ACCEPTABILITY OF RAT-BASED DIAGNOSTIC APPROACH OF TUBERCULOSIS AMONG TUBERCULOSIS HEALTH CARE WORKERS IN DAR-ES-SALAAM, TANZANIA

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Epidemiology in the field of Implementation Science.

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DECLARATION

I, **Tabia Hassan**, declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Science in Epidemiology (Field of Implementation Science) at the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Signature of candidate:

Date: 15/5/2018

DEDICATION

In memory of my father

Hassan S. Magulu

1942 – 2016

Background: Since the start of rat-based TB diagnostic tool in Tanzania in 2008, detection of new TB cases has increased by around 40%. In this study we aimed at examining factors that may affect acceptability of the rat-based TB diagnostic tool among TB health care workers in health care facilities served by APOPO in Dar-es-Salaam, Tanzania.

Materials and Method: This was a mixed method exploratory sequential study design. We used in-depth interviews (IDIs) and structured questionnaire to collect qualitative and quantitative data respectively. Qualitative and quantitative data were analyzed using NVIVO software version 10 and Stata 14 respectively.

Results: Twenty-five (56.8%) of participants aged between 18-34 years old and 26 (57.8%) were males. A total of 25 (55.6%) study participants showed higher levels of acceptability of the rats-based approach. Health care workers or personal factors score (perceived benefit and need, self-efficacy and skill proficiency on this new health innovation) was associated with acceptability having Odds ratio of 3.8 [95% CI: 1.0-14.2]. Through qualitative exploration, acceptability was motivated by support from their superior medical staffs, and relative advantages of the tool like fastness, and quality of the results. Issues found to be negatively associated with acceptability of the rat-based approach included lack of clear policy from specific government authority, limited patient awareness, inability of the rats to quantify concentration of TB bacteria, and failure to predict the resistance to the available drugs.

Conclusion: This study provides critical information that can guide policy makers to expand and integrate this new innovation into the current TB diagnostic algorithm.

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I am grateful to all TB health care workers in all health care facilities served by APOPO, who voluntarily agreed to participate in this study regardless of their busy schedules. My heartfelt thanks to all the administrative staff and lecturers at the School of Public Health, University of the Witwatersrand for good management of the programme.

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OPERATIONAL DEFINITION OF TERMS USED IN THE STUDY

APOPO- (an acronym for Anti-Persoonsmijnen Ontmijnende Product Ontwikkeling: means "Anti-Personnel Landmines Removal Product Development") - Is a registered Belgian non-governmental organization, which trains African giant pouched rats to detect pulmonary tuberculosis from human sputum sample.

Rats-based TB diagnostic tool- These are trained rats to detect TB from heat-inactivated human sputum samples through vapour detection technique.

Acceptability-Is the perception among TB health care workers (implementation stakeholders) that a given diagnostic tool is agreeable, palatable, or satisfactory for diagnosing TB.

TB Health Care Workers- These are study participants including laboratory technologists, and clinicians or doctors who are dealing with TB diagnosis and treatment programs in selected hospitals served by APOPO

Acceptability score - Acceptability level.

Clinicians-Referrers to any medical personnel who diagnoses and prescribed. So in this study clinicians puts together clinical officers, assistant medical doctors, and medical officer (doctors).

Laboratory technologist: Referrers to any laboratory personnel who attend six years of secondary education and 3 years of laboratory professional training (bachelor or degree level of study).

Laboratory technician: Referrers to any laboratory personnel who attend four or six years of secondary education and 2 or 3 years of laboratory professional training (certificate or diploma level of study).

Laboratory assistant: Referrers to any laboratory personnel who attend four or six years of secondary education and 3 years of laboratory professional training (diploma level of study).

Laboratory attendant: Referrers to any laboratory personnel who attend four years of secondary education and 2 years of laboratory professional training (certificate level of study).

ACRONOMY

TDR- Tropical Disease Research, a special program for research and training in tropical diseases

WHO- World Health Organization

NIMR- National Institute for Medical Research

TB- Tuberculosis

DOTS - Direct Observation Treatment Short-Course

DTLC-District Tuberculosis and Leprosy Coordinator

RTLC-Regional Tuberculosis and Leprosy Coordinator

NTLP-National Tuberculosis and Leprosy Program

CTRL- Central Tuberculosis Reference Laboratory

MDR- Multi Drug Resistance

mRDTs - Malaria Rapid Detection (diagnostic) Tests

RDTs - Rapid Diagnostic Tests

GDP-Gross Domestic Product

SGD-Sustainable Development Goals

MGD- Millennium Development Goals

ZN - Ziehl-Neelsen

PCR- Polymerase Chain Reaction

IDIs- In-Depth-Interviews

OR- Odds ratio

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CHAPTER 1: INTRODUCTION

1.1 Background

Tuberculosis (TB) is an airborne infectious disease caused mainly by bacillus *Mycobacterium tuberculosis (M. tuberculosis)*. It may be transmitted from a TB infected person whose bacteria load is not in any way suppressed to another person (1). TB can be categorized as active or latent infection. The commonest form of active and infectious TB is pulmonary TB (2). The TB bacteria may also invade other organs like pleura, lymph nodes, pericardium, spine, joints, abdomen and so called extra pulmonary TB (1,2). TB is commonly found in settings with low standard of living. It is more prevalent among those with compromised immunity including individuals infected with human immunodeficiency virus (HIV), children, pregnant women and diabetic patients (3). According to the World Health Organization (WHO) 2016 report, there were an estimated 10.4 million new TB cases and 1.4 million TB deaths worldwide (1). In sub-Saharan Africa (SSA) TB has the highest incidence rates with Tanzania listed among the top 20 countries with the highest burden of TB (1).

A major precedent event in TB management is an early and correct diagnosis of an active TB disease. This helps in both treatment as well as prevention by reducing the transmission risk (4–6). There are different diagnostic techniques that are used to diagnose TB. These techniques include culture, chest photofluorography, tuberculin, rapid molecular tests, sputum smear microscopy, polymerase chain reaction (PCR), and rapid line probe assays (1,2). However, these TB diagnostic tools take longer time, they are less sensitive, they need steady electricity, trained personnel and special laboratory facilities (1,7,8). In resource-limited settings where TB is endemic, there has been a need for a quicker, accurate and cost effective diagnostic tool to improve TB case detection.

The Anti-Persoonsmijnen Ontmijnende Product Ontwikkeling (APOPO) project came up with a unique, rapid, accurate and cost effective tool for TB detection, which involves the use of giant African pouched trained rats (*Cricetomys gambianus*) (9). These rats have well-developed olfactory receptor genes in their nasal organs which make them extremely sensitive sense to smell. The APOPO project has utilized that unique characteristic to detect specific volatile organic compounds (VOC) produced by TB organisms present in positive TB sputum samples (10,11). Rats are trained for a specific period of time to detect the presence of *M. tuberculosis* in heat inactivated human sputum samples by sniffing and pausing above the hole for confirmed positive sample and not pausing for negative sample (12).

The training starts at 3-6 weeks of age whereby the rats are handled to familiarize them to humans and to a variety of sights and sounds (13). They learn to associate a clicker with a food reward , a process known as operative conditioning by using confirmed positive human sputum samples (9,13). The training period needed for rats to qualify for diagnosis of TB ranges between six (6) and nine (9) months (11).

In Tanzania, the implementation of the APOPO project started in 2008 in a few select health facilities. It was mainly used as a secondary screening tool for TB after the screening had been done by health care laboratories (9). However, the level of and the factors that may be affecting the tool's acceptability as a TB diagnostic tool has not been assessed. Although the tool has showed promising potentials as a TB diagnostic tool, there is a need to evaluate how well it is accepted by TB health care workers before it is rolled out for implementation in wider scale.

1.2 Literature review

1.2.1 The burden of the TB

TB is among the top ten causes of death in humans including children, individuals living with HIV, especially those living in poverty, pregnant women, and diabetic patients (1). The Millennium Development Goal (MDG), Stop TB Partnership and the World Health Assembly target of halving TB prevalence and TB-related mortality by 2015, has not been met (3). The main reason being failure of proper TB diagnostic policies especially in the African region (3). Although the disease incidence and death rates continually drops (1.5% and 22% respectively). The world's efforts at achieving the Sustainable Development Goal (SDGs) of ending TB epidemic by 2030, which was adopted by the United Nation (UN) in 2015 is still too far to be met (1,3). The global target to end TB epidemic strategy identified four barriers in achieving progress in the fight against this epidemic including weak health system, basic determinant of TB (poverty, malnutrition, migration and other factors), lack of effective tool for early diagnosis of TB, and continuous unmet funding needs for proper supply of TB treatment (14) .

Tanzania is a developing country with about 36% of the county's population living below poverty line with gross domestic product (GDP) Per capita income of $3,296 and it is among the 30 tuberculosis high burden countries (1). The prevalence of TB in Tanzania is 295/100, 000 affecting more males than females (1). The estimated mortality rate of TB patients excluding those with TB/HIV co-infection is 56/100,000 of the population and it is 47/100,000 for those with HIV co-infection (1).

1.2.2 TB diagnostic methods

There are several diagnostic tools that are currently available for TB including culture, chest photofluorography, tuberculin, PCR and other molecular tests, sputum smear microscopy, and rapid line probe assays (1,2). WHO has recommended the use of commercially accessible liquid culture systems and molecular line probe assays to rapidly detect TB even with multi-drug resistance gene (1). But due to the tools complexity, cost and the necessity of sophisticated laboratory set-up and trained personnel, their uptake is limited in many low resource settings (1,7). The implementation of sputum smears microscopy which not only misses over half of TB cases but also does not indicate drugs susceptibility to guide appropriate TB treatment remains the standard diagnostic tool in low resource settings (7,15).

1.2.3 TB diagnostic methods used in Tanzania

Like in any other resource-limited settings, in Tanzania sputum smear microscopy is widely used as a diagnostic technique for pulmonary TB (7,15). The detection level of gene expert is the highest compared to microscopy and culture as it provides timely results with relatively high sensitivity and specificity. However, in Tanzania only some referral hospitals and research institutions can afford and implement gene expert (16). The gene expert tool is not cost effective as its cartridges have short life spans; the need for stable electricity, trained operators and payment for annual preventive maintenance pose a challenge. The *M. tuberculosis* culture still remains the gold standard and most available tool for TB diagnosis regardless of its turnaround time being between 6-12 weeks and the requirement of specialized laboratory facilities (8).

