

## Research Article

# Vaccine wastage assessment in a primary care setting in rural India

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### ABSTRACT

**Background:** Knowing the wastage rate helps in assessing vaccine wastage and relative magnitude of its various causes helps to target efforts in reduce this wastage. Area specific wastage rate is useful in tailoring the vaccine vial size. Research question: What is the vaccine wastage in a primary care setting in rural India?

**Methods:** A record based descriptive study was carried out in an immunization clinic of rural health centre in South India. All childhood vaccinations between 1<sup>st</sup> April 2012 and 31<sup>st</sup> March 2013 were included in the study. Number of doses issued and number of children vaccinated were obtained from the registers maintained at the rural health centre. Vaccine wastage rates and wastage factor were calculated.

**Results:** A total of 5013 vaccinations (DPT, OPV, measles, MMR, and pentavalent, hep B, TT) were provided. Wastage rate for liquid vaccines was 3.4% and for lyophilized vaccines 28.2% among vaccines provided under national immunization schedule, wastage was highest for measles (46.5%).

**Conclusions:** All vaccines except measles had wastage within the limits proposed by World Health Organization. Wastage rates have to be calculated routinely and considered during vaccine procurement.

**Keywords:** Vaccine wastage, Primary care setting, Immunization, EPI, Dosage forms

### INTRODUCTION

Vaccines are one of the most successful health interventions that bring about significant reductions in infectious diseases burden and its sequelae. The world's largest Universal Immunization Programme (UIP) in India targets 27 million infants and 30 million pregnant women every year. The coverage of UIP vaccines is more than 70% in 11 states; 50-70% in 13 states and below 50% in the remaining 8 states.<sup>1</sup> One of the reasons for less coverage may be due to programmatic error in terms of vaccine logistic management.

World Health Organization reports over 50% vaccine wastage around the world.<sup>2</sup> Vaccine wastage is a major

economic consideration for most developing countries. The Ministry of Health and Family Welfare, Government of India has recommended that wastage rate of all vaccines should not be higher than 25% (Wastage factor of 1.33).<sup>3</sup> However, the policy encourages to open a vial for even single beneficiary to avoid misses opportunities. Wastage is defined as loss by use, decay, erosion or leakage or through wastefulness. Reasons for wastage are due to discarding the remaining doses at the end of session (open vial wastage), not being able to withdraw the number of doses indicated in the label of the vial, poor reconstitution practices, suspected contamination, and expiry, VVM (Vaccine vial monitor) indication, breakage and missing inventory. Knowing the wastage rate helps in assessing vaccine wastage and relative magnitude of its various causes which help to target

efforts to reduce these losses and to increase funds for increasingly expensive vaccines. Studies done in India and other countries have reported vaccine wastage level mainly in urban areas.<sup>4,6</sup> There is paucity of evidence in primary care settings of rural area in this regard where vaccine wastage may be higher due to electricity failure, lack of trained man power and remote outreach sessions conducted frequently. Moreover, newer vaccine policy has introduced many changes in immunization schedule (introduction of newer vaccines like pentavalent, introduction of single dose vials and multi dose vial policy). Hence, this article attempts to calculate vaccine wastage rates in a rural setting under these contexts in current era of new vaccine management policies.

