VACCINE WASTAGE ASSESSMENT
Vaccine Wastage Assessment

April 2010

Field assessment and observations from
National stores and five selected states of India
# Table of contents

Executive summary........................................................................................................... i

1  Background.................................................................................................................. 1
   1.1  Rationale of the assessment................................................................................ 1
   1.2  Objectives of the assessment............................................................................. 2

2  Methodology.................................................................................................................. 3
   2.1  Selection of sites.................................................................................................. 3
   2.2  Scope of data collection...................................................................................... 4
   2.3  Baseline assumptions ......................................................................................... 4
   2.4  Timeline for retrospective data collection....................................................... 5
   2.5  Team preparation and field visits......................................................................... 5
   2.6  Methods of data collection.................................................................................. 6
   2.7  Data compilation................................................................................................... 9
   2.8  Method of computation of wastage...................................................................... 9

3  Assessment results ....................................................................................................... 11
   3.1  Wastage rates of vaccine at session site........................................................... 12
   3.2  Wastage across type/form of vaccines ............................................................... 14
   3.3  Size of vaccine vial............................................................................................. 15
       3.3.1  Projected wastage rates with different vial sizes..................................... 15
       3.3.2  Doses administered per session.............................................................. 18
       3.3.3  Session held and availability of vials....................................................... 19
   3.4  Cost impact of vaccine wastage.......................................................................... 20
   3.5  Impact on vaccine storage volume....................................................................... 21
   3.6  Detailed analysis of individual vaccine at session site...................................... 22
       3.6.1  BCG vaccine.............................................................................................. 22
       3.6.2  Measles ...................................................................................................... 24
       3.6.3  OPV ........................................................................................................... 27
       3.6.4  DPT ............................................................................................................ 30
       3.6.5  TT ............................................................................................................... 33
       3.6.6  Hepatitis B.................................................................................................. 36

4  Conclusion..................................................................................................................... 40

5  Recommendations........................................................................................................ 41
List of Abbreviations

ANM: Auxiliary Nurse- Midwife
BCG: Bacillus Calmette- Guerin (vaccine against tuberculosis)
DPT: Diphtheria, Pertussis, Tetanus
EPW: Empowered Procurement Wing
FIC: Fully Immunized Child
GMSD: Government Medical Store Depot
HepB: Hepatitis B
HQ: Head Quarter
INR: Indian Rupees
LHV: Lady Health Visitor
MCH: Maternal and Child Health
MCHIP: Maternal Child Health Integrated Project
MIS: Management Information System
MoHFW: Ministry of Health and Family Welfare
NIHFW: National Institute of Health and Family Welfare
OPV: Oral Polio Vaccine
PHC: Primary Health Center
PROMIS: Procurement Management Information System
TT: Tetanus Toxoid
UIP: Universal Immunization Program
UNICEF: United Nations Children’s Fund
USD: United States Dollar ($)
USAID: United States Agency for International Development
WHO: World Health Organization
Executive summary

India has one of the largest Universal Immunization Programs (UIP) in the world. The program budgets more than USD 500 million every year for immunizing children against vaccine preventable diseases, including the polio eradication program.

Effective vaccine utilization is an integral component of vaccine security and vaccine wastage is one of the key factors to be considered with regards to vaccine forecasting and need estimation. The objectives of the vaccine wastage assessment were to provide an estimation of vaccine wastage rate, type and place of occurrence and recommend measures to reduce wastage at various levels.

This assessment was carried out in 5 states of India between October 2009 and February 2010. The states were selected based on the differences in coverage rates of immunization and geographic distribution. Retrospective data from a 6 months period between April 2009 and September 2009 was collected through field visits to selected sites. Both qualitative and quantitative data were collected.

Findings suggested that there were poor documentation of vaccine wastage at all levels. Wastage rates vary from state to state and among different vaccines. Highest vaccine wastage occurs at service delivery level (27% for DPT and 61% for BCG at outreach session site) as compared to the supply chain levels (Measles3.5%, others <1 %). Poor documentation of vaccine wastage at supply chain is one of the responsible factors for this very low value. Session size, vial size, formulation (liquid vs. lyophilized, oral vs. injectable) also influences vaccine wastage.

To reduce vaccine wastage with optimal increase in cold chain space and management, it is recommended that the size of the outreach sessions should be optimized to cover target beneficiaries. Smaller vials have lower wastage; however it should be balanced with available cold chain space. Any change in formulation should be coupled with refresher trainings of health workers and revised micro planning. WHO recommended multi dose vial policy may be considered in fixed sites.
1 Background

India has one of the largest Universal Immunization Programs in the world. The program budgets more than US$ 500 million every year for immunizing children against vaccine preventable diseases, including the polio eradication program. The country is presently developing new strategies to increase immunization coverage and reach more children with quality vaccines. These efforts are challenged by the problems of securing adequate quality and quantity of vaccines for the program. In addition, deficiencies in vaccine management and high wastage increase vaccine demand and inflate overall program cost.

