ASSESSIMENT OF VACCINES DISTRIBUTION SYSTEM IN PUBLIC HEALTHCARE FACILITIES IN COAST REGION, TANZANIA

By

Mohamed Makuru

A dissertation / Thesis submitted in (partial) Fulfillment of the Requirements for the Degree of Master of Science (Pharmaceutical Management) of Muhimbili University of Health and Allied Sciences

Muhimbili University of Health and Allied Sciences

October, 2012

CERTIFICATION

The undersigned certify that she has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences of thesis/ dissertation entitled **‘’Assessment of vaccines distribution system in the public health care facilities in Coast region, Tanzania‘’**, in partial fulfilment of the requirements for the degree of Master of Pharmacy (Pharmaceutical Management) of Muhimbili University of Health and Allied Sciences.

_____

Dr.Kagashe, G.A.
(Supervisor)

Date: _____

DECLARATION AND COPYRIGHT

I, **MOHAMED MAKURU**, declare that I am the sole author of this **Dissertation** as my own original research work, and that it has not been presented and it will not be presented to any other University for the similar or any other degree award; and where other people's research was used, they have been dully acknowledged.

Signature…… Date ……...

ACKNOWLEGEMENT

Achievement of this work would not have been possible without the blessings from the Almighty God. I would like to express my gratitude to all those who, in one way or another, supported this endeavour. I would like to thank my supervisor, Dr. G. A. Kagashe, for her skilful and dedicated supervision, valuable criticism and accessibility during the entire course of this study. She helped me a lot in shaping my research proposal and producing the dissertation in its present form. Also special appreciations are directed to the Ministry of Health and Social Welfare (MOHSW) for sponsoring me for the entire period of my study.

I wish to express my sincere thanks to the course coordinator of Pharmaceutical Management and Head of Department of Pharmaceutics Dr.G.Kagashe and all members of staff of the School of Pharmacy, MUHAS for their advice, huge support including assistance they accorded me during the course study. The friendly cooperation I enjoyed from my colleagues in the MSc Pharmaceutical Management course is also highly appreciated. I wish to extend my thanks to the District Executive Directors of four councils of the Coast region which are Kibaha Town, Bagamoyo, Mkuranga and Rufiji councils for granting me permission to collect data from the respective healthcare facilities.

I obligate deep gratitude to my mother, Nyabanane, my children Mark, Jacqueline, Jennifer and Janeth and my family for their patience including tolerance that enabled me to complete this work. Also I wish to extend my thanks to my employer bagamoyo district council, in particular, the District Executive Director for allowing me to go for further studies. Lastly but not least, I wish to extend many thanks to my wife Colletha Thomas Kisaka for her assistance during the course of this study.

Finally, I would like to stress that while acknowledging assistance from those mentioned, they are in no way associated with any errors that may be found in this work. Responsibility for all errors and shortcomings remain entirely mine.

DEDICATION

This dissertation is dedicated to my lovely parents; mother Nyabanane Nyagokenga and father the Late MR.Makarai Kyamarisy, my son Mark and my daughters Jacqueline, Jennifer & Janeth.

Table of Contents

LIST OF TABLES

TABLE **PAGE**

LIST OF FIGURES

FIGURE **PAGE**

ACRONYMS

MDG –Millennium Development Goal

EPI – Expended programme on Immunization

PMORALG – Prime Minister's office Regional Administration and local Government

MSD – Medical Stores Department

WHO – World Health Organization

CVS – Central Vaccine Stores

RVS – Regional vaccine Stores

DVS- District Vaccine Stores

DCCO –District Cold Chain Officer

RCCO – Regional Cold Chain Officer

FEFO – First Expire First Out

BCG- Bacillus Calmette Guerin

OPV – Oral polioviruses vaccine

TT – Tetanus Toxoid vaccine

DTP-HepB-Hib- Diphtheria, Tetanus, Pertussis, Hepatitis B, and Haemophilus Influenzae type b (Pentavalent)

VVM – Vaccine Vial Monitor

MDVP – Multi Dose Vial Policy

UNICEF- United Nations Children's Fund

RRCHCO- Regional RCH Coordinator

DRCHCO-District RCH Coordinator

Abstract

Background: Extended Programme on Immunization performance is among the four main indicators selected for general budget support to the health sector. The declining trend in performance of the immunization program is a major concern, routine immunization coverage in Tanzania declined from 94% in 2004 to 85% in 2009(MOHSW, EPI REVIEW 2010)

Vaccination is one method that has been proven effective in preventing the transmission of infectious diseases. However to be effective a number of elements in a vaccination program need to be implemented properly, including cold chain management, vaccine management, logistic management and waste management. Failure to properly implement these can reduce the level of protection that is expected from a vaccination program.

Objectives

The study examined current distribution system of vaccines from second level which is Regional stores, third level which is District stores to fourth level which is health facility and storage practices.

Methodology

It was a cross-sectional survey, staff responsible for vaccine distribution system and storage were interviewed about their knowledge and practices of vaccine distribution, handling and storage. Data collection started in April to 16th June 2012. Data was from 40 selected healthcare facilities and 5 warehouses in Coast region based on geographic representation. Vaccine storage conditions were also assessed and determined at different levels. Availability of 6 tracer vaccines for the past 10 months was assessed and this aided in assessing inventory management and stock control of vaccines at the health facilities.

Results

Availability of 6 tracer vaccines during the time of survey was high at regional vaccine store (100%), followed by district vaccine stores (93.3%) and low at healthcare facilities (82%). Stocks out duration were more at healthcare facilities level (72 days) than district vaccine stores (33 days). Most of the parameters of storage conditions were not met by the

facilities. Knowledge level of healthcare givers was inadequate. The study reveals that all personnel involved in handling and storage of vaccines were non pharmaceutical personnel.

Conclusions & recommendations: Managing effective distribution system at public health facilities is associated with many challenges/problems including inadequate vehicles for distribution especially in lower level, poor storage conditions, unreliable electricity and lack/delay of gas, no involvement of pharmaceutical personnel in program, no quantification at low facility level and lack of on job training. It is recommended that MOHSW & PMORALG should strengthen distribution system. MOHSW/EPI needs to involve pharmaceutical personnel in the program.

CHAPTER ONE: INTRODUCTION

BACKGROUND

The Government of Tanzania through Ministry of Health and Social welfare (MOHSW) has strong commitment to achieving the Millennium Development Goal (MDG) number 4 on reduction of Child Mortality as reflected in the MKUKUTA and Joint Action Plan (JAP for MDG 4, 5 and 6.) Extended programme on Immunization (EPI) performance is among the four main indicators selected for general budget support to the health sector (MOHSW EPI REVIEW, 2010).

Vaccination is one of the methods that has been proven effective in preventing the transmission of infectious diseases and hence reduction of infant and child mortality rate in the world. To be effective, however, a number of elements in a vaccination program need to be implemented properly, including cold chain management, vaccine management, logistics management, and waste management. Failure to properly implement these can reduce the level of protection that is expected from a vaccination program. Therefore, staff must ensure the availability of a proper cold chain, and vaccine and logistics management system from the vaccine manufacturer to the end user, and follow-up after the vaccination program is finished.

Innovative technology solutions to help ensure vaccine effectiveness; efficacy, safety and storage are enabling immunization programs to save even more lives in this world. Without vaccines as well as safe and effective distribution systems and delivery practices, disease would become more rampant and the public health and the community would be overburdened with treatment costs and deaths particularly in children.

1.2 STRUCTURE OF NATIONAL HEALTHCARE AND PHARMACEUTICAL SYSTEM IN TANZANIA.

The Healthcare delivery system in Tanzania has two components, the public and the private sector and both are guided by national policies for purposes of achieving of high quality of life for all Tanzanians .The public sector share contribution to healthcare delivery system is approximately 56% while the private sector share is about 44% which comprises faith Based organizations 30% and private for profit about 14%.

The system works at four levels; the community, the ward where there is dispensary and a Healthcare centre at the division level. As one moves further up there is the district and regional hospitals at district and region levels respectively. At the zone and national levels, are the consultant/ referral hospitals (*MOHSW, 2008*).

By the end of 2005 Tanzania had a total of 5,379 healthcare facilities distributed in such a way that 70% of the population is within 5km of facility healthcare and 90% within 10km of facility healthcare.(*Second Health Sector Strategic Plan MOHSW ,July 2003- June 2008).* Administratively, health system is largely decentralized. The MOHSW has direct responsibility for the regional and referral hospitals and regulatory power over all the healthcare facilities in the country.

The district facilities which include district hospitals, health centres, and dispensaries are independently run by the Prime Minister's office Regional Administration and Local Government (PMORALG).

1.3 .PHARMACEUTICAL SERVICES PROVISION IN TANZANIA

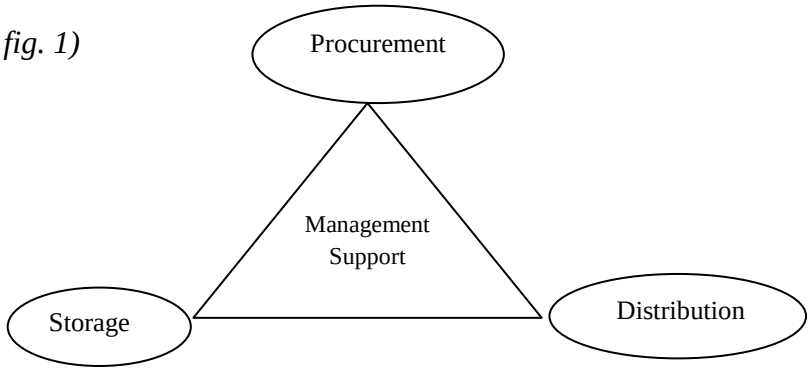
Provision of medicines and medical supplies in Tanzania is through the public non for profit sector system 56% and private sector system 44%.All public healthcare facilities receive their supplies share by using allocated financial budget or draw supplies for use against established budget ceilings (MOHSW, 2008). The immunization services are provided free of charge in both public and private healthcare facilities.

1.3.1 **MEDICINES SUPPLY SYSTEM FOR THE PUBLIC HEALTHCARE FACILITIES IN TANZANIA.**

In Tanzania Mainland the supply system employs Autonomous Supply Agency (i.e Medical Stores Department (MSD) which is a semi-autonomous organization under the MOHSW whose functions include all the activities in the medicines supply management cycle except dispensing (MSD Act No, 13, 1993).

This ranges from the selection of a list of medicines for its catalog from the National Essential Medicines List (NEML), to procurement, storage and distribution to its customers

MSD main functions (fig. 1)



MSD operates a self sustaining revolving drug fund and its main customers are the Zonal Medical Stores (Dar es Salaam, Tanga, Iringa, Dodoma, Moshi, Tabora, Mwanza , Mtwara, and Mbeya), regional and district hospitals, health centres, dispensaries and Faith based healthcare facilities (www.msd.or.tz, Tanzania Medical Directory, 2009/2010).

The supply system of medicines to the healthcare facility level involves four levels; from Central MSD Store, zonal MSD store to district and regional stores. District stores level supplies the primary healthcare facilities (i.e health centres and dispensaries). All healthcare facilities are required to order their medicines through integrated logistics system (ILS) whereby each facility submits its required quantities of medicines according to needs and allocated budget for the period in question to zonal MSD stores this is a pull system.

During planning and budgeting quarters (i.e. 3rd and 4th quarters of each financial year) the primary health facilities channel their annual medicines requirements to the District Pharmacist who in turn performs reconciliation and compilation of all requirements from primary health facilities within the district and that of the district in question before forwarding them to the Zonal MSD store (Euro Health Group and MSH, 2007).

The District Pharmacist is accountable for ensuring that all the annual requirements are sent in time to MSD, timely delivery of medicines from MSD to district store and finally undertakes distribution logistics of the medicines to the respective facilities. At Regional

level the Regional hospital Pharmacist is responsible for quantification of medicines requirements according to needs and availability of funds (ILS-model) for the regional hospital before forwarding the order to Zonal MSD.

1.3.2 PROCUREMENT OF MEDICINES AND MEDICAL SUPPLIES IN PUBLIC HEALTH SECTOR.

Procurement

Procurement is process of obtaining or acquiring supplies and services. Procurement occur in cycles as long as need persists to consume the supplies and services (MSH, Managing Drug supply, 1997)

Procurement of medicines and pharmaceutical supplies in public health sector in Tanzania

Procurement of medicines and medical supplies in the public health sector in Tanzania takes place through central MSD; all public health facilities make their order according to their schedules at MSD. The funds for purchasing medicines and supplies for public health facilities is from central treasury to MOHSW then to central medical stores.

Procurement at central medical stores takes place after forecasting and quantification at MOHSW through Pharmaceutical supplies unit and central medical stores use the data and subject to section 45 of Public Procurement Act 2004 invite **competitive tenders**, the major method is International open competitive bidding. All tenders are under MSD tender board.

Emergency procurement occurs during the crisis of stock out at MSD what they do here is to jump stage 1 and 2 among the 6 stage of procurement process by searching the suppliers among last suppliers who supplied the same medicines or pharmaceuticals supplies and by so doing is possible to reduce lead time from 9 months to 5 months (www.msd or.tz, Tanzania Medical Directory 2009/2010)

1.3.3 DISTRIBUTION SYSTEM OF VACCINES TO THE PUBLIC HEALTHCARE FACILITIES IN TANZANIA.

Distribution

Distribution is the delivery or giving out of an item or items to the intended recipient.

Distribution system

A system of administrative procedures, transport facilities, storage facilities and user facilities through which supplies move from a central point to the user facilities.(MSH, Managing Drug Supply, 1997)

Vaccine

A vaccine is biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease causing microorganism. The agents stimulates the body's immune system to recognize the agent as foreign, destroy it and "remember it", so that the immune system can more easily recognize and destroy any of these micro-organisms that it later encounters (strive-4-five 2005, htt//www.ag.gov.au/cca)

Sources of vaccine

There several type of vaccines sources although is often made from weakened or killed form of microbe or its toxins. Some form type of vaccines sources are as follows:-

1) Killed

Some vaccines contain killed, but previously virulent, micro-organisms that have been destroyed with chemicals, heat, radioactivity or antibiotics examples are the influenza vaccine, cholera vaccine, polio vaccine, hepatitis A vaccine, rabies vaccine and bubonic plaque vaccine.

2) Attenuated

Some vaccines contain live, attenuated micro-organism. Many of these are live viruses that have been cultivated under conditions that disable their virulent properties examples includes the viral disease yellow fever, measles, rubella and mumps and the bacterial disease typhoid.

3) Toxoid

Some vaccines are made from inactivated toxin compounds that cause illness rather than the micro-organism. Examples of toxoids based vaccines include tetanus and diphtheria.

4) Subunit

Protein subunit is used rather than introducing an inactivated or attenuated micro-organism to an immune system. Protein subunit fragment can create an immune response. Examples include the subunit vaccine against Hepatitis B virus that is composed of only the surface protein of virus, Vaccine against human papillomavirus (HPV) that is composed of the viral major capsid protein, and the haemaglutinin and neuraminidase subunits of influenza virus.

5) Conjugate

Certain bacteria have polysaccharide outer coats that are poorly immunogenic. By linking these outer coats to protein (eg toxins) the immune system can be led to recognise the polysaccharide as if it were a protein antigen. This approach is used in the Haemophilus Influenzae type B vaccine.

6) Experimental

A number of innovative vaccines are also in development and in use. These vaccines are synthetically manufactured and composed mainly or wholly of synthetic peptides, carbohydrates or antigens. Examples are Dendritic vaccine, Recombinant vector vaccine, and DNA vaccine which is very easy to produce and store (strive-4-five 2005, htt//www.ag.gov.au/cca)

The distribution system of vaccines is concerning with **maintaining of the cold chain**.

The **cold chain** is the system of transporting and storing of vaccine at the recommended temperature range which is ($+2^0$C to $+ 8^0$C for refrigerator vaccines) and (-15^0C to -25^0C for freezer vaccines). **Cold chain** begins from the time the vaccine is manufactured, stored, distributed and ends when it is administered to client.

Sensitivity of vaccines to heat and cold

Vaccines are delicate biological substances that can become less effective or destroyed if they are:-

1) Frozen- this is the most common reason for vaccine damage

   Freezing of vaccine- this refers to situation whereby vaccines stored at or below 0^0C of temperature for type of vaccines which need to be stored in refrigerator temperature range of $+2^0$C to + 8^0C. Vaccine damage at temperature of 0^0C is common although it may not appear frozen. (Strive for five, 2005)

2) Allowed to get too hot – when vaccines are exposed to repeated episodes of heat the loss of vaccine potency is cumulative and cannot be reversed. (Strive for five, 2005)

3) Exposed to direct sunlight or fluorescent light. (Strive for five, 2005)

SUPPLY OF VACCINES IN TANZANIA.

