

Documentation of vaccine wastage in two different geographic contexts under the universal immunization program in India

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Abstract

Background Government of India is introducing new and relatively costly vaccines under immunization program. Monitoring of vaccine wastage is needed to guide the program implementation and forecasting. Under pilot introduction of rotavirus vaccine in two districts both 5- and 10-doses vials were used, which was considered as an opportunity for documenting the wastage.

Methods A survey conducted in two districts (Kangra, Himachal Pradesh and Pune, Maharashtra) covered 49 vaccine stores, 34 sub-centres and 34 outreach sessions collected vaccine receipt, distribution and usage data for two complete years 2016 and 2017.

Results The overall wastage rates for almost all vaccines were higher in Kangra district (BCG 37.1%, DPT 32.1%, Measles 32.2%, OPV 50.8%, TT 34.1% and pentavalent 18.4%) than Pune district (BCG 35.1%, DPT 25.4%, Measles 21.7%, OPV 14.3%, TT 23.1% and pentavalent 13.2%). Wastage for pneumococcal conjugate and measles-rubella vaccines were 27% and 40.5%, respectively. With transition from 5- to 10-doses vials for rotavirus vaccine, wastage at stores levels increased in both Kangra (29% to 33.2%) and Pune (17.8% to 25.7%) districts. With transition from intramuscular to intradermal fractional inactivated polio vaccine, the wastage increased from 36.1% to 54.8% in Kangra and 18.4% to 26.9% in Pune district.

Conclusions The observed vaccine wastage rates were relatively higher than program assumption for forecasting. The observed variations in the vaccine wastage indicates need for state or region based documentation and monitoring in India for appropriate programmatic action.

Background

Under the Universal Immunization program (UIP) in India the vaccine portfolio has been expanded from six to thirteen vaccines now with ten vaccines universally and three vaccines in select areas. There is also progressive rise in the full immunization coverage, although slower than anticipated. Usually in the program the vaccine requirements are estimated based on the estimated number of beneficiaries, number of doses and the vaccine wastage. Vaccine wastage is an integral part of vaccine logistics. The Government of India have recommended the wastage rate for 50% (BCG), 25% (Measles, Measles and rubella, rotavirus, and Japanese Encephalitis vaccines), and 10% for all other multi-dose vial vaccines including diphtheria-pertussis-tetanus (DPT), liquid pentavalent (LPV), inactivated polio (IPV), oral polio (OPV), tetanus toxoid (TT), and hepatitis B vaccine (HBV) (1). The vaccines are costly commodities and the newer vaccines are even costlier, putting a significant financial burden on the country. For accurate vaccine forecasts and financial projections, vaccine wastage rates are critical for preparing multi-year plans for the UIP. There are several tools and monitoring processes are put into place for periodic monitoring of the vaccine wastage and make efforts to minimise them. An UNICEF study across 5 states of India informed a high vaccine wastage rates for various vaccines ranging from 27–61% for various vaccines (2). The wastage rates varied across the states for different vaccines. World Health organisation (WHO) estimated that about 50% of the vaccines produced globally are wasted (3). According to the available reports for pneumococcal conjugate vaccine (PCV) pipeline planning in 2010, WHO had analysable vaccine wastage data for only 19 of the 72 GAVI (The Global Alliance for Vaccines and Immunization) eligible countries (4). Hence it was recommended to reinforce the vaccine wastage monitoring and documentation at national and sub-national levels for large countries like India, with new costlier vaccines being introduced in the UIP. The increase in cost of vaccines makes the solicitous use of vaccines and interest to minimize the vaccine wastage has risen. To reduce the wastage, India adopted open vial policy for liquid vaccines in 2011. Several factors influence the wastage including the vaccine vial, applicability of open vial policy, beneficiary base, session planning, syringes used, immunisation practices, storage and logistics, and national policies (3).

Pilot introduction of rotavirus vaccine (RVV) was done in two districts (Kangra, Himachal Pradesh and Pune, Maharashtra) of India, prior to the national introduction. Under the pilot introduction, initially five doses RVV vials were supplied, which were changed to ten doses vials synchronising with the national rollout. Additionally PCV was introduced in Himachal Pradesh under first phase of national rollout. This provided an opportunity to document the vaccine wastage for RVV (two different vial sizes) in two different geographic contexts and PCV under the UIP.

Methods

Background setting

Before national introduction of RVV in India, a pilot introduction linked to surveillance of associated adverse events was planned. The RVV was introduced in two districts, Kangra (Himachal Pradesh) and Pune (Maharashtra) in December 2015. District Kangra with population 15 million had one district hospital (DH), one sub-district hospital (SDH), 13 community health centres (CHCs), 84 primary health centres (PHCs) and 440 sub-centers. In the Kangra district about 262 fixed sessions and 903 outreach sessions were organised every month. In Pune district, a selected part of the district covering 10 million population with a network of 29 PHCs and six rural hospitals (RH) was included. The immunization and vaccine logistics related health functionaries in these two districts and community mobilisers were trained for implementation through a cascade training system. The RVV was launched in December 2015 and routinely administered to the infants from January 2016. The birth cohorts targeted in these two districts were 41400 (Kangra 23400 and Pune 18000). Three doses of Rotovac were given at 6, 10 and 14 weeks to the infants. Five doses vials of RVV were used till September 2016 and then ten doses vials were used. The PCV was launched in Himachal Pradesh in May 2017 as part of the national phased introduction with two primary and one booster schedule. The PCV was administered to infants routinely under UIP from July 2017. IPV introduced under UIP underwent transition from 0.5 ml intramuscular to 0.1 ml intradermal (fractional IPV- fIPV) since January 2017.

