



सत्यमेव जयते

Ministry of Health & Family Welfare  
Government of India



# A REPORT ON "ASSESSMENT OF OPEN VIAL POLICY IMPLEMENTATION IN INDIA"



unicef   
for every child

National Cold Chain and Vaccine Management Resource Centre



# Contributors

## Advisors

Dr. Pradeep Haldar, MoHFW  
Dr. M. K. Agrawal, MoHFW  
Prof. Sanjay Gupta, NCCVMRC-NIHF  
Dr. Rija Andriamihantanirina, UNICEF India

## Authors

Dr. Bhrigu Kapuria, UNICEF  
Dr. Snehil Kumar Singh, NCCVMRC-NIHF  
Dr. Sumeet Juneja, NCCVMRC-NIHF

## Core Team

Prof. Sanjay Gupta, NIHF  
Dr. M. K. Aggarwal, MoHFW  
Dr. Bhrigu Kapuria, UNICEF  
Dr. Snehil Kumar Singh, NCCVMRC-NIHF  
Mr. Lokesh Sharma, NCCVMRC-NIHF  
Dr. Sumeet Juneja, NCCVMRC-NIHF  
Mr. Paritosh Panigrahi, NCCVMRC-NIHF  
Er. Hitesh Kumar, NCCVMRC-NIHF  
Dr. Mainak Chatterjee, UNICEF  
Er. Dheeraj Bhatt, UNICEF  
Dr. Yashika Negi, UNICEF  
Dr. Sheenu Chaudhary, UNICEF  
Dr. Ginisha Gupta, UNICEF

## Data Analyst

Mr. Shashi Kant Ray, NCCVMRC-NIHF  
Mr. Rakesh Kumar, NCCVMRC-NIHF

Assessment conducted by National Cold Chain and Vaccine Management Resource Centre (NCCVMRC), NIHF & UNICEF India, under the guidance of MoHFW, Gol.

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# Acronyms

<b>AD</b>	Auto-disabled
<b>AEFI</b>	Adverse Events Following Immunization
<b>ANM</b>	Auxiliary Nurse Midwife
<b>ASHA</b>	Accredited Social Health Activist
<b>AVD</b>	Alternate Vaccine Delivery
<b>AWW</b>	Anganwadi Worker
<b>BCG</b>	Bacillus Calmette Guerin
<b>CCP</b>	Cold Chain Point
<b>DIO</b>	District Immunization Officer
<b>DPT</b>	Diphtheria Pertussis Tetanus
<b>DVS</b>	District Vaccine Store
<b>eVIN</b>	Electronic Vaccine Intelligence Network
<b>FIC</b>	Full Immunization Coverage
<b>fIPV</b>	Fractional dose of Injectable Polio Vaccine
<b>GoI</b>	Government of India
<b>ILR</b>	Ice Lined Refrigerator
<b>IPV</b>	Injectable Polio Vaccine
<b>ITSU</b>	Immunization Technical Support Unit
<b>JE</b>	Japanese Encephalitis
<b>JSI</b>	John Snow Inc.
<b>MDVP</b>	Multi-Dose Vial Policy
<b>MO</b>	Medical Officer
<b>MoHFW</b>	Ministry of Health and Family Welfare
<b>MR</b>	Measles-Rubella
<b>NCCRC</b>	National Cold Chain Resource Centre
<b>NCCVMRC</b>	National Cold Chain and Vaccine Management Resource Centre
<b>NFHS</b>	National Family Health Survey
<b>NIHFW</b>	National Institute of Health and Family Welfare
<b>ODK</b>	Open Data Kit
<b>OPV</b>	Oral Polio Vaccine
<b>OVP</b>	Open Vial Policy
<b>OVW</b>	Open Vial Wastage
<b>PCV</b>	Pneumococcal Conjugate Vaccine
<b>RVV</b>	Rotavirus Vaccine
<b>TT</b>	Tetanus Toxoid
<b>UIP</b>	Universal Immunization Programme
<b>UNICEF</b>	United Nations Children's Fund
<b>UNDP</b>	United Nations Development Programme
<b>VCCH</b>	Vaccine and Cold Chain Handler
<b>VVM</b>	Vaccine Vial Monitor
<b>WHO</b>	World Health Organization

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# Executive Summary

**This report presents the findings of the Open Vial Policy (OVP) implementation in India. The Universal Immunization Programme (UIP) in India targets to fully immunize 26 million newborns and 29 million pregnant mothers each year, making it one of the largest immunization programmes in the world.** Presently, 12 vaccines (10 nationally, 2 sub-nationally) are delivered free of cost to the community under UIP through more than 28,000 vaccine stores in the country.

In recent years, India has introduced many new vaccines along with modern methods of vaccine and logistics management. With the introduction of new and expensive vaccines in the UIP, vaccine wastage is a growing concern which makes it imperative to reduce vaccine wastage for improving immunization coverage. Many studies have also documented that the vaccine wastage rates are higher than expected and have a direct impact on vaccine availability at immunization sessions and government finances which in turn impacts the immunization coverage.

Till the starting of this decade, as per the vaccine management policy of the Government of India (GoI), all vaccine vials opened for an immunization session were discarded at the end of that session, irrespective of the type of vaccine or the number of doses remaining in the vial prior to 2013. Subsequently, the Open Vial Policy was introduced in India in 2013 for reducing both vaccine wastage as well as governmental healthcare costs for immunization. The Open Vial Policy was again revised in September 2015 which superseded all Open Vial Policy guidelines issued earlier. Implementation of Open Vial Policy allows reuse of partially used multi-dose vials of applicable vaccines under UIP

in subsequent session (both fixed and outreach) up to four weeks (28 days), subject to meeting certain conditions and thus reduces vaccine wastage.

The last Open Vial Policy assessment was carried out in 2015, with major policy-level changes and since then several underutilized and lifesaving new vaccines have been introduced. Hence, to assess the current status of Open Vial Policy implementation in India, the National Cold Chain and Vaccine Management Resource Centre - National Institute of Health and Family Welfare (NCCVMRC-NIHFW) conducted an assessment on Open Vial Policy implementation in India in February 2019 with joint collaboration of United Nations Children's Fund (UNICEF) under the able guidance of Ministry of Health and Family Welfare (MoHFW), GoI. The assessment was conducted to assess the implementation status of the latest policy and detail out the gaps in knowledge, and practices of the concerned staff with regard to Open Vial Policy.

This study ensured the active participation of all immunization stakeholders such as the World Health Organization (WHO), UNICEF, United Nations Development Programme (UNDP), John Snow Inc. (JSI), Immunization Technical Support Unit (ITSU), National Cold Chain Resource Centre (NCCRC), NCCVMRC and faculty of medical colleges (Dept. of Community Medicine). The data was collected from different levels of the immunization supply chain where Open Vial Policy is applicable i.e. Last Cold Chain Points (CCPs) and immunization session sites. Additionally, data was also collected from district level staff i.e. District Immunization Officer (DIO) and District level

Vaccine and Cold Chain Handler (VCCH) to understand their view on the implementation of Open Vial Policy. **The data collection was done across 12 states, 24 districts, 71 last CCPs and 93 session sites, using a structured pre-designed mobile application - based tool. It included data on:**

- **Training**
- **Knowledge**
- **Supportive supervision**
- **Practices related to Open Vial Policy at the last CCP and immunization session sites**
- **Perceptions & challenges related to Open Vial Policy implementation**

The data analysis was conducted using the pivot table approach on Microsoft Excel 2016 and was subsequently visualized using appropriate graphs, tables and diagrams.

It was observed that the Open Vial Policy was being implemented at all the CCPs and immunization session sites were assessed. However, the practices related to implementation varied across sampled sites. More than 70 per cent of the health staff interviewed at all levels were found to be trained on Open Vial Policy. About 80 per cent of the personnel interviewed had knowledge regarding the vaccines on which Open Vial Policy is applicable and the segregation and return of reconstituted/open Bacillus Calmette Guerin (BCG, Measles-Rubella (MR), Japanese Encephalitis (JE) and Rotavirus Vaccine (RVV) after the session to the CCP. Medical Officers (MOs) were the least to receive the training and had the least knowledge of the latest Open Vial Policy guidelines. The majority of the CCPs and session sites received some kind of supervision from the higher authorities in the last three months.

The major issues observed regarding Open Vial Policy by the supervisors were:

1. Practice of mentioning the date on open reconstitution vials/open RVV vials and time on liquid non-reconstitution vaccines.
2. Practice of returning the open vials of BCG, Measles/MR, JE and RVV from the session to the CCP and segregating them in the cold chain for 48 hours or the next session (whichever is earlier).

The physical condition of open vials was found to be satisfactory at the CCPs. **More than 90 per cent CCPs had open vials stored in their Ice-Lined Refrigerators (ILRs) and were found to be segregated from unopened vials but the mention of both date and time of opening was found only on 55 per cent of open vials.** The date was found mentioned on the majority of the vials. However, the mention of time on these vials was found to be an area of concern.

The practice of segregating reconstituted vaccines (BCG, MR and JE)/open RVV and storing them inside a cold chain was not found to be implemented at the majority of the CCPs. The stock of open vials was maintained at the majority of the CCPs which was majorly recorded correctly in vials.

At the immunization session sites, the majority of the open vials were found in good and usable condition except for the mention of date or time on some of the open vials. At the end of the session, the practice of segregation of unopened and opened vials was followed at the majority of the session sites. The practice of segregating the open BCG, Measles/MR, JE and RVV and sending them back to the CCP for storage was found at 80 per cent of the sessions. The majority (>90 per cent) of the Auxiliary Nurse Midwives (ANMs) were prioritizing the use of open vials before opening a new vial and were not discarding any open vial before it was empty.

The vaccines were returned to CCPs on the same day from all the session sites majorly through the Alternate Vaccine Delivery (AVD) mechanism (65 per cent).

**More than 90 per cent of the personnel interviewed at different levels of the supply chain felt that the implementation of the Open Vial Policy has benefitted the immunization programme by reducing vaccine wastage. 20 per cent VCCHs and 10 per cent ANMs responded that they faced some kind of difficulty in practicing the Open Vial Policy which was mainly attributed to record-keeping of open vials, recording date and time on the open vials and AVD functionality.**

To further strengthen the implementation of the Open Vial Policy, it is recommended that the existing policy may be expanded to include the following points:

- a. Storage of returned open vials of reconstituted vaccines (BCG, MR and JE)/RVV in the cold chain (in ILRs or passive containers)** - A decision may be made to allow the states to store returned open vials of reconstituted vaccines (BCG, MR and JE/RVV) either in ILRs or in passive containers maintaining the cold chain.
- b. Distribution and return of open and unopen vials to and from the immunization session site** - It is recommended that a policy may be framed for using three zipper pouch/bags while returning the vaccines at the end of the session for segregating unused, usable open/used and unusable open/used vials.

