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Evaluation of Active and Passive Neonatal Tetanus Surveillance Systems in Katsina State, Nigeria

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Abstract

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MPH, Usman Danfodio University, 2011

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Dissertation Submitted in Partial Fulfillment

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Abstract

The incidence and mortality rates of neonatal tetanus (NNT) remain underreported in Nigeria. This cross-sectional study was guided by the Mosley and Chen's model for the elements of child survival in developing countries. The goals of the study were twofold: (a) to compare the NNT prevalence and the mortality rates from the existing surveillance system and active surveillance of health facility records in 7 selected health facilities from 2010 to 2014 in Katsina state, Nigeria and (b) to assess the associations between selected NNT risk factors, number of maternal tetanus toxoid injections, frequency of antenatal visits, place of delivery, and cord care, and neonatal mortality as the outcome variable. Data from 332 NNT records were extracted through retrospective records review and analyzed using a logistic regression model. The prevalence of NNT and mortality rate were 336 cases and 3.4 deaths per 100,000 population, respectively, while the prevalence of NNT and mortality rate reported through the IDSR system were 111 cases and 1.0 death per 100,000 population, respectively. Only neonates whose mothers had 1 dose of tetanus toxoid vaccine were significantly associated with NNT mortality, ($p < 0.05$), OR = 4.12, 95% CI [1.04, 16.29]. Frequency of antenatal visits, place of delivery, and cord care were all not significant predictors of NNT mortality. Implications for positive social change include gaining knowledge on associations between NNT risk factors and neonatal mortality, and strengthening the NNT surveillance system with the capacity for early detection of potential risk factors to develop specific public health interventions aimed at improving the outcome of neonatal tetanus.

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Dedication

I wholeheartedly dedicate this doctoral dissertation to my two angels, Hauwa (Iman) and Farida, who are my source of inspiration; and to my dear wife and sweetheart, Nafisa, for her endless affection, support, and motivation. I love you all.

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First and foremost, I am thankful to Allah (SWT) for making it possible for me to attain this important milestone. My special gratitude goes to my wife, Nafisa, for her unfailing patience, tolerance, and support throughout this doctoral research process. I sincerely appreciate my two charming daughters and joys of my life, Hauwa (Iman) and Farida. I am indebted to my parents Alh Sani Ibrahim Nass and Hajia Hauwa Sani Nass for their commitment and encouragement in my academic career.

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Chapter 1: Introduction to the Study

Introduction

It is well established that neonatal tetanus is grossly under-reported in existing integrated multiple disease surveillance systems globally (Ashar, Raju, Ansell & Bleck, 2011), and for as long as this condition is not addressed, the actual incidence of the disease will continue to remain unclear. Furthermore, recent studies have stressed the need for disease surveillance systems to have the capacity to detect events associated with diseases (Choi, 2012). The Institute of Medicine (IOM) recommended that new approaches in disease surveillance systems are required to strengthen rather than replace the existing ones (May, Chretien & Paulin, 2009). Although the risk factors of developing neonatal tetanus are well documented, the associations between the disease and neonatal mortality are still not well understood (Lambo & Anokye, 2013). This study has two important social change implications: (a) first, as evidence to strengthen the sensitivity of neonatal tetanus surveillance systems through active surveillance, and (b) second, to address an important gap in the literature by identifying risk factors associated with neonatal tetanus mortality rate in order to better inform decision making.

The major sections of this chapter include: (a) the background of the study, which presents a historical overview and analysis of neonatal tetanus surveillance system in Nigeria; (b) the problem statement, which presents the actual interests in both passive and active neonatal tetanus surveillance systems in Katsina state, Nigeria, that this study sought to assess; (c) the purpose of the study as revealed in the goals that the study intended to realize in order to create social change; (d) the research questions and hypotheses, which are focused, concise, and answerable questions that guided the study; (e) the conceptual framework that describes the theoretical foundation for the relationships between the independent and dependent variables that provided solutions to the research problem; (f) a description of the study design and methodology; (g) a definition of terms; (h) the assumptions, which are observations related to the study that were presumed to be true; (i) the scope and delimitations of the study, which are selected area of focus or boundaries imposed by certain constraints when conducting the study; (j) the limitations of the study, which are observations or restrictions related to the study that were not within the researcher's control; (k) the significance of the study, which is the impact that the study intended to make towards addressing the knowledge gap, including potential implications for social change and; a summary provides a review of this chapter.

Background of the Study

Surveillance of neonatal tetanus involves systematic collection and analysis of neonatal tetanus (NNT) data to determine the extent of the disease and risk of transmission so that the information can be used effectively for decision-making. The NNT surveillance system in Nigeria was not well established until 1998 when the federal government introduced a national disease surveillance system termed the Disease Surveillance and Notification System (Tomori, Odubanjo, Lan & Olanipekun, 2013). The Disease Surveillance and Notification System (DSN) was formed in response to a yellow fever outbreak that occurred due in large part to a non-functional disease surveillance system in the country (Federal Ministry of Health, 1991). The surveillance of NNT in the DSN was based on the identification of NNT cases collected at the health facility level and then reported to the Federal Ministry of Health for analysis (Federal Ministry of Health, 1991). However, despite this new approach, under-reporting of NNT cases persisted in the surveillance system because there were no local, state, and national bodies that could regulate the collation, harmonization, and coordination of surveillance data from the different levels of the health facilities (Federal Ministry of Health, 1992).

NNT under the DSN still remained largely under-reported even after the 1989 World Health Assembly (WHA) resolution to eliminate the disease by the year 2015 (Khan, Zahidie & Rabbani, 2013). Detection and reporting of NNT in the early 1990s was challenging because most NNT cases occurred in the underserved and difficult to reach regions (United Nations Children's Fund [UNICEF], United Nations Population Fund [UNFPA], World Health Organization [WHO], 2012). As such, neither incidences nor mortality rates attributable to NNT were reported from these "silent areas." Since then, NNT was termed as a "silent killer" because many newborns died of the disease who were not identified and reported by the disease surveillance system (UNICEF, 2015). This resulted in a relatively high NNT mortality rate of 20.6 deaths per 1,000 live births in Nigeria (Federal Ministry of Health, 2006, p.18). The World Health Organization African Regional Office, (AFRO), introduced the Integrated Disease Surveillance and Response (IDSR) in September, 1998, due to prolonged inconsistencies in the generation of surveillance data for action by its surveillance systems as well as competing vertical disease surveillance systems that focused primarily on a single specific disease or health events. The IDSR system was established with the following objectives: (a) integrated implementation of surveillance activities promotions regarding effective use of resources, (b) use of several organization's processes and personnel for surveillance activities, and (c) strengthening disease surveillance and response systems at community, health facility, state and national levels (Tomori, Odubanjo, Lan & Olanipekum, 2013). The IDSR system differs from the DSN system because the IDSR system utilizes the same human and material resources for the surveillance of all priority diseases while separate human personnel and tools were used for the surveillance of each priority disease in the DSN system. Additionally, the IDSR system promotes community participation for the identification and response to disease outbreaks while only surveillance officers and health personnel are required in the DSN system (Chibueze, 2014). The main initiative towards global elimination of NNT is the UNICEF, UNFPA, WHO, Maternal and Neonatal Tetanus Elimination Initiative (MNT) strategy, which put forth the goal of reducing neonatal tetanus cases to < 1 case per 1.000 live births by the year 2015 (WHO, 2014b). This strategy conforms to the realization of the United Nations Millennium Development Goals (MDGs) and the WHO/UNICEF Global Immunization Vision and Strategy (UNICEF, UNFPA, WHO, 2012).

Strengthening NNT surveillance is a major component for achieving the goal of elimination; however, despite the introduction of IDSR to strengthen the surveillance system, NNT still remains under-reported in many states in Nigeria (Onwasigwe, Adogu, & Onyeonoro, 2012). The World Health Organization (2015a) reported that, Nigeria and other African countries including Guinea Bissau, Mali, Mauritania, Chad, Cameroon, Senegal, Niger, Ethiopia, Angola, Burkina Faso, Liberia and Ghana still report less than 5% of the actual NNT cases. Failure of the IDSR system to promptly report NNT cases for response was probably accountable for the high NNT mortality rate reported from surveys conducted in some health facilities in Nigeria (WHO, 2015a). A health facility-based survey conducted by Emodi, Ikefuna and Obichukwu (2011) in Southeast Nigeria reported an NNT mortality rate of 31.7%. And a similar study conducted in Southwest Nigeria also indicated a high NNT mortality rate of 54% (Adeniyi, Mabogunje, Okoromah & Renner, 2010, p. 148). The NNT mortality rate remains high in Nigeria despite national efforts to eliminate the disease. Of serious concern, little is known of the associations between NNT risk factors and NNT mortality (Lambo & Anokye, 2013), which showed an important gap in the literature that requires further research. The outcome of this study can be used as evidence to strengthen the NNT surveillance system by looking at new approaches as well as introducing identification and analysis of NNT mortality risk factors. The data obtained can then be used to improve the quality and coverage of specific NNT public health interventions that will invariably reduce neonatal deaths (Lawn, Kerber, Enweronu-Laryea & Cousens, 2010). The IDSR framework also includes the private sector and non-governmental organizations as depicted in Figure 1 (WHO, Centers for Disease Control and Prevention [CDC], 2010):

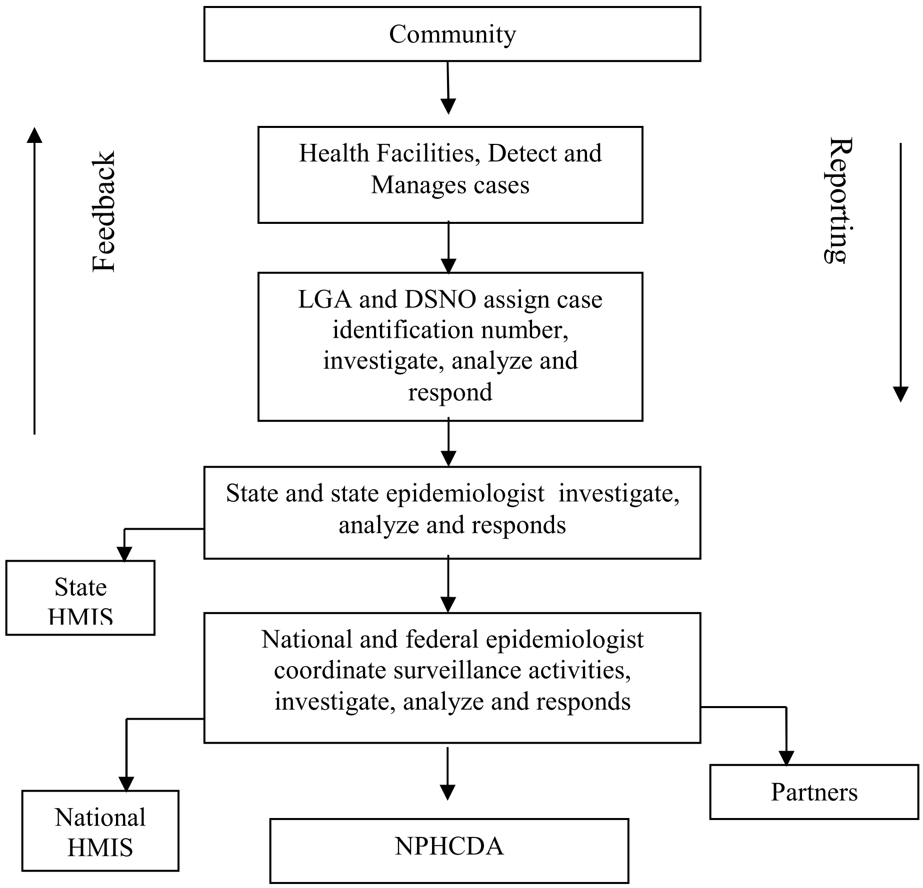

Figure 1. Neonatal tetanus surveillance data flow within the IDSR system in Nigeria. The flow of NNT surveillance information starts from the community then reaches the health facilities were NNT cases are detected and managed. Health facility surveillance focal persons then notify the DSNO who investigates the cases and reports to the state epidemiologist. The state epidemiologist further investigates and verifies the NNT cases. The data is then reported to the national level for further analysis. Data is also shared with the HMIS at both state and national levels for record keeping. The NPHCDA and other partners i.e. WHO and UNICEF cooperate with the federal government for coordination of surveillance activities and response. LGA = local government area. DSNO = disease surveillance and notification officer. HMIS = health management information service. NPHCDA= national primary health care development agency. Adapted from "Integrated Disease Surveillance and Response (IDSR) stakeholders' awareness creation workshop summary, " by O. F. A. Tomori., M. O. Odubanjo., S. M. Lan., A. O. & Olanipekun, 2013, *Nigerian Academy of Sciences.* Reproduced with permission

Problem Statement

NNT is a public health problem in Nigeria that is severely under-reported. Infectious disease surveillance is a fundamental element of public-health policy making and practice (Sahal, Reintjes, & Aro, 2009). The surveillance of many vaccine-preventable diseases is faced with a number of challenges (Phalkey, Yamamato, Awate & Marx, 2013), particularly NNT, which is one of the leading causes of neonatal deaths in the world (Lambo, Khaliro, Memon & Lahari, 2011). Evidence from other studies has indicated a 63% increase in NNT mortality rate attributed to NNT in Nigeria from 23,400 deaths in 1990 to 37,900 in 1997 (Yaguo & Nte, 2009, p. 21). However, Peterside, Duru and George (2012) noted that only 5% of NNT cases were actually reported to health facilities. Further support for this claim comes from studies that have examined the surveillance systems of developing countries and found an NNT detection rate ranging from 2% to 8% (Lambo et al., 2011, p.564). In 2013, the World Health Organization found that only 11% of NNT cases were reported globally; that is, 5,476 NNT cases were reported out of an estimated 61,000 deaths attributed to NNT (WHO, 2014b).

In 2013, Nnebue, Ibeh, Onwasigwe and Adogu reported suboptimal functionality of the disease surveillance and notification system in Southeastern Nigeria. Timeliness of data collection and reporting was found to be 10% among health facilities and almost 16% of the health facilities were out of stock or the disease notification forms. A similar study conducted in Northern Nigeria indicated close to 30% of health workers never reported any notifiable condition within the past 12 months (Bawa, Olumide & Umar, 2003, p.49,).

Though NNT is a notifiable disease in Nigeria, it is still acknowledged that the timeliness, completeness and quality of notification remain major challenges of the IDSR (WHO, 2009). Nigeria alone was responsible for over 40% of a global NNT mortality rate from 1998 to 1999, which should be viewed in consideration of the gross underreporting (Oyedeji, Fadero, Joel-Medewase, Elemile, & Oyedeji, 2012, p.847), which is the second highest in the world after India (Onalo, Ishiaku & Ogala, 2011, p.255). The level of underreporting and inadequate data of the incidence and mortality rate of NNT specifically in Northern Nigeria both remain serious obstacles to the elimination of the disease in Nigeria. Evidence from contemporary literature indicates that evaluations of NNT surveillance systems in Nigeria were mostly conducted in the Southern region (Antai, 2011).

Purpose of the Study

The purposes of this study were two-fold: to compare prevalence and mortality rates of neonatal tetanus reporting between the IDSR and active surveillance of health facility records, and to assess mortality risk factors associated with NNT identified by active surveillance in Katsina State, Nigeria. The active surveillance approach was used to determine the actual prevalence and level of underreporting of NNT cases in the surveillance system. The selected NNT risk factors also referred to as proximal factors were categorized into predelivery: number of tetanus toxoid immunization (TT) injections received by mothers, frequency of antenatal visits attended by mothers, and delivery factors such as the place of child delivery and cord care received by mothers. The information was extracted from NNT clinical records identified through active surveillance. The assessment of these selected proximate factors was relevant to the study because it was hoped that it would be possible to also identify factors that contributed to NNT mortality in NNT surveillance.

Research Questions and Hypotheses

RQ1: Is there any difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State?

$H_0$1: There is no difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State.

H_a1: There is a difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State.

RQ2: Is there any significant association between the number of TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State?

$H_0$2: There is no significant association between the number of TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State

H_a2: There is a significant association between the number of TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State

RQ3: Is there any significant association between the frequency of antenatal care (ANC) visits attended by pregnant women and NNT mortality identified by the active surveillance method in Katsina State?

H_03: There is no significant association between the frequency of ANC visits attended by pregnant women and NNT mortality identified by the active surveillance method in Katsina State.

H_a3: There is a significant association between the frequency of ANC visits attended by pregnant women and NNT mortality identified by the active surveillance method in Katsina State.

RQ4: Is there any significant association between the place of child delivery and NNT mortality as identified by the active surveillance method in Katsina State?

H_04: There is no significant association between the place of child delivery and NNT mortality as identified by the active surveillance method in Katsina State.

H_a4: There is a significant association between the place of child delivery and NNT mortality as identified by the active surveillance method in Katsina State.

RQ5: Is there any significant association between cord care received by neonates during delivery and NNT mortality as identified by the active surveillance method in Katsina State?

$H_0$5: There is no significant association between cord care received by neonates during delivery and NNT mortality as identified by the active surveillance method in Katsina State.

H_a5: There is a significant association between cord care received by neonates during delivery and NNT mortality as identified by the active surveillance method in Katsina State.

