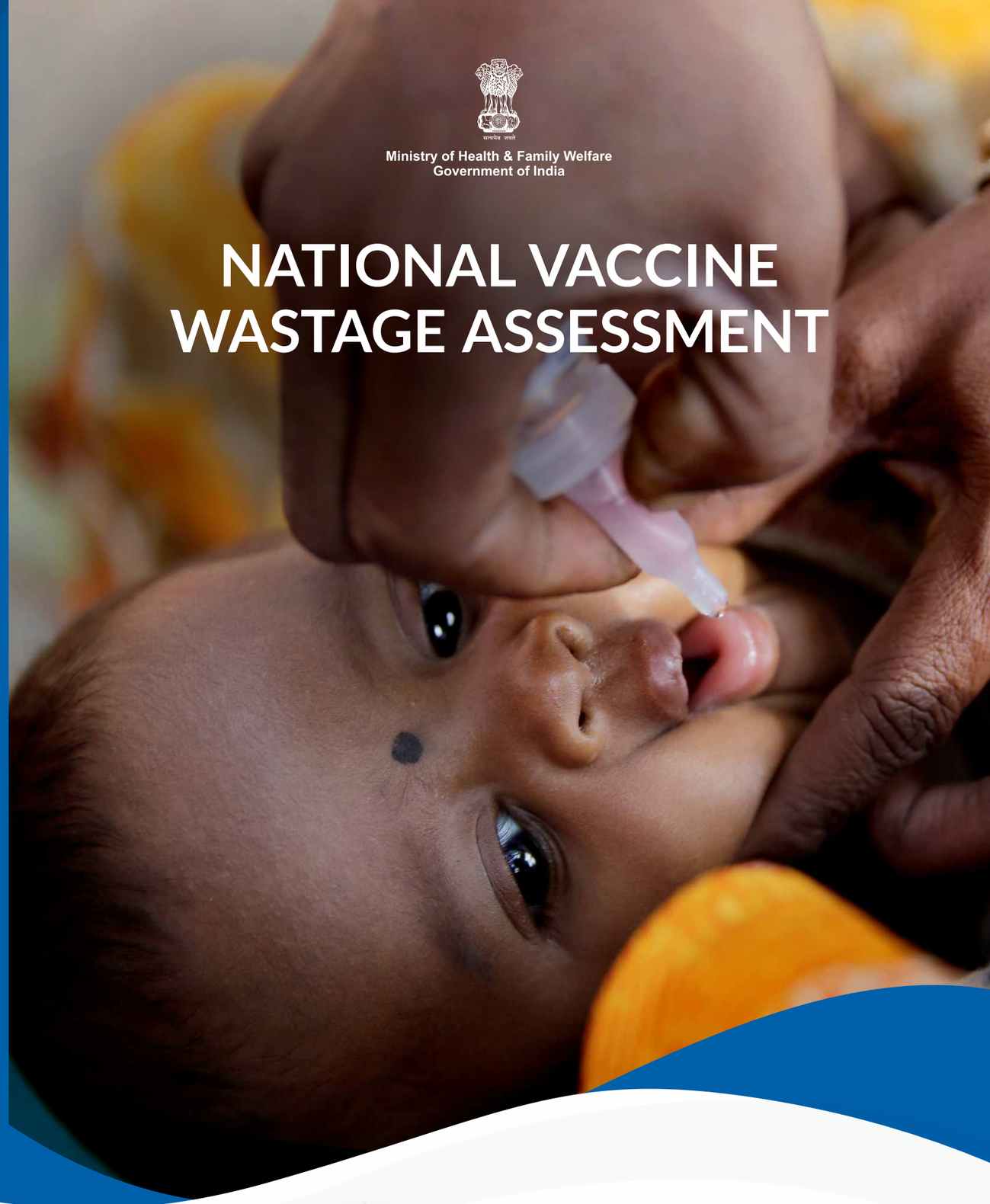

Ministry of Health & Family Welfare
Government of India

NATIONAL VACCINE WASTAGE ASSESSMENT

राष्ट्रीय स्वास्थ्य एवं परिवार कल्याण संस्थान
National Institute of Health and Family Welfare

unicef

National Cold Chain & Vaccine Management Resource Centre

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Assessment conducted by National Cold Chain and Vaccine Management Resource Centre (NCCVMRC), the NIHFW & UNICEF India under guidance from the Immunization Division, Ministry of Health & Family Welfare, Government of India.

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Last but not least distinctive acknowledgement to the entire team of NCCVMRC-NIHFW) for their untiring effort in making this National Vaccine Wastage Assessment successful.

(Prof. Sanjay Gupta)
Nodal Officer, NCCVMRC-NIHFW

Foreword

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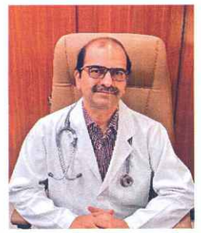

Message

The Government of India has responded to the various challenges faced by the immunization supply system by setting up the National Cold Chain & Vaccine Management Resource Centre (NCCVMRC) at the National Institute of Health & Family Welfare (NIHFW). Over the past few years, NCCVMRC has emerged as a frontrunner in providing immunization cold chain solutions to the country in response to specific requirements of the Ministry of Health & Family Welfare.

The National Vaccine Wastage Assessment 2019 is one of the exemplary achievements by the NCCVMRC team to assess the wastage rates of all vaccines at different levels of the immunization supply chain. An extensive assessment across 4 GMSDs, 12 State Vaccine Stores (SVSs), 24District Vaccine Stores (DVSs), 71 last Cold Chain Points (CCPs), and 93 immunization session sites provided a comprehensive data on unopened and open vial vaccine wastage and associated avoidable/unavoidable reasons at all levels.

I am confident that the recommendations of the National Vaccine Wastage Assessment 2019 will contribute in the strengthening of immunization cold chain supply chain in India.

It is my pleasure to thank all the experts who have contributed in making this National Vaccine Wastage Assessment activity successful. The guidance and involvement of MoHFW in various activities of NCCVMRC-NIHFW always motivate us to deliver quality work.

(Dr.Harshad Thakur)

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UNICEF/2018/Hajra

Acronyms

AD	Auto-Disabled
AEFI	Adverse Events Following Immunization
ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
AVD	Alternate Vaccine Delivery
BCG	Bacillus Calmette Guerin
BRIDGE	Boosting Routine Immunization Demand Generation
CCE	Cold Chain Equipment
CCP	Cold Chain Point
DIO	District Immunization Officer
DPT	Diphtheria Pertussis Tetanus
DVS	District Vaccine Store
EEFO	Early Expiry First Out
eVIN	Electronic Vaccine Intelligence Network
EVM	Effective Vaccine Management
FIC	Full Immunization Coverage
fIPV	Fractional dose of Injectable Polio Vaccine
GoI	Government of India
GMSD	Government Medical Store Depot
HMIS	Health Management Information System
ID	Intra-dermal
IM	Intra-muscular
IPV	Injectable Polio Vaccine
ITSU	Immunization Technical Support Unit
JE	Japanese Encephalitis
JSI	John Snow Inc.
MDVP	Multi-dose Vial Policy
MO	Medical Officer
MoHFW	Ministry of Health and Family Welfare
MIS	Management Information System
MR	Measles Rubella
NCCA	National Cold Chain Assessment
NCCMIS	National Cold Chain Management Information System
NCCRC	National Cold Chain Resource Centre
NCCVMRC	National Cold Chain and Vaccine Management Resource Centre
NFHS	National Family Health Survey
NIHFW	The National Institute of Health and Family Welfare
NVWA	National Vaccine Wastage Assessment
ODK	Open Data Kit
OPV	Oral Polio Vaccine
OVP	Open Vial Policy
PCV	Pneumococcal Vaccine
PVS	Primary Vaccine Store
RI	Routine Immunization
RVS	Regional Vaccine Store
RVV	Rotavirus Vaccine
SC	Sub-cutaneous
SCCO	State Cold Chain Officer
SP	Service delivery Point
SVS	State Vaccine Store
TT	Tetanus Toxoid
T-VaCC	Training on Vaccine and Cold Chain Management
UIP	Universal Immunization Programme
UNICEF	United Nations Children's Fund
UNDP	United Nations Development Programme
VCCH	Vaccine and Cold Chain Handler
VVM	Vaccine Vial Monitor
WHO	World Health Organization

Executive Summary


UNICEF/2021/Reddy

India's Universal Immunization Programme (UIP) is one of the largest immunization programmes in the world, aiming at 26 million (2.6 crores) infants and 29 million (2.9 crores) pregnant women via 12 million (1.2 crores) routine immunization sessions annually. 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.

A recent study shows an average 16 times greater return as compared to the investment made in the National Immunization Programme, proving that immunization is one of the best cost-effective interventions for vaccine- preventable diseases.

In the last few years, several life savings vaccines such as Inactivated Polio Vaccine (IPV), Rota Virus Vaccine (RVV), Japanese Encephalitis (JE), Pneumococcal Vaccine (PCV), Measles Rubella (MR) etc. have been introduced into the system. Wastage of these vaccines has a direct implication on immunization coverage and resource utilization. The last National Vaccine Wastage Assessment was carried out in 2010, following which major policy-level changes and new vaccine introductions have taken place. Hence to assess the current wastage rate in India, the National Cold Chain and Vaccine Management Resource Centre - National Institute of Health and Family Welfare (NCCVMRC-NIHFW) conducted a National Vaccine Wastage Study in February 2019 with joint collaboration of UNICEF under the able guidance of the Ministry of Health and Family Welfare (MoHFW), Government of India (GoI).

This study ensured active participation of all Immunization stakeholders such as World Health Organization (WHO), United Nations Development Programme (UNDP), John Snow Inc. (JSI), Immunization Technical Support Unit (ITSU), National Cold Chain Resource Centre (NCCRC) and medical colleges. The field visit for data collection was held from 24 February to 2 March 2019. The data was collected for a review period of six months (April to September 2018) at different levels of the immunization supply chain including primary stores (Government Medical Store Depots (GMSD), State Vaccine Stores (SVSs)), District Vaccine Stores (DVSs) and last Cold Chain Points (CCPs). The data was collected from 4 GMSDs, 12 SVSs, 24 DVSs, 71 last CCPs and 93 session sites, using a semi-structured pre-designed mobile application-based tool. It included data on vaccines received, issued, stored, and returned to the stores, in addition to the number of beneficiaries vaccinated at the last CCP.

The knowledge and practices of vaccine handling and management at the CCPs and session sites were also assessed to determine the indirect causes affecting vaccine wastage. The data analysis was done using Microsoft Excel 2016. Using pre-defined standard formulas, unopened and open vial wastage rates were calculated up to district level stores and at the last CCP respectively. At the last cold chain point, opened vial wastage rate is inclusive of unopened vial wastage as well.

Among the ten vaccines reviewed for wastage rates, two vaccines (including PCV and Pentavalent Vaccine) had an open vial wastage rate within the GoI-prescribed permissible limit. Among all vaccines assessed the highest open vial wastage rate was recorded for Bacillus Calmette Guerin (BCG), Fractional dose of Inactivated Polio Vaccine (fIPV), JE, RVV, Measles, and Oral Polio Vaccine (OPV).

The unopened vial wastage was calculated at all levels of the supply chain up to the district level stores. The overall unopened vial wastage rate for all ten vaccines was less than one per cent, yet was highest for fIPV, OPV and BCG vaccines. Vaccines with unusable Vaccine Vial Monitor (VVM) were the most common cause of unopened vial wastage. The unopened vial wastage was seen at the district level stores, but was nil at the national and state-level stores.

