ASSESSMENT OF VACCINE COLD CHAIN MANAGEMENT STATUS AT PUBLIC HEALTH FACILITIES IN DAWURO ZONE, SOUTH WEST ETHIOPIA

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Abstract

Back ground: *Cold chain is the system of transporting and storing of vaccine at the recommended temperature range. Cold chain includes three basic components: equipment for transport and storage, trained personnel to manage vaccine storage and distribution, and efficient management procedures. All three elements must be maintained at every link in the chain to ensure that the administration of the vaccine is safe.*

Objectives: *To assess the status of vaccine cold chain management at public health facilities in Dawuro zone, South West Ethiopia.*

Method: *Facility based cross-sectional study mainly quantitative and supplemented by qualitative method was conducted from February 30-March 20 2015. Data was collected from 31public health facilities, 31 vaccine handlers and 12 key informants. The quantitative data were checked for completeness and then entered into SPSS version 16 for analysis. Frequencies and proportions were used to summarize findings. Chi-square was used to test presence of association between socio-demographic variables and knowledge and practice level of vaccine handlers with (p-value< 0.05).. Data from in-depth interview were coded first, then categorized and finally analyzed by thematic content analysis technique. Lastly, triangulation of the qualitative findings with quantitative was carried out.*

Result: *Of 31 public health facilities visited, 1(3.2%), 7(22.6%) and 23(74.2%) had good, medium and poor availability of cold chain equipments respectively to store and transport vaccines. From 31 vaccine handlers interviewed 10(32.3%), 11(35.4%) and 10(32.3%) had good, medium and poor knowledge level respectively on vaccine cold chain management system. In addition, out of 31 facilities assessed regarding vaccine handling and storage practice, 9(29%), 14(45%) and 8(26%) had good, medium and poor practice level respectively. Work experience and types of training on vaccine cold chain had a statistically significant association with knowledge and practice levels of vaccine handlers with (p-value< 0.05). This result was also supported by majority of key informants.*

Conclusion and recommendations*: Vaccines in a third of the facilities were found to be at a high risk of losing their potency. There is an urgent need to distribute equipments, improve knowledge and practice on cold chain management through supportive supervision and training.*

Key words: *Vaccine cold chain, recommended temperature, public health facilities and vaccine handlers.*

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Acronyms and abbreviations

BCG	Bacillus Calmette-Guerin vaccine
DTP	Diphtheria-tetanus-pertussis vaccine
EAG	Empowered Action Group
EPI	Expanded Program on Immunization
EVM	Effective Vaccine Management
GAVI	Global Alliance for Vaccines and Immunization
HepB	Hepatitis B vaccine
Hib	Haemophilus Influenzae type b
HSDP III	Health Sector Development Program three
ICC	Inter-agency Coordinating Committee
IIP	Immunization in Practice
ILR	Ice lined Refrigerator
IPV	Inactivated polio vaccine
MOH	Ministry of Health
NGO	Non-governmental organization
OPV	Oral polio vaccine
PCV	Pneumococcal Conjugate Vaccine
PFSA	Pharmaceutical Fund and Supply Agency
RED	Reaching Every District
SNNPR	Southern Nation, Nationality and People Region
Td	Tetanus-diphtheria vaccine
TT	Tetanus toxoid vaccine
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VVM	Vaccine vial monitor
WHO	World Health Organization

Operational definitions

Cold chain: Is the system of transporting and storing of vaccine at the recommended temperature range which is (+2^{0}C to + 8^{0}C for refrigerator vaccines) and (-15^{0}C to -25^{0}C for freezer vaccines)

Vaccine: Is an antigenic preparation used to stimulate the production of antibodies and provide immunity against a disease.

Vaccine carrier: Is an insulated box with a tight fitting insulated lid used to transportation of small quantities of vaccine at a temperature between 0º and 8º within one working day.

Cold box: Is an insulated container with a tight fitting insulated lid used to collection and transport of large quantities of vaccine at temperatures between 0º to +8º C;

Thermometer: is equipment used to measure the current temperature and the minimum and maximum temperatures that have been reached over a period of time.

Deep freezer: Is equipment used to store vaccine in negative temperature (-15^{0}C to -25^{0}C).

Fridge tag: Is a device used to monitor vaccine temperature continuously

Refrigerator: Is equipment used to store vaccine in temperature range of (+2^{0}C to + 8^{0}C).

Practice level on cold chain: Maintaining a network of cold chain equipments, personnel and procedures to keep vaccines within recommended temperature to safeguard their potency during storage, transport and delivery. This was measured by developing practice scale i.e good, moderate & poor practice by dividing the number of right practice to total practice questions (yes/total X 100%) into 3 parts (1).

- → Poor practice- total score of < 65%
- → Medium practice - total score of 65%-79%
- → Good practice- total score of >=80%.

Knowledge level about cold chain: Having an understanding on storage, handling, distribution system and characteristics of vaccine, and the causes and outcomes of break in cold chain.
This will be measured by developing knowledge scale i.e good, moderate & poor knowledge based on the number of questions answered correctly by respondent in questionnaires dividing 100% into 3 parts. The same scale was used as practice level.

- → Poor knowledge- total score of <65%
- → Medium knowledge - total score of 65-79%
- → Good knowledge- total score of >= 80%

Vaccine handler: A cold chain officer/EPI focal person in charge to manage vaccine cold chain at public health facilities.

Public health facilities: Zonal health department, woreda health offices, public hospitals and health centers.

Ice lined refrigerator: Type of refrigerator is specially designed for vaccine storage and is different from a normal top-opening refrigerator. It can keep vaccine safe with as little as 8 hours electricity supply in a 24hour period, and comes in various sizes for use at different levels in the cold chain.

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1. Introduction

1.1 Back ground

The system used for keeping and distributing vaccines in good condition is called the "cold chain." Cold chain is the system of transporting and storing of vaccine at the recommended temperature range which is (+2^{0}C to + 8^{0}C for refrigerator vaccines) and (-15^{0}C to -25^{0}C for freezer vaccines). This consists of a series of storage and transport links, all of which are designed to keep the vaccine at the correct temperature from where it manufactured until it reaches the recipient. Cold chain has three main components. These are: equipment for transport and storage, trained personnel to manage vaccine storage and distribution, and efficient management procedures. All the three elements must be maintained at every link in the chain to ensure that the administration of the vaccine is safe. The failure in one or other of these components leads to failure of the cold chain system(1–5).

The World Health Organization (WHO) recommends that all childhood vaccines except the oral polio vaccine be kept at 2–8 °C during their in country distribution .Although emphasis has long been placed on avoiding high temperatures during vaccine storage and shipment, exposure to "subzero" temperatures – i.e. temperatures < 0 °C can also damage and reduce the potency of the diphtheria, tetanus and pertussis (DPT), diphtheria and tetanus, tetanus toxoid, hepatitis B and pentavalent vaccines (6).

Any alteration in temperature such as exposure to excessive heat or cold damages the vaccines, resulting in loss of potency and as vaccine potency once lost, it cannot be restored. Therefore, an effective cold chain maintenance system is the backbone of success of any immunization program(2,7).

WHO/UNICEF has designed vaccine management assessment tool (VMAT) to investigate vaccine management, knowledge and practices amongst health staff operating at national, sub national (state level or regional) or intermediate (district) and service delivery (block) levels. The tool is based upon eleven global criteria essential for a performing vaccine and cold chain management system. These are: vaccine arrival procedures, vaccine storage temperatures, cold storage capacity, buildings, cold chain equipment and transport, maintenance of cold chain equipment, stock management, effective vaccine delivery, correct diluents use for freeze dried vaccines, effective vaccine vial monitor (VVM) use, multi-dose vial policy (MDVP) and vaccine wastage control. The EVM initiative encourages countries to achieve or exceed 80% score for all EVM indicators (7).

Ethiopia is getting all the vaccines from overseas on approximately quarterly basis through UNICEF. Vaccine supply chain in Ethiopia shows the supply chain starts from the initial quarterly dispatch of the vaccine from the central vaccine storage to the regional stores and goes down to the zone stores and finally to Woreda and health centers, where it is picked up monthly by the health posts. The regional and zonal stores are taking vaccines on quarterly basis from their respective upper level store. The woredas and health facilities are on monthly basis (1).

In Ethiopia FMOH is responsible for development of EPI policies and guidelines. The pharmaceuticals fund and supply agency (PFSA) manage the supply and logistics part of EPI. Two WHO and one UNICEF officers support programme management of EPI at the federal level. At regional level, there are focal persons responsible for coordination of programme activities while at zonal and district levels the programmes are integrated and there are officers to coordinate all programmes (8).

1.2 Statements of the problem

Vaccines are sensitive biological substances that can lose their potency and effectiveness permanently if they are exposed to temperature outside the recommended ranges and /or to light. Storage and handling errors can cost thousands of dollars in wasted vaccine, revaccination and specialized transportation. This errors can also result in the loss of patient confidence when repeat doses are required (9,10). In 2011, 50% of GAVI (Global Alliance for Vaccines and Immunization) eligible countries reported vaccine wastage rate in excess of WHO recommendations and 2.8 million vaccine doses lost in 5 countries of world due to cold chain failures (11).

The maintenance of vaccine cold chain requires adequate cold chain infrastructure, trained staffs and compliance to standard. But evidences show that trained personnel in charge of vaccine cold chain are commonly available in developed countries than developing country. Studies also reported that the cold chain system is assumed to be at greatest risk, particularly in countries where power supply is unreliable and facilities for its maintenance are not well developed (12–14). In 2013 less than 10% of countries meet WHO recommendations for effective vaccine management practices (11).

Several reports from developing countries indicate that health workers seem to be overwhelmingly concerned with only raising vaccination coverage. The quality of vaccination services that is equally important for achievement of the ultimate goal of disease reduction has been neglected. Sub-optimal sero-conversion rates and outbreaks of vaccine preventable diseases elsewhere were attributed to loss of vaccine potency either during transportation or storage (15).

The routine immunisation coverage in Ethiopia has not reached the targeted figures and planned objectives. As 2004 EPI review this is due to, lack of supervision, high dropout rates, inadequate number of trained health workers and inadequate supplies like cold chain equipments (16).

Comprehessive multi-year plan (2011 – 2015) of Ethiopia on national EPI showed that vaccine stock and inventory management is weak at regional and service delivery levels of Ethiopia. This has resulted in overstocking of vaccines at central level while sub- national cold rooms were not storing adequate vaccines. As a result changing of VVM status of the DPT-HepB-Hib was noted and vaccine wastage, particularly that of BCG is high (8).

As 2013/14 annual report of SNNPR health bureau showed that, despite high immunization rate in regional levels ,BCG 99%, pentavalent3 104%, PCV3 104%, measles vaccine 101% and overall 98%, outbreak of vaccine preventable diseases in most zones and some special woredas of the region were reported. Dawuro zone is one of the zones in which high number of measles outbreak (1040 cases from a total 7749 reported cases in 10 zones, 1 town administration and 2 special Woredas) unpublished source (unpublished source: Regional health bureau of SNNPR, annual report 2014,Dawuro zone health department annual report 2014). Since Dawuro zone had 601,904 populations in the year 2014; the percentage burden of the measles outbreak is high relative to regional outbreak.

To date there were limited studies done in vaccine cold chain management at public health facilities in a study area. Hence, this study was conducted to assess the status of vaccine cold chain management at public health facilities in Dawuro zone.