Conceptual Framework

This study was guided by the Mosley and Chen (1984) model for the elements of child survival in developing countries. The framework proposes that there are certain socioeconomic determinants of child mortality that function through intermediate variables or common biological pathways that influence mortality (Mosley & Chen, 1984). The framework for the study is a modified version the Mosley and Chen (1984) framework. Only variables and constructs relevant to the present study were selected. The model in Figure 2 below shows three categories of independent variables: community factors, socioeconomic factors, and proximate factors. The framework posits that child mortality is a cumulative effect of multiple processes involving community, socioeconomic, and proximate factors and unlikely due to the effect of an isolated disease occurrence (Mosley & Chen, 1984). Figure 3 shows the framework for this study which gives more emphasis on the relationships between selected proximate factors and neonatal mortality. This study only focused on proximate factors that conform to the following independent variables: frequency of antenatal visits to the health facility, number of tetanus toxoid injections during pregnancy, place of delivery, and cord care during delivery. The dependent variable is neonatal mortality. Table 1 provides the definitions of the variables to be used in the study:

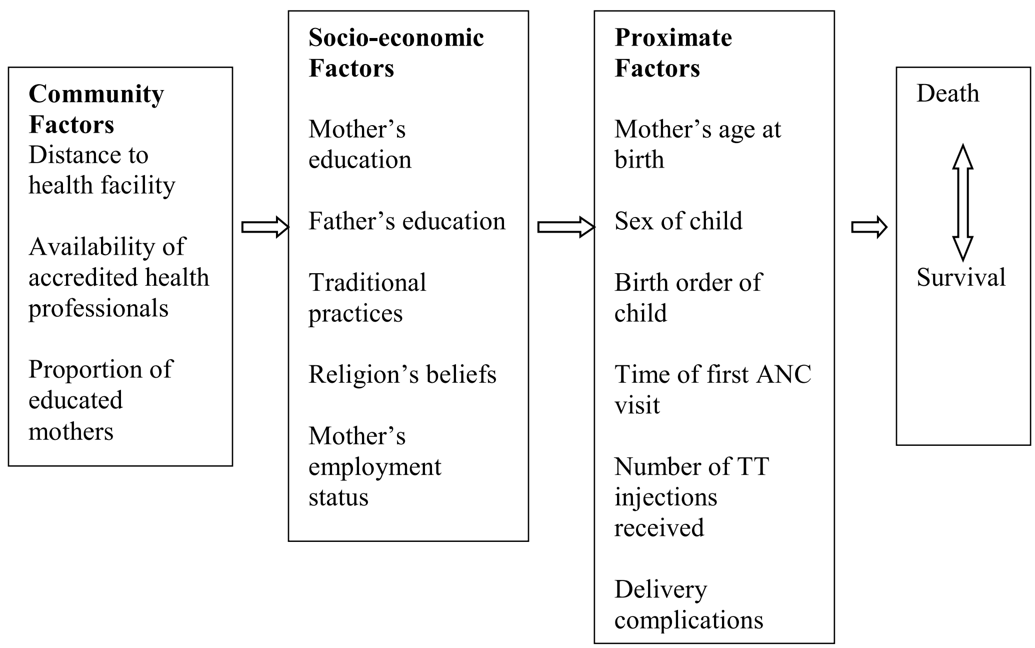

Figure 2 Conceptual framework showing determinants of neonatal mortality. NNT = neonatal tetanus. TT = tetanus toxoid. ANC = antenatal care
Adapted from "Determinants of neonatal mortality in rural India, 2007-2008," A. Singh; A. Kumar, and A. Kumar, 2013, *Peer Journal,* Issue e75, p.5. Reproduced with permission

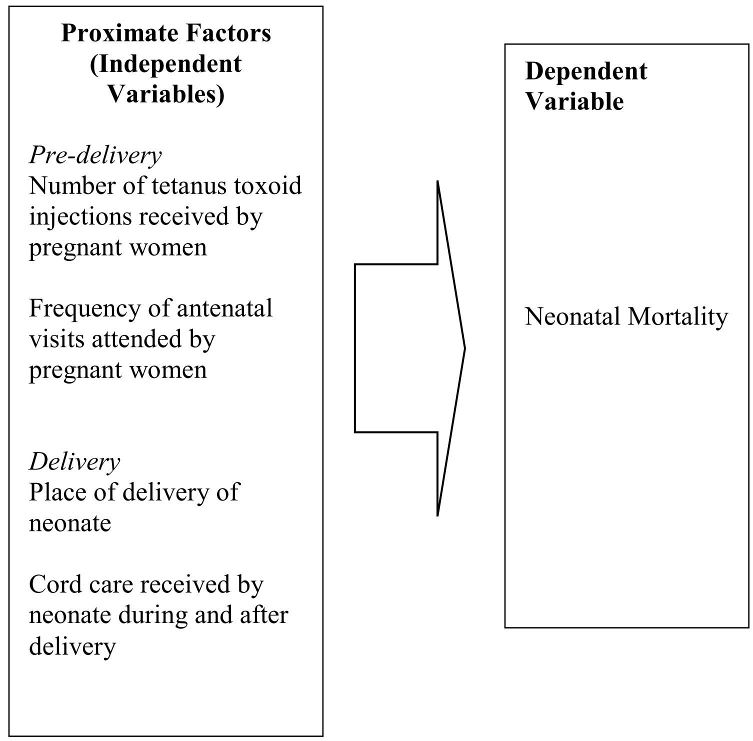

Figure 3. Conceptual framework showing proximate factors and neonatal tetanus mortality used in the study.

Nature of the Study

This study is a cross-sectional survey of surveillance data from 2010 to 2014 obtained from two independent sources: primary sources extracted from passive surveillance, that is, state IDSR data, and secondary sources extracted from active surveillance approach, that is, health facility records. Details on independent variables, number of TT injections, frequency of ANC visits, place of delivery, and cord care, were identified from review of 332 NNT clinical records in seven health facilities and IDSR data of NNT cases diagnosed based on World Health Organization standard case definition (WHO, 2014a). Access to this data was gained by obtaining permission and approval to conduct the study from the Katsina state ministry of health. Descriptive analysis was used to estimate NNT prevalence rates, NNT mortality rate, and any differences in the prevalence of NNT reported in primary sources and cases identified from secondary sources. Binary logistic regression model was used to identify associations between the independent variables, number of TT injections, frequency of ANC visits, place of delivery, and cord care, and neonatal tetanus mortality including adjusted odds ratios and related 95% confidence intervals. Data was analyzed using SPSS.

Definition of Terms

Active surveillance: This is a form of surveillance when a reviewer or public health agency seeks information about health conditions through regular contacts with health care providers or review of health facility records. The frequency of contacts could be on a daily, weekly, or monthly basis.

Antenatal care: Care provided to a pregnant woman by a trained health worker to ensure healthy outcome for both newborn and mother. Services rendered during antenatal care include screening of diseases such as diabetes, HIV/AIDS, Hepatitis B, and hypertension. Tetanus toxoid (TT) immunization for the prevention of neonatal tetanus is also given to pregnant women. Antenatal care commences between the 9th and 12th weeks of pregnancy.

Case definition: Case definition in disease surveillance systems is the standard criterion that is to be met before a disease is considered a “case” (CDC, 2015).

Completeness of reporting: The proportion of surveillance reports received of a particular disease irrespective of the time of submission.

Cord care: A specialized procedure of cleaning the umbilical cord of newborn babies to prevent infection with pathogenic microorganisms including Clostridium tetani, the causative agent of neonatal tetanus. The cleaning continues until the umbilical cord falls off and the site heals. It begins with clamping of the umbilical cord, then cutting it with a sterilized instrument. The cord is cleaned with a variety of antiseptic agents.

Evaluation: Systematic assessment of the significance, competence, efficiency, and progress of a program or policy, in relation with set objectives (WHO, 2015c)

Incidence: Number of occurrences of the start of a disease or of individuals becoming ill during a specified period in a given population.

Neonatal mortality: The death of a baby within the first 4 weeks (28 days) of life.

Neonatal tetanus (NNT): A severe and occasionally fatal generalized form of tetanus that affects newborns. It is transmitted due to infection of an unhealed or severed umbilical stump, usually when the umbilical stump is cut with an unsterilized instrument. Newborns that are most at risk are those who have not acquired maternal antibodies from unimmunized mothers.

Neonatal tetanus mortality rate: The proportion of neonatal tetanus cases that resulted in death.

Notifiable disease: A disease of public health importance that should be reported to the health authorities when a diagnosis is established.

Passive surveillance: A form of surveillance in a public health system that receives information about health conditions from health care providers or informants. The timeliness of reporting of health related data is determined by the reporting system.

Proximate factors in disease causation: Immediate socioeconomic, environmental or physiological factors that influence or determine health events or behaviors.

Sensitivity in surveillance: Capacity of a surveillance system to detect and report the actual number or occurrences of health events

Tetanus toxoid: Sterile vaccine synthesized from detoxified tetanus toxin used to stimulate active immunity in the body to confer permanent protection against tetanus infections. Women of child bearing age (i.e., 15 – 49 years) are expected to receive at least five doses of tetanus toxoid vaccine so as to acquire active protection against neonatal tetanus infection. Tetanus toxoid vaccine also protects neonates against neonatal tetanus infection through passive immunity in which antibodies stimulated by the vaccine pass to through the placenta to the child during pregnancy.

Each tetanus toxoid vaccine has duration of protection against neonatal tetanus infection as depicted in Table 1:

Table 1

Schedule and Duration of Protection of Five Doses of Tetanus Toxoid Vaccine

Dose	**When received**	**Duration of Protection**
Tetanus toxoid 1 (TT1)	At first contact in pregnancy	None
Tetanus toxoid 2 (TT2)	4 weeks after tetanus toxoid 1	3 years
Tetanus toxoid 3 (TT3)	6 months after tetanus toxoid 2	5 years
Tetanus toxoid 4 (TT4)	1 year after tetanus toxoid 3	10 years
Tetanus toxoid 5 (TT5)	1 year after tetanus toxoid 4	For a life time

Note. : TT = Tetanus Toxoid. Adapted from "Vaccine safety basics e-learning: Tetanus toxoid vaccine" by World Health Organization, 2015, retrieved 02/10/15 from http://vaccine-safety-training.org/tetanus-vaccine-example.html

Tetanus: Severe bacterial infection caused by the bacteria Clostridium tetani that usually begins from a severed skin or wound that gets infected by contaminated soils, unsterile instruments, or objects. It is characterized by neck stiffness, fever, and rigidity or spasms of muscles caused by a toxin secreted by the bacteria.

Timeliness of reporting: The proportion of surveillance reports received at a specified period

Type of birth attendance: The competency level of the assistants providing obstetric care.

Underreporting: The occurrence of the disease is not reported to any level of a disease surveillance system.

Verbal autopsy: A process of determining the cause of mortality associated with a disease or event through interviews and discussions in a an area with no health data

Vertical surveillance: A disease surveillance system that primarily focuses on a single and specific disease or health event. Data related to the disease is reported to the disease control system for action (Choi, 2012)

Assumptions

The following assumptions were considered in this study:

- Neonatal tetanus was identified and reported by the Integrated Disease Surveillance and Response System in Katsina State since the introduction of the program in 1998;
- information on risk factors and neonatal mortality obtained from mothers of children affected with neonatal tetanus was reliable and valid;
- the active surveillance approach would lead to identification of unreported neonatal tetanus cases that occurred in the past five years in Katsina state; and
- the logistic regression model would find the association between number of TT injections, frequency of ANC visits, place of delivery, cord care, and neonatal tetanus mortality.

Scope and Delimitations

The study sample for this study was drawn only from public health facilities. Private health facilities could not be sampled in this study due to the unattainability of comprehensive list all private health facilities in Katsina state.

Limitations

The first limitation to the study was the threat to external validity that could have caused selection bias. Although the diagnosis of neonatal tetanus is made based on a "standard case definition" for every clinician (WHO, 2015a), differences in knowledge of NNT among clinicians in the three health care settings (i.e. primary, secondary, and tertiary) have affected identification of NNT cases. This threat was minimized by the use of WHO case definition to screen for NNT cases by data abstractors and review of NNT records by the medical reviewers. The second limitation was related to threat to internal validity which could have caused instrumentation bias. It involves dealing with incomplete or missing NNT data from health facility records during data collection. This threat was minimized by structuring and standardizing the questionnaires with closed ended questions. A pilot study was also conducted to assess the validity of instruments of data collection by calculating the Cohen's Kappa index. An index of less than 60% would have required further training of the data abstractors and medical reviewers.

Significance

This study was relevant because of the following reasons. First, it assesses the concept of the "iceberg phenomenon" that emphasizes that for every disease condition the amount of identified cases is overshadowed by those that are unapparent (Magombedze, Ngonghala, & Lanza, 2013). Second, evidence from contemporary literature indicated that the evaluations of NNT surveillance systems in Nigeria were mostly conducted in the Southern region. Thus, this study provided unique data and a potential insight on the degree of under-reporting of neonatal tetanus cases in the

Northern region which has a higher risk of neonatal mortality than the Southern region (Antai, 2011). This disparity has been attributed to higher level of health literacy in the Southern region, and poor knowledge and practice of child spacing methods as well sa the younger age at first marriage of women in the Northern region (Adebowale, Yusuf & Fagbamigbe, 2012). Third, the persistent underreporting of NNT and scarcity of risk factor information are serious impediments to developing strategies aimed at eliminating NNT in Nigeria. Hence, data on the impact of predelivery and delivery factors on NNT mortality can be used to create positive social change by means of instituting policies that will incorporate NNT risk factors surveillance into the current less effective Integrated Disease Surveillance System.

Summary

According to the World Health Organization, (2006), a functional disease surveillance system is crucial for enhancing evidence-based policy making. In this regard, the Federal Government of Nigeria (FGN) needs to review and strengthen the current status of the neonatal tetanus surveillance system due to the high levels of NNT underreporting in the IDSR system and the high NNT mortality rate in the country.

This study serves as a tool for developing a new framework for NNT surveillance that is more sensitive with the capacity for early detection of potential risk factors of NNT to ensure positive changes in the outcome of NNT through specific interventions.

Chapter 2 provides the literature review for this study. It consists of the theoretical groundwork of contemporary literature related to the Mosley and Chen's (1984) conceptual framework on child survival in developing countries and studies conducted globally regarding constructs of interest and neonatal tetanus

Chapter 3 presents a description of the independent and dependent variables including covariates in the study. Additionally, it describes the threats to validity of the study and provides details of the study research design and how it will address the knowledge gap in the associations between proximate factors and neonatal death.

Chapter 4 presents the description of the data collection procedures and challenges faced during data collection. Additionally, this chapter presents the methods of data analysis and the final the results of the study.

Chapter 5 provides an analysis and interpretation of findings, limitations to the study, recommendations made based on findings, conclusions, and implications for positive social change

Chapter 2: Literature Review

Introduction

The purposes of this study were to evaluate the sensitivity of neonatal tetanus reporting in the IDSR by comparing the already existing passive surveillance system and the adoption of a new active approach as well as to determine the associations between selected NNT risk factors and NNT mortality rate in Katsina State, Nigeria. Reviews of health facility records on the prevalence of NNT and associated risk factors for developing NNT were well documented (Lambo & Anokye, 2012). However, little was known in literature on differences between NNT prevalence and the mortality rates data extracted from health facility reviews and NNT prevalence and the mortality rates data under the IDSR. Active surveillance of NNT entails the active search for identifying NNT cases that were not identified, recorded, and notified under the passive surveillance system. It involves review of health facility neonatal records or community based verbal autopsies (Pan American Health Organization, [PAHO], 2005). Health workers conducting community-based verbal autopsies are required to assess morbidity or mortality rates in neonates that are less than 7 days of age. In doing so, they note place of delivery, cord care provided, and history of the infant's inability to suckle 48 hours after delivery. A diagnosis of NNT mortality is made when a response indicates home delivery, poor cord care, inability to suckle 48 hours after delivery, and mortality (PAHO, 2005). Lawoyin, Onadeko and Asekun-Olarinmoye, (2015), conducted a 5 year (1993-1998) community-based autopsy to assess the risk factors associated with neonatal mortality in a rural settings in Southwestern Nigeria. The researchers conducted a house-to-house survey and administered questionnaires in the study area with an estimated population of 3,013. The results showed a neonatal mortality rate of 33 per 1,000 live births and NNT mortality rate of 3.1%. Similarly, Adetola, Tongo, Orinmadegun, & Osinusi, (2011), utilized community based verbal autopsy to assess the determinants of neonatal mortality in Ibadan, Southwestern Nigeria. The results showed that neonatal infections (41.2%) including NNT were among the leading cases of neonatal mortality (Adetola et al, 2011, p.243).

This study focused on four events associated with NNT that occur during antenatal, natal, or postnatal periods: the numbers of tetanus toxoid injections received by pregnant women, frequency of antenatal visits before delivery, place of delivery, and cord care. This chapter also provides the literature review strategy; an exhaustive review of the current literature on the Mosley and Chen's conceptual framework on child survival in developing countries, and studies conducted globally regarding constructs of interest (i.e., neonatal tetanus, tetanus toxoid vaccine, and ANC, place of delivery, and cord care in regard to neonatal mortality). The chapter concludes with a summary of available literature and gaps in literature that this study fills.

Literature Search Strategy

The literature search strategy for this study was designed to identify quantitative studies that explored associations between neonatal tetanus mortality and certain risk factors such as the number of neonatal tetanus injections, frequency of ANC visits, place of delivery, and cord care. Any publication that contained quantitative data on the subjects of interest, including retrospective record reviews and community-based and health facility-based surveys, were searched. The search strategy was restricted to studies published in the English language. The main search terms used in the study included: *tetanus*, *neonatal tetanus*, *neonatal mortality*, *risk factors*, *cord care*, *tetanus toxoid*, *antenatal care*, *home delivery*, and *health facility delivery*. The search was conducted through a variety of databases including Google Scholar, ProQuest, Medline, PUBMED, and African Journal Online. In some cases, the search was narrowed to Nigeria or developing countries by including *Nigeria* and *developing countries* into the search terms.

Peer-reviewed articles were systematically searched utilizing PsycARTICLES and PsycINFO, while additional papers, abstracts, and publications from various symposia and conference proceedings relevant to this study were searched through the websites of national and multinational organizations such as Federal Ministry of Health, Nigeria (FMOH), Federal Office of Statistics, Nigeria, Nigeria Primary Health Care Development Agency (NPHCDA), WHO, World Bank, UNICEF , CDC and, Walden University Library Electronic Portal.

The initial search contained articles with substantial contemporary literature published between January 1, 2010 and January 31, 2015. The date parameter for searching published articles in areas with little literature was increased to January 1, 2001. A total of 2,171 articles were obtained at the initial stage of the search including 742 duplicated articles that were excluded. In the second stage, of the remaining 1,429 articles, 1,308 articles were screened out due to any of the following criteria: studies conducted in developed countries, qualitative studies, and studies not related to NNT risk factors. In the third stage, of the remaining 121 articles, 66 articles were ineligible for review because the authors focused primarily on NNT risk factors rather than associations between NNT mortality and NNT risk factors. Figure 4 depicts the summary of literature search strategy of the study.

