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BACILLUS CALMETTE GUERIN IMMUNIZATION COVERAGE AND DATA QUALITY IN WANGING'OMBE DISTRICT; NJOMBE REGION, TANZANIA

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requirements for the degree of Masters in Health Supply Chain Management (MHSCM)

By

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DECLARATION

I declare that this dissertation is the result of my own original work except where specifically acknowledged and it has not been presented for any other degree at the University of Rwanda or any other institution. It has also been subjected through the anti-plagiarism system and found to be compliant and this is the approved final version of the dissertation.

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DEDICATION

This work is dedicated to my beloved husband Dr. Patrick Msigwa, my beloved mother Ndenaike Kweka, my children Fridoline, Raymond and Rosemary plus all my siblings for their prayers and tolerance for being deprived of my presence during the period of my study.

ABSTRACT

Background: Immunization coverage is a key measure for performance of immunization programmes. Coverage for pentavalent vaccine third dose is primarily used as an indicator for performance. However, it is also important to know the coverage and issues related to birth doses particularly Bacillus Calmette Guerin (BCG) since the number of doses administered is used as a baseline for computing other immunization indicators like dropout rate. Reliability of the reported immunization coverage depends on the quality of the collected immunization data. Similarly, the accuracy of the reported data is closely linked among other things to knowledge on recording and reporting practices of staff who handle immunization data.

Objective: To estimate BCG coverage and assess the quality of the reported immunization data for the calendar year 2018.

Methods: A cross- sectional descriptive study was conducted in 23 selected health facilities in Wanging'ombe district. Abstraction form was used to retrieve the number of doses administered to children less than one year of age from the tally sheet and this was used as the numerator for coverage estimation. Live births were retrieved from the labour and delivery register and used as the denominator. Accuracy ratio was determined by dividing the number of recounted doses from the tally sheet by the reported doses in the health facility monthly summary form. Interviewer administered questionnaire was used to assess knowledge of vaccinators. Timeliness of reports was ascertained by observing report submission date while completeness was determined by computing the ratio of the number of fields filled out of total.

Results: The estimated coverage was high (177%). Of the fifteen health facilities that were assessed for accuracy, 7 had accurate data, 5 over reported and 3 under reported. Majority of vaccinators 33 (71.7%) had moderate knowledge. Reporting timeliness and completeness was more than 90%.

Conclusion: The estimated proportion of children vaccinated with BCG for the calendar year 2018 was exceptionally high; though the reported number of doses administered was accurate and can be relied for decision making. Standard Operating Procedures with clear instructions for recording and reporting should be emphasized.

Key words: BCG; Coverage; Data quality; Immunization

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LIST OF ABBREVIATIONS

BCG	Bacillus Calmette Guerin
CHMTs	Council Health Management Team
CRVS	Civil Registration and Vital Statistics
DVD-MT	District Vaccination Data Management Tool
DHIS	District Health Information System
DQA	Data Quality Assessment
DQS	Data Quality Self-Assessment
EPI	Expanded Program on Immunization
GVAP	Global Vaccine Action Plan
IVD	Immunization and vaccine Development
HIV	Human Immune Virus
LGAs	Local Government Authorities
HMIS	Health Management Information System
HPV	Human Papilloma Virus
RAs	Research Assistants
TAITAG	Tanzania Immunization Technical Advisory Group
TB	Tuberculosis
TZS	Tanzanian Shillings
UNICEF	United Children's Fund
VIMS	Vaccine Information Management System
WHO	World Health Organization

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CHAPTER ONE

1.0 INTRODUCTION

1.1 Background to the study

Immunization coverage is a key measure of immunization system performance. It is reported that, vaccination of infants in routine immunization programs with an estimated coverage of about 90% can avoid 117,132 Tuberculosis (TB) diseases globally for each birth cohort in the early 15 ages of survival (1). There are several methods used to estimate coverage each with its own strengths and weaknesses. Administrative methods are built on routine number of administered doses divided by the total estimated number of people in the target population and can be totally affected by imprecise numerators or denominators (2). Errors in numerators could be unintentionally or intentionally introduced while tallying, compiling, and reporting the data to the higher level (3). Denominators are usually projected each year from census baseline data and are subject to errors as the accuracy is distorted over time due to disparities in growth rate among districts (3).

Vaccines contribute a lot in prevention of infectious diseases especially those affecting under-fives. Immunization has led to a decrease in illness and death for vaccine preventable illnesses all over the world. The number of children below five years old dying every year has dropped from 12.7 million in 1990 to 6.3 million today and immunization has contributed at large in this significant success (4). The burden of TB in sub Saharan Africa is high may be due to high prevalence of Human Immune Virus (HIV). Tuberculosis control efforts in this Region are not largely inhibited by weak control measures but because of the link between TB and HIV since there is a greater risk of developing active TB in immunologically compromised individuals (5).

In Tanzania the burden of TB is high and is among 22 high burden countries globally (6). Apart from HIV, Malnutrition is among the predisposing factor for TB infection. In 2016, it was estimated that of the 10.4 million incident cases of TB,1.9 million were associated with malnourishment and 1 million to HIV infection (7). Young

children in Njombe region are at high risk of TB infection given the high prevalence of HIV infection of 11.4% as indicated by a recent HIV impact survey of 2016-2017 and the high rate of stunting (49%). It is the second leading region for having malnourished children (8).

BCG efficacy and epidemiology

Bacillus Calmette Guerin is among the traditional vaccines that were introduced by Expanded Program on Immunization (EPI) Tanzania in 1975. According to the National guideline, it should be given at birth or at the earliest opportunity thereafter. It is a live attenuated vaccine for prevention of TB. The vaccine is derived from mycobacterium bovis and about 95% of BCG recipients experience a reaction at the injection site that heals within 2-5 months leaving a superficial scar which is regarded normal(9). However, the WHO suggests that lack of scar following vaccination with BCG does not mean that the child is not protected thus revaccination is unnecessary (10).

BCG vaccination of infants at birth or as soon as appropriate after delivery is considered a cost effective approach and one of the crucial element of the first pillar to control TB morbidity. The causative agent of TB is spread through droplet infection from the infected person to a healthy person. Although the protective effect of BCG vaccine in HIV infected children is debatable (11), it is still the a single vaccine offered for prevention of serious forms of illness in youngsters. The positive outcomes of BCG vaccination might be attributed by high vaccine efficacy in preventing tuberculosis disease in vaccinated infants and reducing the severity of infection as documented in literature (12,13).

BCG coverage and data quality

Administrative coverage data need to be revised at regular intervals in order to improve data quality. Vaccination coverage levels assessed by complete and accurate administrative data, validated repeatedly by high quality surveys would eliminate the need for the World Health Organization (WHO) and United Nations Children's Fund (UNICEF) to do the same. Consolidation, analysis and sharing of the findings is a valuable input (14).

Tanzania is among few sub-Saharan countries observed to achieve higher immunization coverage. Coverage rates are above 100% for all vaccines except for Measles Conjugate Vaccine second dose (MCV-2)(15). Reported coverage of above 100% may happen because of inaccuracy of the numerator, under estimated (targeted children) denominator or both. With regard to BCG vaccine, doses administered in the country began to exceed estimated births in 2011 and in 2014 when it was the highest (15). Inaccurate estimates of BCG coverage depict a false image of program performance and may compromise evidence based program planning. On the other hand, inaccurate estimates may not reflect the protective effect of the vaccine in the targeted children. Some studies have ascertained that the higher coverage for BCG compared to other vaccines is because it can be administered at birth (16).

The WHO recommends that, births categorized by place of birth could be the best target population for children eligible for BCG vaccine (17). To improve program management on everyday basis, inventive rapid evaluations are suggested to tackle specific problems instead of waiting for labour demanding and expensive community surveys (18).

Despite significant improvements in performance of immunization services in developing countries, challenges still persist. Majority of those relate to programmatic areas of policy, standards and guidelines, human resources, data generation and use, governance, organisation and management among other things (19). Other challenges affecting data quality in these countries relate to inadequate capacity for analysing and use of information for making decisions, duplication and multiple parallel reporting systems (20). Most of industrialized countries and few unindustrialized countries have developed National Immunization Technical Advisory Groups (NITAGs) which is a multidisciplinary body to guide evidence based decision on immunization policies (21).

Although immunization data quality is an international focus, global stakeholders have pointed that poor quality of data and low use is a main challenge hindering success of immunization programmes (22). To achieve the goals included in Global Vaccine Action Plan (GVAP) and those in regional and national action plans, there

should be a mechanism to monitor progress and providing accountability. Global Alliance for Vaccines and Immunization (GAVI) has recently introduced new data requirements which include annual desk reviews, regular data quality assessments and coverage surveys (23).

1.2 Problem statement

The Tanzania ministry of health has trained Middle Level Managers on management of immunization services and use of data for decision making through Reach Every Child (REC) strategy in recent years. At sub-national level, health management teams have been conducting supportive supervision, on the job coaching and mentoring and data review meetings through partners support and by use of local resources. To ensure uninterrupted data flow, the National Immunization Programme has put in place immunization data collection tools in addition to Health Management Information System (HMIS) tools which also capture immunization data. With all such efforts, the quality of immunization data has not improved posing queries on the coverage reported at district level.

The latest national Expanded Program on Immunization (EPI) review was conducted in 2015 and focused primarily on immunization coverage and the systems used to collect immunization data. Among the challenges reported by reviewers were inconsistencies between the numerator and denominator data. In Njombe Region, Wanging'ombe district reported coverage of more than 100% for BCG vaccine in 2018. Over reported data may deny decision makers to take a necessary action. Likewise, the fewer number of children who got a vaccine would not be adequately protected.

This study assessed the quality of data and estimate immunization coverage based on the data verified by the researcher from the data sources for the calendar year (2018).