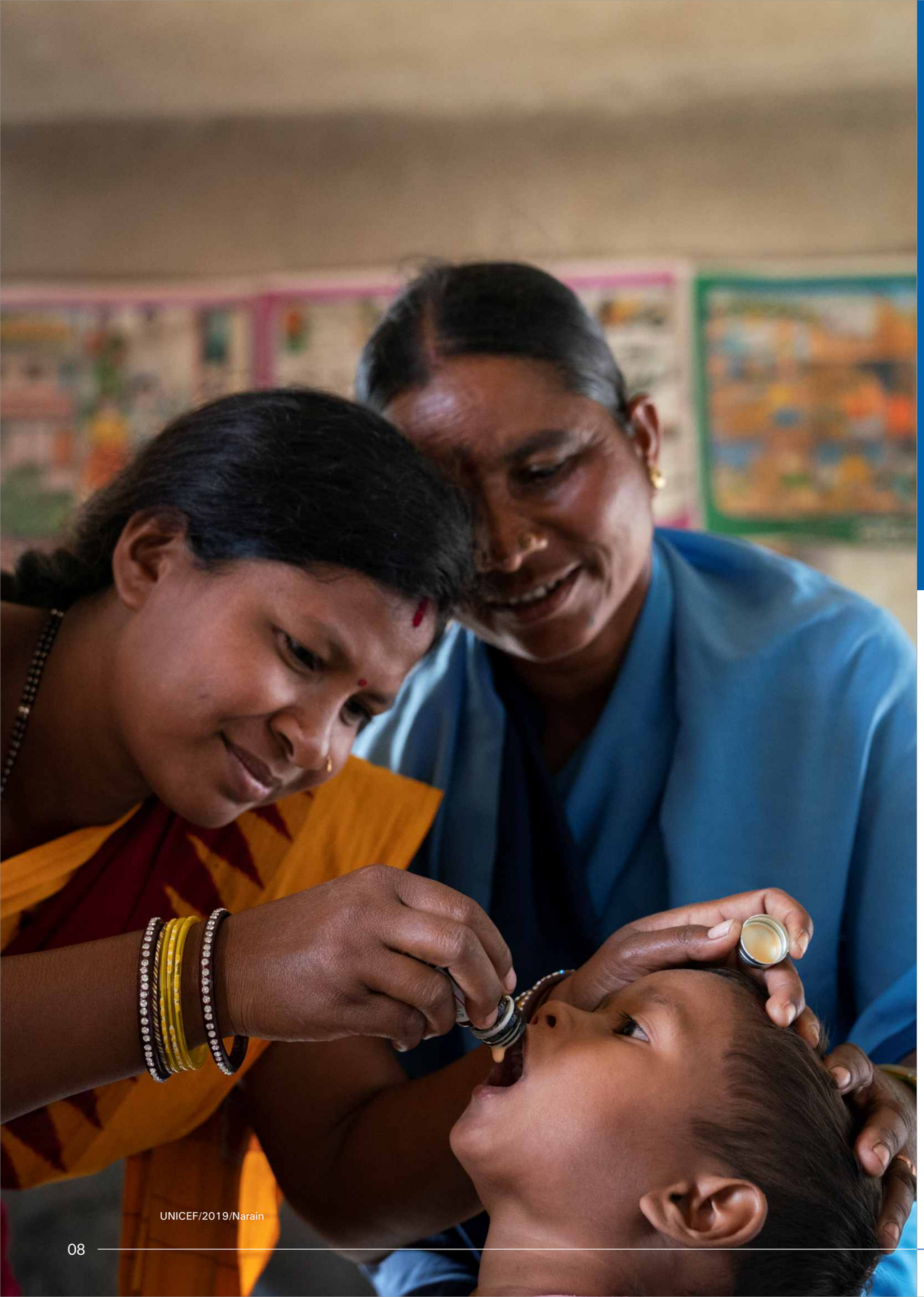
At the last CCPs, the wastage rates were higher for lyophilized vaccines as compared to liquid vaccines. Vaccines administered through the injectable route had a higher wastage rate at last CCP as compared to orally administered vaccines. For most vaccines, wastage was higher in urban as compared to rural CCPs.

The documentation of vaccine wastage was found to be unsatisfactory at all levels. The training, supervision and vaccine management practices were found to be inadequate mostly at the GMSD level. Amongst the health staff that received training, the discussion regarding vaccine wastage and provision of any training material on vaccine wastage was rare. The majority of the staff was not found to be aware of the reasons and calculation of vaccine wastage.

Vaccine management practices at the CCP and session sites that influence vaccine wastage were found to be satisfactory, except for the inadequate temperature recording practices like recording power cuts, defrosting and temperature monitoring review by the facility in-charge.

The recommended measures are to strengthen the uniform implementation of efficient well-monitored immunization supply chain, following Early Expiry First Out (EEFO) principle, maintenance of separate Routine Immunization (RI) and campaign records, maintenance of wastage records, implementation of Multi-dose Vial Policy (MDVP), effective alternate vaccine delivery (AVD) system for timely delivery and return of vaccines, scaling up of eVIN, display of relevant job aids, and adequate training and capacity building among the health staff to ensure vaccine wastage rates below the permissible levels as per the GoI guidelines.

Regular review of wastage rates with on-the-job supportive supervision at all levels of the supply chain, especially GMSD, state and district vaccine stores, should be enhanced to improve vaccine handling and management practices.



UNICEF/2019/Narain

1. BACKGROUND

Immunization is one of the most cost-effective interventions for the prevention of vaccine-preventable diseases. A study conducted recently projected that investment in immunization yields a net return about 16 times greater than the costs incurred over a decade.[1]

India's Universal Immunization Programme (UIP) is one of the largest in the world, in terms of quantities of vaccine used, the number of beneficiaries, the number of Immunization sessions organized, the geographical spread and the diversity of areas covered. It targets approximately 29 million (2.9 crores) pregnant women and 26 million (2.6 crores) newborns with 12 million (1.2 crores) sessions planned per year under a network of more than 28,000 CCPs for vaccine storage.[2,3,4]

India follows a 4-tier system of cold chain supply chain network for managing its vast vaccine demands through Primary vaccine stores (including 4 bulk stores i.e., Government Medical Store Depots), Sub-National (regional/ divisional) vaccine stores, District vaccine stores and Sub-District Cold Chain Points (CCP). Since the inception of UIP, MoHFW has introduced many new vaccines and subsequently strengthened the immunization supply chain increasing the cold chain capacity through procurement of cold chain equipment in large volume.

The role of the supply chain is to ensure effective vaccine storage, handling, and stock management, rigorous temperature control in the cold chain and maintenance of adequate logistics management information systems. MoHFW has conducted various studies including the National Effective Vaccine Management (EVM) and National Cold Chain Assessment (NCCA) to assess the gaps and challenges in the immunization supply chain of the country. These studies have generated evidence for enhanced policy decisions and generated recommendations that have been helpful in strengthening the Immunization supply chain system in a holistic manner.

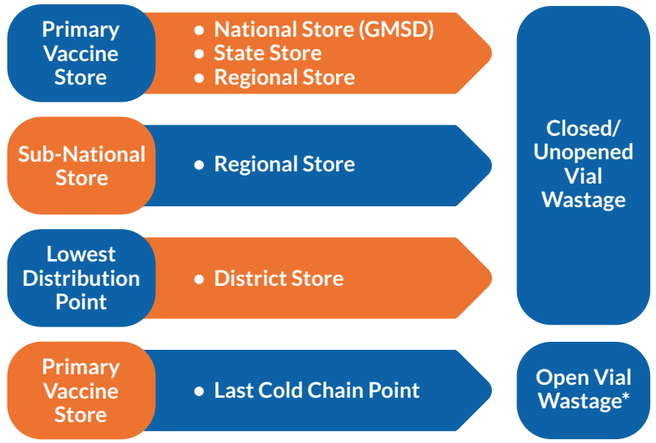
1.1 Scope of Vaccine Wastage

One of the largest impediments of efficient immunization is the wastage of vaccines. Vaccination is a cost-effective and life-saving intervention. However, a recent study in Senegal reported approximately 22 per cent of vaccine-related costs are attributed to vaccine wastage.[5] Recently expansion of UIP in India with newer vaccines generates a necessity to realize factors that contribute to vaccine wastage, so potential solutions can be generated. Monitoring vaccine wastage helps to improve vaccine forecasting and minimize wastage. As the costs of vaccination increases, better vaccine management is essential.

1.2 Types and Causes of Vaccine Wastage

Vaccine wastage is defined by the World Health Organization (WHO) as “loss by use, decay, erosion, or leakage or through wastefulness”, and can be calculated as the proportion of vaccine administered against vaccine issued.[6] Vaccine wastage falls into two categories: wastage in unopened vials and wastage in opened vials. Refer to figure 1.

Figure 1: Vaccine Wastage at All Levels of Immunization Supply Chain



*At service delivery point or last CCP, the opened vial wastage is inclusive of unopened vial wastage too.

In a vaccine's journey from manufacturer to the targeted beneficiary, it travels through a pre-determined supply chain system before reaching its destination at the last service delivery point.

Unopened vial wastage[7] is primarily due to inefficiencies in the supply chain, including temperature control, temperature monitoring, and stock management during storage and transportation. It may result from vaccine expiry, excess heat exposure, freezing, breakage, missing inventory or discard following outreach sessions etc. It is measured at all levels of the immunization supply chain up to district level (or lowest distribution level) stores.

Whereas, **opened vial wastage**[7] can be both avoidable (attributable to immunization workers' practices and include errors in reconstitution, suspected contamination, patients' reaction, excess heat, freezing or breakage) and unavoidable (discarded doses from vials of unused doses of multi-dose vials and determined by vial size, session size and discard time). It is measured at the level of service delivery or last CCPs.

Reasons for open and unopened vial wastage are mentioned in table 1.

Table 1: Factors Affecting Vaccine Wastage

Factors Affecting Vaccine Wastage	
Unopened Vials	**Opened Vials**
	All reasons for **unopened** vial wastage **AND**
Broken vials	Not storing remaining doses in the cold chain after the session
VVM not usable/exposure to heat	Not able to draw indicated doses from vials
Freezing	Wrong reconstitution practices
Expiry	Suspected contamination
Missing inventory	Initial phase of the newly introduced vaccine
Theft	Dead space of syringes

In its journey, the vaccine is subjected to possible wastages at multiple levels in the supply chain network as well as at the service delivery point, thus vaccine wastage is determined for both last service delivery and the supply chain.

The permissible vaccine wastage rates for various vaccines as per GoI norms are mentioned in table 2.[8]

Table 2: Permissible Vaccine Wastage Rate for All Antigens in India

S. No.	Vaccine	Mode of Administration	Applicability of MDVP	No. of Doses per Vial	Permissible Wastage Rate (%)
1	BCG	Injectable	No	10	50
2	Hep B	Injectable	Yes	10	10
3	OPV	Oral	Yes	20	10
4	Penta	Injectable	Yes	10	10
5	PCV	Injectable	Yes	5	10
6-A	Rotasiil	Oral	No	2	10
6-B	Rotavac	Oral	No	10/5	25/10
7	fIPV	Injectable	Yes	25	10
8	Measles/ MR	Injectable	No	5	25
9	JE	Injectable	No	10	25
10	DPT	Injectable	Yes	10	10
11	TT	Injectable	Yes	10	10

1.3 National Vaccine Wastage Assessment 2010

The National Vaccine Wastage Assessment (NVWA) 2010 was carried out by UNICEF and MoHFW in five states of India between October 2009 and February 2010.[9] The states selected were based on the differences in coverage rates of immunization and geographic distribution. Qualitative and quantitative data were collected retrospectively for a six month period between April 2009 and September 2009 through field visits to sampled sites.

Findings suggested poor documentation of vaccine wastage at all levels. Wastage rates varied among different states and vaccines. Higher vaccine wastage rates were observed at the service delivery point (Diphtheria Pertussis Tetanus (DPT): 27 per cent and BCG: 61 per cent at outreach session site) as compared to the supply chain levels (Measles: 3.5 per cent, others: <1 per cent). Poor documentation of vaccine wastage at the supply chain level was one of the probable factors responsible for extremely low wastage rates. Session size, vial size, and vaccine formulation (liquid vs. lyophilized, oral vs. injectable) also influenced vaccine wastage.