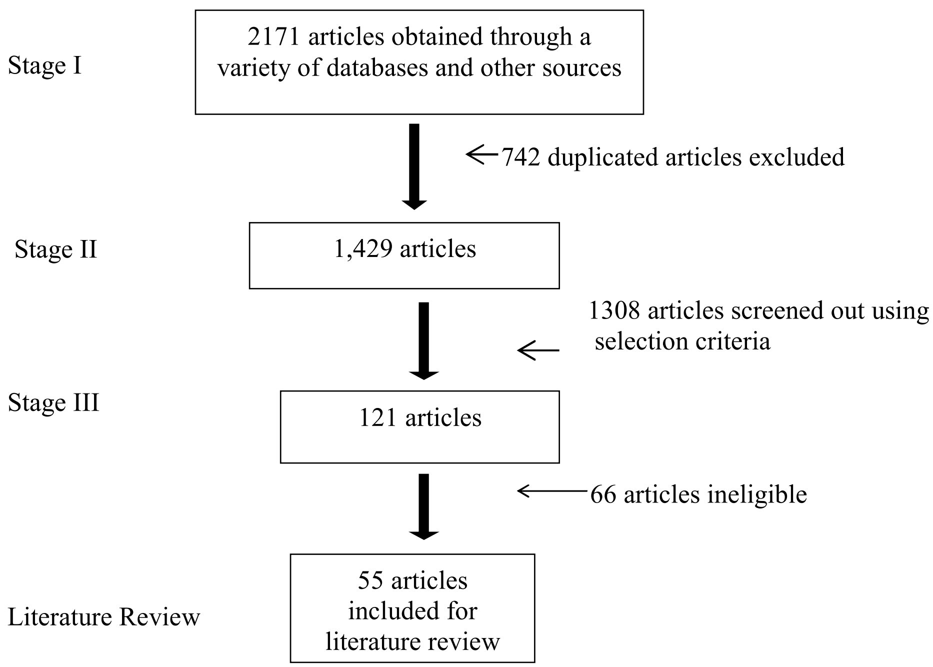

Figure 4. Literature search strategy of the study. A total of 2171 articles were obtained at the initial stage of the search including 742 duplicated articles which were excluded. In the second stage, of the remaining 1,429 articles, 1,308 articles were screened out due to any of the following criteria: studies conducted in developed countries, qualitative studies and, studies not related to NNT risk factors. In the third stage, of the remaining 121 articles, 66 articles were ineligible for review because the authors focused primarily on NNT risk factors rather than associations between NNT mortality and NNT risk factors

Conceptual Framework

This study was guided by the Mosley and Chen's (1984) framework for the study of child survival. The basic concept of the framework is that child mortality occurs due to socioeconomic and cultural factors that operate through intermediate factors also known as proximate factors (Lasen & Carmichael, 2010). The framework was developed as a result of efforts by Mosley and Chen to integrate the roles of socioeconomic and cultural variables with the roles of disease processes in child health (Macassa, Hallqvist & Lynch, 2011). Examples of socioeconomic factors include parental marital and employment status, parental education, race, residence, beliefs, and so on. Proximate factors are those events that are closest to causing an outcome. Table 2 depicts the five classes of proximate factors according to Mosley and Chen (Singh et al, 2013):

Table 2

Mosley and Chen's Classification of Proximate Factors

Category	Sub-category	Examples
Environmental Pollution	Air	Climate change
	Water	Industrial & sewage leaks
	Soil	Oil spills & waste dumps
Malnutrition	Micronutrients	Vitamin deficiency
	Macronutrients	Protein Energy Malnutrition
Injury	Intentional	Sexual Assault, Suicide
	Unintentional	RTA, Burns, Drowning
Self-illness control measures	Preventive	Healthy eating & Exercise
	Curative	Health care services
Maternal	Pre-delivery	Maternal immunization status
	Delivery	Place of delivery, Cord care
	Post-delivery	Child immunization

Note. . RTA = road traffic accident

The modelling of proximate factors of child survival was first used by Davis and Blake in 1956 in a study where the authors assessed the impact of intermediate variables on levels of fertility in a community (Davis & Blake, 1956). They presented three categories of proximate determinants of fertility which were: factors that influenced conception before intercourse, factors that influenced conception following intercourse, and factors that influenced live birth following conception. To date, the Mosley and Chen framework has been suitable for researchers in identifying the various socioeconomic, cultural, and physiological determinants of child morbidity and mortality (Macassa et al., 2011). In contrast to the modelling of proximate factors, other child survival models were developed by Strauss and Thomas (1995) and Caldwell (1979), which only focused on the fundamental determinants of child morbidity and mortality such as sanitation, nutritional status, socioeconomic status, health inequality, and so forth (Masuy-Stroobant, 2001). The framework developed by Meegama (1980) was based on the various roles of biological factors on child mortality. The model did not integrate the roles of socio economic factors and disease processes but rather focused on the classical model of infectious diseases. The concept of the model was that child death was studied through a wide category of determinants of death with the aim of identifying their modes of communication; that is, via water, air, food and so forth, along with the causes of exposure (Gaimard, 2014). In his study conducted in Bangladesh, Meegama (1980) argued that the significant reduction in child mortality in 1920 from 30 per 1000 live birth to 18 per 1000 live birth was attributed to the public health programs implemented in the country. The interventions caused a significant reduction in cases of child malnutrition and diarrheal diseases transmitted through contaminated water (Hague, Hossain, Sultana, Kais & Hague, 2011, p.19). While in the case of the Garrenne and Vimard (1984) framework, determinants of child mortality was not only limited to disease processes and socioeconomic factors alone but also recognized ecological and political variables. The Garrenne and Vimard (1984) framework identified the following classes of variables based on their relationships with child mortality, namely:

- Discriminating variables otherwise referred to as socioeconomic variables. These are factors that did not have any direct impact on child mortality, such as economic status of parents, political system where the child lived, geographic characteristics of the location were the child lived, and so forth.

- Independent variables that were the various levels or dimensions of the discriminating variables, for example, economic status subclassified as low income, middle income, or high income, or geographical characteristics subclassified as tropical or temperate. The model identified these subclasses as to probably have an effect on child mortality through proximate or intermediate factors.
- Intermediate or proximate variables that were factors most likely to directly cause child mortality. There were five subcategories in the model, nutrition, immunity, diseases, birth, and health behaviors.
- Determining variables that were factors that were primarily medical determinants of death. According to Garenne and Vimrad (1984) child mortality was an outcome of complex processes that could hardly be attributed to a single determinant.
- Dependent variables such as the total child mortality rate (Caseli, Vallin, & Wunsch, 2005).

Alberto Palloni (1985) developed a model that focused more on the relevance of implementation of social policies and health interventions aimed at reducing high child mortality rates in developing countries. The concept of his model was that high child mortality rates and the effect of determinants of child mortality were caused by failure to implement health policies and interventions against them (Gairmard, 2014). The framework was made up of three levels: (a) the policy level, which laid emphasis on health education, health communication, access to health care, health equity, and health equality; (b) the individual level, which stressed the importance of respective and collective roles of individual, household, and community characteristics on child mortality, including maternal education, and behavioral and biologic characteristics, and (c) house hold characteristics, which included family resources and structure, overcrowding, and community characteristics including community health system, access to health care services, and the biomedical ecology, that is, immunity and susceptibility to disease and exposure to causative agents (Casell et al., 2005)

In developing countries, several studies aimed at identifying determinants of child mortality were guided by the Mosley and Chen framework. In Bangladesh, Chaudhury, Shafiqul-Islam and Karim (2013) used multivariate proportional hazard models to identify covariates of neonatal and postneonatal mortality. In Brazil, Felisbino-Mendes, Matozinhos, Miranda, Villamor, and Velasquez-Melendez (2014) conducted at 12-year survey to identify the relationship between maternal obesity and child mortality. In Ghana, Bobor, Kumi-Kyereme, Yendaw and Adu-Opong (2014) examined the impact of socio demographic variables on child mortality among children with anemia. Researchers in India assessed the effect of socioeconomic and cultural factors on child mortality in malnourished children (Adak, Dhar, Mitre & Bharat, 2014). Karatepe (2010) also evaluated the associations between socioeconomic factors and child mortality in Turkey. In Vietnan, Pham, Kooreman, Koning, and Wiersma (2011) evaluated the relationship between gender differences and child mortality. In Nigeria, Mesike and Mojekwu (2012) examined the impact of environmental factors on child mortality.

This study was also guided by the Mosley and Chen's (1984) framework for child survival in developing countries with the assumption that intermediate factors or proximate determinants directly affected neonatal mortality in newborns diagnosed with neonatal tetanus. The proximate factors selected for the study were number of tetanus toxoid injections received by mothers, frequency of antenatal visits attended by mothers, place of child delivery, and cord care provided to child after delivery. The choice of these variables was based on a literature gap regarding the associations between the selected proximate factors and neonatal death among newborns diagnosed with neonatal tetanus in Nigeria and sub-Saharan Africa (Lambo & Anokye, 2013). Thus, the study benefited from the Mosley and Chen's framework, having taken cognizance of the statistically significant outcomes from several studies that applied the framework.

Studies Conducted Globally Regarding Constructs of Interest and Neonatal Tetanus

The constructs of interest considered in this study were: number of tetanus toxoid injection received by mothers, frequency of antenatal visits attended by mothers, place of delivery and cord care provided during delivery. It was assumed that each of these constructs had an association with neonatal death among neonates diagnosed with neonatal tetanus.

Tetanus Toxoid Vaccine

Tetanus toxoid vaccine is an inactivated vaccine that is administered to prevent tetanus infection in individuals. The vaccine was first developed in 1924 by Pierre Descombey and later used by the United States military to prevent soldiers from tetanus infection during World War II (CDC, 2011). Since its discovery, the vaccine has significantly reduced the incidence of tetanus in developed countries and has been widely used in developing countries as the main tool for eliminating the disease (Blencowe et al, 2010). To reduce the global burden of neonatal tetanus, the World Health Organization introduced vaccination of tetanus toxoid to pregnant women in national immunization policies and strategies (Singh et al, 2012). According to Blencowe et al. (2010) deaths from NNT still remain endemic in Nigeria and India due to poor coverage of tetanus toxoid vaccines in rural communities. An immunization coverage survey conducted in Nigeria showed that out of 601 mothers surveyed, only 25.2% of the mothers received the first close of tetanus toxoid while only 13.6% of the mothers received the second dose and finally only 61.2% of the mothers received both first and second doses of tetanus toxoid (Kunle-Olowu, Kunle-Oluwu & Emeka, 2010, p. 91). The Nigerian 2007 to 2010 immunization coverage survey indicated a less than 50% national coverage of tetanus toxoid yearly (NPHCDA, 2015, p. 17). Another survey conducted on 1540 pregnant women in Southern Nigeria showed first and second tetanus toxoid coverage of 64% and 50% respectively in 2012 (Nwokeukwu, Ukegbu, Emma-Ukaegbu & Nwogu et al., 2014, p.1272,). Omotara et al. (2012) reported that immunization coverage of vaccine-preventable diseases in Northern Nigeria was lower than the south, however, there is limited evidence of contemporary literature on the actual coverage of tetanus toxoid among pregnant women in Northern Nigeria.

Tetanus toxoid vaccine is administered to pregnant women during antenatal visits to protect both mother and baby against tetanus infection. The recommended dosage for the vaccine is 0.5ml administered intramuscularly. Following administration of the first dose, the vaccine stimulates the immune system to produce anti-tetanus antibodies which are transported to the fetus through the placenta. These anti-tetanus antibodies confer passive immunity against neonatal tetanus infection to the newborn in the first 28 days of life. The level of protection or immunity after the first dose eventually declines, so a second dose (TT2+) is administered 4 weeks after the first dose to boost the immunity for 3 more years. The third dose (TT3+) is administered 6 months after the second dose and provides immunity for 5 years while the forth dose (TT4+) is administered one year after the third dose which confers immunity for 10 years. The fifth and last dose of tetanus toxoid (TT5+) is received one year after the fourth dose and it provides protection against tetanus for a life time (WHO, 2015). The main process and output indicator for tetanus toxoid immunization in a community is the proportion of pregnant women with second dose of tetanus toxoid (TT2+) or the proportion of newborns less than 28days of age who's mothers have received the second dose of tetanus toxoid otherwise referred to as "protected at birth" (PAB). The 2013 PAB for Nigeria is 60% (World Bank, 2015). NNT is often a fatal disease and death can occur in neonates born to mothers who have not received tetanus toxoid vaccine (Demicheli, Barate & Rivetti, 2013). Unimmunized or partially immunized mothers may have insufficient anti-tetanus antibodies to protect the neonate from NNT infection. Death in neonates infected into tetanus often occurs due to prolonged periods of lack of oxygen supply to the brain (hypoxia) as a result tetanus toxin-induced spasms and rigidity to the respiratory muscles (Hassel, 2013). Akinyemi, Bamgboye and Ayeni, (2013) reviewed the Nigerian Demographic and Health Survey data (NDHS), using cox hazard's model between 1990 and 2008 to assess the pattern and effect of proximate factors in NNT mortality rate in Nigeria. Although the authors concluded that tetanus toxoid injection was associated with a decrease in neonatal mortality rate HR= 0.82, Cl [0.64, 1.05], they did not assess the association between relative frequencies of tetanus toxoid vaccines received and neonatal mortality. McCurdy, Kjerulff and Zhu, (2011), focused on assessing the association between prenatal interventions and decrease in neonatal mortality in 17 countries in sub-Saharan Africa using logistic regression models. The researchers found that newborns whose mothers received two or more tetanus toxoid injections were associated with low neonatal mortality rate OR= 0.78, $p < .001$. Nonetheless, Nigeria was not included in the study. On the other hand, Oyedeji et al. (2012) conducted a cross-sectional study to identify the determinants of neonatal tetanus in a tertiary health center in Nigeria. The results showed that lack of receiving tetanus toxoid during pregnancy was associated with neonatal tetanus in 88% newborns admitted. However, the researchers did not assess the association between status of tetanus toxoid vaccination and NNT mortality rate in the study group (Oyedeji et al., 2012, p. 848). This is similar to the findings of Alhaji et al. (2013) were 66.7% of NNT cases were associated with mothers that did not receive tetanus toxoid.

In Asia, Singh, Pallikadavath, Ogoliah, and Stones (2012) analyzed the 2005 and 2006 Indian Family Health Survey using logistic regression model to assess the associations between tetanus toxoid vaccine and neonatal mortality. The researchers reported a significant association between low doses of tetanus toxoid injections (<2) and NNT mortality rate of 16%. Thus, the odds of neonatal mortality reduced with increased number of tetanus toxoid injections. The study however did not take cognizance of the underreported cases NNT cases in the surveillance system. In the same way, Titaley, Dibley, Roberts, Hall and Agho (2010) in Indonesia examined the associations between proximate factors and neonatal mortality extracted from the 1994, 1997, 2002 and 2003 Indonesian Demographic Health Survey data using Multivariate Cox Proportional Hazards. The results indicated a 34%, HR= 066, 95%, CI [0.48, 0.92] decrease in neonatal mortality rate in newborns born to mothers that received more than two tetanus toxoid injections (Titaley, Dibley, Roberts, Hall & Agho, 2010, p. 502).

Antenatal Care

ANC is a systematic medical supervision of a pregnant woman by trained health personnel from conception up to the time of delivery. The World Health Organization defines ANC as when a pregnant woman pays one or more visits to a qualified health worker during pregnancy (Adeoye, Musa, Atoyebi & Babatunde, 2013). WHO and UNICEF have recommended four visits as the minimum number of antenatal visits for each pregnancy from conception to delivery. During ANC, health workers conduct physical examinations and laboratory investigations to assess the health status of the pregnant women and the fetuses to detect and prevent pregnancy-related complications. Nurses and midwives are the commonest ANC providers in Nigeria (Ekabua, Ekabua & Njoku, 2011). Health education on pregnancy risks and complications of labor, breast feeding and family planning is also provided during ANC. Furthermore, tetanus toxoid immunization is one of the essential interventions provided during ANC visits. Other forms of intervention include nutritional supplementation using iron and folic acid to prevent anemia, identification and treatment of pregnancy related ailments like pre-eclampsia, gestational diabetes mellitus and sexually transmitted infectious STIs etc. (Ajayi, Osakinle & Osakinle, 2013).

Evidence from studies has indicated varying levels of utilization of ANC across sub-Saharan Africa (Pell et al, 2012). Despite this, no attempt was made by the researchers to identify the association between the levels of utilization of ANC services and neonatal mortality. Utilization of ANC services among women in African countries also vary by the level of development of the regions within a country. For example, studies conducted in Nigeria, Kenya and Tanzania indicated that women from urban settings utilized ANC services more than women from rural settings probably due to unequal distribution of health centers rendering ANC services which favored the developed regions (Tey & Lai, 2013. The study indicated an urban to rural ANC utilization ratio in Nigeria, Kenya and Tanzania of 70.7% to 8.3%, 88.6% to 21.2% and 72.1% to 22.9% respectively (Tey & Lai, 2013, p.5). Similar findings were obtained by Daira and Owoyokun, 2010, in a health facility in Southern Nigeria were women from urban settings were two times more likely to utilize ANC services than women from rural settings OR= 2.177, 95% CI [1.081 , 4.382]. Tetanus toxoid immunization is the vital component of ANC that determines NNT mortality rate in a community. If the tetanus toxoid coverage is high during ANC then newborns are less likely to get infected with neonatal tetanus. However, there is little empirical evidence on the missed opportunities for immunization against neonatal tetanus among pregnant woman during ANC visits and its association with neonatal mortality in developing countries (Lassi, Mansoor, Salam, Das & Bhutta, 2014). Nevertheless, Babatunde et al. (2014) conducted a five year review (2007-2012) of 1130 clinical case notes in a tertiary health center in Southwest Nigeria. The researchers found only 6 clinically diagnosed NNT cases out of the 1130 cases in the hospital within the five year period. The results showed that 4 of the NNT cases (66.7%) had mothers who did not attend antenatal care during pregnancy (Babatunde, Adebara, Atoyebi & Oluwagbemi, 2014, p. 44). The researchers however did not attempt to assess any association between the lack of antenatal visits and NNT mortality rate during the five year period. On the other hand, Antai, 2011 and Titaley, et al, 2010 both found that neonates whose mothers attended ANC during pregnancy had a higher risk of mortality in Nigeria (Antai, 2011: Titaley et al., 2010, p. 502). However, the outcome variable assessed in both studies was neonatal mortality not NNT mortality. In Asia, Singh et al, 2012, examined the association between ANC visits among mothers and NNT mortality. The researchers found no significant association between of status of antenatal visits among mothers and NNT mortality OR= 1.19, 95%, CI [0.83, 1.75]. In this study, attempt was made to go further to assess the association between frequency of ANC visits among mothers of neonatal tetanus cases and neonatal tetanus mortality in the study area.

Place of Delivery

The place of delivery is an important factor in the prevention of both maternal and neonatal mortalities. Place of birth could be at home or in the health facility. Home births occur when a baby is delivered at the mother's place of residence (Dekker, 2012). A multi-country survey including 48 countries conducted in developing countries from 2003 to 2008 showed that over 70% of women in developing countries delivered at home

(Montagu, Yamey, Visconti & Hending et al, 2011, p. 4). The most common reason for home delivery reported in the study was “not necessary” in 68% of the respondents. Other reasons include “lack of access” (24%) and “cost” (7%). Home births in developing countries are usually attended by unskilled health workers who have little or no capacity to improve both maternal and neonatal pregnancy outcomes (Yakoob, Ali, Ali, Imdad & Lawn, 2011). Conversely, most health-facility based deliveries are likely to be attended by skilled birth attendants. By definition, skilled birth attendants are accredited health workers that include, physicians, nurses, or midwives who are trained in the skills required to attend to or manage pregnancies that are uncomplicated, normal deliveries and during the post natal period, and also identify, manage and refer complications in mothers and newborns (Ultz, Siddiqui, Adegoke, & van den Broek, 2013). Traditional birth attendants (TBAs) are unskilled workers, thus are not included in the definition of skilled birth attendants. Pregnant women that deliver at home are often attended by TBAs in developing countries (Wilson et al., 2011). The proportion of births attended by skilled birth attendants is vital in the reducing neonatal mortality. Skilled birth attendants reduce neonatal deaths through safe and hygienic delivery practices to avoid NNT infection. They often use sterilized instruments to cut and clean the umbilical cord during and after delivery respectively. Some common unhygienic delivery habits practiced by unskilled birth attendants that predisposed neonates to tetanus infection include treatment of umbilical cord with soil or cow feces which is likely to be contaminated with Clostridium tetani, the causative agent of neonatal tetanus (Emeribe &

Akah, 2011) and unclean/unsterilized razor blades (Babu, Ramachandra, Garikipati & Mahapatra, et al., 2012).

A number of studies have indicated significant associations between place of deliveries and neonatal outcomes in communities. Yakoob et al, (2011), conducted a systematic review of 21 studies on the impact of skilled birth attendance in health facilities on neonatal outcomes. The results showed a 23% decrease in neonatal deaths among neonates delivered by skilled personnel in health facilities, RR= 0.77, 95%, CI [0.69, 0.85]. Another study conducted in India has shown that about 84% neonatal deaths occurred at home and were attended by unskilled birth attendants (Gosh & Sharma, 2010, p. 513). Ibrahim, Isa, Collins and Ugoya (2011) conducted a 6 year survey (2003-2009) on neonatal tetanus in Nigeria. The authors reported a significant disparity in the proportion of deliveries conducted in health facilities between the Northern (41%) and Southern (74%) parts of the country respectively. The study showed similar disparity in NNT mortality rate in both regions i.e. 54% in the north compared 45.8% in the south. Babatunde et al, 2014, on the other hand conducted a survey in tertiary health center in southern Nigeria and reported that only one out of six (16.7%) neonates whose mothers delivered in the health facility died of NNT. The sample size for the study was however inadequate to generalize the outcome of the study. Alhaji et al, 2014, conducted a 2 year review (2009-2010) of 71 NNT cases in tertiary health facility in Northern Nigeria. The results showed a NNT mortality rate of 66.7% and a very low proportion of mothers who delivered in a health facility (5.9%). However, the researcher did not assess the association between place of delivery and neonatal mortality in the study (Alhaji, et al, 2014, p. 400). On the other hand, Lawoyin et al. (2010) in a study conducted in southern Nigeria reported a significant association between mothers who delivered outside health facilities and neonatal death but not NNT mortality rate. On the contrary, Fetuga (2010) reviewed 151 neonatal tetanus death cases from 1991 to 2005 in a tertiary hospital in Southern Nigeria using logistic regression model, the authors reported a significant association between delivery outside health facilities (89.6%) and NNT mortality rate.

