e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2025; 17(11); 1624-1629

Original Research Article

Evaluation of Cold Chain Maintenance and Vaccine Handling Practices in the Immunization Clinic, Department of Community Medicine, Nalanda Medical College, Patna

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Received: 19-09-2025 / Revised: 18-10-2025 / Accepted: 19-11-2025
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Conflict of interest: Nil

Abstract:

Background: Effective cold chain maintenance is essential to preserve vaccine potency and ensure safe delivery of immunization services. Assessing real-world storage conditions and handling practices helps identify operational gaps and improve program performance.

Objective: To evaluate cold chain maintenance and vaccine handling practices among health care workers in the Immunization Clinic of the Department of Community Medicine, Nalanda Medical College, Patna.

Methods: A cross-sectional, prospective observational study was conducted during May–June 2025 among 30 health care workers, including ANMs, staff nurses, and interns involved in routine immunization activities. Data were collected using a structured 15-item observation checklist, a brief interviewer-administered questionnaire, and a facility inventory. Each compliant observation received one point, generating a total compliance score (0–15), classified as good (12–15), fair (8–11), or poor (0–7). Descriptive statistics and non-parametric tests were used to compare compliance by cadre and training status.

Results: All 30 eligible health workers participated. The median compliance score was 10 (IQR 8–12). Good compliance was observed in 40% of participants, fair in 40%, and poor in 20%. Correct vaccine placement was maintained in 86.7% of observations, VVM checks in 83.3%, adherence to open-vial policy in 73.3%, and correct reconstitution in 66.7%. Temperature logs were available in 80% of sessions, although twice-daily monitoring was recorded in only 60%. Health workers who had received immunization training within the last three years had significantly higher compliance scores than those without recent training ($p = 0.02$).

Conclusion: The clinic demonstrated adequate cold chain infrastructure; however, notable gaps were identified in temperature monitoring, adherence to reconstitution protocols, and visibility of emergency procedures. Regular refresher training, strengthened supervisory checks, and improved documentation practices are recommended to enhance cold chain maintenance and vaccine safety.

Keywords: Cold Chain Management, Vaccine Handling, Immunization Services, Temperature Monitoring, Health Care Workers, Community Medicine, Patna.

Introduction

Vaccination has long been a cornerstone of public health, with the Universal Immunization Programme (UIP) playing a central role in reducing illness and death from preventable diseases in India. The effectiveness of any vaccine ultimately depends on how well it is preserved before it reaches the beneficiary [1]. Most vaccines are heat-sensitive and lose potency when exposed to temperatures outside the recommended range of 2°C to 8°C. For this reason, a dependable cold chain system—spanning storage, transport, monitoring, and handling—is essential to ensure that every dose delivered retains its intended protective value [2].

The cold chain relies not only on specialized equipment but also on the competency and vigilance of the personnel who manage it. Health care workers are responsible for routine tasks such as reading and documenting refrigerator temperatures, arranging vaccines correctly, checking vaccine vial monitors (VVMs), adhering to open-vial and multi-dose policies, using the correct diluents for reconstitution, and following safe disposal procedures. Any lapse in

these steps can compromise vaccine quality. Factors such as irregular supervision, infrequent training, and excessive workload may contribute to inconsistent practices. Regular assessments of these processes are therefore necessary to maintain quality standards and identify areas needing attention [3,4].

Immunization clinics attached to medical colleges, such as the Preventive Clinic in the Department of Community Medicine at Nalanda Medical College, hold particular importance. These sites not only deliver routine vaccination services but also serve as training environments for nursing students, interns, and postgraduate learners. Ensuring correct vaccine handling in such settings helps maintain service quality and reinforces best practices among future healthcare providers. Despite the clinic's critical role, updated information on how effectively cold chain and vaccine handling protocols are being followed here is limited [5,6,7].

In view of these considerations, the present study was undertaken to assess cold chain maintenance and vaccine handling practices among health care workers in the Immunization Clinic of Nalanda Medical College, Patna. The study focuses on key operational areas such as temperature monitoring, vaccine storage arrangements, VVM use, adherence to recommended policies, reconstitution procedures, and waste management. Findings from this assessment aim to support improvements in routine immunization services and contribute to strengthening the overall quality of vaccine delivery in the region [8].

