearance was sought from the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee. All provisions of the study were strictly adhered to.
- b) Confidentiality and anonymity of the respondents were upheld throughout the research process including at analysis and dissemination phase. Individual names were avoided and participation was voluntary.

CHAPTER FOUR: RESULTS AND INTERPRETATION

4.1 Introduction

This chapter focuses on the findings of this research. The data is summarized into tables and figures of frequencies and percentages. The results are organized based on: general demographic characteristics of the study participants, availability of essential medicines at hospitals, procurement and inventory management practices and management of pharmaceutical information.

4.2 Demographic characteristics of the respondents

A total of 33 respondents drawn from three hospitals participated in the study, response rate of 80.47%. Approximately (57.58%, n=19) females and (42.42%, n=14) males participated possibly reflecting the staffing characteristics of the departments by gender. The mean years of experience for the respondents were 3 with a standard deviation of 1.5 years. Pharmacy department had slightly more respondents (51.52%, n=17) than the procurement department (48.48%, n=16). These demographic characteristics are summarized in table 1 below.

Table 1: Demographic characteristics of respondents

Characteristics	Frequency	Percentage (%)	
Respondents per County Referral Hospital (CRH)			
CRH 1	12	36.33	
CRH 2	10	30.30	
CRH 3	11	33.33	
Gender			
Male	14	42.42	
Female	19	57.58	
Department			
Pharmacy	17	51.52	
Procurement	16	48.48	
Position in Department			
Head	6	18.18	
Deputy	5	15.15	
Operational staff	12	36.36	
Clerk	4	12.12	
Intern	6	18.18	
Years of experience			
<1	5	15.15	
1-2	8	24.24	
3-4	10	30.3	
5-6	6	18.18	
7-8	1	3.03	
9-10	2	6.06	
>10	1	3.03	
Education qualification			
Certificate	2	6.06	
Diploma	12	36.36	
Bachelors	16	48.48	
Masters	3	9.09	

4.3 Availability of essential medicines

4.3.1 Proportion of medicines dispensed or administered

The extent to which hospitals were able to provide prescribed medicines was measured, and the proportion of prescribed medicines actually dispensed or administered in full determined (Figure 2). The data was abstracted retrospectively based on filed copies of prescriptions for a random sample of 30 outpatient encounters at each of the surveyed hospitals. This was done for 3 different days. Of 90 prescriptions sampled at each County Referral Hospital(CRH); 42.22 %

(n=38), 48.88% (n=44) and 46.66% (n=42) had their contents dispensed in full at CRH 1, CRH 2 and CRH 3 respectively. Overall the mean fill rate was 46% (Standard deviation= 0.20%)

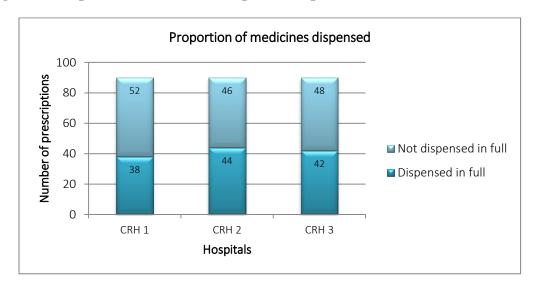


Figure 2: Proportion of medicines dispensed to patients

4.3.2 Availability of essential medicines

The percentage availability of a cluster of five essential medicines was determined in each hospital (Figure 3). The five included: amoxicillin suspension, paracetamol syrup and Artemether/Lumefantrine 6' pack (pediatric medicines), ferrous/folate salt tablets (maternal health medicine) and nifedipine retard tablets (general medicine). The number of stock-in days for each of the 5 medicines was determined over the review period (365 days). Bin cards at respective hospital stores were used for this purpose. The median availability of the five selected essential medicines was determined as 75.34 %.(Range: 0-98%)

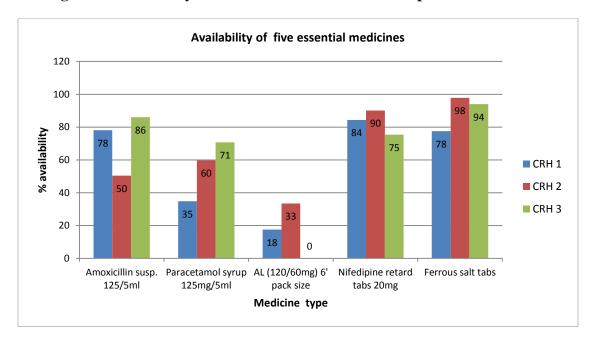


Figure 3: Availability of five essential medicines in hospitals

4.4 Procurement of essential medicines

All the hospitals surveyed had copies of the Public Procurement and Disposal Act (2006), hospital clinical guidelines, medicines and therapeutics committees and EMLs. Variations in procurement practices were nevertheless noted some being deviation from recommended practice. This has been explained below:

4.4.1 Selection and quantification of medicines

Of all the respondents, 45.45% (n=15) were involved in selection and quantification process whereas 54.45% (n=18) were not involved. Selection and quantification of medicines has been summarized in table 2 below. The selection and quantification teams were composed of mainly pharmacy and procurement staff (Figure 4).