Cord Care

Cord care is a specialized care to the umbilical cord of a newborn commenced from delivery up to the time it falls off to prevent the transmission of infection. Studies have shown that about 25% of global neonatal deaths were attributed to poor cord care which lead to umbilical cord infections including NNT (Opara, Jaja & Okari, 2013, p. 32). Umbilical cord infections are collectively referred to as omphalitis. The incidence omphalitis in Turkey was as high as 77 per 1000 live births (Vanisree, Lata & Neelima, 2014) and 217 per 1000 in Pakistan (Mir et al., 2011). Poor cord care practices can cause omphalitis such as: cleansing the umbilical cord with contaminated substances which is a usual practice by unskilled attendants at home delivery and; local sterilization of the umbilical stump using direct thermal heat which destroys the umbilical cord tissue leading to bacterial infection including neonatal tetanus (Joel-Medewase et al., 2014). Unskilled birth attendants in some parts of Southern Nigeria were found to be cleansing the umbilical cord with herbal preparations, cow dung, ash, coconut oil or mud (Opara, Joja, Dotimi & Alex-Hart, 2012). However, little is known in literature on the incidence of NNT due poor cord care practices and its association with neonatal death in Nigeria.

The World Health Organization (WHO), in 2014 recommended the use of 4% chlorhexidine for cleaning the umbilical cord stump for the first seven days of life for newborns delivered at home in countries with neonatal mortality rate of equals to or more than 30 deaths per 1000 live births. While the application of any form of antiseptic to the umbilical cord stump after birth is not recommended for newborns delivered both at home and in health facilities in countries with less than 30 neonatal deaths per 1000 live births (WHO, 2013). This procedure is also known as dry cord care.

Imdad and colleagues (2013) conducted a systematic review and meta-analysis on the effect of chlorhexidine on omphalitis and neonatal mortality in developing countries. The results showed that chlorhexidine application reduced neonatal mortality by 23% in the intervention group as compared to the control group RR = 23, 95%, CI [0.63, 0.94]. Kurumbi et al, 2013, conducted a systematic review on four community based randomized controlled trials in India, Pakistan and Nepal to compare the effect of cord care using chlorhexidine compared with dry care. There were 44,818 neonates assessed in the study and results indicated a 17% decrease in neonatal death as compared to dry care RR = 0.83, 95%, CI [0.74, 0.94]. In a similar study conducted in Bangladesh by Arifeen, Mullay and Shah (2012) the results showed that cord care using chlorhexidine reduced neonatal mortality in 29,760 neonates by 20% as compared to dry care. Another systematic review and meta-analysis conducted in Pakistan, Nepal and Bangladesh by Imdad et al. (2013) showed a 23% decrease in the death of 54,624 neonates in experimental group as compared to the control group RR = 0.77, 95% CI [0.63, 0.94] compared to the control group RR = 23, 95% CI [0.63, 0.94].

Summary and Conclusions

Chapter two described the strategies used to search for literature related to this study including the various search engines, key search terms, and databases utilized. The scope of literature review searched by years for areas with adequate literature ranges from 2010 to 2015 while search for literature in areas with inadequate literature was expanded from 2001 to 2015. Chapter two provided a historical background and current literature on the Mosley and Chen's (1984) model for child survival in developing countries which is the conceptual framework that guides this study. Additionally, an exhaustive assessment of the major themes of the literature review were presented in this chapter namely, tetanus toxoid vaccine, ANC, place of delivery and cord care.

There are a couple of gaps in literature that this study has addressed. First of all, evidence from existing literature indicated that several studies conducted globally that were guided by the Mosley and Chen's model indicated statistically significant outcomes. Secondly, most researchers focused mainly on associations between maternal proximate factors and neonatal mortality. Only few researchers utilized the Mosley and Chen's model to assess the associations between maternal proximate factors and NNT mortality rate. Data on the independent and outcome variables for this study was extracted from retrospective record review of health facility records of newborns diagnosed with NNT in the study area. Thirdly, evidence has shown that most researchers that assessed the association between maternal proximate factors and neonatal mortality in Nigeria focused mostly in the Southern part of the country rather than the North which has a higher neonatal tetanus mortality rate as compared to the south. The study area for this study is located in Northwestern Nigeria. Finally, evidence has shown that most of studies conducted globally that assessed the association between maternal proximate factors and neonatal tetanus mortality did not take cognizance of the under-reported neonatal tetanus cases in the study area. This study assessed the level of under-reported neonatal tetanus cases through active surveillance. Potential confounders to the outcome of this study include: disproportionate distribution of health facilities, distance to health facilities, maternal age, maternal parity, maternal educational status, family income, and pregnancy and childbirth complications.

In recent years studies have explored the future challenges of public health surveillance systems (Choi, 2012: World Alliance for Risk Factor Surveillance [WARFS], 2012). These studies have identified the expansion of public health surveillance systems as a new frontier for exploration. Nishikori and Morishita (2013) both opined that surveillance of risk factors develops our understanding of the role of certain determinants of diseases which can potentially facilitate informed decision making in public health programs and needs further exploration and research (WPRO, 2013). The current neonatal tetanus surveillance system in Nigeria is based essentially on health outcomes, thus, this study will identify probable associations between certain NNT risk factors and neonatal death. There is also dearth of knowledge of the efficiency of individual level control measures NNT in Nigeria (Babatunde et al., 2014). So, hypothetically, the outcome of this study can be used to provide evidence for integrating NNT risk factors surveillance with the IDSR system. Furthermore, insights on NNT associated behaviors and level of child protection from NNT in the study area can be obtained.

Chapter 3 will present a description of the independent and dependent variables including covariates in the study. Additionally, it will describe the threats to validity of the study and provides details of the study design, instrumentation, and sample including how data will be analyzed to address knowledge gap in the associations between proximate factors and NNT mortality.

Chapter 3: Research Method

Introduction

The purposes of this study were two-fold: to compare the prevalence and mortality rates of NNT reporting between the IDSR system and active surveillance of health facility records, and to access the risks associated with NNT mortality rates as identified by active surveillance in Katsina State, Nigeria. This chapter provides a detailed description of the following sections in the following order: (a) search design and rationale, which includes variables, covariates, study design, and research questions; (b) research methodology, which includes target population size, sampling procedures, data collection procedures, and instrumentation; (c) threats to internal and external validity; (d) ethical procedures, which includes Institutional Review Board (IRB) application and approval and ethical issues concerning confidentiality; and (e) summary.

Research Design and Rationale

The study was a cross-sectional survey of NNT IDSR surveillance data and health facility retrospective record review from January 1, 2010 to December 31, 2014. A cross-sectional approach was utilized in this study because it provides a rapid assessment of the prevalence of a disease in a target population (Olsen & St. George, 2004). Cross-sectional surveys are also used to examine the associations between risk factors and variables of interest. Information was extracted by trained nurses as data abstractors and experienced physicians as medical reviewers from the three geopolitical zones (constituencies) of Katsina State, Nigeria. Access to both NNT IDSR data and health facility records was gained with the permission of Katsina State Ministry of Health. The NNT IDSR data included NNT cases line-listed in the IDSR database while health facility records included all NNT cases confirmed based on the World Health Organization (WHO) case definition of NNT as any newborn who could suckle normally in the first 2 days of life but was unable to suckle between the 3rd and 28th days, and has muscles spams or becomes stiff during the period of illness (WHO, 2015a). The data abstractors also screened for double reporting of NNT cases in both IDSR and health facility records. Double reporting occurs when an NNT case is counted twice before the final prevalence rate was calculated.

Descriptive analysis in this study was used to determine the prevalence of NNT in Katsina State by summarizing the total number of NNT cases line-listed in the IDSR database and the total amount NNT cases found in health facility records. The prevalence rate of NNT was then assessed as the total number of NNT cases divided by total number of live births from January 1, 2010, to December 31, 2014, while the NNT mortality rate was assessed as the proportion of NNT cases who died of the disease (CDC, 2015). For analytic analysis, the study aimed to identify whether or not associations existed between proximate factors and neonatal death using a binary logistic regression model. Data was analyzed using SPSS. The proximate factors represented the independent variables, namely: (a) number of tetanus toxoid injections received by mothers, (b) the frequency of ANC visits attended by mothers, (c) place of delivery, and (d) cord care provided after delivery. Neonatal mortality represented the dependent variable which was defined as death of newborn within the first 28 days of life (WHO, 2015a) and was coded as 0 = survived and 1 = death. Both independent and dependent variables were extracted from retrospective record review of NNT health facility records. Figure 5 depicts the association between the five constructs while Table 3 depicts the definitions and categorization of constructs used in the study.

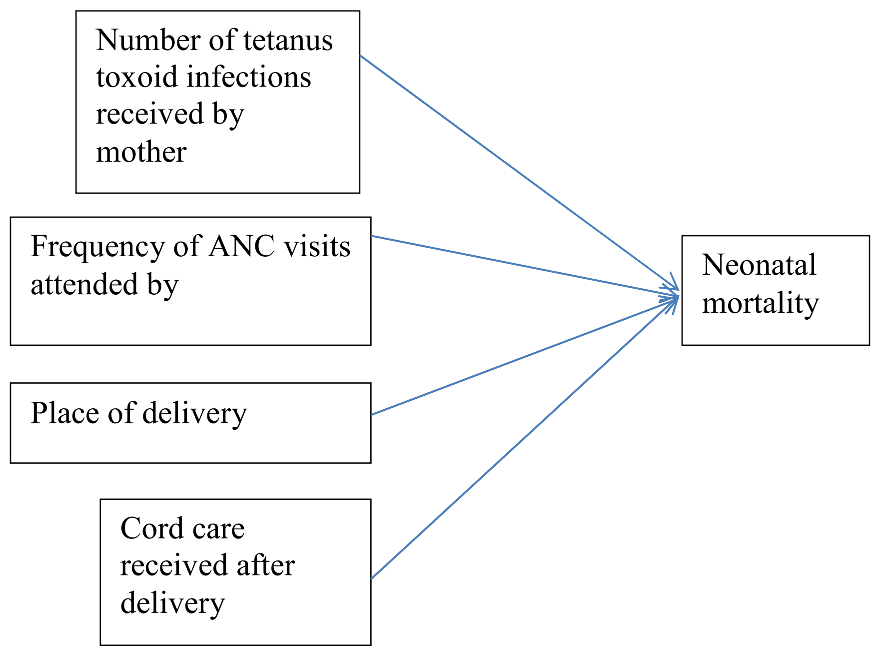

Figure 5. Model of hypothesized association between five constructs in the study. ANC = antenatal care.

Table 3

Definition and Categorization of Variables Used in the Study

Variable	Description	Category
Dependent variable		
Neonatal death	Any death of a child within 28 days of delivery	0=>28days=survived 1=<28 days= death
Independent variables		
Number of TT injection	Number of TT injections received during pregnancy	0= none 1= one 2= two or more
Frequency of ANC visits	Number of ANC visits during pregnancy	0 = No visit 1 = 1- 4 visits 2 = 4 visits
Place of delivery	Place of child delivery	0= Home 1= Health center
Cord care	How umbilical cord cut and stump was treated after delivery	0 = Old razor blade/tying unsterile thread, treatment with soil, cow dump, or any aseptic procedure 1=New razor blade or any septic treatment

Note. NNT = neonatal tetanus. TT = tetanus toxoid. ANC = antenatal care
Adapted from "Determinants of neonatal mortality in rural India, 2007-2008," A. Singh; A. Kumar, and A. Kumar, 2013, *Peer Journal*, Issue e75, p.5. Reprinted with permission

Retrospective record review of health facilities was considered as the appropriate approach for this study because it could determine the prevalence and risk factors of health events (Vassar & Holzmann, 2013). The process involved three key participants: (a) the primary investigator, who was the researcher, (b) the data abstractors who first screened the medical records in the health facility, and (c) the medical reviewers who were clinicians who verified the records screened by the data abstractors (WHO, 2010). The retrospective record review protocol requires the researcher to begin preparation for data collection 3 weeks to data collection while data abstractors and medical reviewers both began preparation for data collection 2 weeks to data collection. The data abstractors and medical reviewers reviewed an estimated 30 to 40 medical records per day. Several studies have been conducted using retrospective record reviews because it can be replicated and used to review wide coverage of medical records (Unbeck, 2012). Ibrahim et al. (2011) conducted a seven year record review of neonatal tetanus cases in a tertiary hospital in Jos, North Central, Nigeria. Other similar examples include studies by Oyedeji et al. (2012) and Emodi et al. (2011), in Southwest and Southeast, Nigeria respectively. Retrospective record reviews are generally easier to extract than other forms of prospective study designs because they are a more efficient approach of collecting and analyzing medical data after exposure to the causative agent (Columbia University, 2015). Thus, a retrospective record review was appropriate for this study because it was used for active surveillance of NNT cases in health facilities and identification of information on the risk factors of NNT in the study area. Additionally, the approach was used to review a wide coverage of NNT cases in the study area, which increased the validity and reliability of the study. Figure 6 below depicts the retrospective review process in the study:

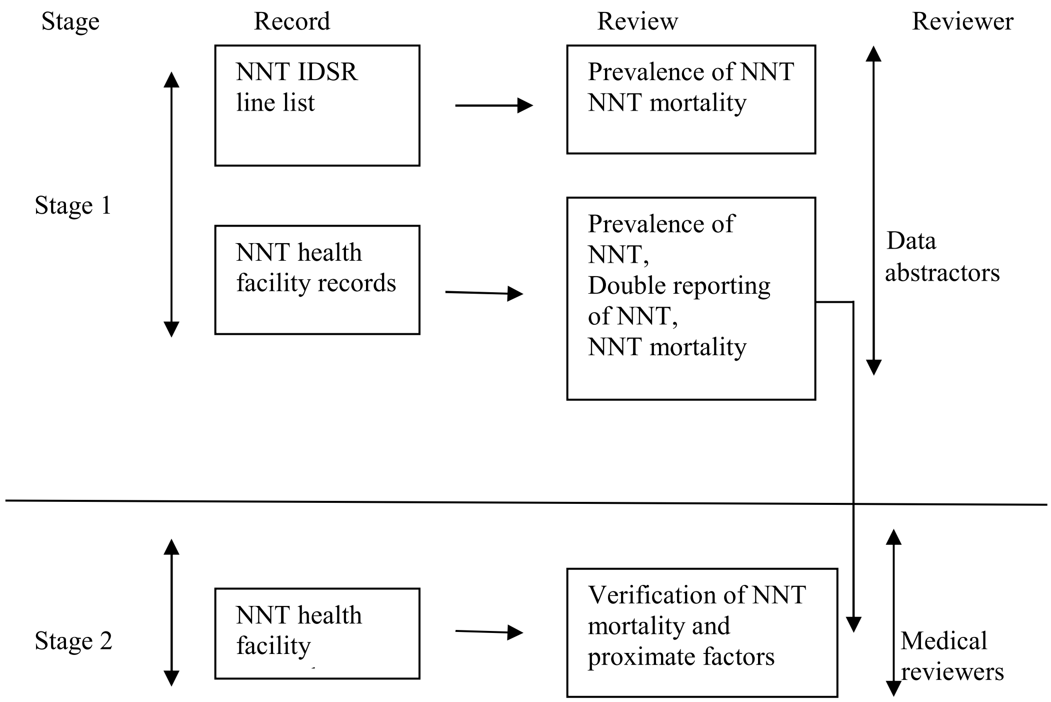

Figure 6. Active surveillance retrospective record review process used in the study**.** NNT = neonatal tetanus. Active surveillance and retrospective record review process used in the study. At the first stage of the review process data abstractors extract information on the prevalence of neonatal tetanus and neonatal tetanus mortality from the IDSR database of each health facility. Secondly, the data extractors will also screen for information on the prevalence of neonatal tetanus, neonatal tetanus mortality and double reporting of neonatal tetanus from health facility records and IDSR line list. The second stage of the review process is the verification of positively screened data by medical reviewers. The medical reviewers will verify information on neonatal tetanus mortality and proximate factors. Adapted from Zegers et al. (2007). Design of a retrospective patient's record study on the occurrence of adverse events among patients in Dutch hospitals. *Biomedical Center Health Services Researc*h, Volume 7, Issue 27. doi:10.1186/1472-6963-7-27. Reproduced with permission.

Methodology

Population

The study population consisted of mothers of NNT patients admitted from January 01, 2010 to December 31, 2014 from seven health facilities in the 3 geo-political zones in Katsina State. Due to limited time and resources, multi-stage sampling technique was utilized to draw samples from each level of healthcare i.e. primary, secondary and tertiary in each of the three geo-political zones in the state. However, there was only one tertiary health facility available in the state; thus, samples could only be drawn from one tertiary, three secondary and three primary health facilities, making a total of seven facilities for the study. The study sample consisted of 332 records of mothers of NNT patients that were pre-determined by three steps: a) setting precision and statistical power, b) calculating effective sample size using power analysis and, c) sample size adjustment using design effect (Israel, 2009).

In the first step, the level of precision or alpha level was set at 0.05 so as to have a 5% chance of rejecting type I error. The statistical power was set at 95% to show that, with the sample size, the study can expect mean association between the proximate factors and neonatal death in 95% of the time. In the second step, the effective sample size was determined with power analysis. Input parameters included: test family = z test, statistical test = logistic regression, type of power analysis = a priori: compute required sample size - given α, power, and effect size. The odds ratio was obtained from a previous study by Fetuga et al. (2010), which indicated a 78.1% NNT mortality rate and 50.4% survival rate in neonates whose mothers did not receive tetanus toxoid vaccine.

The results also showed a total of 96 out of 151 neonates (63.576%) died of hospitalization within the study period (Fetuga et al, 2010, p. 73). Thus, using input parameters such as binomial X distribution, two tails, NNT mortality rate [Pr (Y= 1/X = 1) H1] = 0.781, survival rate [Pr (Y= 1/X = 1) HO] = 0.504, odds ratio = 3.5096, and estimated NNT mortality rate from the previous study (X parm π) = 0.63576, the effective sample size was 166.

In the third step, the effective sample size was adjusted so as to account for the variance caused by multi-stage sampling technique. To adjust for deviation from simple random sampling the effective sample size was multiplied by the design effect (DEFF) (Salganik, 2006). In this study, the design effect was determined from a previous tetanus survey by Orimadegun, Adepoju and Akinyinka (2014) who used a design effect factor of 2 to estimate the sample size required for a tetanus prevalence survey in Nigeria. Thus, if sample size (N) = effective sample size x design effect (DEFF), then N = 166 x 2 = 332.

Sampling and Sampling Procedure

The study population comprised of mothers of newborns affected with neonatal tetanus in Katsina State, Nigeria. Katsina State is located in Northwestern Nigeria with an estimated population of 5,801,584 (male: female ratio =1:1) based on 2006 census (National Bureau of Statistics, 2010, p. 22). The state is composed of 34 local government areas (LGAs) and 3 constituencies also known as geo-political zones namely, Katsina, Funtua and Daura zones (Nigerian Chamber of Commerce, 2015). Daura zone is made up of 12 LGAs while Katsina and Funtua zones are both made up of 11 LGAs each. The sample size for this study was realized through multi-staged sampling technique so as to obtain a representative sample of participants from each of the three zones in the state. The multi-stage sampling technique was conducted in 3 stages.

Stage I: Selection of Local Government Areas in Katsina State.

There are a total of 34 local government areas in Katsina State and one local government area was selected from each zone. Random sampling through balloting procedure (i.e. rolled and packed papers) was utilized for the selection and the LGAs selected are: Katsina LGA, Malumfashi LGA, and Daura LGA from Katsina, Funtua, and Daura zones respectively

Stage II: Selection of Health Facilities.