To reduce vaccine wastage with an optimal increase in cold chain space and management, it was recommended that the size of the outreach sessions (based on injection load or headcount) should be optimized to cover target beneficiaries. The use of smaller vial size may lower wastage; however, a balance with available cold chain space was recommended. Any change in the formulation should be coupled with refresher training of health workers and revised micro-planning. WHO recommended multi-dose vial policy should be considered for implementation in fixed immunization sites. The multi-dose or open vial policy was then implemented in December 2012 and later revised in 2015 with applicability on various vaccines as shown in table 2.

1.4 Government of India's Initiatives to Strengthen Immunization Supply Chain

The GoI follows a 360-degree approach for strengthening the immunization supply chain including expansion of cold chain capacity for new vaccines introduction, electronic systems for real-time management of vaccine logistics and cold chain, institutional strengthening, and capacity building of immunization workforce, etc. Committed to improving immunization coverage and strengthening health systems, the Ministry of Health has implemented various strategies and interventions in the form of supplementary immunization activities like Mission Indradhanush and MR campaigns, strengthening institutional capacity through the establishment of centres of excellence, NCCVMRC and NCCRC and strengthening cold chain-supply chain through implementation and scale-up of NCCMIS and eVIN.

Based on the findings and recommendations of the NVWA 2010 and other relevant studies like National EVM 2013 and NCCA 2014, the MoHFW instituted numerous measures for effective and efficient vaccine management and reduced vaccine wastage, including:

1. Introduction of new and costly vaccines in the National Immunization Schedule (Pentavalent, fIPV, RVV, MR and PCV).
2. Introduction of Electronic Vaccine Intelligence Network (eVIN) for real-time temperature and stock management of the vaccines and logistics.
3. Nation-wide scale-up of National Cold Chain MIS (NCCMIS) for optimal cold chain management.
4. Guidelines and standard protocols for vaccine management practices under UIP (multi-dose vial policy, increased rates for AVDs, standardized tools for supportive supervision).
5. Capacity building of programme managers, cold chain handlers and front-line workers (training on vaccine and cold chain management (T-VaCC), training of the vaccine and cold chain handlers (VCCHs) and frontline workers (BRIDGE).

1.5 Need of Vaccine Wastage Assessment 2019

Since the last National Vaccine Wastage Assessment in 2010, many newer and costlier vaccines have been introduced, hence it is essential to ensure that a maximum number of procured doses reach beneficiaries with minimal wastage at all levels. It is also essential to know prevailing wastage rates for vaccine forecasting and procurement planning. Therefore, it is a good opportunity to conduct the next vaccine wastage study to support the programme in documenting best practices and identifying strengths and bottlenecks to further provide recommendations for reducing vaccine wastage across all levels of the immunization supply chain in the country.

UNICEF/2020/Vishwanathan

2. OBJECTIVES OF THE VACCINE WASTAGE ASSESSMENT

To estimate vaccine wastage rate across all levels of the immunization supply chain.

01

To assess knowledge and document vaccine management practices across the immunization supply chain including the mechanism for recording and reporting vaccine wastage.

02

To assess reasons for vaccine wastage.

03

To recommend measures to reduce wastage at various levels.

04

UNICEF/2017/Sharma

3. METHODOLOGY

A cross-sectional study was planned to assess vaccine wastage and its reasons across the country. The supply chain levels, i.e. Primary Vaccine Stores (PVS) (national/state/regional stores), Sub-National Stores (regional/ divisional vaccine stores), Lowest Delivery Points (district vaccine stores) and Service Points (last CCPs) can be grouped into two sub-heads:

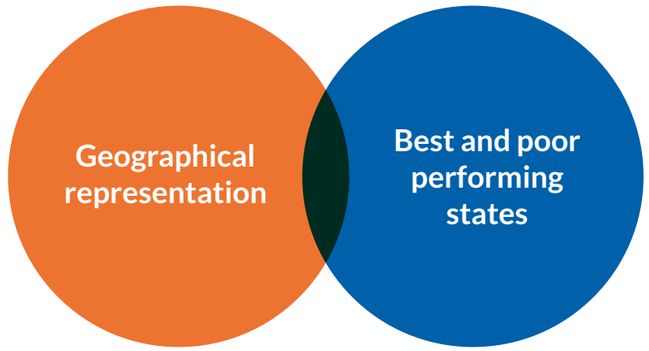
- Stores receiving and supplying only unopened vaccine vial (GMSD, SVS, RVS, DVS) and
- Stores where both open and unopened vaccine vials are stored and distributed (last CCPs)

Based on wastage type, the assessment was divided into two parts i.e., wastage in opened vial and wastage in the unopened vial. Wastage in the unopened vial is directly related to cold chain management, e.g. exposer to heat/freezing, theft, expiry etc. Unopened vial wastage is manageable and should be limited to a maximum of 1 per cent according to WHO guidelines.[10] Sample picked up from stores, which are receiving and supplying only unopened vials, were considered for calculation of unopened vial wastage, and a sample of "service delivery point" or "last CCPs" was used for calculation of opened vial wastage.

3.1 Selection of Sample

A. Sampling Technique and Selection Criteria

Sample selection is extremely vital to any study as it is a subset containing the characteristics of a larger population. 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.



B. Selection of Sampling Sites

Figure 2: Flow Chart Depicting Multi-Stage Sampling of Data Collection Sites

A multistage sampling technique was used for data collection (shown in figure 2). For the study, India was divided into six geographical regions viz. Central, East, North, North-East, South and Western India.

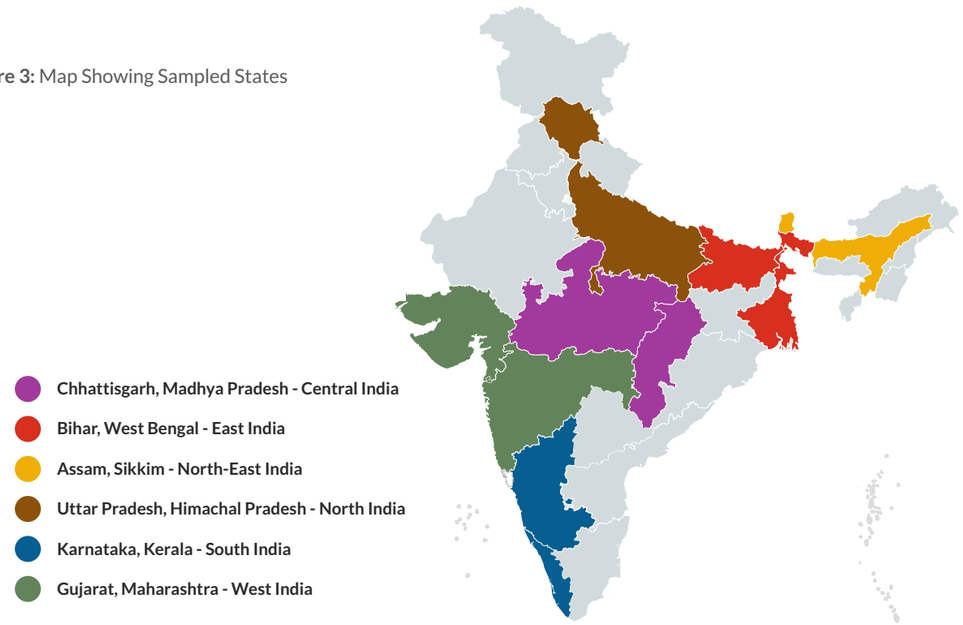
I. Selection of States

The states were selected from each region based on their Full Immunization Coverage (FIC) (Source: NFHS-4). From each region, two states were chosen, one with the highest and one with the lowest FIC. Refer to table 3 and figure 3 for more information.

Table 3: Sample Site Selection

S. No.	State	Zone	FIC (NFHS-4) (%)	Category	Remarks
1	Madhya Pradesh	Central India	53.60	Low FIC	There are only 2 states in this zone
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	In South India, eVIN was not functional at the time of study
10	Kerala		82.10	High FIC	
11	Gujarat	West India	50.40%	Low FIC	
12	Maharashtra		56.30%	High FIC	

Figure 3: 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 4 lists the districts selected from each state based on their FIC.

Figure 4: Selection of Districts Based on FIC (Source: NFHS-4)

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

III. Selection of Cold Chain Points

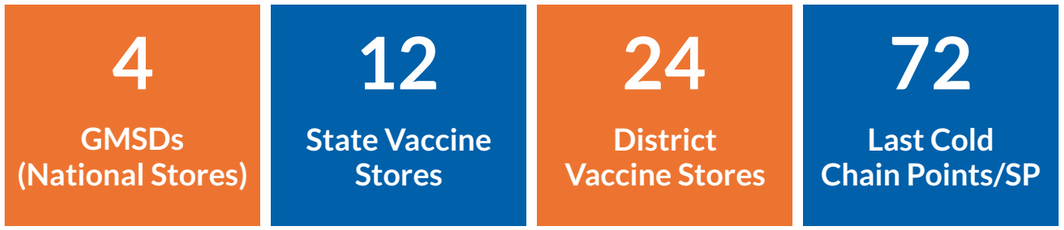
Within each selected district, three CCPs were randomly selected, of which one was from urban/semi-urban area, while the remaining two represented rural CCP.

The focal commitment of the strata while sampling was to secure a sample that rationally represents data from low performing, poor performing, urban, rural and geographically diverse population.

C. Sample Sites Selected

A total of 4 GMSDs, 12 SVSs, 24 DVSs and 72 last CCPs were selected for data collection, shown in Figure 5.

Figure 5: Number of Sample Sites Selected at All Levels



D. Immunization Session sites:

For each last CCP selected, immunization session sites were also covered to understand the practices and knowledge of Vaccinator/Auxiliary Nurse Midwife (ANM) to determine indirect causes of vaccine wastage.

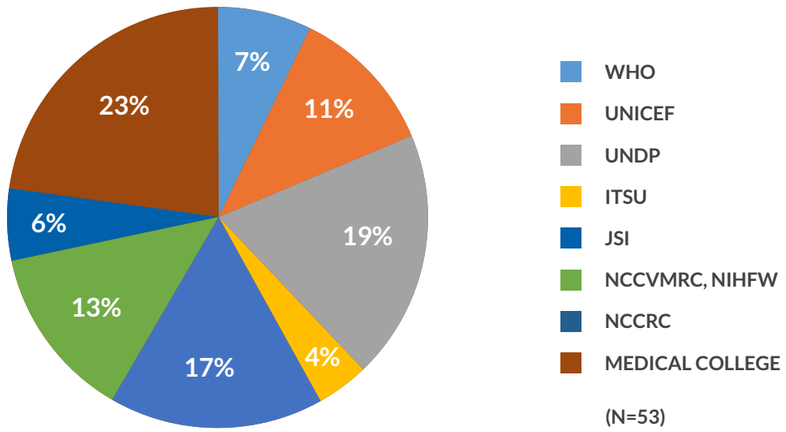
3.2 Data Review Period

The review period for the study was of six months from April to September 2018. Since our data collection was done in February-March 2019, it provided ample buffer time for the administrative data to stabilize and provide an accurate picture of the number of doses issued and administered.

3.3 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 resident doctors from Medical Colleges and external consultants. A total of 27 teams were made 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 shown in Figure 6.

