

**A Cross Sectional Study of Vaccine Wastage Assessment in a District Hospital of Central India**

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Abstract

Background: 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 scaling down childhood infectious diseases burden and its residual outcomes. 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.

Aim: To calculate the vaccine wastage rates in secondary health care setting in parbhani district of Maharashtra in central India.

Material And Method: This record based cross-sectional study was carried out at district hospital of parbhani, 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: Total of 44240 vaccine doses were issued for the immunization against BCG, DPT, OPV, Hepatitis B and Measles vaccination at district hospital on daily basis. The vaccine wastage rate and vaccine wastage factor was

calculated and found highest for D.P.T. i.e. 34.23% and 1.52 respectively followed by Measles which was 21.72% and 1.28 respectively. Lowest wastage was seen in use of Hepatitis B vaccine (5.50%).

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.

Conclusion: Monitoring vaccine wastage is useful as a programme monitoring tool to improve programme quality and increase the efficiency of the programme. The authors endorse that vaccine wastage calculations should be done consistently to assess the loss due to wastage.

Keywords: Vaccine Wastage, Wastage Factor, Immunization, Pentavalent, bOPV, UIP

Introduction

Since the turn of the century, several positive changes have occurred in the world of human development. (1) Vaccines are one of the greatest achievements of biomedical science and public health and represent one of the most effective tools for the prevention of diseases. (2) India's Universal Immunization Program (UIP) is among the largest in the world and is available for all children in

the country free of charge. (3) It was launched in 1985 in India with intent to immunize all eligible children by 1990. (4) The program budgets more than US\$ 500 million every year for immunizing children against vaccine preventable diseases, including the polio eradication program. (5) Since its inception, it is accomplishing a desired aim of child survival interventions to bring about scaling down childhood infectious diseases burden and its residual outcomes. (6) Vaccine wastage is defined by the World Health Organization (WHO) as “loss by use, decay, erosion, or leakage or through wastefulness (1) 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, 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. (7) 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. (5) Vaccines and their management form a major component of the national immunization programme. Regular supply of vaccines and their efficient management is paramount to the success and effectiveness of all immunization programmes. (8) World Health Organization reports over 50% vaccine wastage around the world. Global Alliance for Vaccine & Immunization (GAVI) has requested all countries to bring down vaccine wastage rates: “The country would aim for a maximum wastage rate of 25% set for the first year with a plan to gradually reduce it to 15% by the third year. For vaccine in single-dose or two-dose vials the maximum wastage allowance is 5%.” (9) The manufacturing costs in a multi-dose vial are spread over many doses and therefore they tend to cost less per dose as compared to a single-dose

vial. Further multi-dose vials have lower cold chain costs however they are also thought to be associated with higher wastage. (10) 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. (11) India being a developing economy needs to reduce avoidable vaccine wastage and wasteful budgetary requirements. (12) The goal of any vaccination programme should be to make all doses count towards the success of immunization in protecting health. (13)

A better sense of vaccine utilization and wastage rates can lead to better planning and management of vaccine stocks. (1) However, there is paucity of evidence in secondary care settings of area in this regard where vaccine wastage may be higher, might be due to various operational causes. This article attempts to calculate the vaccine wastage rates in secondary health care setting in parbhani district of Maharashtra in central India.

Material and Method

Study setting & subjects

This record based cross-sectional study was carried out at district hospital of parbhani, 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, and Hepatitis B 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 and Hepatitis B 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 have to be prepared before vaccination while all the other vaccines are delivered in liquid form and can be freely 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. (5)

In district hospital, immunization by all vaccines is done on each working day to the children upto 5 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 calculated accordingly.

Study duration

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)]. (1,9)

Statistical analysis

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 I: - 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	8990	7611	1379	15.34	1.18
2	Penta	15850	13945	1905	12.02	1.14
3	bOPV	6690	6202	488	7.29	1.08
4	Measles	3370	2638	732	21.72	1.28
5	D.P.T.	2670	1756	914	34.23	1.52
6	Hep B	6670	6303	367	5.50	1.06

Total of 44240 vaccine doses were issued for the immunization against BCG, DPT, OPV, Hepatitis B and Measles vaccination at district hospital on daily basis. The vaccine wastage rate and vaccine wastage factor was calculated and found highest for D.P.T. i.e. 34.23% and 1.52 respectively followed by Measles which was 21.72% and 1.28 respectively. Lowest wastage was seen in use of Hepatitis B vaccine (5.50%).

TABLE II: - 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	3370	2638	732	21.72	1.28
	10 Dose vial	18330	15670	2660	14.51	1.17
	20 Dose vial	22540	20147	2393	10.62	1.12
2	Type of Vaccine					
	Lyophilized	12360	10249	2111	17.08	1.21
	Liquid	31880	28206	3674	11.52	1.13
3	Mode of Administration					
	Oral	15850	13945	1905	12.02	1.14
	Injectable	28390	24510	3880	13.67	1.16

Vaccine Vial Size

The vaccine used were categorized in three different sizes of vial i.e. 5 dose (Measles), 10 dose (BCG, HepB & DPT) and 20 dose (bOPV & Penta) per vial. The wastage rate and wastage factor for 5 dose vials was higher than 10 and 20 doses vial. Significant difference in wastage rate for 5 doses versus 10 doses vial size ($\chi^2= 9.78$, $p = 0.001$), for 5 doses versus 20 doses ($\chi^2= 22.88$, $p = < 0.001$) and for 10 doses versus 20 doses ($\chi^2= 9.34$, $p = 0.002$) was found.

