CENTERING PRIMARY HEALTH CARE (PHC) NURSES' EXPERIENCES IN THEIR PRACTICE OF POLICY IMPLEMENTATION - TB DIAGNOSTIC POLICY REFORM IN THE WESTERN CAPE, SOUTH AFRICA

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Part 0: Preamble

PLAGIARISM DECLARATION

I, **Lance Lyle Louskieter (LSKLAN001),** hereby declare that this is my original work and has not been presented before for the award of a Masters' Degree in Public Health.

This work has not in whole or in part been submitted towards another degree at this university or elsewhere. The university is empowered to reproduce either the whole or any portion of the contents for research purpose.

SIGN: Signed by candidate

DATE: October 2017

DEDICATION

This thesis is dedicted to all nurses working in high risk TB settings in the public health sector. Thank you for all your hard work and dedication. You are important.

A special dedication to my mom, who inspired this project. She continues to serve the public health system and patients with compassion, dignity and humility.

THESIS ABSTRACT

This project focused on the recent global reforms in TB diagnostic policy and the implementation of **Xpert MTB/RIF** (GeneXpert) diagnostic technology into the health system, as a case to assess the extent to which software issues - particularly the human qualities of the system – mediates policy implementation. It centres the experiences of frontline workers in local implementation contexts as imperative because of frontline workers' have discretionary power and influence in their practice. The premise of this mini-dissertation is that researchers and policy makers should centre the lived experiences of service delivery level health workers when implementing policy or programmatic reforms. This may deepen people-centred approaches which is essential for health systems strengthening. This mini-dissertation is structured into three parts:

Part A: This is the research protocol that was submitted for ethical review and approval to the Faculty of Health Science Ethical Review Committee (FHSERC). The protocol frames the study objectives and the initial intentions of the research study. The justifications for the research question, theoretical framework, the research design, methods for data collection and analysis and timelines are clearly presented and discussed.

Part B: Using GeneXpert policy reform implementation as a pathfinder, this section presents an undertaking of a structured narrative review of the existing literature addressing the major barriers and enablers for health systems implementation reform. This review assesses the extent to which people issues and people-centred practices are considered in policy implementation research of GeneXpert. The aim of this section of the dissertation is to identify and map-out literature considering the human experiences and relationships of frontline health workers and how these may intersect with hardware, contextual and social systemic factors, that may potentially mediate the implementation of GeneXpert TB diagnostic policy.

Part C: This section presents the background, methodology, findings and interpretations from the research, as a journal-ready manuscript. This paper seeks to contribute to the policy implementation literature in the field of HPSR from the perspective of centering nurses' lived experience – especially nurses who are overburdened and undervalued – as imperative in the field of inquiry. The main findings reflect that nurses are burdened by the pressure to meet policy targets, the encumbrance to enforce administrative and bureaucratic procedure, and the

minimal platforms or pathways to input on challenges and innovations back to higher level management and decision makers. Within the context of top-down, target-driven and highly structured and standardized operational processes for diagnosing TB, nurses navigate multiple overlapping and contradictory modes of being in their interactions with patients as a response to these pressures. This paper seeks to offer voice to nurses' experiences of implementing TB diagnostic policy in PHC settings in SA considering its relationship with broader systemic and contextual influences. It also raises particular issues about tensions between efforts to achieve efficiency and effectiveness through enforcing the system, and facilitating people-centered and responsive practices in implementation.

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ACRONYMS, ABBREVIATIONS & DEFINITIONS

AIDS	Acquired Immunodeficiency Syndrome
HIV	Human Immunodeficiency Virus
NDoH	National Department of Health
PHC	Primary Healthcare
WHO	World Health Organisation
HPSR	Health Policy and Systems Research
TB	Tuberculosis
MDR TB	Multi-drug Resistant Tuberculosis
XDR TB	Extreme-drug Resistant Tuberculosis
GeneXpert	MTB/RIF® Xpert Diagnostic Technology (Test)
Contact	Any person who has been exposed to someone who is TB positive
Health Policy and Systems Research	A field that seeks to understand and improve how societies organize themselves in achieving collective health goals, and how different actors interact in the policy and implementation processes to contribute to policy outcomes. By nature, it is interdisciplinary, a blend of economics, sociology, anthropology, political science, public health and epidemiology that together draw a comprehensive picture of how health systems respond and adapt to health policies, and how health policies can shape − and be shaped by − health systems and the broader determinants of health (Alliance for Health Policy and Systems Research, 2011)

Software Factors	Health system software encompasses the institutions (norms, traditions, values, roles and procedures) embedded within the system.
Hardware Factors	Health system hardware includes the particular organizational, policy, legal and financing frameworks that structure any health system, as well as its clinical and service delivery requirements
Health System(s)	Health system(s) consists of all organizations, people and actions whose primary intent is to promote, restore or maintain health. This includes efforts to influence determinants of health as well as more direct health-improving activities. A health system is therefore more than the pyramid of publicly owned facilities that deliver personal health services. It includes, for example, a mother caring for a sick child at home; private providers; behaviour change programmes; vector-control campaigns; health insurance organizations; occupational health and safety legislation. It includes inter-sectoral action by health staff, for example, encouraging the ministry of education to promote female education, a well known determinant of better health.
People-centred Health Systems	People-centred health systems is an approach to health systems thinking that consciously adopts the perspectives of individuals, families and communities, and sees them as participants as well as beneficiaries of trusted health systems that respond to their needs and preferences in humane and holistic ways. People-centred care requires that people (both patients and

providers) have the education and support they need to make decisions and participate in health systems and healthcare. It is organized around the health needs and expectations of people rather than diseases.

Part A: Protocol

STUDY PROTOCOL

Premise

Implementation of policy is a universal challenge across the health system. This is primarily because the health system is a complex adaptive system (Gilson, 2012). Health systems strengthening through embracing complexity have thus increasingly become the focus to combat gaps in policy implementation (Gilson, 2012). Strengthening the health system demands a greater need to understand the complexity of the system at all levels and how different factors influence the components, processes and relationships that make-up the health system for different policy issues and contexts. This study will use TB control and its associated policy and implementation issues to uncover deeper meanings of factors that mediate the implementation of GeneXpert TB diagnostics.

Tuberculosis (TB) is one of the leading global health challenges (Raviglione & Pio, 2002). For many years new international policies have been implemented within different countries in a global attempt to combat this infectious disease (Raviglione & Pio, 2002). However, TB control strategies and implementation have not been without challenges. Efforts to combat TB are continuously changed and developed, resulting in the perpetual introduction of new and revised policies and technologies (Palamountain *et al*., 2012). The continuous reform in TB control strategies has made it difficult to assess the effectiveness of previous and existing efforts (Palamountain *et al*., 2012). Some reports assert that TB programmes have had limited success for the outcomes of TB outcomes (Dye & Williams, 2010; Storla, Yimer & Bjune, 2008).

Early case detection, treatment initiation, treatment follow up, continuity of care, adherence and multidrug resistant management are some of the areas that are important in TB control, yet many gaps exist in these domains in countries most burdened by the disease (Lönnroth *et al*., 2009; Piatek *et al*, 2013; Raviglione & Pio, 2002). Many report that health system and related challenges in the implementation of TB control policies are significant contributors to these shortfalls (Loveday, Smith & Day, 2013; Storla, Yime r& Bjune, 2008).

Subsequently, it is important to focus to the implementation of TB control policies. It is essential to understand implementation from a health systems perspective (Gilson, 2012). More importantly, health care workers and their experience of the health system are important for effective implementation of TB control strategies (Gilson, 2012). It is thus becoming more significant to hone in on how health workers' experiences and their 'doing'

of policy influences actual implementation processes (Buse, Mays & Walt, 2005), especially for a dynamic policy arena such as TB control.

Background

i. Global impact of TB

Tuberculosis (TB) is a communicable bacterial disease that is caused by *Mycobacterium tuberculosis*. It most commonly affects the lungs but the infection can spread to other parts of body (Knechel, 2009). Although TB can be treated with a six-month regimen of antibiotics it is one of the major contributors to disease and death worldwide (Knechel, 2009). Even with slow declining TB rates internationally it is reported that approximately 9 million new TB cases were detected in 2013 of which 13% of these were HIV infected individuals (Churchyard *et al*., 2014). Furthermore, 1.3 million TB-related deaths were estimated during this time. It is further predicted that approximately 45% of all TB cases globally are undetected (Churchyard *et al*., 2014).The WHO has characterised 22 high TB burdened countries (Churchyard *et al*., 2014). These countries are predominantly low to middle income countries (LMIC) and account for about 82% of all approximated incidences of TB cases internationally. With the rise of HIV infection in many low to middle income countries, TB/HIV co-infection has resulted in increasing mortality and morbidity (Churchyard *et al*., 2014). WHO (2015) reports that 2.1 million people globally became HIV incident cases in 2013 where most of incident cases were found in sub-Saharan Africa. In addition, co-infection has contributed to the increase in more complicated forms of TB that are difficult to manage and treat such as multi-drug resistant (MDR-TB) and extreme multidrug resistant TB (XDR-TB) (Churchyard *et al*., 2014). It is thus evident that countries affected by TB are also burdened by high rates of HIV incidence and prevalence.

ii. TB/HIV co-infection

Human immunodeficiency virus (HIV) infection is the leading risk factor for the TB incidence and contributor to the development of the disease from latent infection to active TB disease (Kochi, 2001). 2008 reports show that there were 1.4 million TB incident cases among HIV-infected individuals, therefore accounting for about 26% of AIDS-associated mortalities worldwide (Churchyard *et al*., 2014). 30% of the 33.2 million people are currently living with HIV are anticipated to be *TB-positive (*Churchyard *et al*., 2014*).* A strong association thus exist with the progression of TB and HIV infection as TB infection worsens

immunosuppression in HIV-infected individuals. Furthermore, TB/HIV co-infection has complicated the diagnosis and treatment of TB in HIV positive individuals (Loveday, Smith & Day, 2013). Key reasons for the gaps in TB control in high TB/HIV burdened countries are related to the complexities and inadequacies to diagnose individuals with TB (Palamountain *et al*., 2012; Perkins & Cunningham, 2007). South Africa is a country that is particularly burdened by high prevalence and incidence rates of people who are co-infected.

iii. TB disease burden in South Africa

South Africa's TB burden is propelled by the HIV epidemic of the country. When adjusting for population size, SA has the highest incidence and prevalence of TB globally (Churchyard *et al*., 2014). It also has the largest number of HIV/TB co-infection cases and the second largest amount of diagnosed MDR-TB cases worldwide (India being the largest) (Churchyard *et al*., 2014). In 1994, the post-apartheid government established the National Tuberculosis Programme (NTP) in attempt to address TB control. This programmed faced challenges related to integrating TB services into inadequate primary health care settings in the context of an emerging HIV epidemic (Churchyard, 2014). Subsequently, TB incidence cases grew substantially post 1994. A further burden was added with the rise in MDR-TB and the emergence of extensively drug-resistant (XDR) TB in 2006 that overstretched health services (Churchyard, 2014). In order to respond to the dual epidemics of HIV and TB rationally, SA formulated the integrated National Strategic Plan (NSP) for HIV, STIs and TB (2012 - 2016). The targets set in the NSP for TB were to reduce TB incidence and mortality by 50% in 2016 and reduce incidence of TB cases by 100%. Although SA has made notable progress in reducing TB prevalence, mortality rates and improving treatment outcomes for new smear-positive TB cases, the burden of TB remains substantially high. This has primarily been attributed to the limitations in and barriers to effective detection and diagnosis of TB. In addition to implementing the fundamentals of TB diagnostics and treatment, strengthening TB control calls for novel approaches including the adoption of new technologies including drugs, diagnostics and technologies. It is foreseen that the scaling up the use of Xpert MTB/RIF as a replacement for sputum smear microscopy has potential to further accelerate progress towards TB control in South Africa and other high burden countries.

Because of its infectious quality, the diagnosis and detection of TB plays an important role in controlling the spread of the disease (Knechel, 2009). TB diagnostics further play a key role in TB control because undetected TB cases and late diagnosis of TB may result in infected persons being left untreated. Not detecting and diagnosing cases at earlier stages may result in the burdening of the health system with aggravated cases of TB that may be difficult to treat and manage (Storla, Yimer & Bjune, 2008). However, current clinical and organization efforts in the health system to facilitate early detection and diagnosis of TB are not successful in mitigating the spread of infection (Wilson *et al*., 2011). Limitations in diagnosing TB have been of the main contributing factors to the negative impacts of the disease in high burdened countries (Storla, Yimer, & Bjune, 2008). There are certain diagnostics tools for a number of years but there is a need for improved or novel approaches. It is hoped that GeneXpert can address some of the limitations in conventional diagnostic technology.

a. Conventional diagnostic methods

Until recently, there has been a high dependence on using sputum smear microscopy and chest X-rays as primary diagnostic tools for TB (Evans, 2011). These methods have their own limitations in addressing contemporary issues associated with the complexities of HIV/TB co-infection and drug resistant strains of TB that are difficult to detect (Palamountain *et al*, 2012). For example, standard TB diagnostic technologies have reduced sensitivity in co-infected persons (Evans, 2011; Perkins & Cunningham 2007). Co-infected persons are likely to have a false negative result when utilizing a sputum smear test diagnostic tool, resulting in significant numbers of active TB incident cases remaining undetected and undiagnosed. In addition, the cost of X-rays as a TB diagnostic tool makes it less feasible for under resourced settings. Overall, diagnosing TB using conventional methods has become increasingly intricate, arduous and expensive for applying to complex TB cases such a MDR/XDR TB and co-infection (Evans, 2011). It is thus argued that efforts to combat TB should focus on strengthening mechanisms for detecting TB cases through innovative diagnostic and screening technologies (Evans, 2011). The MTB/RIF Xpert diagnostic test has been introduced as an innovation that can possibly address the gaps in the current diagnostic efforts in TB control (Chang *et al*., 2010; Dorman, 2010; Piatek *et al*., 2013).

b. MTB/RIFXpert diagnostic technology

The Xpert MTB/RIF diagnostic test is a single test that detects TB faster and is sensitive to resistant strains of TB (Chang *et al*., 2010). It is thus effective in identifying cases of multi-drug resistant[1] (MDR) TB or extreme resistant[2] TB (XDR TB) and is sensitive to co-infection (Chang *et al*., 2010). After the World Health Organization (WHO) endorsed the Xpert MTB/RIF assay in early 2011, over 20 countries accepted and implemented policy reform for TB diagnostics to include the use of this innovative technology in health care settings (Churchyard *et al*., 2014). These are all high TB burdened low to middle income (LMIC) countries. National governments and policy makers have been at the frontline of decision making about adopting, implementation and scaling up the technology (Weyer *et al*., 2013). Apart from increased sensitivity in detecting co-infection and resistant forms of TB, there number of other benefits that support the implementation of GeneXpert.

GeneXpert is argued to be favourable as it is foreseen to contribute effectively to diagnosing TB despite the health system context or circumstance for a given country or facility. The Xpert MTB/RIF diagnostic test is programmed, thus special skilled staff or sophisticated facilities are not required to run the test (Chang *et al*, 2010). The turnaround time for Xpert MTB/RIF result is two hours post commencing the test and does not require intensive operational time, administration and management (Chang *et al*., 2010). In addition to its efficiency, the test has potent TB killing properties, thus eradicating biosafety concerns to a greater degree (Banada, 2010). The main requirements for the Xpert MTB/RIF technology are a steady and stable electrical power source, temperature regulation, and an annual refurbishment of the cartridge components (WHO Rapid Implementation, 2011). This technology is unlike conventional methods in that it provides a more practical solution to low resource health systems as it may facilitate effective and efficient TB diagnosis and treatment in high burden diseases. This is especially at primary care level that serves high burdened communities with limited resources and other health systems constrains (Palamountain *et al*., 2012).

[1]Multidrug-resistant TB (MDR TB) is caused by an organism that is resistant to at least isoniazid and rifampin, the two most potent TB drugs. These drugs are used to treat all persons with TB disease (Chang et al, 2010).

2 Extensively drug resistant TB (XDR TB) is a rare type of MDR TB that is resistant to isoniazid and rifampin, plus any fluoroquinolone and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin) (Chang et al, 2010).

Being directed at low-resource settings and point of care facilities to simplify patients' access to early and accurate diagnosis, MTB/RIF test is anticipated to play a central role in reducing mortality and morbidity associated with diagnostic delay and misdiagnosis (Palamountain *et al*., 2012). This technology thus offers approaches to improve diagnostic capacities of point-of-care services to easily and efficiently identify affected patients to enable and accelerate the initiation of appropriate TB treatment (Palamountain *et al*., 2012). Although there are a number of crucial benefits, the actual effectiveness has yet to be determined. However, there is a need to ascertain the effectiveness of GeneXpert in addressing the challenges in TB diagnosis and control and whether its implementation is meeting its intended expectations.

