EVALUATION OF THE STORAGE AND COLD CHAIN MANAGEMENT OF VACCINES IN THE PRIMARY HEALTH FACILITIES IN ARUSHA CITY, NORTHERN TANZANIA

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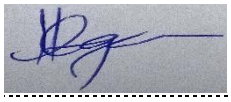
Signature  **Date** 22nd August, 2022

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LIST OF ABBREVIATIONS AND ACRONYMS

BCG	Bacille Calmette Guerin
DTP	Diphtheria-Tetanus-Pertusis
DTP-HepB-Hib	Diphtheria-Tetanus-Pertusis-Hepatitis B-Haemophillus influenza type b
EPI	Expanded Programme on Immunization
FEFO	First Expiry First Out
FIFO	First In First Out
GAVI	Global Alliance for Vaccine and Immunization
HepB	Hepatitis B
ILR	Ice Lined Refrigerator
IVD	Immunization and Vaccine Development Programme
MMR	Measles-Mumps-Rubella
MoHCDGEC	Ministry of Health, Community Development, Gender, Elderly and Children
MR	Measles-Rubella
OPV	Oral Polio Vaccine
RCH	Reproductive and Child Health
TT	Tetenus Toxoid
VPD	Vaccine Preventable Diseases
VVM	Vaccine Vial Monitors
WHO	World Health Organization

GLOSSARY OF TERMS

A vaccine: Is a biological preparation used to stimulate the production of antibodies and provide immunity against one or several diseases. A vaccine is prepared from live, weakened or killed form of disease causing agent.

Adsorbed vaccine: Any vaccine whose antigen has been adsorbed on aluminum phosphate adjunct to increase its half life and immunogenicity.

Cold chain: It is the system used for storage and transportation of vaccines (and vaccine products) in the recommended conditions and acceptable temperature ranges from point of manufacture until it is administered to the beneficiary.

Cold chain handling staff: Any staff (regular/contractual), as assigned by the facility in charge, with the responsibility of vaccine and cold chain management at any level of vaccine stores.

Cold Chain Equipment: It is a set of equipment, which helps in providing recommended temperature for the vaccines to preserve their quality during storage and transportation from the site of manufacture till their administration to the target beneficiary.

Cold box: Is an insulated container that can be lined with 'conditioned' ice-packs to keep vaccines and diluents cold but not frozen during transportation of vaccine supplies from collection site to outreach sites and for temporary storage during Health Post immunization sessions.

Ice-packs: Are flat, rectangular plastic bottles filled with water and then either kept at refrigerator temperature, or frozen and then conditioned for use in vaccine carriers and cold boxes. They are usually frozen to a temperature between -5°C and -20°C before use. Ice-packs are used for transportation of heat sensitive vaccines such as oral polio vaccine.

Cool water-pack: A water-pack pre-cooled to a temperature between + 2°C to +8°C before use.

Diluent: Special liquid substance to be mixed with a lyophilized (powder) vaccine in order to reconstitute it and provide the final vaccine for administration

Freeze indicators: Are devices used for monitoring the exposure of vaccines to freezing. Freeze indicators are packed with batches of freeze-sensitive vaccines (pentavalent and TT), as well as with other freeze-sensitive vaccines such as HepB, which may be used to protect healthcare workers

Health workers: are people whose job it is to protect and improve the health of their communities. Together these health workers, in all their diversity, make up the global health workforce.

Healthcare workers: Healthcare workers include physicians, pharmacists, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, hospital volunteers, and administrative staff.

Primary health-care Facility: A facility that provides services which are usually the first point of contact with a health professional. They include services provided by general practitioners, dentists, community nurses, pharmacists and midwives, among others.

Shake Test: A test done to check if a freeze sensitive vaccine has been damaged on exposure to freezing temperature

Supportive supervisions: are defined by WHO as visits that are carried out in a respectfully non-authoritarian way with a focus on improving knowledge and skills of the health staff.

Thermometer: Is an instrument for measuring temperature of a substance or body. In cold chain, it is used for measuring temperature in refrigerator, cold box or vaccine carrier. At a Health Post, it either a dial or a stem (bulb) thermometer.

Vaccine vial monitor: Is a label that changes colour when the vaccine vial or ampoule has been exposed to temperatures above 8ºC over a period of time. It looks like a square inside a circle. As the vaccine vial is exposed to more heat, the square becomes darker.

Supportive Supervission: Is a process whereby superiors work together with subordinates to improve their performance. It is carried out in a respectful and non-authoritarian way with focus on using supervisory visits as an opportunity to improve knowledge and skills of subordinates.

ABSTRACT

Background: Immunization a process by which a person becomes protected against a disease through administration of vaccine into the body to induce immunity against the disease. Vaccines are stored and distributed in a temperature controlled system called Cold Chain System. This system comprises of personnel; specialized cooling equipment for safe storage and transportation of vaccines; and the procedures to manage the system and control distribution and use of the vaccines. If this system is compromised, vaccines become exposed to unacceptably high or low extremes of temperature outside the manufacturer's recommended range.

Study Objective and Rationale: The main objective of this study was to evaluate the quality of the storage and cold chain management of vaccines in the primary health facilities in Arusha City, Northern Tanzania in 2020. In addition, the knowledge, attitude and practices of personnel working in the vaccine cold chain were evaluated.

Understanding the existing cold chain problems will support to improve vaccine cold chain management of the handlers; quality of immunization and strategic planning of The National Immunization and Vaccine Development Program and Vaccines regulations by the National Drug Regulatory Authority (The Tanzazia Medicines and Medical Devices Authority).

Study Methodology: A cross-sectional study design was applied. The study was conducted in 50 primary health facilities (4 hospitals, 18 health centres, 28 dispensaries). Census (universal) sampling was done. Checklist and structured questionnaires were used to collect data. Data analysis involved both descriptive, inferential and regression methods. The level of significance was set at 0.05.

Results: Dedicated rooms for cold chain were available in 45 (90%) facilities. All facilities had refrigerators, vaccine carriers and ice packs. There were 8 (16%) refrigerators with damaged inner compartments. A total of 43 (86%) refrigerators were not installed with voltage stabilizers. Fridge tags and freeze tags were available and working in 40 (80%) and 38 (76%) facilities respectively, freeze tag were in alarm states in 8 facilities. A total 28 facilities had improperly arranged vaccines. Refrigerators temperature readings were outside the recommended range (2 - 8 °C) in 12 (24%) of the facilities. Twelve (24%) of surveyed health facilities kept products not related to vaccines inside the refrigerators. Preventive maintenance of equipment had not been done in 49 (98%) facilities. A total of 23 (46%) of facilities had some vaccines at vaccine vial

monitors (VVM) stage 2 and 1(2%) facility had one vaccine at deteriorated VVM stage 3. There was no formal appointment of designated cold chain handlers.

Poor knowledge was observed with regard to use of VVM and shake test technologies and on which vaccines are heat and freeze sensitive. Training out of the working station and the increase in the duration of years worked increased the knowledge of respondents.

All (100%) respondents scored above 80% (94.5% average) on attitude toward the quality of vaccines; nearly 80% respondents scored above 80% (88.2% average) on attitude towards self efficacy and motivation to work in the cold chain. Only ten (10%) respondents scored ≥ 80% (52.8% average) on attitude towards satisfaction with availability of resources and need for training.

Training at the working station, higher level of education qualification, working experience (years) and working at health centre (compared to hospitals and health centres) had positive impact on the attitude toward self efficacy and motivation to work as cold chain handler.

The availability and use of inventory records (ledger, requestion/issue voucher and vaccine register) and temperature charts was good. Unfortunately, operational records were rarely available in the facilities. These included, contingency plans (28%), standard operating procedures (14%), cleanliness and defrosting records (6%), dos and don'ts stickers (6%) and maintenance and calibration records (1%). Surprisingly, no facility had equipment breakdown and power outage records.

Conclusion: This study identified several gaps in the storage and cold chain management of vaccines in the primary health facilities studied. This poses risk to preventive care provided to the public. The state of equipment used for storing of vaccines is unsatisfactory. Preventive maintenance of equipment and supply of voltage stabilizers should be done as soon as possible. Training and supportive supervisions needs to strengthened. The city vaccination department should ensure adequate supply and use of all the essential documents and records.

CHAPTER ONE: INTRODUCTION

1.1 Background

The Tanzania National Health System operates in a decentralized system of governance. It is organized in three levels of referral pyramid. These levels are primary, secondary and tertiary levels. The top of the pyramid is the tertiary level and primary level is at the bottom. Primary health facilities (hospitals, health centers and dispensaries) are integral part of the primary level (1). The country's health system aims amongst other things, at improving health services by reducing infant and child mortality. Immunization is one of the preventive health services strategy of infant and child mortality (2).

Immunization is the process by which a person becomes protected against a disease through introduction of a vaccine into the body to induce immunity against the disease (3). Vaccines trigger the body immune response to recognize and fight disease-causing organisms. In promoting the role of immunization, the World Health Organization (WHO) launched a program called Expanded Program on Immunization (EPI) in 1974. The goal of the program by then was to ensure that every child would be protected against six childhood diseases; tuberculosis, poliomyelitis, diphtheria, pertussis, tetanus and measles (4). In 1979 immunization achieved a great milestone in public health after worldwide eradication of smallpox. This eradication has signified the effectiveness of vaccines in improving world health (5,6). In 2000 an estimate of over 2 million deaths were prevented as a result of immunization against measles, pertussis, and tetanus alone (7).

Tanzania adopted EPI program in 1975 just a year after it was launched by WHO. In 1996, the program was made a preventive service sub-division under the Reproductive and Child Health (RCH) immediately after the Health Sector Reform (8). To date, immunization services in Tanzania are provided at national, regional and districts health facilities.

Immunization services comprise of routine vaccination and supplementary immunization activities. Routine program involves administration of Bacille Calmette Guerin (BCG), Oral Poliovirus (OPV), Diphtheria, Tetanus toxoid (TT), Pertussis, Hepatitis B, *Haemophillus influenzae* type b, Pneumococcal, Rotavirus, Rubella and Measles vaccines. Vitamin A

supplementation is also included in the routine program along with these vaccines. Supplementary immunization involves administration of additional doses of oral poliovirus vaccine to all children aged below five years during national immunization times (9).

Effective immunization is largely determined by availability of good quality vaccines. Vaccines are stored and distributed in a temperature-controlled chain called Cold chain. Failure in this cold chain exposes vaccines to undesirable temperature outside the recommended range. This unacceptable temperature damages vaccines resulting into wastage (7). Compromised cold chain is also one of the reasons for emerging of vaccine preventable diseases after use of defective vaccines (10,11). Therefore, good cold chain control is a critical element for any immunization program to be successful (12,13).

The three pillars of a cold chain system are equipment for storage and transporting vaccines, personnel and procedures. Each level of the health care system has a different set of cold chain equipment. The Tanzanian Immunization and Vaccine Development Program which is under the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC), recommends the use of refrigerators and cold boxes at health centers and use of refrigerators and/or cold boxes/vaccine carrier at health posts/dispensaries (9).

Primary Health facilities in Tanzania face both human and financial constraints. Budget is limited and Personnel (healthcare workers) are few and overwhelmed. This has resulted in reduced attention to vaccine cold chain management (14).

1.2 Problem Statement

Immunization is a key element of primary healthcare (13). It requires administration of potent vaccines. Vaccines are sensitive to both heat and cold. They are easily damaged by improper handling. Because of this sensitivity, vaccines are stored and transported in a temperature controlled system called the cold chain. Maintaining this system from point of manufacturing to the last point of use is an expensive and challenging task especially in developing countries (15).

Primary health facilities are the main points of immunization services delivery. In these facilities, there is high chance of errors during storage and distribution (cold chain management) of

vaccines because they are normally less monitored (16). These errors can compromise the quality, safety and efficacy of vaccines and place patients' safety at risk because of impaired protection against vaccine preventable diseases (VPDs). Compromised vaccines are not used again and are usually discarded leading to wastage of resources including money that could be invested in other activities (17,18). They can also lead to revaccination of individuals and loss of faith in both the vaccines and healthcare system (18,19).

In most immunization programs, considerable attention has been focused towards increasing the number of vaccinated individuals and coverage area. Less focus is directed to proper management of the cold chain system whose role is to maintain the quality of vaccines (20,21). Because of its sensitivity and vulnerability, this system requires stead power supply and regular maintenance amongst others. In developing African countries which are mostly under resourced, unreliable power supply is common and facilities for maintenance of a cold chain are not adequate (20). Thus, maintaining cold chain and hence quality of vaccines still remains as a major challenge (11,21).

In spite of all the concerted efforts by the Government of Tanzania, it often lacks sufficient resources to cover recurrent operational costs required to implement the immunization program. Due to this, lack of proper running vaccines cold chain equipment is common. This can lead to poor vaccine storage and cold chain management and can pose risk to quality of vaccine and increase the likelihood of loss of vaccine potency (14).

A number of studies have been done in Tanzania to evaluate the storage and cold chain management of vaccines. The most recent was conducted in 2017 but this study only looked at temperature monitoring in Dar es salaam (22). A second study looked at cost minimization in the storage of vaccines (23). All other studies were conducted before 1997 and the landscape has since changed.

No study that has been done in Arusha to evaluate the storage and cold chain management of vaccines and to the best of our knowledge, no recent study has been done in Tanzania that asssesed the knowledge, attitude and practices of the cold chain handlers. This study was the first of its kind to be conducted in Arusha.

Our study was comprehensive and thought to identify existing gaps in vaccines cold chain system that can be used to improve cold chain management. Specific areas that were studied included state of equipment, exposure of vaccines to inappropriate temperatures and their availabity, expiry and registration status. In addition, we evaluated the knowledge and attitude of cold chain handling staff, existing storage practices and availabity of required documentation.

1.3 Research Questions

1. What is the availability and status of equipment for storage and transportation of vaccines in the primary health facilities in Arusha City?
2. What is the availability and status of vaccines in primary health facilities in Arusha City?
3. What is the status of availability of vaccine cold chain essential documents and completeness of the records in Arusha City?
4. What is the level of knowledge, attitude and practices of staff involved in cold chain handling in the primary health facilities in Arusha City?

1.4 Objectives

1.4.1 Main objective

The main objective of this study was to assess the storage and cold chain management of vaccines in the primary health facilities in Arusha City, Northern Tanzania

1.4.2 Specific objectives

The specific objectives of the study were to:

1. Evaluate the availability and status of cold chain equipment in primary health facilities in Arusha City, Tanzania.
2. Assess the availability and status of vaccines in primary health facilities in Arusha City, Tanzania.
3. Determine the knowledge, attitude and practices of staff involved in cold chain handling in the primary health facilities in Arusha City

4. Determine the availability of essential documents and assess the completeness of the records used in vaccine cold chain management in primary health facilities Arusha City.

1.5 Study Justification and Significance

Despite increase in vaccination coverage in Tanzania, problems still remain in the storage and handling of vaccines. These problems are more in primary health facilities which are habitually less monitored. This study focused on among other things, availability and maintenance of vaccine storage equipment, status of vaccines, documentation, knowledge, attitude and practices of cold chain handling staff at the primary health facilities in Arusha City.

Understanding the existing cold chain management gaps will support to improve vaccine cold chain management practices of the handlers and the quality of immunization.

Moreover, the findings can be used for improvement in strategic planning and quality of immunization service delivery of the National Immunization and Vaccine Development Program with regard to vaccine management. For instance, knowledge of the availability and state of vaccine cold chain equipment can facilitate planning for repairs, maintenance, replacement and expansion of cold chain infrastructure (24).

In addition, the gaps identified help to improve vaccines regulations by the National Drug Regulatory Authority (The Tanzazia Medicines and Medical Devices Authority). The Authority for instance can institute regulatory measures like thorough (special) cold chain inspection at all storage points in the country and measures for enhanced post marketing surveillance program of vaccines.

CHAPTER TWO: LITERATURE REVIEW

2.1 Vaccine, features and characteristics

Vaccines are biological products that offer protection against infectious agents by inducing immunity. They are produced from weakened, inactivated or killed forms of microorganisms and some from part of microbes such as protein subunits and nucleic acids (25,26).

Lack of antigen stability is an innate characteristic of vaccines due to the complexity of their biological polymers (15,27). Due to this, vaccines are fragile and sensitive products with fixed shelf life. They slowly and irreversibly lose their quality, safety, potency and efficacy with time (15,21,28–30). This loss can occur during storage, transportation and even before vaccine is administered (31). It is accelerated if they are exposed to temperatures outside the recommended range (32,33). Most vaccines require 2° C - +8° C with the exception of live oral polio vaccine (10). If not stored at recommended temperature, vaccines can be toxic (34,35). Deaths due to improper storage of vaccines have been reported in South Sudan, Nigeria and Maharashtra, India (16,36,37). Less potent vaccines can lead to ineffective protection against vaccine preventable diseases (28). Therefore, vigilance is needed in vaccine handling both during storage and transportation (38). This forms an indispensable part of any immunization program (16).

2.2 Importance of vaccines

For disease prevention and eradication, immunization is now a worldwide biosecurity strategy (39). It provides equal protection to rich and poor, privileged and marginalized (5). It is an outstanding triumphs in public health (10). It is among the most effective, reliable and affordable disease intervention strategies. It reduces health care costs for patients, society and the government and has measurable impact on morbidity and mortality (27,28). Immunization is the utmost and valuable gift that a healthcare provider can give to an individual (21,32). It is used for disease prevention in both children and adults (27,40,41). Immunization is assumed to avert about 2–3 million deaths globally in each year (42,43). Immunization offers protection to vaccine preventable diseases by use of good quality vaccines (16,44,45).

2.3 Heat and freeze sensitivity of vaccines and diluents

Vaccines are either heat or freeze sensitive. Figure 2.1 shows varying degree of heat and cold sensitivity of vaccines. Figure 2.2 shows recommended storage temperatures and storage durations of different vaccines.

Live Oral Poliovirus (OPV) vaccines are highly delicate to heat. The heat sensitivity of Bacilllus Calmette Guerin Vaccine (BCG) and Measles Rubella (MR) increases after they have been reconstituted with diluent (25,46). Most heat sensitive vaccines like OPV and MR are attenuated live microorganisms. These vaccines do not need adjuvants to enhance the immune responses (45). They are freeze dried (lyophilized) during manufacturing to maintain viability (46) and need to be stored in a frozen state at temperature of –15°C/+5°F to -50°C/-58°F (16,35). These vaccines should be used within 4 hours after reconstitution to avoid loss of stability and decrease risk of bacterial contamination (47).

Freeze sensitive vaccines are inactivated microorganisms and antigens derived from purified protein and carbohydrate. They often need adjuvants to enhance immune responses and are generally stable to heat (45). Most contain aluminum based adjuvants which increases immune response (46). The adjuvants tend form conglomerates and precipitate when frozen resulting to loss of potency (48–50). They are damaged at a temperature 0° C and will completely lose their potency if frozen (47,51). They should not be frozen (16). The most freeze sensitive vaccines are Hepatitis B and *Haemophilus influenzae* type b (Figure 2.1). Bacillus Calmette Guerin (BCG); Oral Polio vaccine (OPV) and Measles and Rubella are not affected by freezing (25,52).

Figure 2.1 shows varying degree of heat and cold sensitivity of vaccines. The upward arrow indicates increasing sensitivity to heat of adjacent list of vaccines from bottom to top. The uppermost vaccines can be easily damaged upon exposure to heat above the recommended range. For example; reconsititued BCG is the most heat sensitive of all. The downward arrow shows decreasing sensitivity to cold from top to bottom of adjacent list of vaccines. This means that, TT vaccine is the most freeze sensitive and BCG and OPV vaccines are the least freeze sensitive.

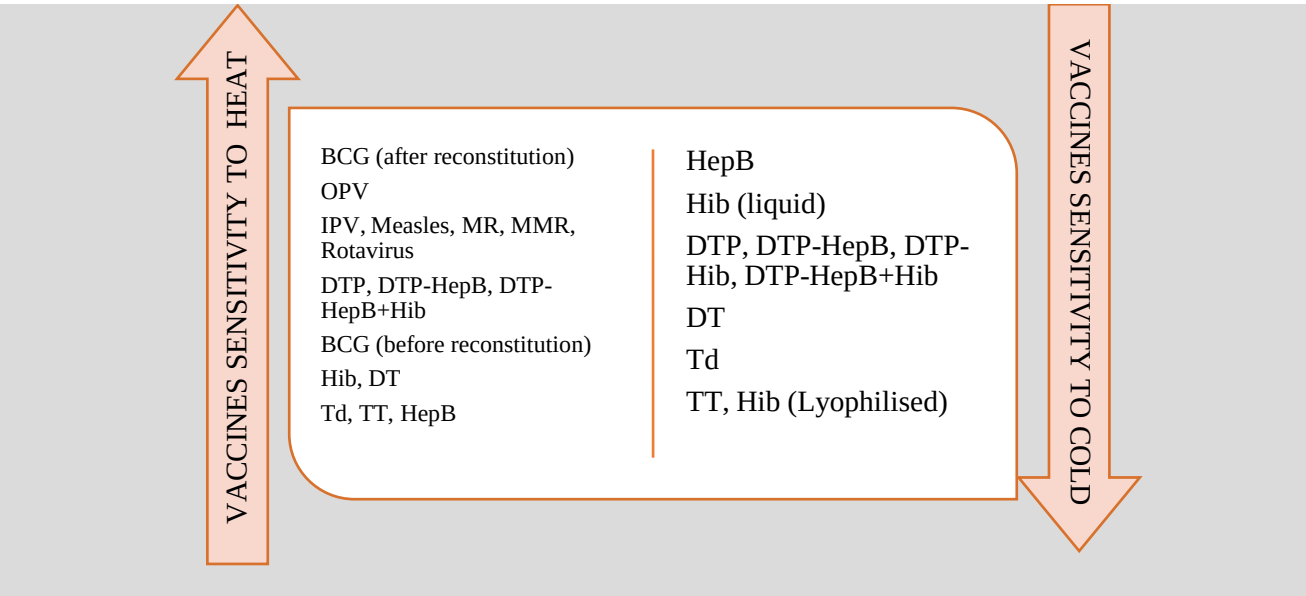

Figure 0.1: Heat and cold sensitivity of vaccines

Freeze sensitive vaccines are commonaly associated body local reactions such as sterile abscesses (51). Freezing the vaccines, increases their likelihood to cause these reactions compared (47).

Lyophilized (freeze-dried) vaccines are reconstituted with a specific (recommended) diluent (in liquid form) prior to injection (53). The Diluents of most vaccines are also sensitive to freezing and need be stored at a temperature range between 2°C - 8°C except those contain only sterile water. Frozen diluent may pose risk of fractures to the vial ehich can cause contamination (35).

Figure 2.2 (adopted from WHO Vaccine Management Handbook, Module VMH-E2) shows recommended storage temperatures and storage durations for vaccines at different cold chain levels (53).

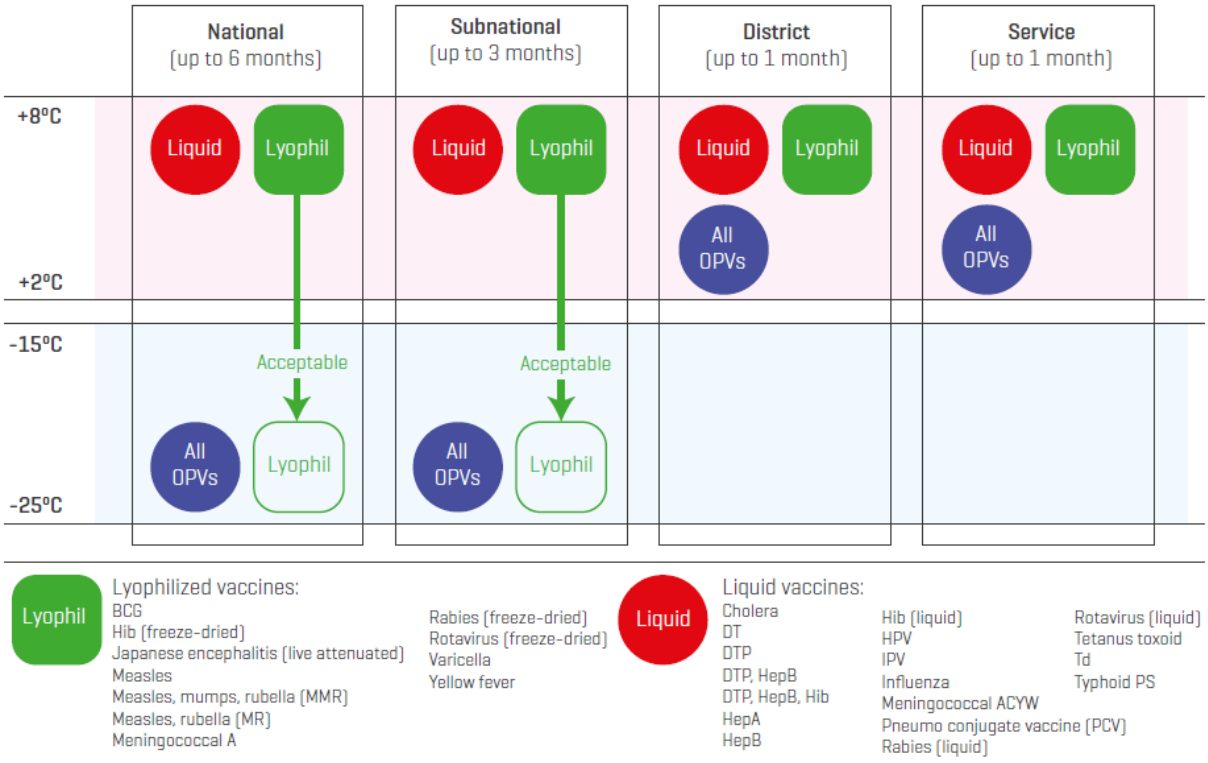

Figure 0.2: Recommended vaccines storage temperature

In addition, Bacille Calmette Guerin, measles-mumps-rubella, measles, mumps, rubella, and measles-rubella vaccines irreversibly lose their potency on exposure to strong sunlight/artificial light (16,25). Relative humidity has also being reported to have a negative effect on some vaccines (16).

Vaccines can also be categorized as single dose vials (SDVs) or multidose vials (MDVs) vaccines. Single dose vials are approved to provide a single dose of vaccines. They lack antimicrobial preservatives. Multi dose vials are approved for delivery of many doses from 2 up to 20 doses. They typically contain an antimicrobial preservative (thiomersal) to limit the growth of bacteria and are potential source of infection if not properly handled (54–56). It is therefore recommended to discard MDVs when the beyond use date has been used reached or when the sterility is in question. Multi dose vials include OPV, DPT, TT, hepatitis B) and BCG and MR vaccines (55). Multi dose vial vaccines can be used up to 28 days after opening the vials if the expiry date has not passed and if they been stored as recommended by the manufacturer (54).

2.4 The vaccine cold chain

Preserving the quality, safety and efficacy of vaccines has been one of the leading defies of immunization programs in African health systems (20). The storage and delivery of potent vaccines is through properly maintained temperature controlled system called cold chain system (19,29,57). The Cold chain begins at manufacturing plant, it goes through vaccines distribution, storage and handling at the provider facility and ends with administration to the patient (18). Figure 2.3 shows the vaccine cold chain flowchart from manufacturer to administration.

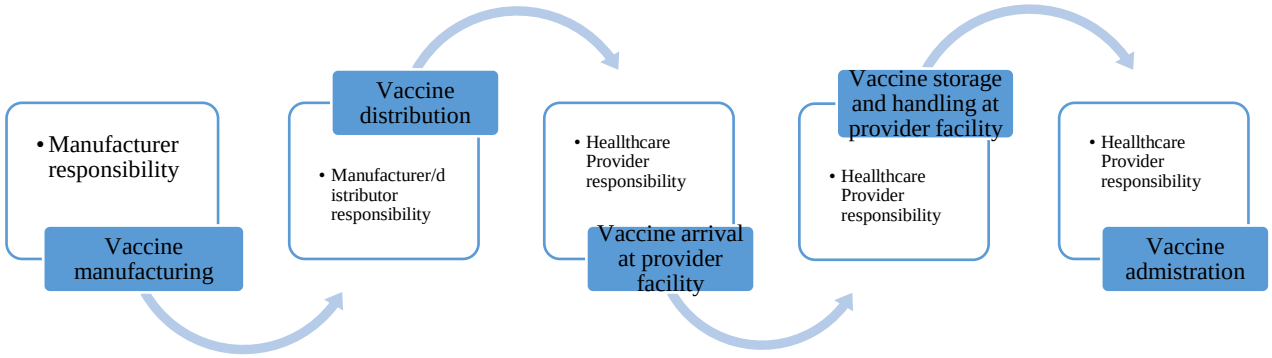

Figure 0.3: Vaccine Cold chain flowchart

The cold chain system consists of personnel, dedicated to maintain the equipment and deliver the health service; specific cooling equipment to store and transport vaccines; and processes to manage the system and govern the distribution and consumption of the vaccines (25,28,43,58). In addition, tools for monitoring temperature such thermometers, Vaccine Vial Monitors (VVM) and temperature logging charts are part of the system (28).

Storage and transportation of vaccines in a compromised system can put them at risk of degradation (50). Degraded vaccines are consequently not used and may result in decreased stock levels and poor immunization coverage (59).

2.5 Cold chain challenges and failure

Cold chain systems in resource challenged countries are struggling to support national immunization programs. They are seem to be noticeable bottlenecks that are deterring the program's development (24). Compromised cold chain system has resulted in reduced potency of vaccines administered, administration of extra doses of vaccines, revaccination of individuals, inadequate availability of vaccines and reduced public confidence in the vaccines and healthcare system (21,39,60). Failure of cold chain system to maintain temperatures in recommended ranges has been reported in India (47). Its consequences had been reported worldwide. For instance, in Metropolitan Sydney City, Australia breakdown of refrigerator used to store vaccines resulted to revaccination of 1178 mothers and 1178 babies who had already been vaccinated (19). In addition, it has been reported that, millions of dollars worldwide are lost every year due to improper vaccine storage (43). Cold chain breakdowns can be due to lack or failures of the physical layer (infrastructure, equipment and consumables such as fuel, spare parts and backup energy); failure of information flow and failure to plan, coordinate and make right decision on cold chain issues (34).

2.6 Vaccine cold chain infrastructures, personnel and temperature monitoring technologies

2.6.1 Vaccine Storage room

Because of risk of cold chain failure and sensitivity of vaccines, a specific room (cold chain room should be dedicated for vaccines storage at every health facility. The room should be clean and well ventilated (57) and secured or restricted for access with lock and key. In addition, vaccines storage equipment within the room should be fitted with lock and key (13,17).

2.6.2 Personnel in the cold chain

It is the duty of the cold chain handling staff to oversee vaccines throughout the cold chain system (46). In his/her absence, a second staff trained on vaccine cold chain can act on behalf (61). This personnel is responsible for vaccines cold chain temperature monitoring, properly arranging vaccines, store water packs, vaccines and diluents, organize or handle preventative maintenance of all cold chain equipment (30). The person should also ensure that records, including temperature readings and preventive maintenance, are complete and updated (21).

He/she should possess knowledge to correctly read and interpret the Vaccine Vial Monitor (VVM), know about Open Vial Policy (OVP), demonstrate the correct way of reading the thermometer and how to conduct a "shake test" (13,32,52).