1.3 Justification of the study

This study was done to estimate BCG immunization coverage in Wanging'ombe district by using live births recorded at health facilities as the denominator. The vaccine was selected because it is often questioned by program officers for having more than 100% coverage and consequently large dropouts when compared with subsequent vaccines administered to children less than one year of age. Coordinators at subnational level have occasionally being able to provide straight answers. It is expected that, the data quality issues identified will bring attention to health facility managers on the importance of verifying the reports before sending to the higher level. The Council Health Management Team will be inspired to conduct targeted training and improve the quality of supportive supervision based on weak areas identified so as to improve the accuracy of the reported immunization data. Other beneficiaries of the findings from this study will be stakeholders like the Tanzania Immunization Technical Advisory Group (TAITAG) which is an advisory body on policy related matters at National level. The TAITAG may use the evidence from this study to advise program managers on guideline review and updating of data collection tools**.** This will ensure that vaccination guideline requirements are in line with the way reporting tools are structured**.** Also the findings will be published to share knowledge on the research topic with other people working in immunization program in the world and propose areas that need further research.

1.4 Research questions

The proposed study addressed the following research questions;

1. What is the proportion of children vaccinated with BCG in Wanging'ombe district in 2018?
2. What is the accuracy of the reported BCG immunization data?
3. What is the knowledge of vaccinators on BCG immunization facts?
4. What is the timeliness of submission of the health facility reports to district level?
5. What is the completeness of the reported BCG immunization data?

1.5 Research objectives

1.5.1 Broad objective

The main objective of the research was to estimate BCG immunization coverage and assess immunization data quality in Wanging'ombe district.

1.5.2 Specific objectives

1. To estimate the proportion of children vaccinated with BCG in 2018
2. To assess the accuracy of the reported BCG immunization data
3. To assess knowledge of vaccinators on BCG immunization facts
4. To determine timeliness of submission of the health facility reports to district level
5. To determine completeness of the health facility reports

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Overview of immunization coverage and data quality

Immunization coverage is often measured at international, national, sub-national and health facility level to measure program performance, detect errors and take necessary actions. Each level is accountable to the higher level with regard to the quality of reported data. There are so many studies that have suggested that the best way to assess coverage of interventions is to complement administrative methods with those obtained through community surveys (24)(25). Survey estimates rely on verifying the number of doses administered to a child by observing health cards or as reported by a mother and are often trusted by global stakeholders and EPI managers (25). However, this method is subject to selection and recall bias among other things (26).

Immunization coverage estimated by use of administrative reports is not free from flaws. The method is subject to errors in the denominators, errors in recording doses administered at health facilities and errors in consolidating reports for submission to higher authorities (26). Several studies have highlighted inconsistencies observed in routine immunization data. A study which was done in Burkina Faso compared coverage estimates obtained through administrative sources with those from EPI Cluster Survey (ECS) and Demographic and Health Survey (DHS). Administrative estimates were higher than ECS and DHS and large discrepancies were observed sometimes reaching up to 30%. There was correlation between geographical area and over estimation or underestimation; rural districts were over estimating while those in urban and near to urban were over estimating the real coverage. Over and under estimation was independent of the vaccine under consideration (27). A similar finding was reported in immunization data quality audit in Uganda where health center level two and three contributed more to over and underreporting. The mean quality indices for recording practices were found to be 66%, storage and reporting 75%, monitoring and evaluation 43%. The study found weak positive correlation between the quality index and health center verification factor ($r= 0.014$, $p=0.92$)

(28). In Mozambique, a study was done to estimate immunization coverage in meringue district in 2011. The study used records of BCG doses administered as the numerator and live births as the denominator. The estimated coverage was found to be 86.3 % (95% confidence interval: 85.1-87.4)(29). The study pointed out that there are weaknesses in the existing recording practices. Doubts in data quality constrain decision makers from making sound decisions like targeting the little resources available to the needy areas.

2.2 Summary of factors related with immunization coverage and data quality

2.2.1 Policy and governance

The Global Vaccine Action Plan (GVAP) calls for countries to achieve immunization coverage of 90% and above for all the antigens scheduled in their routine immunization services by 2020 (30). Higher coverage brings consideration on correctness of target populations more important than it is for low coverage. However, it is challenging to get target population estimates of sufficient accuracy to allow for monitoring of coverage changes at high coverage levels due to lack of robust Civil Registration and Vital Statistics (CRVS) system in most countries (17). Tanzania is similar to other sub Saharan Africa as it uses census population projections to set targets for immunization. Again, this method is subject to bias as the accuracy tends to decrease as time goes from the year of census (17). As such, fluctuations in coverage may be a result of denominator adjustments following a new census or projection. To observe the influence of such denominator adjustments, it is suggested to graph numerators and denominators by years (31).

A countrywide study in immunization coverage in Nigeria compared National reported coverage for Diphtheria Tetanus Pertussis third dose (DTP 3) with district reported coverage and coverage obtained through survey for four consecutive years (2010-2013). Comparison was done to determine annual change in coverage. It was revealed that coverage levels for DTP 3 reported by Local Government Authorities (LGAs) were similar to those available at the national level but there were big variations on coverage reported between LGAs. The volatility was explained to be possibly due to uncertainties in the target population where a constant yearly growth

rate was used to estimate the entire population each year in majority of LGAs. Consequently, many LGAs increased or reduced their target population by more than 5% within a calendar period (32). In Uganda, a cross sectional study following Human Papilloma Virus (HPV) introduction assessed the role of health system in uptake of HPV vaccine. The study utilized both qualitative and quantitative data collection methods. The study discovered that lack of clear target for monitoring and evaluation was one of the theme raised by vaccinators as a challenge to measure performance (33).

In most countries vaccines are given to children above one year by policy or despite existence of restricting policies and there are opportunities to misclassify vaccinations by age (34). The study which was done in America surveyed pediatricians and family practitioners to assess vaccination practices and attitudes. The study concluded that immunization practices varied among providers and they occasionally adhered to established guidelines for vaccination (35). To improve immunization data quality, the practice for vaccinators needs to be improved. Another study which was done in Tanzania identified several challenges in data management at health facilities. Among those was frequent transfer of trained staff to other departments and stock out of registers. However, the challenges were common in health facilities with weak leadership (36). Other findings revealed that responsibility and dedication were associated with poor HMIS (37).

2.2.2 Data collection tools, recording and reporting practices

Loss of data quality can occur at any stage in the data management process; collection, during data entry, recording, storing and archiving, analysis and at the time of presentation. A study in Tanzania revealed that, for every step in data handling there is a double to four times margin of fault (38). In Uganda, a qualitative and quantitative study identified the factors affecting immunization data quality which were arithmetic errors, uniqueness, omission of tally sheet data from HMIS reports, missing tally sheets and poor arrangement of tally sheets among other factors (28). Another study verified the quality and consistency of immunization data in 27 countries including Tanzania and discovered that 40% of health facilities in these countries had over reported DTP-3 doses. Over reporting was more attributed to

information inconsistencies in 22% of health facilities and absent information in 14% (39). The district verification factor correlated with the health facility Quality Index (QI) suggesting that the quality of reporting system at each level is a good determinant of consistency. It was also noted that the reporting forms in most countries were in accordance to the WHO recommendations as they separated infants from children above one year except for one country. However, promising results were reported in Uruguay where upon evaluation of the validity of the vaccination data used to estimate national immunization coverage, numerator accuracy was 100% and national denominators were comprehensive (40). There was excellent storage of data, adequate reporting tools and timely flow of information.

Tallying before administering a vaccine is undesirable practice. The latest EPI review conducted in Tanzania revealed that availability of EPI recording tools was more than 90% in 82% of the health facilities visited. However, less than a third of records were done immediately after vaccination (proper practice). Recording in various data collection tools was done during registering or screening prior to vaccination in more than 70% of the health facilities (15). This practice is prone to data quality errors as children may be recorded to have been vaccinated while in practice they remained unvaccinated. Another study identified training needs in areas of record keeping, reporting, data quality issues, analysis and use of data for action as reported by 81% and 100% of vaccinators in Kenya and Ghana respectively (41).

A study which was done in China assessed the coverage reporting practice in immunizing health facilities and observed that imprecision problem was common due to over reporting rather than underreporting. The study found that 60% of the health facilities had consistent data and the verification factor ranged from 0.94 to 1.04. Likewise, the study found no correlation between the verification factor for DTP 3 and the reporting coverage but there was correlation between the quality of the reporting system and data consistency at the health facility. The study predicted two possible reasons for over reporting: First, the national EPI reviews focused on immunization coverage targets and the need for health facilities to meet targets set by the national EPI but not on the quality of data. Second, frequent transfer of vaccinators, lack of mechanisms for cross checking data, lack of training and

feedback from higher levels were aggravating the situation (42). Similar findings were found in Nepal where upon comparison of immunization data in District Health Office (DHO) and data from immunization registers, figures were higher in DHO reports by 31% for BCG, 44% for DTP, 155% for oral polio vaccine and 71% for measles (43). The study urged that allocation of unrealistic target population by the MOH could be one of the reasons for inflation of data at district level.

2.2.3 Training, knowledge and supportive supervision

To be able to perform their mandated duties effectively, health workers needs to have adequate knowledge. Training of staff and follow up supportive supervision motivates health staff if done effectively. However, strategies undertaken to improve knowledge and skills in resource constrained settings have not been successful in improving the practices of health workers (44). It is suggested that, interventions that target behavior change could have good results in changing attitudes and practices of health care workers towards achieving program impact. However, interventions to improve data quality and desired practices for health workers have yielded heterogeneous results and recommendations in various settings (45). Training of vaccinators has been reported to improve knowledge of health care providers on immunization and cold chain management in Thailand (46). Although in Egypt the study which assessed knowledge and practices on vaccine storage, administration, route and correct dose among other things found no correlation between training and improvements in knowledge and practices. The study found that overall knowledge on BCG dose was sufficient (97.1%) and the practice level of the areas observed was high mainly due to continuous supportive supervision (47).

Another study assessed quality of information collected through Health Management Information System (HMIS) in Kinondoni-Tanzania and possible related factors and found an association between knowledge on basic HMIS concept and improved quality of data. Likewise the study found that training in HMIS and supportive supervision had no influence on the data quality (36). These findings resemble slightly with those in Nigeria where a fair correlation was observed between knowledge and Quality System (48). The study in Nigeria suggested that lack of knowledge, skills and feedback to lower level staff contributes to poor data quality.

