ORIGINAL ARTICLE

Post-Introduction Evaluation (PIE) of Covid-19 Vaccination in Delhi: Application of WHO Framework

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Abstract

The present study was undertaken for the Post-Introduction Evaluation (PIE) of COVID-19 vaccination across different levels of healthcare system in Delhi. It was conducted in accordance with the guideline provided in the WHO PIE tool to assess the COVID-19 vaccine introduction and document strength and weaknesses. The study found that The detailed operational plans were available at state, district and health facility levels. Both electronic and paper-based reporting and recording mechanism were deployed for COVID-19 vaccination. There was neither stock out nor expiry reported for COVID-19 vaccine. There was an AEFI committee functional with availability of a system and written protocol for monitoring and reporting of AEFIs of COVID-19 vaccine

Keywords

Adverse Effect Following Immunization; Covid-19; Cold Chain Points; Cold Chain Handlers; Health Facilities; cPIE; Vaccine Hesitancy

Introduction

The PIE is a systematic method for evaluating the overall impact of the introduction of a new vaccine on a country's national immunization programme. It can rapidly identify areas that need strengthening and it also makes the findings comparable across countries. For conducting PIE, data is to be collected on ten principal evaluation areas.(1)It is recommended to be conducted between 6 and 12 months after introduction of the new vaccine.(1)The evaluation is to be performed at all levels of the health system, spanning from the central, regional, district, health facility (HF) levels till the vaccination sites

Covid-19 Vaccine Post-Introduction Evaluation (cPIE)

The COVID-19 vaccine has been introduced in almost all the countries in a short span of time. The WHO introduced the cPIE strategy, adapted to address several issues such as multiple vaccine products which may be in use in a country, with certain vaccine products targeted to different priority populations, or in certain geographies, some vaccines requiring

special considerations for ultra-cold-chain capacity and management, which has never been required for prior vaccines and in addition, countries may undertake phased introduction by priority population, depending on available vaccine supply.(2)Data is to be collected on nine principal evaluation areas.(3)It was recommended to be conducted 6-18 months after the COVID-19 vaccine introduction at all levels of the health system. The maximum number of sites to be visited will depend on the size of the country, the heterogeneity of its health and vaccination services and the human and financial resources available to conduct the evaluation. The number of site visits required at each level of the health service are comparable to that given for PIE of new vaccines.(2)Sites are to selected based on a purposive sampling strategy and is not designed as a statistically representative survey, such that it can be conducted quickly without a need for statistical support for planning and analysis.

India's COVID-19 Vaccination Programme was rolled out on 16th January 2021.(3,4)The study was conduct across different levels of healthcare system in Delhi State so as to rapidly identify problem the areas needing corrections within the immunization programme either pre-existing or resulting from the introduction of the new vaccine and also document any programmatic and logistical issues relating to the introduction of the vaccine. Due to the sensitive nature of study, its publication was delayed.

Material & Methods

This was a cross-sectional, descriptive study conducted in Delhi during September 2021 – August 2022. The study area consisted of Government Health Facilities (HFs) with Cold Chain stores (Vaccine Stores), identified for COVID-19 vaccination as well as session sites for the vaccination in the selected three districts of Delhi, namely North East, South West and New Delhi districts. The six Health Facilities (HFs) visited were one Primary Urban Health Center (PUHC), four Delhi Government Dispensaries (DGD) and one Polyclinic. The 18 session sites consisted of vaccination session sites in the building of the health facilities, schools, government institutions, Aanganwadi centers and mobile camps. The stratified random sampling technique was used for selection of HFs and sites. Out of the 11 districts of Delhi, three districts with the highest, average and lowest confirmed COVID-19 cases were selected. The data pertaining to the district wise COVID-19 cumulative COVID-19 cases were obtained from the Public Health Wing (PHW-IV), Delhi Government Health Services (DGHS), Government of National Capital Territory (GNCT), Delhi after due permission from the Director DGHS, GNCT, Delhi.

Two Government health facilities with vaccine cold chain stores, identified for COVID-19 vaccination were selected by simple random sampling from each of the three districts, after consultation with their respective District Immunization Officers (DIOs). Under each of these selected health facilities, three session sites were selected randomly. Table 1. shows the study area visited at the state, district and health facility levels.

Table 1. Study area at the State, District and Health facility levels

Level of Facility	Study Area	
State	SEPIO Office, DFW, GNCT Delhi	
	State Vaccine Store-	Rajiv Gandhi Super specialty Hospital, Taharpur, Dilshad Garden
Districts	North East	DPMU Office, DC Office, Shahadara
	South West	DGD Sector-10, Dwarka
	New Delhi	DGD
Health facility	North East	Primary Urban Health Center, Old Mustafabad
		Delhi Government Dispensary, Khajoori Khas
	South West	Delhi Government Dispensary, Rajnagar II
		Delhi Government Dispensary, Nawada
	New Delhi	Delhi Government Dispensary, Mahipalpur
		Aam Aadmi Polyclinic, Basant Gaon

Sample Size: The sample size was determined using the guidelines given in the New Vaccine Post-Introduction Evaluation (PIE) tool of WHO as shown in Table 2.(32)

Table 2. The respondents interviewed and observations conducted at each level

Health Administration Level	Respondent/ Interviewee	Number of Respondents	Number of Observations
National	Programme Manager	1	-
State	State Immunization Officer	1	-
	State Vaccine Store (SVS) Cold Chain Handler	1	SVS X 1
District	District immunization Officer	3	-
	District Vaccine Store (DVS) - CCH	3	DVS X 3
Health facilities	Medical Officer in-charge	6	-
	Health facility, HF-CCH	6	Cold and Dry Vaccine storage areas X 6
Session sites	Vaccinators (at least 2 per session)	36	COVID-19 Vaccination session sites X 18
	Beneficiaries (at least 10 per session)	183	
Total number of Respondents and Observation sites		240	28

The interview was conducted with (1) Programme Managers (Immunization Officers) at the National, State and District levels, (2) Cold Chain Handlers (CCHs) at the State, District and Health facility (HF) levels, (3) Medical officers-in-charge at the HFs, (4) Vaccinators at the Session sites, (5) Beneficiaries at Session sites.