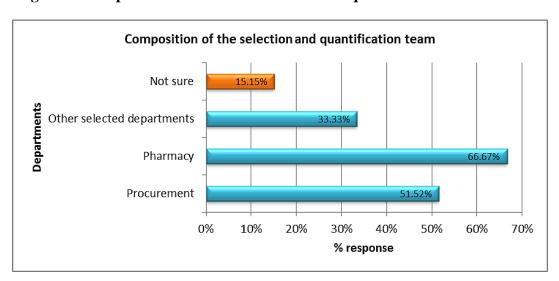


Figure 4: Composition of medicine selection and quantification team

A majority of the respondents (81.82%, n=27) agreed that roles of the selection and quantification team were explicit. Over half, 57.58% (n=19) of the respondents used both morbidity- and consumption-based methods for quantification of medicines, while the rest, 42.42% (n=14) indicated only consumption based method was applied. Almost two thirds of the respondents (65.63%, n=21) indicated that quantification review meetings were held on a quarterly basis. Supply adjustments were done within 30-90 days of such review meetings. Asked whether selection of medicines was restricted to the essential medicines list or formulary lists, 48.48% (n=16) of the respondents negated, 27.27% (n=9) affirmed whereas 24.24% (n=8) were not sure.

Table 2: Selection and quantification of medicines

Characteristics	Frequency	Percentage (%)		
Respondent involved in selection & quantification				
Yes	15	45.45		
No	18	54.55		
Roles of the quantification	team explicit			
Yes	27	81.82		
No	1	3.03		
Not certain	5	15.15		
Quantification method in u	ise			
Consumption	14	42.42		
Morbidity	0	0		
Both	19	57.58		
Frequency of quantification	on review meetings			
Monthly	6	18.75		
Quarterly	21	65.63		
Annually	1	3.13		
Not certain	4	12.5		
Duration of supply adjustments				
Immediately	1	3.03		
<30 days	9	27.27		
30-90 days	19	57.58		
Not certain	4	12.12		
Restriction of orders to EN	AL or formulary lists			
Yes	9	27.27		
No	16	48.48		
Not certain	8	24.24		

The sources of data used in quantification are shown in figure 5 below. Past consumption records (38.88%, n=21), bin cards (25.92%, n=14), and patient workload registers (24.07%, n=13) were mainly used (Figure 5).

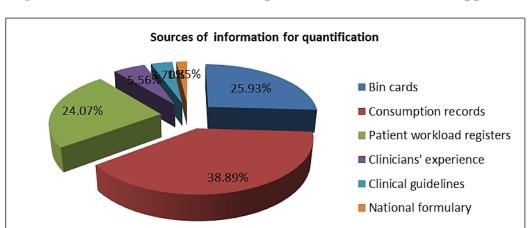


Figure 5: Sources of information for quantification of medicines supplies

Procurement of non-listed medicines was undertaken at hospitals using varied means (Figure 6). Almost thirty six percent (36.36%, n=12) of the respondents cited direct purchases as routinely used whereas 15.15% (n=5) used open tendering.

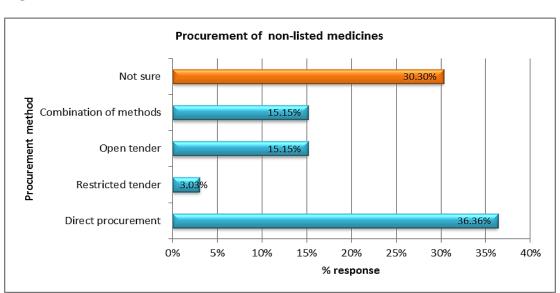


Figure 6: Procurement methods for non-listed medicines

4.4.2 Funding of medicines

Table 3: Funding for medicines

Characteristics	Frequency	Percentage (%)				
Payment duration for supplies						
<30 days	1	3.03				
30-90 days	4	12.12				
>90 days	10	30.3				
Variable	5	15.15				
Not certain	13	39.39				
Existence of unpaid inv	voices for medicines					
Yes	29	87.88				
Not certain	4	12.12				
Existence of revolving	medicine fund					
Yes	10	30.3				
No	19	57.58				
Not certain	4	12.12				
Existence of separate vote for medicines						
Yes	24	72.73				
No	4	12.12				
Not certain	5	15.15				

The respondents indicated that payment duration of medicine supplies varied (table 3 above), 12.12% (n=4) reported payments were made between 30-90 days after delivery of medical supplies whereas 30.30% (n=10) reported this was done after 90 days. Unpaid invoices for medicines already consumed were reported by 87.88% (n=29) of the respondents. Existence of unpaid invoices was significantly associated with delays in medicine supplies (p=0.033).

When asked about the existence of a revolving medicine fund, 57.58% (n=19) of the respondents denied its existence whereas 30.30% (n=10) indicated there was one in place. A majority of the respondents (72.73%, n=24) indicated that medicines funds were remitted via separate vote. However most of the respondents (60.61%, n=20) were not certain of the funding levels for medicines as shown below (Figure 7).

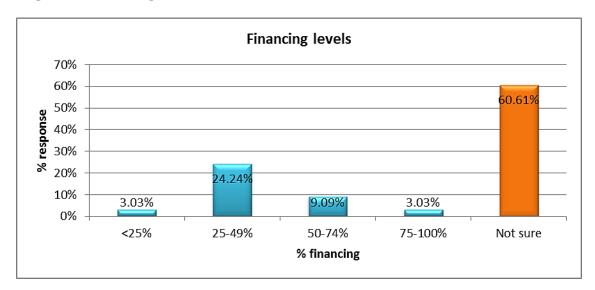


Figure 7: Financing levels for medicines

4.4.3 Ordering and purchase of medicines

Ordering across the three facilities was predominantly done on quarterly basis (63.64%, n=21) as shown in Figure 8 below.