Weaknesses in the monitoring of immunization system were also observed in an audit which involved 27 African countries and revealed that lack of performance monitoring charts, inadequate monitoring of stock of vaccines and supplies and inadequate checking for completeness and timeliness of reporting is common (40).

In Ghana, a cross sectional cluster survey study compared immunization dropout rate (BCG –MR) and immunization coverage among children 12-23 months between administrative and survey data. The study observed higher dropout rate and more than 100% coverage for administrative data compared to survey findings and urged that the discrepancies imply unqualified health staff who handle vaccination data, inadequate supportive supervision and monitoring and low data use in planning and decision making at health facilities (49). The study further observed discrepancies and problems of cohesion for data reported within the same organization (49). A similar study in Nigeria assessed immunization coverage data and observed discrepancies for DTP-3 and Measles Rubella (MR) vaccine. District and facility coverage were found to higher than 100% as compared to community coverage of 70% maximum. The study concluded that lack of attention on the data quality, inadequate knowledge of the effect of poor data quality and high workload of vaccinators were the factors contributing to huge data discrepancies (50). However in Nigeria, the use of District Health Information System (DHIS) version 2 routine immunization dashboard led to improvements in data use for decision making (51).

2.2.4 Pressure to reach targets and performance based initiatives

Pressure to reach targets and initiatives set at international level or local level have been reported to encourage data cooking and over reporting. Universal Childhood Immunization (UCI) and GAVI Immunization Services Support (ISS) initiatives have been reported to contribute to over reporting of the number of children immunized with DTP 3 in some countries (52). In Mozambique it was found that district directors were pressurized to reach higher targets and occasionally motivated to observe trends. This lead to lack of data ownership and lack of attention on data quality (53).

2.3 Summary of literature review

Literature is rich in studies that have compared immunization coverage obtained from official reports and coverage obtained through EPI Cluster Surveys and Demographic Health Surveys. The picture that emerges is clear, coverage reported through official or administrative sources is often inflated either intentionally or unintentionally due to errors occurring in the whole process of data handling (collection, recording, storage, reporting etc.). Studies have also assessed the quality of the reported immunization data by use of data validation tools developed by the WHO like the DQA (2003) and DQS (2005). Inconsistencies in the reported immunization data were common and the overall practice was that of over-reporting than under-reporting. Findings in African countries were also similar to those in other countries.To the best of my knowledge, through literature review, there is no independent study which has been done in Tanzania to estimate BCG immunization coverage and assess the level of knowledge of vaccinators though some grey literature exists.

2.4 Conceptual framework

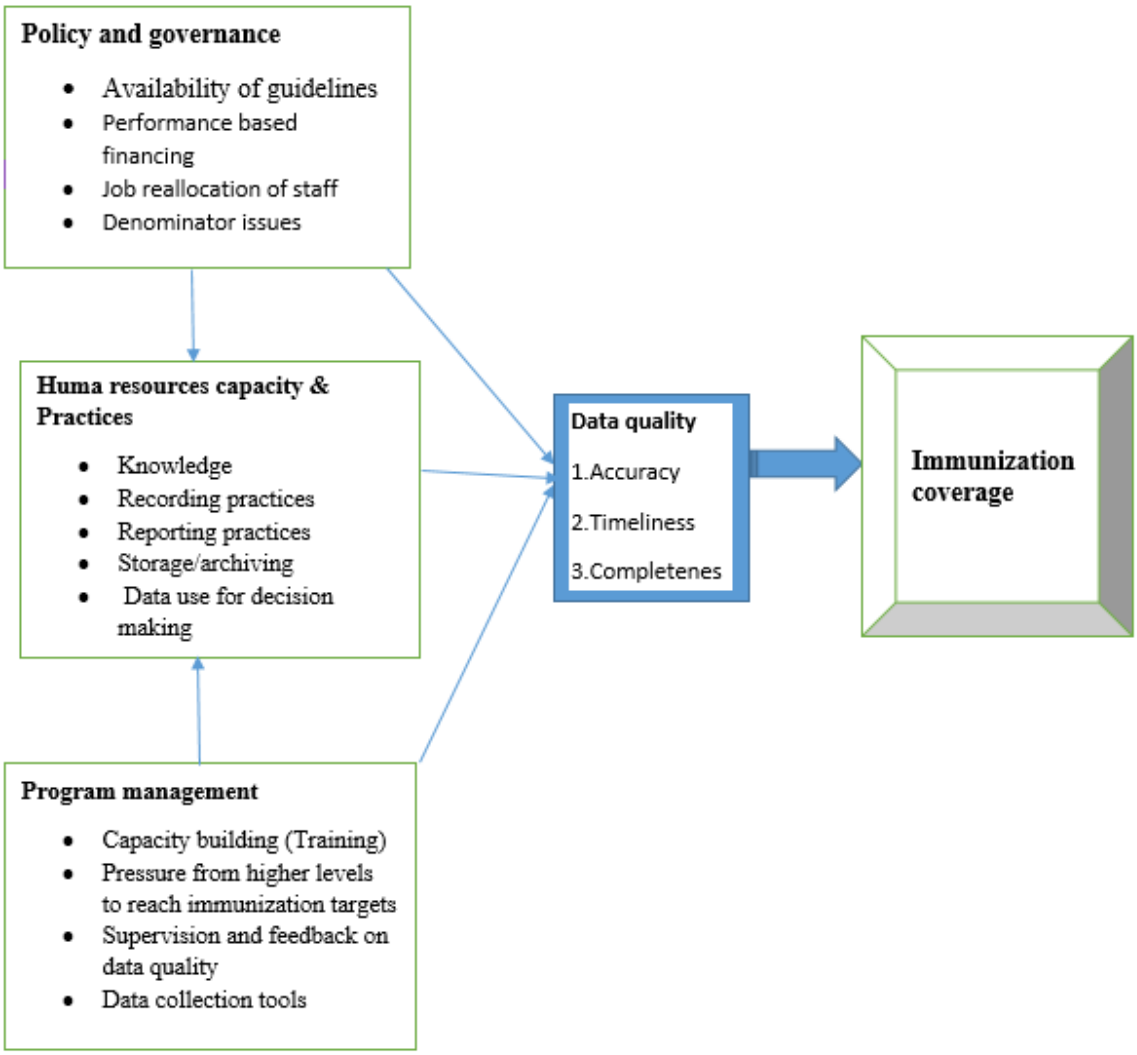

Figure 1: Conceptual framework of the factors contributing to poor immunization data quality

2.4.1 Description of the conceptual framework

In this study there were three variables; independent, intermediate and a dependent variable. The independent variables were categorized broadly into policy and governance, human resource capacity and practices and program management. The intermediate variable was data quality while immunization coverage was a dependent variable. The conceptual framework portrays that immunization coverage reported at the district level depends on the quality of data generated at health facilities.

However, the quality of the reported immunization data depends on knowledge and practices of vaccinators on the data collection and reporting. This is supported by a study which suggested that knowledge on how of the data processes is important in improving data quality but the know-why is the most important mode of knowledge since knowing the principles and reasons for collecting data puts someone in a stage to query poor data quality and suggest solutions (54). Poor recording, reporting, archiving and lack of data use for action also contribute to poor data quality.

On the other side program management issues may influence human resource capacity and practices either positively or negatively. Capacity building of vaccinators through trainings may improve their knowledge on the subject matter. Pressure from higher levels to achieve targets may result in biased reports due to over reporting. Over reporting of the numerator is likely to result in more than 100% coverage. Regular supportive supervision and feedback on data quality is likely to improve data quality and vaccinators' knowledge on proper data management among other things.

Policies and governance issues if not supportive, may influence knowledge and practices of vaccinators, thus compromising data quality. In some health facilities, staffs are transferred regularly from one section to another and this make those knowledgeable or trained on immunization data management to be misplaced. Under those circumstances the quality of reports produced may be unreliable. Performance Based Financing (PBF) have been reported to be associated with an increase in the volume of service provided but compromising quality (55).

In this study we estimated BCG immunization coverage, assessed knowledge of vaccinators in various aspects related to policy, coverage estimation and recording practices. Data quality was also assessed for its dimensions of accuracy, timeliness and completeness of reports. The rest of the variables were not investigated under this study.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study area

The study was conducted in Wanging'ombe district which is one of the six districts constituting Njombe Region. The reason for selecting the district was because it has the largest number of the target population for immunization.The district council covers land area of 3,570 Km^2 and it is the largest district in the Region. The council has a total of 49 health facilities of which 1 is a district designated hospital, 4 health centres and 44 dispensaries. Among the available health facilities, only 4 dispensaries were not providing immunization services in the year 2018.The district has a critical shortage of health staff for all cadres and the deficit stands at around 48.9%. With the exception of medical attendants, the district is dominated by trained nurses and mid wives [Wanging'ombe District Socio-Economic Profile, 2016 (unpublished data)]. There are 108 villages of which 59 have no dispensaries. Children in these villages are reached through outreach services planned at the health facility level. According to the District Vaccination Data Management Tool (DVD-MT), the district had expected live birth of 5588 children in 2018 which was a target for BCG vaccine.

3.2 Study design

The study was a cross-sectional descriptive and facility-based study mainly involving review of vaccination records for the calendar year 2018 and interviewing vaccinators in Wanging'ombe district. The study design was chosen because it can be done given the experience of the researcher and little resources (time, funds) available. Descriptive studies are used to explain a situation, behavior or phenomenon. They can help answer the questions who, what, when, where, and how. This design would also help to prove some assumptions behind more than 100% coverage estimates which the researcher was also curious to know. Time factor was also a major issue for choosing the study design since cross sectional studies are less time consuming.

