

Original Research Article

## A Cross-Sectional Study of Assessment of Vaccine Wastage in Tertiary Care Centre of Central India

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### ABSTRACT

**Background:** Development of vaccine was one of the greatest discoveries as it saved thousands of lives over the period. India has one of the largest Immunization program in the world. Routine immunization is one of the most cost effective interventions. Vaccine wastage is also an expected component of immunization program. This study primarily focuses on the estimation of wastage rate and wastage factor for vaccines used in Immunization clinic.

**Material and Methods:** A record based cross sectional study carried out at Immunoprophylaxis clinic OPD which functions under Community Medicine Department of Govt. Medical College, Nagpur. The data was collected for one year from 01 January 2016 to 31 December 2016 and analysed to find out vaccine wastage, vaccine wastage rate and wastage factor.

**Results:** The vaccine wastage was found highest for BCG (34.75%) followed by DPT (13.55%). Lowest wastage was seen in use of Pentavalent vaccine (2.72%). The wastage rate and wastage factor for 10 dose vials was higher than 5 and 20 doses vial and higher for Lyophilized vaccine than Liquid vaccine used in these settings.

**Conclusion:** Some level of vaccine wastage is unavoidable. The country like India where maximum immunization carried out by outreach immunization sessions, the wastage is inevitable to control. Wastage of vaccine because of break in cold chain, frozen vaccine, loss or breakage during transportation and wastage because of the expiry of vaccine batches can be avoidable with careful handling and monitoring.

**Key words:** Vaccine wastage, Wastage factor, Immunization, Cold chain, UIP

### INTRODUCTION

Immunization is one of the most influential and economical of all health interventions. It averts debilitating illness and disability, and protects millions of lives every year. <sup>(1)</sup> Discovery of vaccine helps us to control, eliminate and even for eradication of infectious diseases from countries and world causing reduction in mortality, morbidity and disability. <sup>(2)</sup>

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. <sup>(3)</sup> Vaccines and their management form a major component of the national immunization programme. Regular supply of vaccines and their efficient management is vital to the success and effectiveness of all immunization programmes. <sup>(4)</sup>

The requirement of vaccine in the UIP is calculated on the basis of the number

of infants/children/pregnant women in the target age group and the number of doses to be administered to each of the beneficiaries. In addition, a wastage factor is taken into account for the anticipated wastage of vaccine during administration as well as left over vaccine, which cannot be subsequently used. The opened vials are then to be discarded after the session and are not to be used after the session or on the subsequent day. <sup>(5)</sup>

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. Vaccine wastage falls into two categories: wastage in unopened vials and wastage in opened vials. Wastage in unopened vials results from expiration, thermo-instability, breakage, missing inventory, and other incidental causes. Vaccine wastage in opened vials seen in discarding remaining doses at end of session, not being able to draw the number of doses indicated on the label of a vial, Poor reconstitution practices, Submergence of opened vials in water, suspected contamination, and Patient reaction requiring more than one dose. <sup>(2,6)</sup>

Over-ordering of vaccines is the leading problem in the distribution chain, and causes the majority of wastage. Thus vaccine wastage is an important factor in forecasting vaccine requirements and while placing vaccine orders. India being a developing economy needs to reduce avoidable vaccine wastage and wasteful budgetary requirements. <sup>(7)</sup>

One of the largest impediments to efficient immunization is the wastage of opened and unopened vaccine vials. As developing countries introduce new and expensive vaccines, there is a need to understand factors that contribute to vaccine wastage so potential solutions can be assessed. <sup>(8)</sup>

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. Moreover, newer vaccine policy has introduced many changes in immunization schedule (like introduction of newer vaccines like pentavalent, introduction of single dose vials and multi dose vial policy). <sup>(9)</sup>

Effective vaccine utilization is a vital component of vaccine security, and vaccine wastage is one of the key factors to be considered with regards to vaccine forecasting and need estimation. However, studies for assessing vaccine wastage in central India are still lacking, hence the present study was undertaken with an objective to assess vaccine wastage in tertiary care centre in Nagpur.