This will support in effective implementation of Open Vial Policy at the session site as well as the CCP by decreasing the chances of mixing and reissue of used BCG, MR, JE and RVV along with usable vaccines.

- c. Location of mentioning the date and time on the open vial** - In addition to the label of the vaccine, the policy may include mentioning the date and time on other parts of the open vials like on top of the vial, neck of the vial and pasting a sticker on the vial with date and time mentioned on it.

In addition to the policy level changes, it is also recommended to:

- **Strengthen the practices of the VCCHs and vaccinators through refresher training, on-the-job mentoring/ supportive supervision and quarterly review meetings**
- **Scale up Electronic Vaccine Intelligence Network (eVIN) across the nation**
- **Develop easy to understand pictorial job aids**
- **Strengthen the review mechanism**





# BACKGROUND

# 1. Background

Immunization against Vaccine Preventable Diseases (VPDs) is one of the most successful child survival interventions across the globe, bringing about significant reduction in adverse health consequences and subsequently improving the health of millions. The Universal Immunization Programme (UIP) in India targets to fully immunize 26 million newborns and 29 million pregnant mothers each year, making it one of the largest immunization programmes in the world.<sup>2</sup>

Since the inception of the National Health Mission in India in 2005, several steps have been taken to strengthen UIP, important ones being:

- **Introduction of Auto-Disabled (AD) syringes**
- **Mobilization of beneficiaries to the immunization session site through Accredited Social Health Activists (ASHAs)**
- **Transportation of vaccines and logistics to the session site and back through the Alternate Vaccine Delivery (AVD) system.**<sup>3</sup>

New vaccines have been introduced along with modern methods of vaccine and logistics management. With the introduction of new and expensive vaccines in the UIP, vaccine wastage is a growing concern which makes it imperative to reduce vaccine wastage for improving immunization coverage. UIP guidelines dictate that a fresh vaccine vial is to be opened at the immunization session even if there was only one child requiring vaccination.<sup>4</sup> Vaccine wastage rates are higher than expected and have a direct impact on vaccine availability at immunization sessions and

government finances. Any vaccine wastage translates into fewer vaccine doses actually available to children and also a higher cost of vaccination.<sup>5</sup>

Open Vial Wastage (OVW) occurs when the vials opened for immunization are not completely utilized. OVW can be reduced if the appropriate vial size of each vaccine would be used but smaller size vials can overwhelm the capacity of many storage facilities and transport vehicles, and simultaneously increase the cost of vaccination. Hence vaccines are usually supplied in multi-dose vials. Effective vaccine utilization is an integral component of vaccine safety and vaccine wastage, in particular, is one of the key factors to be considered with regard to vaccine forecasting and need estimation.

Till the initial part of the last decade, the immunization policy stated that all vaccine vials opened for an immunization session had to be discarded at the end of that session, irrespective of the type of vaccine or the number of residual doses in the vial. This policy led to a high wastage of life-saving vaccines. So, in order to reduce vaccine wastage in open vials, the Government of India (GoI) adopted the Open Vial Policy as a strategy to streamline usage and to prevent the wastage of a potent vaccine. With adequate field training, supervision and monitoring, correct implementation of the OVP can decrease vaccine wastage while ensuring safety, thereby reducing costs in field use and overcoming storage and transport constraints.

# Open Vial Policy

The Open Vial Policy is a globally accepted strategy to optimally utilize multi-dose vaccine vials. The strategy was endorsed by WHO as Multi-Dose Vial Policy (MDVP) in 2000, and the GoI adopted the OVP under the UIP for all non-reconstituted vaccines in February 2013. The Open Vial Policy was revised in September 2015 which superseded all Open Vial Policy guidelines issued earlier.

Implementation of Open Vial Policy allows reuse of partially used multi-dose vials of applicable vaccines under UIP in subsequent session (both fixed and outreach) up to four weeks (28 days), subject to meeting certain conditions and thus reduces vaccine wastage.

Open Vial Policy is applicable on Diphtheria Pertussis Tetanus (DPT), Tetanus Toxoid/Tetanus-Diphtheria (TT/Td), Hepatitis-B, Oral Polio Vaccine (OPV), Haemophilus Influenza type B (Hib) containing Pentavalent vaccine, injectable Inactivated Poliovirus Vaccine (IPV) and Pneumococcal Conjugate Vaccine (PCV). Open Vial Policy does not apply to Measles/MR, BCG, JE and RVV.

Any vial of the applicable vaccines opened/used in a session (fixed or outreach) can be used at more than one immunization session up to four weeks (28 days) provided that:

1. The expiry date has not passed.
2. The vaccines are stored under appropriate cold chain conditions both during transportation and storage in cold chain storage point.
3. The vaccine vial septum has not been submerged in water or contaminated in anyway.

4. Aseptic technique has been used to withdraw vaccine doses (that is needle/septum has not been contaminated in anyway).
5. The Vaccine Vial Monitor (VVM) has not reached/crossed the discard point.

All vaccine vials have to be segregated by the vaccinator into used and unused category and kept inside a properly sealed zipper pouch/bag in the vaccine carrier under the cold chain (reverse cold chain). Also, ensure the carrier is picked up by the AVD mechanism to be delivered at the designated vaccine/cold storage point.

At the CCP, the VCCH should ensure appropriate segregation of the vaccines into opened and unopened vials, and follow the instructions as below:

## Unopened Vials

- If VVM is intact and in the usable stage, retain the vial in ILR as per guideline, and issue accordingly.
- If VVM is not in the usable stage or there is partial/complete defacement of the label, retain the vial in a plastic box clearly marked "Not to be used" in ILR.

## Opened Vials

- Segregate the vials on which Open Vial Policy is not applicable such as BCG, Measles/MR, JE and RVV and retain in a plastic box clearly marked "Not to be used" in ILR. These vials should be discarded after 48 hours or before the next session whichever is earlier. In case of any reported Adverse Events Following Immunization (AEFI), they will not be discarded but retained for investigation.

- Segregate the vials for which Open Vial Policy is applicable such as OPV, DPT, Hepatitis-B, Pentavalent, IPV and PCV as below:
  - If VVM is intact and is in the usable stage, retain the vaccine vial in ILR as per guideline subjected to the condition that vial is within 28 days of opening (as found from date marked on the vial) and reissue in the next session after ensuring that it has not passed 28 days of opening the vial.
  - If VVM is intact and is in the usable stage, but the vaccine vial has crossed 28 days of opening (as found from the date marked on the vial) then these vials should be discarded after ascertaining that they are not required for AEFI investigation.
  - If VVM is not in the usable stage or there is partial/complete defacement of the label, retain them in a plastic box clearly marked “Not to be used” in ILR. These vaccine vials should be discarded after 48 hours or before the next session, whichever is earlier.
  - If there is any vial that has been used and there is a report of AEFI, then that vial (even if it is in the usable stage) has to be kept separately in a properly sealed zipper bag earmarked “For AEFI Investigation” in ILR under special custody and in the knowledge of Medical Officer. This vial should never be issued to anyone unless authorized by DIO.

## Rationale

The OVP is a major policy initiative and directly affects vaccine logistics management practices at the last CCP. It attempts to address vaccine wastage by optimizing the use of opened vials in liquid presentation and thus potentially has an impact on both the government finances and

vaccine availability. However, the guidelines and principles highlighted in the policy needs to be systematically implemented to ensure vaccine safety during storage and handling.

The last national Open Vial Policy assessment was done in the year 2014-15 in which it was concluded that the practice of implementation of Open Vial Policy was different not only from one state to the other but also between various CCPs within one district itself. On an average

**55%**

**of the CCPs segregated the vials (opened and unopened)**

**45%**

**did segregation either antigen wise or date-wise or did not segregate at all**

The practice of mentioning date and time on the open vials was found diverse: with some CCPs mentioning only the date, others mentioning both date and time, and yet others mentioning neither date nor time.

Considering the above findings of the last assessment, issue of revised Open Vial Policy by Gol in September 2015 and introduction of many new vaccines under UIP, it is essential to

- Review the status of implementation of the OVP at the field level
- Assess the knowledge and practices of the health workers related to Open Vial Policy
- Document the perceptions and challenges faced by health workers

This will help central/state governments in identifying OVP implementation gaps and in planning implementation improvement measures.



# OBJECTIVES



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## 2. Objectives

### General Objectives

- To assess the implementation of Open Vial Policy for vaccines as per the latest Open Vial Policy guidelines.

### Specific Objectives

- To assess the knowledge of district-level staff on the latest Open Vial Policy guidelines.
- To assess the knowledge and skills of Cold Chain Handlers and ANMs regarding the latest Open Vial Policy guidelines.
- To assess the perceptions and challenges of the Frontline Workers in the implementation of the Open Vial Policy.
- To provide recommendations for strengthening the existing policy and implementation processes and practices.



# METHODOLOGY

# 3. Methodology

The assessment was conducted jointly by NCCVMRC-NIHFW and UNICEF under the guidance of MoHFW.

## 3.1 Selection of Sample

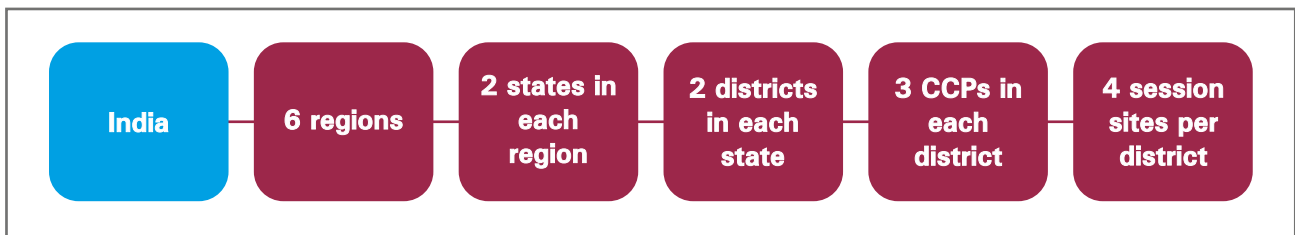
### A. Sampling Technique and Selection Criteria

A multi-stage sampling technique was used to ensure a holistic sample representative of the immunization programme in India. We used the below-mentioned criteria for the selection of our sample.

- Geographical representation
- Best and poor performing states in terms of Full Immunization Coverage (FIC) (NFHS-4)

### B. Selection of Sampling Sites

FIGURE 1 : FLOW CHART DEPICTING MULTI-STAGE SAMPLING OF DATA COLLECTION SITES



For the study, India was divided into six geographical regions viz. Central, East, North, North-East, South and Western India.