Type of Vaccine

The vaccine supplied under National Immunization program comes in Liquid and Lyophilized form. Penta, DPT, bOPV and Hep B 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 significant difference in wastage between Liquid and Lyophilized vaccine ($\chi^2=17.14$, $p = <0.001$).

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 no statistically significant difference between these two modes of administration ($\chi^2= 1.7$, $p = 0.19$).

Discussion

The World Health Organization has also anticipated vaccine wastage rate in order to help in computing 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. (2) During immunization the number of vaccine doses utilized is always higher than number of beneficiary actually immunized. Excess number depicts wastage. (3)

The vaccine wastage rate (VWR) of BCG vaccine in our study was 15.34% and wastage factor (VWF) 1.18. It is below the recommended values by Ministry of Health and Family Welfare, Government of India and WHO. (1,5) VWR and VWF were highest for BCG found in studies done in India by Gupta V et al, Chinnakali C et al (70.9%, 3.4), Parmar D et al (22.93%, 1.30), and Sharma G et al (21.30%, 1.27) found rate higher than our findings. (2,3,6,7) this may be because the vaccine as per national guidelines should be thrown away 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, as reported by other researchers.

The wastage rate for Pentavalent was 7.29% and factor was 1.08 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. (9,11) Sharma G et al (9.39%, 1.10) Patle L et al (33.18%, 1.50) also reported higher findings than our results. (3,14) Patel P et al (8.05%, 1.09) Bagdey P et al (2.72%, 1.03) reported findings lower than our results. (4,12)

The wastage rate for OPV was 12.02% and factor 1.14 which found much lower than UNICEF (47%) and most of the other studies i.e. Gupta V et al (28.97%, 1.40), Mehta S et al (25%, 1.33), Chinnakali P et al (48.1%, 1.9), Mentey V et al (51.2%), and Mukherjee A et al (14.5%, 1.19) but results found by Praveena Daya A et al (2.4%, 1.02), Bagdey P et al (5.19%, 1.05) was much lower than our study. (6,7,9,11,15-17)

The wastage rate calculated for DPT was 34.23% and factor 1.52 which was found higher 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%), Bagdey P et al (13.55%, 1.16). (6,7,9,11,12,15,16)

The calculated wastage rate for Measles vaccine was 21.72% and factor was 1.28 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%), Mentey V et al (51.1%), Mehta S et al (28%). (6,7,9,11,15) Bagdey P et al (11.36%, 1.13), Parmar D (11.00%, 1.12) found results less than our results. (2,12)

The vaccine wastage for Hepatitis B was 5.50% and factor 1.06, 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. (6,9,11,15)

The wastage rate and wastage factor for 5 dose, 10 dose and 20 dose vials were 21.72%, 14.51%, 10.62% and 1.28, 1.17, 1.12 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). (6,11,15)

The wastage rate and wastage factor in our study, for 5 dose vials (Measles) was higher than 10 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. (6,11,15)

In our study, we have found a statistical significant among use of 5 dose, 10 dose and 20 dose vials. (Table 2) Bagdey P et al, Parmar D, Patle L et al found similar results. (2,12,14)

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. (11) The UNICEF found negligible difference in wastage between 5 doses and 10 doses vaccine (approx. 35%) whereas 20 dose vaccine wastage was 47%. (9)

In present study, the vaccine wastage rate and wastage factor for lyophilized vaccine (17.08% and 1.21 respectively) was found higher than Liquid vaccine (11.52% and 1.13 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%). (6,7,9,11,15) The wastage rate for injectable vaccine (13.67%) was found lower than the oral vaccine (12.02%). Mehta S et al in their results found more wastage for Oral vaccine than the Injectable vaccine (Injectable 22%, Oral 25%). (15) Similarly UNICEF also had more wastage for oral vaccine (47%) than injectable (35%). (9) 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%), (6,11) but study conducted by Chinnakali P et al found negligible difference in wastage between Injectable and oral vaccine (Injectable 48.3%, Oral 48.1%) like in our study results. (7)

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. This may because of the Hospital is secondary health care centre and daily vaccination sessions may results in less vaccine wastage in the vaccination sessions.

Conclusion

Present study shows lower wastage rate for DPT (34.23%) when comparing with national and UNICEF limits, which was highest in our study. Vaccine wastage due to certain operational causes like cold chain failure or expiry is zero which stresses the need to minimize the wastage. Vaccine wastage due to these causes can be reduced by continued training and retraining of workers involved in immunization practices. Keeping close eye on vaccine wastage is useful as a programme monitoring tool to improve programme quality and increase the efficiency of the programme.

Strength

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. Findings of our study are unsuccessful for, accurately and consistently quantifying the specific causes of wastage could help rethink immunization practices and policies, and better target wastage reduction efforts. If resources are available, then vaccine wastage can be obtained by actual monitoring of the immunization clinic rather than doing record based study

Recommendations

The authors endorse that vaccine wastage calculations should be done consistently to assess the loss due to wastage. Monitoring vaccine wastage is useful as a programme monitoring tool to improve programme quality and increase the efficiency of the programme. This can save significant funds for an immunization programme if wastage can be reduced without affecting the coverage. Data quality audit should be conducted at health facilities at periodic intervals to ensure data quality and accuracy in the government administrative immunization reporting systems.

In India, like setting with large number of service delivery points, there is growing need for establish technology based solution like internet based reporting and vaccine logistics management system, which will not only

facilitate analysis of reports but also ensure timely availability of vaccines and other critical logistics. Further research is needed.

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