Vaccine management and logistics were some of the key issues that were critically appraised in the National UIP Review conducted in 2004. Some of the specific shortcomings observed were:

a. Large differences between reported and evaluated coverage was impacting vaccine supply;

b. Instances of shortages and stock-outs of different vaccines were affecting the immunization activities at different levels;

c. Wastage was high and not monitored;

d. There was no matching of vaccine requirements and supplies at lower levels;

e. Calculation of vaccine requirements was not linked to micro-planning or realistic coverage or wastage data.

The national cold chain assessment carried out in 2008 conducted by Ministry of Health and Family Welfare, Government of India and UNICEF recommended conducting vaccine wastage study to arrive at actual wastage rate.

1.1 Rationale of the assessment

Effective vaccine utilization is an integral component of vaccine security and vaccine wastage is one of the key factors to be considered for vaccine forecasting and need estimations. The lack of knowledge of wastage rates provides inadequate estimations of needs and subsequent stock-outs and/or overstocks. High vaccine wastage inflates vaccine demand and increases unnecessary vaccine procurement and supply chain costs.
In the context of India, any reduction of vaccine wastage will have a positive impact on the ongoing efforts towards vaccine security. One of the priority actions in India’s multi-year strategic plan 2005-10 is to improve vaccine stock management through developing and implementing guidelines to specify standard processes for ordering and maintaining stock levels; monitor stock-outs and wastage.

A better sense of vaccine utilization and wastage rates can lead to better planning and management of vaccine stocks. This assessment will give some information about the current wastage level, which could then lead to appropriate guidance and trainings to reduce vaccine wastage.

1.2 Objectives of the assessment

- Provide an estimation of vaccine wastage rate, type and place of occurrence
- Provide realistic estimates of vaccine wastage rates to guide procurement and supply of vaccine
- Recommend measures to reduce wastage at various levels
2 Methodology

2.1 Selection of sites

The assessment was carried out in 5 states of India. The states were selected based on the differences in coverage rates of immunization and were geographically distributed across the nation.

Table 1: Criteria for selection of states

<table>
<thead>
<tr>
<th>State</th>
<th>DPT-3 coverage*</th>
<th>Geographical zone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uttar Pradesh</td>
<td>30.0</td>
<td>North</td>
</tr>
<tr>
<td>Assam</td>
<td>44.9</td>
<td>East</td>
</tr>
<tr>
<td>Maharashtra</td>
<td>76.1</td>
<td>West</td>
</tr>
<tr>
<td>Tamil Nadu</td>
<td>95.7</td>
<td>South</td>
</tr>
<tr>
<td>Himachal Pradesh</td>
<td>85.1</td>
<td>Hilly and cold climate</td>
</tr>
</tbody>
</table>

* NFHS 2005-2006

Figure 1: DPT-3 Coverage of selected states for assessment (NFHS 2005-2006)
2.2 Scope of data collection

The assessment required data collection from all levels of the vaccine supply chain network. The reasons of wastage of vaccine at supply chain level (national/state and district stores) are substantially different than at the service delivery level. This required separate preparation of data collection forms for the supply chain level and the service delivery level.

A total of four data collection forms were developed to record the supply and vaccination details of routine immunization. Broadly, data collection forms were classified into quantitative and qualitative, one each for supply chain level and service delivery level. These forms are attached as annexes to this report.

2.3 Baseline assumptions

The assessment covered all the vaccines in the national immunization schedule of India. The assumptions of vaccine vial size (number of doses per vial and storage volume per dose of vaccines) is based on the vaccines supplied for UIP program in India. Table below lists the baseline assumptions used in this assessment.
Table 2: Baseline assumptions

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Type</th>
<th>Number of doses per FIC</th>
<th>Number of doses per vial</th>
<th>Mode of administration</th>
<th>Storage volume per dose (cm³)</th>
<th>Cost per dose In INR</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>Lyophilized</td>
<td>1</td>
<td>10</td>
<td>Injectable</td>
<td>1.2</td>
<td>1.92</td>
</tr>
<tr>
<td>Measles</td>
<td>Lyophilized</td>
<td>1</td>
<td>5</td>
<td>Injectable</td>
<td>5.0</td>
<td>9.09</td>
</tr>
<tr>
<td>DPT</td>
<td>Liquid</td>
<td>5</td>
<td>10</td>
<td>Injectable</td>
<td>3</td>
<td>1.68</td>
</tr>
<tr>
<td>TT</td>
<td>Liquid</td>
<td>3.5</td>
<td>10</td>
<td>Injectable</td>
<td>3</td>
<td>1.25</td>
</tr>
<tr>
<td>HepB</td>
<td>Liquid</td>
<td>3</td>
<td>10</td>
<td>Injectable</td>
<td>3.8</td>
<td>4.95</td>
</tr>
<tr>
<td>OPV</td>
<td>Liquid</td>
<td>4</td>
<td>20</td>
<td>Oral</td>
<td>1</td>
<td>3.6</td>
</tr>
</tbody>
</table>

FIC- Fully Immunized Child

The assessment covered the data of vaccinations done at outreach session sites only and it does not include the fixed vaccination sites in hospitals and PHCs (except in Tamil Nadu where vaccination sessions were predominantly held in PHCs under supervision of doctors).

