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Assessment of Tuberculosis Underreporting by Level of Reporting System in Lagos, Nigeria

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Gidado Mustapha

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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The Office of the Provost

Walden University
2019

Abstract

Assessment of Tuberculosis Underreporting by Level of Reporting System in Lagos,

Nigeria

by

Gidado Mustapha

MSc-HPE, Maastricht University, 2008

MPH, Ahmadu Bello University, 2007

PGDM, Ahmadu Bello University, 2000

MBBS, Ahmadu Bello University, 1997

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health

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November 2019

Abstract

Tuberculosis (TB) is the leading cause of death from a single infectious disease. Unfortunately, 4.1 million cases were missed in 2017 globally, and Nigeria contributes 9% of the missing TB cases. At least 73% of the estimated TB cases in Nigeria were not reported in 2017 to the National TB Program (NTP); therefore, the true burden of TB was not certain, and this affected planning for prevention and control of TB. This quantitative secondary data analysis (NTP Lagos TB Inventory study database) guided by the integrated behavioral model assessed TB underreporting based on the TB reporting process in Nigeria. Chi-square and binomial logistic regression were used to assess the association between TB underreporting and the characteristics of health facilities (HFs), health workers' (HWs) awareness, barriers to TB reporting, and patient-related factors. The results indicate at least 60% of all HFs underreported TB, with an average of 7.4% underreporting between HFs records and TB program reports. There was a statistically significant association between NTP nonengaged health facilities (χ^2 (1) = 20.547, p <.05), HWs' awareness of TB reporting (χ^2 (1) = 6.576, p <.05), and barriers for TB reporting (χ^2 (1) = 4.106, p < .05) with TB underreporting. The following patient factors were statistically significant predictors of TB underreporting with over 50% increased odds, p<0.05: previously treated, extrapulmonary, unknown TB site, HIV negative, and HIV unknown. This study supports social change through NTPs ensuring the establishment of a coordinating mechanism for TB reporting within and between HFs and supply of TB reporting tools to all HFs to know the true burden of TB for better planning and monitoring of quality care for TB patients.

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Dedication

To all TB patients and affected families and front line TB health care workers globally.

Acknowledgment

Thanks to Almighty Allah for making it possible for me to complete this milestone in my career. I wish to thank my entire family for their support and understanding throughout this journey.

My sincere thanks to KNCV Tuberculosis Foundation and Kitty van Weezenbeek, for providing me a partial scholarship for this course and technical support from all colleagues, especially Jens Levy and Ellen Mitchell.

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I pledge to you all that I will share and apply this knowledge as long as it remains relevant in my career.

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Chapter 1: Introduction

Tuberculosis (TB) is a treatable and curable infectious disease (World Health Organization [WHO], 2018b). However, the global burden remains high with over 10.4 million TB cases and 1.7 million deaths, 95% of which occurred in developing countries (WHO, 2017; WHO, 2018a). TB is now ranked the ninth leading cause of death globally and first among single infectious diseases (WHO, 2017; WHO, 2018b). The WHO identified 30 countries as high burden countries (HBC) for TB, multi-drug resistant TB (MDR-TB), and TB/HIV (WHO, 2017); these countries accounted for 87% of all estimated TB cases in 2017 (WHO, 2017). Nonetheless, seven countries accounted for 64% of the global TB burden (India, Indonesia, China, Philippines, Pakistan, Nigeria, and South Africa; WHO, 2017; WHO, 2018a). In 2016, only 6.6 million TB cases were notified to the National TB Programs (NTPs) from estimated global TB cases of 10.4 million, and subsequently to WHO, translating to a global treatment coverage of 61% (WHO, 2017). Similarly, of the 10 million estimated cases for 2017, 3.4 million TB cases were missed or not notified globally (WHO, 2018a). Three factors attributed to the missing cases: underdiagnosing, underreporting, and uncertainty of the estimated incidence (Chin & Hanson, 2017; WHO, 2017).

Nigeria was ranked seventh among the 30 HBCs globally and the first in Africa with an estimated incidence of 219/100,000 population, that is, 420,480 estimated for all forms of TB cases (WHO, 2017; Federal Ministry of Health [FMOH], 2017). The treatment coverage for Nigeria in 2017 was 27%, with more than 302,906 drug-susceptible TB cases, 18,000 drug-resistant TB cases, and 48,550 child TB cases missing

(FMOH, 2017; WHO, 2017). Nigeria was among the top 10 countries contributing to 80% of the missing TB cases in 2017 and contributing 9% of the globally missed cases (FMOH, 2017; WHO, 2018a). TB service delivery in Nigeria covered only 26% of all health care facilities and only 5% of private health care facilities (FMOH, 2017). TB service delivery facilities were skewed towards 75.5% secondary health care facilities and less than 20% of primary health care facilities (FMOH, 2017). Lastly, the number and utilization rate of laboratory services were suboptimal with only 390 GeneXpert sites in the entire country (48% local government area coverage with 38% utilization rate) and 2,650 microscopy centers across the country (FMOH, 2017).

WHO (2018c) Standard 27 states "All providers must report both new and retreatment TB cases, and their treatment outcomes to National Public Health Authorities conform applicable legal requirements and policies" (p. 32). In many countries, including Nigeria, TB is among the notifiable diseases that must be reported on a regular, frequent, and timely basis to designated public health authorities (Mansuri, Borhany, & Kalar, 2014; Uplekar et al., 2016). In Nigeria, the reporting system used the Local Government Area (LGA) as the basic management unit (BMU) where all health facilities report TB cases and, subsequently, refer such reports to the State and Federal Ministries of Health (FMOH, 2010: FMOH, 2015a). TB reporting by all health care facilities and LGAs engaged by the NTP is based on standard definitions and recording and reporting (R&R) tools to ensure standardization (FMOH, 2010; FMOH, 2015a; WHO, 2014). However, only facilities engaged by the NTP are provided with national TB R&R tools through the NTP monitoring and evaluation system, which serves as a vertical disease reporting

system. At the same time, all health care facilities within the LGAs used disease surveillance officers to report all notifiable diseases to the Ministry of Health, including those reporting to the NTP reporting system (FMOH, 2015b).

Complete reporting and quality surveillance systems for TB are central for the planning, implementation, and evaluation of the control strategies and for determining the real burden of TB (Morales-García et al., 2015; Podewils et al., 2015; Tollefson et al., 2016). Underreporting for TB remains a global problem with 40% of the cases globally being invisible (never reported to the NTPs) to the public health system (Ahmadi, Nedjat, Gholami, & Majdzadeh, 2015; Chin & Hanson, 2017; Nagaraja, Achanta, Kumar, & Satyanarayana, 2014; Sulis, Roggi, Matteelli, & Raviglione, 2014). As stated by Sprinson, Lawton, Porco, Flood, and Westenhouse (2006), inadequate data and underreporting may weaken our understanding of the true burden of TB, affect core program functions, and undermine NTP ability to meet TB program goals and objectives. Other impacts of underreporting include poor prioritization of interventions, inadequate geographical or high risk population coverage, misallocation of resources, and weak public health actions or policies (Coghlan et al., 2015; Heidebrecht, Tugwell, Wells, & Engel, 2011; Mlotshwa, Smit, Williams, Reddy, & Medina-Marino, 2017; Onyeonoro et al., 2015; Podewils, Bronner Murrison, Bristow, Bantubani, & Mametja, 2016; Sprinson et al., 2006).

Methods used for assessing the magnitude of TB underreporting include inventory studies and capture-recapture methods (WHO, 2012). TB inventory studies compare the number of TB cases recorded in all, or a sample of health care facilities based on a

standard definition with the records of TB cases notified to local and national authorities

(WHO, 2012). Capture-recapture methods involve cross-matching records from a

minimum of three data sources for the same population and using statistical methods to

estimate the number of TB cases underreported (WHO, 2012).

The magnitude of TB underreporting was studied among private health care

facilities. The associated factors for TB underreporting issues can be summarized as

follows: patient's demographics, type and site of TB, type of health care facility,

availability of NTP reporting tools, multiplicity and cumbersomeness of TB reporting

tools, awareness and capacity to complete NTP forms, weak collaboration and

coordination between TB programs and other public health reporting systems, and

concerns about the patient's confidentiality and stigma (Coghlan et al., 2015; Furtado da

Luz & Braga, 2018; Mansuri et al., 2014; Satpati et al., 2017; Sismanidis et al., n.d.).

This study assessed and described TB reporting at different levels of the existing

TB reporting system and also identified TB underreporting and associated factors

disaggregated by type and level of health care facilities, between TB recorded cases at

health care facilities and LGA TB registers and State TB reports. Understanding this will

ultimately contribute to specific interventions for the strengthening of the TB reporting

system among all types of health care facilities in Nigeria.

This chapter provides the general information on the magnitude of

underreporting, associated factors as documented in the literature, and documented gaps

leading to the problem statement and the research question. It also entails more detailed

information on the purpose of the study, description of the study variables, theoretical

framework, study design and methodology, as well as the definition of terms in the entire document for clarity. Assumptions, delimitations, limitations of the study, and social change from the outcome of the study are all documented in this section.

Background

TB notification is defined as a process of reporting diagnosed TB cases to the appropriate health authorities (WHO, 2014), and in many countries, this is done through the TB program at various levels in the country and eventually to WHO at the global level (Uplekar et al., 2016; WHO, 2014). Mandatory TB notification is one of the integral elements of the overall regulatory framework essential for the implementation of end TB strategy: TB notification is mandatory for routine surveillance and for verifying the burden of TB in a community or country (Podewils et al., 2016; Uplekar et al., 2016). Underreporting for TB is a global problem and a contributing factor for low case notification of TB across the globe and for Nigeria that impedes proper understanding of the disease burden and the impact of the response and control interventions (Oshi et al., 2016; Uplekar et al., 2016; WHO, 2017).

The magnitude of underreporting was described among private health care practitioners with varied results. In a prospective study, Bassili et al. (2010) found 28% of patients in non-NTP facilities unreported to the TB program, while Tollefson et al. (2016), Thomas et al. (2016), and Mlotshwa et al. (2017) observed an underreporting of 21%, 33%, and 34%, respectively, using mixed methods in inventory studies. In addition, Sismanidis (2018) reported a crude TB underreporting of 41.7% in Indonesia.

Reliable and quality surveillance systems and notification are key functions of public health as they provide opportunities for (a) decision-making that is evidence-based, (b) prioritization, and (c) planning of interventions and health care service delivery (Gibbons et al., 2014). Disease notification involves people, tools, processes, and technologies guided by clear roles and responsibilities (Ali et al., 2018). The consequences of TB underreporting as proposed by Mlotshwa et al. (2017) include underestimation of the true burden of the disease, implementation of inappropriate control strategies, and misallocation of resources.

Awareness of mandatory TB notification was reported to be high among private health care workers; 73% of the respondents knew of the mandatory notifications as reported by Thomas et al. (2016) in Chennai, India, and 98% and 84 % of respondents among general practitioners and specialists, respectively (Glaziou, Raviglione, Falzon, & Floyd, 2015). However, lack of knowledge on reporting systems, procedures, processes, and coordination with the public health care system was reported in Karachi, Pakistan, and Alappuzha, India (Mansuri et al., 2014; Philip et al., 2015).

According to Daniel, Adedeji Adejumo, Abdur-Razzaq, Ngozi Adejumo, and Salako, (2013), the reasons identified for the low contribution of private health practitioners to TB case notification included cumbersome TB reporting tools, existing TB reporting tools that do not capture patients referred by private health practitioners, and low engagement of private health practitioners in only 1% and 18.6% of private for-profit and private nonprofit health care facilities, respectively. Underreporting is associated with a high burden of cases diagnosed in private health facilities (Tollefson et

al., 2016). The TB underreporting burden is also associated with cases diagnosed at large and complex facilities with multiple service delivery points, and pretreatment loss to follow-up and cases put on treatment but not reported (Tollefson et al., 2016)

Associated factors for TB underreporting from private health care providers include misconceptions about notification, concerns on patient's confidentiality, and fear of stigmatization and discrimination for the patients (Bassili et al., 2010; Mansuri et al., 2014; Philip et al., 2015; Tollefson et al., 2016; Yeole, Khillare, Chadha, Lo, & Kumar, 2015. More factors for underreporting include lack of cohesion and coordination between the private and public sector, difficult reporting tools, lack of systematic feedback, and workload (Bassili et al., 2010; Mansuri et al., 2014; Philip et al., 2015; Tollefson et al., 2016; Yeole et al., 2015). Conclusively, additional factors identified to be associated with underreporting were (a) inadequate training of health care workers, (b) nonremuneration of private health care workers, (c) the nonsupportive system from the TB program, (d) weak mechanisms for communication and feedback, and (e) no mechanism or responsible body for enforcement of TB reporting (Philip et al., 2015; Uplekar, 2016).

Problem Statement

Nigeria was ranked seventh among thirty TB HBCs in the world, with an estimated incidence of 219 per 100,000 population (FMOH, 2017: WHO, 2018a). The TB case detection rate (treatment coverage) has consistently remained low as only one out of four estimated cases are ever reported to the NTP based on the TB prevalence survey of 2012 (FMOH, 2014). The TB treatment coverage in Nigeria varies across the Federal States with Lagos having the highest estimated burden of TB but reporting less

than 20% of the estimated cases in 2016 (FMOH, 2017). Only 27% of the nationally estimated TB cases were reported to the Nigerian NTP in both 2016 and 2017 (WHO, 2017; WHO, 2018a). Nigeria contributed 9% of globally unreported TB cases, 3.4 million missed or unnotified TB cases in 2017 globally (FMOH, 2017; WHO, 2017; WHO, 2018a).

Low TB treatment coverage was attributed to two main areas, underdiagnosing and underreporting (Bassili et al., 2010; Huseynova et al., 2013). Although TB is a notifiable disease by law (FMOH, 2015b; Nagaraja et al., 2014; Oshi et al., 2016), less than 14% of all health facilities in Nigeria report TB and only 4% among private health care facilities in Nigeria (FMOH, 2017; Johnston, 2014; WHO, 2007). The factors associated with TB underreporting have been linked to low engagement with or low decentralization of TB services to all health care facilities by the NTP in Nigeria. Only 11% of all health care facilities are engaged by the TB program nationally whereas 14% of facilities are engaged in Lagos State (FMOH, 2017; Global Fund, 2015; WHO, 2012). TB underreporting has a significant impact on ascertaining the real burden of TB for Lagos State and Nigeria. TB program planning at all levels including the development of the National Strategic Plan and Global Fund grant applications is based on the TB estimate produced annually by WHO and not based on the true TB burden of Nigeria because of the paucity of the TB data in the country.

The evidence available on the magnitude of TB underreporting and associated factors were primarily based on private health care facilities and studies from Asia (India) and a few African countries (South Africa, Kenya, and Egypt). Available reports on the

associated factors for TB underreporting was based on studies conducted among private health care facilities, mainly from India (Nagaraja et al., 2014; Philip et al., 2015). Current global reports and reports from Egypt, Pakistan, and Yemen on both the magnitude and associated factors of TB underreporting are not disaggregated by different levels of health care facilities, either primary, secondary, or tertiary health care facilities, and reporting levels, NTP system and the routine disease surveillance system of the Ministry of Health (Bassili et al., 2010; Glaziou et al., 2015; Mansuri et al., 2014; Oshi et al., 2016). Disaggregation would enable targeted interventions for improvement in TB reporting (Bassili et al., 2010; Mansuri et al., 2014; Philip et al., 2015; Tollefson et al., 2016; Yeole et al., 2015). Uplekar et al. (2016) in a literature review of published articles on TB reporting among HBCs observed no publications from Nigeria on TB underreporting in 2016. Factors identified for TB underreporting included concern for the patient's confidentiality, fear of stigmatization and discrimination of the patient, lack of cohesion and coordination between the private and public sector, difficult reporting tools and processes, lack of feedback, and health care workers' workload (Bassili et al., 2010; Mansuri et al., 2014; Philip et al., 2015; Tollefson et al., 2016; Yeole et al., 2015). Results obtained from this study will be incorporated into different opportunities for strengthening the TB reporting systems including electronic reporting systems like the District Health Information System Two that is currently adopted by the Ministry of Health in Nigeria.

Purpose of the Study

The main purpose of the study was to assess and describe TB reporting at different levels of the TB Reporting Systems in Lagos, Nigeria. Lagos was selected due to the disease burden, population density of 4193/km^2, high proportion of private health care facilities (87.3%), and the existence of secondary data from a TB inventory study conducted in 2017. The study identified TB underreporting and its associated factors by level and type of health care facility, assessed health care awareness of mandatory TB reporting, and described barriers to TB reporting by health care workers. Identifying and describing these factors associated with TB underreporting, which are likely to differ by types and levels of health care, will enhance targeted public health responses and approaches to improve the underreporting of TB. The study will determine TB reporting issues in the context of the Nigerian health care setting.

The outcome of this study will be used to improve TB case reporting and notification in Nigeria by understanding the magnitude of TB underreporting among the different types and levels of health care facilities and associated factors (health care workers knowledge of mandatory TB reporting, barriers to TB reporting, and patient-related factors to underreporting). It was a quantitative retrospective study using secondary data of an inventory survey conducted in Lagos, Nigeria, in 2017. I assessed the TB underreporting and associated factors by all types and levels of the health care systems. The findings may guide the development of appropriate and targeted public health interventions to strengthen TB reporting in Nigeria.

Research Questions and Hypotheses

RQ1: Is there an association between the cascade (sequence) of TB underreporting by various levels of reporting (facility to LGAs and LGAs to State), and by types of health care facilities (public and private; primary, secondary, and tertiary; NTP engaged and NTP nonengaged by TB program)?

$H_0 1$: There is no statistically significant association in the cascade of TB underreporting by different levels and types of health facilities.

$H_a 1$: There is a statistically significant association in the cascade of TB underreporting by different levels and types of health facilities.

RQ2: Are there differences between health care workers awareness of mandatory TB reporting, reported barriers for TB reporting, types of barriers for TB reporting, feedback on TB data to health care workers, patients and disease characteristics (age, sex, TB disease site, type of patients, HIV status), volume of patients per health care facility, and volume of patients per LGA with TB underreporting?

$H_0 2$: There is no statistically significant difference between health care workers awareness of mandatory TB reporting, reported barriers for TB reporting, types of barriers for TB reporting, feedback on TB data to health care workers, patients and disease characteristics (age, sex, TB disease site, type of patients, HIV status), volume of patients per health care facility, and volume of patients per LGA with TB underreporting.

H_a2: There are statistically significant differences between health care workers

awareness of mandatory TB reporting, reported barriers for TB reporting,

types of barriers for TB reporting, feedback on TB data to health care

workers, patients and disease characteristics (age, sex, TB disease site, type of

patients, HIV status), volume of patients per health care facility, and volume

of patients per LGA with TB underreporting.

RQ3: Is there an association between health care workers knowledge on

mandatory TB reporting, years and type of practice, and identified barriers for TB

reporting by levels and type of health care facilities?

