



ASSESSMENT OF VACCINE WASTAGE IN A TERTIARY CARE CENTRE OF DISTRICT ROHTAK, HARYANA

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ABSTRACT

Background: India released its first national vaccine policy in 2011. India is facing such less coverage and one of the rationales behind it is mismanagement of vaccine logistics. Vaccine wastage is defined as loss by use, decay, erosion or leakage or through wastefulness.

Methods: This was a record based descriptive study carried out at immunization clinic of Pt. B.D Sharma PGIMS, Rohtak. The information of vaccine vials used at immunization clinic and children (up to age of 16 years) vaccinated were retrieved from the immunization registers for the reference period of 1st October 2013 and 31st December 2013.

Results: Among individual vaccines, wastage factor and wastage rate was highest for BCG and was lowest for pentavalent vaccine. Differences in wastage rates for different vial size were statistically significant. Wastage factor and wastage rate were higher in lyophilized vaccines (2.75) and (63.76%) compared to that of liquid vaccines i.e. (1.35) and (26.36%).

Conclusion: Vaccine wastage can be obtained by actual monitoring of the immunization clinic. This can save significant funds for an immunization programme if wastage can be reduced without affecting the coverage.

Keywords: vaccine wastage rate, BCG, polio, pentavalent, Hep-B

INTRODUCTION

It is very well known fact that India has one of the largest Universal Immunization Programs (UIP) in the world, which targets 27 million infants and 30 million pregnant women every year.¹ Since its inception, it is accomplishing a desired aim of child survival interventions to bring about eloquent scaling down childhood infectious diseases burden and its residual outcomes. Yet, despite the concerted efforts of the government and other health agencies, a large proportion of vulnerable infants and children in India remain unimmunized.

India released its first national vaccine policy in 2011 and published outcome on vaccination coverage shows that it is more than 70% in 11 states; 50-70% in 13 states and below 50% in the remaining 8 states; and Haryana (DLHS-4) lies among these eight states with vaccination coverage of 43.4% only.^{1,2} Moreover, newer vaccine policy has introduced many changes such as introduction of newer vaccines like pentavalent, introduction of single dose vials and multi dose vial policy. The country is presently developing new strategies to increase immunization coverage and reach more children with quality vaccines and current one is

"Mission Indradhanush" which was launched in December 2014.³

India is facing such less coverage and one of the rationales behind it is mismanagement of vaccine logistics. Vaccine wastage is defined as loss by use, decay, erosion or leakage or through wastefulness. Vaccine wastage can be classified as occurring "in unopened vials" and "in opened vials". Expiry, VVM indication, heat exposure, freezing, breakage, missing inventory and theft are the forms of vaccine wastage affecting unopened vials. Vaccine wastage in opened vials may also occur because doses remaining in an opened vial at the end of a session are discarded, the number of doses drawn from a vial is not the same as that indicated on the label, reconstitution practices are poor, opened vials are submerged in water, and contamination is suspected.⁴

World Health Organization reports over 50% vaccine wastage around the world. The lack of knowledge of wastage rates provides inadequate estimations of needs and subsequent stock-outs and/or overstocks.⁵ High vaccine wastage inflates vaccine demand and increases unnecessary vaccine procurement and supply chain costs. 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).⁶ Awareness of the wastage rate soothe in appraise the vaccine wastage and relative magnitude of its various causes which help to mark efforts to reduce these over-looking and to increase funds for increasingly new and exorbitant vaccines.

There is dearth of comprehensive study done in India to validate the wastage rate recommended by WHO and Ministry of Health and Family Welfare and also there are very few studies on wastage rate of vaccines, published in India.^{4,9,10,11,12} This article attempts to calculate the vaccine wastage rates in tertiary care centre in district Rohtak, Haryana in context to new vaccine management policy.