The selection of health facilities was from the 3 levels of health delivery i.e. tertiary, secondary and primary levels. One health facility from each of the three levels of health care is to be represented in each local government areas selected. The list of health facilities in the selected LGAs obtained from the state ministry of health was used to develop the sampling frame for the selection of health facilities for this study (See Annex A). The health facilities were sampled using random number of tables and those selected include; General Hospital, Malumfashi (Secondary) and Primary Health Center, Malumfashi (Primary) in Malumfashi LGA; General Hospital, Daura (Secondary) and Primary Health Centre, Dan Nakola (Primary) in Daura LGA; and Federal Medical Center, Katsina (Tertiary), General Hospital, Katsina (Secondary) and Primary Health Center, Kofar Guga, (Primary) in Katsina LGA.

The distribution of health facilities in each of the selected LGAs is depicted in Table 4 below:

Table 4

Distribution of Health Facilities in Selected LGAs for Retrospective Record Review in the Study

	Malumfashi LGA	Daura LGA	Katsina LGA
Tertiary	0	0	1
Secondary	1	1	2
Primary	7	21	11

Note. LGA = local government area

Stage III: Selection of Study Population (Case Files).

Records of the study population was selected through proportional probability sampling (PPS) technique due to the variations in the amount of NNT patients admitted in the health centers. For the retrospective record review, the NNT patients admitted from January 01, 2010 to December 31, 2014 was used as the sampling frame for random selection of neonatal tetanus patients in each health facility. For example, assuming n1, n2, n3, n4, n5, n6, and n7 represented the proportions of NNT records in each of the 7 health facilities selected, number of NNT patients admitted from January 01, 2010 to December 31, 2014 in each of the 7 health facilities are represented as n(a), n(b), n(c), n(d), n(e), n(f) & n(g), total number of NNT patients admitted from January 01, 2010 to December 31, 2014 in all the health facilities is represented as N, then the proportion of NNT records to be reviewed from each health facility was determined as n1= n (a)/N x S, n2 = n (b)/N x S, n3 = n (c)/N x S, n4 = n (d)/N x S, n 5= n (e)/N x S, n6 = n (f)/N x S, and n7 = n (g)/N x S.

Where n (a) = number of NNT cases recorded in Federal Medical Center, Katsina from 2010 to 2014,

n (b) = number of NNT cases recorded in General Hospital, Katsina from 2010 to 2014

n (c) = number of NNT cases recorded in Maternal and Child Health Center, Kofar Guga from 2010 to 2014,

n (d) = number of NNT cases recorded in General Hospital, Malumfashi from 2010 to 2014,

n (e) = number of NNT cases recorded in Maternal and Child Health Center, Malumfashi from 2010 to 2014,

n (f) = number of NNT cases recorded in General Hospital Daura from 2010 to 2014,

n (g) = number of NNT cases recorded in Primary Health Center, Dan Nakola, from 2010 to 2014,

N = total number of NNT patients admitted from January 01, 2010 to December 31, 2014 in all the health facilities,

S = Target population size of the study (332) determined by power analysis

For each health facility, the NNT patients admitted from January 01, 2010 to December 31, 2014 was used as the sampling frame for the random selection of records to be reviewed. Each case file was numbered and then the required number of NNT records was selected using table of random numbers.

Procedures for Data Collection

NNT cases line listed in the IDSR system and recorded in health facilities were collected by trained nurses referred to as data abstractors. Approval for access to IDSR data and data collection was obtained from Katsina State Ministry of Health (see Annex E). The ministry was assured that the surveillance review was strictly for academic research purposes and the outcomes of the study will be treated with confidentiality. In order to ensure confidentiality, information on name of NNT patients, names of parents of NNT patients and their addresses were coded to prevent identification.

Before abstraction of data, the data abstractors and medical reviewers were trained on the retrospective record review procedure, utilization of tools of data collection, and inclusion/exclusion criteria. Medical reviewers were physicians not practicing in public hospitals but were either retired civil servants or in private medical practice so as to reduce the risk of interviewer bias. Three medical reviewers were engaged so that one medical reviewer reviewed all the neonatal tetanus records from a geo-political zone due to financial constraints.

IDSR Data Collection Procedure

The NNT IDSR data was obtained in the health facilities selected. Data abstractors extract information on NNT prevalence and mortality rates from the IDSR database in each health facility using Form A (see Annex B). The form is a modified version of the World Health Organization tool used for the survey of assessing NNT incidence and mortality in the community (WHO, 2002).

Health Facility Retrospective Record Review Procedure

The data abstractors identified and developed a line list of all NNT cases admitted in the health facility from January 01, 2010 through December 31, 2010. Afterwards, each case file was numbered and the required number of case files to be reviewed in each health facility was selected using random number of tables. The data abstractors were trained on how to utilize Form B (see Annex C) while medical reviewers were trained on how to utilize Form C (see Annex D). Form B was used by the data abstractors to screen for NNT cases based on the World Health Organization case definition of NNT. The WHO case definition of NNT has 3 criteria which are; baby was having normal ability to cry and suck breast for the first 48 hours (2 days) after delivery; the illness occurred between the 3rd to 28th days after delivery; and baby was unable to cry and suck breast, followed by generalized body spasms or stiffness (WHO, 2015). Any record that did not meet the WHO NNT case definition was termed as a "negatively screen record" while records that have met the WHO NNT case definition were "positive screened records". The negatively screened records were returned back to the health facility records department whereas all positive screened records were forwarded to the medical reviewers for further evaluation.

Medical records are known to compose of varying interpretations which is an additional challenge to the retrospective record review process (Worster & Haines, 2004). The medical reviewer will reduce the risk of screening errors associated with undetermined variables in individual records and ensure quality, complete and accurate review of data. Medical reviewers filled Form C for each positively screened NNT record. The form contains information about the proximate factors to NNT mortality. Both Forms B and C were modified versions of RF1 and RF2 respectively developed by the World Health Organization Patient Safety Expert Advisory Working Group used to assess the determinants of iatrogenic adverse events in resource poor settings (WHO, 2010)..

Pilot Study

Missing data is major challenge in retrospective record reviews (Vassar & Holzman, 2013). Missing data may occur when data abstractors are poorly trained on identifying variables or not monitored carefully during the review process. Another reason is failure to standardize abstraction forms which may lead to abstraction errors during the retrospective record review (Vassar & Holzman, 2013). Pilot survey is an effective approach used in identifying common problems associated with missing data in retrospective record review (Columbia University, 2015). It is conducted to assess the reliability and validity of instruments of data collection. All data abstractors and medical reviewers were trained on the retrospective review protocol and proper utilization of data collection instruments (Forms A, B and C).before implementing the pilot study.

Additionally, the pilot study enabled the data abstractors to be more aware of inclusion and exclusion criteria and identification of certain challenges with use of survey instruments. The inclusion criteria included: a) only infants born within the neonatal period i.e. first 28 days of life, b) all cases that had met the World Health Organization case definition NNT, c) all NNT cases treated in health facilities, and, d) all NNT cases treated from January 01, 2010 to December 31, 2015. While the exclusion criteria include: a) all infants born outside the neonatal period i.e. above 28 days old, b) all cases that have not met the World Health Organization criteria for NNT, c) all NNT cases treated at home, and, d) all NNT cases treated prior to January 01, 2010 or after December 31, 2014.

An estimated 30 randomly selected NNT were tested in the pilot study at General Hospital, Dutsinma, Katsina zone, Katsina State; and these selected NNT cases were not be included in the larger study. Two independent data abstractors and a medical reviewer administered the survey tools and uniformity and consistency of data entry were evaluated. The consistency and uniformity of the two results is termed as the inter-rater reliability which was measured by calculating the Cohen's Kappa index. According to Landers and Kock, (1977), Cohen's Kappa index values ranging from 60% to 79% are considerate substantial, while index values above 80% are considered outstanding. Kappa levels below 60% are insignificant which will require re-training of the data abstractors and medical reviewers.

Instrumentation and Operationalization of Constructs

Form A was appropriate for this study because it was used to extract NNT prevalence and mortality data from the IDSR database in the seven selected health facilities in Katsina state. The form was adapted from the World Health Organization Death Investigation Form developed in 2002 (WHO, 2015). The format of the form was modified for the abstraction of NNT prevalence and mortality rates in this study. The original instrument was used by Cotter et al. (2003) for the evaluation of neonatal tetanus elimination in Zimbabwe. The results showed 1998 and 1999 NNT incidence rates of

0.03 per 1000 live births and 0.04 per 1000 live birth respectively. The validity of the instrument for this study will be tested in the pilot study. Permission to modify and utilize the instrument for this study was sought from the Department of Vaccines and Biologicals, World Health Organization, Geneva, Switzerland (see Annex F).

The second sets of instruments used for this study include Form B and Form C which were utilized by data abstractors and medical reviewers respectively. Both forms are modified versions of RF1 and RF2 developed by the WHO Patient Safety Working Group for the review of harmful incidents in resource poor settings (WHO, 2010). The forms are appropriate specifically for retrospective record reviews and were used in 2005 by the World Health Organization for the retrospective review of harmful incidences among 18,146 randomly selected patients in 5 African countries namely Egypt, Kenya, South Africa, Sudan, and Tunisia (WHO, 2010). The outcome of the study showed that the commonest forms of harmful incidences in the study area were associated with 19.1% diagnostic errors and 34.2% therapeutic errors. The validity of these instruments for this study was tested in the pilot study. Permission to use modify and utilize both instruments was sought from the World Health Organization (see Annex G).

Form B contains 3 questions that form the criteria for WHO case definition of NNT. The data abstractors' responses for each question was marked as "Yes" if the criteria is fulfilled and "No" if the criteria was not fulfilled. The data abstractors provided further details for each question if the criterion was met. The 3 criteria must be met before a case file was screened and forwarded for medical review. Form C contains 11 questions; the first 6 questions are concerned with sources of information for the review.

The medical reviewers marked “Yes” were applicable and “No” were not applicable. The remaining 5 questions (Q7 to Q11), comprise of the five operational variables for this study. In Q7, the medical reviewers assessed the number of tetanus toxoid doses the mother received during pregnancy and the responses were expressed in normal scale as 0 = none, 1 = one, and 2 = two or more. In Q8, the medical reviewers assessed the frequency of ANC visits attended by the mother during pregnancy and the responses were also expressed in nominal scale as 0 = No visit, 1 = 1 to 4 visits, 2 = 4 visits. In Q9, the medical reviewers assessed the place of delivery which was also measured in nominal scale as 0 = home, 1 = health center. In Q10 the medical reviewers assessed the type of cord care provided to the baby after delivery also measured in nominal scale as 0 = old razor blade or tying with the cord with unsterile thread or treatment with soil/cow dump or any aseptic procedure, 1= new razor blade or septic treatment. Then finally in Q11, the medical reviewers assessed the outcome of neonatal tetanus at discharge which was measured in nominal scale as 0 = survived (alive for more than 28 days) and 1 = death (dies within 28 days of life).

Data Analysis

Data analysis for the study was conducted using SPSS to address the following research questions:

RQ1: Is there any difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State?

$H_0$1: There is no difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State.

H_a1: There is a difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State.

RQ2: Is there any significant association between the number TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State?

$H_0$2: There is no significant association between the number TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

H_a2: There is a significant association between the number TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

RQ3: Is there any significant association between the frequency of ANC visits attended by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State?

$H_0$3: There is no significant association between the frequency of ANC visits attended by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

H_a3: There is a significant association between the frequency of ANC visits attended by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

RQ4: Is there any significant association between the place of child delivery and NNT mortality as identified by the active surveillance method in Katsina State?

$H_0$4: There is no significant association between the place of child delivery and NNT mortality as identified by the active surveillance method in Katsina State.

H_a4: There is a significant association between the place of child delivery and NNT mortality as identified by the active surveillance method in Katsina State.

RQ5: Is there any significant association between cord care received by women during delivery and NNT mortality as identified by the active surveillance method in Katsina State?

$H_0$5: There is no significant association between cord care received by women during delivery and NNT mortality as identified by the active surveillance method in Katsina State.

H_a5: There is a significant association between cord care received by women during delivery and NNT mortality as identified by the active surveillance method in Katsina State.

For descriptive analysis, exploratory analysis with alpha at 0.05 was conducted to determine the frequency of NNT mortality across the proximate factors, NNT prevalence and mortality rates from January 01, 2010 to December 31, 2015 in Katsina State were analyzed. The associations between the proximate factors i.e. number of tetanus toxoid injections, frequency of ANC visits, place of delivery, and cord, and neonatal tetanus mortality were determined by bivariate logistic regression model including adjusted odds ratios and related 95% confidence intervals. Neonatal death was measured as a binary variable where 0 = survived and 1 = death.

Threats to Validity

A threat to external validity reduces the extent to which the outcome of a study is generalized (Laerd Dissertation, 2015). In this study, a potential threat to external validity was selection bias. This could occur when there is knowledge gap among clinicians on the identification of neonatal tetanus during practice which could result to wrong diagnosis of neonatal tetanus recorded in health facility. This threat was addressed through the use of WHO case definition to screen for NNT cases by data abstractors and review of positively screened NNT records by the medical reviewers. Although internal validity is more relevant in prospective studies than retrospective studies (Trochim, 2006), retrospective reviews are vital for generating baseline information for conducting prospective studies (Tofthagen, 2012). A potential threat to internal validity in this study was instrumentation bias. This threat may occur when there is no consistency of results after administering the three instruments of data collections (i.e. Forms A, B, and C) by the data abstractors and medical reviewers. This threat was addressed by ensuring that the measurement procedure is well structured and standardized with closed ended questions (i.e. Yes or No). Secondly, the validity of instruments of data collection was assessed by conducting a pilot study and calculating the Cohen's Kappa index.

A threat to statistical conclusion validity is the extent to which statements or conclusions about the associations between the independent variables and the dependent variables are accurate based on the statistical tests conducted (Garcia-Perez, 2012). In this study, a potential threat to statistical conclusion validity is concluding that there is no association between the proximate factors and NNT when actually there are associations. This threat was addressed by using a high value statistical power of 0.95. This high statistical power ensured that, with the same size, the study can expect mean association between the proximate factors and neonatal death 95% of the time.

Ethical Procedures

The participants for this study were sampled from the IDSR database and hospital records. Because the information required are on state aggregate data and not on identification of information on individuals, informed consent or Health Insurance Portability and Accountability Act (HIPAA) release document was not required. Prior to data collection, approval to gain access to hospital records and IDSR database was obtained from Katsina State Ministry of Health (see Annex E). Similarly, approval to conduct study was sought from Walden University Institutional Review Board (IRB). The IRB approval number for this study is 09-09-15-0368046.

Information from IDSR and health facility records was used strictly for the purpose of this study and be kept confidential in computer database protected by a password. All questionnaires used by data abstractors and medical reviewer are properly archived to ensure that the privacy of participants is protected. And similarly, the names of data abstractors and medical reviewers are coded to ensure anonymity of information.

Summary

In summary the purposes of this quantitative cross-section survey are twofold: to compare the NNT prevalence and mortality rates from existing IDSR system and active surveillance of risks factors associated with NNT through retrospective record review of health facility records; and to determine the associations between selected NNT risk factors and neonatal death rates in Katsina State, Northwestern Nigeria. Records of mothers of newborns affected with NNT in 3 local government areas in Katsina State between January 01, 2010 and December 31, 2014 were extracted by trained nurses and reviewed by experienced physicians.

The chapter presented a description of the study design including independent and dependent variables. Additionally, the chapter described the study population, sampling procedure and sample size, data collection procedure, pilot study, instrumentation and operationalization of constructs, statistical tests and data analysis plan, threats to validity, and ethical procedures.

Chapter 4 will present the final report of the outcome of the pilot study and the final results of the study including challenges faced during data collection.

Chapter 4: Results

Introduction

The purposes of this study were two-fold: to compare the prevalence and mortality rates of NNT reporting between the IDSR system and active surveillance of health facility records, and to assess the risks associated with NNT mortality rates identified by active surveillance in Katsina State, Nigeria. This chapter presents the research questions and hypotheses, the outcome of the pilot study, the demographic features of the target population, the final results of the main study, and a summary of the outcome of the research. The research questions and hypotheses that guided this study are:

RQ1: Is there any difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State?

$H_0$1: There is no difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State.

H_a1: There is a difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State.

RQ2: Is there any significant association between the number TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State?

$H_0$2: There is no significant association between the number TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

H_a2: There is a significant association between the number TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

RQ3: Is there any significant association between the frequency of ANC visits attended by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State?

$H_0$3: There is no significant association between the frequency of ANC visits attended by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

H_a3: There is a significant association between the frequency of ANC visits attended by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

RQ4: Is there any significant association between the place of child delivery and NNT mortality as identified by the active surveillance method in Katsina State?

$H_0$4: There is no significant association between the place of child delivery and NNT mortality as identified by the active surveillance method in Katsina State.

H_a4: There is a significant association between the place of child delivery and NNT mortality as identified by the active surveillance method in Katsina State.

RQ5: Is there any significant association between cord care received by women during delivery and NNT mortality as identified by the active surveillance method in Katsina State?

$H_0$5: There is no significant association between cord care received by women during delivery and NNT mortality as identified by the active surveillance method in Katsina State.

H_a5: There is a significant association between cord care received by women during delivery and NNT mortality as identified by the active surveillance method in Katsina State.

Pilot Study

The pilot study was conducted at General Hospital, Dutsinma, in the month September, 2015, following Walden University Institutional Review Board's approval for data collection. Cohen's K was run to evaluate uniformity and consistency of data entry (inter-rater reliability) among two data abstractors and two medical reviewers. An estimated 30 randomly selected NNT records were tested, and these selected NNT cases were not included in the larger study. The five assumptions for calculating the Cohen's Κ index (Landis & Koch, 1977) were assessed and met before the analysis. They are:

- the responses made by both data abstractors and both medical reviewers were mutually exclusive and assessed on nominal scale;
- both data abstractors and both medical reviewers were assessed the same variables;
- the categorization of each of the responses were the same;
- both data abstractors and both medical reviewers were independent; and
- both data abstractors and both medical reviewers were particularly selected as research assistants for the study.

Table 5 depicts the outcome of the inter-rater reliability indicating substantial agreements between the two data abstractors, Κ = .710, ($p < 0.0005$), 95 CI (.412, 1.01) and the two medical reviewers .760, ($\rho < 0.0005$), 95% CI (.443, 1.08). The 95% confidence intervals were realized using the formula Cohen's Κ +/- 1.96 (expected standard error). According to Landers and Koch, (1977), Cohen's Kappa index values levels below 60% are insignificant while values ranging from 60% to 79% are considerate substantial, both scores were substantial that was why there was no need to reword or change the questionnaires based on the outcome of the pilot study.

Table 5

Inter-rater Reliability Among Data Abstractors and Medical Reviewers

Research Assistants	Κ	N	p	SE	CI
Data Abstractors	.710	30	.000	.152	(0.41, 1.01)
Medical Reviewers	.760	30	.000	.162	(0.44, 1.08)

Note. Note. CI = confidence interval. SE = standard error. N = sample size, Κ = Cohen's Kappa.

Data Collection

Data collection from the seven health facilities commenced in September, 2015 immediately after assessing uniformity and consistency of data entry. The data abstractors extracted information on NNT prevalence and mortality rates from the IDSR database in each health facility using the NNT survey instrument (Form A). This process was followed by NNT screening using the NNT detection questionnaire (Form B) to screen out all NNT cases admitted in each health facility from January 01, 2010 to December 31, 2014. Each NNT case was screened based on the WHO definition of NNT. Consequently, the data abstractors forwarded all positively screened NNT cases to the medical reviewers for evaluation on risk factors of NNT mortality using the medical review form (Form C). The time frame used for the IDSR data collection, neonatal tetanus screening and medical reviewer was approximately 14 days.