Data Collection Techniques

Primary Data

a) Interview using pre-designed interview schedule: The Programme Managers or the Immunization Officers at the National, State and District levels were interviewed. The medical Officers at the HF level and vaccinators and beneficiaries at the session sites were also interviewed. The CCHs at the State, District and HF Cold chain stores were also interviewed.

b) Observation technique through an observation checklist: The Cold chain stores at the State, District and HF levels were observed. At the session sites, the COVID-19 vaccination sessions and vaccine management were also observed.

c) All the infrastructure/facilities/equipment used for management of vaccines and other immunization supplies in the identified government HFs were observed with the help of checklist prepared as per the WHO guidelines.

Secondary Data: Reports and records related to the current immunization delivery system of the COVID-19 vaccine were collected from the selected districts and HFs. They include records such as National COVID-19 Vaccine Deployment plan, sample micro-plan, training materials, COVID-19 Vaccine coverage reports and COVID-19 Vaccine AEFI reporting forms. The review period for the records was selected from 16th January 2021 till 30th May 2022.

Tools for Data Collection: The tools were developed based on New Vaccine PIE tool from WHO adapted to the context of COVID-19 vaccine, in the form of:(32)

1. Five separate standardized interview schedules were designed:

Interview schedule for the National/ State/ District programme managers (Immunization Officers)

Interview schedule for the Medical Officers in-charge at the HFs

Interview schedule for the Cold Chain Handlers (CCHs)

Interview schedule for the Vaccinators

Interview schedule for the Beneficiaries

2. Two Observation checklists:

Checklist for observation of cold chain equipment and vaccine storage at the Vaccine stores

Checklist for observation of the vaccination practices at the session sites.

Data Analysis

The primary data collected from the interviews and observations at each level of the healthcare system was summarized to provide an overview of the vaccine introduction process. The collected data was tabulated and analyzed by using SPSS Version 20.0. The data was analysed in the form of frequency tables and graphs and various statistical analysis viz, mean and proportion. The chi-square is applied.

Ethical Approval: Ethical clearance was obtained from the Institutional Ethics Committee of the NIHFW. Permission was taken from the concerned health officials for conducting the Post-Introduction Evaluation (PIE) of COVID-19 Vaccination. After the data collection, findings were also discussed with concerned officials.

RESULTS

Planning of COVID-19 Vaccination in Delhi

The Operational Guideline on COVID-19 vaccines was prepared and released in December 2020, which guided the introduction process. It was found that detailed operational plans for the introduction of COVID-19 vaccine was available at all levels ie the state and the selected three districts. The micro-plans for the vaccination sessions planned and held were also found to be available at the Health Facilities (HFs) visited. There was close inter-sectoral coordination between the various sectors, such as MoHFW, Education department, Women and Child Development/ Integrated Child Development Services (ICDS), State Police Department, to name a few.

Organization of COVID-19 Vaccination Sessions: In all the three selected districts, the Covid-19 vaccines were introduced on the same day, along with its nationwide launch of Phase I. Two of the health facilities introduced the vaccine from 16th January 2021, rest introduced it subsequently along with the rolling out of Phase II and Phase III. The names of these session sites, the vaccination doses available and the timings were all found to be available and accessible in the CoWIN platform, for the beneficiaries to conveniently book their vaccination slots and visit the sites for their vaccination. Facilities available at 18 vaccine session sites are presented in Table 3.

Table 3. Availability of different facilities in the sites visited (N = 18)

	n (%)
Separate Vaccination stations for different types of COVID-19 vaccines	14 (78%)
Separate Registration counter for each type of COVID-19 vaccines	14 (78%)
Verification of personal identification and registration in CoWIN platform	18 (100%)
Availability of Waiting area	11 (61%)
Availability of Observation area	13 (72%)
Observation of the beneficiaries after the COVID-19 vaccination	14 (78%)
Observation of the beneficiaries after the vaccination for at least 30 mins	10 (56%)
Different entry and exit route	7 (39%)
Vaccination officers present at their stations	18 (100%)

**Multiple observations were made at each session site*

As presented in table 2, most of sites were set-up according to the guideline provided for setting up of a COVID-19 vaccination session site.

Infection Prevention and Control (IPC) Measures at the Session Sites: As shown in table 4, it was found that all (100%) the vaccination session sites were separate from the curative service areas and masks being worn by everyone present at the all session sites but rest of the sites were lacking in other aspects.

Table 4: Observations on IPC practices at the COVID-19 vaccination session sites

Different IPC measures at the sites (N=18)	n (%)
Separation of vaccination sites from curative services by location and hours	18 (100%)
Maintenance of 2 meters distance between people at the vaccination site (e.g., floor markings, seating arrangement, tape, ropes)	12 (67%)
Wearing of masks by HCWs and individuals to be vaccinated	18 (100%)
Adequate number of hand hygiene stations in strategic areas to support appropriate hand hygiene for the public and staff	3 (17%)
Vaccination stations a least 1 meter apart (ideally with installation of physical barriers between vaccination stations)	7 (39%)
Limited number of people present and short waiting period	10 (56%)

**Multiple observations were made at each session site*

Provision of COVID-19 Vaccines: It was found that half (50%) of the samples health facilities and 60% vaccine sites were providing two types of COVID-19 vaccines. The Central and the Delhi government supplied two types, COVISHIELD and Covaxin types of COVID-19 vaccines to health facilities. The allocation of specific type of COVID-19 vaccine to the site was done from the district level according to the number of eligible beneficiaries, number of session sites planned, availability and consumption of the vaccine. However, it was ensured that the beneficiaries get the same type of vaccine in both the first and second doses.

It was found that out of 18 session sites visited, 15 of them were providing vaccine to beneficiaries above 18 years and 3 of them were catering to 15-18 years beneficiaries. The programme managers informed that Vaccine rolled out in three Phases viz, (i) only the Health Care Workers (HCWs) and Field Level Workers (FLWs), (ii) for those who were 60 years and above and all citizens who were between 45 to 59 years of age, with certain specific comorbidities listed by the Government, (iii) eligible beneficiaries, for 18 years and above, 15 years and above and finally 12-14 years of age. The pregnant and lactating females were also allowed to avail the COVID-19 vaccination, with due counselling.

COVID-19 Vaccination and Routine Immunization: The COVID-19 vaccination sessions were being conducted specifically for COVID-19 and not integrated with the curative services at the health facilities or with the routine immunization sessions.