### I. Selection of States

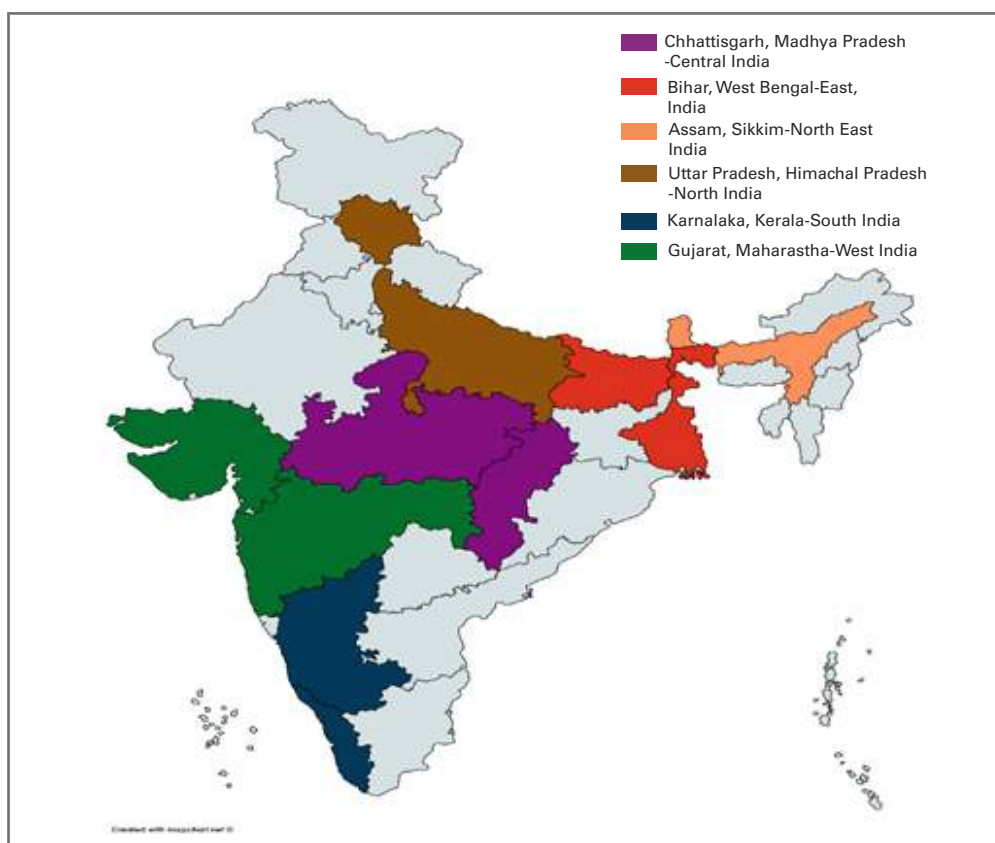
The states were selected from each region based on their FIC (Source: NFHS-4). From each region, two states were chosen, one with the highest and one with the lowest FIC. Refer to table 1 and figure 2.



**TABLE 1: SELECTION OF STUDY STATES BASED ON THEIR GEOGRAPHY AND IMMUNIZATION PERFORMANCE**

Sr. No.	State	Zone	FIC (NFHS-4)	Category	Remarks
1.	Madhya Pradesh	Central India	53.60%	Low FIC	There are only 2 states in central India & both states have been selected
2.	Chhattisgarh		76.40%	High FIC	
3.	Bihar	East India	61.70%	Low FIC	
4.	West Bengal		84.40%	High FIC	
5.	Assam	North-East India	47.10%	Low FIC	Nagaland and Arunachal Pradesh were dropped because of geographic constraints
6.	Sikkim		83.00%	High FIC	
7.	Uttar Pradesh	North India	51.10%	Low FIC	Himachal Pradesh was selected due to its hilly and cold climate zone
8.	Himachal Pradesh		69.50%	High FIC	
9.	Karnataka	South India	62.60%	Low FIC	
10.	Kerala		82.10%	High FIC	
11.	Gujarat	West India	50.40%	Low FIC	
12.	Maharashtra		56.30%	High FIC	

**FIGURE 2: MAP SHOWING SAMPLED STATES**



## II. Selection of Districts

The next stage of sampling included the selection of two districts from each state based on their highest and lowest FIC status (Source: NFHS-4). Figure 3 lists the districts selected from each state based on their FIC.

**FIGURE 3: SELECTION OF DISTRICTS BASED ON FIC (SOURCE: NFHS-4)**

<b>Karnataka</b>	Chikmangalur: 41% Dakshina Kannada: 77%	<b>Chhattisgarh</b>	Jashpur: 50% Durg: 90%
<b>Kerala</b>	Kozhikode: 70% Kottayam: 95%	<b>Madhya Pradesh</b>	Alirajpur: 23% Raisen: 78%
<b>Gujarat</b>	Panchmahal: 30% Navsari: 78%	<b>Bihar</b>	West Champaran: 29% Saharsa: 78%
<b>Maharashtra</b>	Nandurbar: 33% Gadchiroli: 82%	<b>West Bengal</b>	Uttar Dinajpur: 66% Bankura: 96%
<b>Sikkim</b>	West District: 78% South District: 92%	<b>Uttar Pradesh</b>	Ambedkar Nagar: 66% Jyotiba Phule Nagar: 96%
<b>Assam</b>	Dhubri: 20% Sivasagar: 73%	<b>Himachal Pradesh</b>	Hamirpur: 46% Shimla : 87%



### III. Selection of Cold Chain Points

Within each selected district, three CCPs were randomly selected.

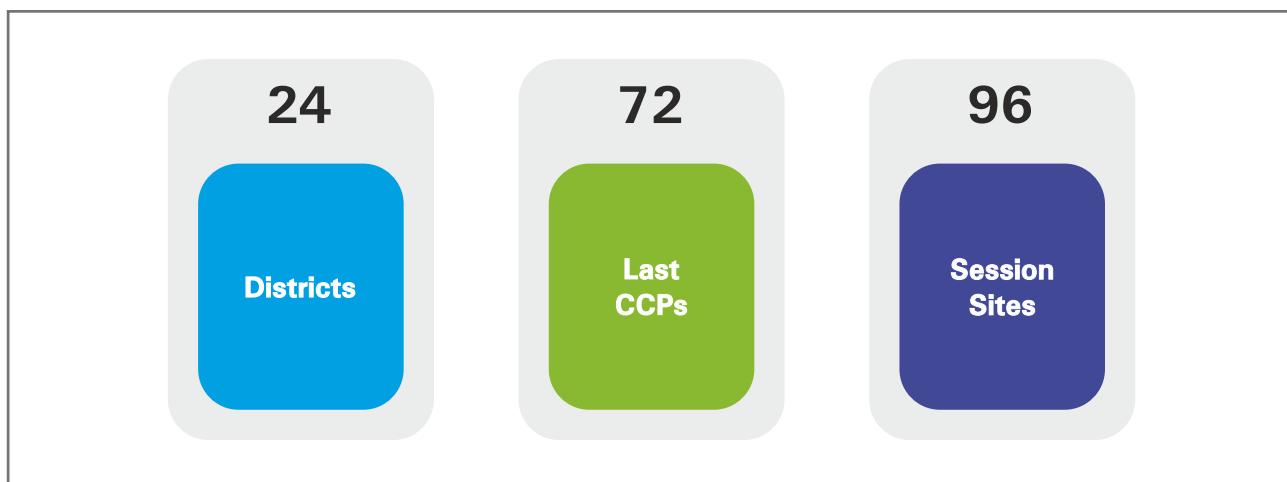
### IV. Selection of Session Sites

Four session sites were selected randomly in each district. A total of 96 session sites were planned to be assessed in the selected 24 districts.

### C. Sample Sites Selected

The assessment was done at the district, CCP and session site level. A total of 24 districts, 72 last CCPs and 96 session sites were selected for data collection as depicted in figure 4.

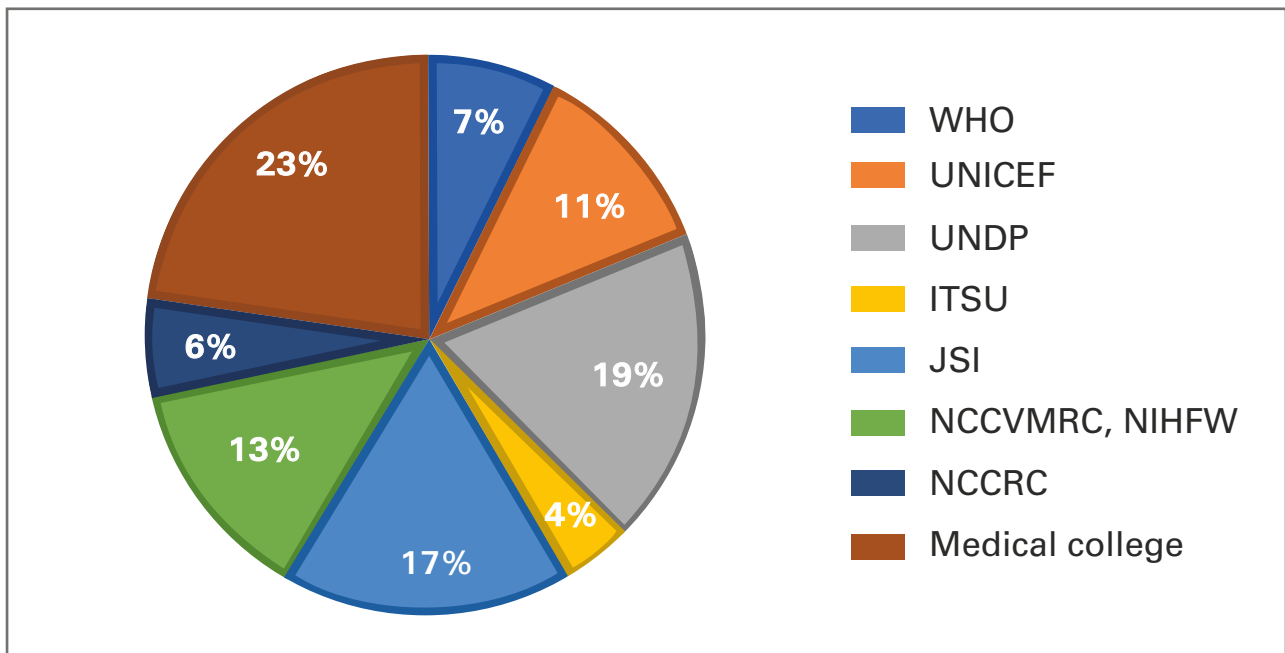
**FIGURE 4 : NUMBER OF SAMPLE SITES SELECTED AT ALL LEVELS**



### 3.2 Data Collection Teams

The data collection was done by immunization experts from various organizations like WHO, UNICEF, UNDP, ITSU, JSI, NCCVMRC, NIHFW, NCCRC, faculty and residents from Medical Colleges and external consultants. A total of 27 teams were created for the data collection activity which comprised of 53 assessors (list attached as annexure). The data collection activity was conducted from 25 February to 3 March 2019. The involvement of various organizations in this activity is depicted in the figure below

**FIGURE 5: PROFILE OF ASSESSORS IN DATA COLLECTION TEAMS (N = 53)**



### 3.3 Training of Assessors

One-day training of assessors was conducted at The National Institute of Health and Family Welfare (NIHFW), Delhi before the field data collection on 22 February 2019 and the training covered the following topics:

- ▶ Overview and methodology of the assessment
- ▶ Update on revised Open Vial Policy guidelines
- ▶ Orientation on Open Vial Policy assessment tool
- ▶ Hands-on session on the mobile application for data collection

### 3.4 Data Sources

At all levels, the data was collected using interviews and observations through a data collection tool. Documents such as training records, stock registers and vaccine distribution records were used to understand the implementation of Open Vial Policy.

