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Assessment of Vaccine Wastage during a Pulse Polio Immunization Programme in India

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ABSTRACT

A study to assess the wastage factor of oral polio vaccine (OPV) in the Pulse Polio Immunization (PPI) programme of the Government of India was undertaken by the Indian Council of Medical Research (ICMR) at approximately 31,000 immunization booths all over the country. The study was conducted through the network of 31 Human Reproduction Research Centres (HRRCs) and other ICMR institutes. Wastage at the point of administration of OPV was estimated to be 14.5% with a wastage factor of 1.17 which is well below the assumed wastage of 33% and the corresponding wastage factor of 1.5 in the PPI programme. The wastage and wastage factor as estimated in the present study were also less than the wastage of 25% and the wastage factor of 1.33 recommended by the World Health Organization. Minimum wastage (6.3%) at Kanchipuram and maximum wastage (22.1%) at Kanpur were observed. Further, the wastage of unopened vials and vials during use was also observed following colour changes on the vaccine vial monitor (VVM), indicating poor cold-chain maintenance at the immunization site. In total, 13 booths reported wastage of nine or more unopened vials, whereas 19 booths reported wastage of nine or more vials during use because of colour changes on VVM. Other reasons for wastage of vaccine were also observed from a sample of booths. The technology of introducing VVM on OPV vials for monitoring the cold-chain proved useful in situations in which mass vaccination programmes such as PPI are carried out.

Key words: Polio vaccine; Immunization; Wastage; India

INTRODUCTION

India, the largest country in which polio is endemic, accounts for over 50% of the cases of poliomyelitis reported globally (1). If the Global Polio Eradication Initiative is to succeed, progress in India is critical. The Government of India launched the Pulse Polio Immunization (PPI) campaign with the first National Immunization Day (NID) observed in December 1995 (2). Since then, a drastic reduction in the number of polio cases has been observed in the country. The strategy of conducting successive rounds of NIDs and sub-NIDs over the years has brought India close to achieving elimination of polio.

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The World Health Organization (WHO) has laid down guidelines for calculating oral polio vaccine (OPV) requirements taking into account wastage and the wastage multiplication factor (WMF). According to this, a wastage/reserve multiplier of 1.33, corresponding to approximately 25% wastage, is used for calculating vaccine requirements (3). In India under the Universal Immunization Programme (UIP), a higher allowance for wastage at 33% and a WMF of 1.5 are used when calculating vaccine requirements (4). However, no studies have been carried out in India either to determine

or validate the rationale for this WMF. Therefore, the Ministry of Health and Family Welfare decided to initiate field studies to determine the wastage factor. The Ministry requested the Indian Council of Medical Research (ICMR) to undertake field studies through the network of its institutes and Human Research Reproduction Centres (HRRCs), located all over the country. Accordingly, ICMR undertook a study to estimate the wastage of OPV during the PPI programme held in the country on 17 January 1999.

Few studies have been conducted in the past to estimate the wastage of OPV in a mass vaccination drive, such as the PPI campaign in India. However, in an important study conducted during NIDs in 1993 to eradicate polio in Egypt, around 25% of OPV doses in 20- and 50-dose vials were wasted in urban fixed-site vaccination centres. In rural fixed sites, 41.5% of multi-dose vial doses were wasted (5).

Furthermore, a special heat-sensitive label known as a vaccine vial monitor (VVM) was introduced on OPV vials in 1996. It has since been delivered with billions of doses of OPV to more than 80 countries of the world. VVM does not directly measure vaccine potency but gives information on the heat exposure of the vial over a period of time (6). Since exposure to heat may lead to degradation of vaccine, the utility of putting VVMs on vials was also evaluated.

The main objective of this study was to determine WMF for OPV during the PPI programme held in the country on 17 January 1999.

MATERIALS AND METHODS

The study was conducted through the network of HRRCs and other ICMR institutes. All types of immunization booths in the PPI programme in the study districts where HRRCs or ICMR institutes were located were covered. In total, 28 HRRCs and three ICMR institutes participated in the study. Furthermore, other reasons for wastage of vaccine were also recorded from a simple random sample of 20 immunization booths within each study district. This was done using the list of booths in each district, assigning serial numbers to all these booths and drawing 20 random numbers (using the random number tables) from the list thus compiled.
Wastage and WMF are defined as (3):

$$\text{Wastage} = \frac{\text{number of doses used-number of children given vaccine}}{\text{number of doeses used}} \times 100$$

WMF= (Number of doses used)/(Number of children given vaccine).

Where the number of doses used was obtained by multiplying the number of vials used by 20 as each vial contained 20 doses of OPV. As soon as a vial was opened, it was considered to be 'used.'