3.2 Coverage, Dropout, Recording and Reporting

System for Recording and Reporting of COVID-19 Vaccination: The system for COVID-19 vaccine recording and reporting was both electronic and paper based (Table 4)The CoWIN platform, created specifically for the COVID-19 vaccination had been used for planning and broadcasting the session sites, vaccination doses available in each session site, registration of the eligible beneficiaries, booking of the vaccination slots and tracking of the beneficiary's dosage schedule, batch/ lot numbers of the COVID-19 vaccine administered. The data in manual registers were updated daily and matched with the data fed in the CoWIN platform.

Table 5: Observations on recording and reporting mechanism of COVID-19 vaccination

Features of data recording and reporting	**Health facility N=6 (%)**	**Session sites N=18 (%)**
System for COVID-19 vaccine recording and reporting was mixed (both electronic, i.e., CoWIN and paper)	6 (100%)	18 (100%)
The electronic recording/ reporting system, CoWIN had been newly instituted for COVID-19 vaccination.	6 (100%)	18 (100%)
Vaccination data were entered into the system in real time during the vaccination session	6 (100%)	18 (100%)
COVID-19 Vaccination status of the beneficiaries were recorded in Digital Vaccination Certificate	6 (100%)	18 (100%)

System could track more than one vaccine product	6 (100%)	18 (100%)
System could track batch/ lot numbers at the beneficiary level (In case of an AEFI)	6 (100%)	18 (100%)

**Multiple observations were made at the health facilities and session sites. Total number of health facilities visited=6, Total number of session sites visited=18*

Although CoWIN platform served multiple functions, there have been few challenges felt by the programme managers and the medical officers. The Programme Managers informed that frequent system updates somehow hindered the vaccination process for some period during that time.

Calculation of COVID-19 Vaccine Coverage: The COVID-19 vaccine coverage was calculated by extracting the number vaccinated against the baseline population of eligible beneficiaries from CoWIN. Home surveys were also conducted by the ASHAs and AWWs to develop line lists of those who were already vaccinated against their respective doses, and those who have been left out under each of the health facilities.

System for Following-Up with the Defaulters: Defaulters were sent a text message in their respective numbers which had been registered in the CoWIN. Those who had already passed their due dates were also called upon/visited by the ASHAs, School teachers and CDOs of their respective areas, via phone call to their registered number and mobilized them to get vaccinated in their nearest session sites.

Monitoring and Supervision

Monitoring of COVID-19 Vaccination: The CoWIN platform has an in-built mechanism for monitoring of COVID-19 vaccination activities in real-time manner. Some of the features which had been used for monitoring were (1) Registration of the beneficiaries in comparison with the baseline eligible population (2) Number of sessions planned and actual sessions held **(3)** Number of beneficiaries vaccinated according to their eligible categories as well as according to their doses (4) Rates of vaccine drop-outs- those who had missed their second dose and precaution dose (5) Number of beneficiaries who have been left-out, those who have not taken any dose (6) Any AEFI case reported amongst those vaccinated beneficiaries.

Supervision of COVID-19 Vaccination: Supervisory visits were conducted in all the vaccination session sites, by a team, comprising of representatives from the State and/or District level besides WHO, UNICEF and UNDP to ensure that the vaccination officers and vaccinators conducting standard procedures. The supervisory visits were reported to be conducted at least once a week.

3.4. Status of Covid-19 Vaccine and Cold Chain Management

COVID-19 Vaccine Supply: The COVID-19 vaccine doses were allotted by the State for each district, according to the availability, consumption and distribution pattern. eVIN (Electronic Vaccine Intelligence Network) portal was used to record the existing stocks of the COVID-19 vaccines and to keep track of the vaccine doses received from the higher centers, the doses consumed and the existing availability of the doses. Stock registers for COVID-19 vaccines were also maintained.

Stock maintenance of COVID-19 Vaccine: The Cold Chain Handlers (CCHs) reported that there had been no stock outs reported at any level. COVID-19 vaccine expiry was not reported by any of the CCHs at the State, districts and health facilities interviewed. During observation of the Cold Chain equipment at the State, District and health facility-cold chain stores, no expired COVID-19 vaccine vial was found.

Handling of COVID-19 Vaccine: The CCHs and the vaccinators reported that there was no vaccine damage due to mishandling of COVID-19 vaccine since its introduction. The vaccines handling practices given in table 5 below:

Table 5: Observations on COVID-19 vaccine handling practices at the session sites

Handling practices of COVID-19 vaccine vials (N=18)	n (%)
The temperature of the vaccine carrier was maintained at the session site	18 (100%)
Only the used vials are kept outside and on the ice pack during the session	18 (100%)

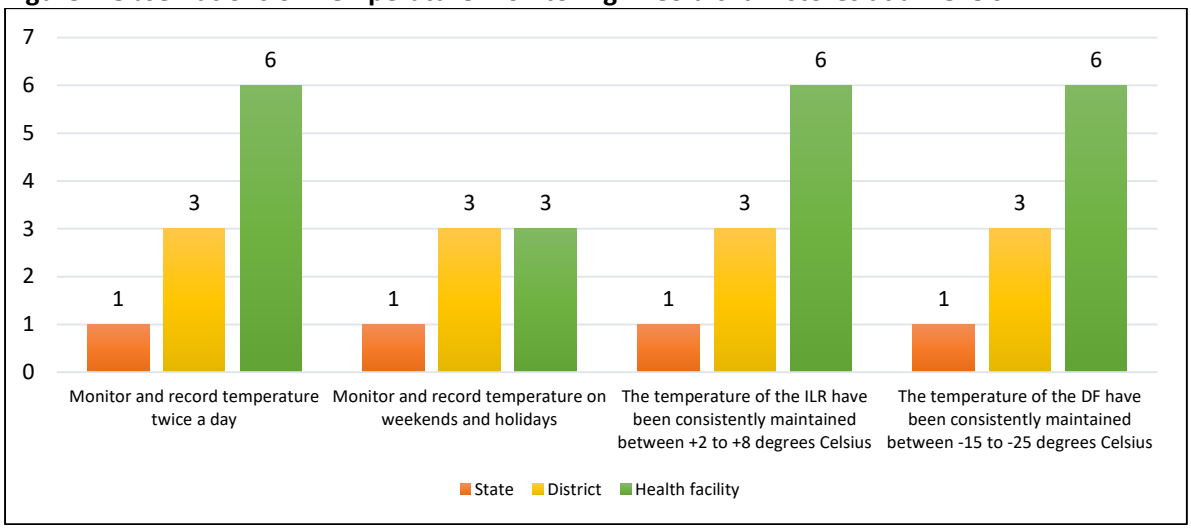
Opening date and time is marked on the opened vaccine vial	18 (100%)

**Multiple observations were made at the session sites*

Vaccine Wastage: No Covid-19 vaccine wastage was reported at any of the 3 levels. With a huge number of beneficiaries available for vaccination, it was almost possible to use up the vaccine doses as reported by the DIOs, medical officers and vaccinators in all the three districts. In order to minimize the vaccine wastage rates, the last vaccine vial was opened with five or ten doses only after enough beneficiaries, around five to ten have gathered at the session sites.