**Availability of the following documents was checked at all levels:**

1. Demographic profile/Routine Immunization (RI) microplan
2. Training materials/reference documents
3. Supervisory visit reports
4. Vaccine stock and distribution records

### 3.5 Data Collection Technique and Study Respondents

Both quantitative and qualitative data were collected using a pre-designed tool at all levels in this study.

One-on-one interviews were conducted with District Level Programme Managers, VCCHs and ANMs to review and understand various operational mechanisms of the programme using the predesigned questionnaire. Observations were done for assessing the practices using the predesigned questionnaire. The study respondents planned to be interviewed at each site are as depicted in table 2.

**TABLE 2 : STUDY RESPONDENTS AT ALL LEVELS**

Sr. No.	Site visited (N)	Personnel interviewed	No. of respondents
1.	District Vaccine Store (DVS) (24)	DIO	24
		DVS Manager/Storekeeper	24
2.	Last CCP (72)	Medical Officer	72
		VCCH	72
3.	Immunization Session Site (96)	ANMs	96
		Total	288

### 3.6 Data Collection Tool

A pre-designed semi-structured questionnaire was used for data collection. The following thematic areas related to Open Vial Policy were covered:

1. Training on Open Vial Policy
2. Knowledge of Open Vial Policy
3. Supportive supervision
4. Vaccine management practices at
  - a. Last CCP
  - b. Immunization session site level

The data collection tool was finalized following a desk review conducted with immunization experts from partner organizations. The finalized tools were converted into a mobile-based Open Data Kit (ODK) platform to enable real-time data capture and transfer from the field to the designated data server, ensuring real-time monitoring of data quality. The mobile-based tools were pilot tested in District Gurugram, Haryana for field applicability prior to actual fieldwork. The data collected during pilot testing of tools has been excluded from the assessment.

### 3.7 Quality Assurance Mechanism

To ensure the quality of data collected, the following steps were taken:

- A WhatsApp group was formed with all the assessors where a regular update was being shared.
- A control room was setup at NCCVMRC, NIHFW to respond to any query raised by the assessors.
- A senior-level monitoring team also visited some data collection sites to monitor the data collection activity as well as provide any necessary support required by the assessors.

### 3.8 Data Analysis

Dummy tables were generated initially. Input, process and output indicators were identified to capture the following thematic areas:

- General profile of the sites visited
- Knowledge regarding the Open Vial Policy
- Training on Open Vial Policy
- Practices at the CCP
- Practices at the immunization session sites

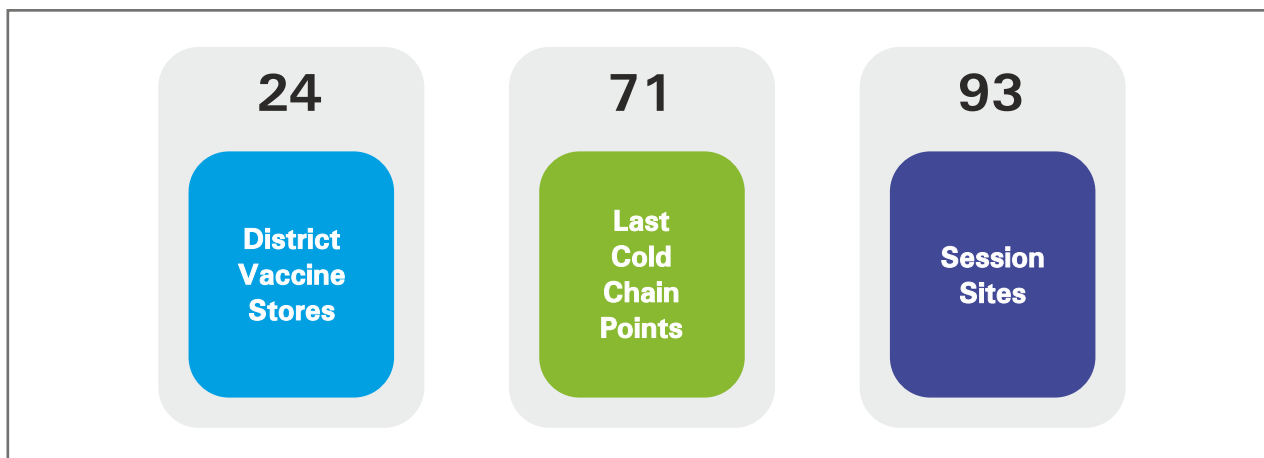
Analysis was done using Microsoft Excel 2016 and descriptive tables were generated to summarize the findings. The data was represented as proportions, percentages and means. All efforts were taken to maintain the confidentiality of all participants. Following the interview, all the participants were communicated the right practices as per the Open Vial Policy.



# ASSESSMENT RESULTS

# 4. Assessment Results

**FIGURE 6: SAMPLE SITES COVERED IN ASSESSMENT**



The data could not be collected from one CCP and three session sites due to time constraints and some administrative issues.

## 4.1 General Profile

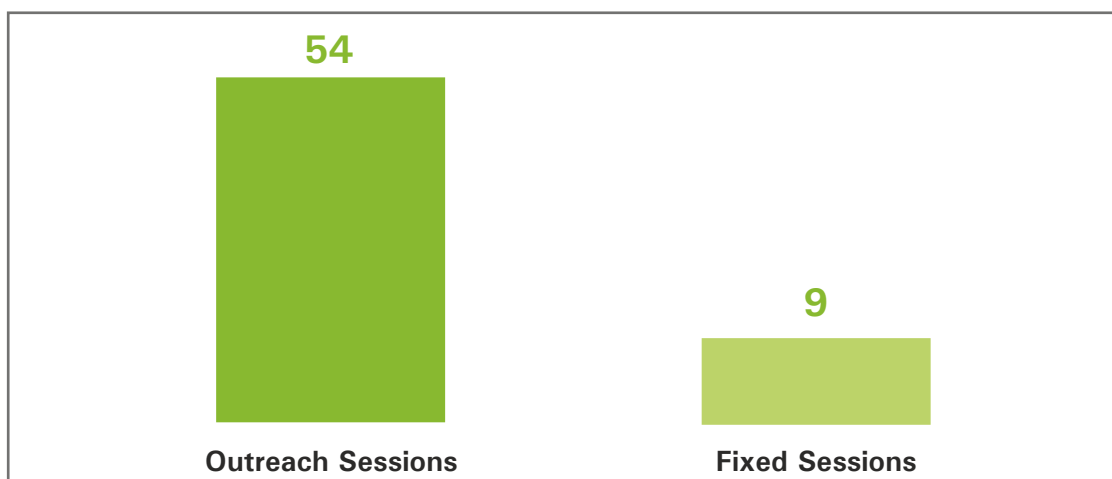
Out of the total 71 last CCPs visited, 70 per cent were rural CCPs and out of 93 immunization session sites visited, 87 per cent were rural session sites. Refer to table 3.

**TABLE 3: DISTRIBUTION OF LAST COLD CHAIN POINTS AND IMMUNIZATION SESSION SITES**

Sr. No.	Facility/Session site (n)	Rural		Urban		Total	
		n	%	n	%	n	%
1.	Last CCP (71)	50	70	21	30	71	100
2.	Immunization Session Sites (93)	81	87	12	13	93	100

The average number of monthly outreach session sites linked to the last CCP was 54 and the average monthly fixed sessions linked to the CCP was nine. Refer to figure 7.

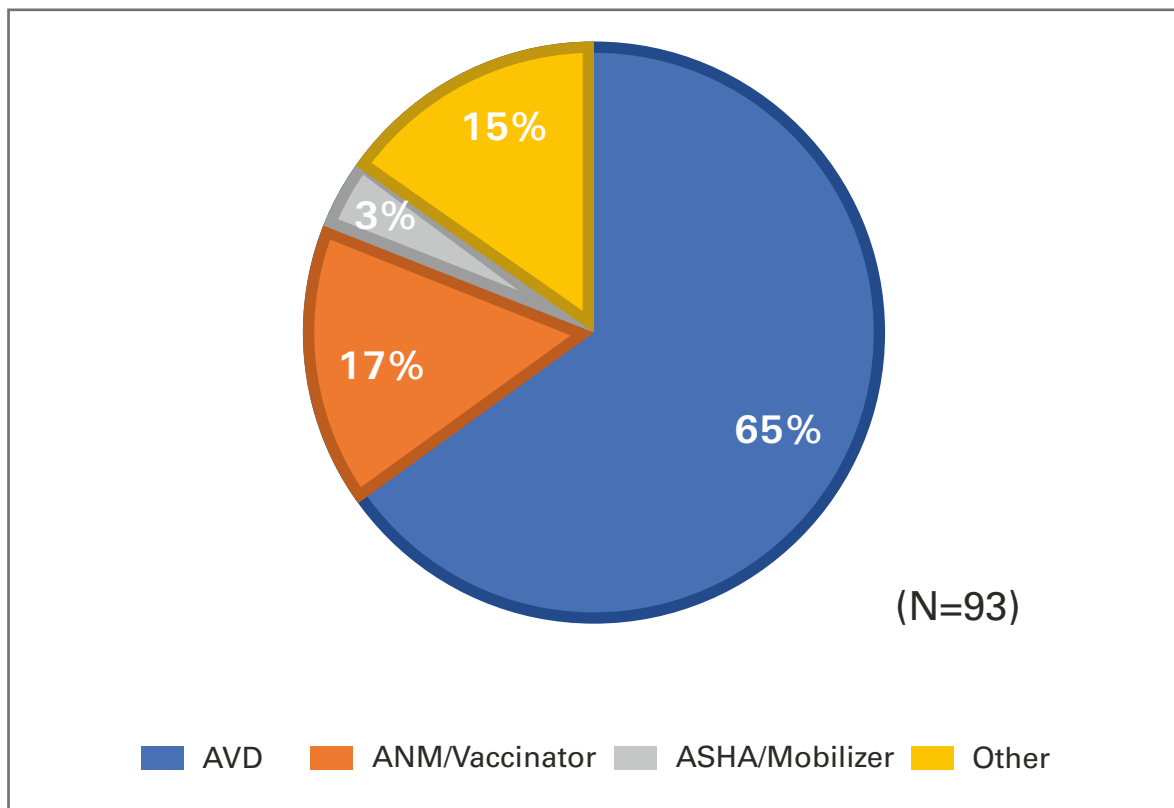
**FIGURE 7: AVERAGE MONTHLY SESSIONS LINKED TO A COLD CHAIN POINT**



**Availability of mobilizers at the session sites:** ASHAs were present at about 81 per cent of the sessions and the availability of Anganwadi workers was 58 per cent.

