AVAILABILITY, STORAGE AND USE OF ANTI-RABIES VACCINES IN PUBLIC HEALTH FACILITIES IN LINDI AND TANGA REGION IN TANZANIA

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MSc (Pharmaceutical Management) Dissertation
Muhimbili University of Health and Allied Sciences
October, 2015

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By

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A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of Science in Pharmaceutical Management of Muhimbili University of Health and Allied Sciences

Muhimbili University of Health and Allied Sciences
October, 2015

CERTIFICATION

The undersigned certify that; she has read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled; ***Availability, Storage and Use of Anti-Rabies Vaccines in Public Health Facilities in Lindi and Tanga regions in Tanzania*** in (partial) fulfillment of the requirements for the Degree of Master of Science in Pharmaceutical Management of Muhimbili University of Health and Allied Sciences.

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Prof. Kagashe G .A .B

Supervisor

_____

Date

DECLARATION AND COPYRIGHT

I, **Rose Zakaria Maingu**, declare that; this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature…… **Date** …….

ACKNOWLEDGEMENT

First and foremost, I would like to thank God who created me and who always guides and protects me.

I am greatly indebted to my supervisor, Prof G.A.B Kagashe for her advice, support, guidance and mentorship during the preparation and accomplishment of this dissertation.

I am equally grateful for the sponsorship offered to me by the Ministry of Health and Social Welfare that has enabled me to pursue my training at MUHAS. Many thanks to Regional Medical Officers of Tanga and Lindi who granted me permission to conduct this study in health facilities in their regions.

I would like to take this opportunity to thank Dr Candida Moshiro, Department of Epidemiology and Biostatistics, who tirelessly and freely gave comments on various drafts of this piece of work which I have shared with her. I would like also to convey my sincere gratitude to Dr. Debora Runyoro, the coordinator of the course for her great support and continued guidance throughout the course.

I would like to thank my classmates especially Waziri Mashaka and Rashidi Kirua for their suggestions during data preparation and analysis prior to writing up my dissertation.

Last but not the least my beloved sons; Rogers and Robert! I say thank you for bearing with me, when I was away and you were in need of me, may the Almighty God bless you all abundantly.

DEDICATION

I would like to dedicate this dissertation work to my mother Tasiana Maingu, and my supervisor Prof G. A. B. Kagashe.

ABSTRACT

Background

Rabies is one of the 17 neglected tropical diseases recognized by WHO. Rabies is enzootic viral disease; main vector of disease is domestic dog. Rabies is 100% fatal if left untreated causing neurologic problems is a preventable disease. Prevention can be done by vaccinating canine (dogs), administering rabies vaccine, rabies immunoglobulin's (RIG's), community participation and public awareness. Procurement and stocking of anti-rabies vaccine in public health facilities is a problem due to the fact that rabies is given low priority due to under-reporting of the disease magnitude [20]. Keeping lots of supplies when demand is low threatens expiry of stock its subsequent unavoidable negative financial impacts.

Objectives

The objectives of the study were to assess availability, source of supply, storage and use of anti-rabies vaccines in public health facilities in Lindi and Tanga region.

Methodology

This was a descriptive cross sectional study which employed quantitative method of data collection. Structured questionnaires were used to collect quantitative data from health care workers that were responsible for ordering and storing of anti-rabies vaccine. This study also assesses knowledge of health care workers regarding the use of anti-rabies vaccines in the health facilities. Observation checklist was used to capture information regarding storage of anti-rabies vaccines in the health facilities. Retrospective review of records was done to calculate stock-out duration of anti-rabies vaccines. Physical count was done to determine the number of anti-rabies vaccine vials on the day of visit.

Results

The study found that mean the stock out duration of anti rabies vaccines was 103 days and 200 days in Lindi and Tanga region respectively. Seven facilities in Tanga had stock of anti-rabies vaccine versus one facility in Lindi on the day of visit. Average score of storage condition of anti-rabies vaccines in facilities in Tanga and Lindi region were 67.6% and 66.8% respectively. These scores were considered satisfactory. MSD and prequalified suppliers were source of vaccines in Tanga region and dividend from RVS was the source of supply of vaccines in Lindi

facilities. Majority of health care workers (52%) interviewed in Tanga had a poor knowledge regarding the use of anti-rabies vaccines as compared to those in Lindi region. Expired anti-rabies vaccines were observed in two health facilities in Korogwe District Hospital and Nyangao-Designated Dstrict Hospital in Tanga and Lindi respectively.

Conclusion

From this study it can be concluded that, availability of anti-rabies vaccines is still a problem in health facilities in the two surveyed regions in Tanzania.

There is a problem of maintanance of cold chain system in storage facilities in both levels (hospitals and health centres)

Based on these findings, poor level of knowledge regarding the use of anti-rabies vaccine among health care workers in surveyed health facilities was observed.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

CDC	Centre for Disease Control
CSSC	Christian Social Services Commission
D.C	District Council
DH	District Hospital
ERIG	Equine Rabies Immunoglobulin
HF	Health Facilities
I.D	Intra-Dermal route of administration
I.M	Intra-Muscular route of administration.
FAT	Fluorescent Antibody Test
FAO	Food and Agriculture Organization of United Nation
FBO	Faith Based Organization
GARC	Global Alliance for Rabies Control
GAVI	Global Alliance for Vaccine and Immunization
HC	Health Centre
MOHSW	Ministry of Health and Social Welfare
OIE	World Organization For Animal Health
PEP	Post Exposure Prophylaxis
RIG	Rabies Immunoglobulin
T.C	Town Council
VP	Vertical Programmes.
WHO	World Health Organisation

DEFINITION OF KEY TERMS

Cold chain

The system of transporting and storing of vaccine at the recommended temperature range which is (+2 ºC to +8 ºC for the refrigeration of vaccines) and (-15 ºC to -25 ºC for freezer vaccine). Essential elements in the cold chain system are:

1. People managing vaccine manufacture, storage and distribution and those working in clinical practise and
2. The equipment used for storing, transporting and monitoring vaccines between the delivery of the vaccine to an immunisation provider and administration to patient.

Zoonosis

A zoonosis is any disease or infection that is naturally transmissible from vertebrate animals to humans. Animals thus play an essential role in maintaining zoonotic infections in nature. Zoonoses may be bacterial, viral, or parasitic, or may involve unconventional agents.

Public health facilities

Are health facilities that are managed by both the government and a Faith Base Organization and they receive funds for management and purchasing medicines from the ministry of health.

Vaccine

A vaccine is any preparation intended to produce immunity by stimulating the production of antibodies. Vaccines are prophylactic medicines designed to prevent rather than treat disease. Vaccines include suspensions of killed or attenuated microorganisms, or products or derivatives of microorganisms. Vaccines may be administered by injection, but some are given by mouth or nasal spray. Anti rabies vaccines that are found in Tanzania are cell cultured rabies vaccines which are from cell culture derived rabies vaccine for pre-and post-exposure prophylaxis.

Rabies Vaccine

Rabies vaccine is a vaccine used to control rabies. Rabies can be prevented by vaccination, both in humans and other animals. It is on the World Health

Organization's List of Essential Medicines, a list of the most important medication needed in a basic health system.

There are three main types of rabies vaccine used for PEP. These include the outdated nerve tissue vaccines, cell culture vaccines, and embrocated egg vaccines. Cell culture vaccines and embryonated egg vaccines have replaced nerve tissue vaccines in industrialized countries and are the ones recommended for use by WHO. They are considered safe and well tolerated. Cell cultured rabies vaccines can be Human diploid cell vaccine, Purified chick embryo cell vaccine and Purified Vero cell rabies vaccine [1]

Human diploid cell vaccine (HDCV)

Contains the Pitman-Moore L503 or Flury strain of rabies virus grown on MRC-5 human diploid cell culture, concentrated by ultra filtration and inactivated with ß-propiolactone [2] this vaccine is licensed for intra-muscular use. It contains no preservative or stabilizer.

Purified chick embryo cell vaccine (PCECV)

Is a sterile lyophilized vaccine obtained by growing the fixed rabies virus strain Flury LEP-25 in primary cultures of chick fibroblasts. The virus is inactivated with ß-propiolactone, purified and concentrated by zonal centrifugation [3, 4]

Purified Vero cell rabies vaccine (PVRV)

Contains inactivated and lyophilized Wistar strain of rabies virus grown on Vero cell cultures in fermenters allowing mass cultivation. These are inactivated by ß-propriolactone and purified by ultracentrifugation [5]

Rabies immunoglobulin

Liquid or freeze dried preparation containing immunoglobulin’s; mainly immunoglobulin G. The preparation is intended for the intramuscular administration. It is obtained from the plasma from donors immunized against rabies. It contains specific antibodies neutralizing the rabies virus.

Rabies free country

Country is characterized as rabies free country as follows;

i. The disease is notifiable and any change in the epidemiological situation or relevant events is reported

ii. An ongoing system of disease surveillance has been in operation for two years, with a minimum requirement being an ongoing early detection programme to ensure investigation and reporting of rabies suspect animals and

iii. No cases of indigenous acquired rabies virus infection have been reported for the past two years.

Pre exposure vaccination (PreEP)

Vaccination offered to people who are at high risk of exposure such as those working in rabies diagnostics or research laboratories, veterinarians, animal handlers including bats handlers, animal rehabilitators, and wildlife officers as well other people especially children living or travelling in high risk areas. Pre exposure vaccination is administered as a one full dose of vaccine intramuscular or 0.1ml intra-dermal on days 0, 7, either day 21 or 28.A few days variation is acceptable

Post exposure prophylaxis (PEP)

Means the prophylaxis given to people and who are exposed to rabies. This should be followed by the complete vaccine series using a potent and effective vaccine that meets the WHO criteria. Rabies PEP is administered as per WHO guidelines as presented in Table 1 bellow. PEP may be administered through intramuscular or intra-dermal route. Intramuscular regime is given in 0, 3,7,14, 28th days. IM route is recommended for HIV infected person and people aged 65 years and above .Intra dermal vaccination route are given on 0, 3, 7 and 28^{th} day, 0.2 ml (0.1ml on left and 0.1ml on right shoulder).

Pre-qualified suppliers

A list of suppliers whose government agency/ council had pre-approved as capable of delivering specific goods or services.

CHAPTER ONE

1.0 BACKGROUND

1.1 INTRODUCTION

Rabies is one of the 17 neglected tropical disease recognised by WHO [6, 7]. Rabies is a viral zoonosis caused by negative-stranded RNA viruses from the (Genus: *Lyssavirus* family: *rhabdoviridae*). Rabies virus is enzootic throughout Africa and Asia with the domestic dog (*Canis familiaris*) being the principal vector [8, 9]. The most common mode of rabies transmission is through bite by an infected animal, usually domestic animals [10]. Other modes of transmission of rabies virus are rare and not often seen, these include organ and tissue transplantation for example cornea transplantation [10] and kidney [11], and these are not common in Tanzania [12].

Rabies icubation period varies widely, but it is usually between 10 days to 3 months depending on the viral load and type of the virus that entered the system, individual immunity and distance of the wound from the Central Nervous System [4,8]

Depending on the symptom, rabies has been categorized into two forms; furious and paralytic rabies. The furious form is more common and is characterised with signs of illness that are not specific these include fever, anxiety, pruritis at the site of animal bite and malaise. After 2-10 days neurological signs become manifest, ranging hyperactivity, hydrophobia, aerophobia, and death by cardio-respiratory arrest which occurs within days [8-11, 13]

Paralytic rabies accounts for about 30% of the total number of human cases. Paralytic form runs a less dramatic and usually longer course than the furious form. Paralytic rabies is characterised by muscles become paralyzed starting at the site of the bite or scratch which ascends (either symmetrically or asymmetrically) with pain and fasciculation in the affected muscles , ssensory disturbance occurs frequently followed by paraplegia and sphincter disturbances; in the end fatal paralysis of the respiratory and deglutitive muscles occur. Coma develops slowly, and eventually death occurs. [8, 14-16]. The paralytic form of rabies is often misdiagnosed as Guillain-Barre´ syndrome, Polio or Tetanus [15]. CSF examination gives the difference in diagnosis between paralytic form of rabies and other diseases. Having the history of an animal bite (if available) aids towards the correct diagnosis [15]

Despite the fact that 15 million people receive rabies post-exposure prophylaxis globally, yet an average of 60,000 people die from rabies every year [8, 9]. Using the modeling approaches developed by WHO, taking into consideration incidence of dog-bite injuries and availability of rabies post-exposure prophylaxis (PEP) it is estimated that human rabies cases are 100 times higher than officially reported with 24,000 deaths in Africa each year [8, 9].

WHO advise washing wound with running water and soap; if available, irrigation with a virucidal agent such as povidone-iodine solution [17-20]. Examination and assessment of category of exposure of the wound are done before anti-rabies vaccinations are given to the bite victim as illustrated by Table 1. If the wound is categorized in category III then Rabies Immunoglobulin (RIG) are given, irrespective of the interval between exposures and beginning of treatment. There are two types of Rabies Immunoglobulin (RIG); Human Rabies Immunoglobulin (HRIG) and Equine Rabies Immunoglobulin (ERIG). The HRIG recommended dose is 20 IU/kg of body weight and 40 IU/kg of body weight of ERIG. RIG's are infiltrated around the wounds if anatomically feasible, the remainder vaccine should be injected intramuscularly into an area as far as possible from the vaccination site [14-15].

Anti-rabies vaccination are given in five doses; if given intramuscular on 0, 3,7,14 and on 28^{th} days and when given by intra-dermal route the doses are on 0, 3^{rd}, 7^{th}, and 28^{th} day as presented by Table 1. For a previously immunized person the re-exposure vaccination schedule is two doses that is on 0 and on 3^{rd} day [21-24]

There are no dietary restrictions during the course of rabies vaccination. Throughout vaccination all immunosuppressive drugs are contraindicated; these include anti-cancer drugs, steroids and chloroquine. If these drugs cannot be avoided and the patient is in immune-compromised state, the intra-muscular regimens have to be followed by infiltration of Rabies Immunoglobulin in the bite-site. [25]

Rabies PEP failure may occur despite adherence to WHO recommendations. These may be caused by inability to maintain cold chain for vaccine or immunoglobulin in developing countries, short rabies incubation period, failure to infiltrate maximum HRIG locally due to anatomic feasibility and suturing of the wound (even though done after PCEV and HRIG administration, incomplete dissolution of the vaccine in the diluents [26-28] .

Moreover, availability of RIG's in public health facilities is a problem resulting in inability to provide complete and adequate rabies immunization to victims of animal bites according to WHO guidelines when a patient is exposed in category three [30-32].

Shortages of PEP vaccines are frequent in Africa and many developing countries, leading to unavailability in the public health facilities thus causing increased costs to bite victims who are forced to travel to multiple centers to obtain treatment [29, 33]

Cost of Rabies PEP vaccines is a burden to low and middle income countries [21, 29]. Many countries spend millions of dollars importing supplies of tissue-culture vaccine ($196 million USD pa) thus impact both government and household budgets [8, 21, 29]. Cost of PEP can be directly from anti-rabies vaccines or indirect (patient-borne) costs associated with travel (particularly given the requirement of multiple hospital visits) [17, 30]. In Tanzania total cost of receiving full course of rabies PEP Vaccination is more than 100USD following the 5 dose regimen excluding direct and indirect cost, and patient escorts [33]

Effort by international community in eliminating rabies (both human and canine) are done in collaboration with FAO, OIE, WHO, GARC and other stakeholders to motivate governments to prioritize and coordinate action and control strategies to eliminate the disease [34]

1.1.1 Rabies situation in Tanzania

Tanzania is one of the countries which are highly affected by the rabies [20,22, 33]. This disease satisfies WHO as previously narrated to be given a priority for control [34-36].

