Original Article

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# Assessment of Vaccine Wastage in an Immunisation Clinic of a Tertiary Care Centre in Western Odisha- A Cross-sectional Study

Community Section

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## ABSTRACT

**Introduction:** Vaccine wastage is an expected component of any immunisation program. Wastage is defined as "loss by use, decay, erosion or leakage or through wastefulness". Vaccine wastage in unopened vial is mostly attributed by cold chain and stock management problem. Vaccine wastage in opened vial is mostly due to discarding of remaining dose at the end of the session, not being able to draw the number of doses in a vial, submergence of opened vials in water and poor vaccine administration practices.

**Aim:** To assess the vaccine wastage in an immunisation clinic of a tertiary care centre in western Odisha, India.

**Materials and Methods:** A record based descriptive cross-sectional study was carried out at Immunisation Clinic, Veer Surendra Sai Institute of Medical Sciences and Research, Burla, Odisha, India. The information regarding children and pregnant women vaccinated were retrieved from immunisation register for the study period 1st October 2019 to 30th September 2020. Vaccine wastage rate at the immunisation clinic was calculated by taking into account the number of doses of vaccines wasted divided by the total number of the doses of vaccines issued multiplied by 100.

**Results:** Vaccine wastage rate and wastage factor was found to be highest in case of Measles-Rubella (MR) vaccine (wastage rate 65% and wastage factor 2.85) and lowest in Hepatitis B vaccine (wastage rate 1.67% and wastage factor 1.01). Wastage rate for 10 dose vial was 28.37% followed by 19.72% for 25 dose vial and 10.11% for 20 dose vial. Wastage rate and wastage factor was found to be higher in lyophilised vaccines when compared to liquid vaccines and the difference was statistically significant. Wastage rate and wastage factor was found to be higher for oral vaccines when compared to injectable vaccines and the difference was statistically significant.

**Conclusion:** It was seen that in case of MR vaccine (supplied as 10 dose/vial), vaccine wastage was more as it didn't follow open vial policy and less number of beneficiary came for MR vaccine per immunisation session. The vaccine wastage can be reduced in lyophilised vaccines if they are supplied in less doses per vial.

**Keywords:** Liquid vaccine, Lyophilised vaccine, Measles-Rubella vaccine, Wastage factor

## INTRODUCTION

Vaccines are one of the greatest achievements of biomedical science and represent one of the most effective tools for the prevention of diseases [1]. Universal Immunisation Programme (UIP) is a vaccination programme launched by the Government of India in 1985. Under this programme vaccines are given free of cost to all children and pregnant women. 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 [2].

Vaccine wastage is defined by the World Health Organisation (WHO) as "loss by use, decay, erosion, or leakage or through wastefulness" [3]. Vaccine wastage may take place both from unopened vials and opened vials. Indication by Vaccine Vial Monitor (VVM), expiry, exposure to high temperatures, freezing, breakage, missing inventory and theft are vaccine wastage which occurs in unopened vials. Wastage may also take place from opened vials when the dose remaining in the vial at the end of the session are discarded, the number of doses drawn from a vial differ from that shown on the label and poor reconstitution practices. Open vials submerged in water and contamination also contribute to vaccine wastage. WHO reports vaccine wastage to be over 50% all around the world [4]. The lack of knowledge of vaccine wastage rates leads to inadequate estimation of needs and thereby leading to problems of vaccine being out of stock and/or there is excess stock of vaccine. High vaccine wastage rate inflate vaccine demands and increase unnecessary vaccine procurement and supply chain costs. The Ministry of Health and Family Welfare, Government of India has recommended that vaccine wastage rate should not more than 25% [5].

There are limited number of studies done in India to find out what is the actual vaccine wastage rates as recommended by WHO and The Ministry of Health and Family Welfare, Government of India [2,6-9]. In most of the studies it was found that vaccine wastage was more of lyophilised vaccine as compared to liquid vaccine [6-8].

The present study was done in an attempt to assess the vaccine wastage in an immunisation clinic of a tertiary care centre in western Odisha, India.

## MATERIALS AND METHODS

A cross-sectional study was carried out in an Immunisation Clinic, which is under direct supervision of the Department of Community Medicine, VIMSAR, Burla, Odisha, India. Data were collected from the records from 1st October 2019 to 30th September 2020 about all children and pregnant women who were vaccinated during this time period in the immunisation clinic. Those children who were vaccinated with optional vaccine {not under National Immunisation Schedule (NIS)} were excluded from the study.

