Research Article

Assessment of cold chain maintenance for routine immunization in Jamnagar district, Gujarat

Nirmika Patel[1], Sumit V Unadkat[2], Amrita Sarkar[3], Mittal Rathod[2], Dipesh V Parmar[2]

[1]Department of Community Medicine, GMERS Medical College, Sola, Ahmedabad, Gujarat, India, [2]Department of Community Medicine, M. P. Shah Government Medical College, Jamnagar, Gujarat, India, [3]Department of Community Medicine, North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong, Meghalaya, India

Correspondence to: Sumit V Unadkat, E-mail: drsumitpsm@gmail.com

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ABSTRACT

Background: Immunization is one of the main components of primary healthcare. At the peripheral level, primary health center (PHC) is the key holder of cold chain system. One of the important elements for improving the immunization is cold chain and vaccine logistics management which is the backbone of immunization program. **Objectives:** The objectives of this study were to assess cold chain and logistics management for routine immunization at PHCs and community health centers (CHCs). **Materials and Methods:** It was a cross-sectional study conducted during November 2013–November 2014 at 20 PHCs and 10 CHCs of Jamnagar district using prestructured and pretested questionnaire. **Result:** A single person was assigned for cold chain handling at 15 out of 20 PHCs, all were trained and 9 out of 10 CHCs of whom only four were trained. At the time of visit, 56.7% cold chain equipments were locked. Only 36.7% cold chain equipments were having digital thermometers. Two PHCs and one CHC had stored other sera or vaccines in ice-lined refrigerators (ILRs). Proper placement of vaccine in ILR was seen at majority of PHCs and CHCs. Temperature records were proper, but alternate power source was available at 70% PHCs only. In only 20% PHCs, Medical Officers cross-checked temperature book at least 4 times in a month. **Conclusion:** Overall, cold chain management for routine immunization was good at all visited PHCs of Jamnagar, but some aspects need improvement such as internal monitoring, training for all cold chain handlers, and alternate source of energy in case of power failure.

KEY WORDS: Cold Chain; Primary Health Centers; Routine Immunization; Vaccines

INTRODUCTION

India has one of the largest immunization programs in the world.[1] Childhood immunization is one of the most cost-effective public health intervention.[2,3] In spite of lots of efforts by government and other health agencies, approximately 10 million children and infants in India remain unimmunized which is the highest in the world.[4] Full immunization coverage rate was 54.8% (all doses up to age of 1 year) in Gujarat and 56.4% in Jamnagar District according to DLHS 3 survey (2007–08).[5] To support an effective routine immunization program reaching all eligible target beneficiaries (27 million children and 30 million pregnant women), Ministry of Health and Family Welfare has made concerted efforts to increase the number of health facilities offering immunization services many times over the past few years (2,88,826 health facilities, i.e., primary health center (PHC)/community health centers (CHCs) servicing 1,48,366 sub-centers).[6] To realize the full benefits of immunization, coverage of vaccination has to be increased and more importantly potent vaccines should reach the beneficiaries for which cold chain maintenance is crucial.[1,3] Cold chain is a system of storing and transporting

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vaccines at recommended temperatures from the point of manufacture to the point of use.[7] Maintaining the vaccine cold chain is an essential part of a successful immunization program because the immunological potency of vaccines can be compromised on exposure to extreme temperatures. Retaining stability of vaccine potency from manufacturer through to delivery requires maintenance at every step of a cold chain infrastructure.[8] Apart from that, the introduction of newer vaccine in routine immunization program requires well-functioning and well-equipped health system including proper cold storage facility. PHC is a key place for the implementation of routine immunization program and storage of vaccines. For the successful implementation of routine immunization service, all its components - planning of immunization sessions, cold-chain, vaccine supply, and logistics management, supervision, etc., should be properly managed. Keeping this view in mind, our objective is to assess the cold chain and logistics management at PHCs and CHCs of Jamnagar district. This will help in finding gaps in existing facility and to take any corrective measures.