Methods

Study Design and Setting: A cross-sectional, prospective observational study was conducted in the Immunization Clinic of the Department of Community Medicine, Nalanda Medical College, Patna. The clinic provides routine vaccination services under the Universal Immunization Programme (UIP) and manages vaccine storage and distribution activities. The study was carried out over two months, from May to June 2025, covering regular immunization days at the clinic.

Study Participants: The study included health care workers directly involved in vaccine storage, handling, and administration. These comprised Auxiliary Nurse Midwives (ANMs), staff nurses, and medical interns posted in the clinic during the study period. A total of 30 individuals were included using a total enumeration approach. Health workers who were absent throughout the study period or who declined participation were excluded.

Data Collection Procedures: Data were collected through direct observation, structured interviews, and facility assessment. Each participant was observed during routine immunization sessions without interfering in service delivery. After the observation, a brief questionnaire was administered to gather additional information on the participant's training, experience, and perceived challenges. A facility walkthrough was conducted to document the availability and condition of cold chain equipment, refrigerator temperature logs, vaccine carriers, ice packs, and waste disposal systems.

Study Tools: A pre-designed 15-item observation checklist was used to evaluate key cold chain and vaccine handling practices. The checklist assessed refrigerator functionality, temperature range adherence, frequency and completeness of temperature logging, vaccine arrangement, verification of vaccine vial monitors (VVMs), adherence to open-vial and multi-dose policies, reconstitution practices, availability and conditioning of ice packs, proper use of vaccine carriers, waste segregation, and visibility of emergency plans.

A short interviewer-administered questionnaire collected demographic details, years of service, recent training related to immunization, confidence in handling vaccines, supervisory visits, and perceived barriers to correct practice. A facility inventory sheet documented cold chain equipment, power backup availability, type of thermometer used, and number of carriers and ice packs.

Variables and Scoring: Compliance with cold chain and handling practices was measured using the observation checklist. Each compliant item received one point, resulting in a total score ranging from 0 to 15. Compliance levels were categorized as: good (12–15), fair (8–11), and poor (0–7). Other variables included cadre of the health worker, years of experience, and history of immunization-related training within the past three years.

Data Management and Analysis: Data were entered into Microsoft Excel and analyzed using descriptive and inferential statistics. Categorical variables were summarized as frequencies and percentages, while continuous variables were expressed as median and interquartile range due to non-normal distribution. Differences in compliance scores across cadres and training status were assessed using the Kruskal–Wallis or Mann–Whitney U test as appropriate. Logistic regression was performed to identify factors associated with good compliance. A p-value <0.05 was considered statistically significant.

Ethical Considerations: Permission for the study was obtained from the Institutional Ethics Committee of Nalanda Medical College. Informed written consent was secured from all participants prior to data collection. Confidentiality was maintained by anonymizing participant information, and observations were used solely for academic and service improvement purposes.

Discussion

The present assessment provides a detailed picture of how cold chain procedures and vaccine handling practices are carried out in a busy immunization clinic. While the clinic demonstrated reliable availability of essential equipment, the performance of routine practices varied among health workers. These variations highlight the practical challenges faced during day-to-day immunization activities, which often go unnoticed unless systematically evaluated through direct observation.

A notable strength identified in the study was the functional status of the clinic's cold chain equipment. The refrigerator, power backup, and vaccine carriers were consistently available and operational, enabling uninterrupted vaccine storage and transport. Such readiness reflects appropriate provisioning and contributes to the stability of immunization services. However, equipment alone cannot guarantee the quality of stored vaccines; the effectiveness of the system ultimately depends on how staff interact with and manage these resources.

One of the key gaps observed was inconsistency in temperature monitoring. While logs were present in most sessions, entries were not recorded twice daily as recommended. This finding suggests that monitoring practices may not always be integrated into workers' routine workflow. Temperature excursions can occur unpredictably, and without regular documentation, deviations may remain undetected. Strengthening accountability—for example, through supervisory reviews or check-and-sign systems—may improve adherence and reduce the risk of compromised vaccines.

