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Vaccine wastage assessment in a primary care setting in urban India

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Abstract:

Research Question: What is the vaccine wastage in a primary care setting in urban India?

Methods: Record based descriptive study carried out in an Immunisation clinic in an urban resettlement colony in South Delhi. All children who got vaccinated in an immunisation clinic between 1st April 2009 and 31st March 2010 were included in the study. Number of vaccine vials procured and issued for immunization sessions was obtained from a stock register. Vaccine wastage rates and Wastage factor were calculated.

Results: A total of 6464 vaccinations (BCG, DPT, OPV, Measles, MMR, DT and TT) had been given to children. Vaccine wastage factor or Wastage multiplication factor for vaccines of 10 dose preparations (BCG, DPT, DT and TT) was 2.0, highest for BCG (3.4) and lowest for DPT (1.6). For vaccines of 5 dose preparations (Measles and MMR), the wastage factor was 1.6.

Conclusions: Vaccine wastage rates are higher than expected in urban primary health care setting despite minimal or negligible loss due to cold chain failure or expiry.

Keywords Vaccine wastage, wastage factor, immunisation

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Introduction

Wastage is defined as loss by use, decay, erosion or leakage or through wastefulness. The World Health Organization reports over 50% vaccine wastage around the world [1]. Despite the availability of many tools for reducing such wastage, high wastage rates are still occurring in countries. Vaccine wastage can be classified as occurring "in unopened vials" and "in opened vials". Expiry, VVM indication, heat exposure, freezing, breakage, missing inventory and theft are the forms of vaccine wastage affecting unopened vials. Vaccine wastage in opened vials may also occur because doses remaining in an opened vial at the end of a session are discarded, the number of doses drawn from a vial is not the same as that indicated on the label, reconstitution practices are poor, opened vials are submerged in water, and contamination is suspected.

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. It is therefore crucial that all immunization points using vaccines and that the stores handling them monitor their use continuously. Such monitoring can provide programme managers with good guidance on the introduction of corrective actions to reduce wastage whenever necessary. With the introduction of new vaccine management policies such as the application of multidose vial policy (MDVP), the effective use of vaccine vial monitors (VVMs), and improved immunization strategies and practices, vaccine wastage is expected to decrease. This article attempts to calculate the vaccine wastage rates in an urban setting in the current era of new vaccine management policies.

Materials and methods

Study Design: Record based descriptive study. **Study Setting:** The study was carried out in an Immunization clinic in an urban resettlement colony in South Delhi which is the field practice area of Centre for Community Medicine, All India Institute of Medical Sciences since 2002. The field practice area consists of six blocks of 21327 population as per census conducted in year 2009. There are 4583 families residing in these six blocks, majority of them were migrated from neighbouring states. Under the Urban Health Programme (UHP) of Centre for Community Medicine, there is a dedicated team of field workers consisting of four Multipurpose Health workers (2 male and 2 female) and one Public Health Nurse (PHN) who conduct immunization sessions at a fixed site on fixed days twice in a week (Thursdays and Saturdays) through a mobile clinic. Besides the children from the field practice area, immunization services are also availed by children outside the area. National Immunization Schedule recommended by Ministry of health and family welfare was followed [ii]. BCG was offered until one year of age. DPT and DT were given to children up to 2 years and 5 years respectively. If the child had not received measles vaccine at 9-12 months of age, it was given up to 5 years of age. BCG, DPT, DT and TT vaccines vials used were 10 dose preparations, Measles and MMR vaccine vials were 5 dose preparations and OPV vials were 20 dose preparations. Immunization sessions are supervised by residents of Community Medicine. A record of the number of vaccine vials used for vaccination during each session and number of children vaccinated was entered in the Immunization Register. Immunization coverage in the field practice area was above 95% for all primary vaccines [iii]. **Study population & Study period:** All children who got vaccinated at the immunization clinic between 1st April 2009 and 31st March 2010 were included in the study. This also included children outside the field practice area. **Data retrieval and analysis:** Number of vaccine vials procured and issued for immunization sessions during the study period was obtained from a stock register maintained by a public health nurse. The distance from the institution (storage level) to the immunization clinic (vaccine delivery level) is about 15 kms and the travel time taken from the vaccine storage site to the immunization site is about half an hour. Hence wastage of vaccine vials due to cold chain failure during transport was negligent or none. None of the vaccine vials was discarded because of expiry, VVM indication, heat exposure, freezing, or breakage. Hence vaccine wastage analysis was done with number of vials used at the immunization clinic. Vaccine Wastage Factor was calculated by using the formula $100 / (100 - \text{vaccine wastage rate})$ [iv]. Number of vials used during immunization sessions and number of children vaccinated were retrieved from the immunization registers for the period of 1st April 2009 and 31st March 2010. Data were entered into Microsoft Excel spread sheet and descriptive analysis was done. Chi square test was applied to find the

difference between wastage rates (proportions) for different vial size and p values were calculated at 95% confidence level.