Between 1990 and 1996 Tanzania reported an incidence of 23,709 sustained dog bites and these increased to 42,669 sustaining animal bites in the year northern part of of Tanzania, human rabies death are estimated to be 100 times higher than officially recorded, with 1 499 (95% confidence interval 891- 2,238) human deaths annually in comparison with the 10-20 human cases typically reported each year by central authorities [20].

Bill and Melinda Gates Foundation fund WHO coordinated projects to control and eventually eliminate rabies in low income countries. Tanzania was one among the

countries that were chosen. The duration of the project was five years (2008-2013). The project intended to achieve the "paradigm shift" in the strategic planning and implementation of the activities and eventually eliminating rabies. The project site was South East Tanzania which include five regions; Dar es salaam, Lindi, Mtwara, Morogoro and Pwani. Pemba Island was included in the site with the aim of making comparison of the dynamics of canine rabies elimination in the island and inland settling [35]

In 14th May 2010 the project was officially launched by Minister of livestock and development Dr John Magufuli. There was inter-ministerial collaboration between two ministries (Ministry of Health and Ministry of Livestock) and two focal persons were chosen from each ministry [34]. Human exposures and human rabies data from all the project areas were collected through the Ministry of Health Infectious Diseases Department to which animal bites and rabies were reported on a weekly basis for monitoring and evaluation of PEP [34].

Findings from the project reveals that number of patients reporting to the hospital with animal bites varied considerably by districts over time (less than 5 to more than 200 per 100,000 people) also human rabies death occurred in periods of relatively high bite incidence and when vaccines were in short supply. It was observed that number of death recorded represent only who attended a health facility [36].

1.1.2 Health care systems in Tanzania

The health care system in Tanzania is made up of largely two components, the public sector and the private sector [37]. The public sector accounts for 56%, private non-profit 30% and private for profit 14%. Providers of health services in Tanzania include the Government, Parastatal organizations, voluntary organizations, religious organizations, Private practitioners and Traditional medicine [38]. In Tanzania 70% of the population is within 5km of health care services and about 90% of the population is living within 10 kilometers of Primary Health Care (PHC) services. Health care services are offered in a pyramidal referral structure with many service delivery points at the base and fewer referral/consultants services at the apex of the pyramid. The referral system starts at the community level going upward to

dispensary level, health centre level, district hospital level, regional hospital level consultant hospital [37-39].

According to the standard treatment guidelines (STG) and National Essential Medicine List (NEMLIT) of Tanzania Mainland requires anti-rabies vaccines to be stocked at hospital and health centres levels and not in the dispensaries [40]

1.1.3 Supply chain of anti-rabies vaccines in Tanzania

Good pharmaceutical supply chain in any country are needed so as to assure steady supply of affordable and high-quality medicines, vaccines and other health products at all health service delivery points [41-2]. Supply chains play a role in all categories identified for health system performance improvement: these include payment, organization, regulation, and also behavioral aspects of the health system. Supply chains not only deliver medicines and health products to the population, they also return critical information regarding need, demand, and consumption to health system planners [43]. Figure 1.1 below shows the structure of public sector and private sector supply chains in most developing countries.

In Tanzania, Medical Stores Department (MSD) procures for almost all Government funds, Global fund, some of bilateral donors, (public and approved NGO/FBO facilities including CSSC-Designated hospitals and health centres). On good technical reasons the government contracted UNICEF as a procurement agent for all vaccines and related supplies. United States government through bilateral donors such as PEPFAR, USAID, UNITAID and World Bank use procurement agents of their own choice with limited information sharing among partners. Therefore there is a significant portion of medicines and supplies bypassing the Medical Store department; in turn makes supply management and quality control even more difficult [44]

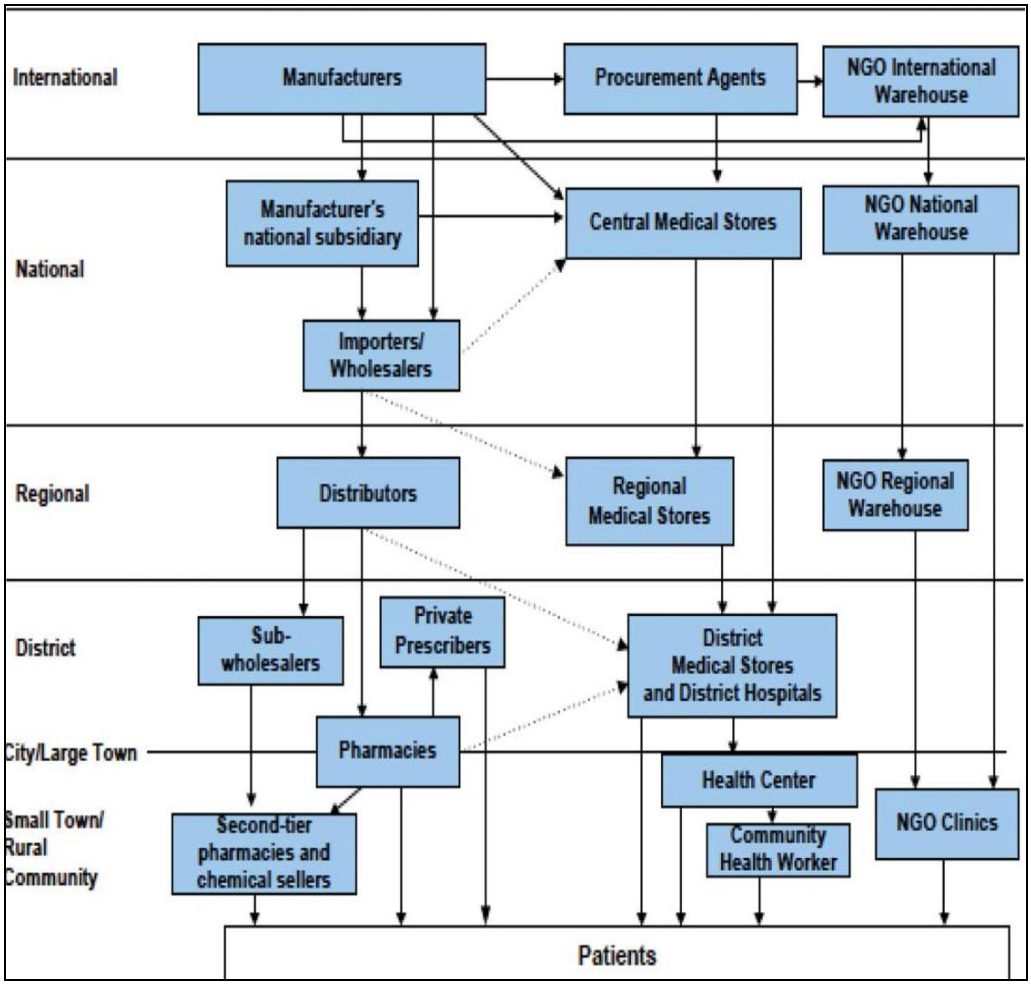

Figure 1.1: Structure of public sector and private sector supply chains in most developing countries.

Source: World Health Organization. Ref. 27, page no 4.2015, Management of Science for Health.

MSD has a responsibility of maintaining the steady supply of pharmaceuticals and vaccines at the public health facilities where they are needed, while ensuring the resources are being used in the most effective way also maintenance of the cold chain is adhered. Distribution of pharmaceuticals is done from time to time upon request of the customer from district of zonal medical store department that is Direct Delivery (DD). Vertical programmes tend to distribute every 3 or 6 months [45]

Normal Programme is a routine sale of medicines and medical supplies from the catalogue; these are bulk items purchased under international competitive tendering.

For example in figure 1.1 above the normal programme supply chain starts sent to order to manufacturer's by procurement agents in the central medical stores, then consignment is sent to the Regional Medical Stores ,District Medical Stores Heath centres and finally to the patients.

Vertical Programme is specific arrangements with the third parties (MoHSW VP) to procure or store or distribute medicines and or medical supplies. For example in the figure 1.1 above supply chain starts when order is sent to manufacturer by procuring agents, for Tanzania all pharmaceutical vaccines inclusive are stored in Central Vaccine Store at MSD. MSD has a task to distribute according to the guidelines given by those NGO's.

These systems (MSD normal and vertical programme) operate separately; they differ in competitive environment, pricing regime, margin and operational aspect. Vertical programme constitute of fundamentally different business charging for services rather than deriving income from margin on sales [45-6]

Procurement of anti-rabies in public health facilities can be done through MSD (by either Normal Programme or Vertical Programme) and procurement from district council's prequalified suppliers.

Figure 1.2 below shows the distribution cycle of pharmaceuticals vaccines inclusive from the point of entry to consumption by patients. Its starts with forecasting and quantification from user department regarding need and demand, for normal programme it is done annually but vertical done according to project guidelines. Then procurement processes are followed and once the consignment is delivered in the country(mainly by airway) port clearance are done followed by receipt and inspection, Inventory control, storage, Order and Issues, Transport and the circle kept revolving.

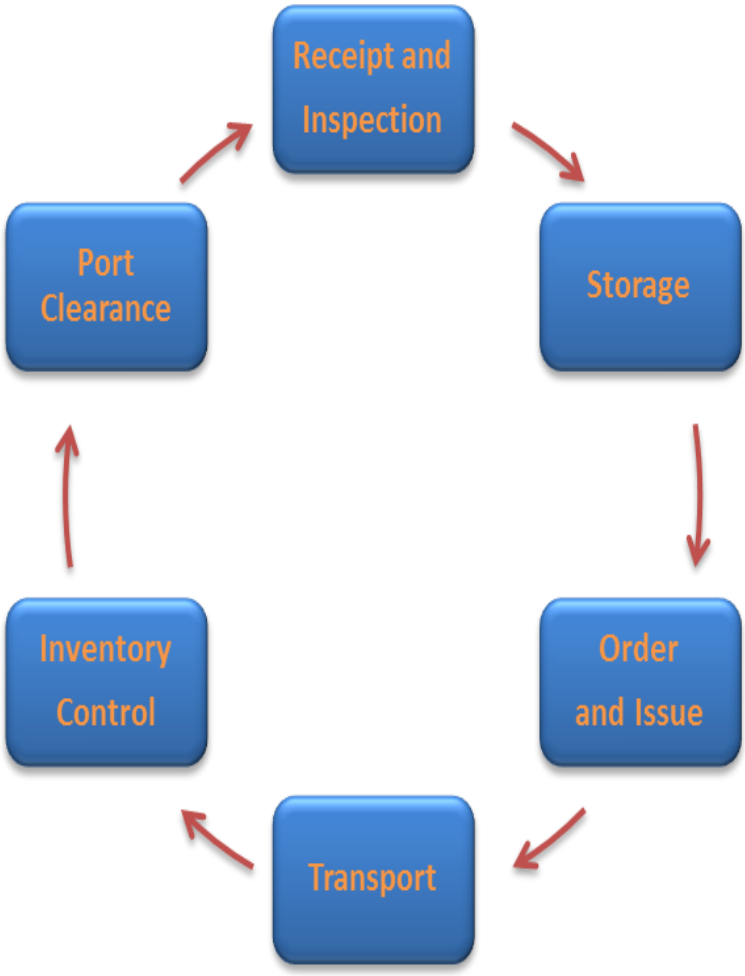

Figure 1.2: Shows the distribution cycle that vaccine follows from the point of entry to the consumption.

Source: Management of Science for Health

I. **Port clearing:** It involves a fast track mechanism for clearance of the vaccine at the airport within 1-2 days after arrival.

II. **Receipt and inspection:** Central Vaccine Store carries a complete inspection of every shipment as soon as it is received from the port of entry that is reviewing data from temperature loggers, vaccine specification and quality control process.

III. **Inventory control:** It involves control system done through Computerized Stock Management (SMT) which was introduced in Central and Regional Levels in 2011. The system was introduced in the council's level in 2012. Inventory control system is used for requisition and during issuing anti-rabies vaccines for financial accounting, preparation of requisition and stock

balance report necessary for procurement. Moreover manual documents records are available at the store which include

- Bin cards
- Ledger books

IV. **Storage:** Vaccine must be stored appropriately to maintain potency. A temperature controlled environment used to maintain and transport vaccine at optimal temperature is called the vaccine cold chain. There are two different vaccines temperature ranges that are +2ºC to + 8ºC for refrigerator vaccines these include rabies vaccine, rota-virus vaccine, tetanus toxoid vaccine and -15ºC to -25ºC for freezer vaccines these include Varicella (chickenpox)vaccine and Zoster (Shingles) vaccine.

Tanzania has four level of vaccine cold chain [47]

1. **National Level;**

   It is the Central Vaccine Store (CVS) at MSD and currently sufficient for primary storage. It has eight Walk in Cold Room with central cold rooms which had $550m^{3,}$ freezers occupying $52m^3$,warehouse in a box (WIB) occupying 282 m^3 (temperature is maintained 0-8ºC) and central chillers occupying $126m^2$ (temperature is maintained 18-26ºC). A national level has a vaccine storage capacity for 6 month stock with buffer stock of 25%. [47]

2. **Regional Level.**

   There are 26 Regional Vaccine Store (RVS). At each Vaccine Store Walk In Cold Room (WICR) is installed and standby water cooled generator of capacity 40KVA.Regional Vaccine Stores have capacity for up to 3 month 25% buffer stock [47].

3. District Level.

   There are 151 council among them 133 (88.1%) have District Vaccine Store. Storage capacity at this level lasts for 3 months [47]. 18 district councils which do not have District Vaccine Store (DVS), stores vaccines in health facility in their district. During immunization session they do outreach programme with vaccine carriers. Some of lots of its vaccine are stored in its respective Regional Vaccine Stores.

4. Health Facilities Level

Tanzania have 6321 Health Facilities (public and private) only 5500 (87%) are conducting the immunization activity. Facilities are equipped with the vaccine storage capacity of six weeks with a buffer stock of 25% of its target population. Each immunization facility has a functional Liquefied Petroleum Gas or Solar Refrigerator [47]

V. Order and Issues

Allocation of anti-rabies vaccines to different MSD zones is done by MSD headquarters.

VI. Transport

MSD delivers the vaccine and related supplies to the Regional Vaccine Store (RVS) except for Dar es Salaam whereby delivery is done directly to the councils and Zanzibar which pick up anti-rabies vaccine

Different means of transport are used to ensure that anti-rabies vaccines reach at the health facility at the appropriate time. Most council (district) use cold boxes from the District vaccines store to deliver these vaccines [33-5].

1.2 Conceptual Framework of anti-rabies supply chain in public health facilities

Public health facilities are procures ant-rabies vaccines from either Medical Store Department (MSD) through normal programmes or through Ministry of Health and Social Welfare through Vertical Programmes and from the district council's pre-qualified suppliers. Pre-qualified supplier are chosen in district level by Councils Health Management Team (CHMT) to supply pharmaceuticals and medical equipments which on that time are out of stock in MSD.