1.3 Significances of study

The quality of vaccines is one of important factor for success of immunisation programme which in turn depends on proper storage and handling of vaccines. Cold chain is an essential component for maintaining the quality of vaccine. The principles of vaccine storage consists of proper installation and use of cold chain equipments, maintenance of appropriate temperatures, recording temperatures, location of the vaccines inside a refrigerator, availability and use of cold chain management guidelines and using the refrigerator exclusively for vaccine storage. To maintain cold chain of vaccines, availability of functioning cold chain equipments, trained staff, appropriate transport and storage area must be ensured at each levels of cold chain.

Therefore, showing the existing status of cold chain equipments, knowledge and practice levels of vaccine handlers on vaccine cold chain management in study areas is helpful to facilitate interventions that aim at prevention and early management of cold chain failure. More over; the findings of this study can be used as an input for local health officials in the study area and policy makers to train healthcare professionals to develop targeted and evidence based strategies so as to improve cold chain management system. It may also serve as base line for further large scale studies across the country on vaccine cold chain management.

2. Literature Review

2.1 Over view

Cold chain is a means for storing and transporting vaccines in a potent state from the manufacturer to the person being immunized. This is a very important component of an immunization programme, since all vaccines lose potency over time, especially if exposed to heat and in addition, some also lose their potency when frozen. It is obviously pointless to immunize with impotent vaccine, and efforts to reach extremely high levels of immunization coverage will be useless if the vaccine being administered has insufficient potency to give the necessary protection. Attention to maintaining correct temperatures during storage and transport of vaccine is thus a major task for health workers (3,4).

In order to provide potent and effective vaccine to the beneficiaries a vast cold chain infrastructure is required, which should have a network of vaccine stores, deep freezers (DF), ice lined refrigerators (ILR), refrigerated trucks, vaccine vans, temperature monitoring devices, cold boxes, vaccine carriers and icepacks from national level up to the outreach sessions (3).

The maximum times and temperatures for storage of EPI (expanded program for immunization) vaccines at different levels of the cold chain as recommended by WHO (world health organization) are; during transport between one level and the next, all vaccines must be maintained at a temperature between $+2^{o}$Cand $+8^{o}$C; vaccines should kept for a maximum of 6 months, 3 months and 1 month at national, regional, district and health facility levels respectively and from national to district levels; OPV (oral polio vaccine), measles, and mumps vaccines should be stored at -15 to -25^{o} C; hepatitis B, DPT (Diphtheria-tetanus-pertussis vaccine), DT(Diphtheria-tetanus), TT (Tetanus toxoid vaccine) and BCG (Bacillus Calmette-Guerin vaccine) at 0 to $+8^{o}$ C; and at health facility level all vaccines should be stored at 0 to $+8^{o}$ C (10,17).

All vaccines are heat sensitive. For example OPV loses its potency at rate of 4% to 13% per day at 25^0c, 11% to 21% per day at 31^0c and 26% to 34% per day at 37^0 C. Reconstituted BCG and measles are the most sensitive to heat and light. Since these vaccines do not contain preservatives, there is risk of contamination (increases chances of AEFIs (Adverse events following immunization). Therefore, BCG and Measles should not be used after 4 hours of reconstitution (3,6).

Most sensitive to heat

OPV

BCG (after reconstitution)

Measles (both before and after reconstitution)

DPT

BCG (before reconstitution)

DT

TT

HepB

Least sensitive to heat

Figure 1**:** Heat sensitivity of some vaccines(3)

Most sensitive to freeze

HepB

DPT

DT

TT

Least sensitive to freeze

Figure 2: Freeze sensitivity of some vaccines(3)

In ILR, BCG, mumps, polio and measles vaccines if not kept in a separate freezer should be kept in the bottom, where it is coldest and DPT, DT and hepatitis B vaccines should be kept in the baskets, nearer to the top. Do not put these vaccines within 15cm of the bottom of the compartment to avoid the risk of accidental freezing. Those vaccines other than these should be kept at the middle part of the ILR (9,17).

A temperature monitoring device is an essential requirement for temperature monitoring of vaccines. Each vaccine refrigerator and insulated container used for vaccine storage and transport must have a temperature monitoring device. The maximum-minimum thermometer sensor should be placed on the middle refrigerator shelf inside an empty vaccine box to help stabilize the temperature readings and to protect the sensor from exposure to sudden breezes of cold or warm air(18).

Ideally, the fridge containing vaccines should not be used to store other drugs in order to prevent two potential dangers: problem of not maintaining the recommended temperature range and wrongly administering drugs that have been packaged in similar color vials as the vaccine vials(19).

Some factors contributing to weaknesses of the cold chain were quality of refrigerators, method of storage, too long storage at the health unit, improper use of refrigerators, power interruption, equipment breakage, and lack of trained personnel capable of managing the cold chain (14).

2.2 Socio-demographic related factors of vaccine handlers

A study conducted in Chhattisgarh, India which was earlier a part of Madhya Pradesh, was declared a separate state in the year 2000, showed that 44% district vaccine stores were handled by untrained and unqualified staffs(20). Similarly the finding in Niassa, Mozambique in which approximately, 60% of the health workers had no pre-service training in vaccine storage and handling (13). In 2006, Tanzania operating at 25% of required staffing levels for cold chain management (11).

A cross-sectional study conducted in 90 primary health care units and 117 respondents to assess healthcare workers' knowledge and practices in cold chain system in Kalasin, Thailand identified

that healthcare workers who had sufficient training on cold chain handling and management had better knowledge than healthcare workers who had no training (P<0.001)(21).

An institution based cross-sectional study conducted in three districts (woredas) of Oromia, SNNP and Amhara regions of Ethiopia identified that, professional qualification and year of service in the immunization program showed a statistically significant association with knowledge of cold chain management (P < 0.05) (22)**.**

An institution based cross-sectional survey conducted in Addis Ababa city, and in Kenbata-Alaba-Timbaro (KAT) and Hadiya zones showed that majority of the immunization centres had no trained personnel for management of the cold chain (14).

2.3 Knowledge related factors of vaccine handlers

A cross-sectional study conducted in municipal corporation of Surat City, Western India identified that vaccine handlers had low level of knowledge for defrosting of ILR and deep freezer (45%), for vaccine shake test(40%), for temperature range to be maintained in deep freezer(70%) and ILR((15%) (23). But study done in territory of Chandigarh in the year of 2006 identified that (94.71%) DF's & ILR's were defrosted periodically (24).

A study conducted in Chhattisgarh, which was earlier a part of Madhya Pradesh, was declared a separate state in the year 2000, showed that most of vaccine handlers do not know how to interpret the readings in temperature recording and supply of vaccine is co-related to the immunisation targets (20). In contrast one study conducted in district of Kangra, India reported that (75%) of the workers could correctly calculate vaccine requirement(25). This study also showed that gaps in knowledge of health workers precipitated measles outbreak(25).

The finding in Niassa, Mozambique showed that 61% of respondents knew that freezing of DPT+HepB vaccine causes it to lose potency. The recommended temperature range for vaccine storage was known by 52% of the respondents (13). This is far from the finding in Kangra, India in which 75% of workers had correct knowledge of storage of different vaccines(25).

A cross-sectional study conducted among general practitioners in Kelantan, Malaysia, indicated that majority of respondents knew that vaccine will be damaged if exposed to heat (98.8%) and freezing state (88.8%) and 92% of respondents knew that they need to place refrigerator away from heat source such as microwave, stove and sunlight (12).

An institution based cross-sectional study conducted in three districts (woredas) of Oromia, SNNP and Amhara regions of Ethiopia identified that, 65% health workers had medium to good (satisfactory) knowledge on cold chain management (22)**.**

2.4 Practice related factors of vaccine handlers

A cross-sectional study conducted municipal corporation of Surat city, western India identified that there was poor temperature-record registration (23). Similarly the vaccine management assessment report of Jharkhand in 2009, cold chain equipment temperature is effectively monitored only in a few districts and though the temperatures were recorded, the frequency of recording was erratic and monitoring and recording was not done on holidays (26); the finding in Kalasin, Thailand in which only 61.1% of primary care units recorded the temperature in the vaccine refrigerator twice a day (21); the finding in three districts (woredas) of Oromia, SNNP and Amhara regions of Ethiopia, in only 59.1% facilities had complete temperature recording of the last month during study period (22) and (57.8%) of the immunization centres had complete temperature record from institution based cross-sectional survey conducted in Addis Ababa city, and in Kenbata-Alaba-Timbaro (KAT) and Hadiya zones (14).

UNICEF report of Jharkhand in 2009 identified that there was no alternate mechanism in place to monitor the cold chain equipment in the absence of the cold chain personnel. There was also lack of supervision for monitoring of cold chain management (26). But the study conducted in

Afghanistan identified that all provinces that manage vaccine had complete set of temperature record for the review period and being reviewed regularly by the supervisors (27) and the finding in territory of Chandigarh in the year of 2006 in which 95.36% temperature charts were up-to-date and signed by supervisors (28).

A cross-sectional study conducted Surat City, western India identified presence of things other than ice packs in deep freezer (10%) and things other than vaccines in ILR (10%), expired vaccines in ILR (5%), vaccines in the "unusable" stages of VVM (15%), lack of emergency contact number nearby in case of cold chain failure (85%) (23). Similarly a study conducted in Chhattisgarh, which was earlier a part of Madhya Pradesh, was declared a separate state in the year 2000, in which temperature monitoring, maintenance of infrastructure and equipment and vaccine management were far from satisfactory and31% district stores fall dismally below the required operating standards (20).

UNICEF report of Jharkhand, which was earlier part of Bihar [a state that is categorized among the Empowered Action Group (EAG) states], in 2009 reported that vaccine wastage was not recorded and there was no mechanism of conscious monitoring of vaccine wastage (26).

One study conducted district of Kangra, India reported that poor cold chain maintenance precipitated measles outbreaks(25).

The study conducted to compares the state of cold chain maintenance during intensive pulse polio immunization campaign in union territory of Chandigarh in the year 2001 with that of 2006 identified that, icepacks were neatly stacked in all the deep freezers (DF) and ice-lined refrigerators (ILR) in 2006 round. All the randomly selected vaccine samples were reported potent (29).

The finding in Niassa, Mozambique showed that approximately, 43% of the respondents said that they had had an EPI manual. But a cross-sectional study conducted in Kalasin, Thailand showed that 63.3% of primary health care units had a flow chart regarding what to do when there is an electric power failure (21).

About 13% of vaccine refrigerators had temperatures outside the recommended range of 2 to 8°C (21). Similarly the finding from study conducted in USA, identified statewide estimates of offices with at least 1 type of suboptimal vaccine storage included freezer temperatures measuring greater than -14°C is 17%, offices with refrigerator temperatures greater than +9°C is 4.5% (30) and a facility based study done in Ghana, Kenya, and Uganda identified that though significant variation was observed between countries (26·2%, 16·3%, and 7·9% for Ghana, Kenya, and Uganda, respectively) in total 16·6% of the sampled facilities had storage outside the recommended ranges (31) and the finding in three districts of Ethiopia, of 19% functional fridges, the thermometer reading was found to be outside the recommended range in 27.3% on the date of data collection (22**).** But the finding from institution based cross-sectional survey conducted in Addis Ababa city, and in Kenbata-Alaba-Timbaro (KAT) and Hadiya zones showed that thermometer reading was found to be outside the optimal range in (10.9%) immunization centres (14).

A facility based study done in three African countries (Ghana, Kenya, and Uganda) identified that facilities that had a written chart to monitor their storage equipment were associated with 6·42 (95% CI 3·09—13·32) times higher odds of storing their vaccines within the recommended range compared with those without a chart (31).