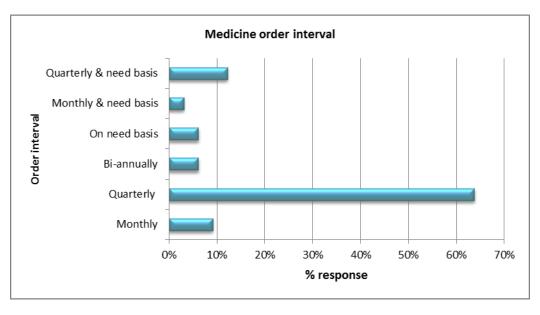


Figure 8: Medicine order frequency

The order interval above was influenced by a number of factors; mainly consumption patterns of medicines (50%) but also by government regulation and funding patterns (Table 4). Almost half of the respondents (48.48%, n=16) indicated that the average lead time for supplies from KEMSA ordered via the County office was 2-3 months while 39.39% (n=13)

reported it took over 3months. On the contrary the average lead time for hospital based orders was 1-14 days as reported by a majority of the respondents (84.85%, n=28). Ordering on quarterly basis was significantly associated with lead times of between 2-3 months (P=0.036). The main causes of delays in medicine supplies were cited as delayed funding (87.88%, n=29) and bureaucracy of the supply chain (42.42% n=14).

Table 4: Ordering process for medicine supplies

Characteristics	Frequency	Percentage (%)
Factors influencing order interval		
Government policy	8	23.53
Consumption pattern	17	50
Funding pattern	9	26.47
Lead time for KEMSA supplies		
2-3 months	16	48.48
>3 months	13	39.39
Not certain	4	12.12
Lead time for hospital based supplies		
1-14 days	28	84.85
1-3 months	1	3.03
Not certain	4	12.12
Single sourcing undertaken		
Yes	12	36.36
No	20	60.61
Not sure	1	3.03
Causes of supply delays		
Delayed/ inadequate funding	29	87.88
Bureaucracy in order process	14	42.42
Shortages of commodities in market	5	15.15
Poor commodity specification	2	6.06

Open tenders formed the bulk of tendering methods used in purchase of medicines (90.91%, n=30) though direct procurement was also undertaken (42%, n=14) (Figure 9).

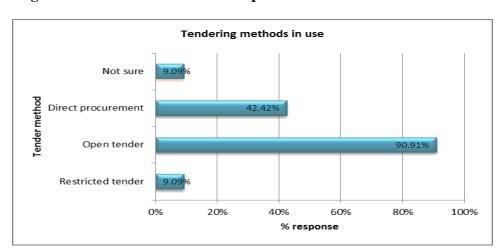


Figure 9: Tender methods used in purchase of medicines

Tender results were disclosed to all stakeholders in the procurement chain in most of the cases; 75.76% (n=25) affirmed that indeed the results were communicated whereas 21.21% (n=7) negated. 60.61% of supplies were not singly sourced from the awarded supplier for various reasons.

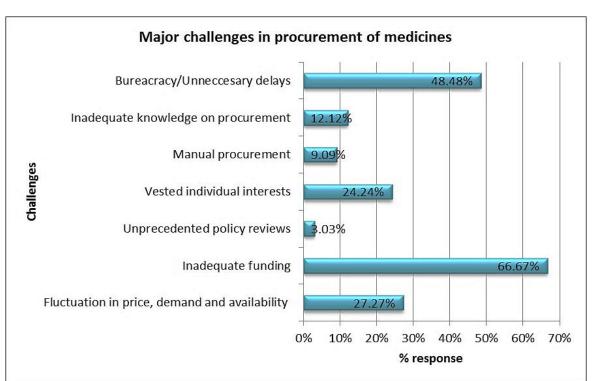


Figure 10: Major challenges in procurement of medicines

The main challenges in the procurement of medicines at hospitals are shown in Figure 10 above. They included mainly inadequate funding (66.67%, n=22) and bureaucracy/unnecessary delays (48.48%).

4.5 Inventory management

Table 5: Inventory management

Characteristics	Frequency	Percentage (%)
Occurrence of stock	shortages	
Yes	31	93.94
No	1	3.03
Not sure	1	3.03
Frequency of stock	checks	
Daily	2	6.06
Weekly	12	36.36
Monthly	12	36.36
Quarterly	2	16.67
Annually	4	12.12
Not sure	1	3.03
Use of ICT in stock	management	
Yes	1	3.03
No	32	96.97
Refresher training		
Yes	5	15.15
No	28	84.85
Staffing adequacy		
Adequate	11	33.33
Inadequate	22	66.67

Occurrence of stock shortages at hospitals was explored (Table 5). A greater majority of the respondents (93.94%, n=31) reported at least an incidence of stock shortage at the hospitals. Varied opinion was given regarding frequency of stock check, slightly over a third (36.36%, n=12) of the respondents indicated that it was done at least weekly, whereas a third (36.36%,

n=12) reported that it was done at least monthly. A significant majority of the respondents (96.97%, n=32) indicated that ICT was not routinely used in inventory management. Stock monitoring was principally done manually.

Refresher trainings for staff were rarely done. A significant majority (84.85%, n=28) of the respondents had not attended any refresher training on inventory management during the period under study. Staffing was a major challenge in inventory management as affirmed by two thirds of the respondents (n=22).

However no statistical significance was established in the association between occurrence of medicine stock-outs and; use of ICT(p=1.000), frequency of stock checks(p=0.477), maintenance of safety stock(p=1.000), refresher training(p=0.284), staffing levels(p=0.562), education level(p=0.773), years of experience(p=0.140) and lead time(0.231).

The main challenges thus encountered during inventory management are summarized below (Figure 11). They included: inadequate skilled manpower to run stores (60.61%, n=20) and reliance on manual inventory management systems.