H_03: There is no statistically significant difference between health care

workers knowledge on mandatory TB reporting, years and type of practice,

and identified barriers for TB reporting by levels and type of health care

facilities.

H_a3: There is a statistically significant difference between health care workers

knowledge on mandatory TB reporting, years and type of practice, and

identified barriers for TB reporting by levels and type of health care facilities.

Theoretical Framework

The research work was based on the integrated behavioral model (IBM). IBM is a

combination of constructs from the theory of reasoned action (TRA), the theory of

planned behavior (TRB) and constructs from other theories with a central construct as

intention but acknowledging the influence of environmental barriers including social and

physical barriers or deficiency in skills and abilities to behavior (Branscum & Lora, 2017;

Glanz, Rimer, & Viswanath, 2008; Rimer & Glanz, 2005;). The IBM theory was applicable to this study on the premise that TB reporting (concrete behavior) involves people, tools, processes, and use of technology (Ali et al., 2018). TB reporting is an expected behavior (standard of TB care) and a requirement by law, therefore, the constructs of IBM form essential determinants of behavior through attitude and the influence of variables like knowledge, experience, the salience of the behavior, habit or maintenance, and engagement in the entire TB reporting process. Figure 1 below provides a summary of the interaction between the multiple variables in IBM.
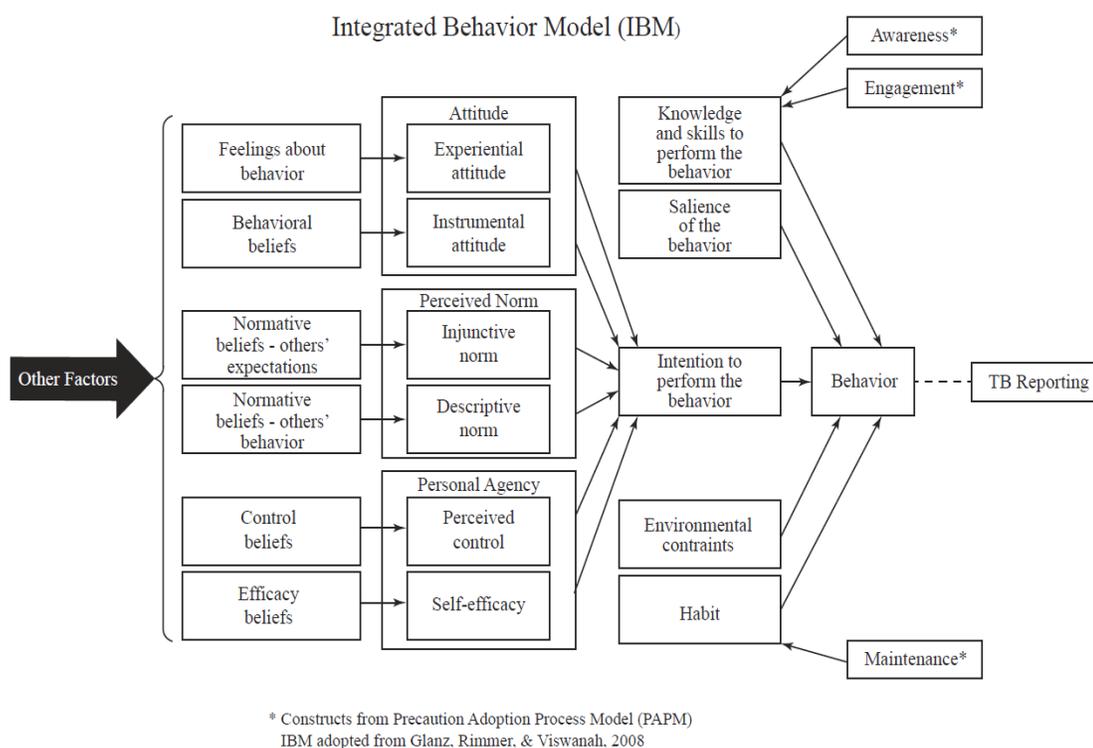
Figure 1. Integrated behavior model (IBM).

Nature of Study

The study was quantitative descriptive using secondary data from an inventory study on TB reporting in Lagos State, Nigeria. I used the quantitative descriptive method for this study to establish an association between TB underreporting (dependent variables) and the different types and levels of health care facilities, different reporting levels, and associated factors such as health care workers knowledge on mandatory TB reporting, availability and ease of use of TB reporting and recording tools, patients demographics, disease characteristics, and volume of patients registered by health care facilities (independent variables). I measured the dependent variable (TB underreporting) once, and I carried out the study on a sample population of health care facilities in Lagos based on the secondary data set of an inventory study. This methodology enabled the description and quantification of the TB underreporting and different associated factors by different health care facilities (type and level). The inventory study was primarily a quantitative retrospective study that used a multistage sampling method from a sampling frame developed from three databases of health facilities in Lagos State: the Health Facility Monitoring and Accreditation Agency, the Millennium Development Goals, and the Strengthening Health Outcomes through the Private Sector (SHOPS). The choice of data analysis depends on three questions: type of data (categorical or interval/ratio), number of samples (either one, two, or three and above), and the purpose of the study, either comparison, association, or assessment of prediction (Sullivan, 2012).

Possible Types and Sources of Data

The data source for all variables was the database obtained from the inventory study conducted in Lagos State, Nigeria, by Koninklijke Nederlandse Centrale Vereniging tot bestrijding der Tuberculose (KNCV) Tuberculosis Foundation, the Lagos State Ministry of Health, and the National TB Control Program in 2017. Types of variables include:

1. category of health care facilities (public and private, NTP-engage facilities and Non-NTP engaged facilities);

2. levels of health care facilities (primary, secondary, and tertiary);

3. the number of TB cases registered by all health care facilities, the number of TB cases reported by LGAs, and the number of TB cases reported by the State TB program;

4. patients characteristic such as age, gender, site, and type of TB disease, and HIV status;

5. knowledge of health care workers on mandatory TB notification years of practices, type of practice, and barriers for TB reporting as reported by health care workers; and

6. other associated factors such as volume of TB patients per facility and number of directly observed treatment short course (DOTS) centers per LGAs.

Analytical Strategies

The choice of data analysis depends on three questions: type of data, categorical or interval/ratio; number of samples, either one, two, or three and above; and the purpose

of the study, either comparison, association, or assessing prediction (Sullivan, 2012). The data analysis entails descriptive statistics like percentages, means, medians, and appropriate tables and graphs based on the level of measurement of the variables. Chi-square test was used to measure the association between the categorical dependent variable, complete reporting and underreporting, and the independent variables types and levels of health care facility, NTP engagement status, the volume of patients at a health care facility, and volume of DOTS centers per LGA. I used a binomial logistic regression to measure the relationship between the multiple independent variables—health care facilities types, levels, NTP engagement status, knowledge of health care workers on mandatory TB notification, barriers to TB reporting, and patient-related factors (demographic and disease-related)—and the dependent variable, TB reporting as dichotomous categorical variables (complete reporting and underreporting). For all statistical tests, $p < 0.05$ was considered significant, while 95% of confidence intervals was generated for all point estimates.

Definitions

Bacteriologically confirmed TB: A case of TB with evidence of Mycobacterium tuberculosis in the specimen either by microscopy, GeneXpert, or culture.

Data quality: Data with the following dimensions: accuracy, reliability, precision, completeness, timeliness, integrity, and confidentiality.

Directly observed treatment: A process whereby the patient's intake of the TB medicines is monitored daily by either a health care worker, a family member, or a volunteer to ensure adherence.

DOTS provider: A health care worker, family member, or volunteer assigned to observe daily intake of TB medications, monitor side effects, record drug intake, and support referral.

DOTS strategy: TB control strategy adapted in 1993 with the following components: ensure political commitment, quality diagnosis, uninterrupted supply of drugs, direct observation of treatment, and effective recording, reporting, and monitoring.

End TB strategy: The global strategy and targets for tuberculosis prevention, care, and control after 2015, which aims to reduce TB deaths by 95% and new cases by 90% between 2015 and 2035 and to ensure that no family is burdened or affected by the catastrophic expenses due to TB. It sets interim milestones for 2020.

Extrapulmonary TB: TB affecting other parts of the body besides the lungs

High burden TB countries: Countries designated by WHO as high incident based on disease burden and severity.

High-TB-incidence country: A country with a WHO-estimated TB incidence rate of ≥ 100/100 000 population

Incomplete TB reporting: An observed variance in TB reporting between different levels, this can either be TB underreporting or TB overreporting.

M&E framework: The descriptive scheme of TB reporting tools, processes, persons, and indicators.

National TB Program: A designated unit within the public health department at different levels of health care system responsible for coordination, and implementation of the public health response to TB.

Non-NTP-engaged facilities: Facilities not linked to the TB program.

Notifiable diseases: Any disease required by law to be reported to designated authorities for which regular, frequent, and timely information regarding individual cases is considered necessary for the prevention and control of the disease.

NTP-engaged facilities: Facilities identified and trained by the National TB Program, linked to the reporting and supply chain management systems (TB program supplies cover the aforementioned three systems, State, LGAs, and HFs). Data from these facilities are collected on a routine basis by the LGA TB supervisors.

TB overreporting: When aggregated TB cases at LG TB register are higher than documented TB cases at the facility level or notified TB cases at state are higher than the aggregated among all LGA TB registers.

Pulmonary TB: A case of TB affecting the lungs.

Patent medicine vendors: Persons without formal pharmaceutical training who sell orthodox pharmaceutical products on a retail basis for profit.

Prevalence: Number of TB cases at a given point in time and area (usually a year).

Recording and reporting (R&R) tools: Standard TB recording and reporting tools at various levels as developed by the NTP.

Reporting completeness: The proportion of cases attending health care whose health events were correctly diagnosed and appropriately reported.

STOP TB strategy: A follow-on strategy after the DOTS strategy in 2006 with six components: (a) pursue high-quality DOTS expansion and enhancement; (b) address

TB/HIV, MDR-TB, and the needs of poor and vulnerable populations; (c) contribute to health system strengthening based on primary health care; (d) engage all care providers, (e) empower people with TB and communities through partnership, and (f) enable and promote research.

Surveillance: The continuous, systematic collection, analysis, and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practices.

TB case: A TB case is an individual with either bacteriologically confirmed TB or clinically diagnosed TB.

TB treatment coverage: The number of new and relapse cases detected and treated in a given year, divided by the estimated number of incident TB cases in the same year, expressed as a percentage.

TB LGA supervisor: Designated TB officer at the LGA level responsible for coordinating and supporting TB activity implementation, including monitoring and evaluation.

TB notification: The process of reporting diagnosed TB cases to relevant health authorities, which in turn report to WHO through the NTP.

State TB program manager: Designated officer at the state ministry of health responsible for coordinating all TB related activities in the state.

Underreported TB case: A TB case that was detected in hospital or laboratory records but not present in the subsequent TB reporting registers, or a gap in collated numbers between the reporting levels.

Assumptions

The current study assumes that data quality checks were ensured during the primary study with the complete database and containing all the necessary variables and information for the secondary research. Furthermore, all NTP-engaged health care facilities are using the same updated TB R&R tools and processes as described in the TB Workers Manual. Finally, the TB case reporting practices in 2015 are still relevant in 2018.

Scope and Delimitations

Data from Lagos State alone was used in this study as it was the only state in Nigeria where the TB inventory study was conducted. The research emphasizes the completion of reporting rather than TB data quality elements. TB diagnostic methods and tools, treatment strategies and regimens, and outcomes were not part of the study. The study did not assess the skills, knowledge, and attitudes of health care workers on the use of TB R&R tools. Implementation of the electronic reporting system was not evaluated since it is currently under phased implementation by the NTP. The primary emphasis of this study was to assess TB reporting by different levels and types of health care facilities and associated factors (volume of TB patients per facility, number of DOTS centers per LGAs, type of TB disease, site of TB disease, HIV status, and patients demographic characteristics) influencing TB reporting practices.

Limitations

The limitations of the study are related to the inherent limitation of a retrospective study design and use of secondary data, which includes challenges with data quality and

the likely misalignment between the secondary dataset and current research questions.

Two unique limitations for an inventory study in a situation like Nigeria include the lack

of unique identification numbers which makes it difficult to match patients between

different levels of registration, and secondly, patient movement and self-referral make it

equally challenging to match patients since only 25% of non-TB engaged facilities were

sampled in the primary study. The data analyzed included TB cases reported in 2015,

while the health care workers and TB staff were interviewed in 2017, therefore, there was

the possibility that the health care workers who reported the TB cases in 2015 were not

the same as the health care workers interviewed in 2017. The study was only conducted

in Lagos which is not representative of Nigeria (the peculiarities of Lagos include

population density, a high proportion of private health care facilities, higher

socioeconomic and educational status of people and the health care worker/population

ratio). Pharmacists and patent medicine vendors were not included in the study despite

constituting a sizable portion of health care providers (40%) and being considered as

first-line providers of care for an average of 50% initial consultations for acute illnesses

(Beyeler et al., 2015). The study was based on the paper-based TB reporting system, even

though the program commenced phased implementation of electronic TB reporting.

Significance

This was a unique study considering the sequence of TB reporting in both private

and public health facilities, including NTP-engaged and non-NTP-engaged facilities with

the assumptions that TB underreporting and associated factors may vary among these

facilities. Furthermore, it assessed the TB underreporting between the different levels of

the NTP reporting system (health care facility to LGA TB registers and LGA TB registers to the State TB program). Another attribute of this study was that it assessed the entire reporting process, from awareness of health care workers, availability of tools, ease of use of reporting tools, workload, and a support system to coordination with the NTP within the context of the Nigerian health care system. The study was based on IBM with additional constructs from the precaution adoption process model (PAPM). IBM implies that a particular behavior is most likely to occur if the person has an intention with adequate knowledge and skills; if there are no environmental constraints or barriers to actualizing the behavior, the behavior is salient, and the individual has significant experience in performing the behavior (Glanz et al., 2008; Yzer, 2008).

Therefore, the findings of this study will have a significant effect on the following levels: patient, community, and health system. The timeliness, accuracy, and completeness of R&R of TB cases will provide information on the quality of care at the patient level by providing information on the type of diagnostic method used and treatment regimens provided, level of adherence and the treatment outcome. At the community level, it will give a better understanding of the burden of TB and its distribution for better planning and community engagement. In addition, at the public health level, it will enable understanding of the burden of TB to facilitate prioritization, planning, and appropriate resource allocation (Sismanidis et al., n.d.; WHO, 2012).

The sequence of the TB reporting approach will give a better understanding of the current situation by a different type of health care facility, including associated factors and will help to develop targeted approaches towards strengthening TB reporting

practices. The findings will be presented in existing TB platforms in Nigeria; annual TB review meetings (a yearly event for all stakeholders within TB program technical and funding agents), and the partners' forum meeting, which is a quarterly activity organized by the national TB program. The findings could assist the TB program and different TB stakeholders with input for reinforcing TB reporting. The resulting improvements in TB reporting would help in understanding the precise disease burden and its distribution, thus allowing effective planning and focusing on resource allocation to where it is most needed. TB reporting (including mandatory TB notification) is highlighted as an integral part of the regulatory framework for implementing the WHO End TB Strategy for ending the TB epidemic by 2030 (Uplekar et al., 2016).

Summary

TB underreporting is a global problem with over 3.6 million TB cases not reported and notified to the NTP with Nigeria contributing 9% of these globally missed TB cases with a current treatment coverage of only 24%. Factors associated with the missing TB cases include underreporting, under-diagnosis, and challenges related to the estimation of TB incidence. In Nigeria, there is a need for a better understanding of the factors associated with TB underreporting by assessing the cascade of TB reporting by all types and levels of TB reporting. The finding will be used to boost the TB surveillance system at all appropriate levels.

Chapter two reviewed available evidence on TB with emphasis on TB R&R tools, monitoring and evaluation frameworks, and gaps in the current evidence related to TB

underreporting. Chapter three described the detailed methodology, choices for analytical

methods, and possible limitations of the study methodology.

Chapter 2: Literature Review

Introduction

Nigeria has an estimated 73% of missing TB cases, with at least 302,906 drug-susceptible TB cases, 18,000 drug-resistant TB cases, and 48,550 childhood TB cases missing in 2017 (FMOH, 2017; WHO, 2018a). Three factors were responsible for the missing TB cases: underdiagnosis, underreporting, and uncertainty with the estimated TB incidence (Chin & Hanson, 2017; WHO, 2017). Inadequate TB data and TB underreporting can conceal the true burden and distribution of TB, leading to weak strategic planning, interventions, and allocation of resources (Sprinson et al., 2006). The purpose of this study was to assess and describe the cascade of TB reporting at different levels of the TB reporting system and to identify underreporting and associated factors.

The subsequent section of the chapter deals with the description of the literature review strategy with an emphasis on the key terms, search engines used, and the selection criteria for appropriate articles. The theoretical framework for the study is IBM with the central theme on intention as the key driver for behavior. Other constructs acknowledged by IBM include knowledge, salient behavior, environmental factors, and experience (habit). I discuss available evidence on TB burden, R&R tools and processes for TB, the magnitude of TB underreporting, associated factors with TB underreporting, and literature gap in the remaining sections of the chapter.

Literature Search Strategy

The literature search was on current evidence on TB burden, TB recording, reporting tools and processes, the magnitude of TB underreporting, and associated factors. Evidence was derived from quantitative, qualitative, and mixed methods studies using the following queries: *tuberculosis, TB reporting, TB notification, TB under-reporting, TB surveillance, TB recording and reporting tools, mandatory disease notification, disease reporting, missing TB cases, TB reporting Nigeria, TB under-reporting magnitude,* and *the performance of the NTP.*

I conducted the search using multiple sources including Google Scholar, PubMed, several databases of the Walden Library (Medline, CIHAHL plus), African Journal online, websites of national, international, and multilateral agencies such as FMOH, WHO, and the World Bank.

I selected articles based on the availability of full text, published from 2014 to 2018, and articles earlier than 2014 that were related to theories and theoretical frameworks. Other documents used included national guidelines and reports, WHO guidelines, policies, and reports, and several assessment reports on the Nigerian health care system, including disease surveillance.

Theoretical Foundation

Introduction to the Integrated Behavioral Model

Behavior is defined as an action directed at a target, performed in a certain context, and at a certain point in time (Yzer, 2008). The determinants of behavior are a complex interaction of multiple variables that are biological, biosocial, cultural, and

situational or context-specific (Bayram & Donchin, 2018). Individual behavior both affects and is affected by multiple levels of influence, and it shapes and is shaped by the social environment (Naestoft et al., 2005). The variables that influence behavior range from intrapersonal level, knowledge, attitude, beliefs, and personality traits; interpersonal level, family, group, peers, and role definition; to community level, rules, regulations, policies, and norms (Glanz et al., 2008; Rimer & Glanz, 2005). Other important factors in shaping or influencing behavior are age, gender, ethnicity/religion, education, income, and environment (Bayram & Donchin, 2018; Davis, Campbell, Hildon, Hobbs, & Michie, 2015).