1.2.4 Implementation of Rat-based TB diagnostic tool

In Tanzania the use of trained African giant pouched rats to detect TB has showed great potentials in TB diagnostics. The trained rats can detect TB at earlier stages than smear microscopy which is routinely and widely used in resource limited settings (17,18). A study conducted to compare the use of trained giant African rat with culture and PCR showed that the sensitivity of 10 rats compare to culture/PCR was 68.4%, and the mean specificity was 87.3%. Sensitivity of rat exceeded that of Ziehl-Neelsen (ZN) done in Direct Observed Treatment (DOTS) centers as part of routine TB screening (18). Unlike sputum smear microscopy, the sensitivity of rats does not seem to be affected by the HIV status of the patient (17).

In Tanzania, since 2008 the trained rats from APOPO project is used as a secondary screening tool for TB (9). All TB suspected patients leave sputum samples at the health care facilities laboratory for classical screening using smear microscopy. Then, all TB negative and positive sputum samples are delivered to APOPO project for further screening (12,19). The trained rats do screen all the samples very quickly (1 sample in 3 seconds) before signaling for “TB suspect” samples missed

from the DOTs centers (20). All “TB positive suspects” by rats are re-evaluated using a concentrated smear light-emitting diode fluorescence microscopy (LED-FM) and other TB screening techniques by qualified laboratory technologists to confirm their positivity status (12,20). The confirmed positive cases are sent to respective hospitals within 24 hours so that the patients can receive immediate and appropriate treatment (13). All the health care facilities where rats-based TB diagnostic tool has been deployed and is being implemented are selected based on high population density and high TB disease prevalence.

1.2.5 Studies on the factors affecting acceptability

The level of acceptability can be assessed in an early stage of implementation before adoption, ongoing for penetration or late stage of implementation for sustainability purpose and in additional can be assessed by an individual provider or individual consumer (21). The evaluation of acceptability and performance of three LED fluorescent microscopes among laboratory technicians in Zambia showed that acceptability of an intervention depends upon the extent of the intervention meeting the needs of the intended beneficiaries. The laboratory technician expressed about comfort, quality of images, fast reading times, easy adjustable microscope and good contrast and resolution are among the factors which increases their acceptability level to a given type of microscope (22). The study done to assess acceptability and performance of the FluoLED Easy™ for TB fluorescence microscopy among technicians in TB reference laboratory in Thailand and Tanzania demonstrated that there was high user acceptance to the extent that technicians refused to return to using ZN. The technician agreed that relative advantage and support from their superior medical staffs are among the factors which motivated them to accepting the TB diagnostic tool (23).

Another study done among TB experts worldwide to evaluate current use and acceptability of novel rapid diagnostic tests for active tuberculosis indicated a high level of acceptability. Although level of education, and income of the country significantly were associated with acceptability level, the respondent having a decision-making role, respondent age and respondent years of experience in the area of tuberculosis showed no association with acceptability (24). Furthermore, presence of sufficient supporting data, reasonable or cheap price, presence of clear policies, and intensive training was among the factors perceived by study participant that positively influence acceptability level (24).

An excellent acceptability level was demonstrated in a study done by A. Banerjee on acceptability of traditional healers as directly observed treatment providers in tuberculosis control in a tribal area of Andhra Pradesh, India. The study findings demonstrated that traditional healers were accessible and acceptable to the population to action as DOTs providers and were easily contacted for treatment of different diseases including treating TB disease (25). It was mentioned that lack of

education among community members about TB treatment, insufficient care from a specialist and being not satisfied with their DOT provider were among the factors which influenced TB patients to highly accept traditional healers for TB treatment (25).

In addition, another study conducted to assess early experiences on the acceptability, feasibility, and use of mRDTs at peripheral health facilities in Uganda. The findings from this study showed that existence of clear policy guidelines, comprehensive training, characteristics of the diagnostic tool (perceived benefit, good design, tools easy to use, and learn) and good support supervision were mentioned to be among the reasons and factors for mRDTs acceptability by the target users (26). It was further described that the acceptance and attitude toward using a given new innovation or health intervention depends on different issues including personal, cultural, and organizational factors (26). Another study done in Tanzania on acceptability of mRDTs, showed positive perceptions, attitudes and acceptance of mothers towards the use of RDT that administered by village health care workers. On-top of that, communities' members expressed the presence of training, good relationship with village health workers, reliable supplies, close supervision, and affordability of mRDTs as among the factors that motivate them to accept the implementation of RDT by village health workers (27) .

There was a study done in war-torn Democratic Republic of Congo on the acceptability (use and limitations) of malaria rapid diagnostic testing by community health workers. The study finding showed that this mRDT is likely to be acceptable to community health workers. However, they mentioned some factors which hinder or motivate them on using mRDT in their setting. They expressed that presence of training, experience, utility and ease of use of RDTs are the reasons which motivate them keeping using the test, although cost remains a major obstacle to the use of RDTs in areas of high malaria burden (28).

Another study conducted in Rwanda to explore factors affecting the acceptability and use of malaria preventive intervention. This study provides direction on the perspectives that there are different factors like cultural, social, knowledge, environmental condition and experience that have been identified as delaying or hindering the acceptability and use of malaria intervention (29).

A 2015 study by Prafulta and colleagues assessed acceptability, feasibility and challenges of implementing an HIV prevention intervention for people living with HIV/AIDS among healthcare providers in Mozambique. They found that positive prevention interventions were acceptable and feasible to providers, though many providers noted social and cultural challenges to implementing positive prevention and improved intervention uptake among patients. They mentioned training as a major factor which influence implementation of this new approach with their patients (30).

There was another study conducted in Tanzania evaluating RDT acceptance and usage by providers and patients. There was a high level of acceptance of and satisfaction with RDTs among providers and patient/caregiver. The results of this study indicated that intensive training, closer supervision,

positive community and/or individual pressure, fast/quickness of test, effective distribution and good management systems are among the factors which positively affect acceptability and usage of RDT (31). There is no study that has been conducted to assess the level of and factors affecting acceptability of rat-based TB diagnostic tool in Tanzania.

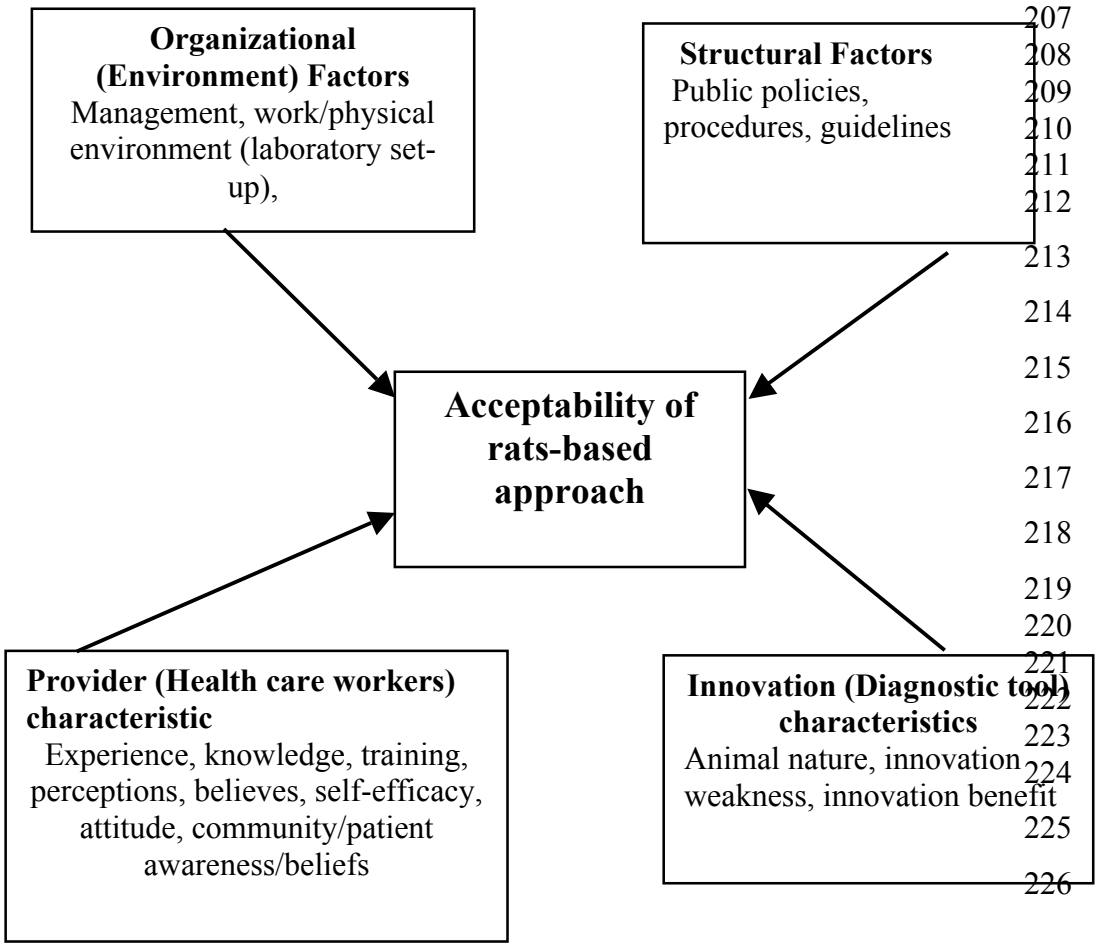
Key findings as per the literature:

In general, the factors that positively affect acceptability for the different health intervention as per the literature section are cost (affordable or cheap price), fast/quickness of intervention, support from superior staffs, presence of clear policies, presence of education, characteristics of that health intervention, formal training, positive community or individual pressure, and good management system.

1.2.6 Conceptual Framework for factors affecting Acceptability

Through synthesizing the present theories and frameworks by Damshroder et al. from a Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science (32), two systematic literature review by Durlak and Dupre (33) and by Chaudoir et al. (34) multi- level conceptual framework that articulates predominant factors that predict or impact implementation outcomes, we hypothesize that the factors affecting acceptability in our study fall under four main constructs. Those four constructs are Structural factors, organizational factors, innovation level factors and provider/ Health care workers level factors. The literature from low resources setting countries and our study interviews guide us to group the identified factors from our study under each construct adapted. The conceptual framework for factors hypothesized to affect acceptability can be seen below.

Figure 1. Conceptual framework, of hypothesized factors affecting Acceptability of the rat-based TB diagnostic tool among health care workers providing TB treatment in health care facilities served by APOPO in Dar-es-Salaam, Tanzania. Adapted and synthesized from Damshroder et al., Chaudoir et al., Durlak and Dupre



1.3 Problem Statement

Although TB is a major cause of mortality in Tanzania, still the main TB diagnostic tool remains sputum smear microscopy (1,35). Sputum smear microscopy in Tanzania is regarded as gold standard tool despite the rate of false negative results being high and its sensitivity being very low (7,15). Since the launch of the rat-based TB diagnostic tool in Tanzania in 2008 reports have showed that new TB cases detection has increased by around 40% (12). However, until to date, rat-based diagnostic tool has not used as a TB diagnostic tool in routine TB diagnosis. Further, there is no data on the reasons for this low uptake and acceptability of the tool. With limited understanding of acceptability and factors that may affect rat-based TB diagnostic tool, it would be difficult to modify and roll out the tool to more health care settings for routine diagnosis.