Ministry of health through Vertical Programmes send the consignment to Regional Vaccinne Store (RVS) which then distributes to DVS inturn to District Hospital, DDH and Health Centre. Moreover,in the Normal Programme Central vaccine store distributes vaccines to its zonal offices through which Regional Vaccine Store, District Vaccines Store, DDH and health facilities procures anti-rabies vaccines. Regional Vacccine Store in the regional hospitals,

District Vaccine Store are mainly located in the district hospital,health facilities like health centres ,DDH and some are stored in the District Medical Stores office with District pharmacist as custodian.

There are factors that contribute to poor availability of ant-rabies vaccines in public healh facilities,these include poor quantification by health personnel responsible, lack of information regarding demand of the vaccine in relation to the number of animal bites, timings of disbursement of funds (uncertain and highly variable) and long lead times.

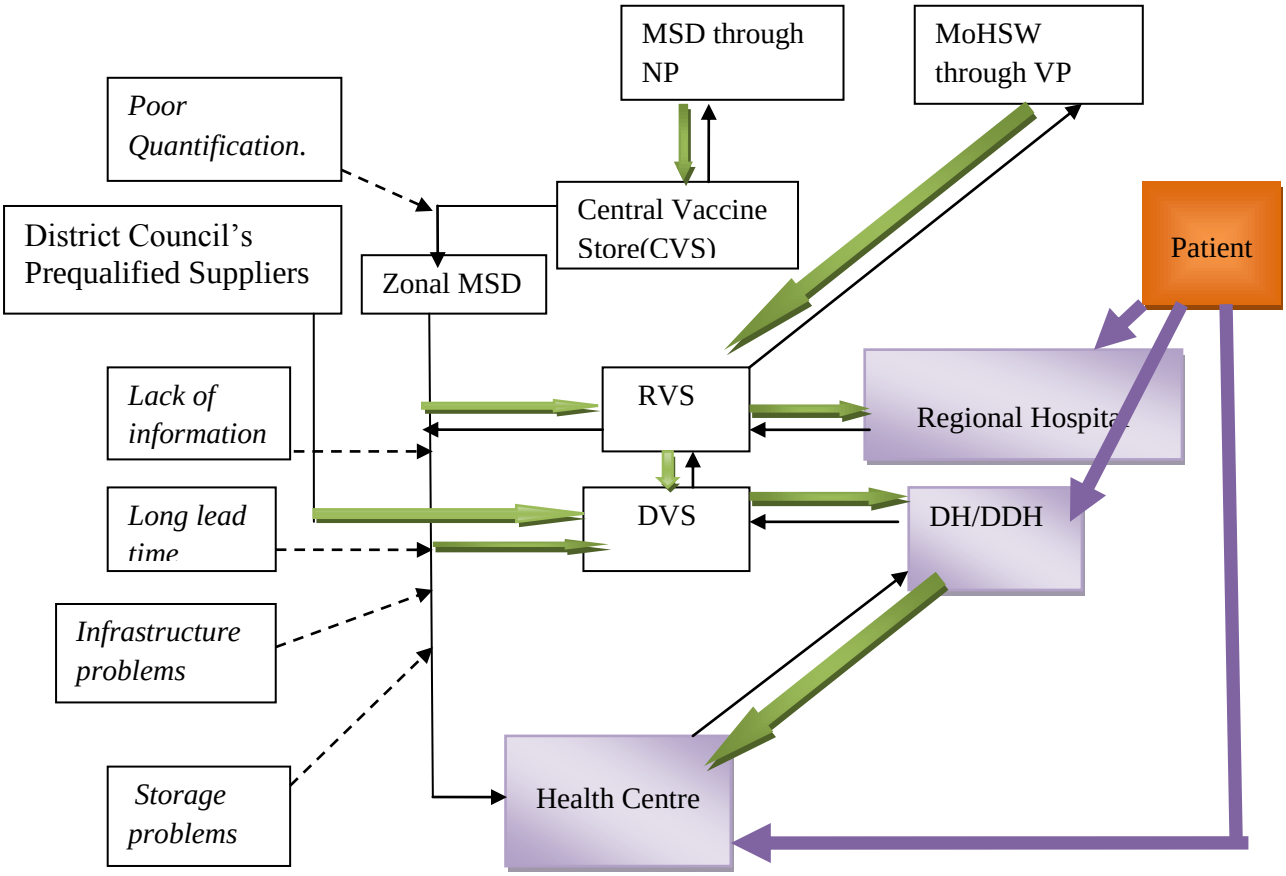

Figure 1.3: Conceptual Framework of anti-rabies supply chain in public health facilities

Source: The researcher (2015)

Key:

Flow of vaccine → Flow of information - - - ▸ Problems encountered

Centres where patient receive anti-rabies vaccination

DH District Hospital DDH Designated District Hospital

DVS District Vaccine Store MoHSW Ministry of Health

MSD Medical Stores Department NP-Normal Programme

RVS Regional Vaccine Store VP Vertical Programme

1.3 Problem Statement

Controlling rabies in developing countries, Tanzania being one of them is still a very big challenge regardless of the fact that rabies is 100% fatal [8,17,20]. Control efforts are stalled by incomplete post-exposure prophylaxis, availability of rabies PEP and lack of awareness [49]. Procurement and stocking of anti-rabies vaccine in public health facilities is a problem due to the fact that rabies is given low priority due to under-reporting of the disease magnitude [20]. A trade-off between need and demand poses a great challenge to the Medical Stores Department since keeping a lot of supplies when the demand is sporadic and unpredictable threatens expiry of the stocks and its subsequent unavoidable negative financial impacts. On the other hand, absence of ant rabies vaccines in an event of outbreak is catastrophic, causing deaths and public outcry. This study intends to establish if there are enough anti-rabies vaccines to rabies prone regions of Lindi and Tanga in Tanzania.

Availability of storage facilities and equipments for anti-rabies vaccines are inadequate in some areas especially in maintaining of the cold chain conditions especially in case of power fluctuations/ failures.

Under-dose administrations of anti-rabies vaccines in some areas are not done according to WHO dosage regimen these lead too many patients not able to finish the dosage as recommended.

1.4 Rationale of the Study

This study will reveal the magnitude of problems related to availability, source of supply, storage conditions and use of anti-rabies vaccine. This in turn will enable health policy makers, donors and all other stakeholders involved in medicines sector to effectively plan to ensure proper availability, storage and proper utilization of anti-rabies vaccine. Ultimately, the problem of rabies will be controlled.

1.5 Research Questions

- Are anti-rabies vaccines available in the health facilities in Lindi and Tanga regions?
- How are anti-rabies vaccines stored in the health facilities in those regions?
- What are the sources of supply of anti-rabies vaccines in the health facilities in those regions?
- How are anti-rabies vaccine used in the health facilities in those regions?
- Is there expired anti-rabies in the health facilities in those regions?

1.6 Objectives

1.6.1 Broad Objectives

To assess availability, storage and use of anti-rabies in the public health facilities in Lindi and Tanga regions.

1.6.2 Specific Objectives

1. To determine the availability of anti-rabies vaccine in public health facilities in Lindi and Tanga regions.
2. To assess storage conditions of anti- rabies vaccine in the health facilities regions
3. To assess the source of supply of anti- rabies vaccine in the health facilities in those regions
4. To assess the providers knowledge in relation to the use of anti-rabies vaccine in health facilities in those regions
5. To determine the presence of anti-rabies vaccine that has expired within the last 12 months in the health facilities in those regions.

CHAPTER TWO

2.0 LITERATURE REVIEW

Study conducted by in South Asia found that rabies was still a serious public health problem. Some of the common constraints that were encountered in the control of rabies include inadequate resources; lack of political commitment to control programs; lack of consensus on strategy; weak intersectoral coordination and inadequate management structure; insensitive surveillance systems; limited accessibility to modern rabies vaccine and supply problems; lack of public awareness and public cooperation; and the existence of myths and religious issues [48]

Report of a WHO Interregional Consultation looking at the strategies for control and elimination of rabies in Asia foud that rabies is given a low priority in listing for disease control programmes. Thus rabies is not a notifiable disease in humans and animals in most developing countries, accurate mortality data are unknown and this poses a question on the reliability of c epidemiological data [50]

Stock out of rabies vaccine for humans and animals is still a problem in many hospitals. Study conducted in Kenya found that there was insufficient supply of rabies vaccine for both human and animals, with stock-outs occurring over long periods in the district hospital [32]

Study conducted in rural South Africa on provision of rabies vaccine and rabies immunoglobulin at the State's expense revealed deficiencies in the availability of vaccine and immunoglobulin at the indicated sites and led to decisive corrective action [52]

Study conducted in eleven Member States in the WHO South-east Asia region found that high cost of rabies vaccine poses a problem in eliminating the disease. Thus introduction of cost-effective intra-dermal rabies vaccination regimens had increased the availability and affordability of post exposure prophylaxis. Cooperation of regional and inter-sectoral sectors was important in elimination of rabies in the region [53]

Study conducted in France and Poland on availability of human rabies vaccine and human Rabies Immunoglobulin found that availability of rabies vaccine was limited

in Europe as compared to North America also stock specific of human rabies immunoglobulin's was more limited [54]

In a study done in low-income countries, found that vaccine shortages were common in developing countries due to limited availability of funds. Bite victims needed to travel long distances to obtain rabies PEP. Thus, patients often incur substantial costs and face dangerous delays in securing PEP and avoidable human rabies deaths occurring as a direct result of poor access to affordable PEP. High costs of anti-rabies vaccine reduce patient compliance to PEP but by giving vaccination free of charge; risks will be minimized [55]

Studies were done to find out availability of anti-rabies vaccine and rabies Immunoglobulin to travellers. It was found that availability of ant-rabies varies with geographical regions thus all travelers to have medical evacuation insurance prior to departure [56]

Study done by Ministry of Health Tanzania in 2009 evaluating the vaccine storage temperature, Vaccine stock management, effective vaccine delivery, knowledge of the health care workers on use of Vaccine Vial Monitor and Mult Dose Vial Policy show that improvement have to be done in continuing health education to health care workers regarding VVM and MDVP [57]

Study conducted in Colombo immunization clinics on practises of health personnel regarding the vaccine storage an integrity of cold chain durinng storage found that there was problem in maintaining the cold chain system in clinics as result showed that there was colour change in 2 out of the 22 WHO cold chain monitors and 76% of the refrigerators were used for other purposes other than storage of vaccines [58]

Study done in health facilities in three districts in central Ethiopia found that there were problems in maintenance of cold chain in health facilities so as to reduce the risk of vaccine of losing their potency. Knowledge and practice on cold chain management needed to be improved by supervision and training [59]

Maintenance of the cold chain system is a problem in many African countries. In study done in eight districts in Cameroon found that there was a failure of maintenance of the cold chain system in the storage facilities in the eight districts. This pose the questions on efficacy and safety of vaccines administered during EPI activities in Cameroun this can have as consequences, adverse events following

immunization among vaccinated persons, loss of potency of administered vaccines, increasing incidence of cases of disease [60].

Maintaining the vaccine cold chain is an essential part of a successful immunization programme, in developing countries faulty procedures may occur. Study done by in three African countries (Ghana, Kenya and Uganda) found that storage equipments were available only 4% of the facilities store vaccine in the cold boxes remaining that is 96 % has refrigerators. 16·6% of the surveyed facilities had storage temperature outside the recommended range, half were 4°C or more outside the recommended range[61]

Study done in Dammam, Saudi Arabia when assessing health workers practice and evaluating availability of cold chain tools in governmental health facilities and private health care rooms found that private health clinics did not comply with standards defined by the MOH or WHO for cold chain tools and needed constant supervision and training as health care professionals [62]

Study conducted at West Berkshire and Aylesbury Vale when assessing the maintenance of vaccines cold chain in general practice in district health authorities found that breaks in the chain were more frequent and compromised potency [63]

A study conducted in Securendebad India concerning the vaccine distribution found that the implementation of an immunization programme in the rural areas was affected by the gap in the distribution system. The study also identified other problem areas such as fault in cold chain and the need for an improved monitoring and control system for better supervision [64]

When assessing problems, challenges and opportunities of vaccination in developing countries: four obstacles were found to affect access to immunization. These obstacles included medical and scientific, structural and demographics, economic and political and societal and cultural reasons. Effective addressing of these obstacles will lead to achievement of widespread immunization coverage goal. Addressing the structural and demographic obstacle it was clearly seen that poor infrastructure, logistic problem and expanding population and diversity leads to difficulties of delivery of vaccine in the desired area. This leads to poor accessibility of health care services villagers have to walk many kilometres in order to get the health services they desire [65]

Study conducted in United States indicated that 4 vaccine doses in combination with rabies immune globulin (RIG) elicited adequate immune responses and that a fifth dose of vaccine did not contribute to more favourable outcomes. For persons previously unvaccinated with rabies vaccine, the reduced regimen of 4 1-mL doses of HDCV or PCECV should be administered intramuscularly. The first dose of the 4-dose course should be administered as soon as possible after exposure (day 0). Additional doses then should be administered on days 3, 7, and 14 after the first vaccination. Recommendations for pre-exposure prophylaxis also remain unchanged, with 3 doses of vaccine administered on days 0, 7, and 21 or 28. Prompt rabies PEP combining with wound care, infiltration of RIG into and around the wound, and multiple doses of rabies cell-culture vaccine continue to be highly effective in preventing human rabies [66-7]

In a survey conducted in Quebec Canada found that the four-site ID regimen reduces the cost of PEP by up to 80%, when compared with the standard intra-muscular Essen regimen, reduces the number of visits required for the patient. These results demonstrated that a new four-site ID PEP regimen is a cost-effective and convenient alternative to IM i.e. Essen or Zagreb [68]

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Design

This was a descriptive cross-sectional study, applying quantitative method of data generation through the use of structured questionnaires and observational checklist.

3.2 Study Area

Study was conducted in Tanga and Lindi region in Tanzania. Tanga was purposively selected among thirty regions. Comparison was made to Lindi as Lindi was a beneficiary of One Health project which aimed to reduce Rabies through canine vaccination.