**Vaccine delivery mechanism at immunization session site:** The vaccine delivery process from the last CCP to the session site was also assessed which is shown in figure 8. At 65 per cent of session sites, the vaccines were delivered to the session sites through the AVD mechanism and at 17 per cent of sessions, vaccines were delivered by ANM/Vaccinator herself. Very few sessions (3 per cent) had vaccines delivered by ASHA/Mobilizer. At the remaining 15 per cent of session sites, the vaccines were delivered through other mechanisms e.g. through the Medical Officer, Supervisor, Pharmacist etc.

**FIGURE 8: MECHANISM OF VACCINE DELIVERY TO SESSION SITE**



## 4.2 Training, Knowledge and Supervision on Open Vial Policy

The average experience of managing the vaccine and cold chain among different healthcare personnel at all levels was found to be more than 10 years, except at the district level where DIOs had an average experience of around 4-5 years. In the case of DIOs, it was also observed that in addition to immunization, the majority (92 per cent) of the DIOs were also handling multiple programmes like Maternal and Child Health, Surveillance etc.

## A. Training

The status of training at all levels on Open Vial Policy is depicted in the table below:

**TABLE 4: STATUS OF TRAINING OF HEALTH STAFF ON OPEN VIAL POLICY AT ALL LEVELS**

Level	Staff cadre	Training received - n (%)	Training material received - n (%)
District	DIOs (n = 24)	20 (83)	19 (78)
	VCCH (n=24)	23 (96)	13 (54)
Last CCP	MOs (n=71)	48 (68)	53 (75)
	VCCHs (n=71)	53 (78)	48 (68)
Session Site	ANMs (n=93)	72 (77)	56 (60)
<b>Total</b>	<b>N = 283</b>	<b>216 (76)</b>	<b>189 (67)</b>

Most of the VCCHs/Storekeepers at DVS (96 per cent) were found to be trained followed by DIOs and VCCHs posted at the last CCPs. Among all personnel interviewed, training on OVP was found to be most limited among MOs (68 per cent). Training material on Open Vial Policy was received by the majority of the DIOs (78 per cent) followed by MOs (75 per cent). Very few district-level VCCHs received the training material on Open Vial Policy (54 per cent).

## B. Knowledge

The knowledge of the staff posted at a different level was assessed on Open Vial Policy, the details of which are given in table 5 below:

**TABLE 5: KNOWLEDGE OF HEALTH STAFF REGARDING OPEN VIAL POLICY**

Level	Knowledge Regarding			
	Applicability of Open Vial Policy on type of vaccines		Segregation and return of reconstituted/open BCG, MR, JE and RVV from session to the CCP	
	n	(%)	n	(%)
DIO (n = 24)	22	91	20	82
VCCH (n = 24)	22	91	18	77
<b>Last CCP</b>				
MO (n = 71)	36	51	51	72
VCCH (n = 71)	66	93	57	80
<b>Session Site</b>				
ANMs (n = 93)	81	87	79	85
<b>Total (N = 283)</b>	<b>227</b>	<b>80</b>	<b>225</b>	<b>80</b>

The majority (80 per cent) of the personnel interviewed had knowledge regarding the vaccines on which Open Vial Policy is applicable and the segregation and return of reconstituted/open BCG, MR, JE and RVV after the session to the CCP. Only 51 per cent MOs were found to be aware of the vaccines on which Open Vial Policy is applicable.

More than 85 per cent of VCCHs at the last CCP could mention mandated conditions required for correct implementation of OVP guidelines, such as:

- ▶ Expiry date
- ▶ VVM status
- ▶ Opened vial should be within four weeks of the date of opening
- ▶ Clearly written date and time on the opened vial

The other two conditions, such as the use of an aseptic technique while withdrawing the dose and non-submerged vaccine vial septum (in water), could be explained by 50 per cent of VCCHs only.

96 per cent VCCHs and ANMs knew that reconstituted BCG and Measles/MR vaccine can be used within four hours after reconstitution but only 76 per cent VCCHs knew that reconstituted JE vaccine can be used within four hours after reconstitution.

Among interviewed respondents, 94 per cent VCCHs and 97 per cent ANMs had correct knowledge regarding the use of open vials of Penta, DPT, TT, OPV and IPV.

### C. Correlation between Training in Open Vial Policy and Knowledge and Practices

The knowledge and practices of the staff posted at different levels were compared with their status of training received in Open Vial Policy implementation. The details are listed in table 6, 7 and 8 below:

**TABLE 6: COMPARISON OF TRAINING OF STAFF REGARDING OPEN VIAL POLICY AND THEIR KNOWLEDGE AT DVS LEVEL**

		Trained, n (%)	Untrained, n (%)
DIO (n = 24)		Trained (n = 20)	Untrained (n = 4)
Having correct knowledge of	Applicability of Open Vial Policy on type of vaccines	19/20 (95%)	3/4 (75%)
	What to be done with the reconstituted/open BCG, MR, JE and RVV vials at the session site?	18/20 (90%)	3/4 (75%)
	Reading VVM	19/20 (95%)	3/4 (75%)

As it can be seen from the table above, that DIOs who had been trained in Open Vial Policy, more than 90 per cent had knowledge on:

- Types of vaccines on which Open Vial Policy is applicable
- Segregation of open reconstituted vaccines
- Reading the VVM

At the DVS level, knowledge of Storekeepers/VCCH was also assessed but is not depicted here due to inadequate sample size for comparison between trained vs untrained as only one VCCH was found to be untrained.

**TABLE 7: COMPARISON OF TRAINING OF STAFF REGARDING OPEN VIAL POLICY AND THEIR KNOWLEDGE AT LAST CCP LEVEL**

		Trained, n (%)	Untrained, n (%)
<b>MO(N= 71)</b>		<b>N = 48</b>	<b>N= 21</b>
<b>Knowledge regarding</b>	Applicability of Open Vial Policy on type of vaccines	30/48 (62.5)	4/21 (19)
	Segregation and return of reconstituted/open BCG, MR, JE and RVV from session to the CCP	40/48 (83.3)	10/21 (47.6)
	Reading VVM	46/48 (95.8)	17/21 (81)
<b>VCCH (N= 71)</b>		<b>N = 53</b>	<b>N= 18</b>
<b>Knowledge regarding</b>	Applicability of Open Vial Policy on type of vaccines	53/53 (100)	13/18 (72.2)
	Knowledge of reading VVM	45/53 (84.9)	12/18 (66.7)
<b>Practice of</b>	Segregating opened vials from unopened vials in ILR	50/53 (94.3)	13/18 (72.2)
	Open vials of BCG, Measles/MR*, JE* and RVV* segregated and kept inside cold chain for 48 hours or next session	38/53 (71.7)	10/18 (55.5)

Among the MOs who had received training, 83.3 per cent had the knowledge of segregating and returning reconstituted open vials to the last CCP, while among untrained only 47.6 per cent had this knowledge. Similarly, the knowledge levels in trained VCCH were higher as compared to untrained VCCH. Practices related to segregating opened vials from unopened vials in ILR was found to be better in trained VCCH (94.3 per cent) compared to untrained VCCH (72.2 per cent).



**TABLE 8: COMPARISON OF TRAINING OF STAFF REGARDING OPEN VIAL POLICY AND THEIR KNOWLEDGE & PRACTICES AT SESSION SITE LEVEL**

		Trained, n (%)	Untrained, n (%)
ANM (N = 93)		N = 72	N = 21
<b>Knowledge regarding</b>	Applicability of Open Vial Policy on type of vaccines	66/72 (91.7)	15/21 (71.4)
	Segregation and return of reconstituted/open BCG, MR, JE and RVV from session to the CCP	64/72 (88.9)	15/21 (71.4)
<b>Practice of</b>	Segregation opened vials from unopened vials in vaccine carrier	40/72 (55.5)	14/21 (66.7)
	ANM prioritizing the use of open vial before opening a new vial	71/72 (98.6)	19/21 (90.4)
	All the unopened and open vials returned to the CCP on the same day at the end of the session	71/72 (98.6)	21/21 (100)

There was not much difference in the practice of segregating opened and unopened vials in vaccine carrier in both trained and untrained ANMs and in both cases, correct practice was found in less than 70 per cent of ANMs. This area needs more emphasis on training.

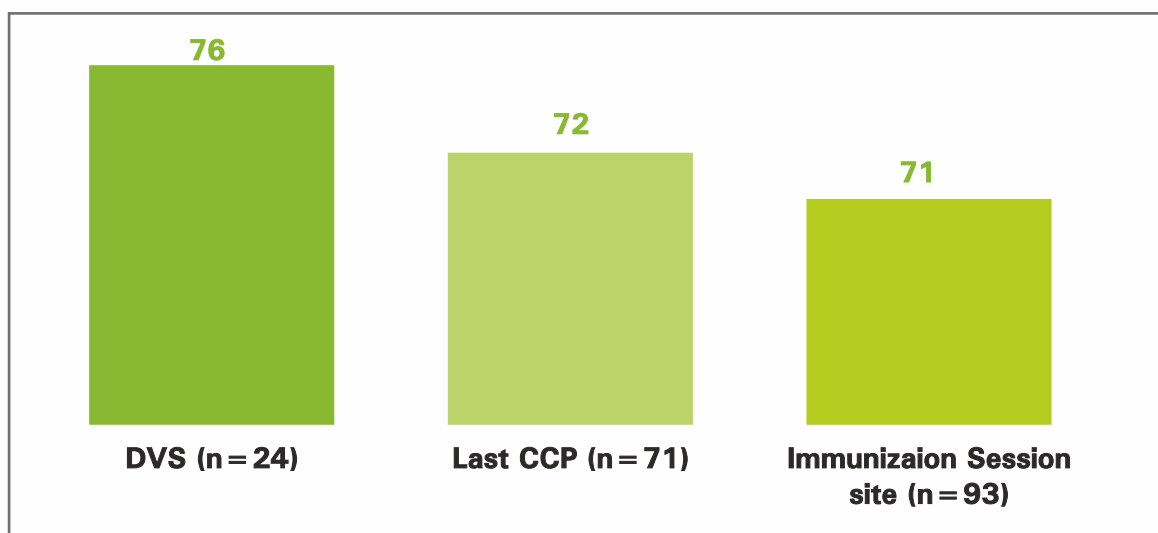
Almost all ANMs, trained (98.6 per cent) and untrained (100 per cent) were following the practice of returning all vials to CCP on the same day at end of the session.



## D. Supervision

More than 70 per cent of CCPs (district and last CCP) and immunization session sites received supervision from higher authorities at least once in the last three months before the assessment. Refer to figure 9.