In most immunization health facilities, cold chain handling staff often lack skills to properly manage the cold chain system and its equipment (6). Inept staff managing the cold chain have limited ability to perform basic tasks such as defrosting the refrigerator, cleaning of equipment, interpretation of vaccine vial monitors and Freeze indicator, proper reading and recording of temperature and documentation. This puts vaccines at risk of damage as any change can occur and go unnoticed (24). Inadequate knowledge of cold chain management could lead to improper handling of vaccines; vaccines damage and failure to recognize a compromised vaccine (37). Regular training in cold chain management is needed so as to imparts new knowledge and gives staff up-to-date information on cold chain handling and practices (37,43).

2.6.3 Equipment in cold chain

Availability of adequate number of ideal cold chain equipment is crucial for Immunization Program. Shortage and/or defective equipment can hamper progress towards a country's immunization coverage as the quality of vaccines is compromised (24). Types of equipment used in cold chain are divided in to active refrigeration systems and passive cooling devices. Freezer rooms, freezers and refrigerators form the active refrigeration system. Passive cooling devices are cold boxes, and vaccine carriers which are mainly used for transportation and temporary storage of vaccines (30,34,62).

The most commonly used vaccine storage device is the Ice Lined Refrigerator. It is fitted with an internal lining of water which usually freezes and can provide continuous cooling at correct temperatures for up to eight hours of power shortage per day (6). Domestic refrigerators unlike ILR are not recommended for vaccine storage because they cannot maintain the inside refrigerator temperature at a range suitable for vaccines for more than one or two hours during electricity cut off (16,63).

In any storage or transportation equipment, vaccines should be arranged and organized basing on First Expiry First Out (FEFO) and First In First Out (FIFO) principles of stock rotation and should retain their original labels up to the point of administration (43,64). In addition, in order to avoid massive temperature fluctuation, opening of a storage equipment should not be more than three time a day except in an emergency situation (37). In addition, proper arrangement is required. The recommended loading of vaccine refrigerators is illustrated in Figure 2.4 (front opening refrigerator) and Figure 2.5 (top opening refrigeratore). These figures have been adopted from The United Republic of Tanzania, Ministry of Health, Community Development, Gender, Elderly and Children. Immunization and Vaccine Development Programme, Immunisation in Practice, January 2016.

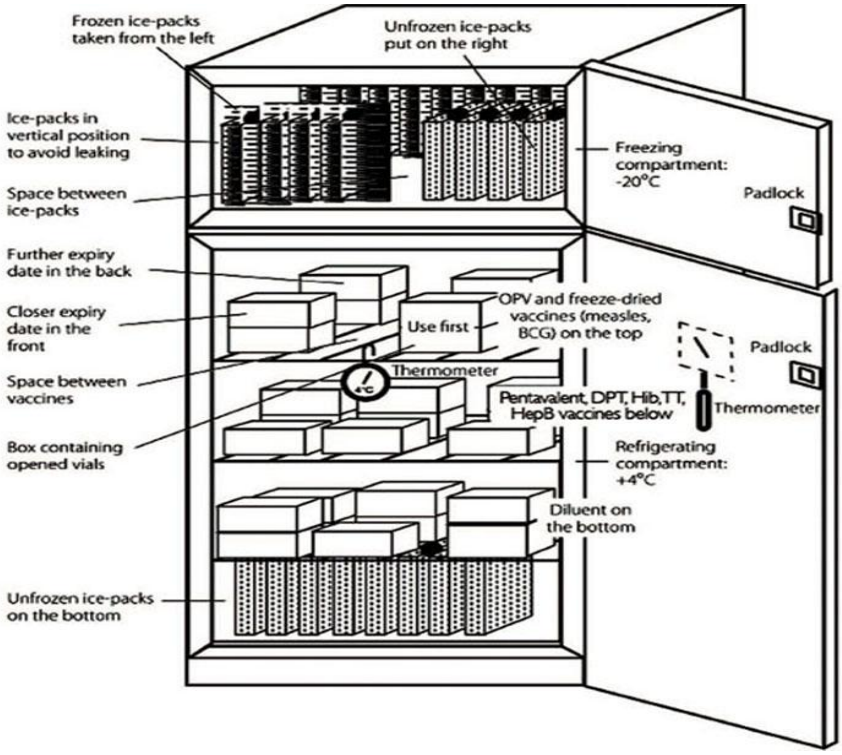

Figure 0.4: Proper loading of a front opening vaccine refrigerator

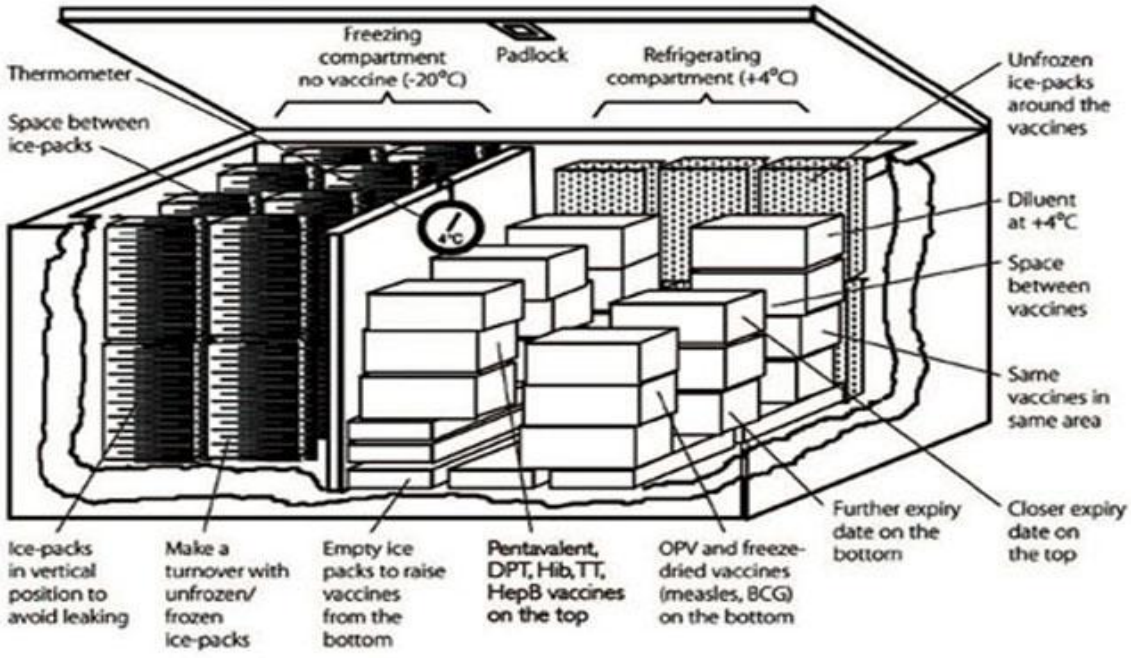

Figure 0.5: Proper loading of a top-opening (chest) vaccine refrigerator

A vaccines refrigerator should be filled to not more than two thirds of its capacity to allow air circulation (18). In addition, packed vaccines should not be in contact with the back or sides of the refrigerator to avoid freezing (17,46). Enclosed plastic materials should not be used for storage because they prevent the flow of cool air and pose risk of warming to vaccines (17). Furthermore, food items, clinical specimens and other biologics should not be kept together with vaccines in the refrigerator (21,46).

Equipment for storage of vaccines (refrigerator and freezer) should be cleaned and checked for integrity of a rubber-like door seal in every quarter of the year or as needed (35). Records of servicing and cleaning should be maintained (61). Refrigerators should be regularly defrosted to improve their efficiency and allow circulation of cold air through it. This should be done if the thickness of the ice is > 5mm (13,57).

Refrigerators for storing vaccines should remain switched on except during electric breakdown, defrost and cleaning activities. If any of these events takes place, vaccines should be transferred to alternative appropriate storage facility (17).

It is also important that, the refrigerator door should not be left open in order to maintain temperature within required range (46). In addition, vaccines should not be kept in the door of the refrigerator as this place is exposed to temperature fluctuations during closing and opening (16).

Cold boxes and vaccine carriers are passive cooling devices used to transport and temporally store vaccines. They only differ in size, cold boxes have 5–25 litres capacity and carriers are smaller with a capacity of 0.5–5 litres (62,65,66). They are filled with ice packs and cool water packs to keep vaccines at recommended temperature during services delivery. These ice packs are water packs must be frozen at –15°C and –25°C. In order to prevent accidental freezing of vaccines in the container, ice packs are 'conditioned' (allowed to melt to above 0°C) before being placed in the cold boxes or vaccine carriers (16,47,59,62,67). An ice pack is assumed to be acceptably conditioned if the ice core in it becomes mobile once the pack is shaken (68). Ice packs are suitable for vaccines that are heat sensitive whereas cool water packs (refrigerated at +2°C - +8°C) are packed with freeze sensitive vaccine. In this case, freeze sensitive and heat sensitive vaccines should not be transported in the same cold box (66).

Ice packs are known to increase risk of freezing to vaccines. Placing vaccines near or in contact with frozen ice packs may compromise their quality (69). This is more dangerous for freeze sensitive vaccines. They should never be kept in direct contact with the ice packs and should be kept in their original packages during transport (16,46). Packing vaccines and conditioned ice packs in a cold box is technical job. The vaccines need to be filled in cardboard, cartons or polythene bags. Conditioned ice packs must be placed to all side of the cold box, at the bottom and above the vaccines. Two rows of icepacks are recommended to be situated at the top of the vaccine vials. A plastic sheet must in addition must be kept on topmost to steadily close the lid of the cold box (70). As a precautionary way to avoid breakdown and associated risk in vaccines quality, storage and transporting equipment should be fixed with "Dos and Don'ts Sticker" (13).

2.6.4 Temperature monitoring in the cold chain

Temperature variation in the cold chain has profound impact on quality of vaccines. It can be caused by increased contents/load of vaccines in storage or transportation equipment, seasonal temperature variation, frequency at which the equipment door is opened and power interruptions (35). Temperature monitoring is therefore a ground program in ensuring the integrity of the cold chain and quality of vaccines. It involves daily monitoring and recording of temperatures in storage and transporting equipment (46). The temperature readings should be taken twice a day and recorded in a temperature sheet and the recording equipment must be calibrated (35). The techniques used to monitor temperature include use of thermometers, vaccine vial monitors, freeze indicator and conducting the shake test. In vaccine storage or transportation equipment, the temperature monitor should be placed in its central position and away from the coils, walls, door, floor and fan (35).

2.6.4.1 Thermometers

The use of thermometers is the traditional practice for temperature monitoring. (16). Themometer gives spot chek tempearature values. They cannot capture temperature variations between the check points. A continuous 30-days electronic temperature recorder (logger) is now preferred compared to use of thermometers as it captures temperature readings throughout the day for 30 days (16,45).

2.6.4.2 Vaccine vial monitors (VVM)

Vaccine vial monitor (VVM) is label attached on each vaccine vial (figure 2.5) to register cumulative temperature exposure. It contains a heat sensitive material which changes colour in response to increasing temperatures above the recommended range (53,71,72). Figure 2.5 has been adopted from The United Republic of Tanzania, Ministry of Health, Community Development, Gender, Elderly and Children. Immunization and Vaccine Development Programme, Immunization in Practice. January, 2016.

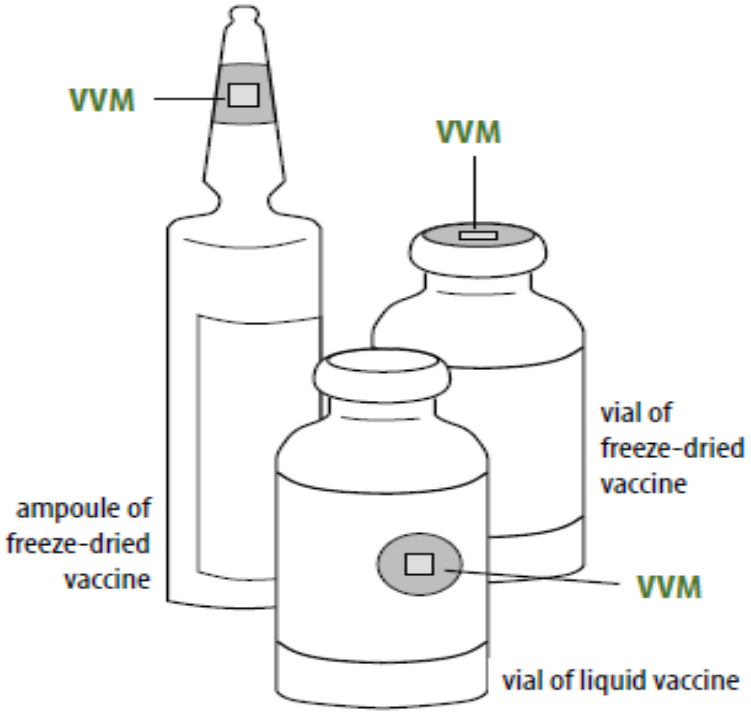

Figure 0.6: Vaccine vial monitor (VVM) on vial/ampoule label or cap

Once the cumulative heat exceeds the recommended range, VVM starts to change its colour until it reaches a point indicative of compromised vaccine, at this point the vaccine is not recommended for use (16,71). The sequence of change in appearance of VVM and its interpretation/recommendation is shown in the Figure 2.6. This figure has been adopted from The United Republic of Tanzania, Ministry of Health, Community Development, Gender, Elderly and Children. Immunization and Vaccine Development Programme, Immunization in Practice. January, 2016.

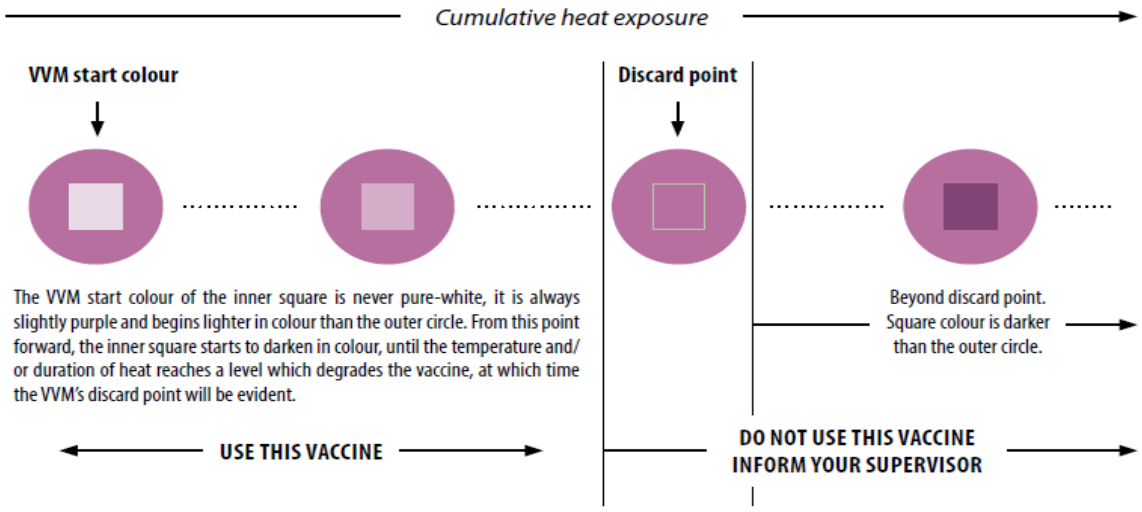

Figure 0.7: VVM colour change sequence and its interpretation

Vaccine vial monitor (VVM) alerts health workers handling vaccines that particular vaccine is safe or not safe to be used (71). In addition, VVM provides an indication of the reliability of the cold chain. For instance, if several VVMs change colour at a given time in the cold chain it is indicative of problems in the cold chain system (72).

2.6.4.3 Freeze indicators

Freeze indicators (freeze tags) are tools used to indicate if vaccine vials have been exposed to temperatures less than 0°C during storage and transportation (47). If the tag is exposed to a temperature of -0.5°C or less for more than 1 hour or temperature above 8°C for more than 10 hours the display changes from "ok" status to "alarm" status indicating that, vaccines have been subjected to freezing (73).

Figure 2.7 show freeze indicator with associated "ok" and "alarm" displays. The figure has been adopted from The United Republic of Tanzania, Ministry of Health, Community Development, Gender, Elderly and Children. Immunization and Vaccine Development Programme, Immunization in Practice. January, 2016

Vaccine OK Do a shake test

Figure 0.8: Fridge tag with "OK" and "Alarm" displays

2.6.4.4 Shake test

The shake test is another technique used to determine vaccine exposure to freezing temperature (51). This test has been reported to have 100% sensitivity, 100% specificity and 100% positive predictive value (45,51). The test involves strong shaking of two vials (test and a control vaccine vials) with the same lot number and from the same manufacturer. The test vial is the one that is suspected to have been frozen, the control vial is a vial frozen overnight at 20°C and then thawed. The vials are placed side by side on a flat surface and their contents are observed for physical variations and the sedimentation rate. If the sedimentation rate of a test vaccine vials similar or faster than that of the control, then the test vial has been frozen (51,74). Shake test can be conducted if a freeze indicator shows "alarm" display, temperature records are in negative values or if there is suspect of damage to freeze-sensitive vaccines (30).

2.7 Infrastructure considerations in the cold chain

In resource limited countries, power supply is unreliable (59). This irregular power supply poses a challenge in maintaining cold chain and is a major risk factor for loss of vaccine potency. In these countries, electricity remains as the cheapest and main power source. Inspite this, its supply remains limited and inconsistent. In order to overcome electricity shortages and keep vaccines safe, alternative sources of power are needed.

These include kerosene, solar, gases and generators (75). In addition, every cold chain point should have in place a contingency plan (75). This plan should be pasted on cold chain equipment and implemented as indicated (60,64).

In order to achieve consistency in cold chain management there must be adherence to established guidelines and standard operating procedure (SOPs) (75). These guidelines and SOPs should be periodically updated and made available at all time throughout the Immunization program activities (64).

A well and effective cold chain system requires availability of both human and financial resources at all of its levels (24,32). To enhance knowledge and skills of personell working in the cold chain should receive supportive supervision from their superiors (21,37). Insufficient supportive supervisions deter good cold chain management (10).

CHAPTER THREE: METHODOLOGY

3.1 Study design

The study design was cross-sectional study. This study design was selected because it allowed to obtain a quick picture (snapshot) of the existing problems.

The advantages of the cross-sectional study are; It is faster and easier to conduct and allows collection of data on multiple variables at the same time (unlike longitudinal studies). A longitudinal design would have been inappropriate as there were no primary exposure and outcomes to be measured.

3.2 Study area

This study was conducted in 50 primary health facilities (4 hospitals, 18 health centers and 28 dispensaries) involved in vaccines storage and which provide immunization services in Arusha City in Arusha region, Northern Tanzania. Arusha is a region located to the north-eastern corner of Tanzania. The region is made up of 6 districts namely Arusha, Karatu, Ngorongoro, Arumeru, Longido and Monduli districts.

Arusha city is the business centre of Arusha region and is the most famous tourist centre in the country. The city has an area of 267 km² and is 100% urbanized. It serves an estimated 416,442 inhabitants as per 2012 census and provides services to about 100,000 people from other close by districts (76,77). The city experiences a biphasic climatic condition of both warm and cold temperatures ranging from 17°C to 34°C. The cold season is between mid April and mid August; the rest of the year is warm (77).

Arusha City has a total of 94 health facilities (5 hospitals, 18 health centres, 66 dispensaries and 5 specialized clinics). In the city, 21 facilities (2 hospitals, 8 health centres and 11 dispensaries) are owned by government and 61 facilities (9 health centres, 47 dispensaries and 5 specialized clinics) are owned by the private sector. In addition, there 12 facilities (3 hospitals, 1 health centres and 8 dispensaries) which are owned by Faith Based Organisations (FBOs) (78) .

In the city there 50 primary health facilities that offer immunization services. The facilities by category include 4 hospitals, 18 health centres, 28 dispensaries (78). In these vaccination points, the cadre of staff normally found mostly involved in handling of cold chain are nurses and clinical officers. In some rare cases, pharmacists or pharmaceutical technicians provide these services.

The City Health Department is renowned for amongst other things, achievement of a high immunization coverage; for instance, above 90% per month for Bacillus Calmette-Guerin (BCG), Oral Poliovirus vaccine, Pentavalent, Rotavirus, Measles and Rubella vaccines among others (79,80).

3.3 Study population

The study population included primary health facilities. In evaluating the knowledge, attitude and self reported practices, the personnel in-charge of the vaccine cold chain or any other qualified personnel designated on his/her behalf were involved. They were drawn from facilities involved in storage of vaccines, they included; Nursing Officers, Assistant Nursing Officers, Nurse Midwifery and Clinical Officers.

Documents and Records were examined to assess their availability of key documents and completeness. The records included Store ledger books; requistion and issue vouchers; temperature recording charts, guidelines for vaccine cold chain management; standard operating procedures; dos and don't stickers; defrosting and cleaning records, records for calibration, preventive maintenance of equipment, training, records for power outage; records of shake test conducted and equipment breakdown records.

3.4 Inclusion criteria and Exclusion criteria

3.4.1 Inclusion criteria

The health facilities included in the study were private or public hospitals, health centers and dispensaries located in Arusha City. The facilities were those involved in vaccine storage and handling and whose medical officer in-charge/cold chain handler gave informed consent.

The cold chain handling staff involved in the study were those permanently employed at the particular facility, appointed as vaccine cold chain handling staff and/or directly responsible for cold chain and who gave informed consent.

Equipment included in the study were those designated for storage and transport of vaccines found with/without vaccines and which were still in use. Furthermore, records that corresponded to procedures and/or equipment used in vaccine cold chain were included in the study.

3.4.2 Exclusion criteria

The study excluded any other vaccine cold chain point which was not a primary health facility and any primary health facility not involved in storage or transportation of vaccine. It also excluded facilities located outside Arusha City and facilities whose medical officer in-charge declined to give consent.

The study excluded all cold chain handling staff or any person on behalf who were not permanently employed and did not work at facility visited and those who declined to give consent.
All equipment not designated for storage and transport of vaccines and records that did not correspond to procedures and/or equipment used in vaccine cold chain were excluded from the study.

3.5 Sample size and sampling process

A list of all primary health facilities involved in vaccine storage and immunization in Arusha city was obtained from City Executive Officer, department of health. This list was used as sampling frame and included 50 primary health facilities (4 hospitals, 18 health centres and 28 dispensaries).

Census (universal) sampling was done where by all the 50 primary health facilities involved in immunization, storage and distribution of vaccines in the city were included. Census Sampling was done because the sampling frame was small consisting of only 50 facilities in Arusha City. Therefore, it was possible to access all study sites.

Secondly Census sampling improve the generalizability of the study findings especially with regard to Arusha City. It also improves the power of the study.

A total of 50 designated cold chain handling staff, one from each of the facility were included in the study. In addition, all cold chain equipment and records pertaining to storage and cold chain management of vaccines found at every particular facility were also included in the study.

3.6 Participants recruitment

Before any visit to primary health facilities was made, a formal approval to conduct the study was sought and obtained from City Medical Officer a month before commencing the study.

The facility in-charges and cold chain handlers were contacted to request for the permission to conduct the study at their mandate place and to arrange for a day and time convenient for the study.

On the day of the meeting, the purpose, intention and confidential nature of the study was explained and permission to participate and access the records was requested in writing and verbally. The cold chain handling staff was asked to provide informed consent with the aid of the form appended (**Appendix 1** and its translated Swahili version **Appendix 2**). The study proceeded after the consent was provided.

3.7 Data collection

Information on vaccine cold chain status and practice (storage/transport equipment, vaccine state, arrangements of vaccines and documentation) was collected by use of structured checklist (**Appendix 3** and its translated Swahili version **Appendix 4**). The checklist was pre-tested during a preliminary fact-finding visit at Mount Meru Regional Referral Hospital in Arusha region for comments and inputs from the field health officers. The pre-tested checklist was then reviewed and validated before is applied.

Equipment observed includes thermometers, refrigerators, vaccine carriers, fridge tags, freeze tags, power supplies and voltage stabilizers involved in vaccine storage and transportation.

The assessment of vaccines included checking the availability in the facilities, expiry, registration status and the state of the vaccine vial monitors.

Review of documents (standard operating procedures, guidelines, temperature charts, vaccine receipt/order/issue voucher, vaccines register, equipment calibration and preventive maintenance status records, records for cleaning, defrosting and breakdown storage equipment) was done as per checklist appended (**Appendix 3** and its translated Swahili version **Appendix 4).** The checklist had 'yes' or 'no' responses used to check the available of documents in the facility. When an affirmative 'yes' response was given, the respondents were requested to show the documents. If the documents were produced, then the appropriate response was selected.

When the document was provided, the last date for the latest entry will was noted. The researcher checked if the last entry was within the accepted stipulated period for recording as specified in the data collection tool.

Data on knowledge, practice and attitude of personnel regarding cold chain handling staff was collected by use of structured researcher administered questionnaire (**Appendix 5** and its translated Swahili version **Appendix 6**).

3.7.1 Assessment of Knowledge

Part II 'A' of the questionnaire had 22 questions that assessed knowledge on the storage conditions for selected vaccines and optimal arrangement of vaccines within a refrigerator and vaccine carriers. A three-point Likert scale was used for positive knowledge item, scores of '3', '2' and '1' for 'Yes', 'Not sure' and 'No' respectively. The responses were reversed for negative items.

A score of 0-24, 25-49, 50-74 and >74 percentage was described as poor, unsatisfactory, satisfactory and good knowledge on storange and cold chain management of vaccines.

3.7.2 Assessment of Attitude

Part II 'C' had a total of 8 questions and the responses were presented on a five-point Likert scale was used for positive attitude item. A rating scale of '5', '4', '3', '2' and '1' was used for 'Strongly agree', 'Agree', 'Not sure', 'Disagree' and 'Strongly disagree' respectively.

The scoring was reversed for negative items. The questions were designaed to capture 3 dimensions of attitude namely; Self efficacy and motivation to do work; confidence on satisfaction with resources available and self express need for more training and lastly confindence in the quality of vaccines administered.

The responses were subjected to correlation analysis using Spearman's rank correlation test. To confirm that a given question was testing the same domain as another, a correlation coefficient of greater than 0.4 confirmed that two or more questions assessed the same domain. For correlated questions, a summary score was obtained. The summary score was used as an indicator of the given aspect of attitude.

For instance, the responses to questions on adequacy of supportive supervision received, level of confidence with regar to the knowledge on vaccine cold chain handling, level of motivation to work as cold chain handler and concerns about deteriorated vaccines were highly correlated.

In this study supportive supervision was assessed three times, appendix 3 was a simple checklist whereby the respondents were asked 2 questions with regard to supportive supervision. In this checklist the respondent was asked whether the District Health Management team conduct supportive supervisory visit on vaccine cold chain management issues in the facility. The second question sought to know whether the last visit was conducted in the year before. The next assessment was a question in appendix 5 whereby respondents were asked whether they were satisfied with the supportive supervisory visit they received.

3.7.3 Assessment of self reported practices

Part II 'B' consisted of 10 questions to capture information on self reported practices. The questions included assessment of selected practices such as arranging icepacks in a criss-cross pattern, adherence to FIFO and FEFO, use and interpretation of vaccine vial monitors and freeze indicators. Self reported practices with regard to reporting of defective vaccines and conducting the shake test was also assessed.

Five-point Likert scale was used for positive practice items. A rating scale of '5', '4', '3', '2' and '1' was used for 'Always', 'Mostly', 'Not sure', 'Hardly' and 'never' respectively. The responses were reversed for negative items. Responses to individual questions were compared to the observed practices to assess for the validity of responses. Discrepancies from self reported practices and observed and noted.

3.8 Quality Assurance

To achieve good quality of data to be collected, a well-designed and clearly defined questionnaire and checklists were used. In addition, careful observation of study criteria and complete documentation of observations were done and there was daily routine cross checking for verification and consistency of data.

All the data collection instruments used in the study were pretested during a preliminary fact-finding visit to Mount Meru Regional Referral Hospital in Arusha city and improved based on feedback received. Data collection involved only personnel designated as in-charges of vaccine cold chain or any other qualified person appointed on behalf to carry out his/her responsibility.

Furthermore, research assistant (pharmacist) was trained for two days on how to collect data and record all observation objectively.

3.9 Data Management

After completion of data collection exercise, data was transcribed into soft copies, entered in to Microsoft excel, cleaned, coded, validated and then exported to **Stata software version 13,0** for analysis.

Data was safeguarded and restricted for access by password protection. Information contained in the database was backed up on a daily basis, stored into an external storage device and sent to email. External storage device, Hard copies of the Data Collection Forms and filled questionnaires were stored in the cabinet under lock and key with controlled access.

3.10 Data Analysis

Data analysis was divided in to three sections

3.10.1 Summary of variables

The study was conducted to assess storage and cold chain management of vaccines in primary health facilities. The main outcome variables were; the availaibility and status of vaccines and equipment, documents and records, knowledge, attitude and practice of cold chain handling staff.

In particular, we assessed the presence of the following variables on cold chain infrastructure which included availability and functionality of equipment such as refrigerators, vaccine carriers, ice packs, thermometers, fridge and freeze tags, voltage stabilizers. Also included availability of temperature record charts, maintenance and calibration records, ledger books, issue and requisition vouchers, contingency plan, dos and donts stickers, guidelines and standard operating procedures.

Then outcome variables (scores on knowledge and attitude of respondents toward vaccine cold chain management) were subjected to linear and logistic regression analyses were. The covariates or potential predictor variables were divided in to two categories:

a) Characteristics of cold chain handling staff (age, gender, role, work experience in years, training status, education qualification, where trained on vaccine cold chain and the time since last training).

b) Characteristics of the health facilities which included level of the facility (hospital, dispensary or health Centre), health facility ownership (private or public) and access to supportive supervision.

3.10.2 Descriptive data analysis

Descriptive data analysis was conducted to obtain summary measures and measures of dispesersion.

The continuous variables (such as age, duration of work experience, temperatures and percentage scores) were tested for normal distribution normal using Shapiro Wilk test and in addition Histogram, p-q and p-p graphs were plotted to examine the distribution. The variables that were normally distributed were summarized as mean and standard deviation and/or stand error of the mean and those which were not normally distributed were summarized as median and interquartile range (IQR) or Range. All the categorical variables were summarized as frequency and percentages.

With regards to scores on knowledge of respodents and on each dimension of attitude, the summative response to questions was calculated for each respondent. The raw score was transformed into 'percent score' by dividing the score with possible maximum score and multiplied by 100. This was done because it was easier to appreciate the score level in the scale of 0 to 100, rather than using the raw score.

3.10.3 Exploratory data analysis

Exploratory data analysis was conducted to examine the relationship between variables.
was divided in to three categories. The relationship between two linear (continuous) variables was explored by plotting a scatter plot overlaid using smoothing lines. In addition, Spearman's rank correlation coefficients were obtained between dependent and independent variables.

For relationship between numerical/continuous variable and categorical variables, the measures of central tendency (mean/median) were compared across the levels of categorical variables.

The inferential test used was ANOVA test for normally distributed continuous variables and Kruskal-Wallis test for variables that werenot normally distributed.

For the relationship between two categorical variables, the frequencies and proportions of one variable was compared across the levels of the main categorical variable of interest. Pearson's Chi-Square or Fisher's Exact were used to explore any association between categorical variables.

The level of significance (alpha) was set at 0.05.

3.10.4 Regression analysis

Both simple and multivariable linear and logistic regression analyses were conducted. For linear regression, three different regression analyses were done. For the first liner model, the outcome measure was the vaccine cold chain management knowledge score, for the second linear model, the outcome variable was the score on attitude toward self efficacy and motivation to work in the cold chain. The third linear model the outcome was score on attitude toward availability of adequate resources and the felt need for training.

