

Practical experience of vaccinators and vaccine handlers in vaccine cold chain management: A phenomenological study

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Abstract

Background: As the means of storing and transporting vaccines while maintaining their potency, cold chain storage is the most critical element of immunization. This study explores factors that contribute to vaccine wastage in public health facilities in Oromia Special Zone, Ethiopia, and focuses on how this knowledge can empower public health governors' efforts in relation to effective vaccine cold chain management.

Methods: A phenomenological study design was employed with key informants (n=13). Data-driven coding was used and content analysis was performed using NVivo 11 plus. A narrative strategy was also employed.

Results: The present study identified a range of factors that contribute to vaccine wastage related to logistics, immunization practices, vial size, health professionals, and institutions. The presence of one these factors may trigger the appearance of another. The identified factors should be considered as complementary, and the notable consensus among key informants made the results generic and relevant to vaccination service around the world.

Conclusions: Various factors contribute to vaccine wastage. The contributing factors for vaccine wastage identified in this study should be considered by health professionals and public health governors when drafting and implementing intervention strategies for improving vaccine cold chain management for similar health facilities operating around the world. [*Ethiop. J. Health Dev.* 2021; 35(1):29-37]

Key words: Vaccine wastage, contributing factors, cold chain management.

Background

Vaccine applies to all biological preparations produced from either the entire disease-causing microorganism or some of its components (1). The global Expanded Programme on Immunization started with vaccination against six diseases (2) and efforts are underway to develop new vaccines against major infectious diseases (3). Vaccines have the power to save and transform lives, giving children the chance to grow up healthy (4). Thus, immunization is one of the most powerful and cost-effective of all health interventions (5).

Cold chain storage is the most critical element of immunization (6) and a means of storing and transporting vaccines while maintaining potency (7). Vaccines can be stored in cold rooms, freezer rooms, refrigerators, or freezers, and transported in insulated vaccine carriers or refrigerated transport vehicles (8). The transport and storage of vaccines under controlled temperatures is critical to maintaining their safety and potency (3).

Proper cold chain management and well-maintained equipment are the keys to safe vaccine storage and delivery (6). However, the vaccine cold chain struggles with the absence of appropriate equipment (9), equipment failure (6), power supply (3), limited knowledge and practice of vaccine storage and handling (10-14), and poor stock management (3). Inefficient vaccine management will result in temperature fluctuations in different compartments of the refrigerator and contribute to high wastage (15).

Unopened vaccine wastage can occur through expiry, vaccine vial monitor change, heat exposure, freezing, breakage, missing inventory, and theft (16). Vaccine wastage in opened vials may occur as a result of

discarding opened vials that contain a number of remaining doses at the end of a session, poor reconstitution practices, submerging opened vials in water, contamination, and bad reaction of a baby during immunization. Discrepancies in the number of doses drawn from a vial compared to the label also cause opened vial wastage (16,17).

It is quite difficult to advocate a universally acceptable vaccine wastage level because wastage levels vary between program experience and local situations (16). The relationship between the vaccine wastage rate and immunization coverage is key to deciding whether wastage is high (17). Due to increasing vaccine costs, more emphasis is placed on vaccine wastage than ever before (16). As a result, reducing vaccine wastage is critical in immunization programs that seek to continue to deliver existing vaccines and add expensive new vaccines to their schedule (18).

The ultimate purpose of this phenomenological study is to reduce individual vaccine cold chain management experiences to descriptions that explore its universal essence. This description consists of how, why, and what these individuals experienced (19). Understanding the practical experiences of vaccinators and vaccine handlers will empower and improve public health facilities and decision-makers' efforts to develop the human resources required to manage and make available cold chain technologies and equipment, and improve the knowledge and attitude of health workers toward cold chain management. Significant improvements can also be made to cold chain management that result in considerable savings in vaccine wastage and children's lives. Thus, this study explores factors that contribute to vaccine wastage in public health facilities in Oromia Special Zone, Amhara Region.

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Research question: The study was conducted with vaccinators and vaccine handlers in Oromia Special Zone, centering on the following research question:

What were the vaccinators and vaccine handlers' practical experiences on cold chain management of vaccines in the Oromia Special Zone?

World Health Organization's conceptual framework on factors that affect vaccine wastage

Factors that contribute to vaccine wastage across the globe, as identified by the World Health Organization

(WHO), guide the design of this study (16). The WHO has identified various interdependent factors ranging from the vaccine to the vaccinator that contribute to vaccine wastage. Factors affecting vaccine wastage are categorized by the WHO into those relating to vaccines and syringes, national policy, logistics, and immunization practice (see Figure 1). According to the WHO, the presence of one factor may trigger the appearance of another, and unopened vial wastage is avoidable and unacceptable. This conceptual framework provides a starting point to fully explore why and how vaccines are wasted.