The IBM was applicable in the assessment of TB underreporting and associated factors because reporting is a concrete behavior, influenced by multiple variables in the context of the health care system. IBM is a mixture of constructs from the TRA, the theory of planned behavior, and constructs from other theories with a central construct of *intention* (Branscum & Lora, 2017; Glanz et al., 2008; Rimer & Glanz, 2005). IBM was developed by Kasprzk & Montano in collaboration with Fishbein in order to further expand the different complementary constructs of TRA/TRB in the 1990s (Rimer & Glanz, 2005). It was modified with the addition of the following constructs: knowledge and skills to perform the behavior, salient attribute (motivational incentive) for the behavior, environmental constraints, and habit (Glanz et al., 2008; Murno, Lewin, Swart, & Volmink, 2007; Rimer &Glanz, 2005).

TRA was developed in the mid-1960s by Fishbein with the underlying assumption that relevant behaviors are under volitional control and behavioral intention is

the most important determinant (as cited in Murno et al., 2007; Rimer and Glanz, 2005). In TRA, it is assumed that the individual attitude towards the behavior and subjective norms influenced the behavior (Glanz et al., 2008; Murno et al., 2007; Rimer and Glanz, 2005). Fishbein and Ajzen modified TRA in the 1970s because the behavior is not always under volitional control of the individual by adding a construct on behavioral control perceived ease or difficulty (as cited in Glanz et al., 2008; Murno et al., 2007; Rimer & Glanz, 2005).

I modified IBM with additional constructs from the PAPM, which specifies seven distinct stages in the journey to behavior from lack of awareness, unengagement, decision about acting or not acting, decision to act, acting (behavior), and maintenance (Bahmani, Saeed, Mahmoodabad, & Enjezab, 2017; Rimer & Glanz, 2005). Three constructs (unaware, unengaged, and maintenance) were added to the existing IBM; unaware and unengaged were related to knowledge and performance of behavior while maintenance was related to habit (Glanz et al., 2008) (Figure 1).

Integrated Behavior Model (IBM)

* Constructs from Precaution Adoption Process Model (PAPM)
IBM adopted from Glanz, Rimmer, & Viswanah, 2008
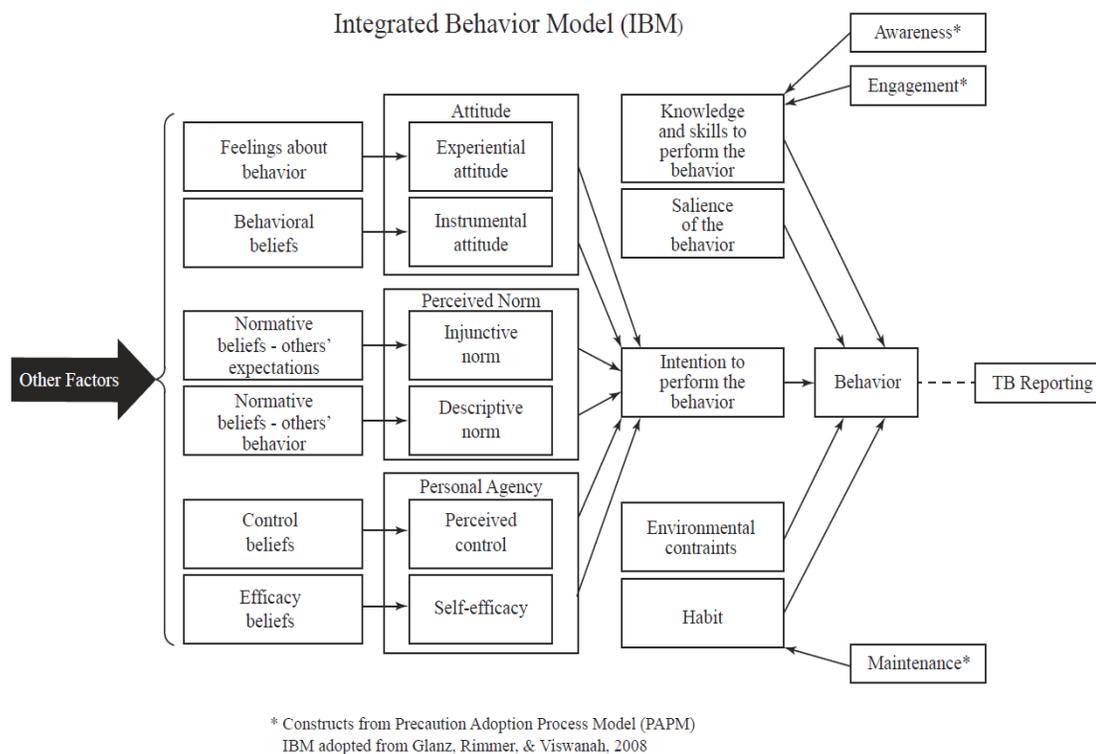
Figure 1. Integrated behavior model (IBM).

Constructs of Integrated Behavioral Model

In IBM, the most important predictor of behavior is the intention, and the strength of intention is mediated by three factors: attitudes toward the behavior, perceived norms, and personal agency (perceived control and self-efficacy; Chaisson et al., 2015; Glanz et al., 2008; Yzer, 2008). Attitude towards a behavior is an individual's evaluation of how favorable or unfavorable the individual is performing the behavior (Chaisson et al., 2015; Glanz et al., 2008; Yzer, 2008). The individual can have an emotional response to the idea of performing the behavior (experiential or affect), perception on the outcome of the behavior, or instrumental attitude (cognitive) on the outcome of the behavioral

performance (Glanz et al., 2008; Yzer, 2008). The social pressure a person expects to perform the behavior is called the perceived norm, which is categorized into injunctive and descriptive norms (Glanz et al., 2008; Yzer, 2008). Injunctive norm is the expectation of social networks and the motivation to comply, while the descriptive norm is the extent to which members of the networks perform the behavior (Glanz et al., 2008; Yzer, 2008). The personal agency consists of two constructs: perceived control and self-efficacy. Perceived control is the perception of the individual on various environmental factors that influence the behavior (either easy or difficult to carry out the activity); and self-efficacy is the degree of confidence in the ability to perform the behavior, which should not be confused with competency (actual skills; Glanz et al., 2008; Yzer, 2008).

The additional constructs in IBM imply that a particular behavior is most likely to occur if the person has an intention supported by knowledge and skills, if there are no environmental constraints or barriers to performing the behavior, if the behavior is salient, and if the individual has significant experience performing the behavior (Glanz et al., 2008; Yzer, 2008). Three constructs from PAPM (unaware, unengaged, and maintenance) were added to the adopted IBM framework, awareness (knowledge) and engagement with the issue, facilitate decision-making to perform the behavior (Glanz & Rimer, 2005; Marlow, Ferrer, Chorley, Haddrell, & Waller, 2018). Behaviors expected to occur more than one time or routinely require a habitual pattern to ensure the maintenance of the behavior; consequently, this requires both experience and a facilitating mechanism or environment (Glanz et al., 2008; Rimer & Glanz, 2005; Marlow et al., 2018).

IBM was applied in studies to increase safe sex in Zimbabwe with a behavioral focus on using condoms all the time with action (using), target (condom), and context (all the time; Glanz et al., 2008, pp. 80-85). Attitude, perceived norm, and self-efficacy significantly influence the use of condoms all the time (Glanz et al., 2008). Branscum and Lora (2017) reported that autonomy significantly influences intention, which in turn significantly predicts the behavior of mothers in monitoring their children's intake of fruits.

Relating Integrated Behavioral Model and Tuberculosis Reporting

IBM was adopted because TB reporting involves people, tools, processes, and the use of technology (Ali et al., 2018). The act of TB reporting (behavior) is a component of quality of care for TB patients and a requirement by law as a public health function (mandatory notification) (WHO, 2018c; Podewils et al., 2016). IBM predicts people act on their intentions when they have the necessary skills, and when environmental factors do not impede behavioral performance (Yzer, 2008). Therefore, adherence to TB reporting can be explored using behavioral theories (Chaisson et al., 2015) especially the adopted IBM as mentioned above which shows the complex relationship between attitude, perceived norm and person agency with other constructs of knowledge, engagement, environmental factors, and maintenance or habit with the behavior.

Considering the fact that TB is a notifiable disease by law, the IBM model provided an opportunity to explore health care workers' attitude to TB reporting. Health care workers who were aware of mandatory TB reporting have a positive attitude to TB reporting even though they pointed out perceived concerns on patient confidentiality

(Glaziou et al., 2015; Iwu et al., 2016; Thomas et al., 2016; Tollefson et al., 2016). The perceived norm among professional colleagues regarding reporting was lack of clarity of roles in TB reporting and lack of trust in and coordination with the public health system (Philip et al., 2015; Satpati et al., 2017; Yeole et al., 2015). Concerning self-efficacy and competence, health care workers reported the cumbersomeness of TB reporting tools and processes (Glaziou et al., 2015; Iwu et al., 2016; Koivu et al., 2017). Knowledge, availability of tools, engagement by the NTP, patient-related factors, non-enforcement by regulatory bodies, and multiple reporting tools formats are all considered as factors associated with TB underreporting, which IBM recognizes (Ahmadi et al., 2015; Coghlan et al., 2015; Glaziou et al., 2015; Thomas et al., 2016; Yeole et al., 2015).

Literature review on Key Variables

Tuberculosis Disease

Tuberculosis (TB) is an infectious disease usually caused by *Mycobacterium tuberculosis complex* (Onuka et al., 2018). The risk of TB acquisition is dependent on many factors including the prevalence of pulmonary TB in a population, early diagnosis and enrollment to care with quality medicine, adherence to treatment, close contact with an infectious TB case and bacillary density in the air (overcrowding or poor ventilation) (Fox et al., 2017; Maail et al., 2004; Sharma &Liu, 2006).

The outcome of TB infection is a spectrum with only 5-15% of individuals ever developing TB disease in their lifetime with the highest risk during recent primary infection (12-18 months) (Fox et al., 2017; Sharma & Liu, 2006). Some predisposing factors associated with progression from TB infection to TB disease identified are

HIV/AIDS, extreme age (<2-3 years and the elderly), chronic malnutrition, diabetes, chronic renal disease, and silicosis (Basera et al., 2017; Sharma et al., 2015). While Fox et al. (2017) grouped the risk factors into the following categories: high-risk (HIV infection, age <2-3 years, chronic renal disease, organ/stem cell transplant, and TNF-α inhibitors), intermediate-risk (age 3-4 years, silicosis, severe underweight, and poorly controlled diabetes) and low-risk (diabetes and steroid therapy).

Strategies for Tuberculosis Control

The underpinning strategies for TB control have been early case finding with quality diagnosis, provision of quality anti TB medicines, patient support to ensure adherence, preventive therapy, improvement of patient access by promoting public-private partnerships, and effective community awareness and engagement (FMOH, 2015b; WHO, 2014). TB control strategies have evolved since WHO declared TB a global emergency in 1993 with the launching of the Directly Observed Treatment Short-Course (DOTS) Strategy in 1995 which evolved into the Stop TB strategy in 2006, and currently, the End TB strategy (Dirlikov et al., 2015; Harries et al., 2018). The DOTS strategy had five key elements which included

- Political commitment with increased and sustained financing

- Case detection through quality-assured bacteriology

- Standardized treatment, with supervision and patient support

- Effective drug supply and management system

- Monitoring and evaluation system and effect measurement.

The Stop TB strategy was an improvement compared to the DOTS strategy. The Stop TB strategy had six components, and the first was an enhancement of the DOTS strategy. The six components were:

- Pursue high-quality DOTS expansion and enhancement

- Address TB and HIV, MDR TB, and other challenges

- Contribute to health system strengthening

- Engage all care providers

- Empower persons with TB and communities

- Enable and promote research.

Finally, this strategy was followed up by the End TB strategy, 2016-2035, launched by WHO in 2015 with clear targets and three strategic pillars. The targets are; a 95% reduction in tuberculosis deaths (compared with 2015), 90% reduction in tuberculosis incidence rate (less than ten tuberculosis cases per 100 000 population), and no affected families facing catastrophic costs due to tuberculosis (WHO, 2014; Dirlikov et al., 2015). The three pillars of the End TB strategy are: integrated patient-centered care and prevention, bold policies and supportive systems, and intensified research and innovation (WHO, 2014; Dirlikov et al., 2015). TB R&R, notification, and surveillance system are consistent with all TB control strategies.

Tuberculosis Burden

TB has remained a global public health challenge, WHO estimates that one-third of the global population is infected with TB (Furtado da Luz & Braga, 2018; Sulis et al., 2014). 23% of the world population is estimated to have latent TB infection (WHO,

2018b). TB is one of the top ten causes of death and the leading cause of a single infectious agent (Floyd et al., 2018). TB affects all countries and all age groups, however, 90% of TB cases are among adults, and 9% are among people living with HIV/AIDS (PLHIV) (WHO, 2018b). In 2017, WHO estimated 10 million cases of TB worldwide, and eight countries accounted for two-thirds of the cases (India, China, Philippines, Pakistan, Indonesia, South Africa, Nigeria, and Bangladesh) (WHO, 2018a). Also, 2.6% and 17% of new cases and previously treated cases were estimated to have drug-resistant TB, respectively (WHO, 2018a; WHO, 2018b). There has been a reduction of TB incidence all over the world by 2% annually and TB mortality reduction from 23% in 2000 to 16% in 2017 (WHO, 2018b).

An average of 40% of estimated TB cases were either not detected or not reported to NTPs and WHO in both 2016 and 2017 and there is no adequate information on the quality of care or treatment outcomes among these groups of TB cases (Tollefson et al., 2016; WHO, 2018b; Chin & Hanson, 2017).

Tuberculosis Routine Surveillance System

Surveillance is a continuous, systematic collection, collation, analysis, and interpretation of data related to disease occurrence and public health-related events and the dissemination of the information for prompt public health action (Mansuri et al., 2014), while disease notification such as TB is a requirement by law for timely reporting of incidence of specific diseases and conditions to designated public health authorities by health care staff, and laboratory staff using designated tools (Mansuri et al., 2014; WHO, 2014; WHO 2008). TB has a structured, vertical and hierarchical reporting and

notification system from health care facility level through the TB BMU to the NTP and eventually to WHO (Sharma et al., 2015; WHO, 2014). The routine TB surveillance system is based on TB reporting and notification using standard definitions, recording, and reporting tools, and processes (WHO, 2014; WHO 2008). Countries can adopt the tools but must obligatorily ensure the use of standard definitions to enable performance monitoring and evaluation and comparison between different BMUs and countries.

The TB R&R tools were placed in line with patients' flow from the community using community referral forms, to the different service delivery points within the health care facility. Figure 2 below provides a schematic diagram on the placement of tools according to the reporting processes and levels. It is noticeably observed in figure 2 that most of the TB R&R tools are at the health care facility level. Within the health care facility, these TB R&R tools are at different service delivery points depending on the size of the facility; from the general outpatient unit, laboratory unit, HIV/AIDS clinic, pharmacist, and other special clinics (pediatrics, surgery, diabetic, and inpatient wards). The TB reporting tools reduce in number and complexity in the hierarchy of the reporting system from health care facilities to the NTP, as shown in Figure 2 below.

Placement of recording and reporting tools
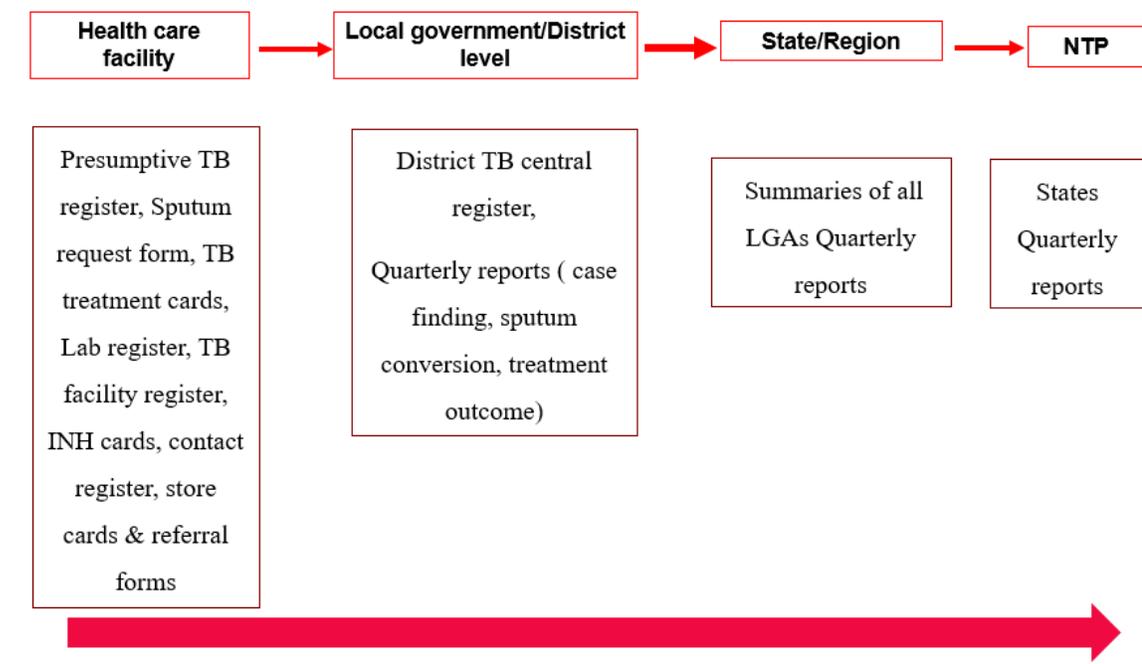
Figure 2. Hierarchy of Tuberculosis reporting process. Adapted from National Strategic Plan for TB Control 2015-2020 (FMOH, 2015b).

Health care workers complete the different forms based on the standard definitions including all variables related to the patient, and laboratory technicians complete the laboratory register with variables documented on the specimen request form (FMOH, 2015b). Subsequently, all records from the different facilities were collated to the TB BMU (LGA) by a designated LGA TB supervisor using the quarterly TB reporting tools (the same reporting tools are used to aggregate TB reports for the regional and national levels using predefined TB reportable indicators) (WHO, 2014; WHO 2008; FMOH, 2015b). Only aggregated TB indicators are reported to NTP and WHO without patient-level data in many countries (WHO, 2014; FMOH, 2015b).

The routine TB surveillance data was used for performance improvement at the facility level and program planning at the LGA/district, state/region, and national level. Quality TB surveillance data is used by WHO as an alternative for measuring TB incidence at national and global levels especially where there are no TB prevalence surveys (Chen et al., 2014; Sismanidis et al., n.d.;). The routine TB surveillance data support the evidence-based decisions, prioritization of TB activities, and resource allocation especially among policymakers and development partners (Chen et al., 2014; Gibbons et al., 2014). Other functions of the surveillance data include planning, monitoring trends, and evaluating interventions and measuring outcomes (Chen et al., 2014).