A total of 336 NNT cases were identified in the 7 health facilities sampled in the study area. Since the estimated sample size for the study was 332, the selection of study participants (NNT records) was based on proportional probability sampling technique due to variations in the amount of NNT cases admitted in the health centers. Consequently, there were no significant challenges faced during the retrospective record review process and no alterations in the retrospective review protocol described in Chapter 3. Figure 7 depicts the participant flow chart for the study.

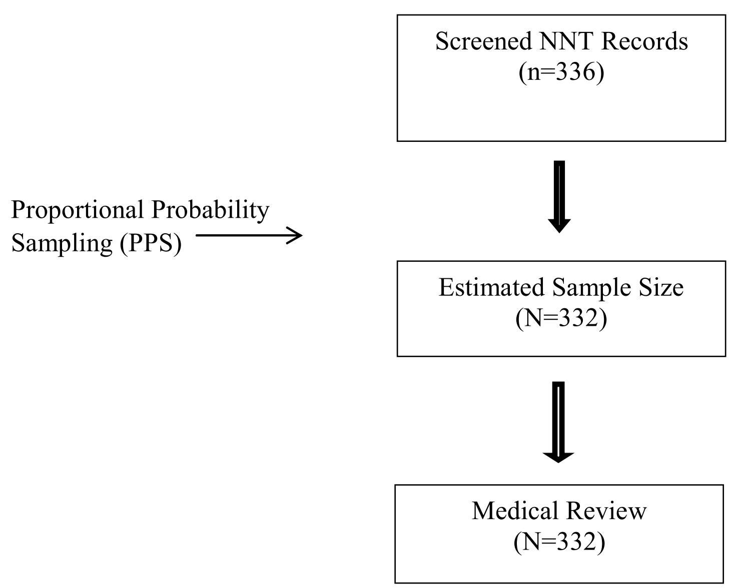

Figure 7. Participant flow chart. NNT= neonatal tetanus. The neonatal tetanus records reviewed for the study were selected from the positively screened records using proportional probability sampling

Demographic Characteristics of the Sample

The target population for the study was NNT cases admitted between Jan 01 2010 to Dec, 31, 2014 in Katsina State, Northwestern, Nigeria. Data was collected from records of 332 NNT cases in seven selected health facilities. The demographic factors for the study included gender, year of admission and sources of information used for the review.

Table 6 depicts the distribution of NNT cases admitted in each health facility by year while Figure 8 shows the frequency of NNT cases admitted from 2010 to 2014. Most of the NNT cases (27.4%) where admitted in 2010, followed by 2011 (24.1%), 2012 (19.0%), 2013 (17.2%) and 2014 (12.3%). In terms of distribution by health facility, MCHC Malumfashi had the highest number of NNT cases 80 (24.1%), followed by General Hospital Katsina 73 (22.0%), General Hospital Daura 53 (16.0%), General Hospital Malumfashi 51 (15.4%), Federal Medical Center Katsina 38 (11.4%), MCHC Kofar Guga 22 (6.6%) and, PHC Dannakola 15 (4.5%).

Table 6

Cross- Tabulation of NNT Cases Year of Admission and Health Facility

	Year of Admission					
Health Facility	2010	2011	2012	2013	2014	Total (%)
General Hospital Katsina	21	17	15	11	9	73 (22.0)
Federal Medical Centre Katsina	11	11	7	6	3	38 (11.4)
MCHC Kofar Guga	7	4	4	5	2	22 (6.6)
General Hospital Malumfashi	13	11	12	7	8	51 (15.4)
MCHC Malumfashi	22	19	12	16	11	80 (24.1)
General Hospital Daura	12	15	11	10	5	53 (16.0)
PHC Dannakola	5	3	2	2	3	15 (4.5)
Total	91	80	63	57	41	332 (100)

Note. PHC = Primary Health Center; MCHC = Maternal and Child Health Center; NNT = Neonatal Tetanus

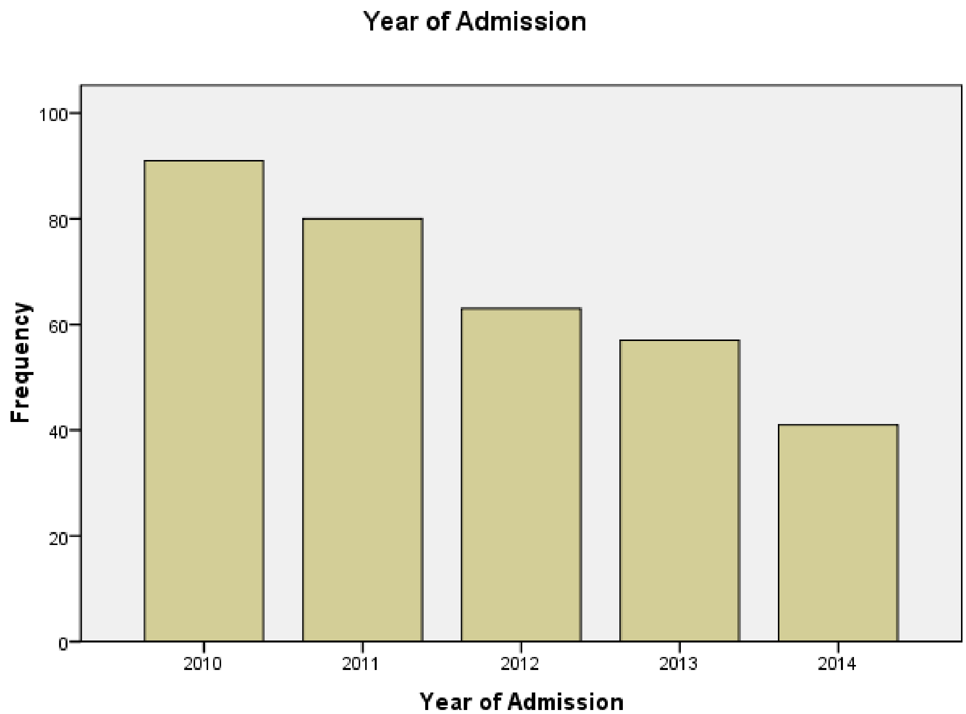

Figure 8: Frequency of NNT cases by year of admission 2010 - 2014

Table 7 depicts the cross-tabulation of gender of NNT cases and health facility. Specifically 55.4% (184) were males and 44.6% (148) were females. Figure 9 depicts the frequency of sources of information for the retrospective record review. Information from 55% (183) NNT case files were extracted from physicians records, 32.8% (100) from head nurses records, 36.4% 121 from nurses records, 33.4% (111) from medical records department, 13% (43) from nursing notes recorded in-patient registers and 0.9% (3) from other sources like prescription notes.

Table 7

Cross- Tabulation of Gender of NNT Cases and Health Facility

	Gender of NNT Cases			
Health Facility	Male	Female	Frequency	Percent
General Hospital Katsina	39	34	73	22.0
Federal Medical Centre Katsina	23	15	38	11.4
MCHC Kofar Guga	15	7	22	6.6
General Hospital Malumfashi	31	20	51	15.4
MCHC Malumfashi	42	38	80	24.1
General Hospital Daura	27	26	53	16.0
PHC Dannakola	7	8	15	4.5
Total	184	148	332	100

Note. . PHC = Primary Health Center; MCHC = Maternal and Child Health Center; NNT = Neonatal Tetanus.

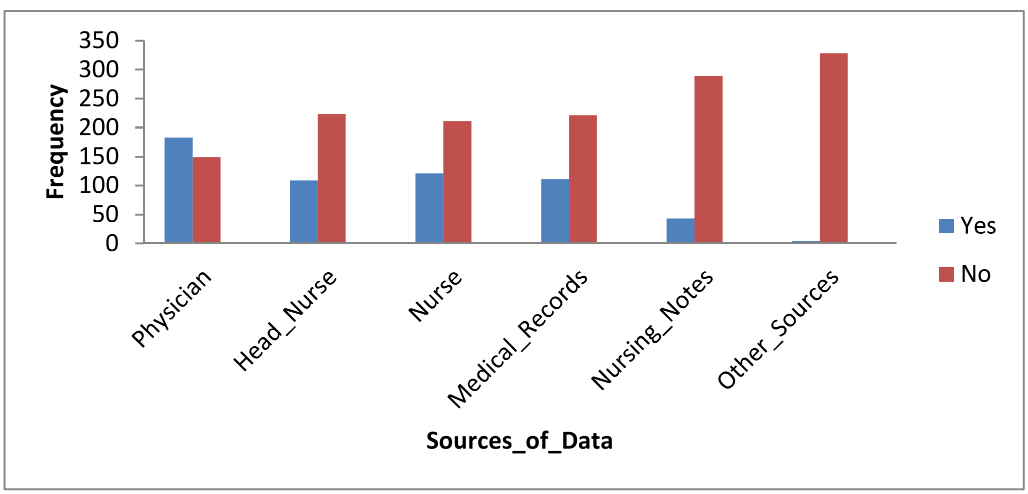

Figure 9: Frequency of sources of information for the retrospective record review

Data Analysis for the Research Questions

The study population used for the logistic regression analysis was selected through proportional probability sampling (PPS) technique due to the variations in the amount of NNT patients admitted in the health centers. The NNT patients admitted from January 01, 2010 to December 31, 2014 was used as the sampling frame for random selection of neonatal tetanus patients in the health facilities selected. To calculate the sample size, the proportions of NNT records in Federal Medical Center, Katsina, General Hospital, Katsina, Maternal and Child Health Center, Kofar Guga, General Hospital, Malumfashi, Maternal and Child Health Center, Malumfashi, General Hospital Daura and Primary Health Center, Dan Nakola were represented as , n1, n2, n3, n4, n5, n6, and n7 respectively. While the number of NNT patients admitted from January 01, 2010 to December 31, 2014 in Federal Medical Center, Katsina, General Hospital, Katsina, Maternal and Child Health Center, Kofar Guga, General Hospital, Malumfashi, Maternal and Child Health Center, Malumfashi, General Hospital Daura and Primary Health Center, Dan Nakola were also represented are represented as n(a), n(b), n(c), n(d), n(e), n(f) & n(g) respectively. The total number of NNT patients admitted from January 01, 2010 to December 31, 2014 in all the health facilities was represented as N, and S was used to represent the target population size of the study (332) determined by power analysis. Therefore the formulae used for estimating the proportion of NNT records reviewed in each health facility were n1= n (a)/N x S, n2 = n (b)/N x S, n3 = n (c)/N x S, n4 = n (d)/N x S, n 5= n (e)/N x S, n6 = n (f)/N x S, and n7 = n (g)/N x S. Thus, the proportion of NNT records reviewed in Federal Medical Center, Katsina = 39/332 x 336 ≈ 38, General Hospital, Katsina = 74/332 x 336 ≈ 73, Maternal and Child Health Center, Kofar Guga = 22/332 x 336 ≈ 22, General Hospital, Malumfashi = 52/332 x 336 ≈ 51, Maternal and Child Health Center, Malumfashi = 81/332 x 336 ≈ 80, General Hospital Daura = 53/332 x 336 ≈ 53 and Primary Health Center, Dan Nakola = 15/332 x 336 ≈ 15. Table 10 below depicts the distribution of NNT cases used for the bivariate logistic regression analysis each health facility for the study:

The parametric assumptions for analyzing data for the study using logistic regression were checked prior to analysis. These 4 assumptions were all met, which were: assumption 1, the dependent variable (neonatal mortality) was a dicotonomous variable i.e. “survived” and “death”; assumption 2, the independent variables were all categorical variables; assumption 3, there was independence of observations and the outcome variable had exhaustive and mutually exclusive categories; assumption 4, there was no high correlation (multicollinearity) between the independent variables. Table 8 shows the outcome of the collinearity diagnostics indicating that the independent variables; number of tetanus toxoid injection, Tolerance = .331; VIF = 3.021, frequency of antenatal visits, Tolerance = .305; VIF = 3.275, place of delivery, Tolerance = .609, VIF = 1.642; cord care, Tolerance = .635, VIF = 1.574. Because all Tolerance values were greater than 0.1 and all VIF values were less than 5, then, multicollinearity was not a concern.

Table 8

Outcome of the Collinearity Diagnostics of the Independent Variables

	Collinearity Statistics	
Independent Variable	Tolerance	VIF
Number of Tetanus Toxoid Injection	.331	3.021
Frequency of Antenatal Visits	.305	3.275
Place of Delivery	.609	1.642
Cord Care After Delivery	.635	1.574

Note. VIF = variance inflation factor

The relationship between the proximate factors and outcome of neonatal tetanus is depicted in Table 9. Concerning number of tetanus toxoid vaccines received, up to 59% (n = 197) neonates died whose mothers did not receive a single dose of NNT vaccine. While only 6% (n = 19) of neonates died whose mothers received more than 2 doses of NNT vaccine. Concerning frequency of ANC visits, about 53% (n = 177) of neonates died whose mothers did not pay single ANC visit during pregnancy while 16.3% (n = 54) of neonates died whose mothers had 1 to 3 visits of ANC visits during pregnancy. And 5% (n = 16) died whose mothers completed the 4 ANC visits during pregnancy. Concerning place of delivery, up to 67.8% (n = 725) of neonates delivered at home died of NNT. A great majority of neonates 63.8% (n = 212) that received aseptic cord care treatment after delivery died of NNT.

Table 9

Relationship between the Proximate Factors and the Outcome of Neonatal Tetanus

	Outcome	
Proximate Factors	Survived (%)	Death (%)
NTT		
None	57 (17)	197 (59)
1	13 (4)	31 (9)
2 or more	15 (5)	19 (6)
FAV		
No visit	54 (16.3)	177 (53)
1 to 3 visits	20 (6.3)	54 (16.3)
4 visits	11 (3)	16 (5)
POD		
Home (67.8)	65 (19.6)	225
Health Center	20 (6.3)	22 (6.6)
CC		
Aseptic Treatment (63.8)	58 (17.5)	212
Septic Treatment 10.5)	27 (8.1)	35 (

Note. NTT = Number Of Neonatal Tetanus Injection; FAV = Frequency of Antenatal Visits; POD = Place of Delivery; CC = Cord Care

Table 10

Distribution of NNT Cases in Each Health Facility (2010 – 2014) Used for Logistic Analysis

	Year				
Health Facility	2010	2011	2012	2013	2014
General Hospital Katsina	21	17	15	11	9
Federal Medical Centre Katsina	11	11	7	6	3
MCHC Kofar Guga	7	4	4	5	2
General Hospital Malumfashi	13	11	12	7	8
MCHC Malumfashi	22	19	12	16	11
General Hospital Daura	12	15	11	10	5
PHC Dannakola	5	3	2	2	3
Total	91	80	63	57	41

Note. PHC = Primary Health Center; MCHC = Maternal and Child Health Center; NNT = Neonatal Tetanus

Results

A binary logistic regression analysis was conducted to predict neonatal tetanus mortality based upon certain proximate factors namely; number of tetanus toxoid injections, frequency of antenatal visits, place of delivery and, cord care. Preliminary analysis was conducted to ensure that the logistic regression model does fit the data, Hosmer and Lemeshow $\chi 2 = 4.94$, $\rho > 0.05$ and there was no violation of the assumption of multicollinearity. The logistic combination of the proximate factors was found to be significantly associated with NNT mortality, $\chi 2 = 19.68$, $p < 0.05$ with df = 6. The logistic regression model indicated 9% (Nagelkerke R2 = 0.09) of the variance in NNT mortality and the overall prediction success of cases was 75%. The Wald criterion indicated that only neonates whose mothers had one dose of neonatal tetanus vaccine were significantly associated with NNT mortality, ($p < 0.05$), OR = 4.12, 95% CI [1.04, 16.29]. Frequency of ANC visits, place of delivery and cord care were all not significant predictors to NNT mortality. The Exp (B) value demonstrates that neonates whose mothers had only one dose of NNT vaccine were 4 times likely to die of NNT tetanus than neonates whose mothers had more the 2 or more doses of NNT vaccine. Table 11 below shows the summary of binary logistic regression analysis for proximate factors predicting the outcome of NNT:

Table 11

Summary of Binary Logistic Regression Analysis for Proximate Factors Predicting the Outcome of Neonatal Tetanus for Neonates (n = 332)

Proximate Factors	β	SE β	Wald's χ2	*p*	e^B	95% CI Upper	95% CI Lower
Constant	0.98	0.47	4.37	.04	2.67		
Number of NNT Injections							
1	1.42	0.70	4.08	04*	4.12	1.04	16.29
2 or more	0.68	0.68	0.10	.32	1. 98	0.52	7.57
Frequency of ANC Visits							
1 to 3 visits	-1.06	0.82	1.65	.20	0.35	0.07	1.74
4 visits	-0.36	0.72	0.25	.62	0.70	0.17	2.90
Place of Delivery	-0.77	0.46	2.83	.09	0.46	0.19	1.14
Cord Care	-0.65	0.39	2.77	.10	0.53	0.25	1.12
Model χ2		19.68			.03*		
Hosmer and Lemeshow		4.94			. 29		
Negelkerke R		0.09					

Note. ANC = Antenatal Care. CI = Confidence Interval. *$p < .05$.

Research Question 1

Research question 1 of the study was: Is there any difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State? The null and alternate hypotheses of the research question were:

> $H_0$1: There is no difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State.
>
> H_a1: There is a difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State.

The neonatal tetanus survey form (Form A) was used to answer research question 1. Table 12 shows the prevalence of NNT cases from 2010 to 2014 identified through active surveillance in the 7 selected health facilities.

Table 12

Prevalence of NNT Cases in the Selected Health Facilities (2010 – 2014)

	Year					
Health Facility	2010	2011	2012	2013	2014	Total (%)
General Hospital Katsina	22	17	15	11	9	74 (22.0)
Federal Medical Centre Katsina	11	12	7	6	3	39 (11.4)
MCHC Kofar Guga	7	4	4	5	2	22 (6.6)
General Hospital Malumfashi	14	11	12	7	8	52 (15.4)
MCHC Malumfashi	23	19	12	16	11	81(24.1)
General Hospital Daura	12	15	11	10	5	53(16.0)
PHC Dannakola	5	3	2	2	3	15(4.5)
Total	94	81	63	57	41	336(100)

Note. PHC = Primary Health Center; MCHC = Maternal and Child Health Center; NNT = Neonatal Tetanus.

MCHC Malumfashi had the highest prevalence of NNT cases with 24.1 % of the NNT cases followed by General Hospital, Katsina (22.2%), General Hospital Daura (16.0%), General Hospital Malumfashi (15.4%), Federal Medical Center Katsina (11.4%), MCHC Kofar Guga (6.6%) and, PHC Dannakola (4.5%) respectively. Table 13 shows comparison between the prevalence of NNT and NNT mortalities reported in the IDSR system and prevalence of NNT and NNT mortality rate identified through active surveillance of the health facility records from 2010 to 2014.

