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"ASSESSMENT OF VACCINE WASTAGE IN PRIMARY HEALTH CARE SETTINGS OF SOUTH DELHI"

Community Medicine

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ABSTRACT

Background: Universal Immunization Program (UIP) of India significantly made achievements in preventing and controlling the Vaccine Preventable Diseases (VPDs). However, despite the concerted efforts of the government and other health agencies, the full immunization coverage is only 65.3% (RSOC 2013-14). Securing adequate quality and quantity of vaccines in terms of vaccine management and reducing vaccine wastage rate are one of the main concerns of the programme.

Methodology: A record based descriptive study, was carried out in the immunization clinics of the health centres (UHTC & RHTC) under the dept. of Community Medicine, Hamdard Institute of Medical Sciences and Research (HIMSR), Jamia Hamdard, New Delhi. Immunization clinics are held twice a week, on Wednesdays and Fridays. All the children (up to 16 years of age) who were vaccinated in the immunization clinics, between 1st July'2016 to 30th June'2017 were included in the study. Information regarding the number of vaccine vials procured and issued for immunization sessions during the study period was obtained from the Stock Register, Vaccinator's Logistic Dairy & Immunization Register.

Results: Out of 8410 doses of vaccines which were issued 6161 numbers of children were vaccinated. The wastage rate was highest for BCG (79.39.50%) and lowest for TT vaccine (8.53%). It has also been observed that in case of live vaccines; BCG (supplied in 10 dose vial preparation) has the highest WR (79.39%), compared to Measles and MMR (35.97%) which are available in 5 dose vial preparation. Again for vaccine vials where open vial policy is applicable, WR for 10 dose vial preparations is much less (12.74%) than the 20 dose vial (21.74%) preparation e.g. bOPV.

Conclusion: The overall vaccine wastage was found to be 26.74%. The wastage of lyophilized vaccines, viz. BCG, Measles & MMR is more (54.84%) and that of other vaccines like IPV, Pentavalent, TT, DPT (12.74%). The vaccine vial size, session size play a significant role in minimizing the wastage of vaccines.

KEYWORDS

Immunization, Vaccine Wastage, Wastage

INTRODUCTION:

Immunization is one of the most cost effective methods for preventing childhood diseases. As per WHO, immunizations prevent 2-3 million deaths a year, and an additional 1.5 million lives could be saved by expanding global immunizations. India has one of the largest UIP in the world in terms of quantities of vaccines used, number of beneficiaries (approximately 27 million infants and 30 million pregnant women) covered, geographical spread (36 States & Union Territories) and manpower involved. India spends approximately 20,000 million INR every year in immunization program (including pulse polio program) to immunize children against vaccine preventable diseases. [1].However, despite the concerted efforts of the government and other health agencies, still around 7.4 million children remain unimmunized. [3] According to Rapid Survey of Children (RSOC 2013-14), the full immunization coverage is 65.3%. [2] Therefore a large proportion of vulnerable infants and children in India remain unimmunized or partially immunized. However, to increase the immunization coverage, Government of India has introduced newer strategies like "Mission Indradhanush" which was launched in December, 2014, to reach more children with quality vaccines. These efforts are challenged by the problems of securing adequate quality and quantity of vaccines for the program.

The vaccine wastage is an important factor in forecasting vaccine requirements and while placing vaccine orders. India being a developing economy needs to reduce avoidable vaccine wastage and wasteful budgetary requirements. An assessment of vaccine wastage in India, conducted in 2009 revealed that highest vaccine wastage occurs at service delivery level (27% for DPT and 61% for BCG at outreach session site) [4] The World Health Organization reports more than 50% vaccine wastage around the world [5]. 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. In addition to this in order to minimize wastage, Government of India has also introduced open vial policy (2013) which allows reuse of partially used multi dose vials of applicable vaccines under UIP in subsequent session (both fixed and outreach) up to four weeks (28 days) subject to meeting certain conditions and thus reducing vaccine wastage. [6]. Despite the availability of many tools for reducing such wastage, high wastage rates are still occurring in the country 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.