Nigerian Tuberculosis Program

Nigerian Health Care System and Governance

The estimated Nigerian population for 2017 was 192 million (WHO, 2018a). Nigerian had 43.9% of the population below 15 years and a growth rate of 3.2% (FMOH, 2015b). Nigeria made progress with health indicators but unfortunately remained among the worse globally with the second largest burden of under-five mortality (850,000 under-five deaths per year) (FMOH, 2015b). Other health indices were infant mortality of 79/1000 live births, 25% of full immunization for children, and skillful antenatal care coverage ranges from 41% in the north-west to 90% in the south-west (FMOH, 2015b; National Population Commission (NPC), 2013).

Only 6.7% of the national budget was spent on health in 2014; 72% of health care expenses were out-of-pocket, 25% by the government, and 3% from other sources (Result

4 Development (R4R), 2014). The FMOH estimated 23,640 health care facilities

nationwide, of which 85.8% were primary health care, 14% secondary, and only 0.2%

were tertiary health care facilities (FMOH, 2015b). The private health care facilities

constituted 38% of the total health care facilities with 60% of the Nigerian population

accessing health care services in the private sector, and 39% of Nigerians used medicine

vendors as their first point of accessing health care (R4R, 2014).

Nigeria operates a Federal System of Government, which constitutes of the

Federal Capital Territory, 36 States and, 774 Local Government Areas. Health is on the

concurrent list with the state government, and LGAs responsible for the financing and

delivery of health care services at the primary and secondary health care levels, while the

federal government supports tertiary health institutions, coordinates, and finance many

national programs like HIV/AIDS, Malaria, TB, and Polio (FMOH, 2010).

The Nigerian health care system is organized in line with the three tiers of

government with clear roles and responsibilities and coordinated complementary roles

(FMOH, 2005; FMOH, 2010). The Federal government provides general policy

documents, guidelines, and standard TB R&R tools and manages all tertiary health care

facilities. The State government manages all secondary health care facilities and plays a

significant role in monitoring, supervision, and evaluation, while the Local government

manages all primary health care facilities including public health interventions at

community levels (FMOH, 2010; FMOH, 2015a).

Structure for Tuberculosis Control in Nigeria

The TB program in Nigeria is structured in line with the health system order; the National TB Program at the FMOH, the State TB program within the State Ministries of Health, and Local Government TB Program within the Primary Health Care (FMOH, 2015a; FMOH 2015b; FMOH, 2017). These structures are for public health responses to TB in the areas of policies and guidelines, planning, coordination, logistics and procurement of commodities, capacity building, monitoring, supervision, and evaluation (FMOH, 2015a). There are designated staff at each level with distinct roles and responsibilities. Below is a summary of the roles and responsibilities of designated TB staff at various levels of the Nigerian TB program (Figure 3)

National coordinator: Coordination, collaboration and resource mobilization

State TBL coordinator: Manage, coordinate and supervise all TB activities in the State

LG TBL supervisor: Plan, coordinate, implement and report all TB related activities at LGA

General Health care workers: Provide cascade of care for TB patients including recording and reporting
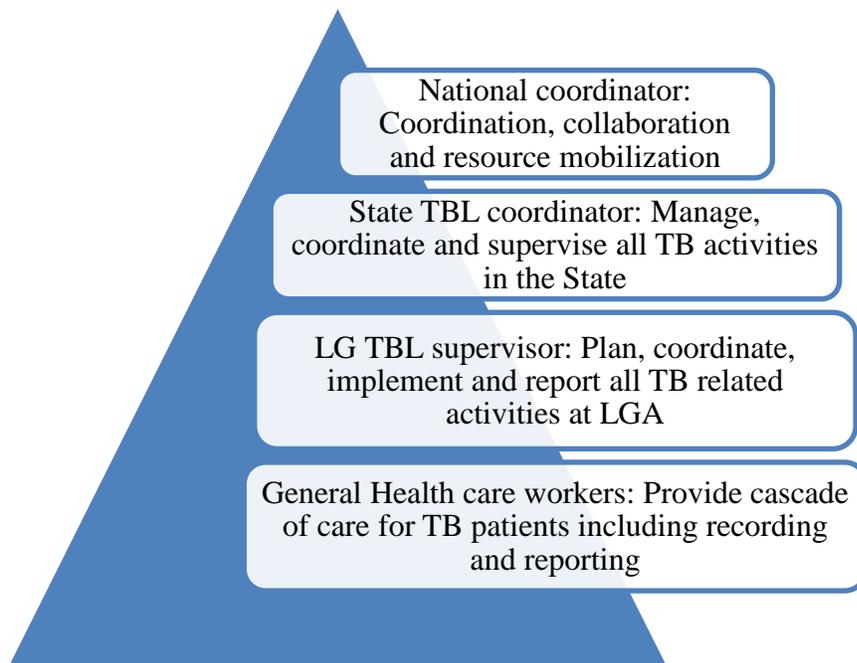
Figure 3. National Tuberculosis Program organizational structure.

TB patient care and support services are delivered at the various levels of the health care system (primary, secondary, and tertiary) including private health care facilities and communities. The National TB Control Program (NTP) has national guidelines for TB management including standard definitions of TB disease, classification, treatment regimens, and treatment outcomes, as well as standard TB R&R tools at all levels (FMOH, 2015a). The NTP develops, prints, and distributes TB reporting and recording tools to all health care facilities within the NTP network (NTP-engage health care facilities) to ensure standardization (FMOH, 2015a). The TB program monitoring and evaluation framework is a reflection of the integrated disease surveillance and reporting framework and process (Figure 4).
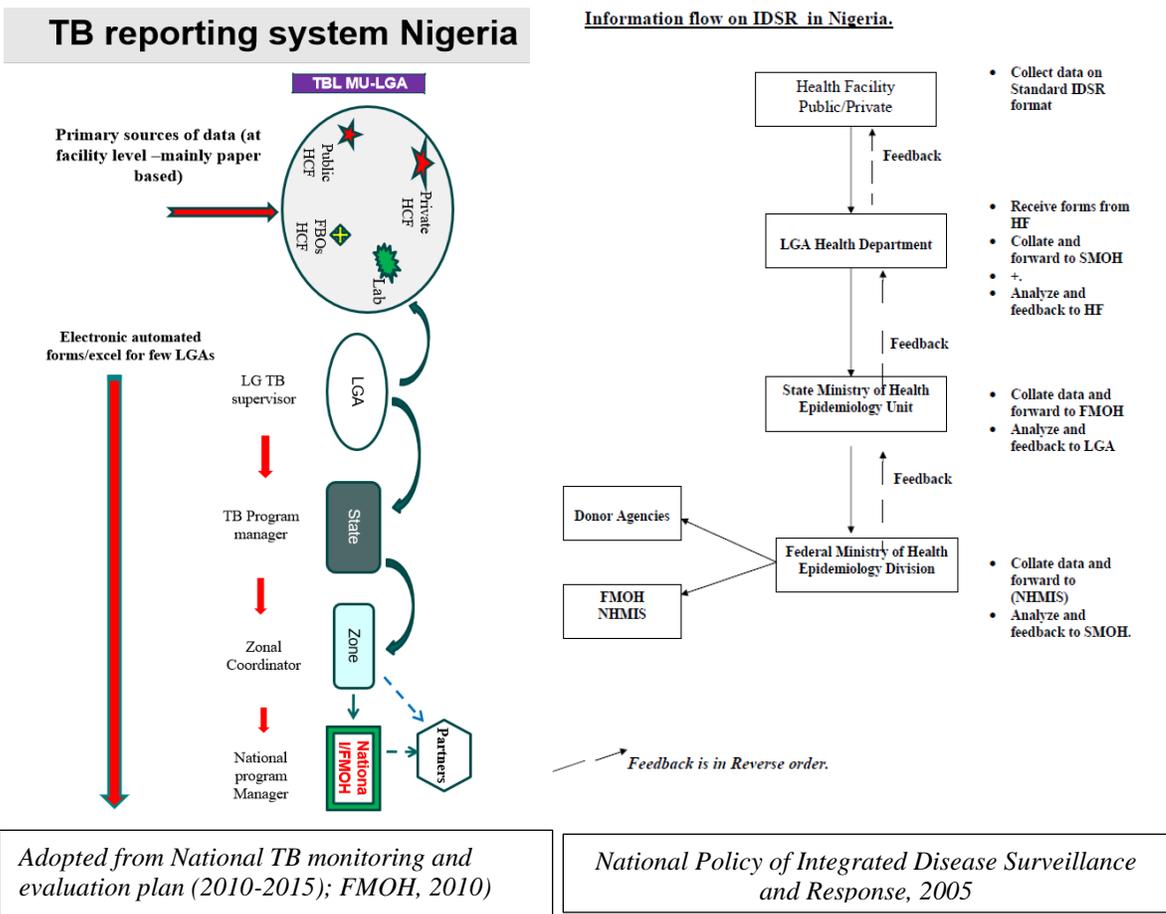
Figure 4. Comparison of Tuberculosis and Integrated Disease Surveillance and Response reporting processes in Nigeria.

As shown in Figure 4, both the TB reporting and Integrated Disease Surveillance and Response (IDSR) have the health care facility as the primary source of data and is mainly paper-based information system (Aruna, Nsofor, Oyediran, 2018; Iwu et al., 2016). Similarly, the LGA is the Basic Management Unit in both TB reporting and IDSR with designated officers called LGA TB Supervisor and Disease Notification and Surveillance Officers (DNSOs), respectively (Aruna et al., 2018; Iwu et al., 2016). The LGA TB supervisor and the DSNO are all within the same departments at the LGA and report to same state ministries of health except at national level where TB is in the FMOH and the IDSR is managed by the Nigerian Center for Disease Control (NCDC) (Aruna et al., 2018; Iwu et al., 2016). The health care workers document all presumptive TB cases in the presumptive TB registers and the TB laboratory register. All confirmed TB cases (bacteriologically or clinically) are commenced on treatment and documented on the TB treatment card, and subsequently, in the TB facility register, this is a similar approach for all other notifiable diseases through the IDSR using appropriate forms (Aruna et al., 2018; FMOH, 2015a; FMOH, 2015b).

In the TB program the LGA is considered as the BMU with a designated LG TB supervisor who among other functions is responsible for regular visits to all TB service delivery facilities in the LGA to collect TB information into a TB LGA central register and update the information of each patient on a regular basis including the treatment outcomes (FMOH, 2015a; FMOH, 2016). The LG TB supervisor uses quarterly reporting tools to summarize TB case findings and treatment outcomes for the LGA and report to the State TB program. At the State TB program office, a designated M&E officer collates

and analyzes TB data from all LGAs in the State to produce a State quarterly report which is reported to the NTP (FMOH, 2010; FMOH 2015a, FMOH, 2015b). The TB program has a structured feedback and data quality assurance mechanism through supervision, regular data quality visits, and quarterly data review meetings to validate TB data (FMOH, 2015a; FMOH 2010).

Therefore, TB is reported through two systems (NTP and IDSR) but the differences between the TB reporting system and IDSR as related to TB include: different variables in the reporting tools (TB tools have more variables including treatment outcomes), three forms for reporting (quarterly case finding form, sputum conversion, and cohort report) and reporting in the IDSR form 003 once a month without details of diagnostic methods, treatment regimens and no treatment monitoring variables and outcome (FMOH, 2016; Aruna et al., 2018). IDSR tools are available in almost all health care facilities, while TB reporting tools are mainly available within the NTP engaged facilities (Aruna et al., 2018).

Both TB M&E, IDSR, and the general Health Information Management System (HIMS) share common problems (Abubakar, Idris, Nguku, Sabitu, & Sambo, 2013; Aruna et al., 2018; FMOH, 2005, 2010, 2015a, 2015b; Isere et al., 2015; Iwu et al., 2016). These are stated below:

- Mostly paper-based reporting with difficulties in the physical storage of the papers.
- Too many R&R tools (24 different forms at the facility level and 43 different reporting templates).

- Irregular supply of the R&R tools.

- Frequent changes in the R&R tools.

- Vertical data reporting system and lateral collection of data by partners.

- Low awareness and capacity among different health care workers on R&R tools.

- Weak coordination between different reporting systems.

- Weak engagement of private health care providers.

- Inadequate logistic support for supervision and data quality assurance interventions.

Tuberculosis Burden in Nigeria

Nigeria is categorized as TB, TB/HIV and MDR-TB high burden country with an estimated TB burden of 219/100,000 population with 4.3% of the new TB cases and 25% of the previously treated TB cases having MDR/RR-TB (FMOH, 2017; WHO, 2017; WHO, 2018a). Nigeria accounts for 4% of the global burden of TB and contributes 9% to all missing TB cases (WHO, 2018a).

Nigerian Tuberculosis Service Delivery and Performance

Nigeria has a TB service coverage of 26.1% (7,389 DOTS facilities) among all health care facilities (public and private), and less than 5% of the TB facilities are among all private health care facilities (FMOH, 2017). The TB facilities are predominantly secondary health care facilities (75.8%) (FMOH, 2017). Nigeria has only 390 GeneXpert sites with 48% LGA coverage and 2,650 microscopy centers (with at least one

microscopy center for every 80,000 population). However, population coverage is not equal to access, functionality, and utilization (Gidado et al., 2018; FMOH, 2017).

By the end of 2017, only 69% of the existing TB facilities (DOTS centers) reported a TB case (FMOH, 2017). The TB treatment coverage for 2017 was 27% (104,904 TB cases reported; 13.4% TB/HIV co-infected) and only 11% of the estimated MDR-TB patients were diagnosed (FMOH, 2017; WHO, 2018a). The number of TB cases reported varies significantly by states in Nigeria, using a case notification rate per 100,000 for comparison with a national average of 54/100,000 population and a range of 11/100,000 population for Ekiti State to 124/100,000 population for Sokoto State (Figure 5) (FMOH, 2017).

CNR per 100,000 pop for all forms of TB in 2017
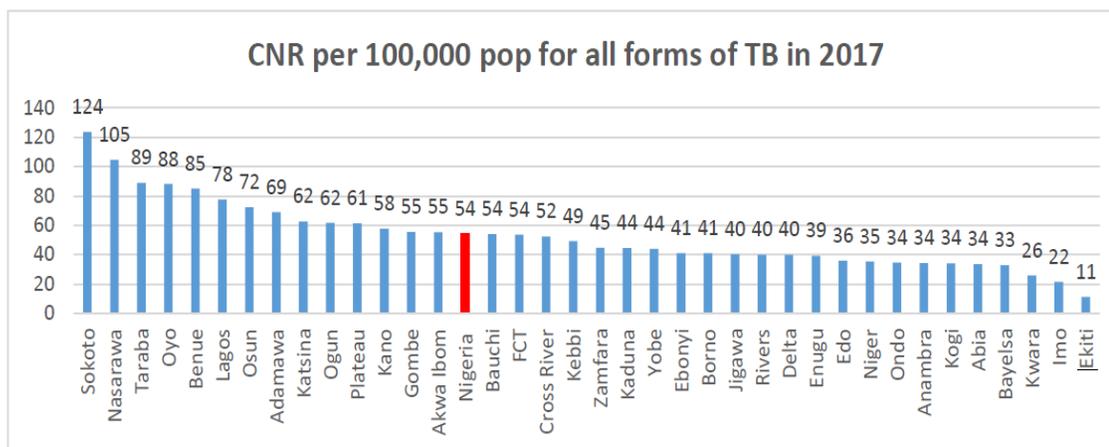
Figure 5. Tuberculosis case notification rate per 100,000 population by states. Source: NTBCP annual report 2017 (FMOH, 2017).

Despite the low case finding for both drug-sensitive and drug-resistant TB, the TB case holding is good with the following treatment success rates among all forms of TB, among TB/HIV coinfected and MDR-TB: 85%, 79.7%, and 74%, respectively (FMOH,

2017; WHO, 2018a). The low performance of the Nigerian TB program with 76% missing or under-reported TB cases is attributed to low TB service coverage with resulting TB under-diagnosis, underreporting of TB among the NTP network facilities, underreporting from private sector, and weak coordination between the TB reporting system and the IDSR system (FMOH, 2017; Iwu et al., 2016; Aruna et al., 2018).

Tuberculosis Underreporting

The global magnitude of TB underreporting was 40% in 2017, and the three attributable factors were under-diagnosis, underreporting, and challenges with TB estimates (Chin & Hanson, 2017; WHO, 2018a). TB reporting is part of the WHO standards of TB care (WHO standard 27) (WHO, 2018c) which states that "all providers *must* report both new and retreatment TB cases and their treatment outcomes to national public health authorities conform applicable legal requirements and policies." TB reporting is a process of reporting diagnosed TB cases from all care providers to relevant health authorities which in turn report to WHO (Uplekar et al., 2016) and this process involves people, processes, and tools with clear roles and responsibilities; standard definitions, standard reporting tools, and, guidelines (Ali et al., 2018; WHO, 2014). Therefore, TB underreporting covers TB cases diagnosed, detected in health care facilities records but not present in the TB registers of the corresponding public health department (Morales-García et al., 2015).

Direct measurement of TB underreporting or under-diagnosis is challenging especially in TB high endemic countries where presumptive TB cases can access care either in the private, public or other non-NTP facilities without effective referrals or

linkages (WHO, 2012). Another challenge to direct TB measurement in High TB Burden

Countries (HBC) is the fact that individuals have no unique identification number or

there is a lack of a comprehensive database for TB patients (WHO, 2012). Inventory

studies are widely used to assess the magnitude of TB underreporting by comparing the

number of TB cases meeting the standard definitions recorded at health care facilities

(public or private) with the TB cases notified to the local and national authorities]

(Sismanidis et al., n.d.; WHO, 2012). This comparisons between facility data and local or

national databases require 'record linkages' which can be done by deterministically

(using unique identification number) or probabilistically using a combination of patient

characteristics (for example, age, sex, phone number) (Sismanidis et al., n.d.; WHO,

2012). The following are important facilitating factors for conducting quality inventory

studies: availability of case-based data at all reporting levels and not only aggregated

data, use of standard definitions by all health care providers, adequate staffing,

involvement of care providers outside the NTP network, and existence of at least three

fairly independent data sources (Sismanidis et al., n.d.; WHO, 2012).

TB underreporting is a symptom of a broader public health surveillance problem

and functionality of the general health system. The magnitude of TB underreporting

varies between nations and within the same country (Uplekar et al., 2016). Sismanidis et

al. (n.d.) stated that: TB underreporting found was context-dependent ranging around

15% in European countries, 20% in Africa, 30% in the Eastern Mediterranean region, and

50% in countries in Asia with a large private sector. Studies in different countries found

different results, for example, Mlotshwa et al. (2017) reported a magnitude of 34%

underreporting of smear-positive TB cases between facility paper-based records and the

NTP records in Kenya. Similar findings were published by Bassili et al. (2010), Furtado

da Luz & Braga (2018), Morales-García et al. (2015), and Fatima (2015) with

underreporting of 29% in Yemen, 40% in Cape Verde, and 14.4% (0 to 45.2%) in Spain

and 27% in Pakistan, respectively. The just-concluded TB inventory study in Lagos

reported an estimated TB underreporting of 42% (Mitchell et al., 2018).