1.4 Justification

This research explores the factors affecting acceptability of rat-based TB diagnostic tool among TB health care workers. Acceptability is an important measure because it highlights the agreeability, palatability and satisfaction of this new tool. It allows for adaptation of a diagnostic tool to fit a given local setting. Thus knowledge, opinions, views and perceptions of health care workers is key to scaling-up of any new diagnostic tool. The findings from this research will inform clinical protocol, implementers and TB policy makers about acceptability views around rat-based TB

diagnosis in Tanzania. It will invariably provide key information that can help in strategic planning to improve the uptake and scale-up of the diagnostic tool across the country.

1.5. 0 Study Objectives

1.5.1 Research Question

What are the factors affecting acceptability of the rat-based TB diagnostic tool among TB health care workers in Dar-es-Salaam, Tanzania?

1.5.2 Aim

To examine the factors affecting acceptability of the rat-based TB diagnostic tool among TB health care workers in health care facilities served by APOPO in Dar-es-Salaam, Tanzania.

1.5.3 Specific objectives

1) To explore the factors affecting acceptability of rat-based TB diagnostic tool among TB health care workers in health care facilities served by APOPO in Dar-es-Salaam.
2) To determine/measure the level of acceptability of rat-based TB diagnostic tool among TB health care workers in health care facilities served by APOPO in Dar-es-Salaam.
3) To determine the association between acceptability score and other factors that may be affecting acceptability of the rats-based TB diagnostic tool.

CHAPTER 2: METHODOLOGY

2.1 Study design

This was a mixed method exploratory sequential study design. Qualitative data was collected first using in-depth interviews (IDIs) to explore TB health care worker's perceptions, knowledge, opinions and views regarding acceptability and factors that might be affecting acceptability of rat-based TB diagnostic tool. The findings from qualitative approach were then used to refine and prepare a structured or close-ended questionnaires for collecting quantitative data.

2.2 Study site

This study was conducted in Dar es Salaam, Tanzania. It involved twenty health care facilities that are served by the APOPO project. Dar-es-Salaam is the largest commercial city in Tanzania consisting a population of over 4.4 million accounting for 10 percent (10%) of the total Tanzania Mainland population (36). It covers a total land area of 1,393 km^2, which is divided into three administrative municipal councils. It is a fast growing city with an estimated population of 6 million by 2020 (37). The high population density and growth rate due to in-migration, increasing birth rates, and other factors affects negatively the health care systems in this city. The high population density and poor infrastructure result in different diseases outbreak and TB is among the top five diseases that cause mortality in Dar-es-Salaam region (37).

2.3 Study population

The study population was the TB health care workers including clinicians or doctors, and laboratory technologists or technicians. All the study participants were working for TB sections in selected 20 health care facilities served by APOPO project.

2.4 Sampling

For the qualitative data collection, 19 study participants (clinicians/doctors and laboratory personnel) were purposively selected among TB health care workers based on their knowledge and experience on rat-based TB diagnostic tool. The selection of the study participants ensured maximum variation in characteristics including gender, age, job category and length of service at TB section. In all health care facility, we purposively selected study participant to participate in the study. Therefore, the final number those who participated in the IDIs was 19.

For quantitative data collection part, all TB health care workers (only laboratory personnel's) in 20 health care facilities served by APOPO project within Dar es Salaam were included in the study. No sampling procedure was needed for this part of the study. The total number of study participants involved in quantitative data collection was 45. For quantitative statistical analysis, this sample size is too small, thus it limits the generalizability of the study findings.

2.4.1 Inclusion criteria

A study participants included in the study was required to be a TB health care worker, who has worked for more than twelve months in a TB section and has attended at least one APOPO project seminars or trainings.

2.4.2 Exclusion criteria

A study participant was excluded if s/he was a health care worker but not in TB section, or working under TB section for less than twelve months and has never attended a single APOPO project seminars or trainings

2.5 Variables and their Definitions

2.5.1 Outcome Variable

Acceptability of rat-based TB diagnostic tool was the outcome or dependent variable in this study. It was defined as the perception among TB health care workers that the rat-based TB diagnostic tool is agreeable, palatable or satisfactory. Acceptability was measured using Likert scale based on a range of questions in the structured questionnaire that assessed the agreeable, palatable or satisfactory about rat-based TB diagnostic tool. The adapted Likert scale used 5 points to score the acceptability (1=strongly disagree to 5=strongly agree). The 5 points score measured respondent attitudes either positive, negative or neutral to a given statement or question regarding the rat-based TB diagnostic tool. The acceptability average score was calculated and categorized into low, moderate and high.

2.5.2 Explanatory variables:

These comprised of a number of factors that have been hypothesized to influence acceptability of rat-based TB diagnostic tool identified from the in-depth interviews. These factors were grouped into four: health care worker (personal) related factors, environmental factors, diagnostic tool (nature of the diagnostic tool), and policy related factors. The personal factors included experience, knowledge, training, perceptions, community/patient awareness, beliefs, self-efficacy and attitude. Environmental factors were the organizational management and working or physical environment. Factors related to nature of the diagnostic tool were the animal or rat nature, innovation weakness and innovation benefits. Policy related factors included public health policy, procedures and guidelines regarding inclusion of rat-based TB diagnostic tool. Other characteristics of health care workers were age, sex, job category, and experience working under TB section.

2.6 Data collection, management and analysis

2.6.1 Qualitative data collection, management and analysis

Face-to-face IDIs were conducted in Swahili using a semi-structured interview guide. The IDIs guide was piloted in one hospital to ensure its validity and reliability before starting the actual study interviews. Open-ended, non-directed questions were asked to explore study participants' general knowledge, views, awareness and their perceptions on acceptability and the factors that

might influence the acceptability of rat-based TB diagnostic tool. Acceptability, willingness to diagnose TB using rats, the use of rats-based results, and their general beliefs in the tool and the results were explored. The interviews were conducted in a private room and the interviewer ensured interviewee's confidentiality of the data being collected to make them talk freely. The process of audio recording and other procedures was introduced to the interviewee before interviews. The interviews lasted between 30-45 minutes, depending on the level of information offered by study participant. All interviews were centered on the main question followed by a probing process to get more information. Also, interviewee's body language and facial expressions were noted by the interviewer as part of data.

The recorded IDIs were transcribed verbatim and translated from Swahili to English language. Transcriptions were reviewed, checked and re-checked against the recorded audio for accuracy and completeness. The identified variations or discrepancies from the data were corrected accordingly. The recorded audios and soft-copies of the interview transcripts were kept in a password-protected computer while hard copy transcripts were kept in a lockable cabinet. The analysis was done using thematic framework analysis in Nvivo version 10. Key steps taken in the analysis included familiarization, identifying thematic analytical framework, indexing, charting, and results interpretation. Briefly, the transcripts were read and re-read in detail in order to be familiar with the content of the data collected. Then, codes were clearly defined and classified into categories in order to develop a thematic framework. The codes were derived inductively from the soft copy transcripts and the categories of the identified themes were aligned with the objective of the research study. The coding was done by carefully reading the transcripts line by line to identify and assign codes to important issues that are related to the study's themes of interest i.e. policies, procedures and guideline, environment, health care workers or personal, and diagnostic tool related factors. The identified codes that had been assigned to different themes or factors were then compared to capture similarities and differences between the two data analysts. Then, these codes were applied to all the transcripts using Nvivo software. The charting process brought all the data related to a particular coding theme together in the same place and Nvivo software was used to organize the charts of the discovered themes or issues. Thereafter, the charted data were analysed, visualised, summarized, and interpreted into specific themes or factors from each transcript making sure that original meanings were retained.

2.6.2 Quantitative data collection, management and analysis

A well-designed and pre-tested questionnaire was administered to the eligible study participants to capture data on acceptability and factors affecting acceptability of the rat-based TB diagnostic tool. Double data entry was performed in Epi-data version 3 database. Data cleaning was performed specifically to check for entry errors, inconsistencies and missing values.

Socio-demographic and other study characteristics were summarized and presented as frequency (n) and percentage (%). Sets of variables describing a given factor or theme were assigned to that particular factor or theme. To simplify the analysis, factors (themes) were grouped into four: health care worker (personal), environment, diagnostic tool (nature of rat-based test) and policies, procedures and guidelines related factors. Then total scores, mean and median (IQR) in five points' Likert scale (1; Strongly disagree up to 5; Strongly agree) for each factor were calculated. Briefly: to create a single variable related to health care worker (personal) factor five questions or variables, were used to calculate the total and mean scores. For policy related factors, four variables or questions were used to obtain the total and mean scores. Environment factors score was calculated from two questions. For nature of diagnostic tool score, three questions were used to create the total score and mean diagnostic tool score.

Acceptability was measured using self-report measures or domains captured by the five questions. These included responses to hypothetical scenarios, satisfaction measures, attitudinal measures, reports of individuals on their perceptions of, and experiences with the intervention. Then, to create the acceptability as a single variable, the total and mean scores were calculated from all the five questions. Then mean acceptability score was categorized into 3 groups (0=low, 1=medium and 2=high) based on the following criterion 1-2.9="low", 3.0-3.99="medium" and 4.0-5="high".

To determine the measure of each variables reliability (internal consistency) that is, how closely related a set of variables are as a group we performed a correlation and Cronbach's alpha test. The importance of each variable was determined by comparing the variable Cronbach's alpha with the overall Cronbach's alpha. The higher the Cronbach's alpha coefficient, the more the variables are correlated or measuring the same outcome. If a variable is dropped from the correlation matrix, its corresponding alpha is indicative of the overall alpha. Thus a variable that reduces the overall alpha if it were to be dropped should be retained i.e. it is an important variable or factor to be kept.

We further performed Exploratory Factor Analysis (EFA) to assess and identify important variables to be kept. All the variables identified by EFA were used in regression model. Ordered logistic regression analysis was performed to identify variables or factors affecting acceptability score (0=low, 1=medium and 2=high) of rat-based TB diagnosis. To determine the association between acceptability of rat-based TB diagnosis and other variables, crude and adjusted odd ratios (OR) were calculated. The variables with a P value ≤ 0.20 in the univariate analysis were eligible for entry into the multivariable logistic regression model, where adjusted OR and 95%CI were calculated accordingly. A two-tailed p-value of 0.05 was considered statistically significant. All quantitative data analyses were performed using Stata 14 (StataCorp, College Station, Texas 77845 USA).