Figure 6: Profile of Assessors in Data Collection Teams, National Vaccine Wastage Assessment 2019



3.4 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 National Vaccine Wastage Assessment
- Overview on vaccine wastage- its types, causes and factors affecting vaccine wastage
- Orientation on vaccine wastage study tool for all levels
- Hands-on session on the mobile application for data collection

3.5 Data Sources

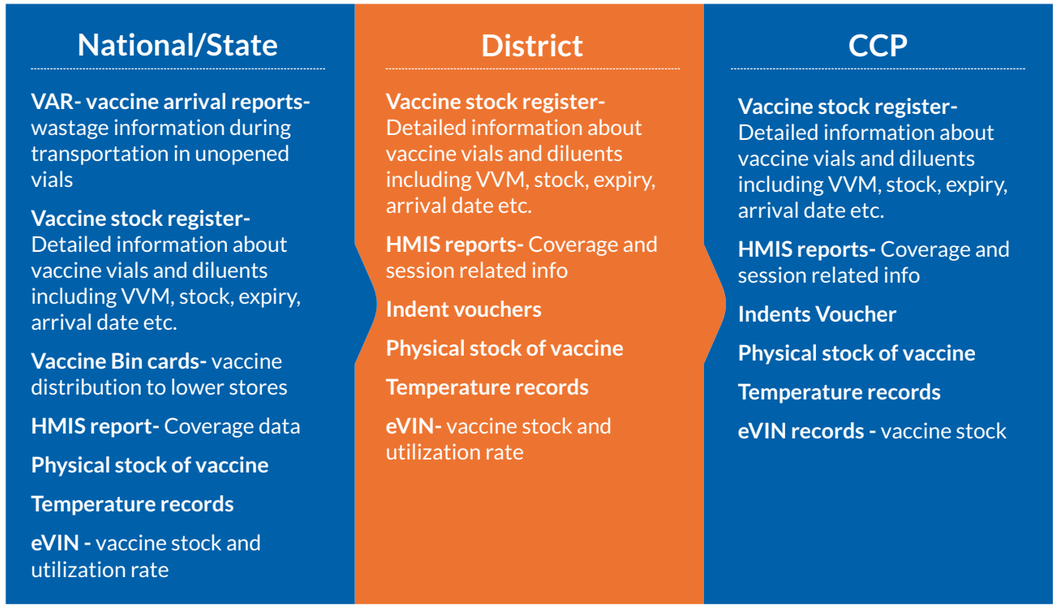
At all levels, the data was collected using pre-existing records and through a data collection tool. Documents such as vaccine arrival reports, stock registers, indent and issue vouchers, eVIN records, issue vouchers or distribution registers were used to capture the vaccine usage. The children immunized were captured from Health Management Information System (HMIS) reports at all levels. Quantitative data was retrieved from the mentioned records to calculate the vaccine wastage. Refer to figure 7 for more information.

So, primarily two types of data i.e., vaccine supply and coverage was collected. For vaccine supply, the vaccine stock register, vaccine distribution register, indents, and the physical stock of vaccine was reviewed. For coverage, the HMIS, tally sheet, reporting formats were reviewed. In eVIN states, vaccine utilization rate and stock status were taken in addition to calculating the wastage rate.

Availability of the following documents was checked at all levels:

- Demographic profile/ RI microplan
- Training materials/ reference documents
- Updated vaccine stock records (stock records, distribution records, eVIN)
- Supervisory visit reports
- Wastage reports
- Vaccine coverage reports

Figure 7: Data Sources used at All Levels



3.6 Data Collection Technique and Study Respondents

Both quantitative and qualitative data were collected using a pre-designed tool (as mentioned in Section 3.7) at all levels in this study. Quantitative data was collected from the pre-existing data sources (as mentioned in section 3.5) to determine the vaccine wastage rate.

One-on-one interviews were conducted with Programme managers, VCCHs and ANMs to review and understand various operational mechanisms of the programme using the pre-designed questionnaire. The study respondents interviewed at each site are as mentioned in table 4.

Table 4: Study Respondents Interviewed at all levels

S No.	Site visited (N)	Personnel interviewed	No. of respondents
1.	GMSD (4)	In-charge	3
		Storekeeper	4
2.	SVS (12)	State Cold Chain Officer	12
		SVS Manager/ Storekeeper	12
3.	DVS (24)	District Immunization Officer (DIO)	24
		DVS Manager/ Storekeeper	24
4.	Last CCP (71)	Medical Officer	71
		VCCH	71
5.	Immunization Session Site (93)	ANMs	93
	Total		**310**

3.7 Data Collection Tool

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

1. RI microplanning
2. RI training
3. Vaccine stock record keeping
4. Supportive supervision
5. Vaccine Management Practices
6. Wastage reports
7. Vaccine coverage reports

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 vaccine wastage assessment.

3.8 Data Quality, Challenges and Mitigation

Immunization coverage was vital to the calculation of the open vial wastage. HMIS is the primary source of self-reported coverage data which is regularly updated by data operators/health officials at the sub-district level/facility level. During the visit to the last CCPs, few sub-centre tally sheets were reviewed manually and data was recorded into the tool to compare the difference. In eVIN states, the vaccine utilization rate was triangulated with the coverage rate.

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

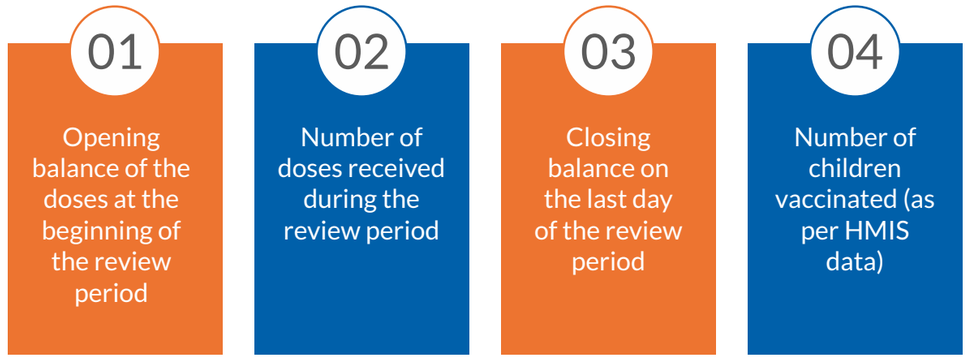
- A WhatsApp group of all assessors and facilitators was formed where regular updates were shared and queries were resolved.
- A control room was setup at NCCVMRC, NIHFW to respond to any query raised by the assessors.
- A senior-level monitoring team also visited some data collection sites to monitor the data collection activity as well as provide any necessary support to the assessors.

3.9 Calculation of Wastage Rate

The calculations for vaccine wastage were done using WHO-recommended standard formulae.[6] The vaccine wastage rate was calculated and segregated into two categories: At the last CCP and supply chain level (up to district level stores).

3.9.1 At the last Cold Chain Point:

At the last cold chain point or the service delivery point, the wastage rate includes wastage of both opened and unopened vials. For calculation of wastage rate at service delivery point (or the last CCP), the following data elements were recorded:



The difference between the collective sum of opening balance and received doses with the closing balance gave the total number of doses issued/consumed in that time period, as shown below in equation 1.

Equation 1: Number of Doses Issued

$$\text{Number of doses issued} = (\text{Opening balance} + \text{Doses Received}) - \text{Closing balance}$$

The vaccine wastage rate at the service delivery point was calculated using the number of doses issued or consumed and the number of doses administered or the number of children vaccinated using the formula as shown below in equation 2 and explained through Example 1.

Equation 2: Wastage Rate at Last CCP

$$\text{Wastage rate at service delivery point (including closed/unopened vials)} = \frac{(\text{Number of doses issued} - \text{Number of doses administered})}{(\text{Number of doses issued})} \times 100$$

Example 1: Consider the following example for calculation of open vial wastage or wastage at service delivery point:

For the month of January 2019, following were the vaccine stock estimates for Pentavalent vaccine in Rampur PHC.

- Opening Balance (as on 1st January 2019): 25,000 doses
- Closing balance (on 31st January 2019): 10,200 doses
- Doses Received (in month of January 2019): 15,000 doses
- Number of Children administered Pentavalent doses (Penta1+Penta 2+ Penta3) in January 2019: 19,220

Calculate the vaccine wastage for Pentavalent vaccine at Rampur PHC.

Answer

Step 1: To calculate the doses issued:

Doses Issued = (Opening Balance + Doses Received) – Closing Balance

= (25,000 + 15,000) – 19,200

= 20,800 doses of Pentavalent vaccine

Step 2: Calculating wastage rate of Pentavalent vaccine for January 2019 at Rampur PHC

$$\text{Wastage rate} = \frac{[\text{Doses issued} - \text{Doses administered (or children received Penta vaccine)}]}{(\text{Doses issued})} \times 100$$

$$= \frac{[20{,}800 - 19{,}220]}{20{,}800} \times 100$$

$$= \frac{1{,}580}{20{,}800} \times 100$$

$$= 7.59\%$$

3.9.2 At the Supply Chain Level (up to District Level Stores):

For the process of calculation of wastage at the supply chain level (up to district level stores), we collected data related to any loss of vaccines due to damage, expiry or breakage etc. as per record. This data was compared with the opening balance on day one and doses received during the period.

The vaccine wastage at the supply chain level is the unopened vial wastage, as no vaccine is administered at this level. The vaccine wastage rate is calculated as shown in below in equation 3 and explained through Example 2.

Equation 3: Wastage Rate at Supply Chain Level

$$\text{Wastage Rate for Closed/Unopened Vials at Supply Chain Level} = \frac{\text{Number of doses lost}}{\text{Opening balance + Number of doses received}} \times 100$$

It is important to understand that while only unopened vial wastage is calculated for the supply chain, opened vial wastage has to be calculated at the last service delivery point.

Example 2: Consider the following example for calculation of close or unopened vial wastage or wastage at supply chain level

For the month of January 2019, vaccine stock levels for Measles vaccine in Shyamabad District Vaccine Store are as follows:

- Opening Balance (as on 1st January 2019): 1,57,000 doses
- Closing Balance (as on 31st January 2019): 1,22,000 doses
- Doses received from RVS (in January 2019): 75,000 doses
- Vaccines lost (in January 2019): 2,500 doses (500 doses due to breakage & 2000 doses to absent VVM)

Calculate the vaccine wastage rate for Measles vaccine in January 2019 at Shyamabad DVS.

Answer

$$\text{Wastage rate at Shyamabad DVS} = \frac{[\text{Doses issued lost}}{(\text{Opening Balance + Doses Received})} \times 100$$

$$= 2{,}500 / (1{,}57{,}000 + 75{,}000) \times 100$$

$$= \frac{2{,}500}{2{,}32{,}000} \times 100$$

$$= 1.07\%$$

3.10 Causes of Vaccine Wastage

Vaccine wastage can be caused by multiple factors, direct or indirect. The major factors affecting unopened and opened vaccine wastage that were evaluated are mentioned in table 1.

Indirect factors such as knowledge and practices of vaccine handling by health workers (cold chain handlers and vaccinators) were also assessed to obtain a broader spectrum of reasons affecting vaccine wastage in India.

3.11 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
- Antigen-wise vaccine wastage rates
- Causes of vaccine wastage
- Training, knowledge and supervision regarding vaccine wastage
- Vaccine and Cold Chain Management
  - At all levels of the supply chain
  - At 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 for qualitative and quantitative data, respectively. All efforts were taken to maintain the confidentiality of all participants. Following the interview, all the participants were educated on the topic of vaccine wastage.

After the data collection, a detailed analysis was done to arrive at the following estimates-

- Current wastage rate in the country in unopened and opened vials for different antigens
- Wastage rate as per type/form of the vaccine (liquid/lyophilized)
- Wastage rate according to the mode of administration (Injectable/oral)
- Wastage rate based on rural and urban CCPs
- Wastage rate based on vial presentation

UNICEF/2013/Singh

4. ASSESSMENT RESULTS

Vaccine wastage is the sum of vaccines discarded, lost, damaged or destroyed. Since the introduction of newer and costlier vaccines, they amount to a larger share of the cost of the immunization programme. Accurate estimation of vaccine wastage is an important factor in calculating vaccine needs, to avoid stock-outs or over-stock, for choosing the most appropriate vaccine vial presentation and immunization session size, and sizing supply chain infrastructure at the country level. It is therefore crucial that all immunization points using vaccines and the stores handling them monitor their use and wastage continuously.

