

Research Article

Determinants of BCG Vaccine Wastage: An Effort towards Vaccine Security

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A B S T R A C T

Introduction: This study attempts to calculate vaccine wastage rates in a district setting and to identify the factors influencing wastage at facilities, which could then lead to appropriate guidance and training to reduce vaccine wastage

Methodology: A Cross sectional study was carried out among the Health Centres of Hassan District. We selected 1 district hospital, 3 taluk Hospitals, 6 Community Health Centres and 32 Primary Health Centres across the district. Centres were visited and data was collected through record review and interview from the staff on a predesigned proforma.

Result: BCG vaccine is administered in all the centres of the District Health System as per the national immunization schedule. At the district level, 40 thousand doses each of 0.1ml of BCG vaccine were procured and 20 thousand beneficiaries vaccinated. At the District hospitals where deliveries were 20 to 40 per day yearly 20000 doses of 0.1ml were availed, 9-10 doses were used in a vial resulting in 50% wastage. In the Taluka Hospitals where deliveries were 5 to 10 per day, 5-6 doses were used in a vial resulting in 75% wastage. In the Community Health centres and PHC where less than 1-2 deliveries happen a day 1 to 2 doses were used results in wastage of 90 - 95%.

Conclusion: The wastage was high because the dose procured, supplied and used were large (0.1ml). In all the centres usage of 0.05ml could increase the safety associated with vaccine and reduce the wastage.

Keywords: UIP, BCG Vaccine, Vaccine Wastage, District Health System

Introduction

In countries with a high incidence of TB and/ or high leprosy burden, a single dose of BCG vaccine should be given to all healthy neonates at birth,¹ for prevention of TB and leprosy.^{2,3} BCG vaccines are among the oldest vaccines and were first used in humans in 1921. BCG is a live attenuated bacterial vaccine derived from *M. bovis* that

was originally isolated in 1902 from a tuberculous cow.⁴ To standardization of BCG vaccines, a lyophilized seed lot system was introduced by the WHO in 1956. Reconstituted vaccine contains both living and dead bacilli. The number of cultivable bacilli per dose and the biochemical composition of the vaccine may vary depending on the strain and vaccine production method. WHO has published recommendations

to assure the quality, safety and efficacy of BCG vaccines.⁵

BCG vaccines are usually administered by intradermal injection. Percutaneous administration using a multi-puncture device is licenced for some products. The available live attenuated vaccines are safe and effective, particularly to prevent the most severe forms of TB such as childhood TB meningitis and military TB disease and provide protection against leprosy.

Among those vaccinated as neonates, protection against Pulmonary Tuberculosis (PTB) was 59% (Relative Risk 0.41, 95% CI: 0.29-0.58). In studies where BCG was given in childhood and with stringent TST screening, protection against PTB was 74% (RR 0.26, 95% CI: 0.18-0.37).⁶ A systematic review concluded that protection after primary infant BCG vaccination could last for up to 15 years in some populations.⁷

Correct vaccine administration technique by a trained health worker is important to ensure correct dosage and optimal BCG vaccine efficacy and safety. Correct intradermal administration can be verified by bleb formation. BCG vaccination usually causes a scar at the site of injection due to local inflammatory processes. However, scar formation is not a marker for protection and approximately 10% of vaccine recipients do not develop a scar.^{8,9}

As reconstituted BCG vaccine does not contain a preservative, all opened multi-dose vials must be discarded at the end of the immunization session, or within 6 hours, whichever comes first. The Universal Immunization Programme recommends standard dose of BCG vaccine is 0.05 mL of the reconstituted vaccine for infants aged <1 month and 0.1 mL for those aged >1 month.¹⁰ BCG vaccines must be administered by intradermal injection in a clean healthy area of skin. The vaccine should be given preferably in the lateral aspect of the upper arm. The Ministry of Health and Family Welfare, Government of India has recommended that wastage rate of BCG vaccine could be maximum of 50%.⁶ Reasons for wastage are due to discarding the remaining doses at the end of session (open vial wastage), not being able to withdraw the number of doses indicated in the label of the vial, poor reconstitution practices, suspected contamination and expiry, VVM (Vaccine Vial Monitor) indication, breakage and missing inventory.