Availability of all these combinations in vaccine vial size, administration route across two different geographies (Kangra- hilly and Pune- plain regions) provided an opportunity to document the vaccine wastages.

The vaccine is supplied from district store to the cold chain stores at CHCs and PHCs on monthly basis. From these CHCs/PHCs, for the sessions at sub-centres and outreach sites, vaccines are supplied using vaccine carriers on the day of session. The unopened and partially used open vials are returned to the store after the session, which are reissued for the next sessions. These vaccine transactions are recorded in the vaccine stock and issue/return register and the children vaccinated numbers are written in the session registers.

Study design

This cross-sectional study was undertaken in two districts, Kangra (Himachal Pradesh) and Pune (Maharashtra). In each district, the facilities (all levels) providing vaccination and session sites (including outreach sessions) in both urban and rural areas were included to obtain a comprehensive picture of vaccine utilisation and wastage. In Kangra, the DH, 14 CHCS, 14 PHCs, 14 sub-centres were included. In Pune, the DH, five RHs, 4 CHCs, 10 PHCs and 20 sub-centres were included.

Data collection

These selected 49 facilities (vaccine store and also service delivery point), 34 sub-centres (service delivery point) and 34 outreach session sites (one per sub-centre) were visited by the trained research staff for data collection. The vaccine supply, logistics and administration data for all UIP vaccines were collected for the period January 2016 to December 2017. Month and vaccine wise data were collected from the multiple registers including sessions held, vaccines supplied and returned, vaccine utilisation, children vaccinated, and vaccines discarded or wasted using structured tools. The interviews with cold chain handlers, vaccinators and facility in-charges were done to gain additional understanding the perceptions, practices and experience related to vaccine usage and wastage handling using semi-structured guide after obtaining informed consent. Double data entry of the data collected was done using a MySQL and PHP based online data entry program followed by matching and corrections. The data was extracted into Microsoft excel format.

Data analysis

The descriptive analysis performed using Microsoft Excel 2013 and Stata 15.0. The wastage rate at facility level and session site levels were estimated using the formula; $\text{Wastage rate} = \text{Doses wasted} \times 100 / \text{Doses used}$, expressed as percentage. For the facilities the doses wasted for specific periods were estimated using the opening stock balance, new doses received, closing stock, and the children vaccinated. For the facilities, all doses administrated at the sessions held at facility and outreach sites under the respective facility were considered. For the outreach sessions, all doses administrated at the outreach session were considered. Wastage for each vaccine for every month for each facility, session site and facility areas and for each different dose type (IPV and fIPV), vial size (5, 10, 20 and 50 doses), vaccine type (lyophilized and liquid), and applicability of open vial policy (open vial or single use) were calculated.

Results

From these selected sites, data for 5,276 sessions (Kangra- 3,044 and Pune- 2,232 sessions) at facilities and 2,502 outreach sessions (Kangra- 2,166 and Pune- 336) were recorded. A total of 1,004,695 vaccine doses (Kangra- 756,575 and Pune- 248,120 doses) at facility sessions and 159,243 vaccine doses (Kangra- 128,514 and Pune- 30,729 doses) at outreach sessions were administered.

Frequency of doses administered during the vaccination sessions: According to the records, the number of doses administered per vaccination session varied widely by vaccine, which ranged between 0 to 45 doses per day. The distribution and dispersion of doses administered for different vaccines for to districts are shown in Figure 1 (1a and 1b).

[Figure 1 about here]

[Figure 1: Number of vaccination sessions by the number of doses administered per session]

The doses administered per session for most of the vaccine doses were higher in Kangra district than Pune. The dosage administered per session for LPV, RVV, OPV and IPV were similar in both districts. There were fewer doses of BCG and HBV administered at these sessions, as most of these birth doses were given at the hospitals immediately after delivery. About 75%-80% of the vaccination sessions administered required less than one vial's worth of vaccine. In Kangra the overall turnout rate for vaccination sessions was 86% with BCG (81%), DPT (83%), HBV (80%), IPV (88%), measles (87%), measles-rubella (MR) (86%), OPV (86%), PCV (86%), LPV (87%), RVV (85%), and TT (85%). In Pune the overall turnout rate for vaccination sessions was 67% with BCG (64%), DPT (53%), HBV (70%), IPV (98%), Measles (68%), OPV (64%), LPV (72%), RVV (75%), and TT (64%). While 3-4 vaccination sessions monthly were conducted under each sub-centre in Pune, usually 1-2 sessions monthly in Kangra district.