Non-Adherence to disease reporting and notification is not only related to TB but

to most notifiable diseases (Aniwada & Obionu, 2016; Iwu et al., 2016; Phalkey et al.,

2015). The common challenges with surveillance systems by health care workers include

low awareness of their roles, ignorance on the reporting guidelines, reporting tools,

processes, and the list of the notifiable diseases. Further considerations are

cumbersomeness of the TB reporting tools, workload, inadequate capacity to complete

the TB reporting tools, and weak coordination and communication between the different

levels of reporting (Iwu et al., 2016; Abubakar et al., 2013; Ledikwe et al., 2014).

Aniwada & Obionu (2016) reported a significant difference between public and private

health care providers' knowledge and practices on disease surveillance and notification.

Only 27.5% of private providers compared to 50% of public providers knew the correct

definition of IDSR, 25% of private health care providers compared to 57.5% public

health care providers had accurate knowledge of reportable diseases, 40% of private

health care providers compared to 85% public health care providers reported a notifiable

disease from their facilities, and only 7.5% of private health care facilities had designated

health care worker for reporting compared to 55% in the public health facilities (Aniwada & Obionu, 2016).

Associated factors for TB underreporting can be grouped under the following: disease and demographic characteristics of the patients, availability and utilization of TB R&R tools, capacity and knowledge of health care workers on TB reporting, coordination between different service points and reporting agencies including weak enforcement mechanism, and concern on patients privacy and stigma (Ahmadi et al., 2015; Aruna et al., 2018; Gibbons et al., 2014; Koivu et al., 2017). The following disease and demographic factors were associated with TB underreporting in both bivariate and multivariate analysis, smear-negative or TB cases with scanty results, extra-pulmonary TB cases, TB cases with normal or non-cavitary lesions or TB cases without symptoms (Furtado da Luz & Braga, 2018; Morales-García et al., 2015; Tollefson et al., 2016). TB underreporting is associated with patients above the age of 55 years, retirement, smoking history, and immigrants (Furtado da Luz & Braga, 2018; Morales-García et al., 2015; Tollefson et al., 2016).

TB underreporting was significantly associated with health care workers' low knowledge and competency on the use of TB reporting tools and understanding of TB reporting procedure and processes (when, where, and to whom?) (Gibbons et al., 2014; Mansuri et al., 2014; Sismanidis et al., n.d.). The workload from multiple disease reporting tools with different formats and deadlines from vertical disease programs were associated with overall disease underreporting by health facility staff (Bassili et al., 2010; Koivu et al., 2017; Yeole et al., 2015; Benson et al., 2018). Health care workers reported

concerns on patients' confidentiality, fear of stigmatization and discrimination as important factors for not reporting TB cases (Bassili et al., 2010; Mansuri et al., 2014; Tollefson et al., 2016; Yeole et al., 2015).

Health system-related factors for TB underreporting include weak linkages, poor coordination, and ineffective referral mechanisms within and between health care facilities and other reporting agencies or programs like HIV/AIDS or DNSO reporting mechanisms (Aruna et al., 2018; Tollefson et al., 2016). TB underreporting was associated with TB cases diagnosed from large health care facilities, private health care facilities, and facilities from TB high burden regions (Tollefson et al., 2016).

Summary and Conclusion

TB is a notifiable disease by law in many countries, including Nigeria. TB reporting by all health care workers is considered as a component of standard care. However, TB underreporting is a global problem, with 40% of all incidence of TB cases not reported to the NTP. In Nigeria, the actual magnitude of TB underreporting is unknown, it is suggested that 76% of estimated TB cases were missing in 2017 (FMOH, 2017; WHO, 2018a). The evidence on TB underreporting was context-dependent ranging from as low as 15% in Europe to 50% in Asia (Sismanidis et al., n.d.).

The associated factors to TB underreporting are grouped as follows: disease and demographic characteristics, availability and utilization of R&R tools, capacity and knowledge of health care workers, coordination between different service points and reporting agencies including enforcement, and concern about the patient's privacy and stigma.

Current knowledge of both magnitude and associated factors for TB

underreporting was not presented based on the cascade (sequence) of TB reporting and

not differentiated by levels of care in many of the existing studies. Nigeria, with its high

proportion of TB missing cases, has no evidence on where or what level and why TB

cases have remained under-reported. Therefore, using secondary data, this study

proposed to approach the assessment of TB underreporting in Nigeria by different levels,

types and reporting agencies to enable better target interventions to improve TB

reporting.

Chapter 3: Research Method

Introduction

The purpose of the study was to assess and describe TB reporting at different levels of the Tuberculosis Reporting Systems in Lagos, Nigeria. The study used the secondary database from a TB inventory study conducted in Lagos, Nigeria. The primary research was conducted in 2017 as an inventory study of TB cases reported in 2015 and a cross-sectional survey among health care workers on TB reporting knowledge, practices, and behavior. In this chapter I describe the study design and the assessment of the secondary database.

Furthermore, I describes the application of the IBM theory to develop a schematic diagram of the relationship between different health care facilities and reporting levels. This chapter describes the relationship between, as well as all variables concerning, the research questions and hypotheses. Conclusively, in this chapter I describe the data analysis plan, the ethical procedure, and considerations for approval and the threats to the validity of the data.

Research Design and Rationale

The study design was a quantitative descriptive study using secondary data from an inventory study on TB reporting knowledge, attitude, and behavior conducted in 2015 in Lagos State, Nigeria. The secondary dataset was used to assess the association between the independent variables of different types of health care facilities (public and private), levels of health care facilities (primary, secondary, and tertiary), NTP-engagement status (NTP-engaged and non-NTP-engaged), health care workers knowledge of TB reporting,

and barriers for TB reporting, and TB reporting as the dependent variable (outcome variables). Other associated factors considered as independent variables included the volume of patients per health care facility, the volume of DOTS centers per LGA (number of TB service delivery points in an LGA), and patients characteristics (a type of TB disease, site of TB disease, HIV status, and patient's age and gender). Mediating variables included the availability of TB R&R tools and the existence of supervision and feedback from NTP at various levels (LG TB supervisor, and State TB program).

Description and Assessment of the Secondary Data Source

Study Setting

Lagos State is one of the most densely populated states in Nigeria, with a population of 12 million people (National Bureau of Statistics, 2017). Lagos State has a population growth of 600,000/year and a population density of 4,193 persons/Km^2; other characteristics of Lagos population include a poverty rate of 64.1% (with 1$ per/day), an unemployment rate of 19.5%, and an adult literacy for both genders above 85% (Adedeji, James, Folarin, & Ngozi, 2016). The health indices for Lagos are a life expectancy of 51 years, an infant mortality rate of 39/1,000 live births, an under-5 mortality rate of 83/1,000 live births, and a maternal mortality rate of 221/100,000 live births (Lagos State Government, 2016). The state has 20 LGAs and 37 Local Council Development Areas (Adejumo et al., 2017; Adejumo, Daniel, Adejumo, Oluwole, & Olumuyiwa, 2015). Health care services are predominantly provided by the private health care facilities in Lagos, which constitutes 87.3% of all health care facilities in the state with more than 90% of the private health care facilities being profit-driven (Adejumo et al., 2017).

Lagos State commenced TB DOTS services in 2003 and introduced public-private mix for TB management in 2008; however, only 23.8% of the TB DOTS centers are located in private health care facilities, and the contribution of the private sector to 2017 TB case notification was 7% (Adejumo et al., 2017; Adejumo et al., 2015; Daniel et al., 2013; FMOH, 2017). TB case notification for Lagos increased by 10% between 2016 and 2017, and Lagos contributed 9.3% to the national TB notification in 2017 (FMOH, 2017). The TB case notification rate for Lagos was above the national figure for 2017, 78/100,000 population and 54/100,000 population, respectively (FMOH, 2017).

The Lagos State TB program reflects the NTP structure, that is, the State TB coordinator organizes the State TB program activities, the LGA TB supervisor manages all LGAs TB program, and each DOTS facility has a TB focal person (Adejumo et al., 2017). The TB focal person in health care facilities is responsible for the day-to-day patient management including all R&R at the facility level, while the LGA TB coordinator is responsible for data collation, analysis, and reporting to the State TB program quarterly (Adejumo et al., 2017).

Description and Assessment of the Secondary Database.

The TB inventory study dataset for Lagos was developed as part of an inventory study on TB notification in Lagos State (Mitchell et al., 2018). The secondary dataset was considered internal as the primary research was done in collaboration with colleagues from the KNCV Tuberculosis Foundation under the Challenge TB project in collaboration with the NTP, and the Lagos State TB program in 2017 with funding support from the United States Agency for International Development.

The primary study was a combination of a quantitative retrospective study design using a multistage sampling method collecting TB data reported in 2015 at various levels of the TB reporting system and a cross-sectional survey among health care workers in selected facilities in 2017. The objective of the primary study was to assess the consequence and scope of TB underreporting by public and private health facilities in Lagos, and the secondary objective was to determine the barriers to TB reporting.

Twenty-two trained data collectors gathered the primary data with one data manager being responsible for supervision and data quality assurance. The data was collected between March and November, 2017. To ensure conventional data quality, the minimum profile for the data collectors included a Higher National Diploma or Bachelor of Science, computer competence (including proficiency in the Microsoft Excel program), and ability to speak the local language (desirable). Following the training, the data collectors were provided with standard operating procedures for the collection and entry of the data. The data manager and a team of investigators organized weekly meetings to review the data collected and discuss all possible challenges.

Data were obtained from the following sources: TB facility-level case-based records, LGA level TB case-based records, aggregated TB data by the LGA TB supervisor (in the quarterly reports), aggregated TB data by the DNSO, and aggregated data at the State TB program level. Data were collected using tablet computers to digitalize all paper-based TB case-base records from the local government TB register. Probabilistic linkages were used in comparing the data available in both the TB facility and laboratory registers. Name of LGA, type, and level of the facility, availability of TB

R&R tools were all collected in addition to detailed patient-level data. Data verification

on TB cases based on standard TB case definition was done between the different data

sources using a six-variable match algorithm (first name, age, gender, date treatment

started, smear status, and treatment outcome). The health care worker survey tool had

self-reported variables on knowledge of mandatory TB notification, TB notification

practices, training on TB reporting tools and processes, and self-reported barriers to TB

reporting.

The sample frame was developed from four databases of health facilities in

Lagos: Health Facility Monitoring and Accreditation Agency, Millennium Development

Goals, Strengthening Health Outcomes through the Private Sector, and State TB program

list of facilities providing TB services.

The study involved all 25 LGAs of Lagos State. Sample size calculation was

based on "prior guess," an estimate of design effect, and an estimate of desired power.

Using the Delphi technique, the estimated TB underreporting ranged from 0-70% and

using a precision of 10% guided the initial sample size of 10% of the private health care

facilities. This was changed to 25% after the pilot as it was realized that TB services in

the private sector were less common than initially thought. All enlisted TB facilities by

the State TB program, five public health facilities, and 25% of 2,224 private health care

facilities were sampled. From the selected health care facilities, a survey questionnaire

was administered to 249 and 278 health care workers from NTP engaged and non-NTP

facilities, respectively. The overall refusal rate among health care workers was 13%. Full

access to TB data among health care facilities ranged from 71% (unengaged private

facilities) to 92% (engaged public facilities). Because the primary research used all

enlisted TB service delivery facilities by the Lagos State TB program and 25% of the

private health care facilities, I endeavored to use all available data accessible.

The Validity of the Data Collection Tool and Processes

WHO developed a standard guide on inventory studies that describes and explains

how to design, implement, and analyze inventory studies to measure TB underreporting

(WHO, 2012). This WHO method of assessing TB underreporting has been adopted in

Netherlands, United Kingdom, South Africa, Yemen, Pakistan (WHO, 2012).

Another validation process used in the primary research was the use of a

combination of four databases to develop a sample framework without duplication of

health care facilities. The data collection tools and web-based data digitalization process

were validated in a prior pilot study in a State adjacent to Lagos State (Ogun State)

(Mtchesll, Adejumo, Ogbudebe, Chukwueme, Adegbola, Umahoin et al., 2018) The pilot

evaluated the functionality of the web-based data application, the data verification

process, the competency of the data collectors, and the questionnaires for respondent

burden, intelligence, and feasibility. Lastly, the TB program uses standard definitions and

TB R&R tools across all NTP-engaged health care facilities. The DNSOs also used a

standard notifiable disease-reporting tool (form003).

Secondary Data Storage and Protection

The primary study (TB inventory study) protocol was approved by the Health

Research and Ethics Committee of the Lagos State University Teaching Hospital. The

NTP under the FMOH and the Challenge TB Project Management Unit in KNCV

Tuberculosis Foundation in the Hague also approved the study. All investigators

completed a required Nigerian research ethics certificate course. All information

regarding health care workers were deidentified, and numerical numbers were assigned to

health care facilities for identification purposes. Data was encrypted, and password

protected as demographic information of patients was used for matching records. The

data is currently stored on KNCV Tuberculosis Foundation own cloud, NTP data storage,

and an external drive secured in KNCV Tuberculosis Foundation office in the Hague.

 Role of the Theoretical Model and Schematic Diagram of the Variables in the Study

Application of Integrated Behavioral Model to the Study Design

The IBM theory was used; this theory was developed by Kasprzak & Montano in

collaboration with Fishbein to further expand the different complementary constructs of

TRA/TRB in the 1990s. It was advanced with the addition of constructs: knowledge and

skills to perform the behavior, salient of the behavior, environmental constraints and

habit (Rimer & Glanz, 2005; Glanz et al., 2008; Murno et al., 2007). IBM was used to

understand the intention and behavior for condom use and other HIV/STD-related

prevention studies (Rimer & Glanz, 2005; Glanz et al., 2008). IBM predicts that people

act on their intentions when they have the necessary skills, and when environmental

factors do not impede behavioral performance (Yzer, 2008). As applied to my study, IBM

holds that I would expect my independent variables (types and levels of health care

facilities, NTP engagement of health care facilities, knowledge of health care workers on

mandatory TB reporting, TB R&R tools, and TB reporting processes) to influence TB

reporting (dependent variable). The covariate in this study includes age, gender,

professional levels, availability of TB R&R tools, as well as supervision and feedback.

This expected influence of the independent variables on the dependent variable as

explained by the constructs of IBM brings to bear that TB reporting by health care

workers can be influenced by their attitude, perceived norms especially from other

professional colleagues and also as a standard of TB care, and the self-efficacy and

competence to use the TB R&R tools. The act of TB reporting can be influenced by

knowledge and skills of the health care workers, awareness of the mandatory TB

reporting requirements, engagement by the NTP reporting system, and a supportive

environment (availability of the R&R tools, the reporting processes, supervision, and

feedback). IBM guided the literature search, development of the research questions, and

the hypothesis for my study.

Schematic Diagram of the Variables in the Study

The primary data source for both TB and all notifiable diseases in Nigeria are the

standard paper-based tools used in health care facilities (Aruna et al., 2018; FMOHa or b,

2015). While the LGA is the management unit, where TB cases from designated health

care facilities are collated and reported quarterly, and all notifiable diseases reported via

the DNSOs monthly report (Aruna et al., 2018; FMOH, 2015a or b). I developed the

schematic diagram (Figure 6) to depict the TB reporting cascade (sequence) and possible

areas of TB case losses in the processes. TB cases can access services either at public or

private health care facilities, and these facilities are categorized as primary, secondary, or

tertiary, and NTP engaged or non-NTP engaged facilities. Since TB is a notifiable disease

by law, it is expected that all health care facilities within the LGA should report TB cases

to the LG TB supervisors quarterly and report to the DNSOs monthly. The LG TB supervisors are expected to collate all TB data within their LGAs and report to state TB program quarterly and State program collate and report from all LGAs in the State to report to the NTP. DNSOs collate data monthly and report to the epidemiology unit of the State Ministry of Health and subsequently to NCDC. Within this reporting pathway there are three possible sources of TB losses: 1) Health care facilities and LGAs, 2) LGA TB registers and State TB reports (aggregated data), and 3) DNOS's reports and LG TB reports (aggregated data).
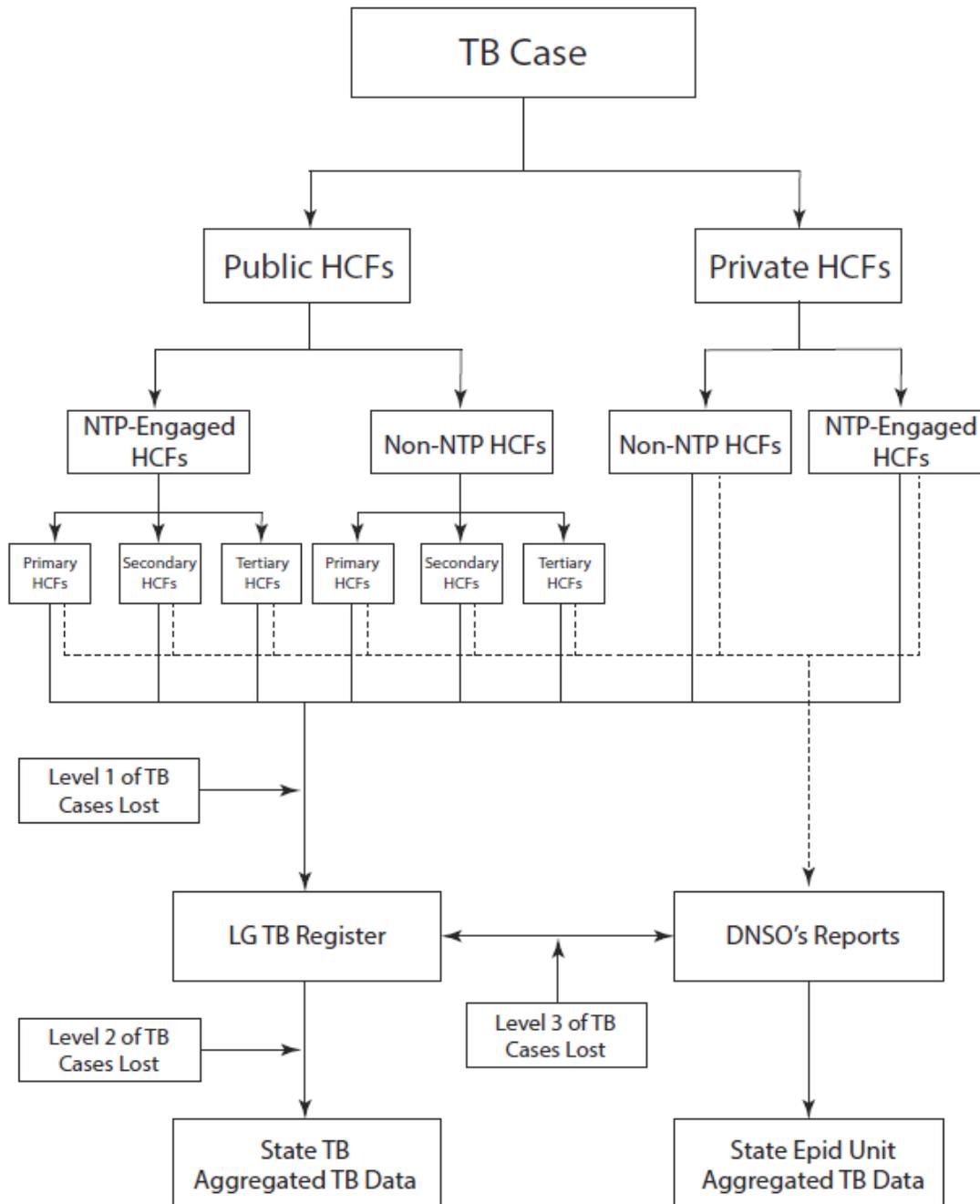
Figure 6. Schematic diagram of Tuberculosis reporting processes and levels.