METHODS

This was a record based descriptive study carried out at immunization clinic of Pt. B.D Sharma PGIMS, Rohtak which is being monitored under the department of Community Medicine. DPT, OPV, measles, hep-B and TT vaccines are administered during the reference period in this immunization clinic as per the national immunization schedule.⁷ Pentavalent vaccine was introduced in

Haryana state during the period of December 2012, so children who were born before the December 2012 were continued on DPT and those who were born afterwards were subjected to the pentavalent vaccine.⁸

BCG, DPT, pentavalent, TT and hep-B vaccines vials used were 10 dose preparations, measles vials were 5 dose preparations and OPV vials were 20 dose preparations. DPT, OPV, TT, pentavalent and hep-B are supplied in liquid form; Measles and BCG are in lyophilized form. Multi dose vaccine vial policy was followed which allows to re-use all liquid vaccines vials which have been taken out for immunization at least three times or has been kept in cold storage for 28 days after opening vial are discarded in order to safeguard the potency of the vaccines and as per recommendation for lyophilized vaccines all vials are discarded after 4 hours of reconstitution.¹

The information of vaccine vials used at immunization clinic and children (up to age of 16 years) vaccinated were retrieved from the immunization registers for the reference period of 1st October 2013 and 31st December 2013 maintained by the staff nurse and cross checked by Medical officer on daily basis. None of the vaccine vials was discarded because of expiry, VVM indication, heat exposure, freezing, or breakage. This method is similar to methods being applied by other studies too.¹¹ The no. of doses wasted was calculated using the formula (No. of doses issued- No. of children benefitted). Hence vaccine wastage analysis was done with number of vials used at the immunization clinic. Vaccine wastage rate was calculated using formula [(No. of doses wasted/ No. of doses issued) X 100]. Vaccine wastage factor was calculated by using the formula [100/ (100-vaccine wastage rate)].⁴

The information of vaccine vials used was entered into Microsoft Excel spread sheet and data was tabulated and for statistical analysis we calculated percentages and applied the Chi-square test wherever necessary and required. p values were calculated at 95% confidence level.

RESULTS

A total 73 immunization sessions were conducted during reference period and 7 different antigen vaccines (BCG, OPV, DPT, pentavalent, TT, hep-B and measles) were given to children. A total 335 vaccine vials (3703 doses) were issued and 2349 children were vaccinated.

The information regarding the no. of vaccine vials and doses used for vaccination, children vaccinated, the wastage rate and wastage factor (WF) for each vaccine are provided in table 1. Among individual vaccines, wastage factor and wastage rate was highest for BCG and was lowest for pentavalent vaccine (Table-1).

The vaccines were supplied in 3 different sizes of vials; 5 doses (measles), 10 doses (BCG, DPT, hep-B, pentavalent and TT) and 20 doses (OPV) per vial. The information regarding the no. of vaccine vials and doses used for vaccination, children vaccinated, the wastage rate and wastage factor (WF) for different doses vial vaccine are provided in table 2. Differences in wastage rates for different vial size were statistically significant (10 dose vs 20 dose: $\chi^2=9$, p value=0.003; 5 dose vs 20 dose: $\chi^2=$

4.07, p value<0.044) except for 5 dose vs 10 dose (p value<0.831). It was observed that wastage rate (40%) was nearly similar in both 5 doses and 10 doses vaccine vials, which was higher than wastage rate (29%) of 20 doses vaccine vial.

The vaccine vials come in liquid and lyophilized forms. Five vaccines namely OPV, DPT, TT, pentavalent and hep-B are supplied in liquid form and 2 vaccines; BCG and measles are freeze dried or lyophilized vaccines. Among these, wastage factor and wastage rate were higher in lyophilized vaccines (2.75) and (63.76%) compared to that of liquid vaccines i.e. (1.35) and (26.36%) Table3. Among these, there was statistically significant difference in wastage between liquid and lyophilized forms of vaccine vials. (p < 0.016).