Existing literature on the effectiveness of diagnostic test in experimental conditions report that MTB/RIF Xpert test has proven to be effective in early and accurate detection of TB, thus reducing aversive outcomes of TB linked with delays in diagnosis (Helb *et al*., 2009). The test is reported to have high sensitivity compared to other diagnostic methods for TB (Palamountain *et al*, 2012). Studies found that Xpert MTB/RIF is more sensitive and specific when detecting TB in both HIV negative and positive patients compared to smear microscopy (Palamountain *et al*, 2012).In addition, a meta-analysis done on the overall accuracy of Xpert MTB/RIF assay for diagnosing TB and RIF-resistance found that the accuracy in diagnosis for MTB/RIF test is higher in smear-positive specimens (Chang *et al*., 2012). Nevertheless, although diagnostic technologies are found to be effective in preliminary studies where they are trialled and tested in smaller and usually close- to-ideal conditions, their robustness and effectiveness often lessen when implemented in 'real-world' settings (Lawn & Nicol, 2011).

Literature available on the implementation of point of care MTB/RIF Xpert provide differing perspectives. For example, Lawn *et al*. (2013) argue that Xpert MTB/RIF has advanced sensitivity and specificity in experimental settings but this is similar to that of microscopy when implemented in clinical settings. In addition, other scholars report that the actual turnaround time for GeneXpert for most patients are not significantly reduced when implemented in a primary health care facility in SA compared to conventional methods (Clouse *et al*., 2012). This is contradictory to the known benefits of GeneXpert which includes a 2 hour turnaround time. It is thus necessary to question the relevance of this new

technology if its sensitivity and specificity for detecting TB is akin to traditional techniques and if other the benefits such as reduced turnaround time does not occur when Xpert is implemented in clinical and point of care facilities. Nevertheless, other scholars report more positive outcomes and that GeneXpert has improved effectiveness (Fielding *et al*., 2014).

Literature reports that GeneXpert has provided a solution to many of the bottlenecks and challenges in the health system (Boehme, 2012). Much of the literature evaluating the effectiveness of Xpert MTB/RIF test against traditional methods in detecting TB in clinical settings has repeatedly shown high efficacy and performance, especially when used under testing conditions and target environments advised by the WHO (Lawn *et al*., 2011; Lawn *et al*., 2013; Weyer, 2013). Some authors found that GeneXpert has more practical benefits for faster diagnosis and detecting complex TB cases compared to traditional microscopy and X-ray TB screening and diagnostic techniques (Boehme, 2012; Lawn *et al*., 2013). These results are consistent with outcomes from initial trial studies on GeneXpert that supported its adoption and implementation. Other authors also state that the implementation of GeneXpert has improved patient access and accuracy in diagnoses when implemented (Lawn *et al*., 2013; Piatek *et al*, 2013).

Despite these reports, there is still much work that needs to be done to uncover the outcomes, performance, effectiveness and efficiency of TB policies and technologies in 'real-world' settings (Lawn & Nicol, 2011; Lawn *et al*., 2013; Van Rie *et al*., 2010). This is the same for XpertMTB/RIF. This is especially for primary care settings with lower level health workers that are often neglected in complex health systems (Van Rie *et al*., 2010). Furthermore, the impact and effectiveness of TB programmes like GeneXpert technology further depends on how it is implemented within the particular settings it is designed to operate in (Piatek *et al*., 2013). SA was of the first countries to roll out GeneXpert where it was decided based on cost considerations to implement instruments in national laboratories and microscopy centres (Clouse *et al*., 2012).

v. GeneXpert in South Africa

South Africa adopted a phased approach to implement GeneXpert technology in health facilities across high TB burden districts in all nine provinces (Fielding, 2004). Initially, Gene Xpert has been tested in facilities in the Western Cape, Kwazulu-Natal and the

Gauteng where approximately 30 machines have been bought by the state. Exactly two years after the launch, 203 instruments have been put in place. 1,180,669 tests have been carried out across all nine provinces. Public officials support reports from piloting phases that argue for an urgent need to have the Gene Xpert in all clinics in South Africa. With plans for rapid implementation and prospective scaling up proposals, the national strategy for the roll out of GeneXpert is to be implemented in 2-3 years.

The national policy for the implementation of GeneXpert is based on the compelling WHO recommendation that the technology be used as the initial diagnostic tool in suspected MDR-TB, XDR-TB and HIV/TB co-infected cases. The National policy does not yet include the exclusive use of Xpert MTB/RIF for diagnosing EPTB (Pulmonary TB), largely for reasons of data insufficiency that proves that GeneXpert can effectively diagnose pulmonary TB compared to conventional methods of TB diagnosis. This demonstrates the complexity of TB diagnosis for different form of TB and how implementation of GeneXpert requires careful consideration to meet positive outcomes.

Despite the need to consider the complexities of TB in the implementation of GeneXpert, earlier findings from process evaluations suggests that case detection for individuals suspected of having active TB has increased to an average of 14% and detection of drug resistant stands of TB is averaged at 7%. However, more impact evaluation reports are needed to ascertain the extent of effectiveness of the implementation to GeneXpert in SA.

While the GeneXpert machine itself is relatively easy to operate, as demonstrated by the Minister in 2011, implementing and integrating the machines into the health system is proving to be less simple (Fielding *et al*., 2014).

vi. Implementation of GeneXpert

Health systems challenges make it difficult for national policy makers to decide to adopt novel programmes and technologies. Experience has showed us that merely introducing technology is not sufficient to undertake and solve multifaceted public health issues (Lonnroth *et al*. 2009; Raviglione & Pio 2002). The complexity of the health system presents specific challenges for the implementation of reform. This is especially for TB initiatives because TB policies constantly undergo reform or revision. As countries start implementing Xpert MTB/RIF, the reform introduces particular technical and organizational

challenges (Dorman, 2010; Schneider, Gilson, Ogden, Lush, & Walt, 2006). There therefore are a number of factors that contribute to implementation.

A wide range of interacting factors mediates the actual implementation of any programme in a particular setting. Factors that mediate the implementation transcends beyond the programme guidelines or the mechanics of the programme itself (Scott *et al*., 2014; Lawn, & Nicol, 2011). These influences operate at the point at which the particular programme and the health system intersect (Gilson, 2012). These influences can be grouped into hardware and software issues.

Hardware elements are defined as the structural components that shape the functioning of the system (Gilson, 2012). An example of hardware factors that influence implementation is limitations in the health system and resource constraints (Gilson, 2012). How a specific country adapts new policy (such as prioritizing target populations for screening and testing) may be determined by the extent of available resources. Despite good policies for delivering suitable innovative technologies and adapted by national policy makers, health system constraints are key influences in contributing to the ineffectiveness of some of TB control policies in LMIC countries (Zumla & Cobelens 2012). Other examples of hardware factors that may influence the implementation include challenges pertaining to financing, monitoring and evaluation, facility preparedness, human resources and capacity issues, and so forth (Lawn, & Nicol, 2011; Schneider, Gilson, Ogden, Lush, & Walt, 2006).

In contrast, software elements are defined as the social, intangible or indirect factors that may also influence implementation (Gilson, 2012). Software elements that may potentially influence implementation include organizational culture, issues of power, decision making, health worker motivation, diffusion and integration of the programme, actor/stakeholder buy-in, health workers' experiences of working in TB care and their experiences of the 'actual' implementation of a reform (Kirwan, Cárdenas & Gilman, 2012; Gilson, 2012; Schneider, Gilson, Ogden, Lush, & Walt, 2006). Furthermore, different actors' experiences and the relationships between these actors are central to programme or policy implementation (Gilson, 2012). In isolation or in combination, these issues interact with one another and influences implementation at various degrees and at different levels of the system. Thus in order to advance health systems strengthening, scholars must consider, identify and implement changes in structural, social and behavioural components that are most likely to guarantee intended policy effects (Gilson, 2012).

In much scientific literature, there still remains a great need to understand how human qualities of the health system influence implementation (Alanen, Välimäki & Kaila, 2009; Boehme *et al*., 2011). There has been a reasonable focus in the implementation literature on the hardware factors (Buse, Mays, & Walt, 2005). However, the knowledge base of how a wider range of software issues influence implementation still needs advancement (Schneider *et al*., 2006). This is especially for the implementation of TB policy, programmes and technology into the health system (Boehme *et al*., 2011; Clouse *et al*., 2012; Van Rie *et al*., 2010). Specifically, there is a greater need to understand how software issues of the health system influence guideline implementation, particular at lower levels of the health system (Gilson, 2012; Schneider *et al*., 2006). Although there are conceptual and theoretical models for the role that complex 'software' issues exist in the general implementation literature, there is opportunity for application of these tools in empirical investigations (Gilson, 2012). In addition, very few of these frameworks are applied to assessing how actors' experiences and human aspects mediate implementation processes, especially for TB programmes.

Despite the impact that software factors have on policy implementation (Gilson, 2012), there is limited empirical evidence accounting for such factors. More specifically, there is paucity in the GeneXpert literature on how actors' perceptions, interpretations and experiences of policy, novel technology, implementation guidelines and other issues facilitate or hinder actual implementation. For example, Boehme *et al*. (2011), Clouse *et al*. (2012) and Van Rie *et al*. (2010) investigated the implementation of GeneXpert in point-of-care and other clinical settings but there is no account of how health workers may influence implementation. The focus of these studies was rather to understand operational elements in implementation such as the specific requirements for the implementation of GeneXpert that are specific to financial, operational and logistical support. Health workers in primary settings thus play an important role in how policy is implemented and they hold strong discretionary power that may influence the effectiveness of policy implementation for a given facility and this need to be more accounted for in the literature (Buse, Mays, & Walt, 2005; Rice, 2013).

Health workers expected to implement policies are people, and people are complex beings. Thus, how they 'do' policy may be influenced by their experiences, which in turn are shaped by their perceptions, understandings and relationships (Buse, Mays, & Walt, 2005; Gilson, 2012). Health workers in SA and in TB policy contribute extensively to implementation processes and the outcomes thereof. Much of the TB reforms in SA have

focused on point of care services in community clinics or primary care facilities. Moreover, many primary care facilities in SA and other LMIC countries are nurse-led and each facility has their own values and principles that shape their functions, operations and the overall quality of their services. How policy directives from national government adopt, translate and diffuse policy is greatly influenced by the existing organizational culture, operations and relationships between actors (Buse, Mays, & Walt, 2005; Rice, 2013). In addition, how exiting relational issues and organizational space operate in combination with the introduction of novel policy and guidelines shapes how health workers will understand, interpret and experience the implementation of that policy. These experiences may further mediate their actions and thus the overall effectiveness of the implementation processes involved in introducing a new policy (Gilson, 2012, Rice, 2013).

Study Rationale

The specific objective of this study was to investigate PHC nurses' experiences of diagnosing TB following the implementation of GeneXpert policy in their practice. This was done to understand the barriers that limit implementation of TB diagnostic policy in nurses' practice. An investigation into nurses' experiences through an analysis of discourse and practice offer important lessons for people-centered health systems in TB diagnostic policy implementation.

Nurses' experiences will be the primary focus of this investigation. This will be coupled with and analysed in relation to 'policy on paper', their interpretations, interactions and actions within the implementation context. Understanding the relationship between their narratives and their practice will be central to this study. Consequently, to better understand this relationship further within implementation contexts, it is crucial to generate better insights into how policies on promising novel technologies from international and national levels are adapted and transferred into health policy implementation by health workers at local levels (Gilson, 2012; McLaughlin, 1987; Rice, 2013). There is a further need for deeper insights into the implementation of GeneXpert policies overall (Piatek, 2013) and how people, being at the centre of policy implementation, are important in contributing to the effectiveness or ineffectiveness of policy implementation (Bergen & While, 2005; Rice, 2013). However, people operate within broader contexts and it is important to consider the broader contexts that govern and shape their practices.

There is a dearth in the GeneXpert and broader TB literature engages with the particular issues this paper seeks explore and grapple with. Little is known about point-of-care experiences of GeneXpert at primary health care level (Clouse *et al*., 2012). This is a broad and particularly complex issue, yet undergoing this investigation can yield many underlying layers of meaning. It is the intention that the findings generated may contribute to a deeper understanding of the nuanced issues in the implementation process 'on the ground', which have potential to generate relevant and constructive ideas for health systems strengthening. Person-centered research approaches are necessary to understand the subjective experiences of lower level actors who practice implementation of policy. This study aims to provide information that may strengthen policy guideline formulation and implementation at cross-cutting levels of the health system. Furthermore, interpretations of information generated in this study will aim to understand the levels at which these factors operate and gain insight into broader systems that shape health workers' experiences of implementation. In essence, this study will attempt to address questions related to the 'how' in Xpert MTB/RIF implementation and scaling up through gathering appropriate 'real world' data and design methods that can contribute to strengthening the assessment and evaluation of processes, experiences, outcomes and impacts of health system reform.

Research Question

The research question for this study is thus as follows:

How do the experiences of local level health workers in primary health care settings in the Western Cape mediate the implementation of the MTB/RIF Xpert diagnostic technology introduced by higher level governance in South Africa?

- How do health workers' experiences influence their practices in the implementation of MTB/RIF Xpert diagnostic technology?

Methods

i. Theoretical Framework

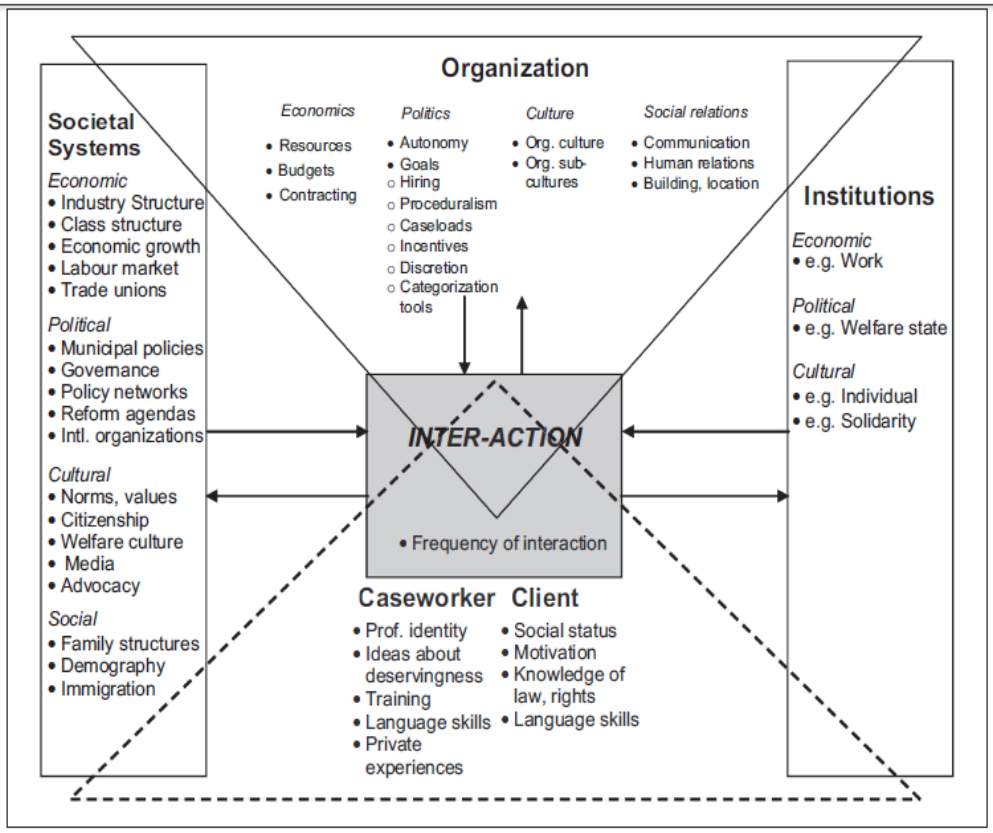

Figure 1: Overview of systems and institutions influencing the caseworker–client interaction.

Figure 1: Micro-Institutionalist Theory of Policy Implementation (Rice, 2013)

The Micro-Institutionalist Theory of Policy Implementation (MITPI) (Rice, 2013) framework (Figure 1) will be used to assist in developing insights into micro-level analyses of programme implementation. In this study the MITPI framework will be used to describe, analyse and interpret health workers' individual experiences and actions in relation to the GeneXpert policy and its implementation, the facility specific facility selected in which the policy is implemented, and the overall context and broader systems and processes. This conceptual framework provides a rationale and lens for analysing low level health workers as the basic unit of analysis within the health system as an institution (Rice, 2013). There has not been sufficient focus on micro-level perspectives recognizing the roles and experiences of low level health system actors in implementation overall (Scott, Schaay, Olckers, Nqana, Lehmann, & Gilson, 2014).This study seeks to direct the focus on primary care health

workers as fundamental in the implementation of policy. For the purposes of this research, the institution refers to the overall health system and the organization to the primary care facility.