In Tanzania mainland the supply system of vaccine employs MSD which is a semi-autonomous agent under MOHSW whose functions in include procurement, clearing, storage at national level and distribution of vaccines and other supplies to the regional level. From regional level to the district level the distribution of vaccines is done by Central Transport Unit. From District level to the public healthcare facilities it's the district's council which deals with distribution of vaccines. (MOHSW EPI REVIEW, 2010)

Ordering of vaccines in public health facilities in Tanzania

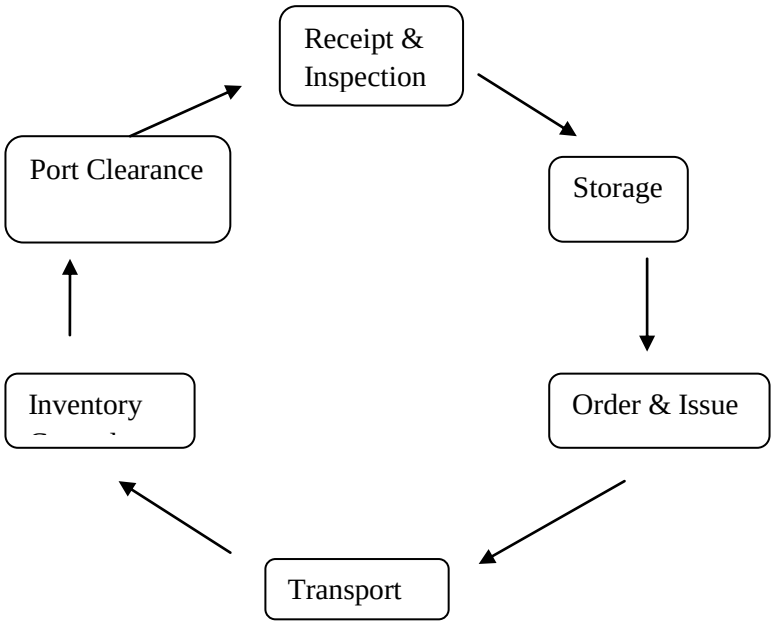
Quantification is a process that involves estimating the quantities of specific medicines needed for procurement and financial requirement needed to purchase the medicines. Estimation of needs done within the following given content Finances, Human resources capacity, Storage capacity and Capacity to deliver services (MSH, Managing Drug supply, 1997)

At Regional level, there is a Regional Cold Chain Officer who is responsible for managing Regional Vaccine Store (RVS), forecasting, quantification and ordering of vaccines at Central Vaccine Store (CVS) for regional needs. At District level, there is a District Cold Chain Officer who is responsible for managing District Vaccine Store (DVS), forecasting, quantification and ordering of vaccine at RVS for the district needs. At health facility level, implementation of immunization activities, record keeping and ordering of vaccines at District Vaccine Store for facility clients' consumption is the duty of Public Health Nurse (MOHSW EPI REVIEW, 2010)

Distribution of vaccines in Tanzania.

After procurement the distribution of vaccines follows the steps of the distribution cycles as shown in figure 2 below

Elements of Distribution System



Source: USAID-MSH/SPS

The distribution sequence intersects the procurement process at the point at which vaccines are available for delivery to the healthcare facilities. Procurement of all vaccines, injection materials and cold chain equipment in Tanzania Mainland is done by MSD through UNICEF procurement channel.

1) **Port Clearing** –This is applied for vaccines and all medicines imported from abroad. The international supplier takes responsibility for it; Port clearing involves identifying shipments as soon as they arrive in port, processing all importation documents, completing any customs requirements, storing properly so as to maintain cold chain until they leave the port, surveying the shipment for losses and signs of damage and collecting the vaccines as soon as they have been cleared. (MSH, Managing Drug Supply 1997)

2) **Receipt and Inspection** –central stores staff must carry out a complete inspection of every shipment as soon as it is received from the port or local supplier. The shipment must be kept separate from other stock until the inspection is completed. Inspector check for damage, missing items and for compliance with contract conditions which concerning with vaccines type, quantity, presentation, packaging, and labelling. (MSH, Managing Drug Supply 1997)

3) **Inventory control** – this is used in inventory management which is the heart of the medicine supply system. Establishing and maintaining effective inventory records and procedures are the basis for coordinating the flow of vaccines through the distribution system. The Inventory control system is used for requisitioning and issuing vaccines, for financial accounting, and for preparing the consumption and stock balance reports necessary for procurement.

   Stock records which are core records in the inventory management can be manual or computerized, manual records include:-

- ✓ **Bincards**- stored with stock
- ✓ **Ledger system –**ledger sheets
- ✓ **Kardex system –**record tray system. (MSH, Managing Drug Supply 1997)

4) **Storage** – storage facilities range from large mechanized warehouses at the national level to small wooden boxes sitting in primary healthcare facilities. (MOHSW EPI REVIEW, 2010)

Tanzania has four levels of vaccine storage:

1) First level: This is the National level which is Central Vaccine Store (CVS) at MSD and all 8 Zonal Medical Stores which are used as a transit point from CVS to the Regional Vaccine Store (RVS) except Dar es Salaam zonal store.

   -Storage capacity –National level is supposed to have a vaccine storage capacity for 6 months stock with buffer stock of 25% and also need to have standby generator.

2) Second level –Region vaccine store

   -Storage capacity –need to have a storage capacity for up to 3 months stock with 25% buffer stock in relation to its target population and also need to have standby generator.

3) Third level –District Vaccine Store

   -Storage capacity-need to have a storage capacity for up to 3 months with 25% buffer stock in relation to its target population.

   -Need to have 1-3 absorption freezers/refrigerators using kerosene/electricity or 1-2 kerosene operated refrigerators and 2 compression freezers and also need to have standby generators

4) Fourth level: this is health facility level

   Storage capacity –facilities have to be equipped with vaccine storage capacity of 6 weeks with buffer stock of 25% in relation to its target population.

   -Need standby generator or kerosene operated refrigerators or freezers.

5) **Requisition of supplies** – vaccines supply systems may operate under **a push or pull** system. In Tanzania pull system of vaccine supply **in public healthcare**

facilities started since 2000. The forms and procedures for requisition are a key part of the inventory control system. **The pull system** also known as **indent supply system** in this system each services level determines what types and quantities of vaccines and supplies are needed and places orders to the supply source. (Euro Health Group and MSH, 2007)

6) **Delivery or Transport** –Transport system in Tanzania depend on road vehicles so vehicle breakdowns, availability of fuel, lubricants and spare parts, seasonal variations in access routes, and safety along specific supply lines must be considered in transport planning to meet delivery schedule. Vaccine transport must use refrigerator vehicles, cool boxes, cooling agent and freezer tags (temperature monitoring indicator). (MOHSW EPI REVIEW, 2010)
7) **Dispensing to patients** – the distribution process achieves its purpose when vaccines reach healthcare facilities and appropriately prescribed and dispensed to patients.

8) **Consumption report** – the closing link in the distribution cycle is the flow of information on consumption and stock balances back up the distribution system to the procurement needs. If adequate inventory and requisition records are kept compiling consumption reports should be straight forward.(MSH, Managing Drug Supply 1997)

1.4 LEGAL & REGULATORY FRAMEWORKS OF PHARMACEUTICALS IN TANZANIA.

In the public sector, medicines are considered as the property of the state, for which accounting procedures in stock management of medicines and medical supplies are necessary (Public Finance Act & Regulations 2004).This applies to both medicines that are procured through normal channels and to in kind (donation) medicines.

In Tanzania the regulatory body for all medicines and medical supplies is the Tanzania Foods, Drugs and Cosmetics Authority (TFDA) and Vaccines are not exceptional. The

TFDA governs licensing, registrations and Inspection to ensure medicine, medical supplies and Biological of assured Quality, Safety and efficacy.

Regulatory Framework of vaccine Quality Assurance consists the following activities:-

- ✓ -Pre marketing assessment marketing authorization/ licensing and regulation this is done by TFDA in Tanzania.
- ✓ -Regulatory elements full spectrum/comprehensive functions include inspection, recall, central & provincial laboratory is done by TFDA.
- ✓ -Technical elements such as Quality specifications, Basic tests and Good Manufacturing Practices are performed by TFDA as in other medicines and medical supplies.
- ✓ -Post marketing authorization surveillance for quality and adverse events and product information/promotion. According to the regulatory framework Pharmacist is the custodian of vaccines as in other medicines.

The Tanzanian MOHSW provides strategic direction of health sector for 2009-2015 known as Health Sector Strategic Plan 3 (HSSP3). The HSSP3 is a guide for strategic planning at the national level and development of annual plans. Within the HSSP3, Extended Programme on Immunization falls within the Maternal, Newborn and Child Health section.DPT-HepB-Hib3 is mentioned as an indicator for performance sector and General Budget support, however the plan does not include the strategic objectives of Immunization Program and until now there are no Immunization specific policy guidelines (MOHSW EPI REVIEW, 2010) but Operational guidelines have been developed for logistics, cold chain and vaccine management.

1.5 PROBLEM STATEMENT

Vaccines must be kept at precisely recommended temperature range from the point of manufacture to the point of administration. An in depth assessment done at the public health facilities found that most of the pharmacies in public healthcare facilities had inadequate storage capacity (MOHSW 2008). Only 33% of the health facilities had

adequate storage capacity, 52% had facilities for cold storage and 22% had storage equipment (MOHSW 2008). Currently there is a problem of electricity which is unreliable and large areas of rural do not have electricity. It has been realized that the vaccine and supplies distribution chain from national to lower levels being broken at regional level (MOHSW EPI REVIEW, 2010) and districts are expected to collect the vaccines from regional level for the lower level facilities. Manpower shortage for health especially at the lower level healthcare facilities could be a probable gap in terms of number of healthcare personnel and knowledge.

Since 2004 the vaccination coverage started gradually decreasing from 94% to reach 83% in 2007. As a result, in 2008/09 Tanzania was among the five countries in the East and Southern Africa block with the highest number of unvaccinated children (WHO, 2009/10). Cases of outbreak of vaccine preventable diseases especially measles have been reported in some area in the country. Not maintaining proper cold chain up to the end user may be one of the factors contributing to poor immunization.

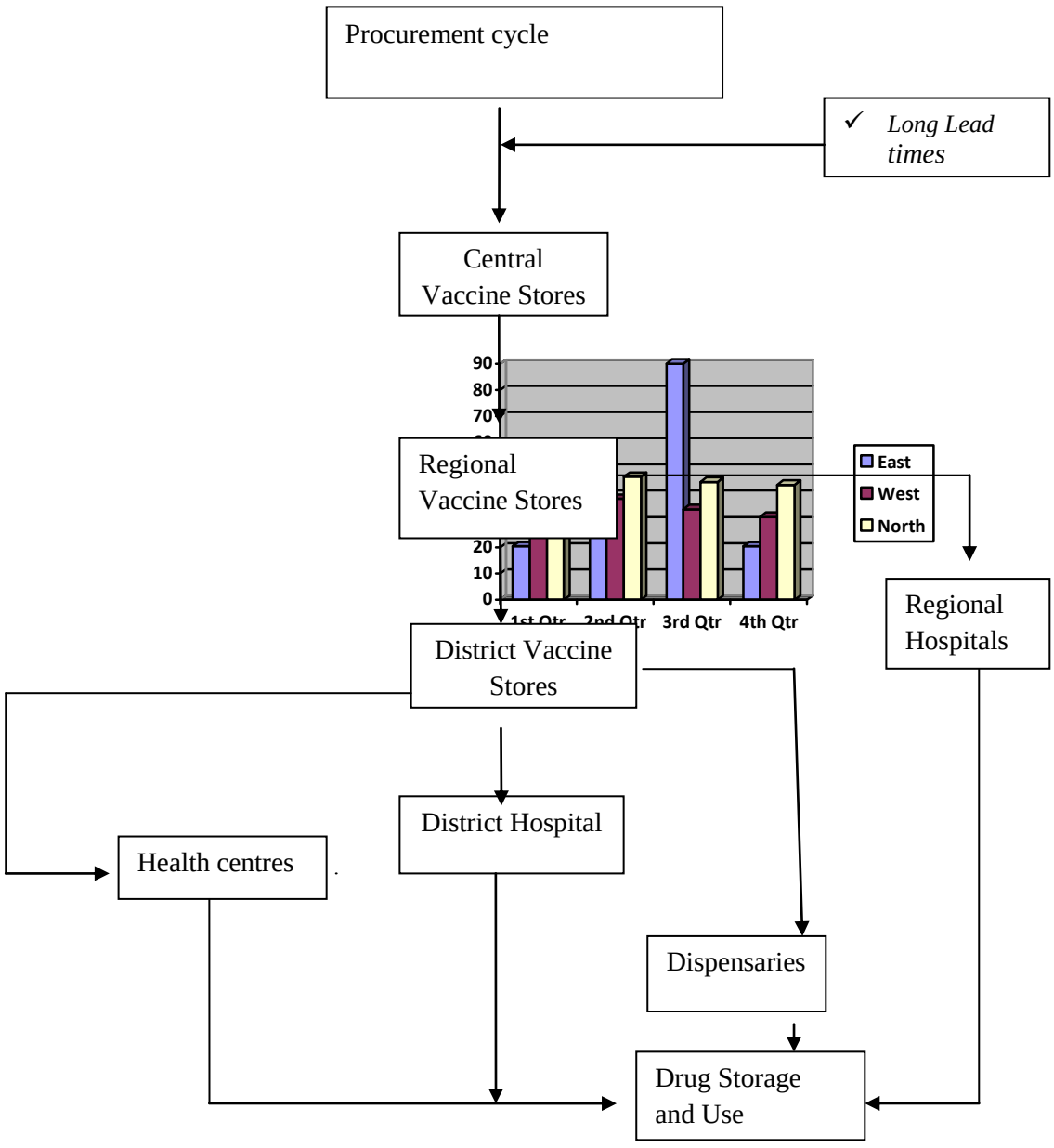
Thus this research assessed the distribution system of vaccine and ascertained whether cold chain was maintained and also assessed whether there was any stock out of vaccines at health facilities as explained in chapter four.

1.6 CONCEPTUAL FRAMEWORK

1.6.1 Conceptual Model for vaccines and cold chain distribution in Tanzania.

This model (fig 3) tries to explain some major causes that may lead to problems in distribution system and poor vaccines storage practices at the healthcare facilities.

Fig 3 Conceptual framework of vaccines distribution system



✓ *Long lead times.*

- ✓ *Poor Storage Conditions of vaccines on transit and in the health facilities.*
- ✓ *Non-adherence to Good Storage Practices*.
- ✓ *Inadequate health workers personnel at facility level.*
- ✓ *Infrastructure Problems especially Road Networks.*
- ✓ *Unavailability of vehicles for distribution of vaccines/lack of reliable transport.*
- ✓ *Unreliable electricity.*
- ✓ *Poor quantification and forecasting of vaccines.*
- ✓ *Less involvement of pharmaceutical personnel in EPI.*

1.7 RESEARCH QUESTIONS

The following questions were considered relevant to the study design -

1) Is cold chain maintained at all levels?

2) Are vaccines available at all levels of healthcare facilities?

3) Are vaccines stored properly?

4) Are healthcare personnel involved in the vaccines (cold chain) management knowledgeable on storage condition of vaccines?

5) Who handles and dispenses vaccines at healthcare facilities?

1.8. STUDY OBJECTIVES

1.8.1 Broad Objective:

- To assess the vaccines cold chain distribution system in public healthcare facilities in the Coast region, Tanzania.

1.8.2 Specific Objectives:-

1) To determine the availability of vaccines at the healthcare facilities.

2) To determine the average stock out duration at the healthcare facilities.

3) To assess the storage conditions of vaccines at the healthcare facilities

4) To determine the level of knowledge of the healthcare workers on storage and handling of vaccines.

5) To identify profession of personnel involved in handling and dispensing vaccines at healthcare facilities.

1.9 RATIONALE OF THE STUDY

The study had contributed valuable information to the available literature on vaccine Distribution system and its storage practices. The study also contributed valuable information for local health policy makers, EPI, healthcare providers, donors and all stakeholders involved in cold chain medicines to effectively plan, manage and supervise the distribution system and storage practices of vaccines in Tanzania.

