Implementation fidelity and challenges of optimal cold chain management in Assossa district health system, Benshangul-Gumuz region, Western Ethiopia

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Abstract

Introduction: Preventive programs which have proven to be effective in clinical trials may not necessarily impact the health and wellbeing of the community unless they are implemented with fidelity. While cold chain is the backbone of immunization programs, limited studies exist to explain fidelity implementation which likely contributes to a lack of evidence-based instructional practices of cold chain management.

Aim: This study aimed to explore the fidelity implementation and challenges of optimal cold chain management in the Benshangul-gumuz region.

Methods: A qualitative approach was utilized to explore the underlying challenges to optimum implementation of cold chain management in Benshangul-gumuz region. Observational techniques and key informant interviews with 12 key-informants were conducted. Data was collected at all levels of the health system including, the regional health bureau, Ethiopian Pharmaceuticals Supply Agency hub, district health offices, Health centers, and health posts. Data analysis and interpretation was performed using the framework analysis approach. Open Code 4.02 software was used for analysis.

Findings: This study identified three main themes including adherence to intervention, human resource development, and availability and use of resources. The findings also revealed that a significant number of the employees were not adhering to the optimal cold chain management guidelines. Staff development, availability and utilization of equipment and related finances were major fidelity implementation challenges of cold chain management.

Conclusions: Across the health facilities under study, implementation fidelity of cold chain management was considered poor. Human resource development, proper allocation and effective management of logistics and related finance could facilitate optimal cold chain management practices, and efforts to save lives through delivery of safe and quality vaccines. [*Ethiop. J. Health Dev.* 2021; 35(SI-3):03-08]

Keywords: Cold chain management, Implementation fidelity, Challenges, Ethiopia

Introduction

The Expanded Program on Immunization (EPI) was launched in Ethiopia in 1980 with six antigens to reduce mortality and morbidity of children and mothers from vaccine-preventable diseases [1]. Today, the number of antigens has increased from 6 to 12 including the recently added Human Papillomavirus (HPV) and Molluscum Contagiosum Virus (MCV) 2nd dose vaccines. Vaccines are temperature sensitive – its efficacy can be affected when exposed to temperature fluctuations (e.g., extreme heat or freezing temperatures) [2], once efficacy is lost, it cannot be regained [3]. Hence, the importance of storing vaccines within their prescribed range of temperature (+2˚C to +8˚C) – to preserve its efficacy throughout their journey (from the manufacturer to the endpoint of vaccine administration) cannot be overstated.

Cold chain remains a backbone of any successful immunization program as it allows health professionals to reach everyone, and everywhere with quality-assured life-saving vaccines. Notwithstanding that, certain factors are key to effective Cold Chain Management (CCM) systems. An effective CCM demands: reliable storage facilities, effective temperature monitoring systems, accurate vaccine inventory management, and availability of well-trained health professionals to enhance service delivery [4]. That is, there should be regular monitoring of temperatures. i.e., Temperatures (in both the freezer and refrigerator units) should be read twice daily, once in the morning and once before leaving at the end of the workday, and information should be recorded in the temperature monitoring chart by trained health professionals. Infrastructure including road and power supply is also significant to enhance proper CCM [5].

Various achievements made to improve CCM in Ethiopia, however, poor commitment of health professionals, staff work overload and its impacts on accurate and consistent record taking and information sharing on the temperatures of the vaccines; inadequacy of refrigerators; shortage of power supply are all challenges which continue to impact CCM systems [5]. Outdated equipment like refrigerators, vaccine carriers as well as inadequate storage capacity of cold chain equipment, have adversely influenced effective distribution and uptake of the vaccines in Ethiopia [4]. Specifically, the recent national cold chain inventory report of Ethiopia, showed that: more than 3357

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refrigerators have been used for over 10 years; about 5,997 refrigerators are 5-10 years old; 8,504 refrigerators are 1-5 years old; and 7668 refrigerators use kerosene as their energy source [6]. Furthermore, studies have also revealed that, only 77% of health facilities in East Gojjam zone [7] and 19% in Afar [8] have functional refrigerators. In Amhara region, about 42% of health facilities practice inappropriate CCM. A study in central Ethiopia showed that, only 58% of the health centers had a complete record on temperature, and 73% had non-working refrigerators. Again, a vast number of health centers had neither trained personnel nor a budget purposely allocated for maintenance of the cold chain [8].