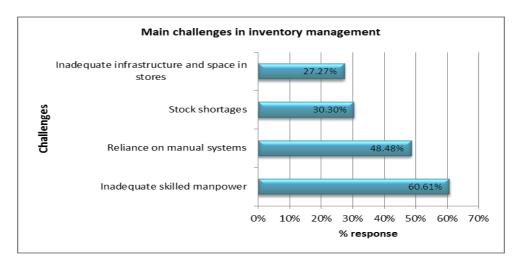


Figure 11: Challenges in inventory management

4.6 Management of Pharmaceutical information system

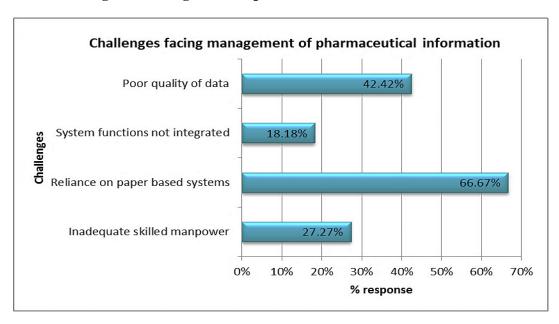
Use and integration of Information Communication Technology (ICT) in routine management of pharmaceutical information was determined (Table 6). A significant majority of the respondents (90.91%, n=30) negated this. Consequently decision making was reportedly not based on accurate and timely data (84.85% n=28).

Table 6: Management of pharmaceutical information

Characteristics	Frequency					
Use/ Integration of ICT in routine management of pharmaceutical information						
Yes	3	9.09				
No	30	90.91				
Availability of timely and accurate data for decision making						
Sometimes	5	15.15				
No	28	84.85				

The main challenges in the management of pharmaceutical information included: reliance on paper based systems (66.67%, n=22) and poor quality of data (42.42%, n=9) (Figure 13).

Figure 12: Challenges in management of pharmaceutical information



CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

In this chapter, study findings related to availability of essential medicines, procurement and inventory management practices and management of pharmaceutical information are discussed and conclusions drawn from the findings. Recommendations have been made based on the study findings and conclusions.

5.2 Discussion

Availability of essential medicines at hospitals

Essential medicines exist in categories and cover a wide variety of elements. This study focused on five tracer commodities used for priority clinical outcome areas within the public health sector, to assess their availability. Less than half of the patients obtained all prescribed medicines from the facilities; they probably had to buy them from private chemists at a higher price or forego the treatment at all. This finding contrasted significantly with the health facility essential medicines survey (MoMs & MoPHS, 2009) where at least 4 out of every 5 patients received all the prescribed medicines at the facility. This was highly attributed to interruption in pharmaceutical management systems between county and national government after devolution of healthcare in Kenya in 2013. Such was the case in Philippines where historical review of decentralization (1992-1997) revealed some negative effects in the immediate and intermediate period that resulted in inefficiency and ineffectiveness of health services management (Grundy, 2003).

The mean availability of a cluster of five essential medicines in the three hospitals was 63.32% (CI 46.82%-79.81%). The 2009 health facility survey established a mean availability of 82.6 % for 15 basic medicines at public health facilities. A similar study in Sudan established average availability of 80.6% for selected essential medicines at public pharmacies (Elfatih Ibrahim Elamin, 2010). This signifies that currently public facilities are experiencing more 'stock-out' days for essential medicines than before.

Procurement practices for essential medicines

Effective pharmaceutical procurement involves key supply-side practices that include: selection, quantification, and product specification, pre-selection of suppliers, tender-evaluation, ordering and financing. These practices need to be separated as they require different expertise (WHO, 1999). Stock-shortages typically represent a break-up in the above functions. Findings of this study indicate that recommended pharmaceutical procurement practices were deficient in the hospitals studied despite the existence of policy guidelines. Selection and quantification teams were mainly composed of pharmacists and heads of procurement. However other important stakeholders: prescribers, suppliers and end-users were not involved. A study on medicines supply outlets in Uganda established that expiries occurred partly due to poor harmonization of medicine quantification with prescribing tendencies and consumer preferences. The study recommended the involvement of prescribers in selection and quantification, and harmonization of medicine quantification with demand estimates for medicines (Josephine, 2010). Facilities relied predominantly on consumption based quantification though this was routinely combined with morbidity approach. Recommended by W.H.O as the most precise method, consumption based approach however requires complete, accurate and properly adjusted data sources. However the method does not address suitability of past consumption patterns, which may or may not match public health priorities and needs. Morbidly based approach is most complex and time consuming and is solely reliant on availability of valid morbidity data (MSH, 2012).

Ordering of medicines at facilities was not restricted to essential medicines or formulary lists despite such lists being a proven cost-effective intervention that promotes access to and rational use of pharmaceuticals and improves quality of care (USAID, 2015). In a related study in rural health facilities of Kirinyaga district, (Agwanda, 1996) established the existence of marked differences between drugs supplied and the actual monthly needs. This implied morbidity patterns were not essentially being used for re-ordering of essential drugs.

Adequate financing is necessary for successful procurement. In this study, unavailability of essential medicines and delayed pharmaceutical procurement were attributed to delayed and /or inadequate funding. Drug-financing mechanisms in public hospitals include: government allocation, health insurance, out-of-pocket and donor financing. When hospitals fail to procure enough medicines, patients either forfeit treatment altogether or buy medicines from private

chemists at higher prices. (Mecca, 2014) demonstrated a change in stock out rate at Webuye district hospital (falling from 21.75% in 2010/11 to 19.47% in 2012/13) after introduction of the national health insurance scheme. This resulted from higher allocation for the 'user fees' and increase in actual expenditure on essential medicines.

Inventory management

Effective inventory management ensures determination of precise order quantities without subjecting the organization to unnecessary costs associated with overstock or under stock. This study established that medicine stock-outs were frequently incurred at hospitals partly due to unreliable record-keeping and inadequately trained staff. Effective record management is a critical function of inventory management that ensures accuracy of records, tracking of inventory movement and estimation of stock levels (Oballah, 2015). Chuchu et.al established a substantial association between automation and correctness of stock records. The study also highlighted unavailability of training opportunities for staffs on stock keeping and reporting for medicines. Consistent findings were reported by (Waako, 2009) regarding training curricula for HIV/AIDS which mainly emphasized clinical care with fewer modules on management of medicines supply. This contributed significantly to the competence gap amongst staff in management of supplies.