Cold Chain Management: The Cold Chain Handlers (CCHs) were monitoring and recording the temperature of the equipment twice a day (Fig 1). However, in only half of the Health Facility, Cold Chain Points (CCPs), temperature was found to be recorded even on weekends and holidays. because there was rarely any power cut in that CCP. On observation of the thermometers, the temperature inside the ILRs and the DFs were maintained.

Figure 1 Observations on Temperature monitoring in Cold chain stores at all levels

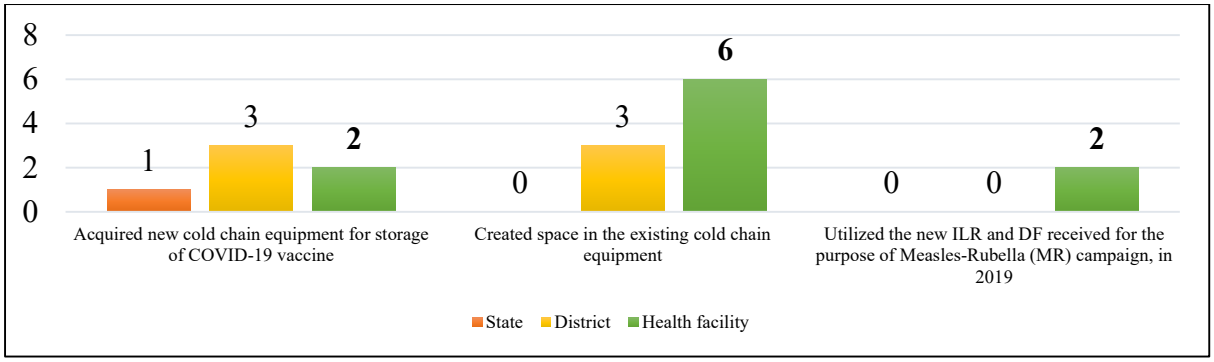


**Total number of vaccine stores visited; SVS=1, DVS=3, HF CCP=6*

Temperature Monitoring: On observation, systematic temperature monitoring via manual recording was found to be done regularly and temperature logbooks were maintained at all the cold chain stores, i.e., SVS, DVS and HF CCPs visited. For temperature recording, thermometers were found in all the equipment, both Ice-Lined Refrigerators (ILRs) and Deep Freezers (DFs) and Fridge-Tags were available in all the ILRs.

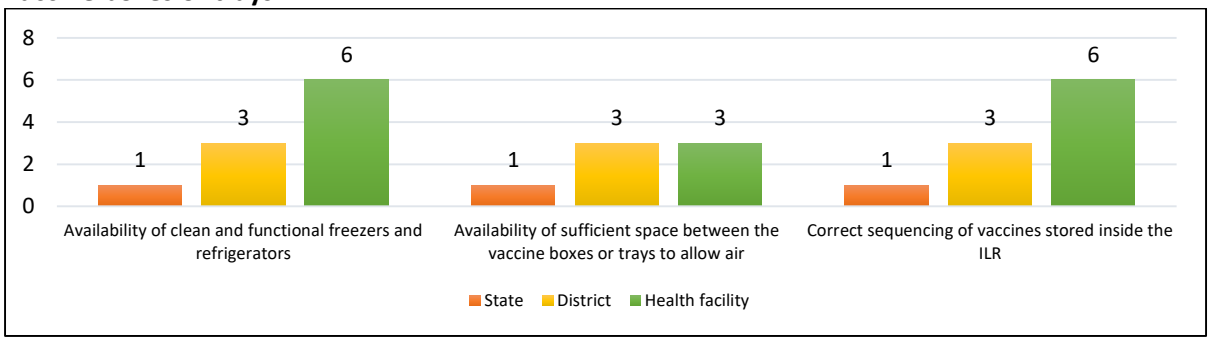
Cold Chain Storage Area of COVID-19 Vaccine: Fig. 2 illustrates that at the District level, all three DVS and only two of HF CCPs acquired new ILRs and DFs for storing COVID-19 vaccine. All the three DVS and 6 HF CCPs reported creating space in the existing equipment. Two of the HF CCPs visited mentioned that they had acquired new equipment in 2019 for the Measles-Rubella (MR) campaign in Delhi, which was not launched, and had utilized those for COVID-19 vaccine.

Figure 2 Changes in the Cold Chain stores to accommodate the COVID-19 Vaccine



**Total number of vaccine stores visited; SVS=1, DVS=3, HF CCP=6*

Figure 3 Informs that only half of the HF CCPs, were found to have sufficient space between the vaccine boxes or trays.

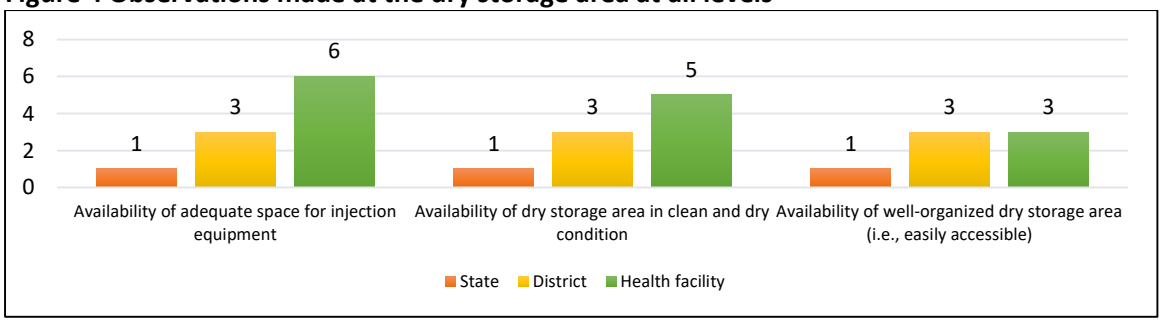


**Total number of vaccine stores visited; SVS=1, DVS=3, Health facility CCP=6*

Fig 3: Observations of Cold Chain Equipment in Cold chain stores at all levels

Dry Storage Area: Observations of the dry storage areas at vaccine stores are depicted in Fig 4. It was found that only five out of six HF-CCPs had clean and dry storage area and only half of the HF CCPs had well organized dry storage area. The reasons cited by the CCHs were that due to space constraints.