Details regarding the total number of vaccines issued and number of doses used were recorded from the immunisation registers. The immunisation clinic is conducted by two staff nurse and one doctor from the Community Medicine Department, twice a week (Monday and Wednesday; 9:00 AM to 1:00 PM). All vaccines such as Bacillus Calmette-Guérin (BCG), Oral Polio Vaccine (OPV), Hepatitis B, Pentavalent, Inactivated Polio Vaccine (IPV), Rotavirus vaccine, Measles-Rubella (MR) Vaccine, Diphtheria Pertusis Tetanus vaccine (DPT) and Tetanus Diphtheria toxoid (Td) vaccines are given following the NIS as recommended by Ministry of Health and Family Welfare, Government of India [10].

BCG, Hepatitis B, DPT, Td, MR, Pentavalent vaccine and Rotavirus vaccine vials used were 10 dose preparations whereas OPV vials were 20 dose preparations and IPV vials were 25 dose preparations. Immunisation sessions are supervised by doctors of Community Medicine Department. All the vaccines are supplied in liquid form except BCG, MR which is supplied in lyophilised form. All liquid vaccines can be readily administered but for BCG and MR which need to be reconstituted with appropriate diluents before use.

As per the centre protocol, the vaccines were used following "open vial policy" according to which liquid vaccines can be used, if they have returned unopened atleast three times after being taken out for vaccination or they have been kept in the cold chain for 28 days after the vial has been opened, whereas the reconstituted vaccines are recommended to be used within four hours after opening the vial [11]. Although rotavirus vaccine is supplied in liquid form it does not follow open vial policy and is used within four hours after opening [12].

The data was recorded in each immunisation session in Immunisation register regarding number of beneficiaries and type of vaccine given. Another immunisation register was maintained where number of doses of vaccines issued, used and wasted was recorded. From that register the information was taken regarding vaccine vials and immunisation done for the reference period.

Vaccine wastage rate and wastage factor were calculated as follows:

Vaccine wastage rate=(No. of doses wasted/No. of doses issued)×100

Vaccine wastage factor={100/(100-vaccine wastage rate)}

## STATISTICAL ANALYSIS

The data collected were analysed using Statistical Package for the Social Sciences (SPSS) version 21.0. Statistical analysis was done using percentages, Chi-square test and p-value was used for interpretation of results. A p-value <0.05 considered statistically significant.

## RESULTS

During the study period, a total of 16,132 doses of vaccine were issued at the immunisation clinic. [Table/Fig-1] shows the wastage rate and wastage factor for different vaccines. Wastage rate and wastage factor was found to be highest in case of MR vaccine (wastage rate 65% and wastage factor 2.85) followed by rotavirus vaccine (wastage rate 39.8% and wastage factor 1.66) and lowest in Hepatitis B vaccine (wastage rate 1.67% and wastage factor 1.01).

| Name of vaccine | No. of doses issued during study period | No. of beneficiary vaccinated during study period | Vaccine wastage rate (%) | Vaccine wastage factor |
|---|---|---|---|---|
| BCG | 2860 | 2154 | 24.68 | 1.32 |
| OPV | 3342 | 3004 | 10.11 | 1.11 |
| Hep B | 2084 | 2049 | 1.67 | 1.01 |
| Penta | 676 | 641 | 5.17 | 1.05 |
| IPV | 517 | 415 | 19.72 | 1.24 |
| Rota | 5250 | 3160 | 39.8 | 1.66 |
| MR | 920 | 322 | 65.0 | 2.85 |
| DPT | 290 | 284 | 2.06 | 1.02 |
| Td | 193 | 180 | 6.73 | 1.07 |

**[Table/Fig-1]:** Vaccine wastage rate and wastage factor for different vaccines.
BCG: Bacillus calmette guérin; OPV: Oral polio vaccine; HepB: Hepatitis B; IPV: Inactivated polio vaccine; MR: Measles-rubella; DPT: Diphtheria pertusis tetanus; Td: Tetanus diphtheria toxoid

In [Table/Fig-2] wastage rate and wastage factor was calculated in relation to number of doses per vial which shows that 28.37% was wastage rate for 10 dose vial followed by 19.72% for 25 dose vial and 10.11% for 20 dose vial. Difference in wastage rate for 10 doses versus 20 doses vial size was found to be statistically significant.