## **MATERIALS AND METHODS**

This record based cross sectional study was carried out at Immuno prophylaxis clinic which functions under Community Medicine department, Government Medical College and Hospital, Nagpur. The national immunization schedule was followed in which seven vaccines, i.e. BCG, Penta (DPT, Hep B, and H. Inf), DPT, OPV, Hepatitis, Measles and TT were given to prevent and protect the children from respective diseases.

The vaccines that provided for immunization are multi dose vials i.e. BCG, DPT, Hepatitis B and TT are 10 dose vial vaccine whereas Measles is 5 dose vial vaccine and Penta and Polio, 20 dose vial vaccine. Measles and BCG are provided as lyophilized form i.e. they need to prepare before vaccination while all the other vaccines are provided in liquid form and can be readily used. According to the multi dose vaccine vial policy, the lyophilized vaccine should be used within 4 hours after opening of vial and reconstitution, but the liquid vaccines are allowed to reuse which has been taken out for immunization at least three times or has been kept in cold storage for 28 days after opening of vial are discarded in order to safeguard the potency of vaccine.

In Immunoprophylaxis clinic (IPC), immunization by Penta, DPT, OPV, Hepatitis B, Measles and TT are done on daily basis and BCG is given on Monday and Thursday, to all the children upto 16 years age group. The data is recorded daily in immunization register and monthly report is prepared which was used to collect the data on total children immunized and monthly wastage.

The data was collected for one year from 01 January 2016 to 31 December 2016

and analysed to find out vaccine wastage, vaccine wastage rate and wastage factor. The vaccine wastage rate was calculated by formula [(No. of doses wasted/No of doses used) x100] and wastage factor by [100/(100-vaccine wastage rate)]. The master sheet was prepared from all the information collected in Microsoft MS Excel, data was analysed and statistical tests were applied using Epi Info 7. p value <0.05 was considered for statistical significance.

## RESULTS

**TABLE 1: - Wastage rate and wastage factor for different vaccines.**

Sr. No	Vaccine	No. of doses issued	No. of children Vaccinated	No. of doses wasted	Vaccine Wastage rate (%)	Vaccine wastage factor
1	BCG	1580	1031	549	34.75	1.53
2	OPV	9570	9073	497	5.19	1.05
3	Penta	5800	5642	158	2.72	1.03
4	Hep B	370	342	28	7.57	1.08
5	Measles	3980	3528	452	11.36	1.13
6	DPT	3410	2948	462	13.55	1.16
7	T.T.	1890	1788	102	5.40	1.06

Total of 26600 vaccine doses were issued for the immunization against BCG, DPT, OPV, Penta, Hepatitis B, Measles and TT vaccination at Immuno Prophylaxis Clinic (IPC). The vaccine wastage rate and vaccine wastage factor was calculated and found

highest for BCG i.e. 34.75% and 1.53 respectively followed by DPT which was 13.55% and 1.16 respectively. Lowest wastage was seen in use of Pentavalent vaccine (2.72%).

**TABLE 2: - Wastage across types/forms of Vaccine.**

Sr. No	Type/Form	No. of doses issued	No. of children Vaccinated	No. of doses wasted	Vaccine wastage rate (%)	Vaccine wastage factor
1	Vial Size					
	5 Dose vial	3980	3528	452	11.36	1.13
	10 Dose vial	7250	6109	1141	15.74	1.19
	20 Dose vial	15370	14715	655	4.26	1.04
2	Type of Vaccine					
	Lyophilized	5560	4559	1001	18.00	1.22
	Liquid	21040	19793	1247	5.93	1.06
3	Mode of Administration					
	Oral	9570	9073	497	5.19	1.05
	Injectable	17030	15279	1751	10.28	1.11

### Vaccine vial size: -

The vaccine used were categorized in three different sizes of vial i.e. 5 dose (Measles), 10 dose (BCG, HepB& T.T.) and 20 dose (OPV, DPT& Penta) per vial. The wastage rate and wastage factor for 5 dose vials was higher than 10 and 20 doses vial. Difference in wastage rate for 5 doses versus 10 doses vial size was not found statistical significant ( $\chi^2= 3.07$ ,  $p = 0.07$ ) but

for 10 doses versus 20 doses ( $\chi^2= 37.53$ ,  $p = <0.001$ ) and for 5 doses versus 20 doses ( $\chi^2= 8.88$ ,  $p = 0.002$ ) was found significant.