Note: Description of abbreviations. HFCs (Health Care Facilities), DNSO (District

Notification and Surveillance officers), and NTO (National TB Program)

Data Analysis Plan

Data Assessment and Extraction

The existing database was assessed for the availability of appropriate variables,

level of measurements of all the variables, and converted the continuous variable (TB

reporting) into a binominal categorical variable (complete and -underreporting) reporting.

All variables were converted to categorical variables. All appropriate data sets were

extracted to the Statistical Package for Social Sciences IBM software version 22 for

analysis based on the research questions and hypothesis.

Research Questions and Hypothesis

RQ1: Is there an association between the cascade (sequence) of TB

underreporting by various levels of reporting (facility to LGAs and LGAs to

State) and by types of health care facilities (public and private; primary,

secondary, and tertiary facilities; NTP-engaged and NTP nonengaged by TB

program)?

$H_0 1$: There is no statistically significant association in the cascade of TB

underreporting by different levels and types of health facilities.

$H_a 1$: There is a statistically significant association in the cascade of TB

underreporting by different levels and types of health facilities.

RQ2: Are there differences between health care workers awareness of mandatory

TB reporting, reported barriers for TB reporting, types of barriers for TB

reporting, feedback on TB data to health care workers, patients and disease

characteristics (age, sex, TB disease site, type of patients, HIV status), volume of

patients per health care facility, and volume of patients per LGA with TB underreporting?

$H_0 2$: There is no statistically significant difference between health care workers awareness of mandatory TB reporting, reported barriers for TB reporting, types of barriers for TB reporting, feedback on TB data to health care workers, patients and disease characteristics (age, sex, TB disease site, type of patients, HIV status), volume of patients per health care facility, and volume of patients per LGA with TB underreporting.

$H_a 2$: There is statistically significant differences between health care workers awareness of mandatory TB reporting, reported barriers for TB reporting, types of barriers for TB reporting, feedback on TB data to health care workers, patients and disease characteristics (age, sex, TB disease site, type of patients, HIV status), volume of patients per health care facility, and volume of patients per LGA with TB underreporting.

RQ3: Is there an association between health care workers knowledge on mandatory TB reporting, years and type of practice, and identified barriers for TB reporting by levels and type of health care facilities?

$H_0 3$: There is no statistically significant difference between health care workers knowledge on mandatory TB reporting, years and type of practice, and identified barriers for TB reporting by levels and type of health care facilities.

H$_a$3: There is a statistically significant difference between health care workers

knowledge on mandatory TB reporting, years and type of practice, and

identified barriers for TB reporting by levels and type of health care facilities.

Research Model With the Expected Association Between the Dependent and

Independent Variables.

Using the Direct Acyclic Graph, the expected relationship between the

independent, and dependent variables with the covariate inclusive is shown in the

diagram below (Figure 7).
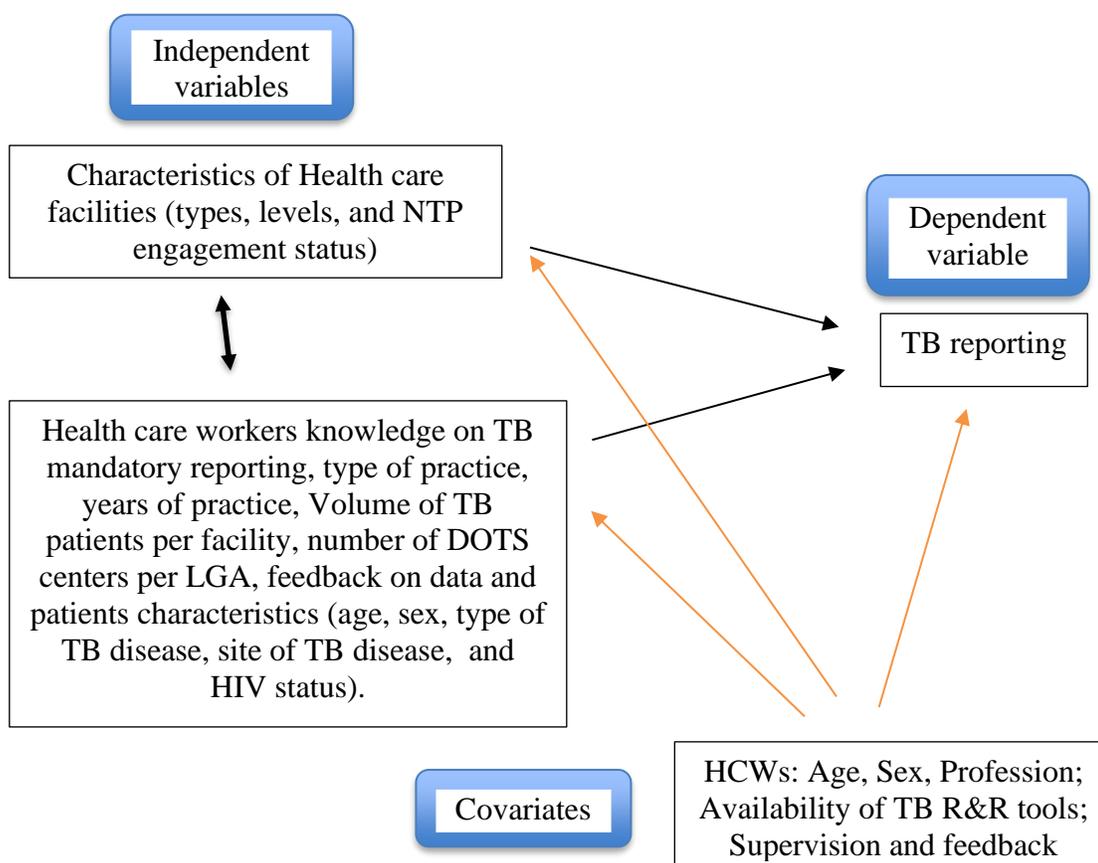
Figure 7. Direct Acyclic Graph of the relationship between dependent, independent, and
covariables.

Table 1

Description of Study Variables

Variables	Description	Category/measurement
Dependent variable TB reporting	TB cases documented on health care facility register, LG TB register, and reported by State; observed variance between the registers. Complete reporting if there is no difference between TB cases on HFs records and LG TB register and State TB aggregated data, and under-reporting if TB cases on LG TB register or State TB aggregated data are less than a number of cases documented in the facility registers.	1. Complete reporting 2. Underreporting
Independent variables		
Type of health care facility	Designation of the health care facility and only those with reported TB case in 2015.	1. Public 2. Private
Level of health care facilities among public health care facilities	Designation of the facilities as documented by State ministry of health.	1. Primary 2. Secondary
NTP-engagement Status	Health care facilities supported by state TB program with an MoU, capacity building, and integrated with medicine and laboratory supplies and monitoring and reporting system	1. NTP-engaged 2. Non-NTP-engage

Variables	Description	Category/measurement
The volume of DOTs center per LGA	Number of DOTS in LGA categorized as low or high.	2. High (≥11)
TB patients age	Age of patients were converted from continuous variables to categorical variables as age groups). Also based on TB reportable indicators as children and adult	1. <15
		2. 15-24
		3. 25-34
		4. 35-44
		5. 45-54
		6. ≥55
		1. Children (<15 years)
		2. Adult (≥15)
TB patients gender	Sex of TB patients as documented in the facility TB register	1. Male
		2. Female
Type of TB patients	TB patients classification based on the previous intake of TB drugs	1. New
		2. Previously treated
Site of TB disease	TB classification based on the body site affected	1. Pulmonary
		2. Extra-Pulmonary (EPT)
HIV Status	HIV test results as documented on TB patient register	1. Positive
		2. Negative
		3. Unknown
Health care workers variables		
Age (years)	Age groups of health care workers	1. <25
		2. 25-34
		3. 35-44
		4. 45-54
		5. ≥55

Table continues

Variables	Description	Category/measurement
Gender	Sex of health care workers as reported	1. Male 2. Female
Knowledge of health care workers on mandatory TB reporting	Awareness of health care workers on mandatory TB reporting	1. Yes 2. No
Type of practice	Health care workers designation of the type of practice	practitioner	1. General 2. Specialist 3. Not sure
Years of practice	Years of practice among health care workers	1. <5 years 2. 5-9 3. 10-14 4. ≥15
Barriers to TB reporting	Experience any barrier to TB reporting	1. Yes 2. No
	Type of barriers among health care workers who experience a barrier to TB reporting:	
Type of barriers to TB reporting	Lack of time	1. Yes 2. No
	TB registers not available	1. Yes 2. No
	TB registers design confusing	1. Yes 2. No
Feedback on TB data to health care facilities	Provision of feedback to health care facilities on TB cases documented and reported by LG TB supervisor	1. Yes 2. No

Descriptive Statistics

The data obtained were summarized using descriptive statistics like percentages, mean, median, and appropriate tables and graphs based on the level of measurement of the variables. A description of the independent variables that are categorical like health care facilities by types, levels, and engagement by the NTP was summarized using frequency tables and percentages. Other independent variables (health care workers knowledge on mandatory TB notification, barriers to TB reporting) were described using frequency tables and percentages, as all the variables were converted into categorical variables. The descriptive statistics of the dependent variable TB reporting (complete reporting and underreporting) as the dichotomous variable was presented as percentages for the overall data and by levels, types, and status of the NTP engagement. Mean and the standard deviation were used to express the health workers age across different types, and levels of health care facilities. While the gender of health care workers, knowledge of TB reporting, and barriers to TB reporting, and feedback on data were summarized using frequency tables and percentages.

Inferential Statistics

Chi-Square test of independence was used to assess the association between the dependent categorical variables (TB complete reporting and TB underreporting) and all categorical independent variables. The Chi-Square is a non-parametric test and does not require the data to be normally distributed. It also does not require equality of variance among the study groups or homoscedasticity in the data (Laerd Statistics, n.d). A binomial logistic regression was used to measure the relationship between the multiple

independent variables (health care facilities types, levels, NTP engagement status, knowledge of health care workers on mandatory TB notification and barriers to TB reporting and patients characteristics), and the dependent variable TB reporting as dichotomous categorical variables (complete reporting and incomplete reporting). The binomial logistic regression assessed the change in the dependent variable for any unit change of one independent variable while the others are held fixed (Sullivan, 2012). Logistics regression can account for confounding variables and assess the effect of modification (Sullivan, 2012). The assumptions for binomial logistic regression includes: the dependent variable is measured or converted to a dichotomous categorical variable, there are multiple independent variables (categorical or continuous), the observation is independent and mutually exclusive and exhaustive, and there should be a linear relationship between the continuous independent variables and the logit transformation of the dependent variable (Laerd Statistics, n.d). For all statistical tests, $p<0.05$ was considered statistically significant, and 95% confidence intervals was generated for all variables.

Ethical Approval Processes

Even though the data is internal to my organization and the Nigerian NTP, which is supported by the Challenge TB Project, permission for secondary analysis of the Lagos inventory study data was sought from the NTP. It was confirmed that there was no additional FMOH IRB approval required for this study since the primary study had ethical approval, and only de-identified information was provided for this study. Walden

Institutional Review Board (IRB) approval was provided before the commencement of the study.

Threats to Validity

Although the TB program has standard definitions, R&R tools for TB reporting for the entire country, Standard Operating Procedures for TB reporting and standard capacity-building package for health care workers on TB including reporting minimizing the threat to the internal validity of the study. However, internal validity can be affected because of frequent changes in the TB R&R tools, if facilities are using old tools, differential capacity to complete the TB R&R tools by different level and types of health care facilities, the likelihood of private sector not using the NTP R&R tools and loss of patient records cards (poor storage of paper-based records). This study was based on data from Lagos state only; using all TB enlisted facilities and 25% sample size of the private health care facilities in Lagos. There are limitations to generalizing the study for the entire country. The threats to the external validity of the study include the fact that the study was conducted with data from only one State out of 36 States and the Federal Capital. Other factors threatening the external validity of my study include variation among private health care facilities across the country by number and quality of staff, differences in standard of care, none standardization or availability of a regulatory agency like HEMFAMA to supervise and monitor private health care facilities in other States, and lastly the unstandardized profile of TB focal persons at facility level and among LG TB supervisors across Nigeria. Therefore, the results that are within the TB structure can

be applied nationwide, and findings within the private sector could be applied

contextually and circumstantially.

Other limitations are inherent factors associated with cross-sectional studies and

use of secondary data, like non-response bias or lack of access to primary patients records

in certain facilities, only association and not causation can be inferred, and challenges

with data quality and completeness. Bias can be a key limitation in this study, especially

self-reported, social desirability, and recall bias with the health care worker surveys on

TB reporting.

Summary

The purpose of the study was to use secondary data analysis to assess the

relationship between different types and levels of health care facilities, TB reporting

levels, and TB underreporting in Lagos State. The secondary database was developed as

part of a TB inventory study conducted in Lagos State in 2017. The data were analyzed

using both descriptive statistics and binomial logistic regression to measure the

relationship between the dependent and independent variables.

This chapter described the application of IBM in the development of the research

questions and hypothesis, explained the study design and rationale, and provided a

detailed assessment of the secondary database including the internal validity of the data.

This chapter also included information on the data analysis plan and identified variables

threatening the generalization of my study.

Chapter 4: Results

Introduction

The purpose of the study was to assess and describe TB reporting at different

levels of the Tuberculosis Reporting Systems in Lagos, Nigeria, using a quantitative

study design with secondary data from the TB inventory study conducted in Lagos,

Nigeria. In Chapter 4 I describe the process of assessing the secondary database,

establishing linkages between different data sets, and the identification of the availability

and appropriateness of variables within the data sets for the current study research

questions. This chapter provides the data analysis process and reports both descriptive

and inferential statistics for each of the research questions. The research questions and

hypotheses analyzed and reported in Chapter 4 were:

RQ1: Is there an association between the cascade (sequence) of TB

underreporting by various levels of reporting (facility to LGAs and LGAs to

State) and by types of health care facilities (public and private; primary,

secondary, and tertiary facilities; NTP-engaged and NTP nonengaged by TB

program)?

$H_0$1: There is no statistically significant association in the cascade of TB

underreporting by different levels and types of health facilities.

H_a1: There is a statistically significant association in the cascade of TB

underreporting by different levels and types of health facilities.

RQ2: Are there differences between health care workers awareness of mandatory

TB reporting, reported barriers for TB reporting, types of barriers for TB

reporting, feedback on TB data to health care workers, patients and disease characteristics (age, sex, TB disease site, type of patients, HIV status), volume of patients per health care facility, and volume of patients per LGA with TB underreporting?

$H_0$2: There is no statistically significant difference between health care workers awareness of mandatory TB reporting, reported barriers for TB reporting, types of barriers for TB reporting, feedback on TB data to health care workers, patients and disease characteristics (age, sex, TB disease site, type of patients, HIV status), volume of patients per health care facility, and volume of patients per LGA with TB underreporting.

H_a2: There are statistically significant differences between health care workers awareness of mandatory TB reporting, barriers for TB reporting, types of barriers for TB reporting, feedback on TB data to health care workers, patients and disease characteristics (age, sex, TB disease site, type of patients, HIV status), volume of patients per health care facility, and volume of patients per LGA with TB underreporting.

RQ3: Is there an association between health care workers knowledge on mandatory TB reporting, years and type of practice, and identified barriers for TB reporting by levels and type of health care facilities?

$H_0$3: There is no statistically significant difference between health care workers knowledge on mandatory TB reporting, years and type of practice,

and identified barriers for TB reporting by levels and type of health care

facilities.

H_a3: There is a statistically significant difference between health care workers

knowledge on mandatory TB reporting, years and type of practice, and

identified barriers for TB reporting by levels and type of health care facilities.

Data Collection

The primary database was accessed in the first week of June, 2019, after receiving

the IRB approval from Walden University and permission for data access and utilization

from the NTP, Nigeria. I accessed five different TB data sets from the database including

the facility TB register, the LGA TB register, TB data from sampled unengaged/private

health facilities, aggregated TB data from the State TB program, and data from the health

care workers survey (all data were already de-identified).

I used the health care facility level TB data set as the primary data source for

assessing the completeness of TB reporting for both the LGA and State TB programs; I

analyzed only data on health care facilities with documented TB patients in 2015. I used

the assigned unique identification numbers for patients, health care facilities, and LGA to

link the different data sets.

I assessed the availability, measurements, and appropriateness of variables in the

data sets for the current study objectives. The knowledge of health care workers on TB

reporting tools and the TB reporting process variables were not available in the primary

data set as expected, and the DSNO data was equally not utilized as it used a different

definition, classification, and patient identification number. Therefore, variables on

barriers to TB reporting by health care workers available in the data set were added as additional independent variables. The following additional categorical variables were developed from the existing data sets: patient's age groups, health care worker age groups, the volume of patients per health care facilities, the volume of DOTS centers (that is, TB service delivery point) per LGA and the number of years of practice of health care workers.

I analyzed data using the Statistical Package for Social Sciences IBM version 22. I summarized data using percentages for numerical and categorical variables. I compared categorical variables using the Chi-square test for independence or Fisher's exact test, and I conducted binomial logistic regression to assess the relationships between the dependent variable (TB reporting) and multiple independent variables. All independent variables that were significant ($p < .05$) on bivariate analysis were entered at once (enter method) at the beginning to assess their predictive ability while controlling for the effect of other variables in the model. The quality of the model was adjudged good when the omnibus tests of model coefficients were significant (that is, $p < .05$) and the Hosmer–Lemeshow goodness-of-fit test value was $p > .05$. Confidence interval (CI) was set at 95% for all statistical tests. A statistical test was considered significant if $p < .05$. All the assumptions for the Chi-square test for independence and binomial logistic regression were met before commencement of analysis.