An institution based cross-sectional study conducted in three districts (woredas) of Oromia, SNNP and Amhara regions of Ethiopia, identified that in 54.5% facilities, vaccine storage in the refrigerator was not proper (22**).** Similarly study conducted in USA, showed that 44% of vaccine cold chain management facilities had at least 1 documented storage problem(30).

But the finding of survey conducted in Addis Ababa city, and in Kenbata-Alaba-Timbaro (KAT) and Hadiya zones identified vaccine storage in the refrigerator was not proper in (73.4%) immunization centres (14).

2.5 Cold chain equipments related

A study conducted at Surat city, Western India identified that absence of separate stabilizer for deep freezers and ILRs (85%), lack of ice packs in deep freezer (65%) and lack of generator (85%) (23). Similarly study conducted in Colombo District USA, reported that, DPT and measles vaccines had been exposed to temperatures outside the prescribed range during power cuts. Oral polio vaccine had adequate storage with power cuts of 2 hours' duration. I.e alternative facilities for vaccine storage during power cuts were not available and the potency of DPT and measles vaccines was compromised with interruptions to power of 2 hours' duration or more (32). Similarly a study conducted in India identified that the irregularity of the power supply was a major challenge of cold chain management in all of the facilities that were investigated (24).

One study conducted in USA, identified major risk factors associated with vaccine storage outside recommended temperature ranges were, lack of thermometer in freezer, use of freezer compartment in small cold storage units, lack of thermometer in refrigerator and failure to maintain temperature log of freezers (30). Similarly Institution based cross-sectional survey conducted in Addis Ababa city, and in Kenbata-Alaba-Timbaro (KAT) and Hadiya zones showed that thermometer was not available in four (6.3%) (14).

An institution based cross-sectional study conducted in three districts (woredas) of Oromia, SNNP and Amhara regions of Ethiopia, identified that, only 19% of health facilities had functional refrigerators (22). Similarly in Nigeria 2011, 41% of fridges were non-functional (11).Frequent cuts in power supply can have a direct impact on storage temperature and non-availability of standby generators will adversely affect vaccine potency at the vaccination centers.

2.6 Conceptual frame work

To show status of vaccine cold chain management depends on the knowledge and practices of the vaccine handlers and availability of functional cold chain equipments/resources for transportation and storage of vaccine in each level of vaccine cold chain management.

By reviewing different articles, the following conceptual framework was prepared for this study

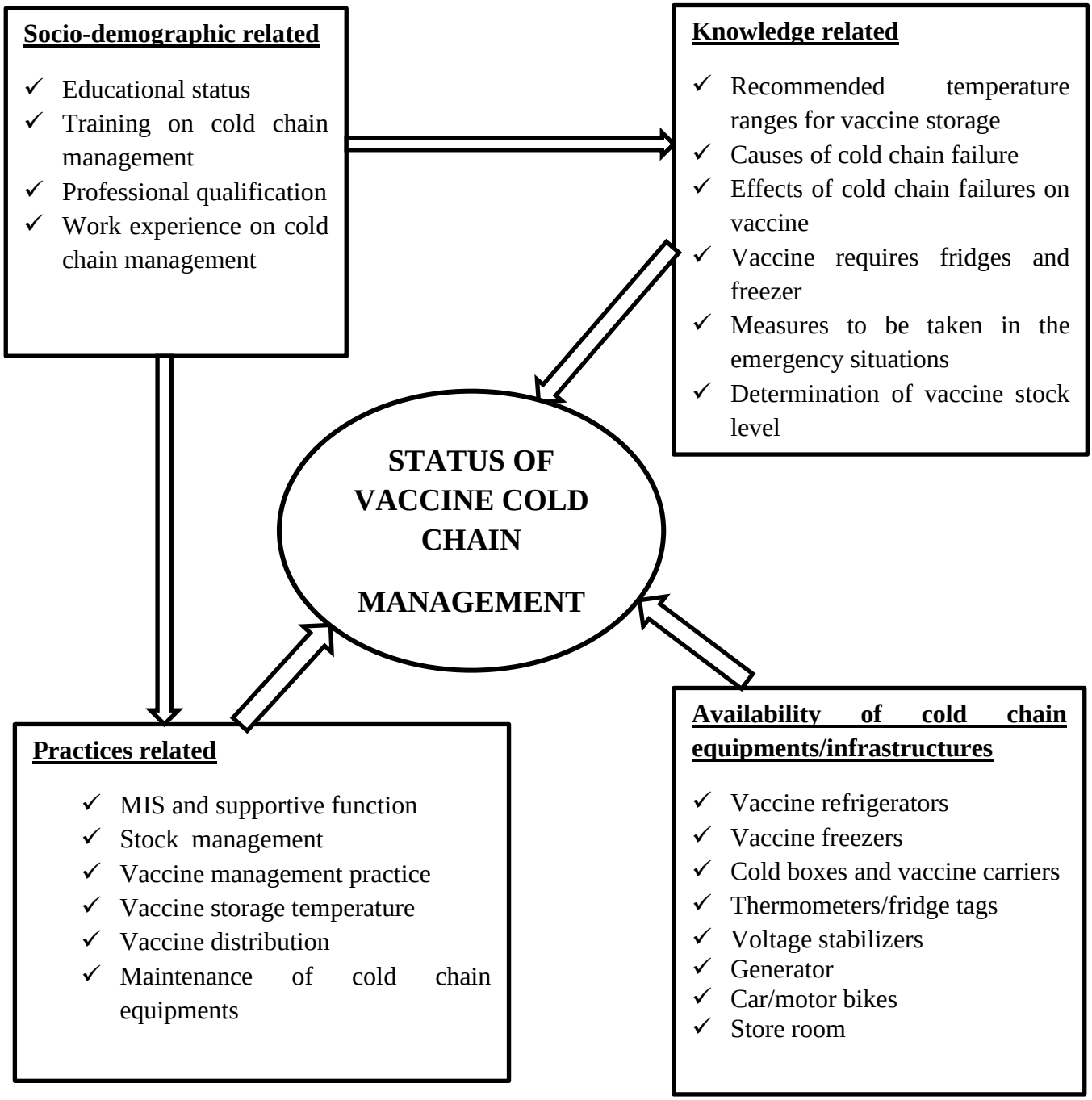

Figure 3: Conceptual framework to show cold chain management of vaccine depends on the knowledge and practice and availability of functional equipments/infrastructures for handling and storage of vaccine.

3. Objectives

3.1 General objective

To assess the status of vaccine cold chain management at public health facilities in Dawuro zone, South West Ethiopia.

3.2 Specific objectives

To determine the availability of functional equipments and infrastructures for transportation and storage of vaccines in public health facilities

To assess knowledge level of vaccine handlers regarding cold chain management system

To assess practice level of vaccine handlers regarding storage and handling of vaccines

To assess perception of key informants on vaccine cold chain management

4. Material and methods

4.1 Study area and period

The study was conducted in Dawuro zone. Dawuro zone is one of 14 zones in the SNNPR (Southern Nation, Nationality and People Region). Based on the 2007 Census, in the year 2014, the zone had an extrapolated population of 601,904 (33).

Administratively Dawuro zone is divided in to 5 woredas and one town administration with, a total of 177 Kebeles. The administrative center of Dawuro zone is Tarcha town which is located at south west of Ethiopia, 517 Kms away from Addis Ababa and 285 Kms away from Hawassa (the capital city of SNNPR). The zone has one general hospital, 23 health centers and 175 health posts with total of 2 specialists, 11 general practitioners, 33 health officers, 27 midwives, 271 nurses (degree and diploma), 7 environmental health officers, 37 laboratory professionals (degree and diploma), 34 pharmacy professionals (degree and diploma), 1 clinical pharmacy specialist, 10 MPH (master in public health), 2 anesthetists, 9 urban health extension worker and 306 rural health extension workers. This study was conducted from February 30-March 20/2015.

4.2 Study design

Facility based cross- sectional study with quantitative and qualitative aspects was used.

4.3 Source population

All health professionals and health facilities in Dawuro zone

4.4 Study population

Public health facilities and health professionals working in these facilities during the data collection period were considered for the study.

4.5 Study unit

Health facilities, vaccine handlers and vaccine key informants

4.6 Inclusion criteria

Health facilities that manage vaccine cold chain or manage vaccine cold chain and provide immunization services, health professional in-charge as cold chain officer or EPI focal person at health facilities for quantitative method; and senior health professional who had experiences on vaccine cold chain management in selected public health facilities for qualitative method were considered in this study.

4.7 Exclusion criteria

Those health professionals, who were not vaccine handlers, had no experience on EPI and those health facilities that not store and manage vaccines

4.8 Sampling procedures and sample size determination

For quantitative method: Since all 31 public health facilities that manage vaccine or manage vaccine and provide immunization services in the zone were included in the study, no sampling method was used.

For qualitative method: 12 key informants purposely selected from decision making and service delivery public health facilities (to include ideas from both decision making and service providing levels) were participated. The selections criteria were: being senior health professional and having experiences on EPI. Seven from decision making facilities (1 from zonal health department and 6 from each district health office and seven from service delivery facilities (1

from general hospital and 6 from health centers which were selected purposively those had large areas of services and senior professionals).

4.9 Study variables

4.9.1 Dependent variable

Status of vaccine cold chain management and knowledge and practice level of vaccine handlers

4.9.2 Independent variables

I. <u>Socio-demographic related factors of vaccine handlers</u>

- ✓ Educational status
- ✓ Training on cold chain management
- ✓ Professional qualification
- ✓ Work experience on vaccine cold chain management

II. <u>Availability of cold chain equipments/infrastructures</u>

- ✓ Vaccine refrigerators
- ✓ Vaccine freezers
- ✓ Cold boxes and vaccine carriers
- ✓ Vaccine thermometers/fridge tags
- ✓ Voltage stabilizers
- ✓ Generators
- ✓ Cars/motorbikes
- ✓ Store rooms

III. Knowledge related factors

- ✓ Recommended temperature range for vaccine storage
- ✓ Causes of cold chain failure
- ✓ Effects of cold chain failures on vaccine
- ✓ Vaccine requires fridges and freezers
- ✓ Determination of vaccine stock level
- ✓ Measures to be taken in the emergency situations

IV. Practice related factors

- ✓ MIS and supportive function
- ✓ Stock management
- ✓ Vaccine management practice
- ✓ Vaccine storage temperature
- ✓ Vaccine distribution
- ✓ Maintenance of cold chain equipments

4.10 Data collection tools

4.10.1 Tools for quantitative

Knowledge level of vaccine handlers was assessed by using structured and pre-tested questionnaires (annex 1). Practice level of vaccine handlers and availability of cold chain equipments were assessed by using a check list for handling and storage of vaccines and observation (annex2). Conversion of questionnaires and checklists to local language was not needed because all participants understand the language.

4.10.2 Tools for qualitative

An open ended interview guide was used to assess the perception of vaccine key informants on vaccine cold chain management system. The interview guide was developed in English. No translation was needed because all key informants were diploma and above.

4.11 Pre-test of tools

Questionnaire, check list and interview guide were pre-tested on a week before actual data collection period in Jimma zone public health facilities (at Jimma zone health department, Shenen Gibe hospital, Dedo woreda health office and Dedo health center). After pre-testing, necessary modification like typographic errors and sequences of questions were edited.

