

Tuberculosis and Leprosy Control in IMO State LGA: Factors Affecting the BCG Vaccination Programme

Omeaku Maris, Ozims Stanley, Azudialu Bede

Abstract— Background: A single dose of BCG vaccine given to a neonate at birth or as soon as possible thereafter is key element for successful protection against mycobacterial infections including tuberculosis, leprosy and other non-tuberculous mycobacterium infections.

Aim: This study aimed to contribute to the vision of ‘the End TB Strategy 2016-2035’ through the determination of the current BCG policy implementation on vaccine uptake by estimating the BCG vaccination rate in IMO State, Southeast Nigeria.

Method: A cross-sectional and community-based study was conducted in Ideato-North local government area (LGA) of IMO State, south east Nigeria; from 2013-2017. Cluster sampling method was used for household selection. A total of 210 children aged 0-11months and their mothers/caregivers were included in the study. Data was collected using a pre-tested, interviewer administered questionnaire, and from review of vaccination records in the national program on immunization unit, public health department of the LGA of study and analyzed using SPSS version 25.

Result: Only a minority of the children (21.9%) were vaccinated with BCG by card-plus history whereas none at all (0%) was vaccinated with BCG from the review of the vaccination records. The factors responsible for the poor BCG vaccination were BCG multi-dose vial policy/fear of vaccine wastage, poor turn-out for vaccination, place of child’s birth, mother’s knowledge on vaccination and mother’s education level.

Conclusion: There is need for a review of the multi-dose vial policy, ensure policy implementation; periodic training and re-training of the health care personnel, human capacity development, data monitoring/evaluation, as well as sensitization campaigns among others, as ways to improve the people’s awareness on and uptake of BCG vaccination, a key component of the very first pillar in the End TB Strategy.

Index Terms— BCG, End TB Strategy, BCG Vaccine Policy/Recommendation, Tuberculosis and non-Tuberculosis Mycobacterium Infections.

I. INTRODUCTION

Bacillus Calmette-Guérin (BCG) vaccine is considered the world’s most widely used vaccine [1] and continues to be the only vaccine in use for the prevention of tuberculosis (TB). First used in 1921, subsequently rolled out in developed countries and included in the WHO Expanded

Programme on Immunization (EPI) since 1974.

The use of BCG in routine infant vaccination programme (estimated coverage at 90%) is estimated to globally prevent 117,132 TB deaths per birth cohort in the first 15 years of life. There is evidence that BCG vaccination has also contributed to the significant decline in leprosy incidence. Despite the considerable success gained on the fight against leprosy, more than 200,000 cases were notified in 2016[1]. Moreso, BCG has been found to be effective against other mycobacterial infections such as Buruli ulcer disease and has also been reported to have beneficial non-specific effects (NSE), in particular reducing all-cause infant mortality in certain settings [3] [4]. WHO Expert Committee on Leprosy held in 2010 recommended that maintaining high levels of BCG immunization in newborns is important in the prevention of leprosy.

An estimated 2–3 billion people are said to be infected with M. tuberculosis globally with about 5–15percent ending up developing TB disease during their lifetime [4]. Nigeria ranked 4th among the 22 high TB burden countries in the world and has the highest burden in Africa with 74225 cases, 6606 coming from the south east [5], and 570,743 in 2013 with rates at 326 per 100,000. This represents a doubling of the estimated incidence from 2012 WHO estimates [4] and is still ranked the highest in TB burden with severe cases [6]. Available data on burden of diseases in IMO State showed a high TB burden with a total of 1119 and a prevalence of 35.5/100,000[5].

Research Questions

- (1) What is the BCG vaccination Status in Imo State LGA?
- (2) What are the factors responsible for the BCG vaccination status in Imo State LGA?
- (3) Is there evidence that coverage in one sub-population is higher than another (such as boys versus girls, educated versus uneducated mothers, mothers that utilized ANC and where versus mothers that did not utilize)?

The WHO member states during the 67th World Health Assembly in May 2014, adopted the End TB Strategy (2016-2035). The goal is to end the global TB epidemic. The End TB Strategy has three pillars: Pillar 1 is Integrated, patient-centred TB care and prevention with vaccination against tuberculosis, a component of the first pillar; Pillar 2 is “Bold policies and supportive systems”, and, Pillar 3 “Intensified research and innovation” [7]. BCG vaccine is highly effective in preventing the severe forms of TB that affect infants and young children. Ending the TB epidemic by 2030 requires an 80% drop in new TB cases; a 90% drop in people dying from TB; and, 100% of TB-affected families

Omeaku Maris Anulika, Department of Family Medicine, Federal Medical Centre Owerri, Imo State, Nigeria;

Ozims Stanley, Professor of Public Health, School of Post Graduate Studies, Imo State University Owerri, Imo State, Nigeria.