Table 1: Wastage rate and wastage factor (WF) for different vaccine

Vaccine	Doses issued for Vaccination sessions	No. of children vaccinated	Wastage rate (%)	Wastage Factor
BCG*	620	137	77.90	4.52
OPV@	1225	870	28.97	1.40
DPT*	370	197	46.75	1.87
Measles#	390	229	41.28	1.70
Pentavalent*	673	623	7.42	1.08
TT*	275	201	36.81	1.36
Hep- B*	150	92	38.66	1.60
All vaccine	3703	2349	36.56	1.57

5 dose vial vaccine; *10 dose vial vaccine; @20 dose vial vaccine

Table 2: Wastage rate and wastage factor (WF) for different doses vial vaccine

Doses/vial vaccine	Doses issued for Vaccination sessions	No. of children vaccinated	Wastage rate (%)	Wastage Factor
5 doses/ vial#	390	229	41.28	1.70
10 doses/ vial*	2088	1250	40.70	1.67
20 doses/ vial@	1225	870	28.97	1.40

#Measles; *BCG, DPT, hep- B, pentavalent and TT; @OPV

Table 3: Wastage rate and wastage factor (WF) for lyophilized and liquid vaccine.

Vaccine type	Doses issued for Vaccination sessions	No. of children vaccinated	Wastage rate (%)	Wastage Factor
Lyophilized#	1615	1099	63.76	2.75
Liquid*	2088	1250	26.36	1.35

#BCG and Measles; *OPV, DPT, TT, pentavalent and hep-B

Table 4: Wastage rate and wastage factor (WF) for modes of administration.

Mode of administration	Doses issued for vaccination sessions	No. of children vaccinated	Wastage rate (%)	Wastage Factor
Injection	2478	1479	40.34	1.67
Oral	1225	870	28.97	1.40

All the vaccines except for OPV are administered through injection. The wastage factor and wastage rate for injectable vaccines (BCG, DPT, HBV and Measles) were found to be 1.67 and 40.34% and for oral (OPV) were found to be 1.4 and 28.97% respectively Table 4. Thus, there is significant difference in wastage between the two modes of administration ($\chi^2= 9.94$, p value< 0.002).

DISCUSSION

In exercise of immunization, number of vaccine doses utilized is always higher than number of beneficiary actually immunized, excess number depicts wastage of dose. 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)⁶ and also recommendation by WHO, projected vaccine wastage rate for lyophilized vaccines is expected to be 50% wastage rate for 10-20 dose vials, and for liquid vaccines 25% wastage rate for 10-20 dose vials.⁵

The present study showed that the vaccine wastage for liquid vaccines (26.36%) and for lyophilized vaccines (63.76%) was higher than the limits provided by the Ministry of health and family welfare, Government of India; and WHO. The wastage rate were higher in lyophilized vaccines (63.76%) compared to that of liquid vaccines (26.36%). This is pattern of lyophilized vaccines having more wastage rate than those of liquid vaccine was similar to the findings from other studies of Unicef [38% (liquid), 50% (lyophilized)],⁴ Shreyash et al [20.16% (liquid), 37.8% (lyophilized)],⁹ Praveena et al [3.4% (liquid), 28.2% (lyophilized)].¹⁰

One reason for high wastage in this center particularly could be that, as follow of national vaccine policy recommendations, which suggests that all liquid vaccines vials which have been taken out for immunization at least three times or has been kept in cold storage for 28 days after opening vial are discarded in order to safeguard the potency of the vaccines and all lyophilized vaccines vials should be discarded after 4 hours of reconstitution.¹

Except for the wastage rate for 5 dose vaccine vial (41.28%), wastage rate for 10 dose vaccine vial (40.70%) and for 20 dose vaccine vial (28.97%) which were lower than the wastage rate obtained by Palanivel C et al (51% and 48.1%);¹² and Shreyash et al (22% and 25%)⁹ for 10 dose vaccine

vial and 20 dose vaccine vial respectively; but it was higher than wastage rate in study of Praveena et al (5.3% and 1%)¹⁰ for 10 dose vaccine vial and 20 dose vaccine vial respectively.