Vaccine wastage at the outreach session level: The doses issued to the session sites and administered and vaccine usage and wastage rates for each vaccine not following open vial policy were calculated for the two districts (Table 1). The wastage for open vials were not calculated as the partially used vials were returned to the cold chain store and there was no entry of number of doses returned were mentioned in the registers.

Table 1: Vaccine wastage by antigen at outreach session level in the two districts

Antigen	Vial size (doses/vial)	Doses administered (A)	Doses issued (B)	Vaccine usage rate C= (A/B) X 100	Vaccine wastage rate D= (100-C)	Vaccine wastage range [@] (D, %)	Wastage Factor E= 100/ (100-D)
Kangra							
BCG	10	1220	1810	67.4	32.6	0-100	1.5
Measles	5	1592	2037	78.2	21.8	10-100	1.3
MR	10	1312	1378	95.2	4.8	0-100	1.1
RVV-5	5	3344	4336	77.1	22.9	15-85.7	1.3
RVV-10	10	2699	4259	63.4	36.6	10-90.8	1.6
RVV pooled	5/10	6043	8595	70.3	29.7	10-90.8	1.4
Pune							
BCG	10	1584	2110	75.1	24.9	25-93.3	1.3
Measles	5	3697	5091	72.6	27.4	25-95.7	1.4
RVV-5	5	1296	1731	74.9	25.1	8-64.6	1.3
RVV-10	10	3445	4200	82.0	18.0	20-72.8	1.2
RVV pooled	5/10	4741	5931	79.9	20.1	8-72.8	1.3

Note: IPV: Inactivated polio vaccine standard 0.5 ml/dose intramuscular, 10 doses per vial; fIPV: Fractional Inactivated polio vaccine, 0.1 ml/dose intradermal, 50 doses per vial; RVV-5: Rotavirus vaccine, 2.5 ml, 5 doses per vial and RVV-10: Rotavirus vaccine, 5ml, 10 doses per vial

No IPV doses were administered at the outreach sessions in Pune district as per the available records.

@ The vaccine wastage levels at the outreach sessions across the different months.

The overall wastage rates for BCG and pooled RVV was higher in Kangra district than Pune. It was also observed that with transition of RVV vial size from 5 doses to 10 doses, the wastage increased in Kangra from 22.9% to 36.2%, but dropped from 25.1% to 18% in Pune district. The wastage rates across the sub-centers and session sites varied widely. In Kangra 44% of the sessions had wastage \leq 25% for the vaccines (28.8%, 11.4%, 2.2% and 1.5% of the sessions for RVV, measles, MR and BCG respectively). The wastage between 26-50% was observed for 19.8% sessions including 4.1%, 12.6%, 2% and 1% of the sessions for RVV, Measles, MR and BCG respectively. The wastage was $>$ 50% in 35.1% of sessions including 13.7%, 11.2%, 3.2% and 4.8% of the sessions for RVV, measles, MR and BCG respectively. In Pune 80.2% of the sessions had wastage \leq 25% for the vaccines (33.6%, 37.5% and 9.2% of the sessions for RVV, Measles and BCG respectively). The wastage between 26-50% was observed for 4.6% sessions including 1.8%, 1.8% and 1.1% of the sessions for RVV, Measles, MR and BCG respectively. The wastage was $>$ 50% in 15.2% of sessions including 5.3%, 2.1%, and 7.8% of the sessions for RVV, Measles and BCG respectively.

Vaccine wastage at the cold chain store level: The vaccine usage and wastage rates for each vaccine for the cold chain stores were calculated using the doses issued for the sessions and administered on monthly basis. The summarised wastage rates for the vaccines and their ranges across various stores are reflected in Table 2.

The wastage rated varied widely across the vaccines and the two districts. The vaccine wastage rates were $>$ 25% for all vaccines in Kangra district. The wastage rates were 26-50% for most of the vaccines except OPV and fIPV which had wastage rates $>$ 50%. The wastage rates were $<$ 25% for HBV, Measles, OPV, LPV, TT, IPV and RVV-pooled in Pune. The wastage rates were 26-50% for BCG, DPT, fIPV and RVV-10 dose vials. No wastage of unopened vials was documented at the cold chain stores. The ranges of wastage for different vaccines at cold chain point level varied widely.