Table 13

5–Year Assessment (2010 – 2014) of NNT Surveillance in the Selected Health Facilities

Health Facility	Prevalence		Reported		Under-reported (%)	
	NNT	Mortality	NNT	Mortality	NNT	Mortality
General Hospital Katsina	74	53	23	17	51(69)	36 (68)
Federal Medical Centre Katsina	39	27	21	12	18 (46)	15 (56)
MCHC Kofar Guga	22	17	8	5	5 (23)	12 (71)
General Hospital Malumfashi	52	28	12	9	40 (77)	19 (68)
MCHC Malumfashi	81	64	27	13	54 (67)	51 (80)
General Hospital Daura	53	45	18	14	35 (67)	31 (69)
PHC Dannakola	15	13	2	2	13 (87)	11 (85)
Total	336	247	111	72	225 (68)	175 (71)

Note. PHC = Primary Health Center; MCHC = Maternal and Child Health Center; NNT = Neonatal Tetanus

The results indicate the 336 NNT cases were identified through active surveillance while only 111 NNT cases were reported through the IDSR system. The estimated NNT mortality rate in Katsina State was calculated using the formula: NNT mortality rate equals NNT mortalities identified through active surveillance (2010–2014) divided by total population and multiplied by100,000. The total population of Katsina State according to 2006 census was 5,801,584 (National Population Commission, 2015) and the average population growth in Nigeria between the 2006 census and 2014 is 2.7 (World Bank, 2015). Thus, the projected 2014 population of Katsina State is 7,179, 763, is depicted in Table 14. Therefore, the NNT mortality rate in Katsina State from January 1st 2010 to December 31st 2014 = 247/7,179,763 X 100,000 = 3.4 deaths per 100,000 population. While the NNT mortality rate reported in the IDSR system within the same period = 72/336 X 100, 000 = 1.0 death per 100,000 population. These discrepancies indicate under-reporting of the prevalence of NNT and NNT mortality rates reported through the IDSR system in Katsina State. Thus, the alternate hypothesis is accepted.

Table 14

Projected Population of Katsina State from 2006 – 2014 Based on 2006 National Population Census

Year	Average National Growth Rate	Projected Population
2007	2.7	5,958,226
2008	2.7	6,119,098
2009	2.7	6,284,314
2010	2.7	6, 453,991
2011	2.7	6. 628,248
2012	2.7	6,807,211
2013	2.7	6,991,006
2014	2. 7	7,179,763

Research Question 2

Research question 2 of the study was: Is there any significant association between the number TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State? The null and alternate hypotheses of the research question were:

*H*0 2: There is no significant association between the number TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

*H*a 2: There is a significant association between the number TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

Table 15 shows that there was significant association between neonates whose mothers had only one dose of NNT vaccine and NNT mortality, ($p = 0.04$), OR = 4.12, 95% CI [1.04, 16.29] ($p = 0.04$). This demonstrates that neonates whose mothers had only one dose of NNT vaccine were 4 times likely to die of NNT tetanus than neonates whose mothers had more the 2 or more doses of NNT vaccine. Thus, the alternate hypothesis is accepted.

Table 15

Binary Logistic Regression Analysis for Number of NNT Injections Predicting the Outcome of Neonatal Tetanus for Neonates (n = 332)

Proximate Factors	β	SE β	Wald's χ2	*p*	e^B	95% CI Upper	95% CI Lower
Constant	0.98	0.47	4.37	.04	2.67		
Number of NNT Injections							
1	1.42	0.70	4.08	04*	. 4.12	1.04	16.29
2 or more	0.68	0.68	0.10	.32	1.98	0.52	7.57

Note. NNT = Neonatal tetanus; CI = Confidence Interval; SE = Standard Error; * $p< .05$.

Research Question 3

Research question 3 of the study was: Is there any significant association between the frequency of ANC visits attended by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State? The null and alternate hypotheses of the research question were:

> $H_0$3: There is no significant association between the frequency of ANC visits attended by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.
>
> H_a3: There is a significant association between the frequency of ANC visits attended by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

Table 16 shows that there was no significant association between any category of frequency of antenatal visits and NNT mortality; 1 to 3 visits (p = .20); 4 visits, (p = .62). Thus, the alternate hypothesis is rejected in favor of the null hypothesis.

Table 16

Binary Logistic Regression Analysis for Frequency of ANC Visits Predicting the Outcome of Neonatal Tetanus for Neonates (n = 332)

						95% CI	
Proximate Factors	β	SE β	Wald's $\chi 2$	*p*	e^B	Upper	Lower
Constant	0.98	0.47	4.37	.04	2.67		
Frequency of ANC Visits							
1 to 3 visits	-1.06	0.82	1.65	.20	0.35	0.07	1.74
4 visits	-0.36	0.72	0.25	.62	0.70	0.17	2.90

Note. ANC = Antenatal Care; CI = Confidence Interval; SE = Standard.

Research Question 4

Research question 4 of the study was: Is there any significant association between the place of child delivery and NNT mortality identified by the active surveillance method in Katsina State? The null and alternate hypotheses of the research question were:

$H_0$4: There is no significant association between the place of child delivery and NNT mortality identified by the active surveillance method in Katsina State.

H_a4: There is a significant association between the place of child delivery and NNT mortality identified by the active surveillance method in Katsina State.

Table 17 shows that there was no significant association between place of delivery and NNT mortality ($p = .09$). Thus, the alternate hypothesis is rejected in favor of the null hypothesis.

Table 17

Binary Logistic Regression Analysis for Place of Delivery Predicting the Outcome of Neonatal Tetanus for Neonates (n = 332)

Proximate Factors	β	SE β	Wald's $\chi2$	*p*	e^B	95% CI Upper	95% CI Lower
Constant	0.98	0.47	4.37	.04	2.67		
Place of Delivery	-0.77	0.46	2.83	.09	0.46	0.19	1.14

Note. ANC = Antenatal Care; CI = Confidence Interval; SE = Standard Error

Research Question 5

Research question 4 of the study was: Is there any significant association between cord care received by women during delivery and NNT mortality identified by the active surveillance method in Katsina State? The null and alternate hypotheses of the research question were:

> $H_0$5: There is no significant association between cord care received by women during delivery and NNT mortality identified by the active surveillance method in Katsina State.
>
> H_a5: There is a significant association between cord care received by women during delivery and NNT mortality identified by the active surveillance method in Katsina State.

Table 18 shows that there was no significant association between cord care and NNT mortality (p = .10). Thus, the alternate hypothesis is rejected in favor of the null hypothesis.

Table 18

Binary Logistic Regression Analysis for Cord Care Predicting the Outcome of Neonatal Tetanus for Neonates (n = 332)

						95% CI	
Proximate Factors	β	SE β	Wald's χ2	*p*	e^B	Upper	Lower
Constant	0.98	0.47	4.37	.04	2.67		
Cord Care	-0.65	0.39	2.77	.10	0.53	0.25	1.12

Note. ANC = Antenatal Care; CI = Confidence Interval; SE = Standard Error

Summary

This chapter has presented the full details of outcomes of both the pilot study and main study. Information about the data collection procedure and timeframe for date collection were also provided. The results of the pilot study indicated uniformity and consistency of data entry (inter-rater reliability) among two data abstractors and two medical reviewers; Cohen's Kappa for data abstractors, .710, ($p < .0001$), 95% CI [0.41, 1.01]; Cohen's Kappa for medical reviewers, $p < .0001$, 95% CI [0.44, 1.06]. The findings of research question 1 showed significant level of under-reporting of the prevalence of NNT and NNT mortality rates reported through the IDSR system in Katsina State, Nigeria. The findings of research question 2 indicated significant association between neonates whose mothers had only one dose of NNT vaccine and NNT mortality, ($p = 0.04$), OR = 4.12, 95% CI [1.04, 16.29] ($p = 0.04$). While the findings of research questions 3, 4 and 5 showed no significant associations between frequency of ANC visits ($p = 0.20$); place of delivery ($p = 0.09$) and; cord care ($p = 0.10$) respectively.

The following chapter (Chapter 5) will provide more detailed discussion of the interpretation of the findings of the main study including limitations of the study, recommendations and finally implications for positive social change.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

NNT remains a preventable global public health concern, and evidence is weak regarding the global effort towards eliminating the disease due to underreporting of NNT mortality in surveillance systems, especially in developing countries (Blencowe et al., 2010). This quantitative, cross-sectional study was undertaken for two main objectives: to compare the prevalence and mortality rates of NNT reporting between the IDSR system and active surveillance of health facility records, and to assess the risks associated with NNT mortality rates as identified by active surveillance in Katsina State, Nigeria. The conceptual framework, Mosley and Chen's (1984) framework for the study of child survival, was used as a guide for this study. The objectives of the study were met through retrospective record review of NNT health facility records using descriptive statistics to answer the first objective, which was to compare the prevalence and mortality rates of NNT between the IDSR reporting system and active surveillance of health facility records from January 1, 2010, to December 31, 2014. Inferential statistics (bivariate logistic regression analysis) was used to answer the second objective, which was to assess the risks associated with NNT mortality rates identified by active surveillance in the study area.

Findings from descriptive statistics indicated that prevalence of NNT in Katsina State from January 1, 2010, to December 31, 2014, was 336, and the NNT mortality rate within the same period was 3.4 deaths per 100,000 population, or 0.0034 per 1,000 live births. This finding shows a far lower NNT mortality rate that that of of 3.1 per 1,000 live births that was obtained by Lawoyin and colleagues, who conducted a 5-year (1993-1998) community based autopsy to assess the risk factors associated with neonatal mortality in a rural setting in Southwestern Nigeria (Lawoyin et al, 2010, p. 21). The reduction in NNT mortality can be attributed to improved tetanus toxoid immunization coverage in developing countries including Nigeria (Blencowe et al., 2010), which consequently increased the level of immunity against NNT (protected at birth) among neonates to up to 60% (World Bank, 2015). Demographic features of the study population indicate that more males (55.4%) were admitted with NNT than females (44.6%). This finding is in contrast with findings by Babatunde et al. (2014), who observed that of those admitted with NNT, 83.3% were females and 16.7% were males. Additionally, the results showed a steady decline in the frequency of NNT cases from 2010 to 2014 with most of the NNT cases (27.4%) admitted in 2010, followed by 2011 (24.1%), 2012 (19.0%), 2013 (17.2%) and 2014 (12.3%). This is similar to findings observed in Northeast Nigeria by Jalal-Eddeen (2014), who obtained 26% NNT cases recorded in 2010 and only 9% NNT cases recorded in 2013. The frequency of NNT cases is inversely proportional to increasing years which is likely attributable to increased awareness of tetanus toxoid immunization during ANC among women of child bearing age in Nigeria, especially in urban settings (Dairo & Owoyokun, 2010). Data on frequency of sources of information showed that 55% (183) NNT case files were extracted from physicians records, 32.8% (100) from head nurses records, 36.4% (121) from nurses records, 33.4% (111) from medical records department, 13% (43) from nursing notes recorded in-patient registers, and 0.9% (3) from other sources such as prescription notes. More NNT records were extracted from physicians' records than other sources of information because most of the diagnoses of NNT were made by physicians, probably due to better knowledge of clinical presentations of the disease.

The following section presents the interpretation of the findings of the main study, followed by the limitations of the study, conclusions, and recommendations and implications for positive social change.

Interpretation of the Findings

The interpretations of the outcomes of the five research questions of the study are as follows:

Research Question 1

Is there any difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State? The null and alternate hypotheses for the research question were:

$H_0$1: There is no difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State

H_a1: There is a difference in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance of the health facility records in Katsina State.

The results confirm differences in the prevalence of NNT and the NNT mortality rate as reported in the IDSR system and the prevalence of NNT and the NNT mortality rate as identified through active surveillance. The results also confirm underreporting of NNT and NNT mortality in the surveillance system in Katsina State. These findings correspond with the outcome of an NNT survey by Peterside et al. (2012) in which the researchers found that only 5% of NNT cases were actually reported to health facilities. This is a vital outcome because it confirms references in contemporary literature that claim a low NNT detection rate found in the surveillance systems of developing countries (Lambo, et al, 2011: WHO, 2014).

Research Question 2

Is there any significant association between the number TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State? The null and alternate hypotheses for the research question were:

$H_0$2: There is no significant association between the number TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State

H_a2: There is a significant association between the number TT injections received by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

Findings from inferential statistics showed significant association between neonates whose mothers had only one dose of NNT vaccine and NNT mortality, (p = 0.04), OR = 4.12, 95% CI [1.04, 16.29] (p = 0.04). The findings confirmed the association between the number of TT injections received by pregnant women and NNT mortality. The findings correlate with an NNT survey by Akinyemi et al. (2013), which used cox hazard's model, that reported that tetanus toxoid injection was associated with a decrease in neonatal mortality rate, HR= 0.82, Cl [0.64, 1.05]. Similarly, McCurdy et al. (2011) found that newborns whose mothers received two or more tetanus toxoid injections were associated with low neonatal mortality rate, OR= 0.78, $p < .001$.

Research Question 3

Is there any significant association between the frequency of ANC visits attended by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State? The null and alternate hypotheses for the research question were:

$H_0$3: There is no significant association between the frequency of ANC visits attended by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

H_a3: There is a significant association between the frequency of ANC visits attended by pregnant women and NNT mortality as identified by the active surveillance method in Katsina State.

No significant associations were found between frequency of ANC visits and NNT mortality ($p = 0.20$). The findings did not confirm the association between the frequency of ANC visits attended by pregnant women and NNT mortality. The findings correlate with results reported by Singh et al (2012) in which the researchers found no significant association between of status of antenatal visits among mothers and NNT mortality OR= 1.19, 95%, CI [0.83, 1.75] (Singh et al., 2012, p. 34).

Research Question 4

Is there any significant association between the place of child delivery and NNT mortality as identified by the active surveillance method in Katsina State? The null and alternate hypotheses for the research question were:

$H_0$4: There is no significant association between the place of child delivery and NNT mortality as identified by the active surveillance method in Katsina State.

H_a4: There is a significant association between the place of child delivery and NNT mortality as identified by the active surveillance method in Katsina State.

No significant associations were found between place of delivery and NNT mortality ($p = 0.09$). The findings did not confirm the association between place of delivery and NNT mortality. The findings correlate with results reported by Babatunde et al, (2014) in which only 16.7% of neonates whose mothers delivered in the health facility died of NNT. This result conforms to the result by Fetuga et al. (2010) in an NNT survey in which the authors reported that 10.4 % of neonates delivered in health facilities were associated with NNT mortality.

Research Question 5

Is there any significant association between cord care received by women during delivery and NNT mortality as identified by the active surveillance method in Katsina State?

$H_0$5: There is no significant association between cord care received by women during delivery and NNT mortality as identified by the active surveillance method in Katsina State.

H_a5: There is a significant association between cord care received by women during delivery and NNT mortality as identified by the active surveillance method in Katsina State.

No significant associations were found between NNT mortality and cord care (p = 0.10).

The findings did not confirm the association between cord care and NNT mortality. The findings are in contrast to results reported by Imdad et al. (2013) in which the authors reported that cord care reduced neonatal mortality by 23%. Similarly, in a study conducted in India, Pakistan and Nepal, Kurumbi et al. (2013) found that cord care reduced neonatal death by 17%, while, findings by Arifeen et al. (2012) in Bangladesh showed that cord care reduced neonatal mortality in 29,760 neonates by 20%.

Relationship of Findings to Conceptual Framework

This study was guided by the Mosley and Chen's (1984) framework for the study of child survival. The basic concept of the framework is that child mortality occurs due to some socioeconomic and cultural factors that operate through some intermediate factors also known as proximate factors (Lasen & Carmichael, 2010). The findings of this study indicate that child mortality occurred when pregnant mothers received inadequate doses (< 2 doses) of tetanus toxoid vaccine before delivery. As described earlier, the main process and output indicator for tetanus toxoid immunization in a community is the proportion of pregnant women who have received a second dose of tetanus toxoid (TT2+) or the proportion of newborns less than 28days of age whose mothers have received the second dose of tetanus toxoid, who are otherwise referred to as "protected at birth"

(World Bank, 2015). Findings from this study show that neonates in Katsina State, Nigeria, whose mothers had only one dose of NNT vaccine were 4 times more likely to die of NNT than neonates whose mothers had two or more doses of NNT vaccine. Inadequate tetanus toxoid vaccines fail to stimulate the maternal immune system to produce adequate antitetanus antibodies that confer passive immunity against neonatal tetanus infection to the newborn in the first 28 days of life, thus leading to NNT mortality. Other findings in the study showed no significant associations between frequency of ANC visits, place of delivery, cord care, and child mortality. However, previous literature supports that there are associations between these proximate factors and child mortality; future research and evaluations need to be conducted to ascertain these associations.

Limitations of the Study

The limitation which relates to threat to internal validity described in Chapter 1 was confirmed in this study. There were some concerns regarding the quality of record keeping faced in primary health centers in the rural communities. Because these challenges were not pronounced during the pilot survey thus were not anticipated in the main study. The reason was probably due to the fact that the health facility were the pilot survey was conducted (General Hospital, Dutsinma) was a secondary health facility located in an urban setting that had a more functional records department with better skilled personnel than the primary health facilities in rural areas.

Recommendations

Recommendations for Action

The outcome of this study is recommended for the following community stakeholders: pregnant mothers, traditional birth attendants (TBAs), community leaders or influencers, Diseases Surveillance and Notification Officers (DSNOs), Directors of Surveillance Health Systems and researchers. Evidence from this study suggests that number of NNT injections is associated with neonatal mortality thus it is imperative to promote tetanus toxoid vaccination in the community as a means of preventing NNT mortality. The target groups for this health promotion are: pregnant mothers, TBAs and community leaders or influencers in Katsina State, Nigeria. Although TBAs are not considered as skilled health personnel, their role and influence in reducing neonatal mortality through health promotion in developing countries is acknowledged [Falle et al., (2009): Pyone et al., (2014)]. Similarly, community leaders have been found to be effective in reducing child mortality through effective communication skills and motivation in developing countries [Glanz, Rimer, & Viswanath, (2008): Kulbok, Thatcher, Park & Meszaros, (2012)]. The focus of health promotion should be on the relevance of receiving and completing the 5 doses of tetanus toxoid injections during antenatal care. Due to the low literacy rate particularly among the mainstream population in Northern Nigeria (Adebowale et al., 2012), mode of communication will be through the use of visual aids like pictograms for better understanding. The outcome of this study is particularly useful to Diseases Surveillance and Notification Officers (DSNOs) and directors of the public health surveillance systems in Nigeria so as to strengthen and expand NNT surveillance by integrating NNT risk factors surveillance with the IDSR system.

Recommendations for Future Research

Missing data was an important challenge faced during the data collection process. In the future studies, pilot surveys involving retrospective record surveys should be conducted in less equipped health facilities so as to identify and find ways of addressing missing data before commencing the main study. Missing data can also minimized by the structuring and standardizing the questionnaires using closed ended questions. This study was focused primarily on the impact of maternal proximate factors on NNT mortality; there is a need conduct studies to identify the impact of community, social and economic factors e.g. distance to health facility, parents' education and, religious beliefs on NNT mortality. Furthermore, future research should be conducted in the communities; findings from such community surveys may provide an in-depth assessment of the associations between risk factors and NNT mortality including the risk factors found not significantly associated with NNT mortality in this study.

Study Implications

Although several studies concerning risk factors of NNT have been conducted; however, contemporary literate has shown that only few studies were conducted that focused on the associations of proximate factors and NNT mortality. This study indicates two important findings: significant association between numbers of tetanus toxoid injections received by mothers and NNT mortality, and under-reporting of NNT in Katsina State, Nigeria. Based on these findings, methodological implications for future research includes conducting a face-to-face community survey which may provide better insight in identifying the associations between socio-economic risk factors and NNT mortality.

Under-reporting of NNT through the existing surveillance system creates irrational estimates of the prevalence, incidence and mortality rates of the disease which eventually makes it challenging for policy makers and stakeholders to decide on the appropriate interventions and resources allocated to eliminate the disease. Implications for positive social change for this study at the organizational/policy level include strengthening the neonatal tetanus surveillance system in Nigeria with the capacity for early detection of potential risk factors to develop specific public health interventions aimed at improving the outcome of neonatal tetanus.