### Type of Vaccine:-

The vaccine supplied under National Immunization program comes in Liquid and Lyophilized form. Penta, OPV and TT are Liquid vaccine whereas BCG, JE and Measles came as Lyophilized or freeze dried vaccine. The wastage rate and wastage

factor was found higher for Lyophilized vaccine than Liquid vaccine used in these settings. There is statistically highly significant difference in wastage between Liquid and Lyophilized vaccine ( $\chi^2= 37.86$ ,  $p = 0.000$ ).

#### **Mode of Administration: -**

OPV is administered by oral route and all the other vaccine has injectable mode of administration. The vaccine wastage rate and wastage factor was found higher in injectable vaccine than oral route administrated vaccine. There is statistically significant difference between these two modes of administration ( $\chi^2= 8.98$ ,  $p = 0.001$ ).

## **DISCUSSION**

The vaccine wastage is of great importance, if reduced, can spare the Government money which can be used for introduction of newer and expensive vaccines which can be used to control other vaccine preventable diseases. <sup>(2)</sup>

The Ministry of Health and Family Welfare, Government of India has recommended that vaccine wastage rate of 25% or wastage factor 1.33 is allowed for all vaccines used in immunization program. <sup>(3)</sup> The World Health Organization has also projected vaccine wastage rate in order to help in calculating vaccine needs. According to the 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. <sup>(1,6)</sup>

The vaccine wastage rate (VWR) of BCG vaccine was 34.75% and wastage factor (VWF) 1.53 which was highest in this study followed by DPT (VWR 13.55% and VWF 1.16). Still they were below the recommended values by Ministry of Health and Family Welfare, Government of India and WHO. VWR and VWF were highest for BCG found in various studies done in India. <sup>(1,9-12)</sup> The vaccine wastage for BCG was 34.75% which is much lower than the results found by UNICEF (61%), Gupta V et al (77.9%), Mehta S et al (45%) and

Chinnakali P et al (70.9%). <sup>(1,10-12)</sup> This may be because the vaccine as per national guidelines should be discarded after four hours of reconstitution. So if the adequate children if not approached to the site, many doses have to be discarded resulted into higher vaccine wastage of this vaccine.

The wastage rate for Pentavalent was 2.72% which found much lower than UNICEF (38%) and Praveena Daya A et al found 0.00%, this might be due to small sample size of their study as only 30 dosages were issued and given to the children. <sup>(6,9)</sup>

The wastage rate for OPV was 5.19% which found much lower than UNICEF (47%) and most of the other studies i.e. Gupta V et al (28.97%), Mehta S et al (25%), Chinnakali P et al (48.1%), Mentey V et al (51.2%), and Mukherjee A et al (14.5%) but results found by Praveena Daya A et al (2.4%) was much lower than our study. <sup>(1,2,9-13)</sup>

The wastage rate calculated for DPT was 13.55% which was found lower than results calculated by UNICEF (27%), Gupta V et al (46.75%), Mehta S et al (16%), Chinnakali P et al (38.6%), and Mentey V et al (29.4%) and Praveena Daya A et al (8.4%) had found lower than our results. <sup>(1,10-13)</sup>

The calculated wastage rate for Measles vaccine was 11.36% which also lower than the wastage rate obtained by UNICEF (35%), Gupta V et al (41.28%), Mehta S et al (28%), PraveenaDaya A et al (46.5%), Chinnakali P et al (39.9%), and Mentey V et al (51.1%). <sup>(1,9-13)</sup>

The vaccine wastage for Hepatitis B was 7.57%, much lower than the results obtained by UNICEF (33%), Gupta V et al (38.66%), and Mehta S et al (21%) but Praveena Daya A et al found only 5.3% of wastage for Hepatitis B vaccine quite similar to our study. <sup>(1,9,11,12)</sup> But lower frequency was observed attributed mainly to introduction of Pentavalent injection.