4.12 Data collectors

Data was collected by 6 trained diploma nurses who had experiences on EPI and supervised by two pharmacists. Two nurses were from Tarcha general hospital and 4 from Tarcha town, Mari, Waka and Wara health centers. The supervisors were from Tarcha general hospital and Dawuro zone health department. They were on their annual vacation during data collection period. To avoid biases the data collectors were sent to health facilities other than they come from. Two days training of data collectors and supervisors on the main objectives of the study, importance of each variable and how to fill the questionnaire and check list were conducted. The training was given by principal investigator in Tarcha general hospital staffs meeting room. After thorough training, they were sent to respective public health facilities with all the necessary tools for data collection.

4.13 Data collection procedures

The principal investigator led the data collection exercise in collaboration with two appointed supervisors. Data was collected from 31 public health facilities (Tarcha general hospital, Dawuro zone health department, 6 woreda health offices and 23 health centers).

For quantitative data: One vaccine handler from each public health facility was interviewed face to face by using structured questionnaire and checklist. Knowledge level of vaccine handlers on cold chain management was assessed by using structured questionnaire (Annex 1). Availability of functional cold chain equipments/infrastructures and practice level of vaccine handlers were assessed by using a checklist for handling and storage of vaccine (Annex 2). During interview of second part (practice part), cold chain equipments, vaccine storage conditions and cold chain maintenance process were observed simultaneously with regards to their condition along with the practices adopted by vaccine handlers for cold chain maintenance (asked to show what they were responding).

For qualitative data: Face to face in-depth interview was conducted with12 key informants by principal investigator. Note was taken in addition to audiotape recorder for data transcription.

4.14 Data quality control

At time of data collection, filled questionnaires were checked for completeness and consistency of information by supervisors on a daily basis. Any ambiguity and other problems related to data collection were addressed by communicating with the data collectors. The in-depth interview was undertaken in private setting to maintain the quality of data. The principal investigator and supervisors closely monitored the data collection procedures in all study sites.

4.15 Data entry, analysis and interpretation

For quantitative data: Data checking, clearing, entry, recoding and analysis were done by using SPSS version 16.0. Thereafter, percent, proportion and correlation analysis were carried out. Availability of cold chain equipments and practice level were analyzed by giving "1" for yes and "2" for no, and then total score were calculated from 100%. Knowledge level also analyzed by giving "1" for correct answers and "2" for incorrect answers, and then total score were calculated from 100%.The chi-square was calculated to test presence of association between knowledge and practice level and professional qualification of vaccine handlers, years of experience in cold chain management and types of training on cold chain at 95% confidence interval (CI). Finally the results were displayed using charts, graphs and tables.

For qualitative data: The transcribed data from in-depth interview were coded, categorized to main thematic areas and analyzed by thematic content analysis technique. Finally, triangulation of the qualitative findings with quantitative results was carried out.

4.16 Ethical considerations

Prior to data collection, appropriate ethical clearance was obtained from Jimma University, College of Health Sciences Institutional Ethical Review Board and submitted to Dawuro zone health department. The permission from Dawuro Zone health Department was submitted to each woreda health offices and Tarcha general hospital. Lastly permission obtained from each woreda health office was submitted to health centers within respective woredas. During data collection, each respondent was informed about the purpose of the study and written consent was taken from each respondents.

4.17 Data dissemination plan

The result of the study will be disseminated to Jimma University College of health science, pharmacy department to Dawuro zone, SNNPR health bureau and other stakeholders. Finally, attempts will be made to publish the research in local or international journals reviewed by peer reviewers.

5. Results

5.1 Types of public health facilities in study area

Among the 31 public health facilities, 23(74.2%) were health centers, 6(19.4%) were woreda health offices, 1(3.2%) was Dawuro zone health department and 1(3.2%) was Tarcha general hospital.

5.2 General characteristics of vaccine handlers

About two-third of vaccine handlers 20(64.5%) were males and the remaining 11(35.5%) were females. The mean age was 27.29 years and SD (standard deviation) (± 2.34) ranging (24-32 years). Out of who 4(12.9%) were pharmacy technicians and 27(87.1%) were nurses. The average number of years of service as vaccine handler was 1.6 years (SD) (±0.49). Their years of service ranged from 8 months and 2 years (table 1).

Table 1: Socio-demographic characteristics of vaccine handlers at public health facilities in Dawuro zone, March 2015

Characteristics		**Frequency (%)**
Sex	Male	20(64.5)
	Female	11(35.5)
Age	<25 years	4(12.9)
	25-30 years	23(74.2)
	>30 years	4(12.9)
Educational background	Pharmacy technician	4(12.9)
	Nurse	27(87.1)
Educational level	Diploma	30(96.8)
	Degree	1(3.2)
Work experiences as vaccine handler	Less than 1 year	12(38.7)
	Greater than/equal to 1 year	19(61.3)
Attended training on vaccine cold chain management	Yes	31(100)
Types of training	Cold chain management	12(38.7)
	Equipment maintenance	8(25.8)
	Both	11(35.5)

5.3 Availability of infrastructure and cold chain equipments/resources for vaccine cold chain management in the study facilities

Among 31 facilities, 29(93.5%) had fridge tag for monitoring temperature, 26(83.9%) had a separate store room for vaccine storage, 25(80.1%) had standard cold boxes and/or vaccine carriers, 23(74.2%) had functional refrigerators, only 2(6.5%) had power generator and none of the facilities had functional deep freezer and voltage stabilizer (table 2).

Table 2 : Availability and conditions of infrastructure and cold chain equipment/resource for vaccine cold chain management at public health facilities in Dawuro zone, March 2015

S.no	Characteristics	Frequency	
		Yes n (%)	No n (%)
1	Availability of functional calibrated min/max thermometer or fridge tag	29(93.5)	2(6.5)
2	Availability of a separate store room for vaccine storage	26(83.9)	5(16.1)
3	Availability of standard cold boxes and/or vaccine carriers	25(80.1)	6(19.9)
4	Availability of functional refrigerators	23(74.2)	8(25.8)
6	Capacity of the store room for permanent storage of vaccines	19(73.1)	7(26.9)
7	Capacity of the store room for temporary handling of campaign vaccines	19(73.1)	7(26.9)
8	Availability of functional car/motorbike	21(67.7)	10(32.3)
9	Availability of trained backup person	20(64.5)	11(64.5)
10	Functionality of the store room	14(53.8)	12(46.2)
11	Availability of planned back-up storage unit(s)	12(38.7)	19(61.3)
12	Availability of standard cold box and/or alternative refrigerator with appropriate temperature monitoring	11(35.5)	20(64.5)
13	Availability of power generator	2(6.5)	29(93.5)
14	Availability of functional deep freezer	0	31 (100)
15	Availability of voltage stabilizer	0	31(100)

The level of availability of infrastructures and cold chain equipments was good in Dawuro zone health department (85.7%), followed by Lomma woreda health office (78.6%), Tarcha general hospital (78.6%) and poor in Boka health center (21.4%), followed by Dissa health center (14.3 %) and Churchura health center (7.2%) (table 3& 4).

Table 3: Level of availability of infrastructures and cold chain equipments/resources for vaccine cold chain management at zonal health department and woreda health offices in Dawuro zone, March 2015

S. no	Name of health facility	Level of availability Yes/total (%)
1	Dawuro zone health Department	85.7
2	Lomma WHO	78.6
3	Tarcha town administration health unity	78.6
4	Mareka WHO	71.4
5	Tocha WHO	50.0
6	Esera WHO	37.5
7	Genna WHO	37.5

Table 4: Level of availability of infrastructures and cold chain equipments/resources for vaccine cold chain management at service delivery health facilities in Dawuro zone, March 2015

S. no	Name of health facility	Level of availability Yes/total (%)
1	Tarcha general hospital	78.6
2	Waka HC	78.6
3	Tarcha HC	78.6
4	Qarawo HC	71.4
5	Wara HC	64.3
6	Dali HC	64.3
7	Yello HC	57.2
8	Kechi HC	57.2
9	Wolde Hanne HC	57.2
10	Mari HC	50.0
11	Tocha Hc	50.0
12	Abba HC	50.0
13	Angela HC	42.9
14	Deshi HC	42.9
15	Gessa HC	42.6
16	Esera Bale HC	42.6
17	Hageli HC	42.6
18	Lomma Bale HC	35.7
19	Gendo HC	35.7
20	Addis Bodari HC	35.7
21	Duga HC	21.4
22	Boka HC	21.4
23	Dissa HC	14.3
24	Churchura HC	7.2

In general, from total of 31 health facilities 1(3.2%), 7(22.6%) and 23(74.2%) had good, medium and poor level of availability of infrastructures/cold chain equipments for transportation and storage of vaccines. With mean (SD) availability score of 50.9% (±2.89) (ranging 7.14% to 85.7%).

Table 5: Knowledge and practice level description

Level of knowledge and practice	Number of knowledge questions responded correctly from total (N=18) for knowledge	Number of "yes" divided by total (N=35) for practice
<65%	≤ 10	≤ 22
65-80%	11-14	23-27
Greater than or equal to 80%	≥15	≥28

→ Poor knowledge/practice level- total score of < 65%
→ Medium knowledge/practice level - total score of 65%-79%
→ Good knowledge/practice level- total score of ≥80%

5.4 Knowledge level of vaccine handlers on vaccine cold chain management system

All (31) vaccine handlers knew that exposure of vaccine to heat, light and cold leads vaccine to lose their potency, (2-8^{o}C) is a recommended temperature range for most vaccine stored in refrigerators and frequency of distributing vaccines to lower facilities is once monthly. More than four-fifth of vaccine handlers knew how to determine vaccine stock level and recording damaged vaccines improves vaccines inventory control system. However, only 14(45.2%) knew (-15^{0}c to -25^{0}c) is the recommended temperature range for most vaccine stored in freezers and 12(38.7%) knew pentavalent vaccine be kept nearer to the top in vertical (top-opening) (table 6).

Table 6: Correctly answered frequency of knowledge questions on vaccine cold chain management system at public health facilities in Dawuro zone, March 2015

S.no	Characteristics	Correct answer frequency (%) (N=31)
1	Exposure of vaccine to heat, light and cold leads lose their potency	31(100)
2	2-8^{o}C is a recommended temperature range for most vaccine stored in refrigerators	31(100)
3	Frequency of distributing vaccines to lower facilities is once monthly	31(100)
4	Determine vaccines stock level by determining sum of stock on hand and stock on order, minus any stock-back ordered to clients	27(87.1)
5	When the stock is sufficient to satisfy demand until the next order it is at maximum stock level	27(87.1)
6	Recording discarded/damaged vaccines improves inventor control of vaccine	25(80.6)
7	HepB, DPT, DT, TT are more sensitive to freeze	24(77.4)
8	When stock is at re-order level, it is at minimum stock level	23(74.2)
9	When stock on hand to prevent stock out, it is at safety stock level	23(74.2)
10	OPV, BCG and Measles vaccines more sensitive to heat	22(71.0)
11	Polio , BCG and measles vaccines; be kept nearer to bottom were it is colder in vertical (top-opening)	22(71.0)
12	By performing vaccine shake test and VVM it possible to tell if a vaccine has been frozen and exposed to heat	20(64.5)
13	Store vaccine in cold box and /or use kerosene and report for immediate vaccine coordinators in case of power failure	20(64.5)
14	Shifting of vaccine to another refrigerator is required if power failure occurs more than 72 hours	16(51.6)
15	Placement of vaccines in the lowest compartment of refrigerator affect vaccine	16(51.6)
16	(-15^{0}c to -25^{0}c) is the recommended temperature range for most vaccine stored in freezers	14(45.2)
17	Check VVM and conduct shake test when vaccine found out of recommended temperature range	14(45.2)
18	Pentavalent vaccine; be kept nearer to the top in vertical (top-opening refrigerator)	12(38.7)

The vaccine handler in Dawuro zone health department and Mareka woreda health office answered all 18 questions correctly (100%) followed by vaccine handlers in Waka and Kechi health center whereas vaccine handlers in Boka, Churchura and Duga health centers responded 9 out of 18 questions (50%) correctly (table 7 & 8).