Additionally, the knowledge gap remains a significant challenge for effective CCM delivery [7]. A Service Availability and Readiness Assessment (SARA) 2018, showed that only 47 % of facilities have CCM guidelines [5]. Also, in a study conducted in Oromiya, Southern Nations, Nationalities and Peoples (SNNP) and Amhara Regions, only 56% of health workers exhibited satisfactory levels of knowledge about CCM and practices [9]. Preventive programs proven to be effective in clinical trials may not necessarily impact the health and wellbeing of the community unless, they are implemented with fidelity [11]. Comprehensive assessment of implementation fidelity provides relevant information to inform implementation and address research to practice gaps. But little is known about implementation fidelity which likely contributes to evidence-based instructional practices pertaining to CCM in the delivery of immunization services at regional and national levels. This study aimed to fill those gaps by assessing implementation fidelity and the challenges associated with advancing CCM practices in Ethiopia.

Methodology

Study design

A qualitative research approach was utilized for this study. An EPI service was implemented at all the health facilities, including the vast majority covered by Health Extension Workers (HEWs), at the community level [10]. This study was conducted in Assossa district, Benshangul-Gumuz regional state, West Ethiopia. Assossa district is one of the 20 districts in the region. The district has one general hospital, 5 health Centres (1 urban and 4 rural), and over 40 Health posts. The district was selected as a study area for its compositions in terms of urban and rural, and all types of health facilities found in the district. Hence, this composition would allow for the exploration of CCM in all contexts.

In the Ethiopian health system, health workers are often assigned with short-term trainings to manage the cold chain system. Cold chain managers are generally assigned between the Central and regional EBSA hubs, to manage supply chains maintaining the cold chain. Cold chain managers were also assigned in regional health bureaus to Woreda health office levels to request supplies and manage the cold chain system. EPI focal persons and health extension workers are also responsible for cold chain management at health facilities and health post levels.

Study population

This study included key informants from the Ethiopian Pharmaceuticals Supply Agency (EPSA), Regional Health Bureau, District Health Office, Hospital, Health Centres, and Health Posts. Participants were purposively selected based on their experience and role in CCM across institutions. Data collection continued until saturation was reached, i.e., after interviewing the 12th participant. Key informants were: one EPI expert in regional health bureau, one cold chain officer in regional EPSA hub, one EPI expert in district health office, one EPI focal each from hospital, four health centers and one HEW each from four health posts (one from each selected cluster health centers).

Data collection

Checklist-based observations were mainly used for exploring adherence to guidelines for CCM. Key informant interviews were mainly used to identify implementation challenges of optimal CCM. Four data collectors and one supervisor were trained and deployed to assist with data collection. The data was collected from February to March 2021. Both the interview guides and observational checklists were conducted in the local language (Amharic), using semi structured interview guides. To acquire a broader understanding of the study, participants across all levels of the health system including, the regional health bureau, EPSA hub, district health offices Health centers and health posts were interviewed. Observational techniques were employed to enhance our understanding of the phenomenon. The observation checklist covered items like availability of resources, vaccine storage, monitoring temperature, monitoring vaccine vials, and related data management. Regarding resources, items like functional cold chain equipment like refrigerators, cold boxes, vaccine carrier and ice-packs were observed. Records on fridge tags, registers, reporting tools and availability of electric power was also closely monitored. Adherence to appropriate storage arrangements of vaccines on shelves such as: keeping Measles, BCG, & OPV on the top shelf, placements of freeze-sensitive vaccines (DPT-HepB-Hib) on the middle shelves, arrangements according to the nearest vaccines to be used, whether cool water packs are stored at the bottom shelf of refrigerator or not, and daily monitoring and recording of temperature using alarming devices and fridge tags were monitored closely. Furthermore, researchers observed how the focal provider constantly performs follow-ups and records the temperature of the refrigerators. The routine Vaccine Vial Monitor (VVM) practice of focal providers was assessed by observing the current VVM of vaccines stored and observing their reports on vaccine disposal. Researchers then went on to assess the reports on data management including recording, reporting, and documentation related to CCM activities. Interviews were audio recorded and pictures were captured based on the consent of the participants.