Data were collected on a pre-coded form at the end of the PPI session at each immunization booth. Information on wastage and other related parameters was provided by the person in-charge of the booth. Each booth maintained a register with information on the number of vials received, number of vials used, number of children given OPV, and number of vials wasted for other reasons. Information was taken directly from these registers, and hence the credibility of these data was ensured.

RESULTS

The study covered 30,767 immunization booths located in 31 districts spread over 11 states and three Union Territories. Wastage of vaccine was analyzed by the type of centre, the person in-charge at the centre, and the number of workers present at the centre. Information on wastage due to colour changes on VVM (7) was also analyzed. Other reasons for wastage of vaccine were also recorded from a sample of immunization booths and analyzed accordingly.

The present study yielded an overall estimate of wastage as 14.5% with a WMF of 1.17 (Table 1) at the point of administration of vaccine. The minimum wastage of OPV was observed in the district Kanchipuram at 6.3% with a WMF of 1.07, and the maximum wastage of 21.8% with a WMF of 1.28 was observed in the Raigarh district. A maximum of 11 districts reported wastage of 16-20% with WMF ranging from 1.19 to 1.25 (Table 2). Ten districts reported wastage of 6-10% with WMF ranging from 1.06 to 1.11. Seven districts reported wastage from 11% to 15% with WMF ranging from 1.19 to 1.25. Three districts reported wastage of more than 20% with a WMF of more than 1.25.

Wastage of OPV was assessed at various immunization sites (Table 3). Bus-stands were the most popular immunization sites, followed by Primary Health Centres (PHCs), Urban Health Centres, Railway Stations, and other places. The maximum wastage of 17.2%, with a corresponding WMF of 1.23, was observed at temples/religious places, and the minimum wastage of 11.8%, with a corresponding WMF of 1.13, was observed at Community Health Centres (CHCs). No apparent association was observed between wastage and site of immunization. However, wastage was less

at health centres compared to other immunization sites. The immunization site either could not be ascertained or was not recorded at 10,097 booths.

Table 1. Wastage (%) and wastage multiplication factor in various districts covered

District	No. of booths covered	No. of doses used	No. of children given oral polio vaccine	Wastage (%)	Wastage multiplication factor
Delhi	532	396,860	369,720	6.8	1.07
Barabanki	504	186,620	155,713	16.6	1.20
Baroda	2,056	316,400	258,878	18.2	1.22
Belgaum	1,632	515,260	427,630	17.0	1.20
Satara	2,049	387,680	314,840	18.8	1.23
Cuddalore	1,452	293,500	263,735	10.1	1.11
Nalbari	539	150,220	120,879	19.5	1.24
Ghaziabad	900	589,820	486,110	17.6	1.21
Hooghly	1,531	545,100	473,076	13.2	1.15
Kolkata	61	27,180	21,343	21.5	1.27
Jabalpur	1,720	392,680	333,938	15.0	1.18
Jaipur	1,273	611,200	537,837	12.0	1.14
Jammu	481	165,180	148,856	9.9	1.11
Kanchipuram	723	118,480	111,047	6.3	1.07
Kanpur	777	301,960	235,087	22.1	1.28
Pune	3,321	891,140	739,437	17.0	1.21
Madurai	1,579	337,600	304,532	9.8	1.11
Meerut	551	267,420	228,307	14.6	1.17
Mumbai	35	6,580	5,400	17.9	1.22
Noida	98	73,680	64,261	12.8	1.15
North Goa	247	61,240	55,973	8.6	1.09
North 24 Parganas	979	37,640	326,095	13.4	1.15
Patna	310	128,520	105,492	17.9	1.22
Raigarh	1,430	207,020	161,878	21.8	1.28
Dibrugarh	447	161,240	147,674	8.4	1.09
Sonepat	395	188,160	156,739	16.7	1.20
Thiruvallore	980	174,040	157,240	9.7	1.11
Thiruvanna-Malai	692	114,680	105,213	8.3	1.09
Trivandrum	2,330	267,800	225,508	15.8	1.19
Vellore	1,048	200,740	182,812	8.9	1.10
Yamuna Nagar	95	77,460	67,917	12.3	1.14
Total	30,767	8,531,920	7,293,167	14.5	1.17

Wastage, when analyzed by the person in-charge at a centre (Table 4), was found to be a maximum of 18.2% with a corresponding WMF of 1.22 when a teacher was in-charge, whereas, with a medical officer (MO) in-charge, wastage was estimated to be the minimum of 11.3% with a corresponding WMF of 1.13. When volunteers were in-charge, wastage was 16.3% with a corresponding WMF of 1.19. With an Anganwadi worker (AWW), female health worker (FHW), and other health functionaries in-charge, the wastage was estimated to be approximately 15% with a corresponding WMF of 1.18. Wastage varied from 12.5% to 13.9% with other types of persons in-charge. Auxiliary nurse midwives (ANM) were most frequently seen as being in-charge of booths. The person in-charge could not be ascertained at 1,391 immunization booths.