Micro-Institutionalist theory draws on the street-level bureaucracy (SLB) theory developed by Lipsky but provides a comprehensive set of ideas for taking into account complex factors in the shaping of micro-level actors' experiences, perceptions and relational issues between different levels at policy implementation operate (Rice, 2013). SLB theory posits that the behaviour of health workers is influenced by two key elements: 1) the organizational context and 2) intrinsic individual cognitive and emotional functions interacting with the organizational context (Lipsky, 2010; Rice, 2013). Organizational context determines with conditions for bureaucratic action and the individual factors interacting with the organizational context determines the way in which health workers adapt or undermine policy implementation (Lipsky, 2010; Rice, 2013) (See Figure 1).

In addition to Lipsky's ideas, micro institutionalist theory incorporates components of sociological institutional theory (Giddens, 1981; Powell & DiMaggio, 1991, as cited in Rice, 2013). This means that the theory is based on an understanding of social reality as governed by individual human experience in combination with behaviour (Giddens, 1981 as cited in Rice, 2013). Institutions exist and interact with larger political, economic, and contextual processes and once established, structure, regulate and limit human action to what is acceptable, relevant, and appropriate to particular circumstances and contexts. The fundamentals for individual action are thus consistently modified by adaptations and reform in the tenets of institutions as prompted by systemic changes (Rice, 2013). The full picture of micro institutionalist framework provides us with an understanding of interactions between institution and individual action, context and institution, and context and individual action are thus intricate and operate as a complex interconnected feedback looping system.

The micro institutionalist framework of policy implementation presents a conceptual tool for understanding how individual health workers' experiences and actions are entrenched in and governed by an interconnected web of economic, political, cultural, and social structures (Rice, 2013). This model will be used to assist in offering directives for building conceptual bridges between the different levels at which the implementation of policy operates, i.e. micro-level health worker experiences, interactions and actions, meso-level organizational context and macro-level broader socio-political systems and structures (Rice, 2013). This model further requires that the South African health system and the context in

which TB control functions to be considered in understanding how health worker's experience policy implementation and how these experiences mediate low level implementation.

ii. Setting and context

South Africa has the highest TB burden in the world and with the largest HIV/TB co-infection rates, the country has faced major challenges associated with an increased prevalence in multidrug resistant TB (MDR-TB) and extreme resistant TB (XDR-TB) (Wood, Lawn, Johnstone-Robertson, Bekker, 2011). The South African public system across all provinces largely deals with the diagnosis and treatment of TB at primary care level and more complex presentations of TB are managed in secondary level specialized facilities (Wood *et al*., 2011). The TB sphere has undergone a number of changes and developments and a lot of these reforms have been implemented in different levels of the public health system (Wood *et al*., 2011). To address the TB issue, country level policy makers were the first to adopt the molecular TB diagnostic test after recommendations were made by WHO (2008; 2011; 2012), thus resulting in the introduction of the GeneXpert diagnostic tool (Schnippel, Meyer-Rath, Long, MacLeod, Sanne, Stevens, & Rosen, 2012). Similar to the adaptation and implementation of all health policy in South Africa, the National Department of Health formulated and establish the policy and different provincial level governments were assigned to implement the policy at different levels of the provincial health system (Gous, Cunningham, Kana, Stevens, & Scott, 2013).

The Western Cape Province has been reported to have the highest rate of all types of TB in South Africa (Claassens *et al*., 2013). This study will be based in the Western Cape Province because of the reported TB burden in this particular province. Over the years, the Western Cape Province has taken active strategies to address the issue of TB (Claassens *et al*., 2013) and changes in approaches in policy will give us richer and more 'realistic' insights into how these complexities shape and mediate implementation. With regards to the anticipated appropriateness of the diagnostic technology for point of care, this study will select a case facility that is located in the City of Cape Town. The justification for this is that the anticipated case facility should be situated in a setting where there are high rates of incidence and prevalence of TB to ensure that implementation of GeneXpert test is aligned with the need for effective diagnostic testing procedures. The case facility will operate at primary care level where GeneXpert reform has been introduced and is in at least in its three

year period of implementation and operation. The facility should also be approximately 10 years in operation, to frame perspectives around historical versus contemporary circumstance and the changes the facility had undergone with TB policy and implementation.

iii. Research design

The overarching design strategy of this investigation is flexible in nature. A case study approach will be utilized in this study. The case study approach to research can be defined as an in-depth empirical inquiry of particular events, systema, persons, relationships, policies, institutions, or other issues that may draw on a combination of research methods (Yin, 2013). A combination of issues or a single issue is studied scrupulously where a number of different of tools and methods are used to collect and analyse information (Hancock & Algozzine, 2006). A particular case is central to a research investigation and is regarded as a main case, as it offers a unit or units for analyses and provides a 'snapshot' for understanding the issue under investigation at particular period in time (Gilson, 2012; Yin, 2009). Other cases can be embedded in the primary case and they are called embedded cases in case study research (Yin, 2013). The case study research approach is most appropriate for this study because of the nature of the research question and the overall purpose of the study. The case study approach is said to be relevant to research projects with both explorative and explanatory features (Yin, 2009; Yin, 2013) thus enabling the study of both the 'how' and 'why' of phenomena. Many scholars in the field of health policy and systems research (HPSR) who have undertaken explorative investigations have successfully generated valuable findings and analytical generalizable claims through the effective use of case study approaches (see Gilson, 2012 for examples). Subsequently, analytical generalizable claims produced from insights regarding processes and strategies observed in a particular setting via the case study approach can be applied to other circumstances, contexts and settings (Gilson, 2012). This approach is further most fitting for this investigation, as the researcher will have little control over the processes and events under study. In addition, the focus of this research is based on a contemporary phenomenon within a real-life context (Gilson, 2012; Hancock & Algozzine, 2006; Yin, 2009). Furthermore, case study research allows for detailed descriptions and interpretations of particular experiences.

Two types of case study research approaches are presented in the literature (Yin, 2009; Yin, 2013). Single case studies and embedded case study approach. Single case studies involve a focus on a specific case or a combination of cases of the nature. The embedded case study research encompass one particular case is situated within a broader case. This study

will be based on the latter approach to case study research where individual health worker experiences in different PHC facilities are embedded in a particular case sub district where GeneXpert has been implemented. The particular sub district under investigation will thus be the overarching case. Health workers from different facilities within the case sub district and their experiences are the primary unit of analysis. In addition, implementation experience of the facility, its contextual factors and broader systems and structures will also form part of the focus of the scientific inquiry (Gilson *et al*. 2011). This study is a therefore a multiple embedded case study as it seeks to interview approximately ten health workers from different PHC TB facilities in a specific sub district in the Western Cape.

Within the overarching case study approach, qualitative data collection and analysis will be employed. By utilizing qualitative investigation approaches, this study aims to gain in-depth understandings of participants' experiences with regards to particular events, interactions, interpretations, actions, relationships and circumstances. Qualitative research methods offer tools to observe actions and interactions, allowing researchers to interpret and explain constructed experiences in relation to observed reality (Miles & Huberman, 1994; Willig, 2001). Qualitative work allows for flexible open-ended strategies, thus making it suitability for the purposes of this research project. The researcher is able to immerse him or herself within the data generated and iterative strategies are encouraged in this research design approach (Langdridge & Hagger-Johnson, 2009). Like case study approaches, qualitative research methods does not aim to generalize findings for the purposes of projecting it onto the population group under study such as with fixed approaches (Hancock & Algozzine, 2006; Gilson, 2012; Yin, 2009). For this inquiry, using qualitative methods allows researchers to adapt to findings that may provide authentic and unanticipated meanings (Langdridge & Hagger-Johnson, 2009).

iv. Case selection and sampling

Because there are three interrelated streams for collecting data in this study, a three-component sampling approach will be employed to sample documents and cases for this investigation. All three components of sampling for data collection will draw on the purposive sampling approach.

a. Policy documents

For the first level of sampling, national policy and implementation documents on GeneXpert will be sampled. This level of sampling will be to gather different policy and program documents, implementation guidelines and protocols. Facility records related to the

formulation and implementation of the MTB/RIF Xpert diagnostic will be sought for. These include meeting minutes and communication trails related to the GeneXpert policy and its implementation (emails, posters, policy briefs and so forth). A purposive sampling method will be employed to sample policy and implementation documents papers to be included for review. Purposive sampling is a kind of non-probability sampling where the researcher selects samples for study on the basis of intentions of their subjective judgment and not to sample to with for the purposes of statistical generalizability (Marshall, 1996). It is best used in studies where the aim is to sample specific characteristics of a population of interest and in relation to the issue being addressed and the questions raised (Burger & Silima, 2006; Kuzel, 1992; Marshall, 1996). Furthermore, this sampling method will be most useful because of the exploratory nature of the investigation, its relevance toward the particular paradigm that this study is situated in, and the kinds of insights this inquiry aims to generate (Marshall, 1996).

b. Case facilities

The second sampling frame will be to sample the sub district, situated in the Western Cape Province in South Africa where the GeneXpert TB diagnostic technology has been implemented for a period of at least two years in different PHC facilities. The population to sample embedded cases from are health workers in TB care who are working in dynamic primary care facilities where the MTB/RIF Xpert diagnostic technology has been implemented. This sub district will be the main case of this research investigation.

The sub district will also be selected using a purposive sampling strategy because of the complexities associated with TB diagnostic policies and the implementation of these policies, particularly at primary care level. Purposive sampling of cases is also best suited because the case associated with the phenomena of interest is difficult to sample and the case is most practically accessible for the purposes of research (Burger & Silima, 2006; Kuzel, 1992; Marshall, 1996). Selection of the sub district will be based on the researchers judgements of the suitability of the sub district and case facilities to the research aims, research question, and the methods for data collection. The implementation period of GeneXpert in the sub district must be at least two years collectively for the facilities where the health workers are working in. This is a good length of time to assess health workers' experiences of the implementation and how actual implementation is mediated by their experiences across the sub district. Given that GeneXpert was incrementally introduced in South Africa, it is foreseen that there will be a limited number of primary care facilities within a particular sub district that has implemented GeneXpert for more than 2 years. In

relation to the characteristics sought for the case facility in this investigation and the broader South African historical and contemporary socio-political realities, the facilities in the sub district where health workers' will be selected must have a reasonably high TB case load. The subdistrict should also have a high incidence and prevalence of TB. These characteristics of the subdistrict and its PHC facilities are anticipated to offer unique contextual perspectives that may generate deeper insights into the implementation of GeneXpert technology. In making interpretations, the geographical location attributes (e.g. rural/urban, size of the community the facility must serve, etc.) and socio-economic and political issues will also be taken into account. Furthermore, the selection of the prospective sub district will be potentially based on existing literature and theoretical arguments about the subdistrict, if available.

c. Health worker case narratives

The third level of sampling will be to sample the embedded cases – frontline health workers (including facility managers) from the PHC facilities in the sub district and who have been directly or indirectly involved in the implementation of GeneXpert. To establish an in-depth understanding of the experiences of health workers with the implementation of GeneXpert, an approximate of 10-12 low level health workers will be selected from the particular case sub district to generate 10-12 health worker case narratives. These health workers must have an understanding of the operational and administrative aspects of the technology from the time the technology was introduced (or when they have started working at the facility) in their primary care facility up until to how it is currently operated. They may mainly include lab staff and nurses. Health managers and workers will also be sampled using a purposive sampling approach. Purposive case selection allows researchers to examine unusual cases and to take into account the contextual factors that are unique to a particular case and how it differentiates from other cases (Hancock & Algozzine, 2006; Yin, 2009). This sampling method will be used to ensure that health workers have the necessary involvement, experience and knowledge about the policy and the implementation of the policy and the facility to validate their narratives. This study will also focus on particular roles that different health workers play in the implementation processes and the sample seeks to include health workers with varied involvement and contributions that they offer to the GeneXpert policy and implementation in the facility. An important inclusion criterion for health workers to be interviewed is that they should have a sound degree of involvement in the implementation of GeneXpert. This may be at any level or area of implementation

including whether they were involved in orientation, operating the technology, referral for testing or any other activity required in the implementation of GeneXpert.

The sub district manager will be asked to serve as a key informant to provide information about the characteristics and issues of interest. They will be further asked to recommend facilities and health workers who are most suitable as sample participants. The sub district manager and the facility managers will also be asked to assist in recruiting participants in that the researcher will request from the facility managers 10 minutes of the weekly meeting time to present the background, purpose and aims of the research study to the health workers of the facility. Health workers who express interest to participate in the study will be asked to meet with the researcher after the meeting where they will be provided with information sheets and will be able to ask questions about the research and the nature of their participation.

vi. Data collection

A useful attribute about the case study approach is that it allows for the gathering of multiple sources of evidence using diverse methodological tools (Gilson, 2012). This study will thus draw on different forms of qualitative research methodologies that will be vital for enhancing the trust worthiness of our findings through the process of triangulation (Gilson, 2012). Qualitative research methodology is most useful for this study because it offers scope and tools to obtain comprehensive accounts and perspectives of experience (Parker, 2005). It further allows researchers to be able to describe, unfold, interpret and develop meanings and understandings of these experiences. Qualitative research methods have proven to be relevant tools in health systems and implementation research because it accommodates for investigating issues of complexity (Gilson, 2012). Drawing on multiple methods of qualitative inquiry will allow the researcher to converge findings and interpretations across data collected through different methods (Gilson, 2012). The data collection procedures will occur in three interrelated streams in the health facility. These streams will not occur in isolation and there is a lot of overlap in the time that these streams of data collection will take place. It is expected that these streams are likely to occur concurrently.

a. Document review of policy and implementation guidelines

The first stream will be to analyse international, national and provincial policy reviews and implementation guidelines, facility documents, meeting minutes, information gathered from modes of communication (e.g. email threads relates to policy under study). During this stream, the researcher will collect data to construct a document review with the

aim of understanding policy directives, anticipated implementation procedures from higher level governance and overall policy and implementation plans of GeneXpert in the facility. This data from the document review will primarily serve as a pathfinder to assess the experiences, interpretations and actions of health workers against a clear set of expectations, procedures and guidelines.

b. Formal in-depth face-to-face interviews

The second stream of data collection will comprise of conducting formal open-ended semi-structured face to face interviews where health workers from the sub district facilities will be asked to uncover their experiences and interpretations of the implementation of the GeneXpert diagnostic test in their specific facility. The aim of this study is to gather and grapple with in-depth copious accounts of health worker experience with the implementation of GeneXpert. To facilitate the direction for an open, intensive and non-intrusive interviewing process, principles of narrative interviewing will be utilized. In the interviews, participants will be asked open-ended semi-structured questions (see Appendix E for interview schedule). The open ended semi-structured approach to interviewing facilitates the exploration of new ideas and thoughts to be expressed that is not limited to the researcher's existing knowledge and allows for probing of information that sparks interest (Connelly & Clandinin, 1990; Corbin, 2003). Semi-structured interviews enable the researcher and the participant to have key roles in the interview process, where both are co-constructors of meaning (Corbin, 2003).

The narrative accounts constructed by health workers about their implementation of experience will allow the researcher to gain access to their experiences through language. By drawing on the narrative research it is recognized that language only offers a window through which experience can be described and interpreted (Emerson & Frosh, 2004). Furthermore, experience through language is socially constructed and are situated within broader social systems that shape the experiences and how they are depicted through language (Emerson & Frosh, 2004). Utilizing narrative research in data collection and analysis processes is therefore aligned the broader aims of this research investigation. Micro, meso and macro level systems, issues and contexts that govern the health workers' narratives about their experiences will be considered. By offering narratives of experience, participants will be able to construct stories based on their own subjectivities in a way that provides them with the agency to give their own explanations and interpretations of their experiences (Langdridge & Hagger-Johnson, 2009; Emerson & Frosh, 2004). Narrative research also considers how

actors' identities, roles, responsibilities, interactions, and so forth are constructed in the stories they tell (Riessman, 2008). This may provide us with insights into how they define their role and position as health workers in relation to the policy and actual implementation of GeneXpert. Finally this approach will allow the researcher to explore a combination of hardware and software issues that they understand to influence their experiences of policy implementation.

c. Direct observations in case facility

The third stream of data collection will constitute direct observations where the researcher will ask to observe and engage with some of the health workers in their day-to-day operations and activities associated GeneXpert in their facilities. Here the focus will be on unstructured direct and indirect observations. Engaging with the health workers directly and observing their actions, interactions and relationships will provide the researcher a better perspective into their lived reality as an external observer. The researcher is able to interpret their behaviour, attitudes, perceptions, and discourses through the participant observation approach. Direct observation will further include gathering information through informal conversations with health facility managers and health workers, notes of meetings, conversations (face to face and telephonic conversations), interactions between health facility managers and higher levels of governance. In relation to the policy document review stream of data collection, policy and implementation material and other files or documents specific to the facility that may give insights into the implementation will also be reviewed on availability. Substantive field notes will be documented using a fieldwork journal.