3.3 Study units

Study units were the records associated with BCG vaccination for the most recent calendar year (January-December 2018). Data retrieved included live births, doses administered by age and number of doses administered to children less than one year reported at district level. The registers from which the data were retrieved included labor and delivery register, health facility monthly summary report, HMIS and Immunization & Vaccine Development (IVD) programme tally sheets.

3.4 Study population

The study population involved vaccinators who work in Reproductive and Child Health (RCH) Department. These were interviewed to assess their general knowledge on BCG immunization facts.

3.4.1 Inclusion criteria

Vaccinators with at least 18 months of working experience in vaccination services were involved in the study.

3.5 Sample size calculation

First, a total of 23 health facilities were selected by the following steps; the district has one District Designated Hospital (DDH) and this was included. There were four (4) homogeneous health centers and 2 were selected randomly, also there were 40 dispensaries where 20 were randomly selected. Secondly, vaccination and vaccination related records for the calendar year (2018) were extracted from the registers. Vaccinators were not selected; instead those available in the selected health facilities at the time of data collection were interviewed. Vaccinators with at least 18 months (1 year and 6 months) of working experience were interviewed.

3.6 Sampling techniques

We used a table of random numbers to select 2 health centers out of 4 that were eligible. First, all eligible health centers were listed on a piece of paper and this was used as a sampling frame. The same was done for dispensaries; where 40 dispensaries were listed. Then, without looking at the table the researcher pin pointed any number on the table which was used as a starting point. The researcher determined beforehand the direction to go across the table; right, left, down or up. For health centers, two single digit numbers ranging from 1 to 4 were picked from the random number table. Likewise the researcher picked 23 numbers which were less or equal to 40. If it happened that a number in the chosen direction across the table was above 4 for health centers or above 40 for dispensaries, that one was skipped. Then all health facilities constituting the numbers picked from the random number table constituted the study sample for health centers and dispensaries.

3.7 Key variables and measurements

3.7.1 Estimating BCG immunization coverage

Immunization coverage for the health facility was estimated by dividing the numerator (recounted value) extracted from the health facility IVD or HMIS tally sheet for the calendar year by the denominator (number of live birth) for the same period times 100%. The numerator was the number of doses administered to children less than one year of age from within the service area plus those from outside the service area. Doses administered to children above one year were excluded in the numerator. Health facilities with missing tally sheets or missing tally sheet data for some of the months were also excluded in coverage estimation because we targeted the information for the calendar year. The denominator was a total of live births recorded in labor and delivery register for the calendar year.

3.7.2 Accuracy of the reported immunization data

Accuracy of the reported immunization data was measured by computing the Accuracy Ratio (AR) or Verification Factor (VF) which is an indicator of the accuracy of reported data. The AR was obtained by dividing the total number of doses administered to children below 1 year of age recorded in a tally sheet (recounted value) with the reported number of doses administered from the monthly summary form times 100%. This is in line with the proposed WHO Data Quality Self-assessment tool (DQS) (56). The AR depicts discrepancy ratio per health facility between the reported data and the verified data from tally sheet.

$$\mathrm{AR} = \frac{Number\ of\ recounted\ doses(0-11) in\ tally\ sheet}{Number\ of\ doses\ reported\ in\ a\ monthly\ summary\ form} \times 100\%$$

In this study, the AR was classified into three categories, AR of less than 100% implied over reporting (vaccinators were reporting a higher number of doses administered to children below one year of age than what was actually recorded in the tally sheet). AR of more than 100% implied under reporting (vaccinators were reporting a lower number of doses administered to children below one year of age than what was actually recorded in the tally sheet and 100% AR implied that the reported value was exactly the same as recorded in the tally sheet (accurate).

3.7.3 Knowledge of vaccinators on BCG immunization facts

The researcher used the interviewer administered questionnaire to assess knowledge of vaccinators on four aspects; the reasons for collecting data, policy issues, knowledge on health facility coverage estimation and recording practices. A total of seven (7) questions were asked and finally a percentage was computed to get the overall score per person for each aspect of knowledge tested. A score of more than 80% was termed as adequate knowledge, 50%- 80% = moderate knowledge and 0%-49% = inadequate knowledge.

I. Knowledge on the reason for data collection

Vaccinators were asked one open ended question; “why do you think you should collect immunization data?” Responses to this question were categorised and coded during analysis to determine the proportion for each response.

II. Knowledge on coverage estimation

One question was asked in this section; “How do you estimate BCG coverage to know performance of your facility?” those who responded, “children less than one year vaccinated within service area divide by the target population times 100%” were knowledgeable and otherwise response was incorrect.

III. Knowledge on vaccination policy

Three questions were asked to assess knowledge on eligibility for BCG vaccine for children above one year, appropriate syringe to use for this age group and revaccination of children who did not develop scar after receiving the first dose. The first question in this category was; “Suppose you met a child who is above one year at the vaccination session, would you vaccinate a child?” those who gave a yes response to this question were regarded to be knowledgeable

The second question was for those who responded yes to the first question and they were asked; “What volume of syringe do you think is appropriate for vaccinating a child who is above 1 year?” Those who would respond that it is a 0.1 mils syringe would be regarded as being knowledgeable.

The third question in the policy section was; “do you think a child who did not develop a scar three months after vaccination should be revaccinated?” a yes response to this question implied a vaccinator was knowledgeable.

IV. Knowledge on recording practices

Recording practices were measured by asking two questions on the practices that may increase or decrease the numerator value. The first question was; "what come first between vaccinations and tallying". If the answer was "vaccination precedes tallying", then it was regarded as a good practice and the vaccinator was knowledgeable and otherwise response was scored 0 to signify inappropriate practice and lack of knowledge.

The second question was for those who responded yes to the third question on vaccination policy. These were asked a question; "Where do you think it is appropriate to tally/record a child who was revaccinated?", if the answer was "recording in the child's card or "improvising and recording in a separate space in a tally sheet" this was regarded as a correct response and otherwise response was incorrect.

3.7.4 Timeliness of submission of health facility report to district

This was measured by observing the date of submission of the report to the district level. A report which was submitted to district level not later than 7^{th} of the next month was regarded as being timely submitted and the one submitted after 7^{th} day of the next month was regarded as being late. Reports without a written date of submission were regarded as being late.

$$\text{Timeliness (\%)} = \frac{Number\ of\ monthly\ reports\ submitted\ to\ district\ before\ 7th\ of\ the\ next\ month}{Expected\ monthly\ reports\ per\ year\ (12)} \times 100\%$$

3.7.5 Completeness of the health facility report

This was measured by computing percentage completeness. First, all the fields that vaccinators were supposed to fill in a health facility monthly summary report were counted to get the denominator value. Again, the number of fields filled was counted to

obtain the numerator value. Then, percentage completeness was computed by dividing the numerator value to the denominator value times 100. The number of fields that were to be filled by a person receiving a report at district level (eg. name of a person receiving a report at district level) was excluded from the denominator.

$$\text{Completeness (\%)} = \frac{Number\ of\ fields\ filled\ in\ a\ monthly\ summary\ report\ form}{Total\ number\ of\ fields\ supposed\ to\ be\ filled} \times 100\%$$

3.8 Data collection techniques

Quantitative data collection approach was applied; where by abstraction forms designed by the researcher were used to extract data from registers. Interviewing the vaccinators to solicit demographic data and assess their knowledge was another technique used to gather data. The questionnaire consisted of one open ended and closed questions. Data collection process in the field took about 10 working days.

3.8.1 Recruitment and orientation of research assistants

The researcher recruited two research assistants from other councils in the region to assist in data collection. These were the health staff with familiarity on the data collection tools used at health facilities. A one day orientation session was organized to orient them on the data collection tools. Research assistants assisted in extracting data from the registers while the principal investigator interviewed the vaccinators.

3.8.2 Data collection tools

An interviewer administered questionnaire translated in Kiswahili language was used to collect demographic information and assess knowledge of vaccinators who were available in the selected health facilities. Abstraction form was used to retrieve the numerical data from the tally sheets and registers (Appendix 1 and 2)

3.8.3 Pretesting of the data collection tools

Data collection tools were pre-tested at Kibena Regional Referral Hospital, one of the immunizing facilities in the neighbouring Council. The identified ambiguities and contradictions in the data collection tools were used to inform content modification, rewording and cohesion in the flow of the questions before the actual field data collection.

3.9 Data management and analysis

The principal investigator aggregated all questionnaires and abstraction forms every day from the research assistants and verified for completeness and clarity. Data was analysed by using computer software SPSS (IBM SPSS Statistics, 20). Microsoft excel was used specifically for drawing tables. Descriptive statistics were used to summarise quantitative data while continuous variables were described by using mean, standard deviation and range. The validity of the data collected was assured by double entry and data cleaning to reduce errors.

3.10 Ethical considerations

Ethical approval was obtained from Muhimbili University of Health and Allied Sciences Research and Publication Ethical Committee. Permission to conduct a study was sought from the Regional Administrative Secretary (RAS) in Njombe and from the District Executive Director (DED) and health facility in-charge. Informed consent (verbal/written) was obtained from vaccinators. Participation in the study was absolutely voluntary with no invasive procedures. Participants were told to be free to drop at any time if they so wish. The information gathered was treated with due confidentiality and respect. The questionnaires used to collect information from vaccinators were assigned numbers instead of names of vaccinators to ensure anonymity. The study objectives, methodology and benefits of the research findings were explained to those who agreed to participate. Participants were assured that there was no risk to participate in the study

as the undertaking has been approved by the local authorities. However, they were informed in advance that there were no payments for participation in the study as the research was done for academic purpose.

CHAPTER FOUR

4.0 RESULTS

In this chapter we present research findings in the order of specific objectives. It includes characteristics of the vaccinators, health facilities and key findings related to the study. In this study, a total of 23 health facilities were involved and this constituted approximately 50% of the total immunizing health facilities in the district. Of the 23 health facilities, 21 health facilities were public and two were private; owned by Faith Based Organizations (FBOs). We interviewed 46 vaccinators who were available on site at the time of data collection.