[Table/Fig-3] shows that the wastage rate and wastage factor was found to be higher in lyophilised vaccines (wastage rate 34.49% and wastage factor 1.52) when compared to liquid vaccines (wastage rate 21.2% and wastage factor 1.26) and the difference was statistically significant.

| No. of doses in one vaccine vial | No. of doses issued during study period | No. of beneficiary vaccinated during study period | Vaccine wastage rate (%) | Vaccine wastage factor |
|---|---|---|---|---|
| 10 dose* | 12,273 | 8790 | 28.37 | 1.39 |
| 20 dose** | 3342 | 3004 | 10.11 | 1.11 |
| 25 dose*** | 517 | 415 | 19.72 | 1.24 |

**[Table/Fig-2]:** Vaccine wastage rate and wastage factor according to number of doses in the vaccine vial.
*BCG, Hep B, Td, DPT, MR, Penta, Rota; **OPV; ***IPV

| Type of vaccine | No. of doses issued during study period | No. of beneficiary vaccinated during study period | Vaccine wastage rate (%) | Vaccine wastage factor |
|---|---|---|---|---|
| Lyophilised | 3780 | 2476 | 34.49 | 1.52 |
| Liquid | 12,352 | 9733 | 21.2 | 1.26 |

**[Table/Fig-3]:** Vaccine wastage rate and wastage factor for lyophilised and liquid vaccine.
$\chi^2$=40.12; df=1; p<0.001: p-value <0.05 considered significant

In [Table/Fig-4], it is found that the wastage rate and wastage factor was higher (wastage rate 28.25% wastage factor 1.39) for oral vaccines and lower in case of injectable vaccines (wastage rate 19.82% and wastage factor 1.24) and the difference was statistically significant (p<0.001).

| Route of administration | No. of doses issued during study period | No. of beneficiary vaccinated during study period | Vaccine wastage rate (%) | Vaccine wastage factor |
|---|---|---|---|---|
| Injection | 7540 | 6045 | 19.82 | 1.24 |
| Oral | 8592 | 6164 | 28.25 | 1.39 |

**[Table/Fig-4]:** Vaccine wastage rate and wastage factor according to routes of administration.
$\chi^2$=21.41; df=1; p<0.001: p-value <0.05 considered significant

## 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 immunisation program [5]. It has also been recommended by WHO that for lyophilised vaccines, the wastage rate should be 50% on an average for 10-20 dose vials whereas for liquid vaccine in should be 25% for 10-20 dose vials [4]. The present study showed that the vaccine wastage rate for MR vaccine and Rotavirus vaccine were higher than the limits given by Ministry of Health and Family Welfare as well by WHO.

In the present study, vaccine wastage rate was highest for MR vaccine (65%), followed by Rotavirus vaccine (39.8%) and BCG vaccine (24.68%). MR vaccine and BCG vaccine once reconstituted should be discarded after 4 hours of reconstitution as per national guidelines. As the study was done in a tertiary care hospital where more number of institutional deliveries was conducted, so more number of new born babies came for BCG vaccination. But less number of children of 9 month/16-24 month came for MR vaccination in each immunisation session. This might be the cause of increased vaccine wastage for MR as compared to BCG vaccine. The vaccine wastage rate for MR vaccine, supplied as 10 doses per vial, was 65% in the present study. MR vaccine has been recently introduced in the NIS. However, measles is a component of MR vaccine and wastage rate of measles vaccine was found to be much lower than in some studies which may be due to 5 dose vial of measles vaccine used in those studies [6-8].

The vaccine wastage for BCG was 24.68% in present study which is much lower than the results found by Chinnakali P et al., (70.9%), which was conducted in a primary healthcare setting (in South Delhi) [7]. This could be due to less number of deliveries are conducted in a primary healthcare setting as compared to tertiary setup hospitals, so the new born babies taking BCG also are less in primary healthcare immunisation sessions.

The wastage rate of OPV was 10.11% with a wastage factor of 1.11, which was similar to the findings by Tiwari R et al., (at a tertiary hospital in Gwalior, Madhya Pradesh, India) [9]. However, some studies [6,13] showed much higher wastage rates for OPV. 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., giving more number of drops of OPV to a child due to faulty vaccine administration, child moving the head at the time of ingestion of vaccine as per Gupta V et al., [6]. As stated by Sharma G et al., child moving the head at the time of ingestion of vaccine and OPV being the most heat sensitive was the factor behind high wastage rate of OPV [13].