This study attempts to provide an estimation of the vaccine wastage rates, type and the reasons for vaccine wastage in the health centres of a medical college in Delhi in the current era of new vaccine management policies. The findings of the study will also help in recommending measures to reduce wastage at service delivery levels

METHODS & MATERIALS:

Study Design: Record based descriptive study.

Study Setting: The study was carried out in the immunization clinics of the health centres- Urban Health Training Centre (UHTC) and Rural Health Training Centre (RHTC) under the dept. of Community Medicine, Hamdard Institute of Medical Sciences and Research (HIMSR), Jamia Hamdard, New Delhi. The Urban Health Training Centre (UHTC) is located in Pul Prahladpur and the Rural Health training Centre (RHTC) is located in Madanpur Khader, which are the field practice areas of Community Medicine department of HIMSR. In both the centres immunization clinic is held twice a week, on Wednesdays and Fridays. On the session days, vaccine vials are

supplied to UHTC from the cold chain point located in the Community Medicine department of HIMSR. The vaccines vials for RHTC are stored in the ILR located in RHTC itself. National Immunization Schedule recommended by Ministry of Health and Family Welfare, Government of India was followed in both the centres and the vaccines are supplied free of cost by the Department of Health, Government of Delhi. The staff involved in the immunization was given training before the starting the immunization programme in the health centre and is also kept updated with the latest changes in the programme through departmental or district level training programmes. All the immunization sessions in the health centres are supervised by the faculty members of Community Medicine.

Mention to be made here that, the OPV which is being used here is the bOPV, as there had been switch of tOPV to bOPV in April'2016. Also one dose of IPV has been introduced along with 3rd dose of OPV. BCG, Pentavalent, IPV, DPT, Hepatitis B and TT vaccines vials used are 10 dose preparations, Measles and MMR vaccine vials are 5 dose preparations and OPV vials are 20 dose preparations. A record of the number of vaccine vials used for vaccination during each session and number of children vaccinated was entered in the Vaccinator's Logistic Dairy &Immunization Register respectively.

Study population &Study period:
All the children (up to 16 years of age) whose vaccination records were maintained in the immunization clinics of RHTC, Madanpur Khader & UHTC, Pul Prahladpur, for the period from 1st July'2016 to 30th June 2017 were included in the study.

Data retrieval and analysis:
Number of vaccine vials received and issued for immunization sessions during the study period was obtained from Stock Registers, Vaccinator's Logistic Dairies& Immunization Registers maintained by the public health nurse. The distance from the institution (cold chain point) to the immunization clinic (UHTC) is about 7 kms and the travel time is less than half an hour.

Vaccine use is defined as the proportion of the vaccine supply that is actually administered to a child or mother. ***Vaccine wastage*** is the proportion of vaccine that is supplied but never administered. [6]

Vaccine wastage is calculated as follows: [7]

$$\text{Vaccine Wastage Rate (VWR)} = \frac{\text{doses supplied} - \text{doses administered}}{\text{doses supplied}} \times 100$$

- Vaccine wastage factor was calculated by using the formula: = [100 / (100-vaccine wastage rate)].

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.

RESULT:
During the study period, a total of 116 immunizations sessions were held. Average size of immunization sessions consisted of 53 children per session. All the vaccines under National Immunization Schedule (NIS), viz. BCG, bOPV, Hep B, DPT, Pentavalent, TT, IPV, Measles & MMR were taken into account. A total of 8410 doses were issued and 6161 numbers of children were vaccinated (Table: 1) A total of 848 vaccine vials had been used.

Vaccine wastage can primarily be divided into two categories of: (1) wastage in unopened vials; (2) wastage in opened vials. It is useful to know what type of wastage is more prevalent in immunization settings to better plan corrective action.