Table 2: Vaccine wastage by antigen at cold chain store unit level in the two districts

Antigen	Vial size (doses/vial)	Doses administered (A)	Doses issued (B)	Vaccine usage rate C= (A/B) X 100 (%)	Vaccine wastage rate D= (100-C) (%)	Vaccine wastage range [@] (D, %)	Wastage Factor E= 100/ (100-D)
Kangra							
BCG	10	33741	53614	62.9	37.1	5-83	1.6
DPT	10	87325	128532	67.9	32.1	5-80	1.5
HBV	10	3450	4952	69.7	30.3	5.5-70.6	1.4
Measles	5	45747	67459	67.8	32.2	0-81	1.5
MR	10	78708	132270	59.5	40.5	0-90	1.7
OPV	20	203011	412723	49.2	50.8	0-75	2.0
PCV	10	19651	26908	73.0	27.0	0-83	1.4
LPV	10	98578	120741	81.6	18.4	0-83	1.2
TT	10	32599	49480	65.9	34.1	4.8-76	1.5
IPV	10	13142	20553	63.9	36.1	0-77	1.6
fIPV	50	27238	60296	45.2	54.8	10-82	2.2
IPV pooled	10/50	40380	80849	49.9	50.1	0-82	2.0
RVV-5	5	40278	56758	71.0	29.0	0-75	1.4
RVV-10	10	73107	109516	66.8	33.2	0-82	1.5
RVV pooled	5/10	113385	166274	68.2	31.8	0-82	1.5
Pune							
BCG	10	12121	18664	64.9	35.1	0-87.5	1.5
DPT	10	13884	18603	74.6	25.4	0-78	1.3
HBV	10	7985	9955	80.2	19.8	6.6-80	1.2
Measles	5	22313	28506	78.3	21.7	0-75	1.3
OPV	20	80787	94308	85.7	14.3	0-74.3	1.2
LPV	10	36432	41985	86.8	13.2	0-78.6	1.2
TT	10	36481	47410	76.9	23.1	0-87.6	1.3
IPV	10	718	880	81.6	18.4	0-60	1.2
fIPV	50	5123	7010	73.1	26.9	9-76	1.4
IPV pooled	10/50	5841	7890	74.0	26.0	0-76	1.4
RVV-5	5	10335	12570	82.2	17.8	0-88	1.2
RVV-10	10	21941	29524	74.3	25.7	0-90	1.3
RVV pooled	5/10	32276	42094	76.7	23.3	0-90	1.3

Note: IPV: Inactivated polio vaccine standard 0.5 ml/dose intramuscular, 10 doses per vial; fIPV: Fractional Inactivated polio vaccine, 0.1 ml/dose intradermal, 50 doses per vial; RVV-5: Rotavirus vaccine, 2.5 ml, 5 doses per vial and RVV-10: Rotavirus vaccine, 5ml, 10 doses per vial

@ The vaccine wastage levels at the cold chain points across the different months.

Vaccine wastage according to the vaccine types and vial sizes: The wastage rates for vaccines according to the type (liquid or lyophilised), reuse type (open vial policy), and vial sizes (number of doses) for oral and injectable routes for two districts for cold chain stores and outreach levels are summarised in Table 3.

Table 3: Wastage rates for antigens according to the composition and vial size

Type/Form	Kangra district		Pune district	
	Cold chain point Site WR (%)	Outreach session sites WR (%)	Cold chain point Site WR (%)	Outreach session sites WR (%)
I: Type of Vaccine				
Liquid	42.2	29.7*	17.4	20.1*
Lyophilized	35.3	19.7 [@]	25.3	26.1 [@]
II: Reuse Type				
Open vial	42.2	-	17.4	-
Single use vial	35.3	22.2 [#]	25.3	24.1 [#]
III: Vial Size-Oral				
5 doses	29.1	22.3 ^{\$}	17.8	25.1 ^{\$}
10 doses	33.2	24.6 ^{&}	25.7	21.4 ^{&}
20 doses	50.8	-	14.3	-
Oral pooled	45.3	23.4	17.1	23.2
IV: Vial Size-Injectable				
5 doses	37.7	21.8 ^{**}	21.7	27.4 ^{**}
10 doses	28.7	18.7 ⁺	21.4	24.9 ⁺
50 doses (fIPV)	54.8	-	26.9	-
Injectable pooled	33.8	20.5	21.7	26.1

Note: WR: wastage rate in percentages

* The wastage rate for liquid vaccine at outreach sessions includes RVV only.

@ The wastage rate for lyophilized vaccines at outreach sessions includes BCG, Measles and MR vaccines.

The wastage rate for single use vial vaccines at outreach sessions includes BCG, Measles, MR and RVV (5/10 doses) vaccines.

\$ The wastage rate for 5 doses vial vaccines at outreach sessions includes Measles and RVV (5 doses) vaccines.

& The wastage rate for 10 doses vial vaccines at outreach sessions includes BCG, MR and RVV (10 doses) vaccines.

** The wastage rate for 5 doses injectable vial vaccine at outreach sessions includes measles vaccine.

+ The wastage rate for 10 doses injectable vial vaccines at outreach sessions includes BCG and MR vaccines.

While the pooled wastage rates for liquid vaccines were higher than the lyophilized vaccines in Kangra, the reverse pattern was observed in Pune. The wastage rate for single use vials and pooled oral vaccines were comparable for the two districts. For the five dose vials, the wastage was lesser in Kangra than Pune.