Table 7: Knowledge level of vaccine handlers on cold chain management system at zonal health department and woreda health offices in Dawuro zone, March 2015

S.no	Name of health facility	Knowledge level (%)
1	Dawuro zone health Department	100
2	Mareka WHO	100
3	Genna WHO	83.3
4	Lomma WHO	72.2
5	Tarcha town administration health unity	72.2
6	Esera WHO	66.7
7	Tocha WHO	61.1

Table 8: Knowledge level of vaccine handlers on cold chain management system at service delivery health facilities in Dawuro zone, March 2015

S.no	Name of health facility	Knowledge level (%)
1	Waka HC	94.4
2	Kechi HC	88.9
3	Qarawo HC	88.9
4	Dali HC	88.9
5	Gendo HC	83.3
6	Tocha HC	83.3
7	Gessa HC	83.3
8	Mari HC	77.8
9	Lomma Bale HC	72.2
10	Hageli HC	72.2
11	Angela HC	72.2
12	Tarcha HC	72.2
13	Wara HC	66.7
14	Dissa HC	66.7
15	Yello HC	66.7
16	Esera Bale HC	61.1
17	Tarcha general hospital	55.6
18	Deshi HC	55.6
19	Wolde Hanne HC	55.6
20	Abba HC	55.6
21	Addis Bodari HC	55.6
22	Boka HC	50.0
23	Churchura HC	50.0
24	Duga HC	50.0

HC- health center, WHO woreda health office

In general, out of 31 vaccine handlers asked 18 questions on vaccine cold chain management system, 10(32.3%) answered 15 and above questions correctly, 11(35.4%) answered 11-14 questions correctly and 10(32.3%) answered 10 and less than 10 questions correctly (had good, medium and poor knowledge level) respectively. With mean (SD) of knowledge scores 12.9 (±2.67) ranging from (9 to 18).

5.5 Practice level of vaccine handlers on vaccine cold chain management

The practice level was assessed by categorizing it to 6 parts (stock management, vaccine distribution procedure, storage temperature, vaccine management, MIS and supportive functions and maintenance of cold chain equipment).

As vaccine stock management concerned, all facilities reviewed vaccine stock level prior to ordering, rotate vaccines on the "first to expire, first out" principle and 21 (67.7%) clearly label close to expiry vaccines. However, out-of-dated vaccines were stocked clearly, labeled, removed from the refrigerator and destroyed timely in only 13(41.9%) of the facilities.

As far as vaccine distribution and maintenance of cold chain equipment was concerned, all facilities had a program for distribution of vaccine from issuing store to each receiving store. But only 8 (25.8%) have used standard cold boxes/vaccine carriers with thermometers and ice packs to transport vaccines to receiving stores.

When we see vaccine storage temperatures, all facilities documented refrigerator temperatures on temperature monitoring and recording log. Although 23(74.2%) of the facilities have recorded the actual temperatures of the refrigerator including the minimum, maximum twice a day, the refrigerator temperature was maintained at (2–8ºC) in only 15(65.2%) of facility having functional refrigerators.

With regard to vaccine management practice, all facilities didn't store anything other than vaccines in the refrigerator, have stored ice packs in the freezers compartment of refrigerator and have systems to reduce the number of refrigerator door opening incidence per day. Twenty one (67.7%) stored vaccines at recommended place in the refrigerator. However, none of the facilities placed "DO NOT UNPLUG" sign next to refrigerator's electrical outlet for the electric supply safety and kept

sealed water bottles on the upper and lower shelves of the refrigerator for maintaining temperature during power failure.

All facilities had cold chain management manual for storage and handling practice of vaccines. However, only 4(12.9%) of them have reviewed the manual annually together with all facility staffs and whenever new staffs are hired.

Twenty one (67.7%) facilities were carried out an emergency repair of cold chain equipments timely and only 12(38.7%) of the facilities had adequate supplies of spare parts for equipment maintenance (table 9).

Table 9: Practice level of vaccine handlers on vaccine cold chain management at public health facility in Dawuro zone, March 2015

Characteristics		**Frequency**	
		Yes (%)	No (%)
Stock Management	Monitor/review vaccine stocks prior to ordering	31(100)	0
	Rotate vaccines on the "first to expire, first out" principle	31(100)	0
	Fill vaccine stock record books correctly and timely	31(100)	0
	Review a routine vaccine management quarterly	31(100)	0
	Check the expiry dates of vaccines at the beginning and end of every month	31(100)	0
	Clearly label close to expiry vaccines	21 (67.7)	10 (32.3)
	Audit vaccine stocks weekly and records of vaccine stocks (at least) monthly	18 (58.1)	13 (41.9)
	Stock clearly, label, remove from the refrigerator and destroy timely the out-of-dated vaccines	13 (41.9)	18 (58.1)
Vaccine distribution procedure	Have a program for distribution of vaccine from issuing store to each receiving store	31 (100)	0
	Know how to condition ice packs for transportation	31(100)	0
	Use standard cold boxes/vaccine carriers with thermometers and ice packs to transport vaccines to outlying stores, eg district, health center, health posts	8 (25.8)	23 (74.2)
	Temperature records readily accessible and retained until the next audit	31(100)	0

Continue…

Vaccine storage Temperature	Document refrigerators temperatures on temperature monitoring and recording log		31(100)	0
	Follow the directions on the temperature log to call appropriate personnel if the temperature in a storage unit goes out of range		31(100)	0
	Record and monitor the minimum, maximum and actual temperature in refrigerator two times in each working day		23 (74.2)	8 (25.8)
	Refrigerator temperature maintained at (2–8ºC)		15(65.2)	8(34.8)
	Freezer temperature maintained at an average temperature of -15°C or colder, but no colder than -50°C		0	31(100)
Vaccine management Practice	Store vaccines in separate, self-contained units that:	Refrigerate only	31(100)	0
		freeze only	-	-
	Store ice packs in the freezers		31 (100)	0
	Have systems to minimize refrigerator/freezer door opening during vaccine delivery/receiving		31 (100)	0
	Not stored anything other than vaccines in the refrigerator (including specimens, food &drink)		31(100)	0
	Lock either the refrigerator or the room for vaccine storage		28 (90.3)	3(9.8)
	Placed the refrigerator/freezer at properly ventilated and not near any heat source, e.g. radiator, window		21 (67.7)	10 (32.3)
	Keep records of regular servicing, defrosting and cleaning as per manufacturers' recommendations		21 (67.7)	10 (32.3)
	Store vaccines at recommended pace		21 (67.7)	10 (32.3)
	Store ice pack on the upper and lower shelves and in the door of the refrigerator		0	31 (100)
	Place a "DO NOT UNPLUG" sign next to your refrigerator's electrical outlet for the electric supply safety		0	31(100)
MIS & supportive functions	Use an up to date cold chain manual for storage and handling practice of vaccines		31(100)	0
	Make the guideline accessible for all staffs		25 (80.6)	6 (19.4)
	Review this guideline with all staff annually and with new staff when they are hired		4 (12.9)	27 (87.1)
	Contact local immunisation coordinator when temperatures are outside +2°C to +8°C		24 (77.4)	7 (22.6)
Maintenance of cold chain equipment	Carry out an emergency repair of cold chain equipment in timely manner		21(67.7)	10(32.3)
	Have plan for preventive maintenance of equipment		16(51.6)	15(48.4)
	Have a plan for replacement of cold chain equipments		7(22.6)	24(77.4)
	Availability of adequate spare parts for equipment maintenance		12(38.7)	19 (61.3)

Table 10: Practice level of vaccine handlers at zonal health department and woreda health offices in Dawuro zone, March 2015

Name of health facility	MIS & supportive function (%)	Stock management (%)	Vaccine management practice (%)	Storage temperature (%)	Vaccine distribution (%)	Maintenance of equipment (%)
Zonal HD	75	87.5	80	83.3	66.7	100
Mareka WHO	100	100	70	83.3	100	75
Tocha WHO	75	87.5	50	66.7	66.7	25
Lomma WHO	75	100	70	83.3	100	50
Esera WHO	50	75	50	66.7	66.7	25
Genna WHO	75	75	80	83.3	66.7	50
Tarcha town health unity	75	87.5	80	83.3	66.7	100

HD- Health department, WHO –Woreda health office

Table 11: Practice level of vaccine handlers at service delivery facilities in Dawuro zone, March 2015

Name of health facility	MIS & supportive function (%)	Stock management (%)	Vaccine management practice (%)	Storage temperature (%)	Vaccine distribution (%)	Maintenance of equipments (%)
Tarcha GH	75	87.5	70	83.3	100	50
Waka HC	100	100	70	83.3	66.7	50
Mari HC	75	75	60	66.7	66.7	25
Gendo HC	75	100	80	83.3	100	75
Deshi HC	75	62.5	50	83.3	66.7	25
Tocha HC	75	100	80	83.3	100	75
Wara HC	50	75	70	83.3	66.7	25
Boka HC	75	75	70	83.3	66.7	25
Kechi HC	50	87.5	80	83.3	66.7	50
Abba HC	75	75	50	50	66.7	25
Gessa HC	75	100	70	83.3	100	75
Lomma Bale HC	75	62.5	70	83.3	66.7	25
Dissa HC	50	75	80	83.3	66.7	50
Yello HC	50	62.5	80	50	66.7	25
Addis Bodari HC	25	62.5	50	50	66.7	0
Esera Bale HC	75	75.0	70	66.7	66.7	25
Hageli HC	50	100	80	83.3	66.7	25
Dali HC	75	100	70	83.3	66.7	50
Churchura HC	50	87.5	50	50	33.3	0
Qarawo HC	75	75	80	83.3	66.7	50
Wolde Hanne HC	75	100	80	83.3	100	50
Duga HC	50	62.5	70	50	66.7	25
Angela HC	50	87.5	60	50	66.7	25
Tarcha HC	75	87.5	80	83.3	100	100

Table 12: Average practice level of vaccine cold chain management at zonal health department and woreda health offices in Dawuro zone, March 2015

S.no	Name of health facility	Cumulative practice level (%) (Yes/total X100%)
1	Mareka woreda health office	85.7
2	Dawuro zone health department	82.9
3	Tarcha town administration health unity	82.9
4	Tocha woreda health office	80.0
5	Lomma woreda health office	80.0
6	Genna woreda health office	74.3
7	Isera woreda health office	57.2

Table 13: Average practice level of vaccine cold chain management at service delivery health facilities in Dawuro zone, March 2015

S.no	Name of health facility	Cumulative practice level (%) (Yes/total X100%)
1	Gendo health center	85.7
2	Tocha health center	85.7
3	Gessa health center	82.9
4	Tarcha health center	82.9
5	Wolde Hanne health center	82.9
6	Waka health center	80.0
7	Tarcha general hospital	77.1
8	Dali health center	77.1
9	Hageli health center	74.3
10	Kechi health center	71.4
11	Qarawo health center	68.5
12	Dissa health center	65.7
13	Boka health center	65.7
14	Isera Bale health center	65.7
15	Lomma Bale health center	65.7
16	Wara health center	65.7
17	Mari health center	60.0
18	Deshi health center	60.0
19	Yello health center	60.0
20	Angela health center	60.0
21	Abba health center	54.3
22	Duga health center	54.3
23	Churchura health center	48.6
24	Addis Bodari health center	45.7

Table 14: Practice level of vaccine cold chain management at zonal health department, woreda health offices and service delivery facilities in Dawuro zone, March 2015

S.no	Indicators	Level		
		Zone	Woreda	Service delivery
1	Stock management	87.5	89.6	80.2
2	Vaccine storage temperature	87.5	87.5	80.7
3	MIS and supportive information	100	75	65.3
4	Vaccine management practice	81.8	78.8	77.7
5	Vaccine distribution	66.7	77.8	70.8
6	Maintenance of cold chain equipment	100	58.3	37.5

Most facilities had good vaccine stock management practice (82.3%) but poor cold chain equipments maintenance practice (43.5%) with relative to EVM criteria (figure 4).