## **METHODS**

### ***Study design and setting***

A record based descriptive study was carried out in the immunization clinic of Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER) Rural Health Centre, located in Ramanathapuram, Pondicherry, South India. It provides services for four villages with a total population of 9101. Immunization sessions are held once weekly. Vaccines are received from State Government Immunization office every month. DPT, OPV, pentavalent, measles, MMR (Measles, mumps, and rubella), hep-B and TT vaccines are administered during the reference period in this immunization clinic as per the national immunization schedule.<sup>3</sup> As per this schedule, at birth BCG, OPV zero dose and Hepatitis B are administered. But in our health centre, as deliveries are not conducted these vaccines were administered at the place of delivery itself. Since, the rate of institutional delivery is 100% in this field practice area, none of the newborns were sent without administration of these vaccines. Hence, the procurement of BCG vaccine is not done at this centre. First, second and three doses of DPT, OPV and hepatitis B are administered at 6, 10 and 14 weeks respectively. Single dose of measles is administered at 9 completed months. DPT and OPV booster are administered at 16-24 months. Second DPT booster is administered at 5-6 years. TT is given at 10 and 16 years. Two doses of TT/booster (single dose) are provided to pregnant women. Booster dose of TT is administered to pregnant women who have received their previous two TT doses within past 3 years. As per the changes proposed in the National Immunization Schedule (2009-10), MMR was introduced in our rural health centre since April 2011. MMR was provided with DPT booster at 16-24 months. Pentavalent (DPT-Hep B-Hib) vaccine was introduced in our rural health centre from February 2013. DPT and TT immunizations were given to school children as part of school health programme at 5 years and 10 years of age. Along with routine immunization, IPPI (Intensive Pulse Polio Immunization) sessions are conducted twice in a year, 4-6 weeks apart to eradicate poliomyelitis in India by vaccinating all children under 5 years with

OPV (2 drops during each session). DPT, OPV, TT and hepatitis B are supplied in liquid form; Measles and MMR are in lyophilized form. Lyophilized vaccines as they lack preservative they must not be kept more than the manufacturer's recommended limit and never longer than six hours after they are reconstituted.<sup>7</sup> Multi dose vaccine vial policy was followed for all vaccines except measles and MMR. This policy allows to reuse the opened liquid vaccines during subsequent sessions provided the cold chain requirements are at satisfactory level. Mean number of beneficiaries for measles vaccine was 2-4 per session. For other vaccines DPT/OPV/hepatitis B, it was 7-12 per session. As pentavalent vaccine was introduced during Feb 2013, hep-B vaccine was given for previous cohort of children. Pentavalent vaccine was administered for 7 sessions during the study period

All vaccinators (Para medical workers) are trained regarding Multi Dose Vial Policy (MDVP) and cold chain maintenance. Vials taken out for outreach sessions, returned for more than three times, are discarded. Since almost all deliveries in this field practice area are occurring in institutions outside the centre, BCG vials are not procured in the centre. MMR single dose vial was in use since April 2011 and pentavalent vaccine was introduced from Feb. 2013 in RHC. Immunization coverage in the field practice area was 95% for all primary vaccines for the past 5 years.

### ***Study population and reference period***

All childhood, antenatal vaccinations administered in the immunization clinic and antenatal clinic between 1<sup>st</sup> April 2012 and 31<sup>st</sup> March 2013 were included in the study.

### ***Data retrieval and analysis***

The information regarding number of doses issued and children vaccinated were retrieved from immunization registers for the reference period. These registers are cross-checked by Medical officer every month. Data was collected in terms of number of doses issued as even for single beneficiary new vials are opened and multi dose vial policy was used during reference period; the number of opened vials was not taken into account for calculation of wastage rate

### ***Vaccine wastage calculation***

Number of doses wasted was calculated using formula (Number. of doses issued - Number of children benefitted). Wastage rate was calculated using formula [(Number of doses wasted/Number of doses issued) x 100]. Vaccine Wastage Factor was calculated using the formula [100/(100-vaccine wastage rate)]. Data were entered into Microsoft Excel spread sheet and proportions were calculated. Chi-square test was applied for finding statistical significance of difference across type/form of vaccines.

## RESULTS

A total of 53 immunization sessions were conducted during the reference period. A total of 5013 vaccinations of (DPT, OPV, measles, MMR, TT, hepatitis B and pentavalent) had been given including IPPI (Intensive Pulse Polio Immunization) sessions and school

immunizations. Wastage factor for vaccines of five dose preparation (Measles) was 1.86, for vaccines of 10 dose preparations (DPT, hep B, TT and pentavalent) was 1.05, vaccines of 20 dose preparations (OPV) was 1.01 and vaccines of single dose preparations (MMR) was 1.01. Among individual vaccines, wastage factor is highest for measles (Table 1).

