Original Article

"Closing Gaps in Routine Immunization – Impact and Cost Assessment on components of New Vaccine Policy in Routine Immunization in Gujarat, India"

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ABSTRACT

Introduction: Introduction of new vaccine supply management policies such as Open Vial Policy and 2nd dose of measles vaccine; vaccine wastage is expected to decrease. Over the period, increase the service utilization with above mentioned policies led to decrease its cost globally and having an uninterrupted supply chain across the country.

Objectives: To estimate vaccine wastage rate and wastage factor at distribution level and to provide Cost Assessment on effect of Open Vial Policy implementation, introduction of Pentavalent and 2nd dose of measles at distribution level.

Methodology: A record based descriptive cross sectional study involving vaccine usage and children immunized at 92 PHCs. Cost Analysis was done on money saved after introduction of new vaccine policy interventions.

Results: Highest Vaccine wastage was seen in OPV and least in Pentavalent. There was significant difference between Vaccine Multiplication Factor for vaccines Pentavalent, OPV and TT in the present study. There was significant difference between Vaccine Multiplication Factor for vaccines Measles vaccine after introduction of 2nd dose ($p < 0.001$). After vaccine policy interventions; one PHC was able to save cumulative of INR 257.54.

Conclusion: In Gujarat, there are specific bottlenecks for higher wastage rate and wastage factor had been observed. In recent era, in absence of national or local valid data of vaccine wastage rate, it is crucial for the stakeholders and programme managers to monitor the vaccine supply and its logistic management. Use of appropriate technology into the logistics management like eVIN will support the program with quality of service delivery.

Key words: Vaccine Wastage, UIP, Cost Analysis, Primary Health Care

INTRODUCTION

India has one of the largest Universal Immunization Programs (UIP) in the world. The program budgets more than USD 500 million every year for immunizing children against vaccine preventable diseases, including the polio eradication program and recently done measles catch up campaign.[1] India is focusing on many strategies to expand immunization coverage and so the service coverage. 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. The previous immunization policy had also stated that all vaccine vials opened for an immunization session had to be discarded at the end of that session, irrespective of the type of vaccine or the number of residual doses in the vial. Later as per the revised open vial policy (OVP), multi-dose vials of oral polio vaccine (OPV), Diphtheria, pertussis and tetanus toxoid vaccine (DPT), tetanus toxoid (TT), diphtheria and tetanus toxoid (DT), pentavalent, hepatitis B virus (HBV) and liquid formulations of Haemophilus influenzae type b (Hib) vaccines from which one or more doses have been removed during an immunization session could be used in successive sessions for a maximum of 4 weeks, provided that all of the World Health Organization (WHO) requirements for effectiveness and temperature stability were met. [2] The WHO

reports that over 50% of vaccines are wasted globally [3].

To reduce Vaccine wastage, stake holders need to utilize the optimum cold chain space, , alternate vaccine delivery plans and well prepared Village Health and Nutrition Day (outreach activity) micro plans to cover all beneficiaries. These efforts are being challenged by problems of securing quality and quantity of vaccine at the PHC level and dissemination of guidelines at the sub center level. In absence of national or local valid data of vaccine wastage rate, it is crucial for the stakeholders and program managers to monitor the vaccine supply and its logistic management. 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 most important Open Vial Policy, vaccine wastage is expected to decrease. Government of Gujarat introduced the pentavalent vaccine in UIP in January 2013, measles 2nd dose in May 2013 and OVP for multi-dose vials was made available from April, 2013 in Gujarat. [4]

OBJECTIVES OF THE ASSESSMENT

1. To estimate vaccine wastage rate and wastage factor at distribution level for the better management of vaccine logistics and its supply chain for the vaccine used in universal immunization program at the primary health care center level.
2. To provide assessment on cost effect of new Vaccine Vial Policy implementation at primary health care center level based on their vaccine wastage rate and vaccine wastage factor

MATERIAL AND METHODS

Study Design: The Study had been conducted in South Gujarat Region covering the 5 districts of the Surat region. The Study was record based descriptive analytical study to estimate the vaccine wastage rate and the vaccine multiplier factor for the vaccine used in immunization sessions under universal immunization programmes at the primary health care level center. Sample Method and Size: Simple Random Sampling was the sampling method and sample size was calculated based on formula of $N = Z^2_{1-\alpha/2}P(1-P)/\varepsilon^2$ This comes 79 PHCs out of 434 PHCs of Surat Region of Gujarat. During study 15% sample wastage were considered and 92 PHCs were taken for the study. Study Subjects: The study had sampled 92 Primary Health Centers from the 5 districts which conducts regular immunization sessions at the outreach sites on the designated days of the week as a form of Village Health and Nutrition Day (VHND) and at facilities at Mamta Clinics.