In combination with information from the document review and the direct observation, health workers' narratives will be used to understand on organizational arrangements, barriers to implementation, administrative and financial functions, governance, power and actor relationships, institutional culture and how these issues operate at the micro level, where micro level experiences are influenced by higher level contexts. Furthermore, a focus on the experiences of lower level health managers is justified by the key role that they play and the discretionary power they have in policy implementation. Through allowing them a platform to share their insights and be actively part of policy and implementation strengthening is a form of empowerment where they may interpret themselves as active players in health systems strengthening through improved low level policy implementation (Gilson, 2012). This is in line with the 'people-centred' approaches (Gilson, 2012) that are pertinent in health systems strengthening discourse.

vii. Data analysis

Analysis of the data across the three integrated streams will be iterative. The story units constructed within the open ended semi-structured interviews will be analysed using the Riessman's (2008) thematic narrative approach. Thematic narrative analysis offers researchers the opportunity to develop rich accounts of interpretation and experience, to gather comprehensive descriptions of action, and to draw out patterns of meaning in the form of themes (Babbie & Mouton, 2007; Riessman, 2008). This method of analysis explores both the content and structure of the participants' told stories (Riessman, 2002).

An initial step in the analysis process will be to identify and code themes from the content of health workers' stories of their experiences of the implementation of GeneXpert (Braun & Clarke, 2006; Riessman, 2008). Narrative components will be categorized into overarching themes and subthemes. Themes developing from narratives are layers of meaning embedded in the content of the stories with the function of directing and informing conclusions (Riessman, 2002). In addition to extracting themes, assumptions of narrative structure, implications, and contexts will also be considered (Riessman, 2002). The researcher will analyse these textual elements of the narratives of health managers. The analysis of both narrative content and structure elevates the analytical process and contributes to the significance of the inferences drawn from the interview data (Riessman, 2008, 2012). It permits for the analysis of how identities are constructed in participants' stories. This method of analysis also allows researchers to take into account the micro and macro contexts and broader societal systems that shape health managers' stories and discourses embedded in them of their experiences of their relationship with provincial health managers. Thus, the combination of the content-driven and structural analytical methods embedded in the thematic narrative approach will be most appropriates for the analysis of participant narratives this study (Riessman, 2008, 2012).

Moreover, the sampled policy documents and substantive hand written notes from short-term ethnographic data will be analysed by utilizing the principles of content and thematic analysis. These frameworks to guide analysis of policy documents and data collected from direct observations will permit for themes and patterns of meaning to be extracted. Health workers' narratives will be analysed in combination with policy review and direct observation data to triangulate and identify patterns of data across these data sources.

viii. Ethical considerations

Ethics is an important aspect of research as it directs appropriate methods that limit harm to the participants and the researcher (Willig, 2007). In order for this study to have been conducted, ethical issues need to be considered and thought through before entering into the research field for investigation.

a. Informed consent.

Before initiating the research process and engaging with participants with research related protocol, participants will be explicitly informed about the nature and purpose of the research (Willig, 2001). Informed consent suggests that the research participants provide an explicit statement of agreement and understanding of the nature of the research investigation and their involvement (Willig, 2001). This will be presented in the form of an informed consent document (attached as Appendix A, B, C and D). The researcher will provide the participants with all the information related to the aims and methods that the research seek to address before undertaking in the study for participants to make an enlightened decision to partake in the study. Outlined in this form are the aims, benefits, risks, costs, role of the researcher, duration of interviews and so forth. Participants will be informed that they have the right to withdraw from the study at any time and that they can decide to end the interview. They will further be informed that the interview would be recorded with an audio recording device and that they can terminate recording at any time of the interview. The researcher will give verbal explanations of the information on the consent forms and signatures of participants will be requested to authorize their consent for involvement in the study. Copies of signed consent forms for the facility and for individual participants will be requested from the participants or necessary parties before the research will take place where it will be kept in a safe place.

b. Harm to subjects.

It is the researcher's responsibility to make sure that the study does not inflict physical, emotional or psychological harm on the participant (Willig, 2001). Participants will be interviewed and observed in confines of the facility where they work and no additional harm is anticipated that may place the participants at risk of physical or emotional harm. It is anticipated that some information that participants may potentially provide in the interviews may have negative consequences for the health workers, the facility and the case sub district. Strict measures will be put in place in the management and reporting of information to maintain the anonymity of the participants, the facility and the case sub district. This is further discussed under the privacy and confidentiality section of this paper.

c. Harm to researcher

The researcher visiting the particular facilities in the sub district will do the data collection. The researcher is aware of the risk of contracting TB in health facilities. The risk is particularly higher in facilities situated in high TB risk communities such as the prospective case facility for this study. The researcher will thus ensure to wear TB masks when conducting participant observations in the case facilities. Interviews with health workers will be conducted in high-ventilated spaces or outside of facility where the risk of contracting TB is reduced. The low level of interaction with patients further reduces the risk for the researcher. In the event that conducting interviews will create an additional burden to the workload of health workers, they will be requested to do the interviews at their own time and in spaces that they prefer (for example, in their home).

d. Privacy and confidentiality

Participants' personal identities and the name and specific details that may make the facility easily identifiable will not be disclosed in the reporting and publishing of the prospective findings of the study. Only the researcher, transcribers and supervisors will be able to obtain access to the recordings of the interviews and interview transcripts. Participants and the facility will thus remain anonymous in the research report and their privacy and confidentiality will be strictly maintained. Pseudonyms will be used to maintain the facility and participants' anonymity. All this information will be included in the informed consent form and a verbal confirmation will be given to the participants before the study commences. Limitations to confidentiality will also be mentioned and stated regarding the research being written up in the form of a master's research project and that it may be published in an academic journal.

xi. Anticipated timeline (revised)

1st October 2015 – 1st February 2016: Narrative Literature Review and preparation for the field

1st Feb 2016– 21st Feb 2017: Data Collection and Field Work

31st May 2017–October 2017: Data Analysis and writing up

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Part B: Structured Literature Review

This chapter begins by framing an argument for focusing on software issues in health systems and policy research - particularly the human attributes of health systems and the experiences of health system actors - and its role in and implications for the implementation of policy reform. Using GeneXpert policy reform implementation as a pathfinder, this paper continues with the objective of undertaking a structured narrative review of the existing literature, to understand the major barriers and enablers for health systems implementation reform. More importantly, this review intends to assess the nature and extent to which people issues and people-centred practices are considered in the policy implementation research of GeneXpert and novel TB diagnostic teachnologies broadly. The aim of this section of the dissertation is to identify literature considering the human experiences and relationships of frontline health workers and how these may intersect with hardware, contextual and social systemic factors, that may potentially mediate the implementation of GeneXpert TB diagnostic policy.

Background

The urgent need for improving the health system is entrenched in public and academic discourse, particularly for Low-and Middle-Income Country (LMIC) settings (Bennett, Mills & Russell, 2011; Berman & Bossert, 2000). Multiple reforms have been implemented in various levels of health systems over time, with intentions to strengthen and improve its performance, efficiency and effectiveness. Despite decade's worth of reform efforts, there still are major gaps in discussing challenges that limit health systems strengthening (Bennett, Mills & Russell, 2011; Berman & Bossert, 2000; Cassels, 1995). Health Policy and Systems Researchers (HPSR) argue that this is because policy makers and researchers of health sector reforms still perceive the implementation process of reform as primarily rational, linear and mechanical (Bennett, Mills & Russell, 2011; Berman & Bossert, 2000).

For many years, implementation scholars and policy makers have understood structural elements as being of most significance in their implementation (Bennett, Mills & Russell, 2011; Berman & Bossert, 2000; Cassels, 1995; Gilson *et al.*, 2011; Gilson & Mills, 1995; Sabatier, 1986). From this perspective, changes in the health system structures and functions will direct standardized procedures and processes that will automatically result in measurable predicted outcomes (Blaauw, Gilson, Penn-Kekana & Schneider, 2003; Gilson & Mills, 1995; Sabatier, 1986). These structural elements with their distinct functions are known as the hardware in health systems and policy implementation (Gilson *et al.*, 2011; Gilson, 2012). They make up the essential building blocks of the health system, described by the World

Health Organization (WHO) as leadership and governance, health information systems, health financing, human resources for health, essential medical products and technologies, and service delivery (Gilson, 2012; World Health Organization, 2000). In contrast, software aspects of the health system are the intangible features and manifestations that drive and influence processes, functions and relationships across different components (Blaauw, Gilson, Penn-Kekana & Schneider, 2003; Freedman, 2005; Gilson, 2012). They include ideas, values, attitudes, power, culture and norms. Software factors interact with hardware elements to influence the processes and outcomes of health policy implementation (Freedman, 2005; Gilson, 2012). People functioning at various levels of the health system - and not only higher-level policy makers - have agency and experiences that are important software factors influencing the system (Blaauw, Gilson, Penn-Kekana & Schneider, 2003; Freedman, 2005; Gilson, 2012; Sheikh, George & Gilson, 2014).

Health systems and policy scholars are increasingly acknowledging the notion that health systems are primarily social institutions through the complex realities of actors and the interactions between them (Freedman, 2005; Gilson, 2012; Sheikh, George & Gilson, 2014). There is growing empirical evidence that recognizes and considers the broader contextual issues and the social, political and economic circumstances and how they intersect, to influence health policy and systems implementations (Sheikh *et al.,* 2011; Freedman, 2005, Gilson, 2012; Mash *et al.,* 2013). These advances are important but for health systems and policy research to contribute to health systems strengthening, people-centric practice needs to emerge in scholarship and policy making (Sheikh, George & Gilson, 2014). This means that scholars and policy makers must appreciate the intersections between hardware components, social systemic and contextual influences, and the strong influence of actors as people with complex lived realities and human factors. Health systems and policy implementation scholars make the compelling argument that the limited gains and failures from past and present health sector reforms is a consequence of ignoring the extent to which software - and particularly human factors - may influence health sector implementation (Sheikh, George & Gilson, 2014). In the past few decades, there has been an unrelenting focus on the hardware in the implementation of health systems reform and limited emphasis on software issues that equally affect implementation (Atkinson, 2002, Bennett, Mills & Russell, 2011; Berman & Bossert, 2000; Cassels, 1995; Gilson & Mills, 1995).

Recent global reforms in TB diagnostic policy offers an interesting case to assess the extent to which software issues - particularly the human qualities of the system - are considered in scholarship. This critical health systems and policy research perspective on understanding the recent TB diagnostic policy reforms may offer insights into how relationships, social networks, personal attributes of front-line workers and them exercising discretion in their practice influence the process of 'real life' policy implementation. This is also because TB policies and implementation systems are dynamic, complex and constantly changing. Understanding the experiences of frontline staff in dynamic and unpredictable local implementation contexts is imperative, because of their discretionary power and how they exercise discretion in their practice (Blaauw, Gilson, Penn-Kekana & Schneider, 2003; Freedman, 2005; Gilson, 2012).

Tuberculosis (TB) is a communicable bacterial disease that is caused by *Mycobacterium tuberculosis*. It most commonly affects the lungs but the infection can spread to other parts of the body (Knechel, 2009). TB is one of the leading global health challenges (Raviglione & Pio, 2002). Although TB can be treated with a six-month regimen of antibiotics, it is one of the major contributors to disease and death worldwide (Knechel, 2009). It is estimated that nine million new TB cases were detected in 2013 of which thirteen per cent of these were HIV infected individuals (Churchyard *et al.*, 2014). The WHO has characterised 22 high TB burdened countries (Churchyard *et al.*, 2014). These countries are Low-and Middle-Income Countries (LMIC) and account for about 82 per cent of all approximate incidences of TB cases internationally. With the rise of HIV infection in many low to middle income countries, TB/HIV coinfection has resulted in increasing mortality and morbidity (Churchyard *et al.*, 2014). WHO (2015) reports that 2.1 million people globally became HIV incident cases in 2013, where most of the incident cases were found in sub-Saharan Africa. In addition, coinfection has contributed to the increase in more complicated forms of TB that are difficult to manage and treat, such as multi-drug resistant tuberculosis (MDR-TB) and extensively drug resistant tuberculosis (XDR-TB) (Churchyard *et al.*, 2014). It is thus clear that countries affected by TB are also burdened by high rates of HIV incidence and prevalence.

For many years, new international policies have been implemented within high burdened countries in a global attempt to combat this infectious disease (Raviglione & Pio, 2002). However, global TB control and diagnostic reform strategies and their implementation have not been widely successful. Efforts to combat TB are continuously being changed and

developed, which means that new and revised policies and technologies are constantly being introduced (Palamountain *et al.*, 2012). Early case detection, treatment initiation, treatment follow up, continuity of care, adherence and multi-drug resistant management are some of the areas that are important in TB control, yet many gaps exist in these domains in countries most burdened by the disease (Lönnroth *et al.*, 2009; Piatek *et al.*, 2013; Raviglione & Pio, 2002). Many report that health system and related challenges in the implementation of TB control policies are significant contributors to these shortfalls (Loveday, Smith & Day, 2013; Storla, Yimer & Bjune, 2008).

The Xpert MTB/RIF diagnostic test (GeneXpert) has been introduced as an innovation that could address the some of the important gaps in global TB control (Chang *et al.*, 2010; Colvin *et al.*, 2015; Dorman, 2010; Piatek *et al.*, 2013). This technological innovation was endorsed by the WHO in 2010. The fully automated test rapidly detects TB in less than two hours and is more effective in identifying cases of multi-drug resistant TB (MDR-TB) or extensively resistant TB (XDR-TB), than conventional methods such as traditional microscopy and X-ray TB screening (Chang *et al.*, 2010). Unlike conventional methods, GeneXpert gives a more workable solution to many of the bottlenecks in low resource health systems, as it may facilitate effective and efficient TB diagnosis and treatment in high burden diseases. It promises to improve diagnostic capacities for point-of-care services to find affected patients easily and efficiently, and to enable and accelerate the initiation of TB treatment (Palamountain *et al.*, 2012).

As more cross-country and cross-contextual operational research evidence is emerging, there is greater understanding of implementation in diverse contexts and settings and the factors that hinder or help effective implementation. Contexts and actors' experiences of different health systems may generate meaningful insights consider in addressing gaps in implementation and research. This is especially prevalent at primary care level that serves high burdened communities with limited resources and other health systems constraints (Palamountain *et al.*, 2012). Nevertheless, both hardware and software elements interact to shape the outcome of GeneXpert implementation in the health system. It may therefore be important to consider how structural hardware components and relational or human software qualities of the health system impact implementation policy-making and research. Moreover, it may be argued that health workers' human experiences and relationships are central in research inquiry to understand how it may enable or constraint GeneXpert implementation.

Objectives of Literature Review

Using GeneXpert policy reform implementation as a pathfinder, this paper sought to undertake a structured narrative review of the existing literature, to understand the major barriers and enablers for health systems implementation reform. More importantly, this review intends to assess the extent to which people issues and people-centred practices are considered in its policy implementation research. The aim of this section of the dissertation is to identify and map-out literature considering the human experiences and relationships of frontline health workers and how these may intersect with hardware, contextual and social systemic factors, that may potentially mediate the implementation of GeneXpert TB diagnostic policy.

Literature Search Strategy

This review focuses on the emergent international policy implementation literature of the recently implemented GeneXpert TB diagnostic technology, to examine the extent to which human elements that make up the health system are accounted for in the GeneXpert policy implementation literature. The review started with the reading of policy documents, implementation guidelines and protocols for GeneXpert TB diagnostics. Government policy documents and papers from global agencies such as the WHO, Foundation for Innovative New Diagnostics (FIND) and Stop TB Partnership were surveyed. This was done to gain a deeper understanding of the policy and implementation process of GeneXpert. A more structured review approach began after the reading of policy and implementation documents, unpublished and published papers, books, articles and scholarly papers.

The search strategy was designed to identify studies that addressed issues related to health workers in the health system in ways that illuminate their experiences, agency and relationships. Searches were conducted across four databases: Academic Search Premier, PsycINFO on EBSCOhost, PubMed, and Scopus. The following set of keywords were used to frame the literature search:

"GeneXpert OR Xpert MTB/RIF AND policy AND implementation AND Health worker*";

"nurses* AND experience AND GeneXpert OR Xpert MTB/RIF";

'primary health care AND nurses AND TB AND diagnosis*';

"GeneXpert AND health systems AND people-centred micro AND practice* AND TB diagnosis* AND software";

"Point of Care OR POC test* AND TB diagnosis* AND implementation."

