Vaccine safety practices and its implementation barriers in Northwest Ethiopia: A qualitative study

Getasew Amare[1*], Tewodros Seyoum[2], Tajebew Zayede[3], Ashenafi Tazebew[4], Alemayehu Teklu[4], Zeleke Abebaw Mekonnen[5], Berhanu Fikadie Endehabtu [6], Alyssa Sharkey[7], Binyam Tilahun[6]

Abstract

Introduction: Even if immunization coverage increases over time, it is imperative to ascertain the safety and efficient coverage of immunization services. However, evidence on the safety practices of vaccines is limited. Assessing the implementation status of vaccine safety practices and its implementation barriers is crucial for program monitoring, interventions, and improvements. Therefore, this study aimed to assess vaccine safety practices and its implementation barriers in the public health facilities of Northwest Ethiopia.

Aim: The objective of this study was to assess the safety practices of vaccines and to explore its implementation barriers.

Methods: A qualitative research approach was adopted for this study. Face-to-face in-depth interviews with key-informants and immunization session-observations were the main data collection methods used in this study. Study participants were purposively selected based on their experience and knowledge about the subject matter and framework analysis was performed.

Result: The study's findings revealed that the safety practices of vaccines from the cold chain system, vaccine administration and waste disposal and management perspective was suboptimal. Many barriers influencing vaccine safety practices were also explored. They are 1) vaccine storage and handling, 2). vaccine administration/delivery, 3) waste disposal and management, 4) communication, 5) monitoring and evaluation and 6) and resource.

Conclusion: Efforts to promote the safety of vaccines and vaccination practices is a complex phenomenon and demands multidisciplinary action. Based on our findings, improved vaccine storage and handling, proper administration of vaccines based on guidelines, proper disposal and management of waste, and effective communication, and monitoring can contribute to the safe delivery of vaccination practices. Furthermore, improving the financial freedom of the facilities could increase the availability of essential resources and equipment that can safely store vaccines. [*Ethiop. J. Health Dev.* 2021; 35(SI-3): 111-117]

Keywords: Immunization safety practice, Qualitative study, Framework analysis, Northwest Ethiopia

Introduction

The 1974 Expanded Program of Immunization (EPI) is among the most cost-effective public health interventions ever launched by the World Health Organization (WHO), aimed at protecting children from vaccine-preventable diseases (1-5). In Ethiopia, EPI was initiated in 1980 and remained a crucial component of primary health care, running through static, outreach, and mobile strategies(6-8).

Globally, vaccination coverage has increased over time. There are about 12 vaccines under the Ethiopian EPI scheme: Measles 1 & 2, BCG, Pentavalent, Rota, PCV, Oral, Inactivated Polio for infants, human papillomavirus for school-age girls and TT reproductive-age women(9).

Vaccine safety is among the main focuses of the immunization programs, especially with regards to monitoring and ensuring quality, storage and handling, administration and waste disposal, and management. For vaccines to be effective, their safety should be maintained from the production phase, through to the consumption phase. Improvements in the cold chain system, safe vaccine administration and proper waste disposal and management need to be assured, as vaccines physical accessibility and utilization by itself cannot assure the vaccines effectiveness(10-12).

Ethiopia has given high priority to immunization and has planned to achieve the 90% of full EPI coverage in 80% of the districts(6). However, despite the progress made in the fight against vaccine-preventable diseases, Ethiopia's EPI has yet to achieve the intended results (13). The EDHS 2011, 2016, and mini-EDHS 2019 reports indicated that full vaccination coverage was 24.3%, 38.3%, and 43%, respectively, which is far below the national targets (14-16). To advance progress, close monitoring and timely assessment of suspected adverse events following immunization (AEFIs) are crucial to prevent loss of confidence and coverage, and the associated risks of outbreaks (17).