Vaccine wastage with transition of vial dosage sizes: At the cold chain point level, with transition from 5- to 10-doses of RVV vials, the wastage rate increased both in Kangra (29% to 33.2%) and Pune (17.8% to 25.7%) (Table 2). The wastage rate for RVV at outreach session level increased with transition from 5- to 10-doses vial in Kangra (22.9% to 36.6%), while it declined in Pune (25.1% to 18%) (Table 1).

Vaccine wastage with transition from IPV to fIPV practice: With transition of IPV dosage from 0.5ml to fractional 0.1ml (fIPV), the wastage rates increased sizably in Kangra (36.1% to 54.8%) and marginally in Pune (18.4% to 26.9%) (Table 2).

Discussion

This report attempted to document the vaccine wastage status for the vaccines in UIP in Kangra and Pune districts representing two different geographies, the hilly and plain regions. The use of two different sizes of RVV vials provided an opportunity for documenting the change in wastage rates. Additionally the transition from regular to fraction dose of IPV in Kangra during the observation period was also captured. We estimated the wastage for UIP vaccines at cold chain points and outreach session sites during two year period. This is the first report on wastage rate of RVV with both five and ten dosage vial package versions. Additionally this is the first report from India on wastage for PCV and transition of IPV to fIPV dosage under UIP.

The present study documented the wastage rates for all the vaccines to be universally higher for all vaccines than the recommended by Ministry of Health and Family Welfare (MOHFW). In Kangra, the wastage rates for OPV and fIPV were above 50%, for most of the other vaccines except LPV were in the range of 26–50%. For most of the vaccines the wastage was > 10% of the prescribed range, except Measles, LPV and RVV-5. In Pune, the wastage rates for most of the vaccines were < 25% except for BCG, DPT, fIPV, and RVV-10. For majority of the vaccines the wastage was within 10% of the prescribed range, except DPT, TT, and fIPV. For Measles and RVV-5, the wastage was lower than the prescribed range. Higher vaccine wastage rates in Kangra compared to Pune may be explained by the target population base, density and beneficiary load for the sessions. No wastage of unopened vials indicated good practices for storage, logistics and stock management at the cold chain stores.

Rise in the wastage rate with transition from RVV 5 doses to 10 doses vial in both districts can be explained by the beneficiary case load. With rising institutional deliveries, fewer beneficiaries for BCG vaccine at outreach session level may explain little higher wastage. The wastage rates for vaccines under open vial policy like DPT, fIPV may be higher due to lower number of beneficiaries within the usable window period of 4 weeks in the same session area. Despite higher wastage for fIPV (50 doses) dose practice, higher number of beneficiaries would have been vaccinated from the unit vial compared to IPV (10 doses) dose practice. Using the opened vaccine vial for sessions other than the session where it is opened may reduce the wastage of these multidose vaccine vials under open vial policy. The observed higher wastage rate for OPV in Kangra may be one off events during the period of observation.

A wastage assessment across nine districts across five states (Utar Pradesh, Himachal Pradesh, Tamil Nadu, Maharashtra, and Assam) in India (2010) by Unicef covering the full vaccine supply chain documented the average wastages for DPT, HBV, TT, Measles OPV and BCG to be 27% (19%-58%), 33% (30%-57%), 34% (20%-55%), 35% (26%-58%), 47% (40%-75%), and 61% (54%-68%) respectively. The wastage for four of the six vaccines were highest for Himachal Pradesh (BCG 65%, OPV 75%, Measles 58%, TT 53%, HBV 57% and DPT 58%) than Maharashtra (BCG 54%, OPV 51%, Measles 44%, TT 55%, HBV 37% and DPT 35%) (2). From Delhi the wastage for UIP vaccines including DPT, Measles, OPV, DT, TT and BCG were observed to be 38.6%, 39.9%, 48.1%, 57.3%, 62.8% and 70.9% respectively (5). A study in 10 districts across 4 states documented wastage for DPT (38.9%), DT (39.1%), and TT (48.1%) with no open vial policy practice, OPV (52.7%), BCG (49.3%) and Measles (38.7%). There was wide variation in the wastage rates across the districts and states (6). From urban area of Gujarat, the wastage for DPT, HBV, OPV, Measles and BCG were reported to be 16%, 21%, 25%, 28% and 45% respectively (7).

At a referral facility in Haryana, the wastage rates for LPV, OPV, TT, HBV, Measles, DPT and BCG were recorded to be 7.4%, 28.9%, 36.8%, 38.6%, 41.2%, 46.7% and 77.9% respectively (8).

At a teaching hospital in Puducherry, the vaccine wastage rates for UIP vaccines including DPT (8.4%), OPV (2.4%), HBV (5.3%), LPV (0%), TT (4.2%) and TT (4.2%) to be within the prescribed limit, but for Measles (46.5%) was higher (9). The wastages for UIP vaccines at a tertiary hospital in Rajasthan were reported to be 9.2%, 9.4%, 12.7%, 21.3%, 27.6% and 29.4% for HBV, LPV, DPT, BCG, Measles and OPV respectively (10). From another referral facility in Madhya Pradesh, the wastage rates for LPV, TT, HBV, OPV, BCG and Measles were recorded to be 5.2%, 7%, 10.5%, 14.5%, 20.7%, and 21.6% respectively (11).

