

Original Research Article

## **A Cross Sectional Study of Vaccine Wastage Assessment in A Primary Health Care Setting In Rural Central India**

**Dr. Lalitkumar Patle<sup>1</sup>, Dr. Hemant Adikane<sup>2</sup>, Dr. Dadasaheb Dhage<sup>3</sup>, Dr. Kishor Surwase<sup>4</sup>, Dr. Shriram Gogulwar<sup>5</sup>**

<sup>1</sup>Taluka Health officer, Ta. Nagbhid, Dist: Chandrapur, Maharashtra, India

<sup>2</sup>Assistant Professor, Department of Community Medicine, Government Medical College, Gondia, Maharashtra, India

<sup>3</sup>Taluka Health officer, Umerkhed, Dist: Yawatmal, Maharashtra, India

<sup>4</sup>Medical officer, Civil Hospital, Parbhani, Maharashtra, India

<sup>5</sup>District Health Officer, Zilla Parishad, Chandrapur, Maharashtra, India

### **\*Corresponding author**

Dr. Hemant Adikane

Email: [dr.hemantadikane@gmail.com](mailto:dr.hemantadikane@gmail.com)

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**Abstract:** India has one of the largest Universal Immunization Programs (UIP) in the world and is available for all children in the country free of charge. 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. Vaccine wastage is an important factor in forecasting vaccine needs. The aim is to calculate the vaccine wastage rates in primary health care setting in central rural India. Material and method: This record based cross-sectional study was carried out at one of the primary Health Centre in Chandrapur district, The data was collected for one year from 01 April 2016 to 30 March 2017 and analysed to find out vaccine wastage, vaccine wastage rate and wastage factor. Total of 10680 vaccine doses were issued for the immunization against BCG, DPT, OPV, Hepatitis B, Measles and TT vaccination. The vaccine wastage rate and vaccine wastage factor was calculated and found highest for BCG i.e. 66.84% and 3.02 respectively followed by Measles which was 29.02% and 1.41 respectively. Discussion: According to the results of this study, the vaccine wastage rate and wastage factor are found lower than the limits of the Ministry of Health and Family Welfare, Government of India and WHO. Systematic monitoring on wastage facilitates logistics management, action plan and decrease vaccine wastage due to avoidable factors.

**Keywords:** vaccine wastage, Wastage factor, Immunization, Pentavalent, bOPV, UIP

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### **INTRODUCTION**

India has one of the largest Universal Immunization Programs (UIP) in the world and is available for all children in the country free of charge [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 [2]. According to instructions under the UIP, a fresh vial of the vaccine is to be opened even if there is only one child demanding vaccination [3].

Vaccine wastage is defined by the World Health Organization (WHO) as “loss by use, decay, erosion, or leakage or through wastefulness [4] and can

be estimated as the proportion of vaccine administered against vaccine issued [5].

Vaccine wastage is an important factor in forecasting vaccine needs. In the absence of local or national data on wastage rates, and if incorrect figures are used, the country concerned may face serious vaccine shortages or be unable to consume received quantities, leading to increased wastage through expiry [6].

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 [7]. With the introduction of

new vaccine management policies such as the application of multi dose vial policy (MDVP), the effective use of vaccine vial monitors (VVMs), and improved immunization strategies and practices, vaccine wastage is expected to decrease [6].

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 [8]. India being a developing economy needs to reduce avoidable vaccine wastage and wasteful budgetary requirements [9].

However, 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. This article attempts to calculate the vaccine wastage rates in primary health care setting in central rural India.

**MATERIAL AND METHOD**

This record based cross-sectional study was carried out at one of the primary Health Centre in Chandrapur district, which functions under public health department of government of Maharashtra. The national immunization schedule was followed in which six vaccines, i.e. BCG, bOPV, Pentavalent, Measles, DPT, Tetanus Toxoid (T.T.) were given to prevent and protect the mother and children from respective diseases.

The vaccines that provided for immunization are multi-dose vials i.e. BCG, DPT and TT are 10 dose

vial vaccine whereas Measles is 5 dose vial vaccine and bOPV, Pentavalent are 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 PHC, immunization by all vaccines are done on Tuesday and Friday on regular basis to mothers and 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 April 2016 to 30 March 2017 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)] [4, 10]. The mastersheet was prepared from all the information collected in Microsoft Excel, data was analysed and statistical tests were applied using Epi Info 7. p value was calculated for 95% confidence level and < 0.05 was considered significant.

**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	950	315	635	66.84	3.02
2	Penta	2140	1430	710	33.18	1.50
3	bOPV	2510	2193	317	12.63	1.14
4	Measles	1320	937	383	29.02	1.41
5	D.P.T.	1000	751	249	24.90	1.33
6	Hep B	180	124	56	31.11	1.45
7	T.T.	2490	1928	562	22.57	1.29

Total of 10680 vaccine doses were issued for the immunization against BCG, DPT, bOPV,

pentavalent, Hepatitis B, Measles and TT vaccination at PHC on regular basis. The vaccine wastage rate and

vaccine wastage factor was calculated and found highest for BCG i.e. 66.84% and 3.02 respectively followed by Measles which was 29.02% and 1.41

respectively. Lowest wastage was seen in use of OPV vaccine (12.63%).