Figure 4 Observations made at the dry storage area at all levels



**Total number of vaccine stores visited; SVS=1, DVS=3, Health facility CCP=6*

Security of Vaccine Storage Areas: As reported by the CCHs as well as on observation, all the vaccine stores at all levels were found to have a CCTV camera installed in order to prevent any theft or misuse. At the SVS and the three DVS, an additional security staff had been stationed outside the vaccine storage room to ensure security of the vaccines as well as the equipment.

3.5 Status of Training of HCWs

Training of HCWs: The responses of the HCWs regarding their status of training on COVID-19 vaccination has been analysed in Table 6.

Table 6 Training of HCWs on COVID-19 Vaccination

Categories of HCWs and their training status	Level of Facility	n (%)
Immunization officers trained before introduction of COVID-19 vaccination	State (N=1)	1 (100%)

	District (N=3)	3 (100%)
Medical officers trained before introduction of COVID-19 vaccination	Health facility (N=6)	6 (100%)
Cold Chain Handlers trained before introduction of COVID-19 vaccination	State (N=1)	1 (100%)
	District (N=3)	3 (100%)
	Health facility (N=6)	6 (100%)
Vaccinators trained before introduction of COVID-19 vaccination	Session sites (N=36)	14 (39%)
Vaccinators trained after introduction of COVID-19 vaccination	Session sites (N=36)	16 (44%)
Vaccinators who did not receive any training on COVID-19 vaccination	Session sites (N=36)	6 (17%)

**Number of HCWs interviewed at each level are State = 1, District = 3, Health facility = 6, Session sites = 36*

The training was done in a cascaded manner for State Official, District level health officials, medical officers and vaccinators in their respective districts. Trainings were conducted physically. The average duration of training was for more than three hours per day for almost three days for both the medical officers and vaccinators at the district level, as reported by them. For the CCHs, one training was conducted for eVIN in 2020 virtually. Almost all the HCWs at the State, District and HF levels felt that the training provided were adequate and covered all the important aspects of COVID-19 vaccination programme. However, only 72% of the vaccinators were satisfied with the training provided as remaining 28% vaccinators did not receive any trainings.

Knowledge of HCWs: The knowledge level of only the medical officers and vaccinators were ascertained by asking them to tick their most appropriate answer on a Likert scale ranging from inadequate knowledge, less knowledge and adequate knowledge. The analysis reveals that all medical officers and health care workers felt they had adequate knowledge on eligibility of COVID-19 vaccination, organizing a vaccination session, administration of COVID-19 vaccine, preparing the vaccine, maintaining CAB, communicating key messages to the vaccinees, observation of the vaccinees, recording and reporting as well as communications with the community. Some of them reported to have less knowledge on the programme, rationale, contraindications, vaccine characteristics, monitoring and management of AEFI.

Vaccine Administration Safety and Waste Management of the Covid-19 Vaccine

Injection Safety of COVID-19 Vaccine Administration: The observations on practices pertaining to COVID-19 vaccine administration safety are presented in Table 7.

Table 7: Observations on Injection Safety Practices at the session sites

Injection safety practices observed (N=18)	n (%)
Auto-disable (AD) syringes were used	18 (100%)
Appropriate vaccine administration techniques were observed	16 (89%)
Needles were not recapped (Observed inside the safety box)	17 (94%)
Hub cutter was present at the session site	17 (94%)

**Multiple observations were made at the session sites*

Injection safety practices were observed at almost all the session sites visited with some deviations.

Waste Management of COVID-19 Vaccination: In all the three districts, BMW disposal was outsourced. The Table 8 depicts the practices.

Table 8: Observations on BMW Management Practices at the session sites

BMW management practices at the session sites (N=18)	n (%)
The BMW color-coded plastic bags and bins were present for disposal of waste at the session site	18 (100%)
AD syringes were disposed of immediately in a safety box	18 (100%)
Discarded needles and syringes were not observed on the ground outside the sites	18 (100%)
Collection and transportation of BMW plastic bags and safety boxes to the health facility done daily	15 (83%)

**Multiple observations were made at the session sites*

At the 3 session sites, bags were collected from the session sites and transported to the health facilities on alternate days because the bags do not get filled up in one day only.

Reporting and Management of AEFI of the Covid-19 Vaccine

Adverse Event Following Immunization (AEFI)

The State and district level AEFI committees were functional. New AEFI reporting formats revised according to the COVID-19 vaccination guidelines were available at all levels. Table 9. describes the AEFI procedures followed at different levels.

Table 9 Observations on preparedness for monitoring, reporting and management of AEFI at all levels

AEFI procedures	Level of facilities	n (%)
Presence of AEFI committee	State (N=1)	1 (100%)
	District (N=3)	3 (100%)
Availability of a system and written protocol for monitoring and reporting AEFIs of COVID-19 vaccine	State (N=1)	1 (100%)
	District (N=3)	3 (100%)
	Health facility (N=6)	6 (100%)
Availability of an expert's phone number to contact in case of an AEFI emergency	District (N=3)	3 (100%)
	Health facility (N=6)	6 (100%)
	Session sites (N=18)	18 (100%)
Mechanisms available at the sites for referral (e.g., ambulances, taxis, personal transport)	Health facility (N=6)	6 (100%)
	Session sites (N=18)	18 (100%)
The site had an AEFI kit	Session sites (N=18)	18 (100%)
Beneficiaries were sensitized to potential adverse events that could occur and what to do if they occur	Session sites (N=18)	5 (28%)
Beneficiaries were asked to stay for observation following vaccination	Session sites (N=18)	14 (78%)
Beneficiaries were observed for 30 mins following vaccination	Session sites (N=18)	10 (56%)

**Multiple observations were made at each level, Number of facilities visited at State = 1, District = 3, Health facility = 6, Session sites = 18*

The reporting for AEFI, even for zero cases were done daily. During observation at the 18 session sites, all (100%) of them were found to have an AEFI kit available with them in case of any emergency. However, at 5 sites only vaccinators were observed to tell and sensitize the beneficiaries regarding the potential adverse events that could happen to them after the vaccination and what they should do in such cases. In 46% sites, the beneficiaries were observed to be given the choice to leave whenever they want, some of them not even sitting down for few minutes.