2.4 Timeline for retrospective data collection
The study was conducted for the period of 6 months from April 2009 to September 2009. The retrospective data was collected through field visits to selected sites.

2.5 Team preparation and field visits
The field visits were planned in consultation with Ministry of Health and Family Welfare (MoHFW), state governments and partner agencies. A total of 5 teams were formed. The field visits were carried out in the period of October-November 2009, except Meerut district of Uttar Pradesh that was visited in the month of February 2010. Visits were planned to cover two districts from each of the selected states except of Himachal Pradesh where only one district was visited. Himachal was selected for geographical challenges of hard to reach areas and sparsely populated terrain.
2.6 Methods of data collection

The quantitative data was collected from sources ranging from stock book registers, indent challan books to ANMs record book of immunization activities. Wherever available, temperature logbooks and electronic temperature records were reviewed. This information can explain the reasons for vaccine wastage whether due to freezing or exposure of vaccine to high temperature. Following table lists the sources of data for various levels.
**Methodology**

**Figure 4: Key activities during assessment**

- **State**: State Immunization Officer, State Cold Chain Officer, Store-in-charge, Logistics manager, Computer operator (MIS)
- **District**: District Immunization Officer, Store incharge, Computer operator (MIS)
- **PHC**: Medical officer, Cold chain handler
- **Sub center**: Medical officer, ANM

**Key Program officials met**
- State Immunization Officer
- State Cold Chain Officer
- Store incharge
- Logistics manager
- Computer operator (MIS)
- District Immunization Officer
- Store incharge
- Computer operator (MIS)
- Medical officer
- Cold chain handler
- Medical officer
- ANM

**Records and reports assessed**
- Vaccine stock books
- Vaccine Bin cards
- MIS reports
- Physical stock of vaccine
- Temperature records
- Vaccine stock books
- MIS reports
- Indents
- Physical stock of vaccine
- Temperature records
- Vaccine stock books
- MIS reports
- Indents
- Physical stock of vaccine
- Temperature records
- MIS reports
- ANM record books
- Indents

**Tasks performed**
- Briefing about mission
- Selection of districts
- Collection of vaccine transactions
- Collection of temperature records
- Briefing about mission
- Selection of PHCs
- Collection of vaccine transactions
- Collection of temperature records
- Briefing about mission
- Selection of sub centers
- Collection of vaccine transactions
- Collection of temperature records
- Briefing about mission
- Collection of vaccination data

**Assessment result**

**Compilation of data**

**Analysis of data**

**Validation of data**
**Methodology**

Table 3: Records reviewed during assessment

<table>
<thead>
<tr>
<th>Level</th>
<th>Stock movement</th>
<th>Immunization activities</th>
<th>Temperature maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMSD</td>
<td>Bin cards; Stock books; Monthly reports; Vaccine Arrival Reports;</td>
<td></td>
<td>Records of data loggers; Temperature trace records of cold rooms; Manual temperature records;</td>
</tr>
<tr>
<td>State store</td>
<td>Stock books; Indents; Shipment logs; Monthly reports;</td>
<td></td>
<td>Manual temperature records;</td>
</tr>
<tr>
<td>District store</td>
<td>Stock books; Indents; Shipment logs; Monthly reports;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHC</td>
<td>Vaccine stock books</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub centers</td>
<td>Vaccine in and out registers;</td>
<td>MCH registers;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ANM record books;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Micro plans;</td>
<td></td>
</tr>
</tbody>
</table>

The qualitative data was collected by interviewing staff at all the levels. Table 4 details the profile of staff interviewed with listed subject of focus.

Table 4: Baseline for qualitative assessment questionnaire

<table>
<thead>
<tr>
<th>Staff profile</th>
<th>Planning</th>
<th>Management</th>
<th>Operational</th>
<th>Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Officer in charge</td>
<td>Source of target estimates;</td>
<td>Schedule of vaccine arrival; Temperature monitoring;</td>
<td>Placement and training of human resources;</td>
<td>Instances of vaccine damages and corrective actions;</td>
</tr>
<tr>
<td>Store in charge</td>
<td>Indent preparation; Shipment verification;</td>
<td>Knowledge of vaccine management;</td>
<td>Vaccine supply network; Stock book maintenance;</td>
<td>Instances of vaccine damages and corrective actions;</td>
</tr>
<tr>
<td>LHV or ANM</td>
<td>Micro plans;</td>
<td>Waste disposal methods; Tracking tools;</td>
<td>Vaccination records; Sessions planned and held;</td>
<td>Monthly reporting;</td>
</tr>
</tbody>
</table>
### Methodology

#### Staff profile

<table>
<thead>
<tr>
<th></th>
<th>Planning</th>
<th>Management</th>
<th>Operational</th>
<th>Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cold chain handler</td>
<td>Maintenance schedules;</td>
<td>POL supply for generators;</td>
<td>Maintenance of temperature and cold chain equipment;</td>
<td>Reporting of faulty equipment;</td>
</tr>
<tr>
<td>Computer operator</td>
<td>Monthly reporting</td>
<td>Data collection for PROMIS;</td>
<td>Data entry into PROMIS system;</td>
<td>Monthly reporting;</td>
</tr>
</tbody>
</table>

2.7 **Data compilation**

The data collected during field visits was compiled using a Microsoft Excel based database. Each site was given a unique number for tracing the data for verification. All the analysis and results included in this report were directly produced through this custom made tool. The comments and qualitative data were captured in this report in narrative form though relative sections.