The study also brought attention to the variation in adherence to certain procedural steps, such as verifying vaccine vial monitors and following the open-vial policy. Although most workers performed these steps correctly, the few instances of non-adherence are significant because such lapses can directly impact vaccine safety. Targeted reinforcement of these specific practices is necessary, especially during busy clinic hours when staff may unintentionally overlook essential checks.

Reconstitution techniques were another area where performance differed across individuals. Some deviations from recommended procedures were noted, underscoring the need for regular hands-on demonstrations and competency-based assessments. Reconstituted vaccines have stricter handling requirements, and errors in dilution or in the use of diluents can compromise both the efficacy and safety of the administered dose. Structured refresher sessions, even brief ones, could help maintain accuracy in these tasks.

An important finding was the association between recent training and higher overall compliance scores. Staff who had received training within the last three years showed more consistent adherence to recommended practices. This emphasizes the role of continuing training in maintaining quality standards, particularly in facilities where new interns rotate frequently. A simple orientation session at the start of each posting, combined with periodic refresher training, may help maintain uniform standards across all cadres involved in immunization.

Finally, the limited visibility of cold chain emergency protocols indicates an area that requires administrative attention. In the event of equipment malfunction or unexpected power loss, immediate action is crucial to prevent vaccine spoilage. Displaying clear, step-by-step instructions in the clinic would ensure that all staff, including new or temporary ones, can act promptly. Addressing this gap, along with the identified procedural inconsistencies, would further strengthen the clinic's overall readiness and safeguard vaccine quality.

Results

A total of 30 health care workers participated in the study, consisting of 12 ANMs (40.0%), 10 staff nurses (33.3%), and 8 interns (26.7%). The median years of experience was 4 years (IQR 2–7). Fourteen participants (46.7%) reported receiving immunization-related training within the previous three years. Most participants were directly involved in vaccine storage, temperature monitoring, reconstitution, and documentation activities within the clinic.

Assessment of cold chain equipment showed that a functional vaccine refrigerator with power backup was available throughout the study period. Temperature logs were present for 24 of the 30 observations (80.0%), although twice-daily temperature entries were completed in only 18 observations (60.0%). Correct vaccine placement within the refrigerator was noted in 26 observations (86.7%), and vaccine vial monitor (VVM) checks were performed in 25 (83.3%). Adherence to the open-vial policy was documented in 22 observations (73.3%), while correct reconstitution practice was followed in 20 (66.7%). An emergency cold chain failure plan was displayed in 9 observations (30.0%).

The overall compliance score ranged from 6 to 15, with a median score of 10 (IQR 8–12). Good compliance (score 12–15) was observed in 12 workers (40.0%), fair compliance (8–11) in 12 workers (40.0%), and poor compliance (0–7) in 6 workers (20.0%). Trained workers showed significantly higher compliance than those without recent training.

Table 1: Compliance With Key Cold Chain and Vaccine Handling Practices (N = 30)

Practice Observed	n	Percentage (%)
Functional refrigerator available	30	100.0
Temperature within 2–8°C	27	90.0
Temperature log present	24	80.0
Twice-daily temperature logging	18	60.0
Correct vaccine placement	26	86.7
VVM checked before use	25	83.3
Open-vial policy followed	22	73.3
Correct reconstitution	20	66.7
Ice packs conditioned properly	18	75.0
Emergency plan displayed	9	30.0

- Category "Good Compliance (12–15)" → **40% (12 workers)**
- Category "Fair Compliance (8–11)" → **40% (12 workers)**
- Category "Poor Compliance (0–7)" → **20% (6 workers)**

If converted to a bar chart, the Y-axis would represent the percentage of participants, and the X-axis would contain the three compliance categories. The highest bars would be seen in the Good and Fair categories, both showing equal height, followed by a shorter bar representing Poor compliance.