CHAPTER TWO

2.1 LITERATURE REVIEW

This chapter reviews various research studies and literatures on effects and consequences brought about by improper vaccine distribution system and poor vaccine storage and handling to the community. The chapter examines various research studies and reports done locally (Tanzania), regionally (Africa) and globally. The chapter also reviews some common types of vaccines currently available in routine immunization at healthcare facility for human being.

2.2 Global perspective on vaccine distribution and management

The study conducted in Bali province Indonesia regarding improving the animal health cold chain and vaccine management indicated that there were urgent needs for improvements in management of vaccine. Approximately half of the refrigerators were unsuitable for vaccine storage generally in poor condition, temperature was not monitored. As a result healthcare workers did not know if the temperature of refrigerator was within the recommended range at 2-8 ^{0}C. In additional vaccines were arranged inappropriately in the refrigerators, and were mixed with other items including expired and partially used vaccine vials. (Vogel, et al, 2011)

In a cross sectional study that was conducted in Toronto Canada from August to December 1992, staff responsible for vaccine storage were interviewed about their knowledge and practices of vaccine handling and storage. Refrigerators were inspected, fewer than 7 (6%) practices staff answered all questions related to vaccines storage and handling correctly, and only 11 (10%) refrigerator had thermometer. One –third of refrigerators had temperatures outside the recommended range of 2 to 8 degrees centigrade. Older refrigerators were more likely to had inappropriate temperature than newer ones. Knowledge and practice of vaccine storage and handling were often inadequate in primary care physicians offices (Yuan, et al, 1995)

The study conducted in Secunderabad India concerning vaccine distribution found that the implementation of an Immunization program in the rural areas was affected by gap in the distribution system. The study also identified other problem areas such as a faulty cold

chain and need for an improved monitoring and control system and for better supervision (Subramanyam, K. 1989)

2.3 African perspective on vaccine distribution and storage management.

A campaign of distributing bed nets in measles campaign was conducted in Lawra District in Ghana as phase 1 in December 2002 as small scale study and then in Zambia which was phase 2 in June 2003 this was a large scale study. It was a campaign of achieving equity in the distribution of Insecticide Treated Bed nets through links with Measles campaigns, targeted all children from 9 months to 15 years. This came after WHO realized that Measles vaccination coverage in most Sub-Sahara countries was around 90% while free ITN distribution coverage was below 20%. Five months post distribution of ITN in both Ghana and Zambia, a two stage cluster survey with population proportional sampling assessed ITN coverage, retention and use (Grobowsky, M. et al, 2005). Both surveys assessed household wealth through an asset inventory. In Ghana overall household ITN ownership increased from 4.4% to 94.4% and in Zambia from 16.7% to 81.1% showing that ITN distribution to measles campaign may be an important opportunity to achieve ITN coverage target (Grobowsky, M. et al, 2005)

2.4 Tanzania perspectives on vaccine distribution and storage management

The vaccine management assessment conducted in December 2009 assessed 2 Central Vaccine Stores (CVS), 13 Regional Vaccine Stores (RVS), 14 District Vaccine Stores (DVS), and 28 Health facilities based on 11 standard criteria (MOHSW, 2010). The overall average score on vaccine management performance was 79% for all levels. The National level was 89%, Sub- national level was 74% (RVS/DVS) and for Service level was 75% .The assessment established that the vaccine arrival procedure is good, the health workers have high knowledge on the use of Vaccine Vial Monitors (VVMs) and the Multi Dose Vial Policy (MDVP). However, vaccine storage temperatures, vaccine stock management, effective vaccines delivery and correct diluents use for freeze dried vaccines need to be improved.

In view of the above studies conducted in Tanzania, it is observed that previous assessment studies focused on vaccine management in totality and there is no specific

study that has been done with a special attention to vaccine distribution system in the public healthcare facilities. Given this existing gap, this study assessed vaccine distribution system and healthcare personnel's knowledge on storage and proper handling of vaccines at healthcare facilities.

The potency of vaccines, and test kits depends on maintaining of cold chain. Vaccines must be kept at precisely controlled temperatures range from the point of manufacture to the point of administration. Cold chain defects are a frequent cause of problems in immunization programs (MSH Managing Drug Supply, 1997). National, Regional, District and healthcare vaccine stores should be equipped with standby generators to ensures that vaccines and other products are protected in the event of a power failure.

Freezing is as damaging as high temperature for some items, including injectables such as adrenaline and ergometrine, contraceptives, insulin and vaccines such as the Diphtheria Pertussis Tetanus, Diphtheria Tetanus, Toxoid Tetanus and hepatitis B vaccines. Toxoids which frozen can be detected by the "shake test" method (MSH, Managing Drug Supply, 1997). As a result loss of potency occurs and medicines need to be discarded.

Vaccines, blood products and some other medicines lose potency if kept, even briefly, at temperatures outside the recommended range. For these products, the cold chain must be maintained at every stage (MSH, Managing Drug Supply, 1997). Any electrical power black-outs must also be recorded including the period during which the vaccines were exposed to uncontrolled temperatures. Vaccines are then discarded or kept depending on the manufacture advice (MSH, Managing Drug Supply, 1997).

CHAPTER THREE

METHODOLOGY

3.1 Study Area and Population

The study was conducted in Coast region. Coast region is estimated to have 203 public health facilities (MOHSW, 2010) of which 47 are in Bagamoyo, 18 in Kisarawe, 40 in Mkuranga, 50 in Rufiji ,17 in Kibaha, 17 in Mafia district councils and 14 in Kibaha town council including Tumbi hospital. The study units were healthcare facilities and the study population were people selected for interview at the healthcare facilities in the region. For the purpose of this study, the healthcare facilities included Regional Vaccine Store (RVS), and District Vaccine Store (DVS), hospitals, health centres and dispensaries.

3.2 Study Design

It was a cross-sectional survey. Staff responsible for vaccine distribution and management was interviewed about their knowledge and practices of vaccine distribution, handling and storage. Refrigerators and freezers were inspected and temperature documented from freezer tags and observation of vaccine storage conditions. Assessment of availability of 6 tracer vaccines stock at the time of facility visiting was conducted. In addition, assessment of average stock out duration of tracer vaccines for the past 10 months was carried out.

3.3 Sampling procedures and Sample Size determination.

The study included regional levels vaccine stores and employed a multi- stage sampling technique in selecting district councils. A multi-stage sampling was done for the districts to ensured representation from the different levels of EPI service delivery. Multi-stage randomly sampling of 7 district councils came up with 4 district councils which were Kibaha town, Bagamoyo, Mkuranga, and Rufiji to got good representative sample of Coast regional. At each district, the district hospital were selected plus 9 healthcare facilities that were randomly selected within each district in which 2 were healthcare centres and 7 were dispensaries and added up to made a large representative sample of the facilities surveyed during the study period which was 10 facilities per district council.

Total for region: 40 public healthcare facilities and 5 warehouses were included in the study to make a total of 45 public healthcare facilities.

.Five warehouses in study included:-

-At Regional level – 1 Regional Vaccine Store were assessed

-At District level – 4 District Vaccine Stores were assessed

Random selecting public healthcare facilities from district councils

Step 1. The District public hospitals were selected from a list of all public healthcare facilities in the District.

Step 2. The selection of second facility were involved identified all primary health facilities in district and randomly selected one.

Step 3. Number the remained primary health facilities that were health centres and dispensaries.

Step 4. Calculate the sampling interval. For example if there were 40 public health facilities in the District and 10 were to be chosen. The sampling interval was calculated by dividing the total number of facilities by the number selected, 40/10=4

Step 5. Identified the third, fourth, fifth up to tenth facilities

-chosen random whole number between 1 and 4, for instance 3.

- The third facility were the one numbered 3

-Added the sampling interval to the randomly chosen number 4 + 3 = 7

-The fourth facility will be number 7

-The fifth facility 4 + 7 = 11 continues until all 10 facilities are chosen.

The same process illustrated above was used to select public healthcare facilities in each of the 4 geographic District councils included in the survey. Selected Districts in Coast regional and their healthcare facilities included in study is in Appendix 9.

Sample size calculations:

Population size, n

In each of the selected levels information were collected from the following:-

-At Regional level were RCCO and RRCHCO =2 people

-At District level DCCO and DRCHCO = 2 people * 4 district=8people

- At healthcare facility level were personnel in charge of vaccine storage and immunization focal person = 2 people

Healthcare facilities that were selected in Coast region= 40

People that were interviewed at public healthcare facilities= 40* 2 =80

People that were interviewed at Regional and Districts administrative level =10

Total number of people who were interviewed was 90 and assessment was on 45 Public Healthcare facilities which consists 1 RVS and 4 DVS.

3.4 Data Collection.

The principal investigator led the data collection exercise in collaboration with other appointed research assistants who were recruited and oriented before commencement of data collection activities. The personnel recruited were pharmaceutical technician.

Under supervision and support of the principal investigator, 2 personnel were recruited and trained on the main objectives of the study, importance of each variable and the use of the results from the study as well as other logistics and protocols. After thorough training, they were sent to respective districts with all the necessary tools for data collection.

3.5 Data Collection Tools

The study employed the following tools in the course of data collection:-

- Field survey observation of the selected facilities were done using facility indicator forms for storage and handling condition (WHO-modified model) at the health facilities and Immunization sessions (APPENDIX 4)
- Interviewed vaccines in-charges personnel, vaccination focal person, vaccine key informants were done by using structured questionnaires which had closed ended and open ended questions (APPENDIX 1&2). These knowledge questions were used to measure if the respondents interviewed were knowledgeable.
- Desk reference reviews (reviewed of available documents that show records of vaccines stocks) assessment of availability of tracer vaccines at a time of visited and if there were stocks out for the past 10 months. (APPENDIX 3, & 5)

3.6 Pre-Testing of Tools

The data collection tools (interview and facility indicator forms) were tested at 4 different facilities in order to validate them prior to roll out to a larger scale. Data collecting tools were modified accordingly upon completing the pilot study.

3.7 Ethical Clearance.

Ethical clearance was obtained from Ethical Review Committee of the Muhimbili University of Health and Allied Sciences (MUHAS). The investigator sought permission from respective council authorities prior to visiting the selected healthcare facilities. Finally consent was sought from participants before enrolling them into the study. The consent form is appended in (Appendix 7)

3.8 Inclusion criteria

Pharmacist in-charges of the healthcare facility vaccines store or any other health personnel employed as in-charges of the vaccines and cold chain store in respective healthcare facilities for a period of not less than 6 months, immunization focal person, DCCO, DRCHCO, RCCO and RRCHCO.

3.9 Exclusion criteria

Those healthcare personnel who were unwilling to participate and those who were on leave during the study.

3.10 Study procedure

Data were collected after giving consent forms which was preceded by explanation of study objectives to the interviewees. Consented candidates were interviewed using structured questionnaires. The investigator reviewed available vaccines records of current stocks and previously dispensed vaccines for period of ten months. In addition we observed the state of the storage area.

3.11 Data quality control

For the captured data to be reliable and valid, during the study measures were taken in order to ensure consistence of data quality. This was included;

-Translation of questionnaire and consent form from English to Kiswahili with similar meaning in back translation. As the study targeted different cadres with different qualification and level of education, both languages (Kiswahili and English) were used depending on the situation. This ensured that same information is captured from different cadres.

- Verification of filled questionnaires and
- Coding of the questionnaires and facility indicator forms (Appendices 1-8).

3.12 Study variables

The study involved Independent and Dependent variables.

INDEPENDENT VARIABLES

Independent variables/explanatory variables were socio demographic factors such as sex, age, and experience at work as vaccine store supervisor, immunization focal person or key informative. Social economic factors includes professional of healthcare provider.

DEPENDENT VARIABLES

They were divided into 4 categories

1) Knowledge of healthcare staff on storage, handling, practices and distribution system of vaccines which was measured by developing knowledge scale i.e Good,

Moderate & Poor knowledge based on the number of questions answered correctly by respondent in questionnaires. The knowledge scale was arbitrary by dividing 100% into 3 parts, 0-33% Poor, 34-66% Moderate and 67-100% Good. Good, Moderate and Poor were dependent variables of assessing knowledge in this study.

2) Availability of 6 key tracer vaccines at all selected facilities at time of visit was assessed and availability of vaccines in stock is dependent variable in this study.

3) Average stock out duration of vaccines at all facilities selected for the study was conducted and Average number of stock out days is dependent variables.

4) Storage and handling practices of vaccines at the facility level by observing temperature monitoring and recording, refrigerator temperature at the time of visited and vaccine storage practice are dependent variables in this study.

3.13 Data treatment, Analysis and Reporting of Results.

After data collection, the preliminary analysis and reporting were done on site at the facility level in order to give feedback to in-charges of the facilities in question. Further analysis using computer software such as SPSS version 15 and EPI-INFO were used for final data analysis. Statistical method used was t- test. Study results have been presented by using tables, Pie charts, histograms and other relevant graphics as exhibited in chapter four of this manuscript.

CHAPTER FOUR

ANALYSIS AND SUMMARY OF RESULTS AND FINDINGS

This chapter provides a detailed analysis of the data collected from the field. It starts by analyzing data according to the research questions which guided this study. Various non parametric tests were used at various stages of data analysis.

4.1 Response Rate

Of the selected 40 public health facilities and 5 warehouses (i.e. district hospitals, health centres and dispensaries). All 40 public health facilities and 5 warehouses respondents agreed and participated in the study. Of the selected 90 people for interviewees only 84 contacted, missing was due to inadequate health workers at facility level working at vaccination area. The overall response rate of the interview that was conducted is 94.7%, however minor discrepancies in some respondents were observed due to respondents' inability to provide answers to some of the questions caused by lack of training and less experience in the vaccination area. Those cases were considered as missing values in the analysis.

4.2 Availability of vaccines at the selected healthcare facilities

This was done during visiting the facility in the survey and availability of six key vaccines used in routine Immunization was used as tracer vaccines. The distribution of availability of vaccines from 40 contacted healthcare facilities and 5 vaccine stores were summarized in the tables below

Table 1: Availability of vaccines at Healthcare facilities level on a day of visiting

N=40

TRACER VACCINES	Facilities with vaccines in percentage (%).
BCG VACCINE	95
PENTAVALENT VACCINE	95
OPV	95
MEASLES VACCINES	95
TETANUS TOXOID VACCINE	97.5
RABIES VACCINE	15
Mean(Average)	82

From the table 1: above the least available vaccine at healthcare facilities was Rabies vaccine (15%; n=40). Mean availability of vaccines at healthcare facilities level is 82% & median is 95%.

Table 2: Availability of vaccines at Vaccine stores level on a day of visiting.

N=5

TRACER VACCINES	Stores with vaccines in percentage (%).
BCG VACCINE	80
PENTAVALENT VACCINE	100
OPV	100
MEASLES VACCINES	100
TETANUS TOXOID VACCINE	100
RABIES VACCINE	80
MEAN (AVERAGE)	93.3

From the table 2: above the least available vaccines at stores level was BCG & RABIES VACCINE. Mean availability at vaccine stores level is 93.3% & median is 100%.

4.3 Average stock out duration at the healthcare facilities.

Average stock out duration of six tracer vaccines was determined as a means of finding out if vaccines were available at all levels of healthcare facilities for the past ten months. The number of days out of stock was calculated within ten months retrospectively.

