# A Pilot Study: Factors Influencing Compliance With Tetanus–Diphtheria Vaccine in Katsina State, Northwestern Nigeria

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#### Abstract

**Background:** Tetanus-diphtheria vaccine (Td+) coverage has been steadily declining in Katsina State, Nigeria. The pilot study was guided by The Andersen and Newman Framework of Health Services Utilization. The goal of the pilot study was to identify the Td+ vaccination coverage and identify any association between maternal residence, educational status, occupational status, access to routine immunization services, availability of routine immunization services, perceived need for Td+, perceived severity of maternal and neonatal tetanus (MNT), and compliance with Td+ in Katsina State.

**Methods:** A cross-sectional survey of 309 randomly selected women in Charanchi district of Katsina State, Nigeria, was conducted. Data were collected using structured questionnaire and analyzed using logistic regression model.

**Findings:** The Td+ coverage was low at 23%. Bivariate analysis showed that age, maternal residence, educational status, availability of Td+, perception of Td+, and perception of MNT significantly affected compliance with Td+ (P < .05, P < .05, P < .05, P < .001, P < .001, P < .001, P < .001, respectively). Multiple logistic regression findings were inconclusive.

**Conclusion:** Effective strategies to improve compliance were awareness creation on Td+ immunization schedule, risk factors associated with MNT, vaccine availability, and safety. Additionally, improving access to routine immunization services, especially in underserved communities, and effective use of Td+ coverage data were used as strategies.

**Implications:** The pilot study suggests that the design can be used to realize more conclusive and generalizable multivariate findings in future studies.

#### Keywords

tetanus, vaccine, compliance, maternal, neonatal, coverage

## Introduction

Tetanus–diphtheria vaccine (Td+) is currently the most effective intervention to prevent maternal and neonatal tetanus (MNT) disease and neonatal mortality. Maternal and neonatal tetanus is still a public health problem in most countries in sub-Saharan Africa.<sup>1</sup> Lately, neonatal tetanus (NNT) mortality rate has been found to be significantly high in Katsina State, Nigeria, with about 3.4 deaths per 100 000 population.<sup>2</sup> Furthermore, the current routine immunization administrative data in the state show suboptimal second-dose tetanus– diphtheria (Td2+) coverage levels.<sup>3</sup> This is so because substantial amount of pregnant women were not "protected at birth," that is, women who have not received the Td2+. The state annual administrative Td2+ coverage levels in the past 3 years have significantly declined with coverage rates of 54%, 49%, and 47% for 2015, 2016, and 2017, respectively.<sup>3</sup> Of the 34 districts in the state, Charanchi district had the least Td2+ coverage rates with 48%, 31%, and 29% for 2015, 2016, and 2017, respectively. Second-dose tetanus–diphtheria coverage is the primary process and output indicator for Td+ immunization in a community.

The study was guided by The Andersen and Newman Framework of Health Services Utilization. The framework was established in the late 1960s to determine the various factors

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**Enabling factors** 

(Access to routine

immunizatior

outine immunization

services)

**Needs factors** 

severity of maternal

and neonatal tetanus

**Figure 1.** Framework of the hypothesized association between the constructs in the study.

that either enable or hinder the utilization of health-care services; however, through time the model has been modified.<sup>4</sup> The framework hypothesizes that the utilization of health-care services by individuals is based on 3 main factors. These factors include predisposing factors, enabling factors, and need factors. In the context of this study, the predisposing factors are the features such as maternal residence, educational status, and occupational status that may influence or make pregnant women liable to complying with the Td+ vaccination schedule

. The enabling factors are the factors such as access to routine immunization services and availability of routine immunization services that facilitate or impede the utilization of routine immunization services, while the needs factors refer to maternal attitudes toward the importance of Td+ or severity of NNT that affect compliance with Td+ schedule. Figure 1 below depicts the framework that guided the pilot study.

The primary aim of this pilot study was to identify the factors associated with Td+ vaccination status among pregnant women in Katsina State, Nigeria. Furthermore, the study was attempted to assess the reliability and validity of instruments of data collection. The findings of the study will serve as a guide for health-care administrators and policymakers on establishing efficient initiatives and policies toward improving the Td2+ immunization coverage and reducing Td2+ dropout rates in Katsina State, Nigeria.