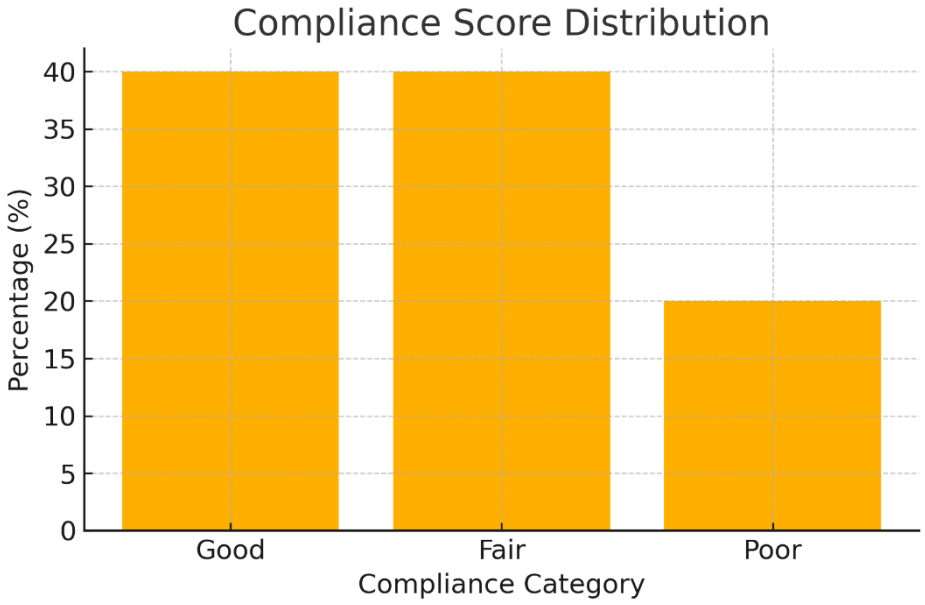

Figure 1: Compliance Score Distribution Among Health Workers

Discussion

The present assessment provides a detailed picture of how cold chain procedures and vaccine handling practices are carried out in a busy immunization clinic. While the clinic demonstrated reliable availability of essential equipment, the performance of routine practices varied among health workers. These variations highlight the practical challenges faced during day-to-day immunization activities, which often go unnoticed unless systematically evaluated through direct observation [9,10].

A notable strength identified in the study was the functional status of the clinic's cold chain equipment. The refrigerator, power backup, and vaccine carriers were consistently available and operational, enabling uninterrupted vaccine storage and transport. Such readiness reflects appropriate provisioning and contributes to the stability of immunization services. However, equipment alone cannot guarantee the quality of stored vaccines; the effectiveness of the system ultimately depends on how staff interact with and manage these resources [11].

One of the key gaps observed was inconsistency in temperature monitoring. While logs were present in most sessions, entries were not recorded twice daily as recommended. This finding suggests that monitoring practices may not always be integrated into workers' routine workflow. Temperature excursions can occur unpredictably, and without regular documentation, deviations may remain

undetected. Strengthening accountability—for example, through supervisory reviews or check-and-sign systems—may improve adherence and reduce the risk of compromised vaccines [12,13].

The study also brought attention to the variation in adherence to certain procedural steps, such as verifying vaccine vial monitors and following the open-vial policy. Although most workers performed these steps correctly, the few instances of non-adherence are significant because such lapses can directly impact vaccine safety. Targeted reinforcement of these specific practices is necessary, especially during busy clinic hours when staff may unintentionally overlook essential checks [14,15].

Reconstitution techniques were another area where performance differed across individuals. Some deviations from recommended procedures were noted, underscoring the need for regular hands-on demonstrations and competency-based assessments. Reconstituted vaccines have stricter handling requirements, and errors in dilution or in the use of diluents can compromise both the efficacy and safety of the administered dose. Structured refresher sessions, even brief ones, could help maintain accuracy in these tasks [16,17].

An important finding was the association between recent training and higher overall compliance scores. Staff who had received training within the last three years showed more consistent adherence to recommended practices. This emphasizes the role of continuing training in maintaining quality standards, particularly in facilities where new interns rotate frequently. A simple orientation session at the start of each posting, combined with periodic refresher training, may help maintain uniform standards across all cadres involved in immunization [18].