[1]Department of Health Systems and Policy, Institute of Public Health, College of Medicine and Health Sciences, University of Gondar, Gondar, Ethiopia
[2]Department of Midwifery, School of Midwifery, College of Medicine and Health Sciences, University of Gondar, Gondar, Ethiopia
[3]Sanja Primary Hospital, Amhara Region, Northwest Ethiopia
[4]Department of Pediatrics and Child Health, University of Gondar, Gondar, Ethiopia
[5]Health System Strengthening Directorate, Federal Ministry of Health, Addis Ababa, Ethiopia
[6]Department of Health Informatics, Institute of Public Health, College of Medicine and Health Sciences, University of Gondar, Gondar, Ethiopia
[7]Primary Health Care-Health Systems Strengthening Unit, UNICEF New York, USA
*Corresponding author

Several factors like poor infrastructure, safety concerns, misconceptions about vaccines, stock shortages of vaccines, data collection and quality, weak AEFI surveillance systems, and unsafe immunization practices affect successful EPI implementation (6, 18-21). Furthermore, inadequate human resources, poor supervision and close follow-up, cold chain logistic problems, and low community awareness are among the significant challenges threatening vaccine safety practices (10, 22).

Like with many other medications, vaccines may have adverse effects, and thus they must be managed appropriately and delivered safely. Adverse events following immunization may erode confidence in vaccines, affecting acceptance and vaccination adherence (23). Safe vaccination practice can reduce avoidable risks of adverse events following immunization (AEFI) (24, 25). However, there is a lack of evidence on best vaccination safety practice guidelines for implementation. This study aimed to examine the barriers to implementing immunization safety practices at Northwest Amhara public health facilities, Ethiopia. The qualitative study design assisted in to analysing the vaccine safety practices and exploring detailed information about the experiences of health professionals and about the barriers of vaccine safety practices(26-28).

Specific research questions

What is the condition of the vaccine safety practices at the public health facilities of northwest Ethiopia?

What are the potential barriers to vaccine safety practices at public health facilities of northwest Ethiopia?

Purpose of the study

The purpose of this study is to analyse the vaccine safety practices and its implementation barriers.

Methodology

Study design

This study employed a phenomenological qualitative study design focusing on assessing the barriers of vaccine safety practices. Data collection began from June through to July 2020. The study was conducted in selected public health facilities in the two districts of Armahiho and Gondar, Ethiopia, including primary hospitals (1), health centers (3), health posts (13), and districts health offices (2).

Researcher characteristics and context

The study's research team were from both academic institutions and health systems organizations. The research team comprised of different health systems and policy disciplines, health informatics, paediatricians, and health system workers from the federal ministry of health and local hospital staff. The study was conducted at the primary health care unit levels, which includes primary hospitals, health centres, and district health offices.

Sample

Gondar and Tach Armachiho Districts were selected randomly among the Northwest Amhara districts. One primary hospital, one health center, six health posts and the district health office from Tach Armachiho district and Two health centers, seven health posts and the district health from Gondar were included. In addition, key informants were selected purposively, and HEWs and health facility EPI focal were selected.

Data collection

Face-to-face in-depth interviews with key-informant and immunization session observations were the main data collection methods.

Immunization sessions across the selected health facilities were attended to observe vaccine safety practices. A 30-point observation checklist was developed by reviewing different literature and the immunization practice guidelines were used to assess vaccine safety practices through the cold chain system, vaccine administration, and waste disposal and management perspectives (29, 30). Items observed included the availability of a vaccine refrigerator, placement of vaccines in the appropriate fridge compartments, fridge tag monitoring, utilization of foam pads, vaccine carriers, and vaccine vial monitoring (VVM) (expiry date). The observation of vaccine safety administration also focused on the pre, intra, and post-administration procedures, including preparation of the session (place and supplies), vaccine labelling, dry vaccine reconstitution, utilization of appropriate auto-disable (AD) syringes, infant card review, and the key-messages when communicating with mothers. In addition, proper infant assessment, use of safety boxes and waste management practices were also observed. A tailored version of the national EPI guideline was developed to serve as an observation checklist. Six midwives and nurses with experience in the immunization program were trained to observe four hundred immunization sessions. After securing written informed consent from participants and relevant institutions, direct observation was done to assess vaccine safety during immunization sessions. The investigators ensured day-to-day on-site supervision and debriefing. The primary aim of the observation was not pre disclosed to the participants to minimize the Hawthorne effect.

Furthermore, a semi-structured interview guide was developed using a general to specific approach to explore the barriers that affect vaccination safety practices in their settings. The guide was developed in English and translated into Amharic (the local language). An invitation letter was then sent to the participants to fix the date and time of the interview. Data collection ended after the 19th interview when no new/unique information emerged (31).

Two investigators conducted face-to-face key informant interviews at the informants' workplace. Notes were also taken during the interview sessions. The interviews lasted between 30 – 45 minutes.