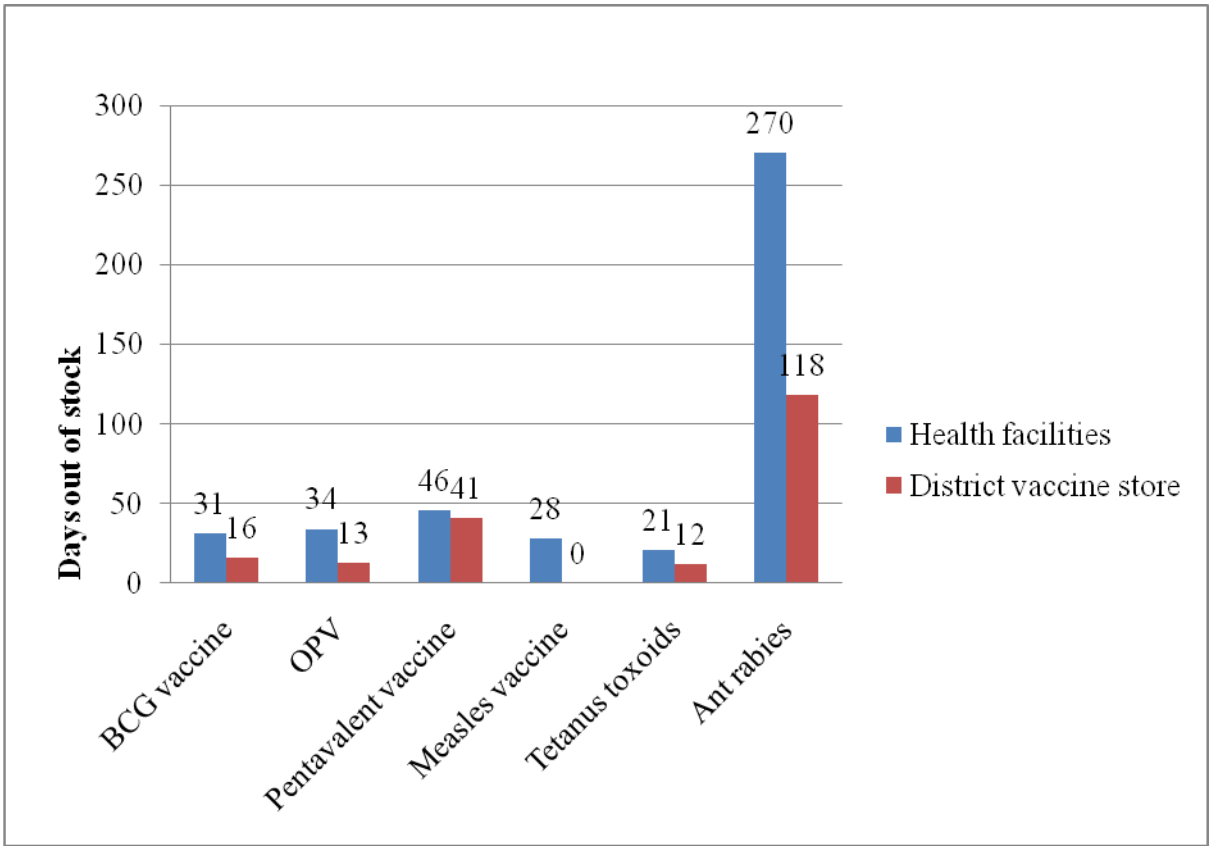


Figure 4: Average stock out days of vaccines between healthcare facilities and district vaccine stores.

The study shows that the average stock out days of vaccines between healthcare facilities and district vaccine stores was statistically significant ($P < 0.0001$). This implies that there is a problem in distribution system.

95% Confidence Interval=MD +/- 1.96(S.E), Mean = 17.5, SE = 6.5, SD = 9.19, Min = 11%

Max = 24%, t = -0.382, 95% C.I = 17.5+- 1.96*6.5 = (5, 30)

It is statistically 95% Confidence that stock out days at the healthcare facilities was between 5 and 30 days for the period of the past 10 months reviewed in this study retrospectively.

The median number of stock out for the 6 tracer vaccines was 32.5 days for healthcare facilities conversely the median number of stock out days for district vaccine stores was 14.5 days. Average stock out days was 72 days, 33 days for healthcare facilities and district vaccine stores respectively.

4.4 The storage conditions of vaccines at the healthcare facilities.

The assessment of storage conditions of vaccines at different level of healthcare facilities was done using Storage and handling indicator form (Appendix 4) .The results of assessment of storage condition are summarized in table 3 below

Table 3: Assessment of storage conditions at the healthcare facilities during visiting, (observation)

PARAMETERS OF STORAGE CONDITIONS	Facilities level, (%, n=40)	Stores level, (%, n=5)	Average of facilities & stores in %
Good arrangement inside refrigerators	40	60	50
Presence freezer tags monitor in refrigerator	0	20	10
Daily monitoring & recording of temperature in chart	20	40	30
Presence of trays which are used for arrangement	65	40	52.5
Mixing other items with vaccine in refrigerator such as fruits & water	25	0	12.5
Presence good storage space for refrigerator	65	60	62.5
`Vaccine refrigerator/ freezer room storage capacity adequate to accommodate all stocks	85	60	72.5
Presence of standard vaccine refrigerators and freezers	92.5	100	96.3
Vaccines found stored in domestic freezer	10	0	5
Presence of standby power supply	15	40	27.5
Vaccine refrigerator maintain recommended temperature range of $+2^0$C to $+8^0$C	60	80	70
Refrigerator not on recommended temperature range	42.5	0	21.25
Quantification performed during ordering	0	60	30
Vaccine freezer maintained at recommended temperature range of -15^0C to -25^0	0	80	40
Vaccines freezer with temperature below -25^0C	0	20	10
Vaccines found frozen in refrigerator	2.5	0	1.25
Presence expire vaccines at facility (any vaccine)	40	80	60

4.5 Distribution of Responses by Professional Cadres

During data collection various health facility vaccines store in-charges/immunization focal person of different cadres and qualifications including; Environmental health officers, clinical officers, nursing officers/nursing midwives and nursing assistants were interviewed as shown in the figure 5 below

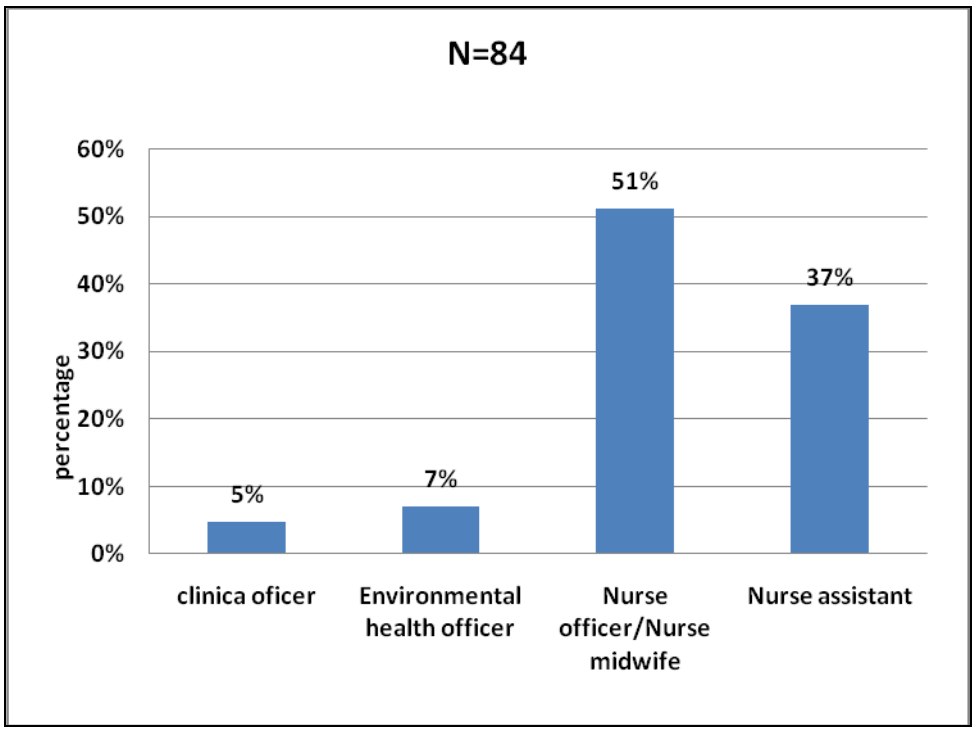


Figure 5: Showing the distribution of professional of the respondents.

From the figure 5 above, the findings show that, 4.8% of the immunization focal person/in-charge of vaccines stores were Clinical officers, 7.1% were Environmental health officers, 51.2% were Nursing Officers/Nurse midwife, and 36.9% were Nursing Assistants.

4.6: Demographic Variables Distribution

Gender, sex and experience at work of the interviewees were the demographic variables that were examined and their distribution is summarized in the table below

Table 4: Demographic Distribution of the Vaccines Store Supervisors/Immunization focal person

N=84

Demographic Variables		**Percent**
GENDER/SEX	Male	6
	Female	94
AGE	25 – 31	12
	32 – 38	31
	Above 39	57
EXPERIENCE AT WORK	Less than 1year	3.6
	1 to 5 years	29.8
	6 to 10 years	16.7
	11 to 15 years	7.4
	More than 15 years	42.9

From table 4: above, the results show that majority (94%) of the contacted respondents were female. Regarding age distribution, majority (57%) of the contacted respondents were above 39 years of age. In case of experience at work many (42.9%; n=84) of the vaccines store supervisors/immunization focal person had worked for more than 15 years and only

(3.6%; n=84) had worked for less than a year of experience as vaccines store supervisor or immunization focal person.

4.7 Level of knowledge on handling of vaccine and Practices of healthcare givers at Public Healthcare Facilities.

In order to determine knowledge on vaccines handling procedure and their practice health facility vaccines stores in-charges and immunization focal person were required to list procedure of handling vaccines (figure 6) and to answer questions related to practices of handling vaccines at healthcare facility.

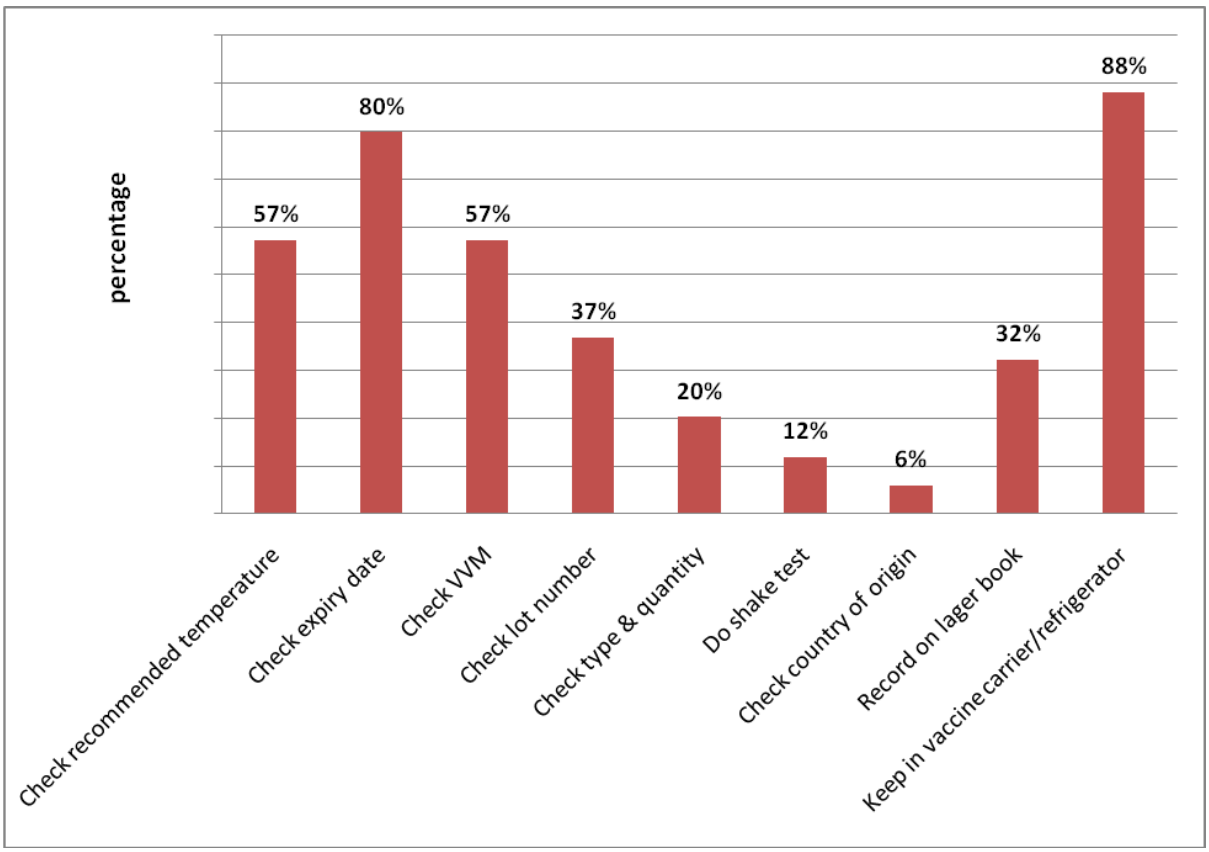


Figure 6: Handling of vaccines from point of arrival up to the point of administration as indicated by respondents.

From figure 6 above majority listed counter checking of expiry date (80%) and keeping the vaccine in vaccine carrier/refrigerator (88%) as the most mentioned procedures while checking country of origin was the least mentioned procedure.

4.8 Frequency of distribution of vaccines to the lower facilities

Responses of respondents with regard to the frequency of distribution of vaccines to the lower health facilities, question aimed at determined the effectiveness of vaccine distribution from stores to lower healthcare facilities were summarized in the table 5 below;

Table 5 Frequency of distribution of vaccines to the lower facilities

N=84

Frequency of distribution of vaccines	Respondents	Percent
once monthly	8	9.5
when necessary	2	2.4
NA	74	88.1

Table 5 above shows that 88.1% of the contacted respondents were not responsible for distribution.

4.9 Methods regularly used to transport vaccines at public healthcare facility.

With regards to question that list all the method regularly used to transport the vaccines at public healthcare facility, the respondents were required to list the method they regularly used to transport vaccines. This question was aimed in determining means vaccines transport.

N=84

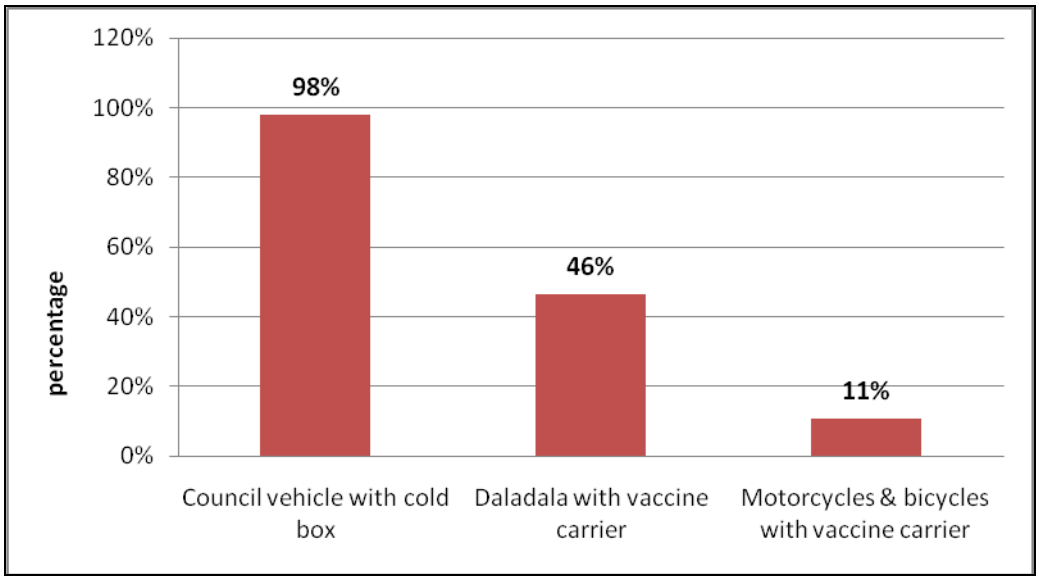


Figure7: Means of transport used to transport vaccine from district vaccine store to health care facilities (n=84).

From the figure 7 above (46%) of respondents listed using public means of transport (daladala) with vaccine carriers to transport vaccines to their facilities.

4.10 Factors that lead to improper storage condition.

Respondents mentioned a number of factors which are shown in figure 8 below, Unreliable electricity was mentioned by about (58%) and low level on knowledge on storage condition was mentioned by only (11%).

N=84

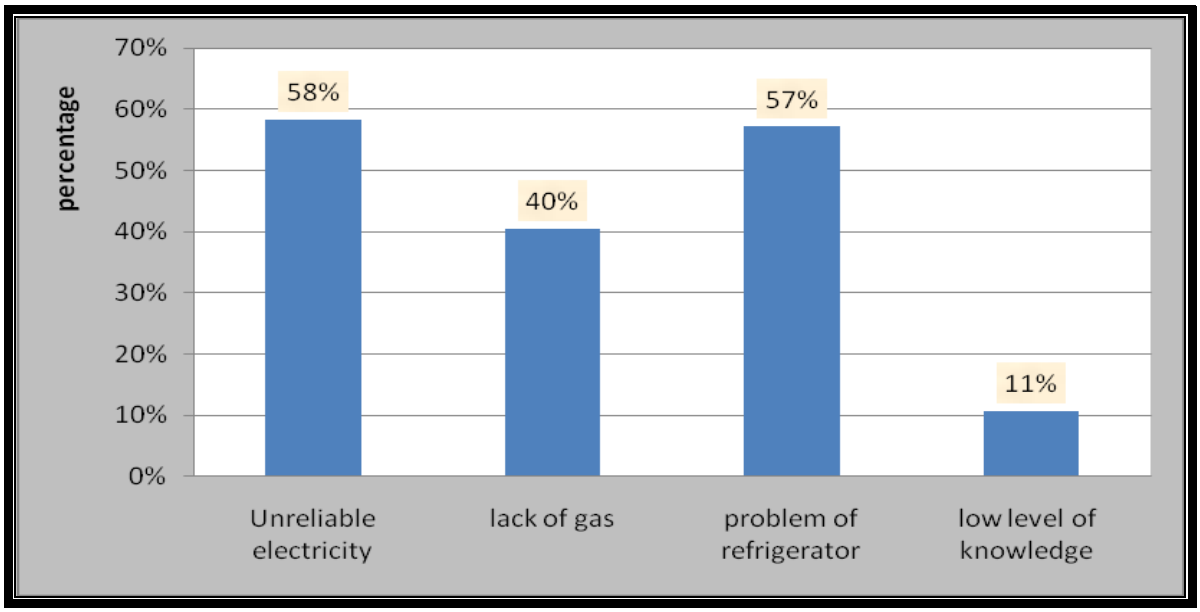


Figure 8: Responses of respondents on the factors that lead to improper storage condition.