MATERIALS AND METHODS

The present study was a cross-sectional study conducted from November 2013 to November 2014, and the study units were PHCs and CHCs of Jamnagar district. There were total 40 PHCs among 10 taluka in the district. 50% of the PHCs, i.e., 20 PHCs and one CHC from each taluka, i.e., 10 CHCs were included in the study. List of all PHCs of Jamnagar district constituted the sampling frame. Two PHCs from each taluka were selected by simple random technique. Selected vaccine storage sites were personally visited and equipments (such as deep freezers [DFs], ice-lined refrigerator [ILR], vaccine carriers, and cold boxes) and records were examined. Predesigned and pretested observational checklist and questionnaire was used to collect detailed information regarding various elements of cold chain such as equipment, maintenance, power supply, storage and supply of vaccine, record keeping, and awareness about relevant guidelines. As the checklist was specially prepared for the study, field testing was done by doing pilot study and necessary modifications were incorporated to make it standardized and uniform. Prior permission was obtained from District Panchayat to include the health centers for the study and confidentiality of the health centers is maintained. Ethical approval was taken before the commencement of the study from the institutional ethical committee. The data entry was done using Microsoft Office Excel 2010 and data analysis was done using Epi Info version 3.5.4.

RESULTS

The present cross-sectional study was conducted at 20 PHCs and 10 CHCs of the district to assess the cold chain and logistics management.

Responsibility of cold chain handling was assigned to a single individual at 15 out of 20 PHCs (75%) and 9 out of 10 CHCs (90%). All the cold chain handlers at PHC and 4 out of 9 cold chain handlers at CHC (i.e., 44.4%) were trained.

Table 1 summarizes that only 56.7% cold chain equipment (ILR/DF) was locked at the time of visit. Dos and Don'ts sticker on ILR and DF were present on 86.7% of cold chain equipments. Working digital thermometer was present in only 36.7% equipments. Proper defrosting was maintained in 76.7% of total DFs. Crisscross ice packs arrangement was present in 76.7% of total ILR. At least 60 frozen ice packs in DF for emergency were available in 85% of PHCs and 60% of CHCs.

ILR at 2 PHCs (10%) and 1 CHC (10%) were found to be having other sera or vaccines. At 11 PHCs (55%) and 9 CHCs (90%), hepatitis B vaccine was placed at the topmost level. Placement of T-series vaccines in the upper compartment of ILR was seen at as high as 95% of PHCs and 90% of CHCs while oral polio vaccine (OPV) was found in the lower compartment of ILR at 85% of PHCs and 80% of CHC [Table 2].

Table 1: Maintenance of cold chain equipments at PHCs (*n*=20)

Variable *n*=30	PHC *n*=20 (%)	CHC *n*=10 (%)	Total *n*=30 (%)
Equipment (ILR/DF) locked at the time of visit	12 (60)	5 (50)	17 (56.7)
DO and DON'T sticker fixed on ILR and DF	16 (80)	10 (100)	26 (86.7)
Working digital thermometer present	8 (40)	3 (30)	11 (36.7)
Proper defrosting status	16 (80)	7 (70)	23 (76.7)
Crisscross ice packs arrangement	17 (85)	6 (60)	23 (76.7)

PHC: Primary health center, CHC: Community health center, ILR: Ice-lined refrigerator, DF: Deep freezer

Table 2: Vaccine status and arrangement in ILR at PHCs (*n*=20)

Variable	PHC *n*=20 (%)	CHC *n*=10 (%)	Total *n*=30 (%)
Antisera, HIV kit, other than vaccines	2 (10)	1 (10)	3 (10)
Hepatitis B at top most level	11 (55)	9 (90)	20 (66.7)
Placement of T-series vaccine properly	19 (95)	9 (90)	28 (93.3)
Placement of OPV properly	17 (85)	8 (80)	25 (83.3)

PHCs: Primary health centers, CHC: Community health center, ILR: Ice-lined refrigerator, OPV: Oral polio vaccine

All PHCs and CHCs have temperature record book available, and at 19 PHCs and 8 CHCs, it was kept near the DF/ILR. Temperature record books were maintained up to date at 75% PHCs and 90% CHCs. Morning temperatures were noted in temperature record book at the time of visit at 16 PHCs (80%) and 9 CHCs (90%). Temperature record book for past 1 year was available at 18 PHCs (90%) and 9 CHCs (90%). Records of power failure were noted in temperature record book at 95% PHCs and 70% CHCs. Alternate source of energy in case of power failure was available at 70% of total PHCs and all the CHCs [Table 3].