Data Collection: The data was collected from the PHC level based on monthly vaccine stocks which includes its consumption, wastage and remaining balance during immunization sessions at outreach and at facility level. Here‘ vaccine consumptions in a session’ imply the number of doses issued and not returned back. The data on immunized children for the each vaccine had been collected from their HMIS reports of form no 6 & 7 from the PHC levels. In January 2013, introduction of pentavalent replaced both DPT and HBV in newly registered children. Those children who had already received one or more doses of DPT were continued on same vaccine including booster dose as per guidelines. In April 2013, measles 2nd dose was included in UIP. So these two new vaccine policy interventions were taken. The data collection was carried out for the vaccination reports of cumulative data of 3 months (Jan to March 2013) before and3 months (April-June 2013) after of vaccine policy related new interventions. Data validation was done by triangulation of reports; namely monthly RCH grading reports, monthly VHND reports, monthly HMIS reports and field verification during VHND sessions.

Data Analysis: The data analysis was carried out in two sets; contained data before and after of New Vaccine Vial Policy implementation. The study had calculated the vaccine wastage rate and vaccine wastage factor from the following formulas. Proportion of wasted dosesfrom total consumed doses was considered as vaccine WR. Vaccine wastage factor (WF) was calculated by using the formula [100/(100-Vaccine WR)] [5]

After calculation of vaccine wastage rate and factor, cost of each vaccine was taken from the previous study. [1,6] Data was analyzed on the cost effect perspective. The data was analyzed in Microsoft Excel 2007 and SPSS Ver. 17.

RESULTS

During the study period, 14126 vials were used and the total 94314 children were immunized in study areas with facility level and outreach sessions conducted through health workers. Here, in present study, universal routine immunization, vaccine wastage rate and vaccine multiplication factor (VMF) was found higher than ideal 25% of total vaccine wastage and 1.33 VMF which we are taking in micro plan for Mamta Sessions of the sub center (Table-1). As per figure -2 showed highest vaccine wastage was seen in 20 dose vial of OPV vaccine

and least in pentavalent because of adequate supply, 10 dose vial and simultaneous 3 doses to immunized child. There was considerable reduction in vaccine wastage rate in measles vaccine after introduction of 2nd dose at the same study period.

Table 1: Data of Vaccine doses and children immunized before and after New Vaccine Policy Interventions across 92 Primary Health Centers

Before New Vaccine Policy Interventions					
Vial of a Vaccine	OPV	Pentavalent	DPT	Measles	TT
No. of doses used	26540	4790	20340	8995	23030
No. of children given vaccine	13271	2498	11662	3364	13361
% Coverage	50.0	52.2	57.3	37.4	58.0
After New Vaccine Policy Interventions					
Vial of a Vaccine	OPV	Pentavalent	DPT	Measles	TT
No. of doses used	29100	14880	10600	10350	16630
No. of children given vaccine	16724	10311	6269	6171	10683
% Coverage	57.5	69.3	59.1	59.6	64.2

Table 2: Association between Vaccine Wastage Factor for vaccines across 92 Primary Health Centers

Name of Vaccine	Vaccine Wastage Factor		t test value	P values
	Before Vaccine Policy Interventions	After Vaccine Policy Interventions		
OPV	2	1.74	3.317	< 0.0001
Penta.	2.1	1.44	5.638	< 0.0001
DPT	1.74	1.69	1.057	= 0.293
Measles	2.67	1.68	6.795	< 0.0001
TT	1.72	1.56	3.742	< 0.0001

Table 3: Partial Cost Assessment of Vaccine Wastage for new Vaccine Policy

Vaccine	Actual cost per dose (INR)	Average doses used before OVP and Measles 2nd	Average doses used after OVP and Measles 2nd	No. of doses saved.	*INR
OPV	3.6	10	12	2	7.2
Penta.	120	5	7	2	240
DPT	1.68	6	6	0	0
MCV	9.09	2	3	1	9.09
TT	1.25	5	6	1	1.25