2.8 **Method of computation of wastage**

Vaccine wastage is an expected component of any immunization program. In order to ensure that no child is missed during an immunization session, the vaccine is procured with estimated wastage. However, this should be balanced with optimal wastage, safety concerns, and timely use of vaccines. The key in optimum use of vaccine supplied is by preventing vaccine shortages while limiting overstocks. Vaccine wastage can be minimized by determining avoidable causes of loss of vaccine and taking corrective action.

Wastage is often defined as “loss by use, decay, erosion, or leakage or through wastefulness”. To understand vaccine wastage, it is important to understand vaccine usage. Vaccine usage is defined as the proportion of vaccine administered against vaccine issued. Equation 1 illustrates formulae used for Computing vaccine usage and wastage. Vaccine wastage is the opposite of vaccine usage. Thus, the Vaccine Wastage Rate can be defined as 100 minus the vaccine usage rate. The wastage rate directly determines the “wastage factor” which needs to be established for each vaccine in the immunization schedule to accurately plan vaccine needs.
Vaccine wastage can primarily be divided into two categories of: (1) wastage in unopened vials; (2) wastage in opened vials. It is useful to know what type of wastage is more prevalent in immunization settings to better plan corrective action. Common causes of wastage in unopened and opened vials of vaccines are listed in table below (source: Vaccine wastage in Bangladesh published in Elsevier 2010).

Table 5: Reasons of vaccine wastage

<table>
<thead>
<tr>
<th>Vaccine wastage in unopened vials</th>
<th>Vaccine wastage in opened vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>The expiry date has reached;</td>
<td><strong>All the causes listed in the left column and:</strong></td>
</tr>
<tr>
<td>Vaccine exposed to heat and vaccine; vial monitor (VVM) reached unusable stage;</td>
<td>Discarding remaining doses at the end of the session;</td>
</tr>
<tr>
<td>The vaccine has been frozen;</td>
<td>Not being able to draw the number of doses in a vial;</td>
</tr>
<tr>
<td>Breakage</td>
<td>Poor reconstitution practices;</td>
</tr>
<tr>
<td>Missing inventory</td>
<td>Submergence of opened vials in the water;</td>
</tr>
<tr>
<td>Theft</td>
<td>Suspected contamination;</td>
</tr>
<tr>
<td>Discarding unused vials returned from outreach session.</td>
<td>Poor vaccine administration practices.</td>
</tr>
</tbody>
</table>

The wastage of vaccine happens at multiple levels during transportation, storage and at vaccination session sites (service delivery levels). The method of computation of wastage rates at supply chain and session site is different, as shown in equation below.

**Equation 1:** Formulas used for computing vaccine wastage rates

\[
\text{Vaccine wastage rate} = \left( \frac{\text{Total doses damaged or expired or lost during the assessment period}}{\text{Total doses supplied during the assessment period}} \right) \\
\text{Vaccine utilization rate} = \left( \frac{\text{Total doses immunized}}{\text{(Total doses issued- total doses returned)}} \right) \\
\text{Vaccine wastage rate} = 100 - \text{vaccine utilization rate}
\]
3 Assessment results

The assessment of vaccine wastage at all levels of the supply chain for the six months period reflects that maximum wastage occurs at the session site (BCG vaccine had the maximum wastage of 61%). At supply chain level, maximum wastage found was of Measles vaccine (3.46% of total supplied) at the state vaccine store. All other vaccines had vaccine wastage of less than 1% at supply chain level.

The other key findings from the field are:

a. There has been poor documentation of vaccine wastage at all levels. It is difficult to reflect the wastage rates based on documentation. The results in the assessment were derived from computation based on stock movements and vaccination records (refer to equation 1 for formula of deriving wastage).

b. The wastage is different for each vaccine, but the supply of vaccines is computed by 25% wastage rate for all vaccines except BCG. BCG requirement is computed either based on session size or using 50% wastage rate;

c. The wastage rate varies across the states;

d. Unopened vials were not returned from many sessions (7% of issued OPV vials discarded unopened);

e. Data mismatch: Doses consumed and number of children immunized does not match at few places;

f. Each session should have at least one vaccine vial of each antigen. This was not always followed as assessment reflected that only 47% of sessions had atleast one vial of all the vaccine available during the session.

The vaccine wastage rates observed during assessment at various levels are summarized below.