Azudialu Bede., Senior Consultant- Family Physician, Department of Family Medicine, Federal Medical Centre Owerri, Imo State, Nigeria.

protected from catastrophic cost through better care and prevention.

This study aimed to contribute to the vision of 'the End TB Strategy 2016-2035' through the determination of the BCG policy implementation by estimating BCG vaccination status in Imo State LGA, Southeast Nigeria, and the factors responsible.

II. STUDY METHODS

A. Study Setting

The study was carried out in Ideato North Local Government Area (LGA), out of 27 LGAs in IMO State, southeast Nigeria. Nigeria operates a federation comprising of 36 states and a Federal Capital Territory (FCT) Abuja. Within these states are 774 local government areas (LGAs) with 9,565 wards. These 36 states and FCT are grouped into six geo-political zones, the South-South, the South-East, the South-West, the North-East, the North-West and the North-Central zones [13]. Ideato North LGA was created in 1976 as Ideato, but later divided into Ideato North and Ideato South LGAs. The administrative quarter is in Urualla. As at 2011, it had a population of 156,161 (2006 Census) and projected population of 215,100 as at 2016 [14]. Only the children 0-11 months of age (under-one) were studied.

B. Study Population

This consisted of 210 randomly selected children aged 0-11 months (Under-one) with their mothers or caregivers in Ideato North Local Government Area of Imo State. The researcher picked this age range to enable her detect any child for BCG catch-up vaccination.

C. Sampling Technique

Ideato-north LGA was randomly selected out of the 27 LGAs in IMO State. The 2015 WHO-EPI cluster sampling method [15] was employed to select study households with consideration of each area/ward as one cluster and proportional allocation of study subjects made. The first child in each zone was selected randomly from the center of the zone and the rest of them were selected from the subsequent household till the required numbers of children were attained. For households with more than one eligible child, all the eligible children were included in the study.

D. Sample size:

Sample size was calculated based on the traditional EPI cluster survey which utilizes a fixed sample of 7 children in 30 clusters (7 x 30) to guarantee a maximum absolute confidence interval width of $\pm 10\%$ at an assumed coverage level of 50% with the assumption of 5% margin of error at 95% confidence level.

E. Study Instruments

Review of vaccination Records: These were the records existing in National Programme on Immunization (NPI) Unit; Public Health Care department of the LGA of study. Personal observations and comparisons of their data were made.

Questionnaire: An interviewer-administered structured questionnaire was used to obtain information from mothers or caregivers of the children by trained interviewers. The instrument was constructed from a review of available

literature on immunization coverage, WHO questionnaire, and Nigerian Demographic and Health Survey for immunization coverage.

On the Spot interviews and Group Discussions: In-depth interviews were conducted with health professionals in the LGA of study (probed on missed opportunities, health information delivery system and any difficulty or barriers to providing BCG vaccination service). Three FGDs were conducted with mothers or caregivers (probed on their knowledge, attitude towards immunization and barriers to vaccinating their children). A single FGD lasted for about an hour.

The questionnaire was reviewed, pre-tested and tested (on 5% mothers or caregivers of children whose age was between 0 to 11 months) in wards which are not primarily selected for the study. The findings were excluded from main study. The necessary amendments were made upon identification of ambiguities of the tools in the wording, logic and skipping order. The collected data were checked for completeness. Data were entered after checking for completeness. Cleaned, prepared and analysed using statistical data analysis software (SPSS) Version 20. Frequencies and other descriptive statistics were determined. Logistic regression was conducted to examine association between dependent and independent variables and the significance decided at a p value of 0.05. Phi measure was employed to determine the strength of association and their 95% CIs were calculated. Observed data were entered and tabulated using Microsoft Word.

Mothers or caregivers were asked to show immunization cards and the dates of immunization were extracted from the cards. For those whose immunization cards were not available or were lost, the mothers or caregivers were asked on immunization status of their children. In order to reduce recall bias, different recalling techniques such as routes of administration (checking injection sites and presence of the scar on the upper arm) were utilized.