In the present study the wastage of unopened vaccine vials due to cold chain failure during transport was negligent or none. None of the vaccine vials was discarded because of expiry, heat exposure (indicated by VVM going to unusable stage), freezing, or breakage. None of the unopened vials were discarded after return from outreach session . During the period of study there no incidence of missing inventory or theft. Hence vaccine wastage analysis was done with number of vials used at the immunization clinic.
The wastage rate and wastage factor for different vaccines are provided in Table No.1. The overall vaccine wastage is 26.74%. Among individual vaccines, wastage factor is highest for BCG (4.85) and lowest for TT (1.09).

Table 1: Wastage Rate and Wastage Factor (WF) for different vaccines

Sl. No.	Name of the vaccines	Total doses issued for vaccination	Total No. of Children Vaccinated	Wastage Rate (WR)	Wastage Factor (WF)
1	BCG	990	204	79.39%	4.85
2	bOPV	2424	1897	21.74%	1.28
3	Measles	1000	693	30.70%	1.44
4	MMR	290	133	54.14%	2.18
5	IPV	465	419	9.89%	1.11
6	Pentavalent	1632	1470	9.93%	1.11
7	DPT	677	571	15.66%	1.19
8	TT	821	751	8.53%	1.09
9	Hepatitis B	111	23	79.28%	4.83
	All Vaccines	8410	6161	26.74%	1.37

Table: 2 Wastage Rate and Wastage Factor (WF) for lyophilized and liquid vaccines

Sl. No.	Name of the vaccines	Total doses issued for vaccination	Total No. of Children Vaccinated	Wastage Rate (WR)	Wastage Factor (WF)	Remarks
1	Lyophilized	2280	1030	54.82%	2.21	BCG, Measles, MMR
2	Liquid	6130	5131	16.30%	1.19	Rest All

Vial Size:
The vaccines are supplied in three different sizes of vials, viz. 5 dose vial (Measles, MMR), 10 dose vials (Penta, DPT, TT, IPV, Hep B, & BCG) and 20 dose vial (bOPV).

Among the lyophilized vaccines, WR is more in the 10 dose vial (79.39%) than that of 5 dose vial which is 35.97% (Table 3a). The difference is statistically significant (χ^2=426.5, p <0.0000001).

Table 3 (a): Wastage Rate and Wastage Factor (WF) in relation to vial size in lyophilized vaccines

Sl. No.	Name of the vaccines	Total doses issued for vaccination	No. of Children Vaccinated	Wastage Rate (WR)	Wastage Factor (WF)	Remarks
1	BCG	990	204	79.39%	4.85	10 dose vial
2	Measles & MMR	1290	826	35.97%	1.56	5 dose vial

Among the liquid vaccines, WR is more in the 20 dose vial (21.74%) than that of 10 dose vial which is 12.74%. The difference is statistically significant (χ^2=7.62, p <0.0002).

Table 3 (b): Wastage Rate and Wastage Factor (WF) in relation to vial size in liquid vaccines

Sl. No.	Name of the vaccines	Total doses issued for vaccination	No. of Children Vaccinated	Wastage Rate (WR)	Wastage Factor (WF)	Remarks
1	bOPV	2424	1897	21.74%	1.28	20 dose vial
2	DPT, TT, IPV, Hep B, Penta	3706	3234	12.74%	1.15	10 dose vial

Lyophilized & Liquid Vaccines:
Usually, the wastage rates are low for liquid vaccines in comparison of lyophilized ones. Our study also reveals that WR is higher among the lyophilized vaccines (54.82%) than the liquid vaccines (16.30%). The difference is statistically significant ($\chi 2=44.35$, $p<0.0000001$).

Mode of Administration:
All the vaccines except for bOPV, are administered through injection. The average wastage rate of injectable vaccine is found to be 12.56% and oral (bOPV) is 21.74%., with WF being 1.28 & 1.14 respectively. (Table 4) The difference is statistically significant ($\chi 2=43.48$, $p<0.000001$).