2.7 Ethical consideration

Ethical clearance for the study was obtained from the Tanzanian National Health Research Ethical Committee of the National Institute for Medical Research (NIMR) with approval number NIMR/HQ/R.8a/Vol.IX/2404. Also the Human Research Ethics Committee (Medical) of the University of the Witwatersrand approved the study with number M161193. A written informed consent was sought from participating before enrolment into the study. Participation in this study was completely voluntary

CHAPTER 3: RESULTS

3.1 Qualitative Results

A total of 19 TB health care workers participated in IDIs. Ten participants were males and nine were females. Out of 19 IDIs, 13 were doctors or clinicians and 6 are laboratory technologists or technicians. Almost all study participants had more than one year of working experience in the TB section in collaboration with APOPO project. A high interplay and inter relationship between the themes or factors affecting acceptability of the rats-based TB diagnostic tool was noted. From this interplay four broad themes came-up after doing thematic framework analysis of the IDIs.

3.1.1 Policies, Procedures and Guidelines related factors

Study participants reported that there were guidelines followed for any diagnostic tool to be used in the health care facility. To be used as a diagnostic tool and for it to be incorporated into the national diagnosis policies, usually a country consults WHO or has to wait until WHO recommends it. In Tanzania, all diagnostic tools used in governmental healthcare facilities are those approved by ministry of health guided by WHO guidelines. Study participants expressed their feeling by seeing that WHO endorsement in any diagnostic tool is mandatory.

"Anything that is not recommended by WHO will not be accepted and there is no possibility to use that thing in our country because anything that is not approved by WHO is invalid to use " (study participant D14)

"*But then to use it as part of the national policies in diagnosis usually we consult WHO or we wait for the WHO policies to at least mention where the test should be placed in diagnostic algorithm".* (study participant D1)

"I see directly people are waiting for WHO to say yes rats from APOPO deserves to be used. But Tanzania as a country still has no mandate to approve its usage directly". (study participant D8)

WHO has not yet endorsed the rats-based TB diagnostic tool, which limits the Tanzanian ministry of health to adopt this technology and integrate it into the TB diagnostic algorithms. Participants went further on indicating that their practices are largely dependent on healthcare policies and recommendations. The inclusion of rats-based TB technology in TB treatment guidelines from ministry of health would be a strong reinforcement towards new TB case detection. The government's endorsement through the ministry of health was deemed crucial to acceptability of the diagnostic tool.

"The time the ministry will say that from now on APOPO technology has been accepted for us we cannot oppose to implement it. But as health care workers, without higher authorities giving us clearance we cannot accept it directly." (study participant D7)

"We are the final users. I mean we depend on the ministry of health...if the ministry of health says no, we don't know this technology we are not going to accept it" (study participant D14)

Another reason mentioned by study participants that affect acceptability of the tool was lack of space in TB logbooks to write the rats-based positive results. Because the tool has not WHO approval, the ministry of health does not prepare TB logbooks to record rats-based positive results. Therefore, the rats-based positive results coming are not recorded in the TB logbook. This results in limited follow-up for rats-based positive patients although those patients were put on TB medications.

"If we get results from APOPO (rats-based results) we don't write in our logbook as it is indicated we administer treatment but we write the previous results the patient got at the beginning as smear negative" (study participant D13)

"*Big problem for the rat's results is patients follow up… that is why as I said is not easy to be accepted."* (study participant D10)

"Even if APOPO says it is positive, am not allowed 100% to write as positive unless I get results from other diagnostic tools like microscopy or gene expert" (study participant D9)

3.1.2 Diagnostic tool related factors

The nature of technology was also found to affect the study participants in satisfaction, trust and comfort with rat-based diagnostic tool. There is a feeling that they are medical personnel trained to handle human beings and no other animals. They do not have much knowledge and experience to deal with animal-based tools.

"*I said these are animals and we as medical personnel are not experts when it comes to animals, so it going to be challenging for us now to start dealing with animals "* (study participant D1).

There is a feeling that the act of repeating the screening process after rat's indication makes study participants to be doubtful of their tool. The study participants indicated that the APOPO project personnel are not confident with rat's ability due to its nature, because after rats' indication they do confirm the results with other techniques before returning the results to the specific health care facilities.

"APOPO are not yet confirming if the results are only rat-based by 100% for patient(s) to start medication. When rats detect TB still they do concentration method, gene x-pert and then culture" (study participant D9)

"Even APOPO themselves are hesitant in believing the rat-based results directly" (study participant D13*)*

Though most of study participant mentioned the advantages of using rats-based TB technology and their contribution in eradicate TB compared to other TB diagnostic tools. Issues of early TB detection, quickness, and cheapest technology compared to molecular tool were repeatedly mentioned. The study participants pointed out that if our goal as a national is to eradicate or combat

TB by 2035, there is a need for the government to accept this rats-based technology and endorse it as TB diagnostic tool.

"*APOPO technology has demonstrated that rats can detect TB in a very early stage compared to many other TB technologies…as you know if there is early TB detection and early TB diagnosis and treatment becomes better"* (study participant D2)

"*Within a minute, rats can screen a lot of sputum samples….and these rats use sense of smell so even when bacteria or bacilli are in a very low concentration which is not possible to detect by microscope, yet the rats can detect it."* (study participant D9)

"Rats do help me to detected more tuberculosis positives, additionally to what I missed from classical diagnostic facilities" (study participant D10)

3.1.3 Health care workers (Personal) related factors.

There were different views or issues related to the study participants themselves that emerged. Perceptions and beliefs appeared to emerge most often as principal factors that may affect in one way or another the implementation of rats-based TB technology. These factors were crosscutting as they closely interrelated with most of other themes i.e. diagnostic tool, environmental and policies, procedures and guidelines related factors. Most of the study participants indicated that they are not ready to work with rats-based TB diagnostic tool because these are animals. In additional, the TB health care workers pointed out that they do not have detailed information and formal training on rats-based technique for them to be competent and comfortable with the rat-based tool.

"*For sure we are not comfortable living with animals"* (study participant D1)

"I don't know ethically how to handle rats…whether or not it is allowed to mix rats with other diagnostic machines in the laboratory" (study participant D5*)*

*"I don't have that knowledge to deal with animals...am not trained on that" (*study participant D15)

Some of the study participants pointed out that the rat's inability to quantify TB bacteria and to predict the drug resistance also lower their acceptability by most health care workers. The negative perceptions and doubts about the rat-based diagnostic tool by some of the study participants impact negatively the delivery of rats-based results to the community members, because they are the ones who are dealing with the community member directly.

"*I do not know if this rats are capable of isolating the mycobacterium or to quantify them… if rats are capable to do that...I will accept it. And also I do not know if rats are trained to detect multi-drug resistance tuberculosis (MDR TB)*" (study participant D12)

Most of the health care workers explained the lack of awareness among community members with regard to the rats-based TB diagnostic tool negatively affects acceptability of this technique. Some

of the study participants indicated that there were some patients still doubting rats' ability in TB detection that resulted in disbelieving rats' results. Sometimes people advise their patients having TB positive results from rats to produce another sputum samples for it to be confirmed by other TB diagnostic tools. This situation reduces healthcare worker's confidence in better engaging patients in decision making towards TB medications after having rat-based positive results. The study participants suggested the need for APOPO project to provide education about the technique to raise awareness among community members.

*"Sometimes patients do not believe the rat-based results…in such occasions they advised the patients to produce another sputum" (*study participant D5)

"Due to limited awareness I was getting hard time to explain to my clients, the TB patients that they were diagnosed by rats and found to be TB positive" (study participant D8)

"*We normally tell him or her that s/he has been discovered to be TB positive by more superior devices… you don't tell him or her that he has been discovered by rats-based technique, because they might not come…. because people are not aware of it yet".* (study participant D13)

"*APOPO should provide education to community members, because most of community members are not aware on this technique, they do not know what APOPO is all about"* (study participant D14)

Some study participants suggested that, there is a need for other people to attend APOPO project seminars and training to increase their knowledge about rats-based TB diagnostic tool. There a perception that, there was a relationship between seminars or training attended and level of acceptability of this diagnostic tool.

"If a person attended a number of APOPO seminars or trainings and see or observe what is going on over there it won't be possible for him/her to resist on rats-based technique" (study participant D14).

"I accept it because I have seen the rats doing the TB detection process…I have already been trained and showed how rats work and they just show me practically" (study participant D16)

3.1.4 Environment related factors.

Factors related to the working environment in particular the laboratory set-up. Some of the study participants expressed that the present laboratory set-up in our health care facilities are not meant for rats-based techniques. The study participants pointed out to the limited laboratory space

available. Currently they are a few small rooms which most of the time only one room or two rooms are available to accommodate all the machines for different disease detection. The study participants felt that limited laboratory space is among the reasons hindering the acceptance of rats as a routine TB diagnostic tool

"L*aboratory set-ups also is a big problem, because even the laboratories located in Dar-es-Salaam where pilot study takes place still does not allow mixing up with rats' technology"* (study participant D10)

"For now our laboratory set-up has has no space special for rats-based technique ". (study participant D12)

*"For the present laboratory…we don't have that infrastructure to accommodate rats" (*study participant D15)

Nevertheless, most of the administration staff from health facilities served by APOPO project do support and accept rats-based TB diagnostic tool and its results. Due to that, some study participants do think that it is better to open standard veterinary laboratories which can serve not only for animals but also for human beings including TB detection.

*"But if we want to accommodate the rats there is a need to build another standard and special laboratory for rats" (*study participant D19)

"*May be they should construct special laboratories for rats only but not in the laboratories of our hospitals"* (study participant D16)

Qualitative: Key findings

Key findings identified are: The factors identified from IDIs which affect acceptability includes: Health care worker related factors (lack of formal training, limited patient awareness, inability of the rats to quantify TB disease and in predicting the resistance to the given drugs), policies, procedures and guidelines related factors (lack of clear policies and treatment guidelines), environment related factors (laboratory set-up, hospital management), and diagnostic tool related factors (compatibility, complexity, and relative advantage of the tool).

603 3.2 Quantitative Results

604 3.2.1 Socio-demographic and other study characteristics

605 Out of 45 study participants, 19 (42.2%) were females and 26 (57.8%) were males. Twenty-five
606 participants (55.6%) were aged between 18 and 34 years old. Twenty-eight participants (62.2%)
607 were laboratory technologist, 12 (26.7%) were laboratory assistant and 5 (1.1%) were laboratory
608 attendants. Twenty-five participants (55.6%) agreed that rat-based TB diagnostic tool is the most
609 accurate TB diagnostic tool and 25(55.6%) reported high level of acceptability of the rats-based TB
610 diagnostic tool (Table 1).