In the context of India, any reduction of vaccine wastage will have a positive impact on the ongoing efforts towards vaccine security. Hence, this study attempts to calculate vaccine wastage rates in a district setting and to identify the factors influencing wastage at different types of facility, which could then lead to appropriate guidance and trainings to reduce vaccine wastage.

Methodology

A Cross sectional study was carried out among the Health Centres of Hassan District to calculate the vaccine wastage

and to assess the knowledge, attitude and practice of BCG vaccination among vaccinators. Hassan District has One District Hospital, 7 Taluks Hospitals, 15 Community Health Centres and 134 Primary Health Centres. The number of centres to be included was calculated using a sample size calculator at 80% Confidence Interval using the Sample size formula of $n = [DEFF * Np(1-p)] / [(d^2 / Z^2_{1-\alpha/2} * (N-1) + p * (1-p))]$, the calculated number was 42. We selected 1 district hospital, 3 taluk Hospitals, 6 Community Health Centres and 32 Primary Health Centres across the district. The district vaccine logistic manager was interviewed to obtain information on the number of doses procured during the years for the entire district and number of doses supplied to the each of the selected centres. The district lady health visitor was interviewed to obtain information on the number of vaccinated beneficiaries across the district and among the different health centres. After enumerating the number of centres to be visited, these centres were visited and data was collected through record review and interview from the staff on a predesigned proforma. After obtaining the information the data was entered in excel format and analysed and expressed as percentages. Ethical Approval was taken from the Institutional Ethics Committee.

Result

BCG vaccine was administered to children in all the centres of District Health System as per the national immunization schedule. BCG vaccine was a freeze dried, available in 20 dose vial and was discarded after 4 hours of reconstitution. At the district level annually 40 thousand doses each of 0.1ml of BCG vaccine was procured and 20 thousand beneficiaries were vaccinated. At the District hospitals where deliveries were 20 to 40 per day yearly 20,000 doses of 0.1ml were availed and 15,000 doses were used. In the Taluka Hospitals where deliveries were 5 to 10 per day, 10,000 doses were availed, and 3500 doses were used. In a Community Health centres and Primary Health Centres where less than 1-2 deliveries occurred in a day 10000 doses were procured and 1500 doses were used.

At the district level wastage of 75% was recorded. At the district hospital where deliveries was 20 to 30 a day, 9-10 doses of vaccine were used in a vial resulting in 50% wastage. Whereas in Taluka Hospitals where deliveries were 5 to 6 per day, 5 to 6 doses were used in a vial resulting in 75% wastage. However, in Community Health centres and Primary Health Centre where less than 1-2 deliveries occurred in a day, 1 or 2 doses of vaccine were used and wastage was 90-95%.

Knowledge about vaccination, 2% said the vaccine should be administered within 24 hours of birth only, 14% said vaccine can be used within 7 days of birth and 78% of the participants said it could be used up-to 1 year of birth. Knowledge about dose of vaccine, about 46% of the vaccinators said 0.1ml as the dose of BCG vaccine and 54%

said the dose of vaccine as 0.05ml at birth, whereas 100% said the vaccine to be injected intradermally into the left arm at the insertion of deltoid. About 26% of the vaccinators had appreciated lymphadenitis and 49% ulcer, as adverse event following BCG Vaccination. 91% vaccinators said peanut sized bleb was appreciated after BCG vaccination and the bleb formation was well appreciated with usage of 0.1ml of BCG Vaccine. Regarding practice all 100% of the vaccinators said there are 10 doses of vaccine in each vaccine vial of BCG, 42% of vaccinators vaccinated the infants within 24 hours of delivery and 95% vaccinated within 7days of delivery, all the vaccinators used the BCG syringes provided with vaccine, marked measurements on the syringe was used for vaccine measurement and injected vaccine onto the left deltoid. Number of doses of vaccine that was withdrawn varied between 1 dose and 9 doses from a vial.