In an urban area of Gujarat, wastage of UIP vaccines like LPV, OPV, DPT and TT to be 47.8%, 50%, 42.7%, and 42% before adoption of open vial policy. The wastage declined by 1.8%, 6.2, 7.5% and 17.1% for DPT, TT, OPV and LPV vaccines respectively after adoption of open vial policy. With introduction of second dose of Measles vaccine, the wastage declined from 63.6–41.4% (12). Another report from urban Gujarat, across 24 health facilities the wastage for OPV declined from 25–13.6% and liquid vaccines (DPT, HBV, and LPV) from 17.9–8% with induction of open vial policy (13). In One district of Karnataka, the wastage rates for LPV, Measles, OPV, DPT and BCG were documented to be 24.5%, 32.5%, 41.4%, 50.2% and 64.6% respectively (14).

There have been some reports from other countries with varied levels of vaccine wastage. In Bangladesh, the wastage rate at primary service delivery level was documented to be 34.8%, 45.1%, 68.6% and 84.4% for the vaccines TT, DPT, Measles and BCG respectively. At the facility level, the wastage rates were 36.6%, 44.2%, 71.2% and 85.1% for the vaccines TT, DPT, Measles and BCG respectively. The wastage was > 25% for majority of the primary service and also facility levels for all vaccines (15). In a prospective study in Gambia, the wastage for lyophilised vaccines were documented to be higher for BCG (54.9%, 20 doses vial) followed by Measles (15.6%, 10 doses vial), LPV, IPV, TT, HBV, and DPT (0.1–5.1%, all 10 doses vials except TT, 20 doses vial). The wastage rates for single dose PCV and RVV were 0.1% and 5.2% respectively (16). Another prospective study in Nigeria, the wastage rates estimated at session sites were highest for OPV (35%) followed by BCG (30%), TT (30%), Measles (23%), HBV (22%), and DPT (21%). The wastage rates for vaccines at store level were highest for TT (28%) followed by Measles (27%), OPV (23%), BCG (22%), HBV (21%) and DPT (18%) (17). Based on reports from 19 countries, the median wastage rates for single, 2- and 10-dose vials were estimated as 5% (IQR 1–10%), 7% (IQR 1–27%) and 10% (IQR 4–44%) respectively (4).

There have been several efforts to make immunization program cost effective through appropriate adjustment in vaccine logistics, operation including session planning, vial reuse policy, vial size package, and vaccinator practice (18). It was estimated that with transition from 10- to 5-dose vials of IPV the open vial wastage would be reduced by nearly half in all countries; Bangladesh by 56% (from 0.25 to 0.11), India by 53% (from 0.17 to 0.08), Mozambique by 53% (from 0.13 to 0.06), and Uganda by 44% (from 0.09 to 0.04) (19).

The two states (Himachal Pradesh and Maharashtra) are common with the Unicef vaccine wastage study in five states (2). The vaccine wastage rates for most of the vaccines in both states have decreased overtime, which may be due to better organisation and logistics management, improved supervision and monitoring and open vial policy adoption. There has been wide variation in the vaccine wastage across the states and most of them have been from urban or tertiary care facilities. Limited information on vaccine wastage at outreach levels is available from different states in India to better understand the determinants. In our study, with transition from smaller to larger dose vial size, the wastage rate increases as documented for RVV and IPV in the current study. Reducing vial size has been an appealing strategy to reduce wastage, but cost-benefit analysis should be conducted considering the logistics and cold chain footprint, especially the costlier vaccines.

This study had several limitations. The study included only two districts and selected facilities in the districts. Some of the stores and outreach sessions had incomplete records, which may have introduced bias in the estimates. The period of record available for MR and PCV were relatively small.

Conclusions

The study conducted in two different geography and population contexts in India documented that the vaccine wastage rates in both districts were relatively higher than the national program assumptions. The hilly district (Kangra) had relatively higher wastage for all vaccines compared to the plain district (Pune). The change in vial size for RVV from 5- to 10 doses increased the wastage in both districts. The transition from intramuscular IPV to intradermal fIPV has also increased the wastage rate, but the children vaccinated from one vial had also increased. The UIP in India face pressure to minimize the wastage and improve coverage with limited vaccine availability and budget. With introduction of newer vaccines the coverage and vaccine wastage needs to be monitored for informing the program and operation. Close monitoring the wastage rates at different levels including the service delivery points; facilities with different case load and outreach levels in different geographies with various microplan types and stores at different levels. India provides opportunity for documenting the vaccine wastage across different contexts and lessons for appropriate programmatic action.

