A study to assess vaccine wastage in an immunization clinic of tertiary care centre, Gwalior, Madhya Pradesh, India

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ABSTRACT

Background: Vaccines are one of the most successful and cost-effective health intervention. It becomes imperative that use of vaccine was done through a proper framework of practical decision-making that confers positive health and economic benefits to the society of which Vaccine Wastage was a key factor. The aim of the study is to assess “Vaccine Wastage Rate” and “Wastage Factor” of different vaccines given to beneficiaries in Immunization Clinic and based on the above data, recommend measures to reduce it in the Immunization clinic

Methods: The present study was a Record Based Retrospective study carried out in Immunization Clinic in Madhav Dispensary of tertiary centre at Gajra Raja Medical College, Gwalior, Madhya Pradesh, India. The data was collected from 1 April 2015 - 31 March 2016.

Results: Immunization Sessions were conducted in Immunization clinic during reference period and 7 vaccines BCG, OPV, DPT, Hepatitis B, pentavalent, measles and TT were given. Among individual vaccines, wastage rate and wastage factor in BCG (20.71 and 1.26), OPV (14.65 and 1.17), DPT (15.6 and 1.18), Hepatitis B (10.56 and 1.12), Pentavalent (5.2 and 1.05), Measles (21.68 and 1.28), TT (7.09 and 1.08), and IPV (10.49 and 1.12) was respectively.

Conclusions: Vaccine wastage could be expected in all programmes and there should be an acceptable limit of wastage. Innovative techniques to be developed not only to reduce wastage but also the operational cost for convenience of children who were to be vaccinated and parents who bring their children for vaccination without compromising coverage.

Keywords: BCG, Hepatitis B, Immunization, Measles

INTRODUCTION

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. According to WHO reports, there is 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. Due to high vaccine wastage, demand of vaccines inflates which consequently 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). By determining wastage rate and factor, and analysing source, type and place of wastage, necessary steps would be taken to reduce these overlooked costs which bleed through the cracks of logistic and supply.
Accordingly, these saved funds would be properly utilized and allocated to the prevention of other vaccine preventable diseases. Also, there is lack of comprehensive studies done in India to validate the wastage rate recommended by WHO and Ministry of Health and Family Welfare.

India spends over Rs. 2.6 billion per year in immunization programmes for immunizing children against vaccine preventable diseases, including polio eradication, where it has maintained zero polio case for the last two years.\(^5\)

An assessment of vaccine wastage in India, conducted in 2009 revealed that wastage rate depends on formulation, presentation and was inversely proportional to session site. Both cold chain requirement and vaccine wastage is expected to increase several fold with the introduction of newer vaccines compared to the UIP vaccines.\(^5\)

India released its first National Vaccine Policy in 2011 and the published outcome on vaccination coverage shows that it is more than 70% in only 11 states, 50-70% in 13 states and is below 50% in remaining 8 states 6,7. In Madhya Pradesh, India fully immunized Children (BCG, measles, and 3 doses each of polio and DPT) aged 12-23 months constitutes 63.0% in Urban, 50.2% in Rural and 53.6% in total in 2015-2016, which was acceptable increase from 40.3% total in 2005-2006.\(^7\)

Wastage is often defined as “loss by use, decay, erosion, or leakage or through wastefulness”. Vaccines are one of the most successful health interventions under specific protection of primary level of prevention.

Immunization bring about significant reductions in infectious diseases and adverse health consequences and improve quality of life in the population. Over the years, vaccines have provided highly cost effective improvements to human health by reducing avoidable human suffering, costs of care and treatment, economic consequences of work i.e. lower productivity and loss of work.\(^3\)

It was well known that India has one of the largest immunisation programmes in the world, catering to nearly 27 million infants and 30 million pregnant women annually. Immunisation services are delivered through about 29,000 health facilities (HFs) in 640 districts of 36 states/Union Territories (UTs). These HFs are equipped with cold chain equipment (CCE) i.e., ice lined refrigerators (ILRs) and deep freezers (DFs) to store vaccines at recommended temperatures. They further provide vaccines and supplies to about 1,50,000 sub-center.