Use of ICT in management of pharmaceutical information

Application of ICTs (including data software) in management of pharmaceutical data and information was not practised at any of the three hospitals; despite all facilities having computers and related accessories for management of stock records. Subsequently all departmental functions in the hospitals related to management of medicines were done manually. Poor quality of data was cited as a key challenge as records were either incorrectly or incompletely filled. This negatively affected procurement processes such as quantification and stock level estimation thereby contributing to medicines unavailability. These findings were consistent with similar study findings where facilities that automated their systems achieved improved medicines control (Muthoni, 2014). Inadequate sensitization of staff on rationale for automated systems was cited as reason for low usage of ICT at public facilities in Nairobi (Chuchu, 2015).

5.3 Study Limitations

a) Methodological

The study focused on public hospitals only excluding periphery primary care facilities which provide a larger proportion of pharmaceutical products and services as well. Their inclusivity in this study would have strengthened the findings.

The dependent variable was estimated using a cluster of five randomly selected essential medicines (SARAM report 2013). This cluster was however not conclusive. Use of retrospective data may also have compromised accurate determination of the dependent variable as a few records were minimally incomplete.

b) Conceptual

The study focused on supply and inventory management systems only. The pharmaceutical system is composed of many inter-related and mutually functioning sectors and systems. These include finance, service delivery, quality and standards. A comprehensive study would have yielded stronger conclusions.

5.4 Conclusion

As reported in other related studies on essential medicines, this study established that county referral hospitals failed to provide all prescribed medicines to a majority of its clients due to stock-shortages. One or more commodities were lacking in stock at any given time. For a cluster of five essential medicines; the median availability was marginally low whereas the stock-out duration was significantly high. Varied pharmaceutical procurement practices were established many of which were suboptimal compared to the recommended policies and guidelines.

5.5 Recommendations for Policy and Practice

Based on the gaps identified above, this study recommends the following interventions aimed at improving availability of essential medicines at public hospitals;

- Need to strengthen the pharmaceutical procurement system in hospitals by ensuring: accurate selection and quantification of medicines, adequate funding, and inclusion of prescribers, suppliers and end-users in planning for pharmaceutical procurement.
- ii. Adoption of effective inventory management mechanisms that prioritise accurate recordkeeping and routine training of staff on supply chain management.

iii. Improve the quality of pharmaceutical information used in planning, resource allocation, monitoring and evaluation of pharmaceutical processes. This can be achieved through full automation of the existent paper-based systems.

5.6 Recommendation for Further Research

Considering the complexity of the pharmaceutical procurement and management systems, there is need for in-depth systematic studies to identify and correlate other immediate factors influencing availability of essential medicines in health facilities particularly in the devolved setup.

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APPENDICES

Appendix 1: Informed consent form

"Organizational practices that influence availability of essential medicines at public hospitals in Nairobi County"

Informed consent for staffs working in procurement and pharmaceutical departments in public hospitals in Nairobi. Source: Modified input from UNHCR (Drug Management Manual 2006) and MSH (Managing access to Medicines and Health Technologies)

Contact information: The study proposal has been reviewed and approved by the Kenyatta National Hospital /University of Nairobi-Ethics Review Committee (KNH/UON-ERC) (P252/04/2015). In case of any questions you can contact the committee through:

The Secretary,

KNH/UON-ERC

P.O. BOX 20723 Code 00202 Nairobi, Kenya

Tel: (020)726300-9

Email: uonknh erc@uonbi.ac.ke

Principal investigator: Dr. Zimbulu Victor,

Organization: University of Nairobi, School of public Health

Supervisors: Dr. Richard Ayah. Lecturer, School of Public Health

University of Nairobi

Dr. Peter Ndirangu Karimi. Lecturer, School of Pharmacy

University of Nairobi

Introduction

My name is Zimbulu Victor a student at the University of Nairobi, School of Public Health. I am conducting a study to determine organizational practices that influence availability of essential medicines at public hospitals in Nairobi County. I am here today to gather information on procurement, inventory management and information management for essential medicines at this health facility. Before we start, I want to tell you more about the study and seek your consent to participate."

Purpose of the research

The results of the study will influence effective operational management of the pharmaceutical system particularly the procurement and inventory management units. Managers and staff will be able to better plan and monitor activities related to procurement and inventory management thereby improving availability of essential medicines.

Type of research intervention

The study will be based on interviewer administered questionnaire

Participant selection

I am inviting you as a staff in this department to participate in the study.

Voluntary participation

You are invited to voluntarily consent to participate in this study with the full understanding of the information outlined above. You are also free to withdraw or end a survey/interview and there will be no consequences regarding any potential benefits from the study.

Confidentiality

All information will be kept confidential and names of respondents will not be quoted, instead codes will be used during analysis and dissemination of the findings.

Benefits

There will be no direct benefits from participating in this exercise. However, the findings and recommendations of the study will be shared to help managers and staff be able to better plan and monitor activities related to procurement and inventory management thereby improving availability of essential medicines. The study will help further inform future research exercises.

Risks and Discomforts:

There are no risks involved for respondents choosing to participate in the study as your interviews will be in private and I shall not identify nor link responses to individual respondents. However, you may refuse to answer any question or not take part in a portion of the assessment if you feel the question(s) are personal or if talking about them makes you uncomfortable.

Consent Status

I therefore consent to participate in this study and fully understand the purpose, benefits, risks and confidentially issues as read and/or explained to me by the interviewer.