Lindi Region is one of Tanzania's 30 administrative regions. The regional capital is the municipality of Lindi. Lindi region has six councils which are Kilwa, Lindi Municipal, Lindi Rural, Liwale, Nachingwea and Ruangwa [69]

Figure 3.1: Showing the administrative districts of Lindi Region

Tanga Region is one of Tanzania's 30 administrative regions. Tanga is divided into 8 councils which are Lushoto, Korogwe, Muheza, Handeni, Kilindi, Pangani, Tanga City, Kilindi and Mkinga. Mkinga is a new district split from Muheza. [70]

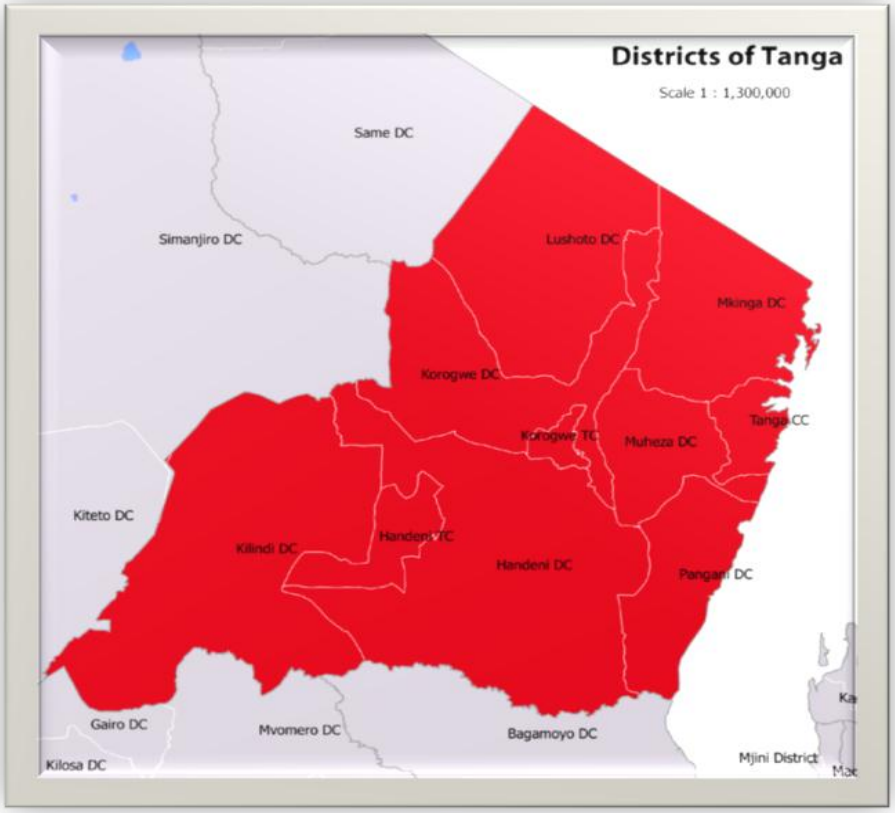

Figure 3.2: Showing the administrative districts of Tanga Region

3.3 Study Population

The study population was storage units in public health facilities (hospitals and health centres) and study units were selected key personnel involved in the ordering and use of anti-rabies vaccines in the health facilities in both regions.

3.4 Sampling Technique

3.4.1: Selection of the Study Units.

Public health facilities (hospitals and health centres) from each district councils in the two regions (Lindi and Tanga) were selected. Sampling of the health facilities was done according to WHO guidelines [71] that required thirty percent of the health facilities in the region from one geographical area. According to medicine stocking

guidelines, anti-rabies vaccine were supposed to be stocked at hospital and health centres only [40]

Lindi region had a total of 197 health facilities these included hospitals, health centres and dispensaries (the ownership may be government, faith based or voluntary and private). Lindi Municipal council had 45, Kilwa had 48, Lindi D.C had 15, Liwale had 30, Nachingwea had 35 and Ruangwa had 24 health facilities [72]

23 health facilities in Lindi were eligible for the study (these include public and some faith based facilities that were partly owned by public, these includes designated district hospitals). Taking 30% of 23 facilities in Lindi, seven health facilities were eligible for the study.

The same technique was applied in Tanga. Tanga had a total of 359 health facilities, these included hospitals, health centres and dispensaries (the ownership may be government, faith based or voluntary and private).

Facilities that were eligible for the study in Tanga were had 30, based on WHO guidelines on health facility survey which require not less than 30% of health facilities to be included in study, ten health facilities were chosen.

Thus the total of not less than 7 facilities in Lindi region and 10 facilities in Tanga region were needed in the study for the two regions.

3.4.2: Selection of the study participants.

Selection of key health care personnel who are involved in either ordering or use of ant rabies vaccines

Selection of key personnel who are involved in ordering, keeping and use of ant rabies vaccines was done purposively in order to capture the necessary information regarding the study purpose. These key people were as follows;

1. **The facility MO/AMO/CO/ACO I/C**

This is a health care worker who is involved with overall administrative issues in the health facility. He is responsible for overseeing all the activities involved with patient treatment and care including authorizing all orders for medicine procurement including anti-rabies vaccines also responsible for placement and training of human resources.

2. The facility pharmacist/acting pharmacist

This is a key person who is involved in the ordering, keeping and issuing of medicines including ant rabies vaccines in the facility.

3. Cold chain personnel

This is a person who oversees the usage part of all vaccines in the health facility; he is responsible for keeping data and all information regarding patients who get bitten, pre and post exposure vaccination.

Based on selection above three public health workers were chosen from each district in the two regions.

Having three public health workers from Lindi region which had six councils a total of 18 public health workers will be selected for the study. The same technique was applied in Tanga which had 8 districts council thus 24 public health workers were selected.

A total of 42 public health care workers from two regions (Tanga and Lindi) were selected in the study.

3.5 Inclusion and Exclusion Criteria

3.5.1 Inclusion criteria

- Public owned Hospitals and Health Centres which stock anti-rabies vaccine in Lindi and Tanga region.
- Key health workers found in the facilities willing to participate.
- Hospitals and health centres from the regions that are stocking anti-rabies vaccine.

3.5.2 Exclusion criteria

- Health workers not willing to participate in the study.

3.6 Data Collection

Data regarding this study were collected by the Principal researcher using data collection tools with collaborations with other research assistance that are going to be recruited and oriented before data collection start.

3.6.1. Data collection tool for availability of anti-rabies vaccine.

All stock out days for 12 months were recorded and assessed from January 2013 to December 2013 for availability of anti-rabies vaccine at the health facilities. A retrospective review of available records from ledger books and bin cards was done. Matching the records of days out of stock in the pharmacy and at the District Vaccine Store or RCH clinic where vaccines were dispensed. Stock out indicator form was used to collect the stock out days of anti-rabies vaccine from the health facilities (*Annex 3*).

Numbers of days anti-rabies vaccine stock out were determined. Availability of anti rabies vaccine was classified as high (0-120 days), moderate (121-240 days) and low (241 -365 days) table 1. Physical count of ant-rabies vaccine available was done at the time of visit.

Table 3.1: Levels stock out duration of anti-rabies vaccine in health facilities.

Range stock out days	Level availability
1-120 days	High availability
121-240 days	Moderate availability
241-365 days	Low availability

3.6.2 Data collection tool for storage condition of anti-rabies vaccine.

Adequate storage conditions and handling of vaccine checklist was another tool that was used to assess factors that can possibly affect the quality and efficacy of vaccines stored in the selected health facilities (73). Referring to the WHO indicators nine (9) observations were adopted in the checklist and the average score of each facility was calculated from each column. The following score chart was used (table 3.2)

Table 3.2: Storage score chart for storage condition

Percentage	Grades
75 – 100	Very satisfactory
50 – 74	Satisfactory
25-49	Dissatisfactory
0-24	Very dissatisfactory

3.6.3 Data collection tool to assess provider's knowledge related to use of anti-rabies vaccine.

Structured questionnaire containing 11 items was used to collect information regarding knowledge related to use of anti-rabies vaccine. Questionnaires were used to interview regional/district vaccine officer and medical officer in-charge and pharmacist or any other person performing the pharmacist duties in the health facility. The questions for the assessment of knowledge had been adopted from the WHO Rabies frequent asked questions (*Annex 1*). A zero (0) point was given for an incorrect answer and one (1) point was given for the correct answer. Then the levels of knowledge were graded as shown below.

Table 3.3: Knowledge score chart related to use of anti-rabies vaccine.

Percentage Scores	Knowledge level
75 – 100	Excellent
50 – 74	Good
25 – 49	Poor
0 – 24	Very poor

3.7 Study variables

Variables that which were included in the study

Dependent variables

- Availability of anti-rabies vaccines in the health facilities.

Independent variable

- Knowledge of the healthcare workers regarding the supply chain of the anti-rabies vaccine.
- Storage and handling practises of ant-rabies vaccine the health facilities by observing the temperature monitoring and recording, refrigerator temperature at the visited time.
- Existing of expired anti-rabies at the health facility.

3.8 Instrument Pre-test

Data collection tools were pre-tested in health facilities (Mwananyamala Hospital, Sinza Hospital) in Kinondoni district, Dar es Salaam to ensure its validity and clarity. The results of pretesting and accompanying comments were used to revise the instrument before distributing it to the actual participants.

3.9 Data Management and Analysis

Raw data were uploaded to an Excel spreadsheet for analysis using Statistical Package for the Social Sciences (SPSS) Version 20. Descriptive statistics was employed. Data was presented in frequency distribution tables and histogram. Percentage availability and storage of anti-rabies were compared between Tanga and Lindi. Chi-square test was performed to show the relationship between categorical variables where p value of < 0.05 will be considered statistically significant.

3.10 Ethical clearance

The ethical clearance was sought from the MUHAS Institutional Review Board (IRB). Study participants were asked on their willingness to participate in the study. A written consent form (*Annex 5*) was given for them to show their willingness to participate in the study. No names of study participants were captured instead code numbers were used during analysis from individually filled in questionnaires. Confidentiality was observed regarding the information given or prevailing in the public health facilities.

Permission to conduct the study was requested from the regions(Lindi and Tanga) where the study was conducted.

CHAPTER FOUR

4.0 RESULTS

4.1: Socio demographic data

This study intended to recruit 42 public health care workers in the selected district councils, in the two regions but only 39 respondents agreed to participate in the study. Twenty one (21) respondents were from Tanga region and 18 were from Lindi region. Thirty three respondents (84.6%) were male. Age distributions of the respondents ranged from 15 to above 44. Majority of the respondents (48.7%) were in the 35-44 age groups. About thirty three percent of the respondents were Health Officers. These and other demographic information are summarized in the table below.

Table 4.1: Social and demographic characteristics of the respondents (n = 39)

	Number of respondents	**Percentage (%)**
Sex		
Female	6	15.6
Male	33	84.6
Total	39	100
Age group(years)		
15-24	2	5.1
25-34	8	20.5
35-44	19	48.7
Above 45	10	25.6
Total	39	100
Profession Qualification of the respondents.		
Medical Officers	7	17.9
Assistant Medical Officers	6	15.4
Pharmacist	5	12.8
Pharmaceutical Technicians	7	17.9
Public Health Nurse	1	2.6
Health Officers	13	25.6
Total	39	100

4.2: Availability of anti-rabies vaccine in the health facilities

Availability of anti-rabies vaccine in the selected public health facilities in the two regions was assessed by two ways using stock out duration and counting the ant-rabies vaccine vials on the day of visit.

Stock out duration of anti-rabies vaccine in public Health Facilities in Tanga region.

Numbers of stock out days were calculated within 12 months retrospectively (from January 2013-December 2013). It was observed that Lushoto DH, Kisosora, Makorora, Mkuzi and Mwera HC had more days of out of stock of anti rabies vaccines. Least stock out days was observed in Tanga Referral Regional Hospital (TRRH), Pangani DH, and Muheza-DDH. Tanga Referral Regional Hospital (formerly known as Bombo) was the only health facility which had no stock out of anti-rabies vaccine i.e. (January 2013-December 2013). The mean stock out duration of anti-rabies vaccine at the health facilities was 200 days.

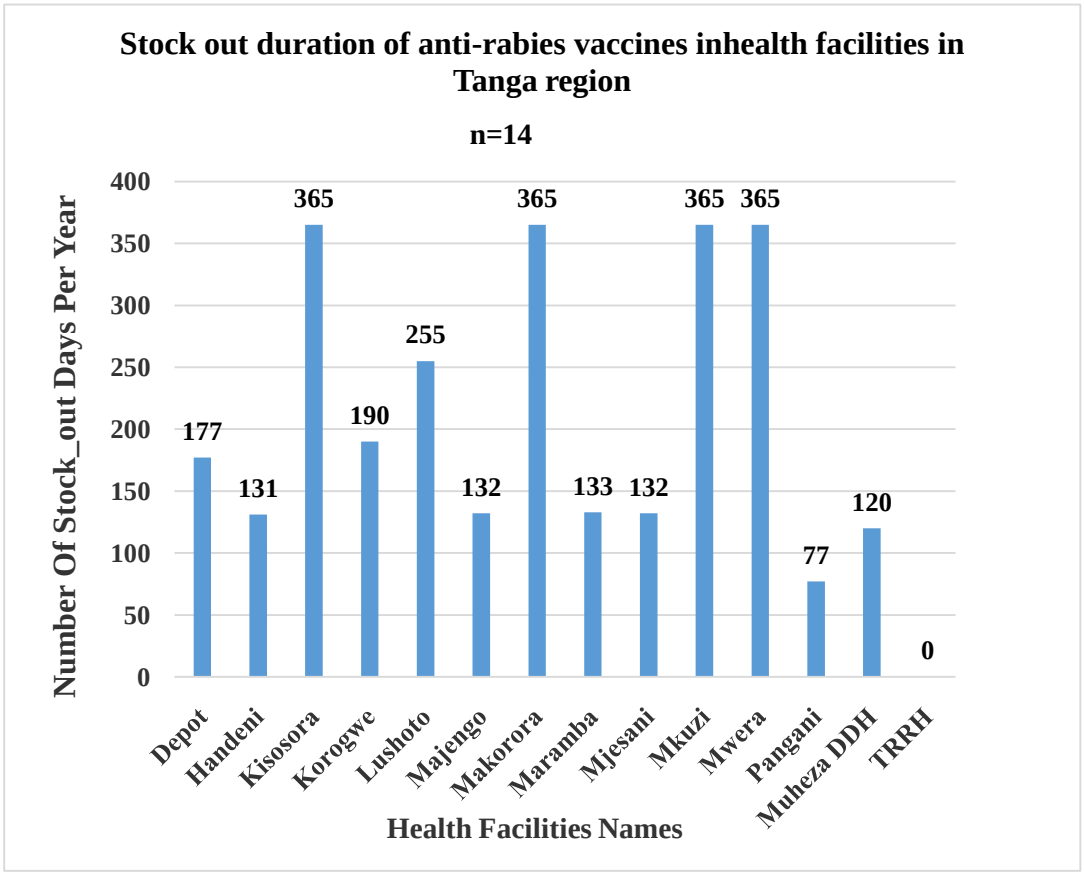

Figure 4.1: Stock out duration of anti-rabies vaccine in Tanga facilities.

Stock out duration of anti-rabies vaccine in Lindi facilities.

Figure 4.2 below shows the average stock out duration of anti-rabies vaccine in public health facilities in Lindi region. Least days out of stock were observed in Nyangao Hospital while more ant-rabies days out of stock were observed in Nyamangara hospital. The mean stock out duration of anti-rabies vaccine at the health facilities was 103 days.