4.11 Records of discarded vaccines.

With regards to records of vaccines discarded due to incorrect storage temperature majority of respondents (92.9%) said that there were no records.

Table 6 Records of discarded vaccines

Response	Percentage (%)
YES	7.1
NO	92.9

4.12 Barriers to efficient distribution system of vaccines

The research looked into barriers to efficient distribution system that health facilities face whenever they plan to distribute vaccines. With regards to this question respondents interviewed were asked to respond by mentioned some of the barriers she/he knows and results of which have been summarized below.

N=84

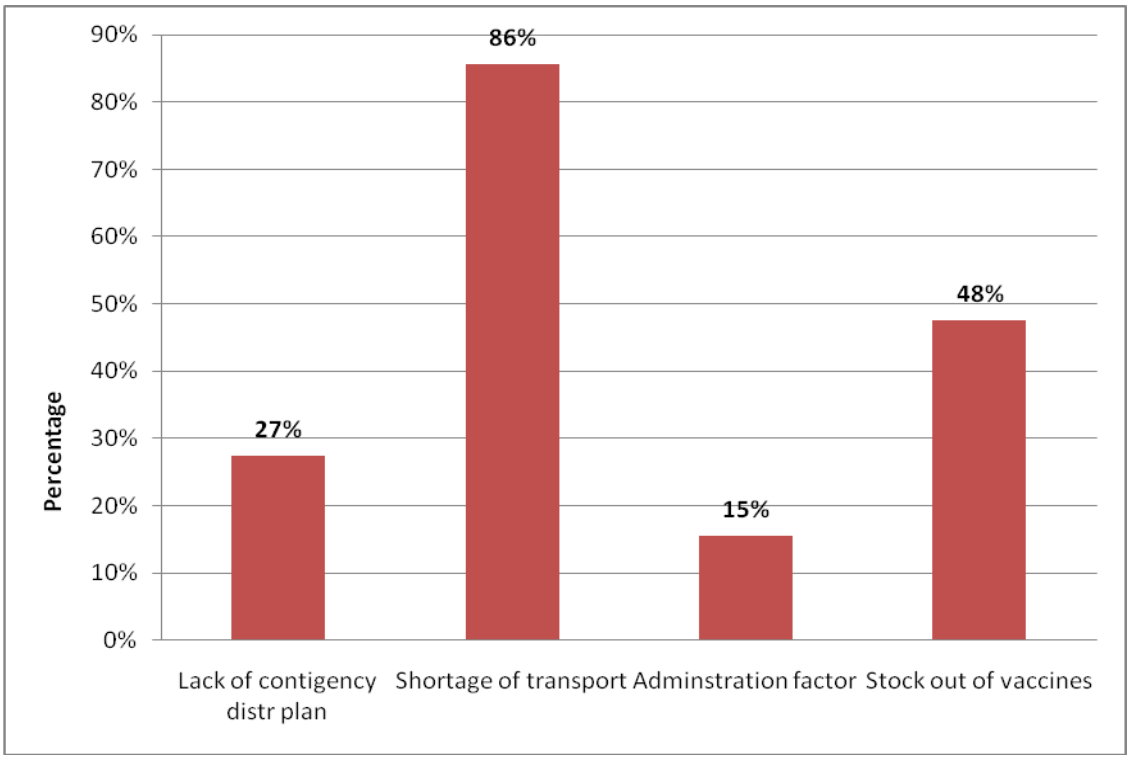


Figure 9: Barriers to efficient distribution system of vaccines.

From the figure 4.12 above many (86%) of respondents mentioned shortage of transport as a barrier to efficient distribution.

4.13 Vaccines Store Supervisors and Immunization focal person Recommendations to the Ministry of health and social welfare.

The following recommendations (table 7 below) were made by the interviewed facility store supervisors and immunization focal person with regard to the functioning of the Ministry of health and social welfare (MOHSW) through Expanded Programme on Immunization (EPI) on various issues relating to distribution system of vaccines and its storage.

Table 7: Recommendations to the Ministry of health and social welfare as suggested by respondents N=84.

Variables	**Percentage**
Reducing the strength pack dose of BCG from 20 to 5 doses	62.2
Strengthen vaccine management assessment to the lower facility level	39.8
Strengthen availability of gas & its distribution in timely manner	47
To introduce solar refrigerator	22.9
To update health workers through on job training especially when changes occurs.	55.4
To increase availability of new modern Refrigerator RCW 50EG &Freezer TCW 3000	15.7
To enhance transport in distribution and in mobile clinic	55.4
To increase availability of vaccines, diluents ,syringes and trays	27.7
To improve or build vaccines stores (absent in many facilities)	18

From table 7 above, majority (62.2%) of the contacted vaccines store in-charge and Immunization focal person recommended MOHSW/EPI should reduce the current pack dose of BCG vaccines so as to reduce the high volume of wastage rate and to create user friendly environment to the client. It also noted that (55.4%) of the contacted respondents recommended that MOHSW should enhance transport (vehicles, fuel and maintenance) in vaccines distribution system.

4.14 Availability of EPI Guidelines for vaccine management

Health facilities were assessed on presence of EPI Guidelines for vaccine management which is a very important tool for health professionals engaged in daily vaccines store management transactions and in immunization session, results of which are summarised in the figure 10 below

N=84

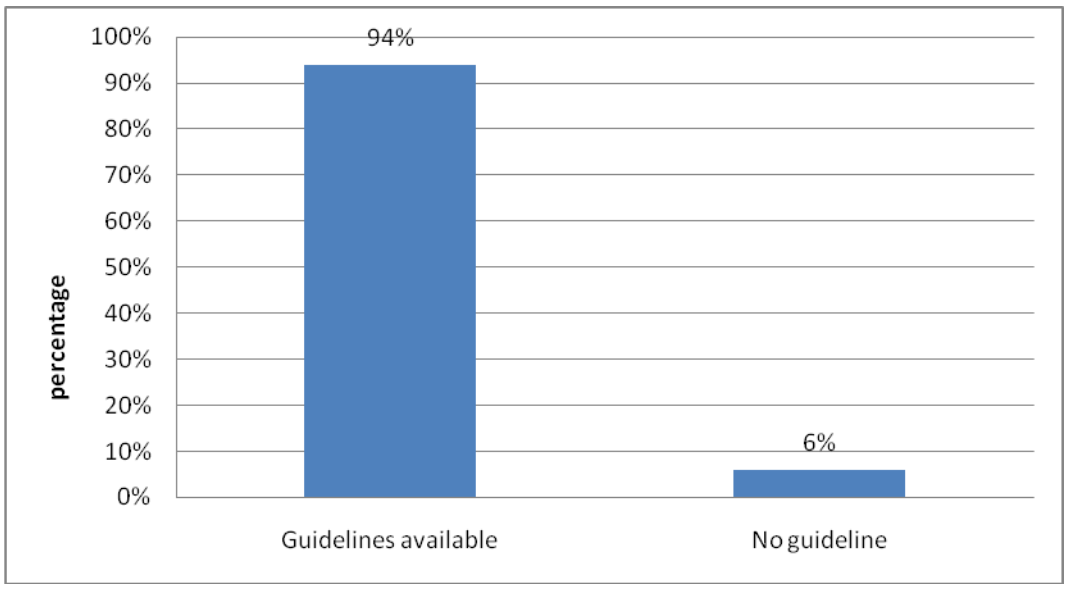


Figure 10: Availability of EPI Guidelines for vaccine management

Figure 10 above entails that for (94%) of contacted respondents their healthcare facilities had EPI Guidelines.

4.15 Level of Knowledge on Storage.

In the process of measuring the level of knowledge on storage, the following parameters were used which are Previous training, Knowledge of respondents on recommended temperature range for storage of vaccines in refrigerator and freezer, Knowledge level of respondents on vaccine stock management and need in professional training.

N=84

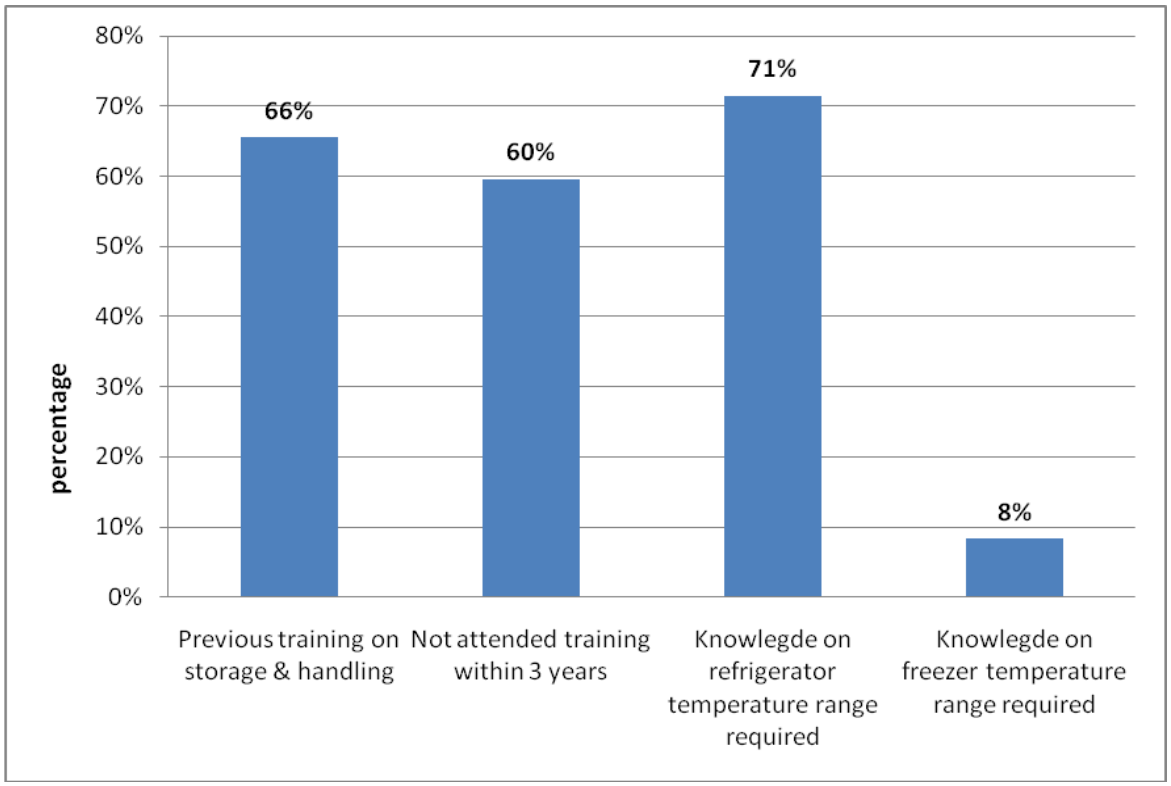


Figure 11: Knowledge of healthcare personnel involved in the vaccine storage as indicated by respondents.

From figure 11 above it shows that (60%) of respondents interviewed had not attended training on storage, distribution and handling of vaccines within the last three years and only 8% of all respondents had knowledge on recommended temperature range for vaccine freezer storage.

4.16 Knowledge levels of respondents on recommended temperature range for vaccine stored in refrigerators.

Respondents were asked question regards to the recommended temperature range for vaccines stored in refrigerators such as Pentavalent, TT, BCG, Ant rabies and diluents and results are summarised in figure 12 below

N=84

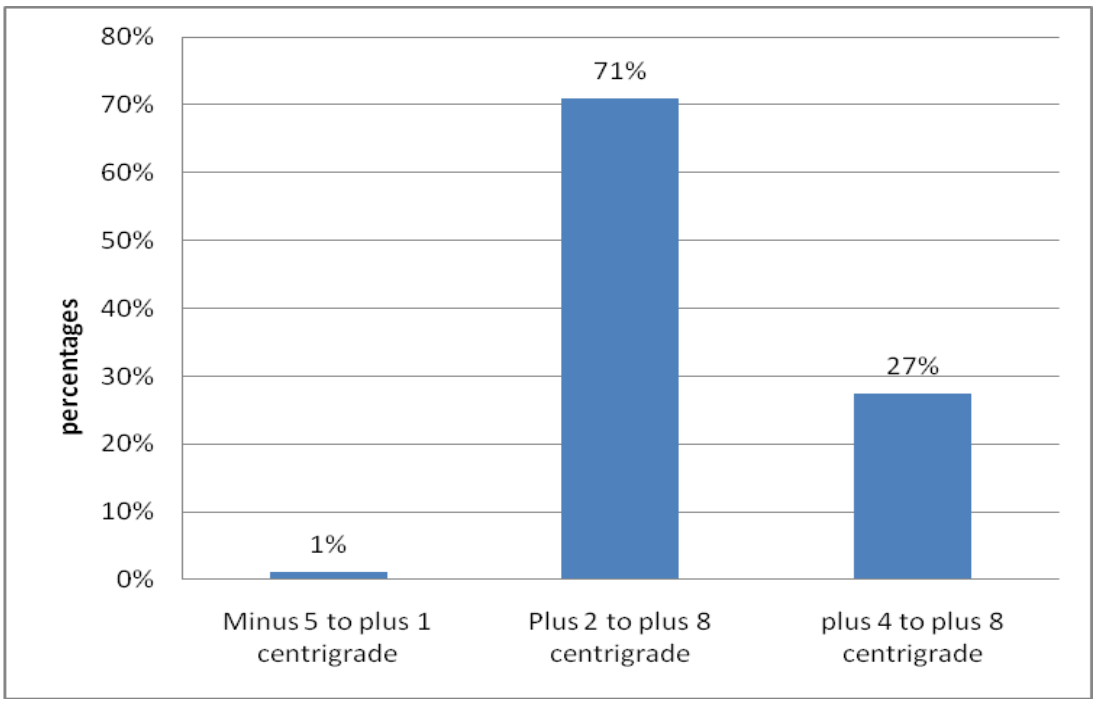


Figure 12: Knowledge level of respondents on recommended temperature range for vaccines stored in refrigerator.

Majority (71%) of respondents had knowledge on recommended temperature range of vaccines stored in refrigerator.

4.17 Knowledge levels of respondents on recommended temperature range for vaccine stored in freezers.

Respondents were asked question for the recommended temperature range for vaccines stored in freezer such as Measles vaccines and OPV and results are summarised in figure 13 below

N=84

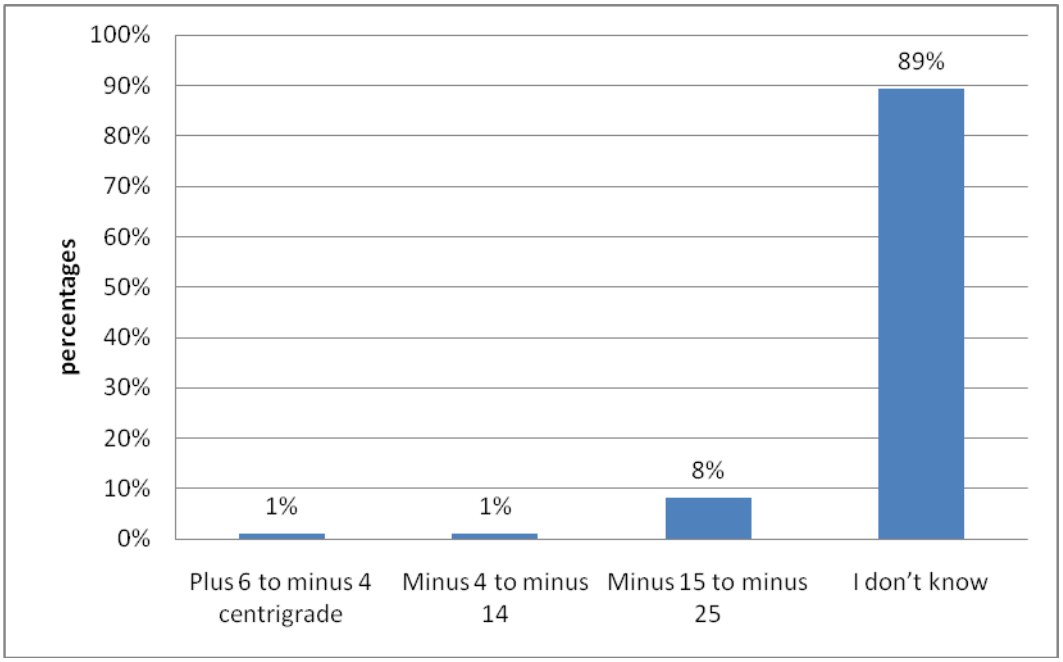


Figure 13: Knowledge level of respondents on recommended temperature range for vaccines stored in freezer.

