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Assessment of vaccine wastage in an immunization clinic of a tertiary care hospital, Kolkata, West Bengal

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ABSTRACT

Background: Universal Immunization Programme was launched by Government of India in 1985 with the aim of immunizing all children and pregnant women across the country free of cost. However high vaccine wastage and lack of proper vaccine management could not meet the demand and increased the cost.

Methods: A descriptive record based study was conducted in the immunization clinic of KPC Medical College and Hospital. Vaccination records of all children and pregnant women attending clinic from 1st July 2018 to 30th June 2019 was retrieved from the immunization registers.

Results: Wastage rate was found to be highest for bacillus Calmette–Guérin vaccine vaccine (68.9%) and lowest for oral polio vaccine (27.7%). Wastage rate was higher for 10 dose vial vaccine compared to 5 dose vial and 20 dose vial vaccine and the differences were statistically significant (p<0.00001). The wastage rate was higher for lyophilized vaccine compared to liquid vaccine and for injectable vaccine compared to oral vaccine. These differences were also statistically significant (p<0.00001).

Conclusions: Thus regular monitoring of immunization sessions should be done to estimate the vaccine wastage in each session. Reducing wastage is expected to increase the quality and efficiency of the programme and also reduce the cost without compromising the coverage.

Keywords: Vaccine wastage rate, Bacillus Calmette-Guérin vaccine, Pentavalent, Measles and rubella virus vaccine,

INTRODUCTION

Vaccines can be considered as one of the most potent and cost effective tool for disease prevention worldwide and is a great advancement in the field of medicine as well as public health. Universal Imunization Programme is a vaccination programme launched by the Government of India in 1985. It is currently one of the key areas under National Health Mission. Under the programme, immunization services are provided to all children and pregnant women across the country free of cost. Inspite of all the efforts of increasing coverage, it has been found that out of 27 million children born in India every year, around 10 million children remain unimmunized or partially immunized. To overcome this problem, new strategies like mission Indradhanush was launched in

December 2014 with the aim of reaching more children and increasing coverage.³ However, difficulties in getting vaccines in required quantity and quality is a serious challenge to get desired outcomes. Also, high vaccine wastage and inadequate management fails to meet the vaccine demand and escalates the cost. The first National Vaccine Policy in India was released in 2011 and it was found that only 11 states have vaccination coverage more than 70%, whereas in another 13 states it was found to be 50%-70% and in the remaining eight states immunization coverage was less than 50% (The District Level Household and Facility Survey (DLHS-4)).^{4,5}

Worldwide, the vaccine wastage has been found to be more than 50%, as per WHO reports. 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.⁷

Proper knowledge on vaccine wastage as well as local and national data is required for estimation of vaccine needs and also maintenance of adequate stocks.⁸ As per the recommendation of the Ministry of Health and Family Welfare, Government of India vaccine wastage rate should not be more than 25%.⁷

Thus vaccine usage should be continuously monitored both at the immunization points using the vaccines as well as the stores involved in vaccine handling to enable authorities to take action for reducing wastage whenever and wherever necessary. Newer vaccine management strategies viz. introduction of open vial policy, use of VVMs and improved immunization practices is expected to reduce vaccine wastage.⁹

There is scarcity of studies in India corroborating with the recommendations of World Health Organization and Ministry of Health and Family Welfare, Government of India. There are very few studies on vaccine wastage rates in India. So, in context of newer vaccine management policies, the present study was undertaken in the immunization clinic of a tertiary care hospital in Kolkata, West Bengal to find the wastage rate of different vaccines used in the clinic.

METHODS

The present study is a descriptive, record based study conducted in the immunization clinic which is under direct supervision of the department of Community Medicine, KPC Medical College and Hospital. The study period was taken from 1st July 2018 to 30th June 2019 and the study population included all children and pregnant women who were vaccinated in this time period. Details regarding total number of vaccines issued and number of doses used was recorded from the immunization registers. The immunization clinic is conducted by two Public Health Nurse and one Medical Officer daily during outpatients department (OPD) hours of the hospital (9:00 A.M. to 2:00 P.M.). All vaccines viz. Bacillus Calmette-Guérin (BCG), oral polio virus (OPV), Hepatitis B, Pentavalent, inactivated polio vaccine (IPV), Measles and rubella virus (MR), Japanese encephalitis (JE) and Tetanus toxoid (TT) vaccines were given following the National Immunization Schedule as recommended by Ministry of Health and Family Welfare, Government of India.15

Multidose vaccine vials were provided for immunization. The vials used for BCG, DPT, Pentavalent, Hepatitis B, IPV, MR and TT obtained 10 doses and for JE, it was available in 5 dose vial whereas 20 dose vials were used for OPV. All the vaccines were in liquid form and can be readily administered except BCG, MR and JE which were present in freeze dried (lyophilized) forms and had to be reconstituted with appropriate diluents before use.