---

1 Assessment teams referred to various sources of information recorded at session sites. Data reported had inconsistencies.
### ASSESSMENT RESULT

#### Table 5: Wastage rates

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Vaccine wastage rate</th>
<th>State store</th>
<th>District store</th>
<th>PHC</th>
<th>Session site</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>0.005%</td>
<td>0.345%</td>
<td>0.857%</td>
<td>60.99%</td>
<td></td>
</tr>
<tr>
<td>DPT</td>
<td>0.426%</td>
<td>-</td>
<td>0.053%</td>
<td>26.80%</td>
<td></td>
</tr>
<tr>
<td>TT</td>
<td>0.002%</td>
<td>-</td>
<td>-</td>
<td>33.71%</td>
<td></td>
</tr>
<tr>
<td>HepB</td>
<td>-</td>
<td>-</td>
<td>0.080%</td>
<td>33.15%</td>
<td></td>
</tr>
<tr>
<td>OPV</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>47.47%</td>
<td></td>
</tr>
<tr>
<td>Measles</td>
<td>3.463%</td>
<td>-</td>
<td>-</td>
<td>35.09%</td>
<td></td>
</tr>
</tbody>
</table>

#### 3.1 Wastage rates of vaccine at session site

The BCG vaccine had the maximum wastage rates followed by OPV and Measles, TT, HepB and DPT.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Average wastage rate</th>
<th>Uttar Pradesh</th>
<th>Himachal Pradesh</th>
<th>Tamil Nadu</th>
<th>Maharashtra</th>
<th>Assam</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>61%</td>
<td>58%</td>
<td>65%</td>
<td>65%</td>
<td>54%</td>
<td>68%</td>
</tr>
<tr>
<td>OPV</td>
<td>47%</td>
<td>40%</td>
<td>75%</td>
<td>46%</td>
<td>51%</td>
<td>56%</td>
</tr>
<tr>
<td>Measles</td>
<td>35%</td>
<td>26%</td>
<td>58%</td>
<td>35%</td>
<td>44%</td>
<td>41%</td>
</tr>
<tr>
<td>TT</td>
<td>34%</td>
<td>20%</td>
<td>53%</td>
<td>32%</td>
<td>55%</td>
<td>41%</td>
</tr>
<tr>
<td>HepB</td>
<td>33%</td>
<td>57%</td>
<td>30%</td>
<td>37%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DPT</td>
<td>27%</td>
<td>19%</td>
<td>58%</td>
<td>20%</td>
<td>35%</td>
<td>34%</td>
</tr>
</tbody>
</table>

The bars below shows the average wastage rate of each vaccine while the arrow line shows the maximum and minimum wastage as found in states.
Himachal Pradesh had maximum wastage of all the vaccine except for TT and BCG. TT and BCG are also at higher side compared to average wastage of all the states. This high wastage of vaccine is clearly due to sparsely populated area of Himachal Pradesh. Uttar Pradesh being the most populated state had the lowest wastage rate. This implies that the wastage rate is inversely proportionate to density of population.

The difference between the maximum and minimum wastage rate is as much as 39% (DPT) and as low as 14% (BCG). This demonstrate that the wastage of lyophilized vaccine remains high in all the states but wastage of vaccine, that can be used through multiple sessions, can be reduced through optimum planning of sessions.

The detailed assessment of individual vaccine is included in section 3.6 below.
3.2 Wastage across type/form of vaccines

The vaccines in immunization schedule are of different sizes and come in liquid and lyophilized form. Comparison of wastage rate across these different forms of presentation is explained below:

**Liquid and Lyophilized**: Four vaccines, namely, OPV, DPT, TT and HepB are supplied in liquid form and two vaccines, BCG and Measles are freeze dried or lyophilized vaccines. The average wastage rates of liquid form were found to be less (38%) than the lyophilized form (50%). This is because the lyophilized vaccine needs to be discarded within four hours after re-constitution.

![Wastage across type/form of vaccines](image)

**Vial size**: The vaccines are supplied in three different sizes of vials; five doses (Measles), 10 doses (BCG, DPT, TT and HepB) and 20 doses (OPV) per vial. Among these, there was negligible difference in
wastage between five doses and 10 doses vials (both averaging approximately 35%) whereas OPV in 20 dose vial had the wastage rate of 47%. This instigated the detailed analysis on the optimum vial size for each vaccine, which is covered in section 3.3.

**Mode of Administration:** All the vaccines except for OPV are administered through injection. OPV is orally given. The average wastage rate of injectable vaccine is 35% and oral (OPV) is 47%. Since OPV is the only vaccine that is supplied in size of 20 dose per vial and only vaccine that is administered orally, there is insufficient ground to conclude that mode of administration affects vaccine wastage.

### 3.3 Size of vaccine vial
The vaccines used in India come in the different vial sizes (refer to Table 2). The number of doses per vial can be crucial in reducing the vaccine wastage. The combination of the average size of the outreach sessions, the cold chain storage space required and cost of vaccine can help in deciding the optimum size of vaccine vials to be used in the immunization program.

#### 3.3.1 Projected wastage rates with different vial sizes
Table below shows the vial sizes typically available for each type of vaccine in the UIP schedule.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Available vial sizes (Doses per vial)</th>
<th>Used in India</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>BCG</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Measles</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>DPT</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>TT</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>HepB</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>OPV</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

The vaccination coverage data from the assessment (number of doses immunized per session) is used below with different vial sizes to arrive at projected wastage of vaccine. It is shown that the wastage is least with a vial size of 5 doses. But the possible reduction of wastage
by introducing smaller size vials should not result in incremental need of cold chain storage space.