The wastage for TT vaccine was only 5.40% in present study, much low wastage than studies by UNICEF (34%),

Gupta V et al (36.81%) and Chinnakali P et al (62.8%) but PraveenaDaya A et al found only 4.2% of wastage, lower than present study result. (1,9-11)

According to the results of this study, the vaccine wastage rate and wastage factor are found much lower than the limits of the Ministry of Health and Family Welfare, Government of India and WHO. This may be because of the Hospital is tertiary care centre and daily vaccination sessions may results in low vaccine wastage in the centre.

The wastage rate and wastage factor in our study, for 10 dose vials (BCG) was higher than 5 and 20 doses vial. The findings of other studies were also consistent with the present study. (9,11,12) The wastage rate and wastage factor for 5 dose, 10 dose and 20 dose vials were 11.36%, 15.74%, 4.26% and 1.13, 1.19, 1.04 respectively. These values were much lower than the studies by Gupta V et al, Mehta S et al and Chinnakali P et al. (10-12) The study conducted by Praveena Daya A et al found high value of vaccine wastage rate and factor i.e. 46.5% and 1.86 respectively for 5dose vial which was higher than our study values but the VWR and VWF for 10 dose and 20 dose vial (VWR 5.3%, 1% and VWF 1.05, 1.01) was much lower than present study results. (9) The UNICEF found negligible difference in wastage between 5 doses and 10 doses vaccine (approx. 35%) whereas 20 dose vaccine wastage was 47%. (1)

In present study, the vaccine wastage rate and wastage factor for lyophilized vaccine (18.00% and 1.22 respectively) was found higher than Liquid vaccine (5.93% and 1.06 respectively) used for vaccination. Similar results that vaccine wastage more for Lyophilized vaccine were found by UNICEF (Lyophilized 50%, Liquid 38%), Gupta V et al (Lyophilized 63.76%, Liquid 26.36%), Mehta S et al (Lyophilized 37.8%, Liquid 20.16%), and Praveena Daya A et al (Lyophilized 28.2%, Liquid 3.4%) but the Chinnakali P et al found negligible difference in wastage for both Lyophilized

and Liquid vaccine (Lyophilized 48.4%, Liquid 48.2%). (1,9,10,12)

The wastage rate for injectable vaccine (10.28%) was found more than the oral vaccine (5.19%). Similar results that injectable vaccine had more wastage than oral vaccine was found by Gupta V et al (Injectable 40.34%, Oral 28.97%), and Praveena Daya A et al (Injectable 10.9%, Oral 1.03%), but Mehta S et al in their results found more wastage for Oral vaccine than the Injectable vaccine (Injectable 22%, Oral 25%). (9,11,12) Similarly UNICEF also had more wastage for oral vaccine (47%) than injectable (35%). (1) A study conducted by Chinnakali P et al 8 found negligible difference in wastage between Injectable and oral vaccine (Injectable 48.3%, Oral 48.1%). (10)

## CONCLUSION

Some degree of vaccine wastage is inevitable. To increase the vaccination coverage, children should be immunized irrespective of the wastage occurred causing wastage of rest of doses. Monitoring vaccine wastage is useful as a programme monitoring tool to improve programme quality and increase the efficiency of the programme.

### STRENGTHS: -

Our study is first to report Pentavalent vaccine wastage in urban setting.

### WEAKNESS: -

Design of our study is record based. It may introduce biases due to poor record keeping; inadequate reporting and this can be overcome with help of follow up studies or observing each session for a particular duration of study.

### RECOMMENDATIONS: -

Vaccine wastage can be expected in all programmes and there should be acceptable limit of wastage. This might differ from location depending on many factors like urban and rural setting, immunization coverage etc. Vaccine wastage due to operational causes can be reduced by continued training and retraining of workers involved in immunization practices. Innovative techniques and more multivalent

vaccines need to be developed to not only reduce wastage and operational cost but also for convenience of children who are to be vaccinated and parents who bring their children for vaccination. Further research is needed.

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