

Can reduction in vaccine wastage spare financial resources for introduction of new and expensive vaccines?

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Abstract: Communicable diseases are placing high economic burden on poorer countries like India. Most of these diseases can be prevented through universal coverage of vaccination. Most of the nations are striving hard to cover all the populations but in spite of the efforts in implementation of the programmes for decades, the coverage is unsatisfactory. Gross variations in coverage are observed across population groups, and geographies. Most of the vulnerable groups are under covered due to various reasons. Some of the reasons for low coverage are inadequate resources and improper allocation of budget for health sector. Mismanagement of allotted budget is another area.

Though Immunization is a cost effective programme, universal coverage is of high burden nature to the nation. Presently, the nations are facing difficulty in allocation of required budget for the preventive programs like Immunization. The alternative approach to avoid burden is optimum utilization of allocated budget and minimising of wastage of resources.

A study has been undertaken in this connection to identify the area of wastage in three districts of Uttar Pradesh. In the present study, gross wastage was observed for various vaccines. A mean wastage of vaccines ranging from 28-50% for various vaccines was observed in the study due to various reasons.

Keywords: Wastage, Vaccines, VPD, Misuse.

1. Introduction

Background:

India's Universal Immunization Program (UIP) targeting approximately 27 million infants and 30 million pregnant women each year have made a significant impact on the burden of Vaccine Preventable Diseases (VPD) and have directly contributed to reduction in child mortality in the country. All the vaccines that are being provided to children and pregnant women through government's primary health care system are free of cost and have significant financial implication on the overall national health budget.

Among 194 member countries of World Health Organization (WHO), India was one of the 66 countries where 100% expenditure on Routine Immunization (RI) was financed by government funds in the year 2012 ^[1]. In the National Health Budget for year 2011-12 an amount of Rs. 17840 Crores was approved for implementation of various schemes and programs envisaged under National Rural Health Mission

(NRHM) including Rs. 343.17 Crores for RI program ^[2]. According to WHO estimates, out of this total immunization budget approximately Rs. 280 Crores (81.6% of immunization budget) were incurred on procurement of RI vaccines during year 2012 ^[1].

In immunization program, the number of vaccine doses used is always higher than the number of beneficiaries actually immunized ^[3]. This excess number of doses which remain unutilized contributes to wastage of vaccines at the service delivery level. Reasons for vaccine wastage may be classified into two broad groups: (1) wastage in opened vials due to practice of discarding remaining doses in opened vials at the end of immunization session, and (2) wastage in unopened vials due to cold chain maintenance related factors (e.g. Vaccine Vial Monitor (VVM) at discard point, frozen DPT, TT or Hepatitis B vaccine vials), breakage during transportation and handling or expired vaccine batches. The Ministry of Health and Family Welfare (MOHFW), Government of India recommends that wastage rate of all vaccines should not be higher than 25% (i.e. wastage multiplication factor of 1.33) ^[5]. The indicative vaccine wastage rates that could be used for estimation of vaccines as per World Health Organization is

50% (10-20 dose vials) and 10% (2-6 dose vials) for lyophilized vaccines and 25% (10-20 dose vials) and 10% (2-6 dose vials) for liquid vaccines [6].

Effective vaccine utilization is an integral component of vaccine security, and vaccine wastage is one of the key factors to be considered with regards to vaccine forecasting and need estimation [4]. However, systematic reviews for assessing vaccine wastage trends in primary health care service delivery settings and its financial implications in the country so as to guide policy makers and program managers are lacking.

Assessment of vaccine wastage in 3 districts of Uttar Pradesh, India:

The present review was undertaken as part of technical support provided by Maternal and Child Health Integrated Program (MCHIP) funded by United States Agency for International Development (USAID) for strengthening immunization programme in three focus districts of Uttar Pradesh viz. Banda, Gonda and Varanasi. The objective was to assess the actual wastage rate of vaccines included in the National Immunization Schedule through retrospective analysis of administrative records and reports, and recommend measures for building efficient mechanisms for reducing vaccine wastage and streamlining vaccine management practices.

Data for receipt, distribution and consumption of four primary infant vaccines (i.e. BCG, DPT, trivalent OPV (or tOPV) and Measles) was collected following informed consent from respective facility in charges. For each of these vaccines the number of doses for calculation of target infants was taken according to the National Immunization Schedule. Thus for BCG vaccine (lyophilized vaccine with ten doses per vial) single injectable dose, for DPT vaccine (liquid vaccine with ten doses per vial) three primary and two booster doses i.e. total five injectable doses, for trivalent OPV vaccine (liquid vaccine with 20 doses per vial) one birth dose, three primary doses and one booster dose i.e. total five oral doses and for Measles vaccine (lyophilized vaccine with five doses per vial) single injectable dose were considered for making calculations.