**Table 1: Wastage rate and wastage factor for vaccines in an immunization clinic of RHC, Pondicherry, South India (N= 5013) (April 2012 - March 2013).**

Vaccine	No. of doses issued	No. of children vaccinated	No. of doses wasted	Vaccine wastage rate (%)	Vaccine wastage factor
<b>DPT</b>					
Routine immunization	570	522	48	8.4	1.09
School immunization	160	131	29	18.1	1.22
<b>OPV</b>					
Routine immunization	630	615	15	2.4	1.02
IPPI campaign	2454	2437	17	0.7	1.00
<b>Hepatitis B</b>	397	376	21	5.3	1.05
<b>Pentavalent</b>	30	30	0	0	1
<b>Measles</b>	230	123	107	46.5	1.86
<b>MMR</b>	146	144	2	1.4	1.01
<b>TT</b>					
Routine immunization	311	298	13	4.2	1.04
School immunization	360	337	23	6.4	1.06

**Table 2: Wastage across type/form of vaccines in an immunization clinic of RHC, Pondicherry, South India (April 2012 - March 2013).**

Type/form	Wastage rate (%)	Wastage factor
Lyophilized (Measles, MMR)	28.2	1.39
Liquid (DPT, OPV, hep B, TT, pentavalent)	3.4	1.04
<b>Vial size</b>		
1 dose (MMR)	1.1	1.01
5 dose (Measles)	46.5	1.86
10 dose (DPT, hep B, TT, pentavalent)	5.3	1.05
20 dose (OPV)	1.0	1.01
<b>Mode of administration</b>		
Oral (OPV)	1.0	1.01
Injectable (DPT, measles, MMR, hep B, TT, pentavalent)	10.9	1.12

There was significantly more wastage ( $\chi^2=438.8$ ,  $P < 0.001$ ) found among lyophilized forms of vaccines (28.2%) vis a vis among liquid forms (3.4%). Differences in wastage rates among different vial size were statistically significant (5 dose vs. 10 dose:  $\chi^2=369.6$ ,  $P$  value  $< 0.001$ ; 5 dose vs. 20 dose:  $\chi^2=1068$ ,  $P$  value  $< 0.001$ , 10 dose vs. 20 dose:  $\chi^2=79.99$ ,  $P$  value  $< 0.001$ ).

The wastage rate for injectable vaccines (DPT, hep B, MMR, measles and TT) were found to be 10.9% and for OPV it was 1.03% respectively. There is significant difference ( $P < 0.001$ ) in wastage between two modes of administration (Table 2).

## DISCUSSION

In practice of immunization, number of vaccine doses used is always higher than number of persons actually immunized, excess number represents doses lost. In this study, wastage rate and wastage factor for all the vaccines were within the MOHFW, Government of India suggested limits of less than 25% and less than 1.33 respectively, except Measles which had a higher wastage rate (46.5%) and wastage factor (1.86). WHO recommends the following maximum wastage rates for the estimation of vaccine needs: for lyophilized vaccines: 50% wastage rate for 10-20 dose vials; 10% wastage rate for 1-2 dose vials. For liquid vaccines: 25% wastage rate for 10-20 dose vials; In this study all the liquid vaccines and lyophilized vaccine MMR are within the projected limit of WHO.<sup>8</sup>

Wastage rates obtained from this study for 10 and 20 dose vials are 5.3% and 1.0% respectively, which were lower than wastage rate obtained in a study conducted in urban resettlement area of Delhi (51.0%) and (48.1%)

respectively. Wastage rate for measles from this study was higher (46.5%) compared to this Delhi urban based study (39.9%).<sup>4</sup>

Mehta et al did a vaccine wastage evaluation study in urban centre of Surat and they stated a high wastage rate for DPT (16%), OPV (25%), Hepatitis B (21%) and low wastage rate for Measles (28%) in their routine immunization sessions.<sup>5</sup> Study from Bangladesh reported high wastage rate for DPT (44.4%), TT (35.5%) and Measles (69.7%) compared to present study.<sup>6</sup> National Rural Health Mission (NRHM) and UNICEF, from field based assessment, showed a high wastage rates for DPT (27%), OPV (47%), hepatitis B (33%), TT (34%) and low wastage rate for Measles (34%) compared to the current study.<sup>9</sup> Difference in study settings (outreach vs. facility based), implementation of multi dose vial policy might have caused this difference.