For binary logistic regression, the outcome variable was confidence in the quality of vaccines that were administered to patients. This variable was obtained by dichotomizing the response to the question on if the respondents were confident about the quality of the vaccines they administer to patients.

For both linear and logistic regression, model building was done using a forward stepwise approach. Variables that were significantly associated with the outcome on bivariable analysis were included in the multivariable model. The level of significance was set at $p < 0.05$ for all associations.

3.11 Results Dissemination plan

The results of this study will be presented in a Master of Pharmacy in Pharmacoepidemiology and pharmacovigilance thesis. Study findings will be shared with the Kenyatta National Hospital – University of Nairobi Research and Ethics committee (KNH/UoN-ERC), Tanzania National Institute for Medical Research (NIMR), Ministry of Health, Community Development, Gender, Elderly and Children, Immunization and Vaccines Development Program Tanzania and Tanzania Medicines and Medical Devices Authority. Results will be published in a peer reviwed journal.

An exuctive summary as well as policy brief will be written and submitted to Immunization and Vaccines Development Program in Tanzania and the Arusha City Health Department.

3.12 Ethical Considerations

Ethical approval for the study was sought and obtained from the University of Nairobi, Kenyatta National Hospital, Ethics and Research committee (Ref: KNH-ERC/A/77) and the Tanzania National Institute of Medical Research (Ref. No: NIMR/HQ/R.8a/Vol.1X/3418). Copies of the letters of approval are attached in Appendix 7 and 8.

Informed consent was obtained with aid of the informed consent form in Appendix 1. Participants were required to read the consent form and were allowed to ask any question relating to his/her participation or to the study itself. The individuals were allowed to freely decide whether to participate or not. Those who accepted to participate by signing the consent forms were included in the study.

To ensure confidentiality of information unique identifiers were used and all documents were kept under lock and key.

CHAPTER FOUR: RESULTS

4.1 Summary of number of facilities and participants recruited into the study

In this study, fifty (50) primary healthcare facilities were included. All the facilities met inclusion criteria and none of the respondents declined to participate. Most were dispensaries 28 (56%), others were health centers 18 (36%) and hospitals 4 (8%). Majority were owned by the government 20 (40%). The rest were owned by the private sector 19 (38%) and Faith Based Organizations 11 (22%).

4.2 Baseline Socio-demographic Characteristics of Healthcare Workers Interviewed

The socio-demographic characteristics of the respondents were compared by type of facility. The results are presented in Table 4.1. There were no statistically significance differences in the socio-demographic characteristics of the participants by type of health facility.

Half of all respondents (50%) were aged 40 years and above. The median age was 39.5 years and ranged from 20 to 69 years. Less than forty percent (37.8%) of the respondents in health centers were aged below 30 years compared to 25% and 28.6% of the respondents at similar age in hospitals and dispensaries respectively.

Most of the respondents were females 43 (86%) and the rest 7 (14%) respondents were male and were drawn from health centers and dispensaries. Majority of respondents 31 (62%) were holders of a diploma in nursing (assistant nursing officers) and 15 (30%) were holders of a certificate in nursing (nurses). The rest were medical attendants 3 (6%) and clinical officer 1 (2%).

Table 4. 1: Socio demographic characteristics of respondents who work in vaccine Cold chain in Arusha city (N=50)

Type of Health Facility	**Hospitals (N=4)** n (%) or median [IQR]	**Health centers (N=18)** n (%) or median [IQR]	**Dispensaries (N=28)** n (%) or median [IQR]	**Total (N=50)** n (%) or median [IQR]	**P value**
Gender					
Male	0 (0.0%)	2 (11.1%)	5 (17.9%)	7 (14%)	0.833
Female	4 (100%)	16 (89.9%)	23 (82.1%)	43 (86%)	
Age (years)	37 [30.5,50]	40 [28,48]	38.5 [27.5,49]	39.5 [28,48]	0.958
Age group (years)					
20-29	1 (25%)	5 (37.8%)	8 (28.6%)	14 (28%)	0.984
30-39	1 (25%)	3 (16.7%)	7 (25%)	11 (22%)	
≥40	2 (50%)	10 (55.6%)	13 (46.4%)	25 (50%)	
Education Qualification					
Assist Nursing Officer	4 (100%)	10 (55.6%)	17 (60.7%)	31 (62%)	0.663
Nurse	0 (0.0%)	6 (33.3%)	9 (32.1%)	15 (30%)	
Medical Attendant	0 (0.0%)	2 (11.1%)	1 (3.6%)	3 (6%)	
Clinical Officer	0 (0.0%)	0 (0.0%)	1 (3.6%)	1 (2%)	

Inferential tests used; Kruskal-Wallis for continuous variables, not normally distributed and Fischer's exact for categorical variables

4.3 Respondents' role, experience, training and access to supportive supervision

The role of respondents, duration of working experience, training and supportive supervision received varied by facility type. The results are presented in the Table 4.2.

All health facilities had specified personnel to manage and oversee cold chain activites. These personnel had no formal letters of appointment. They all worked in the Reproductive and Child Health (RCH) clinic. Eight percent (88%) of the respondents were the individuals who had been informally assigned the responsibility of overseeing the cold chain system. The other 20% responded on behalf of them.

The median working experience of respondents in the vaccine cold chain was 3 years and ranged from 2 to 6 years. The majority of respondents 22 (44%) had worked in the vaccine cold chain for less than 3 years; exceptionally, there were 7 (14%) who had worked for more than 10 years.

It was noted that in terms of training on vaccine cold chain management, all of respondents in hospitals had been trained. A significant proportion (16.7% and 39%) of respondents in health centers and dispensaries respectively had not received any training on vaccine cold chain management. Out of the 36 (72%) participants trained, 91.7% were trained out of their service station compared to only 8.3% who received training at their workplace (on job or in service training). Fortunately, 72.2% of participants reported to have been trained a year ago (in 2019).

Supportive supervision of cold chain activities was reported to be conducted regularly in the visited healthcare facilities. The majority of the facilities 46 (92%) reported that they received supportive supervision in the last two years (2019 and 2020). Supportive supervision is provided mostly by city vaccination officers (VCO) and in some cases by regional and national immunization programs.

The respondents described the kind of supportive supervision that they received. This entails administrative visits by superiors working in the city vaccination department and by individuals from the regional and national immunization. It involved working of supervors collaboratively with the staff at the facility during the visit. Gaps identified by the supervisor were noted and discussed collaboratively with the facility staff. The term given by the facility workers to such visits was “SS” which meant “Supportive Supervission”.

The facility staff never felt intimidated by such visits because they were conducted in a friendly collaborative manner. Every visit was documented by signing visitor register and the purpose of the visit was described. To date there are no formal mechanism for assessing the effectiveness of the visit and the optimal number of visits. There were no statistical significant differences with regards to supportive supervision in the hospitals, health centres and dispensaries ($p=0.187$). The facilities that reported that they did not receive supportive supervision in the last two years were 1 hospital, 2 health centers and 1 dispensary.

Table 4.2: Comparison of the respondents' role, experience, training and supportive supervision by facility (N=50)

Type of Health Facility	Hospitals (N=4) n (%) or median [IQR]	Health centers (N=18) n (%) or median [IQR]	Dispensaries (N=28) n (%) or median [IQR]	Total (%) or median [IQR]	P value
Respondent's role in the cold chain					
Cold chain handler	4 (100%)	12 (66.7%)	24 (85.7%)	40 (80%)	0.243
Personnel on behalf	0 (0.0%)	6 (33.3%)	4 (14.3%)	10 (20%)	
Experience in vaccines cold chain management (years)					
Duration (years)	5.5 [3.5, 7]	2.5 [1, 8]	3 [2, 4.5]	3 [2, 6]	0.584
Experience in vaccines cold chain management (years)					
<3	1 (25%)	9 (50%)	12 (42.9%)	22 (44%)	0.734
3 - <10	3 (75%)	6 (33.3%)	12 (42.9%)	21 (42%)	
≥10	0 (0.0%)	3 (16.7%)	4 (14.2%)	7 (14%)	
Training					
Once	2 (50%)	11 (61.1%)	7 (25%)	20 (40%)	**0.079**
More than once	2 (50%)	4 (22.2%)	10 (35.7%)	16 (32%)	
Not Trained	0 (0.0%)	3 (16.7%)	11 (39.3%)	14 (28%)	
How training on cold chain management was done					
On Job	0 (0.0%)	3 (20%)	0 (0.0%)	3 (8.3%)	0.15
Out of Job	4 (100%)	12 (80%)	17 (100%)	33 (91.7%)	
Time since last Training (years)					
≤1	2 (50%)	13 (86.7%)	11 (64.7%)	26 (72.2%)	0.198
>1- 3	0 (0.0%)	1 (6.7%)	4 (23.5%)	5 (13.9%)	
>3	2 (50%)	1 (6.7%)	2 (11.8%)	5 (13.9%)	
Supportive supervision received					
Yes	3 (75%)	16 (89.9%)	27 (98.4%)	46 (92%)	0.187
No	1 (25%)	2 (11.1%)	1 (3.6%)	4 (8%)	

Inferential tests used; Kruskal-Wallis for continuous variables, not normally distributed and Fischer's exact for categorical variables.

4.4 Funding for cold chain vaccine activities

Funding for maintenance of cold chain activities in most 43(86%) facilities is provided by City Vaccination Department. A small proportion 7(14%) facilities had independent facility-level

budgetary allocations for cold chain activities. The facilities that had a budgetary allocation were; 2 hospitals, 4 health centers and 1 dispensary. There was a statistically significant difference in the availability of a budgetary allocation by type of facility (p=0.013). Dispensaries were most affected by lack of an independent budget; 96% of the respondents in dispensaries reported lack of budgetary allocation at their facilities compared to 77.8% in health centers.

4.5 Availability and State of Cold chain infrastructure

The availability of various type of equipment is presented in the Figure 4.1. In most facilities, all equipment was available except for the voltage stabilizers.

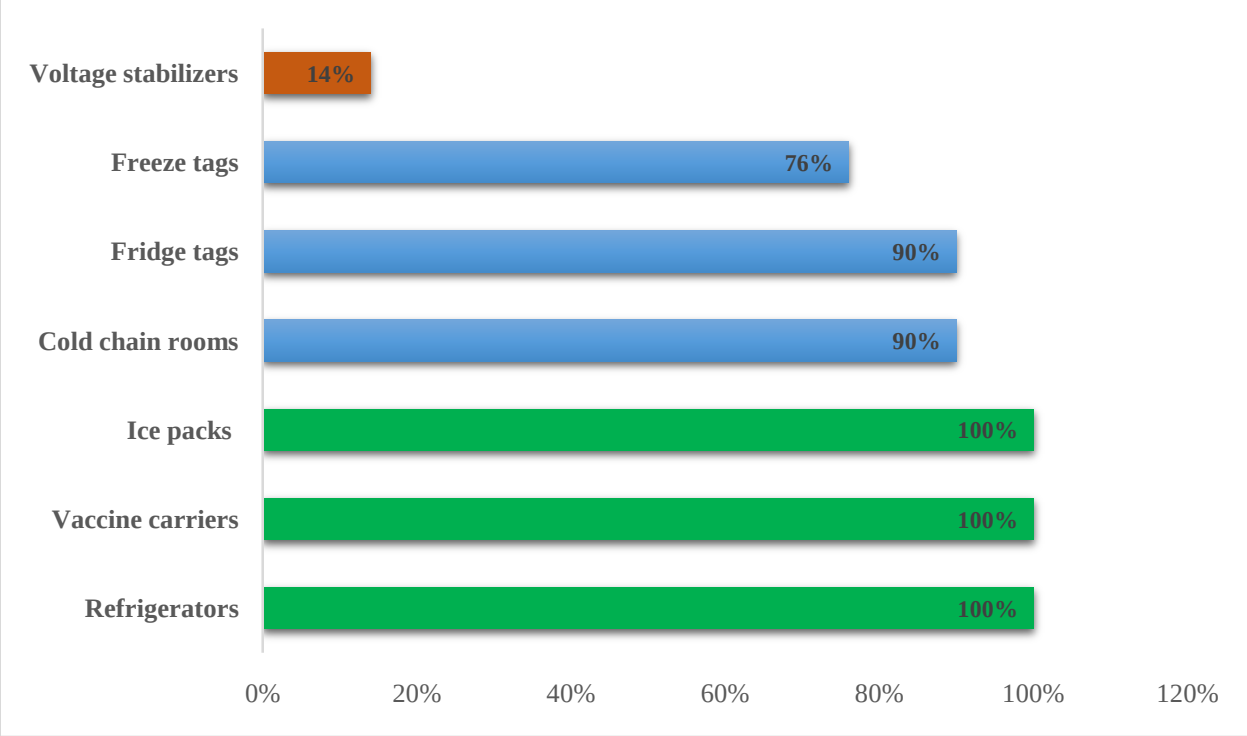

Figure 4. 1: The availability of cold chain infrastructure in the surveyed health facilities

4.5.1 Availability of Refrigerators, vaccine carriers and ice packs

All health facilities had at least one (1) refrigerator in place for storage of vaccines. All the refrigerators were the top open model; no refrigerator was chest open. There were four (4) types of refrigerators. The Electrolux RCW 50 EG refrigerators and Electrolux RCW 42 EK refrigerators which were found in (32, 64%) and (17, 34%) facilities respectively. In addition, one government owned facility had Vest frost MK 404 PQS E003/12 refrigerator and one domestic refrigerators was found in a privately owned dispensary. The thermostats in domestic refrigerators are not designed to maintain strict temperature control with the desired range. Domestic refridgerators are therefore not suitable for vaccine storage as the temperatures tend to fluctuates beyond limts (81).

All the refrigerators had been pre-qualified by World Health Organization (WHO) except the domestic version. Two (2) refrigerators in two (2) different health centers were found not working. It was reported that, these refrigerators had stopped working for almost 1 month and the information has been shared with the city vaccination office. The facilities whose refrigerators stopped working stored vaccines in the nearby health facilities that had working refrigerators. On the day of immunization session, vaccine carriers were used to transport and temporarily store the vaccines in facilities that had malfunctioning refrigerators. Immediately after completion of immunization, vaccines in the carrier(s), if any, were taken back, as soon possible, to the neighboring facilities for storage.

All facilities had at least 1 vaccines carrier; the median number of vaccine carriers per facility was 2 and ranged from 1 - 2. Majority of facilities 33 (66%) had more than 1 carrier. In particular, these were hospitals (75%) and health centers (77.8%) and dispensaries (57.2%).

All health facilities had ice packs both frozen and unfrozen. The overall median number of ice packs was 8. The number of ice packs per facility ranged from 7-12. The sufficiency of these ice packs in every facility was also examined. The sufficiency was examined based on WHO requirements which entails that, each facility should have a minimum of 8 ice packs per each vaccine carrier at disposal. The level of sufficiency of the packs in facilities based on this requirement (1/8 ratio) was of varying degree, the number of ice packs in 42% of the facilities was not sufficient (quantity < 1/8 ratio. Health centers had much deficit compared to dispensaries. The deficit was in 55.6% health centers compared to 35.7% dispensaries. In hospitals, only 25% did not comply with this requirement.

4.5.2 Availability of cold chain rooms, fridge and freeze tags

The availability of cold chain rooms, fridge and freeze tags in hospitals, health centers and dispensaries was satisfactory. A total of 45 (90%) of facilities had dedicated rooms for cold chain infrastrucure. These rooms were found in all hospitals and health centers except in 5 (17.9%) of the 28 dispensaries surveyed. In these dispensaries, cold chain equipment, in particular refrigerators, were placed in corridors or open uncontrolled spaces.

Fridge tags for temperature monitoring were found in 45 (90%) of the facilities; each fridge tag was kept inside the refrigerator. In 5 (10%) of the facilities which had no fridge tags, temperature readings were solely obtained from the thermometer. Surprisingly, most of the refrigerators without fridge tags were found in health centers (38.9%) as opposed to dispensaries (17.9%).

Compared to fridge tag, the availability of freeze tag was not optimal; a total of 12 (24%) health facilities had no freeze tags. Freeze tags are used to alert if the temperature inside a vaccine storage device has fallen below zero (0°C).

4.5.3 Availability and stability of power supply

There were different sources of power for running refrigerators in the primary health facilities. Electricity was the main power source in 48 (96%) facilities. The remaining 2 (4%) facilities used gas as main source of power. The 2 gas powered refrigerators were found in 1 health center and 1 dispensary.

It was encouraging that, every health facility had an alternative source of power to handle potential power breakdown. The most commonly used alternative power sources were gas and generators. These power sources were used in 21 (42%) and 17 (34%) health facilities respectively.

There were two types of generators; automated and non-automated ones. The former was found in 6 facilities (4 hospitals and 2 health centers) while the later was found in 11 facilities (4 health centers and 7 dispensaries).

The least frequently used alternative sources of power were solar energy and kerosene. Solar energy was used in 1 (2%) facility; likewise, kerosene was also used as an alternvative source of

power in 1 (2%) facilities. All the facilities that used either solar energy or kerosene were health centers. Hospitals relied exclusively on generators.

In order to avoid the consequences unanticipated power fluctuations that can occurs and damage the vaccine refrigerators, voltage stabilizers must be connected to the refrigerators. Unfortunately, our study observed that, only 7 (14%) of the facilities had voltage stabilizers. All these 7 facillities had their voltage stabilizers working and connected to refrigerators.

4.6 Findings on inspection of the refrigerators

4.6.1 Damage to refrigerators and the state of fridge and freeze tags

We examined the physical state of refrigerator compartments. We observed that, majority 42 (84%) of the refrigerators had their compartments in good state. There were 8 (16%) refrigerators whose compartments had been damaged. These damaged refrigerators were found in health centers and dispensaries in equal proportion. There were no damaged refrigerators in hospitals. The refrigerators with damaged compartments were the Electrolux RCW 42 EK. In these refrigerators, the wall that separates the two refrigerator compartments (fridge compartment and freezer compartment) was broken or completely removed.

The integrity of the refrigerators' door rubbers was also checked by visual inspection and we found that, 16 (32%) of refrigerators had broken/loose door rubbers. Refrigerators with compromised door rubbers were located in the health centers 8 (16%) and dispensaries 8 (16%). All the door rubbers in hospital refrigerators were whole, intact and firm.

Fridge tags were found inside 45 (90%) health facilities refrigerators. They were working in 40 (88.9%) of the facilities. They were able to measure and display the temperature inside the refrigerators and when taken out. All the 40 fridge tags displayed different temperatures when they were removed from the refrigerator. In the remaining 5 (11.1 %) facilities, the fridge tags were not working. These facilities were 2 health centers and 3 dispensaries.

Freeze tags were available in 38 (76%) facilities and were all working. The physical damage to refrigerators and the state of fridge and freeze tags are presented in the Table 4.3.

Table 4.3: Damage to refrigerators and the state of fridge and freeze tags (N=50)

Type of Health Facility	**Hospitals (N=4)** n (%) or median [IQR]	**Health centres (N=18)** n (%) or median [IQR]	**Dispensaries (N=28)** n (%) or median [IQR]	**Total (N=50)** n (%) or median [IQR]	**P value**
Refrigerator compartments physical state					
Good	4 (100%)	14 (77.8%)	24 (85.7%)	42 (84%)	0.726
Damaged	0 (0.0%)	4 (22.2%)	4 (14.3%)	8 (16%)	
Refrigerator door rubber Integrity					
Firm	4 (100%)	10 (55.6%)	20 (74.4%)	34 (68%)	0.260
Broken/ loose	0 (0.0%)	8 (44.4%)	8 (25.6%)	16 (32%)	
Fridge tag working					
Yes	3 (100%)	14 (87.5%)	23 (88.46%)	40 (88.9%)	1.000
No	0 (0.0%)	2 (12.5%)	3 (11.54%)	5 (11.1%)	
Freeze tag working					
Yes	4 (100%)	11 (100%)	23 (100%)	38 (100%)	
No	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	

Inferential tests used; Fischer's exact for categorical variables.

4.6.2 Maintenance and calibration of equipment

We found that, preventive maintenance and calibration of equipment had been done in only 1(2%) facility which was a hospital. In this facility, the refrigerator used to store vaccines was found affixed with preventive maintenance and calibration status label. The label showed that, preventive maintenance and calibration had been done in 2015. All the equipment in the health centers and dispensaries had never been subjected to preventive maintenance and calibration (records of preventive maintenance and calibration were not availed).

4.6.3 Presence of extraneous materials inside refrigerators

It is recommended that, a vaccine storage device should not be used to store any other materials not related to vaccines. This is important so as to avoid repeated opening of the storage device which can lead to temperature fluctuations inside the device. We found that, majority of the fridges 38 (76%) did not have extraneous materials. However, 12 (24%) of surveyed health facilities had kept products not related to vaccines inside the refrigerators. The facilities were 5 dispensaries and 7 health centers. Dispensaries stored erythropoietin, insulin, salmonella antigens and Widal test reagents in their vaccine refrigerators. Whereas, health centers stored erythropoietin, insulin and oxytocin injections and antisera reagents, meat was also found in one of the refrigerator in a health center.

4.6.5 Temperature inside refrigerators

In order to keep vaccines at recommended temperature range, refrigerators must be in good state and working. They must always be switched on and closed under lock and key. We observed that, 49 (98%) of the refrigerators were all working. The refrigerators were on in 47 (94%) of the surveyed health facilities at the time of the visit.

All the refrigerators except in 1 (2%) government health center were found under lock and key (including the one that stopped working). Unfortunately, 3 (6%) of the facilities (1 government health center, 1 private health center and 1 Faith Based Organization health center) had switched off their refrigerators.

The spot check of refrigerator temperatures was done by reading the temperature values on the external display of the in-built thermometers and the fridge tags. The recommended temperature ranage was 2 to 8°C. Respondents did not trust the in-built thermometers and for the purpose of temperature monitoring, they relied on fridge tags. The inbuilt thermometer was used in the absence or on malfunction of the fridge tags.

Figure 4.2 summarises the refrigerators temperature readings by the fridge tags and the in-built thermometers. The temperatures on the fridge tags were lower than that of the inbuilt thermometer.

The median in-built thermometer reading was 6.5°C and ranged from 5 to 10°C. The median fridge tags temperatures reading was 4.75°C and ranged from 3.2°C to 6.4°C. The lowest and the highest temperature reading displayed on in built thermometer and fridge tags were 3 to 20°C and 1.2 to 17.2°C respectively.

There was no difference in the median temperature when a comparison was done across facilities. The temperature reading was above 8 °C in 10 (20%) and below 2°C in 2 (4%) of the facilities. These facilities were 4 health centers and 8 dispensaries.

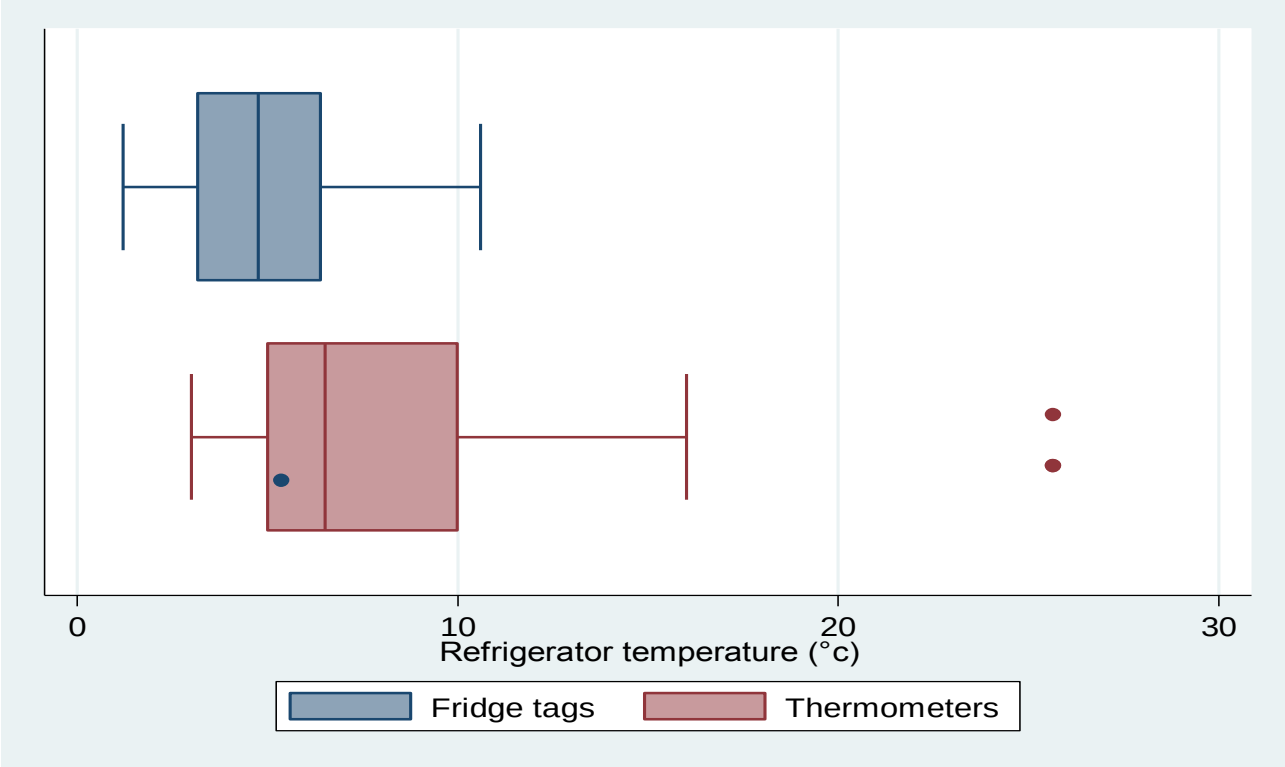

Figure 4. 2: Refrigerator temperature reading displayed by fridge tags and in-built thermometers

Freeze tags are used to determine if vaccines have been exposed to freezing conditions in the refrigerator. Freeze tags were available and working in 38 (76%) facilities. In these facilities with freeze tags, 30 (79%) had freeze tags in (√) 'ok' status and 8 (21%) facilities (4 health centers and 4 dispensaries) had freeze tags in the 'alarm' state (x). Freeze tags in the alarm state indicates that, at some point in time freezing had occurred in the refrigerators. All freeze tags that have reached alarm state cannot be used again unless they are recalibrated otherwise have to be replaced.

4.6.6 Cleanliness, defrosting and arrangement of vaccines and ice packs in refrigerators

A proper functional refrigerator is self defrost and does not gather excess ice that warrant defrosting. Despite that, it is recommended to thoroughly clean the refrigerators atleast once in every 3 months (and defrost if there is excess ice). Defrosting involves melting of the excessive ice that accumulates inside the refrigerators. In addition, vaccines should be arranged in good order for proper air circulation and avoidance of exposure to extreme heat and cold.

All facilities reported that they cleaned and defrosted their refrigerators at least once in a month. The frequency of cleaning and defrosting varied among facilities. It was done once a week in 26 (52%) of facilities; after every 2 weeks in 7 (14%) of facilities; once in a month in 13 (26%) of facilities and 4 (8%) of facilities defrosted and cleaned the refrigerators whenever required every month. Unfortunately, our study did not look on how cleanliness and defrosting was conducted. Reports of any defrosting is an indicator of a faulty refrigerator.

To ensure optimal temperature control, the two compartments of a refrigerator (freeze and fridge compartments) should be loaded with an adequate number of either frozen ice-packs and cool water/unfrozen ice packs. All ice/cool water containing packs (whether frozen or unfrozen) should be vertically arranged in the compartments to avoid leakage. The bottom side of the top open (chest) refrigerator is colder compared to the top.

Empty ice packs should be placed horizontally at the very bottom part of the refrigerator. This is called crisscross arrangement of ice and cool water packs. The purpose of this arrangement is to raise vaccines from the bottom basement of the refrigerator which is usually very cold compared to the upper part. This helps to avoid unexpected freezing of the vaccines.

All vaccines should be placed in the fridge compartment at facility level and surrounded by unfrozen ice packs (cool water packs). Frozen ice packs are melted (conditioned) and used in the vaccine carrier during immunization session. They are also used to maintain temperature inside the refrigerator in case of power blackout. Cool water packs, also called unfrozen ice packs in some publications, are kept together with vaccines in the refrigerating/fridge compartment.

We found that, all vaccines were kept in the fridge compartment as per requirements. However, there was poor compliance with regard to placement of ice packs in the freezing compartment. A total of 29 (58%) had not kept ice packs in this compartment. With regard to placement of cool water packs in the fridge compartment, 98% of facilities complied.

The vertical alignment of all cool water and ice containing packs varied greatly among facilities. Only 30 (60%) of the facilities placed the packs vertically.

No single facility kept empty ice packs horizontally at the bottom of the refrigerator as recommended; instead, 4 (8%) facilities had kept cool water packs to the bottom side of their refrigerator.

The number of ice packs (frozen and unfrozen) in the facility were limited such that, there was sufficient space left between the packs in all the 49 (98%) refrigerators that had vaccines.

In pharmaceutical inventory management, it is recommended that drugs, including vaccines should be arranged on the basis of First Expiry First Out (FEFO) and First In First Out (FIFO) principles so as to avoid unnoticed expiry of products. In a top-opening (chest) vaccine refrigerator, it is recommended to keep vaccines with closer expiry date on top and those with a longer expiry date at the bottom. It was observed that, the number of vaccines in every facility was small such that abiding to this recommendation of top-bottom arrangement was impractical. In addition, because of the small number of vaccines, FIFO principle was at all not used.

Facilities deployed varying methods for arranging vaccines by expiry date. This involved division of all the trays that had vaccines into two equal parts; and placement of vaccines with closer expiry dates on one side and those with further expiry date on the other part. This was a widely used technique in 45 (90%) of all the facilities. In addition, respondents reported that it was difficult for a vaccine to expire because they usually order and receive a small quantity that is sufficient to meet the immediate demand. This was evident because only in one health center we found a single vial of expired Human Papilloma Virus.

In a top-opening (chest) vaccine refrigerator, vaccines should be loaded in stacks from bottom to top depending on their heat and freeze sensitivity. The recommended order from bottom to top is as follows: Oral poliovirus vaccine (OPV), Bacillus Calmette-Guerin (BCG) vaccine, Measles Rubella (MR) vaccine, Rotavirus vaccine, Pneumococcal Conjugate Vaccine (PCV), Tetanus Toxoid (TT) vaccine, inactivated polio vaccine (IPV), Human Papillomavirus (HPV), Pentavalent vaccine and Hepatitis-B. Vaccines such as OPV, BCG and MR that are less sensitive to freezing/ freeze drying are kept at the bottom whereas, heat sensitive such as Pentavalent and Hepatitis-B vaccines are loaded at the top. This arrangement of vaccines was abided to by only 21 (42%) of the facilities. It was observed that, 9 (32.1%) of dispensaries, 18 (50%) health centers and 25% hospitals had a disorderly arrangement of vaccines with (deviation from standards). All health facilities placed vaccines in plastic perforated trays. The trays were labeled with names of vaccines.

The walls of the refrigerator are usually colder compared to space between them. Therefore, freeze sensitive vaccines should not be in direct contact with the linings.

Unfortunately, we found 8 (16%) of the facilities had placed either of pentavalent vaccine, tetanus toxoid and rotavirus vaccines in contact with the wallis. These vaccines were not placed on the trays that are normally used to hold them in the refrigerators.