Searches were narrowed to include only peer reviewed journal articles published between 1 January, 2010 (the year that GeneXpert was endorsed by WHO) and 30 April, 2017. The literature search was not explicitly framed according to a country or context but low to middle income country (LMIC) settings were prioritisd in reviewing abstracts. Only studies from high income countries were considered if their research aims and findings were strongly alligned to issues that this review sought to investigate. The decision not to exclude country settings in the search strategy was also based on the idea that GeneXpert is a recent innovation and experiences from different country contexts and settings are important. Furthermore, GeneXpert promises to be an effective point-of-care test in local contexts. Hence, the reviewer was intentional about including papers that reported on Point-Of-Care (POC) diagnostic implementation experiences that were not limited to GeneXpert or TB diagnostic implementation. Only articles published in English were considered. Relevant literature was also searched through, snowballing from relevant articles selected for review that best address the issues explored in this review. Dominant themes were identified inductively from using the review objectives as a lens. The following set of factors were considered in reviewing abstracts:

- Studies that specifically sought to understand implementation in real world settings and existing health systems contexts. Studies from clinical control trials and laboratory settings were excluded from this review.

- Studies specifically focusing on primary care, primary health care, or point of care. A focus on other settings were not strictly excluded but depended on whether "software" issues were explored.
- Studies that centred or included frontline or health workers experiences in clinical settings – especially POC or primary care settings.
- Studies conudcted in low to middle income country (LMIC) settings were prioritised in the reviewing of abstracts.

Summary of Literature

Most papers included for review were empirical in nature. Two papers (Theron *et al*, 2014; Cox *et al*, 2014) that conducted pragmatic randomized control trials and one paper (Churchyard *et al*, 2015) that conducted a cluster randomized control trial were found from the search strategy that sought to investigate the feasibility, accuracy, and clinical effect or impact of point-of-care Xpert MTB/RIF testing for tuberculosis in primary-care settings. Much of the research acknowledges that more research is needed about the process and impact of GeneXpert on implementation practices at frontline levels. A total of 5 studies were found that explicitly sought to explore the social and relational aspects of the implementation of point of care diagnostic TB technologies. Only three studies (Colvin *et al,* 2015; Engel, 2012; Engel *et al,* 2015) were found that accounted for the experiences and agency of front line workers and how their experiences of implementation may influence the implementation of point of care diagnostic technologies. One review paper (Albert *et al,* 2016) was found that mapped out key lessons for the implementation for new TB diagnostics that may be considered at all levels of the health system but is very useful for considering implementation practice for frontline workers. Many of the papers and research from the search strategy were from low to middle income country (LMIC) settings and many papers from South Africa and other African contexts were found. No study sought to account of front line narratives and focusing on giving voice to front line workers in the implementation of TB novel diagnostic implementation. This shows that there are explicit gaps in the literature for health workers being recognized as both people with lived realities and experts with discretionary power and agency. However, this literature review is by no way exhaustive and the search strategy does not represent the rigor of a systematic literature review.

Interpretation of Literature

Innovation in TB diagnostic technology and POC testing holds a lot of promise, but understanding the integration of technologies and programmes into complex health systems, and identifying major barriers to successful implementation is important (Pai *et al.*, 2012). Literature investigating factors that mediate the implementation of TB diagnostic technology and associated policy and programmatic reform, is emerging. Findings from this review offer some important insights into the barriers and facilitators for the effective implementation of GeneXpert Diagnostic Policy. It further underscores some of the gaps in the current evidence-base in diagnostic policy implementation and offers some recommendations for future research and policy-making.

Although GeneXpert seemed to be a simple solution to addressing the limitations of conventional diagnostic procedures in low resource settings and highly burdened health systems, there is strong recognition that programmatic and operational aspects are more important for implementation than the promise of technological solutions (Colvin *et al.*, 2015; Palamountain *et al.*, 2012; Salje *et al.*, 2014). Having innovative diagnostic technologies is not enough for reform implementation because they alone do not define TB diagnostic testing (Piatek *et al.*, 2013). It is the integration and use of these tests into diagnostic programmes that will decide how effective the technology addresses diagnostic and treatment gaps (Pai *et al.*, 2012; Engel *et al.*, 2015). The broader POC literature for diagnostic testing, particularly, suggests that POC diagnostic testing technologies will be futile if their implementation into practice does not lead to successful use and uptake.

More importantly, scholars acknowledge that ensuring prompt same-day diagnosis and treatment initiation are all determined by the programmatic implementation environment and process (Cowen *et al.*, 2015; Pai *et al.*, 2012; Piatek *et al.*, 2013, Salje *et al.*, 2014). GeneXpert can begin to address TB diagnostic and treatment challenges only if it is implemented within capable health systems and where existing health systems constraints are thoroughly considered (Piatek *et al.*, 2013). Colvin *et al.* (2015) cautions against techno-optimism and dependence on technological innovations to address complex health systems challenges, without a deepened consideration of the process and programmatic issues throughout implementation.

Some of the recent literature that assessed the implementation of recent TB diagnostic technologies in POC settings in Low-and Middle-Income Countries (LMIC) argues that a health systems approach that supports a comprehensive technical implementation within and across various organizational settings is lacking (Albert *et al.*, 2016; Clouse *et al.*, 2012; Colvin *et al.*, 2015; Cowan *et al.*, 2015; McNerney *et al.*, 2012; Zumla *et al.*, 2012). This means that all aspects of implementation - from programme and policy planning and formulation, to policy transfer and implementation practice, to monitoring and evaluation and back to planning and formulation – needs to be considered.

For example, empirical papers studying the implementation of GeneXpert technology in POC settings in both India and South Africa, found that management and frontline staff described several avoidable delays, inconsistencies and inefficiencies in the implementation of these tests in practice (Albert *et al.*, 2016; Clouse *et al.*, 2012; Colvin *et al.,* 2015; Engel *et al.,* 2015). Similarly, there are other reports that reflect gaps in the links between policy development and demonstration studies (Albert *et al.*, 2016; Colvin *et al*., 2015; Kampen *et al.,* 2015; Pai *et al.*, 2012; Rendell *et al.*, 2017; Weyer *et al.*, 2013; Zachariah *et al.*, 2012). Consequently, some authors raise issues of policy makers not adopting health systems, in the implementation of GeneXpert (Albert *et al.*, 2016; Colvin *et al.*, 2015; Pai *et al.*, 2012; Engel *et al.*, 2015). Adopting and maintaining health systems thinking and considering the context of health systems may facilitate policy implementation.

Research shows that organizational health systems contexts are major barriers to the implementation of GeneXpert and POC diagnostic policies (Albert *et al.*, 2016; Pai *et al.*, 2012; Rendell *et al.*, 2017; Clouse *et al.*, 2012). Organizations are faced with operational and logistical challenges because of changes in laboratory and staff arrangements, added workload because of institutionalizing reform practices, diagnosing algorithms, and resource demands (Albert *et al.*, 2016; Kampen *et al.,* 2015; Pai *et al.*, 2012; Rendell *et al.*, 2017; Weyer *et al.*, 2013; Zachariah *et al.*, 2012).

The financial and resource costs of implementing GeneXpert into the health system have been substantial. Implementing one GeneXpert test in one POC facility is more expensive than running the tests from reference laboratories (Albert *et al.*, 2016; Menzies *et. al.,* 2012). These costs are elevated in organizational settings that are under-resourced, severely burdened, fragmented and highly privatised. Not only is the equipment and consumables of the technology more expensive than conventional technologies, but implementation needs

added programmatic costs for infrastructure development, health worker capacity, an increase in both first-line and second-line TB treatment demands, an increase in HIV testing and treatment demands for co-infected individuals, and other indirect costs (Menzies *et. al.,* 2012; Meyer-Rath *et al.*, 2012). Operational, implementation and economic evaluation literature underscores financial resources, presenting barriers for implementing GeneXpert effectively in health systems in low level primary care settings (Dowdy *et. al.,* 2011; Menzies *et. al.,* 2012; Meyer-Rath *et al.*, 2012). A key challenge reported in the literature is the integration of GeneXpert calling upon existing human resources and infrastructure, to support its implementation in incapacitated and constrained organizational settings.

The resource demands associated with modifications to physical and organizational clinical and laboratory infrastructure to guarantee successful uptake and implementation of the diagnostic technology, is a major barrier for GeneXpert diagnostic reform (Albert *et al.*, 2016; Menzies *et. al.,* 2012; Rendell *et al.*, 2017). The literature reports that inadequate and unmaintained infrastructure resulted in poor uptake. Operational challenges where GeneXpert machines were placed in district or sub-district level POC facilities limited implementation in these settings (Rendell *et al.*, 2017). Environmental issues such as humidity and dust resulted in equipment failure in some settings and there were challenges in sustaining suitable local power supply systems in others (Albert *et al.*, 2016; Colvin *et al.*, 2015; Cowan *et al.*, 2015). Limitations in supply and demand management, namely the maintenance, repair or replacement of equipment – limited implementation (Albert *et al.*, 2016; Colvin *et al.*, 2015; Rendell *et al.*, 2017). Although infrastructural capacity is a critical issue to consider in preparing organizations, effective implementation needs organizations to meet human resource requirements – another critical issue that stood out in the literature.

Inadequate staffing arrangements and limited staff capacity is a barrier to effective implementation of reform; especially in high burden settings and with diseases such as TB (Rendell *et al.*, 2017; Kampen *et al.,* 2015). Despite GeneXpert low staff capacity and technical ability requirements, already limited resource capacities in many low resource settings was a major barrier to implementation. High-level policy makers took for granted the considerable human resource requirements for policy reform implementation (Clouse *et al.*, 2012; Palamountain *et al.*, 2012; Rendell *et al.*, 2017; Salje *et al.*, 2014).

Operational managers and frontline staff report that the implementation of GeneXpert resulted in increased workload, with no added human resource capacity (Colvin *et al.*, 2015;

Cowan *et al.*, 2015). This is compounded by the added procedures and standardized practices for example, changes in the diagnostic algorithm – which added pressure to an already heavy administrative load and other already existing organizational challenges that management did not discuss before implementation.

In addition, training and readily available technical support was lacking, especially in settings that were not targeted for demonstration studies in the first phases of implementation (Albert *et al.*, 2016; Menzies *et. al.,* 2012; Rendell *et al.*, 2017; Colvin *et al.*, 2015; Cowan *et al.*, 2015). Clinical staff had to depend on unplanned and irregular training opportunities, with no consideration from management to discuss the stockpile in workload (Albert *et al.*, 2016; Menzies *et. al.,* 2012; Rendell *et al.*, 2017; Colvin *et al.*, 2015; Cowan *et al.*, 2015). This results in nurses not wanting to attend training sessions. Consequently, nurses are not informed and knowledgeable about programme guidelines – another barrier in implementation (Rendell *et al.*, 2017). It is recommended that standardised training can address this issue (Rendell *et al.*, 2017).

Limited staff capacity, poor training, and overburdened work load, compounds technical shortfalls and bottlenecks within organizational settings, and between centralised or reference laboratory systems and local clinical settings (Albert *et al.*, 2016; Menzies *et. al.,* 2012; Rendell *et al.*, 2017; Colvin *et al.*, 2015; Cowan *et al.*, 2015).

Communication and coordination is a major barrier for the implementation of GeneXpert in local organizational contexts. Lack of communication and coordination between clinical staff and the laboratory results in the following issues:

1) lack of understanding of error messages from the laboratories;
2) continued collection of inferior quality and quantity samples;
3) lack of follow up on scanty results;
4) conflicting information between clinical staff and the laboratory about the type of specimen needed for GeneXpert testing and clear indications when a GeneXpert must be done with all the required information; and

5) misunderstanding of the laboratory request forms and procedures (Albert *et al.*, 2016; Menzies *et. al.,* 2012; Rendell *et al.*, 2017; Colvin *et al.*, 2015; Cowan *et al.*, 2015; Pai *et al.*, 2012; Palamountain *et al.*, 2012).

In some instances, implementation has been eased by adequate transportation systems for specimen collections and administration paperwork. However, paper based systems for tracking and communication, lack of information and computer training (ICT) impedes the implementation of GeneXpert (Albert *et al.*, 2016; Menzies *et. al.,* 2012; Rendell *et al.*, 2017; Colvin *et al.*, 2015; Cowan *et al.*, 2015; Pai *et al.*, 2012; Palamountain *et al.*, 2012). In some studies, it was found that nurses do not prefer electronic databases for record keeping, coordination and communication (Albert *et al.*, 2016; Rendell *et al.*, 2017; Cowan *et al.*, 2015). This is despite the challenges with communication and record keeping systems – which include paper-based communication (for example lab request forms, lab result printouts), which is dependent on the accuracy of written information, and the added work of manually capturing information from paperwork into electronic databases. Literature reports that low uptake of electronic databases and systems is due to low availability of online systems and existing systems not coordinating with each other. This results in repeated capturing of information, creating more work rather than alleviating the workload (Albert *et al.*, 2016; Cowan *et al.*, 2015; Colvin *et al.*, 2015; Rendell *et al.*, 2017).

Nevertheless, communication and coordination within and between organizations is not only contingent on the mechanisms that are put in place. The success of policy implementation within the health system transcended beyond the adequacies of the health systems building blocks. Social relationships, human agency, values, norms, attitudes and experiences and how they interact with health systems hardware, drives effective implementation in organizational settings.

Although lacking there is some acknowledgement in the broader POC diagnostic literature about the contribution of deepened social science research to understanding barriers to implementing diagnostic policy reform. Some studies have relied on interview, focus group and some limited direct observational data to understand actors' perceptions of POC diagnostic implementation (Albert *et al.*, 2016; Rendell *et al.*, 2017; Colvin *et al.*, 2015; Cowan *et al.*, 2015; Pai *et al.*, 2012; Palamountain *et al.*, 2012; Kampen *et. al.,* 2015). These studies focused on making interpretations from health workers and managers responses about barriers, related to resource constraints and barriers associated with organizational hardware,

that is, financing, human resource constraints, infrastructural challenges, and communication and coordination mechanisms.

Although these interpretations are important to understanding operational aspects of policy implementation, there still is a gap in the literature contributing to the understanding of how diagnostic practices are shaped by the social and human elements of the health system and how they interact with hardware components to shape implementation outcomes. There are a few scholars in the broader POC diagnostic literature and GeneXpert literature that account for health worker-patient relationships in relation to the social realities associated with the patients' diagnosis (Chandler *et al.*, 2011; Colvin *et al.*, 2015; Engel *et. al.,* 2012; Engel *et al.*, 2015; Angotti, 2010). For example, Engel *et al.*, (2015) explored relationships among providers and between patients and providers, and found that they may form a major barrier for POC diagnostic implementation. One of Engel *et al.*'s (2015) main findings are that relationships and coordination between providers, labs and patients is important for succesful POC testing and that POC and follow up testing is more likely to take place if there is relationship and coordination between providers and patients. For example, they report that how in India's private sector coordination between doctors and labs means that testing is often accomplished within the same day. A patient is seen in a clinic in the morning, goes to a nearby or in-house lab for tests and usually returns to the doctor with the results in the afternoon or evening. Labs and doctors have adjusted opening hours and try to cater to patients' schedules. Private facilities usually have the required human resources and infrastructure to do this and coordination between providers results in efficient service delivery, which in turn facilitates a relationship and coordination with patients. In contrast, they found that in the public sector a lack of coordination among clinic providers, influenced by human resources shortages, fosters a culture of blame and mistrust among staff. High workload, staff shortages, coupled providers being over-burdened, over-worked, insufficiently supported, and lack of accountability had implications for whether providers had the time or was willing to carry out POC testing effectively. 'The different actors blame each other for poor quality of sample collection or laboratory work, and for inadequate numbers of investigations ordered to reach targets of disease control programs' (Engel *et al.*, 2015, p. 9). This study offers pertinent insights into how POC diagnostic technology, procedures, demands and infrastructure has the potential to constrain and to facilitate relationships and coordination, but also how coordination and relationships may support clients to follow through with diagnostic cycles (Engel *et al.*, 2015).

Then, Chandler *et al.*, (2011) and Angotti (2010) also found that the socio-cultural context and organizational norms in which diagnostic practices work is linked to health worker-patient relations and shape the outcome POC diagnostic implementation (Engel *et al.*, 2015). While recognizing that organizational norms are influenced by broader structural contextual factors, Chandler *et al.*, (2011) found that social distance at public health clinics is charatcerised by a set of norms in the space of the clinic and the nature of health worker–patient relationships. Their participants told stories of their experiences of blatant power assymmatries between providers and patients. 'Front-line workers treated them rudely, even shouting at them, and did not have time or inclination to care for each patient' (Chandler *et al.*, 2011, p. 939). This serves as a barrier to accessing POC testing services and for patients to return for follow up testing which has implications for case detection and treatment (Chandler *et al.*, 2011).