Written consent:	
Signature of respondent:	 Date:
Interviewer:	 Signature:
Date:	

Contact of principal investigator: Dr.Zimbulu Victor 0704-507-823

Appendix 2: Data abstraction tool

a) Proportion of medicines dispensed in full

Record the number of prescriptions out of 30 randomly sampled prescriptions that had the indicated medicines dispensed in full on 3 different days?

No	Hospital code	Medicines dispensed versus prescribed						
		Day 1(6/9/14)		Day 2	(1/8/14)	Day 3(1/7/14		
		D	P	D	P	D	P	
1.	MDH		30		30		30	
2.	MLKH		30		30		30	
3.	PMH		30		30		30	

b) Number of stock-out days of 5 basic medicines over 12 months

No	Name of tracer medicine	Ni	umbe	r of c	lays (out of		k bet 2014		Janu	ary t	o De	cemb	er
	Month -	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	TOTAL
4.	Amoxicillin suspension 125mg/5ml													
5.	Paracetamol syrup 120mg/5ml													
6.	Artemether/Lumefantrine(120/60 mg) 6' pack													
7.	Nifedipine retard tablets 20mg													
8.	Ferrous salt tablets(alone or with folic acid)													

Appendix 3: Key informant guide

Source: Modified UNHCR (Drug Man	nagement Manual 2006) ar	nd MSH (Managing access to Medicines and Health				
Technologies)						
County						
Date of interview:/_/2015 Ho	ospital Name:	Department				
Respondents : Hospital administrators and Heads of Procurement and Pharmaceutical departments.						
Interviewer: Before administering this tool, please read out the consent form to the interviewee. Only after the						
consent has been granted by the interviewee shall the interviewer proceed.						

PART 1: General and demographic information

No.	Question	Code	Coding category
11.	Gender	I.	Female
11.	Gender	II.	Male
12.	Name of your department		1
13.	What is your current position in the department?		
14.	For how long have you been in this position?		YearsMonths
15.	What is your profession?		
16.	What is your highest completed level of	I.	Certificate
	education?	II.	Diploma
		III.	Bachelors
		IV.	Masters
17.	What are your main roles and responsibilities in		1
	this department?		
18.	How many staff do you directly		
	supervise?(Indicate the number)		

PART 2: Procurement of medicines and medical supplies

No.	Question	Code	Coding category		
Α.	SELECTION AND QUANTIFICATION OF MEDICINES				
19.	Are you involved in selection and quantification of medicines?	I.	Yes(Elaborate the role played)		
		II.	No		
20.	Who are the other members involved in the selection and quantification process?(List their				

No.	Question	Code	Coding category
	titles and/or positions)		
21.	Are roles of the various members clearly defined	I.	Yes
	and/or documented?	II.	No
22.	Are resolutions and decisions made by these	I.	Yes
	members at meetings routinely implemented?	II.	No
23.	How is quantification for medicines done? Probe		
	method used(Consumption method, Morbidity		
	method)		
24.	What sources of information are used for an		
	accurate quantification process?		
25.	Were stock shortages incurred in this facility in		
	the last 12 months?		
26.	Were stock surpluses incurred in this facility in		
	the last 12 months?		
27.	IV		
21.	How often are quantification review meetings held?		
	noid:		
28.	How soon are supply adjustments made following		
	such reviews? (Specify the period)		
29.	Is selection of medicines limited to essential	I.	Yes
2).	medicines/formulary lists?		
	·	II.	No(Elaborate answer)
30.	Explain the procedure used in procurement of		
	non-listed medicines?		
	ELINDRIC FOR MEDICINES		
В.	FUNDING FOR MEDICINES		
31.	How soon are payments for medicines made?		
_			

No.	Question	Code	Coding category
32.	Are there current unpaid invoices for medicines	I.	Yes
	already supplied and/or consumed?	II.	No
33.	Are funds for medicines remitted via a separate	I.	Yes
	vote?	II.	No
34.	Does the hospital have a revolving medicine	I.	Yes
	fund?	II.	No
35.	In your opinion what is the extent of financing for		
	the medicines budget?(Probe percentage of		
	budget funded)		
36.	How often are the medicines accounts audited?		
	(When was the last audit-date/month/year)		
37.	Are the audit findings for medicines disclosed to		
	all stakeholders?		
C.	ORDERING AND PURCHASING OF MEDICI	NIEC	
38.	How frequent are orders for medicines placed?	I.	Annually
36.	flow frequent are orders for medicines placed:	II.	Bi-annually
		III.	Quarterly
		IV.	Other
39.	What influences the order interval above?		
40.	What is the average lead time for medicine		
	supplies?(Time in days or months)		
41.	What are the major causes of delays in medicine		
	supplies?		
42.	Which procurement method is routinely used in		
	purchase of medicines?		
43.	Are results for the tendering process disclosed to	I.	Yes
	the general public?	II.	No
44.	Are supplies sourced solely from the 'awarded	I.	Yes
	supplier'?	II.	No
45.	What are the major challenges in procurement for		
		<u>I</u>	

No.	Question	Code	Coding category
	medicines in this hospital?		
D.	INVENTORY MANAGEMENT		
46.	How often is stock checked and updated?		
47.	Which reporting tools are used in stock		
	validation?(List the tools used)		
48.	Is Information Communication Technology (ICT)	I.	Yes (Probe ICT type in use)
	used in routine stock management?		
		II.	No
49.	Does this pharmacy maintain adequate safety	I.	Yes
	stock?	II.	No
50.	How are medicine stock losses accounted for in		
	the department?		
51.	How many of your staffs have been trained on		
	inventory management in the last 12 months?		
52.	In your opinion, is this department adequately	I.	Yes
	staffed?	II.	No (Elaborate the answer)
53.	What are the major challenges encountered during		L
	inventory management?		
Е.	PHARMACEUTICAL INFORMATION SYSTE		
54.	Is Information Communication Technology (ICT)	I.	Yes(Describe ICT type in use)
	integrated in routine management of		
	pharmaceutical information?	II.	No
55.	Are all departmental functions related to	I.	Yes
	management of medicines captured by the system		
	in (54) above?	II.	No
56.	Is the system programmed to automatically	I.	Yes
	generate summary reports for decision making?		
		II.	No
57.	Are you conversant with input and retrieval of		
	information from the system? How many of your		