III. ETHICAL CONSIDERATIONS

The research was approved by the research ethics review committee of the School of Post graduate studies, Imo State University Owerri, the immunization unit head of public health care department of the local government area of study. Permission to undertake the study was obtained from every relevant authority in the zone, local government area and respective wards. Applicable consent form and the information sheet were duly integrated along with the respective data collection instruments. All the study participants were clearly informed about the objectives or purposes, procedures, risks and benefits, privacy and confidentiality issues of the study. Finally, verbal informed consent was obtained from each study participant before interview. This method of consent was specifically approved by the ethical committee that approved the study.

IV. RESULTS

Table 1: BCG Vaccination Status In Imo State LGA (Ideato North), Southeast Nigeria by 2017

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Vaccinated	46	21.0	21.9	21.9
	Unvaccinated	164	74.9	78.1	100.0
	Total	210	95.9	100.0	
Total		219	100.0		

Table 2: Reasons for Failure to Vaccinate the Children (0-11months) With BCG Vaccine

		Frequency	Percent
Valid	Not applicable	47	25
	Fear of Vaccine wastage	35	16
	Poor Turn-out for Vaccination	32	15
	Vaccine Stock-out	12	6
	Forgetfulness	21	10
	Distance From Health Coverage	11	5
	Lack of Knowledge on Need BCG Vaccination	14	6
	Others	38	17
	Total	210	100
	Total	210	100.0

Table 3: Logistic Regression of Variables Associated with BCG Vaccination

Variable		Vaccinated	Unvaccinated	Total (%)	Sig.	95% C.I for Lower
Age of Children	0-2months	10	25	35 (16.7)	0.265	
	3-5months	7	47	54 (25.7)		
	6-8months	15	43	58 (27.6)		
	9-11months	14	49	63 (30.0)		
Gender	Males	26	96	122 (58.1)	0.468	
	Females	20	68	88 (41.9)		
Maternal Age in years	18-25	16	50	66 (31.4)	0.097	
	25-34	18	92	110 (52.4)		
	35-44	10	20	30 (14.3)		
	45-54	2	2	5 (1.9)		
Maternal Education Level	No formal Education	6	23	29 (13.8)	0.443	
	Primary level/Basic Education	11	101	112 (53.3)		
	Secondary level education	23	36	59 (28.1)		
	Tertiary level and above education	6	4	10 (4.8)		

Immunization Card Retension	Yes	31	89	120	0.077	
	No	15	75	(57.1) 90 (42.9)		
Place of ANC/Birth	District Hospitals	9	146	155	0.499	
	Mission Hospital	37	17	(73.8) 54 (25.7)		
Source of BCG Vaccination	District Hospitals	5	157	162	0.225	0.199
	Mission Hospital	34	5	(77.1)		
	Supplementary Immunization	7	2	39 (18.6) 9 (4.3)		
Reasons for Failure to vaccinate	Fear of Vaccine Wastage	0	35	35 (16.1)	0.997	
	Poor turnout for vaccination	1	31	32 (15.2)	1.000	
	Vaccine Stock out	0	12	12 (5.7)	0.998	0.05
	Forgetfulness	0	21	21 (10)	1.000	
	Distance from Health Facility	0	11	11 (5.2)	1.000	0.11
	Lack of knowledge on need for vaccination	0	14	14 (6.7)	1.000	0.71
	Others	0	18	38 (18.1)	1.000	0.71

V. DISCUSSION

Bacillus Calmette-Guérin (BCG) vaccine is considered the world's most widely used vaccine [1] and continues to be the only vaccine in use for the prevention of tuberculosis (TB). The findings of this study shows a BCG vaccination rate of 21.9% by card-plus history and 0% from the review or records. A study conducted in Zaria, North Western Nigeria in 2015 showed BCG vaccination rate of 76.7% [16]. The 76.7% rate contrasts the findings from this study. It is however in keeping with a low rate of 37% for BCG as reported by Babalola and Lawan (2009) in the northern part of Nigeria [17]. Also, Preliminary 2018 DHS result suggest 67% of infants were vaccinated with BCG in Nigeria ⁽²¹⁾.

Reason for failure to vaccinate (Fear of vaccine wastage, poor turnout for vaccination), source of BCG vaccination, place of ANC/Birth and maternal education level were the associated factors of BCG vaccination. Maternal or caregiver educational status was significantly associated with the BCG vaccination rates seen in mothers or caregivers who attended secondary and above level than mothers unable to read and write. Results of this study contrasts the results of a study conducted in Kiandutu slums of Kenya which showed that the literacy level of the mother did not significantly predict the immunization status of the child [20] but is in agreement with the 2008 demography and health survey in Nigeria which had shown that mothers level of education is strongly related to immunization coverage with mothers with secondary education more than eight times more likely to immunize their children than mothers without education. This further reiterates that better education informs better health seeking behavior.