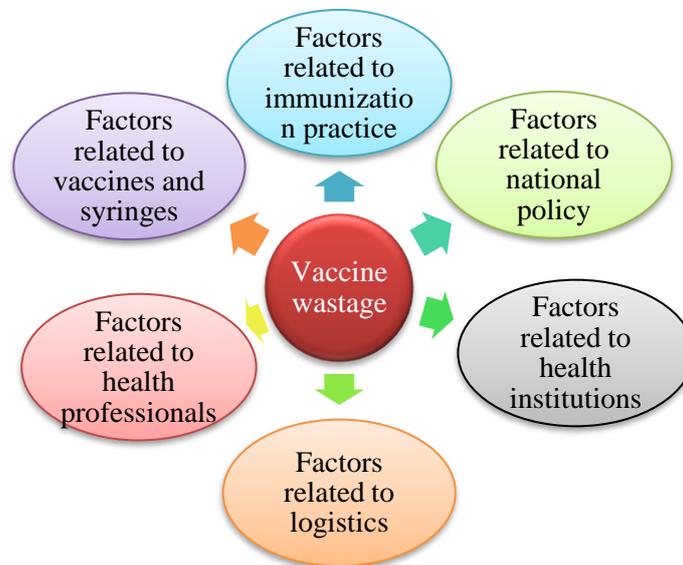


Figure 1: **Conceptual framework**

Methods

A phenomenological study design was employed to fully explore why and how vaccines are wasted, based on discussions with key informants. A phenomenological study explores what all key informants have in common as they experience phenomena (20). In this case, this study described the meaning for key informants of their lived experience of the factors that contribute to vaccine wastage.

Study area and period: The study was conducted in public health facilities in Oromia Special Zone, Ethiopia, on 01–30 September, 2019. Oromia Special

Zone is one of the 10 zones (see Figure 2) in Amhara Regional State that has a tropical climate which can compromise the potency of vaccines. Kemisie is the capital town of the zone, located 326 kilometers from Addis Ababa, the capital city of Ethiopia. The administrative zone has two town administrations and five *woredas* (districts). Oromia Special Zone has a total population of 459,847 (21). According to the 2018/19 annual report of the Oromia zonal health department, Oromia Special Zone had two hospitals, 28 health centers, and 115 health posts during the survey period (22).

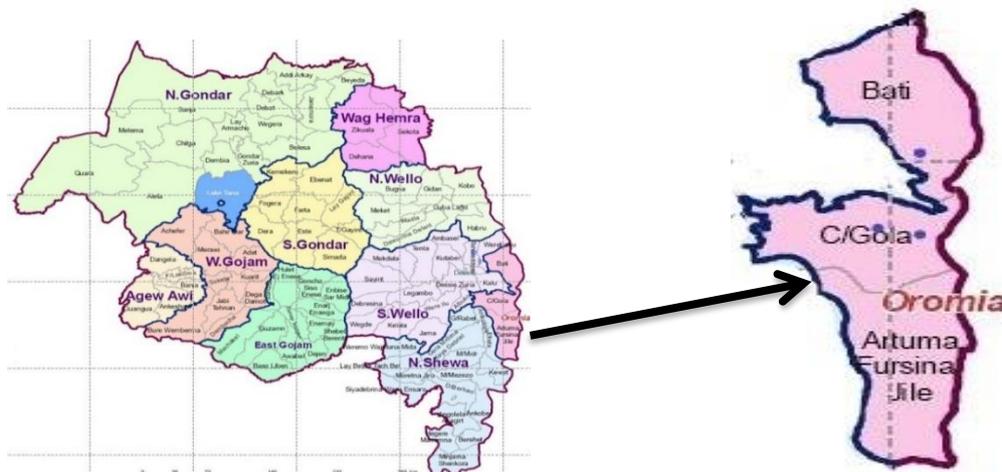


Figure 2: (A) Map of Amhara Region showing all zones; (B) Map of Oromia Special Zone showing administrative town and *woredas*, 2019 (24)

The Ethiopian Pharmaceutical Logistics Master Plan aims to integrate all vertical programs into one supply chain and deliver pharmaceuticals directly to health facilities (23). Despite this effort, vaccines were not part of an integrated system until January 2016. After integration, the Ethiopian Pharmaceuticals Supply Agency (EPSA) started delivering to the zonal health department store, and health facilities received vaccines from their respective *woreda* health offices via the zonal health department. Since January 2018, EPSA has been responsible for the whole vaccine supply chain management and has started to transport vaccines to *woreda* health office stores each month.

Sample size determination and sampling procedures:

In consultation with the zonal vaccine logistics officer, the researchers chose to focus on eight health centers. Health facilities in the zone are homogenous in terms of climatic conditions, health professionals and vaccination services. The selected health centers were: Bati, Kemisie, Senbetie, Bete, Gerbi, Chereti, Chefarobit and Woledi. Three health professionals (vaccine handler, vaccinator, and head of the vaccination service) were selected from these health centers. Key informants were selected by the zonal vaccine logistics officer and respective *woreda* health office vaccine logistics officers based on their level of expertise on vaccine cold chain management. Purposive sampling was used to select vaccinators and vaccine handlers in the selected health facilities on the basis that they are rich in key information related to vaccine wastage.

All health professionals who engaged in vaccination and vaccine handling, had vaccine cold chain management experience of two years or more, and who were acknowledged for their engagement in vaccination practice were included in the study. Since health posts are considered as one of the dispensing units of the health center, professionals who engage in their supervision were also included. The sample size was decided when the saturation point of emerging information was reached. The final sample size was determined when nothing new was emerged after three consecutive key informants' in-depth interview.