**FIGURE 9: STATUS OF SUPERVISION RECEIVED AT ALL LEVELS IN THE LAST 3 MONTHS**



It was found that during the supervisory visits, very few issues related to Open Vial Policy were raised. The major issue raised during the supervisory visits was the vaccinator not mentioning the date and time of reconstitution/opening the vial at the session site. The practice of not returning the reconstituted/open BCG, MR, JE and RVV vials was also a finding during the supervisory visits.

### 4.3 Implementation of Open Vial Policy

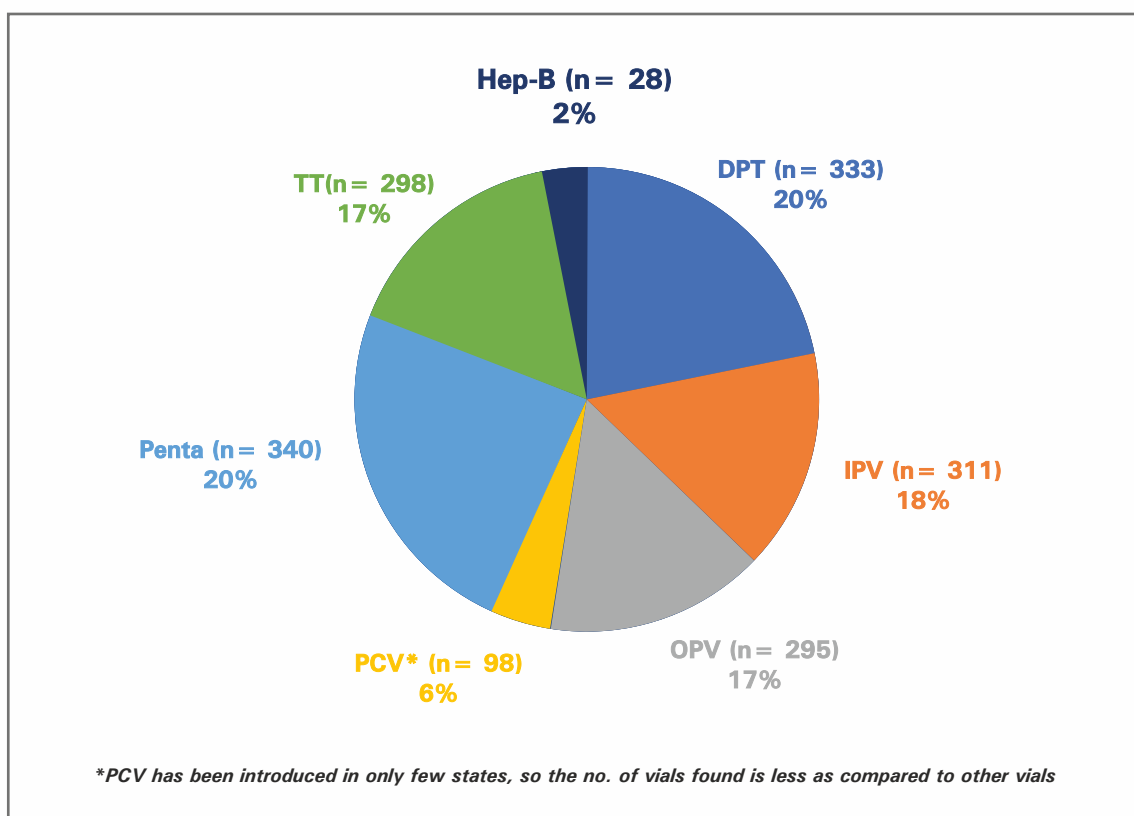
It was observed that the Open Vial Policy was being implemented at all CCPs and immunization session sites assessed, though practices related to implementation varied across sampled sites. The details of practices related to implementation at the last CCPs and immunization session sites are given below.

#### A. At Last Cold Chain Points

At each CCP, at least one designated staff working as VCCH was found. A total of 1,703 open vials (DPT, IPV, OPV, PCV, Penta, TT and Hepatitis-B) were found stored inside in ILR in 69 (97 per cent) out of 71 last CCPs. The figure below depicts the type and distribution of open vials observed at the last CCP.



**FIGURE 10: TYPE AND DISTRIBUTION OF OPEN VIALS OBSERVED AT THE LAST COLD CHAIN POINTS**



### Condition of Open Vials

The details of the parameters depicting the condition of the observed open vials are given in table 9 below.

**TABLE 9: PARAMETERS DEPICTING THE CONDITION OF OPEN VIALS OBSERVED AT THE LAST COLD CHAIN POINTS**

Sr. No.	Parameters	N	(%)
1.	Number of open vials observed	1,703	100
2.	Septum visibly okay and non-leaking	1,702	99.9
3.	Readable label	1,701	99.9
4.	Open vial within the expiry date	1,701	99.9
5.	VVM visible	1,698	99.7
6.	VVM in usable stage	1,683	98.9

## Recording Date and Time on Open Vials

Out of 1,703 open vials observed (excluding BCG, MR, JE and RVV), the practice of recording date on vial was found on 98 per cent of vials. The practice of mentioning both the date and time of opening the vials was recorded only on 936 vials (55 per cent) of which the lowest recording was found on Hepatitis-B vials (43 per cent). The practice of mentioning time on the open vial was found to be an area of concern. In more than 90 per cent of open vials where the date is mentioned, the date of opening was found to be within 28 days of the date of vial opening.

## Practices at the last CCPs

- At 65 (91.5 per cent) CCPs, unopen and open vials were found segregated and kept inside ILR.
- At 43 (63 per cent) CCPs, open vials of reconstituted vaccines (BCG, MR and JE)/open RVV) were segregated and kept inside the cold chain for 48 hours.
- At 18 (25 per cent) CCPs, the open vials were found to be segregated ANM/Sub-Centre wise. At 48 (68 per cent) CCPs, the open vials were segregated in a mixed manner. At the remaining five CCPs, other mechanisms were followed like supervisor wise segregation, vaccine vial wise segregation etc.
- The record of 1,553 (91.2 per cent) vials out of 1,703 vials were found in the vaccine distribution register.
- At 64 (90 per cent) CCPs, the records of the distribution of open vials were found. Out of these 64 CCPs, 57 (89 per cent) CCPs had the open vials correctly recorded in vials and the rest seven (11 per cent) had the record in doses.
- At 58 (81.6 per cent) CCPs out of 71, the record of open vials received back from the session site was found. Out of these 58 CCPs, 54 (93 per cent) CCPs had the open vials correctly recorded in vials and the rest four (7 per cent) had the record in doses.



**Open vials stored inside an ILR at the CCP**

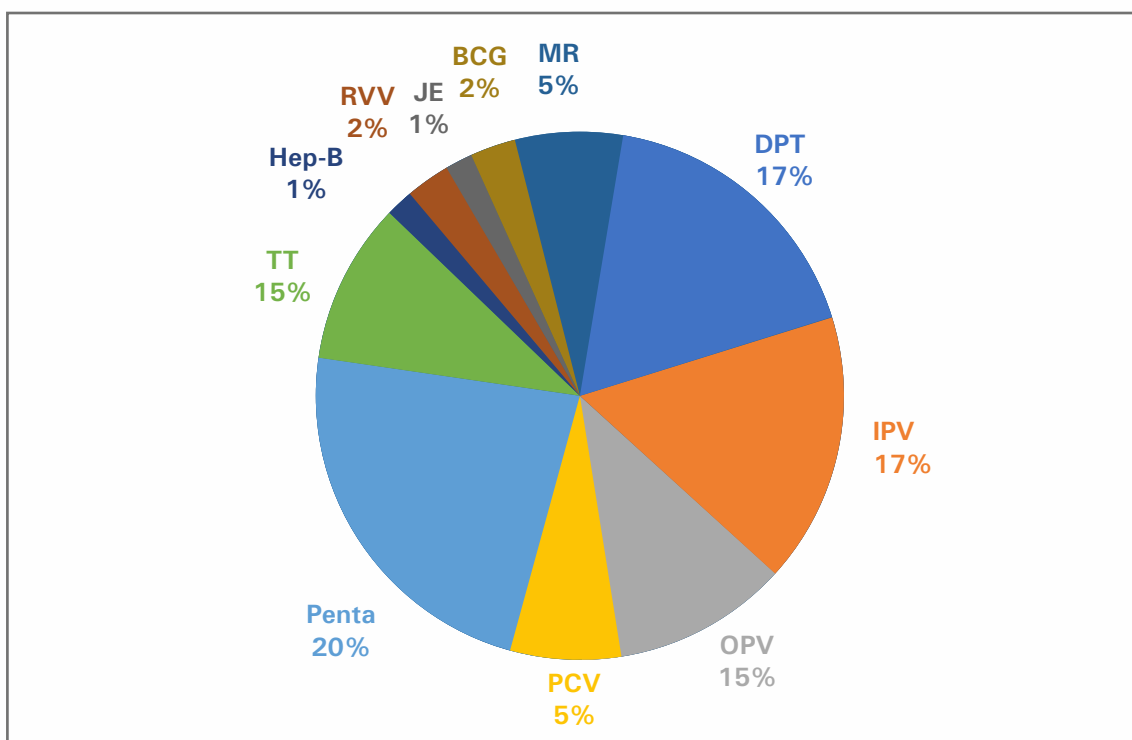
## B. At Immunization Session Sites

A total of 402 open vials were found at the 93 immunization session sites. Figure 12 depicts the type and distribution of open vials observed at the last CCP.

**FIGURE 11: IMMUNIZATION SESSION CONDUCTED IN PRESENCE OF MEDICAL OFFICER AT DISTRICT KOTTAYAM, KERALA**



**FIGURE 12: TYPE AND DISTRIBUTION OF OPEN VIALS OBSERVED AT THE IMMUNIZATION SESSION SITES**



### Condition of Open Vials

Among 402 open vials across 93 session sites, 360 open vials (DPT, IPV, OPV, PCV, Penta, TT and Hepatitis-B) and 42 reconstituted vials (BCG/MR/JE) and open RVV were observed at the immunization sessions. The details are depicted in table 10.

**TABLE 10: PARAMETERS DEPICTING THE CONDITION OF OPEN VIALS OBSERVED AT THE IMMUNIZATION SESSION SITES**

Sr. No.	Parameters	N	(%)
1.	Number of open vials observed	402	100
2.	Septum visibly okay and non-leaking	392	97.5
3.	Readable label	394	98
4.	Vial within the expiry date	402	100
5.	VVM visible (n = 360, not applicable for open BCG, MR, JE and open RVV)	352	97.8
6.	VVM in usable stage (n = 360, not applicable for open BCG, MR, JE and open RVV)	348	96.7

## Recording Date and Time on Open Vials

Out of these 402 open vials, 360 (90 per cent) were the vials on which Open Vial Policy is applicable (DPT, IPV, OPV, PCV, Penta, TT and Hepatitis-B) and 42 (10 per cent) were reconstituted/open RVV vials. The table below depicts the status of the recording date and time on all open vials observed at the immunization session sites.