Numerous studies have been conducted to identify the factors influencing noncompliance to vaccine-preventable diseases. However, few literature reviews were found to have focused on identifying factors associated with Td+ vaccination uptake in pregnancy. In 2017, Goodlyne and colleagues conducted a Td+ coverage survey in Niger Delta, Southern Nigeria, and found a Td2+ coverage rate of 79.7% in the study area. The study also indicated that maternal age and educational status were significant predictors to compliance with Td+.<sup>5</sup> In Zamfara State, Northern Nigeria, Gidado et al identified causes of routine coverage, but Td+ was not among the vaccines assessed in the study.<sup>6</sup> Similarly, Gunnala et al measured the coverage of the third dose of diphtheria–pertussis–tetanus vaccine in a district-level routine immunization survey in Northern Nigeria, but Td+ coverage was not included in the study.<sup>7</sup> For the purpose of this pilot study, the following research questions were addressed to fill the gap in the literature: (1) What is the Td2+ vaccination coverage in Katsina State? (2) Is there any significant association between maternal residence, educational status, occupational status, access to routine immunization services, availability of routine immunization services, perceived need for Td+, perceived severity of MNT, and compliance with Td2+ vaccine in Katsina State?

## **Research Methodology**

## Study Area, Study Participants, and Sampling Procedure

The study was conducted in Charanchi district in Katsina State, Northwestern Nigeria. Based on the projected 2006 national population census, the state has an estimated population of 5 801 584 people,<sup>8</sup> while Charanchi district has an estimated population of 196 203 people. The state is composed of 34 strata (districts) and 16 673 clusters (settlements), while Charanchi district is composed of 224 settlements. Inclusion criteria included pregnant women and women who had given birth in the last 12 months regardless of gestational age in the study area.

Exclusion criteria included all nonpregnant women and women whose last child birth was >12 months in the study area. The sampling procedure for the study was based on the World Health Organization vaccination coverage cluster survey sampling protocol,<sup>9</sup> which included (1) effective sample size (ESS) estimation which requires estimation of the expected coverage (statistical power) and the desired precision. For this survey, the statistical power was set at 70% and the desired precision was  $\pm 10\%$ ; thus, based on the immunization cluster coverage guideline, the estimated sample size was 103.<sup>9</sup> (2) The second step was design effect (DEFF) estimation using the formula  $DEFF = 1 + ([m - 1] \times intracluster correlation)$ coefficient [ICC]), where m was the number of respondents per cluster; for this pilot study, 15 respondents were interviewed per cluster. The ICC is the measure of the correlation of responses within clusters; for this pilot study, the ICC was presumed to be 0.167. Therefore,  $DEFF = 1 + (m - 1) \times ICC$ ;  $1 + (15 - 1) \times 0.167 \approx 3$ . Therefore, the sample size for the pilot survey (N) = effective sample size (ESS)  $\times$  DEFF  $= 103 \times 3 = 309.$ 

## Study Design, Data Collection, and Statistical Analysis

The study was a cross-sectional survey. Quantitative approach was used to analyze the data using SPSS version 21. Descriptive data (Td2+ coverage rates, variables) are presented in frequency tables, charts, and graphs, while binary analyses (associations) are displayed as cross tabulations showing associations between variables. Data were collected using an