Table 4 summarizes the status of cold chain monitoring. External cross-checking was done by Taluka health officer, surveillance medical officer (MO) or reproductive, and child health officer and record for the same were available at 85% PHCs and 80% CHCs. MO cross-checked the temperature record at 18 PHCs (90%) and 9 CHCs (90%) but only at four PHCs and three CHCs, MO cross-checked record adequately according to guideline.

Table 3: Temperature maintenance in electric cold chain equipment at PHCs (*n*=20)

Variable	PHC *n*=20 (%)	CHC *n*=10 (%)	Total *n*=30 (%)
Temperature record book available	20 (100)	10 (100)	30 (100)
Temperature record book near to DF/ILR	19 (95)	8 (80)	27 (90)
Temperature record book up to date	15 (75)	9 (90)	24 (80)
Morning temperature noted in record book	16 (80)	9 (90)	25 (83.3)
Availability of temperature record book of past 1 year	18 (90)	9 (90)	27 (90)
Record of power failure in temperature record book	19 (95)	7 (70)	26 (86.7)
Alternate source of energy available	14 (70)	10 (100)	24 (80)

PHC: Primary health center, CHC: Community health center, DF: Deep freezer, ILR: Ice-lined refrigerator

Table 4: External and internal monitoring of cold chain at PHCs (*n*=20)

Variable	PHC *n*=20 (%)	CHC *n*=10 (%)	Total *n*=30 (%)
External cross-checking and record available	17 (85)	8 (80)	25 (83.3)
Cross-checked by MO	18 (90)	9 (90)	27 (90)
Frequency of cross-checking of temperature record by MO ≥4 times in month	4 (20)	3 (30)	7 (23.3)

PHC: Primary health center, CHC: Community health center, MO: Medical officer

DISCUSSION

In the present cross-sectional study, management of cold chain at PHCs and CHCs was evaluated. Proper management of cold chain is very crucial in maintaining efficacy of vaccines in routine immunization. We have assessed 20 PHCs and 10 CHCs of Jamnagar district of Gujarat for various components of cold chain.

Around three-fourth of the PHCs and 90% of CHCs had assigned responsibility of cold chain handling to a single individual. All the cold chain handlers at PHCs were trained but at CHCs only two-fifth were found to be trained for cold chain handling. Cold chain handler is the key person for maintenance of cold chain and vaccine management and responsible for safe storage of vaccine. More than 40% DFs/ILRs were not locked at the time of visit of which more were at CHCs. Equipments should be kept locked and should be opened only when required.[1] Majority of the equipments had Dos and Don'ts sticker present. Working digital thermometer was present in only 36.7% equipments. Unavailability of digital thermometer outside the ILR/DF may result in unnecessary opening of the equipment to note down the temperature. Mehta *et al*. in their study of cold chain management system at urban PHC of Vadodara city found that 94.7% ILR and all the DFs had working thermometers available.[9] Temperature in the ILR/DF cannot be maintained if there is a thick layer of ice around the freezer or along the walls and bottom of ILRs. It is, therefore, necessary to defrost them periodically. This should be done if the ice in the freezer is >5 mm thick.[1] More than three-fourth of the DF were found with proper defrosting condition. This was more than that shown by Sanghavi M in his study that 21.43% freezers were defrosted.[10] This suggests lack of regular defrosting by the cold chain handlers, which need to be improved and monitored subsequently by the MO of the respective PHC and CHC. Ice packs should be stacked on the floor of the DF horizontally (not flat) on its edge by keeping 1–2 mm space from each other for air circulation, in a crisscross manner.[1] Crisscross arrangement of ice packs has maintained in 76.7% of total DFs with higher percentage at PHCs. In a study by Sanghavi M, only 21.43% of the DF showed crisscross placement of ice packs.[10] Overall maintenance of cold chain equipments and practice was better at PHCs than CHCs. Vaccines should be properly arranged in ILRs for maintaining its efficacy. DFs should be used to prepare and store ice packs only; UIP vaccines should not be stored in it.[4] It is customary, not to keep other vaccines or drugs in ILR.[1] In our study, at 3 (10%) health centers, things other than vaccines/diluents, like empty water bottles, were kept inside the ILR. Sanghavi M found almost similar findings in his study conducted in 2013 that 7.14% PHCs were having items other than vaccine kept in ILR/DF.[10] Rathod *et al.* also reported that 13.4% cold chain equipments were found with other things stored in it. Arrangement of hepatitis B vaccine at the topmost level was found at only 55% of PHCs but majority of the CHCs. Proper