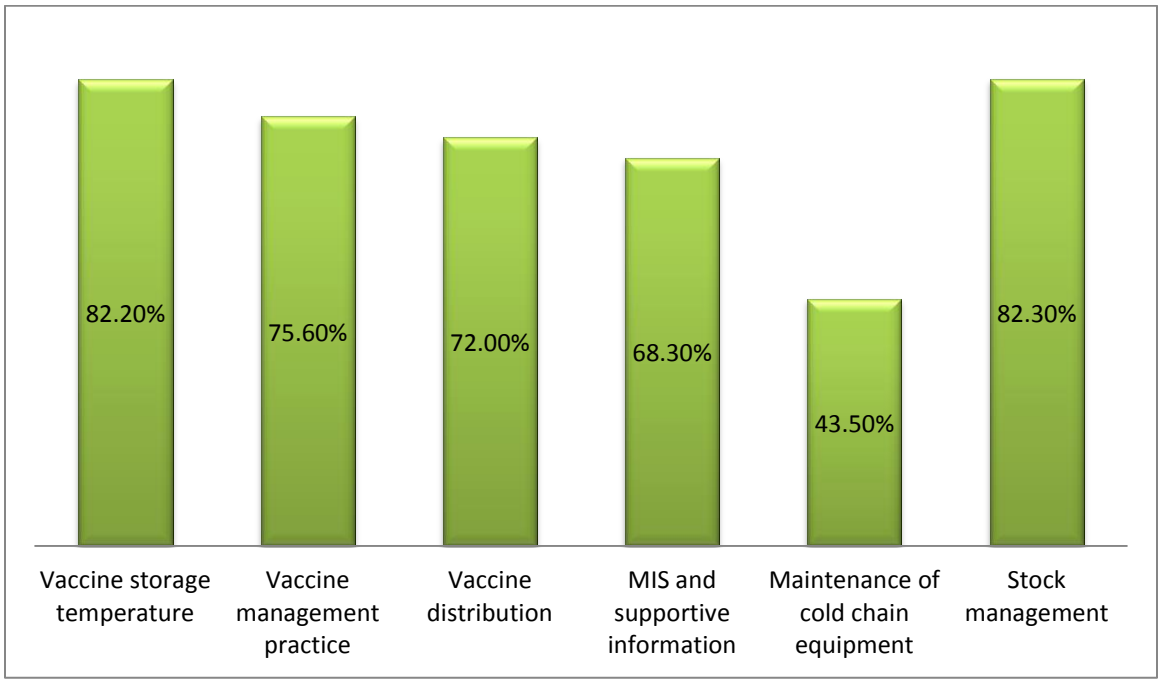

Figure 4: Summery of practice level of vaccine cold chain management at public health facilities in Dawuro zone, March 2015

In over all, from total 31 facilities assessed for their practices on vaccine cold chain management, 11(35.5%), 11(35.5%) and 9(30%) had good, medium and poor level of practice respectively. With mean (SD) of practice scores 69.5% (±4.2), ranging from (45.7% to 85.7%).

5.6 Factors associated with knowledge and practice level of vaccine handlers on vaccine cold chain management

5.6.1 Factors associated with knowledge level

Professional qualification of the vaccine handlers, levels of education, years of service working in vaccine cold chain management and types of training on vaccine cold chain system were considered as factors and assessed for their effect on the knowledge of vaccine handlers on cold chain management. In bivariate analysis (chi-square test), among the factors, only years of service working in vaccine cold chain management and types of training on vaccine cold chain had a statistically significant association with the level of vaccine handlers' knowledge on cold chain management(table 15).

Table 15: Bivariate analysis of vaccine handlers' knowledge on vaccine cold chain management at public health facility in Dawuro zone, March 2015

Variables	**Chi-square test (X^2-test)**	**P-value**
Years of service in vaccine cold chain management	6.26	0.044*
Types of training on vaccine cold chain	7.77	0.021*
Professional qualification	6.72	0.151
Level of education	2.33	0.311

*p-value <0.05 is statistically significant.

This shows that 1 year and above years of service and received training on both cold chain management and equipment maintenance has positive association with vaccine handling practice.

5.6.2 Factors associated with practice level

Professional qualification of the vaccine handlers, levels of education, years of service working in vaccine cold chain management and types of training on vaccine cold chain were factors considered and evaluated for their effect on vaccine handling practice. A test of association between years of service and types of training received and vaccine handling practice showed a presence of significant association (table 16).

Table 16: Bivariate analysis of vaccine handlers' practice on vaccine cold chain management at public health facility in Dawuro zone, March 2015

Variables	**X^2-test**	**P-value**
Years of service in vaccine cold chain management	8.24	0.016*
Types of training on vaccine cold chain	11.28	0.004*
Professional qualification of the vaccine handlers	6.50	0.164
Level of education	2.33	0.311

*p-value <0.05 is statistically significant

5.7 Result of key informants in-depth interview

Twelve key informants (KIs) were identified for in-depth interview. All of KIs were willing to have their responses recorded. Six of them were from service delivery points and the other 6 were from decision making health facilities. From 12 KIs three-fourth was degree holders. The remaining was diploma with one exception (MPH) with mean work experience of 6.42 years (range 4 years to 25 years). With regards to their roles in their organization, majority of them were professionals in service delivery and officers in decision making facilities. The remaining 2 were team leaders for disease prevention and control case team. The average age of key informants was 32.4 years (range 24-50 years)

5.7.1 Barriers of vaccine cold chain management

More than four-fifth of key informants stated that shortage and turnover of trained man power, electrical power interruption, shortage of cold chain equipments and spare parts and lack of maintenance for equipments were the main barriers for effective vaccine cold chain management; while one-third of key informants perceive lack of accountability of health professionals to vaccine cold chain management is also another barrier. One key informant stated: *"….most health professionals assume managing vaccine cold chain is the responsibility of the vaccine handlers only….."* Topography of the woreda also affects the vaccine cold chain management. This is stated by one key informant "*…topography of the woreda for distribution of vaccines to service delivery points is one of barrier for effective vaccine cold chain management. For example some health centers are far from main road and the ways to this health center is challenging……, it may take long time to reach the health centers. This may expose vaccines to extreme temperature……"* Lack of budget for kerosene is also perceived another barrier of vaccine cold chain management. This is stated by one of key informant "*……shortage of kerosene/budget for kerosene is also another barrier of effective vaccine cold chain management.*" Monitoring temperature by using kerosene is perceived as barrier for effective vaccine cold chain management. This is supported by one key informant as he stated: "*….managing cold chain system by kerosene should be discontinued; because it is very challenge full to maintain temperature at recommended range. For example it doesn't stay at amount of light you adjusted and sometimes the glasses may be broken and wind may enter to it. This may leads the light either off or increase in amount."*

5.7.2 Mechanisms how the barriers of vaccine cold chain managements were tackled

Almost all key informants stated they had overcome the challenges of vaccine cold chain management by coordinating with other health facilities, giving on-site training and supportive supervision and maintenance of equipments at site by trained person. The problems of vaccine cold chain management were also solved by distributing cold chain equipments.

One key informant stated "……*we have distributed cold chain equipments especially, vaccine carriers to health facilities having shortage and through maintenance of equipments on site by trained person."*

5.7.3 Proposed solutions for effective vaccine cold chain management

Almost all key informants agreed that capacity building, distribution of cold chain equipments with adequate spare parts, solving electric power interruption and following cold chain management manual for minimizing cold chain problems should be done. The other one-third of key informants agreed that care should be given for vaccines during storing, handling and administering. This is supported by one of them as she stated *"…..putting vaccine in circle on icepack during administration of vaccine may causes freezing of vaccine….leads to compromise of vaccine cold chain. Imagine that after passing several steps vaccines may loss its potency that may not seem great challenge….most of the time we worry about large issues like shortage of equipments……."*

Availability of equipments like fridge tag and solar refrigerator are perceived very important for effective vaccine cold chain management. As one key informant stated "….*availability of fridge tags which record temperature continuously and report the out of range temperatures; vaccine guard during transportation of vaccine which show alarm when vaccines exposed to out of range temperature were good practice on vaccine cold chain management that should be continued."* Another key informant described that "….*availability of solar fridge is a good practice. Since it doesn't need electric power/kerosene and has self- adjustable constant temperature, it maintains vaccines at recommended temperature at any time. So by only monitoring expire date, stock balance and VVM of vaccine; it is possible to manage vaccine cold chain."*

6. Discussion

The cold chain management system is the backbone of success of any immunization program. Careful attention to the three main components of cold chin management system (equipment for transport and storage, trained personnel to manage vaccine storage and distribution and efficient management procedures) is essential to ensure optimal potency of vaccines and to maximize the resulting efficacy of vaccination. The failure in one or other of these components leads to failure of the cold chain system (2–5).

In this study the level of availability of cold chain equipments and infrastructures for transportation and storage of vaccines, level of knowledge and practice of vaccine handlers on cold chain management system, factors associated with knowledge and practice level of vaccine handlers and perception of key informants on vaccine cold chain management were assessed.

The overall finding showed that 1, 7 and 23 of the facility had good, medium and poor level of availability of cold chain equipments for transportation and storage of vaccines with mean (SD) availability level of 50.9% (±2.89) ranging (7.14% to 85.7%). Eleven, 11 and 9 of the facilities had good, medium and poor level of practice of vaccine cold chain management with mean (SD) of practice levels 69.5% (±4.2), ranging (45.7% to 85.7%). From total of 31 vaccine handlers, 10 11 and 10 vaccine handlers had good, medium and poor level of knowledge on vaccine cold chain management system with mean (SD) of knowledge level of 71.7% (± 2.67) ranging (50% to 100%). Years of service working in vaccine cold chain management and types of training on vaccine cold chain had a statistically significant association with the knowledge and practice level of vaccine handlers. These results were also supported by most of key informants.

Availability of cold chain equipments and infrastructures

In order to provide potent and effective vaccine to the beneficiaries, a vast cold chain infrastructure is required, which should have a network of vaccine stores, deep freezers, ice lined refrigerators, temperature monitoring devices, cold boxes, vaccine carriers and icepacks from

national level up to the outreach sessions (3). This study showed that 93.5% of facilities had fridge tag. This finding is consistent with the finding in Addis Ababa city, Kenbata-Alaba-Timbaro (KAT) and Hadiya zones where thermometer was available in (93.7%) of health facilities (14). Each vaccine refrigerator and insulated container used for vaccine storage and transport must have a temperature monitoring device (18).