Results

A total of 97 immunization sessions were conducted during the study period. 1216 vaccine vials had been used in total. A total of 6464 vaccinations (BCG, DPT, OPV, Measles, MMR, DT and TT) had been given to children. 2327(36%) vaccinations were given to children outside field practice area. Vaccine wastage factor or Wastage multiplication factor for vaccines of 10 dose preparations (BCG, DPT, DT and TT) was 2.0. For vaccines of five dose preparations (Measles and MMR), the wastage factor was 1.6. Among individual vaccines, wastage factor is highest for BCG (3.4) and lowest for DPT and MMR (1.6) (Table-1).

Table-1: Wastage rates and Wastage Factor for different vaccines (2009)

Vaccine	No of vials issued for vaccination sessions (Doses)	No of children vaccinated	Wastage rate (%)	Wastage Factor
BCG	78 (780)	227	70.9	3.4
OPV	212(4240)	2201	48.1	1.9
DPT	315(3150)	1933	38.6	1.6
Measles	171 (855)	514	39.9	1.7
MMR	186 (930)	581	37.5	1.6
TT	140(1400)	521	62.8	2.7
DT	114(1140)	487	57.3	2.3

Liquid and Lyophilized vaccines: The vaccine vials are of different sizes and come in liquid and lyophilized form. Four vaccines, namely, OPV, DPT, TT and DT are supplied in liquid form and three vaccines, BCG, Measles and MMR are freeze dried or lyophilized vaccines. Among these, there was negligible difference in wastage between liquid and lyophilized forms of vaccine vials (both averaging approximately 48%) (Table2).

Vial size: The vaccines are supplied in three different sizes of vials; five doses (Measles and MMR), 10 doses (BCG, DPT, TT and DT) and 20 doses (OPV) per vial. Among these, there was difference of 12.4% in wastage between five doses and 10 doses vials whereas OPV in 20 dose vial had the wastage rate of 48.1%. Differences in wastage rates for different vial size were statistically significant (5 dose vs 10 dose: $\chi^2=85.6$, p

value<0.0001; 10 dose vs 20 dose: $\chi^2=8.7$, p value=0.003; 5 dose vs 20 dose: $\chi^2= 45.3$, p value<0.001).

Table-2: Wastage across type/form of vaccines

Type/Form	Wastage rate (%)	Wastage factor
Type of vaccine		
Liquid	48.2	1.9
Lyophilized	48.4	1.9
Vial Size		
5 dose	38.6	1.6
10 dose	51.0	2.0
20 dose	48.1	1.9
Mode of Administration		
Oral	48.1	1.9
Injectable	48.3	1.9

Mode of Administration: All the vaccines except for OPV are administered through injection. The average wastage rate of injectable vaccine is 48.3% and oral (OPV) is 48.1%. There is negligible difference in wastage between the two modes of administration.

Discussion

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) [v]. The World Health Organization has also projected vaccine wastage rate in order to help in calculating vaccine needs [vi]. 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. The present study showed that the vaccine wastage for all liquid vaccines was higher than the limits given by the Ministry of Health and Family Welfare, Government of India, as well as by WHO. As far as lyophilized vaccines were concerned, though the wastage rate exceeded the limit set by the national government, Measles and MMR were within the projected wastage rate by the WHO, except for BCG. One reason for high wastage in this centre particularly could be that, as a rule, all liquid vaccines vials (DPT, DT,TT) which have been taken out for immunization outreach sessions three times are discarded in order to safeguard the potency of the vaccines, especially during hot summer months; and as per recommendation for lyophilized vaccines (BCG, Measles, MMR), all vials are discarded after every immunization session.