The retrospective review of administrative records and reports was done for the period from April 2011 to March 2013 (two complete reporting years) at 32 Community Health Centres (CHC) and Primary Health Centres (PHC) of three focus districts having cold chain facilities for vaccine storage. The information collected was amount of vaccine received and distributed every month from vaccine stock book and month-wise coverage achieved from monthly progress reports. The data was compiled in MS Excel and vaccine wastage rates for each of the four individual vaccines were calculated month/quarter wise, district wise as well as combined for all three districts. Standard formula recommended by WHO was utilized for calculating the vaccine wastage rates [7].

$\text{Vaccine usage rate} = \frac{\text{No. of doses administered}}{\text{No. of doses consumed}} \times 100$
$\text{Vaccine wastage (\%)} = 100 - \text{Vaccine usage (\%)}$

Here, number of doses “administered” are those which were used for vaccinating beneficiaries and doses “consumed” includes doses administered, as well as doses discarded at the

end of session or rejected for any other reason including expiry, VVM at discard point, cold chain failure, freezing and missing inventory.

2. Observations:

It was revealed that overall all four vaccines included for the assessment had high vaccine wastage rates in all three districts as compared to the allowable rates as recommended both by MOHFW and WHO (Table 1). Cumulative data from three districts shows highest wastage rate for BCG vaccine (64.9% in 2011-12 and 67.4% in 2012-13), followed by Measles (47.7% in 2011-12 and 51.1% in 2012-13) – both lyophilized single dose injectable vaccines. Wastage rates were also observed to be high for tOPV (43.6% in 2011-12 and 51.2% in 2012-13) and DPT (26.9% in 2011-12 and 29.4% in 2012-13). However no significant difference was observed in wastage rates of these four vaccines among the three districts when year wise compiled data was analyzed.

Table-1 District & Year wise Vaccine wastage Rates

District	Year	BCG (%)	DPT (%)	tOPV (%)	Measles (%)
Banda	2011-12	66.9	33.1	48.9	47.1
	2012-13	64.1	34.2	47.1	54.1
Gonda	2011-12	61	21	41.2	43.9
	2012-13	66.7	22.2	47.6	45.1
Varanasi	2011-12	68.4	30.6	43.3	53
	2012-13	70.3	35.6	57.4	58
Total	2011-12	64.9	26.9	43.6	47.7
	2012-13	67.4	29.4	51.2	51.1

Month wise analysis was done to find the range of variation in the wastage rates and any month wise trend when wastage rates are high or low (Table 2).

Table-2 Month wise wastage rates cumulative for 3 districts

Period-2011-12	BCG (%)	DPT (%)	tOPV (%)	Mesles (%)
April	64.4	28.9	41.0	49.1
May	73.4	36.1	56.3	52.7
June	76.3	46.1	63.2	54.1
July	70.9	36.2	51.6	45.7

August	68.6	35.4	43.8	52.1
September	61.5	30.9	39.4	47.2
October	62.7	27.1	41.2	52.7
November	56.2	29.2	45.9	52.2
December	57.0	22.6	42.7	53.0
January	58.0	7.0	26.5	29.9
February	59.7	13.2	31.2	46.3
2012-13	62.7	21.3	37.7	46.6
March	58.8	23.8	44.2	46.2
April	66.8	25.6	59.1	50.2
May	66.8	32.1	52.8	48.7
June	70.3	33.5	59.3	49.7
July	71.4	40.5	57.1	55.4
August	69.5	35.5	56.3	55.3
September	69.4	36.3	55.6	51.4
October	64.5	31.8	44.3	56.0
November	62.5	22.4	38.0	45.9
December	61.7	22.0	40.7	49.8
January	72.1	25.9	43.0	55.8
February	64.3	11.0	46.1	45.3
Range	7.0% - 46.1%	26.5% - 63.2%	29.9% - 56.0%	29.9% - 56.0%
Mean	28.1%	46.5%	49.6%	49.6%
Median	29.1%	44.2%	50.0%	50.0%

Overall when all four vaccines were considered it was observed that wastage rates are of lower magnitude towards the end of reporting year i.e. between January and March for both reporting years. Range of wastage rates for different vaccines was also different and did not revealed any specific trend. For BCG vaccine the range was from 56.2% to 76.3%, for DPT vaccine range was from as low as 7% to 46.1%, for tOPV rates ranged from 26.5% to 63.2% and for Measles vaccine it was from 29.9% to 56%.

3. Implications:

An assessment of vaccine wastage in India, conducted in 2009 revealed that wastage rate depended on formulation, presentation and was inversely proportional to session size¹.