**Predisposing factors** 

interviewer-administered questionnaire that had 4 sections: The questionnaire was standardized with closed-ended questions to minimize threat to internal validity caused by instrumentation. Likewise, threat to external validity caused by selection bias was minimized by selecting only pregnant women or women who had given birth in the last 12 months regardless of gestational age in the study area. In addition, reliability and validity of the questionnaire was confirmed by calculating the Cohen k index. The first section contained questions concerned with respondents' age, type of settlement, educational status, and occupational status. The second section contained questions concerned with respondents' status of Td+ vaccination card, Td+ dosses received, and sources of information on Td+. The third section contained questions concerned with respondents' access to routine immunization services and availability of Td+. The fourth section contained questions concerned with respondents' perception of Td+ and perception of MNT. Ten research assistants were trained and recruited for the study. Charanchi district is composed of 10 political wards, and each research assistant collected data from the randomly selected clusters (settlements) in 1 ward. An average of 15 households was visited per settlement. The selection of households and eligible participants was realized through the lot quality assurance sampling methodology used in monitoring the quality of supplemental immunization activities in Nigeria.<sup>10</sup> Both binary logistic regression model and  $\chi^2$ tests were employed to assess the associations between the identified predictors (independent variables) and maternal Td2+ vaccination status (dependent variable). The logistic regression model was used to estimate crude odds ratios and 95% confidence intervals (CIs). The statistical significance was set at P < .05. Parametric assumptions for analyzing the study data using logistic regression were checked prior to analysis.

### Results

The total Td2+ coverage in the study area was 23% (n = 71), as depicted in Table 1. Moreover, Figure 2 depicts the sloping linear trend of Td2+ coverage rates in the study area ranging from 48%, 31%, 29%, and 23% for 2015, 2016, 2017, and May 2018 (study coverage), respectively. Table 1 also shows that 39.9% (n = 43) of the respondents were <18 years of age, while up to 74.8% (n = 231) of the respondents were within the age of 18 to 29 years. Only 11.3% (n = 35) of the respondents were above 29 years of age. Most of the respondents (88.3%; n =273) were residing in rural areas, which implies that only 11.7% (n = 37) were residing in urban areas. Educational status indicate that almost 81.9% (n = 251) of the respondents had no formal education, while about 11.7% (n = 36) had primary level education. Only 6.5% of the respondents had secondary level education, while none of the respondents had tertiary level education. Occupational status indicate that about 21.7% (n = 67) of the respondents were only housewives with no means of income, while up to 78% (n = 241) of the respondents were self-employed local traders. Only 1 (0.3%) of the respondents was employed as a civil servant. About 39.8% (n =

Table I. Frequency Distribution of Variables.<sup>a</sup>

	Frequency	Percent
Td vaccination status		
Vaccinated	71	23.0
Not vaccinated	238	77.0
Age		
<18	43	13.9
18-29	231	74.8
>29	35	11.3
Maternal residence		
Rural	273	88.3
Urban	36	11.7
Educational status		
No formal education	251	81.9
Primary	36	11.7
Secondary	20	6.5
Postsecondary	0	0.0
Occupational status		
Unemployed (housewives)	67	21.7
Self-employed	241	78.0
Employee	I	0.3
ANC card status		
No	123	39.8
Yes	186	60.2
Source of information		
Radio	15	4.9
Television	15	4.9
Health worker	154	49.8
Religious leader	125	40.5
No knowledge of Td $+$	0	0.0
Access to RI services		
>30 minutes	77	24.9
<30 minutes	232	75.1
Availability of Td+		
No health worker	19	6.1
Fixed post	257	83.2
Outreach services	33	10.7
Perception of Td $+$		
Harmful	10	3.2
Don't know	85	27.5
Protective	214	69.3
Perception of MNT		
Spiritual illness	149	48.2
Don't know	103	33.3
Severe illness	57	18.4

Abbreviations: ANC, antenatal care; MNT, maternal and neonatal tetanus; RI, routine immunization; Td+, tetanus–diphtheria vaccine;  $^{a}N = 309$ ; P < .05.

123) of the respondents were found not to be having antenatal care (ANC) cards, which implies that only 60.2% (186) of the respondents had ANC cards. Only 4.9% (n = 15) received information on Td+ through radio and television, while about 49.8% (n = 154) of the respondents got informed through health workers. Additionally, up to 40.5% (n = 125) of the respondents received information on Td+ through religious leaders. Access to routine immunization services indicates about 75.1% (n = 232) of the respondents were within 30 minutes reach to routine immunization services, which implies



Figure 2. Trend of Td2+ coverage rates for 2015, 2016, 2017, and May 2018.

that 24.8% (n = 77) of the respondents were at more than 30 minutes reach to routine immunization services. Also, up to 83.2% (n = 257) of the respondents received Td+ through fixed postsessions, while 10.7% (n = 33) of the respondents received Td+ through outreach sessions. Only 6.1% of the respondents did not receive Td+ due to lack of health workers. Only 3.2% (n = 10) of the respondents believed Td+ was harmful, while about 69.3% (n = 214) of the respondents believed Td+ was protective against MNT. About 27.5% (n = 25) of the respondents did not know the benefits of Td+. About 48.2% (n = 149) of the respondents perceived MNT to be a spiritual illness, while only 18.4% (n = 87) of the respondents believed MNT was a severe illness. About 33.3% (n = 103) of the respondents did not have any perception of MNT.