4.7 Findings on inspection of vaccine carriers

In order to maintain the quality of vaccines upto the point of administration to clients, vaccines should be stored carefully throughout immunization service delivery. Vaccine carriers are used to temporary store the vaccines during immunization sessions. Vaccine carriers are lined with four conditioned ice packs (one in each side the box) to keep vaccines and diluents at optimal temperature. Inside the carriers, vaccines and diluents should be kept in the plastic bags to avoid direct contact with the ice packs. On top of the loaded box, conditioned ice packs and soft (foam pads) are fitted as a temporary lid to keep unopened vaccines cool. In addition, temperature control devices (fridge tag and freeze tag) are to be placed inside the carrier to monitor any temperature fluctuation.

In our study, all facilities we visited had at least one vaccine carrier box. The median number of vaccine carriers per facility was 2. Seven (14%) of facilities had more than 2 carriers and 26 (52%) of facilities had 2 carriers. The maximum number of vaccine carriers in a single facility was 4. The difference in number of vaccine carriers by facility type was not statistical significance (p =0.436).

Twenty-two (44%) facilities were offering immunization services at the time of study visit. These facilities had carriers loaded with vaccines. All their carriers had cool waterpacks. The median number of ice packs in the carriers was 4 and ranged from 3 to 4. There were 8 (36.4%) facilities that had less than 4 ice packs contrary to the WHO requirement. The facilities which failed to comply were 6 dispensaries and 2 health centers.

We found that, 20 (90.9%) out of the 22 facilities whose carriers were loaded with vaccines, placed their vaccines in contact with the ice packs. In addition, no single facility, monitored the temperature inside the carrier during immunization service; neither a fridge tag nor a freeze tag was placed together with the vaccines. We also noted that, 9 (18%) of the facilities had no foam pad(s) in their carriers. These were significant deviations from the WHO requirements.

4.6.4 Availability and state of vaccines

The Tanzanian immunization programme, requires every facility to have in stock 9 types of vaccines. These vaccines are closely monitored and are therefore called tracer vaccines. These vaccines are; oral polio vaccine (OPV), inactivated polio vaccine (IPV), Bacillus Calmette-Guerin (BCG), Pneumococcal Conjugate Vaccine (PCV), Tetanus Toxoid vaccine, Rotavirus vaccine, Measles Rubella (MR) vaccine, Human Papillomavirus (HPV) vaccine and diphtheria-tetanus-pertussis-hepatitis B-Haemophilus influenzae type b (DTP-hepB-Hib) vaccine. In addition, other vaccines provided are; Hepatitis B vaccine and rabies vaccine.

The availability of tracer vaccines is presented in Figure 4.4. All the tracer vaccines were available in only 8 (16%) of the facilities. Health centers were mostly affected by stock-outs with only 7.1% of them stocking all these vaccines. Almost quarter (25%) of hospital and dispensaries had the tracer vaccines. The vaccines that were least likely to be available are rabies and Hepatitis B vaccines. These vaccines were available in only 2 and 12% of the facilities respectively. Among the tracer vaccines, Measles Rubella and oral poliovirus vaccines in were available in majority of facilities except in 11 (22%) and 15 (30%) of the facilities respectively.

The most widely available vaccines were; Human Papillomavirus vaccine and Tetanus Toxoid vaccine in 96% of facilities. All the facilities (100%) had Bacillus Calmette-Guerin vaccine, Pneumococcal Conjugate Vaccine, Rotavirus vaccine and pentavalent vaccines.

There were no statistically significance differences in the availability of the vaccines by type of health facility.

The state of vaccines was assessed by looking at the vaccine vial monitors (VVM), expiry date, checking of physical damage and registration status. The results are presented in Table 4.4.

Vaccine vial monitors (VVM) are visual techniques used to assess if vaccines have been exposed to extreme temperature. The monitors are attached on each vaccine vial. They change colour on exposure to extreme temperature.

The colour change occurs by progressive darkening of the inner square in four phases (stages). In a well-controlled cold chain, VVM remain in their initial phase (stage 1) throughout its life time. Stage 2 is indicative of some degree of deterioration of the vaccines due to malpractice in the cold chain. At this stage, it is recommended to use vaccines immediately. Stage 3 and 4 is

indicative that, the vaccine has been damaged by temperature and its contents have deteriorated. It is recommended not to use vaccines at these stages; they should therefore be discarded.

Our study observed that, 26 (52%) of the facilities had all vaccines at VVM stage 1, a total of 23 (46%) of the facilities had some vaccines at VVM stage 2 and only 1 (2%) of the facilities had one vaccines at VVM stage 3.

The vaccine vial monitors of inactivated polio vaccine, rotavirus vaccine, Tetanus Toxoid vaccine and pentavalent vaccines (less heat sensitive but more freeze sensitive) were at stage 2 in 16 (32%), 12 (24%), 4 (8%) and 1 (2%) of the facilities respectively.

One vial of oral poliovirus vaccine (most heat sensitive) was at stage 3 in 1 (2%) of the facilities (a health centre). In addition, there was one vial of expired vaccine (human papilloma virus (HPV) vaccine) in 1 health centre.

While all the vaccines in the hospitals were at stage 1, half (50%) of dispensaries and health centers had some vaccines at VVM stage 2 and one health center had oral poliovirus vaccine at stage 3. Respondents complained that, they are often supplied with vaccines at stage 2 from city vaccination office.

The 2 vials of unfit vaccines (expired and VVM stage) required disposal, we asked on why they had not been disposed, respondents said that, there is a functional waste disposal system. The facility is required to list unfit items to be disposed and then apply online to the Tanzania Medicine and Medical Device Authority (TMDA). On receiving the application TMDA arranges disposal in consultation with the National Environmental Management Council (NEMC) and City Health Department.

Fortunately, all vaccines in all healthcare facilities visited had been registered by the National Medicine Regulatory Authority.

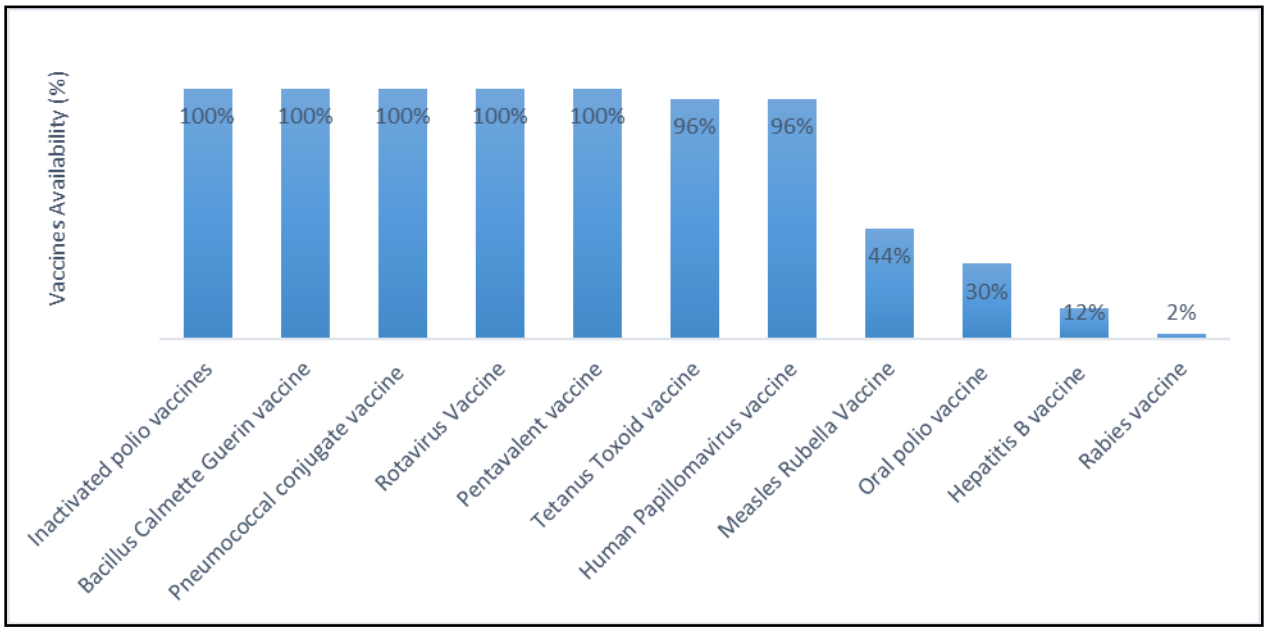

Figure 4. 3: Availability of vaccines in health facilities

Table 4.4: The state of deterioration, expiry and registration of the vaccines across types of health facilities in Arusha City (N=50)

Type of Health Facility	**Hospitals (N=4)** n (%) or median [IQR]	**Health centers (N=18)** n (%) or median [IQR]	**Dispensaries (N=28)** n (%) or median [IQR]	**Total (N=28)** n (%) or median [IQR]	**P value**
Vaccine vial monitor (VVM) stages					
Stage 1	4 (100%)	8 (44.4%)	14 (50%)	26 (52%)	0.193
Stage 2	0 (0.0%)	9 (50%)	14 (50%)	23 (46%)	
Stage 3	0 (0.0%)	1 (5.6%)	0 (0.0%)	1 (2%)	
Rota virus vaccines at VVM stage 2					
Yes	0 (0.0%)	4 (22.22%)	8 (28.57)	12 (24%)	0.607
No	4 (100%)	14 (77.78%)	20 (71.43%)	38 (76%)	
Inactivated polio vaccine at VVM stage 2					
Yes	0 (0.0%)	7 (38.89%)	9 (34.62%)	16 (32%)	0.472
No	4 (100%)	11 (61.11%)	19 (65.38%)	34 (68%)	
Tetanus Toxoid vaccine at VVM stage 2					
Yes	0 (0.0%)	0 (0.0%)	4 (14.29%)	4 (8%)	0.275
No	4 (100%)	18 (100%)	28 (100%)	46 (92%	
Pentavalent vaccine at VVM stage 2					
Yes	0 (0.0%)	0 (0.0%)	1 (3.57%)	1 (2%)	1.000
No	4 (100%)	18 (100%)	27 (96.43%)	49 (98%)	
Oral Poliovirus vaccine at VVM stage 2					

Yes	0 (0.0%)	0 (0.0%)	1 (3.57%)	1 (2%)	1.000
No	4 (100%)	18 (100%)	27 (96.43%)	49 (98%)	
Oral Poliovirus vaccine at VVM stage 3					
Yes	0 (0.0%)	1 (5.56%)	0 (0.0%)	1 (2%)	0.440
No	4 (100%)	17 (94.44%)	28 (100%)	49 (98%)	
Expired vaccines					
None	4 (100%)	17 (94.4%)	28 (100%)	49 (98%)	0.40
Found	0 (0.0%)	1 (5.6%)	0 (0.0%)	1 (2%)	
Damaged vaccines					
None	4 (100%)	17 (94.4%)	28 (100%)	49 (98%)	0.40
Found	0 (0.0%)	1 (5.6%)	0 (0.0%)	1 (2%)	
All vaccines registered					
Yes	4(100%)	18(100%)	28(100%)	50(100%)	
No	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	

Inferential tests used; Fischer's exact for categorical variables.

4.8 Knowledge of respondents on vaccine cold chain management

4.8.1 Aspects of knowledge on storage and management of the cold chain

Our study noted that, respondents had different levels of knowledge on various aspects of storage and cold chain management of vaccines. We divided knowledge scores in three (3) categories on the basis of the proportion of respondents who gave correct responses on a particular knowledge parameter.

The first sets of items are those whereby less than 50 of respondents gave correct responses. These represented areas of significant knowledge gaps and may need to be addressed. They other items in the questions are grouped into those where correct responses were provided by between 50-75% and more than 75% of respondents. The knowledge scores are presented in the Figure 4.4.

All respondents (100%) correctly stated that, extreme heat can reduce vaccine potency. Nearly all the respondents knew about the the multi dose vial policy as 49 (98%) of them agreed that there are vaccines that can be used up to 28 days from the time that the vials are first opened. A significant proportion 49 (98%) of respondents were aware that, the required temperature for storage of most vaccines is 2-8°C.

Most of respondents (96%) were aware that, temperature recording devices should be placed centrally in the vaccine storage equipment. Majority of respondents 48 (96%) were aware that opening the refrigerator more than 3 times in a day can affect the quality of vaccines. On impact of freezing on vaccines, 88% of respondents agreed that, extreme cold can reduce vaccine potency and the same proportion (88%) of respondents agreed that, freeze sensitive vaccines (pentavalent and hepatitis B) cannot be frozen. The use of domestic refrigerators to store vaccines was stated as inappropriate by 88% of respondents.

Eighty-four percent of the respondents were aware of maximum duration of use of vaccines such BCG and MR that are reconstituted at the facility. They correctly stated that reconstituted vaccines cannot be used for up to 1 day. Eighty-two percent of the respondents knew that storing other medicines together with vaccines in the refrigerator can affect vaccine quality. Seventy-six (76%) of respondents disagreed that, diluents cannot be kept at room temperature.

A large proportion (74%) of respondent had knowledge that frozen ice packs should be conditioned before they are used in cold boxes or vaccine carriers. Seventy-two percent (72%) of respondents agreed that, freeze tags are used to determine if vaccines have been exposed to temperatures less than 0°C during storage and transport. It was worrying that, only 68% agreed that, exposure of some vaccines to light can affect their quality. Sixty-four percent (64%) of respondents correctly ruled out that, an ice lined refrigerator cannot keep thetemperature at 2-8°C for 1 day during power outage. Sixty-two percent (62%) of respondents agreed that, the quality of vaccines can be affected by the status of a storage equipment. Sightly more than half (54%) of the respondents were conversant with the fact that, reading and recording temperature has to be done twice a day; they declined that it can be done only once a day.

Few respondents (<50%) had correct knowledge on on the use of vaccine vial monitor (VVM) to determine exposure of vaccines to extreme temperature, respondents incorrectly stated that the VVM is used to determine if a vaccines have been frozen. Minority of respondents (42%) were well informed that, food stored with vaccines can affect the quality of vaccines. Only 42% knew that the minimum number of ice packs (4) required to be placed in vaccine carrier; the rest thought that, 2 or 3 icepacks placed in the carrier are enough to keep vaccines safe. The concept that, there are vaccines which can be frozen was hardly known by respondents; only 36% were aware that, BCG, MR and OPV vaccines can be frozen. The knowledge that, ice lined

refrigerators (ILR) can keep temperature at 2-8°C for not more than 16 hours seemed not well understood as 36% agreed that, these kind of refrigerators can keep temperature at 2-8°C for up to 1 day. Only a small proportion (34%) of respondents knew that quantity of vaccines and diluents placed in a storage device can effect temperature in that device.

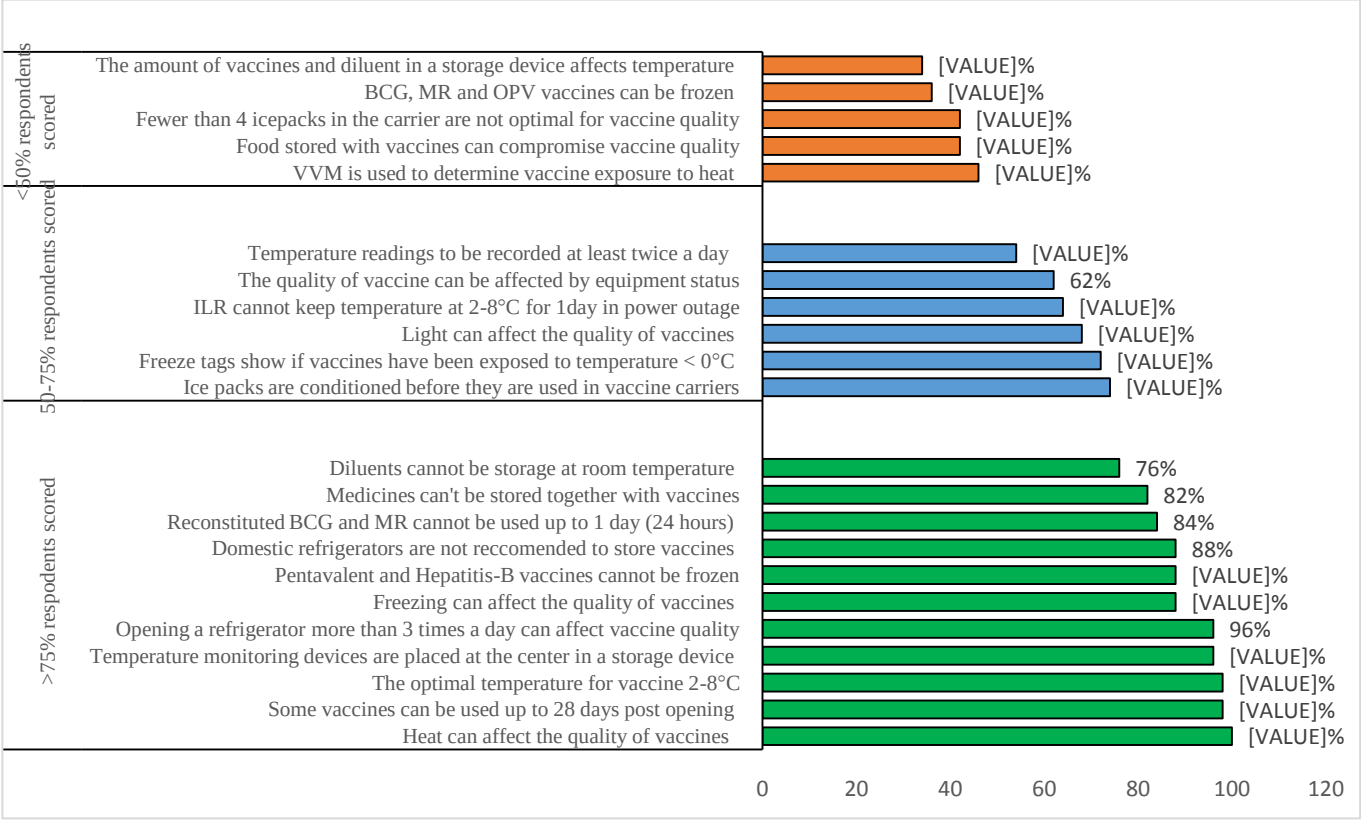

Figure 4. 4: Proportion of respondents who scored correctly on various aspects of vaccine cold chain management

4.8.2 Determinants of the overall knowledge score

The overall knowledge of respondents regarding cold chain management was satisfactory. The mean score was 71.6% with a standard deviation of 10.9%. The minimum score was 50% and the maximum score was 90.9%. A total of 20 (40%) scored above 74%.

Exploratory data analysis was conducted to determine how the mean score varied across sub-groups and the findings are presented in Table 4.5. The mean score of respondents working in the hospitals was higher (80.7%) compared to those in health centers (69.4%) and dispensaries (71.6%). Male respondents outscored female with the mean score of 74.7% and 71.4%

respectively. Respondents aged ≥40 years had a mean score that was slightly higher (73.1%) compared to those aged 20 - 39 years (70.2%). Personnel who were main cold chain handlers had better a mean score (72.5%) compared to personnel who respondended on behalf of the key persnnel (68.2%).

Knowledge on storage and cold chain management of vaccines among respondents appeared to increase as duration of working experience increased. Respondents who had worked for less than 3 years had a mean score of 69.8% compared to 71.2% and 78.6% for those worked 3-10 years and more than 10 years respectively.

Training appeared to increase the level of knowledge among respondents. Respondents who had been trained on storage and cold chain management of vaccines scored 73.1% compared to those not received training who scored 67.9%.

The score varied by cadre. Clinical officers scored the highest with a mean of 77.3% while the mean score for assistant nursing officers was 72.9%. Medical attendants scored more than nurses with a mean of 72.7% and 68.5% respectively. The mean duration of working experience of medical attendants was 10 years as opposed to nurses who had a shorter duration of work experience (4.6 years).

Table 4.5: The mean knowledge score of respondent involved in vaccines cold chain management by socio-demographic characteristics

Description of a variable		% Score Mean(sd)	P value
Facility type	Hospitals	80.7 (10.1)	0.176
	Health centres	69.4 (10.9)	
	Dispensaries	71.8 (10.7)	
Gender	Male	74.7 (6.3)	0.214
	Female	71.1 (11.4)	
Age (years)	<40 years	70.2 (10.9)	0.174
	≥40 years	73.1 (10.8)	
Respondent role	Cold chain handler	72.5 (11)	0.132
	Personnel on behalf	68.2 (10.9)	
Duration of working experience (years)	<3 years	69.8 (11.1)	0.176
	3 - 10 years	71.2 (11.1)	
	>10 years	78.6 (7.3)	
Training Status	Trained	73.1 (10.8)	0.063
	Not trained	67.9 (10.5)	
Education Qualification	Assist Nursing Officer	72.9 (9.9)	0.592
	Nurse	68.5 (12.9)	
	Medical Attend	72.7 (12)	
	Clinical Officer	77.3	

We conducted linear regression analysis to determine the predictors of knowledge score among respondents. The results are presented in Table 4.6. On simple linear regression, there was no statistical significance association between knowledge score and all but 2 covariates. A statistical significant positive association was observed between duration worked and the knowledge score (crude beta coefficient 0.507, 95% CI (0.206, 0.809; p=0.001) and between training site (whether in service or out of service) and knowledge score (crude beta coefficient 12.009, 95% CI (0.155, 23.864; p=0.047).

When we conducted multivariate linear regression analysis, the key predictor variables appeared to be the same as in simple linear regression; duration of working experience in year and the site were training was conducted whether in house (in service/on job) or out of job with (adjusted beta coefficient 0.368, 95% CI (0.037, 0.699; p= 0.030), and (adjusted beta coefficient 11.069, 95% CI (0.223, 21.915; p=0.046) respectively.

Table 4.6: Linear regression analyses for Predictors of respondents' knowledge scores on vaccine cold chain handling

Predictor variable(s)	Bivariate regression		Multivariate regression	
	Crude β (95% CI)	P-values	Adjusted β squared (95% CI)	P-values
Type of Facility	-1.607 (-6.504, 3.290)	0.513	-	-
Facility ownership	-0.955 (-5.585, 3.675)	0.680	-	-
Supportive Supervision	1.264 (-7.160, 9.688)	0.764	-	-
Training status	5.251 (-1.371, 11.873)	0.117	-	-
Age	0.582 (-0.180, 0.296)	0.626	-	-
Role	-4.335 (-11.342, 2.672)	0.220	-	-
Qualification	-0.969 (-5.132, 3.195)	0.642	-	-
Experience	0.507 (0.206, 0.809)	0.001	0.368 (0.037, 0.699	0.030
Gender	-3.543 (-9.301, 2.214)	0.222	-	-
Training site	12.009 (0.155, 23.864)	0.047	11.069(0.223, 21.915)	0.046
Time since last training	-0.241 (-2.219, 1.737)	0.806		

4.9 Respondents attitude toward storage and cold chain management of vaccines

There were three (3) dimensions of respondents' attitude toward storage and cold chain management of vaccines. These dimensions are attitude toward self-efficacy and motivation to do work, attitude toward resources and felt need for training and attitude toward quality of vaccines.

4.9.1 Attitude toward self-efficacy and motivation to do work

Self efficacy and motivation (work engagement) are intrinsic attitude (internal beliefs) of respondents. These include the respondents' confidence in the knowledge and competence they have and their motivation to work. It is reflected in practices such as concern about damaged vaccines and the stated confidence in their knowledge and self-motivation. We included a question on satisfaction with supportive supervision given that, studies have shown there is a positive association between self efficacy, supportive supervision and motivation to work (work engagement) (82).

All respondents had confidence on the knowledge they had on storage and cold chain management of vaccines, 19(38%) agreed and 31(62%) strongly agreed. A large proportion 47

(94%) of participants were concerned whenever a vaccine gets damaged. Out of 47 respondents, majority 29(58%) stated they were very concerned and the remaining 18(36 %) stated simply that they were concerned. Unfortunately, 2(4%) were not concerned on vaccine damaged. A large number 47 (94%) of respondents were highly motivated to work as cold chain handling staff; 1 individual (2%) was not sure about her/his level of motivation; and 2 (4%) were not motivated were not motivated. A high proportion 48 (96%) of respondents believed that, the level of supportive supervision they receive from city and regional vaccination officers is adequate. The belief was stronger in 60.4% (29 out of 48) of respondents compared to rest 19 (39.6%).

Unfortunately, supportive supervisory visits were part of general administrative visits on immunization services and did not only focus on cold chain management which made them less effective. Supportive supervisory visits were reported to comprise a mixture of educations on vaccine storage, documentation and administration procedures.

The responses to questions related to intrinsic attitude on self-belief and motivation of respondents to work in the vaccine cold chain were correlated (correlation coefficients from 0.438 to 0.587) which is considered significant and moderate (83,84). The correlation coefficients (spearman's rank correlation) are presented in the Table 4.7**.**

Table 4.7: Correlation Matrix of the responses to questions on Self efficacy and Motivation

	I have confidence on knowledge I have on vaccine cold chain management	**Highly motivated to work as cold chain handler**	**Concerned about damaged vaccines**	**Adequate supportive supervision**
I have confidence on my knowledge	1.000	-	-	-
Highly motivated to work in cold chain	0.438*	1.000	-	-
Concerned about damaged vaccines	0.485*	0.470*	1.000	-
Adequate supportive supervision	0.516*	0.587*	0.515*	1.000

The responses to 4 questions on self-efficacy and motivation were added to obtain a maximum score of 20. A histogram of the total score is presented in Figure 4.5. The intrinsic attitude (internal self-belief) of respondents and motivation to work as cold chain handling staff, was generally high (Figure 4.6). A small proportion of respondents 7 (14%) scored 60-75% while the

rest scored above 80%. This meant that, respondents had confidence in the knowledge they have on cold chain issues, were very motivated to work and believed that the supportive supervision they received was adequate.

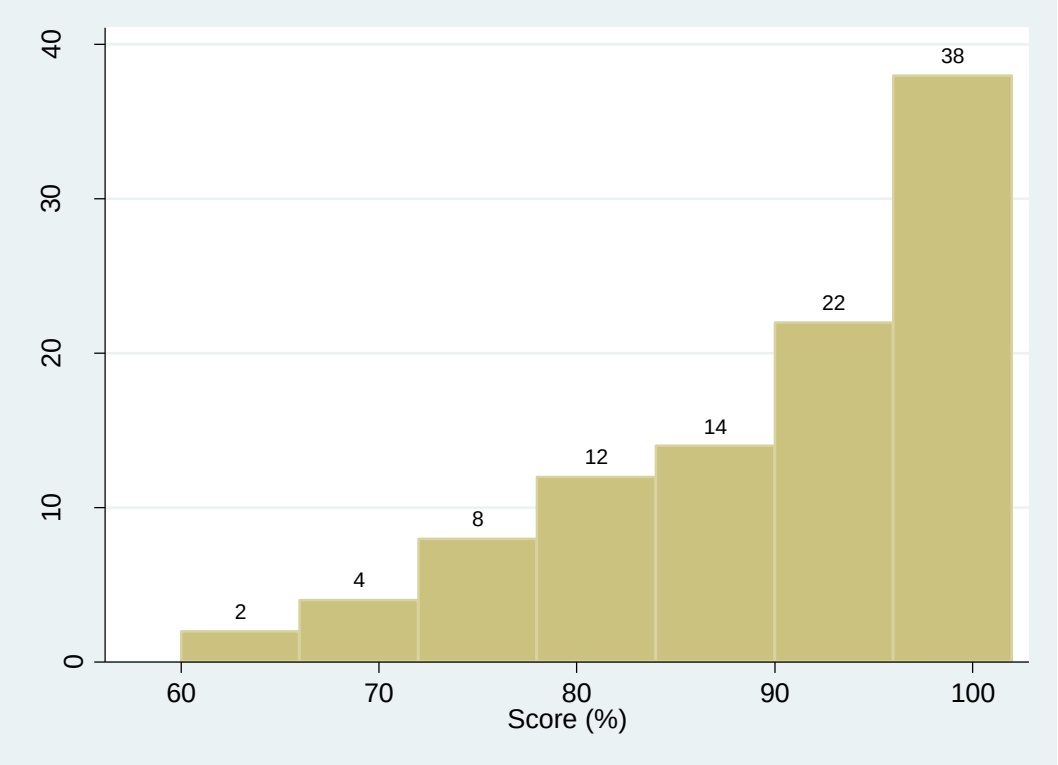

Figure 4. 5: Histogram of respondents' score for attitude on self-motivation and efficacy

We conducted both simple and multivariate linear regression analysis with robust estimation to determine the predictors of the score on attitude towards self-efficacy and motivation to work as cold chain handling staff.

Simpe linear regression resulted in to lack of statistical significance in all but four variables **(Table 4.8).** A statistical significant relationship was observed between the scores and age (crude beta coefficient 0.248, 95% CI (-0.016, 0.480; p=0.037); between score and and working experience in years (crude beta coefficient 0.476, 95% CI (0.199, 0.753; p=0.001); between score

and in service training versus (not trained and out job training) (crude beta coefficient 6.986, 95% CI (0.564, 13.408; p=0.034); and between the score and Health centers versus other types of health facilities (hospitals plus dispensaries) (crude beta coefficient 6.788, 95% CI (0.555, 12.022; p=0.012).

Table 4.8: Linear regression analysis for Predictors of respondents' self efficacy and motivation to work as cold chain handling staff

Predictor variable	Crude β (95% CI)	P-values	Adjusted β (95% CI)	P-values
Gender	0.116 (-7.780, 8.032)	0.977	-	-
Age	0.248 (-0.016, 0.480)	0.037	-	-
Role	-0.750 (-7.450, 5.950)	0.823	2.941 (-4.173, 10.056)	0.409
Qualification	2.966 (-0.258, 6.190)	0.071	3.336 (0.518, 6.154)	0.021
Experience	0.476 (0.199, 0.753)	0.001	2.774 (1.450, 4.098)	<0.001
Training site	-5.000 (-11.616, 1.616)	0.134	-	-
In service training versus (not trained and out job training)	6.986 (0.564, 13.408)	0.034	13.137 (7.199, 19.075)	<0.001
Training status	7.083 (-0.170, 14.337)	0.055	-	-
Time since last training	-1.656 (-3.464, 0.155)	0.072	-	-
Facility ownership	-1.331 (-4.905, 2.244)	0.458	-	-
Supportive Supervision	-5.326 (-12.388, 1.736)	0.136	-	-
Type of Facility	-1.339 (-6.698, 4.022)	0.618	-	-
Health centers versus (hospitals and dispensaries)	6.788 (1.555, 12.022)	0.012	5.186 (0.520, 9.852)	0.030
Interaction term between role and experience	-	-	-2.238 (-3.446, -1.030)	0.001

Multivariate linear regression revealed that self efficacy and motivation were dependent on role, qualifications, working experience, type of health facility, training status and site. In addition, there was observed interaction between role and working experience.

There was a very strong positive associative between the score and having had received training on cold chain handling in service as opposed to out of service training and no training at all (adjusted β coefficient = 13.137, 95% CI (7.199, 19.075; p=<0.001). Respondents trained at their working place (in service) had better attitude toward self-efficacy and motivation compared to those trained out of their working (out of job) and those not trained.

The median score was 100% for those trained in service trained, 95% and 85% and for those who received off-site training and those who were not trained respectively.

With regard to the type of facility, respondents in health centers had the higher scores on self-efficacy and motivation compared to those in hospitals and dispensaries (adjusted β coefficient = 5.186 95% CI (0.520, 9.852; p=0.030). There was a positive correlation between qualification and the score on attitude towards self-efficacy and motivation (adjusted β coefficient = 3.336 (0.518, 6.154; p=0.021).