Data collection tools and procedures: A semi-structured interview guide was prepared to explore an in-depth understanding of key informants on vaccine wastage and possible contributing factors. The interview guide was initially prepared in English and translated into Amharic and finally back-translated into English language to maintain consistency and standardization of the instruments. In-depth interviews were conducted by the lead investigator/author, lasted from 15 to 30 minutes, and proceeded until no new ideas emerged. The interviews were conducted in Amharic and field notes were also used to write up the experiences and observations made. All interviews were audio-recorded and transcribed verbatim.

Early coding of Amharic transcripts, simultaneous with data collection, was conducted after multiple readings. All written transcripts were read several times to obtain

the overall feeling of them. All sections of original transcripts were translated into English to facilitate coding and each transcript was coded line by line using NVivo 11 plus. The data were analyzed using the principles of content analysis. Data-driven coding was used and codes were organized into themes. For each transcript, significant phrases or sentences that pertain directly to vaccine wastage and its contributing factors were identified. Key informants' professions, sex, and work experiences were used to elucidate their verbatim portrait. Key quotes were considered to be illustrative of the emerging themes. From 13 verbatim transcripts, 240 significant statements were extracted. Arranging the statements into clusters resulted in five themes. A narrative strategy was employed for the presentation of qualitative findings.

To enhance the validity of in-depth interviews, the interview guide was tested to assess its validity of content by an expert from a social and administrative pharmacy group. It was prepared in the English language and back-translated into Amharic and then to English to check message consistency. The Amharic version was used to interview key informants. More than one investigator was involved. The validity was also enhanced by employing both methodological triangulation (data collected through field notes, observations, and individual in-depth interviews were compared and contrasted) and investigator triangulation (three research team members participated in data coding and analysis) (25). Moreover, the conceptual framework was used to explore theories made so far to had all factors and Amharic versions of the transcripts were returned to the key informants for their individual signatures.

Issues of reflexivity: lead author's/investigator's status

as an insider: The principal investigator's status as a 'professional' offers certain strengths and limitations for this study. He approached a member of the educated elite and senior pharmacy professional and operated with an awareness of insider bias and the nature of his conflicting roles. He employed a non-judgmental approach and maintained an awareness of professional impartiality in his work. He was also faced with the challenge of being perceived as a powerful individual based on his position. Although he had competing roles and perceptions related to the concept of insider bias, the use of open-ended questions and engaging informal conversations with informants, on other topics they raised were some of the measures taken to solve these limitations.

Bracketing: A phenomenological study seeks to understand the experienced phenomena of several key informants. It requires an understanding of basic philosophical assumptions and the need to define how key informants understanding will be introduced in the study (19). In this study, key informants were chosen carefully to be individuals who had working experience in question. The researchers also separated themselves from the text by their understanding in a reflexive way (26). The researchers narrate the finding of key informants in-depth interview.

Results and discussion

A total of 13 vaccine handlers and vaccinators participated in the in-depth interviews. Five key informants were female and eight were male. Key informants were between the ages of 27 and 38, with a mean and standard deviation (SD) of 31.5 ± 2.9 . Key informants were four midwives, eight nurses, and one health officer. Concerning their level of education, 11 had a degree and two had a diploma. The work experience of key informants ranged from two to 11 years, with a mean and SD of 6.46 ± 2.5 . Five of the informants had experience of the role of 'focal person' for the Expanded Programme on Immunization in more than one health facility.

Factors contributing to vaccine wastage: All key informants pinpointed the availability and effective management of the vaccine cold chain system as essential to optimal performance of the immunization program. Nearly all vaccine wastage was attributed to improper vaccine cold chain management.

We begin by presenting factors related to logistics (cold chain equipment availability and usage), followed by factors related to vial size and national policy, then factors related to immunization practice (session size, reconstitution practice, and contamination). All these factors are identified and listed under the World Health Organization conceptual framework (16). The researchers added factors into the conceptual framework related to health professionals and health institutions as possible contributing factors for vaccine wastage.

Factors related to logistics: Key informants mentioned that cold chain equipment availability and use, temperature monitoring, power supply, distribution and transport, communication and supervision, maintenance, and near expiry supply were factors related to vaccine wastage. Two of the key informants mentioned that near expiry and vaccines at stage 2 vaccine vial monitor were sent from the supplier to health facilities. Because they do not use these sent vaccines at all, the leftover vaccines will go to waste. A statement made by one key informant demonstrated this:

"Nearly expiry vaccines were supplied. We use them till their expiry date. Then if their date [has] passed, we will discard them... In particular, the occasional vaccine vial monitor on polio was stage 2 when supplied." (Nurse, Male, 9)

This situation on vaccine wastage is reflected in a study conducted in India, where vaccine wastage was reported during use because of color changes on vaccine vial monitor (exposure to freeze or hot temperature) (27). The expiry of vaccine was also a factor responsible for vaccine wastage (28-30).