To measure the uniformity and consistency of data entry, 2 randomly selected surveyors administered the study questionnaire, and Cohen k was run. The inter-rater reliability for the raters indicated good agreement between the 2 surveyors,  $\kappa =$ 0.800 (95% CI, 0.43-1.17), P < .05. Collinearity diagnostics results indicated low level of multicollinearity among the predictors of the study. The bivariate relationship between variables and compliance with Td+ is depicted in Table 2. Only 1.4% (n = 3) of women <18 years of age were vaccinated with Td2+, while 18.1% (n = 56) of women within the age group of 18 to 29 years were vaccinated with Td2+ ( $\chi^2 = 8.96$ , df = 2, P < .05). About 70% (n = 218) of women residing in rural settlements were unvaccinated with Td2+ vaccine, while only 5.2% (n = 16) were vaccinated with Td2+ vaccine among those living in urban settlements ( $\chi^2 = 10.61$ , df = 1, P <.05). About 66% (n = 205) of women with no formal education were unvaccinated with Td2+ vaccine, while only 3% (n = 9) of women with secondary school level education were vaccinated ( $\chi^2 = 12.92$ , df = 2, P < .05). About 59.2% (n = 183) of self-employed women were found to be unvaccinated with Td2+ vaccine, while only 4.2% (n = 13) of unemployed women (housewives) were vaccinated with Td2+ vaccine ( $\gamma^2$ = 0.94, df = 2, P = .62). Only 21% (n = 65) of women with ANC cards were found to be vaccinated with Td2+ vaccine, while up to 37.9% (n = 117) of women without ANC cards were found unvaccinated with Td2+ vaccine ( $\chi^2 = 37.82$ , df = 1, P < .05). About 16.2% (n = 50) of women who were informed about Td+ through health workers were vaccinated, while only 0.6% (n = 2) who were informed through television

were vaccinated ( $\chi^2 = 17.37$ , df = 3, P < .05). About 58.3% (n = 180) of women within 30 minutes reach to routine immunization services were found to be unvaccinated with Td2+ vaccine, while only 6.1% (n = 19) of women with more than 30 minutes access to routine immunization services were found to be vaccinated with Td2+ vaccine ( $\chi^2 = 0.17$ , df = 1, P = .68). None of the women (n = 0) were found to be vaccinated through outreach immunization sessions, while about 60.2%(n = 186) of the women did not get vaccinated through fixed post routine immunization session ( $\chi^2 = 18.65$ , df = 2, P <.001). About 46.6% (n = 144) of women who believed Td+ was protective against MNT were not vaccinated with Td2+, while only 0.3% (n = 1) of the women who believed Td+ was harmful got vaccinated ( $\chi^2 = 37.76$ , df = 2, P < .001). About 37.9% of women who believed MNT was a spiritual illness were vaccinated with Td2+, while only 8.4% (n = 26) of women who believed MNT was a severe illness got vaccinated with Td2+ ( $\chi^2 = 22.93$ , df = 2, P < .001). Multiple logistic regression was attempted; however, the findings were inconclusive as depicted in Table 3.