Units of the study

The unit of the study for research was health facilities for session observation and health professionals for key-informant interviews.

Unit of analysis

The unit of analysis for this research were individual health professionals who were the potential source data for key-informant interviews. In addition, immunization sessions were another unity of analysis for which vaccine safety practices were observed.

Data management and analysis

Recordings were transcribed into the Amharic language and translated back into English by experts who were fluent in both languages. Data was exported and analysed through the use of thematic analysis (32, 33). The analysis went through the following steps: First, the transcribed text was carefully read several times to get a general sense of the content. Then general and condensed meaning units were identified, and codes were assigned. The meaning units and discrepancies in the coding were discussed, and a consensus was reached. Thereafter, sub-themes were created by merging those codes that were related in meaning. Furthermore, sub-themes were combined to establish themes based on the proximity of ideas. In the last phase, a general description of the research topic was formulated through generated images.

Techniques used to enhance the trustworthiness

For this study, and to minimize the Hawthorne effect, the primary aim of the research was not pre-disclosed to the health professionals during immunization session observations. Furthermore, the key informants were selected purposively based on their knowledge and understanding of the context.

Results

Participants' characteristics

A total of 19 key informants responded to the interviews. All the participants were female, and the participants' ages ranged from 22 to 41 years. Among the participants, 13 were health extension workers, and six were EPI focal persons (4 Nurses 2 Midwifes). The participants' experience ranged from 2 years to 15 years (the detail is presented in table 1).

Table 1: **Characteristics of study participants for exploring vaccine safety practice in Northwest Ethiopia, 2020**

Characteristics		Frequency
Age	25-29	9
	30-34	8
	≥35	2
Profession	HEW	13
	Nurse	4
	Midwifery	2
Educational status	Certificate Level- IV	13
	Diploma	2
	BSc	4
Work experience	≤5 years	3
	5-10 years	10
	≥10 Years	6

Vaccine Safety Practices

The results of this study revealed that, from most session observations, the vaccine safety practices were suboptimal from all the identified safety practices (cold chain, vaccine administration and waste management). Most immunization session observations indicated that most health facilities didn't have proper and functional cold chain systems. Furthermore, during vaccine administration majority of the immunization sessions omitted, proper infant handling and communication, which are key in immunization. The practice of health professionals on waste disposal and management was relatively good even if poor waste disposal practices were observed at some health posts.

Barriers of vaccine safety practices

Six interrelated and encompassing themes concerning immunization safety practices were identified and explained here. They are 1). vaccine storage and handling, 2). vaccine administration/delivery, 3) waste disposal and management, 4) communication, 5) monitoring and evaluation and 6) Resources.

Vaccine storage and handling.

The observations regarding the status of safety practices of immunization from the cold chain perspective focused on the availability of functional vaccine refrigerators, appropriate placement of vaccines in the fridge compartments, fridge tag monitoring, use of vaccine carriers with conditioned ice-pack, usage of the foam pad, and the status of VVM and expiry date of vaccines.

Based on our findings, most health posts did not have a vaccine fridge to store vaccines at the site. Instead, health professionals collected vaccines from the cluster health center on immunization session dates. Again, we observed that few health posts were not using foam pads, and in a few health posts, the vaccine carrier was not conditioned to four icepacks compared to health centers and hospitals. Also, most health facilities were using fridge tag monitoring, and recordings were done twice daily without any interruption. Moreover, the vaccines' VVM and expiry date statuses were checked from randomly selected vaccines, and across all facilities visited were within the acceptable range. Also, the vaccines were appropriately placed in the fridges.

Vaccine administration/delivery

This section focused on intra, during, and post-administration procedures and activities followed by healthcare providers. Based on our observations, most health facilities practiced proper labelling of vaccines (an opening hour at BCG and opening date for OPV and TT). They also used appropriate and new AD syringes and suitable diluents for reconstitution (0.05 mm BCG and 0.5 mm for others). On the other hand, the infant's card review was not correctly done at a few health posts. Besides, communication of key-message (about what the vaccines are and their advantages, potential minor, and severe adverse effects after receiving them, and when to receive the vaccines and how to use immunization cards) was not done correctly. Furthermore, we observed safe and proper injection delivery practices by most health professionals.