4.1 Characteristics of the interviewed vaccinators

Age

Among 46 vaccinators interviewed in all health facilities, the majority, 43 (93.3%), were females. Half of them were registered nurses, 19 (41.3%) were medical attendants and six were clinical officers, assistant clinical officers and assistant health officer. Their mean age was 35 (SD = 9.2) years, ranging between 23 and 59 years.

Working experience

The median duration of working experience was 48 months (range 222) months. The majority, 19/46, of vaccinators had a similar work experience of at least 72 months. In table 1, we present distribution of vaccinators by their working experience.

Exposure to on-job orientation or off site training

In table 2, we present the distribution of vaccinators by the most recent on-job orientation or off site training. Forty-five (45) vaccinators reported to have received on job orientation or off site training. Only one had never been exposed to any orientation or training. The majority of vaccinators 24 (52.2%), reported to have received on-job orientation or off site training related to immunization within the most recent four months.

Table 1: Working experience (in months) of the 46 vaccinators

Experience (months)	Number (%)
Less than 24	4 (8.7)
24 - 35	10 (21.7)
36 - 47	5 (1.9)
48 - 59	5 (1.9)
60 - 71	8 (17.4)
Above 71	14 (30.4)

Table 2: Time period since last training or most recent on job orientation of vaccinators (n=45)

Duration (months) since last orientation or training	Number (%) of vaccinators
Less than 4	24 (53.3)
4-6	8 (17.7)
7-9	1 (2.2)
9-12	0 (0.0)
More than 12	12 (26.7)

4.2 Knowledge assessment

There were seven questions that were asked to assess knowledge of vaccinators on various aspects. Table 3 summarises the responses for each assessment aspect.

Overall knowledge score on why immunization data are collected was 100% as all vaccinators provided good reasons. Likewise, 26 (56.5%) vaccinators were knowledgeable on how to calculate health facility coverage for BCG. Responses on the vaccination policy related questions showed that 37 (80.4%) of vaccinators were knowledgeable that children above one year are eligible for BCG vaccination. However, none of them knew the appropriate syringe to use for vaccinating that age group. All of them (100%) were knowledgeable that children who did not develop scar at least three months after the first dose should be revaccinated. Majority 36 (78.3%) of vaccinators said that the best practice was to record or tally before vaccinating a child. Majority said they record revaccinations in a child's card 26 (56.5%) but, they were not conversant on where specifically to record in a tally sheet.

Table 3: Knowledge of vaccinators (n = 46)

Assessment aspect	Number (%)
Reasons for collecting immunization data	
Vaccine forecasting	7 (15.2)
Understand coverage and follow-up for schedule completion	23 (50.0)
Planning and budgeting	2 (4.3)
Enable analysis for Vaccine Preventable Disease outbreak	11 (23.9)
Evaluate ourselves	3 (6.5)
Health facility coverage estimation	
Knowledgeable	26 (56.5)
Not knowledgeable	20 (43.5)
Vaccinating children above one year	
Acceptable	37 (80.4)
Not acceptable	9 (19.6)
Size of syringe to vaccinate children aged above one year (ml)	
1	1 (2.7)
0.5	8 (21.6)
0.05	20 (54.1)
0.005	2 (5.4)
Don’t know	6 (16.2)
Revaccination after three months required	
Yes, required	46 (100.0)
Recording practice	
Tallying then vaccination	36 (78.3)
Vaccination then tallying	10 (21.7)
How revaccinations are recorded	
Children within service area	7 (15.2)
Improvised in a tally sheet	3 (6.5)
Children out of service area	3 (6.5)
Vaccination card	26 (56.5)
Others (not recording, use of other tools)	7 (15.2)

Overall knowledge of vaccinators on BCG immunization

The overall knowledge of vaccinators was then computed by taking a number of questions answered correctly out of total. The majority, 33 (71.7%) had moderate knowledge (scored between 50-79 points), 5 (10.9%) had adequate knowledge (scored at least 80 points) and 8 (17.4%) had inadequate knowledge (scored below 50 points).

4.3 Timeliness for submission of health facility reports

Fifteen (15) health facilities had reports for the calendar year and these were assessed for timeliness. Percentage timeliness was 100 for 12 health facilities and 91 for 3 health facilities. Overall, all the reports were timely submitted (timeliness 90% and above).

4.4 Completeness of health facility reports

Fifteen health facilities which were assessed for timeliness were also assessed for report completeness. The ratio of number of fields a vaccinator supposed to fill out of total times 100 gave percentage completeness. Out of 15 health facilities assessed, completeness was more than 90% for all health facilities. A few numbers of fields that were not filled in most health facilities were dropout rate, Adverse Events Following Immunization (AEFI), surveillance data, and information on community activities on immunization.

4.5 Estimation of BCG coverage

Table 4: Estimated BCG coverage by health facility in Wanging'ombe District, 2018

Health facilities	A	B	C	D	E	F	G
Health facility 1	1821	1244	0	5	0	1249	146
Health facility 2	531	279	18	7	0	304	175
Health facility 3	74	26	0	0	1	27	274
Health facility 4	88	19	0	0	0	19	463
Health facility 5	125	57	0	3	0	60	208
Health facility 6	102	7	1	3	0	11	927
Health facility 7	275	107	0	1	0	108	255
Health facility 8	133	74	0	0	0	74	180
Health facility 9	100	40	0	0	0	40	250
Health facility 10	34	21	1	0	0	22	155
Health facility 11	125	70	0	0	0	70	179
Health facility 12	66	39	2	0	0	41	161
Health facility 13	76	33	0	0	0	33	230
Health facility 14	41	21	0	0	0	21	195
Health facility 15	25	6	0	0	0	6	417
Health facility 16	166	37	0	0	0	37	449
Health facility 17	75	37	0	2	0	39	192
Health facility 18	54	49	0	0	1	50	108
TOTAL	**3911**	**2166**	**22**	**21**	**2**	**2211**	**177**

A: Number of recounted doses administered to children less than one year
B: Number of live births delivered at health facility
C: Number of live births delivered at home
D: Born Before Arrival (BBA)
E: Born from Traditional Birth Attendants (TBAs)
F: Total live births per year
G: Estimated Coverage

We were able to verify the number of doses administered for children aged below one year for 2018 in 18 health facilities. These were the only facilities with tally sheets. Five health facilities had either missing tally sheets or data for some of the months were not available; so we excluded them when estimating coverage. Nevertheless, all 23 health

facilities had the data for live births for the whole year. Table 4 shows the estimated coverage by health facility in 2018. The overall estimated coverage was 177%; ranging between 108% and 927%.

4.6 Accuracy of the reported BCG immunization data

Of the 23 health facilities, we were able to verify 15. These were the facilities with tally sheets and the corresponding monthly summary forms for the calendar year. The overall accuracy ratio was 93% with a discrepancy of 7%. Seven health facilities had accuracy ratio of 100% with no discrepancy while five health facilities had an estimated accuracy ratio below 100% and three health facilities had accuracy ratio of above 100%. The accuracy ratio ranged between 88% and 109% (Table 5).

Table 5: Accuracy of the reported BCG immunization data

Health facilities	C1	C2	C3	C4	C5	C6	C7	C8
Health facility 1	787	102	1034	0	2067	1821	88	12
Health facility 2	74	0	0	0	74	74	100	0
Health facility 3	42	0	46	0	88	88	100	0
Health facility 4	111	0	25	0	125	136	109	-9
Health facility 5	102	5	0	0	97	102	105	-5
Health facility 6	241	3	31	1	276	272	99	1
Health facility 7	73	1	0	0	73	73	100	0
Health facility 8	95	0	38	0	133	133	100	0
Health facility 9	60	1	40	10	111	100	90	10
Health facility 10	95	0	30	0	125	125	100	0
Health facility 11	65	0	1	0	65	66	102	-2
Health facility 12	58	0	18	0	76	76	100	0
Health facility 13	41	0	0	0	41	41	100	0
Health facility 14	116	2	50	4	168	166	99	1
Health facility 15	25	0	0	0	26	25	96	4
TOTAL	**1985**	**114**	**1313**	**15**	**3545**	**3298**	**93**	**7**

C1: BCG doses administered < 1 year within services area

C2: BCG doses administered > 1 year within services area

C3: BCG doses administered < 1 year outside services area

C4: BCG doses administered >1 year outside services area

C5: Doses administered reported in monthly report

C6: Recounted number of doses (numerator)

C7: Accuracy ratio (%)

C8: Discrepancy (%)

CHAPTER FIVE

5.0 DISCUSSION

The primary importance of data is in its quality and reliability for decision making. The quality of data produced at health facilities is affected by a multitude of factors. This implies that, efforts to improve data quality have to address the multiple issues that affect quality. This ranges from program management, human resource capacity and practices and policy related issues. Our study is exceptionally important as it estimated both the coverage and assessed the quality of the reported data. More important, we also assessed the characteristics of the personnel who vaccinate and handle immunization data. There are so many assumptions behind more than 100% coverage attained for BCG vaccine and this study provides some insights. In this chapter we discuss major and unexpected findings and the likely implications.

5.1 Estimated coverage by health facility

The overall estimated coverage observed in this study was unexpectedly high and was above 100% in all health facilities. This implies that the number of children vaccinated for BCG in all health facilities was higher than the actual number of births registered in these facilities. However, this is not a concern at peripheral health facilities since it is normal for people to cross geographical borders to get services from accessible health facilities. The overall coverage of 177% observed in this study brings more argument on the accuracy of the denominator which is live births. Ideally, births are registered and categorized by place of occurrence in all health facilities and this is done regardless of whether a mother who delivered came from outside a service area or from a distant district.