## Discussions

Findings from descriptive statistics indicated low (23%) Td2+ coverage in Charanchi district of Katsina State, which is even less than the annual administrative Td2+ coverage rates of the past 3 years in the district. The findings are in contrast with the findings of Nwokeukwu and colleagues who reported an upward linear trend of Td2+ coverage rates in a tertiary health institution in Southeast Nigeria ranging from 28% in 2003 to 50% in 2012.<sup>11</sup> Evidence suggests that confidence and trust in routine immunization is relatively more common in the South than in the Northern part of Nigeria.<sup>12</sup> Similarly, rejection of Td+ due to misconceptions of perceived benefits among women attending ANC is still prevalent in some Northern states.<sup>13</sup> Bivariate results indicated that age, maternal residence, educational status, availability of Td+, perception of Td+, and perception of MNT significantly affected compliance with Td+(P < .05, P < .05, P < .05, P < .001, P < .001, and P < .001).001, respectively). The findings correlate with a Td+ survey conducted in 2018 by Goodlyne and colleagues who reported associations between maternal age and educational level with Td+ coverage.<sup>5</sup> Findings by Muhammad-Idris et al in 2017 also indicated significant statistical relationships between educational status and compliance with Td2+ vaccine ( $\chi^2 = 23.80$ , df = 12, P = .022). Similarly, in 2007, Hasnain and Sheikh found that Td2+ coverage was directly proportional to maternal levels of education.<sup>14</sup> Evidence shows that maternal education influences the likelihood of access to information on routine immunization, hence increasing compliance with Td+.15

#### Recommendations

Effective strategies to improve compliance with Td+ in Charanchi district, Katsina State consist of awareness creation

	Table 2	<ol><li>Relationship</li></ol>	b Between	Variables and	Compliance to	o Td+.ª
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	0	95% CI				
Predictors	Vaccinated (%)	Not Vaccinated (%)	Р	OR	Upper	Lower
Age						
< 18	3 (1.4)	40 (12.9)	.011			
18-29	56 (18.1)	175 (56.6)		5.35	1.37	20.92
>29	12 (3.9)	23 (7.4)		0.49	0.17	1.39
Maternal residence						
Rural	55 (17.8)	218 (70.6)	.001	2.25	0.65	7.76
Urban	16 (5.2)	20 (6.5)				
Educational status	( )	( )				
No formal education	48 (15.5)	205 (66.3)	.002			
Primary	14 (4.5)	22 (7.1)		0.87	0.28	2.78
Secondary	9 (2.9)	11 (3.6)		0.50	0.14	1.83
Postsecondary	0 (0)	0 (0)				
Occupational status						
Unemployed (housewives)	13 (4.2)	54 (17.5)	.62			
Self-employed	58 (18.8)	183 (59.2)	.00	0.00		
Employee	0 (0)	1 (0.3)	.00	0.00		
ANC card status	• (•)	. ()				
No	6 (1 9)	117 (37 9)	000	5 29	1 79	15.63
Yes	65 (21)	121 (39.2)				
Source of information	00 (21)	(37.2)				
Radio	0 (0)	15 (4 9)	001			
Television	2(06)	13(42)		0 92	0.00	
Health worker	50 (16 2)	104(337)		0.95	013	6 99
Religious leader	19 (6 1)	106 (34 3)		0.61	0.15	1 44
No knowledge of Td+	0 (0)	0 (0)		0.01	0.20	
Access to BI services	0 (0)	0 (0)				
>30 minutes	19 (6 1)	58 (18 8)	0.68	0 54	0.25	117
< 30 minutes	52 (16.8)	180 (58 3)	0.00	0.51	0.25	1.17
Availability of $Td+$	32 (10.0)	100 (30.3)				
No health worker	0 (0)	19 (6 1)	000			
Fixed post	71 (23)	186 (60.2)	.000	0.08	0.00	
Outreach services	0 (0)	33 (10.7)		0.00	0.00	
Perception of $Td \perp$	0 (0)	55 (10.7)		0.00	0.00	
	1 (0 3)	9 (2 9)	000			
Don't know	0 (0)	95 (27 5)	.000	1 43	013	16 14
Brotostivo	0 (0) 70 (22 7)	(27.5)		1.45	0.13	10.14
Paragetian of MNIT	70 (22.7)	144 (40.0)		1.25	0.00	
	22 (10 4)	117 (27 9)	000			
Don't know	32(10.7)	90 (29 1)	.000	2 29	0 90	6 77
Sovera illass	13 ( <del>1</del> .2) 26 (0 1)	70 (27.1) 31 (10.0)		2.30	0.70	0.27 دە 1
	20 (0.7)	31 (10.0)		1./7	0.05	-1.73

Abbreviations: ANC, antenatal care; CI, confidence interval; MNT, maternal and neonatal tetanus; OR, odds ratio; RI, routine immunization; Td+, tetanus– diphtheria vaccine.