Place of delivery showed that mothers whose babies were delivered in the mission-owned hospitals received BCG vaccine, compared to the babies delivered in district health facilities. The study from CSA, Maryland [19] indicated significant association between place of delivery and vaccine completion among 0-11 month old children. From the study, the reasons cited by the mothers for non-immunization of their children were forgetfulness, un-availability of vaccine, distance from the hospital, fear of adverse reactions, religion among others. The mothers who cited forgetfulness argued that they were engaged in other responsibilities which are livelihood generating activities that they considered more important at the time. This reflects the unmet basic needs of those living in impoverished communities, which make health seeking a secondary responsibility. Finding of this study is in agreement with a study conducted in Lucknow District India, where 17.2% of mothers interviewed argued that they were pre occupied in fending for their families, forgetting seeking immunization services for their children [18]. The 21.9% BCG vaccination recorded by Card-plus history was among mothers/caregivers who had their children in the mission-owned hospital. They were better informed and had their children vaccinated. 0% however, was recorded from the review of BCG vaccination records over the pre-ceding five years (2013-2017).

In- depth interviews conducted with health care providers in the LGA of study attributed this 0% BCG vaccination rate to a cautionary measure that prevents vaccine wastage, as in the departmental guideline/directive and poor turn up for BCG vaccination by mothers of the children. Each BCG vial used in the centre was said to contain 20 dose ampoule. In handling an opened multi-dose vial, World Health Organization recommends that the opened vial be discarded within six hours of opening [17]. In an attempt to cut down on

vaccine wastage, the health care workers delay opening a BCG vial until a minimum of 8 newborns are present for vaccination. Hence, vaccine wastage was thus highly favoured over primary disease prevention via vaccination. This poses great health challenge and amounts to sabotage of the intensified effort on control of Tuberculosis, Leprosy and other endemic diseases in the country.

VI. CONCLUSION

There was regrettably poor BCG vaccination rate. Major factors responsible were low turn-up for vaccination, Fear of vaccine wastage, Knowledge of mothers on BCG vaccination, maternal education level, and a knowledge gap.

VII. RECOMMENDATIONS

BCG vaccination is a cost-effective intervention against severe childhood tuberculosis which ought to be retained in high-incidence countries as a strategy to supplement the chemotherapy of active tuberculosis. Thus, concerted efforts need be made to ensure implementation of the BCG vaccine policy.

The Nigerian Federal Ministry of Health, Department of Public Health need review their goals' targets for the Adopted End TB Strategy of the WHO, by ensuring BCG vaccine policy implementation as a key tool for Tuberculosis (and leprosy) prevention; evaluate and monitor data on immunization.

Periodic training and retraining of health workers, as well as human capacity development is essential.

Review of the multi-dose vaccine policy is highly advocated as a number of new tuberculosis (TB) vaccines aimed at replacing or boosting the existing BCG vaccine have been entering clinical trial. This will ensure children are vaccinated, against all odds.

Pharmaceutical companies in Nigeria and elsewhere need rise to the challenge of local manufacture of BCG vaccines. This will ensure availability of fewer dose BCG vaccines. Government is to provide subsidies and inventions where necessary.

REFERENCES

[1] Dye C. Making wider use of the world's most widely used vaccine: bacille Calmette–Guerin revaccination reconsidered. *J R Soc Interface* (2013) 10:20130365. doi:10.1098/rsif.2013.0365
WHO (2017), Report on BCG vaccine use for protection against mycobacterial infection including tuberculosis, and other non-tuberculosis mycobacteria (NTM) infections. Available at www.who.int/immunization/sage/meetings/2017/october/1_BCG_report_revised_version_online.pdf.

[2] Merle et al. BCG vaccination and leprosy protection: review of current evidence and status of BCG in leprosy control. *Expert Review of Vaccines*. Volume9, 2010-issue 2.

[3] WHO, (2018) Guidelines for the Diagnosis, Treatment and Prevention of Leprosy. ISBN:978 92 9022 6383

[4] WHO Global TB Report 2016. Available at http://www.who.int/tb/publications/global_report/en/, accessed September 2017.