List Of Abbreviations

BCG	Bacillus Calmette–Guérin
CHC	Community health centres
DH	District hospital
DPT	Diphtheria-pertussis-tetanus
fIPV	Fractional Inactivated polio vaccine
GAVI	The Global Alliance for Vaccines and Immunization
HBV	Hepatitis B vaccine
IPV	Inactivated polio vaccine
LPV	Liquid pentavalent vaccine
MOHFW	Ministry of Health and Family Welfare
MR	Measles-rubella vaccine
MySQL	An open-source relational database management system
OPV	Oral polio vaccine
PCV	Pneumococcal conjugate vaccine
PHC	Primary health centres
PHP	Personal Home Page (a server language for web development)
RH	Rural hospital
SDH	Sub-district hospital
TT	Tetanus toxoid
RVV	Rotavirus vaccine
UIP	Universal Immunization program
WHO	World Health organisation

Declarations

Ethics approval and consent to participate: The study protocol was reviewed and approved by INCLEN Ethics Committee (Ref: IIEC 47). The interviews with stakeholders were done after obtaining written informed consent.

Consent for publication: Not applicable

Availability of data and materials: The datasets collected and analysed for the current study are available from the corresponding author on request.

Competing interests and conflict of interest: The authors declare that there is no competing interests and conflict of interest.

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Authors' contributions: MKD conceptualised the study, tool development, analysis and written the manuscript. MS, BP, RG, and CK implemented, monitored and supervised the immunization program implementation. MT, TKD, MAP, JBS, NMS, and SSP collected the data and entered. MKD and MS analysed the data and written manuscript. All authors read and approved the final manuscript.

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References

1. Immunization Handbook for Medical Officers (2017) | Ministry of Health and Family Welfare | GOI [Internet]. [cited 2019 May 10]. Available from: <https://mohfw.gov.in/basicpage/immunization-handbook-medical-officers2017>
2. Unicef, Ministry of Health and Family Welfare. Vaccine Wastage Assessment. Field assessment and observations from National stores and five selected states of India [Internet]. Unicef; 2010. Available from: https://www.mofa.go.jp/mofaj/gaiko/oda/seisaku/kanmin/chusho_h24/pdfs/a20-12.pdf
3. World Health Organization. Monitoring vaccine wastage at country level. Guideline for program managers [Internet]. World Health Organization, Geneva; 2005. Available from: https://apps.who.int/iris/bitstream/handle/10665/68463/WHO_VB_03.18.Rev.1_eng.pdf;jsessionid=730EE8B87C3491E389BF252E2F042C0C?sequence=1
4. Parmar D, Barua EM, Zuber P, Kone S. Impact of wastage on single and multi-dose vaccine vials: Implications for introducing pneumococcal vaccines in developing countries. *Hum Vaccin*. 2010 Mar;6(3):270–8.
5. Chinnakali P, Kulkarni V, S K, Nongkynrih B. Vaccine wastage assessment in a primary care setting in urban India. *J Pediatr Sci*. 4(1).
6. Mukherjee A. An Assessment of Wastage Multiplier Factor (WMF) and Percent Wastage of Vaccines during Routine Immunization Under the Universal Immunization Programme (UIP), Government of India (GOI). *J Vaccines Vaccin* [Internet]. 2013 [cited 2019 May 29];04(03). Available from: <https://www.omicsonline.org/an-assessment-of-wastage-multiplier-factor-wmf-and-percent-wastage-of-vaccines-during-routine-immunization-under-the-universal-immunization-programme-uip-government-of-india-goi-2157-7560.1000181.php?aid=13085>
7. Mehta S, Umrigar P, Patel P, Bansal RK. Evaluation of vaccine wastage in Surat. *Natl J Community Med*. 2013 Jan;4(1):15–9.
8. Gupta V, Mohapatra D, Kumar V. Assessment of vaccine wastage in a tertiary care centre of district Rohtak, Haryana. *Natl J Community Med*. 2015 Sep;6(2):292–6.
9. A P, Selvaraj K, Am V, Nair D, Ramaswamy G, Chinnakali P. Vaccine wastage assessment in a primary care setting in rural India. *Int J Contemp Pediatr*. 2015;2(1):7.