In contrast, another constraining factor that may limit POC testing is the extent to which providers have room to manipulate standard procedure to accommodate patients' needs. Engel *et al.,* (2012) explored the tension between recognizing health workers agency for innovation and the need to control the diagnostic process, through standardized practices and procedures that may implicate programmatic outcomes. Engel *et al.,* (2012) argues 'that a balance is needed between the extremes of controlling the diagnostic process through standardization, in such a way that it becomes exclusive for particular local settings or ability, and innovating a diagnostic test without standardizing operational processes; which is not programmatically possible'. Similarly other studies have shown how issues of power and asymmetrical relationships between global, national and local policy may hinder or help front-line implementation in that these broader structural relations and dynamics impact on provider and patient-provider relationships within local settings (Albert *et al.*, 2016; Colvin *et al.*, 2015; Kampen *et al.,* 2015). These implications may impact on access, uptake and delivery of POC diagnostic tests.

Issues illuminated in these studies are often taken for granted in policy implementation and may form part of the reasons for the lack in improvements in policy reform implementation. These studies contribute immensely to policy implementation reform for health systems strengthening them holistically.

Gaps or Needs for Further Research

A review of the literature about barriers and enablers of diagnostic implementation reforms yields important insights about the gaps and opportunities for future research and policy considerations for GeneXpert policy implementation, as well as for scaling-up TB diagnostic reform. Although this was not a comprehensive review of existing literature, it is clear that emerging findings are increasingly proving the need for holistic health system perspectives as important for policy making and research inquiry. This means considering the ways in which health systems contextual issues – structural, functional and social elements govern implementation. This also means that centering low level health workers in GeneXpert policy implementation, is important to understand their challenges, values, agency and contributions diagnostic reform. In considering their experiences, agency, voice and values, it may be valuable to locate these issues within broader institutional structures and consider power relations and its implications for social and working relationships at various levels of the health system as demonstrated by Colvin *et al.*, 2015 and Engel *et al.,* (2012). Both these studies deomstarte the importance of focusing on the voice of frontline workers, as both people with lived realities and experts with discretionary power and agency. Although the literature reviewed here argue for major gaps in accounting for health workers as people with lived realities, and who must respond to patients with complex needs, these studies are limited. They only represent a small percentage of the broader TB diagnostic and GeneXpert literature that considers software elements of the health system as important for pragmatic implementation. These papers also demonstrates that there is a gap in the literature for focusing on the voice and agency of nurses and frontline workers in diagnostic implementation. For scholarship and policy-making to contribute to advancing people centred health systems, in the implementation of policy reform; there is a need for:

1) an intentional focus on social and human elements, as on hardware factors in operational organizations for implementation;

2) operational research needs to centralise the voice of frontline workers, as both people with lived realities and experts with discretionary power and agency; and

3) a deeper consideration for relationships and power in implementation across different layers and actors within health systems.

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Part C: Journal "Ready" Manuscript

Target Journal: Social Science & Medicine

'Doing things right but not doing the right thing': Centering Primary Health Care (PHC) Nurses' Experiences of their Practice in Health Policy Implementation - TB Diagnostic Policy Reform in the Western Cape, South Africa

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Abstract

Health systems are socially constructed through the complex realities of actors and the interactions between them. People-centered scholarship, policies and systems have been argued by some health policy and systems researchers to contribute meaningfully to health systems strengthening. This means that scholars and policy makers must appreciate the intersections between hardware components, social systemic and contextual influences, and the strong influence of actors as people with complex lived realities and human agency. Recent global reforms in tuberculosis (TB) diagnostic policy and the implementation of **Xpert MTB/RIF** (GeneXpert) diagnostic technology into the health system offer an interesting case to assess how software issues - particularly the human qualities of the system - are considered in scholarship. Understanding the experiences of frontline staff in local implementation contexts is imperative because of their discretionary power in their practice. Yet, there is little written about point-of-care diagnostic experiences of nurses who are the principle actors of TB diagnostic policies and technologies at primary health care (PHC) levels. This paper seeks to contribute to the policy implementation literature in the field of Health Policy and Systems Research (HPSR) through an exploration of nurses' lived experience – especially from the perspective of those nurses. A total of 10 nurses were interviewed from three PHC facilities in a Western Cape sub-district, South Africa. Direct observations were conducted to support the interview data. Findings reflect that within the context of top-down, target-driven and highly structured and standardized operational processes for diagnosing TB, nurses navigate multiple overlapping and contradictory modes of being in their relationships with patients. These contentions in their roles, actions and

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responses, as well as apparent contradictions between discourse and practice, are mediated by broader organizational and systemic ideologies and processes that are entrenched in health systems. These include pressures to meet policy targets, the encumbrance to enforce administrative and bureaucratic procedure, and the minimal platforms or pathways to provide management and decision-makers with their own input on challenges and innovations. Nurses struggle to navigate these pressures and challenges, especially in relation to having to deal with and respond to the complex realities of patients. Based on their discourse, it seems that nurses make sense of implementation as being driven by service delivery through dignified and people-centred care. However, the system limits this in practice. The findings of this study offers voice to nurses' experiences of implementing TB diagnostic policy in PHC settings in South Africa considering that nurses' experiences are situated within broader systemic and organizational contexts. This study also highlights tensions between efforts to achieve efficiency and effectiveness through enforcing the system, and facilitating people-centered and responsive practices in implementation. Researcher and policy makers should consider these tensions for low level health workers when implementing reforms that seek to strengthen health systems.

Keywords: *Implementation; Nurses; Experience; People-centred; Health Systems and Policy; TB Diagnostic policy, GeneXpert, Primary Health Care (PHC); South Africa*

KEY MESSAGES:

- There is a need for intentional and deliberate consideration for the human qualities of the health system in policy implementation. A focus on the human and relational elements is essential for advancing responsiveness and people-centeredness.
- TB targets, highly bureaucratized, routinized and heavy administration, and autocratic approaches to communication and engagement with nurses undermine their capacities to be responsive to the needs and complex realities of individual patients.
- It is important for policy makers and researchers to be critical of the extent to which targets, bureaucracy and administration are prioritized over dignity, responsiveness and humanity in the process of diagnostics care in TB policy implementation.
- There is a need for public health officials and different levels of management to offer opportunities and platforms for nurses to share their voices, input and prowess in the policy process. Research and policy efforts must seek to actualize the contributions of nurses.

Background

Policy implementation, defined by practices or actions in the 'real world' following policy formulation, is a universal challenge across health systems. This is mainly because health systems are complex adaptive systems (Gilson, 2012; Plsek, 2001). A complex adaptive system in health systems thinking is a complex and dynamic web of interrelated sub-systems and processes including the interactions and relationships of different components simultaneously affecting and being shaped by the system (Gilson, 2012). These components include health system actors and they can often behave in ways that are unpredictable and, thus, may influence changes in context as well as the actions of other actors (Plsek & Greenhalgh, 2001). These complexities have been and continue to be taken for granted. Scholars in the field of health policy and systems research (HPSR) argue for the consideration of complexity in policy implementation as imperative for strengthening health systems (Gilson, 2012; Plsek & Greenhalgh, 2001; Sweeney & Griffiths, 2002). Embracing complexity requires a deepened understanding of different components, processes and relationships that operate at different levels of health systems. In particular, special focus needs to be drawn to the interaction between the structural or bureaucratic and human elements that make up the system (Gilson, 2012; Plsek, 2001). Implementation scholars need to acknowledge that strengthening the health system requires going beyond addressing issues

pertaining to physical health. Rather, there is a need to consider the social, political and economic realities of people in society and the promotion of respect and dignity in the delivery of services to persons (Gilson, 2003; World Health Organization, 2000; 2007).

This paper seeks to contribute to the policy implementation literature in the field of health policy and systems research (HPSR) by exploring the lived experiences and voices of low-level frontline workers - especially nurses who are overburdened and undervalued. By drawing on people-centred scientific approaches (Sheikh, George, & Gilson, 2014), this paper argues that foregrounding the humanity of nurses in their organizational and social systemic policy contexts can strengthen health systems implementation.

The gaps in health policy implementation research focusing on health workers' experiences as an important factor in implementation

From this perspective, effective implementation of international policy requires global policy makers and researchers to reflect on the plurality within the global health system. They should also have a strong regard for local realities, spaces and voices (Hyder *et al*., 2007; Martin, 2008; Gostin & Mok, 2009). Policy implementation mainly relies on front-line workers in low level organizations. At this level, local complex realities and challenges make it difficult for novel global and national policies and technologies to be adopted (Colvin *et al*, 2015). Experience has shown us that merely introducing new technologies and policies is not sufficient to undertake and solve multifaceted public health issues (Walt & Gilson, 1994; Campillo-Artero, 2012; Dussault & Dubois, 2003; Lonnroth *et al*., 2009; Raviglione & Pio, 2002). A wide range of interacting factors mediate the implementation of policy in a 'real-world' setting. Factors that mediate the implementation transcend beyond the programme guidelines or the mechanics of the programme itself and are described as ‘software’ factors (Gilson, 2012).

Software elements are defined as the social, intangible and nuanced factors (such as attitudes, beliefs, values, norms, roles, procedures, and relationships within the health system) that may also influence implementation (Gilson, 2012). Actors’ experiences and their relationships are central to policy implementation (Gilson, 2012). In isolation or in combination, these issues interact with one another to various degrees and at different levels of the system and may present various challenges for the implementation of policy (de Savigny & Adam 2009; Gilson, 2013; Sheikh *et al.* 2011).

In advancing people centredness for health systems strengthening, scholars and policy-makers must acknowledge that, similarly to patients, health workers are people with complex lived realities and this adds to the complexity of the health system (Eade, 1997; Namakula & Witter, 2014; Sheikh, George & Gilson, 2014). Their lived experiences are shaped by the complex issues, interactions and relationships that drive their practice. Based on the implementation science literature, there appears to be a great need to understand how health policy implementation practices are mediated by health workers' experiences, interactions and relationships (Buse, Mays, & Walt, 2005; Gilson *et al*, 2011; Rice, 2013; Walker & Gilson, 2004). This paper discusses the findings from an inquiry into frontline primary health care (PHC) nurses' experiences of the implementation of recent tuberculosis (TB) diagnostic policy reforms in their practice.

Novel TB diagnostic policy implementation offers a unique lens for understanding low level health workers' experiences of policy implementation

Global advances and innovations in TB diagnostic technology have called for new policies and programmes to be integrated into local settings (Colvin *et al*, 2015). The MTB/RIF Xpert diagnostic test has been introduced as an innovation that could possibly address the gaps in current TB diagnostic efforts (Chang *et al*., 2010; Colvin *et al*, 2015; Dorman, 2010; Piatek *et al*., 2013). The Xpert MTB/RIF diagnostic test (GeneXpert) is a single test that detects TB rapidly, and is sensitive to resistant strains of TB (Chang *et al*., 2010). Compared to previous conventional methods, this test is reported to be more effective in identifying cases of multi-drug resistant[1] (MDR) TB or extremely resistant TB[2] (XDR-TB) and is more sensitive to co-infection (Chang *et al*., 2010). This novel diagnostic technology has the potential to improve diagnostic capacities of point-of-care services. In particular, this test can easily and efficiently identify affected patients which will, therefore, accelerate the initiation of appropriate TB treatment (Palamountain *et al*., 2012). Unlike conventional methods, GeneXpert provides a more practical diagnostic approach for primary care in low resource health systems which often serve communities with a high disease burden (Palamountain *et al*., 2012). However as discussed earlier, the implementation of

[1] Multidrug-resistant TB (MDR TB) is caused by an organism that is resistant to at least isoniazid and rifampin, the two most potent TB drugs. These drugs are used to treat all persons with TB disease (Chang et al, 2010).

[2] Extensively drug resistant TB (XDR TB) is a rare type of MDR TB that is resistant to isoniazid and rifampin, plus any fluoroquinolone and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin) (Chang et al, 2010).

promising diagnostic technologies and associated policies does not automatically translate into clinical impact.

In addition to the limitations of research studies investigating the influence of software factors in policy implementation, there also appears to be limited empirical evidence accounting for these factors in the TB diagnostic literature and in the GeneXpert policy implementation literature (Clouse *et al*, 2012; Colvin *et al*, 2015; Engel *et al*, 2015; **Pai *et al*, 2012; Piatek *et al*, 2013;** Rendell *et al*, 2017). More specifically, there seems to be a dearth of TB diagnostic literature of that explores front-line workers' perceptions, interpretations and experiences of new technologies and how their relationships may facilitate or hinder actual implementation of TB diagnostic policies. Although Boehme *et al*. (2011), Clouse *et al*. (2012) and Van Rie *et al*. (2010) investigated the implementation of GeneXpert in point-of-care and other clinical settings, there is limited information available concerning nurses' experiences and how these experiences impact their implementation practices. This is surprising considering that these low level health workers are central to the implementation of policy. Front-line health workers are described as Street Level Bureaucrats (SLBs) as they operate at the level where policies are transferred into action (Rice, 2013). SLBs are people, and people are complex beings that consistently position and reposition themselves in proximity to different policy issues, processes and activities in health systems (Buse, Mays, & Walt, 2005; Gilson, 2012; Rice, 2013). They may adapt their practices to cope with health systems challenges, which may cause further diagnostic delays for patients (Engel *et al*, 2015). In this way they hold agency and discretionary power that may influence the effectiveness of policy implementation, and this needs to be more accounted for in the literature (Buse, Mays, & Walt, 2005; Rice, 2013).

Nurses are at the forefront of implementation South African Health Systems and their voices are important

The majority of the primary health care facilities in SA and other LMIC countries are nurse-led. Nurses are at the frontline of the TB epidemic in SA. Most of the recent TB diagnostic policy innovations in SA have focused on point-of-care services in community clinics or primary care facilities. This is the level at which the role and practice of nurses influence all layers of policy implementation in its entirety. TB is a challenging disease to work with since it is airborne, highly stigmatized, possibly drug-resistant, and often life-threatening. Nurses must face these threats whilst still delivering patient care which involves

providing health education to patients, families and the broader community; treatment management and observation; sputum collection, management and coordination; and contact tracing and screening. Nurses put their own lives at risk in their practice and during the implementation of TB policies. Yet, there is little written about point-of-care TB diagnostics that focuses on nurses' experiences and voice as key to their practice of the implementation of TB policies and technologies at primary health care levels (Clouse *et al*., 2012). This calls for a need for deeper insights into how nurses as people are important in contributing to effective TB policy implementation (Bergen & While, 2005; Rice, 2013). Previously, there has not been sufficient focus on the complex experiences that may deter practices of TB diagnostic testing and diagnosing at point-of-care (Scott *et al*., 2014).

The first objective of this study was to investigate PHC nurses' experiences of diagnosing TB following the implementation of GeneXpert policy in their practice. This was done to understand how nurses' experiences mediate the implementation of TB diagnostic policy in nurses' practice. An investigation into nurses' experiences through an analysis of discourse and practice offer important lessons for people-centered health systems in TB diagnostic policy implementation. A second objective of this study was thus to explore whether and how GeneXpert policy implementation may or may not be contributing to fostering people-centeredness in health systems.

Methods

Research design

The design of this investigation was explorative in nature. A case study approach was used.. This approach was appropriate because of the explorative features of this study (Yin, 2009; 2011; 2013). This approach enabled us to explore how nurses' subjectivities are deeply situated within contexts. This approach was further relevant for this investigation as the researcher had little control over the processes and events under study because it was based on a contemporary phenomenon within a real-life context (Gilson, 2012; Hancock & Algozzine, 2006; Yin, 2009). Within the overarching case study approach, qualitative data collection and analysis tools were employed. Qualitative research methods offer tools to obtain narratives about nurses' experiences and to observe actions and interactions in their organizational contexts. This allows researchers to interpret and explain constructed experiences in relation to observed reality (Miles & Huberman, 1994; Willig, 2001).

Qualitative research methods have proven to be relevant tools in health systems and implementation research because it enables the investigation of complex issues (Gilson, 2012).

Theoretical Framework

The Micro-Institutionalist Theory of Policy Implementation (MITPI) framework developed/detailed by Rice (2013) was used to guide the analysis of nurses' narratives and their implementation practices of TB diagnostic policies (*Figure 1*). The MITPI framework draws on the street-level bureaucracy (SLB) theory developed by Lipsky but provides a comprehensive set of ideas for taking into account complex factors in the shaping of health workers' experiences and practices at the different levels of policy implementation (Rice, 2013). The theory posits that the social realities of health workers are influenced by four interacting domains: 1) intrinsic individual cognitive and emotional processes, 2) the organizational context, 3) institutions characterized as norms or procedures that shape practices, and 4) the social systemic context (Lipsky, 2010; Rice, 2013). Individual human experience governs behaviour, and organizational and systemic contexts determine the conditions for bureaucratic action. These four contexts interact to influence the way in which health workers facilitate or constrain implementation (Lipsky, 2010; Rice, 2013). This framework was meaningful in the design of this research study as a thinking tool to understand complex interactions between different policy contexts operating at different levels of the health system.