Data analysis

Audio data, field notes and observational checklists were transcribed in Amharic then translated to English. The transcripts were read repeatedly by the research team. This enabled familiarization with the data before coding. A hybrid approach of inductive and deductive

coding and theme development was employed, using OpenCode software. Analysis was undertaken based on the themes namely: adherence to intervention, human resource development, and availability and use of resources. Codes were identified from the transcript and further categorized into the themes. The completeness of the data, for each category was checked. A matrix for data reduction was utilized after sorting out non-essential data using study objectives as a benchmark. Interpretation and analysis were conducted using framework analysis. Data concerning implementation fidelity and general challenges to CCM were prioritized. patterns, relationships, contradictory responses, and gaps in each theme were examined. Quotes that represented most participants' shared perceptions were selected.

The quality of the data was maintained by providing a one-day training for data collectors. The tools were also tested in similar contexts prior to actual data collection. Close supervision during data collection was undertaken. The completeness of the data was checked, and daily feedback was provided during the data collection period.

Findings

Characteristics of study participants

A total of 12 key informants were interviewed, comprising of 7 females and 5 males. The age of the participants ranged from 22 to 42 years of age. Among the participants interviewed, five were nurses, four health extension workers, and a participant each from the field of environmental health, pharmacy, and health education. Six of the participants were diploma (level-IV training) holders, four of them possess a first degree, and two participants hold a certificate (Level-III in health extension program). The experience of the participants in the current position ranged from 1 year to 19 years. Participants were positioned across all levels of the health system, i.e., from the regional health bureau through to health post level, and the regional EPSA hub, to enhance the comprehensiveness of information.

This study findings were based on the three themes - adherence to intervention, human resource development, and availability and use of resources.

Adherence to intervention

Our observations of intervention sessions in most of the health posts revealed poor adherence to guidelines, aimed at enhancing vaccine safety and quality. For example, vaccine vial arrangement, storage of diluents, and arrangements of vaccines in the order of relative importance (the first-to-use vaccines) were not fully adhered to. Also, vaccines were not arranged according to its sensitivity to heat and freezing – most of the vaccine vials were stored in one compartment. Furthermore, all vaccine vials were stored together in plastic bags – preventing free circulation of air. Again, in the hard-to-reach facilities, health professionals had to store vaccines for a long time in vaccine carriers. We also observed inappropriate storage of diluents together with vaccines in some of the health posts – only one health facility categorized the fridge compartments and labeled it in a way to easily identify first-to-use vaccines. In our observation, the temperature records showed normal range in most of the facilities for the previous month (from the day of visit). Furthermore, in our observation of registers and reports, although most facilities had daily records of temperature, few facilities had incomplete information. On the other hand, we observed fabricated recording of the temperature. For instance - in one of the facilities, the temperature has been recorded at once for both morning and evening temperature. During our visiting, time the thermometer indicated 12°*C* but it was negligently recorded earlier as 4°*C* without considering the appropriate time.

Many experts have demonstrated VVM to be a routine practice of facilities. For example- many facilities posted VVM charts on how to identify the expiry date of vaccines, and a contingency plan for emergency management of the cold chain. One of the health posts had displayed a plan indicating how to transfer vaccines to the cold box, prepare standby generators, and transfer vaccines to the nearby facility or Woreda (refers to district) health office, and report to the concerned bodies for action.