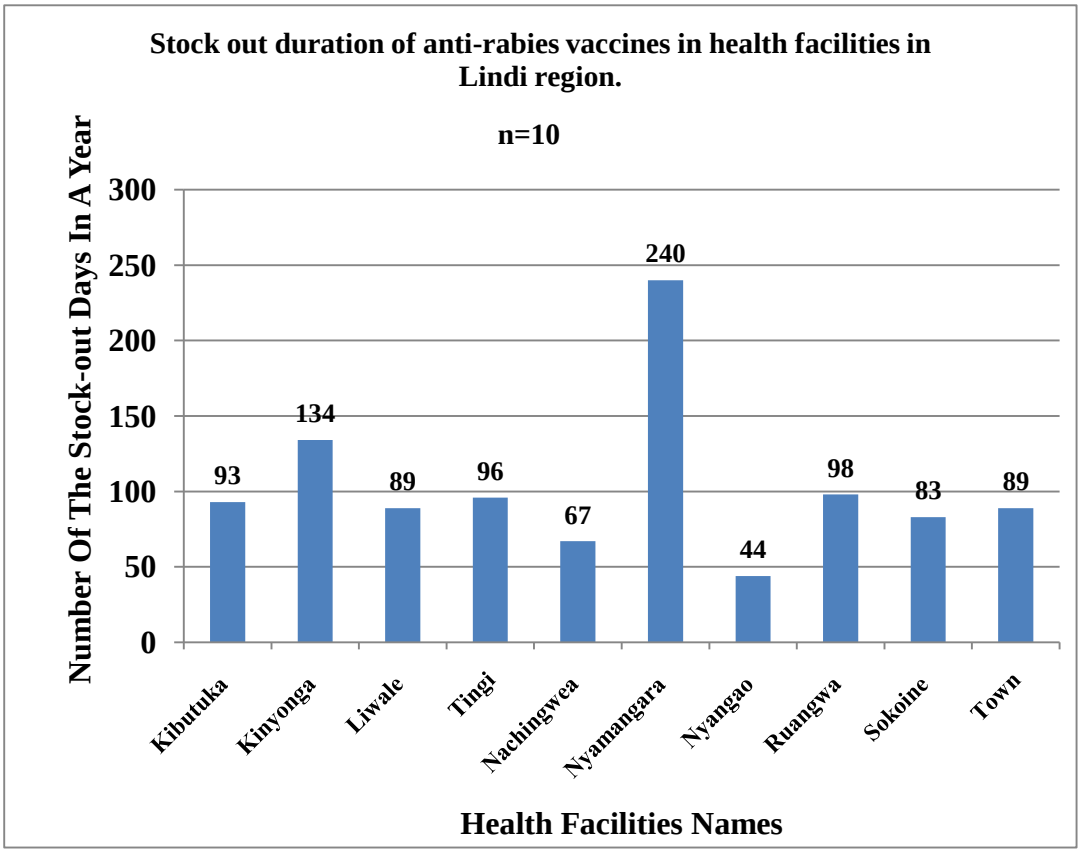

Figure 4.2: Stock out duration of anti-rabies vaccine in Lindi facilities.

Stock out duration of anti-rabies vaccines were higher in Tanga health facilities as compared to Lindi facilities. Four of selected facilites in Tanga qualify to stock vaccine but it was never stocked. This difference was statistically significant ($\chi 2$ =8.224 ,df =2 and p value < 0.05) p value was 0.016.

Table 4.2: Stock out duration of anti-rabies vaccine in health facilities in two regions.

Stock out days of anti-rabies vaccines	Number of HF's in Tanga	Number of HF's in Lindi
1-120 days(High availability)	3	8
121-240 days (moderate availability)	6	1
241-365 days(Low availability)	5	1
Total number of the health facilities	14	10

Availability of anti rabies vaccine in two regions on the day of visit in two regions.

It was observed that only seven out of fourteen public health facilities in Tanga region had stock of anti-rabies vaccine on the day of the visit. Moreover, ant-rabies vaccines vials were physically counted for each selected health facility visited. It was observed that, amounts that were entered in the bin card and ledger books matches the physical count (refer table 4.3 below).

Table 4.3: Health Facilities in Tanga region that had a stock anti-rabies vaccine at time of visit.

Names of the health facilities	**Amount of ant-rabies vaccine vials present on the day of visit**
Depot Health Centre	140
Handeni District Hospital	72
Kisosora Health Centre	0
Korogwe District Hospital	39
Lushoto District Hospital	20
Majengo Health Centre	0
Makorora Health Centre	0
Maramba Health Centre	0
Mjesani Health Centre	0
Mkuzi Health Centre	0
Muheza DDH	84
Mwera Health Centre	0
Pangani District Hospital	44
Tanga Refferal Regional Hospital	57

The same observation was done in Lindi region facilities. One public health facilities in Lindi region that is Sokoine Hospital, had stock of anti-rabies vaccine on the day of visit (refer table 4.4 below). Anti-rabies vaccine vials were physically counted. Remaining Councils Ruangwa, Nachingwea, Lindi DC, patients were sent to nearby Council that is Masasi in Mtwara region.

Table 4.4: Health Facilities in Lindi region that had a stock anti-rabies vaccine on the day of visit.

Names of the health facilities	**Amount of ant-rabies vaccine present on the day of visit**
Kibutuka Health Centre	0
Kinyonga Hospital	0
Liwale District Hospital	0
Nachingwea District Hospital	0
Nyamangara Health Centre	0
Nyangao DDH	0
Ruangwa District Hospital	0
Sokoine Hospital	10
Tingi Health Centre	0
Town Health Centre	0

Availability of anti rabies vaccine on the day of visit in the health facilites in two regions were higher in Tanga as compared to Lindi. These differences were statistically significant . ($\chi 2 = 4.21$,df =1 and p value < 0.05) p value was 0.04.

Types of anti rabies preparation found in the regions.

Study reveals that there were two preparations of anti rabies vaccine found in the health facilities in the two regions. These are intra-muscular and intra-dermal preparation. The results are summarised in the table 4.5 below.

Table 4.5: Types of anti-rabies vaccines found in selected health facilities in two regions

Facility Names	**I.M Preparation**	**I.D preparation**
Depot Health Centre	V	X
Handeni District Hospital	V	X
Kisosora Health Centre	-	-
Korogwe District Hospital	V	X
Lushoto District Hospital	V	X
Majengo Health Centre	V	X
Makorora Health Centre	V	X
Maramba Health Centre	V	X
Mjesani Health Centre	V	X
Mkuzi Health Centre	-	-
Muheza DDH	V	X
Mwera Health Centre	-	-
Pangani District Hospital	V	X
Tanga Refferal Regional Hospital	V	X
Kibutuka Health Centre	X	V
Kinyonga Hospital	V	V
Liwale District Hospital	V	V
Nachingwea District Hospital	X	V
Nyamangara Health Centre	X	V
Nyangao DDH	X	V
Ruangwa District Hospital	X	V
Sokoine Hospital	V	V
Tingi Health Centre	X	V
Town Health Centre	V	X

Key: V = Available X = Not Available,- means the vaccine was not stocked

4.3: Storage conditions of anti- rabies vaccine in the regions Lindi and Tanga.

Out of 24 health facilities visited majority incharge / supervisors of anti rabies vaccines store were health officers.

The storage conditions of anti-rabies vaccines at the healthcare facilities in the two regions.

Assessment of anti-rabies vaccines storage conditions was done in the health facilities using Storage indicator form (*Appendix 111*). Results of assessment of storage condition are summarized in table below:

Table 4.6: Assessment of anti-rabies vaccine storage condition in the regions

S/N	STORAGE INDICATOR	Number of the health facilities in Tanga	Number of the health facilities in Lindi
1.	Availability of cold chain equipment for storage of vaccine (these include refrigerators, freezers; vaccine carriers i.e. Cool boxes, ice packs.	7	8
2.	Storage room having adequate capacity to accommodate anti-rabies stock.	9	9
3.	Presence of fridge and freezer tag monitor in the refrigerator.	7	8
4.	Presence of thermometer in the refrigerator.	7	8
5.	Vaccine storage properly done(i.e. no vial in the door, no vial without label, no drink/food)	8	7
6.	Refrigerator not on the recommended temperature range.	7	5
7.	Maintenance of temperature at correct level for the last 3 months.	7	6
8.	Availability of standby supply power in case of power fluctuation(for example gasoline generator)	4	7
9.	Presence of Expired/Damaged anti-rabies vaccines and segregated from undamaged ones	1	1

Storage condition in health facilities in Tanga region:

All selected health facilities had their storage equipments, tools and rooms assessed using checklist (*Appendix 111*). Table 3.2 in the methodology shows anti-rabies vaccines storage condition score chart. Average percentage scores of all health facilities in Tanga region was 67.6% which was considered as satisfactory. Tanga Refferal Regional Hospital, had the highest score with 89% ,while lowest score was 44% shared with Makorora Health Centre and Mwera Health Centre as depicted in the table below.

Table 4.7: Score status of storage conditions of anti-rabies vaccines in Tanga region.

N=14

Names of health facilities	**% Average scores of storage condition**	**Score status**
Depot Health Centre	78	Very satisfactory
Handeni District Hospital	78	Very satisfactory
Kisosora Health Centre	56	Satisfactory
Korogwe District Hospital	67	Satisfactory
Lushoto District Hospital	78	Very satisfactory
Majengo Health Centre	67	Satisfactory
Makorora Health Centre	44	Dissatisfactory
Maramba Health Centre	56	Satisfactory
Mjesani Health Centre	78	Very satisfactory
Mkuzi Health Centre	56	Satisfactory
Muheza DDH	78	Very satisfactory.
Mwera Health Centre	44	Dissatisfactory
Pangani District Hospital	67	Satisfactory
Tanga Referral Regional Hospital	89	Very satisfactory.
Average Score	**67.6**	**Satisfactory**

Storage condition in health facilities in Lindi region:

In the public health facilities, average score for all facilities visited was 66.8% as shown in the table below. This was considered satisfactory (refer to table 3.2 in the methodology which shows anti-rabies vaccines storage condition score chart). However,certain facilities like Town Health Centre and Nyamangara Health Centres had the lowest score considered as dissatisfactory as depicted by table below.

Table 4.8: Storage condition of health facilities in Lindi region

N=10

Names of health facilities	**% Average scores of storage condition**	**Score status**
Kibutuka Health Centre	56	Satisfactory
Kinyonga Hospital	78	Very Satisfactory
Liwale District Hospital	78	Very Satisfactory
Nachingwea District Hospital	67	Satisfactory
Nyamangara Health Centre	44	Dissatisfactory
Nyangao DDH	78	Very Satisfactory
Ruangwa District Hospital	67	Satisfactory
Sokoine Hospital	89	Very Satisfactory
Tingi Health Centre	56	Satisfactory
Town Health Centre	44	Dissatisfactory
Average Score	**66.8**	**Satisfactory**

Availability of cold chain equipments and tools used for storage of anti-rabies vaccines in the health facilities in the two regions.

Cold chain equipments and tools in the selected health facilities were assessed. It was observed that, equipments and tools were highly available in Lindi as compared to Tanga region. One facility in Lindi region stores the vaccine in the cold box facility stores vaccine in the refrigerator. Equipments include refrigerators, freezers and vaccine carriers i.e. cool boxes, tools include ice packs. Cold boxes are not powered; ice packs are placed inside the box so as to lower temperature.

It was observed that in many facilities there was low availability of ice packs in the health facility as` depicted in figure 4.3 below.

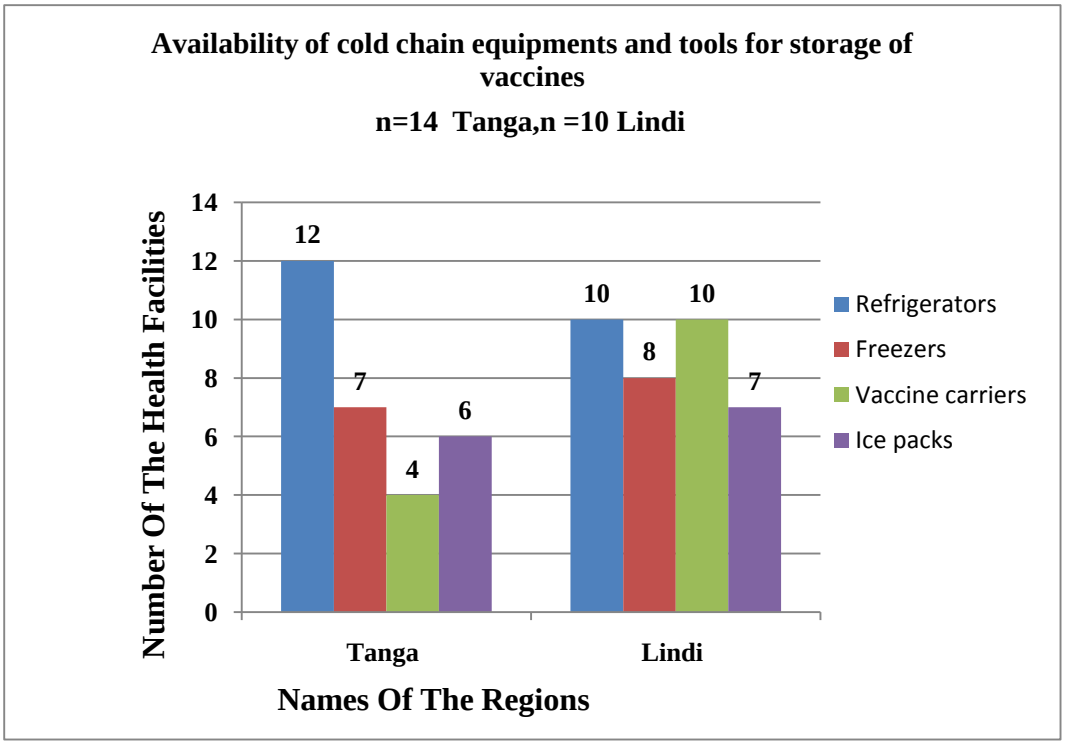

Figure 4.3: Availability of cold chain equipments and tools for storing vaccines.

In the health facilites availability of cold chain equipments and tools for storage anti rabies vaccine was higher in Tanga region as compared to Lindi. The differences were statistically significant . ($\chi 2$ =3.429 ,df =1 and p value >0.05) that is p value was 0.064.

Presence of fridge and freezer tag monitor in the refrigerator.

Study reveals that seven facilities in Lindi had fridge tag in the refrigerator. Nine (9) Health facilities in Tanga had fridge tag in the refrigerator as presented in figure 4.4 below. Fridge tags were observed mainly in the storage facilities in hospital settling (District &Regional) along side with thermometer in ice lined refrigerators.