The vaccines were used following "open vial policy" according to which liquid vaccines can be used ,if,they have returned unopened at least 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 4 hours after opening the vial. ¹⁶

Vaccine wastage rate and wastage factor were calculated as follows:

Vaccine Wastage Rate =
$$\frac{\text{No. of doses wasted}}{\text{No. of doses issued}} \times 100$$

VVaccine Wastage Factor
$$=\frac{100}{100-\text{Vaccine Wastage Rate}}$$

The data collected were analysed using SPSS 20 and P value were used for interpretation of results.

RESULTS

During the study period, a total of 11,680 doses of vaccine were issued of which 5,880 doses were required to vaccinate all the children and pregnant mother who visited the immunization clinic in the above mentioned time period. Table 1 shows the wastage rate and wastage factor for different vaccines and it was found to be highest in case of BCG vaccine (wastage rate 68.9% and wastage factor 3.21) and lowest in OPV vaccine (wastage rate 27.7% and wastage factor 1.38).

According to the number of doses in one vaccine vial, wastage rate was 55.8% and wastage factor 2.26, in 10 dose vials (BCG, Hepatitis B, DPT, Pentavalent, IPV, MR and TT), in 5 dose vials (JE) the wastage rate and wastage factor were 42.3% and 1.73 respectively and for 20 dose vial (OPV) the wastage rate was 27.7% with wastage factor being 1.38 (Table 2). The differences between wastage and wastage factor of different vial sizes were statistically significant (10 dose vs 20 dose: p value<0.00001, 10 dose vs 5 dose: p value<0.00001, 5 dose vs 20 dose: p<0.00001).

Table 3 shows wastage rate and wastage factor according to nature of vaccine and the wastage rate and wastage factor was found to be higher in lyophilized vaccines (wastage rate 61.8% wastage factor 2.61) when compared to liquid vaccines (wastage rate 41.3% and wastage factor 1.70) and the result is statistically significant

(p<0.00001). From Table 4 it is found that the wastage rate and wastage factor is higher (wastage rate 54.7% wastage factor 2.57) for injectable vaccines and lower in

case of oral vaccine (wastage rate 27.7% and wastage factor 1.38) and the difference is statistically significant (p<0.00001).

Table 1: Wastage rate and wastage factor for different vaccines.

Name of vaccine	Doses issued during the study period	No. of children vaccinated	Wastage rate (%)	Wastage factor
BCG	2800	870	68.9	3.21
Hepatitis B	1200	696	42.0	1.72
OPV	2200	1590	27.7	1.38
IPV	780	522	33.1	1.50
Pentavalent	840	516	38.6	1.63
JE	820	450	45.1	1.82
MR	1100	480	56.3	2.28
DPT	1060	366	65.4	2.90
TT	920	390	57.6	2.35

Table 2: Wastage rate and wastage factor according to no. of doses in the vaccine vial.

No. of doses in one vaccine vial	Doses issued during the study period	No. of children vaccinated	Wastage rate (%)	Wastage factor
5 dose vial	780	450	42.3	1.73
10 dose vial	8700	3840	55.8	2.26
20 dose vial	2200	1590	27.7	1.38

Table 3: Wastage rate and wastage factor according to form of the vaccine.

Vaccine form	Doses issued during the study period	No. of children vaccinated	Wastage rate (%)	Wastage factor
Lyophilized	4720	1800	61.8	2.61
Liquid	6960	4080	41.3	1.70

Table 4: Wastage rate and wastage factor according to routes of administration.

Route of administration of vaccine	Doses issued during the study period	No. of children vaccinated	Wastage rate (%)	Wastage factor
Injection	9480	4290	54.7	2.20
Oral	2200	1590	27.7	1.38

DISCUSSION

According to the Ministry of Health and Family Welfare, Government of India, the vaccine wastage rate should not exceed 25% with a wastage factor of 1.33⁷. It has also been recommended by WHO that for lyophilized 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. The results of the present study showed a higher wastage rate for all the vaccines exceeding the limits given by Ministry of Health and Family Welfare, Government of India as well as WHO.

In the present study, the wastage rate for 5 doses, 10 doses and 20 dose vial were 42.3%, 55.8% and 27.7% respectively. The study by Gupta et al also showed similar results.¹⁷ The wastage rate of 5 dose and 10 dose

vial were similar to the study by Palanivel et al where the wastage rate was 38.6% and 51% 5 dose and 10 dose vial respectively. However the wastage rate for 20 dose vaccine was much higher in the study by Palanivel et al (48.1%). Again, the wastage rate for 10 dose and 20 dose vials in this study was much higher than the findings by Praveena et al where the wastage rate was 5.3% and 1% for 10 and 20 dose vial respectively whereas the wastage rate for 5 dose vial (46.5%) was similar to the present study.