Human resource development

Study participants reported a lack of cooperation and support by higher officials in ensuring effective CCM, including monitoring and evaluation of practices.

> *"Cold chain is an ignored field, it lacks support, monitoring, and evaluation. Generally, it lacks attention from higher officials (Facility head, District, Zonal and Regional EPI experts)…"* 29 years old, female, EPI focal person

Participants also reported shortages of EPI focal points – largely influenced by high turnover. Interviewees also emphasized that there were limited training opportunities for health professionals, particularly at newly recruited focal points.

> *"We were not given any training – I can't even identify the cause of a problem should a refrigerator stops working. We don't have the basic skills in fixing to fix a common technical problem of a refrigerator and other cold chain equipment."* - A 38-year-old, male EPI focal person
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> *"I [respondent] received a CCM training last year and yet no other refreshment or some other training related to CCM …"* A 41-year-old, male EPI focal person

Participants also indicated their dissatisfaction with the existing working conditions as a major hindrance to better CCM, including lack of incentive.

> *"… overloaded with tiresome routine activities, seven days of the week throughout the year; we got par time payment but still underpaid. It needs more financial incentives for workers in the field."* A 38-years-old male EPI focal person

Availability and use of resources

Many facilities visited had equipment including, refrigerators, thermometers, cold boxes, and icepacks. However, majority of these equipment were not

functioning. Although guidelines and CCM manuals were available in most health facilities, but functionality was low in almost all facilities. A shortage of tools used for recording and reporting purposes was also observed at the sites.

> *"We have all the instructions and manuals related to cold chain equipment in our facility, but majority are non-functional..."* A 28-years, *female, health extension worker*

Although solar was the major source of power in many of the visited facilities, most of the participants complained about unreliability during the rainy season.

> *"Since our source of power is solar, we don't have power during rainy seasons. So, there is a need for grid power source during that periods, to power facility refrigerators."* A 26-years-old, female EPI focal person

Participants also reported the following problems, the use of old refrigerators as a cause for concern, an unstable cold chain system, and demands for frequent maintenance support.

> *"Our refrigerators are obsolete that frequently need maintenances. Maintenance often takes a long time from reporting the issue to the Woreda health office to the time to fix the problem. As a result, it has a direct impact on the safety of the vaccine."* A 26-years-old, female EPI focal person

Furthermore, according to respondents, although paper-based registration, reporting, and documentation results in several technical challenges (such as delayed responses, errors and loss of data, exports for data manipulations, etc.). However, there is no digital system for documenting and reporting data for CCM. Participants asserted that, there have been pilot projects of electronic vaccine supply chain management systems in certain areas, none has been scaled-up.

> *"We provided Mobile apparatus installed with m-Brana APP to Woreda health offices to foster supplies and easy monitoring, but there was a problem with its implementation: some Woreda officers lost the apparatus; others did not effectively utilize it too. Warning letters signed by the head of the Regional health bureau were sent to each Woreda to ensure the problem is, yet nothing changed – the challenge still exist."* A 42-years-old, male, officer

Moreover, inadequate funding was identified as a major contributor to CCM related barriers. Almost all health extension workers raised a financial challenge for vaccine transportation often paid by workers and their expense has not been reimbursed. Interviewees believe that the problem can be addressed through improved political commitments to increase budget allocation to health and CCM.

> *"As an organization, we evaluated that budget deficit, was the current and main challenge of the region for optimal implementation of CCM."* A 42-year-old male officer

Additionally, according to interviewees, although, the initiative receives external financial support from international organizations, funding is often mismanaged or misallocated.

> *"…for example, last year we received external financial support from the United Nations Children's Emergency Fund (UNICEF), however, our administration has re-directed the funds to other non-related activities."* A 28-years-old, male EPI focal person

Discussion

The study has shown low adherence to the guidelines for CCM. It has indicated poor supply, and improper management of logistics related to CCM. In addition, there was inadequate human resource management for CCM in the area.