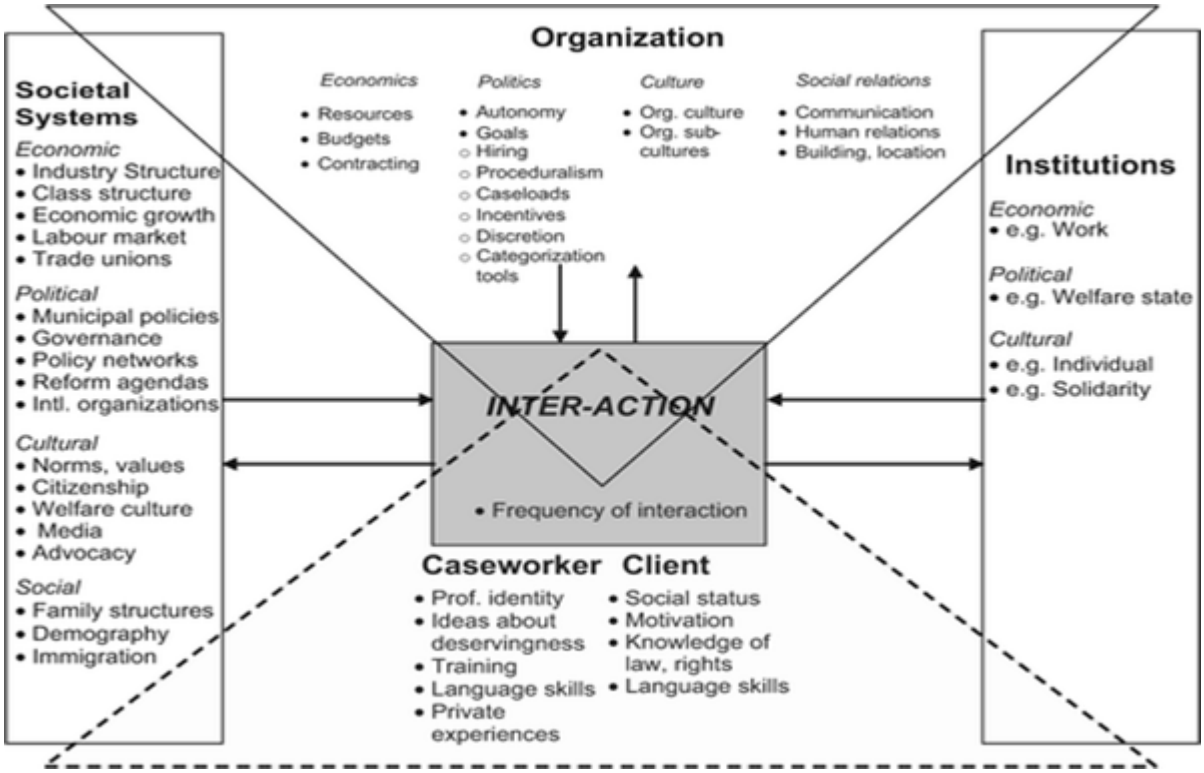

Figure 1: Micro-Institutionalist theoretical framework for policy implementation (Rice, 2013)

Setting and context

TB is major contributor to mortality in South Africa. SA has high HIV-TB co-infection rates and has a high incidence of drug resistant TB cases. In order to rationally respond to the dual epidemics of HIV and TB, SA formulated the integrated National Strategic Plan (NSP) for HIV, STIs and TB (2012 - 2016) (South African National AIDS Council, 2012). The targets set in the NSP for TB were to reduce TB incidence and mortality by 50% in 2016 and to reduce incidence of TB cases by 100% (South African National AIDS Council, 2012). Although SA has made notable progress in reducing TB prevalence and mortality rates, and has improved treatment outcomes for new smear-positive TB cases, the burden of TB remains substantially high. This has primarily been attributed to the limitations in and barriers to effective detection and diagnosis of TB. TB is managed largely within the public healthcare system in which TB diagnosis and treatment occur at the primary health care (PHC) level. This means that SA provided an ideal setting for the implementation of the global GeneXpert diagnostic policy framework in 2011. The decision to adopt this policy was made by the National Department of Health (NDoH) who are responsible for the national roll-out of health policies. They adopted a phased approach to implement GeneXpert

technology in health facilities across high TB burden districts in all nine provinces (Fielding *et al.,* 2014).

The Western Cape Province has been reported to have the highest rate of all types of TB in South Africa (Claassens *et al*., 2013). This study was based in a sub-district in the Western Cape Province. The province and the sub-district have high incidence and prevalence of TB. Three PHC clinic facilities were selected in the sub-district and formed the three cases for the research inquiry.

Sampling and recruitment of cases

Three PHC case facilities were selected within a specific sub-district in the City of Cape Town Metropole Region. PHC day clinics managed by the City of Cape Town Metropole mainly diagnose, manage and treat TB cases. TB patients diagnosed at hospitals and community health centres are referred to clinics for management and treatment. The strategy adopted for sampling and selecting the clinic case facilities for this study was based on the accessibility of the case facilities and the feasibility of carrying out the data collection methods. Caseloads and performance outputs were considered to select facility cases with differing expectations, challenges and successes and this allowed for richer cross-contextual case analysis. The organization of the three TB rooms which exist in the three district clinic facilities is characterized by different actors, contexts and attributes. Each case facility has its unique facility manager, TB room coordinator, facility staff composition, TB room staff composition, caseloads and suspect loads, and is situated in different communities with distinct characteristics. Nonetheless, all three case facilities are governed by the same sub-district management team, and they are mostly similar in terms of resources availability, infrastructure, coordination mechanisms, and accountability structures.

Data collection methods

Data collection started with a document review of the TB policy documents. The following policy documents were purposively sampled to inform the researchers of the broader TB policy framework at global, national and local levels. The documents included global and national policy frameworks and guidelines, diagnostic algorithms, Clinical Practice Guidelines, Standard Operational Procedures, meeting minutes available in the facilities and documents made available by the different facility managers and the sub-district TB

coordinator. The document review data was triangulated with interview and direct observational data.

Face-to-face interviews were conducted with ten nurses across the three case facilities. These nurses included the three facility managers, three Clinical Practice Nurses coordinating the TB rooms, and four staff and assistant nurses. The researcher spent five months in the three PHC facilities to conduct direct observations. To facilitate an open, intensive and non-intrusive interviewing process, principles of narrative interviewing was utilized. In the interviews, participants were asked open ended questions. The narrative thematic analysis approach by Riessman (2002, 2008) was used. This was most useful because nurses' experience was obtained through language. Narrative inquiry recognizes that language is socially constructed and is situated within broader social and contextual systems that shape lived experiences (Emerson & Frosh, 2004). Utilizing narrative research in data collection and analysis processes was, therefore, aligned to the broader aims of this research investigation.

In addition, direct non-participant observations were conducted in the three case facilities over a period of six months. The researcher was mostly based in the TB room of these clinics and interacted with nurses working in the TB room, administrative staff in the facility and the facility managers. The researcher also sat in on a series of clinic staff meetings and TB policy meetings in each facility. Direct observations also allowed for data from informal continuous conversations with nurses, facility managers, and the sub-district TB coordinator. Field notes were taken and the researcher mainly observed activities and interactions in the TB rooms of the case facilities.

Drawing on different forms of qualitative research methodologies was important for enhancing the trustworthiness of the findings of this paper through the process of triangulation (Gilson, 2012).

Data Analysis

Audio files and notes were transcribed and cross-checked. Interview transcripts were coded and analysed using Riesmann's (2008) thematic narrative analysis approaches. Observational and document review data were analysed using a thematic analysis approach. A code book

was created with relevant codes that addressed the research question. Codes were further grouped into categories of emerging themes in an iterative manner using thematic analysis. Different sources of data were triangulated to analyse for similarities and contradictions. Data was also analysed to account for patterns and linkages between emerging themes and codes across different clinic cases.

Ethics

This study was approved by the Faculty of Health Science Research Ethics Committee (HREC REF 821/2015) at the University of Cape Town, South Africa. Written and verbal informed consent was provided by the nurses and facility managers for the in depth face-to-face interviews and direct observations. All signed informed consent forms were collected prior to participation. Notices were placed in facilities to notify clients that a researcher would be gathering observational data. In the event of personal and private consultations between nurses and patients, the researcher would leave the TB room or the nurses would move the consultation to a private room if available. The nature of personal and private consultaitons were assessed according to the nurses' interpretive judgements and patients' requests. All patients were told by the nurses about the role and purpose of the researcher in the TB room and patients were asked for verbal consent by the nurses for the researcher to be present in general consultations. Professional roles were used to mask nurses' identities. Approval to conduct interviews and observations at public healthcare facilities was sought from the City of Cape Town Metropole Health authorities, as necessary.

Findings and Discussion

From the plethora of factors that affect implementation, nurses' experiences of their practice of implementation are important to consider when assessing the barriers and facilitators for successful implementation. Their experiences offer access to understanding the realities of implementation needs, gaps and failures that are not always accounted for by policy makers, implementation guidelines and the perspectives of higher level management. They also provide an understanding how historical and present contexts and personal attributes shape implementation processes. This study found three broad health systems issues most prominent in nurses' discourse and practices that impact TB diagnostic policy implementation. These are: 1) the strong culture of target driven approaches, 2) highly bureaucratized systems and administrative pressures, 3) Gaps in the engagement between sub district management and nurses. These issues limit the ability to foster people-centeredness in health systems because of contradictions, demands and pressures that result in feelings of anxiety, confusion and voicelessness.

1) 'Management will rather ask us: What did you do to keep the patient in the system? You know how numbers tell our story'. Nursing for targets rather than nursing patients with complex lives.

TB programmes in South Africa are highly target-driven (National Strategic Plan [NSP] for HIV and AIDS, TB and STIs 2012 – 2016). Although numerical targets set direction and can help drive systems behaviour, they have unintended consequences for nursing practice (Meadows, 2008). The impact of a target-driven culture on nurse-patient interactions was central in nurses' narratives. Nurses talked about management valuing achieving and maintaining programmatic target rates (such as case finding rates, smear conversion rates, treatment outcome rates and defaulter rates – see National Tuberculosis Management Guidelines 2014) more than focusing efforts on delivering the best possible care and curing patients. All nurses in this study reported that the quality of care for their patients is negatively impacted by target-driven approaches in TB policy implementation.

Many nurses constructed narratives about the support from sub-district management which tends to be limited to nurses *'doing things right but not whether we are doing the right thing' (Facility Manager, Facility 2)*. It was apparent from the narratives that management at the sub-district level does not acknowledge how nurses interpret quality-of-care, nor their effort in offering their patients the best service and care. Rather, these nurses indicated that

management seems to emphasise targets, numbers and statistics more than the values of the nursing profession – which they explained to be defined by principles of compassion, treating clients with dignity, and the quality of care for the patients. This perspective from health workers is evident in contemporary health systems contexts where the successful implementation of programmes is mainly based on quantified outcomes (Baillie & Gallagher, 2010).

The following quote explains how nurses talk about how this emphasis on numerical targets may be a potential barrier for the effective implementation of TB programmes in their nursing practice:

> *'The city is target driven and all our outcomes are target driven… and that actually puts a lot of strain on the facility. It's all about the rates and stats…This is the biggest challenge for implementation for us' (Facility Manager, Facility 2)*

Furthermore, this target-centred approach has been shown to make nurses feel undervalued and adds additional pressure to an already demanding working environment (Allan, Traynor, Kelly & Smith, 2016; Anderson, 2016; Sawbridge & Hewison, 2011*)*. These issues were evident in the current study, as illustrated in the quote below:

> *'Sometimes it feels like the people (management) do not care or worry about us. They will just preach stats, or they will just see the negatives and not see the positives. They will not see that we try and they hammer us a lot – especially in TB.' (CPN, Facility 3)*

The strong emphasis on targets was also observed in practice. In one observed scenario, a facility manager expressed her disappointment in the TB nurses after the sub-district TB coordinator[1] informed her that the TB nurses were failing to reach their targets. This scenario provides evidence to suggest that the success of implementation is determined only by numerical goal achievement and performance targets, and does not include aspects of care encapsulated in nurse's relational work with patients (Bender *et al.,* 2011).

Nevertheless, similar to Harper's (2010) findings, nurses in this study understood that achieving programmatic targets is dependent on patients' compliance and that patient

1 Sub-district TB coordinators are responsible for the provision of TB services within the local health sub-district. They are responsible for planning, organizing, implementing, and evaluating activities of a district TB control programme.

compliance can only be facilitated through being responsive to patients' lived realities. In their discourse, nurses emphasized that the behaviour of their patients has direct implications for achieving performance targets in nursing practice.

> *"Patients defaulting and not complying is a big thing for us. We struggle with our patients because they do not listen to us. They can make our jobs very difficult, you know… and when [management] come back to us, they ask: What did we do to keep the patient in the system? The patient can make or break us... but it's like [management] don't see our struggles with patient in the stats' (CPN, Facility 3)*

In addition to poor patient compliance, another issue that emerged from the narratives was that some patients expressed distress concerning the challenges of coming to the clinic for follow up visits which are important for relaying diagnostic results and initiating treatment. Reasons for this distress are often related to transportation costs, the possibility of being too physically weak to travel, or having to take care of dependents. This is congruent with findings reported by Gebremariam, Bjune and Frich (2010), and Needham, Foster, Tomlinson and Godfrey-Faussett (2001). Some patients had challenges producing sputum samples because they were too weak or found it painful to cough. In addition, similarly to Møller and Erstad (2007)'s findings, other patients refused to provide personal information about where they lived because of the stigma associated with TB and the fear of rejection by friends, family and colleagues. Issues of patient compliance, loss to follow up and the spread of infection are strongly associated with issues of psychosocial issues of communities (Murray *et al*, 2012). Substance abuse, lack of formal education, unemployment, mental health and poor living conditions all influence policy implementation (Gebremariam, Bjune & Frich; Murray *et al*, 2012; Needham, Foster, Tomlinson & Godfrey-Faussett, 2001).

Care-giving, responsiveness and relational work is a crucial part of nursing practice (Baillie & Gallagher, 2010; Benner, Tanner & Chesla, 2009; Escott & Walley, 2005). However, it was clear from the narratives that nurses felt a definite tension between wanting to be responsive to the needs of patients with complex realities and having to achieve performance targets which sometimes requires them to *'turn a blind eye to patients' needs' (Facility Manager, Facility 2)*. Observational and narrative data reflects how nurses deal with these tensions. Overall, nurses in this study responded to the conflict associated with the

pressures of targets and the demands of responding to the complex realities of patients by navigating contradictory modes of being in their practice.

For example, it was observed that some nurses from all three clinics would shout at patients, refuse to listen to pleas, and enforce the rules of diagnostic policy over the realities of patients. Some would act ambivalently when requested to make exceptions for patients' personal circumstances and would focus on strictly following the prescriptive regimens set out by higher management. In other cases, nurses would insist that, following diagnosis, patients should present to the clinic daily after for treatment even though some patients pleaded that daily presentation would be challenging. In one instance, a patient refused to provide information about where he lived and the contact details of his landlord for the fear that his landlord and people in the community would find out that he had TB. The nurse grew increasingly frustrated because, according to the policy, all people who have been in close contact with someone with TB must be screened. The nurse remained resolute despite the patient expressing his concerns about being evicted if his landlord finds out.

Yet, in other instances the same nurses would act or allow patients to behave outside the diagnostic policy instruction. For example, some nurses allowed clients who were struggling to produce sputum due to weakness or it hurting when coughing to take the sputum jars home. The understanding was that the patient could produce sputum at home without supervision and return the sputum jars to the clinic the following day. This action may result in patients producing scanty or poor quality specimens, and is also risky because a patient might not return to the facility. Despite these risks, the nurses acknowledged patient struggles and used their discretion based on their value judgements.

> *"We should not shout and scream at patients for not presenting proper sputums or not coming to the clinic after we phone them to tell them to come because they have TB... [rather] we must show them that we are disappointed but remain supportive and understanding. It is difficult and that is why you will see me shout. Our role should not be to police or hold guns to their heads. We must help them to take control of their TB but we have so much pressure that we need to control them. There is no time to listen to their problems, they must just do what we need them to do at the end of the day".* (Staff Nurse, Facility 1)

This quote from nurses' narratives reflects how nurses make sense of the conflict between having to achieve targets whilst also responding to the needs and realities of patients. It also illustrates the contestation in discourse and practice. Nurses make sense of these contradictions by discursively recognizing patients' agency in the diagnostic and treatment process and talk about themselves as facilitators for patient well-being rather than regulators of the health outcomes of patients.