Results

General Description of the Study Population

A total of 304 health care facilities had documented TB cases, of which 258 (84.9%) had reported TB cases in the LGA TB register. Table 2 shows that about 60% of the health care facilities were public, of which 82.5, 14.8, and 2.7% were primary, secondary, and tertiary health care facilities, respectively. An aggregate of 9,350 TB patients was recorded at the facility level for 2015. Of the registered TB cases at the facility level, 58.7% were male, 28% were between the ages of 25–34 years and 16.8% were HIV positive. Private health care facilities contributed 12.4% of all the cases (Table 3).

Table 2

Frequency Distribution of Types and Level of Health Care Facilities

Variables	Frequency	%
Type of facility		
Public	183	60.2
Private	121	39.8
Total	304	
Level of public health facilities		
Primary	151	82.5
Secondary	27	14.8
Tertiary	5	2.7
Total	183	
NTP engagement status		
Engaged	261	85.9
Nonengaged	43	14.1
Total	304	

Table 3

Characteristics and Distribution of Tuberculosis Patients Recorded at Health Care Facilities

Variables	Frequency (*n* = 9350)	%
Gender		
Male	5,492	58.7
Female	3,858	41.3
Age group (years)		
< 15	582	6.2
15 – 24	1,578	16.9
25 – 34	2,619	28.0
35 – 44	2,216	23.7
45 – 54	1,248	13.3
>= 55	1,067	11.4
Disease site		
Pulmonary	8,920	95.4
Extrapulmonary	320	3.4
Unknown	110	1.2
Type of patient		
New patient	8,603	92
Previously treated patient	747	8
HIV Status		
Positive	1,573	16.8
Negative	7,000	74.9
Unknown	777	8.3
NTP engagement status		
Engaged	9,190	98.3
Nonengaged	160	1.7
Facility type		
Public	8,188	87.6
Private	1,162	12.4

Variables	Frequency ($n = 9350$)	%
Public health care facility level	n = 8,188	
Primary	4,285	45.8
Secondary	2,975	31.8
Tertiary	928	9.9
Total	8,188	87.6

Descriptive and Inferential Statistics for Research Question 1

RQ1: Is there an association between the cascade (sequence) of TB underreporting by various levels of reporting (facility to LGAs and LGAs to State), and by types of health care facilities (public and private; primary, secondary, and tertiary; facilities engaged and nonengaged by TB program)?

$H_0 1$: There is no statistically significant association in the cascade of TB underreporting by different levels and types of health facilities.

$H_a 1$: There is a statistically significant association in the cascade of TB underreporting by different levels and types of health facilities.

Table 4 revealed the differences in the aggregated TB data between the health care facilities, LGA, and State TB records by LGA. Less than 40% of all health care facilities had complete TB reporting with a mean percentage difference of 7.4% (649) and 7.0% (580) of TB patients documented at the facility registers that were underreported by the LGA and State TB programs, respectively (Table 4).

Table 4

Distribution of Tuberculosis Reporting Difference by Local Government Area and Type of Tuberculosis Register

LGA ID	Total patients facility register	Total patients LGA register	% difference between facility and LGA	State-level data	% difference between facility and state
1	422	407	3.6	398	5.7
3	800	710	11.3	710	11.3
4	770	705	8.4	713	7.4
5	297	268	9.8	268	9.8
6	237	219	7.6	212	10.5
7	638	644	-0.9	642	-0.6
8	164	154	6.1	152	7.3
9	346	310	10.4	319	7.8
10	72	71	1.4	71	1.4
11	315	287	8.9	287	8.9
13	479	417	12.9	412	14
14	616	550	10.7	576	6.5
15	462	409	11.5	416	10
16	695	682	1.9	680	2.2
17	1044	1025	1.8	1059	-1.4
18	424	407	4	417	1.7
20	564	546	3.2	541	4.1
21	399	362	9.3	358	10.3
22	304	261	14.1	262	13.8
23	302	267	11.6	277	8.3
Mean	*468*	*435*	*7.4*	*439*	*7*
Total	9350	8701		8770	

I conducted a Chi-squared test of independence to assess the association between TB reporting and type, level, and NTP engagement status of health facilities and volume of DOTS centers per LGA. A significant association was found between NTP engagement status (χ^2 (1) = 20.547, p <.05) and TB reporting, as shown in Table 5.

Table 5

Tuberculosis Reporting Between Health Facilities and the Local Government Areas Register by Levels and Types of Health Care Facilities

Variables	Complete reporting frequency (%)	Underreporting frequency (%)	χ^2	p
Type of HCF				
Public	56 (36.6)	97 (63.4)	0.96	0.327
Private	29 (30.5)	66 (69.5)		
Total	85	163		
Level of Public HCF				
Primary	49 (36.8)	84 (63.2)		
Secondary	7 (38.9)	11 (61.1)	1.199	0.549
Tertiary	0 (0.0)	2 (100.0)		
Total	56	97		
NTP engagement Status				
Engaged	85 (39.7)	129 (60.3)	20.547	<.001
Unengaged	0 (0.0)	34 (100.0)		
Total	85	163		
Volume of DOTS Centers per LGA				
Low	17 (29.3)	41 (70.7)		
Medium	16 (40.0)	24 (60.0)	3.89	0.143
High	52 (44.8)	64 (55.2)		
Total	85	151		

Note. HCF = health care facility.

Descriptive and Inferential Statistics for Research Question 2

RQ2: Are there differences between health care workers awareness of mandatory TB reporting, reported barriers for TB reporting, types of barriers for TB reporting, feedback on TB data to health care workers, patients and disease characteristics (age, sex, TB disease site, type of patients, HIV status), volume of patients per health care facility, and volume of patients per LGA with TB underreporting?

$H_0 2$: There is no statistically significant difference between health care workers awareness of mandatory TB reporting, reported barriers for TB reporting, types of barriers for TB reporting, feedback on TB data to health care workers, patients and disease characteristics (age, sex, TB disease site, type of patients, HIV status), volume of patients per health care facility, and volume of patients per LGA with TB underreporting.

$H_a 2$: There are statistically significant differences between health care workers awareness of mandatory TB reporting, reported barriers for TB reporting, types of barriers for TB reporting, feedback on TB data to health care workers, patients and disease characteristics (age, sex, TB disease site, type of patients, HIV status), volume of patients per health care facility, and volume of patients per LGA with TB underreporting.

Association of TB underreporting with health care workers awareness of TB reporting, reported barriers, and types of barriers for TB reporting were assessed using the Chi-square test for independence. A statistical significant association was found

between the awareness of TB reporting (χ^2 (1) = 6.576, p <.05), reported barriers for TB

reporting (χ^2 (1) = 4.106, p< .05) and TB register not available (χ^2 (1) = 4.760, p < .05)

with TB under-reporting (Table 6). There was no significant association between

feedback on data and TB underreporting among engaged health care facilities (χ^2 (1)

=0.115, p=0.734) (Table 7).

Table 6

Awareness and Barriers of Tuberculosis Reporting by Health Care Workers

| Variables | Reporting | | χ^2 | p |
	Complete $n = 85$ (%)	Underreporting $n = 85$ (%)		
Awareness of TB reporting				
Yes	85 (36.0)	151 (64.0)	6.576	0.010[#]
No	0 (0.0)	12 (100.0)		
Total	85	163		
Barrier to TB reporting				
Yes	15 (23.8)	48 (76.2)	4.106	0.043
No	70 (37.8)	115 (62.2)		
Total	85	163		
Type of barriers				
Lack of time				
Yes	3 (23.1)	10 (76.9)	1.094	0.296
No	75 (37.5)	125 (62.5)		
Total	78	135		
Register not available				
Yes	1 (7.7)	12 (92.3)	4.76	0.035[#]
No	76 (37.6)	126 (62.4)		
Total	77	138		
TB register confusing				
Yes	2 (40.0)	3 (60.0)	0.027	1.000[#]
No	75 (36.4)	131 (63.6)		
Total	77	134		

Table 7

Association Between Feedback on Data and Completeness of Tuberculosis Reporting Among Engaged Health Care Facilities

Variables	Reporting		χ^2	p
	Complete $n = 85$ (%)	Underreporting $n = 129$ (%)		
Feedback on data reported				
Yes	77 (40.1)	115 (59.9)	0.115	0.734
No	8 (36.4)	14 (63.6)		

As shown in Table 8, only disease site, type of patients, HIV status and volume of patients per health care facilities and volume of DOTS centers per LGA were significantly associated with TB underreporting ($p <.001$). Logistic regression was conducted to assess the predictive relationship and odds ratio between TB underreporting and gender, age, disease site, HIV status, the volume of patients per health care facilities and volume of DOTS centers per LGA.

The model was deduced as a good quality based on significant Omnibus tests (that is, $p<0.05$) of model coefficients and the full model containing all the predictor variables was statistically significant (χ^2 (11) =316.479, $p<.001$) (Table 9). The Hosmer–Lemeshow goodness-of-fit test was significant (χ^2 (8) =25.174, $p<.001$) (Table 11). The R^2 was 0.073, meaning only 7.3% of the variance was explained by the independent variables (Table 10). The logistic regression indicated that previously treated TB patients, extra-pulmonary TB, unknown TB site, HIV negative, HIV unknown status, the low and medium volume of patient per health care facilities were all significant predictors of TB underreporting (Table 12).

Table 8

Patient's Characteristics and Tuberculosis Reporting

Variables	Complete reporting $n = 8320$ (%)	Underreporting $n = 1024$ (%)	χ^2	p
Gender				
Male	4886 (89.0)	603 (11.0)	0.01	0.921
Female	3434 (89.1)	421 (10.9)		
Age group (years)				
< 15	522 (89.8)	59 (10.2)		
15 – 24	1413 (89.6)	164 (10.4)		
25 – 34	2348 (89.7)	270 (10.3)	4.69	0.455
35 – 44	1987 (89.70	228 (10.3)		
45 – 54	1118 (89.6)	130 (10.4)		
≥ 55	932 (87.5)	133 (12.5)		
Disease site				
Pulmonary	7993 (89.7)	921 (10.3)		
Extra pulmonary	280 (87.5)	40 (12.5)	246.168	<0.001
Unknown	47 (42.7)	63 (57.3)		
Type of patient				
New	7714 (89.7)	883 (10.3)	52.147	<0.001
Previously treated	606 (81.1)	141 (18.9)		
HIV status				
Positive	1486 (94.5)	87 (5.5)		
Negative	6319 (90.3)	677 (9.7)	464.56	<0.001
Unknown	515 (66.5)	260 (33.5)		
Volume of patient Per HCF				
Low	269 (62.9)	159 (37.1)		
Medium	1068 (84.60	195 (15.4)	364.957	<0.001
High	6983 (91.2)	670 (8.7)		
Volume of DOTS Centers per LGA	n = 8320	n = 865		
Low	3134 (90.5)	329 (9.5)		
Medium	2168 (92.0)	189 (8.0)	8.591	0.014
High	3018 (89.7)	347 (10.3)		

Table 9

Omnibus Tests of Model Coefficients

		Chi-square	Difference	Significant
Step 1	Step	316.479	11	0
	Block	316.479	11	0
	Model	316.479	11	0

Table 10

Model Summary

Step 1	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
	5416.668[a]	.034	.073

a. Estimation terminated at iteration number 6 because parameter estimates changed by less than .001.

Table 11

Hosmer and Lemeshow Test

Step 1	Chi-square	Difference	Significant
	25.174	8	0.001

Table 12

Regression Analysis of Patient-Related Factors Associated With Tuberculosis Reporting

Variables	B	S.E	Wald	Difference	Significant	Exp (B)	95% CI	Exp(B) Lower	Exp(B) Upper
Male							1		
Female	0.078	0.075	1.071	1	0.301	1.081		0.933	1.252
Adults							1		
Children	0.086	0.152	0.317	1	0.574	1.090		0.808	1.469
New patient				1					
Previously treated patients	0.606	.114	28.317	1	.000	1.833		1.467	2.292
Disease site			109.111			.000			
PTB							1		
EPT	0.449	0.176	6.481	1	0.011	1.567		1.109	2.213
Unknown	2.175	.212	104.89	1	0.000	8.803		5.806	13.34
HIV status			33.49	2	0.000				
Positive							1		
Negative	0.498	0.121	16.799	1	0.000	1.645		1.297	2.087
Unknown	0.944	0.164	33.276	1	0.000	2.569		1.864	3.540
Volume of Pt/HCF			75.291	2	0.000				
High							1		
Low	1.016	0.148	46.943	1	0.000	2.763		2.066	3.695
Medium	0.615	0.096	41.268	1	0.000	1.851		1.534	2.233
Volume of DOTS Per LGA			6.376	2	0.041				
High							1		
Low	0.118	0.086	1.885	1	0.170	1.126		0.951	1.333
Medium	0.133	0.101	1.726	1	0.189	0.876		0.718	1.068

Descriptive and Inferential Statistics for Research Question 3

RQ3: Is there an association between health care workers knowledge on mandatory TB reporting, years and type of practice, and identified barriers for TB reporting by levels and type of health care facilities?

$H_0$3: There is no statistically significant difference between health care workers knowledge on mandatory TB reporting, years and type of practice, and identified barriers for TB reporting by levels and type of health care facilities.

H_a3: There is a statistically significant difference between health care workers knowledge on mandatory TB reporting, years and type of practice, and identified barriers for TB reporting by levels and type of health care facilities.

A total of 248 health care workers in health care facilities that reported TB cases in 2015 were surveyed. The median age was 44 years (IQR 35, 52 years), the male: female ratio was 1:4, the median age of practice was six years (IQR 3, 20 years), and the majority of health care workers (90.7%) were general practitioners (Table 13).

Table 13

Frequency Distribution of Health Care Workers Characteristics

Variables	Frequency	%
Gender		
Male	48	19.4
Female	200	80.6
Age group (years		
<25	3	1.2
25 – 34	41	16.5
35 -44	71	28.6
>=45	88	35.5
Unknown	45	18.1
Years of Practice		
<5	107	43.1
5 – 19	46	18.5
10 – 14	14	5.6
>=15	29	11.7
Unknown	52	21
Type of Practice		
General Practitioner	225	90.7
Specialist	21	8.5
Not sure	2	0.8

Over 95% of the health care workers were aware of mandatory TB reporting, and 20% reported to have experienced barriers to TB reporting. Of those that experienced barriers to TB reporting, 16.3, 24.5, and 4.1% were due to lack of time, non-availability of TB reporting forms and a confusing TB register design, respectively (Table 14).

Table 14

Frequency Distribution of Awareness, Barriers, and Type of Barriers for Tuberculosis
Reporting Among Health Care Workers

Variables	Frequencies	%
Awareness of TB reporting		
Yes	236	95.2
No	12	4.8
Total	248	
Barriers to TB register		
Yes	49	19.8
No	199	80.2
Total	248	
Lack of time*		
Yes	8	16.3
No	27	55.1
No response	14	28.6
Total	49	
TB register not available*		
Yes	12	24.5
No	26	53.1
No response	11	22.4
Total	49	
TB register design confusing*		
Yes	2	4.1
No	33	67.3
No response	14	28.6
Total	49	

*Multiple answers allowed.

Chi-square test of independence was conducted to assess the association between the awareness of TB mandatory reporting and types and NTP engagement status of health care facilities. A significantly higher proportion of the private (χ^2 (1) =20.309, p <.001) and NTP non-engaged health facilities (χ^2(1)= 79.370, p <.001) were not aware of TB mandatory reporting as shown in Table 15. As Table 16 shows, there is a significantly higher proportion of private (χ^2 (1) = 39.796, p<.001) and NTP non-engaged health care facilities (χ^2 (1) = 116.537, p<.001) that had barriers to TB reporting. There was no association between the lack of time and the confusing TB register design with the types of health facilities and NTP engagement status. There was a significant association of TB registers not available with the type of health care facility (χ^2 (1) =5.443, p=0.036) and the NTP engagement status (χ^2 (1) =14.198, p<0.001) (Table 17).

Table 15

Awareness of Tuberculosis Reporting by Type and Levels of Health Care Facilities

Variables	Awareness of TB reporting		χ^2	p
	Yes	No		
	n = 236 (%)	n = 12 (%)		
Type of facility				
Public	153 (100.0)	0 (0.0)	20.309	<0.001[#]
Private	83 (87.4)	12 (12.6)		
NTP engagement status				
Engaged	214 (100.0)	0 (0.0)	79.37	<0.001[#]
Non engaged	22 (64.7)	12 (35.3)		

NB: #= Fishers' exact p-value.

Table 16

Barriers of Tuberculosis Reporting by Type and Levels of Health Care Facilities

Variables	Barriers to TB reporting		χ^2	p
	Yes	No		
	$n = (\%)$	$n = (\%)$		
Facility type				
Public	11 (7.2)	142 (92.8)	39.796	<0.001
Private	38 (40.0)	57 (60.0)		
Total	49	199		
Public health facility level				
Primary	10 (7.5)	123 (92.5)	0.090	1.000*
Secondary	1 (5.6)	17 (94.4)		
Total	11	140		
NTP engagement status				
Engaged	19 (8.9)	195 (91.1)	116.537	<0.001
Non engaged	30 (88.2)	4 (11.8)		
Total	49	199		

Fischer's exact p-value.

Table 17

Types and Levels of Barriers of Health Care Facilities

Variables	Types of Barriers to TB reporting		χ^2	*P*
	Yes	No		
	Frequency (%)	Frequency (%)		
Lack of Time				
Type of facility	3 (33.3)	6 (66.7)	0.754	0.396[#]
Public	5 (19.2)	21 (80.8)		
Private	8	27		
Total				
Public health facility levels				
Primary	2 (25.0)	6 (75.0)	Invalid	
Secondary	1 (100.0)	0 (0.0)		
Total	3	6		
NTP engagement status				
Engaged	6 (35.5)	11 (64.7)	2.9	0.121[#]
Not engaged	2 (11.1)	16 (88.9)		
Total	8	27		
TB Register not available				
Type of facility				
Public	0 (0.0)	9 (100.0)	5.443	0.036[#]
Private	12 (41.4)	17 (58.6)		
Total	12	26		
NTP engagement status				
Engaged	0 (0.0)	17 (100.0)	14.198	<0.001[#]
Non engaged	12 (57.1)	9 (42.9)		
Total	12	26		
TB register confusing				
Type of facility				
Public	0 (0.0)	9 (100.0)	0.734	1.000[#]
Private	2 (7.7)	24 (92.3)		
Total	2	33		

Variables	Types of Barriers to TB reporting			
	Frequency (%)	Frequency (%)	χ^2	*P*
NTP engagement status				
Engaged	1 (5.9)	16 (94.1)	0.002	1.000#
Non-engaged	1 (5.6)	17 (94.4)		
Total	2	33		

#Fishers' exact p-value.

Summary

Overall, 7.4% (649) and 7.0% (580) of TB patients documented at the facility registers were under-reported at the LGA and State TB programs, respectively. There was TB underreporting among the health care facilities and at all levels, but on bivariate analysis, only NTP non-engaged health care facilities were significantly associated with TB underreporting (χ^2 (1) = 20.547, *p* <.05).