Finally, the limited visibility of cold chain emergency protocols indicates an area that requires administrative attention. In the event of equipment malfunction or unexpected power loss, immediate action is crucial to prevent vaccine spoilage. Displaying clear, step-by-step instructions in the clinic would ensure that all staff, including new or temporary ones, can act promptly. Addressing this gap, along with the identified procedural inconsistencies, would further strengthen the clinic's overall readiness and safeguard vaccine quality.

Conclusion

In this study, cold chain maintenance and vaccine handling practices at the immunization clinic demonstrated adequate infrastructure but variable adherence to essential operational procedures. While equipment availability and correct vaccine placement were generally satisfactory, inconsistencies in temperature monitoring, reconstitution techniques, and adherence to procedural checks indicate areas requiring improvement. Higher compliance among workers who had received recent training highlights the importance of regular capacity-building activities within the clinic. Strengthening supervision, reinforcing documentation practices, and ensuring the visibility of emergency protocols may further enhance the reliability of vaccine storage and handling. As the clinic also serves as a training environment for interns and nursing staff, maintaining high standards is essential not only for service quality but also for shaping correct practices among future health personnel. Implementing targeted corrective actions based on these findings can support safer vaccine delivery and contribute to improved immunization program performance.

References

1. World Health Organization. Immunization in practice: A practical guide for health staff. 2015 update. Geneva: WHO; 2015.
2. Ministry of Health and Family Welfare. Handbook for Vaccine and Cold Chain Handlers. New Delhi: Government of India; 2016.
3. Ministry of Health and Family Welfare. Operational Guidelines: Universal Immunization Programme. New Delhi: Government of India; 2021.
4. Babiker A, Saeed S, Abdallah A. Assessment of cold chain management in primary health care facilities. East Mediterr Health J. 2020;26(7):826-832.
5. Matthias DM, Robertson J, Garrison MM, Newland S, Nelson C. Freezing temperatures in the vaccine cold chain: A systematic literature review. Vaccine. 2007;25(20):3980-3986.
6. Kartoglu U, Milstien J. Tools and approaches to ensure quality of vaccines throughout the cold chain. Expert Rev Vaccines. 2014;13(7):843-854.
7. Ashok A, Brison M, LeTallec Y. Improving cold chain systems: Challenges and solutions. Vaccine. 2017;35(17):2217-2223.
8. Murhekar MV, Roy T, Das MK, et al. Assessment of cold chain and vaccine management in India, 2018. Indian J Public Health. 2020;64(4):373-379.
9. Rao S, Naresh A, Chandrakanth P. Evaluation of cold chain practices in immunization centers. Int J Community Med Public Health. 2019;6(5):2152-2157.
10. Shastri D, Patel P, Chaudhary S. Cold chain maintenance in immunization centers: An assessment in Gujarat. Natl J Community Med. 2018; 9(4):247-252.
11. Thakre SS, Dhakne-Palwe S, Thakre SB, et al. Quality assessment of vaccine cold chain in

urban health centers. J Prev Med Hyg. 2013;54(2):100-103.
12. Pradeepkumar B, Joseph N, Nelliyanil M, et al. Evaluation of vaccine storage and handling practices in primary health centers. J Clin Diagn Res. 2016;10(12):LC01-LC04.
13. Miles M, Ryman TK, Dietz V, et al. Freeze protection and exposure studies in vaccine supply chains. Vaccine. 2011;29(43):7219-7226.
14. Al-Zahrani R, Al-Quwaidhi A, Al-Mazrou Y. Assessment of cold chain management in vaccine storage facilities. Int J Health Sci. 2019; 13(6):22-28.
15. Mri R, Singh A, Gupta V. Evaluation of immunization logistics and cold chain system in UP. Indian J Child Health. 2019;6(10):517-521.
16. Choudhary TS, Reddy NS, Apte A, et al. Operational challenges in vaccine handling in India: A field evaluation study. Vaccine. 2019;37(11):1470-1476.
17. Samant Y, Lanjewar H, Block L, et al. Relationship between vaccine vial monitor status and temperature exposure in vaccine supply chains. J Public Health Manag Pract. 2007;13(5):406-412.
18. Deb AK, Mukherjee S, Kang G, et al. Vaccine cold chain and logistics management: A review from developing countries. Trop Med Int Health. 2018;23(6):642-650.