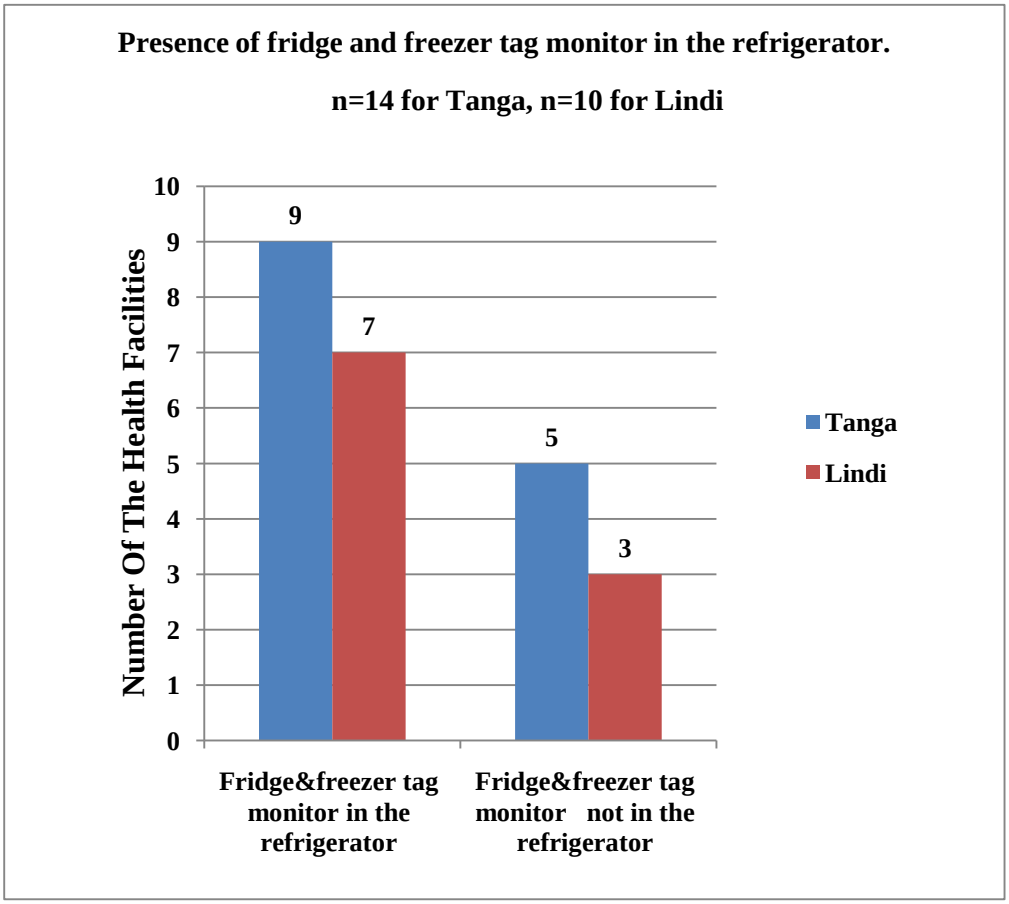

Figure 4.4: Presence of fridge and freezer tag in the storage equipments in the two regions.

In the health facilities availability of fridge and freezer tag were more in Tanga as compared to Lindi facilities. This difference was statistically significant. ($\chi 2$ =5.714, df =1 and p value <0.05) that is p=0.017.

Refrigerator not on the recommended temperature

Results shows that most of selected health facilities in both regions stored the ant-rabies vaccine at recommended temperature (+2ºC to+8ºC) however some of the health facilities stored anti rabies vaccine at temperatures above the recommended level.

Table 4.9: Temperature of anti-rabies storage equipments and tools

Temp in ºC	**Number of Health Facilities in Tanga**	**Number of Health Facilities in Lindi**
2	0	0
3	1	0
4	1	2
5	1	1
6	1	2
7	1	0
8	2	0
9ºC or More	6	5

Availability of standby power supply source in case of power fluctuation/failure in the health facilities in the two regions.

Result showed that alternative standby power supply was available in selected health facilities in Lindi region as compared with facilities in Tanga. Standby power source include gasoline generator in the facilities (especially Regional &District Hospitals) and gas that is used in TCW and RCW refrigerators.

Availability standby power in-case of power fluctuation in facilities in the two regions were higher in Lindi as compared to Tanga. Six facilities in Tanga had no reliable source of standby power. But this difference was not statistically significant. ($\chi 2$ =3.311, df =1 and p value <0.05) that is p=0.069).

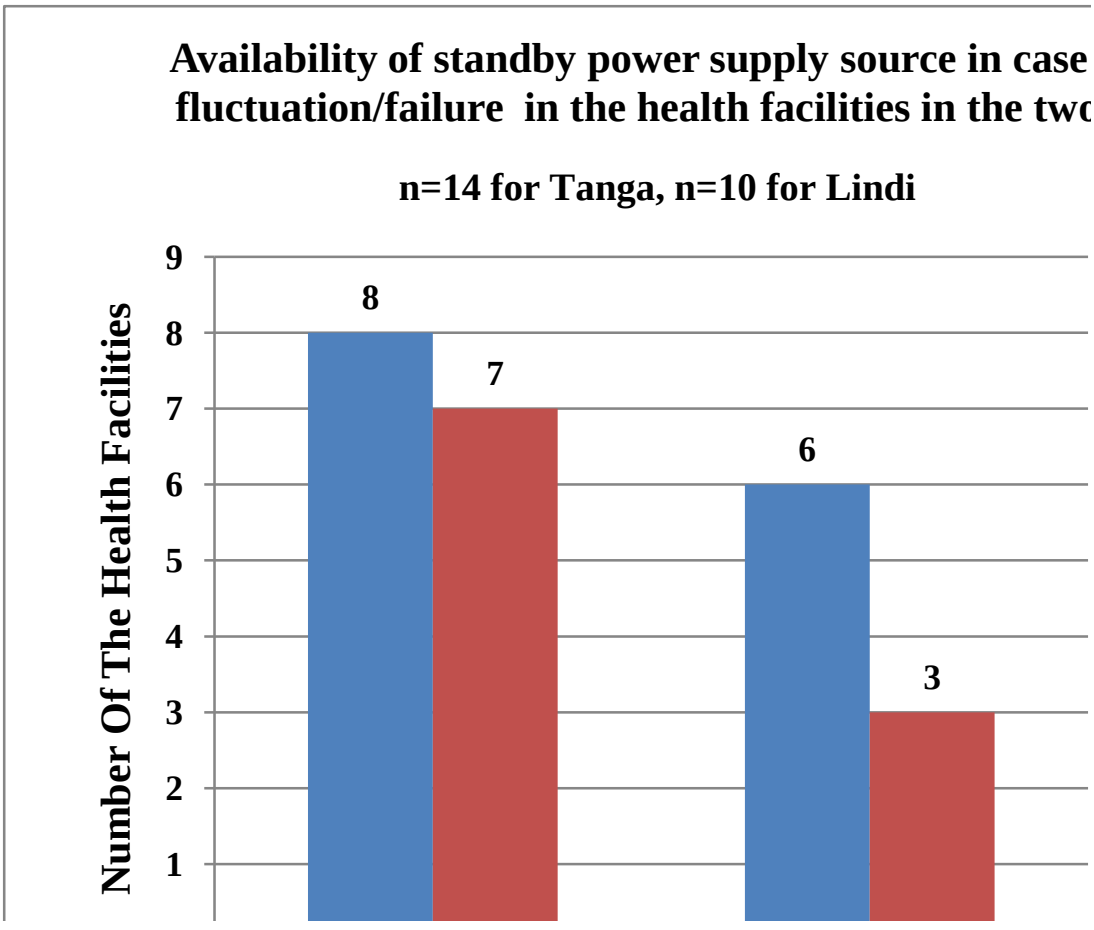

Figure 4.5: Availability of standby power supply in case of power fluctuation / failure.

Anti-rabies vaccine storage of done properly.

Assessment was done on anti-rabies vaccines that were available in the facility on the day of visit to see whether they were stored properly. Three out of seven facilities in Tanga region had vaccine in the refrigerator door. One facility kept anti-rabies vaccine in a box inside the refrigerator which was not necessary as depicted in the table below.

In Lindi region none of anti-rabies vaccine vials were in the refrigerator door, it was found in one facility some labels in the vaccine vials were distorted that is detached and not readable easily.

Figure 4.6: Showing the storage equipments of anti-rabies vaccine in health facilities.

4.4: Source of supply of anti- rabies vaccine in the regions

Tanga procures anti-rabies vaccine from Medical Stores Deapartment and if there is stock out of vaccine in MSD, they procure from prequalified suppliers. Korogwe and Handeni District councils are good example of the council that procure vaccines from council's prequalified suppliers. It was observed that Lindi receive anti rabies vaccines from Regional Vaccine Stores (from the Rabies Demonstration elimination Project) and dividend fom Regional Vaccine Stores. Figure 4.7 below shows the source of anti-rabies vacccine found in the health facilities in the two regions.

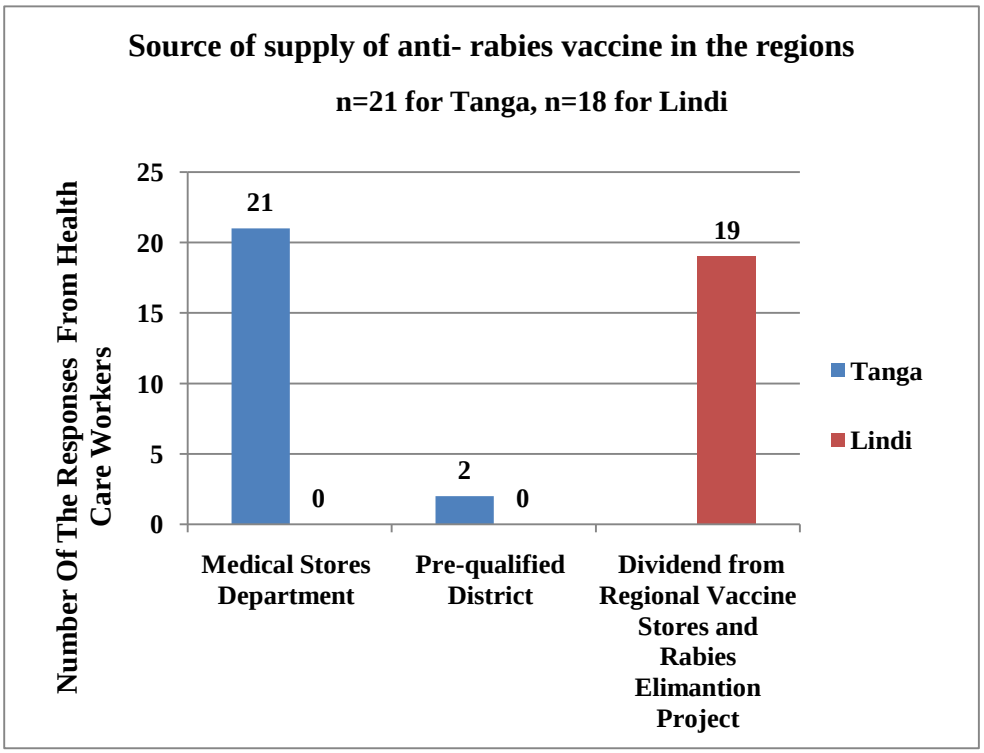

Figure 4.7: Source of supply of anti- rabies vaccine found in the health facilities in the regions.

In the facilities, Medical Stores Department (MSD) was the main source of supply of anti- rabies vaccine.The difference of anti-rabies vaccine supply source in the surveyed regions were statistically significant as $p < 0.05$. $\chi 2 = 39$, df = 1, p-value <0.0001, this in turn explains higher availability of anti-rabies vaccines in Tanga facilities on the day of visit.

4.5: Provider's knowledge regarding use of anti-rabies vaccine in health facilities in the regions.

In relation to the provider's knowledge regarding the use of anti-rabies vaccine several parameters were used, these include indication of administering rabies PEP, standard schedule for rabies pre and post exposure, changing route of administration of rabies PEP before one finishes the dose, and re-exposure vaccination schedule. Generally a person was considered to be knowledgeable if she/he scores more than 50% (refer to table 3.3 of the knowledge score chart in the methodology)

Knowledge regarding the standard vaccination schedule for rabies PEP.

The question aimed to assess knowledge regarding the use of anti-rabies vaccine after a person had been bitten by a rabid animal. It was observed that health care workers in Tanga had poor knowledge regarding the use of PEP.

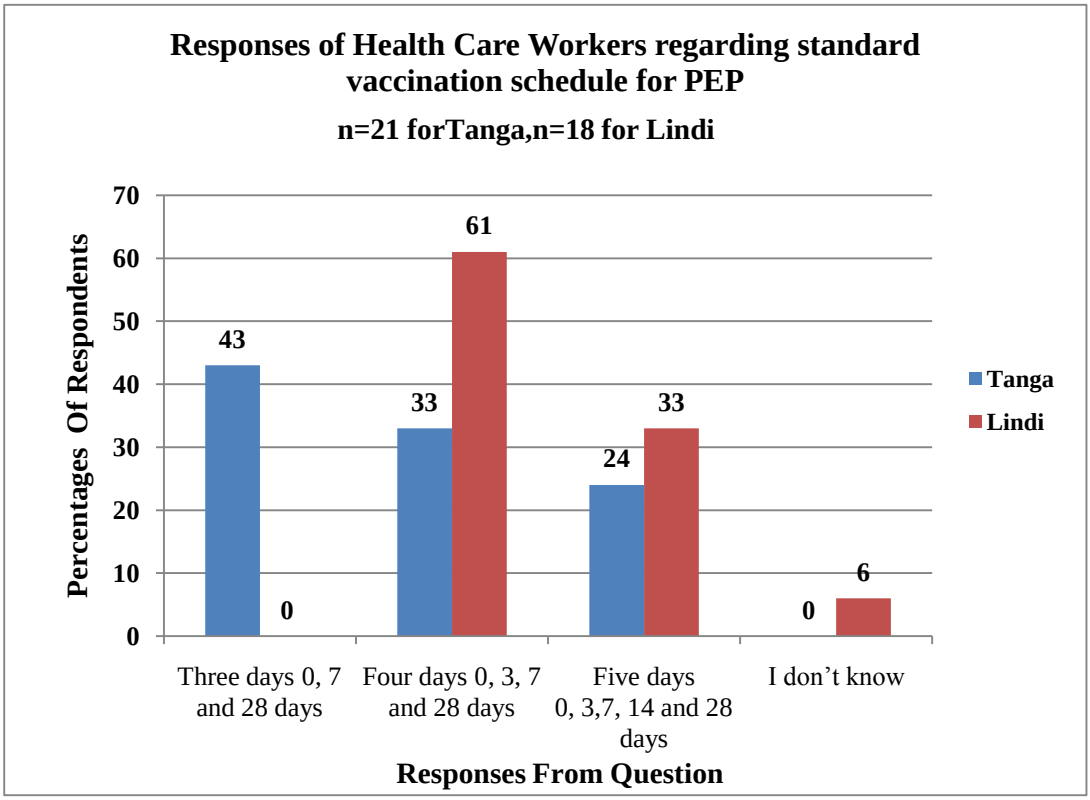

Figure 4.8: Responses of Health Care Workers regarding standard vaccination schedule for PEP

As can be seen in Figure 4.8 above, there is a relationship between the knowledge regarding the standard vaccination schedule for PEP and usage of anti-rabies vaccines. Hence, those with poor knowledge in regarding the standard vaccination schedule for PEP were likely to give wrong vaccination schedule to patient inturn produce delayed immunity. These differences were significantly significant . $\chi 2$ =10.813, df =3, p-value =0.013.

Knowledge of the respondents regarding the indications for post Exposure Rabies Prophylaxis.

It was observed more than 85% of health care workers in Lindi region had good knowledge regarding indication for Rabies PEP than 70% Tanga counterparts.