We found a statistical significant interaction between the variables, role and work experience in years. Personnel working as main cold chain handling staff or working on behalf of him acted as an effect modifier. It was evident that, if cold chain was one's primary responsibility, as years of working experience increases, self-confidence and motivation to work in the cold chain increases. However, if it is an-add on responsibility as they worker longer on a job, their self-efficacy and motivation to work in the cold chain decreased. Figure 4.6 illustrates the effect measure modification (interaction) between role and experience

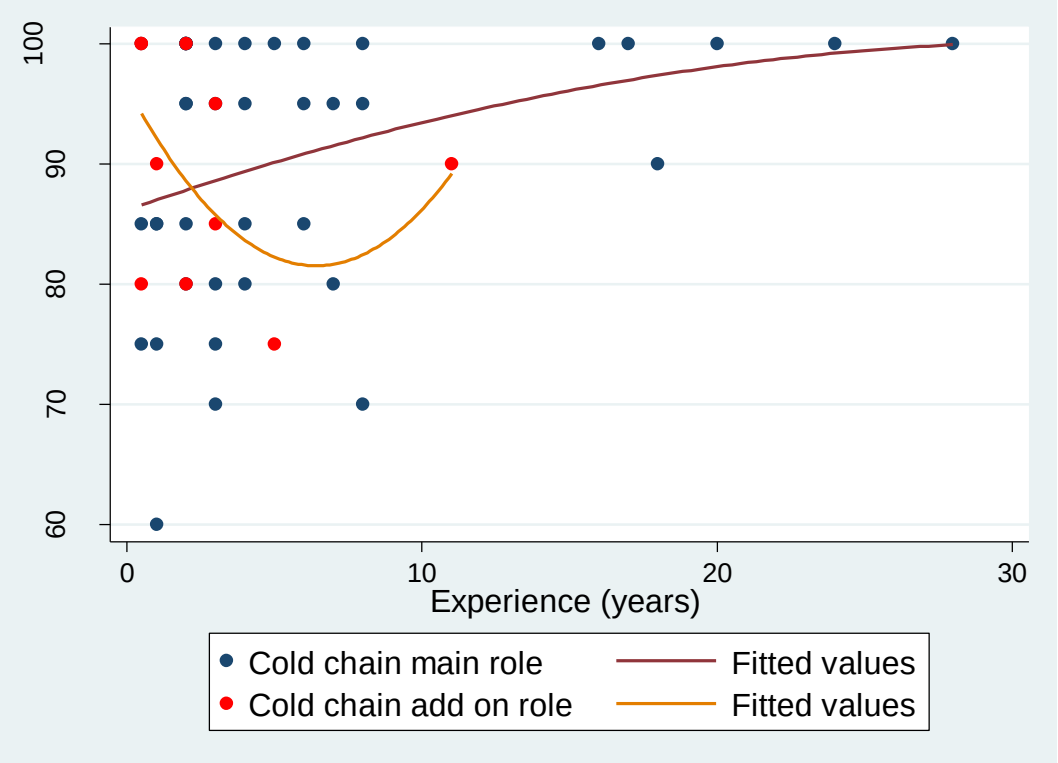

Figure 4. 6: Effect measure modification (interaction) between role and experience

4.10 Attitude toward adequacy of resources and need for training

There were three questions that reflected the respondents' attitude towards the availability of resources to conduct their work and adequacy of training that they are received. The question on if cold chain handling was an add-on activity reflected the attitude towards the adequacy of the work force or rational distribution of responsibilities. There was a moderate positive correlation between the attitude that resources were inadequate and cold chain handling was an add-on activity (spearman's rho = 0.573) Table 4.9.

Table 4.9: Spearman's rank correlation of responses to questions on resource availability

	Need for extra training	Cold chain as an add on activity	No adequate resource
Need for extra training	1.0000		
Cold chain as an add on activity	0.2310	1.0000	
No adequate resource	0.238	0.5727*	1.0000

The sum of the responses to the 3 questions on adequacy of resources was obtained and the overall percentage score obtained. A histogram of the responses is presented in Figure 4.7.

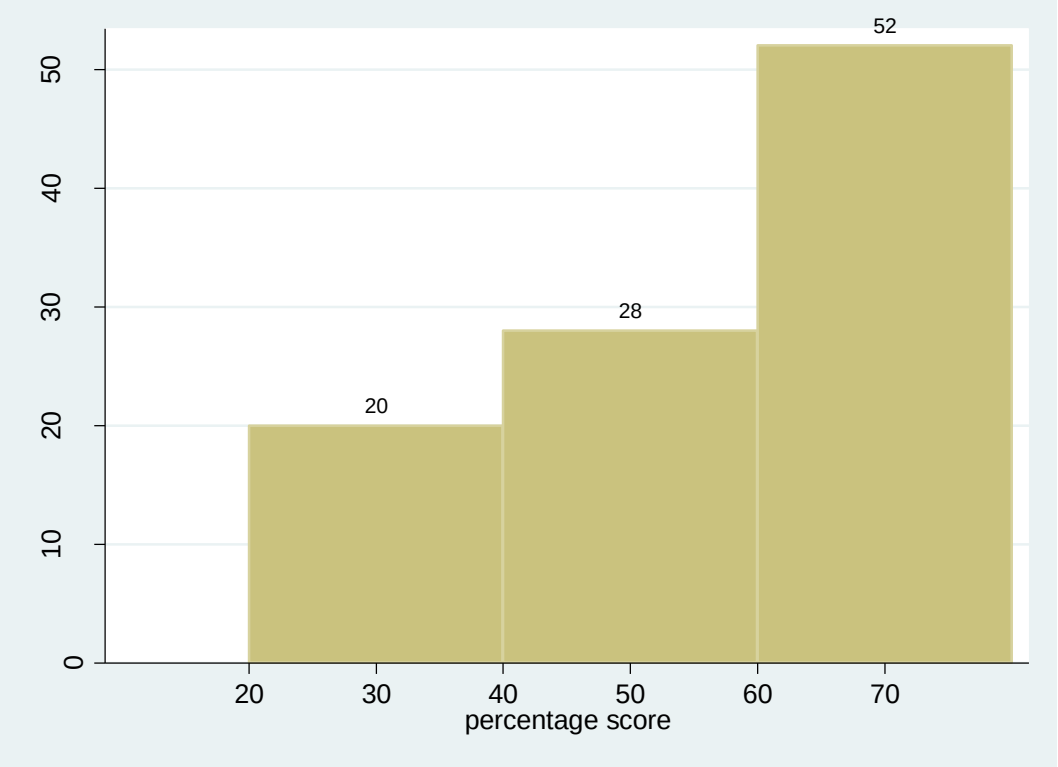

Figure 4. 7: Histogram of respondents' scores for attitude on adequacy of resources and need for extra training

The attitude toward resources and need for training was right skewed with about half (52%) respondents scoring above 60% to 80%. There were no any single respondents who scored above 80%, This is contrarily to attitude on self-efficacy and motivation were nearly 80% of the respondents scored above 80%. This implies that human, training and material resources could be a measure source of concern (show median and IQR).

Linear regression analyses were conducted to identify risk factors for the attitude towards availability of resources. The key predictors for attitudes towards availability of adequate resources are presented in Table 4.10.

Table 4.10: Linear regression analyses for predictors of attitude towards availability of adequate human and material resources and the need for training

Predictor variable	Crude β (95% CI)	P-values	Adjusted β coeff (95% CI)	P-values
Gender	10.588 (-2.430, 23.605)	0.109	-	-
Age	0.279 (-0.102, 0.660)	0.147	-	-
Role	0.999 (-10.955, 12.952)	0.867	-	-
Qualification	-1.885 (-8.611, 4.841)	0.576	-	-
Experience	1.262 (0.794, 1.730)	<0.001	-4.679 (-8.693, -0.665)	0.023
Training site	-6.668 (-21.885, 8.550)	0.380	-	-
Training status	8.016 (-4.023, 20.056)	0.187	-	-
Time since last training	-0.115 (-3.378, 3.147)	0.943	-	-
Type of Facility	-0.625 (-9.769, 8.520)	0.891	-	-
Facility ownership	6.517 (0.032, 13.002)	0.049	5.472 (-0.517, 11.462)	0.072
Supportive Supervision	20.507 (2.660, 38.355)	0.025	-10.490 (-42.699, 21.716)	0.515
Interaction term between supportive supervision and experience	-	-	5.953 (1.908, 9.998)	0.005

On both simple and multivariate linear regression, the attitude toward resources and need for training was determined to depend on type of facility ownership (whether government, private or Faith Based Organization), Supportive supervision whether conducted a year before or not and duration of years worked in the vaccine cold chain. There was a positive association between the score on attitude toward resources and need for training and the type of facility ownership (adjusted β coefficient = 5.472 (0.517, 11.462)). The participants drawn from Faith Based Organizations were the most satisfied followed by those in the private and government facilities. The median score of respondents working in the government facilities was the lowest 50 [33.33, 66.67] compared to those in the private facilities 60 [46.67, 66.67]. Respondents working in facilities owned by Faith Based Organizations had the highest median score 66.67 [46.67, 73.33].

We also found an interaction relationship between supportive supervision and duration of working experience. The p value of the interaction term was 0.005, to understand the nature of the interaction we plotted two separate scatter plots of duration of working experience against score on satisfaction with resources and need for training. The findings are presented in Figure 4.8. From the graph we found that, there was a positive association between duration worked and

the satisfaction score for respondents who stated that, they received adequate supportive supervision. On the other hand, we observed a negative association for respondents who stated that they did not receive adequate supportive supervision. This meant that, the longer they worked the less satisfied they were with the resources availed to them.

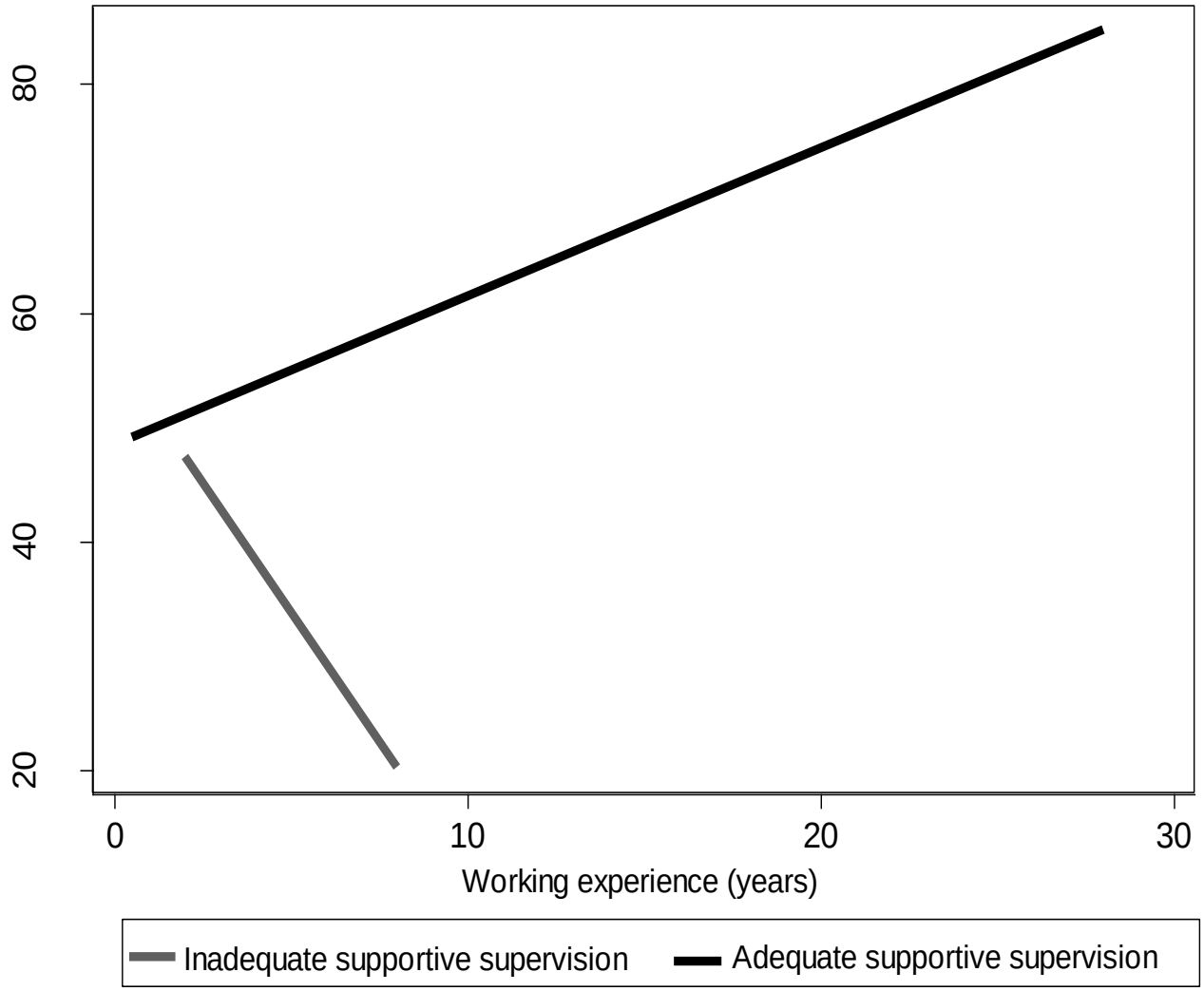

Figure 4. 8: Effect measure modification (interaction) between supportive supervision and duration of working experience (years) in the vaccine cold chain.

4.11 Attitude toward the quality of vaccines administered

All respondents were confident that the vaccines they administered to clients were of good quality. The level of confidence for the majority of respondents 41 (82%) was higher compared to others (9, 18%). The binary outcome of the attitude score on the confidence toward quality of vaccines was those who strongly agreed and those who just agreed.

Logistic regression with robust estimation analyses were conducted to identify risk factors for the attitude towards the quality of vaccines administered. The key predictors for this attitude are presented in Table 4.11. There was no statistical significant association between the covariates and the outcome meaning that there were other variables that explain confindence in the quality of vaccines (a measured confounding).

Table 4.11: Logistic regression analyses for predictors of attitude towards the quality of vaccines administered

Predictor variable	Crude OR (95% CI)	P-values
Gender	2.057 (0.324, 13.049)	0.444
Age	1.032 (0.969, 1.099)	0.328
Role	0.848 (0.145, 4.975)	0.856
Qualification	0.837 (0.383, 1.829)	0.655
Experience	1.035 (0.913, 1.174)	0.589
Training site	1.000	-
Training status	1.364 (0.290, 6.415)	0.695
Time since last training	0.792 (0.474, 1.326)	0.376
Type of Facility	0.790 (0.288, 2.167)	0.648
Facility ownership	1.092 (0.476, 2.505)	0.835
Supportive Supervision	1.000	-

4.12 Respondents Self Reported Practices in the cold chain management of vaccines

Respondents were asked whether they complied with a number of good practices. The results are presented in Figure 4.9 and are as described.

Nearly all respondents 48 (96%) reported they routinely check the status of freeze tags before any vaccine is dispensed and 1 (2%) reported to forget in some cases.

A vast of respondents (90%) reported to use vaccine vial monitors (VVM) to check the quality of vaccines; 86% reported they check the VVM always before the vaccine is administered with 4% admitting to sometimes forgetting and 2% rarely checked the VVM. However, the fact that 46% and 2% of facilities did not notice that, some vaccines in their refrigerators were in stage 2 and 3 respectively depicted that, vaccine vial monitors are rarely checked. Therefore, respondents' self reported compliance to this practice did not reflect real situation. Respondents complained that, they receive some vaccines when they were already at stage 2.

The abidance with First In First Out principle (FIFO) was generally good. A total of 84% of respondents declared they always issue and use earliest received batches of vaccines and 2% admitted to forget to do so sometimes. Six percent (6%) of the respondents stated that they did not practice FIFO. In addition, respondents reported that they usually order and receive small quantities of vaccines such that there was no real need to adhere to FIFO. We found that, only 1 health center had a single vial of expired Human Papilloma Virus. This provided some evidence that, expiration of vaccines rarely occurred.

The respondents were asked whether they reported to their superiors, defective or damaged vaccines. Most of respondents were attentive to report to their superiors once they notice a defective/damaged vaccine. The level of commitment to give reports was higher in 80% respondents who declared to always report any damaged vaccine compared to 4% respondents who missed in some cases and 16% who acknowledged to report rarely.

A large proportion of respondents (76%) reported to always arrange ice packs in a crisscross pattern inside the refrigerator, a further (8%) of them reported to abide with the pattern in most cases. A small proportion of respondents (8%) hardly arranged ice packs in that pattern. The rest did not arrange in that pattern and some were not sure if they arrange in that pattern. Once we observed the icepacks in the refrigerators, we found that, the numbers were such small that, it was difficult to attain the criss-cross arrangement.

It is recommended that, all vaccines at primary facility level should be placed in the fridge compartment. Sixty-four percent (64%) reported to stongly adhere to this practice and 2% rarely keeps vaccines in the freezer compartment.

There were 4% respondents who were not sure whether they kept vaccines in the freezer compartment or not and 30% strogly agreed to keep vaccines in the freezer compartment. In real practice, we found that, all vaccines were kept in the fridge (refrigerating) compartment as per requirements.

Sixty-two (62%) reported to suspended use of freeze sensitive vaccines until the shake test is conducted if they found freeze tags in alarm state. Fifty-six (56%) strongly compared to the others (6%). Unfortunately, 32% reported that they continued to use their vaccines regardless of whether the freeze tag is in an alarm state and 6% were not sure. In real practices, we found that, out of 38 facilities with freeze tags, 8 facilities had their freeze tags in the alarm status. These 8 facilities still used freeze sensitive vaccines. The proportion of respondents who reported to always carry out shake tests after coming across with freeze tag in alarm state to determine if vaccines have frozen was 54% with 16% occasionally forget. Unfortunately, there was no any report of the shake tests conducted. Contrary to the WHO recommendations, it seems that freeze sensitive vaccines whose freeze tags are in the alarm state are routinely used.

Half of the respondents (50%) stated they use cool water packs during transportation and storage of oral poliovirus vaccines; of which 44% gave strongly affirmation than the rest (6%). Thirty-eight (38%) strongly declines to use cool water packs in handling oral poliovirus vaccines, they reported to use frozen ice packs. There were 12% who were not sure what type of water/ice packs they used.

The respondents were asked on what they did with vaccines whose vaccine vial monitots had reached 2. Forty percent (40%) reported that they used the particular vaccine(s) immediately. A significant proportion (50%) of respondents reported that, they discarded (not used) any vaccine at stage 2. Ten percent (10%) were not sure what was to be done. It is recommended that, any vaccine at VVM stage 2 should be used immediately. From the observations of the researcher, this was rarely practised as a large number of facilities (46%) had a lot of vaccines in VVM stage 2 inside their refrigerators.

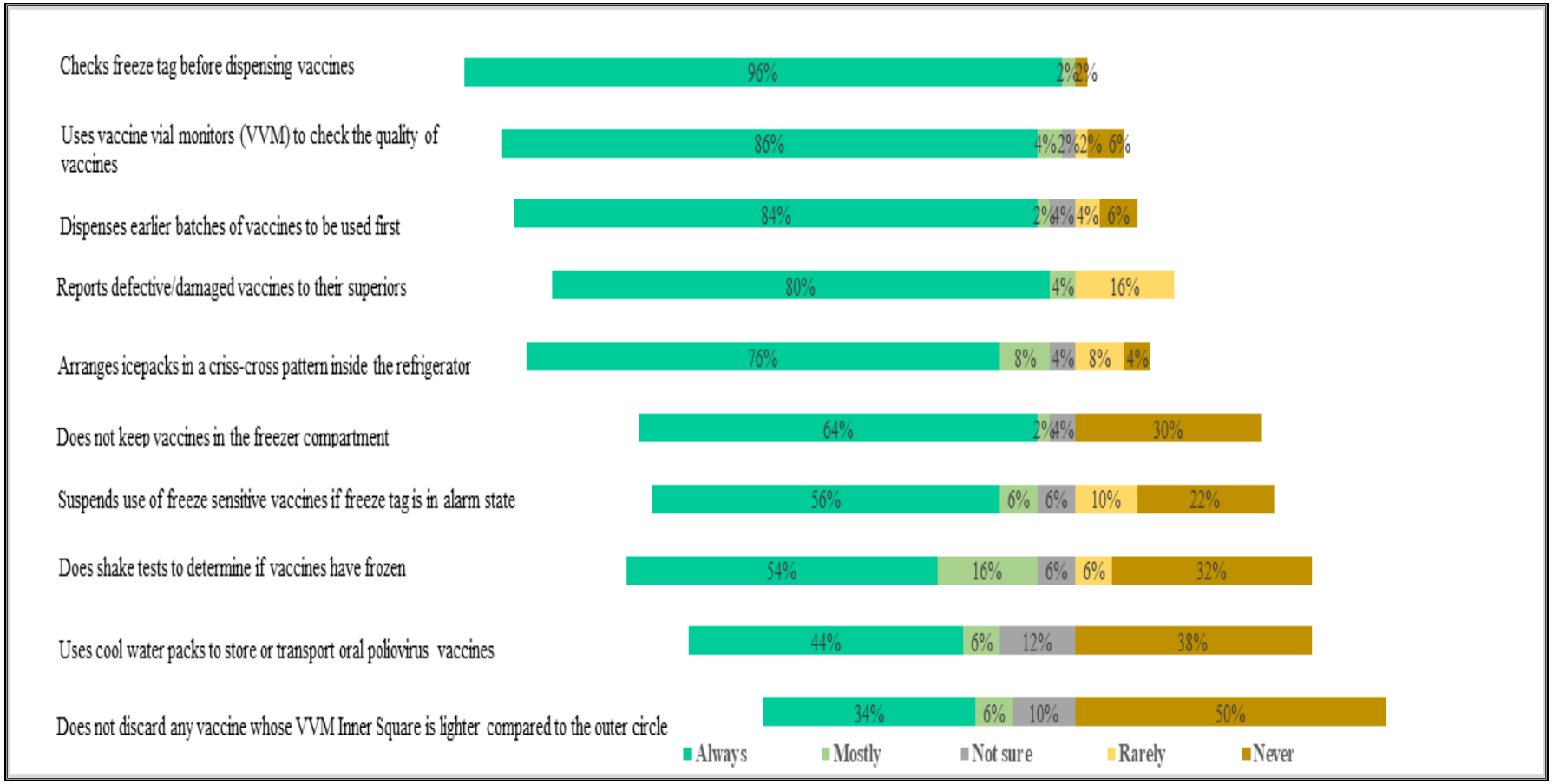

Figure 4. 9: Respondents Self Reported Practices in Storage and Cold chain management of vaccines

4.13 Availability of essential documents and Completeness of the records used in vaccines cold chain management

We looked at the availability of vaccine cold chain essential documents and examined the completeness of the records. We divided the types documents that are essential in vaccine cold chain management in three (3) categories: a) store inventory records: store ledger books and store issue (receipt) vouchers and vaccine register b) operation records: guidelines, standard operating procedures (SOPs), temperature record charts, dos and don'ts stickers and c) maintenance records: contingency plans, cleaning and defrosting records, equipment calibration and maintenance records, equipment breakdown records and power outage records.

4.13.1 Availability of documents

The documents that were most in facilities are; store issue (requistion) vouchers (100%), vaccine register (100%), up-to-date temperature record charts (94%), store ledger books (90%) and guidelines on vaccine cold chain (76%). The facilities that did not avail up-to-date temperature record charts were; 1 hospital, 1 health center and 1 dispensary. Store ledger books and guidelines were available in all hospitals surveyed. The cold chain guidelines were incorporated in the national immunization guidelines hand books that were availed.

The documents that were rarely available in facilities include; contingency plans 14 (28%), standard operating procedures (14%), cleanliness and defrosting records (6%), dos and don'ts stickers (6%) and maintenance and calibration records (2%). Surprisingly, no facility had equipment breakdown and power outage records despite verbally reporting incidences of breakdown of equipment and power outage. The difference in availability of standard operating procedures (SOPs) by facility type was statistically significant ($p = 0.013$). Dispensaries performed poorly as 96.4% did not have SOPs as opposed to 77.8% of health centers and 50% of hospitals.

4.13.2 Completeness of the records

The completeness of record was assessed by examining the proper filling of store ledger books, requestion/issue/receipt vouchers, vaccine registers and temperature charts, inclusion of vaccines and diluents in the ledger and the inclusion of labels on multidose vials.

It was observed that, ledger books, requestion/issue/receipt vouchers, vaccine registers were filled as required (all product details and quantities were captured), recipients had also appended their signatures. Requisition of vaccines was done through an online system (Tanzania Immunization Management Reporting System).

With regard to inclusion of vaccines and diluents in the store ledger, the store ledger books availed by 45(90%) facilities were examined. Four 4 (8.9%) of these facilities had not included in the ledger the last stock of vaccines they received. This anomaly was detected by examining if the goods lastly received (appearing in the store issue and receipt voucher) were entered in the ledger book. These facilities were 3 dispensaries and 1 health center.

With regard to temperature records, records from 47 (94%) facilities were examined. All the temperature charts examined were filled twice in a day (morning and evening). However, at the time of the visit only 57.5% of the 47 facilities had morning temperature entry filled in.

This gave a worrying indication that, in the 42.5% facilities there are times when temperatures are just filled in by estimation at any time of day. A large proportion 33 (70.2%) of 47 facilities had temperature records pasted on the fridge. The 14 (29.8%) facilities which did paste these charts on the fridge included 10 dispensaries and 4 health centers.

Bacillus-Calmette-Guerin and Measles Rubella vaccines are reconstituted at the facility prior to administration to clients. Reconstitution involves mixing the vaccines with specific diluents tailored for individual vaccines. The diluents of these vaccines need to be monitored and recorded in the vaccines ledger books. It was observed that 14 (31.1%) of the 45 facilities whose ledgers were examined had not included the diluents in their ledger books.

Multi dose vaccines such as pentavalent vaccine, Tetanus Toxoid vaccine and Hepatitis B vaccine can be used more than once for up to 28 consecutive days (multi-dose vial policy). In order to avoid use of these vaccines beyond 28 days, it is recommended to attach or write on the vial the opening time and date.

Unfortunately, 45 (90%) of all the facilities surveyed did not comply with this requirement except 4 dispensaries and 1 health center. The degree of non-compliance was 100% in hospitals.

4.14 Summary of research findings

This section summarizes the major gaps and strength identified that may need interventions by the city vaccination department. The summary will be divided in to thematic subsections.

4.14.1 Appointment, training, supportive supervision and knowledge gaps

All facilities had pesornnel designated as a cold chain handler. However, all did not have a formal letter of appointment. A positive finding was that, 36 (72%) of respondents had been trained on cold chain management. Supportive supervision was provided in 92% of faciliites.

With regard to knowledge, over 95% of respondents correctly stated that extreme heat can reduce vaccine potency. They also knew that, the optimal temperature for storage of most vaccines is 2-8°C. They also stated that, temperature monitoring devices should be placed at the centre of the refrigerator. Over 95% of respondents knew that, some vaccines can be used up to 28 days post opening and that opening the door of the refrigerator more than 3 times a day can affect vaccine quality.

The key 2 determinants of knowledge were work experience which was positively correlated with knowledge score (adjusted beta coefficient 0.368, 95% CI (0.037, 0.699; p= 0.030). Those who received training out of the service station had a higher score than those who received training in-house (adjusted beta coefficient 11.069, 95% CI (0.223, 21.915; p=0.046) respectively.

All personnel working in hospitals had received training on cold chain management compared to 16.7% and 39% of respondents in health centres and dispensaries.

We noted a number of gaps on knowledge. The areas where less than 55% of the respondents were able to give the correct responses were; types of vaccines that can be frozen, optimal number of ice packs in the carrirer, requirement that temperature readings be taken at least twice daily, use of VVM to determine exposure to heat and overloading the refrigerators with vaccines can affect temperature.

4.14.2 Funding and cold chain infrastructure

All facilities had refrigerators, vaccine carriers and ice packs. Ninety percent (90%) of facilities had dedicated rooms for cold chain equipment. Ninety percent (90%) of facilities had fridge tags and 76% had freeze tags. All freeze tags were working. Availability of electricity was good with only 2 facilities lacking grid supply. All facilities had alternative sources of power.

The major gap noted was that, only 7 (14%) facilities had an independent budgetary allocation for maintenance of equipment. Only 7 (14%) of facilities had voltage stabilizers connected to their refrigerators. A total of 8 (16%) facilities had damaged refrigeratiors' compartments, 32% of the facilities had broken/loose door rubbers. Fridge tags in 5 facilities were not working.

Despite the fact that all facilities had ice pack containers, 55.6% of health centres had less than the optimal recommended number. The shortage of ice packs was less acute in dispensaries with only 35.7% having less than the recommended number.

Only 6 facilities had automated generators for use in case of blackouts. Contrary to WHO recommendations, solar energy was under utilized as a source of alternate power with only 1 facility using solar energy.

4.14.3 Cold chain Practices and state of vaccines

Refrigerators were cleaned and defrosted regulary at least once in a month. All vaccines were kept in the fridge compartments. Ninety-eight percent (98%) of facilities placed cool water packs in the fridge compartment as recommended.

There was no need for strict adherence to the FIFO principles as the quantity of the vaccines stores was very small and many were used almost as soon as they were received.

Practitioners relied on fridge tags for temperature monitoring and the in-built refrigerator thermometers were ignored. The temperature of the fridge tags ranged between 3.2 - 6.4 °C with a median of 4.75 °C. This is within the WHO recommended range of 2 - 8 °C. There were significancy discrepancies between the fridge tags temperatures and that of the in-built thermometers. The in-built thermometers had a wide temperature variation of 1.2 to 17.2 °C.

Most of the self reported practices did not match with what was observed. For instance, most practioners stated that they recorded the temperatures twice daily yet examination of the records showed that, the morning entry had not been documented in 42.5% of 47 facilities with functional refrigerators at the time of the visit.

A gap that was noted was that, 24% of facilities stored extraneous materials in the fridges; this included other drugs and food items.

All trace vaccines were available in only 8(16%) of facilities. Rabbies and Hepatitis-B vaccines were the least likely to be available. Fourty six percent (46%) of facilities had some vaccines at VVM stage 2 and 1 facility had 1 vaccine at VVM stage 3. One (1) expired HPV vaccine and 1 heat damaged OPV vaccines were found in 2 facilities respectively

Twenty-one percent (21%) of 38 facilities had freeze tags in the alarm state showing some vaccines have been frozen. Most (60.4%) facilities with functional refrigerators did not have ice packs in the freezer compartment. Only 59.2% of the facilities had vertically aligned all cool water and ice packs against the wall. Only 4 facilities kept empty ice packs horizontally at the bottom of the refrigerators as recommended. Only 42.9% of facilities arranged vaccines in order of freeze and heat sensitivity. This order requires that, in a top-opening fridge, the most freeze sensitive vaccines are kept at the top. Eight (16.3%) of the facilities placed freeze sensitive vaccines in direct contact with the walls of the fridge.

In 20 (90.9%) of 22 facilities whose vaccines carriers were loaded with vaccines, the temperature inside the carriers was not monitored by placing a fridge or freeze tags. Nine (18%) facilities had no form pads in their vaccine carriers. Ninety (90%) of facilities did not label the multi-dose vaccines vials with the opening date.

4.14.4 Attitude towards cold chain management

Most of respondents attained a high score of above 80% when motivation to work and self efficacy were assessed. Only 3 individuals had low level of self efficacy and motivation. Nearly all (96%) strongly believed they received adequate supportive supervision from regional and city vaccination officers.

On linear regression analysis, duration of working experience was positively associated with the score on self-efficacy and motivation. Role acted as effect modifier; individuals whose official role was cold chain handling scored higher. Respondents working in health centre had a better attitude score on self-efficacy and motivation compared to those in hospitals and dispensaries. In addition, in service training increased the score on self-efficacy and motivation when compared to out of service training and those not trained.