Vaccine wastages are broadly divided under two major heads viz. unopened vial wastage and open vial wastage.

In its journey from manufacturer to the targeted beneficiary, a vaccine travels through a pre-determined supply chain system before reaching its destination at last service delivery, subjecting it to face possible conditions leading to wastage at multiple levels of the immunization programme.

It is important to understand that while only unopened vial wastage is calculated for supply chain level up to DVS (i.e., GMSD, SVS and DVS), the wastage at the service delivery point (or the last CCP) includes both unopened and open vial wastage.

Among the total sample sites selected, the data was collected from 4 GMSDs, 12 SVSs, 24 DVSs, 71 last CCPs and 93 immunization session sites (Figure 8). One rural CCP could not be covered because of the temporary inaccessibility of the CCP. Since the implementation of MDVP in 2015, it is difficult to calculate wastage at immunization sessions sites, however, practices leading to vaccine wastage were assessed (as discussed in Chapter 5). Vaccine wastage rates were calculated for all vaccines administered under UIP except Hepatitis B, due to the following reasons:

- Since the launch of the Pentavalent vaccine in 2014, Hepatitis B is administered as a component of the Pentavalent vaccine at 6, 10 and 14 weeks, and the Hepatitis B vaccine is only administered within 24 hours of birth in institutional deliveries, under the UIP.
- Selected CCPs may not necessarily be a delivery point.
- The number of last CCPs with complete Hepatitis B vaccine data were less, hence was excluded due to lack of generalizability of findings.

Figure 8: Sample Sites Covered in Assessment

4	12	24	71	93
GMSDs (National Stores)	State Vaccine Stores	District Vaccine Stores	Last Cold Chain Points	Session Sites

Setting of the Sites Visited

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 5 for more information.

Table 5: Distribution of Last Cold Chain Points and Immunization Session Sites

S No.	Facility/Session Site (n)	Rural		Urban	
		n	(%)	n	(%)
1.	Last CCP (71)	50	(70)	21	(30)
2.	Immunization Session Site (93)	81	(87)	12	(13)

4.1 Vaccine Wastage at the Last Cold Chain Point

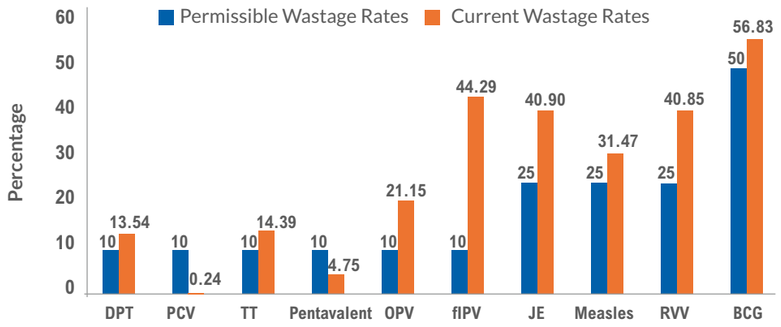
After the introduction of the multi-dose vial policy in 2010-11, the Government of India introduced a revised multi-dose vial policy with modification in September 2015.[11] The use of multi-dose vial policy aims to utilize certain left-over vaccines in multi-dose vials for 28 days from opening, while maintaining a mandatory set of conditions, including storage and transport at recommended temperatures, sterile vial, clear labels, etc. The maximum allowable wastage rates for opened vials, as per GoI guidelines, have been mentioned in table 2 earlier.

Vaccine wastage at the last cold chain point is inclusive of both unopened and opened vial wastage. The vaccine wastage rates, as calculated at the last CCP, are mentioned in table 6 and shown in comparison to permissible wastage levels in figure 9.

Table 6: Vaccine Vial Wastage at Service Delivery Point

Vaccines	Wastage at Service Delivery (%)
DPT	13.54
JE	40.90
Measles	31.47
PCV	0.24
TT	14.39
RVV	40.85
Pentavalent	4.75
BCG	56.83
OPV	21.15
fIPV	44.29

Figure 9: Current Vaccine Wastage Rates at Service Delivery Point in Comparison with Permissible Vaccine Wastage Rates



At the service delivery or the last cold chain point, the vaccine wastage was considerably high for all vaccines. The highest wastage rate was recorded for BCG (56.83 per cent), fIPV (44.29 per cent), JE (40.90 per cent), RVV (40.85 per cent), Measles (31.47 per cent), and OPV (21.15 per cent) vaccines.

Pentavalent Vaccine

The wastage rate of Pentavalent vaccine (4.75 per cent) is less than permissible wastage, i.e., 10 per cent, which is probably attributed to its applicability of MDVP.

Pneumococcal Vaccine (PCV)

The wastage rate of PCV (0.24 per cent) is less than the allowable wastage rate, i.e., 10 per cent, also attributable to its small dose vial (5-dose vial) and applicability of MDVP.

Inactivated Polio Vaccine - fractional dose (fIPV)

The highest difference between permissible (10 per cent) and actual wastage (44.30 per cent) was found in fIPV. The major reason for high wastage may be due to higher vaccine vial presentation (one vial of fIPV contains 25 doses).

Rotavirus Vaccine (RVV)

Rotavirus vaccine has higher wastage (40.85 per cent) in comparison to allowable wastage rate (25 per cent). High wastage in Rotavirus vaccines may be attributable to the introductory phase of the vaccine and the non-applicability of MDVP.

Japanese Encephalitis (JE)

JE vaccine also reported high wastage (40.90 per cent) as compared to permissible level (25 per cent) possibly because of the non-applicability of MDVP and its restricted use within four hours of reconstitution.

Oral Polio Vaccine (OPV)

OPV showed 21.15 per cent wastage in comparison to the permissible level of 10 per cent. High vaccine wastage of OPV can be attributed to higher vial presentation (20-dose). Due to ongoing supplementary immunization activities, there is a probable mixed use of RI and campaign OPV vials.

Bacille Calmette-Guérin (BCG)

BCG showed wastage of 56.83 per cent against the permissible level of 50 per cent. It may be attributed to a single dose of BCG administration at birth, non-applicability of MDVP, and its restricted use within four hours of reconstitution.

Measles

Measles vaccine shows a wastage rate of 31.47 per cent against the permissible level of 25 per cent, which is possibly due to the non-applicability of MDVP and its restricted use within four hours of reconstitution.

Tetanus Toxoid (TT)

TT vaccine showed a wastage rate of 14.39 per cent in comparison to allowable wastage of 10 per cent. High drop out of children aged 10 and 16 years may be a reason for the higher wastage of vaccines.

Diphtheria, Pertussis and Tetanus (DPT) vaccine

DPT vaccine shows a wastage rate of 13.54 per cent in comparison to allowable wastage of 10 per cent. High drop out of children for booster doses (at 1.5 years and 5 years) can attribute to a higher wastage rate.

4.2 Vaccine Wastage up to District Level Stores

All vaccine stores up to the district level only handle unopened or closed vaccine vials. Hence at all levels of the immunization supply chain up to district level stores, the unopened vial wastage rates are calculated. The unopened vial wastage rates at different levels of the immunization supply chain are mentioned in table 7.

Table 7: Unopened Vial Wastage for All Antigens, India, 2019

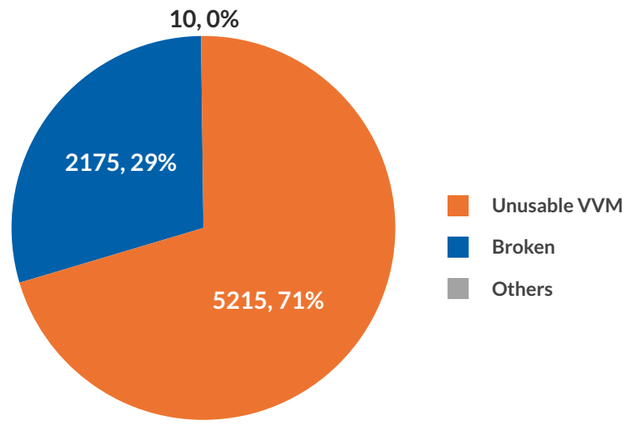
Vaccine	Unopened Vial Wastage (in %)			
	Overall	GMSD	SVS	DVS
DPT	0.00001	0	0	0.00064
JE	0	0	0	0
Measles	0	0	0	0
PCV	0	0	0	0
TT	0	0	0	0
RVV	0.00009	0	0	0.00118
Pentavalent	0.00009	0	0	0.00477
BCG	0.00079	0	0	0.04524
OPV	0.00077	0	0	0.05307
fIPV	0.00373	0	0	0.14640

At the supply chain level, the unopened or closed vial wastage for all antigens was within the acceptable limit of one per cent across all levels of the immunization supply chain, including nil at the level of GMSD and SVS.

Reasons for Unopened Vaccine Wastage

Figure 10 is showing the overall reasons for unopened vial wastage of all antigens at all levels of the immunization supply chain (up to district level stores). The wastage has been categorized into four different categories i.e. Broken, Expiry, Unusable VVM and Others(including unreadable or damaged labels, absence of VVM, unknown reason, visible contamination of vials, etc.). Out of approx. 1.1 billion doses at GMSD/SVS/DVS, 7,400 doses were wasted. Among the doses wasted, the maximum wastage (71 per cent) has been recorded due to unusable VVM. Almost 29 per cent of vaccines have been recorded wasted due to breakage or any other reasons (unreadable label). Refer to figure 10 for more information.

Figure 10: Reasons for Unopened Vial Wastage for All Antigens (n=7,400)



Level-wise Wastage:

GMSD

During the review period, no vaccines were discarded at GMSD, hence zero wastage rate for all antigens.

SVS

During the review period, no vaccines were discarded at SVS, hence zero wastage rate for all antigens.

DVS

At DVS, four vaccines (JE, Measles, PCV, and TT) have reported zero wastage rates. The reasons for vaccine wastage at the level of DVS are mentioned in table 8.

Table 8: Reasons for Vaccine Wastage at DVS

Vaccine	No. of Doses Discarded	Wastage Rate for Unopened Vials at DVS (in %)	Reasons for Wastage (Number of doses)
JE	0	0	-
Measles	0	0	-
PCV	0	0	-
TT	0	0	-
DPT	10	0.0006	Broken
RVV	10	0.0011	Broken
Pentavalent	140	0.0047	Broken (130), Unreadable label (10)
BCG	1,000	0.0452	Unusable VVM
OPV	3,390	0.0530	Broken (1,950), Unusable VVM (1,440)
fIPV	2,850	0.1464	Unusable VVM (2,775), Broken (75)

4.3 Stratified Wastage Rates

4.3.1 Wastage Rate as per Type or Form of Vaccine

The vaccines can be divided into lyophilized and liquid vaccines, based on their type or form. Lyophilized vaccines are available in the form of freeze-dried powder and must be reconstituted using a suitable diluent to obtain the liquid vaccine for administration. BCG, Measles/MR, JE, and Rotavirus vaccine are available in freeze-dried or lyophilized form. Rotavirus vaccine is available in both liquid and freeze-dried form in India. During this vaccine wastage assessment, only liquid RVV was included in the analysis as Jharkhand (the only state with freeze-dried RVV) was not selected during the sampling. The liquid vaccine can be administered as such without any reconstitution. The vaccine wastage rates among lyophilized and liquid vaccines at the service delivery point are mentioned in table9.

Table 9: Vaccine Wastage Rate Stratified by Form of Vaccine at Last CCP

Vaccines According to Form of Vaccine	Wastage Rate at Last CCP (%)
Lyophilized vaccines (BCG + Measles + JE)	43.06
Liquid vaccines (DPT + PCV + TT + Pentavalent + OPV + RVV + fIPV)	28.27

Lyophilized vaccines such as BCG, Measles, and JE have a higher vaccine wastage rate than liquid vaccines, attributed to the non-applicability of MDVP and their discard point of four hours after reconstitution.