Status of Advocacy, Communication and Acceptance of the Covid-19 Vaccine

Advocacy and Communication: Main activities undertaken in order to generate acceptance and demand for COVID-19 vaccine at the district and health facility levels were as follows:

Meeting with the community members and the district level officials

Meeting with the local and religious leaders

Public announcements made via autos driving around a community

Counselling during OPD hours at the health facilities by the HCWs

Home visits and social mobilization by the ASHAs, AWWs and CDOs

Setting up of posters and banners on various aspects of COVID-19 vaccination such as eligibility, CoWIN Registration, importance of COVID-19 vaccination at strategic places such as markets, outside health facilities, schools and religious places

Profile of the Beneficiaries: 183 beneficiaries were selected from 18 Vaccination Sites randomly to elicit their views regarding vaccination. Table 10 informs that number of male and female beneficiaries interviewed were comparable. Most (76%) belonged to the age group of 18-44 years, married (65.6%). And literate (71%).

Table 10: Socio-demographic characteristics of the beneficiaries interviewed

Characteristics		n (%)
Sex	Female	87 (47.5%)
	Male	96 (52.5%)
Age group	14 - 17 years	14 (7.7%)
	18 - 44 years	139 (76%)
	45 - 59 years	21 (11.5%)
	60 years and above	9 (4.9%)
Marital Status	Married	120 (65.6%)
	Unmarried	63 (34.4%)
Children	Yes	99 (54.1%)
	No	84 (45.8%)
Educational Qualification	Illiterate	29 (15.8%)
	Primary	5 (2.7%)
	Upper primary	25 (13.7%)
	Secondary	49 (26.8%)
	High school	39 (21.3%)
	Graduate	30 (16.4%)
	Postgraduate	6 (3.3%)

**Total number of beneficiaries interviewed, N = 183*

The Table 11 shows that common source of information were their family members (89%), friends (63%) and television (83%).

Table 11 Different sources of information about COVID-19 vaccine

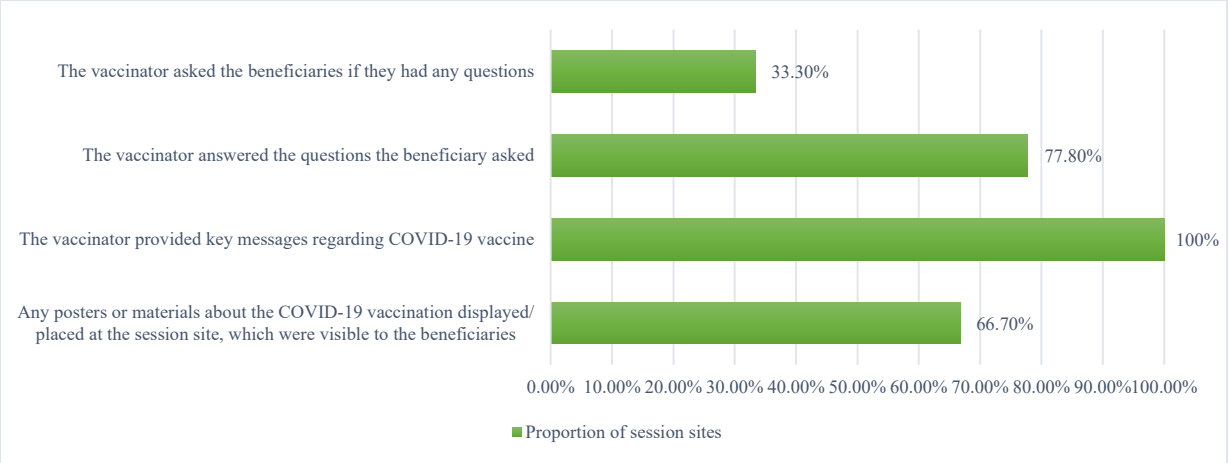
Sources of information (N=183)	n (%)
Family member	163 (89%)
Friend	115 (63%)
Healthcare provider	24 (13%)
Community organization	28 (15%)
Employer	24 (13%)
School/ Class teacher	15 (8%)
Television	152 (83%)
Printed media (newspaper, magazine)	82 (45%)
Banner / Billboard	79 (43%)
Radio	33 (18%)
Social media	24 (13%)

**Multiple responses were given by the beneficiaries interviewed*

The information disseminated through print media (45%), banners and billboards (43%) were also found to be useful as the community was informed about the vaccine and its availability in their own locality. Some other sources were also HCWs (13%), employers (13%), social media (13%) and school/ class teachers (8%).

The Figure 5. informs that the vaccinators were found to be providing key messages to the vaccinees, but at many sites detailed information were lacking.

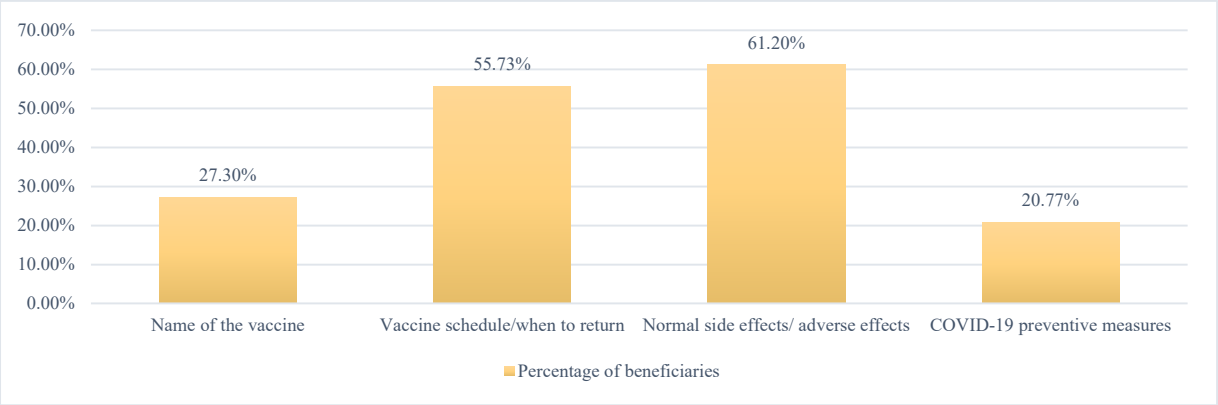
Fig. 5: Observations on Communication about COVID-19 vaccine at the Sites



**Multiple observations were made at the session sites, Number of session sites visited, N=18*

The beneficiaries were interviewed after vaccination and Figure 6 presents analysis of key messages provided by the vaccinators to the beneficiaries. All were being informed about schedule for next dose but rest of the information were not provided at all the sites.