placement of T-series vaccines and OPV was found at 93.3% and 83.3% of centers, respectively. Sanghavi M reported almost similar findings that 92.86% PHCs had proper placement of T-series vaccines in ILR.[10] Another study conducted by Rathod *et al.* in Ahmedabad and Gandhinagar district revealed that proper arrangement of vaccines was seen at 86.6% of total PHCs.[11] Lalitha *et al*. in their study reported that though training was provided on storage code in ILR, good storage practice was seen in only 57% of ILR.[12] Sinha *et al.* in their study found that in 85% ILRs T-series and hepatitis B vaccine were stored in top of ILRs.[13] Similarly, Rao *et al*. in their study done at Primary Health Care Centres in South India found improper storage of vaccine in 10% of study centers.[14] In other studies done in various areas of Gujarat state, similar findings were reported by Sharma *et al.* (90%) and Tushar *et al*. (93.2%) that vaccines were properly arranged in the ILR.[15,16] Vaccines lose their potency due to exposure to excessive heat or excessive cold. OPV and measles vaccines can be kept at bottom of the basket while BCG, DPT, DT, and TT vaccines should be kept in upper part of the baskets.[1] Temperature maintenance is the key component of cold chain. Temperature in the ILR and DF must be monitored twice daily.[1] A break in the cold chain is indicated if temperature rises above +8°C or falls below +2°C in the ILR; and above −15°C in the DF.[1] The ILR and DFs each should have a separate temperature record book and should be kept near or where easily available.[1] Past 1 year, temperature record should be kept at all cold chain points. In the present study, 90% PHCs and CHCs had temperature record of past 1 year. At the time of visit, temperature log book was available at all the PHCs and CHCs but at 90% centers, it was kept near to ILRs and DFs or was easily available. In the present study, it is observed that only at 75% of PHCs and 90% CHCs, temperature log book was up to date (twice a day) and morning temperature was also noted at 83.3 % centers. A note on power failure was written at almost all the PHCs. The cold chain is dependent on electrically operated machines on which one cannot depend completely. Alternative storage locations will have to be identified in advance.[1] Suitable posters should be designed and pasted on machines with clear instructions in local languages on how to handle such emergency situations, especially during electricity failure. It would be prudent to identify more than one alternative at each PHC and CHC for tackling the situation.[1] In present study, alternate power source was available at 70% of PHCs. Monitoring is the day-to-day follow-up of activities during their implementation to ensure that they are proceeding as planned and are on schedule. Cold chain system also requires internal and external monitoring at all cold chain points. An evidence of external cross-checking (by THO, BHO, surveillance MOs, RCHO, etc.) of various cold chain equipments and vaccine-related documents were available at 83.3% of centers. According to guideline, internal monitoring of cold chain should be conducted at least once in week.[1] At majority of the PHCs and CHCs (i.e., 90%), internal monitoring was done by MO, but it was not at recommended frequency. Once in a week monitoring by MO was done at only 20% of PHCs and 30% CHCs.

Limitation

In present study, only 50% PHCs of the district were covered and enquiry was not done to assess the difficulties faced by MO or assigned person in cold chain and vaccine management.

CONCLUSION

Study shows that there is lack of trained cold chain handler at majority of CHCs and PHCs of study district. Equipments of cold chain were not locked all the time. Placement of hepatitis B vaccine was not proper at some PHCs. Lack of adequate internal monitoring by MO was seen at most of the PHCs and CHCs.

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