 $^{a}N = 309; P < .05.$ 

primarily focusing on younger, uneducated women and women in rural communities. Based on the pilot survey, it is apparent that maternal education influenced Td+ compliance in the study area. For that reason, a robust and strategic communication plan is required to improve tetanus–diphtheria compliance. Pregnant women and mothers should be well informed on Td+ immunization schedule, risk factors associated with MNT, vaccine availability, and safety. Religious and community leaders should also be recognized and involved in the communication plan, as they can assist in reducing misconceptions on Td+ and improve trust and acceptance of the vaccine. Tetanus-diphtheria vaccine immunization coverage can also be improved by improving access to routine immunization services, especially in hard-to-reach and underserved communities. Sustainable funding from the government and partner organizations is required for logistics and human resources for health to provide Td+ to women in the underserved communities. Tetanus-diphtheria coverage data at both district and health facility levels should regularly be used to identify and track Td+ defaulters including areas of low Td2+ coverage and develop strategies to address them.

						95%	6 CI
Predictors	β	SE $\beta$	Wald $\chi^2$	Р	OR	Upper	Lower
Constant	39.36	4.06	0.00	.99	1.24		
Maternal residence							
Rural			0.00	1.00			
Urban	0.75	0.52	2.09	.14	2.12	0.76	5.90
Educational status							
No formal education			2.68	.26			
Primary	0.19	0.54	0.13	.71	1.21	0.42	3.52
Secondary	-0.52	0.64	0.68	.41	0.59	0.16	2.07
Postsecondary	0.00	0.00	0.00	.00	0.00		
Occupational status							
Unemployed (housewives)			1.00	.60			
Self-employed	<b>- 19.81</b>	4.01	0.000	1.00	0.00	0.00	
Employee	-20.23	4.01	0.000	1.00	0.00	0.00	
Access to RI services							
>30 minutes			0.00	1.00			
<30 minutes	-0.59	0.37	2.51	.11	0.55	0.26	1.15
Availability of Td+							
No health worker			0.00	1.00			
Fixed post	<b>-1.23</b>	9.67	0.00	1.00	0.29	0.00	
Outreach services	<b>-19.77</b>	6.25	0.00	.99	0.00	0.00	
Perception of Td+							
Harmful			0.00	1.00			
Don't know	-0.01	1.17	0.00	.99	0.98	0.09	9.92
Protective	19.82	3.99	0.00	. 99	4.07	0.00	
Perception of MNT							
Spiritual illness			4.00	.13			
Don't know	0.86	0.43	3.95	.04	2.37	1.01	5.57
Severe illness	0.66	0.48	1.86	.17	1.94	0.74	5.03
Model $\chi^2$		89.41		.00			
Hosmer and Lemeshow		1.18		.99			
Nagelkerke <i>R</i>		0.38					

Table 3. Summary of	of Binary Logistic	<b>Regression Analysis</b>	for Independent Variable	s Predicting the Outcome o	of Compliance to Td+. <sup>4</sup>
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Abbreviations: CI, confidence interval; MNT, maternal and neonatal tetanus; OR, odds ratio; RI, routine immunization; SE, standard error; Td+, tetanusdiphtheria vaccine.

 $^{a}N = 309; P < .05.$ 

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#### **Author Biography**

Shafique Sani Nass is a global health physician and an epidemiologist. He received his PhD in Public Health from Walden University, Minneapolis, MN, USA and a Master of Public Health degree from Usman Danfodio University, Sokoto, Nigeria. He trained as a medical doctor with the MBBS degree from Bayero University, Kano, Nigeria. Dr Nass is a member of the American College of Epidemiology and has vast experience serving in both local and international public health programs. His research interests lie in the area of infectious diseases, child health and neglected tropical diseases. He currently serves as a monitoring and evaluation officer with the World Health Organization (Immunizations, Vaccines and Emergencies Cluster) in Nigeria.