Wastage was also analyzed by the number of workers present at the immunization booths. With one worker present at the booth, wastage was estimated to be 19.1% with a corresponding WMF of 1.24. When the number of workers varied from two to more than five at the booth, wastage varied from 13.4% to 15.8% with a corresponding range of WMF being 1.15 to 1.19.

Table 2. Classification of districts by wastage (%) and wastage multiplication factor

District	Wastage (%)	Wastage multiplication factor
Delhi, Jammu, Kanchipuram, Madurai, Thiruvannamalai, North Goa, Thiruvallore, Dibrugarh, Vellore, Cuddalore	6-10	1.06-1.11
Hoogly, Jabalpur, Jaipur, Meerut, Noida, North 24 Parganas, Yamuna Nagar	11-15	1.12-1.18
Barabanki, Baroda, Belgaum, Satara, Nalbari, Ghaziabad, Pune, Sonepat, Trivandrum, Mumbai, Patna	16-20	1.19-1.25
Kolkata, Kanpur, Raigarh	>20	>1.25

rejection of 4-5 unopened vials. Rejection of six or more unopened vials was reported by the remaining 48 booths (10.7%). The average number of unopened vials rejected because of colour changes on VVM was 2.7 with a standard deviation (SD) of 2.0. Therefore, rejection of nine or more unopened vials, which goes even beyond the limit of mean + 3 x SD, reflects poor maintenance of the cold-chain. Rejection of nine or more unopened vials took place at one booth each in Cuddalore, Ghaziabad, Jaipur, and North 24 Parganas, at two booths in Pune, and at six booths in Dibrugarh.

Furthermore, 255 booths also reported rejection of one or more vial(s) during use because of colour changes on VVM (Table 6). Ninety-four (36.9%) booths reported rejection of one vial during use, 51 (20.0%) booths reported rejection of two vials, and 28 (11.0%) booths reported rejection of three vials during use. The remaining 82 (32.0%) booths reported rejection of four or more vials during use. The average number of vials wasted during use because of colour changes on VVM was 3.3 with a standard deviation of 2.7. Five booths in Belgaum, four booths each in Dibrugarh and Pune, one booth each in Cuddalore, Jabalpur, and Jaipur reported wastage of nine or more vials during use.

Table 3. Wastage (%) and wastage multiplication factor at different site of immunization

Site of immunization	No. of booths covered	No. of doses used	No. of children given oral polio vaccine	Wastage (%)	Wastage multiplication factor
Urban health centre	1,170	577,780	501,765	13.2	1.15
Bus-stand	10,773	2,603,960	2,193,244	15.8	1.19
Railway station	1,165	390,020	330,905	15.2	1.18
Primary healthcare	3,335	1,073,060	930,445	13.3	1.15
Temple/religious place	365	131,160	108,635	17.2	1.21
School	1,070	290,180	244,008	15.9	1.19
Community Health Centre	445	69,380	61,194	11.8	1.13
Others	2,347	646,660	542,633	16.1	1.19

Table 4. Wastage (%) of oral polio vaccine by person in-charge of booth

In-charge of booth	No. of booths covered	No. of doses used	No. of children given oral polio vaccine	Wastage (%)	Wastage multiplication factor
Medical officer	2,041	1,021,760	906,131	11.3	1.13
Auxiliary nurse midwife	7,948	2,510,360	2,165,456	13.7	1.16
Lady health volunteer	680	208,780	179,663	13.9	1.16
Male health worker	716	193,400	168,130	13.1	1.15
Female health worker	2,603	747,700	636,538	14.9	1.17
Other health functionaries	4,055	1,053,960	896,894	14.9	1.18
Anganwadi worker	4,564	856,640	726,743	15.2	1.18
Teacher	4,779	946,860	774,667	18.2	1.22
Volunteers	1,441	331,020	277,159	16.3	1.19
Others	549	149,720	131,048	12.5	1.14

In total, 448 booths reported rejection of one or more unopened vial(s) because of colour changes on VVM (Table 5). In total, 160 (35.7%) booths reported rejection of one unopened vial, 113 (25.2%) reported rejection of two unopened vials, 67 (15%) reported rejection of three unopened vials, and 30 booths (6.7%) each reported

Finally, other reasons for wastage of vaccine were also recorded and analyzed from a sample of 849 booths

(Table 7). At 10% of the booths, the other reasons quoted were movement of baby/lack of cooperation from child/ spillage/wastage during administration. Vomiting/spitting was the reason for wastage at about 5% of the booths.