Our argument on the accuracy of the denominator disagrees with the findings in Uruguay where upon validation of the immunization data used to estimate national coverage, denominator accuracy was estimated at 100%. This could be because Uruguay had a good birth registration system at health centers; a well-coordinated information system which allowed tracking of the number of children vaccinated for BCG by place of birth and coverage was also estimated by use of cohort based

denominators. More important BCG was one of the precondition for discharge at health facilities (40).The estimated coverage found in this study also differs from that of a similar study which was done in Maringue district in Mozambique (29). In Mozambique the estimated coverage was 86.3% which was lower by 22.3% when compared with the official data reported in 2011. The reason for the difference might be the same as described earlier; availability of a strong registration system at health units

Literature supports that survey data are more reliable than routinely collected data. According to the Tanzania Demographic and Health Survey and Malaria Indicator Survey (TDHS-MIS) of 2015/16 the percentage of live births in 5 years prior the survey that was delivered in health facility was 63% in Tanzania mainland and 87% in Njombe region (57). Unfortunately, the survey did not go beyond the regional level so we cannot ascertain the percentage specifically for Wanging'ombe district. However, the District Health Information System (DHIS) version 2 data for 2018 shows that the proportion of women who delivered at health facility in a district was 97.3%. Since DHIS 2 data originate from health facilities we can assume that approximately 97.3 % of children vaccinated for BCG could be recorded at health facilities if the system was perfect. Using 97.3% of the number vaccinated as the proxy denominator, the estimated coverage would be 103%. Likewise, the number of births occurring at the community might have been under reported due to weak community linkage and inadequate incentives for Community Health Workers (CHWs) and Traditional Birth Attendants (TBAs).

Earlier, before the National EPI review of 2015, the study by Nyamtema AS that was done in Kilombero district in Tanzania explored the weaknesses in the implementation of HMIS (59). The study revealed that among the tools used for collecting data at health facilities, the most common that was occasionally filled were those for delivery, where 55% of the health facilities did not record (58). The gaps in filling HMIS tools for delivery observed in Kilombero agrees with the National EPI review report of 2015 (unpublished data) which emphasized that the number of BCG doses administered in the country was the highest than the number of registered

births at health facilities especially in the year 2014 (15). Apparently, we argue that most of the births occurring in health facilities are not registered. Under registration of live births might be common in hospitals where large numbers of children are born per day and there is critical shortage of staff. We suggest that, although the WHO proposes that births categorized by place of occurrence could be the best target for BCG vaccine (17), the reliability of such an estimate would be as good as the strength of the established system for capturing every single birth occurring. Establishment and strengthening of CRVS system could be a long term solution for improving health and providing realistic targets to monitor local and country wide development programmes (59).

In the past years, UCI and GAVI Immunization Services Support (ISS) initiatives have been reported to contribute to over reporting of the number of children less than a year immunized with DTP3 in some countries. We presuppose that such initiatives would have little incentive to over report the number immunized with BCG since the vaccine is not used as a criteria for funding.

5.2 Accuracy of the reported BCG immunization data

The overall accuracy of the reported BCG immunization data was found to be 93% meaning that health facilities are over reporting. Over reporting was observed in both higher and lower level health facilities. This finding is different from the study reported in Uganda where lower level health facilities were contributing more to over reporting (28). In some settings tallying was not smart as the number of tallies in the tally sheet were not adequate enough compared to the number of children supposed to be tallied. As a result, vaccinators were forced to tally children vaccinated less than one year of age outside the tally sheet margins, frequently skipping to the next pages or tallying in inappropriate age category. This would have contributed to inaccuracies in counting the marked tallies at the end of the month. In support of this, we observed that in august, 102 children were tallied in the category of children vaccinated above one year of age in one of the facility, but during data verification

the vaccinators themselves claimed that it was wrongly recorded as those were children less than one year.

In this study, the accuracy ratio (AR) of the 15 health facilities ranged between 88% and 109%. This is to some extent similar to the assessment results in East-China which involved all 20 vaccinating clinics and assessed 20 vaccine doses except BCG in Shangyu district. The accuracy ratio for the district in China was 98% and that of vaccinating clinics varied extensively from 57% to 107%, with 60% of the clinics having accurate data (42). A similar study verified reporting accuracy in 27 African countries including Tanzania. The study used the same decision rule as that used in China and found out that of the 557 health units assessed, 53% had accurate data(39). The lower proportion (46%) of health facilities with accurate data observed in our study might be due to a small sample size and stringent decision rule that was applied to regard data as accurate (AR=100%) as compared to China and African countries (AR $\geq$85% and $\leq$ 115%).

When we were recounting the doses administered in the tally sheets, we were surprised that two dispensaries were using the tally sheet for the previous year (2017) to tally data for 2018 by over writing with a marker of different colour. This could also have contributed to inaccuracy as a result of omission or addition of tally sheet data when counting the doses at the end of the month. Errors occurring in the data source stress the importance of extending the scope of supportive supervision and data quality check. There is a need not only to look for a justification between the number of children vaccinated and doses used to signify an accurate data as this is impractical for multi-dose vials like BCG; but it makes more logic to verify both a report and a data source(tally) at the time of report submission and during supportive supervision. A study in Mozambique, observed poor data quality despite the fact that health facilities were supervised quarterly (60). The study pointed out that lack of comprehensive data quality check during supportive supervision and feedback on data quality contributed to persistence of the problem poor data quality.

In our study we also calculated a discrepancy rate. Negative discrepancy implies the extent to which the data was under reported and a positive rate implies the extent to which the data is over reported. However, most health facilities had a discrepancy of less than 10% that could be considered acceptable. A study in Ghana, suggested that a discrepancy of more than 10% disqualifies a data for decision making (61). Likewise for children who do not complete subsequent immunization doses, the WHO recommends a cut-off point of less than 10% dropout rate. Based on that, we are on the opinion that 14 out of 15 health facilities assessed for accuracy had the data that could be relied for decision making. Unlike our study, a study in Ghana also assessed data storage and retrieval status at immunizing health facilities. Data storage and retrieval was a challenge in some facilities, and this does not differ with what we found in this study, we targeted 23 health facilities but few were assessed for each objective due to poor archiving and retrieval system.

5.3 Capacity building and knowledge of vaccinators

All vaccinators except one reported to have been exposed to on job orientation or off site training in the most recent three months. This reflects that capacity building as one of the interventions in programme management component is good. This might also be attributed to the efforts done by one of the partner "Clinton Health Access Initiative (CHAI) who facilitated participatory data verification among vaccinators (one from each facility) in the region for past three years (2017, 2018 and 2019). Likewise, the IVD program had recently introduced the electronic based data collection system [Tanzania Immunization Registry (TimR)] and trained one vaccinator from each health facility.

We found that the overall knowledge level of vaccinators on various aspects of BCG immunization was moderate. The number of questions in which the proportion of vaccinators who scored correct were few were about health facility coverage estimation, appropriate syringe for vaccinating children above one year of age and recording practices. However, vaccinators provided good reasons for collecting immunization data. The responses imply that they know that data is collected for

their own use and not for the purpose of sending to the higher level as observed in the previous HMIS study in Kilombero (58). However, the low knowledge on health facility coverage estimation suggests lack of data analysis and weak monitoring and evaluation practices at health facilities. This is also supported by a study that assessed the quality of immunization monitoring system in a number of African countries. Results indicated that, of the five components of the immunization monitoring system (monitoring and evaluation, recording, system design, denominators, reporting and archiving), monitoring and evaluation was the weakest at all levels and registers for the previous calendar year were available in only 60% of the health units (39). Another study that was conducted in Kenya and Ghana supports the weak monitoring system prevailing at health facilities as it revealed that more than half of the facilities reported to review immunization data monthly but majority did not display performance by use of updated charts (41). This poses another question on what is reviewed if after all data analysis is not done.

In Tanzania, children above one year of age are eligible for BCG vaccination up to the age of five years. However, the IVD program does not distribute syringe for vaccinating this age group which is of 0.1 mils. This might be a reason for all vaccinators failing to respond correctly. If we exclude the 102 children from Ilembula hospital that vaccinators insisted they were not above one year but rather mistakenly tallied in that age group, the number of children vaccinated above this age becomes 27 (column C2 + column C4). This number is very small but it implies that those children were under dosed since majority of vaccinators said they would use the 0.05 mils syringe which is currently used to vaccinate children less than one year. Since the WHO recommends that the appropriate dose for this age group is 0.1 mils; it is high time for the program to provide clear instructions on what to do with this age group once encountered. Studies report that immunity gained through BCG vaccination associate with reduced mortality in children (62). Based on this fact, immunity of these children should be a concern.

Pertaining to appropriate recording practices, majority of vaccinators responded that the appropriate procedure for recording in tally sheets was to collect the cards,

tallying and finally vaccinating a child. This practice makes work simple given a few numbers of staff available at health facilities. This observation concurs with the finding of the National EPI review in 2015 where vaccinators were physically observed to do most of the registration and recording before vaccinating a child (15). Inadequate implementation of the desired practices for data collection among other things have been said to contribute to poor data quality in Uganda (63).

Vaccinators were knowledgeable that a child who did not develop scar three months after the first dose should be revaccinated. Though, they added that they occasionally encounter such children in immunization sessions. With exception of a child card, majority were not conversant where revaccinations should be tallied in tally sheets. Lack of confidence on where to tally might be because current tools provide no room to record revaccinations except in a child card. Most important is to ensure the tools provide room for recording and reporting repeated administered doses without compromising data quality. This information is crucial to inform the technical challenges in administering the vaccine, vaccine potency and program management issues among other things.

5.4 Completeness and timeliness of reports

The health facility reports were more than 90% complete and timely throughout the year. This might be because apart from the general requirement that health facilities should submit reports to district level not more than 7th day of the coming month, the CHMTs in Wanging'ombe district has made it not more than 5th day. Despite the fact that timeliness and completeness of reports was good, accuracy was compromised in some of the health facilities. This may be partly because at the end of the month there are so many reports to be consolidated thus increased workload and pressure to reach the deadline impairs data quality. For this indicator our finding concur with those in Uruguay where upon validation of the higher coverage generated by official reports, completeness and timeliness of reports were perfect (40).