Waste disposal and management

We also observed activities about the safety box utilization and waste disposal practices of healthcare providers. Based on our findings, most health facilities practiced proper use of safety boxes – placed it at a safe place and used it up to its capacity (75%). Moreover, most health facilities (health center and health post) had incinerators to dispose of waste. We observed that most health professionals take the waste to the main disposal site daily and after every immunization session at the health posts. We also found a few situations where health posts practiced appropriate use of vaccine safety box but improper disposal of waste.

Communication

Poor communication and information sharing within and between facilities were also major barriers to proper vaccine safety practices. This idea is narrated by a 26-year-old EPI focal from the health center as;

"The communication between the under-five clinic and EPI room is weak. So, for example, suppose if there is an infant case came to U-5 clinic related to EPI related conditions, like AEFI, we don't have structured communication means which affects the detection of problems at the early stage."

Another 28-year-old, a Health extension worker explained

"When mothers give birth at the health centers, and when they link them to us, mostly the facilities didn't share the full information about the infant what was done for the infant, what was given and what will be the plan. We face challenges starting immunization and other services since the mothers didn't know what was done for their babies.

Monitoring and Evaluation (M&E)

Many participants also revealed weak M & E practices which also affect the immunization safety practices by creating a weak and irresponsive health system. However, since there is no close follow-up of the immunization activities, it isn't easy to know how the program is progressing and its implementation challenges.

"*I think the attention given to the EPI program now is very low. When I do my job, nobody monitors and checks what and how I am doing my job and what challenges I am facing. I feel the supervisors emphasize and focus on very urgent report-oriented activities, emphasizing top-level health managers' interest. They ask us reports, and nobody closely follows what is happening at ground level."* – A 26-year-old health centre EPI focal.

Another 30-year-old, Health extension worker also respond as saying:

"There were review meetings and supportive supervisions, which was done occasionally, not as per the set schedule. The supervisors mostly come either when they need a report or when another high-level supervisor planned to supervise them, which doesn't solve our problems that affect our performance."

Another 32-year-old, Health extension worker added:

"*The supervisors try to communicate with us by using different approaches like phone calls, but the culture of checklist-based supportive supervisors and regular review meetings is poor. So mostly they call when they need us, or when the guests are coming."*

The above ideas are also supported by the district's health office-level EPI focal as,

'*We are highly responsive to give more attention to timely and emerging activities, and I think this makes us not give more attention to the immunization program."*

Resources

Our study revealed inadequate energy/power supply, vaccine fridge, poor transportation systems and working rooms as major interconnected barriers to the safety practices of immunization:

"*When we have immunization sessions, we will ask community health workers or other individuals who are in it the community to collect the vaccines from the health center and bring them to us. We may not always go to the health center to collect vaccines because of the distance and transportation problems. When those assigned individuals asked to bring the vaccines, their different problems on vaccine safety, like during transportation, they may be delayed."* –Health extension worker

Another 25-year-old health extension worker also narrated the following.

"We are facing the shortage of vaccine fridges, and we can avail vaccine fridges at the health posts, especially which are very remote. However, now, those partners who distribute vaccine fridges are not accessing vaccine fridges. This affects vaccines' efficacy when they are transported for remote health posts since they collect vaccines during the immunization outreach date."

But another 30-year-old health extension workers revealed;

"My health post is near the cluster health center, and even the main asphalt road is accessible. Therefore, I can collect the vaccines based on the number of children immunized on the same day of the immunization outreach date. I didn't face any

challenge in collecting vaccines because I use vaccine carriers and foam pads, and I will return the remaining and unused vaccines daily to the health center."

Furthermore, our study revealed an irregular refresher training plan for health professions, thereby affecting infants' effective and safe vaccine delivery (especially for the newly integrated vaccines). According to participants, although integrated refresher training (IRT) is sometimes organized for health professionals, it is mostly inadequate. Moreover, it lacks the financial commitments to enhance its effectiveness and the number of health professionals to be trained. As a result, we also observed situations where health workers (although few) were not following all the principles of immunization safety, including the improper use of foam pads, neglect, or poor assessment of infant and unsafe injection practices, as well as poor delivery of key messages.

"I have been working in the EPI room for three years now, and I only practice what I know or what I have been informed or learnt from my colleagues. I haven't received any special training specific to my job (vaccine safety-related training), which makes me work what I think as of right." – Nurse, EPI focal of the health center

Discussion

The present study aimed to assess the status and barriers hindering the safety practices of vaccinations in Ethiopia. Most health posts did not have the required fridges to store vaccines at the site. This is further hindered by the fact that most facilities do lack a sustainable power supply. As a result, healthcare providers must collect vaccines from the nearest health post to embark on immunization exercises. Furthermore, most health facilities used foam pads and vaccine carriers with conditioned icepacks during immunization sessions. This finding reflects that the safety and quality of the vaccines provided in remote and inaccessible areas is challenging.