4.3.2 Wastage Rate according to the Mode of Administration

The vaccines in Universal Immunization Programme in India can be administered through the oral or parenteral route. The vaccine that can be administered orally includes OPV and RVV. Injectable or parenterally administered vaccines include intradermal (BCG), sub-cutaneous (Measles, MR), and intra-muscularly (all other injectables) vaccines. The different vaccine wastage rates are as mentioned in table 10. Orally administered vaccines had a lower vaccine wastage rate than injectable vaccines.

Table 10: Vaccine Wastage for Oral and Injectable Vaccines

Oral versus Injectable Vaccines	Wastage Rate (%)
Oral vaccines (OPV + RVV)	31.00
Injectable vaccines (BCG + fIPV + Measles + JE + DPT + PCV + Pentavalent + TT)	34.59

4.3.3 Wastage Rate based on Vial Presentation

In India's UIP, vaccine vials come in varied presentation, ranging from 5-dose to 25-dose vials. Vaccine presentation is usually determined by varied factors such as the number of doses required per beneficiary, stability of antigen, cost-effectiveness, vaccine storage and handling practices, etc. Vaccines with high presentation are prone to more wastage, especially if not covered under MDVP. In India, most of the vaccines (BCG, Pentavalent, RVV, JE, DPT and TT) are 10-dose vials. The wastage rate for different vaccines, based on their vial presentation, is shown in table 11.

Table 11: Vaccine Wastage Rate Stratified by Vaccine Vial Presentation

Vaccine Vial Presentation	Wastage Rate (%)
≤ 5 doses/vial (Measles + PCV)	15.91
10 doses/vial (BCG + Pentavalent +RVV + JE + DPT + TT)	33.61
≥ 20 doses/vial (OPV + fIPV)	32.72

Vaccines with higher vial presentation (10 doses or more per vial) have a higher wastage rate, even with applicability of MDVP.

4.3.4 Comparison of Wastage Rate between Rural and Urban Areas

According to NFHS-4 data, the FIC is variable across rural (61.3 per cent) and urban (63.9 per cent) areas. The vaccine wastage rates stratified by rural and urban areas are mentioned in table 12.

Table 12: Vaccine Wastage Rate at Last CCP Stratified by Rural and Urban Areas

Vaccine	Wastage Rate at Service Delivery Point	
	Rural CCP (%)	Urban CCP (%)
JE	28.92	**60.18**
Measles	28.34	**39.03**
PCV	0.43	**3.47**
TT	11.55	**20.35**
DPT	10.10	**21.04**
RVV	**41.59**	39.29
Penta	4.36	**5.65**
BCG	**61.71**	49.03
OPV	**9.47**	5.77
fIPV	**45.92**	40.53

Higher wastage rates have been highlighted in bold.

Vaccine wastage is considerably higher for urban CCPs as compared to rural CCPs for most antigens, except BCG, OPV, and fIPV. In urban areas, a higher proportion of institutional deliveries and consequently higher consumption of vaccines at birth (BCG and OPV) may be the probable reason for lower wastage rates.

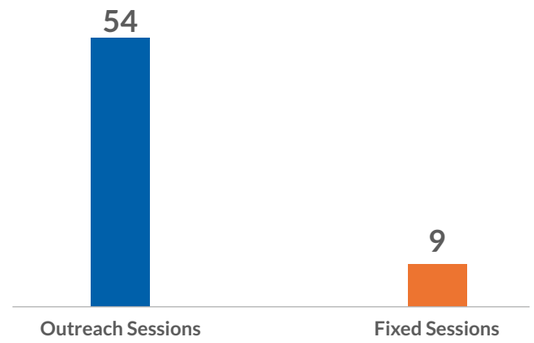
UNICEF/2008/Khemka

5. KNOWLEDGE AND VACCINE MANAGEMENT PRACTICES

One CCP caters to an average of 13 sub centres, a population of 84,000 and an annual infant target of 1,760. Since the implementation of MDVP, most of the open vaccine vials (except BCG, RVV, JE, Measles and fIPV) are returned to the CCP for repeated use for 28 days from the date of opening. However, the vaccine management practices followed by health workers at the session sites can indirectly contribute to vaccine wastage, which are discussed further in this section.

The average number of monthly outreach session sites linked to the last CCP was 54 whereas the average monthly fixed sessions linked to the CCP was 9. Refer to figure 11.

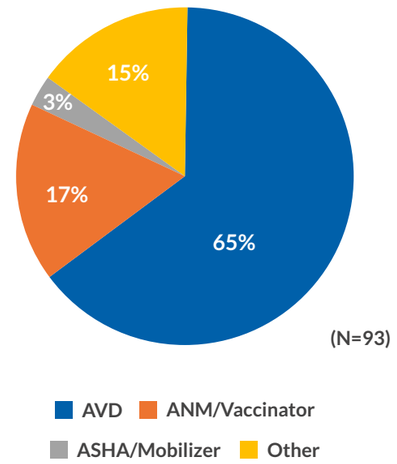
Figure 11: Average Monthly Sessions Linked to a Cold Chain Point



Availability of Mobilizers at the Session Sites: Accredited Social Health Activists (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 12. 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 Medical officer, Supervisor, Pharmacist etc.

Figure 12: Mechanism of Vaccine Delivery to Session Sites



5.1 Training, Knowledge and Supervision

The average experience of managing the vaccine and cold chain among different health care 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 four years. In the case of DIOs, it was also observed that in addition to immunization, the majority of the DIOs were also handling multiple programmes like Maternal and Child Health, Surveillance etc.

5.1.1 Training

It was observed that none of the respondents at GMSD received the training on VCCH module 2016 (in the last three years) where vaccine wastage was discussed. However, 75 per cent of them were aware of vaccine wastage, through hands-on training conducted by NCCVMRC-NIHFW in July 2018. On the other hand, the training status of health staff was better at other levels of the immunization supply chain. The status of training at all levels is mentioned in table 13 below.

Table 13: Status of Training of Health Staff on VCCH Module 2016 at All Levels

Level	Personnel (n)	Training Status	
		n	(%)
GMSD	In-charge (n=3)	0	(0)
	VCCH (n=4)	0	(0)
SVS	SCCO (n=12)	10	(83)
	VCCH (n=12)	8	(67)
DVS	DIO (n=24)	15	(63)
	VCCH (n=24)	22	(90)
Last CCP	MO* (n=71)	49	(69)
	VCCH (n=71)	52	(73)
Total	n=217	154	(71)

*trained in RI training on Medical Officer Handbook

The above table shows that most of the VCCHs/ Storekeepers at DVS are trained (90 per cent) followed by State Cold Chain Officers (SCCOs) (83 per cent) and VCCHs (73 per cent) at the last CCP. In most of the training session, a discussion was done on the topic of vaccine wastage (more than 80 per cent at all levels) but only a few received any training material/guidelines on vaccine wastage (ranging from 23 per cent in ANM training to 55 per cent in State and District level training). It was also found that many of the health staff did not receive training on standard modules but received orientation on cold chain management during training on new vaccine introduction, MR campaign, eVIN etc.

5.1.2 Knowledge

The knowledge of the staff posted at CCPs at all levels was assessed on vaccine handling and management practices, including their knowledge on reasons for vaccine wastage and wastage rate calculation.

The majority of the personnel had adequate knowledge regarding vaccine storage temperature (88 per cent) and reading of VVM (96 per cent). The knowledge regarding freeze sensitivity of vaccines was also found to be satisfactory (80 per cent). Very few staff (especially at the last CCP) had required knowledge regarding shake test (55 per cent), causes of vaccine wastage (55 per cent) and wastage rate calculation (41 per cent). Refer to table 14 for detailed information.

Table 14: Knowledge of Health Staff Regarding Vaccine Wastage

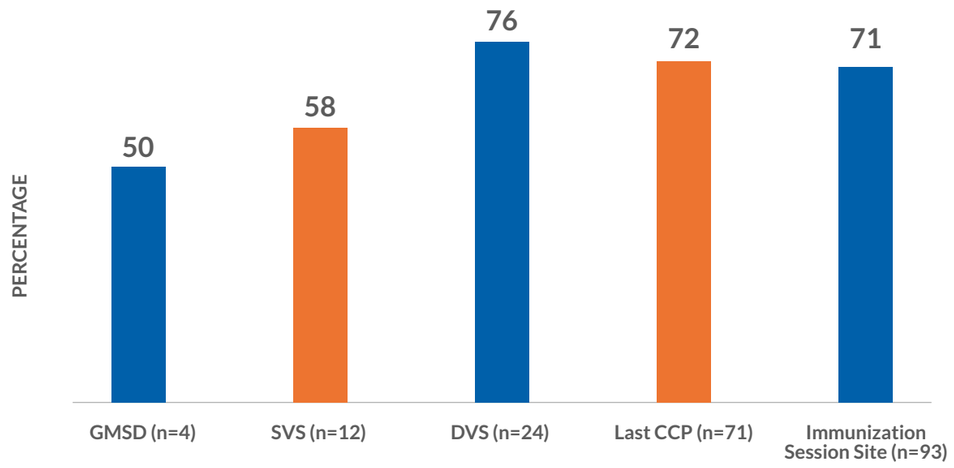
Level of Supply Chain and Personnel	Knowledge Regarding											
	Correct vaccine storage temperature		Freeze sensitivity of vaccine		Correct reading VVM		Correctly performing shake test		Causes of vaccine wastage		Calculating vaccine wastage rate	
	n	(%)	n	(%)	n	(%)	n	(%)	n	%	n	(%)
GMSD												
In-charge (n=3)	3	(100)	2	(67)	3	(100)	1	(33)	2	(67)	1	(33)
VCCH (n=4)	4	(100)	4	(100)	4	(100)	3	(75)	3	(75)	0	(0)
SVS												
SCCO (n=12)	11	(92)	11	(92)	11	(92)	9	(75)	9	(75)	9	(75)
VCCH (n=12)	11	(92)	12	(100)	12	(100)	12	(100)	11	(92)	7	(58)
DVS												
DIO (n=24)	21	(86)	18	(75)	24	(100)	16	(67)	19	(79)	16	(67)
VCCH (n=24)	23	(96)	23	(96)	24	(100)	14	(59)	17	(72)	12	(50)
Last CCP												
MO (n=71)	57	(80)	47	(66)	64	(90)	28	(41)	19	(27)	22	(31)
VCCH (n=71)	64	(90)	59	(83)	68	(96)	38	(54)	32	(45)	22	(31)
Total (n=219)	**194**	**(89)**	**176**	**(80)**	**210**	**(96)**	**122**	**(56)**	**122**	**(56)**	**89**	**(41)**

5.1.3 Supervision

Cold chain points at all levels are regularly monitored through supportive supervision by national/state/ district level officials. Standardized supportive supervision formats are used by government officials and partner agencies to collect data, which is further analysed and communicated as feedback to CCPs.

Figure 13 shows that some supervision related to vaccine and cold chain management was received at all levels. More supervisory visits were found at the lower level of the immunization supply chain (DVS, last CCP and immunization session sites) as compared to bulk stores (GMSD and SVS).

Figure 13: Proportion of CCP/Sessions which Received Supervision in the Last 3 Months



It was found that during the supervisory visits, very few issues related to vaccine wastage were raised. Some of the key issues raised during the supervisory visits of the stores are listed below:

- Lack of maintenance of vaccine wastage records due to the absence of a column or separate register for recording vaccine wastage
- Excess supply of vaccines from the manufacturer to bulk stores and then from bulk stores to lower stores leading to high vaccine wastage
- Non-compliance with the practice of EEFO principle resulting in the supply of short expiry vaccines to the lower stores
- No review of vaccine wastage at any level of the immunization supply chain
- Non-adherence to the practice of multi-dose vial policy as per the guidelines resulting in vaccine wastage

5.2 Vaccine and Cold Chain Management Practices

5.2.1 At Cold Chain Points

A. Cold Chain Equipment

The condition of cold chain equipment determines the quality of the vaccines. The better the condition of cold chain equipment (CCE), the less are the chances of vaccine wastage. A total of 608 CCE at all levels were observed for their functionality. Among 608 CCE, the majority (88 per cent) was functional, 7 per cent non-functional or under-repair, and 5 per cent were beyond economic repair. It was observed that each CCP had at least one functional ice-lined refrigerator (ILR) at the time of visit. At the last CCP, an equipment ratio of 1.72 and 1.76 was observed for ILR and deep freezer (DF) respectively. The level-wise status of the cold chain equipment is mentioned in table 15 below.