**TABLE 11: STATUS OF DATE AND TIME RECORDING ON THE OPEN VIALS OBSERVED AT THE IMMUNIZATION SESSION SITES**

Sr. No.	Types of vials	Recording of date and time on open vials							
		Both date and time mentioned		Date mentioned		Time mentioned		Neither date nor time mentioned	
		n	%	n	%	n	%	n	%
1.	Liquid vials (Non-Reconstituted) N = 360 (90%)	221	61.4	350	97.2	225	62.5	6	1.7
2.	Reconstituted vaccines (BCG, JE and MR)/open RVV vials N = 42 (10%)	38	90.5	39	92.9	40	95.2	1	2.4

The recording of both date and time was found to be considerably higher in the reconstitution vaccines (BCG, MR and JE)/open RVV vials (90.5 per cent) than the liquid non-reconstituted vials (n=221, 61.4 per cent). The recording of date was found to be higher on the liquid non-reconstitution vials (97.2 per cent) as compared to the reconstitution vaccines (BCG, MR and JE)/open RVV vials (92.9 per cent). The recording of time was found to be considerably higher on reconstitution vaccine vials/open RVV (95.2 per cent) as compared to the non-reconstitution vaccines (62.5 per cent).

Very few open vials had nothing recorded on them (seven out of 402 vials -1.7 per cent). In the majority of the open vials where the date is mentioned, the date of opening was found to be within 28 days of the date of vial opening (97.3 per cent).

**Out of 93 ANM, it was observed that the date and time of vial opening/reconstitution were mentioned as follows:**

- 41 (44 per cent) on the label of the vaccine
- 28 (30 per cent) on the neck of the vial
- 22 (24 per cent) on the top of the vial (near septum)
- 2 (2 per cent) pasted a sticker on the vial



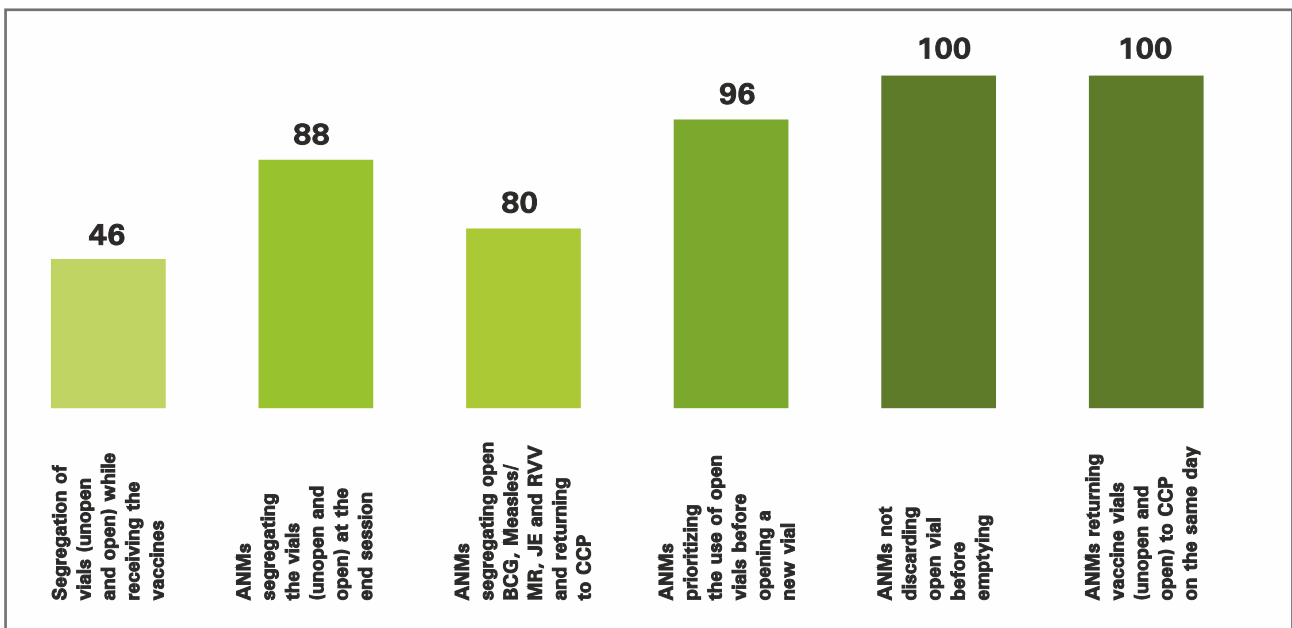
**FIGURE 13: DATE AND TIME MENTIONED ON DIFFERENT PARTS OF OPEN VIALS**



**Practices at the Immunization Session Sites**

The graph below shows that in only 46 per cent of the session sites, the open vials were segregated from the unopen vials in the separate zipper bag while receiving the vaccines at the session site. In 88 per cent of session sites, the ANMs were segregating the open vials and unopened vials in the separate zipper bags while returning the vaccines to the CCPs at the end of the session.

**FIGURE 14: PRACTICES OBSERVED AT THE IMMUNIZATION SESSION SITES (%)**



It was found that in 88 per cent of sessions, the open vials of Penta, DPT, TT, IPV, OPV and PCV were sent back to CCP for further use, whereas segregation of the reconstituted BCG, Measles/MR, JE and open RVV was sent back to the CCP for storage upto 48 hours in only 80 per cent sessions.

Further, it was observed that at 96 per cent of session sites, the ANMs were prioritizing the use of open vials before opening a new vial. It was found that the vaccine vials (open and unopen) were returned to the respective CCPs on the same day from all sessions.

## 4.4 Perceptions and Challenges related to Open Vial Policy Implementation

### A. Perceptions

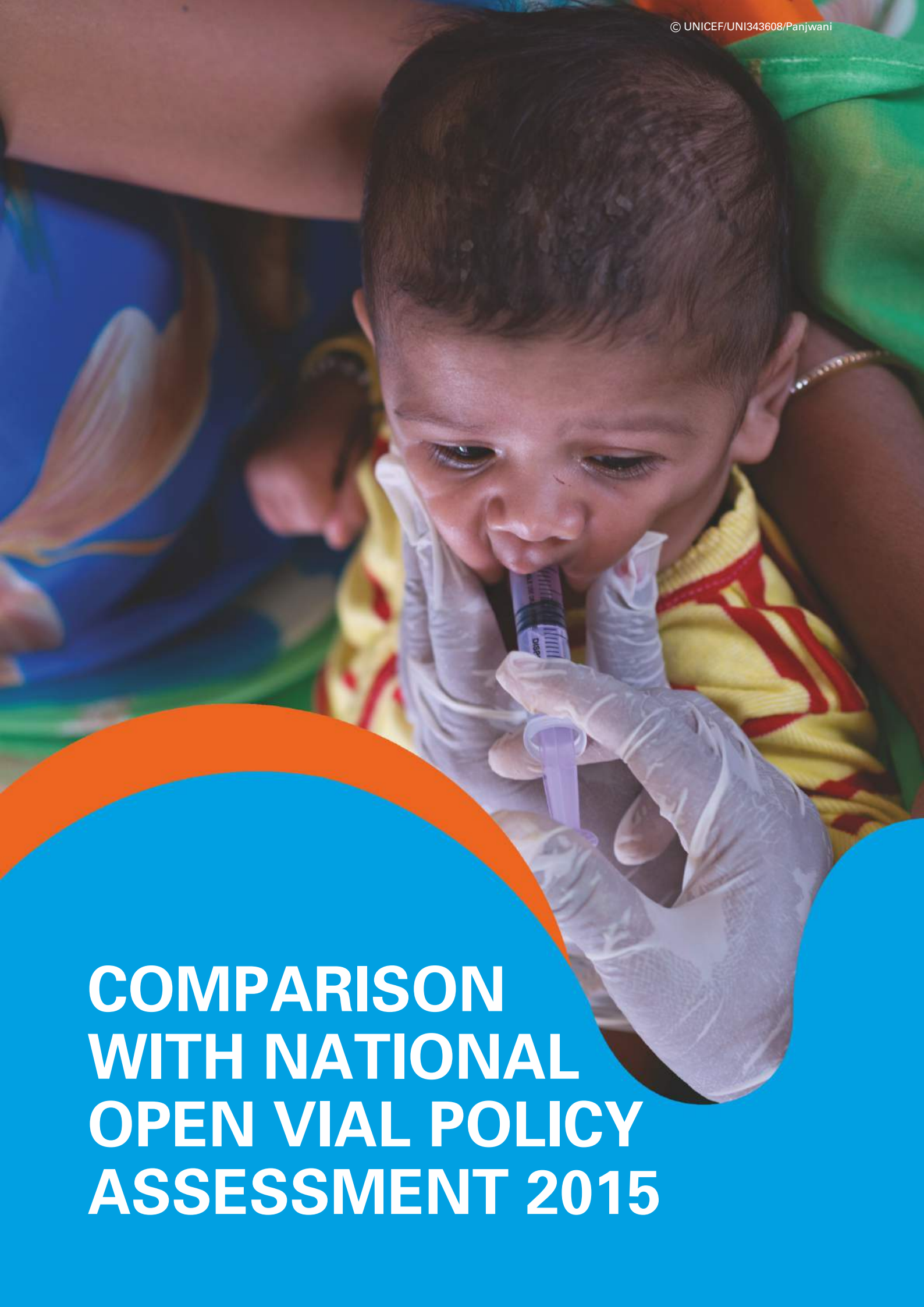
The majority of the VCCHs (97 per cent) and ANMs (93 per cent) were of the opinion that Open Vial Policy is beneficial to the programme. The majority of the health workers responded that Open Vial Policy has helped in reducing the vaccine wastage considerably, saving the government's money, ensuring availability of life-saving vaccines and in turn improving immunization coverage.

### B. Challenges

14 (20 per cent) out of 71 VCCHs and 10 (11 per cent) out of 93 vaccinators responded that they faced some kind of challenge in implementing the Open Vial Policy.

- The majority of the VCCHs faced difficulty in maintaining the stock of open vials once they come back from the session site.
- Some VCCHs responded that they are still not clear whether to record the open vial in doses or vials.
- Some VCCHs from the states where eVIN was not implemented, did not have the standard stock register with a separate column for recording the open vials.
- In some states, VCCHs also stressed the change in policy regarding the storage of open returned reconstituted vials (BCG/MR/JE) and open RVV vials in the passive equipment (cold box and vaccine carrier) with proper cold chain in place of mandatorily storing them in ILRs.
- The vaccinators faced difficulty in recording the date and time on the vial. Many did not have the right kind of pens/markers to record the date and time on the vial.
- Few vaccinators also faced difficulty in sending the vials back to the CCP due to the lack of AVD mechanism.





**COMPARISON  
WITH NATIONAL  
OPEN VIAL POLICY  
ASSESSMENT 2015**

# 5. Comparison with National Open Vial Policy Assessment 2015

In comparison to the last Open Vial Policy assessment conducted half a decade back, there has been improvement in the implementation of the policy. Not much difference was observed in the training status of the Cold Chain handlers but the availability of the training materials related to Open Vial Policy increased as compared to the last assessment.