Some of the health extension workers do not properly transport vaccines from the health center. They will tell anyone who visits the health center to bring the vaccine. The health care provider also issues the vaccine for fear of service interruption. One of the key informants mentioned:

"Health extension workers ask us to send the supply to the person we meet. We give it to anyone who comes from the community. This person carries the vaccines in the market overnight and going to take them out health post." (Health officer, Female, 6)

The majority (eight) of the key informants stated that because the vaccine lasts for a long time until it reaches the health posts, it can cause different reactions. One key informant described that:

"When they travel from here to the health post, they have road problems. It's sunny and at least they will not be able to use the vaccine carrier properly." (Midwife, Male, 4)

Some studies conducted outside of Ethiopia indicate that vaccines are often not stored at correct temperatures. For example, vaccines might be exposed to freezing temperatures at one or more points of shipments in Bolivia (31). A similar study also reported that vaccines were exposed to $> 8^{\circ}\text{C}$ during transportation (32). The Centers for Disease Control states that excessive heat, cold, or light exposure can damage vaccines (33) and further exposure to improper conditions will further result in reduced potency (15).

Proper cold chain equipment is required to maintain the quality of the vaccine. However, the majority (eight) of key informants revealed that there is not enough cold chain equipment to manage vaccines. Although few fridge used to store vaccines were available, the existing refrigerator does not adequately handle the vaccines received. This contributed to the vaccine being wasted. A key informant portrayed:

"Right now there is a single fridge in the district. We have divided it up and we store vaccines and other medicines by registering our names... Not enough. Although it was large, it's small to hold the vaccines." (Nurse, Female, 6)

Many other key informants confirmed that due to storage space, the vaccine diluent was kept outside the refrigerator. For example, one key informant stated:

"It sits in the district. It just sits in a dry place outside the fridge." (Nurse, Female, 6)

Equipment should be chosen based on operational reliability and space requirements (8) and the cold chain system must have sufficient storage capacity to accommodate all vaccines, diluents, and injection supplies needed for the Expanded Programme on Immunization (34). An absence of appropriate equipment to store and transport vaccines is a bottleneck to the cold chain system (9).

What makes the issue worse is that the refrigerators used by most health facilities are electrically powered. All (13) key informants mentioned that electricity has been interrupted several times for various reasons, with vaccines stored warm. A key informant stated:

"We had lost the electric power for about four months. The transformer was burned... The power interruption"

causes the vaccine vial monitor to change. We are having a problem with this. Sometimes the fridge gets too cold. It will get warm when the electricity goes." (Nurse, Male, 9)

They use an alternative energy source to prevent the effect of the electric cut-off on vaccine potency. Half (six) of key informants revealed that a generator is available at most health care facilities but does not operate as its broken. An female nurse with 11 years' experience stated:

"The generator sometimes does not work and it may not be ready for use." (Nurse, Female, 11)

Almost all (12) key informants explained that a generator is not available full-time. The generator is switched on for normal use rather than for vaccination, so the generator is turned off when the normal working hours are completed. Often, refrigerators are unable to provide the required cold storage service due to fuel supply problems. A key informant emphasized:

"24 hours doesn't work. For example, when you work you turn it on, and off when you are idle... The top managers always stand to save fuel. No one bothers about vaccines." (Midwife, Male, 4)

Although generators often provide power all day in some health facilities, there is often not enough power generated for fridges to operate properly. This is substantiated by one key informant's statement:

"The generator is not effective. Even if we use it, it doesn't freeze properly. It works for a long time and does not freeze properly." (Nurse, Male, 8)

Electric power remains the dominant power source for vaccine refrigerators. Studies conducted in Cameroon (35) and the Philippines (36) reveal that the majority of health facilities had no secure power sources. The problem is compounded by the non-availability of non-electrical cold chain equipment (13). The absence of a solar refrigerators, and inadequate ice packs and cold boxes in most health facilities, have magnified the problem. According to the WHO, the reliability of electricity supply is a concern when refrigeration equipment is chosen (3). As a result, the use of ice-lined refrigerators and high-performance freezers is strongly recommended for bulk vaccine storage when electricity supplies are rarely completely reliable (8). When electrical outages are less frequent, solar refrigerators may provide savings in total cost per dose administered over electrical refrigerators (37).

Nine of the key informants stated that disruption of energy and lack of alternative power sources urges them to temporarily move vaccines to other health centers or health posts until the problem is resolved. This was supported by one of the key informants:

"We have a health post nearby. We take vaccines to the health post if the fridge gets too hot. We take them frequently." (Nurse, Male, 9)

All key informants said that there is more than one vaccine refrigerator in all health facilities, but many fridges fail to provide services for various reasons. Health facilities use different methods to keep vaccines safe. Some are stored in cold boxes until a broken fridge starts working. If they are not fixed quickly, they will be taken to another health facility. Breaks in the chain are frequent and compromise potency (38). The major causes appeared to be refrigeration (cold chain) lapses (30,39). When there is an equipment failure, large quantities of vaccines can be destroyed (6).