METHODS

The present study was a record based descriptive study carried out in “immunization clinic” of Madhav Dispensary under Department of Community Medicine, Gajra Raja Medical College, Gwalior Madhya Pradesh, India. BCG, OPV, DPT, Hepatitis B, Pentavalent, IPV, Measles and TT were administered during the reference period in this clinic as per National Immunization Schedule, to prevent and protect the children and pregnant women from respective Vaccine Preventable Diseases.

Pentavalent Vaccine was given from November 2014. Children born before November 2014 were vaccinated with DPT and those born afterwards were given Pentavalent vaccine. IPV was introduced from 1st January 2016.

The vaccines provided for Immunization were in Multi-dose Vials i.e. BCG, DPT, Hepatitis B, Pentavalent, IPV and TT was 10 doses per vial, Polio 20 doses per vial whereas Measles was 5 doses per vial. BCG and Measles were in Lyophilized (Freeze Dried) form i.e. they need to reconstitute with diluents before vaccination while all other vaccines were provided in Liquid form which can be readily used.

Multi-dose Vaccine Vial Policy was followed according to which the lyophilized freeze dried vaccines should be used within 4 hours after opening of vial and reconstitution while all Liquid Vaccine Vials which have been taken out for immunization and returned unopened at least three times or that has been kept in Cold Chain for 28 days after opening of vial are discarded in order to maintain the potency of vaccine.\(^7\)

The data was recorded daily in Immunization registers and EVIN (Electronic Vaccine Intelligence Network) and monthly report was prepared which was used to retrieve information regarding vaccine vials and children immunized for the reference period.

The Vaccine wastage rate and Wastage factor which were calculated by the formula as: Vaccine Wastage Rate = No. of doses wasted / No. of doses issued ×100. Vaccine Wastage Factor = 100 / 100-Vaccine Wastage Rate. The data was collected, analysed, interpreted and statistical analysis was done using percentages, chi-square test and p values were calculated.

RESULTS

As shown in Table 1, the wastage rate in Measles was 21.68% and for BCG it was 20.71% followed by Pentavalent vaccine which was 5.2%.

Table 1 showing vaccine wastage rate and wastage factor for different vaccines. As shown in Table 2 wastage rate is calculated in relation to Doses/Vial which shows that 21.68% was wastage rate for 5 dose vial followed by 10 dose vial and 20 dose vial as 12.14% and 14.65% respectively.
Table 3 shows the categorization in relation to lyophilized and liquid vaccine which depicts 21.02% and 11.12% respectively.

Table 4 shows for mode of administration as for injection it is 13.29% and for oral it is 14.65% respectively.

### Table 1: Vaccine wastage rate and wastage factor for different vaccines.

<table>
<thead>
<tr>
<th>Name of vaccine</th>
<th>Doses issued in the study period</th>
<th>Number of children vaccinated</th>
<th>Wastage rate (%)</th>
<th>Wastage factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG **</td>
<td>7180</td>
<td>5693</td>
<td>20.71</td>
<td>1.26</td>
</tr>
<tr>
<td>OPV***</td>
<td>13300</td>
<td>11351</td>
<td>14.65</td>
<td>1.17</td>
</tr>
<tr>
<td>DPT **</td>
<td>1910</td>
<td>1612</td>
<td>15.6</td>
<td>1.18</td>
</tr>
<tr>
<td>Hepatitis B **</td>
<td>3580</td>
<td>3202</td>
<td>10.56</td>
<td>1.12</td>
</tr>
<tr>
<td>Pentavalent **</td>
<td>4920</td>
<td>4664</td>
<td>5.2</td>
<td>1.05</td>
</tr>
<tr>
<td>Measles*</td>
<td>3210</td>
<td>2514</td>
<td>21.68</td>
<td>1.28</td>
</tr>
<tr>
<td>TT **</td>
<td>5460</td>
<td>5073</td>
<td>7.09</td>
<td>1.08</td>
</tr>
<tr>
<td>IPV **</td>
<td>410</td>
<td>367</td>
<td>10.49</td>
<td>1.12</td>
</tr>
</tbody>
</table>