The findings in this study are subject to a couple of potential limitations. First; the sample size of the assessed health facilities was reduced from the original estimate

due to lack of data in some of the health facilities. Thus, may lack the power in our estimates. Second, the number of questions for knowledge assessment was only seven; hence, any incorrect response brought a wide gap in knowledge scores. So the percentages in knowledge scores should be interpreted with caution. Third, although there could be some similarities of our findings to other districts, the findings in this study are only limited to Wanging'ombe District and generalization to other districts in Tanzania may be misleading. Fourth, in interviewing the vaccinators to assess their levels of knowledge, the researcher could have been familiar to the vaccinators and in their working environment. Therefore, this could have introduced social desirability responses leading to information bias. Finally, in estimating coverage, lack of data made it impossible to exclude the number of doses administered to children who were revaccinated at least three months after the first dose due to lack of scar. This could have overestimated the coverage.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The estimated proportion of children vaccinated with BCG for the calendar year 2018 was exceptionally high; though the reported number of doses administered was accurate and can be relied for decision making. Vaccinators had moderate knowledge on various aspects of immunization with BCG. Timeliness and completeness of the health facility monthly reports was generally good.

6.2 Recommendations

1. The MoHCDGEC in collaboration with NBS, PORALG and other stakeholders should work on establishing countrywide CRVS system that could provide reliable data for monitoring country wide development programmes and become a sustainable solution for denominator issues as far as immunization targets are concerned.

2. The MoHCDGEC-IVD programme should translate policy statements into Standard Operating Procedures (SOPs) with clear instructions on appropriate recording and reporting practices as these are simple and easy to refer at service delivery point.

3. The MoHCDGEC-IVD programme should consider provision of modified tally sheets which have more tallying options in areas with large number of children to be vaccinated. This could reduce errors in recording as hospitals serve more children than lower level health facilities. Aligning the design of data collection tools with immunization policy requirements and regular updating of guidelines is mandatory to preserve data quality.

4. Locally planned training sessions should base on needs assessment in order to fill knowledge gaps

5. Vaccinators should be regularly reminded on 0 (zero) reporting since 0 is also a value.

6. There is scarce published literature in the country on operational research related to immunization. We recommend a house-to-house enumeration of live births for a particular year in Wanging'ombe district for comparison with the current practice. Also other studies should assess the challenges in birth registration at health facilities and the extent of scar formation in children vaccinated with BCG.

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APPENDICES

Appendix 1A: Immunization tally sheet and monthly summary form data

Name of health facility……Type of health facility……Owner……..

Month	BCG doses administered < 1 year within service area	BCG doses administered >1 year within service area	BCG doses administered < 1 year outside service area	BCG doses administered >1 year out of service area	Doses administered reported in Monthly report	Recounted number of doses (Estimated numerator)	Timely or Late report (T/L)	Completeness (number of fields filled/Total number of fields)
	A	**B**	**C**	**D**	**E**	**A+C**		
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
Total								

Appendix 1B: Live births at health facilities

Name of health facility……Type of health facility……Owner……

MONTH	LIVE BIRTHS				
	Health facility delivery	Home delivery	BBA	TBA	Total
	A	**B**	**C**	**D**	**A+B+C+D**
January					
February					
March					
April					
May					
June					
July					
August					
September					
October					
November					
December					
Total					

Appendix 2 A: Questionnaire for vaccinators (English Version)

Questionnaire ID. NO……...

Section one: Socio demographic characteristics

1. For how long have you worked at vaccination services section?.....Months[don't continue to other sections if duration is less than 18 months]
2. How old are you now? …….. (Years)
3. Staff qualification
    0. Enrolled nurse
    1. Medical Attendant
    2. Assistant Health Officer
    3. CO/ACO
    4. Any other (specify)……
4. Sex

    0. Male

    1. Female

5. Have you been oriented on site or ever attended any training off site related to immunization services? [skip the next question if the response is no]
    0. No
    1. Yes
6. When was your last on site orientation or off site training?
    1. Within the recent 3 months
    2. Within the last 4-6 months
    3. Within the last 7-9 months
    4. Within the last 9-12 months
    5. More than twelve months ago

Section two: Knowledge on general immunization facts

I. Knowledge on why data are collected

Why do you think you should collect vaccination data?

.....

II. Knowledge on vaccination policy and guidelines

Suppose you met a child who is above one year at the vaccination session, would you vaccinate a child?" (Skip the next question if the response isNo)

0. No
1. Yes

What volume of syringe do you think is appropriate for vaccinating a child above 1 year?" ……mills

Do you think a child who did not develop a scar three months after vaccination should be revaccinated? (If No skip question 13)

0. No
1. Yes

III. Knowledge on coverage estimation

How do you estimate BCG coverage to know performance of your facility?

0. Any other response
1. Children less than one year vaccinated within service area divide by the target population times 100%

IV. Knowledge on recording practices

What come first between vaccination and tallying?

0. Tallying then vaccination
1. Vaccination precedes tallying;

Where do you think it is appropriate to tally/record a child who was revaccinated?

1. Children below one year vaccinated within the service area

2. Improvise and record in a separate space in a tally sheet
3. Record in children vaccinated out of service area
4. Vaccination card
5. Others (specify)……

Appendix 2B: Dodoso la mchanjaji (Swahili version)

Namba ya utambulisho ya dodoso…….....

Sehemu ya kwanza: Utangulizi

1. Umefanya kazi kwa muda gani katika kitengo cha chanjo?------(Miezi) [Usiulize maswali yanayofuata kama muda ni chini ya miezi 18]
2. Umri wa mchanjaji …….. (miaka)
3. Cheo cha mchanjaji
    0 Muuguzi
    1 Mhudumu wa afya
    2 Msaidizi waafisa afya
    3 Tabibu/tabibu msaidizi
    4 Cheo kingine (taja)……..
4. Jinsia
    0. Mwanamme
    1. Mwanamke

    Ni kwa muda gani umefanya kazi katika kitengo cha chanjo?..... [Miezi]

5. Umewahi kupata maelekezo yoyote kazini au mafunzo nje ya kituo cha kazi kuhusu huduma za chanjo? (Usiulize swali la sita kama jibu ni hapana)
    0. Hapana
    1. Ndio
6. Mara ya mwisho ulipata lini maelekezo au mafunzo?
    1. Kati ya miezi 3 iliyopita
    2. Kati ya miezi 4 –6 iliyopita
    3. Kati ya miezi 7 –9 iliyopita
    4. Kati ya miezi tisa 9 –12 iliyopita
    5. Zaidi ya miezi 12 iliyopita

Sehemu ya pili: Uelewa wa mchanjaji juu mambo ya msingi katika utoaji wa chanjo ya BCG

I. Uelewa juu ya sababu ya kukusanya takwimu

Unafikiri ni kwa nini unakusanya takwimu za uchanjaji?.....

II**. Uelewajuuya sera na miongozo ya uchanjaji**

Iwapo motto wa umri zaidi ya mwaka mmoja atakuja kliniki kwa ajili ya chanjo, utampa chanjo ya BCG? (Usiulize swali linalofuata kama jibu ni hapana)

0. Hapana
1. Ndio

Unadhani sindano ya ujazo gani inafaa kutumika kumchanja motto wa umri zaidi ya mwaka mmoja? …… mils.

Je, unafikiri motto ambaye kovu halikuonekana miezi mitatu baada ya kupata chanjo anapaswa kuchanjwa mara yapili?(usiulize swali la 7 kama jibu ni hapana)

0. Hapana
1. Ndio

III. Uelewa juu ya namna ya kukokotoa kiwango cha chanjo katika kituo

Ni namna gani unakokotoa kiwango cha uchanjaji wa BCG ili kupima utendaji wa kituo chako?

0. Jibu jingine lolote
1. Watoto chini ya mwaka mmoja waliochanjwa ndani ya eneo la huduma gawanya kwa walengwa zidisha kwa 100%

IV. Uelewa juu ya namna ya kuchati taarifa ya uchanjaji

Unadhani kipi kinatafaa kuanza kati ya uchanjaji na uwekaji wa kumbukumbu kwenye chati?

0. Uwekaji wa kumbukumbu kwenye chati kasha uchanjaji
1. Uchanjaji kasha uwekaji wa kumbukumbu kwenye chati

Unafikiri ni mahali gani utachati mtoto aliyerudia kuchanja baada ya kovu kutoonekana?

1. Watoto chini ya mwaka mmoja waliochanjwa ndani ya eneo la huduma
2. Nitachora na kuchati sehemu nyingine kwenye fomu ya kuchati
3. Watoto waliochanjwa nje ya eneo la huduma
4. Kwenye kadi ya motto
5. Jibu jingine lolote (ainisha)……

Appendix 3A: Informed consent to participate in research; English version.

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

SCHOOL OF PUBLIC HEALTH SOCIAL SCIENCES

DIRECTOR OF RESEARCH AND PUBLICATIONS

INFORMED CONSENT FORM

ID NO …….

Consent to participate in this study

Dear sir/madam!

I am called ……...I am conducting this research work with the objective of assessing knowledge of vaccinators on immunization facts among other things in Wanging'ombe district.

Purpose of the study

The purpose of this study is to estimate coverage, evaluate data quality and assess knowledge of vaccinators who handle immunization data. You are being requested to participate in this study because you have a particular knowledge and experience in this area that may be important to this study.

What participation involves

If you agree to participate in this study the following will be done;

1. You will be asked some questions by the interviewer to understand your knowledge on various aspects of BCG immunization. The interviewer will record all your responses in a questionnaire.
2. No identifying information will be collected from you during this interview.

3. You will be interviewed individually for approximately 20 minutes in a private setting.

Confidentiality

I assure you that the information you will provide will be kept confidential. Only persons working on this research will have access to the information. We will consolidate the information collected from all vaccinators but we will not put your name or any identifying information on the records of the information you provide.

Risks

We do not expect any harm to occur to you because of participating in this study.

Rights to withdraw from the study

Taking part in this study is completely non coercive. If you agree to participate or if you decide to stop participating you will be allowed. You can stop at any time if you wish. Refusal to participate or withdrawal from the study will not involve any punishment or loss of any benefits to which you are entitled to.

Benefits

If you agree to participate, the information you will provide will enable us to recommend to the Council Health Management Team (CHMT) and the Ministry of Health- Immunization and Vaccine Development (IVD) Programme on the operational challenges related to policy, human resource capacity, data collection tools and program management issues.