Figure 7 and 8 below show the comparative analysis of projected wastage of vaccines against different vial sizes and the storage volume required per dose.

The storage volume of 5 doses per vial size is not available for most of the vaccines. The incremental vaccine storage volume for 10 doses vials from 20 doses vials is 20% for DPT and TT, 33% for HepB and 100% for OPV. Considering the similar ratio between 10 doses vials and 5 doses vials, the reduction of vial size will have a substantial incremental impact on storage volume requirements, which will increase the demand of storage and transportation facilities.

Figure 7 show that all the vaccine except OPV are supplied using the optimal size (number of doses per vial). The vaccine vials with less number of doses (5 for example) does reduce the vaccine wastage however, figure 8 show that vials with lesser doses needed higher volume of storage. The equilibrium of quantities wasted and optimizing storage space lies in two factors of supply capacity of these vaccines by manufacturers and cost of procuring the vaccine.
**Assessment Result**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Average wastage</th>
<th>Cost per dose (INR)</th>
<th>Number of doses per FIC</th>
<th>Cost per FIC including wastage</th>
<th>% share in FIC cost</th>
<th>% share in FIC including wastage</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>61%</td>
<td>1.92</td>
<td>1</td>
<td>1.92</td>
<td>4%</td>
<td>6%</td>
</tr>
<tr>
<td>OPV</td>
<td>47%</td>
<td>3.60</td>
<td>4</td>
<td>14.4</td>
<td>27%</td>
<td>31%</td>
</tr>
<tr>
<td>DPT</td>
<td>27%</td>
<td>1.68</td>
<td>5</td>
<td>8.41</td>
<td>16%</td>
<td>13%</td>
</tr>
<tr>
<td>Measles</td>
<td>35%</td>
<td>9.09</td>
<td>1</td>
<td>9.09</td>
<td>17%</td>
<td>16%</td>
</tr>
<tr>
<td>TT</td>
<td>34%</td>
<td>1.25</td>
<td>3.5</td>
<td>4.38</td>
<td>8%</td>
<td>8%</td>
</tr>
<tr>
<td>HepB</td>
<td>33%</td>
<td>4.95</td>
<td>3</td>
<td>14.85</td>
<td>27%</td>
<td>28%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>53.06</td>
<td></td>
<td>86.4</td>
</tr>
</tbody>
</table>

Even though Measles vaccine is the most expensive vaccine per dose, the OPV and HepB share the 55% of total cost of fully immunizing the child. Reduction in wastage of these two vaccines will have an impact on total budget for the program. Likewise, even though the wastage of BCG vaccine is high among all the vaccine, BCG being the cheapest vaccine in immunization schedule, the reduction in wastage of BCG will have negligible impact on program budget.

![Figure 8: Storage volume of various vial sizes](image-url)
3.3.2 Doses administered per session

Wastage of vaccines has a direct relationship with session size (number of beneficiaries per session) and vial size. Taking OPV as an example, for about 17.5% of sessions where up to 5 doses per session were given, the wastage was more than 75% (as less than 5 doses were drawn from a 20-dose vial.)

**Figure 9: Percentage of sessions where the vaccine vial was opened for administration**

About 36% of sessions, 11 to 20 doses of OPV were administered per vial, which means that vial size of 20 dose of OPV is suitable for only 36% of the total sessions. For the remaining 64% of sessions a vial size of 10 doses would have resulted in less wastage of OPV vaccine.

The analysis of vaccination data of lyophilized vaccine (BCG and Measles) shows that in about 86% (measles) and 76% (BCG) of sessions, vaccine was administered less than 5 doses per session. This suggests the ideal size of these vaccines to be 5 doses per vial.

The analysis shows that with an increase in session size the wastage of vaccine will reduce substantially.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Percentage of sessions where the vaccine was opened</th>
<th>Upto 5 doses administered per session</th>
<th>6 to 10 doses administered per session</th>
<th>11 to 20 doses administered per session</th>
<th>More than 20 doses administered per session</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPV</td>
<td>17.51% 32.00% 36.31% 13.98%</td>
<td>17.51%</td>
<td>32.00%</td>
<td>36.31%</td>
<td>13.98%</td>
</tr>
<tr>
<td>DPT</td>
<td>19.32% 42.63% 28.26% 9.78%</td>
<td>19.32%</td>
<td>42.63%</td>
<td>28.26%</td>
<td>9.78%</td>
</tr>
<tr>
<td>HepB</td>
<td>31.60% 31.29% 23.62% 13.50%</td>
<td>31.60%</td>
<td>31.29%</td>
<td>23.62%</td>
<td>13.50%</td>
</tr>
<tr>
<td>TT</td>
<td>36.02% 45.30% 15.87% 2.81%</td>
<td>36.02%</td>
<td>45.30%</td>
<td>15.87%</td>
<td>2.81%</td>
</tr>
<tr>
<td>Measles</td>
<td>86.17%</td>
<td>86.17%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BCG</td>
<td>76.24% 23.38% 0.38%</td>
<td>76.24%</td>
<td>23.38%</td>
<td>0.38%</td>
<td></td>
</tr>
</tbody>
</table>