# 5 doses/vial, * 10 doses/ vial, ***20 doses/vial; χ² =75.172, df=7, p value =0

### Table 2: Vaccine wastage rate and wastage factor for different multi-dose vial.

<table>
<thead>
<tr>
<th>Doses/vial</th>
<th>Doses issued in the study Period</th>
<th>No. children vaccinated</th>
<th>Wastage rate (%)</th>
<th>Wastage factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 doses/vial*</td>
<td>3210</td>
<td>2514</td>
<td>21.68</td>
<td>1.28</td>
</tr>
<tr>
<td>10 doses/vial**</td>
<td>23460</td>
<td>20611</td>
<td>12.14</td>
<td>1.14</td>
</tr>
<tr>
<td>20 doses/vial***</td>
<td>13300</td>
<td>11351</td>
<td>14.65</td>
<td>1.17</td>
</tr>
</tbody>
</table>

*Measles; **BCG, DPT, Pentavalent, Hepatitis B, TT, IPV; ***OPV; χ² =17.55, df=2, p value =0.001

### Table 3: Vaccine wastage rate and wastage factor for lyophilized and liquid vaccine.

<table>
<thead>
<tr>
<th>Type of Vaccine</th>
<th>Doses issued in the study period</th>
<th>Number of children vaccinated</th>
<th>Wastage rate (%)</th>
<th>Wastage factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lyophilized*</td>
<td>10390</td>
<td>8207</td>
<td>21.01</td>
<td>1.27</td>
</tr>
<tr>
<td>Liquid**</td>
<td>29580</td>
<td>26269</td>
<td>11.12</td>
<td>1.13</td>
</tr>
</tbody>
</table>

*BCG and Measles; **OPV, DPT, Pentavalent, Hepatitis B TT, IPV; χ² =47.35, df=1, p value =0.001

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

<table>
<thead>
<tr>
<th>Mode of administration</th>
<th>Doses issued in the study period</th>
<th>Number of children vaccinated</th>
<th>Wastage Rate (%)</th>
<th>Wastage factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection</td>
<td>26670</td>
<td>23125</td>
<td>13.29</td>
<td>1.15</td>
</tr>
<tr>
<td>Oral</td>
<td>13300</td>
<td>11351</td>
<td>14.65</td>
<td>1.17</td>
</tr>
</tbody>
</table>

All vaccines except OPV were administered via injection; χ² =1.03, df=1, p value =0.31

### DISCUSSION

In immunization, the total number of vaccines doses utilized is always higher that the number of beneficiary actually immunized and the excess number depicts Vaccine wastage. The Ministry of Health and Family Welfare Govt. of India has recommended that wastage rate of all vaccines should not be higher than 25%, wastage factor of 1.33. The World Health Organization has also projected vaccine wastage rate in order to help in calculating vaccine needs. According to WHO projected vaccine wastage rate for lyophilized vaccines is expected to be 50% wastage rate for 10-20 dose vial, and for liquid vaccines 25% wastage rate for 10-20 dose vials. 3 The present study showed that the vaccine wastage rate for OPV was higher than the limits given by Ministry of Health and Family Welfare as well by WHO.2,3

The wastage rate for 5 doses vaccine vial (Measles) was 21.68%, for 10 dose vaccine vial (BCG, DPT, HBV) was 12.14% and for 20 dose vaccine vial was 14.65% which is lower than the wastage rate obtained by Ministry of Health and Family Welfare, WHO Field based Assessment and observation done by NRHM and UNICEF. The findings were also similar with the other studies also.8,10
The study conducted by Daya P et al.\textsuperscript{10} Found high value of vaccine wastage rate and factor i.e. 46.5% and 1.86% respectively for 5 doses vial which was higher than present study and values but the vaccine wastage rate and vaccine wastage factor for 10 doses and 20 doses vial (VWR 5.3% and VWF 1.05, 1.01) was much lower than present study results. The UNICEF found negligible differences in wastage between 5 doses and 10 doses vaccines (approx 35%) whereas 20 dose vaccine wastage rate was 77%.\textsuperscript{4,5}