Majority (89%) of respondents had no knowledge on recommended temperature range of vaccines stored in freezer.

4.18 Observation on recommended temperature range of refrigerators on visiting healthcare facilities

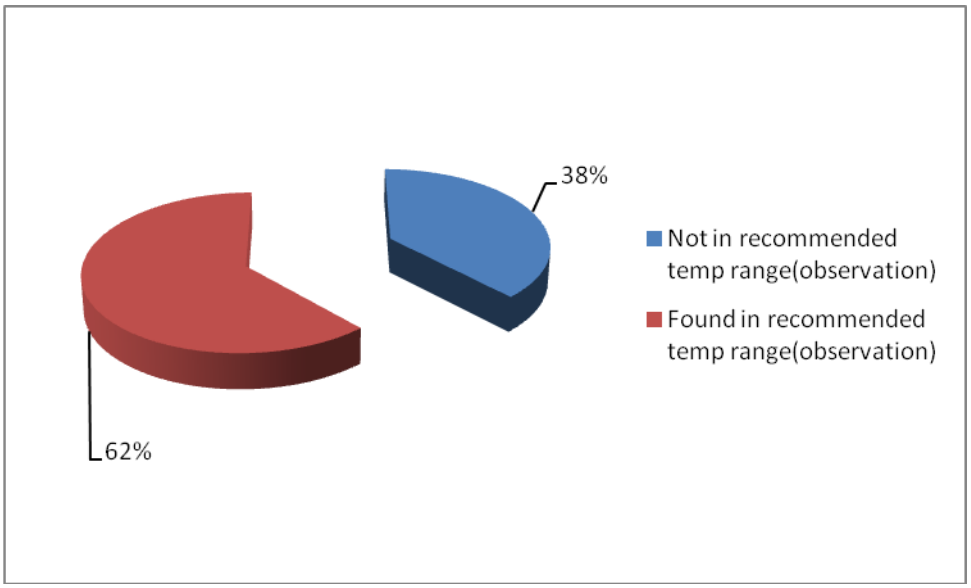


Figure 14: Refrigerators found not in recommended temperature range.

From figure 14, it was observed that 38% of healthcare facilities visited had refrigerators not in recommended temperature range of vaccine by observation.

4.19 Recorded recommended temperature range of refrigerator found not matching the observed at a time of visiting.

From table 3 (40%) of all healthcare facilities and (20%) of all vaccines stores which found to have recommended temperature range of refrigerator above $+8^0$C only one facility (6%) recorded the truth of being out of the recommended range of temperature .Presented by figure 15 below

N=17 (for those found out of range)

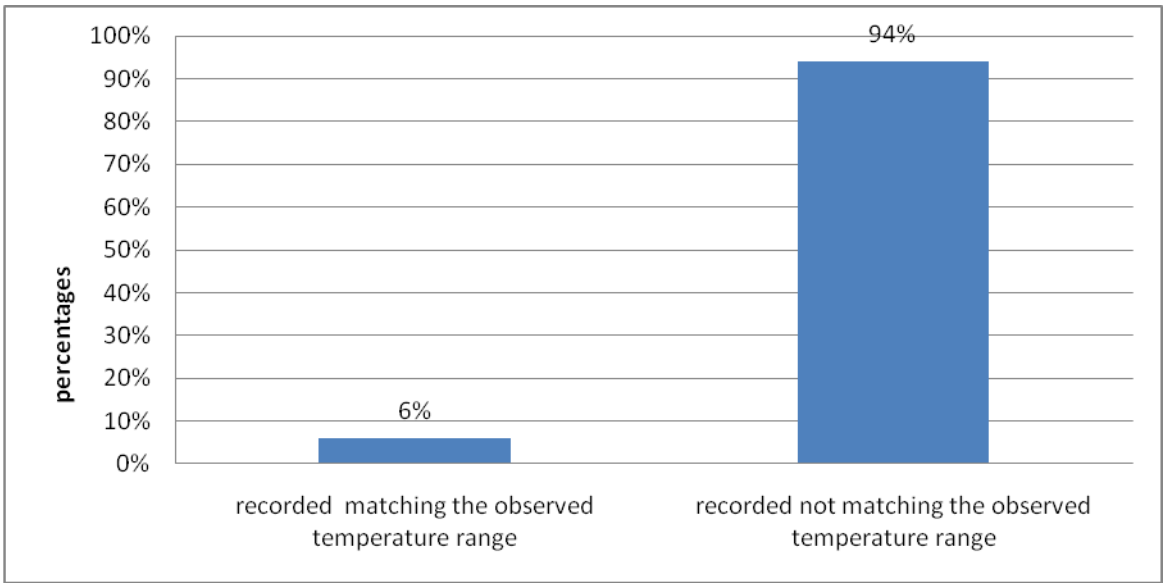


Figure 15: Showing the temperature range recorded not matching the observed temperature in the healthcare facilities.

Figure 14 above revealed that among (38%) healthcare facilities refrigerators found out of recommended temperature range in figure 13 only 6% recorded the temperature range matching the observed.

4.20 Response of respondents to the action taken when vaccines are found out of recommended temperature range.

The results are summarized in table below

Table 8. Action/measure taken by respondents when vaccines were found out of recommended temperature range.

N=58

Action/Measure	Percentages
Continue stored in cold chain for future use	65.5
Stop using and recorded in discarded book	5.2
Others(Transfer to nearest facility or adjust refrigerator)	29.3

From the table 8 above 65.5% of contacted respondents responded by saying continue storing vaccines in cold chain system for future use. Only 5.2% of respondents said they stoped using the vaccines and recorded in the larger for discarded items.

4.21 Knowledge levels of respondents on vaccine stock management.

In order to determine the knowledge levels of vaccine store supervisor and Immunization focal personnel on effective vaccines stock management, respondents were asked to responds to the questions related to vaccine stock management and summarised in the figure below

N=84

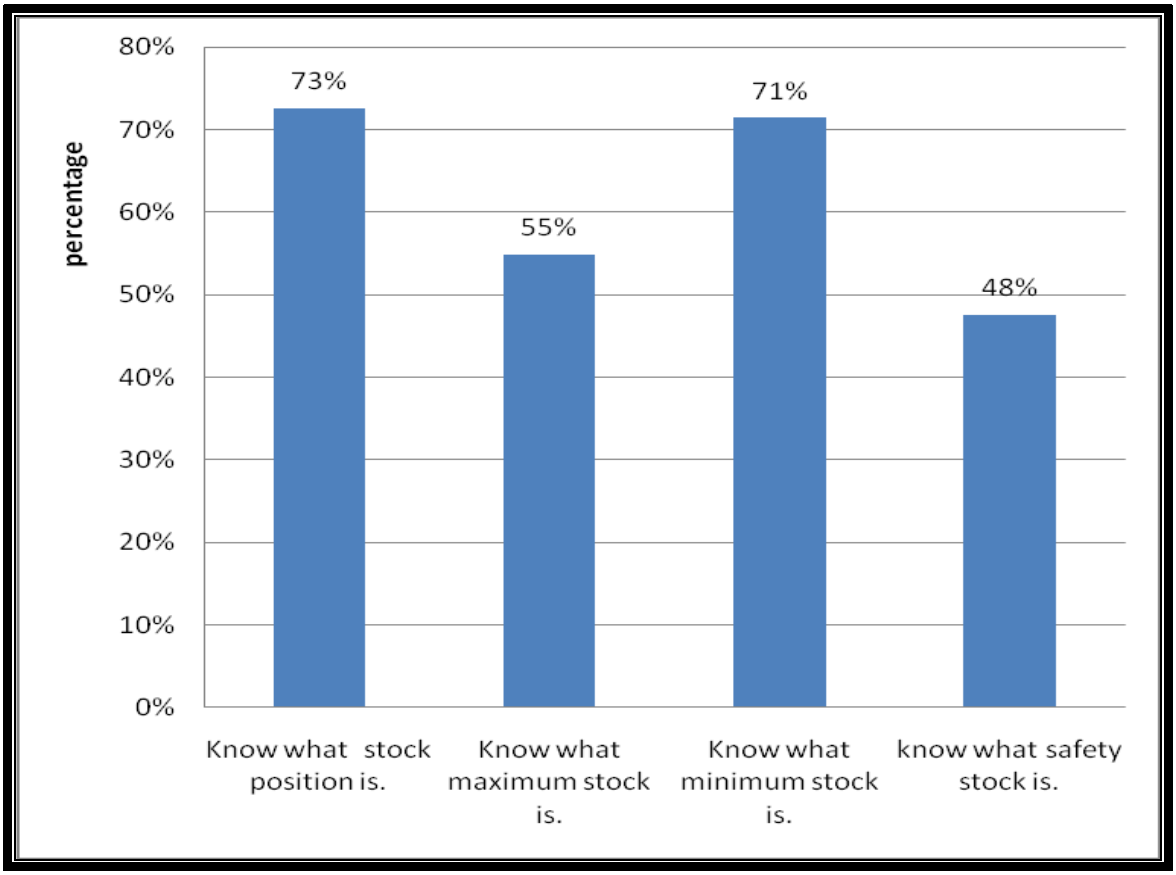


Figure 16: Knowledge levels of respondents on vaccine stock management indicated by respondents.

Figure 16 above shows that (71%) of respondents know what knowledge on minimum stock level is.

CHAPTER FIVE

DISCUSSIONS

This chapter presents detailed discussions pertaining to the research study. Results obtained in chapter four formed the basis for these discussions and then conclusions and recommendations in chapter six for way forward in addressing the problem of vaccines distribution system at public health facilities. Areas for further research have also been sited.

5. DISCUSSIONS.

In this research assessment of availability of 6 tracer vaccines was conducted at the time of visiting the selected public healthcare facilities to determine the availability of vaccines. The distribution of availability of the six tracer vaccines indicates that vaccines were more available in district vaccine stores level compared to the healthcare facilities level. Missing vital medicines like vaccines in the public healthcare facilities of any level is threat to our national and clients particularly under five children and pregnant women who are at high risk if they not vaccinated on time. Poverty eradication through prevention of diseases will be difficult in our country if vaccines are not available at all time in the supply chain system.

Determination of average stock out duration of six tracer vaccines was done. The stock out situation was determined by the number of days tracer vaccine has been out of stock in a facility for period 300 days retrospectively and then average stock out days were calculated for each type of vaccine in each level.

The comparison of average stock out days between healthcare facilities and district vaccine stores, average stock out days is higher at healthcare facilities as compared to district vaccine stores. Average stocks out days were 72 and 33 days for healthcare facilities and district vaccine stores respectively (figure 4).

Statistically the study shows that the average stock out days of vaccines between healthcare facilities and district vaccine stores was statistically significant ($P < 0.0001$).This implies that there is a high stock out days at health facilities as compared to district vaccine stores. The study reveals that there were high availability of tracer vaccines and low stock out days at district vaccines stores compared to healthcare facilities where there was low availability and high stock out days. Similar study conducted in Secunderabad India (Subramanyam, K. 1989) indicates that implementation of immunization program in the rural areas was affected by gap in the distribution system.

The main causes of stock out at health facilities were delays in delivery from district vaccine stores. The main cause delay was shortage or lack of transport to distribute the vaccine. Lack of means of transport from districts level to lower level resulted in healthcare workers using public transport eg daladala to transport vaccine carrier to their facilities. This is dangerous as daladala take long time and the temperature in the carrier may change because of the length of the time.

The distribution of vaccines from the region to the district vaccine stores is not as recommended. Instead of the region vaccine stores level to distribute the vaccines to the district vaccine stores level; the districts stores level have to collect the vaccines from regional stores level and distribution to the health facilities. This however has been affected by lack of reliable transport at district level and this contributes to shortage of vaccines at health facility level (Figure 7).

An assessment of storage conditions was done using facility indicator form (Appendix 4) and sixteen parameters were set for data collection and result are summarised in (table 3). Standard vaccine refrigerators were found in most of the healthcare facilities visited. Among these healthcare facilities and stores moderate were found to maintain vaccine refrigerators at a temperature range of $+2^0$C to $+8^0$C at time of visiting which is the recommended temperature range. Only few of healthcare facilities & stores were found recording and monitoring temperature in the chart at morning and evening as they were required, this is good practice. The main reason of not being able to maintain temperature was mentioned as lack of reliable power supply. Unfortunately not all health facilities had standby power supply. Standby power supply were found in few of the visited public

healthcare facilities and stores but this was not a solution since in some health facilities they were still facing the problem of fuel shortage and maintenance for generators. Absent of standby power supply in most of public healthcare facilities made it necessary for vaccine in-charge to transfer vaccines from one facility to another in many areas (Table 8). In this situation it is difficult to maintain the cold chain and storage condition because many circumstances can happen between and who knows it depends to the faithful of all involved in storage and transferring. The efficacy of vaccines is difficult to maintain under this condition since it required being stored in the recommended temperature range from point of manufacture up to the point of administration. Similar results from other studies conducted in Bali province Indonesia (Vogel, et al., 2011) and Toronto Canada (Yuan, et al., 1995) indicates that approximately half of refrigerators were unsuitable for vaccine storage and temperature was not monitored. As a result health care did not know if the temperature of the refrigerators was within the recommended range.

Assessment of good arrangement practices of vaccines revealed that only half of all visited healthcare facilities and stores had good arrangement practices. On average 12.5% of all healthcare facilities were found storing other items such as fruits and water with vaccine in the refrigerators. This is bad storage practice and it is not recommended at all. Only half of healthcare facilities had trays for vaccines storage and arrangement.

No healthcare facility visited was found maintaining recommended temperature range of vaccines freezer ie of -15^0C to -25^0C and yet these facilities store vaccines like OPV and Measles vaccines which require freezing temperature. On the other hand 80% of vaccine stores maintain this temperature. Fridge/freezer tag monitor in refrigerator was present on average only in 10% of all visited healthcare facilities; specifically these tags were present only in regional vaccine store. Ten percent (10%) of the surveyed healthcare facilities were found using domestic refrigerator for vaccine storage, this is bad storage practice and it is not recommended at all. For the case of refrigerator storage space only 65% of healthcare facilities visited had good storage space while 60% of visited stores had good storage space for refrigerator. By looking on the parameter of good storage condition and percentage scores on each level and its average storage condition there is an urgent need of improving storage condition so as to maintain the efficacy and quality of vaccines as recommended.

The study also shows that no involvement of Pharmaceutical personnel in the program although it's known in all medical cadres the pharmaceutical personnel especially pharmacist is custodian of medicines. The study reveals that all 100% respondents involved in handling were non pharmaceutical personnel so they need advisor or supervisor who is competent in medicines.

Majority of contacted respondents in study were female. In case of age majority who involved in handling and storage of vaccines were adult above 39 years. Respondents with little experience were 33.4% of the contacted respondents. The study shows that in the last 3 years majority of respondents were not attended any training on storage, distribution and handling procedures of vaccines.

Regarding knowledge on recommended temperature range for refrigerator majority had knowledge but they did not practice that. Only 8% knew about the temperature range recommended for freezers. Despite the fact that they are responsible for keeping both vaccines stored in refrigerator such as Pentavalent, Tetanus Toxoid vaccine, BCG and Ant rabies which are commonly used in our healthcare facilities and vaccine stored in freezers such as OPV and Ant measles which require freezing temperature range. Similar result from study that was conducted in Toronto Canada (Yuan, et al., 1995) indicates that knowledge and practice of vaccine storage and handling were often inadequate in primary care physicians.