Table 4: Wastage Rate and Wastage Factor (WF) for modes of administration

Sl. No.	Name of the vaccines	Total doses issued for vaccination	No. of Children Vaccinated	Wastage Rate (WR)	Wastage Factor (WF)
1	Oral	2424	1897	21.74%	1.28
2	Injectable	5986	4264	12.56%	1.14

Session Size:
Wastage of vaccines has a direct relationship with session size (number of beneficiaries per session). (Table 5). In this study, a total of 116 immunization sessions were conducted in one year. Average session size consisted of 53 children per session. Taking BCG as an example, average 2 children were immunized per session, leading to wastage of remaining 8 doses per session. It is similar with other vaccines like OPV, Measles, MMR etc.

Table 4: Wastage Rate and Wastage Factor (WF) for modes of administration

Sl. No.	Name of the vaccines	Total No. of Children Immunized	Wastage Rate (WR)	No. of children Immunized per session
1	BCG	204	79.39%	2
2	OPV	1897	21.74%	16
3	Measles	693	30.70%	6
4	MMR	133	54.14%	1
5	IPV	419	9.89%	4
6	Pentavalent	1470	9.93%	13
7	DPT	571	15.66%	5
8	TT	751	8.53%	6
9	Hepatitis B	23	79.28%	1
	All Vaccines	6161	26.74%	53

Immunization Practices: None of the vials were discarded with remaining doses. Open Vial Policy is being followed strictly by both the centres. Reconstitution of vaccine was being done with the recommended diluents and as per guidelines for lyophilized vaccines all vials are discarded after 4 hours of reconstitution. There was no incidence of adverse event following immunization or suspected contamination during the study period. Recommended vaccine administration practices were being followed in both the health centres.

DISCUSSION:

Many factors contribute to vaccine wastage, ranging from the vaccine to the vaccinator. Factors affecting vaccine wastage may be many, viz. damage by heat/freezing, and expiration before usage, physical damage, incomplete use of the nominal number of doses in multi-dose vials, dead space in syringes etc.

As per the guidelines of the Ministry of Health and Family Welfare, Government of India, the allowable wastage is 10% for Hepatitis B, Pentavalent, DPT, TT, IPV and OPV; 25% for MCV, JE and RVV and 50% for BCG [16].

The present study showed that the vaccine wastage for all vaccines is 26.74% and that for BCG is 79.39%, which is higher than the limits provided by GOI. The wastage for all vaccines is also higher than the national average, which can be due to high wastage of lyophilized vaccines, getting reflected in all vaccines. The findings are similar to the studies conducted by Centre of Community medicine, AIIMS (2012) [8], one study conducted in Bangladesh in 2009[9], & Gupta.V et al in 2015 [10]. The reason for high BCG wastage can be attributed to fewer beneficiaries during the session & vial has to open for even one child.

The study revealed that the wastage of lyophilized vaccines is more (54.82%) than that of liquid vaccines (16.30%), which is similar to the findings of Gupta.V et al in 2015 [10] & Mehta. S et al 2013[11]. The reason can be due the fact that lyophilized vaccines are to be discarded after 4 hours of reconstitution.

One more important finding has been observed in this study is that the bigger the vial size more is the vaccine wastage. It has been found that among the lyophilized vaccines, BCG has more wastage (79.39%) than that of Measles & MMR (35.97%). It is to be mentioned here that BCG comes as 10 doses/vial and Measles and MMR comes in 5-doses/vial. It is similar even with the liquid vaccines. As OPV which comes in 20 doses/vial, wastage is more (21.74%) than other liquid vaccines like DPT, Penta, IPV, Hep B, TT (12.74%) which comes in 10 doses/per. These findings are similar to that of Sharma.G et al (2016) [12]. Whereas Gupta.V et al in 2015 [10], observed that wastage rate (40%) was nearly similar in both 5 doses and 10 doses vaccine vials, which was higher than wastage rate (29%) of 20 doses vaccine vial. Moreover, it has to be mentioned that in our Urban Health Centre, the beneficiary load is low, which can further contribute towards more wastage. Wastage rates are dependent on formulation, presentation and are inversely proportional to session size [13]