The present study shows that vaccine wastage rate was more for lyophilized vaccine (61.8% with a wastage factor of 2.61) as compared to liquid vaccine (41.3% with wastage factor 1.70). Similar observations were found by UNICEF where vaccine wastage was found to be higher in case of lyophilized vaccine than liquid vaccine (lyophilized 50%, liquid 38%), study by Shreyash et al

(lyophilized 37.8%, liquid 20.16%) Praveena et al (lyophilized 28.2%, liquid 3.4%) and Gupta et al (Lyophilized-63.76%, Liquid-26.36%). 10-12.17

In the present study, wastage rate and wastage factor was more for injectable vaccines (wastage rate 54.7%, wastage factor 2.20) than oral vaccines (wastage rate 27.7%, wastage factor 1.38). The studies by Praveena et al and Gupta et al showed similar results.¹⁷

The vaccine wastage was highest for BCG vaccine with a wastage rate of 68.9% and wastage factor 3.21. Similar results were found by Palanivel et al where the wastage rate for BCG was 70.9%. ¹⁴ The highest wastage rate for BCG was also found by UNICEF (61%), Gupta et al (77.9%) and Mehta et al (45%). ^{10,11,17} A single dose of BCG vaccine is given at birth or within one year of birth. BCG, being a lyophilized vaccine has to be reconstituted and used within 4 hours. If there are fewer deliveries or lesser number of children attending the immunization clinic, the remaining doses in the vial has to be discarded after 4 hours which may be a cause of high wastage rate of BCG vaccine.

The wastage rate of OPV was 27.7% with a wastage factor of 1.38 which was lowest among all vaccines given in the clinic. In similar studies by Gupta et al and Sharma et al the wastage rate of OPV was found to be 28.97% and 29.45% respectively. ^{17,19} However studies by UNICEF, Palanivel et al and Mehta et al found much higher wastage rates for OPV which were 47%, 48.1% and 51.2% respectively whereas studies by Tiwari et al and Praveena et al showed much lower wastage rates of 14.65% and 2.4% respectively. ^{10-12,14,20}

The wastage rate for MR vaccine 56.3% in the present study. Since MR vaccine has been recently introduced in the National Immunization Schedule, limited studies are found regarding its wastage rate. However Measles is a component of MR vaccine and wastage rate of Measles vaccine was found to be much lower in other studies viz. 35% by UNICEF, 41.28% by Gupta et al, 28% by Mehta et al, 16.5% by Praveena et al, 39.9% by Palanivel et al. 10-12,14,17 Since MR is a lyophilized vaccine and the vaccine has to be used within 4 hours after reconstitution, so lesser number of children in a session may result in such high wastage of MR vaccine.

The wastage rate calculated for DPT vaccine was 65.4% in the present study which is higher than the studies by UNICEF (27%), Praveena et al (8.4%), Palanivel et al (38.6%), Mentey et al (29.4%), Gupta et al (41.28%) and Mukherjee et al (38.7%). ^{10-13,17,18} DPT is given as booster doses, first one at 16-24 months age and second one at five years. The high wastage rate of DPT can be attributed to the fact that lesser number of children are attending the clinic for booster doses after completing primary immunization.

For TT, the vaccine wastage rate was 57.6% in the present study. The study by Palanivel et al also showed comparable results where the wastage rate for TT vaccine was slightly higher 62.8%. However it was found to be much lower in studies by Gupta et al (36.81%), Mukherjee et al (48%), Praveena et al (4.2%) and UNICEF (34%). ^{10,12,13,17} TT is given to children at 10 years and 16 years as well as pregnant women. The higher wastage rate of TT may be due to the fact that less number of children of that age and pregnant women are attending the clinic.

The wastage rate of hepatitis B was found out to be 42% in the present study. The study by Gupta et al shows a slightly lower wastage rate for Hepatitis B vaccine which was 38.66%.¹⁷ The wastage rate was lower in other studies viz. 34% by UNICEF, 21% by Mehta et al, 5.3% by Praveena et al and 10.56% by Tiwari et al.¹⁰⁻¹³ Hepatitis B vaccine is given within 24 hours of birth to prevent perinatal transmission.Lesser number of deliveries in the hospital is probably the cause of such high wastage rate of Hepatitis B vaccine.

Pentavalent, fractional IPV and JE being newly introduced vaccine, limited data are available regarding their wastage rate and wastage factor. In this study the wastage rate of Pentavalent vaccine and fractional IPV were 33.6% and 38.1% respectively which were higher than the proposed limit of 25% as recommended by Government of India as well as WHO for liquid vaccines. This higher wastage rate can be attributed to lesser number of children in the immunization sessions. The wastage rate for JE was found to be 45.1% which was higher than the limits recommended by Government of India but lower than WHO limits for lyophilized vaccine which is 50%. The lower wastage rate of JE can be attributed to the 5 dose vials used for JE vaccine.

CONCLUSION

Vaccine wastage is inevitable in any vaccination programme, if the wastage is within acceptable limits. Some amount of wastage can be allowed to increase vaccine coverage such as opening of a multidose vial for a small number of children so that no child misses a single opportunity to get immunized. This helps to increase coverage in low coverage areas. However, vaccine wastage due to freezing or expiry or cold chain failure is not acceptable. The operational causes of vaccine wastage can be reduced by training of the health workers involved in vaccine handling and administration of vaccines. Thus vaccine wastage should be estimated in each immunization session and can be used as an effective tool to increase programme quality as well as efficiency.

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Institutional Ethics Committee

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