Table 1: Characteristics of the surveyed TB laboratory personnel in Dar-es-Salaam

Characteristics	No.	%
TB screening results used in the facility		
Microscope	45	100
Gene expert	34	75.6
Culture	8	17.8
Rats-based	45	100
Age category for participants		
18-34	25	56.8
35+	19	43.2
Sex		
Female	19	42.2
Male	26	57.8
Job category (laboratory education levels)*		
Assistant	12	26.7
Attendant	5	11.1
Technologist	28	62.2
Time working in TB section		
Between one year and two years	10	22.2
>2 years	35	77.8
Level of acceptability[&]		
Low	6	13.3
Medium	14	31.1
High	25	55.6
Accuracy of microscope		
More accurate	32	71.1
Mostly accurate	12	26.7
Not accurate	1	2.2
Accuracy of gene expert		
More accurate	20	58.8
Mostly accurate	14	38.2
Not accurate	1	2.9
Accuracy of culture		
More accurate	3	37.5
Mostly accurate	5	62.5
Accuracy of rats-based		
More accurate	19	42.2
Mostly accurate	25	55.6
Not accurate	1	2.2

[&]Acceptability scale: <=2.99 (Low), 3-3.99 (medium),>=4 (High)

*Attendants are laboratory personnel with certificate

*Assistants are laboratory personnel with diploma

*Technologist are laboratory personnel with degree

611
612 3.2.2 Exploratory Factor Analysis and correlation of health care worker's (personal) related factors

613 The correlation of each variable (factor), Cronbach's alpha (**α**) and Exploratory Factor Analysis
614 (EFA) were performed to identify Health care worker's (personal) related factors (Table 2). There
615 is a positive correlation between all the personal related factors that may affect rat-based diagnostic
616 tool acceptability among healthcare workers. Mean and median score (IQR) in five points' Likert
617 scale (1; Strongly disagree up to 5; Strongly agree) for no doubts if rats-based technique should be
618 used with other confirmation tools and not as a stand-alone tool was 4.20 and 4 (4-5) respectively,
619 with a correlation of 0.4788, Cronbach's alpha (**α**) of 0.6104 and uniqueness value of 0.4139. The
620 mean and median score (IQR) for the importance of attending APOPO seminars in ultimately
621 increasing knowledge and acceptability of rats-based TB diagnostic tool was 4.42 and 5 (4-5)
622 respectively, with a correlation of 0.4738, Cronbach's alpha (**α**) of 0.6113 and uniqueness value of
623 0. 5212. The mean and median score (IQR) of not having knowledge to deal with rats-based TB
624 tool because healthcare workers are human based laboratory personnel's was 4.0 and 4 (4-5)
625 respectively, a correlation of 0.5337, Cronbach's alpha (**α**) of 0.5999 and uniqueness value of 0.
626 4578.

627 3.2.3 Exploratory Factor Analysis and correlation of environment related factors

628 The mean and median score (IQR) for the present laboratory set-up that the laboratories cannot
629 accommodate rats-based TB diagnostic tool was 4.09 and 4 (4-5) respectively, a correlation of
630 0.5681, Cronbach's alpha (**α**) of 0.5931 and uniqueness value of 0.5795. Suggesting the view that
631 specialized veterinary laboratories should be constructed. The mean and median score (IQR) for
632 the hospital management to support rats-based results and put rat's positive patients under
633 medication was 3.93 and 4 (4-5) respectively, a correlation of 0.3487, Cronbach's alpha (**α**) of
634 0.6334 and uniqueness value of 0.2937 (Table 2).

635

636 3.2.4 Exploratory Factor Analysis and correlation of diagnostic tool (nature of rat-based test)
637 related factors

638 The mean and median score (IQR) of resulting in stigmatization for rats' positive patients because
639 of its animal nature was 2.64 and 2 (2-3) respectively, a correlation of 0.3985, Cronbach's alpha
640 (**α**) of 0.6249 and uniqueness value of 0.6657. The mean and median score (IQR) of rats-based not
641 being approved by WHO because of its animal nature was 2.93 and 3 (2-4) respectively, a
642 correlation of 0.2669, Cronbach's alpha (**α**) of 0.6468 and uniqueness value of 0.6387 (Table 2).

643

644 3.2.5 Exploratory Factor Analysis and correlation of policies, procedures and guidelines related
645 factors

646 The mean and median score (IQR) for the variable investigating that there are problems in doing
647 follow-up for rat-based positive patients due to lack of WHO endorsement was 3.71 and 4 (4-5)
648 respectively, a correlation of 0.3062, Cronbach's alpha (**α**) of 0.6405 and uniqueness value of
649 0.6611. The median score (IQR) of repeating all the samples after rats' indication to confirm its
650 positivity was 4 (4-5), a correlation of 0.6888, Cronbach's alpha (**α**) of 0.5677 and uniqueness
651 value of 0.3967 (Table 2).

Table 2: Exploratory Factors Analysis for the factors affecting acceptability of rats-based TB diagnostic technique in Dar-es-Salaam, Tanzania

Factors or Reasons	**Mean(SD)**	**Median(IQR)** [#]	**Item-test correlation**	**Alpha**[$]	**Uniquenes**
I will have no doubt if rats-based technique used with other confirmation tool and not a stand-alone tool	4.20(0.99)	4(4-5)	0.4788	0.6104	0.4139
I am not aware on the ability of rats based technique on differentiating between normal TB bacteria and non-TB bacteria	2.98(1.23)	3(2-4)	0.2358	0.6517	0.5039
I believe that rats-based TB diagnostic technique will result in stigmatization because of its animal nature	2.64(1.15)	2(2-3)	0.3985	0.6249	0.6657
I know it is un usual for WHO to approve an animal based technique	2.93(1.05)	3(2-4)	0.2669	0.6468	0.6387
I think lack of WHO endorsement of rats-based TB diagnostic tool cause a big problem in doing follow-up for rats positive patients	3.71(1.27)	4(4-5)	0.3062	0.6405	0.6611
I am sure the laboratory set-up present in our health care facilities cannot accommodate rats as TB diagnostic tool	4.09(1.12)	4(4-5)	0.5681	0.5931	0.5795
I think that it is more expensive to use the rat-based TB diagnostic tool as a routine TB screening technique	3.60(1.16)	4(3-5)	0.4320	0.6189	0.5197
Attending APOPO seminars increases my knowledge and acceptance of rats-based ability in TB detection	4.42(0.92)	5(4-5)	0.4738	0.6113	0.5212
I am a human based laboratory technologist I do not have much knowledge to deal with animal based tools	4.0(1.21)	4(4-5)	0.5337	0.5999	0.4578
I think is tedious work to use rats-based as a routinely diagnostic tool because needs someone to confirm it after rats indication	3.98(1.06)	4(4-5)	0.6888	0.5677	0.3967
I believe that community member are still skeptics on the rats-based technique	3.93(1.12)	4(3-5)	0.3952	0.6255	0.4557

I know when APOPO bring back the positive results am not using those results directly as positive because these rats technology still not validated not even accepted by government as a diagnosis technology	2.87(1.25)	3(2-4)	0.3593	0.6316	0.5427
I believe rat-based diagnostic results has improved my individual confidence to discuss with TB patients	3.93(0.96)	4(4-5)	0.3788	0.6283	0.2478
I feel that the hospital management in this health facility support rat-based diagnostic results	3.93(0.94)	4(4-5)	0.3487	0.6334	0.2937
Total Cronbach's alpha				0.6386	

[$]Cronbach's alpha
[#]Likert scale range: 1-Strongly disagree up to 5-Strongly agree

3.2.6 Exploratory Factor Analysis and correlation of Acceptability score

The analysis showed the overall mean and median (IQR) for all variables describing acceptability in 5-points Likert scale was 3.8 and 4 (4-5) respectively. Specifically, the variables with the highest scores were for the variable explaining about trusting rat's ability in TB detection whose mean and median (IQR) score was 3.71 and 4 (3-5) respectively, a correlation of 0.8270, Cronbach's alpha (**α**) of 0.8156 and uniqueness value of 0.4073. Recommending rats based technique to be placed in TB diagnostic tool algorithm and be used as a routine TB screening in the hospital with mean and median (IQR) score was 3.91 and 4 (4-4) respectively, a correlation of 0.8125, Cronbach's alpha (**α**) of 0.8214 and uniqueness value of 0.3488 (Table 3)

Table 3: Exploratory Factors Analysis for acceptability score of rats-based TB diagnostic tool

Acceptability Questions	**Mean(SD)**	**Median(IQR)** [#]	**Item-test correlation**	**Alpha**[$]	**Uniqueness**
I trust the ability of the rat-based technique in TB detection compared to that from other diagnostic tools.	3.71(1.14)	4(3-5)	0.8270	0.8156	0.4073
I like rats-based results because it has high quality compared to the results from other TB diagnostic tool.	3.60(0.97)	4(3-4)	0.7958	0.8279	0.4103
I am satisfied with the ability of the rat-based TB diagnostic technique in TB detection and the result coming from it	3.87(1.04)	4(3-5)	0.7563	0.8425	0.4937
It is very enjoyable to use the rat-based TB diagnostic technique over other methods	3.96(1.09)				

for TB screening.		4(3-5)	0.7955	0.8280	0.4114
I would recommend rat-based technique to be placed in TB diagnostic tool algorithm and be used as a routine TB screening in the hospital	3.91(0.97)	4(4-4)	0.8125	0.8214	0.3488
Total Cronbach's alpha				0.8568	

[$]Cronbach's alpha
[#]Likert scale range: 1-Strongly disagree up to 5-Strongly agree

3.2.7 A descriptive analysis of the determinants of the acceptability.

In order to assess the level of acceptability of rat-based technology on the TB screening among TB health care workers, a descriptive analysis of determinants was done using the mean and median of estimated determinants identified in the survey. The analysis presented the mean (SD) and median (IQR) of the determinants of the acceptability in 5-point Likert scale ranging from 1-Strongly disagree to 5-Strongly agree (Table 4). Personal and environmental factors contributed the highest scores especially in the high acceptability category. Personal factors showed a mean (SD) 4.07(0.51) and median (IQR) 4.0 (3.67-4.33) while environmental factors showed a mean of 4.12(0.71) and median (IQR) of 4.0 (4.0-4.5). This means that, for the 45 study participants who completed the survey, most of them agreed that personal and environment factors highly influenced their acceptability of the rat-based technology. This was followed by policy factors as well as factors related to the diagnostic tool itself. Sex, age and job category of the TB health care workers showed mean and median ranging from strongly disagreed to neutral to have influence in acceptability.