The current study revealed poor adherence to guidelines purposed to enhance effective CCM, pertaining to standard arrangement of vaccine vial, monitoring of temperature, documentation, and reporting structures. Despite most of the facilities' recording normal temperature ranges, however, a short span of temperature recordings does not guarantee for quality of cold chain as evidenced by similar studies [11]. Our observation also indicated fabricated recordings. Failure to adhere to the guidelines of CCM systems particularly on vaccine vial arrangement, monitoring of temperature and documentation have been major challenges as also confirmed in other studies [12]. Poor perception about CCM practices, and dissatisfaction of working conditions by health professionals have been associated with a negative influence on improving CCM [7, 13-16]. To guarantee an improvement, stakeholders should be engaged at all stages of designing and implementation of CCM activities.

This study has shown gaps in human resource management for CCM that includes staff turnover and inadequate training as major barriers of implementation fidelity on CCM. This finding is supported by previous studies suggesting the need for resources and innovations not just to address the shortages of human resources but to also embark on capacity building exercises that enhance the skills and competencies of work [7, 14-16]. It implies that capacity building, motivation and retention of human power requires a holistic approach from the training manual revision and development to effective leading and management of human power to successfully implement the CCM system.

Availability of adequate resource is paramount to foster progress in vaccine development and immunization delivery systems like CCM [13]. However, based on our findings, material resources are inadequate and/or obsolete. The findings are consistent with previous studies which also revealed insufficient, outdated, broken cold chain equipment, and lack of spare parts as major challenges limiting effective vaccine management [14, 17, 18]. It implies that the lack of access to appropriate cold chain equipment could lead to poor adherence to optimum CCM.

In addition, the study indicated that manual-based data management including recordings and reporting has been practiced for CCM. Furthermore, the manual-based data management system is often associated with inefficiency in recording, reporting, the documentation process, and quality of service delivery [14]. However, the digitization process requires a reliable source of power that could have its own challenges to implement particularly in resource-limited settings [14, 19].

This study implies that a continuous capacity building and development of human resources could be an essential element for improving CCM. Similarly, effective logistic management could also significantly reverse the problem. Digitizing the cold chain system would facilitate an efficient logistic supply, data management and data-informed decision-making for CCM practices.

Limitation of the study

Data was collected during the COVID-19 pandemic where all routine health care delivery systems were compromised. So that the findings of the study may vary from the regular situations. data collectors were encouraged to adhere to infection prevention protocols and try to explore the data as efficiently as possible.

Conclusion

Implementation fidelity of CCM was found to be ineffective – largely influenced by barriers like, adherence to intervention, human resource development, and availability and use of material and financial resources. Capacity building and motivation of staff, provision of adequate and well-functioning equipment and shifting towards digital recording and effective and timely reporting, could facilitate proper CCM practices. We recommend further studies to be conducted at the national level to enhance the comprehensiveness of findings.

Abbreviations

BCG: Bacille Calmette-Guérin; CCM: Cold Chain Management; EPI: Expanded Program on Immunization; EPSA: Ethiopian Pharmaceuticals Supply Agency; HPV: Human papillomavirus; MCV: Molluscum Contagiosum virus; SARA: Service Availability and Readiness Assessment; SNNP: Southern Nations, Nationalities and People; VVM: Vaccine Vial Monitor; WHO: World Health Organization.

Declaration

Ethical approval and consent to participate

Ethical clearance was obtained from the Institutional Review Board (IRB) of the University of Gondar, and institutional permission from Benshangui-Gumuz RHB, from Zonal Health Department, from Woreda Health Office, and Cluster Health Centres were sought before commencing data collection.

Written informed consent was obtained from all study participants after explaining the purposes of the study. Also, consents were taken during every essential step including, audio recording, snapshotting, and observing vaccine vial arrangement. We assured participants of the privacy and confidentiality of information provided.

Availability of data and materials

Data will be available upon reasonable request from the corresponding author.

Competing interests

The authors declared that there is no competing 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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