Respondents' knowledge was average (moderate) even though they had more knowledge on some aspects of stock management and poor in other aspects. Vaccine are sensitive products therefore managing stock properly can help in avoiding wastage in terms of vaccine expiry due to overstocking if no proper reorder levels are set.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions.

Managing distribution system at public health facilities is highly associated with many challenges that cannot be sorted out by just one player but rather all players involved in the vaccines distribution system such as MSD, Regional Vaccine Store, District Vaccine Store, district councils authorities and the Ministry of Health and Social Welfare at large.

The study has identified about 8 main challenges that hinder effective distribution system of vaccine; these include unreliable/inadequate vehicles for distribution of vaccines to public healthcare facilities, distribution from regional level to district level and district level to healthcare facilities. Stock out condition the study reveals average stock out days was high at lower health facility level as compared to the district level and the comparison confirm that there is statistical significance difference between stock out in health facilities and vaccine stores. Lack of on job training with special emphasis on storage, handling and distribution of vaccines. Lack of or improper quantification and forecasting at healthcare facility level appear to be some of the factor which causes stock out. Poor or lack of proper storage conditions in the health facility also hinder effective distribution system because in order for a vaccine to maintain its efficacy it required good storage condition (cold chain) from point of manufacture up to point of administration.

Another challenge identified is unreliable electricity and lack/delay of gas these appear to be a problem in maintaining the recommended temperature range needed. Last but not least non-adherence to good storage practices arrangement was not proper within refrigerator, no temperature monitoring & recording chart in most of the facilities visited, domestic refrigerator used and storing vaccines with other items eg fruits. Fridge/freezer tag monitor found only in Regional Vaccine Store refrigerators and absent in the rest of all refrigerators in healthcare facilities refrigerators visited. No involvement of pharmaceutical personnel to manage vaccine stores or immunization site provided is known to be custodian in the field of medicines than other cadres. All these may contribute to facilities not being able to maintain the required storage condition which may lead to deterioration of the vaccine.

6.2 Recommendations.

The following are recommendation in response to the above challenges revealed by study

- ❖ MOHSW/EPI –Need to involve pharmaceutical personnel in the supply chain of vaccines because the study reveals no involvement of pharmaceutical personnel in this programme. Pharmacists are custodian in medicines once involved in the programme it's our hope the problems of poor storage practices, poor quantification of need and storing vaccines out of recommended temperature range can be reduced and controlled under his/ her supervision.

- ❖ MOHSW – Need to strengthen supportive supervision at lower healthcare facilities delivery site so as to improve their performance in chart monitoring and recording for recommended temperature range because this system are not working in most healthcare facilities.

- ❖ MOHSW/EPI – Need to supply freezer tags to all healthcare facilities which can help in monitoring and recording temperature even when the stores in charge and immunization focal personnel were absent.

- ❖ MOHSW/EPI –Need to strengthen the storage practices of vaccines by providing on job training, so as store in-charge and immunization focal personnel they can know how to use refrigerator and good practice of storing vaccines.

- ❖ MOHSW and District Authorities (District Medical Officer & District Cold Chain Officer) should abide to the vaccines distribution scheduled plan.

6.3 Areas for Further Research

6.3.1 Because this study just focused on public health facilities located in Coast region, further research can be carried out to cover the whole country to assess the magnitude of the problem.

6.4 Study Limitations

- More meaningful results would have been produced if the scope of the study was extended to more than one region for one to get a better understanding of the prevailing challenges of vaccines distribution system at public health facilities across the country.
- Also the area which was difficult to reach because inaccessible transport for example Mafia district councils which is Island.
- It should also be noted that the composition of the sample units was not homogeneous since it comprised of regional vaccine store, district vaccine store, district hospitals, health centres and dispensaries each having different capacities of operations hence introducing some outliers in the data analysis for some parameters.

REFERENCES:

1. Bonhoeffer, J., Heinnger, U., (2007). "Adverse events following immunization perception and evidence" curr opin infect Dis 20(3): 237-46.
2. Brudon, P., Rainhorn, J.D., Reich, M., (1994). Indicators for monitoring national drug policies.
3. Euro Health Group, (2007). Tanzania Drug Tracking Study.
4. Grobowsky, M., et al, (2005). Ghana and Zambia: Achieving equity in distribution of Insecticide Treated Bed nets through links with measles vaccination campaign.
5. Immune Australia website http:// Immunise.health gov.au/vaccine storage htm.
6. Indonesia MOA (2011). Cold chain and Vaccine management Assessment for Animal vaccination program in Bali Province.
7. Management Sciences for Health (MSH), 1997: Managing Drug Supply, 2nd Edition, Kumarian Press, Connecticut, USA. Pg 317-20,332,347-48,366-68.
8. MSH, (1995). Rapid pharmaceutical assessment — An indicator-based approach. Washington DC: MSH.
9. Meri, S., Jorden, M., Jarva, H., (December 2008). "Microbial complement inhibitors as vaccines" vaccine 26 suppl 8, 1113-7.
10. MOHSW (2008). Immunization coverage survey.
11. MOHSW (2008). In-depth Assessment of the Medicines Supply System in Tanzania Report).
12. MOHSW (2010). Tanzania Mainland EPI Review Pg 5, 16, 22.
13. MOHSW (2009). Vaccine Management Assessments.
14. National Vaccine Storage guidelines http//www.ag.gov.au/cca.
15. Stern, A.M., Markel, H., (2005). The history of vaccines & immunization: Health Aff. 24(3) 611-21
16. Strive FOR five, (2005).National Vaccines Storage guidelines. Retrieved April 2005, from http//www.ag.gvr au/cca.
17. Subramanyam, K., et al (1989). Vaccine Distribution: an operations research study.
18. Van Sant J.E., (2008). "The vaccinator: smallpox, medical knowledge, and the opening of Japan" JHist Med Allied Sci, 62(2) 276-9.

19. WHO, 1997. Comparative analysis of national drug policies. Report of second workshop. Geneva: DAP/97.6.
20. WHO Report, (2008). Global pandemic influenza action plan to increase vaccine supply. Retrieved April 2009, from www.who.int/vaccine documents/.
21. WHO (2008), Health Metrics Network, http/www.healthmetricsnetwork.org.
22. WHO (2005), Vaccine management assessment. Retrieved April 2005, from www.who.int/ Vaccine-documents http//www.ag.gvr.au/cca.
23. www.msd or.tz, Tanzania Medical Directory 2009/2010.
24. Yuan, L., et al (July 1995).Vaccine storage and handling. Knowledge and practice in primary care physicians' officers. 41, 1169-76.

APPENDICES

APPENDIX 1 Questionnaire (English version)

INTERVIEW QUESTIONNAIRES TO ASSESS DISTRIBUTION SYSTEM AND KNOWLEDGE, PRACTICE OF VACCINE STORAGE AND HANDLING IN PUBLIC HEALTHCARE FACILITIES IN COAST REGION

Code No…….

Name of Healthcare Facility (i.e Hospital, Health centre, Dispensary, CVS, RVS, DVS.)

…….

1. Professional of in-charge/coordinator/ immunization focal person of the facility cold chain or vaccine medicines store

    a) Pharmacist
    b) Pharmaceutical technician
    c) Medical doctor
    d) Clinical officer
    e) Environmental health officer
    f) Nursing officer/Nurse midwife
    g) Nurse assistant
    h) Others (mention)……..

2. Sex
    a) Male
    b) Female
3. Age (in years) …….
    a) 18-24
    b) 25-31
    c) 32 – 38
    d) Above 39

4. Experience at work of the vaccine medicine store supervisor (in years)
   a) Less than 1
   b) 1 to 5
   c) 6 to 10
   d) 11 to 15
   e) More than 15
5. What type of vaccines do you stock at your healthcare facility?
   a) Bacillus Calmette Guerin (BCG)
   b) DTP-HepB-Hib or pentavalent (Diphtheria, Tetanus, Pertussis , Hepatitis B, Heamophilus influenzae B)
   c) OPV (Oral polio vaccine)
   d) Measles virus vaccine
   e) Rabies vaccine
   f) TT (Tetanus toxoid vaccine)
   g) Others……..
6. Have you ever attended training on storage, distribution and handling procedures of vaccines and cold chain medicines?
   a) Yes (go to next Question)
   b) No
7. How many times have you attended such a course within last three years?
   a) Once
   b) Twice
   c) Thrice
   d) Not attended

8. What is the recommended temperature range for most vaccine stored in refrigerators?

a) $-5\ ^{0}C$ to $+1^{0}C$

b) $+2^0C$ to $+8^0C$

c) $+9^0C$ to $+15^0C$

d) $+4^0C$ to $+8^0C$

9. What is recommended temperature range for most vaccine stored in freezers?

a) $+6^0C$ to -4^0C

b) -4^0C to -14^0C

c) -15^0C to -25^0C

d) Don't know

10. Does it happen that vaccines in refrigerator or freezer are not in recommended temperature range during storage?

a) Yes (if yes go to question 11)

b) No

11. If yes what measure or action you have taken when vaccine in stock storage were found out of recommended temperature range?

a) Continue stored in cold chain for future use

b) Stop using and recorded in book for all vaccine discarded due to incorrect storage temperature.

c) Others ……

12) Is there any record for all vaccine discarded due to incorrect storage temperature?

a) Yes (if yes ask to see)

b) No

13. What do you think are underlying factors that lead to fault in storage conditions at your facility?

……

……

14. Explain in short how you handle vaccine medicines from the point of arrival up to the point of administration……

……

……

15. What reference material(s) is (are) available in your pharmacy store used as reference during your practice?

a) EPI Guidelines for vaccine management
b) Martindale
c) Good Dispensing Manual
d) Others (Mention)……..

16. If you have the EPI Guidelines for Safe vaccine management, have ever gone through it to find out proper ways of storage and handling vaccine medicines at your facility up to the point of administration?

a) Yes (if yes go to next question)

b) No

17.Did you find the EPI Guidelines fit for routine vaccines storage management and distribution ?

a) Yes

b) No (if No) state/mention any deficiencies that you think should be rectified to smoothen the distribution system and handling procedures

……

……

18. How often do you distribute vaccines to lower facilities?

a) Once monthly

b) Twice a year

c) Quarterly a year

d) When necessary (no specified time period)

e) NA

19. List all the methods that you regularly use to transport vaccine and cold chain medicines at your facility

……...

……

20. How do you determine your vaccines stock position at your facility?

a) By determining only safety stock

b) By determining only maximum stock level

c) By determining only minimum stock level

d) By determining sum of stock on hand (working & safety stock) and stock on order, minus any stock-back ordered to clients.

21. When do you say the vaccine stock is at Maximum stock level?

a) When stock is at Re-order level

b) When the stock is sufficient to satisfy demand until the next order

c) When you have safety stock

d) When there is over stock

22. When do you say the vaccines stock is at Minimum stock level?

a) When stock is at Re-order level

b) When the stock is sufficient to satisfy demand until the next order

c) When you have safety stock

d) When there is stock out

23. When do you say the vaccines stock is at Safety stock level?

a) When you have vaccines maximum stock

b) When you have vaccines minimum stock

c) When you have vaccines stock on hand to prevent stock out

24. What do you put in consideration when you need to prepare the vaccines order at your facility?

a) Quantity used since last delivery

b) Storage volume within the refrigerator

c) Vaccines currently in the refrigerator

d) Disease outbreak

e) Seasonal variation

f) OTHERS……

25. In your own opinion, what do you think are the barriers to efficient distribution system of vaccines?

……

……

26. Do you think you need more professional training on vaccine distribution and its management in order to strengthening your pharmaceutical management skills on cold chain at your facility?

a) Yes
b) No

If yes, mention few areas that you need more exposure through on job training

……

……

27. What do you finally recommend to the MOHSW/ EPI on storage and distribution?

……

Thank you for your participation.

APPENDIX 2: QUESTIONNAIRE (Swahili version)

DODOSO KWA AJILI YA KUPIMA UFAHAMU WA UTUNZAJI NA MFUMO UNAOTUMIKA KATIKA USAMBAZAJI WA DAWA ZA CHANJO KWA MATUMIZI YA BINADAMU KATIKA BOHARI, HOSPITALI, VITUO VYA AFYA NA ZAHANATI MBALIMBALI ZA UMMA MKOA WA PWANI. .

Fomu Namba…….

Jina la Bohari, Hospitali, Kituo cha Afya, na Zahanati ……

1. Taaluma ya msimamizi wa stoo ya dawa/mtoaji dawa za chanjo katika hospitali au kituo cha afya
   a) Mfamasia
   b) Fundi dawa sanifu
   c) Daktari
   d) Afisa tabibu
   e) Afisa afya
   f) Muuguzi mkuu/Muuguzi Mkunga
   g) Muuguzi Msaidizi
   h) Nyingine (taja) …….
2. Jinsia
   a) Mme
   b) Mke
3. Umri (miaka)
   a) 18-24
   b) 25-31
   c) 32-38
   d) Zaidi ya 39
4. Uzoefu katika usimamizi na kutoa dawa za chanjo (miaka)
   a) Chini ya mwaka 1
   b) 1- 5

c) 6- 10
d) 11- 15
e) Zaidi ya miaka 15

5. Ni dawa gani za chanjo unatunza katika kituo chako ?

a) BCG (chanjo ya kifua kikuu)

b) DTP –Hep B-Hib (pentavalent)

c) OPV (chanjo ya matone ya polio)

d) Chanjo ya surua

e) Rabies (chanjo ya kichaa cha mbwa)

f) TT (tetanus)

g) Nyinginezo ……

6. Je, umewahi kuhudhuria mafunzo endelevu yoyote yahusuyo utunzaji, umilikaji na usambazaji wa dawa za chanjo kwa matumizi ya binadamu?
   a) Ndiyo (nenda swali linalofuata)
   b) Hapana
7. Je, ni mara ngapi umehudhuria mafunzo kama hayo katika kipindi cha miaka mitatu iliyopita?
   a) Mara moja
   b) Mara mbili
   c) Mara tatu
   d) Sijahudhuria
8. Eti ni kiwango gani sahihi cha joto kinatakiwa kwa ajili ya kuhifadhia dawa za chanjo kwenye jokofu ?
   a) -5^0C to $+1^0$C

   b) $+2^0$C to $+8^0$C

   c) $+9^0$C to $+15^0$C

d) $+4^0C$ to $+8^0C$

9. Vipi ni kiwango gani sahihi cha joto kinatakiwa kwa ajili ya kuhifadhia dawa za chanjo kwenye freezer?

a) $+6^0C$ to -1^0C

b) -4^0C to -14^0C

c) -15^0C to -25^0C

d) Sijui (Sifahamu)

10. Vipi ilishawahi kutokea dawa za chanjo zikawa nje ya kiwango cha joto kinachotakiwa kwenye Jokofu au freezer kabla ya kutumika katika kituo chako?

a) Ndiyo (kama ndiyo nenda swali linalofuata)

b) Hapana

11. Kama ndiyo, ni hatua gani kawaida unazichukuaga inapotokea dawa za chanjo zimehifadhiwa nje ya kiwango cha joto kinachokubalika?

a) Kuendelea kuzitunza kwenye mfumo kwa ajili ya matumizi ya baadae

b)Kuacha kuzitumia na kuziweka kwenye leja ya dawa zilizoharibika kwa kuhifadiwa kwenye joto lisilofaa

c)Nyingine ……..

12.Vipi zipo kumbukumbu zozote za dawa za chanjo zilizoondolewa kwenye mfumo kwa kuhifadhiwa nje ya kiwango cha joto.

a) Ndiyo (omba kuziona)

b) Hapana

13.Kwa uzoefu wako unafikiri ni sababu gani zinachangia au kusababisha dawa za chanjo kuhifadhiwa vibaya katika kituo chako ? Taja.

……

……

14.Elezea kwa ufupi jinsi unavyosimamia na kutunza dawa za chanjo tangu zinapofika hadi kuzigawa kwa mtumiaji wa mwisho.

….……

……

15.Aina ya vitabu vilivyopo katika famasi yako ambavyo hutumika kama rejea wakati wa kutoa huduma na usimamizi wa ujumla dawa za chanjo ndani ya stoo ya dawa.

a) Mwongozo wa utoaji sahihi wa dawa za chanjo
b) Mwongozo wa Martindale
c) Mwongozo wa usambazaji sahihi wa dawa za chanjo
d) Vingine (taja)……..