Table 4: A descriptive analysis of the constructed acceptability and the estimated determinants

DETERMINANTS ESTIMATED		Total	ACCEPTABILITY LEVEL		
			LOW	MEDIUM	HIGH
Personal factors	Mean±(SD*)	3.91(0 .53)	3.41(0.40)	3.8(0.49)	4.07(0.51)
	Median(IQR^)	4.0(3.67- 4.33)	3.25(3.17-3.83)	4.0(3.67-4.17)	4.0(3.67- 4.33)
Environment factors	Mean±(SD*)	4.01(0.70)	3.42(0.97)	4.07(0.43)	4.12(0.71)
	Median(IQR^)	4.0(3.5-4.5)	3.5(3-3.5)	4.0(4.0-4.5)	4.0(4.0-4.5)
Diagnostic tool factors	Mean±(SD*)	3.06(0.71)	2.67(.37)	2.95(0.65)	3.21(0.77)
	Median(IQR^)	3(2.67- 3.33)	2.67(2.33-2.67)	3.0(2.33 -3.33)	3.0(2.67-3.67)
Policy factors	Mean±(SD*)	3.52(0.79)	3.44(1.03)	3.29(0.73)	3.67(0.76)
	Median(IQR^)	3.67(3-4)	3.5(2.33-4.33)	3.33(3.33-3.67)	4.0(3.0-4.0)
sex	Mean±(SD*)	1.58(0.50)	1.67(0.52)	1.5 (0.52)	1.6 (0.5)
	Median(IQR^)	2.0(1.0-2.0)	2.0(1.0-2.0)	1.5(1.0-2.0)	2.0(1.0-2.0)
Job category	Mean±(SD*)	2.4(0.88)	2.83(0.41)	2.86(0.36)	1.96(0.98)
	Median(IQR^)	3.0(1.0-3.0)	3.0(3.0-3.0)	3.0(3.0-3.0)	2.0(1.0-3.0)
Age category	Mean±(SD*)	1.43(0.50)	1.5(0.55)	1.28(0.47)	1.5(0.51)
	Median(IQR^)	1.0(1.0-2.0)	1.5(1.0-2.0)	1.0(1.0-2.0)	1.5(1.0-2.0)
SD*- Standard Deviation					
IQR^- Inter Quarter Range					

3.2.8 Univariate Analysis

Univariate analysis was performed to determine crude odd ratios (ORs) for each factor on acceptability score of rat-based TB diagnosis tool (Table 5). Gender, job category, working experience (years working under TB section), and age of study participants were not associated with acceptability score of rat-based TB diagnosis. Health care workers (personal) factor is the only factor that was significantly associated with acceptability score. The odds of high (compared to low and medium) acceptability score increases with increase in mean score of health care workers (personal) factors; OR: 4.99 [95% CI: 1.42-17.5]

Environment and diagnostic tool (nature of rat-based TB diagnostic tool) factors were marginally associated with acceptability score. The odds of high acceptability score increases with the increase in mean score of environment factors; OR: 2.29 [95% CI: 0.92-5.71], p=0.076. The odds of high acceptability of rat-based TB diagnosis increases with the increase in mean score of diagnostic tool (nature of rat-based TB diagnostic tool) factors; OR: 2.18 [95% CI: 0.92-5.20]

Table 5: Crude Odds Ratios (OR) of acceptability of rat-based TB diagnosis

Factor	OR	95% CI	p-value
Health care workers (personal) factors (mean score)	4.99	[1.42-17.5]	0.012
Environment factors (mean score)	2.29	[0.92-5.71]	0.076
Diagnostic tool (nature of rat-based test) factors (mean score)	2.18	[0.92-5.20]	0.078
Policies, procedures and guidelines factors (mean score)	1.63	[0.77-3.46]	0.201
Sex			
Female	1.00		.

Male	1.09	[0.35-3.40]	0.887
Age (years)			
<=34	1.00		.
35+	1.55	[0.48-5.05]	0.467
Job category (Lab. Education level)			
Attendant	0.00	[0.00-.]	0.991
Assistant	1.00	[1.00-1.00]	.
Technologist	0.00	[0.00-.]	0.991

3.2.9 Multivariate analysis

A multivariate analysis was performed to estimate the adjusted ORs for acceptability score of rat-based TB diagnostic tool (Table 6). The odds of health care workers (personal) factors adjusted for environment factors (model A) was 4.2 [95% CI: 1.2-15.2], $p<0.05$. This means that for a one-unit increase in mean score of health care worker's (personal) related factors adjusted for environment factors, the odds of high acceptability increases by a factor of 4.2 compared to low and medium acceptability levels

The odds of health care worker (personal) factors adjusted for diagnostic tool or nature of rat-based TB diagnostic tool factors (model B) was 4.4 [95% CI: 1.2-15.9], $p<0.05$. Meaning that for a one-unit increase in mean score of health care worker (personal) factors adjusted for diagnostic tool factors, the odds of high acceptability increases by a factor of 4.4 compared to low and medium acceptability levels

The odds of health care workers (personal) factors adjusted for policies, procedures and guidelines factors (model C) was 4.8 [95% CI: 1.4-17.2], $p<0.05$. For a one-unit increase in mean score of health care workers (personal) factors adjusted for Policies, procedures and guidelines factors, the odds of high acceptability increases by a factor of 4.8 compared to low and medium acceptability levels

The odds of health care workers (personal) factors adjusted for all other factors (model D) was 3.8 [95% CI: 1.0-14.2], $p<0.05$. For a one-unit increase in mean score of health care workers (personal) factors adjusted for all other factors, the odds of high acceptability of rat-based TB diagnosis increases by a factor of 3.8 compared to low and medium acceptability levels.

Table 6: Adjusted Odd Ratio (OR) of acceptability of rat-based TB diagnosis

Factors	Model A	Model B	Model C	Model D
health care workers factors	4.2*[1.2-15.2]	4.4* [1.2-15.9]	4.8*[1.4-17.2]	3.8* [1.0-14.2]
Environment factors	1.8 [0.7-4.6]			1.6 [0.6-4.6]
Diagnostic tool factors		1.9 [0.8-4.5]		1.6 [0.6-4.1]
Policies, procedures and guidelines factors			1.5[0.7-3.4]	1.4 [0.6-3.3]

AOR; 95% Confidence Interval (CI) in brackets

* p<0.05, ** p<0.01, *** p<0.001

Model A= health care worker factors adjusted for Environment factors;

Model B= health care worker factors adjusted for diagnostic tool factors;

Model C= health care worker factors adjusted for Policies, procedures and guidelines factors;

Model D= fully adjusted model (health care worker factors adjusted for all other factor)

Quantitative key findings

The level of acceptability of the rats-based TB diagnostic tool and its results reported in this study was high (55.6%). Health care workers (personal) factor is the only factor that was significantly associated with acceptability score while environment and diagnostic tool (nature of rat-based TB diagnostic tool) factors were marginally associated with acceptability score. Policies, procedures and guidelines, gender, job category, working experience(years working under TB section) and age were not statistically associated with the acceptability level of rats-based TB diagnostic tool

CHAPTER 4: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

4. 1 Discussion

In this chapter, results of major findings are discussed in detailed. Opinions, strength and limitation of this study that need to be taken into consideration in future studies, conclusion and recommendations are also explained. This study aimed to examine the factors affecting the acceptability of the rat-based TB diagnostic tool using IDIs and semi-structured questionnaires. It involved all TB health care workers in all health care facilities served by APOPO in Dar-es-Salaam, Tanzania. It is the first study that has been conducted to investigate implementation and acceptability of a unique evidence-based diagnostic technology that uses giant African pouched rats trained to detect TB disease. The research findings from the IDIs demonstrated the multifactorial nature of introducing new health intervention or technology in limited resources settings. It highlighted some health care worker (personal), environment, nature of diagnostic tool and policies, procedures and guidelines related factors that are associated with the acceptability of the rats-based TB diagnostic tool and its results in TB detection and TB disease management. The study findings suggest that the introduction and process of scaling up of any new health intervention or technology in Tanzania needs a clear policy from specific government authority, needs formal health care workers training, reliability or availability of that technology, community awareness and support supervision.

During IDIs, health care worker (personal) related factors appeared to be affecting the acceptability of rats-based TB diagnostic tool and its results. It was noted that study participants who had attended seminars and training regarding APOPO and rat-based diagnosis of TB expressed high acceptance of the tool. This led to majority suggesting that trainings and seminars would hugely improve acceptability of rats-based TB diagnostic tool. However, the rat's inability to quantify TB disease and predict drug resistance appeared to negatively affect acceptance of the tool. It was further found that community awareness (as reported by study participants) is one among the factors that hamper the acceptability of the rats-based TB diagnostic tool and the results. The issue of community's skeptics regarding rat's results makes healthcare workers more demoralized and negatively affected to keep using rats-based results. Healthcare workers become dishonest by telling patients that they have been diagnosed using more superior devices without mentioning rat's technique. This situation also reduces healthcare workers' confidence in engaging patients in decision making towards TB medications after having positive rat's results. These findings are comparable with other acceptability studies that had previously reported the effect of health care worker (personal) factors in acceptability of diagnostic tools (22,25–27). This factor can be explained further using social cognitive theory factor, which explains the impact of personal factor (personal goal and self-efficacy), environment (social pressure), and individual cognitive (individual behavior) in influencing an individual to accept or reject an intervention or technology.

This theory means that the acceptance and use of a new innovation or health technology depends on an individual goal and self-efficacy, social pressure including community or patient awareness as well as individual behavior. However, all the negative perceptions and doubts regarding rats-based technology underscores the need for APOPO project to provide detailed information regarding rat's ability in TB detection.

The environmental related factors were also identified to affect the acceptability of rats-based TB diagnostic tool and its results. Most of the study participants agreed that the present laboratory set-ups in health care facilities couldn't accommodate rats as a routine TB diagnostic tool. These findings are comparable with other studies documenting that acceptance of diagnostic tool or intervention was too affected by some environment factors (26,29,31). Hospital management and administration staff in all hospitals served by APOPO however were supporting the rats-based TB diagnostic and its results. In fact, rat-based diagnosis is so important in that it helps identify positive TB patients that were missed out by classical or conventional bacteriological TB diagnostics tools. Given that importance, it should be advocated that the government plans to build dedicated veterinary laboratories for housing trained rats that can serve as TB diagnostic centers.