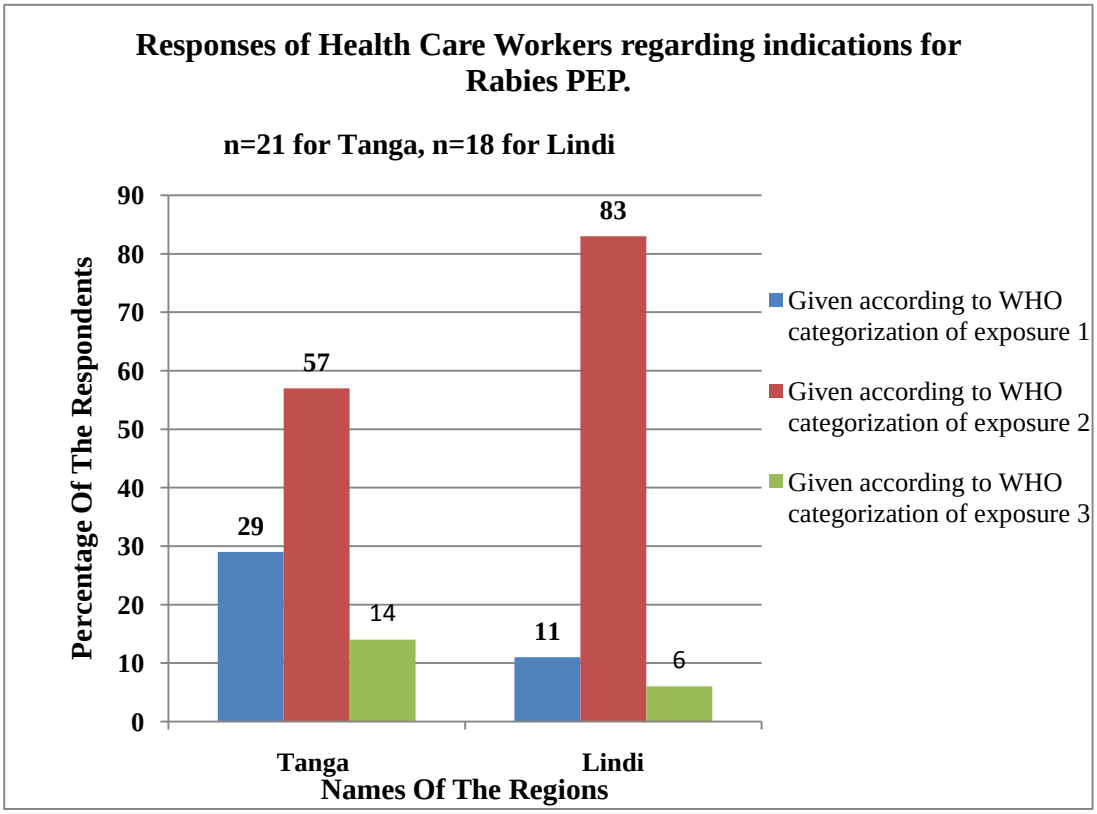

Figure 4.9: Responses of Health Care Workers regarding indications for Rabies PEP.

As it can be seen in the Figure 4.9 above majority of health care workers in the two regions have knowledge regarding indication for administering PEP.

Knowledge of respondents regarding using a different route of adminstration of ant-rabies vaccines route (IM versus ID).

It was observed 57% of the Health Care Workers in Tanga did not know if changing route of adminstration was possible before one finishes the dosage regimen compared to 59% of Lindi counterparts.

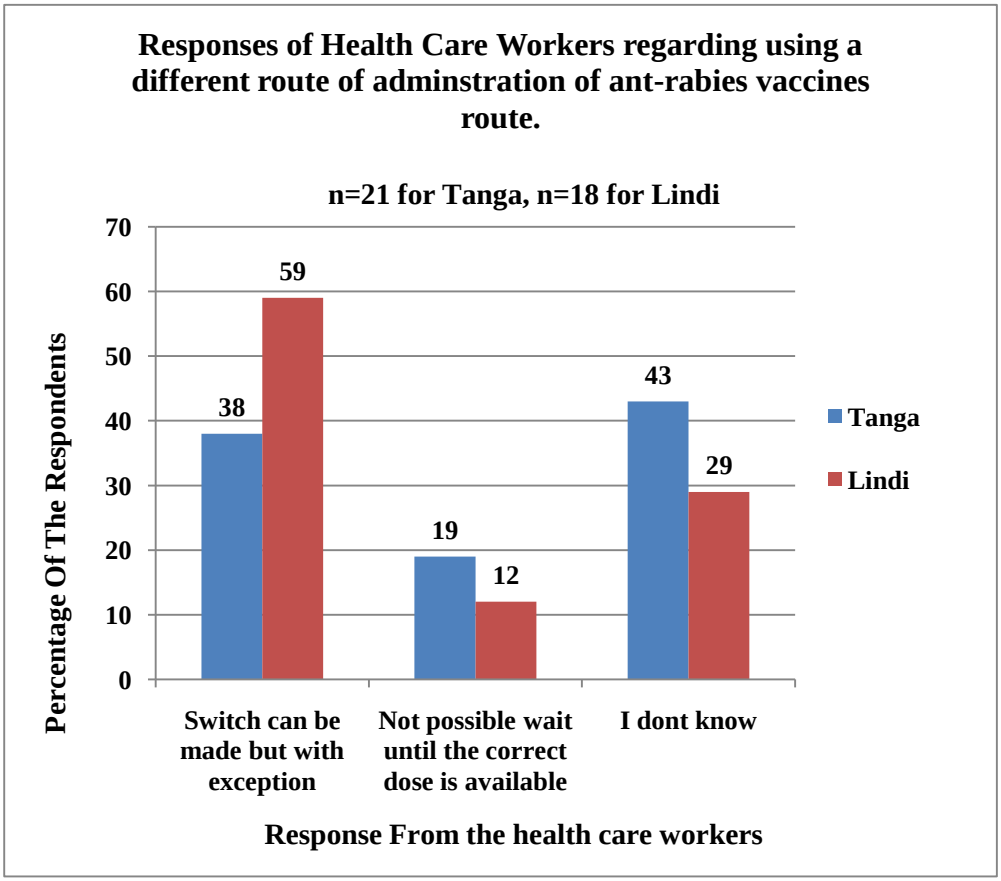

Figure 4.10: Responses of Health Care Workers regarding using a different route of adminstration of ant-rabies vaccines route.

Majority of respondents (59%) in Lindi had`knowledge regarding changing route of adminstration before one finishes the dosage regimen compared to and (38%) in Tanga . Based on Figure 4.10, there was no significant difference (p value>0.05) between knowledge of respondents and use ($\chi 2$ =1.629, df =2, p-value =0.443).

Knowledge of health care workers on re-exposure vaccination of anti rabies vaccine.

For a person previously bitten by a rabid animal rabies PEP is given in two doses (0 and 3rd days). Results showed health care workers in Tanga region (> 38%) did not know the importance of re-exposure vaccination of anti-rabies vaccine to a previously immunized person. Results are illustrated in figure 4.11 below.

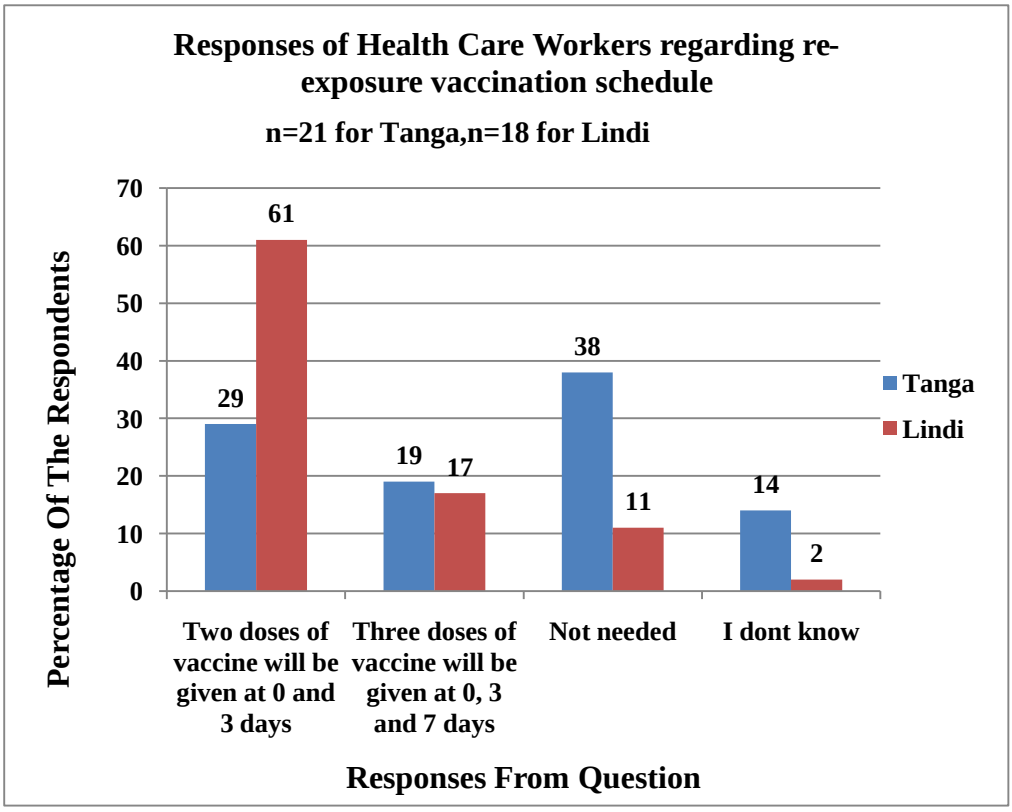

Figure 4.11: Responses of Health Care Workers regarding re-exposure vaccination schedule

Lindi respondents were more knowledgable (61%) in Lindi than Tanga(29%) counteparts ($\chi 2$ =5.124, df =3, p-value =0.157).

Overall, knowledge of the health care workers in Lindi region regarding use of anti-rabies vaccines in the health facilites was better as compared to the respondents in Tanga region as presented on Table 4.10 below. The differences were statistically significant($\chi 2$ =19.168, df =8, p-value =0.014).

Table 4.10: Knowledge score chart among health care workers regarding use of anti-rabies vaccines.

n=21 for Tanga and n=18 in Lindi

Knowledge level	**Percentages of respondents in Tanga**	**Percentages of respondents in Lindi**
Excellent (75 – 100)	9.5%	16.7 %
Good (50 – 74)	38.1%	66.7 %
Poor (25 – 49)	47.6 %	16.6 %
Very poor (0 – 24)	4.8%	0
Mean	25%	33%

4.6: Presence of expired anti rabies vaccine in the health facilities.

One health facility in Tanga (Korogwe District Hospital) and one in Lindi (St Walburg's Nyangao Hospital) had expired anti rabies vaccine while the remaining facilities did not have expired vaccines in their store. Korogwe district hospital has 155 vials of anti rabies vaccine expired since 19/02/2013 but were not discarded. St Walburg's Nyangao Hospital 72 expired anti-rabies vaccine.

Expired vaccines were kept separately from un-expired ones in a box waiting for disposal after the procedure of reporting to the relevant regulatory authority Tanzania Food and Drug Authority (TFDA) and ministry of Health (MOHSW) and Finance (MOF) was done. It was not possible to see physically the expired vaccine as the box were sealed and documented "ready for disposal".

CHAPTER FIVE

5.0 DISCUSSION

This study aimed to assessing the availability, duration of stock out and storage of anti-rabies vaccines in selected health facilities in two regions. Moreover study intended to find out knowledge regarding use of anti-rabies vaccine among health care workers in those regions.

At the health facility level, availability of medicines is often considered a major factor in building trust to patient when seeking intervention for their health problems [55]. Patients have a tendency to equate medicine availability with quality of care leading to satisfaction with the health services.

In this study, assessment of stock out duration was done by determining number of days, anti- rabies vaccines were out of stock at each facility by retrospective review of ledger books. Absence of anti-rabies vaccine in facilities is very risk since rabies is 100 percent fatal, moreover if a person does not receive vaccination in time death is likely to occur. [22, 50]

This study found that mean stock out duration of anti rabies vaccines was 103 days and 200 days in Lindi and Tanga regions (figure 4.1 and 4.2) respectively. That means, there were stock out of anti-rabies vaccines for more than 3 months and 6 months in Lindi and Tanga respectively, this in-turn led patients to incur substantial cost when travelling long distance in search of anti- rabies vaccine.

Taking an example of a person bitten by a rabid animal in Ruangwa District Council goes to Ruangwa district hospital to receive vaccination, if there are stock out of anti-rabies vaccine at that district hospital, bite victim had shuttle more than 50 km to access treatment. Findings from this study are higher than obtained by Lubango when assessing the stock out duration of essential medicines in public health facilities. Stock out were 98 days [74]

Insufficient funds allocated from the central Government and development partners, human resource shortages, inefficiencies in the supply chain and issues of monitoring and oversight are among the factors contributing to persistent stock-out of essential medicines [75]. The high cost involved in purchasing these medicines deter pharmacist procuring these medicines from MSD and pre-qualified supplier.

The stock out situation showed that there is an obligation to ensure anti-rabies vaccines are available in health facilities all the time because they are life saving.

There is high prevalence of animal bites in Tanzania and they are underreported, therefore developing immediate intervention will help to minimize frequent stock out of ant-rabies vaccine in the health facilities.

Availability of ant-rabies vaccines on the day of visit in the two regions was statistically significant (P- 0.04). Seven facilities in Tanga region had stock of anti-rabies vaccine compared to only one facility in Lindi region. This means that, availability of anti-rabies vaccines on the day of visit in Lindi region was less than that of Tanga region as nine health facilities lacked anti- rabies stocks. Visiting a facility and finding stock doesn't mean that it is available all the time hence the need to assess availability over time, that is why we had to review stock records by retrospectively.

Other studies have linked stock-out problems to inaccurate forecasting at the facility, inadequate budget allocations to health facilities and stock-outs at the national warehouse run by Medical Store Department [76-7] Twenty to thirty percent stock out occur at government facilities these force patients to travel long distances for those who can afford but majority would go without treatment due to rampant overt poverty in our communities [78].

Assessment of storage condition of anti-rabies vaccine at health facilities revealed that average score of storage condition of anti-rabies vaccines in Tanga and Lindi region were 67.6% and 66.8% (table 4.7 and 4.8) respectively. These scores from facilities in the regions were considered satisfactory. It was observed some facilities have 365 days out of stock, yet the scores were satisfactory, this can be explained as those facilities were supposed to stock anti-rabies vaccine according to STG&NEMLIT, vaccines were mixed up together (in a fridge there are anti-rabies, DPT, Rotavirus vaccines) thus apart from the fact that there were stock out at that time we were interested to see if present what were the storage environment. This means storage conditions were maintained within the specified standards, this means vaccine potency was maintained and capable to produce the immunological response when given to patients. Findings from this study were higher than results reported by Oliveira when assessing quality of vaccine storage and conservation in primary

health care centers and found that vaccine storage and conservation quality levels were inadequate in 59.3% and critical in 26.9% of these facilities that means adequate quality were 13.8% [79]

Proper temperature monitoring is the key to proper cold chain management. Thermometers were placed in the storage units adjacent to the vaccines. It was observed that six out of 14 health facilities in Tanga (43%) and five out of ten health facilities in Lindi had their optimal temperature for storage of anti-rabies vaccine above the recommended range. This was contributed by many factors one among them is unreliable power source. Having temperature above or below the recommended temperature range results in vaccines loosing the potency, inturn result in undesirable immunologic response. Study done by Burstein (from mid-2012 to late 2013) found that 16.6% of sampled health facilities refrigerator's temperature were outside the recommended range [61]

Overall assessment of availability of cold chain equipments and tools in the two regions showed that majority of facilities (23) had a functioning refrigerator, one facility (4%) in Lindi region had refrigerator that was not working, thus vaccines were transported for storage in nearby facility. Daily vaccination schedules were accomplished by using vaccine carriers which transported the vaccines to and from the temporary storage site. These findings are similar to a study which was done in three African countries (Ghana, Kenya, and Uganda) by Burstein; the resullts were 4% of health facilities surveyed store vaccine in the cold boxes all the time. [61].