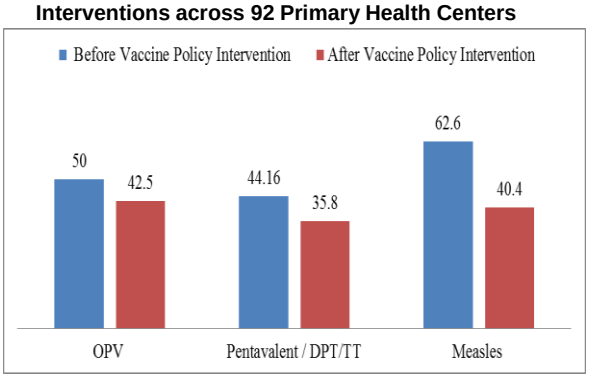
Table-2 showed that there was significant difference between Vaccine Wastage Factor for vaccines of OPV and TT, where for OPV t-test value 3.317 and p value $p < 0.0001$ and for TT vaccine t-test value 3.742, $p < 0.001$. For Pentavalent Vaccine, t-test value 5.638, p value < 0.0001. There was no significant difference between Vaccine Wastage Factor for vaccine DPT in the present study, for DPT vaccine. (T-test value 1.057, $p = 0.293$). There was significant difference between Vaccine Wastage Factor for vaccines Measles vaccine after introduction of 2nd dose. (T- test value 6.795, $p< 0.001$.) The cost of each vaccine was analyzed in direction of before and after implementation of Open Vial Policy and introduction of measles 2nd dose. These finding showed that for each vial of OPV and Pentavalent 2 doses were saved and for measles and TT vials; 1 dose of vaccine was saved due to these vaccine policy interventions.

Interventions across 92 Primary Health Centers

Table- 3 shows the effect of implementation of new vaccine policy interventions on the cost perspectives. The OPV, Pentavalent, DPT, Measles and TT vaccines' vial have total approximate cost of INR 1346.75. INR 576.24 was wasted before and Rs. 358.7 after vaccine policy interventions. So the study revealed that average money saved per vial because of new vaccine policy interventions was INR 257.54. As per finding, taking into conversion for approximate 13,00,000 live births of Gujarat as

per HMIS (2013-14); estimated INR 252.43 lakhs could have been saved for full immunization of a child.

Figure 1: Comparison of vaccine wastage rate of each vaccine before and after New Vaccine Policy Interventions across 92 Primary Health Centers



DISCUSSION

The World Health Organization has also projected vaccine wastage rate in order to help in calculating vaccine needs.[7]According to the WHO, projected vaccine wastage rate for lyophilized vaccines is expected to be 50% wastage rate for 10-20 dose vials, and for liquid vaccines 25% wastage rate for 10-20 dose vials.[8] The Ministry of Health and Family Welfare, Government of India has recommended that wastage rate of all vaccines is should not be higher than 25% (Wastage factor of 1.33). The study revealed that health facilities had higher side of vaccine wastage at service delivery level which was same findings in previous study [1,9,10] In present study areas; the reasons could be unequal distribution of vaccines from region to the districts and vaccine distribution was not monitored at session site resulted in high wastage rate. Earlier studies done in same areas showed less vaccine wastage rate. The reason could be limited data collection points compared to present study.[11] In absence of national or local valid data of vaccine wastage rate, it is crucial for the stakeholders and programme managers to monitor the vaccine supply and its logistic management and develop session's micro plan with realistic vaccine requirement by calculation of wastage factor. During study it was observed that inadequate and unplanned utilization of alternate vaccine delivery strategy in UIP across data collection points. At all levels Vaccine Vial Monitors still plays a crucial role in UIP implementation across the State. The study did not include the wastage rate above the supply chain level which was a limitation. No comprehensive study has been done in India to validate the wastage rate recommended by WHO and Ministry of Health and Family Welfare. Usually, the wastage rates are low for liquid vaccines in comparison of lyophilized ones. In this study, wastage rates of liquid vaccines were almost similar to lyophilized ones. The reason can be understood by the number of doses used were more in numbers compared to lyophilized vaccines.

Vaccine supply is core activity borne by Government to implement immunization universally. Effective Vaccine Management requires holistic approach which includes timely repairing of ILR and DF, review of vaccine stock and wastage, strong supportive supervision and sensitization of new vaccine policy interventions at each level. Recent development of Electronic Vaccine Intelligent Network (eVIN) will help in vaccine management at larger scale. Vaccine Intelligence Network (eVIN), which is comprised of trained Vaccine and Cold Chain Managers (VCCMs), integrated into a supportive supervision approach, user-friendly appropriate technology. eVIN has been adopted by the Ministry of Health, Government of India for the National Immunization Programme.[12]

CONCLUSION

This coverage and cost assessment study suggested that high vaccine wastage translates into less coverage of immunized children and more expenditure for vaccine supply. These new vaccine policy interventions increase cost effectiveness and increase in effective immunization coverage against vaccine preventable diseases. This study helped the program managers to identify the factors behind vaccine wastage and to prepare directions for strengthening of UIP across the Region.

LIMITATION

The study was conducted in 5 districts areas at distribution level; not supply chain level as described. The sampling frame included only Primary Health centers; as outreach VHND sessions gets vaccine supply from the Primary Health Centers; a vaccine distribution centers in Gujarat. The change in vaccine efficacy due to Open Vial Policy needs to be evaluated separately.

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