Further, in a few of the health facilities attended, researchers observed that the foam pad was not used to keep unopened vaccines inside the carrier cool. This finding is consistent with a study conducted in the Southern part of Ethiopia(34). This might be due to healthcare providers' poor perception and attitude towards the use of foam pads and their associated vaccination sessions. In almost all the observed health facilities, both the VVM and expiry dates were within the accepted range. Perhaps this might be because vaccines are procured regularly and as per the health facilities' demands. We also observed proper preparation of vaccines, reconstitution, and labelling. Health professionals were observed using matched diluents for lyophilized vaccines for reconstitution and separate AD syringes. In addition, most health providers practiced proper assessment of infants and safe injection. Only a few health professionals at the health posts, displayed a gap in assessing infants properly and injecting vaccines safely as compared to observations at the health centres and hospitals. This might be since healthcare providers at the health centres and hospitals have a higher education or receive consistent on-the-job training. However, card reviews before immunization and communication of key immunization messages for mothers were practiced relatively better at the health posts. Perhaps because health centers are situated in the urban settings; hence, health providers might have perceived that client already have a better awareness of immunization services.

This study also analysed the waste disposal and management challenges for vaccine safety practices. In a few health facilities, poor waste disposal practices were observed. However, proper waste disposal and management were also observed at many health facilities, and this might be due to the availability of safety boxes and waste disposal incinerators.

This study explored Intra and intercommunication gaps between facilities and healthcare providers and clients as one of the immunization safety practice barriers. This finding was also supported by Ethiopian studies, (27, 28) in which communication and information sharing gaps affected the immunization program effectiveness. Therefore, regular communication and information among key actors on the immunization program are considered crucial for safe immunization practices and overall immunization program improvement(35).

The other explored vaccine safety practice barriers were week monitoring and evaluation practices and culture at the health system. This result was supported by studies conducted in different countries(36-38). Thus, the culture of good monitoring and evaluation practices was crucial for timely program intervention and improvement.

Also, the scarcity of both human and material resources was explored as barriers to immunization safety practices. To deliver the vaccines safely, the infrastructure should be well structured. In this study, the lack of infrastructure and the resource problem was narrated as a barrier for immunization safety practices. This result was also supported by the national EPI evaluation document(39).

Strengths and limitations of the study

This study has the following strengths and limitations. Firstly, the study included a diverse sample of participants and tried to explore the experience of health professionals regarding the challenges of vaccine safety practices. However, since we used immunization session observations to assess the vaccine safety practices, observer bias (Hawthorne effect bias) may affect the findings even if the primary aim of the research was not disclosed.

Conclusion and recommendation

The study's findings revealed several factors influencing the safety practices of immunizations in Ethiopia, including vaccine storage and handling, vaccine administration/delivery, waste disposal and management, communication, monitoring, evaluation and resource.

Efforts to promote the safety of vaccines and vaccination practices is a complex phenomenon and demands multidisciplinary action. Based on our findings, improved vaccine storage and handling, proper administration of vaccines based on guidelines, proper disposal and management of waste, effective communication, and monitoring can contribute to the safe delivery of vaccination practices. Again, improving the financial freedom of the facilities could increase the availability of essential resources and equipment that can safely store vaccines.

Abbreviations

AD: Auto-disable; **AEFIs**: Adverse events following immunization; **EDHS**: Ethiopian Demographic and Health Survey; **EPI**: Expanded Program on Immunization; **IRB:** Institutional Ethical Review Board; **IRI:** Integrated Refresher Training; **UNICEF** United Nations Children's Fund; **VVM:** Vaccine Vial Monitor; **WHO:** World Health Organization

Declarations

Ethical approval and consent to participate

This study was approved by the Institutional Review Board of the University of Gondar and received ethical clearance. Furthermore, study permission was obtained at each level of the health system. Additionally, informed written consent was obtained from each study participant.

Availability of data and materials

Data will be available upon reasonable request from the corresponding author

Competing interests

All authors declared that they have no conflict of interest

Author Contributions

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current Journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work.

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