The study has also highlighted that the vaccine wastage rate of injectable vaccine is 12.56% and that of oral (OPV) is 20.17%., which is similar to the findings of Gupta.V et al. [10], whereas others, Palanivel C et al[8] & Mehta S et al [11] found negligible difference. The higher wastage rate for oral (bOPV) may be due to the fact that there might be wastage of bOPV at time of administering of vaccine e.g. administering more drops than that are required to be given per dose due to faulty vaccinating technique of vaccinators, child moving the head at the time of ingestion of vaccine etc

However, our study also revealed that in case of individual vaccine like IPV, Pentavalent, TT, DPT the wastage is far below the national average. This is a positive finding which can be due to the application of Open Vial Policy for these vaccines as well as the efficiency of the service provider. These findings are similar with Gupta. V et al [10] where they also recorded less wastage of Pentavalent vaccine (7.42%). However the wastage of Hep B vaccine is found to be high (51.61%). This is due to very few beneficiaries for Hep B due to introduction of Pentavalent vaccine & no birth dose is also given.

In this study, vaccine wastage at the storage level is nil. Also wastage for other reasons like expiry date, freezing of vaccines, breakage, cold chain failure etc. were nil.

Wastage of vaccine is expected in the immunization programme. In order to avoid missed opportunities, it is mandated to open a vaccine vial for even for a single beneficiary and this is applicable for lyophilized, in spite of the fact that 9 doses would be wasted. This might differ for many reasons, depending on many factors like urban or rural setting, immunization coverage, session size, training of service provider etc. However, it should be taken into consideration that vaccine wastage due to preventable reasons should be taken care of as because Government of India (GoI) spends huge amounts of money to purchase vaccines for the program. In 2013-14, 618.38 crores and in 2014-15, 614.84 crores were spent by GoI to purchase vaccines from different national and international vaccine manufacturers [15].

Therefore, regular monitoring of the vaccine wastage is important is minimizing the wastage. The analysis of immunization coverage and vaccine wastage rates over a period of time allows health workers and immunization managers to identify areas that need improvement [14]

CONCLUSION & RECOMMENDATIONS:

The present study revealed that the overall vaccine wastage is 26.74%. As per the guidelines of the Ministry of Health and Family Welfare, Government of India, the allowable wastage is 10% for Hepatitis B, Pentavalent, DPT, TT, IPV and OPV; 25% for MCV, JE and RVV and 50% for BCG [16]. However, the wastage rate of lyophilized vaccines, viz. BCG, Measles & MMR is higher (54.84%) than that of other vaccines like IPV, Pentavalent, TT, DPT (12.74%). In terms of individual antigens, the wastage rates of only IPV, Pentavalent and TT

are within the allowable wastage limits.

Further it has been revealed that the size of the vaccine vials is directly proportional to the vaccine wastage. The wastage rate is more in the 20 dose vial (21.74%) than that of 10 dose vial which is 12.74%. The study also highlighted that the immunization session size is inversely proportional to the vaccine wastage. The study also highlighted that the wastage of oral vaccines (bOPV) is more (21.74%) than that of injectable vaccines (12.56%). However mention must be made that there was no wastage of vaccines because of cold chain failure, expiry dates, and breakage of vaccine vials or mismanagement of open vials.

Therefore, to further reduce vaccine wastage, it is recommended that, there should be regular training of the vaccinators, multi dose open vial policy should be strictly implemented and manufacturers should be encouraged to cut down vial size. Also measures to be taken to mobilize more beneficiaries to increase the size of session site. In light of the recent announcement by Government of India to introduce new costlier vaccines in UIP namely Rotavirus vaccine (RVV), Pneumococcal conjugate vaccine (PCV) and Measles Rubella (MR) vaccine, regular monitoring and prevention of vaccine wastage assumes greater importance in minimizing vaccine wastage.

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