Figure 6 Key messages recalled by the beneficiaries after vaccination at the session sites



**Multiple responses were given by the beneficiaries*

Vaccine Acceptance in the Community: Our analysis found that out of 183 beneficiaries interviewed, 175(96%) of them reported to have been recommended to take the COVID-19 vaccine. These 175 beneficiaries were further asked about who made the recommendation, the responses of which are shown in Table 12.

Table 12. Different sources who recommended the beneficiaries to get vaccinated

Sources who made the recommendation (N=175)	n (%)
Family member	135 (77%)
Friend	52 (30%)
Healthcare provider	23 (13%)
Employer	23 (13%)
Community Organization	6 (3%)
Others (School teacher)	13

**Multiple responses were provided by the beneficiaries interviewed*

As shown in Table 12, mostly family members (77%) and friends (30%) recommended the beneficiaries to get vaccinated. About half (51%) of the 183 beneficiaries were willing to come and receive the next dose. All 183 acceptors of Covid-19 vaccination were willing to recommend others, who have not taken even first dose, or those who missed their second dose to get their COVID-19 vaccination complete. were ready to recommend to others. Analysis is presented in the table 13.

Table 13. Factors which encouraged the beneficiaries to get vaccinated

Factors (N=183)	n (%)
Protecting my family	180 (98.4%)
Protecting myself	179 (97.8%)
Protecting others not in my family	37 (20.2%)
Was mandatory for my job	22 (12.0%)
Due to recommendation by family member/ friend/ community member	18 (9.8%)
Because of recommendation by a healthcare provider	6 (3.3%)
Mandatory for school	5 (2.7%)
Was mandatory for my place of residence	5 (2.7%)
I am in a high-risk category (age-related, Health status related)	3 (1.6%)

**Multiple responses were provided by the beneficiaries*

As can be seen from Table 13 that majority of beneficiaries mentioned that they came to get the vaccine mostly because they believed that COVID-19 vaccination would protect themselves (97.8%), and also their family members (98.4%)

Association of Sociodemographic factors with 'Willingness to Receive the Next Dose of COVID-19 Vaccine'

The Table 14 shows that association of 'Willingness to receive next dose of Covid-19 vaccine' with age groups, marital status, educational qualification and having children was statistically significant ($p<0.05$).Table 14.

Association of Sociodemographic characteristics of beneficiaries with their willingness to receive the next dose of COVID-19 vaccine

Socio-Demographic Characteristics		Willingness to receive the next dose		p-Value
		No	Yes	
Sex	Female	39 (44.8%)	48 (55.2%)	0.327
	Male	50 (52.1%)	46 (47.9%)	
Age Groups	14 - 17 Years	0 (0.0%)	14 (100.0%)	0.001**
	18 - 44 Years	73 (52.5%)	66 (47.5%)	
	45 - 59 Years	13 (61.9%)	8 (38.1%)	
	60 years and above	3 (33.3%)	6 (66.7%)	
Marital Status	Married	71 (59.2%)	49 (40.8%)	0.000***
	Unmarried	18 (28.6%)	45 (71.4%)	
Educational Qualification	Illiterate	19 (65.5%)	10 (34.5%)	0.001**
	Primary	3 (60.0%)	2 (40.0%)	
	Upper Primary	18 (72.0%)	7 (28.0%)	
	Secondary	17 (34.7%)	32 (65.3%)	
	High School	11 (28.2%)	28 (71.8%)	
	Graduate	21 (58.3%)	15 (41.7%)	
Have Children	No	31 (36.9%)	53 (63.1%)	0.003**
	Yes	58 (58.6%)	41 (41.4%)	

**p<0.05, **p<0.01, ***p<0.001*

DISCUSSION

The Operational Guideline on COVID-19 vaccines was formulated and released in December 2020, which guided the a massive COVID-19 vaccination programme launched all over the country, with its pre-introduction planning, training of stakeholders and mapping of vaccination session sites done well ahead of its launch.(5) In India also, PIE studies done for Pentavalent in Tamil Nadu and Kerala, RVV in Andhra Pradesh, Haryana, Himachal Pradesh and Odisha reported development of respective operational guidelines for these vaccine introductions.(6,11,12,13)

M&E :The COVID-19 vaccination had shown how a digital platform, CoWIN, could be used for real-time monitoring of the vaccination activities such as number of beneficiaries vaccinated, vaccination sessions and AEFI cases. The PIE of Pentavalent vaccine in five states mentioned that there was poor monitoring and supervision mainly due to shortage of staffs and multiple duties of the officials at the state, district and block levels, with no standard reporting formats for monitoring and inadequate documentation and feedback mechanisms after supervisory visits.(14,15,16)

Vaccine Management, Transport and Logistics

For COVID-19 vaccine, the present study reported that eVIN was being used for tracking of the vaccine doses, and the distribution of the doses was based on the availability and consumption pattern of the districts.