The wastage rate of hepatitis B vaccine was found out to be 1.67% in the present study, which was lowest among all vaccines given in the immunisation clinic. The wastage rate of hepatitis B vaccine was higher in other studies [7,9]. Hepatitis B vaccine is given within 24 hours of birth to prevent perinatal transmission. More number of deliveries in this hospital as compared to the above-mentioned hospitals [7,9] is probably the cause of such low wastage rate of Hepatitis B vaccine.

The wastage rate for DPT vaccine was 2.06% in the present study, which was much lower than some studies conducted in a primary healthcare setup [14,15]. In the present study setup, DPT vaccine was administered to those children who came for the vaccine (mostly 16-24 month child and 5-6 year age child) irrespective of immunisation session days, as DPT vaccine follows open vial policy. Pentavalent, fractional IPV, Rota and Td being newly introduced vaccine in the NIS limited data are available regarding their wastage rate and wastage factor. In the present study, the wastage rate of Pentavalent vaccine, fractional IPV, Rota and Td vaccine were 5.17%, 19.72%, 39.8% and 6.73%, respectively. As Rotavirus vaccine didn't follow the open vial policy it may have contributed for the high wastage rate of the vaccine.

In the present study, the wastage rate for 10 dose vaccine vial was 28.37% and for 20 dose vaccine vial was 10.11%. In a study by Palanivel C et al., wastage rate for 10 dose vaccine vial was 51% and for 20 dose vaccine vial wastage was 48.1% [14]. As OPV comes as 20 doses per vial, due to more number of beneficiaries and good vaccine administration techniques, the wastage rate was less in the present study. Fractional IPV comes in a 25 dose vial and wastage rate for the vaccine was 19.72% in the present study. As fractional IPV given intradermally so there is more wastage during the administration process (0.1 mL is the dose, but the vaccinators were drawing little bit more amount than 0.1 mL from the vaccine vial as sometimes during the procedure of air freeing of the syringe there is certain amount of wastage of vaccine).

The present study showed that vaccine wastage rate was more for lyophilised vaccine (34.49%) with a wastage factor of 1.52 as compared to liquid vaccine (wastage rate 21.2%) with wastage factor 1.26. Similar observations were found by Mehta S et al., (37.8%-lyophilised, 20.16%-liquid) [8]. In another study by Gupta V et al., they also found that wastage rate for lyophilised vaccine (63.76%) were higher as compared to liquid vaccine (26.36%) [6]. As lyophilised vaccines should be used within four hours of reconstitution so wastage rate was high in them as compared to liquid vaccines. So, if the lyophilised vaccine vials were supplied as five doses per vial instead of 10 doses then the wastage can be reduced to some extent.

In the present study, the wastage rate for injectable vaccines (19.82%) was found lower than the oral vaccines (28.25%). Similar results found in a study done by Mehta S et al., (wastage rate for injectable vaccines was 22% whereas for oral vaccines wastage was 25%) [8]. Similarly, in a study by United Nations Children's Fund (UNICEF) wastage for oral vaccine (47%) was higher than injectable (35%) [3]. Injectable vaccines had more wastage (40.34%) than oral vaccines (28.97%) as found by Gupta V et al., [6]. Praveena DA et al., also found wastage rate for injectable vaccines10.9% and for oral vaccines wastage was 1.03%) [16].

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 immunisation clinic at frequent intervals.

### Limitation(s)

As the data had been collected for one year from the records, if the wastage rates were calculated at small intervals frequently, then the actual vaccine wastage could be determined and compared.

## CONCLUSION(S)

Certain extent of vaccine wastage is inevitable in any immunisation programme, but there should be an acceptable limit of wastage. This might differ from location depending on many factors like urban and rural setting, immunisation coverage, etc. Higher wastage rates are acceptable to increase vaccine coverage in a low vaccine coverage setting. Vaccine wastage due to operational causes can be reduced by continued training and retraining of workers involved in vaccine handling and administration of vaccines. Thus, vaccine wastage should be estimated in each immunisation session so that it can act as an effective tool to increase programme quality as well as efficiency.

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