Findings from this study are lower than those obtained from a study done by Rogie B which showed 19% of the facilities had functional refrigerators (vaccines were kept in the refrigerator) remaining facilities (81%) stored their vaccines in nearby health facilities which had functional refrigerators and store in the cold boxes [59]

Health Care Workers involved in ordering, storage and use of anti-rabies vaccines are supposed to have adequate anti-rabies vaccine knowledge this will help them in provision of proper vaccination to patient when seeking rabies, assuarance of availability of anti-rabies vaccines throughout the year and avoidance of financial loss due to expiry.

Findings from this study shows that 43% of health care workers in Tanga didnot know the rabies PEP vaccination schedule. Recommended vaccination shedule is

four doses (0, 3,7 and 28th) if given intradermally and five doses (0, 3,7, 14 and 28th) if given via intramuscular route. This indicates poor knowledge with regard to standard vaccination schedule which inturn produce delayed immunity , result in avoidable death.

Studies show that four vaccine doses in combination with rabies immunoglobulins elicit adequate immune response. This inturn support the four doses regimen which continues to be highly effective in preventing human rabies than three doses schedule.[66-7].

Percentage of health care workers who didnot know re-exposure vaccination schedule seem consistent with the number of providers that gave incorrect answers to how rabies vaccinations were given. Results in Figure 4.11 showed that 71% of health care workers in Tanga region did not know the dose and importance of vaccination to a previous immunized person compared to 39% of health care workers in Lindi region.

Findings from this study show that majority (52.4%) of Health Care Workers in surveyed health facilities in Tanga region had good knowledge regarding the use of anti-rabies vaccines as compared to those in Lindi region (83.4%). The observed discrepancy could be explained by the fact that Lindi region had been involved in a two years rabies demonstration elimination project which had guidelines, fliers, posters at the disposal of health care workers who were involved in the program.

The findings from this study by taking average of the scores i.e 64% are in line with those found by Tadesse Guadu (2013) in Ethiopia which found 64.1 % of the respondent had good knowledge regarding the use of ant-rabies vaccines [80].

Results from Tanga region are slightly lower than 78% reported by the Ministry of Health and Social Welfare in 2008 [38]. Health care workers in Tanga did not follow guidelines from Ministry of Health and Social Welfare for example Standard Treatment Guidelines which instructs them on proper use and dosage and regimen of anti-rabies vaccines.

Expired anti-rabies vaccine were found in only two health facilities; Korogwe District Hospitals and St Walburg Nyangao Hospital found in Lindi DC. Other facilities had no expired anti-rabies vaccine due to stock out of the vaccine in most of the time. Disposal process took a very long time and involves bureaucratic

procedures. Guidelines from Tanzania Food and Drug Authority (TFDA) published in April 2009 are advised to be reviewed the disposal guidelines to make them user-friendly to all stakeholders.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

From this study it can be concluded that, availability of anti-rabies vaccines is still a problem in health facilities in the two surveyed regions in Tanzania.

There is a problem of maintanance of cold chain system in storage facilities in both levels (hospitals and health centres)

Based on these findings, poor level of knowledge regarding the use of anti-rabies vaccine among health care workers in surveyed health facilities was observed.

6.1 RECOMMENDATION

From the findings and implication of the study,the following are recommended:

1. Anti-rabies vaccines should be given a priority during selection and procurement in councils since anti-rabies vaccine are life saving vaccines.
2. Vaccines for free policy to be implemented due to the fatality of the rabies disease.
3. Proper maintenance of cold chain in storage facilities should be implemented like having a workable gasoline generator, solar system or gas in case of power failure/fluctuation.
4. Continuing education especially to health care workers involved in ordering, storing and administering vaccines also on job training of health care workers and patients

6.2 STUDY LIMITATION

- Insufficient funds to conduct the research and geographical location of health facilities in the regions: it was difficult to reach some health facilities especially during the rainy season.

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ANNEXES

Annex I: Questionnaire (English form)

AVAILABILITY, DISTRIBUTION, STORAGE AND USE OF ANTI-RABIES VACCINE IN LINDI AND TANGA REGIONS

Code No …….. Date.....

Part 1: General Information and Health Facility Profile

1. Name of the health facility.....
2. District .....
3. Type of the health facility.

a) Regional hospital.

b) District hospital.

c) Health centre.

d) Private hospital.

e) Private health centre.

4. Sex

a) Male

b) Female

5. Age (years)

a) 15-24

b) 25-34

c) 35-44

d) 45 and above

6. In-charge/supervisor of the vaccine store.

a) Pharmacist

b) Pharmaceutical technician

c) Pharmaceutical Assistant

d) Clinical officer

e) Nursing officer/Nurse midwife

f) Nurse Assistant

g) Others (specify)…….

Part 2: Knowledge of storekeeper regarding use of anti-rabies vaccine.

7. Is there a single-dose human rabies vaccine which will provide life- long immunity?

a) No there is no single dose rabies vaccine that is available.

b) Single does are available.

c) I don't know.

8. What are the indications for Post Exposure Rabies Prophylaxis?

a) Given according to who categorization of exposure 1.

b) Given according to who categorization of exposure 2.

c) Given according to who categorization of exposure 3.

9. Can the rabies vaccine and immunoglobulins be given to a lactating mother or pregnant women?

a) Yes they can be used.

b) No they are not recommended.

10. What is the standard vaccination schedule for rabies pre exposure prophylaxis for intradermal/intramuscular route?

a) Three days 0, 7 and 28 days.

b) Four days 0, 7, 21 and 28 days.

c) Five days 0, 3,7,14 and 28 days.

d) I don't know.

11. What is the standard vaccination schedule for rabies post exposure prophylaxis?

e) Three days 0, 3 and 7 days.

f) Four days 0, 3, 7 and 14 days.

g) Five days 0, 3,7,14 and 28 days.

h) I don't know.

12. What are the precautions should be taken while administering RIGs?

a) RIG administered before administering anti-rabies vaccine.

b) RIG administered in same syringe as the vaccine or at the same site as vaccine.

c) Patient should not be given RIG on an empty stomach.

d) Pregnancy is not a contraindication for RIG and anti-rabies vaccination.

13. Are there adverse effects of rabies vaccination?

a) There are no adverse effects.

b) Some occur which are self-limiting and rarely need medication.

14. Are there contraindicated drugs during anti-rabies vaccination?

a) Yes.

b) No.

15. If one rabies vaccine has been used for PEP and it is not available for the last two doses, is it possible to interchange rabies vaccine or vaccination route (IM versus ID)?

a) Switch can be made but with exception.

b) Not possible wait until the correct dose is available.

c) I don't know.

16. Is there any possibility of failures after PEP?

a) There are no failures after vaccination.

b) Yes there may be few results from delayed vaccination or incomplete course of vaccination.

c) I don't know.

17. If a previously immunized person is bitten by a rabid dog again what re-exposure vaccination schedule?

a) Two doses of vaccine will be given at 0 and 3 day.

b) Three doses of vaccine will be given at 0, 3 and 7 day.

c) Not needed because the person has immunity from previous vaccination.

d) I don't know.

18. What are the sources of ant-rabies vaccine found in our health facility?

a) MSD

b) Dividend from RVS

c) Don't know.

Thank you for participation

Annex II: Stock out Duration Indicator Form

MUHIMBILI UNIVERSITY SCHOOL OF HEALTH AND ALLIED SCIENCE

DEPARTMENT OF PHARMACEUTICS

Msc PHARMACEUTICAL MANAGEMENT

SURVEY AREA: HEALTH FACILITIES IN LINDI AND TANGA REGIONS

Name of Hospital	
Address	
Date visit	
Name of Data Collector	
Name of person who provide the data	
Months	**Number of the days out of the stock**
January 2013	
February 2013	
March 2013	
April 2013	
May 2013	
June 2013	
July 2013	
August 2013	
September 2013	
October 2013	
November 2013	
December 2013	
Ant- rabies vaccine available at the time of visit.	

Annex III: Storage Indicator Form

DISTRICT…….....

NAME OF THE FACILITY …….....

NAME OF THE INVESTIGATOR ……

DATE …….....

S/N	STORAGE INDICATOR	Answers YES=1, NO=2
1.	Availability of cold chain equipment for storage of vaccine (these include refrigerators, freezers; vaccine carriers i.e. Cool boxes, ice packs.	
2.	Storage room having adequate capacity to accommodate anti-rabies stock.	
3.	Presence of fridge and freezer tag monitor in the refrigerator.	
4.	Presence of thermometer in the refrigerator.	
5.	Vaccine storage properly done(i.e. no vial in the door, no vial without label, no drink/food)	
6.	Refrigerator not on the recommended temperature range.	
7.	Maintenance of temperature at correct level for the last 3 months.	
8.	Availability of standby supply power in case of power fluctuation(for example generator)	
9.	Availability of stock that is sufficient until the next supply arrives (i.e. stock sufficient for 1 month or 2 weeks)	
10.	Availability of stock record books/sheet that shows lot/batch numbers and expiry dates.	
11.	Presence of expired anti-rabies vaccine in the health facility.	
12.	Expired /Damaged anti-rabies vaccine segregated from undamaged ones.	

Source: WHO Operation package for Monitoring and Assessing country pharmaceuticals.

Annex IV: Consent Form (English version)

STUDY PARTICIPANTS INFORMED CONSENT FORM ON AVAILABILITY, DISTRIBUTION, STORAGE AND USE OF ANTI RABIES VACCINE IN PUBLIC HEALTH FACILITIES IN LINDI AND TANGA REGIONS.

Identification number: _____

Introduction

Greetings! This consent form contains information about the research named above. In order to be sure that you are informed about being in this research, we are asking you to read or have read to you this consent form. You will also be asked to sign it or make a mark in front of the witness. You will be given a copy of this form. This consent form might contain some words that are unfamiliar to you. Please do not hesitate to ask so that explanation can be given to whatever you might not understand.

Reason for the research:

You are being asked to take part in this study which intends to assess availability, distribution, storage and ant-rabies vaccine challenges and health personnel's knowledge on supply of vaccine.

General information and your part in research:

The research will involve answering questions depending on your position at your institution / working place. The interview will be carried at your working place thus you will incur no cost.

Possible Risks: No harm is expected because of joining the research study.

Possible Benefits: Your participation will have input on the foreseen findings of the study that might improve the current situation of availability, storage use of anti-rabies vaccine.

Rights to participate or discontinue

You are free to decide if you want to be in this research after brief explanation on the aim and procedure of the research. You will be allowed to disagreed in taking part on the study or discontinue from the study any time as you wish. The discontinuation or refusal to participate will not affect your right at any point in time.

Confidentiality: All the information obtained from you regarding this study will be treated with high degree of confidentiality.

Staying in the Research

When agree to participate in this research only the tools designed for this study will be used.

In case of problem/query contact:

If case of any problem/question/query as a study participant, please contact Ms. Rose Maingu phone no; 0768 397089), or Prof. G. Kagashe who are the coordinators of this study, MUHAS P.O BOX 65001, Dar es Salaam.

Your rights as a Participant

This research has been reviewed and approved by the IRB of Muhimbili University of Health and Allied Sciences. An IRB is a committee that reviews research studies in order to help protect participants. If you have any questions about your rights as a research participant you may contact Prof. Mainen Moshi, Chairman of the College Research and Publication.

Volunteer agreement

The above document describing the benefits, risks and procedures for the research titled AVAILABILITY, DISTRIBUTION, and STORAGE AND USE OF ANTI-RABIES VACCINE IN LINDI AND TANGA REGIONS has been read and explained to me.

I .....have been given an opportunity to have any questions about the research answered to my satisfaction. I agree to participate as a volunteer.

Date: ..... Signature of volunteer.....

TABLES

Table 1: Summary of management of rabies exposed individuals

Category of the exposure	**Type of the exposure domestic or wild rabid animal**	**Recommended post exposure prophylaxis**
I	Touching or feeding animals, licks on the skin	No treatment
II	Nibbling of uncovered skin, minor scratches or abrasions without bleeding, licks on broken skin	Wash wound with running water and soap for 15 minutes. Administer ant rabies vaccines: - 0.2ml (ID) in divided doses of 0.1 ml on deltoid on one hand and another 0.1ml on the deltoid of the second hand on days 0, 3, 14 and 28 **OR** - 1 ml (IM) on deltoid muscle for days 0, 3,7,14, and 28 **Note:** Children are given the same doses but vaccine should be administered on the lateral part of the thigh.
III	Single or multiple transdermal bites or scratches with bleeding, contamination of mucous membrane with saliva from licks; Exposure to bat bites or scratches	Wash wound with running water and soap for 15 minutes. **Administer Rabies Immunoglobulin (RIG) on day 0** 40 IU/kg body weight for Equine (ERIG) 20 IU/kg body weight for Human (HRIG) **Administer ant rabies vaccines** - 0.2ml (ID) in divided doses of 0.1 ml on deltoid on one hand and another 0.1ml on the deltoid of the second hand on days 0, 3, 14 and 28 **OR** - 1 ml (IM) on deltoid muscle for days 0, 3,7,14, and 28 **Note 1:** Children are given the same doses but vaccine should be administered on the lateral part of the thigh. **Note 2:** The World Health Organization recommends ID route of vaccination administration because it is cost effective.

Source: Standard Treatment Guidelines for Mainland Tanzania (2013)

Table 2: Visited Health Facilities Lindi Region.

DISTRICT	HEALTH FACILITY
LINDI T.C	1. SOKOINE HOSPITAL
	2. TOWN HEALTH CENTRE
KILWA D.C	1. KINYONGA HOSPITAL
	2. TINGI HEALTH CENTRE
NACHINGWEA D.C	1. NACHINGWEA HOSPITAL
LIWALE D.C	1. LIWALE DISTRICT HOSPITAL
	2. KIBUTUKA HEALTH CENTRE
LINDI D.C	1. ST WALBURG'S NYANGAO HOSP
	2. NYAMANGARA HEALTH CENTRE
RUANGWA D.C	1. RUANGWA DISTRICT HOSPITAL

Source: MoHSW Online Health Facility Registry

Table 3: Visited Health Facilities in Tanga Region

DISTRICT	**FACILITY**
HANDENI D.C	1. HANDENI DISTRICT HOSPITAL
LUSHOTO D.C	1. LUSHOTO DISTRICT HOSPITAL
PANGANI	1. PANGANI DISTRICT HOSPITAL
	2. MWERA HEALTH CENTRE
TANGA C.C	1. TANGA REGION REFERAL HOSPITAL
	2. MAKORORA HEALTH CENTRE
	3. KISOSORA HEALTH CENTRE
	4. DEPOT HEALTH CENTRE
KOROGWE M.C	1. MAJENGO HEALTH CENTRE
KOROGWE D.C	1. KOROGWE DISTRICT HOSPITAL
MUHEZA D.C	1. St BENEDICT-MUHEZA DDH
	2. MKUZI HEALTH CENTRE
MKINGA DC	1. MJESANI HEALTH CENTRE
	2. MARAMBA HEALH CENTRE

Source: MoHSW Online Health Facility Registry