While awareness of TB reporting (1) = 6.576, *p*<.05), reported barriers for TB reporting (χ^2 (1) = 4.106, *p*< .05) and TB register not available (χ^2 (1) = 4.760, *p*< .05) were statistically associated with TB underreporting. Other patient-related factors such as previously treated TB patients, extra-pulmonary TB, unknown TB site, HIV negative, HIV unknown status, the low and medium volume of patient per health care facility were all significant predictors of TB underreporting.

Lastly, over 95% of the health care workers were aware of mandatory TB reporting, and 20% reported to have experienced barriers to TB reporting. The barriers identified by health care workers include lack of time (16.3%), non-availability of TB

reporting tools (24.5%, and a confusing TB register design (4.1%). A significantly higher proportion of the private (χ^2 (1) =20.309, p <.001) and NTP non-engaged health facilities (χ^2 (1) = 79.370, p <.001) were not aware of TB mandatory reporting. There was a significantly higher proportion of private health care facilities (χ^2 (1) = 39.796, p<.001) and NTP-non-engaged health care facilities (χ^2 (1) = 116.537, p<.001) that experienced any form of barrier to TB reporting.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The purpose of the study was to assess and describe TB reporting at the different levels of the Tuberculosis Reporting Systems in Lagos, Nigeria, using a quantitative study design with secondary data from a TB inventory study conducted in Lagos, Nigeria. The emphasis in this study was to assess TB underreporting along the TB reporting cascade (sequence) and identify associated or predictive variables among the independent variables for TB underreporting.

TB underreporting occurred at all levels, and among all health care facilities in Lagos; less than 40% of health care facilities with documented TB cases had complete TB reporting. Generally, 7.4% (649) and 7.0% (580) of TB patients recorded at the facility registers were not reported at the LGA and State TB programs, respectively. Awareness of mandatory TB reporting, nonavailability of TB reporting forms, and NTP engagement status of health care facilities were significantly associated with TB underreporting. The patient-related factors such as previously treated TB patients, extrapulmonary TB, unknown TB site, HIV negative, HIV unknown status, and the low and medium volume of patient per health care facility were all significant predictors of TB underreporting.

In Chapter 5 I give a detailed description of the study results in comparison with available evidence in the literature. The results are discussed in the context of the theoretical framework used in the study. In the chapter I describe the application of the

study results in TB program (social change). Finally, Chapter 5 presents the limitations of the study, programmatic recommendations, and recommendations for further studies.

Interpretation of findings

Of the 304 health care facilities with documented TB cases at facility registers, only 84.9% had reported cases in the LG TB register. This is higher than the national (Nigeria) figure of 69% of health care facilities providing TB services reporting cases to the NTP (FMOH, 2017). Other general descriptive statistics results of the study are similar to the 2017 NTP report. These include the proportion of male TB patients (58.7% compared to 62% national), childhood TB rate (6.2% compared to 7%), HIV positivity rate (16.8% compared to 14%), and the contribution of private health care facilities to TB cases notification (12.4% compared to 12%; FMOH, 2017). The contribution of private health care providers to overall TB case finding in Nigeria and as observed in this study is lower than reported by Yeole et al. (2015) in India at 20%.

Under-Reporting and Health Care Facility and Health System-Related Factors

TB underreporting occurred at all levels, and among all health care facilities in Lagos: less than 40% of health care facilities with documented TB cases had complete TB reporting in 2015. Overall, 7.4% (649) and 7.0% (580) of TB patients recorded at the facility registers were not reported to the LGA and State TB programs, respectively. A higher TB underreporting of 15% and incompleteness of TB reporting between health care facilities and LGA TB registers were reported among six southern states in Nigeria (Onyeonoro et al., 2015). The finding of at least 7% TB underreporting in this study is similar but less compared to results of other studies (Furtado da Luz & Braga, 2018;

Morales-Garcia et al.,2015; Naidoo et al., 2017; Podewils et al., 2015; Tolleson et al.,

2015; Li et al.,2018) with TB underreporting of 15% in Cape Verde, 14.4% among

Spanish hospitals, 12% to 20% in South Africa, 15.4% among smear-positive cases in

Kenya, and 19.3% in a recent inventory study in China.

Based on the inventory study conducted in Lagos State, Nigeria, Mitchell et al.

(2018) estimated the magnitude of TB underreporting of 42%, which is above the average

estimated TB underreporting for the African region of 20% (Sismanidis et al., n.d).

However, the magnitude of the TB underreporting was comparable to what was reported

in other works (Chin & Hanson, 2017; Furtado & Braga, 2018; Hong et al., 2012;

Huseynova et al., 2013; Mloshwa et al.,2017; Sismanidis,2018). In these works, 34% of

TB underreporting was observed in three regions of South Africa, 40% in Cape Verde,

42.9% in Brazil, Korea had 31% estimated TB underreporting in a capture-recapture

method, 40% in a review of finding the missing TB cases in Iraq,, and 41% for Indonesia.

The magnitude of TB underreporting for Nigeria was, however, higher than the

magnitude reported in some countries: Yemen (29%), Pakistan (27%), and Malawi

(14%)(Bassili et al., 2010; Fatima, 2015; Tolleson et al.,2016).

TB underreporting was observed among all the LGAs and all types and levels of

health care facilities. The mean percentage of TB underreporting was higher between

health care facility TB reports and LGA TB registers, that is, 7.4% (range 14.1% to-

0.9%), compared to the mean percentage of TB underreporting between LGA TB

registers and State TB program report of 7.0% (range 14% to -1.4%; Table 4). TB

underreporting was 100% among tertiary institutions and NTP nonengaged health care

facilities. TB underreporting was higher among private health care facilities compared to public health care facilities (69.5% compared to 63.4%). This is similar to the findings of Tolleson et al. (2016), which stated that large health facilities are statistically associated with TB underreporting in Kenya, and also results by Coghlan et al. (2015), which noted that private health care facilities not engaged by NTP provide no TB data to NTP in Indonesia, Nigeria, and Pakistan. Wells (2017) equally identified non-NTP engagement and weak linkages with non-TB part of health facilities among the 10 factors for missed TB cases or TB underreporting in analysis and quantification of TB case-finding gaps.

It was paradoxical to find in this study that health care facilities and LGAs considered high TB burden with a higher volume of patients and a high number of DOTS centers have smaller percentage difference in TB underreporting, which was contrary to the findings of Tolleson et al. (2016) in Kenya, where high burden regions are likely to under-report TB. This finding was, however, in line with the result of an investigation in Korea by Hong et al. (2012), which showed that TB underreporting was common among the smallest health care facilities and low burden towns or cities. The likely explanation is the fact that TB reporting is hinged on the performance of LGA TB supervisors who are responsible for the distribution of all TB reporting tools to facilities. Their responsibilities include visiting all engaged health care facilities for supervision, data collection, and updating of LG TB register, and subsequently, collating and reporting TB data quarterly to the State program (Aruna et al., 2018; FMOH, 2015a). Therefore, the LGA TB supervisors in Lagos, Nigeria, are probably prioritizing high volume facilities and high burden LGAs for TB reporting practices and supervision.

Awareness of Mandatory Tuberculosis Reporting and Barriers to Tuberculosis

Reporting

At least 95% of the health care workers were aware of mandatory TB reporting; unfortunately, despite the high knowledge of TB reporting, over 64% of the health care workers were underreporting TB, and this is statistically significant (χ^2 (1) = 6.576, p <.05). Despite the general high awareness of mandatory TB reporting, a significantly higher proportion of the private (χ^2 (1) =20.309, p <.001) and unengaged health facilities (χ^2(1)= 79.370, p <.001) were not aware of TB mandatory reporting. The finding of 95% awareness of mandatory TB reporting in this study is higher than findings previously reported (Philip et al., 2015; Thomas et al., 2016; Yeole et al., 2015) with 73% in Chennai, South India, 88% among private health care providers in Kerala, India, and a majority of health care workers in Pune, India, respectively. It is clear from my research that despite the high awareness on mandatory TB reporting, there was a gap between awareness and practice of TB reporting among health care workers as 64% of health care workers who were aware of TB reporting still underreported TB. The reasons for these gaps could be explained by earlier studies (Abubakar et al., 2018; Iwu et al., 2016; Yeole et al., 2015). This includes unclarity of the roles of health care workers in the TB reporting process, health care workers not fully understanding the rationale and potential benefit for TB reporting to NTPs, while some experienced several barriers to TB reporting. Another reason for the gaps between awareness of mandatory TB reporting and actual practice was pointed out in Delhi, India, as lack of complete knowledge of the TB reporting process and mechanism among health care workers (Satpati et al., 2017). In the

context of Nigeria, the role of health care workers in TB reporting is recording TB

treatment cards as well as facility registers. All subsequent reporting practices are hinged

on the functions of the LGA TB supervisor (Aruna et al., 2018; FMOH, 2015a).

Twenty percent of the health care workers identified the following as barriers to

TB reporting: lack of time, nonavailability of TB reporting tools, and a confusing TB

register design. A statistically significantly higher proportion of private (χ^2 (1) = 39.796,

$p<.001$) and NTP nonengaged health care facilities (χ^2 (1) = 116.537, $p<.001$)

experienced barriers to TB reporting. Of the identified barriers, only TB registers not

available was statistically significant (χ^2 (1) =4.760, $p<.05$). Iwu et al. (2016) had similar

conclusions in the Southeast of Nigeria on disease notification, where 67.3% of health

care workers identified the inadequate supply of reporting forms and the complex nature

of all the reporting forms as barriers to disease notification. Coghlan et al. (2015) and

Yeole et al. (2015) reported nonavailability of patients records in over 50% of health care

facilities in Nigeria and lack of simplified reporting tools in Pune, India. Lastly, Mansuri

et al. (2014) and Thomas et al. (2016) affirmed that over 50% of health care workers

complained of workload and lack of time as a barrier to TB reporting in Pakistan and

Chennai, India. At least 95% of health care workers among NTP engaged health care

facilities claimed to have received feedback on TB data. However, there is no statistically

significant association with TB underreporting. This percentage is higher than was

reported in the Southeast of Nigeria where only 49.7% of health care workers received

feedback on data (Iwu et al., 2016). Issues not explored in this study were frequency,

quality, and documentation of feedbacks and the possible influence of self-reporting bias (for example, recall, social desirability, and sampling approach bias).

Patient-Related Factors to Tuberculosis Underreporting

The following patient-related factors were significant predictors of TB underreporting with more than two-folds odds of underreporting; previously treated TB patients (OR 1.8, 95% CI=1.5-2.3), EPT (OR 1.6, CI 1.1-2.2), site of TB disease unknown (OR 8.8, 95% CI=5.8-13.3), HIV negative TB (OR 1.5, 95% CI=1.3-2.1), and HIV status unknown (OR 2.6, 95% CI=1.9-3.5). The common predictors of TB underreporting in a multivariate analysis reported in other studies include age (<14 years and above 55 years), smear-negative TB cases, and EPT (Furtado and Braga, 2018; Hong et al., 2012; Li et al., 2018; Morales-Garcia et al., 2015; Tolleson et al., 2016). These types of TB cases (children, smear-negative, and EPT) were all likely diagnosed from specialized clinics and different service delivery points in big health care facilities, and therefore, inadequate coordination on reporting, between designated TB service delivery points and these specialized clinics, consequently resulting to TB underreporting. Weak linkages, coordination, and ineffective referral mechanism within and between health care facilities are associated factors for TB underreporting (Aruna et al., 2018; Tolleson et al., 2016).

The Study Results in the Context of the Theoretical Framework

A modified IBM theory with additional constructs from the PAPM on awareness, engagement, and maintenance was used for this study. This was based on the premise that the central construct for IBM is *intention* (Branscum & Lora, 2017; Rimer & Glanz,

2005; Glanz et al., 2008) and also on the basis that TB reporting is a concrete behavior which involves people, tools, and processes (Ali et al., 2018). IBM was used in similar studies on behaviors with the use of condoms for safe sex in Zimbabwe (Glanz et al., 2008, pp. 80-85) and adherence to TB reporting (Chaisson et al., 2015).

The following constructs from the modified IBM theory: knowledge and skills to perform the behavior (including awareness and engagement), environmental constrain and the need for maintenance of the behavior explained the findings of TB underreporting. There was a statistically significant association between awareness of mandatory TB reporting, identified barriers to TB reporting, lack of time, and non-availability of TB reporting tools with TB underreporting. Other environmental factors that were not statistically significant were the "confusing design" of TB tools, which were cumbersome to use and provision of feedback to health care facilities on data. Since the study design was quantitative using secondary data, certain constructs in IBM were not assessed, amongst which are variables on attitude, perceived norm, and perceived control over TB reporting. However, there are studies that mentioned some of these qualitative variables as perceived norm among professional colleagues regarding reporting was lack of clarity of roles on TB reporting and lack of trust in and weak coordination with the public health system (Philip et al., 2015; Satpati et al., 2017; Yeole et al., 2015).

Conclusions

TB underreporting was observed among all types and levels of health care facilities and between the different levels of TB reporting (facility to LG TB and State

TB programs). There was a significant association between NTP non-engaged health care facilities, health care awareness of TB mandatory reporting and non-availability of TB reporting forms with TB underreporting. A significantly high proportion of private health care facilities and NTP non-engaged health care facilities were not aware of the mandatory TB reporting and experienced barriers to TB reporting (lack of time, TB registers not available and confusing design of TB registers). Other health care system predictors of TB underreporting included low volume health care facilities and LGAs with a low volume of DOTS centers. Patient-related predictors of TB underreporting include previously treated TB patients, extra-pulmonary TB patients, HIV negative, and HIV status unknown TB patients, these factors are related to weaknesses in linkages and referral within and between health care facilities.

Limitations of the Study

The study limitations are grouped into two, those related to the study design and inherent factors in the TB reporting processes. The inherent weakness in the study design (secondary data and cross-sectional study) includes insufficient information or variables to address the current research objectives and data existing in a different format or measurement not aligning to present the research work (Johnston, 2014; Laureate Education, Inc. [video], 2013). Examples in this study were the missing variables on the health care workers survey and significant inconsistencies with the DSNO data. Other factors related to the study design were bias, which in the case of this study could be from either recall, social desirability, and the sampling approach. Recall and social desirability bias were possible based on the health care worker survey on awareness of mandatory TB

reporting and barriers to TB reporting and the sampling bias given that only 25% of the

private health care facilities were selected in the primary study (inventory study). The

health care worker survey was done in 2017, while the TB notification data and practices

were for 2015, and only one health care worker per facility was interviewed. Therefore,

the certainty of the representativeness of all health care workers providing TB services in

those facilities by number and period cannot be assured. Conclusively, on the design, the

study was only based on one state (Lagos) with different health care service coverage and

private sector engagement compared to other states in Nigeria.

The limitations related to the TB program monitoring and reporting system

includes difficulties in linking multiple paper-based registers within the health care

facilities, especially the presumptive TB register, laboratory register, and the facility TB

register. Secondly, the TB reporting is only among patients who commenced treatment

with assigned LG TB number, therefore, initial loss to follow up (ILFU) (that is,

individual with confirmed TB who did not initiate treatment) are automatically not

reported. The ILFU can be as high as 12% in South Africa and 7% in India (Naidoo et al.,

2017).

Recommendations

Programmatic Actions for Social Change

The study recommendations are made to both the NTP, State TB, and LG TB

programs as well as partners and stakeholders supporting the TB program. Some of the

proposed actions require the TB program to work in collaboration with other departments

in the ministries of health, including the Nigerian Center for Disease Control (NCDC)

and the National Primary Health Care Development Agency.

1. Engage and build the capacity of all health care workers with emphasis on private health care facilities on TB reporting by the provision of TB reporting tools and creating a coordination mechanism with NTP.

2. Design a coordination and referral mechanism within and between different health care facilities to strengthen TB reporting especially for childhood TB, smear-negative and EPT and TB/HIV co-infected as most of these cases are managed by other units within big health care facilities.

3. Work with NCDC and National Primary Health Care Development Agency to identify possible areas of collaboration and coordination on TB reporting as part of routine health information management system.

4. Simplify TB reporting tools especially for community health care workers and private health care providers as part of the roll-out of an electronic reporting system.

5. NTP to ensure adequate and continuous availability of TB R&R to all health care facilities.

Recommendation for Further Studies

The current study design (secondary data analysis) does not adequately address the contextual issues involved in TB reporting. This is attributable to the complex nature of TB reporting with the need to understand the perception of health care workers on barriers for TB reporting, the design of TB reporting tools and acceptable options of

reporting processes which includes clear roles, responsibilities, and coordination at various levels. Therefore, further investigations will help provide answers to questions highlighted in this study: These include the conduct of a multi-state assessment of TB underreporting to identify regional variation considering the significant difference between the states and regions in Nigeria to increase the generalizability of the findings. A qualitative study on health care workers perception and practice of TB reporting, including data utilization for decision at various levels, which was not feasible using the current study design with secondary data. A prospective study to assess the feasibility and benefit of integrating or linking TB reporting with DSNO's and District Health Information System Two reporting systems. Finally, an advanced study to assess TB reporting completeness between paper-based reporting and electronic TB reporting system in the process of scaling up an electronic reporting system for TB.

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Publications.

Appendix A: Walden Institutional Review Board Approval Number

The Walden university Institutional Review Board approval number for this study was

05-28-19-0466709.

Appendix B: National Tuberculosis Program Permission

FEDERAL MINISTRY OF HEALTH
DEPARTMENT OF PUBLIC HEALTH
NATIONAL TUBERCULOSIS, LEPROSY AND BURULI-ULCER CONTROL PROGRAMME

S.H.M. Complex, 3rd Floor, Plot 1186 Cadastral Zone B06, Mabushi District, FCT, Nigeria
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MH/3781/S6/Vol.II/265   7th May, 2019

Dr. Gidado Mustapha
KNCV
Netherlands

DATA USAGE PERMISSION FOR DR. GIDADO MUSTAPHA

In line with your mail to the National TB programme requesting permission to access and use our secondary data, our figures, diagrams from previously published TB reports and manuals as part of your Ph. D programme dissertation. NTBLCP agrees to share a *de-identified dataset* with him for this purpose, as described below.

- NTBLCP wishes to permit you to have access to and utilize the TB programe data for your Ph. D. study.
- This access is only limited to aggregated data with no access to patient-level information.
- It is a one-time permission and is only for your current Ph. D study.
- This permission does not include collecting additional data at the site level as this will require additional approval.
- It is the understanding and expectation of the TB program that the research finding should be disseminated to the national TB program stakeholders in Nigeria.

2.   Based on this, kindly sign the attached Data user agreement attached to this mail. You can sign and send it electronically to enable us sign our part. An electronic copy of the signed agreement will be sent back to you.

3.   Thank you and please accept my warm regards.

Dr. A. Lawanson