[5] 2014 Global TB report. Straightnews.ng (2018). Nigeria is among 22 nations with Tuberculosis burden – President Available at <https://straightnews.ng/nigeria-among-22-nations-tuberculosis-burden-president>

[6] Federal Ministry of health, department of public health, National TB and Leprosy Control Programme (NTBLCP) (2006 Annual TBL Programme Report). <https://www.ntblcp.org.ng/download>.

[7] WHO. The End TB Strategy. Global strategy and targets for tuberculosis prevention, care and control after 2015. WHO, 2015. Available at http://www.who.int/tb/strategy/End_TB_Strategy.pdf?ua=1, accessed September 2017.

[8] Zimmermann and Curtis et al. Does BCG vaccination protect against non-tuberculous mycobacterial infection? 2017, unpublished (Department of Paediatrics, The University of Melbourne, Parkville, Australia).

[9] Röltgen K and Pluschke G. Epidemiology and disease burden of Buruli ulcer: a review. *Research and Reports in Tropical Medicine*, November 2015.

[10] Portaels, F et al Prophylactic effect of *Mycobacterium bovis* BCG vaccination against osteomyelitis in children with *Mycobacterium ulcerans* disease (Buruli ulcer). 2002. *Clin. Diagn. Lab. Immunol.* 9:1389-1391.

[11] Portaels F et al. *Mycobacterium bovis* BCG vaccination as prophylaxis against *Mycobacterium ulcerans* osteomyelitis in Buruli ulcer disease. *Infect Immun.* 2004 Jan; 72(1):62-5.

[12] Nackers F et al. BCG vaccine effectiveness against Buruli ulcer: a case-control study in Benin. *Am J Trop Med Hyg.* 2006 Oct; 75(4):768-74.

[13] Nigerian National Routine Immunization Strategic Plan (2013-2015) PDF www.nationalplanningcycles.org Nigeria.

[14] IMO State in Nigeria <https://www.citypopulation.de/php/nigeria-admin.php?adm1id=NGA017>

[15] World Health Organization Vaccination Coverage Cluster Surveys :Reference Manual Version 3 working document.

[16] Asuke S, Ibrahim J, Ibrahim MS and Asuke UA, 2015. *Survey on Coverage and Factors Influencing Delays in BCG Immunization in Hayin Mallam Zango, Zaria, North Western Nigeria-2329-9088-1000188.php?aid=56412*

[17] Babalola S, Lawan U. Factors Predicting BCG Immunization Status in Northern Nigeria: A behavioural-Ecological Perspective. *J. Child Care* 2009; 13:46-62.

[18] Nath B., Singh J., Awashi S., Bhusan V. and Khumar V. (2007). A study on determinants of immunization Coverage Among 12-23 Months Old Children in Urban Slums of Lucknow District, India. *India J. Med.* Vol 61 No 11.

[19] Central Statistical Agency (CSA), ORC Macro, Ethiopia Demography and health survey 2011, Addis Ababa, Ethiopia and Calverton, Maryland: USA CSA and ORC Macro, 2012.

[20] Arphaxad C.K. (2012): Child Immunization Coverage in Kianduta Slums, Thika District, Kenya; *Journals.Jkuat.Ac.KE(Abtract of Postgraduate Thesis)_Abs/Article?View/304*.

[21] Hazel M. Dockrell and Steven G. Smith (2017) What Have We Learnt About BCG Vaccination in the Last 20 Years? Faculty of Infectious and Tropical Diseases, Department of Immunology and Infection, London School of Hygiene and Tropical Medicine, London, United Kingdom. *Frontiers in Immunology*, volume 8, Article number 1134. Doi 10.3389/fimmu.2017.01134

[22] Arphaxad C. K. (2012); Child Immunization Coverage in Kandiatu Slums, Thika District, Kenya; *Journals Jkuat.Ac.Ke (Abstract of postgraduate Thesis)_Abs/Article/View/304*.

[23] WHO and UNICEF Estimates of Immunization Coverage by Vaccine :2018 revision; https://www.who.int/immunization/monitoring_surveillance/routine/coverage

Omeaku Maris Anulika,
Department of Family Medicine, Federal Medical Centre Owerri, Imo State, Nigeria;

Ozims Stanley,
Professor of Public Health, School of Post Graduate Studies, Imo State University Owerri, Imo State, Nigeria.

Azudialu Bede.
Senior Consultant- Family Physician, Department of Family Medicine, Federal Medical Centre Owerri, Imo State, Nigeria.