¹ National Vaccine Policy , Ministry of Health and Family Welfare, Government of India, April 2011, page 24

The combined data for DPT usage for the three districts show minimum wastage of 8.6% during certain month and as high as 42% during another month. This is indicative of mobilization factor at the immunization session sites. As per the guidelines vaccine vial has to be opened even if one beneficiary approaches for vaccination. Therefore in case of poor mobilization or when the location or time of session is not appropriate for the community the turnout of beneficiaries would be less leading to higher wastage.

BCG and Measles are lyophilized vaccines which have to be constituted by adding diluent provided along with them. These vaccines as per the national guidelines have to be discarded after four hours of reconstitution. So in case if adequate number of beneficiaries does not approach the session site many doses will have to be discarded. This is one important reason for higher wastage rate of these vaccines. Even the minimum wastage rate for these vaccines (as per the range) is very high as compared to recommended wastage rate.

OPV vaccine is supplied in 20 dose vial and any opened vial has to be discarded at end of session even if there are remaining doses in the vial. Therefore when the wastage rate of OPV is compared to that of DPT (which comes in 10 dose vials and all its primary doses and one booster dose are to be given along with OPV vaccine) it is evident that if number of doses in OPV vial is equal to that of DPT, significant reduction can be brought into its wastage.

There are instances when wastage rate is very less and in some case even negative. This indicates towards the correctness of recorded and reported data. Higher wastage can also result from poor planning of immunization sessions in terms of injection load. Properly planned sessions at appropriate time and locations can bring more beneficiaries leading to reduction in wastage rates. Some studies done to assess wastage of individual vaccines are as follows:

Mukherjee *et al* while assessing vaccine wastage during Pulse Polio Immunization Program in India found that at the point of administration wastage of Oral Polio Vaccine (OPV) was 14.5% with wastage factor of 1.17².

Palanivel *et al* conducted a study on vaccine wastage in primary care setting in urban India and found that wastage rate was highest for BCG (70.9%), followed by TT (62.8%), DT (57.3%), OPV (48.1%), Measles (39.9%), DPT (38.6%) and MMR (37.5%)³.

Another study conducted in Bangladesh by Guichard *et al* revealed that average vaccine wastage rates were highest for BCG (84.9%, range 55-93%), followed by measles vaccine

² Ajit Mukherjee, Tej Pal Ahluwalia, Laxmi Narayan Gaur, Rakesh Mittal, Indira Kambo, Nirakar Chandra Saxena, and Padam Singh. Assessment of Vaccine Wastage during a Pulse Polio Immunization Programme in India. J HEALTH POPUL NUTR 2004 Mar; 22(1):13-18.

³ Palanivel C, Kulkarni V, Kalaiselvi S, Baridalyne N. Vaccine wastage assessment in a primary care setting in urban India. Journal of Pediatric Sciences. 2012;4(1):e119

(69.7%, range 28-86%), DPT (44.4%, range 16-77%) and TT (35.5%, range 10-73%)⁴.

4. Conclusion:

To build upon the existing evidence on vaccine wastage, the present review is a small reiteration of the problem prescribing rather simplistic solutions to a complex problem. The focus during this review was to determine vaccine wastage rates through administrative immunization reports, and how proper recording and reporting practices may strengthen overall program management.

During the last decade there have been conscious efforts at the policy level which acknowledge the weak systems of vaccine and logistics management. India's comprehensive Multi Year Strategic Plan (2005-2010) strategizes to strengthen coordination activities to reduce vaccine wastage and implement open vial policy.

with the objective to ensure an efficient vaccine and logistics management system⁵.

Vaccine wastage is an expected component of any immunization program. In India since a large proportion of service delivery is through outreach, a high vaccine wastage rate is acceptable if the immunization coverage is high. However, this should be balanced with optimal wastage, safety concerns, and timely use of vaccines. Vaccine wastage can be minimized by determining avoidable causes of loss of vaccine and taking timely corrective action

Information collected has also been organized in a manner to analyze trend of vaccine wastage against coverage of different vaccines. This review is not intended to be statistically representative, and looks into both program-related and process-related aspects underlying wastage of vaccines.

5. Recommendations:

Some level of vaccine wastage is unavoidable and looking into wastage rates seen in isolation may not lead to reasonable conclusions on the wastage rates as being high, low or rather being justified. For countries like India where a large proportion of the population is reached through outreach immunizations sessions it is important to monitor vaccine wastage rates with immunization coverage rates at all service delivery points for ensuring timely corrective actions in terms of estimation and forecasting of vaccine needs. Irrational estimation without looking into the coverage and consumption may lead to frequent shortages and over stocking of different vaccines.