The assessment conducted for HepB vaccine in India reported that the higher-level stores were not receiving regular indents for the vaccines, and were sending vaccines by “push mechanism”. The stock registers were maintained at majority of the stores. However, at few districts and PHC stores, critical information such as batch numbers and expiry dates of the vaccines were missing. Vaccine stock-outs were reported in at least 56% of the state or district level cold chain stores and 60% of the PHC level stores., which lasted for few weeks at a time. In Tamil Nadu and Kerala, PIE for pentavalent vaccine found that there was inappropriate re-distribution of DPT and HepB vaccine in the period immediately after pentavalent vaccine introduction, at the field level which led to excess stocks of DPT at majority of HFs and HepB vaccine at a few facilities. (6)

Vaccine Wastage

The current PIE study reports that COVID-19 vaccine wastage rate was non-significant at all levels.For PCV and IPV in Bangladesh, the cumulative wastage of PCV in reviewed districts (9%) and HFs (8%) was found to be within the accepted threshold for PCV but higher for the IPV vaccine. In India also, tracking vaccine wastage rates was found to be a challenge. As reported for Pentavalent vaccine in Tamil Nadu and Kerala, it was noted that the vaccine wastage was not monitored at many places visited in both states. Likewise, PIE of Pentavalent vaccines and MCV the five States of India reported that the information regarding vaccine wastage was not available at any level and it was not being tracked. (6,15)

Cold Chain Management

The present study found systematic temperature monitoring of the COVID-19 vaccines during their transportation as well as at vaccines stores in the State, district and HF levels.The new vaccine introductions in India were found to encounter cold chain space constraints. With Hep B introduction, 3 of the 5 states (KA, MP and WB) reported cold chain space constraint for storing Hep B vaccine. In Karnataka, it was found that the cold chain handers were not adequately sensitized. Thermometers were found to be missing in some parts of Haryana and Karnataka, while in Goa and Gujarat, temperature recording was not observed on weekends and holidays at HFs. (6)

Training and Knowledge of HCWs

All these PIE studies(16)reported similar trainings for Pentavalent vaccine in Tamil Nadu and Kerala, and also in Goa, Gujarat, Haryana, Jammu and Kashmir, Karnataka and Puducherry, for RVV in AP, Haryana, HP and Odisha, and for HPV vaccine in Sikkim. reported that the trainings were conducted to cover all the key areas of the new vaccines that were introduced.

Injection Safety and Waste Management

This PIE study on COVID-19 vaccine found that appropriate injection safety practices were being followed in almost all the session sites visited. Similar to the current study, the assessment in Bangladesh also found correct administration of vaccines, proper disposal of syringes and needles in a safety box in all the HF, needles were not re-capped in 97% of the HF. (7,8) In India, PIE for Pentavalent and MCV-2 in the five States found that the knowledge of the health workers was sufficient and most of them correctly followed the injection safety practices, though there was some inconsistency at the subdistrict levels, such a recapping was found in Goa and Karnataka, and hub cutters not available or not used in some sites of Goa and Jammu and Kashmir. However, it was a different scenario during the PIE for RVV as the injection safety practices were found to be weak. During the observation sessions appropriate vaccine administration techniques, use of AD syringes and separate use of RVV droppers for RVV and OPV droppers for OPV was observed but almost all the ANMs were found to practice re-capping of needles, 11% of ANMs in Andhra Pradesh and 39% in Odisha were not disposing syringes in safety boxes after use. (6,11)

Adverse Event Following Immunization (AEFI)

The present study found a system and written protocol for monitoring and reporting of any AEFI at all levels with state and district level AEFI committees constituted. In Tamil Nadu and Kerala, the AEFI committees were reconstituted as part of planning for introduction of Pentavalent vaccine and there was also high level of awareness about reporting for AEFI in all cadre of HCWS. The RVV introduction was also taken as an opportunity to strengthen the AEFI surveillance system by preparing an AEFI crisis communication plan, provided to all the programme managers, and revising and updating AEFI reporting forms, which were made available at various levels. Similar finding was reported during the PIE study for HPV vaccine in Sikkim that there was strong AEFI monitoring mechanism, along with availability of AEFI kits at the session sites. But, it was found that the surveillance of AEFI was weak for Pentavalent and MCV-2 in most states studied for PIE in India, with staffs not being sensitized to the need for reporting AEFI and

the staffs were not trained to handle serious AEFI cases. (9,10)

Advocacy and Communication

This PIE study on COVID-19 Vaccination found out that there was high profile launching ceremony of COVID-19 vaccination programme by the Honorable Prime Minister of India. For other vaccine introductions in India also, the PIE studies highlighted high-profile State ceremonial launches for Pentavalent vaccine in Tamil Nadu and Kerala in December 2011, and in five States and Union Territories - Goa, Gujarat, Haryana, Karnataka and Puducherry in 2012-2013. The RVV was also launched in a public ceremony in March 2016 by the Union Health Minister, GOI, at Bhubaneshwar, Odisha. The ceremonial launch was also reported for HPV vaccine in Sikkim with the presence of State Chief Minister, and high media coverage.(7)

In the current PIE on COVID-19 vaccine, it was found that at the community level, majority, i.e., 175 beneficiaries out of 183 came for the vaccination after getting recommended, mainly by the family members as told by 77% of those who got recommended and 30% by friends. Similar finding was reported in PIE of MCV-2 in Gujarat also, where the parents were keen to protect their children from measles and hence led to an increase in uptake of MCV-2.(6,11)

Conclusion

COVID-19 Vaccination programme is different from the routine immunization programme and was rolled out in a short period of time and at such a massive scale. The Post-Introduction Evaluation (PIE) of COVID-19 vaccination across different levels of healthcare system in Delhi. It generates many learnings and experiences for future introduction of new vaccines at such a scale.

Limitations of the Study

The study was conducted for COVID-19 vaccine introduction and the methodology and tools of the study were adapted from the WHO New Vaccine Post-Introduction Evaluation Tool (PIE) guideline and not on the COVID-19 Vaccine Post-Introduction Evaluation Tool (cPIE).

Authors Contribution

All authors have contributed equally.

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Nil

Conflict of Interest

There are no conflicts of interest.

Recommendations

The changes and updates to be brought in CoWIN may be informed in advance to the HCWs closely involved in the reporting, recording and monitoring using this platform.

The cold chain maintenance at the health facilities may be strengthened for the overall improvement of the system for immunization programme as a whole.

The HCWs must also be made aware of the necessity to dispose of the BMW daily and ensure that they follow the guidelines.

The HCWS need further training and supervision on monitoring and management of AEFI of other vaccines also.

The vaccinators empowered to deliver all the important messages during the vaccination as the beneficiaries are found to more receptive during this time.

Declaration Of Generative AI And AI Assisted Technologies In The Writing Process

The authors haven't used any generative AI/AI assisted technologies for preparing this article.

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