As the Open Vial Policy guidelines were revised in 2015, many VCCHs and vaccinators were not found to be fully aware of the latest guidelines of storing the returned reconstituted vaccines/open RVV in the ILR for 48 hours or till the next session (whichever is earlier). In the last Open Vial Policy assessment, the majority of the VCCHs and vaccinators were found to be fully aware of the OVP guidelines prevailing at that time.

The opinion of the VCCHs and vaccinators regarding the benefit of the Open Vial Policy was found to be similar in both the assessments where the majority believed that Open Vial Policy has benefitted the immunization programme by reducing vaccine wastage.

The percentage of VCCHs and vaccinators facing any challenge related to the practice of Open Vial Policy was found to be lower in comparison to the VCCHs and vaccinators facing any challenge during the last assessment. The challenges they faced remained the same i.e no AVD mechanism, difficulty in record keeping and difficulty in recording date and time on the open vial. The location of mentioning date and time on the vial was also found to be an area of concern in both the assessments.





# CONCLUSION

## 6. Conclusion

Open Vial Policy is in place to minimize preventable vaccine wastage under UIP. Open Vial Policy has been in practice since the introduction of the Pentavalent vaccine in the country. Since then, there have been multiple revisions done in the policy to strengthen the immunization programme of the country. The latest Open Vial Policy was introduced in 2015 which is being implemented currently.

**This assessment gives an insightful overview of the implementation status, knowledge, practices, perceptions and challenges related to Open Vial Policy in India. The assessment was conducted in 2019 across 12 states and 24 districts. A total of 71 CCPs and 93 immunization session sites were assessed in 24 districts.**

The training and knowledge on Open Vial Policy guidelines were found to be lowest among MOs followed by ANMs, and highest among the district level staff. The status of availability of training material on Open Vial Policy was found to be non-uniform with less availability with VCCHs and ANMs and higher availability with DIOs and MOs.

The physical condition of the majority of open vials observed at the last CCPs and the immunization session sites was found to be satisfactory. One of the major issues found through this assessment was the absence of recording of the date and time on open vials. On more than 50 per cent of open vials observed at the last CCPs and more than 35 per cent open vials observed at the immunization session sites, both date and time of opening or reconstitution were not mentioned but wherever date and time were mentioned, it was mostly readable and found to be within 28 days or four hours (reconstitution/open RVV) of opening. On the positive side, the date (alone) was mentioned on more than 90 per cent of the vials observed.

One of the major modifications that was done in the latest Open Vial Policy of 2015 was the policy of returning the reconstituted BCG, MR and JE vaccines/open RVV from the session site to the CCP and storing these open vials separately in the cold chain for 48 hours or till the next session (whichever is earlier). Although these vaccines were being returned by 80 per cent of the immunization session sites assessed but at only 64 per cent CCPs, the open vials were found to be stored in the cold chain. The stock of open vials was maintained at the majority of the CCPs and was majorly recorded in vials.

At less than half of the session sites, the open vials were segregated from the unopen vials in the separate zipper bag while receiving the vaccines at the session site. At 88 per cent of session sites, the vaccinators were segregating the open vials and unopened vials in the separate zipper bags while returning the vaccines to the CCPs. Vaccinators were prioritizing the use of open vials before unopened vials, and the majority of them did not discard the vaccine vials before they were completely empty.

The majority of the VCCHs and vaccinators believed that the Open Vial Policy was beneficial in improving the performance of the programme by increasing vaccine utilization and reducing vaccine wastage. 20 per cent VCCHs and 11 per cent vaccinators responded that they face some kind of challenge while implementing the Open Vial Policy which was mainly related to record-keeping of open vials, recording date and time on the open vial and AVD functionality.

This assessment benefited in highlighting the key gaps in knowledge and practices of ANM and VCCH in the implementation of Open Vial Policy guidelines. Few policy changes, robust supportive supervision and on-the-job training can help in correctly implementing the OVP guidelines and reduce open vial vaccine wastage at the service delivery level.



# LIMITATIONS

## 7. Limitations

- The assessment was conducted from a national-level perspective. The sampling frame did not include all the states, and the states included in the assessment had a small sample size of districts, CCPs and session sites. Hence, the assessment does not provide state and district level comparisons.
- The CCPs and the immunization session sites included in the study were selected randomly by the assessors. The hard-to-reach areas and the areas affected with left-wing extremism might have been excluded by the assessors.





# RECOMMENDATIONS

# 8. Recommendations

## 1. Revision in Open Vial Policy Guidelines

The current Open Vial Policy may be expanded to include:

**a. Storage of returned open vials of reconstituted vaccines (BCG, MR and JE)/ RVV in the cold chain (ILR or in passive Cold Chain Equipment(CCE))** - The current Open Vial Policy states that these vials should be retained in a plastic box clearly marked “Not to be used” in the ILR. These vials should be discarded after 48 hours or before the next session whichever is earlier. During the assessment, it was observed that many states are not storing these vials inside the ILR but storing them in passive CCE (cold box and vaccine carrier) with ice packs. A decision may be made to allow the states to store these vaccines either in ILRs or in passive containers maintaining the cold chain.

**b. Distribution and return of open and unopen vials to and from the immunization session site** - The current guidelines states that ANM should segregate the vaccine vials (used and unused) and keep them inside in a properly sealed zipper pouch/bag in the vaccine carrier under the cold chain (reverse cold chain). In the current guideline, there is only a mention of segregation of used and unused vials but there is no mention of segregation of used vials into:

**a.** Vials usable for subsequent sessions (Penta, DPT, PCV, Td, OPV and IPV)

**b.** Vials unusable for subsequent sessions (BCG, MR, JE and RVV)

It is recommended that a policy may be framed for using three zipper pouch/bags while returning the vaccines at the end of the session for segregating unused, usable open/used and unusable open/used vials. This will support in effective implementation of Open Vial Policy at the session site as well as the CCP by decreasing the chances of mixing and reissue of used BCG, MR, JE and RVV along with usable vaccines.

**c. Location of mentioning the date and time on the open vial** - The current guidelines states that date and time of reconstitution/opening should be mentioned on the label of the vial but it was observed in the field that the vaccinators are finding it feasible to mention the date and time on other parts of the open vials like on top of the vial, neck of the vial and pasting a sticker on the vial with date and time mentioned on it. The suitable permanent marker pens for mentioning the date and time on the open vials may be purchased by the states/districts at the local level.

MoHFW, Gol may constitute a national expert group to review the current gaps and challenges in this assessment and may consider revising the Open Vial Policy guidelines with the incorporation of the above-mentioned points.

## 2. Practices related to Open Vial Policy

- a. Strengthen the capacity of staff with special focus through refresher trainings, on-the-job mentoring/supportive supervision, online training modules etc. Special focus should be given to the training of Health Facility MOs who are the primary supervisors.
- b. Stress should be on the practices like, segregation of open vials, storage of open reconstituted vials/open RVV in the cold chain for 48 hours, time recording on the liquid Open Vial Policy applicable vials etc.
- c. Ensure measures such as frequent data analyses of supportive supervision findings and feedback to state and districts to strengthen the uniform application of Open Vial Policy guidelines.
- d. The current job aid used for Open Vial Policy is text-heavy and only available to be displayed at the CCPs. So, a new job aid (majorly pictorial) should be developed for a better understanding of the health workers. This may be made available to both the VCCHs and the vaccinators for quick reference and visual reminders.
- e. To strengthen the practice of correct stock management, the eVIN may be scaled up across the nation. Along with eVIN, standard immunization stock registers should be made available to all the CCPs across the nation.
- f. Vaccine wastage along with a review of Open Vial Policy implementation should be made a part of the agenda for the quarterly immunization review meetings.
- g. AVD mechanism should be strengthened to implement the Open Vial Policy guidelines effectively.





# Annexure: Profile of Participants in Data Collection Team

Team	Name	Organization	Name	Organization
1.	Dr. Vijay Kumar	JSI	Ms. Sujata Rao	UNDP
2.	Dr. Ajit Basantaray	UNDP	Dr. Niraj Kumar	NIHFW
3.	Dr. Sourabh Saxena	ITSU	Mr. Akshay Saulakhe	NCCRC
4.	Dr. Maulik Shah	UNICEF	Dr. Manoj	NIHFW
5.	Dr. Deep Thacker	JSI	Mr. Shashi Kant Ray	NCCVMRC
6.	Mr. Prem Kamal	UNDP	Mr. Rakesh Kumar	NCCVMRC
7.	Dr. Subhasis Bhandari	JSI	Er. Dheeraj Bhatt	UNICEF
8.	Mr. Anshuman Moitra	UNDP	Dr. Jayesh Mehta	WHO
9.	Dr. Vanesh	UNICEF	Dr. Ahmad Abbas Agha	UNDP
10.	Dr. Brajesh	UNICEF	Dr. Sukamal Basumatary	UNDP
11.	Er. Hitesh Kumar	NCCVMRC	Ms. Ruma Bhargava	ITSU
12.	Dr. Srinivas Selvamani	WHO	Dr. Ajit	NIHFW
13.	Dr. Praful Bharadwaj	UNICEF	Dr. Negi	NIHFW
14.	Dr. Puskarr Deshmukh	JSI	Dr. Lokesh Alahari	WHO
15.	Dr. Deenadayalan Chandran	JSI	Mr. Manish Kumar	NCCVMRC
16.	Dr. Sumeet Juneja	NCCVMRC		
17.	Mr. Vijay Agarwal	JSI	Dr. Sonika Badalia	UNDP
18.	Dr. Vikas Kokare	WHO	Dr. Deepak Mili	UNDP
19.	Mr. Subhajit Chakraborty	JSI	Dr. Ajitendra Kumar	UNDP
20.	Dr. Ayushi Agrawal	JSI	Mr. Arbaz Sundke	NCCRC
21.	Ms. Deepti	NCCVMRC	Dr. Krupal Joshi	Medical College
22.	Dr. Sheenu Choudhary	UNICEF	Dr. Bhavesh	NIHFW
23.	Mr. Lokesh Sharma	NCCVMRC	Mr. Prabir Roy	JSI
24.	Dr. Ginisha Gupta	Medical College	Dr. Sheetal	NIHFW
25.	Dr. Dolma	Medical College	Dr. Ravi	NIHFW
26.	Dr. Pankaj Somani	UNDP	Ms. Ashvini Dudhabhate	NCCRC
27.	Dr. Mangesh Arun Gadhari	UNICEF	Dr. Himanshu	Medical College



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## **UNICEF India Country Office**

UNICEF House, 73 Lodi Estate, New Delhi - 110 003

Tel: + 91 11 2469-0401 | + 91 11 2469-1410

Email: [newdelhi@unicef.org](mailto:newdelhi@unicef.org)



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