**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	1320	937	383	29.02	1.41
	10 Dose vial	4620	3118	1502	32.51	1.48
	20 Dose vial	4650	3623	1027	22.09	1.28
2	Type of Vaccine					
	Lyophilized	2270	1252	1018	44.85	1.81
	Liquid	8320	6426	1894	22.76	1.29
3	Mode of Administration					
	Oral	2140	1430	710	33.18	1.50
	Injectable	8450	6248	2202	26.06	1.35

**Vaccine Vial Size**

The vaccine used were categorized in three different sizes of vial i.e. 5 dose (Measles), 10 dose (BCG, DPT, Hep B and TT) and 20 dose (bOPV & Penta) per vial. The wastage rate and wastage factor for 10 dose vials was higher than 5 and 20 doses vial. No significant difference in wastage rate for 5 doses versus 10 doses vial size ( $\chi^2= 3.94$ ,  $p = 0.048$ ) but for 10 doses versus 20 doses ( $\chi^2= 0.07$ ,  $p = 0.79$ ) and for 5 doses versus 20 doses ( $\chi^2= 20.07$ ,  $p = < 0.001$ ) was found significant.

**Type of Vaccine**

The vaccine supplied under National Immunization program comes in Liquid and Lyophilized form. Pentavalent, DPT, bOPV, Hep B and TT are Liquid vaccine whereas BCG 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 ( $\chi^2= 75.23$ ,  $p = <0.001$ ).

**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 ( $\chi^2= 7.09$ ,  $p = 0.007$ ).

**DISCUSSION**

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 [2]. 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 [11]. During immunization the number of vaccine doses utilized is always higher than number of beneficiary actually immunized. Excess number depicts wastage [1].

The vaccine wastage rate (VWR) of BCG vaccine was 66.84% and wastage factor (VWF) 3.02 which was highest in this study followed by OPV (VWR 33.18% and VWF 1.50). They were above the recommended values by Ministry of Health and Family Welfare, Government of India and WHO [5, 10]. VWR and VWF were highest for BCG found in studies done in India by Gupta V *et al.*, [1] Chinnakali C, [2] Parmar D, [6] and Sharma G *et al.* [11] found rate lower than our findings. 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 12.63% which found much lower than UNICEF (38%) and Praveena Daya A *et al* found 0.00%, this might be due to minor sample size of their study as only 30 dosages were issued and given to the children [4, 8].

The wastage rate for OPV was 33.18% 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 [2-4,6,8,12,13].

The wastage rate calculated for DPT was 24.90% which was found lower than results calculated by UNICEF (27%), Gupta V *et al* (46.75%), , Chinnakali P *et al* (38.6%), and Mentey V *et al* (29.4%) and higher than Mehta S *et al* (16%), Praveena Daya A *et al* (8.4%) [2,4,6,8,12].

The calculated wastage rate for Measles vaccine was 29.02% which also lower than the wastage rate obtained by UNICEF (35%), Gupta V *et al* (41.28%), Praveena Daya A *et al* (46.5%), Chinnakali P *et al* (39.9%), and Mentey V *et al* (51.1%) and higher than Mehta S *et al* (28%) [2,4,6,8,12].

The vaccine wastage for Hepatitis B was 31.11%, much lower than the results obtained by UNICEF (33%), Gupta V *et al* (38.66%), and Mehta S *et al* (21%) along with Praveena Daya A *et al* found only 5.3% of wastage for Hepatitis B vaccine quite similar to our study [2,4,8,12]. But lower frequency was observed attributed mainly with introduction of Pentavalent injection.

The wastage for TT vaccine was only 22.57% 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 Praveena Daya A *et al* found only 4.2% of wastage, lower than present study result [4,6,8,14].

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 studies conducted by Praveena Daya A *et al*, Gupta V *et al*, Mehta S *et al* also consistent with the present study [2,8,12].

The wastage rate and wastage factor for 5 dose, 10 dose and 20 dose vials were 29.02%, 32.51%, 22.09% and 1.41, 1.48, 1.28 respectively. These values

were much lower than the studies by Gupta V *et al* (41.28%, 40.70%, 28.97% and 1.70, 1.67, 1.40), Mehta S *et al* (28%, 22%, 25% & 1.39, 1.28, 1.33) and Chinnakali P *et al* (38.6%, 51.0%, 48.1% & 1.6, 2.0, 1.9) [2,8,12].

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 5 dose 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 [8]. The UNICEF found negligible difference in wastage between 5 doses and 10 doses vaccine (approx. 35%) whereas 20 dose vaccine wastage was 47% [4].

In present study, the vaccine wastage rate and wastage factor for lyophilized vaccine (44.85% and 1.81 respectively) was found higher than Liquid vaccine (22.76% and 1.29 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%) [2,4,6,8,12]

The wastage rate for injectable vaccine (26.06%) was found lower than the oral vaccine (33.18%). Similar results that Mehta S *et al* in their results found more wastage for Oral vaccine than the Injectable vaccine (Injectable 22%, Oral 25%) [12]. Similarly UNICEF also had more wastage for oral vaccine (47%) than injectable (35%) [4]. And 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%) [2,8] but A study conducted by Chinnakali P *et al* found negligible difference in wastage between Injectable and oral vaccine (Injectable 48.3%, Oral 48.1%) [6].

According to the results of this study, the vaccine wastage rate and wastage factor are found higher than the limits of the Ministry of Health and Family Welfare, Government of India and WHO. This may because of the Hospital is primary health care centre and twice a weekly vaccination sessions may results in high vaccine wastage in the centre.

## CONCLUSION

Present study shows higher wastage rate for BCG (66.84%) when comparing with national and UNICEF limits. Systematic 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. Vaccine wastage calculations should be done routinely to assess the loss due to wastage. This can save significant funds for an immunization programme if wastage can be reduced without affecting the coverage.

## STRENGTH

Present study is first to report Pentavalent vaccine wastage in rural Indian setting. Records were well maintained in terms of number of vials received, used, wasted, number of beneficiaries vaccinated 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.

## WEAKNESS

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.

## RECOMMENDATIONS

Vaccine wastage can be anticipated in all vaccination programmes and there should be tolerable 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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