* Only those sessions where the corresponding vaccine vial was opened
### 3.3.3 Session held and availability of vials

The Ministry of Health and Family Welfare’s (MoHFW) guidelines for immunization session sites recommend the following with regards to vaccine logistics:

a. Each session planned and held should have at least one vial of each vaccine available;

b. The vial should be opened for vaccination even for one child due for vaccination;

c. Unopened vials should be returned to the cold chain point at the end of the day. The returned vials should be clearly marked with the date of return. The returned vial can be re-issued maximum three times, after that it should be discarded;

d. Open vials of DPT, TT, HepB and OPV should be discarded at the end of the day during routine immunization session;

e. BCG and Measles should be discarded within four hours of reconstitution.

It was evident through the assessment that one vial of each vaccine per session recommendation is not followed at session sites. Only 47% of sessions held had at least one vial of each vaccine available.

![Figure 10: Availability of vaccines at session sites](image)

Among the states assessed, Himachal Pradesh has the lowest number of sessions held (10%) where all the vaccine vials are available.
Uttar Pradesh had maximum number of sessions with all the vials taken (about 65%).

It is evident that the one vial of each vaccine per session guideline was not always observed. This indicates that there is certainly a scope of improving the session size such that there is equal demand for vaccines across sessions. This will result in reduction of wastage.

3.4 Cost impact of vaccine wastage

The vaccine is procured in India based on a coverage assumption of 100% of the target population and a wastage factor of 1.33 for all vaccines except for BCG. For BCG, the requirements are based on session planning. Adding the cost of vaccine (per dose) is to the derived wastage rates from this assessment, the total amount spent to procure vaccines about 61% is the base cost of immunizing every fully immunized child (FIC) and 39% is to cover the vaccine wasted.

Graph below shows the breakup of base cost per FIC and additional cost incurred as a result of wastage for each vaccine in immunization schedule.

Figure 11: Proportion of sessions with all vials taken
Refer to Table 2 for the baseline cost of each vaccine as used in this assessment.

**3.5 Impact on vaccine storage volume**

The storage volume of each vaccine (per dose) is mentioned in Table 2. The total vaccine storage volume needed is the aggregation of the number of doses required per FIC for each vaccine and its relevant wastage rate. The analysis suggests that about 34% of extra space is required per FIC to accommodate the additional vaccines resulting from the wastage rate as observed from this assessment. The additional volume required per FIC is shown in graph below.

**Figure 14: Required storage volume**
3.6 Detailed analysis of individual vaccine at session site

3.6.1 BCG vaccine

The wastage rate of BCG vaccine varies from 54% in Maharashtra to 68% in Assam with the average rate of 61% across all the session sites observed.

Among the sessions where the BCG vaccine was administered, about 76% of the sessions used only up to 5 doses. About 24% of the sessions administered between 6 and 10 doses.
In about 35% of the observed sessions, BCG vaccine was not available at the session site. In 5%, vials were returned unopened at the end of the session day. In 60% of sessions, a BCG vaccine vial was opened for immunization.
3.6.2 Measles

The wastage rate of Measles vaccine varies from 26% in Uttar Pradesh to 58% in Himachal Pradesh with the average rate of 35% across all the session sites observed. There is a gap of 34% between the maximum and minimum wastage. There is a noticeable difference in the session sizes of these two extreme end states (UP having the large session sizes as compared to Himachal Pradesh). With a vial size of 5 doses per vial, the wastage is evidently least in the state with higher session size.
Among the sessions where the Measles vaccine was administered, about 86% of the sessions used up to 5 doses per session. In about 11% of the sessions between 6 and 10 doses were administered, and in 3% of sessions up to 20 doses were administered.
In about 15% of the total sessions observed, measles vaccine was not available at the session site. Further, 5% of the total available vials were returned unopened at the end of the session day. In 80% of the total sessions observed, a Measles vaccine vial was opened for immunization.

**Figure 22: Measles- Number of doses administered per session**

**Figure 23: Measles- Availability of vial**
Figure 24: Measles – Availability of vials per state

3.6.3 OPV
The wastage rate of Oral Polio Vaccine varies from 40% in Uttar Pradesh to 75% in Himachal Pradesh with an average rate of 47% across all the session sites observed. There is a gap of 35% between the maximum and minimum wastage.
Among the sessions where OPV was administered, about 18% of the sessions used up to 5 doses per session. About 32% of the sessions administered between 6 and 10 doses, and 36% and 14% of sessions administered between 11-20 doses and more than 20 doses respectively.