It was also found out that lack of clear policies and diagnostic guidelines were one among the contributing factors, which make health care workers' misconception of the role of rat-based TB diagnostic tool in TB management. Otherwise the rat-based TB technology would be welcomed as an addition technology to their clinical TB diagnostic technology. Healthcare facilities need support from ministry of health to include this technology in TB diagnostic tool algorithm. They are a feeling that if the government adopts this technology it would increase accessibility. This finding was comparable with research findings from a study done by Asiimwe (26) and by Ood P (24) which reported that the presence of the clear, supportive policies and treatment guidelines play a major role in the acceptance of any new health technologies and the uses of the test results. It is crucial time for the government to clear out the doubt and provide scientific evidence on the benefit of rats over other TB diagnostic tool.

The nature of the rats-based TB diagnosis itself was a factor that could affect its acceptability. It was noted that for medical personnel trained to deal with human, there is lack confidence to handle rats. This observation could be explained using diffusion of innovation model where by adopter of the new innovation adopt the technology depending on the innovation characteristics. Those characteristics are observability, relative advantage, compatibility, trial ability, and complexity are key to adoption of an innovation. There is a perception that rat-based TB diagnostic tool cannot quantify TB bacteria which is very challenging on their side during follow-up. Incompatibility of the rat-based technology with existing laboratory set-up, and the perception that handling rats is complex is another challenge towards acceptability. This calls for APOPO to advocate and expand trainings and seminars among TB health care workers.

On the other hand, we quantitatively assessed the level of acceptability of rat-based TB diagnostic tool among TB healthcare workers in health care facilities served by APOPO in Dar-es-Salaam. The level of acceptability of the rats-based TB diagnostic tool and its results reported in this study was high (55.6%). This study's acceptability level was relatively higher than the acceptability level (40%) of Leapfrog computerized physician order entry evaluation tool reported by Insook et al. in South Korea (38). The acceptability level in this study was comparable with other studies that had previously reported acceptability levels on newly introduced diagnostics tool. A comparable acceptability level of 50% for FluoLED Easy™ microscopy for TB screening in TB reference laboratory in Thailand and Tanzania (23), and high acceptability of LED fluorescent microscopes among laboratory technicians from government health centers in Zambia by Turnbull (22). However, the acceptability level reported in this study (55.6%) was relatively lower than the reported acceptability level of 84% on traditional healers as DOTs providers in TB control in India (25). There could be several factors for this study's observed acceptability level of rats-based TB diagnostic tool in Tanzania. It could be due to the fact that majority of study participant knowing that there was confirmation process by other TB diagnostic tools following the rat's indication. Also, study found out that rat-based TB diagnostic tool have shown potential in detecting TB at earlier stage than other conventional bacteriological TB diagnostic tool. Although, in the community there was lack of awareness on the use and ability of rats-based TB diagnostic tool in TB diagnosis. This was explained by the fact there were sceptics to that rat-based positive result and sometimes or patients were reported to refuse to be treated based on rats positive results. To address this, it was recommended that there should be community advocacy regarding the existence and use of rat-based TB diagnostic tool. These findings are comparable with studies (27,31) that had previously reported the effect of community awareness in using the given tool. The successfully implementation of any new diagnostic tool or intervention is dependent on the community knowledge, environment background and awareness (39).

In this study we further analyzed several factors that could affect the acceptability level of rats-based TB diagnostic tool. Health care workers (personal) related factors appeared to be significant ($p=0.012$) predictors for the acceptability of rats-based TB diagnostic tool. The odds of high (compared to low and medium) acceptability score appeared to increase with the increase in mean score of health care worker (personal) factors (OR: 4.99). These findings are comparable with other acceptability studies that had previously reported the effect of health care workers (personal) factors in acceptability level (22–24,26,28,31). The plausible reasons for this could be the perceived benefit and need for this health innovation, self-efficacy and health care workers' skill proficiency. This is because, the acceptance and attitude toward using a given new innovation or health intervention depends on perceptions, beliefs, attitude and the extent at which it meets the needs of the intended beneficiaries of that technique. The quickness (speed) of the rats, so one

trained rat can screen a number of specimen in few second or minute that is good because it reduces workload for them in the laboratory to take too much time by using microscope or gene expert to screen the same number of sample. Also, relatively cheaper when compared with gene expert and other molecular techniques. This is because rats do not need cartridges, stable electricity, annual re-calibration, reagents and temperature monitoring. Although, the issue of lacking a substantial information on the use of the trained rats as an effective TB diagnostic tool was voiced out. This was further expressed by point out that the attendance to APOPO seminars and training would increase knowledge to implement and acceptance of rats-based TB technology.

Acceptability level of using rats-based TB diagnostic tool seemed to be marginally (p=0.076) affected by environment related factors. The odds of high acceptability score increases with the increase in mean score of environmental factors (OR: 2.29). These findings are comparable with the study done by Williams HA (31) documenting that acceptance of RDT was mostly influenced by environmental factors (good management systems). Although we observed a weak influence of environmental related factors on rats-based TB diagnostic acceptability level. It was evident that the hospital management in health facility support rat-based diagnostic results. We noted further during our investigation that the laboratories in these health care facilities cannot accommodate rats as TB diagnostic tool in the current set ups, because the present laboratory rooms are small. It is absolutely not capable of mixing rats may be to construct special laboratories for trained rats only but not in the laboratories in our health care facilities. This is because, the available laboratories do not have a required standards to mix with animal based diagnostic tool. Also, you will find few small laboratory rooms contain machines for diagnosing every disease not possible to accommodate this trained rats. Although everything needs preparation, if government approval this rats-based TB diagnostic tool the government with the help from different sponsors will build another special laboratories for rats-based TB diagnostic tool.

The diagnostic tool (nature of rat-based test) itself was investigated to determine its influence on the acceptability level of rats-based TB diagnostic tool. The diagnostic tool (nature of rat-based test) was a weak predictor (p=0.078) of rats-based TB acceptability. The odds of high acceptability of rat-based TB diagnosis increases with the increase in mean score of diagnostic tool (nature of rat-based test) factors (OR: 2.2). This could be due to the fact that, the trained rats do detect TB at earlier stage of which other TB diagnostic tool like microscope failed. These study findings are comparable with other acceptability studies (24,27,31) that had previously reported the effect of diagnostic tool factors in acceptability level. Although, this factor can be explained based on the adaptability (program modification) and compatibility (fitness or appropriateness of the innovation to our setting) of this health care intervention. The trained rats are not like microscope that you put in the cupboard and not look at it for a month. The trained rats you need to put them on the cages

inside the room, routinely feeding, breeding them, and providing a proper shelter and treatment if they get some infection. However, not sure if government will manage to pay those cost if rats used as TB diagnostic tool in all parts of Tanzania. This is because sometimes in health care facility even miss reagents for microscope. Furthermore, the issues of adaptability of this new health intervention. They are not sure if rat-based TB diagnostic tool can be modified to fit their preferences, health care facility practices, and community needs because of animal nature. However, APOPO project are advised to transfer rats based ability of detecting TB from animal based into device (electronic device) or something of that nature like RDT. This will be more acceptable than rats nature. This is because some of them their big interest from APOPO project is to see the ability of trained rats in early detection of TB transferred to a device (electronic device) or a RDT.

In our study, policies, procedures and guidelines, gender, job category, working experience(years working under TB section) and age were not statistically associated with the acceptability level of rats-based TB diagnostic tool.

4.2 Strengths and Limitations

The research findings obtained from this study are likely to represent some of the higher score that would be found among other health care facilities in Tanzanian using this diagnostic tool. In additional, the mixed method study design provides complete understanding on the factors affecting acceptability of the rat-based TB diagnostic technique as a tool for TB diagnosis among TB health care workers in the health care facilities served by APOPO. The study has limitations, that there is possibility of lack of generalization of this study findings for the whole of Tanzania. This is because, study sample size is small and only health care facilities that had long experience with this rats-based TB diagnostic tool were involved. Another limitation of the study may be the potential loss of true meaning that can occur through the direct transcription and translation from Swahili language to English language by the study team.

4.3 Conclusion

This study provides critical information that can guide policy makers in developing a model to integrate this new and unique innovation into TB diagnostic tool algorithm.

4.4 Recommendations

Our study recommended similar studies should be conducted on other implementation outcomes like feasibility, fidelity, sustainability, cost effectiveness of this new and unique rats-based TB diagnostic tool to provide more evidence to support scaling-up of this new innovation

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APPENDICES

Clearance Certificate: Human Research Ethics Committee (Medical) of the University of the Witwatersrand

R14/49 Ms Tabia Hassan

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M161193

NAME: (Principal Investigator)	Ms Tabia Hassan
DEPARTMENT:	Epidemiology and Biostatistics School of Public Health Health Care Facilities Covered by APOPO TB Project in Dar es Salaam, Tanzania
PROJECT TITLE:	Acceptability of Rat-Based Diagnostic Approach of Tuberculosis among Tuberculosis Health Care Workers in Dar-es-Salaam, Tanzania
DATE CONSIDERED:	25/11/2016
DECISION: CONDITIONS:	Approved unconditionally
SUPERVISOR:	Dr J. Ncayiyana, Dr J. Massaga and Dr D. Nyogea
APPROVED BY:	Professor P Cleaton-Jones,Chairperson, HREC (Medical)
DATE OF APPROVAL:	13/01/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 301, Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in November and will therefore be due in the month of November each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

30th JANUARY 2017
Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

1062

Clearance Certificate: National Health Research Ethical Committee of the National Institute for Medical Research (NIMR)-Tanzania

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16th February 2017

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CLEARANCE CERTIFICATE FOR CONDUCTING MEDICAL RESEARCH IN TANZANIA

This is to certify that the research entitled: Acceptability of Rat-Based Diagnostic Approach of Tuberculosis among Tuberculosis Health Care Workers in Dar es Salaam, Tanzania (Hassan T *et al)*, whose Local Investigator is Dr Julius Massaga, NIMR HQ, Dar es Salaam, has been granted ethical clearance to be conducted in Tanzania.

The Principal Investigator of the study must ensure that the following conditions are fulfilled:

1. Progress report is submitted to the Ministry of Health, Community Development, Gender, Elderly & Children and the National Institute for Medical Research, Regional and District Medical Officers after every six months.
2. Permission to publish the results is obtained from National Institute for Medical Research.
3. Copies of final publications are made available to the Ministry of Health, Community Development, Gender, Elderly & Children and the National Institute for Medical Research.
4. Any researcher, who contravenes or fails to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III Section 10(2).
5. Site: Twenty Health Centres in Dar es Salaam covered by APOPO TB project.

Approval is for one year: 16th February 2017 to 15th February 2018.