No.	Question	Code	Coding category
	staffs are conversant?		
58.	Is the system's information routinely used to	I.	Always
	support decision making?	II.	Sometimes
		III.	Never
59.	What are the main challenges in management of		
	pharmaceutical information?		
		1	
F.	OBSERVATION CHECKLIST(tick appropriate	tely for av	vailability of the following at the hospital)
	Item	Availab	le?
60.	Kenya essential medicine list 2010/or hospital	I.	Yes
	formulary list	II.	No
61.	Clinical guidelines for level 4-6 hospitals	I.	Yes
		II.	No
62.	Latest minutes of the procurement/medicines and	I.	Yes (Note the date)
	therapeutic committee		
		II.	No
63.	Public procurement and disposal guidelines 2006	I.	Yes
		II.	No
64.	Latest audited medicines accounts	I.	Yes(Note date)
		II.	No

Appendix 4: Survey tool

Respondents: Staff working in the pharmaceutical and procurement departments at county referral hospitals.

Interviewer: Before administering this tool, please read out the consent form to the interviewee. Only after the consent has been granted by the interviewee shall the interviewer proceed.

If self-administered: Leave the tool with respondent only after obtaining informed consent. Indicate to the respondent that you will return after 40 minutes to pick the form

PART 1: General and demographic information

No.	Question	Code	Coding category
9.	Gender	I.	Male
		II.	Female
10.	Name of your department		
11.	What is your current position in the department?		
12.	For how long have you been in this position?	Ye	ears
		M	onths
13.	What is your profession?		
14.	What is your highest completed level of	I.	Certificate
	education?	II.	Diploma
		III.	Bachelors
		IV.	Masters
15.	What are your main roles and responsibilities in		
	this department?		
16.	How many staff do you directly		
	supervise?(Indicate the number)		

PART 2: Procurement of medicines and medical supplies

No.	Question	Code	Coding category
A.	SELECTION AND QUANTIFICATION OF MI	EDICINES	
17.	Are you involved in selection and quantification	I.	Yes
	of medicines?	II.	No
18.	Who are the other members involved in the		
	selection and quantification process?(List their		

No.	Question	Code	Coding category
	titles and/or positions)		
19.	Are roles of the various members clearly defined	I.	Yes
	and/or documented?	II.	No
20.	Are resolutions and decisions made by these	I.	Yes
	members at meetings routinely	II.	No
	implemented?(Evidenced by minutes and reports)	11.	
21.	Which method is used during the quantification	I.	Consumption based method
	process?	II.	Morbidity based method
		III.	Both
		IV.	Other (Elaborate)
22.	Name the sources of information used for		
	accurate quantification?		
23.	Were stock surpluses incurred in this facility in		
	the last 12 months? (Elaborate your answer)		
24.	Were stock shortages incurred in this facility in		
	the last 12 months? (Elaborate your answer)		
25.	How often are quantification review meetings		
	held?		
26.	How soon are supply adjustments made following		
	such reviews? (Specify the period)		
			1
27.	Is selection of medicines limited to essential	I.	Yes
	medicines/formulary lists?	II.	No
28.	Which procedure is used in procurement of non-		
	listed medicines?		
В.	FUNDING FOR MEDICINES	1	
29.	How prompt are payments for medicines made?		
30.	Are there unpaid invoices for medicines already	I.	Yes
	supplied and/or consumed?	II.	No
31.	Are funds for medicines remitted via a separate	I.	Yes
	1	<u> </u>	

No.	Question	Code	Coding category
	vote?	II.	No
32.	Does the hospital have a revolving medicine	I.	Yes
	fund?	II.	No
33.	In your opinion what is the extent of financing for		
	the medicines budget? (Percentage of budget		
	funded)		
34.	How often are the medicines accounts audited?		
	(When was the last audit?-date/month/year)		
35.	Are the audit findings for medicines shared		
	amongst all the relevant stakeholders? (Probe for		
	the media used)		
C.	ORDERING AND PURCHASING OF MEDICI	NES	
36.	How frequent are orders for medicines placed?	I.	Annually
		II.	Bi-annually
		III.	Quarterly
		IV.	Other
37.	What influences the order interval above?		
38.	What is the average lead time for medicine		
	supplies?(Probe for the time in days)		
39.	What are the major causes of delays in medicine		
	supplies?		
40.	How is tendering for medicines done at this		
	hospital? (Probe for the procurement method)		
41.	Are results for the tendering process disclosed to	I.	Yes
	the general public?(Probe for the media used)		
		II.	No
42.	Are supplies sourced solely from the cheapest	I.	Yes
	supplier?	***	N. CH.
		II.	No (Elaborate answer)
43.	What are the major challenges in procurement for		
	medicines in this hospital?		