In the present study, the vaccine wastage rate and wastage factor for lyophilized vaccine was 21.01% and 1.27 respectively and was found higher than the liquid vaccine which was 11.121 and 1.13% respectively. Similar results that vaccine wastage was more for Lyophilized vaccine were found by UNICEF i.e. for lyophilized 50% and Liquid Vaccine 38%.\textsuperscript{4} Gupta V et al (Lyophilized-63.76%, Liquid-26.36%), Mehta S et al (Lyophilized-37.8) The wastage rate for injectable vaccine was 13.69% which was less than the oral vaccine i.e.14.65%.\textsuperscript{8,9} In the study done by Gupta V et al and Daya P et al it was just reverse but in the study done by Mehta S et al the results were similar to the present study.\textsuperscript{8,10} Similarly UNICEF study had also more wastage for oral vaccine which was 47% in comparison to injectable vaccine which was 35%.\textsuperscript{9,11} In the study done by Chinnkali P et al found negligible differences between injectable and oral vaccines (injectable 48.3%, oral 48.1%).\textsuperscript{11}

The vaccine wastage rate of BCG vaccine was 20.71% and the vaccine wastage factor was 1.26 which was lower in this study followed by Measles in which vaccine wastage rate was 21.68% and vaccine wastage factor was 1.28. 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 in India which is dissimilar to the present study.\textsuperscript{7,9,11,12}

The vaccine wastage rate for BCG was 20.71% which is much lower than the results found by UNICEF i.e.61%. Gupta V et al quoted 77.9%. Mehta et al quoted 45%, Chinnkali P et al quoted 70.9%,\textsuperscript{4,8,9,11} This might be because the vaccines as per national guidelines should be discarded after 4 hrs of reconstitution. So, if the adequate children if not coming to the site many doses have to be discarded resulted into higher wastage of the vaccine but since it is a tertiary centre the children are enough on every date so the wastage is less.

The wastage rate for OPV was 14.65 % in the present study which was found lower than the UNICEF which was 47% and in most of the other studies i.e. Gupta V et al it was 28.97%, Mehta S et al quoted 51.2%.\textsuperscript{8} Mukherjee et al quoted 14.5% which was very close to this study but results found by Praveena Daya A et al quoted 2.4% which was very much lower than this study.\textsuperscript{9,10,12}

The vaccine wastage rate Gupta V et al showed much higher rates calculated for DPT was 15.6% which was again found lower than the results calculated by UNICEF which was 27%,\textsuperscript{4,8} The results of Mehta S et al was closer to the present study but that of Daya P et al was 8.4% which was lower to the present study.\textsuperscript{9,10} The results of Chinnkali P et al was 38.6% and Mentey V et al was 29.4% which was also more in comparison to the present study.\textsuperscript{11,12}

The calculated wastage rate for Measles vaccine was 21.68 % which was highest among all the vaccine in the present study but still lower than the rate obtained by UNICEF which was 35%.\textsuperscript{4} Gupta V et al quoted 41.28%, Mehta S et al quoted 28% which was higher in comparison to the present study.\textsuperscript{8,9} Daya P A et al showed 16.5% which was lower in comparison to the present study.\textsuperscript{10} Chinnkali P et al quoted 39.9% and Mentey V et al showed much high rates.\textsuperscript{11,12}

The vaccine wastage rate for Hepatitis B was 10.56% which was still lower than the results obtained by UNICEF i.e. 33%. Praveena Daya A et al found only 5.3% of wastage for Hepatitis which was quite low i.e. almost half in comparison to the present study.\textsuperscript{5,10} The results of the study done by Gupta V et al were almost three times more i.e. 38.66% and of Mehta S et al was 21%,\textsuperscript{8,9}

The wastage for TT vaccine was only 7.09% in the present study and it was lower than the studies of UNICEF which was 34%. Gupta V et al quoted 36.81%which was almost five times higher than the present study and the Chinnkali P et al showed 62.8%.\textsuperscript{4,8,11} In the study done by Daya P A et al which quoted 4.2% which was very low in comparison to the present study.\textsuperscript{10}

**CONCLUSION**

Vaccine wastage could be expected in all the programmes and there should be an acceptable limit of wastage. This might differ from location depending on many factors like urban and rural setting, immunization coverage etc.

Some level of vaccine wastage is unavoidable. To increase the vaccination coverage children should be immunized irrespective of the wastage occurred causing wastage of rest of the doses. Higher wastage rate are acceptable to increased vaccine coverage in a low vaccine coverage setting. Vaccine wastage due to operational causes could be reduced by continued training and retraining of workers involved in immunization practices. The details of the vaccine wastage could be obtained by the actual monitoring of the vaccination session. Monitoring vaccine wastage would be useful as a programme monitoring tool to improve programme quality and to increase the efficiency of the programme.
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