With regard to attitude towards availability of resources to do their work, the score was lower reflecting negative dissatisfaction with availability of resources. People working in private and Faith based organization were more satisfied with the availability of resources compared to other respondents.

All respondents were confident that, the quality of vaccine they administer to patients were of good quality. There was no single variable that was a key predicator of confidence in the quality of vaccines administered.

4.14.5 Documentations on cold chain management

All facilities had issue vouchers; store ledge book were available in 90% of the surveyed facilities. Nearly all (94%) facilities had up to date temperature records. Most (72.2%) of 47 facilities with functional refrigerators pasted temperature records on the fridges.

A notable gap in documention was that, no facility had equipment break down and power outage records. In addition, nearly all (96.4%) dispensaries did not have SOPs as opposed to 77.8% of health centers and 50% of hospitals. Nearly a third (31.1%) of 45 facilities with up to date ledger books did not include the diluents for BCG and MR in the ledger book as recommended. All facilities except 1 had no records of preventive maintenance and calibration of equipment. Unfortunately, in this 1 facility, preventive maintenance was last conducted in 2015.

CHAPTER FIVE: DISCUSSION

In this study, we identified gaps in the storage and cold chain management of vaccines in Arusha City, Northern Tanzania. The gaps identified can be summarized using the framework of cold chain disruptions taxonomy outlined by Comes et al., 2018 (34). The cold chain disruptions that we identified in this study are classified into three categories using this framework. These are classified as; disruptions of material flows, information gaps and failure of decision making. The discussion that follows is in that order.

5.1 Disruption of materials flow

According to Comes et al., 2018, disruptions of material flows includes: power blackouts, poor transportation, equipment failure and lack of essential supplies such as fuel, spare parts and alternative sources of energy (34). In our study we evaluated the power supply, sources of alternative energy and equipment failure. Given that within the facilities vaccine carriers are used for transportation and temporary storage of vaccines during immunization sessions, the carriers were also considered under material flow.

5.1.1 Availability and stability of power supply

In our study, the availability of sources of power (both main and alternative sources) to run the refrigerators was sufficient because nearly all facilities were linked to the national electric grid with the exception of 1 health center and 1 dispensary that used gas as the main power source. The alternative sources of power were; generators, gas, kerosene and solar systems.

All facilities had alternative sources of power. Power outages in the facilities with no alternative sources of power can lead to waste of expenditure of finances related to deteriorated vaccines. In 2014, WHO reported that, an estimate of 2.8M doses of vaccines were lost due to cold chain failure in five countries (85). Lack of alternative sources of power, reduces effectiveness of vaccines and increases their toxicity (34). In our study, solar refrigerators were only available in 2 (4%) facilities. These highlight the need to increase availability of solar refrigerators. This technology is considered cheap and robust to power outages.

In many developing countries, the reliability of grid electricity is of great concern. Many power blackouts and brownouts are encountered. When these events occur, immediate protective measures must be taken to safeguard vaccine inventories.

The requirement of backup power system is therefore critical (81). For many years, kerosene and gas driven refrigerators have acted as backup for electricity in running refrigerators. Despite this, problems with gas supply interruptions, low efficiency, poor temperature control, and frequent maintenance needs has hindered their use (86). Solar refrigeration provides a relatively reliable alternative source of power and is therefore the method of choice for the cold chain in areas with no electricity or extremely unreliable electricity supply (less than 4 hours per average day) and sufficient sunlight (86).

In uncontrolled power supply system, voltage fluctuation occurs and can damage the refrigerators and affect the quality of vaccines. To protect the refrigerators from this fluctuation, a voltage stabilizer has to be fixed with each refrigeretor. The function of the voltage stabilizer is to monitor fluctuations in the main voltage of 90-280 V and maintain voltage in a required range of 220 + 10 V (12). In our study we found that 43 (86%) of the facilities had no voltage stabilizers. A shortage of voltage stabilizers was also reported in almost a similar proportion (85%) of facilities in a study conducted in Urban Health Centers of Municipal Corporation of Surat City, Western India (12). This observation was also reported in another study conducted in Tikamgarh district of Madhya Pradesh, India (87).

5.1.2 Availability of cold chain rooms, refrigerators, vaccine carriers, ice packs and temperature monitors

A total of 45 (90%) facilities had dedicated rooms for cold chain. The facilities that lacked the rooms were 5 dispensaries. In these facilities, cold chain equipment in particular refrigerators were found placed in unrestricted corridors or uncontrolled open spaces. This practice increases risk of theft, unwarranted access to the refrigerators and can cause temperature variation due to the inflow of cold air and uncontrolled exposure to light. In a study conducted in Tikamgarh district of Madhya Pradesh, India, it was reported that, dedicated rooms for vaccine cold chain activities were available in all surveyed facilities (87). It is therefore necessary that every facility involved in storage of vaccines should set apart a special room for cold chain and this room should have restricted access.

One encouraging findings of this study was that all the 50 health facilities had refrigerators, of which 48 (96%) were functional. The 2 (4%) facilities whose refrigerators were not functional kept vaccines in the nearby facilities with functional refrigerators. The proportion of functional refrigerators revealed in our study was encouragingly high when compared with 3 studies conducted in different sites in Ethiopia; one in the Bale Zone Southeast, which reported that, there were 56 (20.2%) health facilities with refrigerators of which only 35 (62.5%) had functional refrigerators (21). Another study in East Gojam zone in Amhara region revealed presence of 60 health facilities with refrigerators of which 46 (76.7%) had functional refrigerators (88). Similarly, a study in Ezha District, Gurage Zone found that, only 8 (22.8%) of facilities had refrigerators (11).

The availability of cooling devices (refrigerators and freezers) for storage of vaccines is vital to any immunization program, lack of which poses risk to quality of vaccines and individivuals vaccinated. In May 2017, 15 children died of "severe sepsis" and "toxicity" from contaminated vaccines in Kapoeta in South Sudan. A joint WHO/UNICEF report stated that the vaccination team did not follow the cold chain protocols as specified in the Measles Supplementary Immunization Activities guidelines, and that the vaccines were stored in a building without cooling facilities for four days (34).

5.1.3 Equipment Failure

In our study, 38% of respondents did not know if the status of the storage device (damaged or not damaged) can have a profound impact on the quality of vaccines kept in it. This lack of knowledge was also reported in 44.5% of the respondents in a study that was conducted in Giwa, Northwestern Nigeria (89). On physical examination of equipment status, we observed that 8 (16%) refrigerators had damaged compartments whereby the wall that separates the two refrigerator compartments (fridge compartment and freezer compartment) was broken and in some completely removed. The freeze compartment is principally used to freeze the ice packs for future use. The fridge compartment is mainly used to store vaccines at temperatures between 2-8°C. Any destruction of the wall between these two compartments can expose vaccines to freezing which is harzadous to most vaccines. In addition, 16 (32%) refrigerators had broken/loose door rubbers. A similar study which was conducted in Sarolangun, Brebes, and Temanggung in Indonesia; problems in door rubber intergrity were also reported in nearly all facilities in three districts(29).

Broken or loose refrigerators door rubbers can allow entry of fresh air and particulate matter into the refrigerators. This can compromise the storage temperature.

A key problem we found in surveyed health facilities was that preventive maintenance was not being done in most (98%) of the facilities. This could be attributed to lack of an independent budgetary allocation for cold chain activities. Although there was no question that specifically addressed the impact of lack of independent budgetary allocation for cold chain issues, respondents complained that they experience significant delay whenever they needed repair of malfunctioning equipment. This is because whenever equipment breaks down they report to city vaccination department who come to the facility to assess the damage and prepare a budget for the repair. This delay in servicing equipment could have been avoided if the facilities had an independent budget for repairs and other cold chain management.

5.1.4 Temperature monitoring in the refrigerator and in vaccine carriers

In our study, nearly all (98%) of respondents were aware that, the optimal temperature for safe storage of vaccines is 2 - 8 °C. This observation is in line with the study conducted in Boalemo District, Gorontalo, Indonesia which reported 94.6% of study subjects were aware of this recommended temperature range (90). The proportion (98%) observed in our study is much greater compared to that (71.8%) observed in Giwa, Northwestern Nigeria (89).

In our study, the knowledge that heat and freezing can affect the quality of most vaccines was good in 100% and 88% respondents respectively. In a study conducted in Meerut District, Uttar Pradesh, India, it was reported that all 100% study participants had knowledge on the impact of heat to vaccines (52). Our findings on the proportion of respondents who were aware about the effect of heat and freezing is higher compared to that observed in a study conducted in Giwa, Northwestern Nigeria where 60.1% and 50.5% of respondents were aware that heat and freezing can damage vaccines respectively (89).

In our study when we tested the knowledge on which vaccines were heat and freeze sensitive, it was worrisome that, 36% respondents did not know that BCG, MR and OPV vaccines can be frozen and 88% of respondents were aware that, pentavalent and Hepatitis-B vaccines cannot be frozen.

The tools used to monitor temperatures in the cold chain system are themometers, fridge tags, freeze tags, vaccine vial monitors and the shake test. In our study, all the tools except shake tests were available and in use. For temperature readings, in-built thermometers with external display of dial thermometer and fridge tags were used. Respondents did not trust the in-built thermometer and for the purpose of temperature monitoring, they relied on fridge tags. The in-built thermometers were used in the absence or malfunction of the fridge tags. On examination, the temperature on the fridge tags were lower than that of the in-built thermometers. The median thermometers reading was 6.5°C and ranged from 5 to 10°C. The median fridge tags temperatures reading was 4.75°C and ranged from 3.2°C to 6.4°C. There was no difference in the median temperature when a comparison was done across facilities. The superiority of fridge tags to thermometers has been reported in other studies (91). One advantage of fridge tag is the ability to log temperatures over a long time. In-built thermometers can not be used to generate a temperature log.

The variance in temperature reading could have been attributed by lack of preventive maintenance and calibration of equipment. Most facilities reported problems with the in-built dial thermometer. Though it is recommended that, the spot temperature checks be done at least twice daily, this does not capture most temperature deviations out of the recommended range which occur between the spot checks. This technique is not enough for proper monitoring of temperature. The use of 30-days electronic refrigerator temperature data loggers is therefore recommended (45,92,93).

The vaccine vial monitor (VVM) is a technology that registers cumulative heat exposure of vaccines over time. The VVM label provides an indication of the integrity of the cold chain (54,72). In our study, all surveyed vaccines in the facilities had VVMs attached on vials. The results of a systematic review that was conducted in 2017 reported that in low and middle income countries supported by the Global Alliance of Vaccines and Immunization (GAVI-eligible countries), despite access to VVM-labeled vaccines, the inclusion of VVMs in vaccines was below 100%. VVM inclusion was most prevalent in Africa where 84% of estimated vaccine doses in routine immunization programs carried VVMs. In the Eastern Mediterranean region, the prevalence of VVM inclusion on vaccines was 82%, while it was lower in Southeast Asia (56%) and Western Pacific (30%) regions. This study found that low VVM inclusion was associated with failure to include VVM labels in vaccine specification in tender documents, among other reasons (54,72).

In our study, many 45 (90%) respondents reported they use vaccine vial monitors (VVM) to check the quality of vaccines but there was significant proportion 23 (46%) of respondents who did not know if VVM is used to determine cumulative exposure of vaccines to high temperature or heat. They incorrectly agreed that, VVM is used to determine if vaccines have been frozen. The interpretation of VVM colour change among respondents was also poor. For instance; 64% of the respondents did not agree and were not sure if the vaccine can still be used when its VVM has reached stage 2 (Inner Square is lighter compared to the outer circle). A total of 36% reported that they the vaccines immediately after any vaccine reached VVM stage 2. A similar observation was documented in Uganda whereby 30 (60%) of respondents did not know what VVM is used for (94). The findings of this study were also consistent with a study conducted in Valsad and Vapi in India which reported that, 51.6% of study subjects had not heard of VVM and the remaining 49.4% did not know how to interpret VVM colour changes (95). Contrary to this, one systematic review revealed high knowledge on VVM among health workers as well as decision-makers in low and middle-income countries (72).

It is recommended to promptly use vaccines whose VVM has reached stage 2 so as to avoid loss and risk of deteriotion thereafter. Deteriorated vaccines can lead to loss of finance that could have been invested in other fields. It might also risk the health of an individual immunized if the vaccine is erroneously administered. The knowledge that, ice lined refrigerators (ILR) can keep temperature at 2-8°C for not more than 16 hours seemed not well understood as 36% agreed that, these kind of refrigerators can keep temperature at 2-8°C for up to 1 day.

We conducted spot temperature checks in the refrigerator and found that, 12 (24%) of the refrigerators had temperatures outside the recommended range. Exposure of vaccines to temperatures below 2°C was found in 2 (4%) facilities (dispensaries) and a total of 10 (20%) had vaccines exposed to temperatures above 8°C. A similar observation was reported in 3 studies; two conducted in north west region of Cameroon and one multiregional study involving three African countries (Ghana, Kenya and Uganda) which revealed that, temperatures were outside the recommended range at the moment of data collection in 25.9, 32.7 and 16.6% of health facilities respectively (32,64,96). The prevalence of unacceptable temperatures we found in our study falls within the range reported in developing countries where studies have been conducted. This could be attributed to poor maintenance of the refrigerators.

The lives of individuals can be saved if vaccines only remain cool. Most vaccines are developed for a temperature range of 2-8°C (35-46°F). Although usually heat exposure is in focus, freezing is still a the most important threat to the quality of vaccines in over 75% vaccine cold chain (34,97). Freezing of vaccines occurs when vials are exposed to temperatures below 0°C either during storage or transport (45).

Freeze tags and freeze indicators are devices used to monitor freezing in the cold chain. They must be available and kept inside refrigerators. In our study, freeze tags were available and working in 76% of the facilities. A finding of concern was that the available freeze tags were in an unacceptable state (alarm state) in 21 % of surveyed facilities. This indicated that, unnoticed freezing in the refrigerators had previously occurred. It also showed that, replacement of freeze tags that reached alarm state is not done promptly. The unnoticed freezing in the refrigerator can damage vaccines quality. A study conducted in 2018 in two provinces in Lao People's Democratic Republic reported exposure of vaccines to freezing temperature at many stages during distribution (10). A study conducted in Tunisia on temperature monitoring in vaccine storage devices had a similar observation that, a total of 335 freezing alarms in 43 domestic refrigerators occurred between January and February, 2012 (69). The occurence of suboptimal temperature in storage units has been reported in both higher and lower income countries. One literature review reported that, nearly similar proportion (33.3% in better-off countries and 37.1% in resource limited countries) of storage facilities were vaccines were exposed to temperatures below optional ranges (49). In addition, a study conducted in US documented exposure of vaccines to temperatures below 0°C in 24% refrigerators and to above 8°C in 9% of refrigerators at the time of data collection (92). Similarly, a study in three states of India reported same observation (93).

The exposure of vaccines to sub-optimal temperatures may reduce their efficacy and patients may not be adequately protected from disease (15). A study conducted in Houston found a strong correlation ($r = 0.76$, $p < 0.05$) between the percentage of refrigerators with temperature < 0°C and the pertussis rate per health region. They reported a possibility that, improper vaccine storage may have contributed to the observed increases in pertussis rates (92). Therefore, more stringent temperature monitoring is required.

Exposure to freezing does not necessary mean a particular vaccine is damaged until confirmed by shake test. The shake test is the only test with 100% sensitivity, 100% specificity and 100% positive predictive value to determine whether aluminum-adjuvant freeze sensitive vaccines have been affected by freezing (45).

In this present study 48 (96%) respondents reported to suspend use of vaccines if freeze tags are in alarm states, 19 (38%) respondents reported that they carry out shake tests thereafter to determine if vaccines have been damaged by freezing. A total of 8 (21%) facilities had freeze tags in alarm state (requiring shake test) but none of them had reports of suspension of use of freeze sensitive vaccines and of the shake tests conducted. These respondents were not even able to explain what the test is. We therefore concluded that, despite the self reported shake test practice, it is not conducted at all. This is contrary to study done in India whereby at least 11.6% of cold chain handlers had knowledge of the shake test (52). Another study in Giwa, Northwestern Nigeria demonstrated that, majority (81%) of respondents had knowledge that shake test is used to determine if vaccines have been damaged by freezing (89).

In our study we observed that, monitoring of temperature during storage was exclusively done in the refrigerator. It was worrisome that only 21 (42%) were aware that, the number of ice packs required to be placed in vaccine carrier for optimal control of temperature is 4. The majority 29 (58%) participants understood that vaccines in the carrier can remain safe for longer even if 2 or 3 icepacks are placed inside it.

In addition, only few (34%) respondents had knowledge that the load of vaccines and diluents placed in a storage device can impact temperature in that device. It was noteworthy that, in the practice, all refrigerators and vaccines carriers with vaccines were found not loaded with many vaccines and there was suffient space between them. Therefore, the impact of the load of vaccines and diluents to temperature could not probably be felt.

5.1.5 Supply and receipt of deteriorated vaccines

On physical examination we found that, VVM had reached stage 2 and stage 3 of deterioration in 46% and 2% of facilities respectively. This revealed exposure of vaccines to temperatures above the recommended range and was indicative of poor storage practices. It was reported that, most of vaccines were shipped from City Vaccination Store in a deteriorated state as indicated by VVM.

This deteriorated state might have been due to damage in 8 (16%) health facilities refrigerators, broken/loose door rubbers in 16 (32%) refrigerators and lack of preventive maintenance and calibration of cold chain equipment in 98 % of facilities. It might have also been contributed maybe by the weaknesses in the supply chain that originate from the central stores thus reflecting poor flow of materials.

5.2 Information gaps in the vaccine cold chain

Comes et al., 2018 defined information gap as lack of ability to manage the information stream, and working with delayed, lacking or uncertain information. It is a breakdown of the communication and information system. Information gaps manifests as failure to use the temperature monitoring and track system. In our study we examined the effective use of the information system that provides data on control. These were vaccine vial monitors; and temperature records (34,69).

5.2.1 Breakdown of communications

We will only discuss two types of communication failure that were encountered. The first is failure to indicate the date of opening multi-dose vials vaccines on the label. The second is failure to report defective vaccines

5.2.1.1 Labels on used multi dose vial vaccines

In good immunization, it is advised to attach or write on multidose vials (MDVs) the opening time, date and month when the vial are opened (54,56). We observed a great deviation in this practice; 45 (90%) of respondents in the surveyed facilities did not attach or write the time and date the vaccines vials were opened. There were only 4 dispensaries and 1 health center that complied. The use of MDVs vaccines beyond 28 days puts at risk the health of individuals administered due to the risk of contamination that can lead to nosocomial infections (56). Respondents reported they were not aware of the importance of writing the date and month when the vaccine was opened. Unlike our study, a study conducted in Tikamgarh district of Madhya Pradesh, India found that all the facilities had written on vaccine vails the date and time at which the vials were first opened (87).

5.2.1.2 Failure to report damaged vaccines

We asked respondents if they reported to their superiors any defective or damaged vaccines. Sixteen (16%) of respondents declared they rarely report; a further 4% admitted that they occasionaly miss to report. The level of commitment to give reports was high because 80% of

respondents declared they always report any damaged vaccine. Unfortunately, there was no document containing the report of defective or damaged vaccines at any facility. Respondents claimed to report verbally to the City Vaccination Department. They complained of lack of reporting tools. It is unclear what the respondents did with the damaged vaccines. Failure to document the handling of damaged could be attributed to lack of both reporting tools and standard operating procedures.

5.3 Failure of decision making in vaccine cold chain management

According to Comes et al. (2018), for the people involved in vaccines cold chain handling, there are 4 essential components that promote effective decision making. The first and most important is training of all personnel on cold chain management. Secondly trained personnel require operational decision support tools such as Standard Operating Procedures, contingent plans, guidelines, temperature record charts and availability of required equipment. The third component that supports decision making is mitigation planning. Poor decisions are reflected in poor practices. A number of poor practices were identified that reflected failure of decision making despite adequate knowledge of the respondents. Some of these poor practices included; storage of extraneous materials in the vaccine refrigerators, use of freeze sensitive vaccines despite the freeze tags being in the alarm states and storage of vaccines in defective refrigerators.

5.3.1 Lack of decision support tools, preventive maintenance strategies and mitigation plans

We studied the availability of essential documents in vaccine cold chain management and found that many facilities lacked key documents. The documents that were most prevalent in facilities are; store issue (receipt) vouchers (100%), up-to-date temperature record charts (94%), store ledger books (90%) and guidelines on vaccine cold chain (76%). The documents that were rarely available in facilities include; contingency plans (14, 28%), standard operating procedures (14%), cleanliness and defrosting records (6%), dos and don’ts stickers (6%) and preventive maintenance and calibration records (1%). Surprisingly, no facility had equipment breakdown and power outage records despite verbal reports of incidences of the events. These proportions are smaller when compared with a study conducted in Jamnagar district in India which reported availability of Dos and Don’ts sticker in majority of the equipments (13). The same study noted memos on power failure in almost all the facilities studied contrary to ours. The percentage (28%) of facilities with

contingency plans in our study was almost similar to 22.7% reported in a study conducted in Cebu, Philippines (75).

Of note, the difference in availability of standard operating procedures (SOPs) by facility type was statistically significant (p = 0.013). Dispensaries performed poorly as 96.4% did not have SOPs as opposed to 77.8% of health centers and 50% of hospitals. This could have been attributed to the fact that, dispensaries are mainly staffed assistant nursing officers and nurse midwives who lack sufficient knowledge on SOPs development. Health centres and hospitals are mostly run by clinical officers and degree holder who may assist in the development of SOPs. Facilities are required to develop their own SOPs to be able to operate with consistency.

In Arusha City, health facilities had been provided with software for registration and recording of immunization services they offer. This included recording of vaccines administered to every individual. The software was titled "Tanzania Immunization Management Registration and Records (TIMR). All facilities had been provided with tablets to enable access to the software. The cold chain managers were expected to receive monthly internet bundles from the National Immunization Program. At the time of the study, respondents reported failure to receive such bundles and instead they relied on paper work in inventory management. The availability of software despite the reported challenges is a milestone in the national immunization when compared with other programs. The availability and use of vaccine inventory management was also reported in a study conducted in Thailand. This study documented that, most facilities were able to utilize the software in place; some hospitals had to pay for software whereas health centers had free access for the software. (50).

Another major finding of our study was that, preventive maintenance and calibration of equipment had not been done in nearly all 49 (98%) facilities survey. There was only one hospital whose cold chain equipment were affixed with status label for maintenance and calibration which was done in 2015. WHO in 2014 reported that in Ethiopia in 2011, lack of maintenance led to 30% of cold-chain equipment being unserviceable (85). These findings were supported by Boeck et al. (2019), who documented that, in low and middle income countries, preventive maintenance to avoid equipment failures is not often performed. Spare parts are often not available, and repair of cold chain equipment can take months. As a result, vaccines are exposed to heat or freezing, making some unusable and resulting in vaccine wastage or impaired vaccine efficacy (98).

A study conducted in Boalemo District, Gorontalo, Indonesia reported lack of equipment maintenance (90). We suggest that, all cold chain equipments should undergo preventive maintenance and calibration. This can be done in consultation with organizations that are approved to offer maintenance and calibration of equipment. These institutions include Tanzania Bureau of Standards (TBS) and the Weight and Measures Agency (WMA).

Our study noted that, the level of supportive supervision of cold chain activities was conducted regularly in the healthcare facilities. The majority of the facilities (46, 92%) reported that they received supportive supervision in the last two years (2019 and 2020).

5.3.2 Selected practices that reflected poor decision making - Presence of extraneous materials inside refrigerators and arrangement of ice packs and vaccines

Refrigerators used to keep vaccines should not be opened more than three times a day. Almost all 48 (96%) of respondents were aware of this requirement. This proportion was greater compared to 71.8% of study subjects found to have similar knowledge in a study conducted in Giwa, Northwestern Nigeria (89). Frequency opening of the refrigerators can lead to temperature fluctuations and hence deviations from the recommended range of 2-8°C which can damage vaccines. Keeping of extraneous materials (food, drinks and medicines) together with vaccines increases the frequency of opening the refrigerator. In this study, 76% and 42% of respondents were aware that, keeping of other medicines and food respectively in the vaccines refrigerators is not recommended. The lack of this knowledge among respondents has been reported in other studies (11,37).

Majority 38 (76%) of the facilities surveyed had not kept extraneous materials together with vaccines. However, we found poor practices such extraneous materilas in the refrigerators. Out of 50 facilities surveyed, 12 (24%) stored vaccines together with erythropoietin, oxytocin and insulin injections, antisera, salmonella antigens, widal test reagents and meat in the vaccine refridgerator. Our observation aligned with a study conducted in South Africa which reported that refrigerators were used to store insulin and HIV medication (incorrectly) with the vaccines (99). Similar observation was also reported in the study conducted in Urban Health Centers of Municipal Corporation of Surat City, Western India were by 10% of facilities had kept products not related to vaccines in the vaccines refrigerators (12).

The same finding was also reported in Ezha where at time of data collection they found laboratory reagents and medicines (insulin and ergometrine injection) kept in the refrigetor with vaccines in 2 (25%) health facilities (11) . Other studies have also documented the same observation (13). This malpractice might have been contributed to the fact that, most respondents (58%) had little knowledge on the impact of keeping food together with vaccines. With regard to keeping medicines with vaccines, 82% respondents knew that it was not an appropriate practice.

No single facility kept empty ice packs horizontally at the bottom of the refrigerator as recommended; instead, 4 (8.3%) facilities had kept cool water packs to the bottom side of their refrigerator. The number of ice packs (frozen and unfrozen) in the facility were limited such that, there was sufficient space left between the packs in all the 49 (98%) refrigerators that had vaccines.

5.4 Knowledge gaps and inadequate training

In our present study, the overall knowledge of respondents on cold chain monitoring was satisfactory and good. The mean score of all respondents was 71.6% with a standard deviation of 10.9%. The minimum score was 50% and the maximum score was 90.9%. A total of 20 (40%) of respondents scored above 74%. This figure is much greater compared to the study of knowledge of cold chain management conducted in Ezha District, Gurage Zone, Ethiopia whereby 51.3% respondents were reported to have satisfactory knowledge (11). In another study in Edo state Nigeria, 64.0% respondents had overall poor knowledge of cold of cold chain management (37). However, different studies have used different types of tools for knowledge assessment. Therefore, the findings of our study cannot be directly compared with those in literature.

The observed high knowledge level among respondents could have been attributed by the fact that, most respondents had received training a year before this study was conducted. It is expected that, if the personnel knowledge of cold chain management is poor, the practice of storage and cold chain monitoring will definitely be poor as well. For instance, respondents may fail to detect problems occurring in the cold chain and this may lead to deterioration of vaccines quality, damaged vaccines can be discarded culminating in wastage of resources including money. Knowledge also has a positive influence on respondents' attitude toward cold chain, It may strengthen their wish to do better in preserving vaccine potency (37).

The key predictors of knowledge were; duration of years worked in the vaccine cold chain and the site at which training was conducted (on service or out of service station). There was a positive association between duration worked and knowledge on vaccine cold chain management (adjusted β coefficient 0.368, 95% CI (0.037, 0.699 p=0.030)). For each year worked the knowledge score of respondents increased by 0.368 units. Respondents worked below 3 years had least knowledge compared to others. The dependence of knowledge on working experience was also reported in a study done in Ezha District, Gurage Zone, Ethiopia (11). As one works longer in a particular field, he gains new knowledge and skills every time. Therefore, experience improves practice; more experienced workers may perform better than their counter parts (100,101).

Positive association was also observed between knowledge and training site (adjusted β = 11.069, 95% CI (-0.223, 21.915; p= 0.046)). Respondents trained out of their working station had greater knowledge score compared to those trained at their work station. The mean difference in the knowledge score between those trained out of job versus in job training was 11.069. This implies that, any future training should be conducted out of the work station.

Training in cold chain management serves to remind the respondents of what they had learnt previously, impacts new knowledge and teaches them how best to apply the knowledge they have gained to yield effective results. In addition, regular training is very important as this affords them an opportunity to obtain up-to-date information on cold chain management in line with the world's best practices at that (37).

5.5 Attitude towards vaccine cold chain management

The achievement of best cold chain management practices depends on the attitude of the cold chain handling staff. Good attitude promotes best management of the cold chain (89). In this study, respondents had generally a good attitude toward self efficacy and motivation where nearly 80% respondents scored above 80%. Positive attitude in the cold chain management has also been reported in other study (89).

This dimension of attitude was dependent on the qualifications (adjusted β coefficient = 3.336, 95% CI (0.518, 6.154; p= 0.021)), training status and site; in service training versus out of service plus not trained (adjusted β coefficient = 13.137, 95% CI (7.199, 19.075; p= <0.001)) and type of health facility;

health centres versus dispensaries plus hospitals (adjusted β coefficient = 5.186, 95% CI (0.520, 9.852; p= 0.030)). In addition, there was statistical interaction between role and working experience (adjusted β coefficient = -2.238, 95% CI (-3.446, -1.030; p= 0.001)). There was a positive correlation between qualification and the score on attitude towards self-efficacy and motivation. Clinical Officers performed better than nurse officers who also outperformed assistant nursing officers. This was expected as people who are highly trained generally have more self-confidence and are more knowledgeable.

With regard to the type of facility, respondents in health centers had higher scores on self-efficacy and motivation compared to those in hospitals and dispensaries. This could be attributed to the fact that, health centers primarily provide preventive services as opposed to hospitals who mostly offer curative services and dispensaries which are generally poorly resourced.

With regard to interaction between the variables, role and work experience in years. Personnel working as main cold chain handling staff or working on behalf of him acted as an effect modifier. It was evident that, if cold chain was one's primary responsibility, as years of working experience increases, self-confidence and motivation to work in the cold chain increases. However, if it is an add - on responsibility as they worker longer on a job, their self-efficacy and motivation to work in the cold chain decreased.

Some of the determinants of attitude observed in our study were also captured in other studies. In a study conducted in Edo state in Nigeria, a positive attitude towards cold chain management depended on training status (respondents trained or not), time from lasting training and supportive supervision conducted (37).

In contrast to self efficacy and motivation, attitude towards availability of resources and need for training was not that good. Nearly half (48%) of respondents scored below 60% with regard to satisfaction with availability of work related resources. The highest score was 80%, This implies that human, training and material resources could be a major source of concern. This observation was in tandem with a study conducted in the United Mexican City which reported that, 91% of staff

thought they did not have essential tools to detect temperature deviations outside 2–8°C range (102).

The attitude toward resources and need for training was highly dependent on type of facility ownership; whether government, private or Faith Based Organization ((adjusted β coefficient = -5.472, 95% CI (0.517, 11.462; p= 0.072)) and the interaction between access to supportive supervision and the duration of year worked (experience) in the cold chain (adjusted β coefficient = 5.953, 95% CI (1.908, 9.998; p= 0.005)).

Supportive supervision helps cold chain managers to improve their own work related knowledge and skills. This enables them to overcome many operational obstacles and hence less need for resources. Supportive supervision is usually conducted by the city, regional or national immunization programme departments over facility cold chain handlers at their work place. It is a two-way traffic that facilitates problem solving and helps to make things work. It is therefore expected that, facilities that receive regular supportive supervissions, have lower needs for resources and training.

5.6 Study strengths, limitations and mitigation strategies

The fact that, all facilitilies involved in storage and cold management of vaccines in Arusha city were included in this study. Therefore, this study was not affected by selection bias. Also, the data collectors were trained before being sent to the field and they were thoroughly supervised during the collection. Some of the responses were validated by observing actual practice.
Some data were collected based on what the participants said. Some of the responses may have been untrue and may have been affected by poor memory. The fact that the study was done only at a particular period of the year can also bias the results since we could hardly know what happens throughout the year.