Conclusion

NNT is said to be eliminated when the prevalence rate in a country is less than 1 case per 1000 live births. Although a total of 38 countries reached this milestone between 2008 and June 2015 (UNICEF, 2015), the disease is still endemic and was accountable for the high neonatal mortality rate in some surveys conducted in Nigeria (WHO, 2015). Evidence from this study suggests that NNT reporting is ineffective in the existing IDSR system which is vital gap towards the elimination of the disease in Nigeria. Thus it is imperative to: adopt a novel surveillance approach by introducing NNT mortality risk factors identification and analysis and, promote tetanus toxoid vaccination among pregnant women in order to reduce the burden of the disease and attain elimination goals.

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Appendix A: List of Health Facilities

S/N	KATSINA LGA	DAURA LGA	MALUMFASHI LGA
1	Federal Medical Center, Katsina (Tertiary)	General Hospital, Daura (Secondary)	General Hospital, Malumfashi (Secondary)
2	General Hospital, Katsina (Secondary)	PHC Binga (Primary)	PHC Dayi (Primary)
3	Turai Umar Yar'adua MCH (Secondary	PHC Madobi (Primary)	PHC Dansaka Gora (Primary)
4	CHC Kofar Kaura (Primary)	MCHC Sharawa (Primary)	PHC Karfi (Primary)
5	MCHC Kofar Guga (Primary)	MCHC Kurneji (Primary)	MCHC Malumfashi (Primary)
6	MCHC Kofar Marusa (Primary)	PHC Suduji (Primary)	PHC Na'alma (Primary)
7	MCHC Kofar Sauri (Primary)	PHC Mazoji (Primary)	PHC Ruwan Sanyi (Primary)
8	MCHC Rafindadi (Primary)	PHC Yamadawa (Primary)	PHC Dansara (Primary)
9	MCHC Shinkafi (Primary)	PHC Dannakola (Primary)	
10	MCHC Kwado (Primary)	PHC Gara (Primary)	
11	MCHC Tudunyanlihiddda (Primary)	MCHC Gurjiya (Primary)	
12	MCHC Abbatoir (Primary)	MCHC Kanti (Primary)	
13	MCHC Police Clinic (Primary)	MCHC Kalgo (Primary)	
14		PHC Shadanbu (Primary)	
15		PHC Urban (Primary)	
16		PHC Hindatu (Primary)	
17		PHC Dunu (Primary)	
18		PHC K/badala (Primary)	
19		PHC Baraji (Primary)	
20		PHC Rahamawa (Primary)	
21		PHC Fsc (Primary)	
22		CHC Daura (Primary)	

Appendix B: Neonatal Tetanus Survey Instrument (Form A)

Neonatal Tetanus Survey Form						
Zone	**Name of LGA**	**Name of Health Facility**	**Reported NNT cases**	**Reported NNT mortalities**	**Identified NNT cases**	**Identified NNT mortalities**
Zonal Summary (Total)						

Appendix C: Form B (Neonatal Tetanus Detection Questionnaire)

Reviewer

Reviewer ID number: ☐ ☐ Name of Health Facility…………………………..

Date of admission: ☐ ☐ / ☐ ☐ / ☐ ☐

Time commenced review: ☐ ☐ ☐ ar ☐

Time finished review: ☐ ☐ ☐ a ☐

Case number

Case number: ☐ ☐ ☐

Birthdate: ☐ ☐ ☐ ☐ ☐ ☐

d d m m y y

Indicate age in months if date of birth was not known………………………………

Gender: ☐ 1= male, 2 = female

Date of review: ☐ ☐ / ☐ ☐ ☐ ☐

Date of discharge: ☐ ☐ / ☐ ☐ ☐ ☐

d d m m y y

SCREENING CRITERIA

Please indicate for all of the below if the criteria are fulfilled and if so give details

…………………………………………………………………………………………………

1. Was patient having normal ability to suck breast and cry for the first 2 days after delivery?

   Yes ☐ No ☐

2. Did the illness occur between the 3rd and 28th days after delivery? Yes ☐ No ☐

3. Was the patient unable to suck breast or cry, followed by generalized body spasms or stiffness?

   Yes ☐ No ☐

4. Are any criteria present? ☐ Yes ☐ No, (then STOP; do not submit for medical review).

   If yes, total number of criteria ☐

Appendix D: Form B (Medical Review)

Reviewer ID number: Case Number: [ ] [ ] [ ]

(same number as in form A)

Date of data collection: [ ] [ ] [ ] [ ] [ ] [ ]

d d m m y y

Time commenced review: [ ] [ ] [ ] [ ]

Time finished review: [ ] [ ] [ ] [ ]

Information Sources Used For Review

Q1. Physician ________________________________ 1 = Yes, 2 = No [ ]

Q2. Head nurse ________________________________ 1= Yes, 2 = No [ ]

Q3. nurse____________________________________ 1 = Yes, 2 = No [ ]

Q4. Medical Record _____________________________ 1 = Yes, 2 = No [ ]

Q5. Nursing notes______________________________ 1 = Yes, 2= No [ ]

Q6.other source________________________________ 1 = Yes, 2=No [ ]

Number of Tetanus Toxoid Injection

Q7. How many doses of tetanus toxoid vaccines did the mother receive during pregnancy?

0 = none, 1 = one, 2 = two or more [ ]

Frequency of Antenatal Visits

Q8. How many times did the mother attend antenatal visits during pregnancy?

0 = No visit, 1 = 1- 4 visits, 2 = 4 visits ☐

Place of Delivery

Q9. Where was the child delivered and who attended the delivery?

0 = Home, 1 = Health Center ☐

Cord Care

Q10. How was the umbilical cord cut and treated after delivery?

0 = old razor blade/tying with unsterile threated, treatment with soil, cow dump, or any aseptic procedure,

1= New razor blade or any septic treatment ☐

Neonatal Mortality

Q11. What was the outcome of treatment during discharge?

0 = >28days of life = survived, 1= < 28days of life = death ☐

Appendix E: Permission to Gain Access to Data

MINISTRY OF HEALTH
KATSINA STATE

Tel" Hon. Commissioner 065-434537 (DL)
434518(DL)
Permanent Secretary 065-34554

State Secretariat Complex,
I. B. B. Way Dandagoro
P.M.B. 2075, Katsina

Our Ref: MOH/ADM/SUB/1174/1/164 Date: 01/06/2015

Your Ref:

KATSINA HREC FULL ETHICAL CLEARANCE CERTIFICATE

Re: "Evaluation of Active and passive Neonatal Surveillance systems in Katsina State, Northwestern Nigeria"

Katsina HREC assigned number - MOH/ADM/SUB/1174/1/164
Name of Principal Investigator -Dr Shafique Sani Nass
Address of Principal Investigator -Walden University, College of Health Sciences
Date of Receipt of valid Application -13/02/2015
Date of ERC meeting and approval -12/05/2015

This is to inform you that the research described in the submitted protocol, the consent forms, and other participants information materials have been reviewed and given full approval by the Katsina State Health Research Ethics Committee and accordingly by the Honorable Commissioner of Health.
Please note; this approval dates from 01st June 2015 to 01st June 2016
No participant recruited into this research may be conducted outside these dates.

All informed consent forms in this study must carry the Katsina HREC assigned number and the duration of the Katsina HREC approval for the study.

The HREC expects that you submit your application as well as an annual report for ethical clearance renewal 3 months prior to the expiration of the study dates. This is to enable you obtain renewal of your approval and avoid interruption of your research.

If there is a delay in starting the research, please inform the Katsina HREC so that starting dates can be adjusted accordingly.

No changes are permitted to the research without prior approval by Katsina HREC except in circumstances outlined in the national code for health research ethics. http://www.nhrec.net

Katsina HREC reserves the right to conduct compliance assessment to your research site without prior notification.

Dr Abduljalil U Abdullahi
Director Public Health
Chairman, Katsina HREC

"Home of Heritage and Hospitality"

Appendix F: Permission to Use Data Collection Instrument A

ID: 161298 - Form to request permission to reproduce or reprint WHO copyrighted material

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Kind regards,

WHO Press

Appendix G: Permission to Use Data Collection Instrument B

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Kind regards,

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Appendix H: Permission to Reproduce Figure and Table

from:	
to:	Shafique Nass <drshafique.nass@waldenu.edu>
date:	Fri, Oct 2, 2015 at 3:00 PM
subject:	Re: PERMISSION TO REPRODUCE FIGURE & TABLE IN YOUR ARTICLE
mailed-by:	gmail.com
signed-by:	gmail.com
:	Important mainly because of your interaction with messages in the conversation.

Thanks for you mail, Shafique. You can reproduce the figure and table (if it fits the description of your variables). All the best.

Appendix I: Permission to Reproduce Figure (A)

from:
to: drshafique.nass@waldenu.edu
date: Thu, Oct 15, 2015 at 3:24 PM
subject: RE: PERMISSION
mailed-by: radboudumc.nl

: Important mainly because it was sent directly to you.

Dear Shafique,

That's okay! Please refer to my paper in your paper and Figure.

Kind regards,

Van: Shafique Nass [mailto:drshafique.nass@waldenu.edu]
Verzonden: donderdag 15 oktober 2015 12:28
Aan:
Onderwerp: PERMISSION

Appendix J: Permission to Reproduce Figure (B)

from: The Nigerian Academy of Science <admin@nas.org.ng>
reply-to: admin@nas.org.ng
to: Shafique Nass <drshafique.nass@waldenu.edu>
date: Mon, Oct 19, 2015 at 12:26 PM
subject: Re: PERMISSION

: Important mainly because it was sent directly to you.

Dear Shafique Nass,
Thank you for your mail. Please be informed that your permission has been granted provided. However, you are to reference the NAS report appropriately in your publication. Thank you.

Administrative Officer (Communications)
For: Executive Secretary

Appendix K: Descriptive Statistics (Frequencies)

Heath Facility ID

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	General Hospital Katsina	73	22.0	22.0	22.0
	Federal Medical Centre Katsina	38	11.4	11.4	33.4
	MCHC Kofar Guga	22	6.6	6.6	40.1
	General Hospital Malumfashi	51	15.4	15.4	55.4
	MCHC Malumfashi	80	24.1	24.1	79.5
	General Hospital Daura	53	16.0	16.0	95.5
	PHC Dannakola	15	4.5	4.5	100.0
	Total	332	100.0	100.0	

Figure K1: Research question 1 descriptive statistics

Number of Tetanus Toxoid Injection

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	None	254	76.5	76.5	76.5
	One	44	13.3	13.3	89.8
	Two or More	34	10.2	10.2	100.0
	Total	332	100.0	100.0	

Figure K2: Research question 1 descriptive statistics

Frequency of Antenatal Visits

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No Visit	231	69.6	69.8	69.8
	1-4 Visits	74	22.3	22.4	92.1
	4 Visits	26	7.8	7.9	100.0
	Total	331	99.7	100.0	
Missing	System	1	.3		
Total		332	100.0		

Figure K3: Research question 1 descriptive statistics

Place of Delivery

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Home	290	87.3	87.6	87.6
	Health Centre	41	12.3	12.4	100.0
	Total	331	99.7	100.0	
Missing	System	1	.3		
Total		332	100.0		

Figure K4: Research question 1 descriptive statistics

Cord Care After Delivery

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Aseptic Treatment	269	81.0	81.3	81.3
	Septic Treatment	62	18.7	18.7	100.0
	Total	331	99.7	100.0	
Missing	System	1	.3		
Total		332	100.0		

Figure K5: Research question 1 descriptive statistics

Neonatal Mortality

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Death	85	25.6	25.6	25.6
	Survived	247	74.4	74.4	100.0
	Total	332	100.0	100.0	

Figure K6: Research question 1 descriptive statistics

Year of Admission

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2010	91	27.4	27.4	27.4
	2011	80	24.1	24.1	51.5
	2012	63	19.0	19.0	70.5
	2013	57	17.2	17.2	87.7
	2014	41	12.3	12.3	100.0
	Total	332	100.0	100.0	

Figure K7: Research question 1 descriptive statistics

Appendix L: Descriptive Statistics (Cross-Tabulations)

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Number of Tetanus Toxoid Injection * Neonatal Mortality	332	100.0%	0	.0%	332	100.0%
Frequency of Antenatal Visits * Neonatal Mortality	332	100.0%	0	.0%	332	100.0%
Place of Delivery * Neonatal Mortality	332	100.0%	0	.0%	332	100.0%
Cord Care After Delivery * Neonatal Mortality	332	100.0%	0	.0%	332	100.0%

Figure L1: Research question 1 cross tabulations

Crosstab

			Neonatal Mortality		Total
			Survived	Death	
Cord Care After Delivery	Aseptic Treatment	Count	58	212	270
		% within Cord Care After Delivery	21.5%	78.5%	100.0%
	Septic Treatment	Count	27	35	62
		% within Cord Care After Delivery	43.5%	56.5%	100.0%
Total		Count	85	247	332
		% within Cord Care After Delivery	25.6%	74.4%	100.0%

Figure L2:

Crosstab

			Neonatal Mortality		Total
			Survived	Death	
Place of Delivery	Home	Count	65	225	290
		% within Place of Delivery	22.4%	77.6%	100.0%
	Health Centre	Count	20	22	42
		% within Place of Delivery	47.6%	52.4%	100.0%
Total		Count	85	247	332
		% within Place of Delivery	25.6%	74.4%	100.0%

Figure L3: Research question 1 cross tabulations

Crosstab

			Neonatal Mortality		Total
			Survived	Death	
Frequency of Antenatal Visits	No Visit	Count	54	177	231
		% within Frequency of Antenatal Visits	23.4%	76.6%	100.0%
	1-4 Visits	Count	20	54	74
		% within Frequency of Antenatal Visits	27.0%	73.0%	100.0%
	4 Visits	Count	11	16	27
		% within Frequency of Antenatal Visits	40.7%	59.3%	100.0%
Total		Count	85	247	332
		% within Frequency of Antenatal Visits	25.6%	74.4%	100.0%

Figure L4: Research question 1 cross tabulations

Crosstab

			Neonatal Mortality		Total
			Survived	Death	
Number of Tetanus Toxoid Injection	None	Count	57	197	254
		% within Number of Tetanus Toxoid Injection	22.4%	77.6%	100.0%
	One	Count	13	31	44
		% within Number of Tetanus Toxoid Injection	29.5%	70.5%	100.0%
	Two or More	Count	15	19	34
		% within Number of Tetanus Toxoid Injection	44.1%	55.9%	100.0%
Total		Count	85	247	332
		% within Number of Tetanus Toxoid Injection	25.6%	74.4%	100.0%

Figure L5: Research question 1 cross tabulations

Appendix M: Logistic Regression Test Results

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Model	19.676	6	.003

Figure M1: Research questions 2 – 5 test results

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	358.045[a]	.058	.085

Figure M2: Research questions 2 – 5 test results

Hosmer and Lemeshow Test

Step	Chi-square	df	Sig.
1	4.941	4	.293

Figure M3: Research questions 2 – 5 test results

Classification Table[a]

Observed			Predicted: Neonatal Mortality Survived	Predicted: Neonatal Mortality Death	Percentage Correct
Step 1	Neonatal Mortality	Survived	16	69	18.8
		Death	14	233	94.3
	Overall Percentage				75.0

Figure M4: Research questions 2 – 5 test results

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)	95.0% C.I.for EXP(B) Lower	95.0% C.I.for EXP(B) Upper
Step 1[a]	NTT			4.416	2	.110			
	NTT(1)	1.416	.701	4.075	1	.044	4.120	1.042	16.288
	NTT(2)	.683	.684	.995	1	.318	1.979	.518	7.568
	FANV			2.559	2	.278			
	FANV(1)	-1.058	.823	1.651	1	.199	.347	.069	1.743
	FANV(2)	-.359	.724	.246	1	.620	.698	.169	2.884
	POD	-.769	.457	2.832	1	.092	.463	.189	1.135
	CC	-.646	.388	2.768	1	.096	.524	.245	1.122
	Constant	.982	.470	4.374	1	.036	2.670		

Figure M5: Research questions 2 – 5 test results

Appendix N: Inter-rater Reliability A

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Data Abstractor A * Data Abstractor B	30	100.0%	0	0.0%	30	100.0%

Figure N1: Pilot study reliability test results

Data Abstractor A * Data Abstractor B Crosstabulation

			Data Abstractor B
			Unable to Feed and Cry within 48hrs
Data Abstractor A	Unable to Feed and Cry within 48hrs	Count	5
		% within Data Abstractor A	100.0%
		% within Data Abstractor B	62.5%
		% of Total	16.7%
	Normal Ability to feed and Cry within 48hrs	Count	3
		% within Data Abstractor A	12.0%
		% within Data Abstractor B	37.5%
		% of Total	10.0%
Total		Count	8
		% within Data Abstractor A	26.7%
		% within Data Abstractor B	100.0%
		% of Total	26.7%

Figure N2: Pilot study reliability test results

Data Abstractor A * Data Abstractor B Crosstabulation

			Data Abstractor B	Total
			Normal Ability to feed and Cry within 48hrs	
Data Abstractor A	Unable to Feed and Cry within 48hrs	Count	0	5
		% within Data Abstractor A	0.0%	100.0%
		% within Data Abstractor B	0.0%	16.7%
		% of Total	0.0%	16.7%
	Normal Ability to feed and Cry within 48hrs	Count	22	25
		% within Data Abstractor A	88.0%	100.0%
		% within Data Abstractor B	100.0%	83.3%
		% of Total	73.3%	83.3%
Total		Count	22	30
		% within Data Abstractor A	73.3%	100.0%
		% within Data Abstractor B	100.0%	100.0%
		% of Total	73.3%	100.0%

Figure N3: Pilot study reliability test results

Symmetric Measures

		Value	Asymp. Std. Error[a]	Approx. T[b]	Approx. Sig.
Measure of Agreement	Kappa	.710	.152	4.062	.000
N of Valid Cases		30			

Figure N4: Pilot study reliability test results

Appendix O: Inter-rater Reliability B

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Medical Reviwer A * Medical Reviwer B	30	100.0%	0	0.0%	30	100.0%

Figure O1: Pilot study reliability test results

Medical Reviwer A * Medical Reviwer B Crosstabulation

			Medical Reviwer B	
			Aseptic Treatment	Septic Treatment
Medical Reviwer A	Aseptic Treatment	Count	24	1
		% within Medical Reviwer A	96.0%	4.0%
		% within Medical Reviwer B	96.0%	20.0%
		% of Total	80.0%	3.3%
	Septic Treatment	Count	1	4
		% within Medical Reviwer A	20.0%	80.0%
		% within Medical Reviwer B	4.0%	80.0%
		% of Total	3.3%	13.3%
Total		Count	25	5
		% within Medical Reviwer A	83.3%	16.7%
		% within Medical Reviwer B	100.0%	100.0%
		% of Total	83.3%	16.7%

Figure O2: Pilot study reliability test results

			Total
Medical Reviwer A	Aseptic Treatment	Count	25
		% within Medical Reviwer A	100.0%
		% within Medical Reviwer B	83.3%
		% of Total	83.3%
	Septic Treatment	Count	5
		% within Medical Reviwer A	100.0%
		% within Medical Reviwer B	16.7%
		% of Total	16.7%
Total		Count	30
		% within Medical Reviwer A	100.0%
		% within Medical Reviwer B	100.0%
		% of Total	100.0%

Figure O3: Pilot study reliability test results

Symmetric Measures

		Value	Asymp. Std. Error[a]	Approx. T[b]	Approx. Sig.
Measure of Agreement	Kappa	.760	.162	4.163	.000
N of Valid Cases		30			

Figure O4: Pilot study reliability test results