Data quality audit should be conducted at health facilities at periodic intervals to ensure data quality and accuracy in the government administrative immunization reporting systems. Setting up of district level immunization cell

⁴ Guichard S, Hymbaugh K, Burkholder B, Diorditsa S, Navarro C, Ahmed S, Rahman MM. Vaccine wastage in Bangladesh. *Vaccine*. 2010 Jan 8; 28(3):858-63. Epub 2009 Aug 27.

⁵ Multi Year Strategic Plan (2005-2010) – Universal Immunization Program, Department of Family Welfare, Ministry of Health and Family Welfare, Government of India, January 2005

for collecting coverage and vaccine utilization data may help to closely monitor and support in program implementation at different levels. Similarly monitoring of data at national and state levels also needs strengthening.

Gap in documentation and correct recording reporting practices indicates towards regular capacity building of staff members for effective data management. For instance in this review the data on unavoidable and avoidable vaccine wastage was not available at any level, which otherwise could have indicated towards specific system or program related aspects, further facilitating local planning and/or national and state policy.

In India like setting with large number of service delivery points there is demanding need to establish technology based solution like internet based reporting and vaccine logistics management system, which will not only facilitate analysis of reports but also ensure timely availability of vaccines and other critical logistics.

Taking a broader agenda, vaccine wastage monitoring should not only be seen with perspective to strengthen vaccine logistics management, rather it may also help in diagnosis of other existing but hidden problems in program management, microplanning, cold chain management, validity of reporting etc.

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Author's Profile:

First Author

- Working as a Professor and Head, Department of Community Medicine, Malla Reddy Medical College for Women, Suraram Hyderabad.
- Worked in the Public health field for more than 38 years
- Has more than 20 years of teaching experience

- Worked with WHO India in Polio eradication program
- Acquired a Diploma in Advanced Vaccinology from Annecy France.
- Participated and contributed to many community based surveys.
- Participated in five Maternal and Neonatal elimination validation programs (4 in India and one in Indonesia as a Global Associate from WHO)
- Participated in American Public Health Association conference in Boston in 2007 and presented a paper on Supportive Supervision
- Presented papers in National and International conferences

Second Author:

- Working as Professor in Dept. of Social and Preventive Medicine in Malla Reddy Medical College for Women ,Hyderabad
- Experience of 37 years of teaching for both UG and PG students
- Is a internal and External examiner for PG and UG students
- Participated in public health projects in HIV /AIDS, Safe Injection practices and UIP

Third Author :

- Working with John Snow India as Team Leader (Strategic Planning) for BMGF support Uttar Pradesh Technical Support Project, based at Lucknow.
- A Medical Doctor and Public Health Graduate with over 14 years of experience and wide exposure of working with government health department, development partners, and bilateral and non-governmental agencies in different health settings.
- Completed MBBS in in 1997 and obtained Doctor of Medicine (MD) in Social and Preventive Medicine in 2003. Also completed Masters Course (MBA) in Operations Management and Human Resource Management (2010) and Diploma course in Computer Application (DCA).
- Worked at progressively responsible positions for different public health programs – as State Representative of Uttar Pradesh with USAID supported Maternal and Child Health Integrated Program (MCHIP) and IMMUNIZATIONbasics project. Prior to this served as Field Research Manager (Population Council supported research project, 2003), Technical Officer Immunization (UNICEF, 2004), and District & State Routine Immunization Officer (WHO/National Polio Surveillance Project, 2005-06).

- Participated in many research activities organized by national government and organizations like WHO, UNICEF and IPEN with different capacities; and has authored more than 15 scientific articles and abstracts published in various national and international journals.
- Contributed to Government and various bilateral agencies in development of training modules, standard guidelines for planning, implementation and supervision of immunization program, and in development of various computer based tools and pictorial job-aides.

Fourth Author:

- Working as Professor in Dept. of Social and Preventive Medicine in Malla Reddy Medical College for Women, Hyderabad.
- Completed 20 years of teaching experience in Govt Medical Colleges
- Acquired Diploma in Community Eye Health from London School of tropical medicine and hygiene, London, UK
- President of Community Ophthalmologist Association, India
- Member of All India association of SPM
- Participated in many community surveys as Principal investigator
- Participated in Rapid Assessment of Avoidable Blindness survey conducted by Govt. of India
- Conducted health camps in 108 villages as part of study conducted to collect baseline data around Uraium Project located at Tummalapalli Village of Kadapa district of AP with financial assistant of GOI
- A Demographic study conducted among the population of villages surrounding Uranium Project located at Tummalapalli village of Kadapa, AP with financial assistance from BARC, Mumbai & GOI.
- Two Scientific papers were presented for the 18th National Symposium on Environment conducted in December 2013 organized by JNTUA, Anantapur, AP & BARC, Mumbai
- Involved in academic activities for UG and PG students
- Assisting in PG dissertation work

Presented papers in State, Zonal CME programmes, state, national and international conferences