Observation of temperature by use of both in-built thermometers and fridge tags which were mostly not calibrated might have predisposed our results to measurement bias as the instruments in the facilities were not calibrated. This study only reported the exposure of vaccines to sub-optimal

temperature at the storage facilities. However, vaccines can equally be exposed to sub-optimal temperatures during transportation.

Observer bias was mitigated by training and insisting to data collectors on the need to be as objective as possible. In addition, the checklist was designed so that an objective assessment was required as opposed to subjective judgment. Hawthorne effect affected the study. In this type of bias respondents change their behavior and responses because they are aware that they are being investigated. This bias was addressed by comparing the responses with regard to self reported practices to the findings on physical inspection.

Response bias by the respondent was minimized by requesting the respondent to show the written responses as opposed to giving verbal responses. Written choice reminded respondents on things they might have forgotten. The questionnaire was also designed such that the respondents were forced to make a choice (forced choice response). In addition, respondents were encouraged to be as truthful as possible).

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS FOR PRACTICE AND FUTURE RESEARCH

6.1 Conclusion

The state of equipment used for storing of vaccines is unsatisfactory, a number of gaps need to be addressed as soon as possible. These include; lack of voltage stabilizers and poor maintainance of equipment amongst others.

There was no formal appointment of designated cold chain handlers.

Training and supportive supervision needs to be strengthened and should in specific target vaccine cold chain management. This will help to improve the knowledge and attitude of the cold chain handlers.

Training out of the working station and the increase in the duration of years worked increased the knowledge of respondents.

The city vaccination department should ensure adequate supply and use of all the essential documents and records. The department should in addition maintain a distribution list for the documents.

6.2 Recommendations for practice

We recommend formal appointment in writing of the main cold chain handlers by the city medical officer. We believe this can increase their commitment in cold chain management. In parallel with this, we recommend that, if nurses are to appointed as cold chain handlers, they should have a minimum requirement of diploma in nursing.

We also recommend that, training of cold chain handlers should be done both in service and out of their work places.'

We recommend that, the national immunization programme should support facilities with regard to preventive maintenance and calibration of equipment and all damaged equipment should be refurbished or replaced with new ones.

We recommend that, the national immunization program introduce a computerized temperature monitoring systems at all vaccine cold chain points. This will help to provide real time data of temperatures. We recommend that, electronic fridge tags that can maintain a temperature log should replace the existing manual temperature record system which is based on subjective review This will help in capturing any temperature deviations and could improve protection of vaccines.

We recommend that, the city immunization and vaccines department should conduct separate supportive supervisory visits that are specifically targeted to vaccines cold chain management rather than being part of routine administrative visits on immunization activities so that they can be more effective.

We also recommend that, the city immunization and vaccines department should replace the 22 (44%) facilities that have gas and kersone as alternative sources of power with solar refrigerators.

We recommend that, city immunization and vaccines department in consultation with the national immunization program should ensure ensure availability of voltage stabilizers in all facilities involved in storage of vaccines. In addition, it should supply all essential documents required for vaccine cold chain management.

We recommend that, city immunization and vaccines department should conduct training on vaccine cold chain management. The training should specifically focus on vaccine sensitivity to heat and cold; on temperature monitoring technologies and on proper documentation and keeping of records.

6.3 Recommendations for future research

We recommend a multi-regional study should be conducted by the national immunization program to assess the national state of storage and cold chain management of vaccines in Tanzania. Similar studies could be conducted in the Eastern Africa region. Given that, a spot check on the temperatures were done, studies in which the temperatures that vaccines are exposed over longer period should be done in order to obtain a better picture of the prevalence of exposure to suboptimal temperatures.

We also recommend that, studies aimed at identifying the most effective intervention for improving the knowledge, attitudes and practices of cold chain handlers should be conducted. Given that, the respondents claimed that, they received deteriorated vaccines at VVM stage 2 from the City Vaccines Department, storage and transportation of vaccines in this department should be investigated.

Reliability studies are required to compare temperature readings of fridge tags and in-built thermometers and a longitudinal study is required to systematically evaluate the temperature variations.

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APPENDICES

APPENDIX 1: PARTICIPANT INFORMATION AND CONSENT FORM (ENGLISH VERSION)

PARTICIPANT INFORMATION

Title of the Study: Evaluation of the storage and cold chain management of vaccines in primary health facilities in Arusha City, Northern Tanzania

Principal Investigator: Emmanuel Masunga Gedi, Post Graduate Student (Master of pharmacy in Pharmacoepidemiology and Pharmacovigilance, Department of Pharmacology and Pharmacognosy, University of Nairobi)

Supervisors: Prof. Anastacia N. Guantai, PhD; Prof. Appolinary Kamuhabwa, PhD; Dr Margaret Oluka, PhD

Consenting Process

This document (consenting form) contains information about this study. The purpose of this consent form is to give you information that will help you to decide whether or not to participate in the study. Feel free to ask any questions about the purpose of this study, your role as a participant the possible risks and benefits that may arise, or any other clarification that you may need to help you make a decision on whether to participate in the study or not. Please understand the following principles:

i) Your decision to participate in this study is voluntary
ii) You are free to withdraw from the study at any time without feeling obliged to give a reason for your withdrawal
iii) Refusal to participate in the research will not cause you any disadvantages or affect the quality of services you are entitled to receive.

When we have answered your questions to your satisfaction, you may decide to participate in the study or not. Should you agree to take part in the study, we will request you to sign your name on this form.

What is this study about?

I want to find out the status of storage and cold chain management of vaccines, state of storage and transportation equipment, the practices, knowledge and training status of cold chain handling staff and the status of vaccine cold chain documentation practices in primary health facilities in Arusha City, Northern Tanzania.

This is important because, effective immunization is largely contributed by availability of good quality vaccines. Vaccines are stored and distributed in temperature controlled chain called in Cold chain. Cold chain failure exposes vaccines to unacceptably high or low extremes of temperature which results in vaccine wastage, revaccination and decreased faith of vaccinated individuals to both vaccine and healthcare providers.

Purpose of the study

The main objective of this study is to evaluate the storage and cold chain management of vaccines in primary health facilities in Arusha City, Northern Tanzania.

Procedures to be followed

With your permission, we will go through all vaccine storage and transportation equipment available at your facility and obtain information on equipment themselves and vaccines storage status using a structured checklist. I will also provide you with a questionnaire to choose and fill the correct information you know on vaccine cold chain system.

Risk or/and discomforts

If you feel any discomfort at any time during the conduct of this study, be free to express it, we can even postpone and arrange for another convenient day and time.

Right and Safety

The Kenyatta National Hospital – University of Nairobi Research and Ethics committee (KNH/UoN-ERC) and the Tanzania National Health Research Ethics Review Committee, National

Institute of Medical Research (NIMR) will review the study protocol and the informed consent process to ensure that your rights and safety as a participant in this study are safeguarded prior to starting the research process.

Benefits

The study will not provide any monetary benefit to you. However, you will contribute to the advancement of vaccine cold chain management practices in our country and the world at large since the information you provide will help to detect the prevailing situation and improve storage practices by making recommendations to immunization programme and medicine and medical devices regulatory Authority.

Assurance on Confidentiality

All the information you provide will be kept strictly confidential. We will use a code number to identify you and your name will not be used anywhere during data handling or writing reports. All your response documents including the checklist used at your facility will be kept under lock and key and only authorized personnel will be able to access.

CONSENT FORM

University of Nairobi

School of Pharmacy

Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilence

Participant's statement

I have read the information to participant form and discussed this research with the study investigator. I have had my questions answered in a language that I understand. The risk and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form. I have not given up any of the legal rights that I have as a participant in research study.

I agree to participate in this research study **Yes** **No**

I agree the research to go through my cold chain system **Yes** **No**

Participant Signature/Thumb Stamp: _____

Date: _____

Participant printed name: _____

CONTACTS

For further information about this study, you may contact me, my academic department, the lead supervisor and other supervisors, Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee or Tanzania National Health Research Ethics Review Committee, National Institute of Medical Research (NIMR) using contacts provided:

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The Chairperson

The Kenyatta National Hospital/ University of Nairobi Research and Ethics Committee

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The Chairperson

National Institute of Medical Research (NIMR), National Health Research Ethics Committee

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Researcher's Statement

I, the undersigned have fully explained the relevant details of this research study to the participant named above and believe that participant has fully understood and has freely given his/her consent.

Researcher name: _____

Date: _____

Signature: _____
Role in the study: _____

For more information, contact the principal investigator: Emmanuel Masunga Gedi
Tell: +255 782 091 632/ +255 759 287054/ +254 787 309 570

APPENDIX 2: PARTICIPANT INFORMATION AND CONSENT FORM (SWAHILI VERSION)

KIAMBATISHO NA.2: FOMU MAELEZO KUHUSU UTAFITI NA UKUBALI WA KUSHIRI KATIKA UTAFITI

MAELEZO KUHUSU UTAFITI

KICHWA CHA UTAFITI: Tathmini ya utunzaji na usimamizi wa mfumo baridi wa chanjo kwenye vituo vya awali vya afya katika jiji la Arusha nchini Tanzania

Mtafiti Mkuu: Emmanuel Masunga Gedi, mwanafunzi wa shahada ya uzamili katika fani ya Famasi inayohusu matumizi na matokeo/madhara ya dawa (masters of pharmacy in Pharmacoepidemiology and Pharmacovigilance), katika chuo kikuu cha Nairobi nchini Kenya.

Wasimamizi wa Utafiti: Prof. Anastacia N. Guantai, PhD; Prof. Appolinary Kamuhabwa, PhD; Dr Margaret Oluka, PhD

Maelezo ya makubaliano ya kushiriki utafitii

Fomu hii ina maelezo kuhusu utafiti huu. Lengo la fomu ni kukupa taarifa au maelezo kuhusu zoezi la utafiti ili uweze kuelewa na kisha kuamua bila kushawishiwa kushirika au kutokushiriki katika utafiti huu. Una uhuru wa kuuliza swali lolote kuhusu utafiti huu, wajibu wako kama mshiriki, hatari, hasara na faida zinazoeweza kutokea na lolote utakalotaka kufamu ili uweze kuamua au kutoamua kushiriki. Tafadhari fahamu mambo yafuatayo kabla hujatoa maamuzi ya kushiriki au kutokushiri: -

i) Maamuzi yako kushiriki ni ya hiari
ii) Uko huru kujitoa katika utafiti muda wowote bila hata kutoa sababu
iii) Kukataa kushiriki hakutakusababishia hasara yoyote au kuathiri ubora wa huduma utakayotoa au kupokea

Tutakapokuridhisha katika kujibu maswali yako, utatakiwa kuamua kushiriki au kutoshiriki katika utafiti huu. Ukiridhia kushiriki, tutakuomba uandike jina lako na kusaini katika fomu hii.

Utafiti huu unahusu nini?

Utafiti huu unalenga kufahamu hali ya utunzaji wa chanjo na vifaa vinavyotumika kutunzia chanjo hizo, ufahamu juu ya mfumo baridi wa chanjo, utendaji na mtazamo wa watunzaji chanjo. Pia utalenga kutathmini utunzaji wa taarifa/takwimu/kumbukumbu na nyaraka zinazazohusu chanjo na mfumo baridi wa chanjo. Utafiti huu utafanyika kwenye vituo vya afya na zahanati katika jiji la Arusha tu.

Kama unavyofahamu, utoaji chanjo wenye tija unategemea sana ubora wa ubora wa chanjo zenyewe, Chanjo hizi zinatakiwa kutunzwa na kusambazwa kwenye mfumo maaulumu wenye udhibiti madhubuti wa joto. Mfumo huu usipofanya kazi vizuri, unahatarisha ubora na usalama wa chanjo hizo ikiwa ni pamoja na afya ya mtoto/mtu yeyote atakayepewa chanjo hiyo. Vile vile chanjo zilizopoteza uwezo wake wa kufanya kazi huharibiwa na kuathiri uchumi wan chi, husasabishwa kuchanjwa tena kwa watu waliokwishwa tena na mbaya Zaidi unapelekea watu kupoteza Imani na chanjo au mfumo mzima wahuduma ya afya.

Lengo la Utafiti

Lengo kuu la utafiti ni kuangalia hali ya utunzaji wa chanjo na mfumo mzima wa usimamizi wa utunzaji baridi wa chanjo katika jiji la Aruhsa nchini Tanzania.

Utaribu utakaofuatwa

Kwa ruhusa yako, tutaangalia vifaa vyote mnavyotumia kutunzia na kusafirishia chanjo. Tutatumia orodha maalumu tuliyoiandaa kuangalia vipengele vinavyotakiwa kwenye vifaa vyote vya utuzanji wa chanjo. Pia, nitakupa orodha ya maswali ya kuchagua jibu sahihi juu ya taratibu na taarifa mbali mbali zinazohusu chanjo na mfumo mzima wa kutunza chanjo.

Hatari au Usumbuufu unaoweza kujitokeza

Inawezekana utajihisi kuchoka wakati wa zoezi hili la utafiti, kuwa huru kusema na tunaweza kukupa muda wa kupumzika au pale utakapopata dharura tunaweza kupanga siku nyingine.

Haki zako na Usalama wako

Tume ya utafiti na maadili wakati wa utafiti ya Hospitali ya Taifa ya Kenya, Chuo kikuu cha Nairobi na Taasisi ya Taifa ya utafiti wa mambo yanayohusu Afya nchini Tanzania zitapia utaratibu mzima wa utafiti huu ili kuhakikisha kuwa usalam na haki ya mshiriki italindwa na pia kuona kama utafiti unafaa.

Faida zitakazotokana na kushiriki katika utafiti huu

Japokuwa utafiti huu hautakupa fedha, ila utasaidia kuboresha utendaji katika usimamizi wa mfumo wa utunzaji baridi wa chanjo katika taifa letu na duniani vile vile. Taarifa zitakazopatikana zitasaidia kugundua hali halisi ya utunzaji wa chanjo na kupendekeza maboresho kwenye idara ya chanjo ya taifa na Mamlaka ya Dawa na Vifaa Tiba Tanzania.

Hakikisho la Usiri

Taarifa zote utakazozitoa zitafanywa siri kubwa. Tutatumia namba kukutambua au kutambua fomu yako, jina lako halitatumiwa popote wakati wa kuchanganua na kuandika ripoti ya utafiti huu. Nyaraka zote za majibu zitawekwa kwenye kabati na watu wanaohusika tu na utafiti huu ndiyo wataruhusiwa kuziona.

FOMU YA KURIDHIA KUSHIRIKI UTAFITI

Chuo Kikuu cha Nairobi

Shule ya Famasi

Shahada ya uzamili katika Matumizi na Madhara ya Dawa, (Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilence)

Kauli ya mshiriki

Nimesoma fomu ya utafiti huu na kujadili na mtafiti. Maswali niliyokuwa nayo yamejibiwa. Hatari, hasara na faida ya utafiti huu zimeelezwa kwangu. Naelewa kuwa ushikiri wangu ni hiari na kwamba naweza kujitoa muda wowote. Nimekubali kwa hiari kushiriki katika utafiti huu.

Naelewa kuwa jitihada zote zitafanywa kulinda taarifa zinazonihushu mimi binafsi.

Kwa kuweka sahihi kwenye fomu hii sijasalimisha haki zangu za kisheria kama mshrirki katika utafiti.

Nakubali kushiriki katika utafiti huu	**Ndiyo**	**Hapana**
Nakubali utafiti ufanyike kwenye kituo changu	**Ndiyo**	**Hapana**

Sahihi ya mshiriki/dole gumba: _____

Tarehe: _____

Jina la mshiriki: _____

MAWASILIANO

Kwa taarifa/maelezo Zaidi, unaweza kuwasilina na mimi, idara pharmacology na pharmacognosy, chuo kikuu cha Nairobi, wasimazi wangu au Tume ya utafiti na maadili wakati wa utafiti ya Hospitali ya Taifa ya Kenya, Chuo kikuu cha Nairobi na Taasisi ya Taifa ya utafiti wa mambo yanayohusu Afya nchini Tanzania (NIMR) kwa kutumia njia za mawasiliano ainishwa hapa chini:

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Mwenyekiti
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Kauli ya Mtafiti

Mimi, niliyeweka sahihi hapa chini, nimeeleza umuhimu wa utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini ameelewa maelezo yote na amekubali kushiriki katika utafiti huu kwa hiari yake.

Jina la Mtafiti: _____
Tarehe: _____
Sahihi: _____
Majukumu katika utafiti: _____
Kwa maelezo Zaidi wasiliana na mtafiti mkuu: Emmanuel Masunga Gedi

APPENDIX 3: VACCINE COLD CHAIN SYSTEM STATUS CHECKLIST

PART I: BASELINE CHARACTERISTICS OF A COLD CHAIN HEALTH FACILITY

INSTRUCTIONS: Fill the particulars in the space provided below each item.

Health facility unique number (e.g. F01 ….):	Date:
☐	☐
level of health facility (tick 1)	Location of the facility
☐ Health Center ☐ Dispensary	☐
Health Facility ownership (, private, Faith based Organization etc.):	Types of vaccines provided (Mention in the space provided)
☐ Government ☐ Private ☐ Faith Based Organization ☐ Others (mention) _____	☐ ☐ ☐ ☐ ☐

PART II: HEALTH FACILITY COLD CHAIN SYTEM STATUS CHECKLIST

INSTRUCTIONS: For item in the table provided below, indicate **"Y"** if the response is **"Yes"** and **"N"** if the response is **"No"**. Please make sure that all required sections are filled as per description provided.

No.	Indicator	YES	NO
1.	**Facility**		
	The facility has a dedicated room for vaccine cold chain		
	The facility has a person designated as cold chain handling staff		
	cold chain handling staff or another person on his behalf (cancel one) was found at the facility at the time of study		
	The person found has been trained on storage and cold chain management of		

No.	Indicator	YES	NO
	vaccines		
	Does district health management team do supportive supervisions on vaccines cold chain issues at this facility?		
	Was supportive supervision conducted in the year ended December, 2019? If no: When was the last (mention)		
	Had there been any budget allocated for vaccines cold chain maintenance activities at facility level in the last 2 years? If not: When was the last budget allocated? (fill).		
2	**Equipment**		
	Refrigerator		
	Is refrigerator for storing vaccines available?		
	Is refrigerator closed at time of visit?		
	Had the vaccine refrigerator been prequalified by WHO?		
	Is the refrigerator undamaged? If no: what type of damage is it? (mention)		
	Is the Refrigerator Ice Lined?		
	Were there vaccines in the refrigerator at the time of visit?		
	Was the refrigerator found switched on?		
	Is the found refrigerator functional?		
	Is there no vaccine stored in the door of refrigerator?		
	Are DOs and DON'Ts sticker fixed on ILR?		
	Does a refrigerator has thermometer placed in it?		
	If the refrigerator has thermometer, what type is it (tick one)		
	a) Digital Thermometer with probe that goes to the center b) Built in thermometer with external electronic display c) Dial thermometer d) Stem thermometer		
	Is the thermometer correctly situated at the central position in the refrigerator?		
	Does the thermometer indicate the temperature inside the device?		

No.	Indicator	YES	NO
	Is the thermometer calibrated?		
	Frozen Ice packs found placed in the freezer compartments and water packs in the fridge compartment of the refrigerator?		
	Cool water packs found vertically arranged in the refrigerator compartment		
	Ice packs and cool water packs adequately parked		
	Is there correct placement of ice packs inside Deep freezer, the crisscross pattern (with space of air circulation) of ice packs in deep freezer		
	Temperature found in correct range (2°C - 8°C) at the moment of observation		
	Temperature monitoring chart present		
	Temperature record sheet(s) complete and up to date?		
	Is temperature read and recorded twice daily? If not: what other frequency? Mention		
	Temperature records pasted on refrigerator		
	Preventive maintenance and calibration done in the last 1 year		
	Products other than vaccine, diluents and ice packs present in the refrigerator		
	Space in the refrigerator left empty to allow air to circulate around the vaccines and diluents to keep them cool		
	Voltage stabilizer available		
	Is the refrigerator self-defrost?		
	If refrigerator is not self-defrost, do you carry out manual Defrost?		
	No vaccine found in contact with the back or sides of the refrigerator		
	Do you clean the refrigerator? If yes: What is the cleaning frequency mention		
	Has there been any refrigerator breakdown?		
	Total number of YES and NO		
	Cold box/vaccine carrier		
	Is there a cold box and/or vaccine carrier at the facility (tick one or both)? Number of col boxes (mention) Number of vaccine carrier (mention)		
	Is the cold box and/or vaccine carrier correctly loaded with icepacks/cool		

No.	Indicator	YES	NO
	water packs		
	Are conditioned ice packs placed at the bottom and sides of the cold box?		
	Are there vaccines in the cold box and/or vaccine carrier??		
	Are freeze-sensitive vaccines not in direct contact with the ice packs?		
	Was preventive maintenance and calibration conducted in the last one year?		
	Is thermometer placed in the cold box/vaccine carrer?		
	Is thermometer situated at the central position in the cold box/vaccine carrier?		
	Does the thermometer indicate the temperature inside the device?		
	Is the thermometer calibrated?		
	Is the temperature within range the range of 2°C - 8°C?		
	Total YES and NO		
3.	**Vaccines status and storage**		
	Are there vaccines store at the facility?		
	Are vaccines stored under lock and key?		
	Are vaccine vial monitors all unchanged?		
	Are vaccines arranged by type and FEFO?		
	Are there expired vaccines in cold chain chambers?		
	Are freeze sensitive vaccines placed away from fridge, cold box or vaccines carrier compartment lining?		
	Are OPV, BCG, measles, DPT and TT vaccines placed in the freezer compartment ?		
	Are boxes of vaccines arranged in stacks?		
	Is there Multi-dose vaccines vials?		
	Are multi-dose vaccines vials marked with date and time they were first opened?		
	Are damaged and expired vaccines labelled and quarantined?		
	Total YES and NO		
4	**Power supply**		

No.	Indicator	YES	NO
	Does the facility has access to electricity?		
	Electricity as main source of power supply		
	Gas as main source of power supply		
	Kerosene as main source of power supply		
	Is power supply permanent?		
	Refrigerator found not disconnected from power source		
	Had the facility experienced any power failure/cuts off?		
	Presence of standby power generator/emergency power supply		
	Presence of inverter and automated voltage stabilizer connected to the refrigerator.		
	Total YES and NO		
5	**Document Review**	**YES**	**NO**
	Is there a vaccine receipt/order/ issue voucher		
	Vaccine receipt/order/ issue voucher was availed		
	Vaccine receipt/order/ issue voucher used in the last 3 months		
	Is there vaccine stock management registers?		
	Vaccine stock management register was availed		
	Was the last entry made within the last 2 weeks		
	Does the stock register include diluents?		
	Is there contingency plan for handling vaccines in case of emergency?		
	Is the contingency plan pasted on the fridge?		
	Is there a national guidelines on immunization (Immunization in Practice-IIP)		
	The responsdent availed guidelines as a hard copy/soft copy		
	The guidelines availed was a current version (The United Republic of Tanzania, Immunization in Practice, January, 2016)		
	Is there cold chain Standard Operating Procedures?		
	The standard Operating Procedures were availed		
	The standard Operating Procedures were up-to-date		
	Are cleaning records for storage equipment in place?		
	Cleaning records were availed		

No.	Indicator	YES	NO
	Was the last entry made within the last 3 months?		
	Are there records of refrigerator defrosting in place?		
	Defrosting records were availed		
	Was the last entry made within the last 3 months?		
	Are the records of servicing and maintenance of equipment available?		
	Records of servicing and maintenance of equipment were availed		
	Was the last entry made within the last 6 months?		
	Is there records for equipment breakdown in the last 1 year?		
	Equipment breakdown records were availed		
	Was the last entry made within the last 1 years?		
	Is there records for power failure/cut off in the last 1 year?		
	Equipment breakdown records were availed		
	Was the last entry made within the last 1 years?		
	Total YES and NO		

APPENDIX 4: VACCINE COLD CHAIN SYSTEM STATUS CHECKLIST (SWAHILI VERSION)

KIAMBATISHO NA.4: ORODHA YA VIPENGELE VITAKAVYOTAZAMWA KWENYE MFUMO WA UTUNZAJI WA CHANJO

SEHEMU YA I: TAARIFA YA KITUO CHENYE MFUMO WA UTUNZAJI WA CHANJO

MAELEKEZO: Cheza taarifa za kituo kwenye nafasi iliyoachwa wazi chini ya maelezo ya kwenye jedwali hili

Namba ya utambulisho wa kituo (mfano FO1 …)	Tarehe:
☐	☐
Daraja la kituo (weka alama ya vema)	Mahali kituo kilipo (Mtaa, kata)
☐ Kituo cha Afya ☐ Zahanati	☐
Mmiliki wa kituo	Aina ya chanjo zinazotolewa (Taja majina hapa chini)
☐ Serikali ☐ Mtu/Shirika Binafsi ☐ Shirika la Dini ☐ Wengineo (taja) _____	☐ ☐ ☐ ☐ ☐

SEHEMU YA II: VIPENGELE VINAVYOTAZAMWA KWENYE MFUMO WA KITUO WA KUTUNZIA CHANJO

MAELEKEZO: Kwa kila maelezo au swali lililopo kwenye jedwali hapa chini, weka alama ya "N" kama jibu ni "Ndiyo" na "H" kama jibu ni "Hapana".

Na.	Kiashilio	Ndiyo	Hapana
1.	**Kituo**		
	Je, kituo kimetenga chumba maalumu kwa ajili ya kutunzia chanjo?		
	Je, kituo kimeteua mtu wa kusimamia utunzaji wa chanjo?		
	Mtunzaji wa chanjo/au mbadala wake alikutwa wakati wa utafiti. (kata		

Na.	Kiashilio	Ndiyo	Hapana
	ambaye hakukutwa)		
	Mtunzaji wa chanjo aliyekutwa amepata mafunzo ya utunzaji wa chanjo		
	Je, idara ya afya ya jiji au mkoa huwa inakuja kuangalia na kukagua mfumo wa utunzaji wa chanjo?		
	Je, ukaguzi huo umefanyika kwa mwaka jana? Kama hapana: Mwisho wa kufanyika ukaguzi huo ilikuwa lini (taja)		
	Je, kwa miaka miwili iliyopita, kumekuwa na fedha yoyote inayopangwa kwenye bajeti ya afya ya kituo kwa ajili ya kusimamia na kuboresha utunzaji wa chanjo? Kama hapana: Mara ya mwisho kutengwa bajeti hiyo ilikuwa lini? (jaza)		
	Jumala ya Ndiyo na Hapana		
2.	**Vifaa**		
A	**Jokofu/Friji**		
	Je, kuna friji ya kutunzia chanjo kwenye kituo hicho?		
	Je friji hiyo imekutwa imefungwa wakati wa utafiti?		
	Je, Friji iliyokutwa imethibitishwa na Shirika la Afya dunia (WHO) kwa ajili ya kutunzia chanjo?		
	Je, friji iliyokutwa ni nzima na haijaharibika? Kama hapana: taja ain ya uharibifu uliokutwa		
	Je, friji hiyo ni Ice Lined (ILR)?		
	Je, chanjo zimekutwa kwenye friji wakati wa utafti?		
	Je, friji hiyo yenye chanjo imekutwa imewashwa?		
	Je, Friji iliyowashwa inafanya kazi?		
	Je, kuna chanjo zimekutwa zimewekwa kwenye mlango wa friji?		
	Je, juu ya friji kumebandikwa stika za zinazoonesha mambo yanayotakiwa kufanyika (Dos) na yasiyotakiwa kufanyika (DON'Ts)?		
	Je, kumewekwa kipima joto (thermometer) kwenye friji?		
	Kama kipima joto kimewekwa, chagua aina yake hapa chini kwa kuzungushia jibu		
	e) Thermometer ya dijitali yenye waya unaoenda ndani katikati ya friji (Digital		

Na.	Kiashilio	Ndiyo	Hapana
	Thermometer with probe that goes to the center) f) Thermometer ya ndani ya friji yenye kifaa cha kusomea joto kilichowekwa nchi ya friji (Built in thermometer with external electronic display) g) Thermometer ya mshale (Dial thermometer) h) Thermometer ya tubu (Stem thermometer)		
	Thermometer inafanya kazi (inauwezo wa kuoyesha joto lililo kwenye friji)?		
	Thermometer imesanifishwa (calibrated) na wakala wa vipomo?		
	Kwenye jokofu hilo, pakiti za barafu (Frozen Ice packs) zimekutwa zimewekwa kwenye chumba cha friza (freezer compartments) na pakiti za maji yaliyopoa (cool water packs) zimewekwa kwenye chumba cha friji (fridge compartment).		
	Pakiti za maji yaliyopoo (cool water packs) zimekutwa zimepangwa wima (vertically arranged) kwenye chumba cha friji (fridge compartment).		
	Pakiti za barafu na za maji ya baridi yaliyopoa zimekutwa kwenye kiwango kinachoridhisha		
	Pakiti za barafu na za maji ya baridi yaliyopoa zimepangiliwa kwenye mfumo wa “crisscross” na zimeachiana nafasi		
	Joto limekutwa kwenye kiwango cha 2°C - 8°C wakati wa utafiti		
	Chati ya kurekodi joto imekutwa		
	Chati ya kurekodi joto imekutwa imejazwa kila siku hadi siku ya utafiti (complete and up to date)		
	Je, vipimo vya joto vinachukuliwa mara mbili kwa siku? Kama hapana: vipimo vinachukuliwa baada ya muda gani au mara ngapi? Taja		
	Rekodi za joto zimekutwa zimebandikwa juu ya friji		
	Je matengenezo na usanifishaji (Preventive maintenance and calibration) wa vifaa vya chanjo ulifanyika mwaka jana? Kama hapana taja mwaka/kipindi ulipofanyika		

Na.	Kiashilio	Ndiyo	Hapana
	Je kumekutwa na bidhaa zingine mbali na chanjo, maji ya chanjo, pakiti za barafu na pakiti za maji zimewekwa ndani ya friji?		
	Je, bidhaa tajwa hapo juu zimepangiliwa kwa kuacha nafasi ndani ya friji ili kuruhusu mzunguko wa hewa?		
	Je, kumekutwa na kituliza umeme (voltage stabilizer) kikiwa kimeunganishwa na friji?		
	Je, friji inauwezo wa kuyeyusha barafu ambayo huwa inaganda ndani yake kila baada ya muda fulani (Is the refrigerator self-defrost) ?		
	Kama haina uwezo wa kuyeyusha barafu hiyo, kuna takwimu zozote zinazoonyesha kuwa mnaondoa/kupunguza barafu iliyoganda ndani ya friji hiyo?		
	Je, kumekutwa na chanjo yoyote ikiwa imegusa kitako au kuta za friji?		
	Je, mnasafisha friji? Kama ndiyo: Mara ngapi kwa wiki/mwizi au mwaka? taja		
	Je, friji ilishawahi kuharibika?		
	Jumla ya Ndiyo na Hapana		
C	**Cold box/vaccine carrier**		
	Je, kituo kina vifaa vya kusafirishia chanjo (Cold box and/or vaccine carrier)? Tiki kimoja au vyote kama vipo Taja idadi ya cold boxes zilizopo Taja idadi ya vaccine carrier zilizopo		
	Je, vifaa hivyo vya kusafirishia chanjo vimekutwa na chanjo ndani???		
	Je, vifaa vilivyokutwa na chanjo vimekutwa na pakiti za barafu au maji ndani yake?		
	Je, Pakiti za barafu au maji zimewekwa china na pembeni ya vifaa vya kusafirishia chanjo		
	Je, chanjo ambazo zinaharibiwa na barufu kwa urahisi (Freeze-sensitive vaccines) zimepangwa bila kugusana na pakiti za barafu.		
	Matengenezo na usanifishaji wa vifaa vya kusafirishia chanjo ulishawahi		

Na.	Kiashilio	Ndiyo	Hapana
	kufanyika? Mara ya mwisho ilikuwa lini (taja)		
	Je, kuna kipima joto ndani ya cold box au vaccine carrier?		
	Je, kipima joto hicho kimewekwa katikati ya cold box au vaccine carrier?		
	Je, kipima joto hicho kinafanya kazi (kinasomo joto vizuri)?		
	Je, kipima joto kimesanifishwa?		
	Joto limekutwa liko kwenye kiwango kinachotakiwa cha 2°C - 8°C wakati wa utafiti.		
	Jumala ya Ndiyo na Hapana		
3.	**Hali ya chanjo na utunzaji**		
	Je, kumekutwa na chanjo zimetunzwa kwenye kituo?		
	Je, chanjo zimekutwa zimefungiwa chumbani na kwenye kifaa cha kutunzia chanjo kwa kufuli na funguo (under lock and key?		
	Je, kuna *vaccine vial monitors* iliyokutwa kwenye chanjo ikiwa imebadilika rangi?		
	Je, chanjo zimepangwa kwa mfumo wa FIFO na FEFO?		
	Je, wakati wa utafiti, kumekutwa na chanjo iliyoisha muda wake wa matumizi ?		
	Je, kuna chanjo inayoharibiwa na barufu imewekwa kwa kugusa kuta au kitako cha friji?		
	Je, chanjo aina ya OPV, BCG, measles; DPT na TT zimekutwa zimepangwa kwenye chumba cha friza ndani ya friji?		
	Maboksi ya chanjo yamepangiliwa kwa mkusanyiko (Boxes of vaccines arranged in stacks)		
	Je, kwenye friji kumekutwa na chanjo zinazotumika zaidi ya mara moja?		
	Chanjo zinazotumika zaidi ya mara moja zimekutwa zimeandikwa tarahe zilipofunguliwa kwa mara ya kwanza		
	Chanjo zilizoharibika na zilizokwisha muda wa matumizi zimewekewa lebo na kutengwa pembeni.		