Availability of separate store room for vaccine is important for efficient storing and handling of vaccines. It also enhances efficient inventory management. In present study, although 26(83.9%) of facilities had a separate store room for vaccine storage, only 14(53.8%) of them were functional. The possible reason for non-functionality might be even separate room available; it may be exposed for light or not favorable for vaccines storage.

In order to effectively maintain the cold chain system, there should be at least one refrigerator in every health facility since these facilities are expected to maintain vaccines at recommended temperature and /or provide vaccination services for their communities on a daily basis. This study also showed that, 74.2% of facilities had functional refrigerators. Health workers from the remaining 8(25.8%) facilities transport vaccines to facilities having functional refrigerators, which may increase the chance of vaccine to be exposed to external temperature and be a cause for cold chain breakage. The result from the present study was better than the previous finding in Ethiopia, in which only 19% of health facilities had functional refrigerators (22) and in Nigeria, 59% facilities had functional fridges (11). The possible reason for this difference might be increasing attention of EPI to vaccine cold chain management like distributing cold chain equipments to health facilities.

Only 2(6.5%) of the facilities had generator to maintain cold chain in case of electric failure and none of the refrigeration units were protected through voltage stabilizers in all facilities. A similar study conducted in India showed a better finding; lack of generator in (85%) and absence of stabilizer for deep freezers and ice-lined refrigerator in (85%) of facilities (23). This difference might be due to resource and trained man power differences between India and Ethiopia. These results were also supported by almost all key informants and one key informant stated that shortage and turnover of trained man power, electrical power interruption, shortage of

cold chain equipments and spare parts and lack of maintenance for equipments were the main barriers for efficient vaccine cold chain management.

Knowledge on vaccine cold chain management

It is obviously pointless to immunize with impotent vaccine. Since all vaccines lose potency over time, especially if exposed to heat and some also lose their potency when frozen. Attention to maintaining correct temperatures of vaccine is thus a major task for health workers (3,4). In this study, 67.7% of vaccine handlers had medium to good on vaccine cold chain management system which is consistent with the previous finding in Ethiopia, in which, 65% of health workers had medium to good knowledge on cold chain management (22)**.**

All (31) vaccine handlers knew that exposure of vaccine to heat, light and cold leads vaccine to lose their potency, (2-8^{o}C) is a recommended temperature range for most vaccine stored in refrigerators. It is different when compared with the findings in different parts of India, in which 75% of workers had correct knowledge of storage of different vaccines, 15% vaccine handlers had knowledge for temperature range to be maintained in refrigerator and in Mozambique, which showed 52% of the respondents knew the recommended temperature range for vaccine storage (13,23,25) but comparable with finding in Malaysia, indicated that majority of respondents knew that vaccine will be damaged if exposed to heat (98.8%) and freezing state (88.8%) (12).The possible reason for this difference might be training, as all vaccine handlers were trained on vaccine cold chain management, as nearly two-third (62%) of vaccine handlers trained more than one type of training on vaccine cold chain.

Since vaccination is a public issue, managing vaccine stock properly is a key practice for avoiding overstocking and stock out. As mentioned above, one of the criteria essential for a performing vaccine cold chain management system designed by WHO/UNICEF was vaccine stock management and every facility should achieve or exceed 80% score for all EVM criteria to maintain effective vaccine cold chain management system (7). In present study, more than four-fifth of vaccine handlers knew how to determine vaccine stock level and recording damaged

vaccines improves vaccines inventory control system. However, the finding in India reported 75% of the workers could correctly calculate vaccine requirement (25). The possible reason for this difference might be trainings like IPLS (integrated pharmaceutical logistic system) in addition to training on cold chain management.

Since some vaccines are more sensitive to heat and some others are more sensitive to cold, understanding the characteristics of each vaccine in EPI is very important for effective cold chain maintenance system (3). In current study, types of vaccines that were more sensitive to freezing and heat were correctly identified by 24(77.4%) and 22(71.0%) of vaccine handlers respectively. This finding was better than the finding in Mozambique in which, 61% of respondents knew that freezing of DPT+HepB vaccine causes it to lose potency (13). The possible reason for this difference might be difference in health policy in Ethiopia and Mozambique (Ethiopia health policy now a day giving high attention to mother and child health) and training as all vaccine handlers participated in this study were attended training on vaccine cold chain.

Practice on vaccine cold chain management

In this study, all visited facilities were reviewed vaccine stock level prior to ordering, rotate vaccines on the **"**first to expire, first out" principle. Twenty one (67.7%) clearly label close to expiry vaccines. However, out-of-dated vaccines were stocked clearly, labeled, removed from the refrigerator and destroyed timely in only 13(41.9%) of the facilities with overall inventory management level of 83.5%. This finding showed a good improvement from the UNICEF report of Jharkhand, in 2009 in which vaccine wastage was not recorded and there was no mechanism of conscious monitoring of vaccine wastage and report of Ethiopia, in which vaccine stock management was poor in all levels of cold chain management (1,26). The possible reasons for this difference might be difference in trained man power to manage inventory, work experience of vaccine handlers as some of them worked as store man before being vaccine handler and turnover of trained man power.

It is difficult to know cold chain and storage condition of vaccines without recording minimum, maximum and actual temperature. In the present study, refrigerator temperatures were documented on appropriate log book in all facilities, the minimum, maximum and actual temperatures of the refrigerator were recorded two times each working day in 23(74.2%), refrigerators temperature was not maintained at (2–8ºC) in 8(34.8%) out of 23 facilities having functional refrigerators and none of the facilities was maintained freezer temperature at (-15^{0}C to -25^{0}C) yet these facilities store vaccines like OPV and Measles vaccines which require freezing temperature. However, other studies in Thailand, in three Africa countries (Uganda, Ghana and Kenya) and in other parts of Ethiopia (13%, 16.6%, 27.3% and 10.9%) of facilities had refrigerators temperatures outside the recommended range (14,21,22,31). It is also different when compared with studies in India, in which there was poor temperature-record registration(23) and the vaccine management assessment report of Jharkhand , in which cold chain equipment temperature is effectively monitored only in a few districts (26). The possible reason of not being able to maintain temperature might be lack of reliable power supply, infrastructures like standby power generator and deep freezer.

Ideally, the fridge containing vaccines should not be used to store other drugs in order to prevent two potential dangers: problem of not maintaining the recommended temperature range and wrongly administering drugs that have been packaged in similar color vials as the vaccine vials. Assessment of handling and storing practice showed that all facilities had not stored anything other than vaccines in the refrigerator, had stored ice packs in the freezers compartment of refrigerator, had systems to minimize refrigerator door opening, 21(67.7%) of facilities stored vaccines at proper place in the refrigerator. However, other studies reported that in India (10%) of the facilities had things other than vaccines in refrigerators (23) and in other parts of Ethiopia (45.5% and 26.6%) vaccine storage in the refrigerator was proper(14,22). The possible reason for this difference might be onsite capacity building training and awareness creation and the gap between studies (2000, 2012, 2013 and 2015) in which more information about vaccine cold chain management could be shared in current study area.

One of the promising practice identified in present study was all facilities were using a manual for storage and handling of vaccines. In contrast, the finding in Mozambique, 43% of the respondents said that they had had an EPI manual (13). The difference may be due to increased awareness of vaccine handlers for EPI manual and increased attention of government to follow the manual by distributing it to all health facilities that manage vaccine. This is supported by key informants as they had overcome challenges of vaccine cold chain management especially skill gap by following EPI manual.

As indicated above, since all vaccines are heat sensitive products that need to be continuously maintained within a recommended narrow range of temperature and improperly maintained cold chain equipments contribute to the weakness of the existing cold chain (3,13,34). In this respect the availability of a plan for both replacement and preventive maintenance and spare parts for timely maintenance of cold chain equipment at the health facility levels are a mandatory to manage vaccine cold chain effectively. In present study, very few 7(22.6%) facilities had a plan for replacement of cold chain equipments that have served long period of time and 12(38.7%) had adequate supplies of spare parts for equipment maintenance. This is also supported by more than four-fifth of key informants. As stated one of key informant stated that shortage of cold chain equipments and spare parts and lack of maintenance for equipments were the main barriers for efficient vaccine cold chain management.

The result of chi-square test pointed out that vaccine handlers who had one year and above work experience in vaccine cold chain management and trained on both vaccine cold chain management and cold chain equipment maintenance had good knowledge and practice compared to those who had less than one year work experience and who trained either vaccine cold chain management or equipment maintenance. Similarly a study in Thailand identified that healthcare workers who had sufficient training on cold chain handling and management had better knowledge than healthcare workers who had no training ($P<0.001$) (21). A finding in Ethiopia identified that year of service in the immunization program showed a statistically significant association with knowledge of cold chain management ($P < 0.05$) (22)**.** The possible reason might be duration of work and training improved the knowledge and skill of vaccine handlers.

7. Strength and limitation of the present study

Strength: As it was institutional based study, primary data were collected from both vaccine handlers and vaccine key informants. The study included both quantitative and qualitative parts, which helped to understand the opinions and feelings of key informants on vaccine cold chain management in depth in addition to quantitative results.

Limitation: There may be over or under report of vaccine handlers on practice checklists and vaccine key informants. Study design being cross-sectional. Storage capacity of facilities was not assessed because there was shortage of data for positive and negative capacity of equipments.

8. Conclusion

Despite medium percentage of knowledge and practice, majority of the facilities have poor availability of cold chain equipments and infrastructures. In over all, vaccines in a third of facilities were found to be at a high risk of losing their potency.

9. Recommendations

To EPI/FMOH

To improve the status of vaccine cold chain management, distribution of cold chain equipments and infrastructures like, at least one refrigerator per health facility, deep freezer where it is needed, power generator and adequate supply of spare parts for equipments maintenance should be carried out. An updated capacity building training on both cold chain management and equipment maintenance should be continued meanwhile there may be vaccine handlers' turnover and vaccine cold chain management is not the duty of only vaccine handlers.

To SNNPRB, Dawuro zone health department and woreda health offices

Awareness creation and on-site training supported with practical demonstrations and well-designed supportive supervision should be given for health professionals. There should be a plan for preventive and emergency maintenance of cold chain equipments and timely equipment maintenance.

To health professionals

Since the up to dated guide lines are available in all facilities, it should be followed and vaccine cold chain management should be considered as responsibility of all health professionals. Further large scale study should be done at regional and country level using both qualitative and quantitative methods to identify gaps and recommend possible solutions.

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Annexes

Informed consent form for questionnaires and checklist

My name is ---------- I am working as a data collector temporarily for post graduate student of Jimma University College of health Sciences, department of pharmaceutical supply chain management. The objective of this study is to assess the status of vaccine cold chain management at public health facilities in Dawuro zone, South West Ethiopia. During the interview you will be asked some short questions about your background; the recommended storage temperature range for vaccines in refrigerators/freezers, measures to be taken in the emergency situations, vaccine inventory management and the effects of freezing on vaccine and fill checklist, main contents of it will be information on policy and procedures, ordering and monitoring of stock, receipt of vaccine, vaccine refrigerators and freezers, refrigerators' and freezers' thermometers and storage of vaccine. During the interview cold chain equipment and cold chain maintenance process will be observed. Your answers will be recorded on a survey questionnaire. No personal identifiers will be attached/ recorded to the interview.

All the data obtained will be kept strictly confidential by using only code numbers. Your participation in the study is upon purely voluntary basis. The interview will be conducted individually and will take 20-30 minutes. During the interview (discussion) period, if you feel inconvenient, you can interrupt and clarify inconvenience, appoint to other time or even withdraw any time after you get involved in the study. Your honest and genuine participation in responding to the questions prepared is very important & highly appreciated. If you agree to participate in this study I will interview you.