Table 1. BCG Vaccine Utility at District Health System

Facility	No of Doses (0.1ml each)	No of Infant Vaccinated
District	40000	20000
District Hospital	20000	15000
TH	10000	3500
CHC & PHC	10000	1500

Table 2. No. of Doses of BCG Vaccine Used per Vial at Facility

	Vaccine Vial	No. of Doses Used	Wastage (%)
District Hospital	1	9-10	50 -55
TH	1	5-6	70-75
CHC	1	1-2	90-95
PHC	1	1	95

Table 3. Factor associated with BCG Vaccine Utilization

Knowledge		N=42 (%)
Age of Vaccination	Within 24 Hours	1 (2)
	Within 7 Days	6 (14)
	Upto - 1 year	32 (78)
	Upto - 5 year	3 (06)
Dosage	0.05	23 (54)
	0.1	19 (46)
Site/ Deltoid	Right	0 (0)
	Left	42 (100)
No of Doses in a Vial	10	42 (100)
AEFI	Ulcer	11 (26)

	Lymphadenitis	21 (49)
	None	9 (25)
Measurement on syringe	Marked	42 (100)
Attitude		
Bleb	Not of Peanut Size	4 (9)
	Should be of Peanut Size	38 (91)
Practice		
Age	Day 1	18 (42)
	Day 7	22 (53)
Dose	0.05	8 (19)
	0.1	23 (53)
	Not administering	11 (28)
Site	Deltoid	
	Left	31 (72)
No of Doses Used in a Vial	1-10	31 (72)

Discussion

BCG Vaccine wastage was highest at facilities where deliveries were 1-2 per day and lowest at facilities where deliveries were 20 to 40 per day.

BCG vaccine wastage ranges from 50%-95% in the Hassan District Health System according to the present study, which is higher than that are recorded by Mukherjee et al.: 30.3% to 70.2% and Gupta et al 63.76%,¹¹⁻¹⁴ in India, this may be because the dose of 0.1ml is taken into consideration but the study outcome is comparable with the findings from a study done by Guichard S et al in Bangladesh which estimate overall vaccine wastage rates for BCG of 84.9%, range 55-93%.¹⁵

Government of India recommends administration of BCG vaccine to new-borns up-to 1 year of age,¹⁶ however only 78% of our study participants were aware that the vaccine could be administered up-to 1 year of age.

About 46% and 54% of the vaccinators said 0.1ml and 0.05ml as the dose of vaccine used at birth, which is not satisfactory as Government of India, recommends 0.05ml dose of BCG to new-borns below 1 month of age and 0.1ml up to 1 year of age.¹⁶ Whereas all 100% were aware that the vaccine is injected intradermally into the left arm at the insertion of deltoid. Which is satisfactory as per the GOI guidelines.

About 26% and 49% of the vaccinators had appreciated lymphadenitis and ulcer as adverse event following BCG Vaccination. This findings are appreciable, because most of the newborns receive vaccine within the first few days of birth, as the skin of the newborn is thin, the intradermal injection of 0.1ml is more likely to break the skin, penetrate into the deeper tissues and cause local abscess and lymphadenitis. Which is comparable with the Government of India records that the Common Program errors leading to Adverse Events Following immunization with BCG are local reaction, abscess, and lymphadenitis are attributed to vaccine given subcutaneously.¹⁶

Interestingly, 91% vaccinators said peanut sized bleb formation is required to accept intradermal vaccination and it was very well appreciated with usage of 0.1ml of BCG Vaccine. However Government of India, recommends 0.05ml dose of BCG to new-borns below 1 month of age¹⁶ and does not support the need for peanut size bleb at the injection site.

As almost all the newborn receives the vaccine within first week of birth with the 0.1ml marked auto-disposable syringes implies the babies are receiving more than that of the government of India specified dose of vaccine.

The maximum number of Vaccine that could be withdrawn was 9 doses, Whereas according to the manufacturers' specifications, one vial of reconstituted vaccine contains 1 ml, corresponding to 10 doses for adults and children aged 12 months and over (0.1 ml) or 20 doses for infants less than 12 months (0.05 ml).¹⁷ Also a Schaltz-Buchholzer F 2017: In their study to know the real-life number of doses in a 20-dose vial recorded that the median number of doses possible to withdraw from the vials was 13 (range 11-17): 13 (11-16) for BCG-Denmark and 15 (12-17) for BCG-Russia.¹⁸ Which means the marked measurement 0.05ml on the syringe was used to draw the vaccine.

Conclusion

At the district level annually 50% of the doses procured are wasted as the procured doses are 0.1ml each. Also marked measurement of 0.1ml on the BCG syringe was used to measure the dose by the vaccinators. Hence, 50% wastage can be reduced if 0.05ml dose per beneficiary of vaccine is procured at the district level and another 50% wastage can be reduced per beneficiary, if 0.05ml marked BCG syringes are supplied to the vaccinators.

Conflicts of Interests: None

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