Factors related to vial size and national policy: Key informants stated that the vial size of the vaccine contributes to the wastage of vaccines. After the vaccine is properly mixed with diluent, children who come to seek service will not balance with the dose. The majority (12) of key informants mentioned that leftover vaccines will be discarded when the deadline has passed. One key informant said:

"Because we are wasting time and creating service delay, we open the program on time. If there aren't enough children, we will discard vaccine and this often occurs." (Nurse, Male, 8)

The adaptation/non-adaptation of opened vial policy matters the discarding the time of all opened vials (7). Unused vaccines and vaccines that were fewer than nominal doses can occur in multi-dose containing vials (30). On the other hand, since lyophilized vaccines do not contain preservatives, they should never be used beyond six hours after they have reconstituted (18). Of course, a high wastage rate attributed to opening a multi-dose vial for a small session size to avoid missed opportunities is more acceptable than wastage attributable to freezing or expiry (16,40).

Factors related to immunization practice: Session size, reconstitution practice, and contamination were the stated factors contributing to vaccine wastage. When the vaccines are mixed with the diluent, the correct solution might not be created. The composition may be suspended or precipitated. The key informant portrayed his experience:

"Measles was unable to form a solution. I got something precipitated. Just then, I tried, you never swing a lot. I discard." (Nurse, Male, 9)

After the vaccine is disrupted, measurement errors also occur. Five key informants stated that the number of children who are thought to have been vaccinated may not always match the number of doses that have been used from the vial. One of the key informants explained the scenario:

"The vaccines we want to reconstitute drain our efforts to extract air and form a bubble. Once I take a 5ml I can take an extra 0.5ml and I have medication wastage." (Midwife, Male, 2)

The risk of contamination from vial septum is higher in a multi-dose vial than in a single-dose vial because of repeated exposure when the dose is withdrawn (18).

Thus, opened vial policy recommends that opened vials of all vaccines should be discarded at the end of each working day (7). As the number of beneficiaries per session decreases, the wastage per session increases (41). The WHO also notes that higher wastage is expected with lyophilized vaccines, since liquid vaccines can be used in subsequent sessions for up to four weeks (16).

Factors related to health professionals: Training, commitment, shortage of professionals, the placement of other items alongside vaccines, and management support were mentioned by key informants as factors relating to health professionals being responsible for wastage. In addition to vaccines, they put other things in the fridge. Almost all (11) key informants described that they put drinking water containers and vaccines together. One key informant said:

“We store water in the vaccine refrigerator. We put it along saying that we will drink later when we are thirsty.” (Midwife, Male, 2)

The informants also put other drugs together with vaccines in the absence of other fridge used for storing other drugs and if a freezer breaks down. The most common drugs are oxytocin, ergometrine, and collected laboratory samples. Keeping other things together increases the chance of vaccine wastage by reducing the space inside the refrigerator. A key informant emphasized the situation this way:

“Oxytocin, ergometrine, and collected laboratory samples are now stored here with vaccines. But it wasn’t like we want to be. When we have a refrigerator, we fix it, but it would still be stored...” (Nurse, Female, 6)

Vaccines are sensitive biological products that have vastly different sensitivities to heat and freezing (6). Laboratory reagents, anti-rabies vaccines, and maternity medicines were placed with vaccines in similar studies conducted in Ethiopia (42-44), Cameroon (45), Mozambique (10), and Nigeria (46). Each year, storage and handling errors result in the revaccination of many patients due to loss in potency and significant financial loss due to wasted vaccines (47).

Two key informants stated that vaccinators and vaccine handlers, other than the Expanded Programme on Immunization focal person, are only utilizing the knowledge they learnt at school. These professionals, unlike those in other departments, made no effort to keep themselves up to date in different ways. A key informant stated:

“What we are doing here is based on what people normally do, not on the basis of training for the Expanded Programme on Immunization.” (Midwife, Male, 8)

If the Expanded Programme on Immunization focal person resigns from work for any reason, other professionals in the immunization department will not be able to cover the coordinator’s position properly. As

a result, vaccine wastage occurs. Key informants described that:

“On weekends or if I go training, most of the vaccines were freezes due to lack of follow up. When this happened, I call the guards to unplug the socket. There are monitoring problems. Although we have a mandated assignment, there is a problem with implementation... It freezes more than it should.” (Nurse, Male, 8)

All key informants revealed that the vaccinators and vaccine handlers have knowledge gaps regarding vaccine cold chain management. Most of them cannot even ask for the required number of doses for the health facility on their own. A study in southern Ethiopia reported a similar knowledge gap (42), while a study in health facilities in southern Nigeria showed that knowledge of appropriate management of the cold chain in two districts was poor (38). Of course, increased temperature sensitivity and complicated immunization schedules demand adequate training on vaccine cold chain management (2). In Ethiopia, the majority of the health centers had no trained personnel (29).

Also, four key informants described that vaccinators and vaccine handlers had caused waste in neglecting and forgetting vaccines. The key informant portrayed the following scenario:

“The habit of forgetting vaccines on ice packs is something we often experience. We’ll open a new one when each service started. The vaccine will be available on the ice pack overnight... I recently forgot vaccines on ice pack.” (Midwife, Male, 2)

The researchers also confirmed the placement of vaccines outside the cold chain by their own observation. Proper cold chain management is an important factor in maintaining the potency of vaccines, but the poor attitude and negligence of vaccinators and vaccine handlers contribute to compromised cold chain management. The majority of respondents had a poor attitude and poor adherence to cold chain guidelines (48), and the attitude of many vaccine handlers was suboptimal (49,50).