16.Kama unacho kitabu cha Mwongozo wa dawa za chanjo dawa kutoka EPI, Je ulishausoma na kutambua njia mbalimbali zilizoainishwa za usambazaji, utunzaji na usimamizi wa dawa za chanjo kabla ya kuzitumia?

a) Ndiyo (kama ndiyo jibu swali linalofuata)
b) Hapana

17. Vipi mwongozo huo una manufaa kwako na unafaa katika mfumo mzima wa utunzaji na usimamizi wa dawa za chanjo?

a) Ndiyo

b)Hapana (kama hapana); Taja mapungufu ambayo unafikiri yamo ndani ya mwongozo huo yanayoweza kukwamisha zoezi zima la utunzanji, usimamizi na usambazaji wa dawa za chanjo.

……

18. Kwa kawaida mnasambaza mara ngapi dawa za chanjo kwenye mfumo wa usambazaji ?

a) Mara moja kwa mwezi
b) Mara mbili kwa mwaka
c) Mara nne kwa mwaka
d) Kila inapobidi (hakuna kipindi maalumu)
e) Hapahusiki (NA)

19.Taja njia mnazotumia kusafirisha dawa za chanjo kwenye kituo chako.

……...

20.Unawezaje kutathimini/kufahamu kiwango cha shehena ya chanjo ulichonacho kwenye kituo chako?

a) Ni kwa kutathimini tu kiwango salama cha shehena ya chanjo.

b) Ni kwa kutathimini tu kiwango cha juu kabisa cha shehena ya chanjo

c) Ni kwa kutathimini tu kiwango cha chini kabisa cha shehena ya chanjo.

d) Ni Kwa kutathimini jumla ya shehena ya chanjo uliyonayo kituoni na shehena chanjo uliyoagiza haijafika toa shehena ya chanjo ya nyuma ulioagizwa na wagonjwa.

21. Ni wakati gani unasema shehena ya chanjo ipo kiwango cha juu kabisa?

a) Ni wakati shehena ya chanjo ipo katika kiwango cha kutakiwa/kurudiwa kuagizwa

b) Ni wakati shehena ya chanjo inatosheleza mahitaji ya kituo vizuri hadi agizo litakalofuata.

c) Ni wakati shehena ya chanjo ipo katika kiwango salama

d) Ni wakati shehena ya chanjo imezidi kiwango cha mahitaji ya kituo.

22. Ni wakati gani unasema shehena ya chanjo ipo kiwango cha chini kabisa?

a) Ni wakati shehena ya chanjo ipo katika kiwango cha kutakiwa/kurudiwa kuagizwa

b) Ni wakati shehena ya chanjo inatosheleza mahitaji ya kituo vizuri hadi agizo litakalofuata.

c) Ni wakati shehena ya chanjo ipo katika kiwango salama

d) Ni wakati shehena ya chanjo imeisha kabisa kituoni.

23. Ni wakati gani unasema shehena ya chanjo ipo katika kiwango cha usalama?

a) Ni wakati unakuwa na shehena ya chanjo katika kiwango cha juu kabisa cha mahitaji

b) Ni wakati unakuwa na shehena ya chanjo katika kiwango cha chini kabisa cha mahitaji

c) Ni wakati unakuwa umebakiwa na shehena ya chanjo inayozuia kutokea hali ya kuishiwa kabisa na chanjo kituoni.

24. Nini unachukua kama maangalizo wakati unataka kuandaa mahitaji ya dawa za chanjo kituoni kwako?

a) Kiwango ulichotumia kituoni tangu upokee shehena ya mwisho ya chanjo

b) Ujazo ndani ya jokofu/freezer

c) Chanjo zilizopo kwa sasa ndani ya jokofu

d) Kuzuka kwa ugonjwa

e) Kubadilika kwa majira/msimu

f) Mengineyo ……

25.Kwa maoni yako unafikiri ni vikwazo/vitu gani vinakwamisha mfumo mzima wa usambazaji wa dawa za chanjo katika kituo chako? Vitaje

……

26.Unafikiri unahitaji mafunzo ya kila mara kipindi cha utumishi yahusuyo usambazaji,usimamizi na utunzaji wa dawa za chanjo ili kuimarisha ujuzi wa usimamizi na utunzaji dawa katika kituo chako cha kazi ?

a) Ndiyo

b) Hapana

Kama ni “ ndiyo” taja maeneo/aina ya mafunzo ambayo unahitaji kupata fursa kama hiyo

……

27. Je ungependa kushauri Wizara ya afya na ustawi wa jamii mambo/hatua gani za kuchukua hususani mradi wa chanjo (EPI) juu ya tatizo la utunzwaji usiokidhi wa dawa za chanjo na usambazwaji wake

Asante sana kwa ushiriki wako.

APPENDIX 3, AVAILABILITY INDICATOR FORM

Indicator- Availability of key vaccines.

Name of the Facility……. Date……

District……. Investigator name ……..

% vaccine expired.

Availability of Key Vaccines used in routine immunization [A]	Vaccines in stock YES=1 , NO=0 [B]	Expired vaccines in refrigerator YES=1, NO=0 ,[C]
1.BCG vaccine		
2.Oral polio vaccine		
3.Penta vaccine		
4.Measles vaccine		
5.Tetanus toxoids vaccine		
6.Rabies vaccine		
	$[B^1]$=sum of B $[B^2]$=% in stock $B^1/6 * 100$	$[C^1]$=sum of C $[C^2]$=% Expired C1 / B1 * 100

SOURCE-WHO Operational package for Monitoring & Assessing Country Pharmaceuticals,2005.

APPENDIX 4, STORAGE AND HANDLING INDICATOR FORM

FACILITY INDICATORS, REPORTING FORMS, MODIFIED WHO INDICATORS.

DISTRICT……NAME OF THE FACILITY……..

NAME OF INVESTIGATOR……DATE……

	Daily collection of Data for medicines with records covering at least for 6 months		
S/N		STORAGE AND HANDLING OF VACCINES AT THE FACILITY LEVEL	
1	Storage Indicators	Storeroom YES = 1 ,NO = 0 [A]	Vaccination Area/Room YES =1 , NO = 0 [B]
1.1	Vaccine cold/freezer room storage capacity-adequate to accommodate all stocks		
1.2	Good arrangement in refrigerator		
1.3	Are there standard vaccine refrigerators and freezers		
1.4	Presence of fridge/freezer tags monitor in refrigerator		
1.5	Mixing other items in vaccine refrigerator such as fruit & water etc		
1.6	Is there standby power supply in case of Unreliable electricity supply (eg generator)		
1.7	Do all vaccine refrigerator/cold room maintain a temperature of $+2^0$C to $+8^0$C (by freezer tags monitor or chart)		
1.8	Do all vaccine freezer/freezer room maintain a temperature of -15^0C to -25^0C(by freezer tags chart)		
1.9	Vaccines found in domestic refrigerator		
1.10	Are vaccines found frozen in refrigerator		
1.11	Presence of good storage space for refrigerator		
1.12	Presence of trays which are used in arrangement		
1.13	Refrigerator not on recommended temperature range		
1.14	Quantification done during ordering		
1.15	Expire vaccines found at facility		
1.16	Freezer found with temperature below -25^0C		

		[A^2] = Score = A^1 ÷ 8 x 100 =		**[B] = Sum = B^1 ÷ 8 x 100**
2	Level of knowledge on vaccine storage by vaccine store personnel/ Immunization focal personnel	Good	Moderate	Poor

APPENDIX 5: AVERAGE STOCK OUT DURATION INDICATOR FORM

Indicator: Average stock out duration. Adequate record keeping

District:_____ Investigator:_____

Facility:_____ Date:_____

Key Vaccines used in Routine immunization	Records cover at least 6 months within the past 12 months Yes=1, No=0 [B]			
		Number of days out of stock [C]	Number of days covered by the review (at least 6 months)[D]	Equivalent number of days per year [E] = C x 365/D
1.BCG vaccine				
2.Oral polio vaccine				
3.Penta vaccine				
4.Measles vaccine				
5.Tetanus toxoids vaccine				
6.Rabies vaccine				

[B_1] = Sum of B

[E_1] = Sum of E

[B_2] = % adequate Records = $B_1 \div 6 \times 100$

[F] = Average number of stockout days = $E_1 \div B_1$ =

SOURCE-WHO Operational package for Monitoring & Assessing Country Pharmaceuticals

APPENDIX 6: HEALTHCARE FACILITY INDICATORS CONSOLIDATION FORM.

***G- Good , M- Moderat , P- Poor**

Facility name	Vaccine cold room-storage capacity adequate (YES/NO)	Presence of Good storage practice(YES/NO	Presence of std vaccine refrigerator or freezer (YES/NO)	Presence of standby power supply (eg Generator) (YES/NO)	Vaccine refrigerator maintain temp $+2^0$C to $+8^0$C(YES/NO)	Vaccine freezer maintain temp -15^0C to -25^0C (YES/NO)	Types of vaccines found out of stock in the past 6 months	Knowledge on vaccine storage and handling	Refrigerator or vaccine frozen (YES/NO)

APPENDEX 7: CONSENT FORM (English version)

CONSENT TO PARTICIPATE IN A SURVEY STUDY TO VACCINES DISTRIBUTION SYSTEM AND KNOWLEDGE OF HEALTHCARE WORKERS ON VACCINES STORAGE AND HANDLING AT HEALTHCARE FACILITIES IN COAST REGION.

Greetings!

My name is Mohamed Makuru from Muhimbili University of Health and Allied Sciences. I am conducting a survey study on the problem of ineffective distribution system of Vaccines and knowledge of healthcare workers on vaccines storage and handling in public health facilities found in Coast region.

Purpose of the Study

The study will examine knowledge, currently used in vaccines storage and distribution system and finally identify challenges encountered in the proper distribution system and good practices of vaccines storage and handling in Tanzania.

Participation

If you agree to join the study, you will be required to answer all the questions that will be asked by the investigator in form of interview.

Confidentiality

All information that will be collected from you will be treated confidential and will not be used for any other purpose other than this study.

Risks

We do not expect that any harm will happen to you because of joining in this study.

Rights to Withdraw and Alternatives

Taking part in this study is completely your choice. If you choose not to participate in the study or if you decide to stop participating in the study you will continue to be treated normally. You can stop participating in this study at any time, even if you have already given your consent and if for any reason you would wish to come back into the study after withdrawal, we will be ready to accept you to continue with the study. Refusal to participate or withdrawal from the study will not involve penalty or loss of any benefits to which you are otherwise entitled.

Benefits

Taking part in this study you will contribute towards alleviating the problem of poor vaccines storage and improper vaccines distribution. Your information and others participating in the study will collectively be used by policy makers in addressing this problem hence protecting the health of Tanzanians. You will receive the new information about this study upon completion.

Who to Contact

If you ever have questions about this study, you should contact the following:

Mr. Mohamed Makuru (Principal Investigator)

School of Pharmacy,

Muhimbili University of Health and Allied Sciences,

P.O. Box 65001, Dar es Salaam.

Mobile phone: 0754488064 OR

Dr G. A. Kagashe (Study Supervisor)

School of Pharmacy,

Muhimbili University of Health and Allied Sciences,

P.O. Box 65013, Dar es Salaam.

Mobile : 0713 310511

Also, if you will have questions about your rights as a participant, you may call Prof. M. Aboud, Chairman of the College Research and Publications Committee,

P.O. Box 65001, Dar es Salaam. Tel: 2150302-6.

Signature

Do you agree to participate? *Write the word 'Yes' if you agree……..*

I, _____ have read the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of participant _____

Signature of investigator _____

Date of signed consent _____

APPENDEX 8: CONSENT FORM (Swahili version)

FOMU YA KUKUBALI KUJIUNGA KWA HIARI KATIKA UTAFITI KUHUSU UFAHAMU WA UTUNZAJI WA DAWA ZA CHANJO NA MFUMO ULIOPO WA USAMBAZAJI WAKE KWA KATIKA HOSPITALI, VITUO VYA AFYA NA ZAHANATI MBALIMBALI ZA UMMA MKOANI PWANI.

Salamu!

Mimi naitwa Mohamed Makuru kutoka Chuo Kikuu cha Sayansi za Afya Muhimbili. Ninafanya utafiti kuhusu uelewa wa utunzaji wa dawa za chanjo na mfumo uliopo wa usambazaji wake katika hospitali na vituo vya afya vya umma, mkoani Pwani.

Malengo ya utafiti:

Utafiti huu umelenga kuangalia uelewa wa wataalam wa afya juu ya utunzaji wa dawa za chanjo na mfumo uliopo wa usambazaji wake na kuainisha changamoto za mfumo mzuri wa usambazaji na utunzaji.

Ushiriki katika utafiti

Kwa kushiriki katika utafiti huu utatakiwa kujibu kwa kujaza maswali yaliyopo utakayokuwa unaulizwa na mtafiti.

Usiri

Taarifa zote zitakazopatikana kutoka kwako zitakuwa ni siri na hazitatumika sehemu nyingine isipokuwa katika utafiti huu tu.

Madhara

Hatutegemei kitu chochote kibaya kutokea kwa kushiriki katika utafiti huu.

Kukubali kwa hiari kushiriki kwenye utafiti:

Ushiriki wako kwenye utafiti huu ni kwa hiari. Unaombwa kukubali kwa hiari. Endapo utaamua kutoshiriki au endapo utaamua kujiondoa katika utafiti utaendelea kubaki na haki zako za msingi kama kawaida. Unaweza kujiondoa katika utafiti wakati wowote, na pale

utakapotaka kujiunga tena utakubaliwa kuendelea na utafiti. Kukataa kujiunga ama kujitoa katika utafiti hakutasababisha adhabu au kupoteza haki yako ya msingi.

Faida za utafiti

Ukikubali kujiunga na utafiti utakuwa mmojawapo wa wale watakaofanikisha kuboresha utoaji wa taarifa za madhara yatokanayo na utunzaji mbaya na usambazaji dhaifu wa dawa za chanjo Tanzania.

Utasaidia kuwawezesha watunga sera na wataalamu wa afya kufanya maamuzi yenye faida kwa umma mzima. Utapatiwa taarifa zozote mpya zitakazopatikana kupitia utafiti huu. Hatutegemei utaingia gharama zozote kwa kushiriki kwenye utafiti huu.

Mawasiliano

Kama una swali lolote kuhusu utafiti huu tafadhali wasiliana na:

Bw. Mohamed Makuru (Mtafiti Mkuu)

Chuo Kikuu cha Sayansi za Afya, Muhimbili,

S.L.P 65013, Dar es salaam

Simu ya mkononi : 0754488064,

Dk G. A. Kagashe (msimamizi wa utafiti)

Chuo Kikuu cha Sayansi za Afya ,Muhimbili,

S.L.P 65013, Dar es salaam

Simu Na: 0713 310511

Kama utakuwa na suala lolote kuhusu haki yako kama mshiriki katika utafiti huu wasiliana na Prof. M. Aboud, Mwenyekiti wa Kamati ya Utafiti na Uchapishaji, Chuo kikuu cha Afya na Sayansi ya Tibai, S.L.P 65001, Dar es Salaam.

Simu Na : 2150302-6.

Sahihi kwa wanaokubali

Je, unakubali? Andika ndio kama umekubali……

Mimi ……nimeisoma fomu hii na kuelewa lengo la utafiti huu na maswali yangu yamejibiwa na sasa nakubali kwa hiari kujiunga na utafiti huu.

Sahihi ya mshiriki…….....

Sahihi ya mtafiti……

Tarehe ya kusaini……

APPENDIX 9: SELECTED DISTRICTS IN COAST REGION &THEIR HEALTHCARE FACILITIES

No	**BAGAMOYO DISTRICT**	**KIBAHA TOWN COUNCIL**	**MKURANGA DISTRICT**	**RUFIJI DISTRICT**
1	Bagamoyo District hospital	Tumbi hospital	Mkuranga District hospital	Utete District hospital
2	Chalinze health centre	Mkoani health centre	Kalole health centr	Ikwiriri health/ c
3	Miono health centre	Mwendapole dispensa	Mkamba health ce	Kibiti health/cent
4	Lugoba health centre	Kongowe dispensary	Bupu dispensary	Mohoro health/c
5	Yombo dispensary	Visiga dispensary	Mwanambaya disp	Jaribu dispensary
6	Zinga dispensary	Miswe dispensary	Vianzi dispensary	Bungu dispensary
7	Kiwangwa dispensary	Misugusugu dispensar	Vikindu dispensar	Kindwiti dispens
8	Msata dispensary	Kongowe forest disp	Kitomondo disp	Nyamisati disp
9	Kiromo dispensary	Mbawa dispensary	Lukanga dispe	Nyamwage disp
10	Fukayosi dispensary	Viziwaziwa disp	Magawa dispens	Ruaruke dispensa
11	DVS-Bagamoyo	DVS-Kibaha TC	DVS-Mkuranga	DVS-Rufiji

PLUS REGIONAL VACCINE STORE