Would you be willing to participate? Yes ☐ No ☐

If yes, proceed. If no, thank and stop here.

Annex 1: Questionnaires to assess knowledge of vaccine handlers

Name of health facility_____

Encircle your choice

Note: One some questions may have more than one choice, so encircle all your choices

Part I: General direction

1. Sex
    A) Male
    B) Female
2. Age (in years) _____
3. Professional of person in-charge of the facility cold chain or vaccine store.
    A) Pharmacy
    B) Nurse
    C) Health officer
    D) Environmental health
    E) Others (mention) _____
4. Educational level
    A) Diploma
    B) Degree
    C) Above degree
5. Work experience on vaccine management (in years) _____
6. Have you ever attended training on vaccine cold chain management system within last two years?
    A) Yes
    B) No
7. If yes for Q no_6 types of training?
    A) Vaccine cold chain management(handling, storage and distribution of vaccine)
    B) Cold chain equipment maintenance
    C) Both

8. Do you need more training on vaccine cold chain management system?
    A. Yes
    B. No
9. If yes for question no-8, in which area
    A. On cold chain management
    B. On cold chain equipment maintenance
    C. On both cold chain management and equipment maintenance

Part II: knowledge on vaccine cold chain management related

10. What do you think causes vaccines to lose their potency? Encircle all applicable.
    A. Exposure to heat
    B. Exposure to light
    C. Exposure to cold
    D. All above
11. What is the recommended temperature range for most vaccine stored in refrigerators?
    A) -5 ^{0}C to +1^{0}C
    B) +2^{0}C to + 8^{0}C
    C) +9^{0}C to +15^{0}C
    D) +4^{0}C to +8^{0}C
    E) Don't know
12. What is recommended temperature range for most vaccine stored in freezers?
    A) +6^{0}c to -4^{0}c
    B) -4^{0}c to -14^{0}c
    C) -15^{0}c to -25^{0}c
    D) Don't know
13. Does it happen that vaccines in refrigerator or freezer are not in recommended temperature range during storage?
    A) Yes
    B) No

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

    A) Continue storing in cold chain for future use.
    B) Stop using and recorded in discarded book
    C) Adjust refrigerator
    D) A and C

15. Placement of vaccines in the lowest compartment of refrigerators affect vaccines

    A) Yes
    B) No

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

    A) By determining only safety stock
    B) By determining only maximum stock level
    C) By determining only minimum stock level
    D) By determining sum of stock on hand (working & safety stock) and stock on order, minus any stock-back ordered to clients.

17. When do you say the vaccine stock is at maximum stock level?

    A) When stock is at re-order level
    B) When the stock is sufficient to satisfy demand until the next order
    C) When you have safety stock
    D) When there is over stock

18. When do you say the vaccines stock is at minimum stock level?

    A) When stock is at re-order level
    B) When the stock is sufficient to satisfy demand until the next order
    C) When you have safety stock
    D) When there is stock out

19. When do you say the vaccines stock is at safety stock level?

    A) When you have vaccines maximum stock
    B) When you have vaccines minimum stock
    C) When you have vaccines stock on hand to prevent stock out

20. Shifting of vaccine to another refrigerator is required if power failure occurs more than 72 hours

    A) Yes B) No

21. Vaccines more sensitive to freezing are?
    A) HepB
    B) DPT
    C) DT
    D) TT
    E) All above
    F) Don't know
22. Vaccines more sensitive to heat are?
    A) BCG
    B) OPV
    C) Measles
    D) All above
    E) Don't know
23. If not kept in a separate freezer; where should BCG, polio and measles vaccines; be kept in vertical (upright refrigerator)?
    A) In the bottom, where it is coldest
    B) Nearer to the top
    C) In middle
    D) On top part where it is hot
24. Where should DPT, DT, TT, hepatitis B vaccines and Haemophilus influenza type B (Pentavalent vaccine); be kept in vertical (upright refrigerator)?
    A) In the bottom, where it is coldest
    B) Nearer to the top
    C) In middle
    D) On top part where it is hot
25. How can you tell if a vaccine has been frozen?
    A) By performing vaccine shake test
    B) By using vaccine vial monitor
    C) A and B

26. What do you think causes freezing of vaccine to occur in the cold chain?

A) Power failure

B) Storing freezing sensitive vaccine at bottom of top opening freezer

C) Storing vaccine below recommended temperature range

D) B and C

27. What do you do in case of power failure?

A) Store vaccine in cold box prepared for emergency case

B) Leave vaccines in refrigerator/freezer until power maintained

C) Report for immediate vaccine coordinators/supervisors

D) Use kerosene

E) A,C and D

28. Should discarded vaccine due to incorrect storage condition be recorded?

A) Yes (if yes ask to see)

B) No

29. If yes, for Q.no-26 why?

A) To facilitate the removing process of vaccine damaged

B) To monitor inventory of vaccine efficiently

C) To prevent mixing of damaged and undamaged stock

D) All above

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

A) Once monthly

B) Quarterly a year

C) Twice a year

D) When necessary (no specified time period)

Annex 2: Check list to assess cold chain practices

Tick (✓) for Yes and (✗) for No under Yes & No according to the respective questions.

A. Infrastructure and cold Chain equipment/resource availability	**Yes**	**No**
A01- Does your facility has functional refrigerators?		
A02-Does your facility have operational deep freezer?		
A03- Are they (refrigerators/freezers) equipped with a calibrated functional min/max thermometer or fridge tag?		
A04- Do standard cold boxes and vaccine carrier are available?		
A05- Does your facility has a separate store for vaccine storage?		
A06-If yes for Q.no-A05, is it operational and maintained at recommended temperature?		
A07- If yes for **Q.no-A05** does it has sufficient permanent capacity for storage of vaccine (at $+2^{o}$ C to 8^{o}C and -15^{o}C to -25^{o}C); and syringes & supplies for vaccination?		
A08-If yes for **Q.no-A05** does it has sufficient temporary capacity for handling campaign vaccine (at $+2^{o}$ C to 8^{o}C and -15^{o}C to -25^{o}C); and syringes & supplies for vaccination?		
A09- Does your facility has power generator to maintain cold chain in case of electric failure?		
A10- Does every refrigeration and freezing unit protected through voltage stabilizer?		
A11- Is there planned back-up storage unit(s) in the event of a power failure or other unforeseen event?		
A12- Is there an approved cool box with appropriate temperature monitoring or alternative refrigerator available to store vaccines during servicing, defrosting and cleaning?		
A13- Are there at least two trained persons responsible for the ordering, receipt and care of vaccines?		

A14-Availability of functional car/motorbike in the facilities to use in case of refrigerator failure?		
B. MIS and supportive function	**Yes**	**No**
B01- Do you use an up to date cold chain guideline (reviewed within the last two years) for storage and handling practice of vaccines?		
B02-Do you make the guideline accessible for all staffs?		
B03- Do you review this guideline with all staff annually and with new staff, including temporary staff, when they are hired?		
B04- Do you contact your local immunisation coordinator when temperatures are outside +2°C to +8°C?		
C. Stock management	**Yes**	**No**
C01- Do you monitor/review vaccine stocks prior to ordering?		
C02- Do you audit vaccine stocks weekly and records of vaccine stocks (at least) monthly?		
C03- Do you review a routine vaccine management quarterly?		
C04- Do you check the expiry dates of vaccines at the beginning and end of every month?		
C05-Do you clearly label close to expiry vaccines? (ask to see)		
C06-Do you rotate vaccines on the **"**first to expire, first out**"** principle?		
C07-Do you stock clearly, label, remove from the refrigerator and destroy timely the out-of-dated vaccines?		
C08- Do you fill vaccine stock record books correctly and timely (update)? (ask to see)		
D. Vaccine management practice	**Yes**	**No**
D01-Do you store vaccines in separate, self-contained units that refrigerate or freeze only?		
D02-Do you lock either the refrigerator or the room for vaccine storage?		
D03-Have you placed the refrigerator/freezer at properly ventilated and not near any heat source, e.g. radiator, window?		

D04-Have you placed a **"**DO NOT UNPLUG**"** sign next to your refrigerator's electrical outlet for the electric supply safety? (ask to see)		
D05-Do you keep records of regular servicing, defrosting and cleaning as per manufacturers' recommendations?		
D06-Do you store sealed water bottles (if space allows) on the upper and lower shelves and in the door of the refrigerator? (ask to see)		
D07-Do you store ice packs in the freezers? (ask to see)		
D08- Do you have systems to minimize refrigerator/freezer door opening during vaccine delivery/receiving (eg. Opening at morning only)?		
D09-Do you store vaccines in the middle shelves of refrigerator and not on the shelves in the door, bottom drawers or adjacent to the freezer plate? (ask to see)		
D10- have you not stored anything other than vaccines in the refrigerator (including specimens, food &drink)? (ask to see)		
E. Vaccine storage temperature	**Yes**	**No**
E01-Do you monitor temperature continually with a maximum– minimum thermometer/fridge tag?		
E02-Is refrigerator temperature maintained at (2–8ºC)? (ask to see)		
E03-Is freezer temperature maintained at an average temperature of -15°C or colder, but no colder than -50°C? (ask to see)		
E04-Do you record and monitor the minimum, maximum and actual temperatures in the refrigerator at least once each working day?		
E05- Are temperature records readily accessible and retained until the next audit?		
E06-Do you document refrigerator and freezer temperatures on the appropriate log?		
E07-Do you follow the directions on the temperature log to call appropriate personnel if the temperature in a storage unit goes out of range?		
F. Vaccine distribution	**Yes**	**No**
F01- Do you have a program for distribution of vaccine from issuing store to		

each receiving store?		
F02-If you need to transport vaccines to outlying stores, eg district, health center, health posts, do you use validated cold boxes with thermometers and ice packs?		
F03-Do you know how to condition ice packs for transportation?		
G. Maintenance of cold chain equipment	**Yes**	**No**
G01-Do you have a plan for replacement of cold chain equipments that have served long period of time (>10 years)?		
G02-Do you have a plan for preventive maintenance of cold chain equipments?		
G03-Do you carry out an emergency repair of cold chain equipment in timely manner?		
G04-Do adequate supplies of spares and consumables are available for equipment maintenance?		
Total Yes and No		

Source: (34,35)

Thank you!

Annex 3: Interview guide for in-depth interview of vaccine cold chain management key informants

Sex,

Age,

Educational status,

Work experiences,

Responsibility in this facility

1. In your own opinion, what are some barriers if any, that you encountered to efficient vaccine cold chain management? Please list.
2. How did you overcome the barriers?
3. What worked well in vaccine cold chain management? Please elaborate.
4. What strategies, interventions, tools should be discontinued for vaccine cold chain management? What do you dislike about it?
5. In which area do you think you need more professional training on vaccine cold chain management? Please list.
6. What are the major reasons you prefer that areas?
7. What do you finally recommend to the FMOH/ EPI on storage and handling of vaccines?

Thank you!

ASSURANCE OF PRINCIPAL INVESTIGATOR

The undersigned agrees to accept responsibility for the scientific ethical and technical conduct of the research project and for provision of required progress reports as per terms and conditions of the college of health sciences in effect at the time of grant is forwarded as the result of this application.

Name of the student: Abebe Kebede

Date._____ **Signature** _____

Approval of the first advisor

Name of the first advisor: Mr. Seid Mussa

Date._____ **Signature** _____

Approval of examiner

Name of examiner: _____

Date _____ **signature** _____