Figure 14: Cold Chain Room

Table 15: Functionality Status of Cold Chain Equipment at All Levels

Level	Equipment (n)	Functional n (%)	Non-Functional n (%)	Beyond Economic Repair n (%)
GMSD	WIC (n=19)	17 (90)	0 (0)	2 (10)
	WIF (n=19)	15 (79)	2 (10.5)	2 (10.5)
	DF (n=4)	2 (50)	2 (50)	0 (0)
SVS	WIC (n=33)	29 (88)	4 (12)	0 (0)
	WIF (n=16)	13 (81)	3 (19)	0 (0)
	ILR (n=46)	44 (96)	2 (4)	0 (0)
	DF (n=68)	67 (99)	1(1)	0 (0)
DVS	ILR (n=96)	86 (92)	3 (3)	5 (5)
	DF (n=60)	57 (95)	3 (5)	0 (0)
Last CCP	ILR (n=122)	101 (83)	7 (6)	14 (11)
	DF (n=125)	106 (85)	12 (9)	7 (6)
Total	**n= 608**	**537 (88)**	**39 (7)**	**30 (5)**

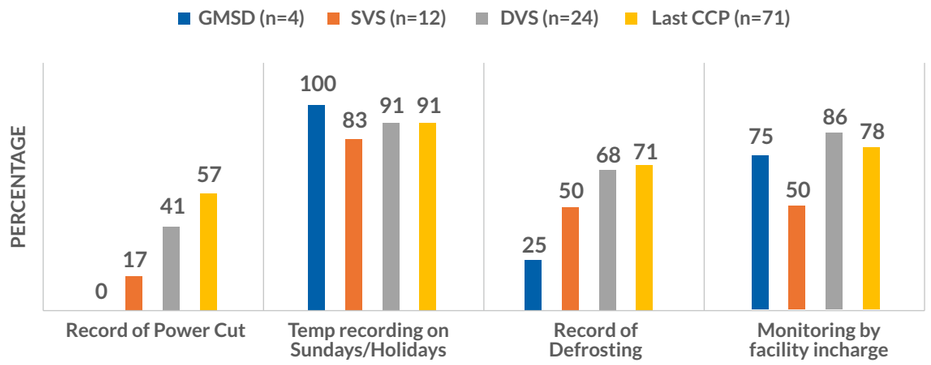
*WIC = Walk-in-cooler, WIF = Walk-in-Freezer, ILR = Ice-Lined Refrigerator, DF = Deep Freezer

B. Vaccine Temperature Maintenance

As per the standard guidelines, each functional CCE should have a functional thermometer placed inside it and temperature should be recorded twice daily on all days in the temperature logbook. Out of 537 functional (in-use and standby) CCE observed, 439 (82 per cent) CCE had functional thermometers with the highest proportion in DVS (96 per cent) followed by last CCP (81 per cent) and lowest in GMSD (67 per cent). More than 75 per cent of functional CCE also had a temperature logbook attached to it with maximum proportion in DVS (91 per cent) and last CCP (78 per cent). Almost all (99 per cent) temperature logbooks were found to be updated with twice-daily temperature recording. Other temperature recording practices are mentioned in figure 16 below:

Figure 15: Temperature Monitoring Logbook

Figure 16: Temperature Recording Practices at All Levels



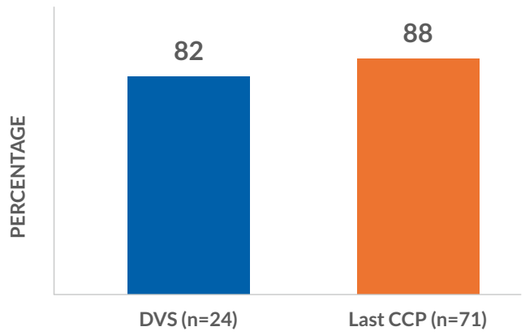
C. Ice Pack Conditioning

Conditioning of ice packs is done to prevent freezing of the freeze sensitive vaccines (shown in figure 17). Freezing of vaccine can also take place during storage or during transport (cold box, vaccine carrier). Freeze sensitive vaccines can be damaged if comes in direct contact with the frozen ice packs. Conditioning of ice packs prevents freezing of vaccine during transport, in emergency storage in cold box.

Figure 17: Ice Pack Conditioning in a Cold Chain Point

During the assessment, the VCCHs at DVS and last CCP were interviewed about the practice of ice pack conditioning as per the WHO guidelines (Figure 18).

Figure 18: Proportion of CCP Conducting Ice Pack Conditioning as per the WHO Guidelines



D. Record Keeping

The vaccine stock register was found to be available at all the GMSDs, SVS and DVS. At the last CCPs, 96 per cent of them had vaccine stock registers. The stock records were also found to be updated at the majority of the stores (GMSD: 100 per cent, SVS: 92 per cent, DVS: 86 per cent and Last CCP: 88 per cent).

The majority (>90 per cent) of the GMSD, SVS, DVS and last CCP were found to have the following parameters in the stock register:

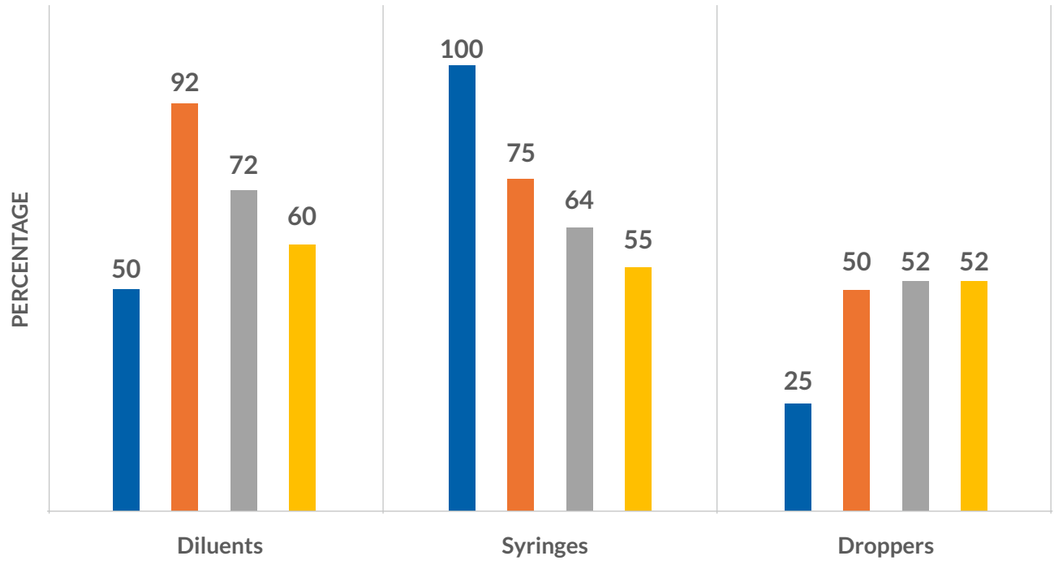
- Opening balance
- Amount received
- Amount issued
- Vaccine's batch number
- Vaccine's expiry date
- Closing balance

Standard recording formats do not contain space/column for vaccine vial presentation and vaccine wastage rate. The details of the manufacturer were recorded at all GMSDs and the majority of the SVS (92 per cent) but were found to be moderately low in the last CCP (81 per cent) and DVS (77 per cent).

Recording of the VVM in the stock records is one of the critical parameters to be recorded in relation to vaccine wastage. The practice of VVM recording was found to be variable at all levels, varying to be high at SVS (92 per cent) and last CCP (86 per cent), moderate at DVS (76 per cent) and relatively low at GMSDs (50 per cent).

The practice of maintaining a separate record of diluents, syringes and droppers was also found to be non-uniform. The practice of recording droppers' stock was found to be considerably low at all levels. The detailed status is shown in figure 19 below:

Figure 19: Practice of Recording of Logistics Stock at All Levels



E. Maintaining the Record of Vaccine Wastage

The record of vaccine wastage in stock registers was found to be low at all levels. Only 1 GMSD (25 per cent), 7 SVSs (58 per cent), 12 DVSs (50 per cent) and 43 last CCPs (62 per cent) maintained a record of vaccine wastage in stock registers. Almost 80 per cent of the stores at all levels had completed issue vouchers against each delivery of vaccine during the assessment review period but in only 10 per cent of the stores, any record of vaccine wastage was recorded in the issue vouchers. The main reason found for vaccine wastage in the issue vouchers was mostly breakage or expiry. In one of the last CCP few vaccines were discarded because of unreadable labels also which was recorded in the issue vouchers. The details are given in table 16 below.

Figure 20: Separate Register for Maintaining Discarded Stock of Vaccines

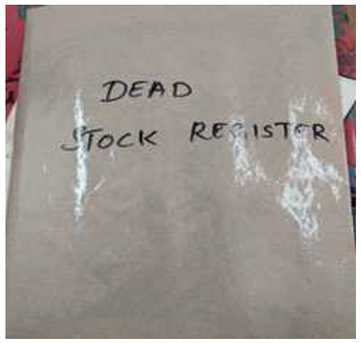


Table 16: Reasons for Vaccine Wastage Recorded at All Levels

Level	Store with completed issue vouchers against each delivery n (%)	Store with vaccine wastage recorded in issue voucher n (%)	Reason of vaccine wastage
GMSD (n=4)	3 (75)	0 (0)	-
SVS (n=12)	11 (92)	1 (8)	Breakage
DVS (n=24)	22 (95)	1 (4)	Breakage
Last CCP (n=71)	52 (73)	8 (11)	Breakage, Expiry and Unreadable label
Total (n=111)	**88 (79)**	**10 (9)**	

The other practices like calculating vaccine wastage rates on a regular basis and carrying out internal reviews for estimating vaccine loss/damage were found to be rare practice at all levels.

5.2.2 At Immunization Session sites

At the immunization session sites, the practices affecting the vaccine wastage like the upkeep of the vaccine carrier, maintenance of cold chain, availability of zipper bag/container for distribution of vaccines, implementation of multi-dose vial policy etc. were assessed. The major findings are shown in the graph below (Figure 21). The vaccine management practices followed at the immunization session site which directly affects vaccine wastage were found to be satisfactory at more than 90 per cent of session sites.

The vaccinators were also interviewed regarding vaccine wastage caused in the last three months due to faulty auto-disabled (AD) syringes, reconstitution error, serious adverse events following immunization (AEFI) or any suspected contamination. It was found that very few vaccinators could recall any vaccine wastage due to suspected contamination (5 per cent), reconstitution error (1 per cent) and serious AEFI (1 per cent) but a considerably high number of vaccinators (21 per cent) could recall that there was at least one vaccine dose wasted in the last three months due to faulty AD syringe (defective plunger causing breakage upon withdrawal of vaccine from the vial).