The wastage rate for injectable vaccines (48.34%) was found to be higher than wastage rate for oral vaccines (28.97%). Similar pattern injectable vaccine having more wastage rates than those of oral vaccines was observed in the study of Praveena et al [10.9% (injectable vaccines), 1% (oral vaccines)]¹⁰ but pattern was differed for other studies of Shreyash et al⁹ [22% (injectable vaccines), 25% (oral vaccines)]; Unicef [35% (injectable vaccines), 47% (oral vaccines)].⁴ But wastage rate for injectable vaccines in our study was similar to study of Palanivel C et al (48.3%).¹²

In our study among the vaccines, BCG has got the highest wastage rate (77.90%) and lowest for pentavalent (7.42%). This pattern of BCG being ranked highest in wastage rate was similar to other studies of Unicef (61%),⁴ Palanivel et al (70.9%),¹² Shreyash et al (45%), except mukerjee11 et al (49.3%).¹¹ This may be due to more number of doses of Pentavalent/DPT/ OPV/ hep-B (3 or 4 doses of Pentavalent/DPT/OPV/hep-B vs single dose of BCG) required and hence number eligible children would be available per immunization session. But wastage rate of BCG was highest among our study when compared to other study.

The wastage rate for OPV obtained from some studies such as unicef (47%)⁴, Palanivel C et al (48.1%)¹² and Mukherjee et al (52.7%)¹¹ were higher than that obtained from our study (28%) but was lower in Shreyash et al study¹² (25%)⁹ and Praveena et al (1%).¹⁰ The higher wastage rate for OPV may be due to the fact that there might be wastage of OPV at time of administering of vaccine e.g. administering more drops than that are required to be given per dose due to faulty vaccinating technique of vaccinators, child moving the head at the time of ingestion of vaccine etc.

The wastage rate calculated for DPT was 46.8% which is higher than the wastage rate calculated by other studies Unicef (27%),⁴ Palanivel et al (38.6%),¹² Mukherjee et al (38.9%),¹¹ Shreyash et al (16%)⁹, Praveena et al.¹⁰

The wastage rate calculated for measles vaccine was 41.28% which was similar to wastage rate obtained by other studies Palanivel et al (38.6%),¹² Mukherjee at al (38.7%),¹¹ Praveena et al (46.5%)¹⁰ but much higher than Shreyash et al study (28%)⁹ and lower than Unicef (35%).⁴

Vaccine wastage for TT in our study was 36.81% which is lower than wastage rate calculated by Mukherjee et al (48%),¹¹ Palanivel et al (62.8%)¹² but higher than Praveena et al (4.2%) study.¹⁰

The pentavalent was recently introduced so studies related to it is very limiting. But in one study Praveena et al¹⁰ wastage rate for pentavalent was 0% where as in our study it was coming out to be 7.42%.

CONCLUSION

In this study vaccine wastage due to cold chain failure or expiry is zero which stresses the need to minimize the wastage. Vaccine wastage can be expected in all programmes and there should be acceptable limit of wastage. This might differ from location to location depending on many factors like urban or rural setting, immunization coverage etc. The questions arise as to whether the wastage is preventable and, if so, how to prevent it. Unlike rural areas in India, where there are grass root level health workers for every 1000 population, (known as Accredited Social Health Activists and Anganwadi workers) who help in identifying the unimmunized and mobilizing the eligible children, in urban areas there is a shortage of grass root level workers. Mobilizing the eligible children with the help of community mobilizers will help to reduce the wastage. It is also important to know the type of vaccine wastage. A high wastage rate attributable to opening a multi-dose vial for a small session size in order to avoid missed opportunities is more acceptable than wastage attributable to freezing or expiry. Higher wastage rates are acceptable to increase vaccine coverage in a low vaccine coverage setting.

RECOMMENDATIONS

The authors recommend that vaccine wastage estimations should be done routinely to assess the loss due to wastage like any other vital statistics like birth rate and death rate. Vaccine wastage can be obtained by actual monitoring of the immunization clinic. This can save significant funds for an immunization programme if wastage can be reduced without affecting the coverage. Monitoring vaccine wastage is useful as a programme monitoring tool to improve programme quality and increase the efficiency of the programme.

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