10. Sharma G, Sethia R, Acharya R, Meena R. Assessment of vaccine wastage in the immunization clinic attached to S. P. Medical College, Bikaner, Rajasthan. *Int J Community Med Public Health*. 2016;675–8.
11. Tiwari R, Dwivedi S, Swami P, Mahore R, Tiwari S. A study to assess vaccine wastage in an immunization clinic of tertiary care centre, Gwalior, Madhya Pradesh, India. *Int J Res Med Sci*. 2017 May 27;5(6):2472.
12. D S, H S, Ketan P, Surendra J. Closing Gaps in Routine Immunization - Impact and Cost Assessment on components of New Vaccine Policy in Routine Immunization in Gujarat, India. *J Res Med Dent Sci*. 2016;4(1):70.
13. Patel PB, Rana JJ, Jangid SG, Bavarva NR, Patel MJ, Bansal RK. Vaccine Wastage Assessment After Introduction of Open Vial Policy in Surat Municipal Corporation Area of India. *Int J Health Policy Manag*. 2015 Dec 8;5(4):233–6.
14. Duttagupta C, Bhattacharyya D, Narayanan P, Pattanshetty SM. Vaccine wastage at the level of service delivery: a cross-sectional study. *Public Health*. 2017 Jul;148:63–5.
15. Guichard S, Hymbaugh K, Burkholder B, Diorditsa S, Navarro C, Ahmed S, et al. Vaccine wastage in Bangladesh. *Vaccine*. 2010 Jan;28(3):858–63.
16. Usuf E, Mackenzie G, Ceesay L, Sowe D, Kampmann B, Roca A. Vaccine wastage in The Gambia: a prospective observational study. *BMC Public Health* [Internet]. 2018 Dec [cited 2019 May 29];18(1). Available from: <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-018-5762-5>
17. Wallace AS, Willis F, Nwaze E, Dieng B, Sipilanyambe N, Daniels D, et al. Vaccine wastage in Nigeria: An assessment of wastage rates and related vaccinator knowledge, attitudes and practices. *Vaccine*. 2017 Dec;35(48):6751–8.
18. Heaton A, Krudwig K, Lorenson T, Burgess C, Cunningham A, Steinglass R. Doses per vaccine vial container: An understated and underestimated driver of performance that needs more evidence. *Vaccine*. 2017 Apr;35(17):2272–8.
19. Yang W, Parisi M, Lahue BJ, Uddin MdJ, Bishai D. The budget impact of controlling wastage with smaller vials: A data driven model of session sizes in Bangladesh, India (Uttar Pradesh), Mozambique, and Uganda. *Vaccine*. 2014 Nov;32(49):6643–8.

Figures

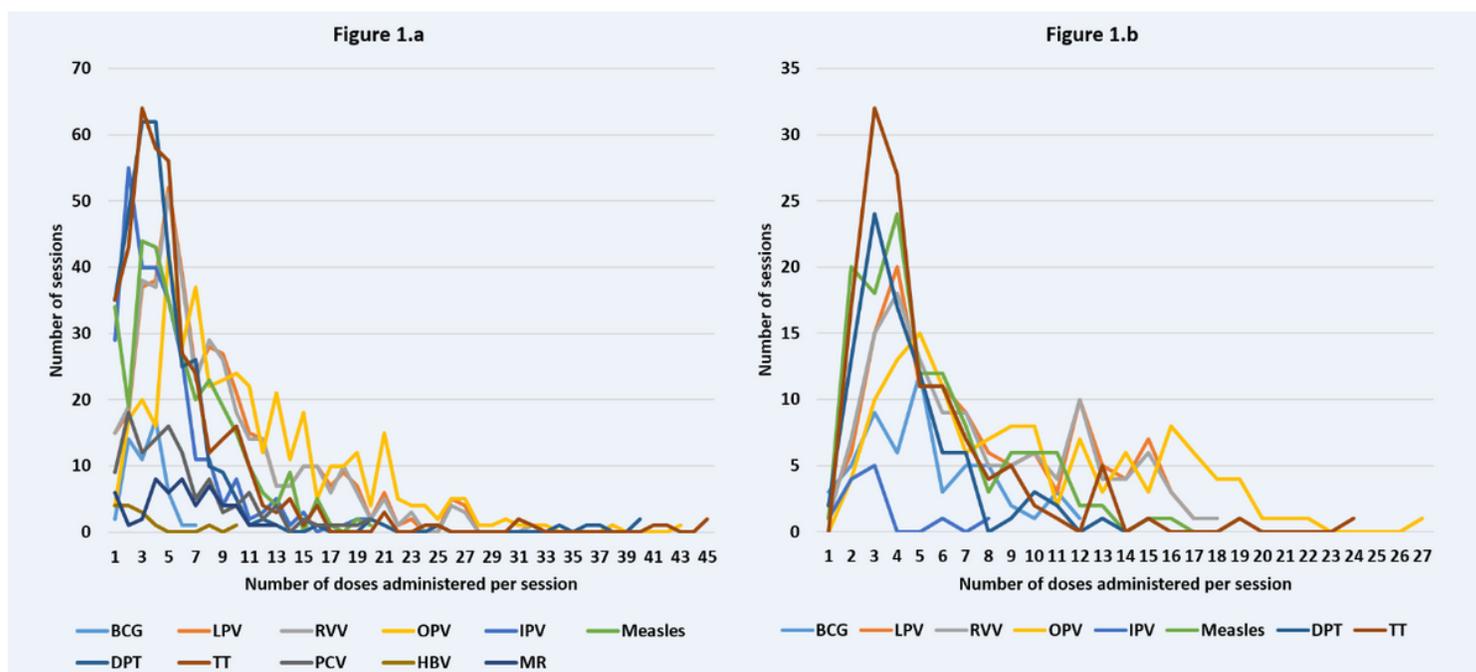


Figure 1

Number of vaccination sessions by the number of doses administered per session 1.a- Vaccine doses administered during sessions in Kangra district 1.b- Vaccine doses administered during sessions in Pune district