Figure 21: Vaccine Management Practices at Session Sites

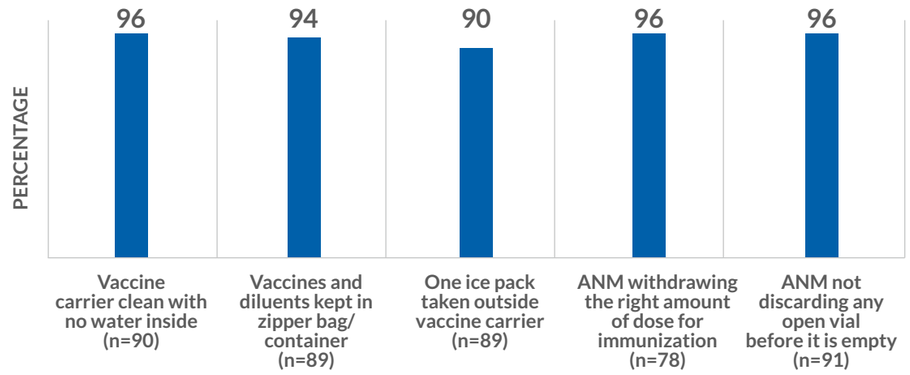


Figure 22: Maintaining Cold Chain at Session Site

Figure 23: Open Vials with Readable Date and Time

Figure 24: Open Vial with Unreadable Label

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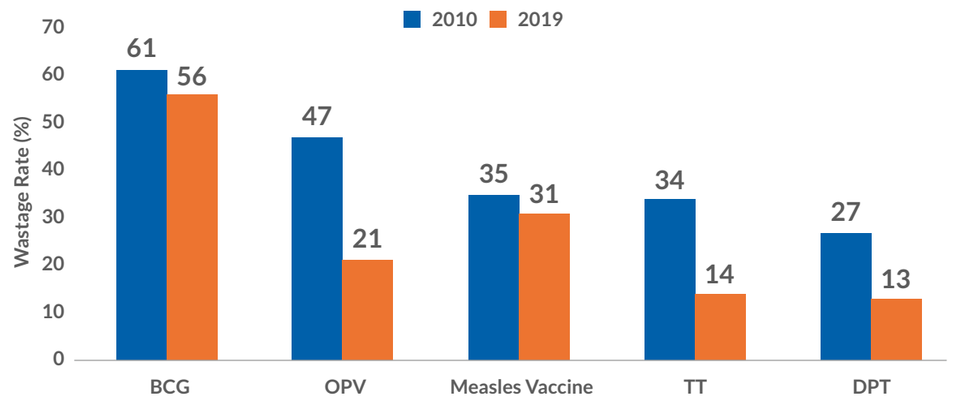
6. COMPARISON WITH NATIONAL VACCINE WASTAGE ASSESSMENT 2010

The previous National Vaccine Wastage Assessment 2010 was conducted for the review period of April to September 2009. During the previous assessment, there were six vaccines in the Universal Immunization Programme, which have been compared below. As compared with the VWA 2019, the open vial vaccine wastage rates for all vaccines (BCG, OPV, Measles, TT, and DPT) have reduced since the last assessment in 2010. Refer to table 17 and figure 25 for more information.

Table 17: Comparison of Wastage Rates of Selected Vaccines between 2010 and 2019

Vaccine	Wastage Rates (%)	
	NVWA 2010	NVWA 2019
BCG	61	56
OPV	47	21
Measles	35	31
TT	34	14
DPT	27	13

Figure 25: Comparison of Vaccine Wastage between NVWA 2010 and NVWA 2019



A maximum reduction in wastage rates was seen for TT, OPV, and DPT vaccines. The reduction in wastage rates for the above vaccines can be attributed to the implementation of multi-dose vial policy guidelines in December 2012. BCG and Measles vaccines show the least decline in wastage rate as multi-dose vial policy is not applicable on them.

Major recommendations given during the previous NVWA 2010 included the adoption of WHO multi-dose vial policy and the optimization of outreach sessions to minimize vaccine wastage. Constant efforts to improve microplanning, session planning and execution, implement MDVP, improve vaccine handling practices, and strong policy decisions by GoI, have led to focused efforts towards reducing vaccine wastage in India.

UNICEF/2018/Altaf Qadri

7. CONCLUSION

The National Vaccine Wastage Assessment 2019 gives an insightful overview of vaccine wastage and vaccine management practices in India. Both unopened and opened vial wastage were calculated at different levels of the immunization supply chain.

Negligible unopened vial wastage (less than 1 per cent) was recorded for all antigens, whereas high opened vial wastage was recorded at the last CCP or service delivery point. Unopened vaccine wastage rate was highest for fIPV, whereas opened vial wastage was highest for BCG, fIPV, JE and RVV.

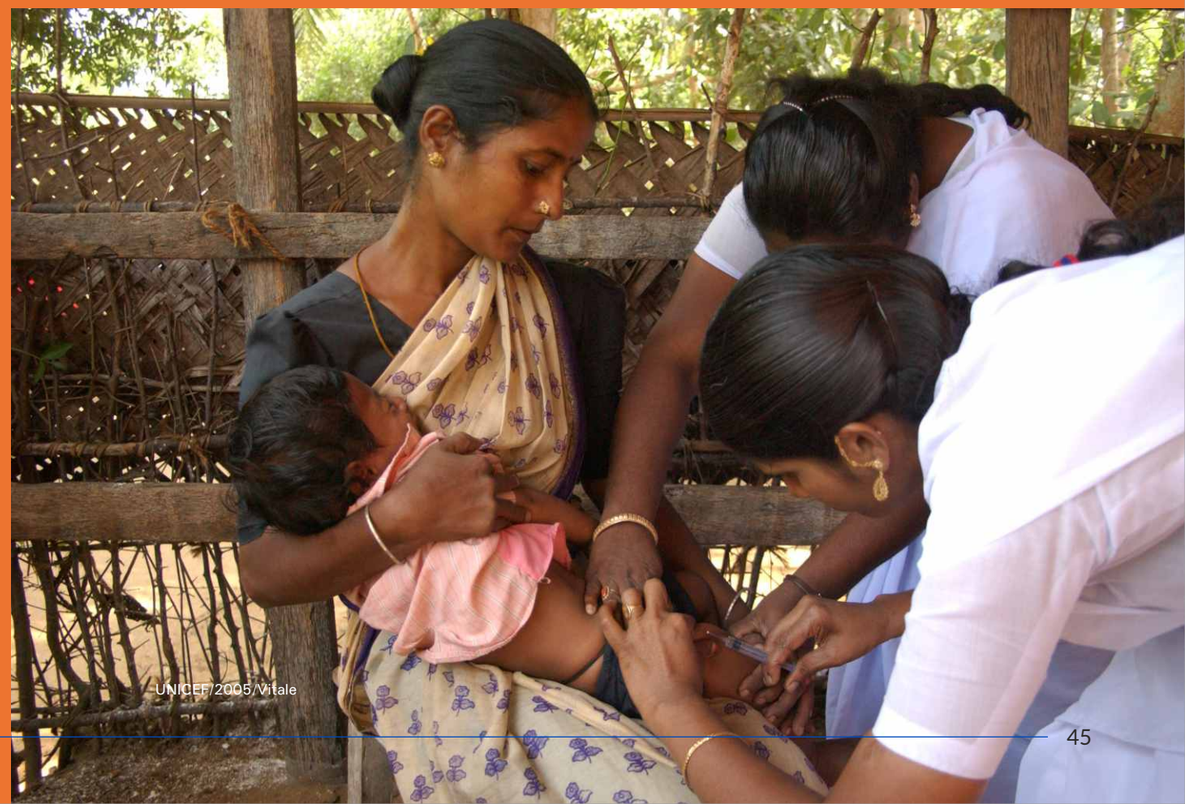
Among all vaccines, higher vaccine wastage was recorded for lyophilized vaccines (vs. liquid vaccines) and injectable vaccines (vs. orally administered). The documentation of vaccine wastage was unsatisfactory at all levels.

The training, supervision and vaccine management practices were better at lower levels of the immunization supply chain, in comparison to GMSD and other primary stores. Albeit the good training status of health staff, the knowledge about vaccine wastage (calculation, reasons, prevention, etc.) and provision of training material/job aids was inadequate.

Vaccine management practices at the CCP and session sites that influence vaccine wastage were satisfactory, except for the recording of power cuts, defrosting and review of temperature logbooks by the facility in-charge.

In almost a decade since the last vaccine wastage assessment in 2010, the wastage rate has declined for all vaccines, which can be attributed to the implementation of MDVP and better vaccine handling practices. However, this assessment was able to identify the various strengths and gaps of the programme related to vaccine wastage which can be helpful in further strengthening the overall vaccine management practices in India.

Considering the long journey of vaccines from manufacturers to the beneficiaries, some amount of vaccine wastage is acceptable (as per the GoI guidelines). However, the adoption of better vaccine handling and vaccine management practices, with strong policy decisions, can help achieve minimal wastage rates at all levels of the immunization supply chain.



UNICEF/2005/Vitale

UNICEF/2018/Altaf Qadri

8. RECOMMENDATIONS

Based on the findings of the National Vaccine Wastage Assessment 2019, recommendations can be broadly summarized at the level of practices and policymaking.

8.1 At the level of Practices

1. To invest in capacity building of staff at national and sub-national stores through refresher training and supportive supervision to strengthen the vaccine management practices like the practice of Early Expiry First Out (EEFO).
2. To ensure maintenance of stock and distribution records and vouchers through regular monitoring and supervision:
   i. For all vaccines, diluents and dry goods (including syringes, droppers, hub cutters, etc.)
   ii. Mandatory recording of vaccine wastage rates using a dedicated column in registers, vouchers, eVIN, SS checklist, etc. at all levels of immunization supply chain
   iii. Record the site of placement of vaccines, logistics and dry goods in the store
   iv. Maintain separate records for RI and campaign vaccines
3. To include the regular review of vaccine consumption and wastage rates during routine supportive supervision, monthly review meetings and monitoring at all levels of the immunization supply chain.
4. To ensure measures such as frequent data analyses of supportive supervision findings and feedback to state and districts to strengthen the uniform application of multi-dose vial policy (MDVP) guidelines by GoI.
3. To increase the monitoring and supportive supervision of primary and sub-national vaccine stores, considering the bulk of vaccines handled by the stores. A separate checklist for primary stores should be developed under the Supportive Supervision (SS) app for use by NCCVMRC.

*If standardized registers inclusive of all components is not available at any cold chain point, separate columns for recording missing components can be created and used.

8.2 At the level of Policy Making

1. To prepare and disseminate job aids related to reducing vaccine wastage to the concerned stakeholders at cold chain point and for training. Job aids may be prepared by NCCVMRC with the help of RI stakeholders.
2. To revise the stock and distribution registers to incorporate missing components including wastage rate, vaccine placement and vaccine vial presentation.
3. To decide an optimal vial presentation (or vial size) considering factors, including, but not limited to:
   i. Reduced wastage in small dose vials
   ii. Cost-effectiveness of vaccine based on its presentation
   iii. Less burden on vaccine storage and transportation
   iv. Less burden on vaccine handling and management in the field
4. To develop a mechanism for random screening of vaccine logistics (esp. auto-disabled (AD) syringes) to ensure supply and use of good quality products and minimize vaccine wastage. This process may be ensured through the utilization of the "National Technical Advisory Body" (NTAB).
5. For effective implementation of MDVP and reducing vaccine wastage, it is essential to ensure effective Alternate Vaccine Delivery (AVD) system for timely delivery and return of vaccines, as it is essential for implementing multi-dose vial policy and preventing vaccine wastage. NCCVMRC may be asked to conduct a systematic AVD system assessment to identify challenges and strengths for strengthening the 'last-mile vaccine delivery' system.
6. To ensure scaling up of the Electronic Vaccine Intelligence Network (eVIN) across the country for effective stock management and real-time temperature monitoring of Cold Chain Equipments (CCE).
7. To address the issue of limited knowledge on vaccine wastage among health staff, a separate session should be included in the ongoing immunization related training. Additional points, such as wastage rate calculation, causes of vaccine wastage, shake test, ways to prevent vaccine wastage and conducting regular wastage review, can be included in the revised Vaccine and Cold Chain Handler (VCCH) module.

UNICEF/2017/Vishwanathan

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10. 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
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17.	Mr. Vijay Agarwal	JSI	Dr. Sonika Badalia	UNDP
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