Factors related to health institutions: Although there is an Expanded Programme on Immunization focal person who provides and monitors immunization services, four key informants stated that the staff numbers are insufficient. The key informant explained this shortage of human power:

“Human resources are not enough. If we are not there, we bring health extension workers to run the service.” (Nurse, Male, 9)

The adaptation of the opened vial policy requires offering services twice a week to reduce vaccine wastage and missed opportunities for vaccination. This requires adequate staff matched with workloads. However, there was an insufficient number of staff to handle vaccines in health facilities (9).

Nearly half of the key informants revealed that health department officials and governors were not responding quickly to repair the refrigerators despite they notice that the refrigerator at the health facility was inadequate. One of the respondents mentioned:

“Most can be fixed easily but they just sat there due to bureaucracy. Nothing repaired timely.” (Nurse, Male, 9)

In all health facilities, there was at least one nonfunctional cold chain equipment confirmed through observation. The Federal Ministry of Health also revealed that there was nonfunctional cold chain equipment in health centers and health posts (28). To avoid breakdowns, preventive and curative maintenance systems for storage buildings and vaccine cold chain equipment should be introduced (34), as well as a recording and reporting system for breakdowns (6). When equipment malfunctions, immediate steps should be taken to restore it to working condition (51).

Practical implications

The quality of immunization services can be improved by a proper vaccine cold chain system (52) at all levels for maintaining vaccine potency, which narrows the gap between vaccinated and immunized (53) and further reduce the number of deaths caused by vaccine-preventable diseases.

Storage and handling errors can result in revaccination and poor protection against disease, resulting in a loss of patient confidence (15,47). This is an obstacle to attaining national immunization coverage (4). Even so, vaccine wastage is expected in all programs – some level of vaccine wastage is unavoidable – but some wastage can be controlled (54) and there should be an acceptable limit (40). Therefore, it is prudent to minimize vaccine wastage and maintain vaccine potency to make vaccines available for vaccination.

Determining the vaccine wastage level and having an in-depth understanding of contributing factors will empower public health governors and decision-makers to develop the most appropriate interventions to tackle challenges and to improve vaccine management strategies and smooth operations. Thus, significant improvements can be made in cold chain management, resulting in considerable savings in vaccine wastage and children’s lives (55).

Limitation of this study

The key informants’ experiences were considered to be typical and the subjectivity of the data made it difficult to establish the reliability and validity of findings. Moreover, vulnerability to errors in judgment by researchers and a low level of reliability and bias are limitations associated with purposive sampling. These made the research team unable to generalize the findings.

Conclusions

The study identified a range of factors contributing to vaccine wastage related to logistics, immunization practices, vial size, health professionals, and institutions. The presence of one factor may trigger the

emergence of another, and the identified factors should not be considered discrete but as overlapping and complementary. Although the nature of the qualitative study alters confidence in the generalizability of the findings, the notable consensus among key informants made the results generic and relevant to vaccination service. Exploring how and why vaccine wastage occurs at health facilities will help health professionals and public health governors to adopt appropriate interventions to improve vaccine cold chain management, reduce wastage and increase immunization coverage.

Authors’ contributions

SAM conducted the in-depth interviews and analysis. All authors (SAM, BDW, and MHK) read the interviews repeatedly, interpreted the findings, and wrote the manuscript. Finally, all the authors proofread and approved the final version of this manuscript.

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Availability of data and materials

The datasets are available from the corresponding author upon reasonable request.

Ethical considerations

The research was initially approved by the Ethics Review Committee of the College of Medicine and Health Sciences, Wollo University (CHMS/405/13/11) and Oromia Special Zone health department (አዞ/ጤ/ጠ/544/2011). Moreover, study participants who consented to participate were fully informed about the confidentiality and privacy of the data.

References

1. Pharmaceutical Research and Manufacturers of America. Vaccine fact book. Washington, DC: PhRMA; 2012. www.phrma-jp.org/wordpress/wp-content/uploads/old/library/vaccine-factbook_e/vaccine_factbook_2012_en.pdf
2. World Health Organization. Principles and considerations for adding a vaccine to a national immunization programme: From decision to implementation and monitoring. WHO; 2014. www.who.int/immunization/programmes_systems/policies_strategies/vaccine_intro_resources/nvi_guidelines/en/ 2014.
3. World Health Organization. Global immunization vision and strategy: 2006-2015. Geneva: WHO; 2005. www.who.int/immunization/givs/en/
4. World Health Organization. State of the world’s vaccines and immunization, 3rd ed. Geneva: WHO; 2009. www.who.int/immunization/sowvi/en/
5. Zhou F, Bisgard KM, Yusuf HR, Deuson RR, Bath SK, Murphy TV. Impact of universal Haemophilus influenzae type b vaccination starting at 2 months of age in the United States:

- An economic analysis. *Pediatrics*. 2002;110(4):653-61.
6. World Health Organization. WHO-UNICEF effective vaccine store management initiative: modules 1-4. Geneva: WHO; 2005. <https://apps.who.int/iris/handle/10665/68993>
 7. World Health Organization. Safe vaccine handling, cold chain and immunizations: A manual for the newly independent states. Fact sheet. Geneva: WHO; 1998. <https://apps.who.int/iris/handle/10665/64776>
 8. World Health Organization. Guideline for establishing or improving primary and intermediate vaccine stores. Geneva: WHO; 2002. <https://apps.who.int/iris/handle/10665/67807>
 9. Lloyd J, Cheyne J. The origins of the vaccine cold chain and a glimpse of the future. *Vaccine*. 2017;35(17):2115-20.
 10. de Timóteo M, Bjune G. Cold chain management: Knowledge and practices in primary health care facilities in Niassa, Mozambique. *Ethiopian Journal of Health Development*. 2007;21(2):130-5.
 11. Dairo D, Osizimete O. Factors affecting vaccine handling and storage practices among immunization service providers in Ibadan, Oyo State, Nigeria. *African Health Sciences*. 2016;16(2):576-83.
 12. Akoh W, Ateudjieu J, Nouetchognou J, Yakum M, Nembot F, Sonkeng S, *et al*. The Expanded Program on Immunization service delivery in the Dschang Health District, west region of Cameroon: A cross sectional survey. *BMC Public Health*. 2016;16(1):801.
 13. Mallik S, Mandal PK, Chatterjee C, Ghosh P, Manna N, Chakrabarty D, *et al*. Assessing cold chain status in a metro city of India: An intervention study. *African Health Sciences*. 2011;11(1):128-33.
 14. Rao S, Naftar S, Unnikrishnana B. Evaluation, awareness, practice and management of cold chain at the primary health care centers in coastal south India. *Journal of Nepal Paediatric Society*. 2012;32(1):19-22.
 15. Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit. Atlanta: US Department of Health and Human Services, CDC; 2014. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
 16. World Health Organization. Monitoring vaccine wastage at country level: Guideline for program managers. Geneva: WHO; 2005. <https://apps.who.int/iris/handle/10665/68463>
 17. UNICEF. In support of the Global Polio Eradication Initiative: Guidance note on cold chain logistics and vaccine management during polio supplementary immunization activities. 2017. http://polioeradication.org/wp-content/uploads/2016/09/Cold-chain-logistics-and-vaccine-management-during-SIA_Nov2015_EN.pdf
 18. World Health Organization. Adopting global vaccine management policies for national use. Geneva: WHO; 2002. <https://apps.who.int/iris/handle/10665/67809>
 19. Moustakas C. Phenomenological research methods. Thousand Oaks, CA: Sage; 1994.
 20. Creswell J. Qualitative inquiry and research design. Choosing among five traditions. . Thousand Oaks, CA: Sage; 2007.
 21. Central Statistics Agency of Ethiopia. Summary and statistical report of the 2015 population and housing census. Population size by age and sex. Addis Abeba: CSAE; 2015.
 22. Oromia Special Zone Health Department. Annual Report for 2018/19. Kemisie: Oromia Special Zone Health Department; 2019.
 23. PFSA. Standard Operating Procedures (SOP) Manual for the Integrated Pharmaceuticals Logistics System in Health Facilities of Ethiopia. Second Edition. Addis Ababa: Ethiopia. 2015. https://www.academia.edu/41440688/Standard_Operating_Procedures_SOP_Manual_for_the_Integrated_Pharmaceuticals_Logistics_System_in_Health_Facilities_of_Ethiopia_Second_Edition.
 24. OCHA. Map of Amhara region showing all administrative zones and woredas. United Nations Office for the Coordination of Humanitarian Affairs; 2019. www.ocha-eth.org/Maps/downloadables/AMHARA.pdf
 25. Bryman A. Social research methods (4th ed.). New York: Oxford University Press; 2012.
 26. Le Vasseuer J. The problem with bracketing in phenomenology. *Qualitative health research*. 2003;31(2):408-20.
 27. Mukherjee A, Ahluwalia T, Gaur L, Mittal R, Kambo I, Saxena N, *et al*. Assessment of vaccine wastage during a Pulse Polio Immunization Programme in India. *Journal of Health, Population and Nutrition*. 2004;22(1):13-8.
 28. Federal Ministry of Health. Extended Program on Immunization (EPI) coverage in selected Ethiopian zones: A baseline survey for L10K's Routine Immunization Improvement Initiative. Addis Ababa: FMOH; 2015. <https://110k.jsi.com/Resources/Docs/EPI-baseline-report.pdf>
 29. Berhane Y, Demissie M. Cold chain status at immunisation centres in Ethiopia. *East African Medical Journal*. 2000;77(9):476-9.
 30. Setia S, Mainzer H, Washington M, Coil G, Snyder R, Weniger B. Frequency and causes of vaccine wastage. *Vaccine*. 2002;20(7-8):1148-56.
 31. Nelson C, Froes P, Van Dyck AM, Chavarría J, Boda E, Coca A, *et al*. Monitoring temperatures in the vaccine cold chain in Bolivia. *Vaccine*. 2007;25(3):433-7.
 32. Kitamura T, Bouakhasith V, Phounphenghack K, Pathammavong C, Xeuatvongsa A, Norizuki M, *et al*. Assessment of temperatures in the vaccine cold chain in two provinces in Lao People's Democratic Republic: A cross-sectional pilot study. *BMC Research Notes*. 2018;11(1):261.