With reference to MOHFW programme guidelines, this study showed lower vaccine wastage for both liquid and lyophilized vaccines except measles. Higher wastage of lyophilized vaccines compared to liquid vaccines was reported in all studies including the present study. Measles has a wastage rate exceeding the national limits, this is because being a lyophilized vaccine can't be stored more than 6 hours after reconstitution and mean number of beneficiaries also less (2-4/session) compared with other vaccines (DPT/OPV/hepatitis B) (7-12/session). Even though the wastage rate for measles is high because of the above mentioned reasons, as per guidelines it is necessary to open a new vial even for a single beneficiary and it is being done in our health centre. When considering MMR, even though it is a lyophilized vaccine, mean number of beneficiaries were also less, the wastage rate is not same as measles. Since, MMR vaccines are supplied as single dose vials it's wastage cannot be compared with Measles.

Vaccine wastage rates in this study are relatively less when compared to other studies; the reasons for this may be due to role of uninterrupted electrical supply with well-functioning generators in cold chain maintenance. National institute guidelines for vaccine procurement are followed and the staffs maintain a logbook for beneficiaries for immunization and if any of the children have missed their dose, public health nurses will make a note and during their home visits, they will remind and motivate them to get immunized. So it assures coverage and prevents loss of vaccines due to expiry resulting from long term maintenance. Being a teaching institute, frequent monitoring would have played a role in reducing vaccine wastage.

Much wastage occurs at clinic level when health care workers open a multi-dose vaccine vial which cannot be used in subsequent sessions leading to open vial wastage but vaccine policy strategies recommend opening vials even for single beneficiary to avoid missed opportunities. So when considering single dose vials in place of multi

dose vials they are advantageous in terms of decreasing chances of contamination, more accurate dose delivery, facilitating outreach strategies but has its own drawbacks in terms of increasing burden on requirement of cold chain capacity, reconstitution syringes, waste disposal etc. So the decision can be made after considering all these factors.

Though cold chain capacity is not a barrier for current vaccination schedule, considering newer vaccine introduction it could be an anticipated constraint against single dose vial. During intensive pulse polio immunization campaign, cold chain capacity can exceed the normal limits. So the choice between single-dose and multi-dose vial formats is a balance between their relative benefits and drawbacks, that may shift based on local circumstances based on coverage rate, session size and regular/Non-routine immunization session.

Multi dose vials can be preferred in settings where mean number of beneficiaries are more, vaccine is relatively inexpensive, disposing of medical waste is difficult, and cold-chain storage capacity is constrained. Conversely, if the vaccine is expensive, vaccine contamination risk is high, and patients arrive to the clinic with irregular frequency, single-dose forms may be more appropriate.

### **Strengths**

It is a record based study. Records were well maintained in terms of number of vials procured, used, wasted, number of beneficiaries for each session etc. without any missing data by the public health nurses under the direct supervision of medical officer and so the results obtained from this data are reliable.

### **Limitations**

Results obtained from this study focused mainly on wastage rates among the vaccines and the exact magnitude of wastage by reasons has not been studied and so further studies may need focus towards exploring the reasons for wastage. Since this study was carried out in rural health centre functioning under medical college, wastage rate may differ in other rural areas. Hence, the results cannot be generalized to other settings.

### **CONCLUSION**

This study shows higher wastage rate for measles (46.5%) when comparing with national limits. Regular monitoring on wastage facilitates logistics management, action plan and decrease vaccine wastage due to avoidable factors like cold chain failure, inadequate mobilization of beneficiaries etc. Evaluation of wastage in isolation, without consideration on coverage makes it impossible to conclude whether it should be considered high or acceptable, so all immunization points should monitor their vaccine usage, wastage and coverage regularly on a monthly basis. This has to be done as a

self-audit rather than submitting data to higher levels. This helps health workers and immunization managers to identify areas that need improvement and bring additional value to this quality performance indicator.

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