No.	Question	Code	Coding category
D.	INVENTORY MANAGEMENT		
46.	How often is stock checked and updated?		
47.	Which reporting tools are used in stock		
	validation?(List the tools used)		
48.	Is Information Communication Technology (ICT)	I.	Yes (Explain ICT type in use)
40.	used in routine stock management?	1.	res (Explain ICT type in use)
	used in routine stock management.	II.	No
49.	Does this pharmacy maintain enough safety	I.	Yes
	stock?	II.	No
50.	How are medicine stock losses accounted for in		1575
	the department?		
51.	Have you attended any short-course training on		
	inventory management in the last one year?		
52	To accompanie in this department of superlands	т	V
52.	In your opinion, is this department adequately staffed?	I.	Yes
	statieu?	II.	No (Elaborate the answer)
53.	What are the major challenges encountered during		1
	inventory management?		
	,		
E.	PHARMACEUTICAL INFORMATION SYSTI	EM	
54.	Is Information Communication Technology (ICT)	I.	Yes(Explain ICT type in use)
	integrated in routine management of	II.	No
	pharmaceutical information?		
55.	Are all departmental functions related to	I.	Yes
	management of medicines captured by the system	II.	No
7.0	in (54) above?		
56.	Is the system programmed to automatically	I.	Yes
	generate summary reports for decision making?	II.	No
57.	Are you conversant with input and retrieval of		
	information from the system?		
58.	Is the system's information routinely used in	I.	Always
	decision making?	II.	Sometimes
		III.	Never

No.	Question	Code	Coding category
59.	What are the main challenges in management of		
	pharmaceutical information?		
F.	OBSERVATION CHECKLIST(tick appropriat		•
	Item	Available	e?
60.	Kenya essential medicine list 2010/Formulary list	I.	Yes
		II.	No
61.	Standard treatment guidelines	I.	Yes (Specify)
		II.	No
62.	Latest minutes of the procurement /drugs	I.	Yes (Note date)
	committee	II.	No
63.	Public procurement and disposal guidelines 2013	I.	Yes
		II.	No
64.	Latest audited medicines accounts	I.	Yes(Note date)
		II.	No

Appendix 5: List of public hospitals In Nairobi by ownership

Facility	Hospital name	County	District	Division	Hospital Type	Owner
code						
13000	Kamiti prison hospital	Nairobi	Kasarani	Kasarani	Other	Prisons Dept.
13023	K.N.H	Nairobi	Dagoretti	Dagoretti	National Referral	M.O.H
17411	Mama Lucy Kibaki Hospital	Nairobi	Embakasi	Embakasi	County Referral	Nairobi County
13076	Mathari Hospital	Nairobi	Starehe	Kariokor	National Referral	M.O.H
13080	Mbagathi Hospital	Nairobi	Kibra	Kibra	County Referral	Nairobi County
13194	National Spinal Injury	Nairobi	Westlands	Westlands	National Referral	М.О.Н
13095	Moi Air Base	Nairobi	Kamukunji	Eastleigh	Other Hospital	D.o.D
13156	Pumwani Maternity Hospital	Nairobi	Kamukunji	Pumwani	Maternity Hospital	Nairobi County

	Facilities selected to	participate in the study

Appendix 6: List of tracer medicines to be assessed

No	Name of tracer commodity	Category of medicine
1.	Amoxicillin suspension 125mg/5ml	Essential medicine for children
2.	Ferrous salt tablets(alone or with folic acid)	Maternal health
3.	Artemether/Lumefantrine 120/60 mg 6' pack	Malaria
4.	Nifedipine retard tablets 20mg	Non-communicable diseases
5.	Paracetamol syrup 120mg/5ml	General medicine

Appendix 7: KNH/UON ERC approval



UNIVERSITY OF NAIROBI COLLEGE OF HEALTH SCIENCES P O BOX 19676 Code 00202 Telegrams: varsity (254-020) 2726300 Ext 44355

Ref: KNH-ERC/A/335

Dr. Zimbulu Victor H70/69478/2013 School of Public Health College of Health Sciences University of Nairobi

Dear Dr. Zimbulu



KENYATTA NATIONAL HOSPITAL P O BOX 20723 Code 00202

Tel: 726300-9 Fax: 725272 Telegrams: MEDSUP, Nairobi

31st July 2015

Research proposal – Organizational practices that influence availability of essential medicines at Hospitals in Nairobi county (P252/ 04/2015)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and approved your above proposal. The approval periods are 31st July 2015 – 30th July 2016.

KNH/UON-ERC

Website: http://www.erc.uonbi.ac.ke Facebook: https://www.facebook.com/uonknh.erc Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

Email: uonknh_erc@uonbi.ac.ke

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
- c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
- d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
- e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
- Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- Submission of an executive summary report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website http://www.erc.uonbi.ac.ke

Protect to discover

Yours sincerely.

PROE M. L. CHINDIA SECRETARY, KNH/UON-ERC

The Principal, College of Health Sciences, UoN The Deputy Director CS, KNH C.C.

The Chair, KNH/UoN-ERC

The Director, School of Public Health, UoN Supervisors: Dr.Richard Ayah, Dr. Peter Ndirangu Karimi

Appendix 8: County Health Services approval

NAIROBI CITY COUNTY

Telephone 020 344194

web: www.nairobi.go.ke



City Hall, P. O. Box 30075-00100, Nairobi, KENYA.

COUNTY HEALTH SERVICES

REF: PHD/1/13/ (08) - 015

TO:

ZIMBULU VICTOR UNIVERSITY OF NAIROBI P O BOX 19676

NAIROBI

DATE: 20TH AUGUST, 2015

RE: RESEARCH

Authority is hereby granted to you to carry out research on "Organizational practices that influence availability of essential medicines at Hospitals (Mbagathi Hospital, MLKH and PMH in Nairobi County".

Please note that your research runs One for (1) month

w.e.f from 31st August, 2015 to 30th September, 2015.

You will also be expected to submit a copy of your research project to the office of the undersigned.

You will be expected to pay a research fee of Kshs. 5,000/-.

By a copy of this letter, the Medical Superintendents of the above mentioned Hospitals are requested to accord you the necessary assistance.

LILIAN SHIKANDA

FOR: CHIEF ADMINISTRATIVE OFFICER - (CHS)

Cc:- Medical Superintendent – Mbagathi, MLKH, PMH. Hospital Administrator – Mbagathi, MLKH, PMH.