33. Centers for Disease Control and Prevention. Vaccine storage and handling: Quick reference guide for those that handle vaccines. Atlanta: US Department of Health and Human Services, CDC; 2015. www.canvax.ca/vaccine-storage-and-handling-quick-reference-guide-those-handle-vaccines.
34. World Health Organization. Immunization supply chain and logistics: A neglected but essential system for national immunization program: A call to action. Geneva: WHO; 2014. www.who.int/immunization/call-to-action_ipac-iscl.pdf
35. Ateudjieu J, Kenfack B, Nkontchou BW, Demanou M. Program on immunization and cold chain monitoring: The status in eight health districts in Cameroon. *BMC Research Notes*. 2013;6(1):101.
36. Maglasang P, Butalid M, Pastoril M, Pratama A, Tan E. A cross-sectional survey on cold chain management of vaccines in Cebu, Philippines. *Pharmacy Practice (Granada)*. 2018;16(2):1167.
37. Haidari L, Brown S, Wedlock P, Connor D, Marie Spiker M, Lee B. When are solar refrigerators less costly than on-grid refrigerators: A simulation modeling study. *Vaccine*. 2017;35(17):2224-8.
38. Ogboghodo EO, Omuemu VO, Odijie O, Odaman OJ. Cold chain management practices of health care workers in primary health care facilities in Southern Nigeria. *Pan African Medical Journal*. 2017;27:34.
39. Lennon P, Atuhaire B, Yavari S, Sampath V, Mvundura M, Ramanathan N, *et al*. Root cause analysis underscores the importance of understanding, addressing, and communicating cold chain equipment failures to improve equipment performance. *Vaccine*. 2017;35(17):2198-202.
40. Sharma G, Sethia R, Acharya R, Meena R. Assessment of vaccine wastage in the immunization clinic attached to SP Medical College, Bikaner, Rajasthan. *International Journal of Community Medicine and Public Health*. 2014;3(3):675-8.
41. Mehta S, Umrigar P, Patel P, Bansal R. Evaluation of vaccine wastage in Surat. *National Journal of Community Medicine*. 2013;4(1):15-9.
42. Woldemichael B, Bekele D, Esmael A. Cold chain status and knowledge of vaccine providers at primary health care of units Bale Zone, southeast Ethiopia: Cross-sectional study. *Immunome Res*. 2018;14(152):2.
43. Rogie B, Berhane Y, Bisrat F. Assessment of cold chain status for immunization in central Ethiopia. *Ethiop Med J*. 2013;51(Suppl 1):21-9.
44. Yassin ZJ, Yimer Nega H, Derseh BT, Sisay Yehuala Y, Dad AF. Knowledge of health professionals on cold chain management and associated factors in Ezha District, Gurage Zone, Ethiopia. *Scientifica*. 2019:Article ID 6937291.
45. Yakum M, Ateudjieu J, Walter E, Watcho P. Vaccine storage and cold chain monitoring in the North West region of Cameroon: A cross sectional study. *BMC Research Notes*. 2015;8(1):145.
46. Ameen H, Salaudeen A, Bolarinwa O, Uthman M, Musa O, Aderibigbe S. Vaccine storage and handling practices among routine immunization service providers in a metropolitan city of north-central Nigeria. *Journal of Community Medicine and Primary Health Care*. 2014;26(2):18-28.
47. Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit. Atlanta: US Department of Health and Human Services, CDC; 2019. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.
48. Azira B, Norhayati M, Norwati D. Knowledge, attitude and adherence to cold chain among general practitioners in Kelantan, Malaysia. *International Journal of Collaborative Research on Internal Medicine & Public Health*. 2013;5(3):157.
49. Shah J, Agarwal M, Patel J, Trivedi A. Quality assessment of immunization services: A cross sectional study at UHCs of Ahmedabad Municipal Corporation. *Int J Health Sci Res*. 2015;5(7):21-5.
50. Ogboghodo E, Omuemu V, Odijie O, Odaman O. Cold chain management: An assessment of knowledge and attitude of health workers in primary health-care facilities in Edo State Nigeria. *Sahel Med J*. 2018;21:75-82.
51. CDC. Cold Chain Protocol: Vaccines and Biologics. Atlanta: US Department of Health and human Services, Center for Disease Control and Prevention. 2013. www.gov.mb.ca/health/publichealth/cdc/protocol/ccp.pdf.
52. Gupta A, Gupta R. Study of cold chain practices at community health centers of damoh district of Madhya Pradesh. *National J Community Med*. 2015;6(4):528-32.
53. Krishnappa L, Anniappan AB, Voderhobli NH, Krishna SK, Yathiraj S, Sreekantaiah P. Evaluation of cold chain practices in urban health centers of a metro city in India. *National J Community Medicine*. 2014;5(3):288-92.
54. Bagdey P, Narlawar U, KishorSurwase D, Dhage D, Adikane H, Zurmure S. A cross sectional study of assessment of vaccine wastage in tertiary care centre of central India. *Int J Health Sci Res*. 2017;7(4):12-7.
55. Turner N, Laws A, Roberts L. Assessing the effectiveness of cold chain management for childhood vaccines. *Journal of Primary Health care*. 2011;3(4):278-82.