Who to contact

If you have any question about this study, you should contact the study coordinator or the principal investigator**, LINDA CHATILLA**, Regional Commissioner's office, P.O Box 668, Njombe. (Tel. No. 0753096518). If you have questions about your rights as a participant, you may call **Dr. M. Moshi,** Chairman (Research and Publications Committee, MUHAS, P.O Box 65001, Dar es salaam. Tel. No.+2552150302/6 or prof. Method Kazaura who is the supervisor of this study.(Tel. No. 0715767719).

Signature …….

Do you agree?

Participant agrees [____]

Participant disagree [_____]

I_____ have read and understood the contents in this form. My questions have been answered. I therefore agree to participate in this study

Signature of participant_____

Signature of witness (if participant cannot read) _____

Signature of researcher/research assistant_____

Date of signing consent_____

Appendix 3B: Informed consent form; Swahili version

MUHIMBILI CHUO CHA ELIMU YA AFYA NA TIBA SHIRIKISHI

IDARA YA UTAFITI NA MACHAPISHO

FOMU YA RIDHAA

Namba ya utambulisho …….

Ridhaa ya kushiriki katika utafiti

Habari! Jina langu naitwa ……..Nafanya utafiti katika eneo la huduma za chanjo. Pamoja na mambo mengine, lengo kubwa nikujua uelewa wa wachanjaji katika masuala mbalimbali yahusuyo uchanjaji katika wilaya ya Wanging'ombe.

Malengo ya utafiti

Utafiti huu una malengo mahsusi ya kufanya makadirio ya kiwango cha uchanjaji kwa mwaka 2018 kwa chanjo ya BCG, kutathmini ubora wa takwimu na kupima uelewa wa wachanjaji katika masuala mbalimbali ya chanjo. Unaombwa kushiriki katika utafiti huu kwa sababu unauelewa na uzoefu ambao ni muhimu katika kufanikisha utafiti huu.

Ushiriki wako unajumuisha;

Ukikubali kushiriki katika utafiti huu yafuatayo yatafanyika;

1. Utakaa na msaili ambaye atakuhoji maswali machache juu ya uelewa wako kuhusiana na masuala mbalimbali katika utoaji wa chanjo ya BCG. Msaili atakuwa akiandika majibu unayoyatoa.
2. Hakutakuwa na taarifa zozote za utambulisho tutakazokusanya wakati wa usaili
3. Utahojiwa mara moja tu kwa takribani dakika 20 kwenye sehemu ya faragha.

Usiri

Nakuhakikishia kuwa taarifa zote utakazozitoa zitakuwa ni siri. Watu wanaokusanya taarifa hizi tu ndio wanaweza kuziona. Tutafanya majumuisho ya taarifa yenye majibu kutoka kwa wachanjaji wengine. Pia hatutaweka jina lako au taarifa yoyote ya utambulisho kwenye kumbukumbu za taarifa utakazotoa.

Madhara

Hatutegemei kuwa kutatokea madhara yoyote kwa ushiriki wako katika utafiti huu.

Haki ya kujitoa na mbadala wowote

Kushiriki katika utafiti huu ni hiari yako, kama utaamua kutoshiriki hutapata madhara yoyote. Unaweza kusitisha kushiriki katika utafiti huu muda wowote utakapoona inafaa. Aidha, kukataa kushiriki au kujitoa katika utafiti huu hakutaambatana na adhabu yoyote au upotevu wa faida yoyote unayostahili kupata**.**

Faida

Iwapo utakubali kushiriki taarifa utakazotupa zitatuwezesha kutoa mapendekezo kwa timu ya ushauri ya usimamizi wahuduma za afya ya halmashauri ili kuboresha takwimu na pia kuishauri wizara ya afya hususani Mpango wa Taifa wa Chanjo ili kutatua changamoto za kiutendaji zinazotokana na sera, rasilimali watu, vitendea kazi na usimamizi wa huduma za chanjo kwa ujumla.

Watu wa kuwasiliana nao

Kama una maswali kuhusiana na utafiti huu unaweza kuwasiliana na msimamizi mkuu wa utafiti **Bi. Linda C. Chatilla,** Ofisi ya Mkuu wa Mkoa wa Njombe, S.L.P 668, Njombe. Kama una hoja yoyote kuhusu haki zako kama mshiriki unaweza kupiga simu kwa **Dkt. M. Moshi,** (Mwenyekiti wa kamati ya chuo ya utafiti na machapisho, S.L.P 65001, Dar es salaam. Tel. +2552150302/6) au Prof. Method Kazaura ambaye ni mshauri wa kitaalamu wa utafiti huu (simu nambari.0715767719).

Sahihi ……..

Unakubali?

Mshiriki amekubali [ ]

Mshiriki amekataa [ ]

Mimi……. Nimesoma/nimeelewa maelekezo yaliyopo katika fomu hii na maswali yangu yamejibiwa. Nakubali kushiriki katika utafiti huu.

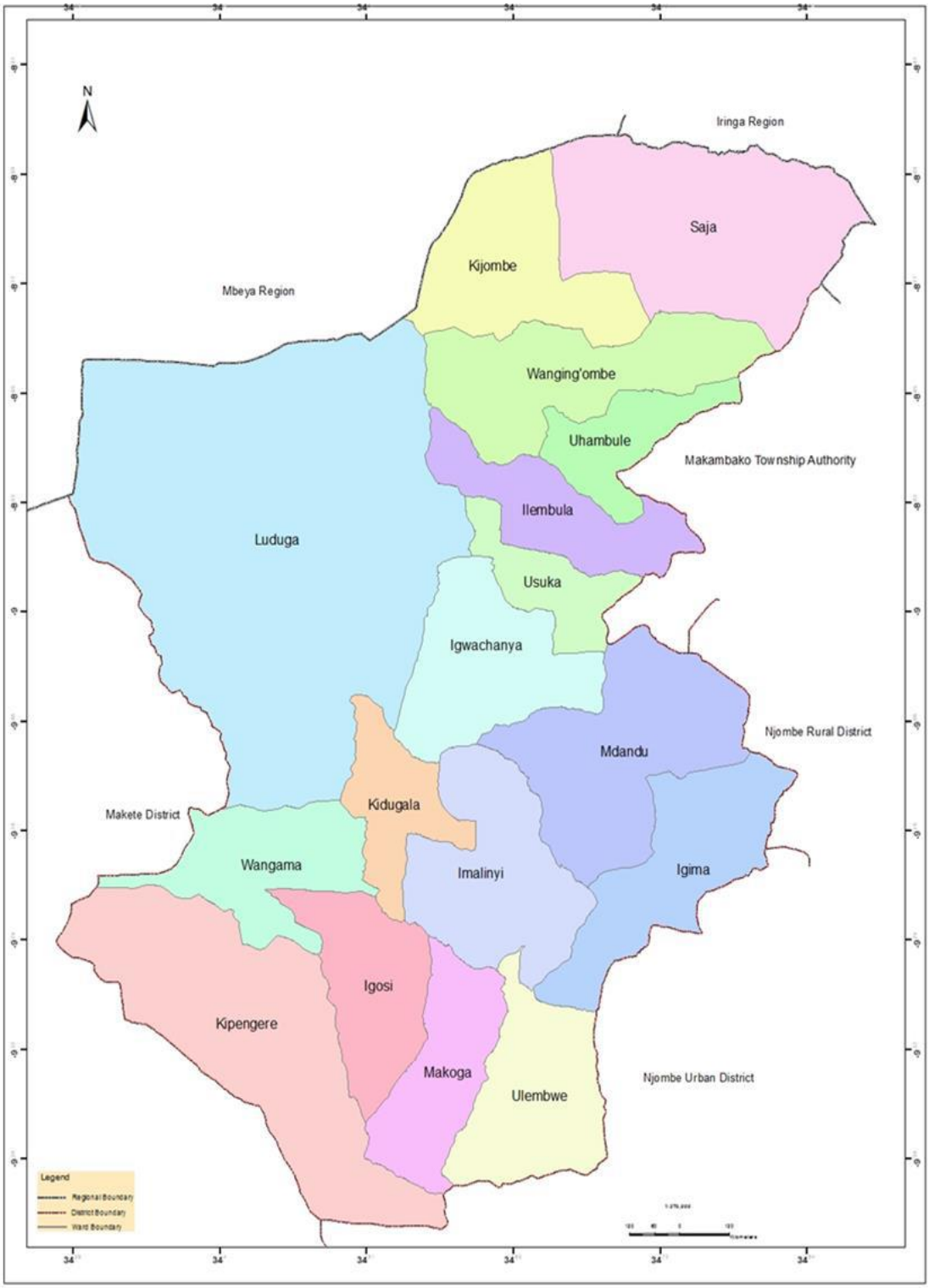
Sahihi ya mshiriki ……

Sahihi ya shahidi (kama hawezi kusoma na kuandika) ……

Sahihi ya mtafiti muandamizi ……

Tarehe ya makubaliano ……

Appendix 4: Map of Wanging'ombe District showing ward boundaries



Appendix 5: Approval for ethical clearance

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF RESEARCH AND PUBLICATIONS

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Ref. No.DA.282/298/01.C/ 20th June, 2019

Linda Cassian Chatilla,
University of Rwanda
College of Medicine and Health Science,

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED "BACILLUS CALMETTE GUERIN IMMUNIZATION COVERAGE AND DATA QUALITY IN WANGING'OMBE DISTRICT: NJOMBE REGION – TANZANIA"

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above mentioned study, on recommendations of the Senate Research and Publications Committee meeting.

The validity of this ethical clearance is one year effective from **22nd May, 2019** to **21st May, 2020.** You will therefore be required to apply for renewal of ethical clearance on a yearly basis if the study is not completed at the end of this clearance.

You will be expected to provide adverse events report where applicable, six monthly progress reports and a final project report upon completion of your study.

Dr. Bruno Sunguya
Ag. Chairperson, Senate Research and Publications Committee