**Figure 25: OPV- Wastage rate per state**

**Figure 26: OPV- Doses administered per session**
In about 7% of the total sessions observed, OPV was not available at the session site. About 1% of the total available vials were returned unopened at the end of the session day. An OPV vial was opened for immunization in a total of 92% of the total sessions observed.
3.6.4 DPT
The wastage rate of DPT vaccine varies from 20% in Tamil Nadu to 58% in Himachal Pradesh with the average rate of 27% across all the session sites observed. There is a gap of 38% between the maximum and minimum wastage. There is a noticeable difference in the session sizes of these two extreme end states.
Among the sessions where DPT was administered, about 19% of the sessions used up to 5 doses per session. In about 43% of the sessions, between 6 and 10 doses were administered and 11-20 doses were administered on 28% of sessions. In about 10%, more than 20 doses per session were administered.

Figure 30: DPT- Wastage rate

Figure 31: DPT- Doses administered per session
In about 8% of the total sessions observed, DPT was not available at the session site. About 1% of the total available vials were returned unopened at the end of the session day. A DPT vial was opened for immunization in 91% of the total sessions observed.
The wastage rate of TT vaccine varies from 20% in Uttar Pradesh to 53% in Maharashtra with the average rate of 33% across all the session sites observed. There is a gap of 33% between the maximum and minimum wastage. The session size of these two states is substantially different (Target population of Maharashtra sub centers selected for assessment is 47% of selected sub centers of UP).
Among the sessions where TT was administered, about 36% of the sessions used 5 doses or less per session. About 45% of the sessions administered between 6 and 10 doses and 16% between 11-20 doses. Only 3% of the sessions used more than 20 doses.

Figure 35: TT· Vaccine wastage

Figure 36: TT Doses administered per session
TT was not available at the session site in about 7% of the total sessions observed, about 2% of the total available vials were returned unopened at the end of the session day, and a total of 91% of sessions opened a TT vial.
Among the selected districts for assessment, the HepB is included in the routine immunization programs in the states of Himachal Pradesh, Maharashtra and Tamil Nadu. The wastage rate of HepB vaccine varies from 30% in Tamil Nadu to 57% in Himachal Pradesh with the average rate of 34% across all the session sites observed. There is a gap of 27% between the maximum and minimum wastage. The session size of these two states with extreme wastage rate is substantially different. Himachal Pradesh with difficult terrain and sparsely population has small session size.
Vaccine wastage among the sessions where HepB was administered, about 32% of the sessions used 5 doses or less per session about 31% of the sessions administered between 6 and 10 doses and 24% of sessions between 11 to 20 doses. More than 20 doses per session were administered in about 13% of the sessions.

Figure 41: HepB- doses administered during sessions
Among all the sessions observed, 22% of sessions did not have a HepB vial available at the session site. In 78% of the total sessions observed, a HepB vial was opened for immunization.

Figure 42: HepB- Number of doses administered during sessions

Figure 43: HepB- Availability of vials
Figure 44: Availability of vials by state
4 Conclusion

The result from this assessment leads to following conclusion:

a. The documentation of vaccine wastage is poor at all the levels. The reporting of vaccine wastage was observed at some places but was not adequately reported from many sites.

b. The wastage of vaccine at supply chain is negligible from the selected sites and during the selected time frame of assessment. However, an assessment of the wastage at supply chain should be conducted for a larger period of time (at least one year).

c. The wastage of vaccine is substantially proportionate to the session size observed. Higher wastage is observed with smaller session sizes.

d. Wastage rate varies among different vaccines. Wastage of Lyophilized vaccine is substantially higher than of liquid formation of vaccine. Also wastage among 5 dose, 10 dose and 20 dose vial differs. Vaccine with 5 dose vial (Measles, though being a Lyophilized vaccine) has lower wastage rate compared to 10 dose vials. OPV being a 20 dose vial has the highest wastage rates in doses per vial category.

e. There have been instances of vaccine returned unopened and vials discarded unopened. This indicates the scope of improving the session size and logistics management.
5 Recommendations

1. Maximum vaccine wastage occurs at the outreach session sites, optimization of outreach session (Weekly/Monthly/Quarterly based on injection load) will greatly influence overall vaccine wastage.

2. Adopting WHO multi dose vial policy should be considered to reduce the vaccine wastage at the session site.

3. Smaller vial size though occupies more cold chain space however has lower wastage, therefore smaller vial size is recommended for:
   a. Vaccines which have only one dose in UIP schedule (e.g. BCG and institutional HepB and OPV).
   b. Newer and underutilized expensive vaccines (e.g. Pentavalent, Pneumococcal, Rotavirus vaccine etc)

4. In mass vaccination campaigns targeting high number of beneficiaries, wastage is minimal hence larger vial size will be appropriate to save on cold chain space.

5. Any change in vaccine vial size, or formulation should be complimented with revised micro-plans and training of frontline workers.
This assessment was carried out by Ministry of Health and Family Welfare with support from UNICEF India.

Active support was provided by partner organizations: WHO, MCHIP-USAID, EPW-MoHFW and NIHFW.

The field assessment was possible by support from Government Medical Store Depots (GMSDs), State Governments of Assam, Himachal Pradesh, Maharashtra, Tamil Nadu and Uttar Pradesh.

The technical inputs for assessment were provided by WHO-HQ and UNICEF-HQ.