Na.	Kiashilio	Ndiyo	Hapana
	Jumala ya Ndiyo na Hapana		
4	**Nishati**		
	Kituo kimeunganishwa na mfumo wa umeme wa Jiji/taifa		
	Umeme ndiyo chanzo kikubwa cha nishati kwenye utunzaji wa chanjo		
	Gesi ndiyo chanzo kikubwa cha nishati kwenye utunzaji wa chanjo		
	Mafuta ya taa (Kerosene) ndiyo chanzo kikubwa cha nishati kwenye utunzaji wa chanjo		
	Chanzo cha nishati ni cha kudumu?		
	Friji imeunganishwa kwenye chanzo cha nishati		
	Je, kituo kilishawahi kupata tatizo la upatikanaji wa nishati?		
	Rekodi za kukosekana kwa nishati zipo?		
	Je kuna jenereta mbadala ya kutumia kutunzia chanjo wakati wa ukosefu wa nishati?		
	Je, kibadilisha umeme (inverter) na kipozeo cha umeme (voltage stabilizer) zimekutwa zimeunganishwa kwenye friji?		
	Jumla ya Ndiyo na Hapana		
5	**Nyaraka**		
	Je, kuna foma ya kuombea na kutolea chanjo kwenye stoo?		
	Foma ya kuombea na kutolea chanjo ilionyeshwa		
	Foma ya kuombea/kutolea chanjo imetumika ndani ya miezi 3 iliyopita		
	Je, kuna rejista ya chanjo?		
	Rejista ya chanjo ilionyeshwa		
	Rejista ya chanjo imejazwa ndani ya wiki 2 zilizopita		
	Je, rejista ya chanjo inajumisha maji ya kuchanganyia chanjo (diluents)?		
	Kuna mpango wa ziada (contingency plan) wa kutunza chanjo wakati dharura zinapotokea kwenye mfumo/vifaa vya kutunzia chanjo?		
	Je, mpango huo wa dharura umebandikwa kwenye friji?		
	Je, kuma mwongozo wa taifa wa chanjo?		
	Kitabu kilichochapishwa cha mwongozo wa taifa wa chanjo		

Na.	Kiashilio	Ndiyo	Hapana
	kilionyeshwa		
	Mwongozo huo ulikuwa ni toleo la sasa (The United Republic of Tanzania, Immunization in Practice-IIP, January, 2016)		
	Je, kuna taratibu sanifu za utendaji kazi (Standard Operating Procedures) zinazohusu utunzaji wa chanjo?		
	Taratibu sanifu hizo za utendaji kazi zilionyeshwa		
	Je, taratibu sanifu hizo ziko ndani ya kipindi kinachotakiwa (up to date)?		
	Je, kuna rekodi za kusafisha vifaa vya kutunzia chanjo?		
	Rekodi za kusafisha vifaa vya kutunzia chanjo zilionyeshwa		
	Je, ndani ya miezi 3 iliyopita, rekodi hizo zimejazwa?		
	Je, kuna rekodi za kuyeyusha friji?		
	Rekodi za kuyeyusha friji la kutunzia chanjo zilionyeshwa		
	Je, ndani ya miezi 3 iliyopita, rekodi hizo zimejazwa?		
	Je, kuna rekodi za matengenezo ya vifaa vya kutunzia chanjo?		
	Rekodi za matengenezo ya vifaa vya kutunzia chanjo zilionyeshwa		
	Je, ndani ya miezi 6 iliyopita, rekodi hizo zimejazwa?		
	Je, kuna rekodi za kuharibika kwa vifaa vinavyotumika kwenye mfumo wa kutunzia chanjo?		
	Rekodi za kuharibika kwa vifaa hivyo zilionyeshwa		
	Je, ndani ya mwaka 1 uliopita, rekodi hizo zimejazwa?		
	Je, kuna rekodi za kukatika kwa nishati inayotumika kutunzia chanjo?		
	Rekodi za kukatika nishati hiyo zilionyeshwa		
	Je, ndani ya mwaka 1 uliopita, rekodi hizo zimejazwa?		
	Jumla ya Ndiyo na Hapana		

APPENDIX 5: QUESTIONNAIRE FOR ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICES OF COLD CHAIN HANDLING STAFF ON STORAGE AND COLD CHAIN MANAGEMENT OF VACCINES (ENGLISH VERSION)

PART I: BASELINE SOCIALDEMOGRAPHIC CHARACTERISTICS OF COLD CHAIN HANDLING STAFF (RESPONDENTS)

INSTRUCTIONS: Fill your particulars in the space provided below each description

<table>
<tr><td>Cold chain staff unique number (e.g P01 etc.):</td><td>Date:</td></tr>
<tr><td>☐</td><td>☐</td></tr>
<tr><td>Gender (Tick one):</td><td>Age (years):</td></tr>
<tr><td>☐ Male ☐ Female</td><td rowspan="2">☐</td></tr>
<tr><td>Educational Qualification (Tick one):</td></tr>
<tr><td rowspan="2">☐ Clinical Officer ☐ Medical Doctor
☐ Pharmacist ☐ Pharmaceutical Technician
☐ Enrolled Nurse ☐ Registered Nurse
☐ Laboratory Technician ☐ Health Officer
☐ Others</td><td>Duration of working experience (in years) as cold chain handling staff:
☐</td></tr>
<tr><td>Vaccine cold chain Training status</td><td>If trained (when was the last training)</td></tr>
<tr><td>☐ Trained ☐ Not trained</td><td>☐</td></tr>
</table>

PART II: KNOWLEDGE, ATTITUDE AND PRACTICE OF VACCINE HANDLING STAFF ON VACCINES STORAGE AND COLD CHAIN MANAGEMENT OF VACCINES

INSTRUCTIONS:

1. This part of questionnaire consists of III sections with series of questions
2. The questions aim to evaluate your knowledge, practices and attitude on storage and cold chain management of vaccines.
3. There are 22, 10 and 8 questions for each section of knowledge, practice and attitude respectively

4. Please choose the appropriate answer and tick the small box behind the option your choice.
5. Please let me know if you need more clarification in any of the questions.

PART II (A): KNOWLEDGE OF VACCINE HANDLING STAFF ON STORAGE AND COLD CHAIN MANAGEMENT OF VACCINES

1. Thermometers/fridge tags should be placed at the center of a vaccine storage device: -
   - ☐ Yes
   - ☐ No
   - ☐ Not sure
2. The amount of vaccines and diluents placed in the storage device has no impact on vaccine quality
   - ☐ Yes
   - ☐ No
   - ☐ Not sure
3. Food items can be stored together with vaccines without affecting vaccines potency
   - ☐ Yes
   - ☐ No
   - ☐ Not sure
4. Opening of the door of vaccine a storage equipment more than 3 times can reduce vaccine quality
   - ☐ Yes
   - ☐ No
   - ☐ Not sure
5. Some vaccines can be used for up to 28 days after their vials are opened
   - ☐ Yes
   - ☐ No
   - ☐ Not sure
6. Vaccines can get spoiled if exposed to heat
   - ☐ Yes
   - ☐ No
   - ☐ Not sure

7. Vaccines can get spoiled if exposed to freezing

- ☐ Yes
- ☐ No
- ☐ Not sure

8. Light exposure has insignificant effect on vaccine quality

- ☐ Yes
- ☐ No
- ☐ Not sure

9. 2-8°C is an optimal temperature for the cold chain

- ☐ Yes
- ☐ No
- ☐ Not sure

10. The temperatures in a vaccine storage device should be read at least once a day

- ☐ Yes
- ☐ No
- ☐ Not sure

11. Vaccines diluents can be stored at room temperature

- ☐ Yes
- ☐ No
- ☐ Not sure

12. Bacille-Calmette-Guerin (BCG), Oral Poliovirus and Measles vaccines can be frozen

- ☐ Yes
- ☐ No
- ☐ Not sure

13. Diphtheria-Pertusis-Tetenus Toxoid (DPT) and Hepatitis B vaccines can be frozen

- ☐ Yes
- ☐ No
- ☐ Not sure

14. An ice-lined refrigerator (ILR) maintains the temperature required for storing vaccines for the maximum of one day (24 hours) in case of a power breakdown

    - ☐ Yes
    - ☐ No
    - ☐ Not sure

15. Ice-packs should start melting and become mobile once shaken before they are used in cold boxes or a vaccine carrier

    - ☐ Yes
    - ☐ No
    - ☐ Not sure

16. A vaccine vial monitor is used to determine if a vaccine has been frozen

    - ☐ Yes
    - ☐ No
    - ☐ Not sure

17. Freeze indicator is a tool used to indicate if vaccine vials have been exposed to temperatures less than 0°C during storage and transport

    - ☐ Yes
    - ☐ No
    - ☐ Not sure

18. The quality of vaccine cannot be affected by the status of a storage/transporting equipment

    - ☐ Yes
    - ☐ No
    - ☐ Not sure

19. A reconstituted vaccine can be used up to the next day

    - ☐ Yes
    - ☐ No
    - ☐ Not sure

20. Few number of ice packs in the cold box can preserve vaccine quality

- ☐ Yes
- ☐ No
- ☐ Not sure

21. Domestic refrigerator can be used to store vaccine

- ☐ Yes
- ☐ No
- ☐ Not sure

22. Medicines that require cold storage can be put together with vaccine in the refrigerator

- ☐ Yes
- ☐ No
- ☐ Not sure

PART II (B): PRACTICE OF COLD CHAIN HANDLING STAFF ON STORAGE AND COLD CHAIN MANAGEMENT OF VACCINES

1. I arrangement vaccines in a specific criss cross pattern during storage

    - ☐ Always
    - ☐ Mostly
    - ☐ Not sure
    - ☐ Hardly
    - ☐ Never

2. I use cool water packs instead of ice packs during storage and transportation of Oral Poliovirus (OPV) vaccine

    - ☐ Always
    - ☐ Mostly
    - ☐ Not sure
    - ☐ Hardly
    - ☐ Never

3. I select the earliest batch of vaccines received when dispensing

    - ☐ Always
    - ☐ Mostly
    - ☐ Not sure
    - ☐ Hardly
    - ☐ Never

4. I use the vaccine vial monitors to check the integrity of vaccines

    - ☐ Always
    - ☐ Mostly
    - ☐ Not sure
    - ☐ Hardly
    - ☐ Never

5. When I find the inner square of a vaccine vial monitors (VVM), is lighter colour than the outer circle I remove the vaccine for disposal

    - ☐ Always
    - ☐ Mostly
    - ☐ Not sure
    - ☐ Hardly
    - ☐ Never

6. I check the freeze indicator before I dispense the vaccines

   - ☐ Always
   - ☐ Mostly
   - ☐ Not sure
   - ☐ Hardly
   - ☐ Never

7. If I find the display of a freeze indicator has changed from “ok” to “alarm” status, I decide not to dispense freeze sensitive vaccines

   - ☐ Always
   - ☐ Mostly
   - ☐ Not sure
   - ☐ Hardly
   - ☐ Never

8. I conduct the shake test when I suspect a vaccine has been exposed to heat

   - ☐ Always
   - ☐ Mostly
   - ☐ Not sure
   - ☐ Hardly
   - ☐ Never

9. I report to my supervisor when I find a defective vaccine

   - ☐ Always
   - ☐ Mostly
   - ☐ Not sure
   - ☐ Hardly
   - ☐ Never

10. I put some vaccines in the freezing compartment of a refrigerator to preserve their quality

    - ☐ Always
    - ☐ Mostly
    - ☐ Not sure
    - ☐ Hardly
    - ☐ Never

PART II (C): ATTITUDE OF COLD CHAIN HANDLING STAFF ON STORAGE AND COLD CHAIN MANAGEMENT OF VACCINES

1. Vaccine cold chain management is an add on activity

   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Not sure
   - ☐ Disagree
   - ☐ Strongly disagree

2. Vaccines I administer to clients are of good quality

   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Not sure
   - ☐ Disagree
   - ☐ Strongly disagree

3. I don't have adequate resources to enable better management of vaccine cold handling

   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Not sure
   - ☐ Disagree
   - ☐ Strongly disagree

4. I am confident about my knowledge on vaccine cold chain handling

   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Not sure
   - ☐ Disagree
   - ☐ Strongly disagree

5. I receive adequate level of vaccine cold chain supportive supervision from district/regional team

   - ☐ Strongly agree
   - ☐ Agree

- ☐ Not sure
- ☐ Disagree
- ☐ Strongly disagree

6. I am highly motivated to perform my duties as vaccine cold chain handling staff

   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Not sure
   - ☐ Disagree
   - ☐ Strongly disagree

7. A damaged vaccine in the cold chain should always make me very concerned

   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Not sure
   - ☐ Disagree
   - ☐ Strongly disagree

8. I need continuous training on vaccine cold chain management

   - ☐ Strongly agree
   - ☐ Agree
   - ☐ Not sure
   - ☐ Disagree
   - ☐ Strongly disagree

APPENDIX 6: QUESTIONNAIRE FOR ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICES OF COLD CHAIN HANDLING STAFF ON STORAGE AND COLD CHAIN MANAGEMENT OF VACCINES (SWAHILI VERSION)

KIAMBATISHO NA.6: ORODHA YA MASWALI YA UCHUNGUZI WA UELEWA, MTAZAMO NA UTENDAJI WA WASIMAMIZI WA MFUMO WA UTUNZAJI WA CHANJO

SEHEMU YA I: TAARIFA ZA MSIMAMIZI WA UTUNZAJI WA CHANJO

MAELEKEZO: Jaza taarifa zako kwenye nafasi zilizoachwa wazi chini ya kila kipengele kwenye jedwali hili hapa chini.

<table>
<tr><td>Namba ya maalumu ya utambulisho (mfano P01…):</td><td>Tarehe:</td></tr>
<tr><td>☐</td><td>☐</td></tr>
<tr><td>Jinsia (weka alama ya vema):</td><td>Umri (miaka):</td></tr>
<tr><td>☐ Mwanaume ☐ Mwanamke</td><td rowspan="3">☐</td></tr>
<tr><td>Taaluma (weka alama ya vema):</td></tr>
<tr><td>☐ Daktari ☐ Daktari Msaidizi

☐ Mfamasia ☐ Fundi Sanifu Dawa ☐ Muuguzi
☐ Muuguzi Msaidizi ☐ Mteknolojia Maabara

☐ Nyingine</td><td>Muda uliofanya kazi kama msimamizi wa utunzaji wa chanjo (jaza kwa miaka/miezi)
☐</td></tr>
<tr><td>Umeshapata mafunzo ya mafunzo ya utunzaji wa chanjo?)</td><td>Muda/kipindi cha mwisho kufundishwa (taja)</td></tr>
<tr><td>☐ Ndiyo ☐ Hapana</td><td>☐</td></tr>
</table>

SEHEMU YA II: UELEWA UTENDAJI NA MTAZAMO WA WATUNZAJI WA CHANJO KUHUSU UTUNZAJI WAKE NA MFUMO MZIMA WA USIMAMIZI WA CHANJO

MAELEKEZO:

1 Sehemu hii imegawanywa kwenye vipengele vitatu vyenye maswali.
2 Maswali haya yanalenga kupima uelewa, utendaji na mtazamo wako kuhusu utunzaji na mfumo mzima wa chanjo.
3 Kuna maswali 22, 10 na 8 kwenye kila kipengele cha kupima uelewa, utendaji na mtazamo kwa mtawaliwa
4 Chagua jibu lililosahihi kwa kuweka alama ya vema kwenye kisanduku cha jibu ulilolichagua.
5 Tafadhari, nijurishe pale utakapohitaji maelezo ya ziada kuhusu swali lolote.

SEHEMU YA II (A): UELEWA WA WASIMAMIZI WA MFUMO WA MNYORORO BARIDI WA CHANJO KUHUSU UTUNZAJI NA USIMAMIZI WA MFUMO HUO

1. *Thermometers/fridge tags* lazima ziwekwa katika kwenye kifaa cha kutunzia chanjo
    - ☐ Ndiyo
    - ☐ Hapana
    - ☐ Sina uhakika

2. Kiasi cha chanjo na cha maji ya kuchanganyia chanjo (diluents) kinachohifadhiwa pamoja na chanjo hakina athari kwenye ubora wa chanjo
    - ☐ Ndiyo
    - ☐ Hapana
    - ☐ Sina uhakika

3. Chakula kinachohifadhiwa pamoja na chanjo hakiwezi kuathiri ubora wa chanjo
    - ☐ Ndiyo
    - ☐ Hapana
    - ☐ Sina uhakika

4. Kufungua mlango wa chombo cha kutunzia chanjo zaidi ya mara 3 kunaweza kupunguza ubora wa chanjo

    - ☐ Ndiyo
    - ☐ Hapana
    - ☐ Sina uhakika

5. Baadhi ya chanjo zinaweza kutumika hadi siku 28 tangu chupa zake zifunguliwe

    - ☐ Ndiyo
    - ☐ Hapana
    - ☐ Sina uhakika

6. Chanjo zinaweza kuharibika zikiwekwa kwenye mazingira ya joto

    - ☐ Ndiyo
    - ☐ Hapana
    - ☐ Sina uhakika

7. Chanjo zinaweza kuharibika zikiwekwa kwenye ubaridi sana

    - ☐ Ndiyo
    - ☐ Hapana
    - ☐ Sina uhakika

8. Mwanga hauna madhara kwenye ubora wa chanjo

    - ☐ Ndiyo
    - ☐ Hapana
    - ☐ Sina uhakika

9. Joto la 2-8°C ndiyo linalotakiwa kwenye mfumo wa utunzaji wa chanjo

    - ☐ Ndiyo
    - ☐ Hapana
    - ☐ Sina uhakika

10. Inatakiwa kusoma joto kwenye chombo cha kuhifadhia chanjo walau mara 1 kwa siku

- ☐ Ndiyo
- ☐ Hapana
- ☐ Sina uhakika

11. Unaweza kutunza maji ya kuchanganyia chanjo kwenye chumba cha kawaida

- ☐ Ndiyo
- ☐ Hapana
- ☐ Sina uhakika

12. Chanjo aina ya Bacille-Calmette-Guerin (BCG), Oral Poliovirus and Measles zinaweza kugandishwa

- ☐ Ndiyo
- ☐ Hapana
- ☐ Sina uhakika

13. Chanjo aina ya Diphtheria-Pertusis-Tetenus Toxoid (DPT) and Hepatitis B zinaweza kugandishwa

- ☐ Ndiyo
- ☐ Hapana
- ☐ Sina uhakika

14. Friji yenye ukuta wa barafu (ice-lined refrigerator) inaweza kutunza joto linalotakiwa kwenye chanjo kwa muda usiozidi siku moja (1) wakati ambapo hakuna na nishati (mfano umeme n.k)

- ☐ Ndiyo
- ☐ Hapana
- ☐ Sina uhakika

15. Pakiti za barafu (ice-packs) zinatakiwa ziyeyuke kidogo kabla ya kutumiwa kuhifadhia chanjo kwenye *cold boxes* au *vaccine carrier*

    ☐ Ndiyo
    ☐ Hapana
    ☐ Sina uhakika

16. Kifaa aina ya *vaccine vial monitor* kinatumika kuangalia kama chanjo zimeganda

    ☐ Ndiyo
    ☐ Hapana
    ☐ Sina uhakika

17. Kifaa aina ya *freeze indicator* kinatumika kuangalia kama chanjo zimewekwa kwenye joto chini ya 0°C

    ☐ Ndiyo
    ☐ Hapana
    ☐ Sina uhakika

18. Ubora w chanjo hauwezi kuathiriwa na ubora kifaa kinachotumika kuzitunzia au kuzisafirishia

    ☐ Ndiyo
    ☐ Hapana
    ☐ Sina uhakika

19. Chanjo iliyochanganywa inaweza kutumika mpaka siku inayofuata

    ☐ Ndiyo
    ☐ Hapana
    ☐ Sina uhakika

20. Pakiti chache za barafu (ice packs) zinatosha kutumika kwa ajili ya kuhifadhia chanjo kwenye *cold box*

    - ☐ Ndiyo
    - ☐ Hapana
    - ☐ Sina uhakika

21. Friji ya nyumbani inaweza kutumika kutunzia chanjo

    - ☐ Ndiyo
    - ☐ Hapana
    - ☐ Sina uhakika

22. Dawa zinazohitaji kutunzwa kwenye ubaridi zinaweza kuwekwa pamoja na chanjo kwenye friji

    - ☐ Ndiyo
    - ☐ Hapana
    - ☐ Sina uhakika

SEHEMU YA II (B): UTENDAJI WA WASIMAMIZI WA MFUMO WA MNYORORO BARIDI WA CHANJO KATIKA USIMAMIZI WA MFUMO WA HUO

1. Napangilia chanjo kwa mfumo unaotakiwa wa *criss-cross* wakati wa utunzaji

   - ☐ Kila mara
   - ☐ Mara nyingi
   - ☐ Sina uhakika
   - ☐ Mara chache
   - ☐ Hapana

2. Natumia pakiti za maji yaliyopoa (cool water packs) badala ya pakiti za barafu (ice packs) wakati nasafirisha au kutunzia chanjo aina ya Oral Poliovirus (OPV)

   - ☐ Kila mara
   - ☐ Mara nyingi
   - ☐ Sina uhakika
   - ☐ Mara chache
   - ☐ Hapana

3. Nachagua chanjo ya toleo la nyuma nikiwa natoa kwa ajili ya kutumika

   - ☐ Kila mara
   - ☐ Mara nyingi
   - ☐ Sina uhakika
     Mara chache
   - ☐ Hapana

4. Natumia vaccine vial monitors kuangalia ubora wa chanjo

   - ☐ Kila mara
   - ☐ Mara nyingi
   - ☐ Sina uhakika
   - ☐ Mara chache
   - ☐ Hapana

5. Ninapoona mraba wa ndani (inner square) wa *vaccine vial monitors* una rangi iliyofifia ukilinganisha na mduara wa nje (outer circle), naiiondoa chanjo hiyo isitumike tena

   - ☐ Kila mara
   - ☐ Mara nyingi

- ☐ Sina uhakika
- ☐ Mara chache
- ☐ Hapana

6. Naangalia *freeze indicator* kabla sijatoa chanjo itumike
   - ☐ Kila mara
   - ☐ Mara nyingi
   - ☐ Sina uhakika
   - ☐ Mara chache
   - ☐ Hapana

7. Nikiona alama ya freeze *indicator* imebadilika kutoka “ok” na kuwa “alarm” huwa nazuia chanjo zinazoharibika kwa kuganda zisitumike
   - ☐ Kila mara
   - ☐ Mara nyingi
   - ☐ Sina uhakika
   - ☐ Mara chache
   - ☐ Hapana

8. Huwa nafanya jaribio la kutikisa chanjo (shake test) ninapohisi chanjo imepatwa na joto kali
   - ☐ Kila mara
   - ☐ Mara nyingi
   - ☐ Sina uhakika
   - ☐ Mara chache
   - ☐ Hapana

9. Ninatoa taarifa kwa Mkuu wangu wa kazi ninapobaini chanjo imeharibika.
   - ☐ Kila mara
   - ☐ Mara nyingi
   - ☐ Sina uhakika

- ☐ Mara chache
- ☐ Hapana

10. Huwa naweka baadhi ya chanjo kwenye chumba cha kugandisha (freezing compartment) cha friji ili kuhifadhi ubora wake

    - ☐ Kila mara
    - ☐ Mara nyingi
    - ☐ Sina uhakika
    - ☐ Mara chache
    - ☐ Hapana

SEHEMU YA II (C): MTAZAMO WA WASIMMAZI WA MFUMO WA MNYORORO BARIDI WA CHANJO KUHUSU UTUNZAJI NA MFUMO HUO

1. Usimamizi wa mfumo wa chanjo ni kazi ya ziada

    - ☐ Nakubali kabisa
    - ☐ Nakubali
    - ☐ Sina uhakika
    - ☐ Sikubali
    - ☐ Sikubali kabisa

2. Chanjo ninazotoa kwa wateja zina ubora mzuri

    - ☐ Nakubali kabisa
    - ☐ Nakubali
    - ☐ Sina uhakika
    - ☐ Sikubali
    - ☐ Sikubali kabisa

3. Sina rasilimali za kuniwezesha kufanya kazi ya usimamizi wa chanjo vizuri

    - ☐ Nakubali kabisa

- ☐ Nakubali
- ☐ Sina uhakika
- ☐ Sikubali
- ☐ Sikubali kabisa

4. Nina Imani na uelewa nilionao juu ya utunzaji na usimamizi wa chanjo

   - ☐ Nakubali kabisa
   - ☐ Nakubali
   - ☐ Sina uhakika
   - ☐ Sikubali
   - ☐ Sikubali kabisa

5. Ninapata kiwango kizuri cha usimamizi elekezi (supportive supervision) kwenye mfumo wa chanjo kutoka idara ya chanjo ya wilaya au mkoa

   - ☐ Nakubali kabisa
   - ☐ Nakubali
   - ☐ Sina uhakika
   - ☐ Sikubali
   - ☐ Sikubali kabisa

6. Nimehamasika vya kutosha kufanya kazi kwenye mfumo baridi wa chanjo

   - ☐ Nakubali kabisa
   - ☐ Nakubali
   - ☐ Sina uhakika
   - ☐ Sikubali
   - ☐ Sikubali kabisa

7. Chanjo iliyoharibika huwa inanifanya nijihisi kuwa na wasiwasi

   - ☐ Nakubali kabisa
   - ☐ Nakubali
   - ☐ Sina uhakika

- ☐ Sikubali
- ☐ Sikubali kabisa

8. Nahitaji mafunzo zaidi kwenye utunzaji na usimamizi wa mfumo wa chanjo

- ☐ Nakubali kabisa
- ☐ Nakubali
- ☐ Sina uhakika
- ☐ Sikubali
- ☐ Sikubali kabisa

APPENDIX 7: TANZANIA NATIONAL INSTITUTE OF MEDICAL RESEARCH (NIMR) APPROVAL TO CONDUCT RESEARCH

THE UNITED REPUBLIC OF TANZANIA

National Institute for Medical Research
3 Barack Obama Drive
P.O. Box 9653
11101 Dar es Salaam
Tel: 255 22 2121400
Fax: 255 22 2121360
E-mail: nimrethics@gmail.com

Ministry of Health, Community Development, Gender, Elderly & Children
University of Dodoma, College of Business Studies and Law
3rd dling No. 11
P.O. Box 743
40478 Dodoma

NIMR/HQ/R.8a/Vol. IX/3418

07th May, 2020

Emmanuel Masunga Gadi
Pharmacist
Tanzania Medicine and Medical Devices Authority
P.O. Box 16009
Arusha

RE: ETHICAL CLEARANCE CERTIFICATE FOR CONDUCTING MEDICAL RESEARCH IN TANZANIA

This is to certify that the research entitled: Evaluation of the storage and cold chain management of vaccines in the primary health facilities in Arusha city, northern Tanzania (Gadi M. et al), has been granted ethical clearance to be conducted in Tanzania.

The Principal Investigator of the study must ensure that the following conditions are fulfilled:

1. Progress report is submitted to the Ministry of Health, Community Development, Gender, Elderly & Children and the National Institute for Medical Research, Regional and District Medical Officers after every six months.
2. Permission to publish the results is obtained from National Institute for Medical Research.
3. Copies of final publications are made available to the Ministry of Health, Community Development, Gender, Elderly & Children and the National Institute for Medical Research.
4. Any researcher, who contravenes or fails to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III Section 10(2).
5. Sites: Arusha City.

Approval is valid for one year: 07th May, 2020 to 06th May, 2020

Name: **Prof. Yunus Daud Mgaya**

Signature
CHAIRPERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

Name: **Prof. Abel Nkono Makubi**

Signature
CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY & CHILDREN

CC: Director, Health Services-TAMISEMI, Dodoma
RMO of Arusha region.
DMO/DED of Arusha Urban district.

APPENDIX 8: KENYATTA NATIONAL HOSPITAL, UNIVERSITY OF NAIROBI RESEARCH AND ETHICS COMMITTEE (KNH/UON-ERC) APPROVAL TO CONDUCT RESEARCH

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

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/77

21st February 2020

KENYATTA NATIONAL HOSPITAL APPROVED 21 FEB 2020 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI

Emmanuel Masunga Gedi
Reg. No.U51/19461/2019
Dept. of Pharmacology and Pharmacognosy
School of Pharmacy
College of Health Sciences
University of Nairobi

Dear Emmanuel

RESEARCH PROPOSAL - EVALUATION OF THE STORAGE AND COLD CHAIN MANAGEMENT OF VACCINES IN THE PRIMARY HEALTH FACILITIES IN ARUSHA CITY, NORTHERN TANZANIA (P966/12/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 21st February 2020 – 20th February 2021.

This approval is subject to compliance with the following requirements:

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

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

Protect to discover

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Pharmacy, UoN
The Chair, Dept. of Pharmacology and Pharmacognosy, UoN
Supervisors: Prof. Anastasia N. Guantai, Dept. of Pharmacology and Pharmacognosy, UoN
Prof. Appolinary Kamuhabwa, School of Pharmacy, Muhimbili University of Health Allied Sciences, Tanzania
Dr. Margaret N. Oluka, Dept.of Pharmacology and Pharmacognosy, UON