No comprehensive study has been done in India to validate the wastage rate recommended by WHO and Ministry of Health and Family Welfare. Very few studies in India have studied the wastage rate of OPV but not of other vaccines [vii, viii, ix]. The study by Mukherjee et al to assess the wastage factor of oral polio vaccine (OPV) in the Pulse Polio Immunization (PPI) programme of the Government of India at approximately 31,000 immunization booths all over the country estimated that wastage at the point of administration of OPV was 14.5% with a wastage factor of 1.17. Though the wastage rates are less compared with the present study, this study cannot be compared with the present study as Pulse Polio program involves mass mobilization and it is not a routine immunization program. Studies by Jain et al and Samant et al were assessing the wastage due to cold chain failure and didn't attempt to estimate the wastage rates of OPV.

Usually, the wastage rates are low for liquid vaccines in comparison of lyophilized ones. In our study, wastage rates of liquid vaccines were almost similar to lyophilized ones. The reason behind this can be understood by comparing the number of immunization sessions (n=97) and total number of vials of liquid and lyophilized vaccines opened. Though the number of liquid vaccine vials (DT and TT are 10 dose vials) compared with lyophilized vaccines (Measles and MMR are 5 dose vials) is less, the number of doses left and wasted would be more in liquid vaccines which are 10 dose vials. Though BCG is a lyophilized vaccine and single dose like measles and MMR, higher wastage rate for BCG would be because of vial size (10 dose vial), less number of beneficiaries due to BCG vaccination at birth for institutional deliveries and the narrower age range of eligible children.

Among the vaccines, BCG has got the highest wastage rate (70.9%). Similar high wastage rates are documented in Bangladesh (84.9%) [x]. The reason for high BCG wastage rates in this study is due to small number of eligible children available for the immunization. This may be due to the higher proportion of institutional deliveries in urban areas, frequent immunization sessions (weekly twice in study area) and higher number of service providers in urban setting like private practitioners, non-governmental organizations and urban health centres/posts of Delhi government.

Wastage rates for DPT/OPV are less compared to BCG. The study done in Bangladesh also reported lower wastage rates for DPT (44%) compared to BCG. This may be due to more number of doses of DPT/ OPV (3 or 4 doses of DPT/OPV vs single dose of BCG) required and hence number eligible children would be available per immunization session. This doesn't hold true for measles and MMR vaccines which have lower wastage rates which is not explainable.

India has one of the largest Universal Immunization Programs in the world. The program budgets more than US\$ 500 million every year for

immunizing children against vaccine preventable diseases, including the polio eradication program [xi]. Deficiencies in vaccine management and high wastage increase vaccine demand and inflate overall program cost. Lower demand for vaccine favors the way for fewer dose preparations. The cost of 10 dose Measles vial is 1.40\$ ((\$0.14/dose) compared to 0.40\$ (\$0.40/dose) of single dose vial [xii]. The cost of fewer dose preparations is higher as vaccine filling in vials is expensive, but cost to the programme may be less even if some vaccine remaining in multi-dose vials must be thrown away.

Vaccine wastage can be expected in all programmes and there should be acceptable limit of wastage. This might differ from location to location depending on many factors like urban or rural setting, immunization coverage etc. The questions arise as to whether the wastage is preventable and, if so, how to prevent it. It is also important to know the type of vaccine wastage. A high wastage rate attributable to opening a multidose vial for a small session size in order to avoid missed opportunities is more acceptable than wastage attributable to freezing or expiry.

Higher wastage rates are acceptable to increase vaccine coverage in a low vaccine coverage setting [xiii]. In this study vaccine wastage due to cold chain failure or expiry is zero and the immunization coverage is also high which stresses the need to minimize the wastage.

In this study vaccine wastage due to cold chain failure or expiry is zero and the immunization coverage is also high which stresses the need to minimize the wastage. Unlike rural areas in India, where there are grass root level health workers for every 1000 population, (known as Accredited Social Health Activists and Anganwadi workers) who help in identifying the unimmunized and mobilizing the eligible children, in urban areas there is a shortage of grass root level workers. Mobilizing the eligible children with the help of community mobilizers and organizing the immunization sessions in collaboration with government, private clinics in the locality will help to reduce the wastage.

The authors recommend that 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.

Conclusion

Vaccine wastage rates are higher than expected in urban setting despite minimal or negligible loss due to cold chain failure or expiry. 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. Monitoring vaccine wastage is useful as a programme monitoring tool to improve programme quality and increase the efficiency of the programme.

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