Name: Prof. Yunus Daud Mgaya

Signature
CHAIRPERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

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CHIEF MEDICAL OFFICER
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PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I TABIA HASSAN (1506192) am a studentregistered for the degree of MASTERS OF SCIENCE IN EPIDEMIOLOGY FIELD OF IMPLEMENTATION SCIENCE in the academic year 2016/2017.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature: _____ Date: 16/08/2017

26/04/2015
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IN-DEPTH INTERVIEW GUIDE_SWAHILI VERSION

KIAMBATANISHO 1: TOLEO LA KISWAHILI

MWONGOZO WA MAHOJIANO YA KINA

Cheo/nafasi: ….....

Shirika / Kitengo: ….....

1) Je,hapa nchini kuna chombo cha ndani (utaratibu wa ndani/wizara) wa kupitisha teknologia ya uchunguzi/utambuzi wa ugonjwa fulani kwa ajili ya matumizi ya taifa?
   Ulizia zaidi: Unaweza kuelezea kwa undani zaidi juu ya hilo.
2) Je, hapa nchini kunahitaji mapendekezo kutoka shirika la afya duniani (WHO) ili kupitisha teknologia au chombo cha uchunguzi/utambuzi wa kifua kikuu kwa ajili ya matumizi ya taifa?
   Ulizia zaidi: Kwanini ni ivyo?
3) Je, inawezekana kutumia teknologia au chombo cha uchunguzi/utambuzi wa kifua kikuu ambacho kimetathiminiwa ndani ya nchi kwenye mpango wa kutambua ugonjwa wa kifua kikuu bila kupitishwa na shirika la afya duniani?
   Ulizia zaidi: kivipi? Elezea kwa undani zaidi
   -Je, kuna jitihada zozote zinazofanyika ili kuwezesha teknologia au chombo cha uchunguzi/utambuzi wa kifua kikuu kutoka APOPO (Panya) kupitiswa kama chombo cha utambuzi wa kifua kikuu.
   - Je, ipo hatua gani kwa sasa?
4) Je, wewe unaikubali teknologia ya panya kama chombo cha uchunguzi/utambuzi wa kifua kikuu na majibu yanayotokana na teknolojia hiyo?
   Ulizia zaidi: Sababu ya kukubali au kutokukubali teknologia hiyo
5) Je, unaweza kupendekeza kupitishwa kwa teknologia ya panya kama chombo cha uchunguzi/utambuzi wa kifua kikuu?
   Ulizia zaidi: Kwanini ivyo?
6) Nini mtazamo wako kwa hii teknologia ya panya kama chombo cha uchunguzi/utambuzi wa kifua kikuu?
   Ulizia zaidi: Au sio sayansi?

-Je, inastahili au inavigezo vya kuwa chombo cha uchunguzi/utambuzi wa kifua kikuu?

7) Ni sababu zipi zinazopelekea ukubalikaji huu uliopo sasa wa hii teknologia ya panya kama chombo cha uchunguzi/utambuzi wa kifua kikuu?

-Ulizia zaidi: maabara ilivyokuwa, asili ya chombo chenyewe cha uchunguzi (panya), gharama, msaada wa usimamizi kutoka uongozi wa juu, mambo binafsi (ufahamu wa teknologia).

8) Ni kwanini mpaka sasa hivi teknologia ya panya haijawekwa kwenye mpango wa kumaliza kifua kikuu kama teknologia ya kugundua kifua kikuu.

9) Kwa mtazamo wako, nini faida na hasara za kutumia teknologia ya panya kama chombo cha uchunguzi/utambuzi wa kifua kikuu?

NASHUKURU SANA NA ASANTE KWA KUSHIRIKI!

IN-DEPTH INTERVIEW GUIDE_ENGLISH VERSION

APPENDIX 1: ENGLISH VERSION

IN-DEPTH INTERVIEW GUIDE

Position: ….....

Organization: ….....

1) Does the country have an organization/ministry or in-house procedure to approve a test or technology for disease detection for a national use?
   Probe: Can you briefly describe it?
2) Does the country through the specific ministry require WHO recommendation to approve a tuberculosis diagnosis test for national use?
   Probe: Why?
3) Can an in-house evaluated diagnostic test be used in the TB programme?
   Probe: Has there been any effort to get the APOPO diagnostic test approved?
   What is the status with this test?
4) Do you accept rat-based (an animal based) tuberculosis diagnosis technique/ test and test results generated?
   Probe: Reasons for acceptance or not acceptance?
5) Can you recommend the rat-based tuberculosis diagnosis technique to be approved and used routinely as tuberculosis diagnosis test?
   Probe: Why?
6) What is your perception on the rat-based tuberculosis diagnosis test/technique?
   Probe: Is it not science?
   -Does it qualify as tuberculosis diagnosis test/ tool?
7) What are the factors (reasons) for the current uptakes of rat-based tuberculosis diagnosis test/technique?

Probe: Laboratory set-up, nature of diagnostic tool (Animal based), Cost, support supervision from management, personal factors (Awareness), quality of results

8) Why rats-based TB diagnostic tool is not integrated in tuberculosis program to be used as tuberculosis diagnostic tool?
9) What are the pros and cons of rat-based tuberculosis diagnosis technique for your perceptions?

Thank you very much for your participation.

ACCEPTABILITY QUESTIONNAIRE - ENGLISH VERSION

Part A: TB Health Worker's Socio Demographic Characteristics

INSTRUCTIONS- we would like to ask you some questions about general information include social demographic status. Your honest answers will help us come up with true conclusion about this study. Tick one answer of your choice which is the most appropriate.

i. Date of birth: D / M / Y
/ / / /

ii. Sex
a) Male
b) Female [ ]

iii. Job Category:
Laboratory technologist [ ]
Laboratory assistant [ ]
Laboratory attendant [ ]

iv. Hospital Name.....

Part B: Laboratory information

Instruction: Now we are going to ask you some questions about your laboratory knowledge and experiences. Tick one answer which is the most appropriate to your knowledge and experience.

1. How long have you been working in the TB diagnostic section?
[ ] One year or less [1]
[ ] Between one year and two years [2]
[ ] > 2 years [3]
2. How long do you spend in the laboratory per day?
[ ] < 5 five hours [1]
[ ] 5-8 hours [2]
[ ] > 8 hours [3]
3. In this health facility, Which TB screening results are you using for TB diagnosis? (Tick all that apply)
[ ] Microscope (if "NO" do not answer question number 4 and 8)
[ ] Gene expert (if "NO" do not answer question number 5 and 9)
[ ] Culture (if "NO" do not answer question number 6 and 10)

[ ] Rats-based (if "NO" do not answer question number 7 and 11)
[ ] Other (*Please specify*) …….....

4. How long have you been using microscope results for TB diagnosis?
[ ] One year or less [1]
[ ] Between one year and two years [2]
[ ] > 2 years [3]
[ ] We don't use this method[4]

5. How long have you been using Gene expert results for TB diagnosis?
[ ] One year or less [1]
[ ] Between one year and two years [2]
[ ] > 2 years [3]
[ ] We don't use this method[4]

6. How long have you been using culture results for TB diagnosis?
[ ] One year or less [1]
[ ] Between one year and two years [2]
[ ] > 2 years [3]
[ ] We don't use this method[4]

7. How long have you been using rat-based results for TB diagnosis?
[ ] One year or less [1]
[ ] Between one year and two years [2]
[ ] > 2 years [3]
[ ] We don't use this method[4]

8. How accurate do you think the results coming from the microscope?
[ ] More accurate [1]
[ ] Mostly accurate [2]
[ ] Not accurate [3]

9. How accurate do you think the results coming from Gene expert ?
[ ] More accurate [1]
[ ] Mostly accurate [2]
[ ] Not accurate [3]

10. How accurate do you think the results coming from culture?
[ ] More accurate [1]
[ ] Mostly accurate [2]
[ ] Not accurate [3]

11. How accurate do you think the results coming from the rat-based technique?
[ ] More accurate [1]
[ ] Mostly accurate [2]
[ ] Not accurate [3]

Part C: Factors affecting acceptability of rats-based TB diagnostic technique

Instruction: We are interested in assessing the factors affecting acceptability of the rat-based technique on TB screening. Tick one answer of your choice which is most appropriate to your knowledge, perception and believes about rat-based TB screening technique.

1. I will have no doubt if rats-based technique used with other confirmation tool and not a stand-alone tool
[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

2. I am not aware on the ability of rats based technique on differentiating between normal TB bacteria and non- TB bacteria?

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

3. I believe that rats-based TB diagnostic technique will result in stigmatization because of its animal nature?

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

4. I know it is un usual for WHO to approve an animal based technique

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree5

5. I think lack of WHO endorsement of rats-based TB diagnostic tool cause a big problem in doing follow-up for rats' positive patients

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

6. I am sure the laboratory set-up present in our health care facilities cannot accommodate rats as TB diagnostic tool?

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

7. I think that it is more expensive to use the rat-based TB diagnostic tool as a routine TB screening technique?

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

8. Attending APOPO seminars and trainings increases my knowledge and acceptance of rats-based ability in TB detection

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

9. I am a human based laboratory technologist I do not have much knowledge to deal with animal based tools

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]

[ ] Agree[4]
[ ] Strongly agree[5]

10. I think is tedious work to use rats-based tool because needs someone to confirm it after rats' indication

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

11. I believe that community members are still skeptics on the rats-based technique?

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

12. I know when APOPO bring back the positive results am not using those results directly as positive because these rats' technology still not validated not even accepted by government (specific ministry) as a diagnosis technology

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

13. I believe rat-based diagnostic results has improved my individual confidence

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree4
[ ] Strongly agree[5]

14.I feel that the hospital management in this health facility support rat-based diagnostic results

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree4
[ ] Strongly agree[5]

Part D: Acceptability of rat-based techniques

Instruction: We are interested in assessing the level of acceptability of rat-based TB diagnostic tool. Tick one answer of your choice which is most appropriate to your acceptability of the rat-based TB screening technique.

1. I trust the ability of the rat-based technique in TB detection compared to that from other diagnostic tools?

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

2. I like rats-based results because it has high quality compared to the results from other TB diagnostic tool

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

3. I am satisfied with the ability of the rat-based TB diagnostic technique in TB detection and the result coming from it

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

4. It is very enjoyable to use the rat-based TB diagnostic technique over other methods for TB screening?

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

5. I would recommend rat-based technique to be placed in TB diagnostic tool algorithm and be used as a routine TB screening in the hospital?

[ ] Strongly disagree[1]
[ ] Disagree[2]
[ ] Neutral[3]
[ ] Agree[4]
[ ] Strongly agree[5]

6. Any comments on using rat-based technique as a routine technique for TB screening…….

This is the end of the questionnaire, thank you for your participation in this study!