Table 5. No. of unopened vials rejected because of colour changes on VVM

No. of unopened vials rejected	Booth	
	No.	%
1	160	35.7
2	113	25.2
3	67	15.0
4	30	6.7
5	30	6.7
6	16	3.6
7	17	3.8
8	2	0.4
9	8	1.8
≥10	5	1.1

VVM=Vaccine vial monitor

Table 6. No. of vials rejected during use because of colour changes on VVM

No. of vials rejected during use	Booth	
	No.	%
1	94	36.9
2	51	20.0
3	28	11.0
4	11	4.3
5	16	6.3
6	13	5.1
7	9	3.5
8	14	5.5
9	8	3.1
≥ 10	11	4.3

VVM=Vaccine vial monitor

Residual vaccine left in the vial was another reason for wastage reported at 4.5% of the booths. Tight/hard dropper of the vial and excessive drops being given were the reasons quoted at 3.1% and 3.5% of the booths. Loss of vaccine while opening/seal difficult to open was yet another noticeable reason quoted for the wastage of vaccine at 2.4% of the booths. Some other reasons were also quoted at less than 2% of the booths. No reasons for wastage were reported at 666 (78.4%) booths.

DISCUSSION

The present study yielded an overall estimate of wastage as 14.5% with a WMF of 1.17, during the administration of vaccine. The actual wastage might have been slightly higher had the wastage during the time since the vaccine vials arrived been taken into account. However, this was beyond the scope of the present study. Furthermore, the present estimate of wastage is good enough for any operational evaluation of wastage for calculating vaccine requirements.

Places like bus-stands and PHCs were the most popular sites for immunization. Since the maximum wastage was found to be at religious places, such as temples, etc., it would be interesting to analyze the reasons for wastage at these places.

Surprisingly, with teachers in-charge at the immunization booths, the wastage was maximum. The teaching community in India is widely acceptable, particularly among the rural masses. Therefore, if teachers are to be involved in mass campaigns like PPI, they should be provided extensive training on handling vaccine vials.

The presence of a VVM on vaccine vials also played an important role in taking the decision to reject both unopened and opened vials that have been exposed to heat. This clearly emphasizes the need for putting a VVM on vials of vaccines sensitive to heat, thereby acting as a cold-chain monitor.

Other reasons for wastage of vaccines were also recorded at a sample of immunization booths. Some very important and interesting facts emerged from this analysis. Under this category of wastage, the majority of booths reported lack of cooperation from the child as a primary reason for wastage. Residual vaccine left in the vial and tightness of the dropper of the vial also turned out to be the contributing factors in the wastage of vaccine. Therefore, the manufacturer should pay some attention and design the vials in such a manner so that no residual vaccine is left in the vial and the dropper works smoothly.

This study has shown an overall wastage of 14.5% and a WMF of 1.17 of OPV at the point of administration of vaccine in the PPI programme. The estimates of wastage and WMF reported are well below the assumed wastage of 33% and WMF of 1.5. The estimates obtained in the present study are also less than the WHO-recommended wastage of 25% and WMF of 1.33. Even the maximum wastage (22.1%) observed at Kanpur was well below both assumed wastage and wastage as recommended by WHO. The technique of putting a VVM on OPV vials also proved quite useful in a mass-vaccination drive like the PPI programme as it helped health workers identify vaccines exposed to heat. This prevented many children from receiving vaccines that might have been damaged by exposure to heat.

Setia *et al*. also dealt with the subject of vaccine wastage and had listed various important factors affecting wastage (8). The present study had a limited mandate, and wastage was estimated only at the point of administration of the vaccine, and hence the figures are not really comparable. However, some of the factors as described by Setia *et al*. were taken into account when we looked at vaccine wastage due to other reasons (Table 7).

Table 7. Other reasons for wastage of Oral Polio Vaccine at various booths

Reason	Booth	
	No.	%
Movement of baby/lack of cooperation from child/spillage/wastage during administration	86	10.1
Residual vaccine left in vial	38	4.5
Tight/hard dropper of the vial	26	3.1
Excessive drops being given	30	3.5
Vial containing less amount of vaccine	9	1.1
Leakage while giving doses	9	1.1
Vomiting/spitting	42	4.9
Loss of vaccine while opening/seal difficult to open	20	2.4
Vial broke while opening/accidentally	10	1.2
Other reasons	14	1.6
No reasons reported	666	78.4
Total	849	100.0

OPV=Oral polio vaccine

Furthermore, house-to-house delivery of OPV may decrease vaccine wastage but may add to the total cost due to the number of personnel required (5). The data in the present study were collected at the end of the PPI session. Wastage could have also occurred during the process of procurement and distribution which has not been taken into account in this study. Moreover, this was not an observational study, and the findings are based on the information provided by the person in-charge at the booth.

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