At face value it may seem that practices which contradict policy may compromise effective diagnostic practice procedure. This may be interpreted from nurses' making concessions for patients and behaving outside of standard policy directives. However, responding to patients' complex realities is more important to them as reflected in their decisions to behave outside policy, trusting that this will facilitate the process of diagnosing an individual patient (Pires, 2011). This reflects how human agency of both nurses and patients in their relationship, and its interaction with broader societal structures, shape TB diagnostic implementation in health systems (Engels *et al*, 2015; Gilson, Schneider & Orgill, 2014). However, the pressure of performance targets limits this agency and forces them to act as regulators instead of nurses facilitating care through being responsive to complex realities of patients (Pires, 2011).

These pressures and how they affect nurses' practice of policy implementation has unintended consequences. For example, a number of researchers have pointed out that pressures to achieve targets may result in already vulnerable patients not feeling considered, trusted or supported which could cause alienation and disenfranchisement (Escott & Walley, 2005; Gebremariam, Bjune, & Frich, 2010; Stack, 2003). Furthermore, top down, target driven approaches place strain on health facilities and heightens pressure on nursing staff which may result in feelings of anxiety and being overwhelmed, and possible burnout (Stack, 2003). In this study, nurses' narratives about the implementation of diagnostic policy in their practice relates to challenges reported in the literature for nurses in strengthening and promoting dignity conserving care (Baillie & Gallagher, 2010). An over emphasis on targets in practice presents challenges for advancing people-centeredness for health systems strengthening (Sheikh, George, & Gilson, 2014). This is exacerbated by the heavy administrative demands as a result of enforcing structured, standardized and routinized practices in TB implementation practices.

2) 'I do not like nursing paperwork- I came to be a nurse to work with patients and care for them'. Dealing with heavy administrative demands in nursing practice of TB diagnostic implementation

Although nurses recognize the importance of the administrative processes in their practice of policy implementation, many of them report the frustration of navigating between what they consider effective patient care and '*nursing books*'. All nurses in this study felt that their administrative demands hinder their quality of care. The following narratives provide some evidence for how nurses view administrative demands and how these impact their practice of TB policy:

> *'Here in the TB room, we have to do so much admin. It is a challenge for us because there will be times when we do not have someone to help us with the admin and then we have to do the admin stuff ourselves because the person they will give us will be new and know nothing and we will be stuck. Now you can imagine seeing all the patients and then also all the admin.' (CPN PHC nurse 2, Facility 1)*

> *'The bosses will not see that they can't expect us to have such a big admin load and then also expect us to be there for our patients. Something's got to give.' (CPN PHC nurse 1, Facility 2)*

TB reform implementation requires good monitoring and evaluation systems and standardization of operational and technical processes which can only be established with good information and administration systems (Albert *et al*., 2016; McNerney *et al*., 2012). However, administrative demands were a prominent issue in all the nurses' narratives in this study as noted in the narratives above. These demands include filling out patient files accurately, filling out lab request forms, following up on these requests, capturing data into information system databases, filing patient results, booking consultations, following up with specific patients that need to present to the facility on specific days, recording instructions from doctors, recording clinic observation data (National Tuberculosis Management Guidelines, 2014; Escott & Walley, 2005; Engel, 2012; Rendell *et al.*, 2017). Administration is also linked to the processes that help with tracking patients and assessing targets, outputs and outcomes of implementation (Lomas, 2012).

This links to findings from previous studies that showed how paper-based administrative and communication systems, as well as gaps in coordinated information and computer training (ICT) and online communication systems in low resource settings, represent the major barriers for effective implementation of GeneXpert diagnostic technology (Albert *et al.*, 2016; Menzies, Cohen, Lin, Murray & Salomon, 2012; Rendell *et al.*, 2017; Colvin *et al.*, 2015; Cowan *et al.*, 2015; Pai *et al.*, 2012; Palamountain *et al.*, 2012). Nurses in this study acknowledged the importance of paperwork in their practice to promote service delivery, health systems reporting, and coordinated communication. Yet, the current administrative load as well as the bureaucratic procedures nurses have to navigate limits their care for patients (Cunningham, Kennedy, Nwolisa, Callard & Wike, 2012; Michel, Waelli, Allen & Minvielle, 2017). In this study, nurses talked about these processes became increasingly overwhelming with high TB caseloads and increasing suspect cases.

Moreover, the reinforcement of existing institutionalised administrative procedures and beauracratic control systems hinder innovation (Bergen & While, 2005; McSherry & Douglas, 2011), resulting in conflict for nurses in making sense of how they can contribute to alleviating administrative demands to ensure that patient care is not compromised (Cunningham, Kennedy, Nwolisa, Callard & Wike, 2012; Lomas, 2012). Many nurses in this study report that audits and highly structured top-down bureaucratic control procedures from sub-district TB coordinators and management, compromised dignified patient care and limited them responding to patient needs. Anxieties triggered by bureaucratic and administrative control and processes devalue the humanity of nurses and the complex realities of patients, thus limiting people centeredness in the health system (Engel, 2012; Street, 1992). In this study nurses use their discretion as a means to offer personal input (Fletcher, 1984) to cope with the administrative demands in their practice to alleviate the pressure of heavy administrative and bureaucratic procedures in their implementation practices of TB diagnostics and care (Bergen & While, 2005).

The nurses working in the TB room at Facility B noted that there was an old computer in the store room that was not currently being used by the administrators working in the record room and reception. The nurses persistently requested that the computer be set up in the TB room to assist them with the administrative demands in their practice. Once this had been achieved, the nurses reported that the computer contributed to *'getting a better system going in the TB room to help with the paperwork' (CPN PHC nurse 2, Facility 2)*. These

nurses felt more motivated to catch up with administrative tasks and found it easier to engage more with patients while having access to databases for obtaining laboratory data and capturing patient information directly into the system. This reflects how nurses engage in innovative practices within their organizational contexts to promote people centeredness in their TB policy implementation practices (McSherry & Douglas, 2011). Compared to the other facilities, these nurses reported that they had contributed meaningfully to policy implementation and this promoted job satisfaction.

Nevertheless, this innovation caused some problems because these nurses failed to complete paperwork and hardcopy patient files appropriately, and preferred to add information directly into the online database. This observation supports arguments from the existing GeneXpert literature that propose that electronic and online systems need to be sufficiently co-ordinated to help alleviate administrative pressure instead of adding to their workload (Albert *et al.*, 2016; Menzies, Cohen, Lin, Murray & Salomon, 2012; Rendell *et al.*, 2017; Colvin *et al.*, 2015; Cowan *et al.*, 2015; Pai *et al.*, 2012; Palamountain *et al.*, 2012). This study shows that nurses readily utilized electronic databases, but they neglected the process of "paperwork first". This begs the question of why paperwork is a core part of administrative systems when functioning electronic systems exists. Nevertheless, we cannot take for granted the need for mmore efficient and coordinated electronic and online systems in the implementation of GeneXpert. Current electronic systems thus need to be strengthened to alleviate the burden of admiration demands.

Despite the limitations of this innovation, this example demonstrates that nurses' value being more responsive to patients' needs over heavy administrative procedures in their implementation practice. It reflects that nurses exercise their agency to cope with heavy administrative demands and, although their contributions may hinder implementation processes, they perceive their contributions to be important for their practice of patient care. They interpreted their decision as an attempt to reduce the paperwork load so that they could better respond to the needs of their patients.

The above findings also show that although the structured and routinized practices enforced by management may help nurses to cope with heavy patient loads and effectiveness through prescriptive and familiar practices, they may also pose challenges for nurses when they are overly rigid and structured (Engels, 2012; Lipsky, 2010). This may limit the extent to which nurses innovate and may stifle their priorities to deliver care effectively. A balance is needed between the extremes of controlling the diagnostic and administrative load through

standardization and bureaucracy, but still allowing for sufficient innovation that are relevant to local contexts and experiences (Cunningham, Kennedy, Nwolisa, Callard & Wike, 2012; Engels, 2012; Lipsky, 2010; Lomas, 2012).

The contention between nurses using their discretion to cope with the demands of heavy administration procedures and the sub-district TB coordinator problematizing their innovation on the basis of them not following procedures correctly, speaks to the extent to which top-down control approaches to standardization of operational and technical processes are entrenched in sub-district governance. It also raises issues about the nature of engagement between sub-district management and nurses.

3) 'Communication is a big challenge for us… It is difficult to say when it is difficult for you or when something is not working'. Gaps in the engagement between sub district management and nurses.

Most TB nurses in this study interpreted their engagement with sub-district management to be top down and autocratic. Nurses talked about how this fuels gaps in communication and policy transfer which ultimately limit effective implementation in their practice. This is reflected in the following quote:

> *'...many times we just sit in the meetings and we are told that this and this and this must be implemented in the clinic. We will sit there and we will not know what these things will be about and how it will improve our practice but when we go back to the clinic, we must start making changes and they will come and see if we are making the changes without us even knowing what we should actually be doing. Sometimes we will not even know how to do the changes and the bosses up there will not understand why we are struggling to implement these changes'. (Staff Nurse, Facility 2)*

Valuing low level health workers' contributions and input – especially that of nurses – is important for implementation of health care policy and the advancement of people-centredness in health systems (Lipsky, 2010; Sheikh, George, & Gilson, 2014; Walker & Gilson, 2004). TB and Primary Health Care (PHC) policy frameworks encourage managements to create environments that acknowledge local contexts and frontline workers' input to help shape practice in new and improved ways (Beaglehole *et al*, 2008; National Tuberculosis Management Guidelines, 2014; Walley *et al*, 2008). Yet, many studies report

that frontline workers are still not meaningfully included in policy formulation processes. Furthermore, they are not effectively communicated with when there are shifts in policy and implementation practice guidelines and procedures, and they have minimal platforms or pathways to provide feedback to management and decision makers (Chandler *et al.*, 2011; Colvin *et al.*, 2015; Engel, 2012; Engel *et al.*, 2015; Angotti, 2010). This is despite evidence showing the importance of communication in policy implementation processes (Chandler *et al.*, 2011; Colvin *et al.*, 2015; Engel, 2012; Engel *et al.*, 2015; Angotti, 2010).

In this study, nurses, facility managers and the TB coordinators accounted for how policy travels from sub-district management to the facility manager, from the sub-district management directly to the staff working in the TB room and from the facility manager and the staff in the TB room. Similar to findings reported by Albert *et al.* (2016), Colvin *et al.* (2015) and Rendell *et al.* (2017), all nurses in this study agreed that communication and coordination is central to policy implementation practice. All nurses specifically talked about how gaps in communication between them, the facility manager and the TB coordinator disrupt their practice. In the context of TB and HIV care where there are constant policy and procedural changes with the aim of strengthening implementation, when and how these changes are communicated to frontline workers will implicate their practice (Colvin *et al.*, 2015; Engel, 2012; Engel *et al.*, 2015; Angotti, 2010; Rendell *et al.*, 2017).

Nurses spoke about times when they were expected to change their practices to accommodate shifts in policy and practice guidelines. Generally, nurses reported that there was a lack of clear directives to guide how these changes should take shape in their practice. For them, policy directives that are communicated vaguely and inconsistently are particularly difficult to follow. For example, during the time of the study, nurses in two of the three case facilities experienced some confusion about the results they requested from laboratory. When these nurses requested a GeneXpert test on the lab request form, smear microscopy test results would be returned instead. When nurses told the sub-district TB coordinators about this, they followed up and it became apparent that the laboratory request procedures and instructions had not been clearly communicated to these nurses. The laboratory requirements was that when nurses requested a GeneXpert sputum sample, the two plastic sleeves that contained the two sputum samples must be attached. If the two sleeves were not attached, the laboratory would send smear results instead of GeneXpert results. The failure to clearly relay these instructions to the nurses had major consequences for the outcome of the diagnosis for

those patients who needed a GeneXpert result. This is an example of how clear communication is important for nursing implementation practice.

Health policies with heavy information loads and with many different instructions can be overwhelming and sometimes contradictory for management to communicate to nurses (Graber, 2002). Low level management needs to devise strategies and instructions to incorporate policy and implementation changes in already overburdened health systems and ensure that nurses can follow through with these changes (Albert *et al.*, 2016; Cowan *et al.*, 2015; Lipsky, 2010; Rendell *et al.*, 2017). This process is challenging if appropriate channels have not been established to communicate policy effectively with nurses.

Nurses in this study said that when they made mistakes due to being unaware of changes or directives not being sufficiently clear, they felt that management engages with them as if they are responsible for many of the consequences. Many nurses were very clear in their narratives that they cannot be held responsible for not following policy guidelines if they are not sufficiently trained or if instructions were not effectively communicated. Insufficient training capacity is a major barrier for TB diagnostic policy implementation, especially in LMIC settings (Albert *et al.*, 2016; Cowan *et al.*, 2015; Rendell *et al.*, 2017), Added to the issue of feeling like they are not adequately trained before changes are implemented in their organizations, a key challenge for nurses in this study was how policies guidelines are communicated and the nature of engagement with management.

Nevertheless, nurses talked about how the sub-district TB coordinators have become increasingly proactive in ensuring that they are informed. TB coordinators bridge some of the gaps in communication between nurses in the TB room and sub-district management and facilitate their engagement to address the inherent asymmetrical power relations and autocracies. As a means for continuous quality improvement, TB coordinators are tasked with providing ongoing support via telephone and email, as well as via periodic visits that offer face-to-face support and the opportunity to discuss policy and practice (National Tuberculosis Management Guidelines 2014; Natoli *et al.,* 2015). Nurses talked about how the TB coordinators offer a number of different strategies and pathways that facilitates proactive engagement. This is especially important for when changes in policy and practice guidelines need to be communicated to nurses. The TB coordinator for the three facilities in this study said that they support the TB nurses by translating the policies and instructions into actions which facilitates policy uptake. Many nurses' narratives were congruent with this. Nurses

explained that there is a continuous point of communication from coordinators and management where errors and changes for improvement are always communicated to them.

'So we do have regular meetings and it is not just a piece of paper…. the coordinator is very good, I must give him an A for that- he will also come and check – especially when there is something new, he will come around, he will come and audit our folders and admin and he will try and be supportive. When he sees that maybe we are struggling or when we gets new information then he will ask you, did you receive this or that? He will go over documents and paperwork with us, he will emphasize things if it is not clear to us. Sometimes, he will come across as so (action to show assertiveness)- but it just to like print these things into you." (CPN 2, Facility 2)

Although TB coordinators address some of the communication issues in policy implementation practice for nurses and facilitate the transfer of information from management to nurses, some nurses stated that management does not consider their input. This finding supports the argument by Escott and Walley (2005) that the voices of frontline staff are taken for granted in policy implementation. The following quote from a nurse in this study alludes to this notion:

> *'It is difficult to say when it is difficult for you or when something is not working... even if I make suggestions, it is never taken up. Because now, when you bringing things onto the table, you say, this is how my TB room is suffering or this making the TB implementation difficult, you are talking to the person who has no clue about what is happening here...[management] don't walk in my shoes. [Management] don't see what you need to do in the TB room for it to survive'. (PCN 1, Facility 3)*

The majority of the nurses in this study felt that management and the TB coordinator have not considered sufficient methods or strategies for nurses to provide input or feedback about their successes, challenges or grievances. Suggestions for improvements come from management i.e. top-down communication pathways. Similarly to Escott and Walley's (2005) findings, nurses felt that they are not able to provide input into key decisions during different phases of implementation. It was observed that even if nurses had suggestions and innovations to strengthen policy, these were limited by engagements that focused mainly on

targets, routine and bureaucracy. This is reflected in the example of nurses' innovation discussed earlier. Facility managers and the majority of the nurses across the three facilities felt that they had limited voice and opportunity to make recommendations for various factors that may stifle their implementation practice. These issues illuminate how issues of power and asymmetrical relationships between global, national and local policy may hinder or facilitate TB diagnostic policy implementation (Albert *et al.*, 2016; Colvin *et al.*, 2015; van Kampen, 2015). These issues pose major barriers for advancing people centeredness in health systems and the implementation of policy reform.

Study Limitations

Although this study offers rich insights into nurses' experiences of policy implementation in their practice, the authors acknowledge that their interpretations are based on subjective accounts and individualized explanations. Narrative and observational data is limited to the city of Cape Town, an urbanized setting with reasonably sufficient resources and adequate laboratory and PHC facility infrastructure that is relatively well-managed compared to PHC service delivery facilities elsewhere in South Africa and in other LMIC countries (Colvin *et al*, 2015). Nevertheless, this study did not set out to make generalizable claims but, rather, to offer critical and credible insights from analytical interpretations of the empirical data.

Another limitation of this study is that some nurses were not part of the restructuring process when GeneXpert was initially introduced and could not account for how changes in policy affected change in their practice. However, this was not necessarily the main aim of this investigation. Rather, our purpose was to assess the relational and human elements of the health system that may impact the process of policy reform implementation. These nurses could meaningfully reflect on their current experiences of working in the 'reformed' system of TB diagnostic policy and provide insight into the factors that facilitate and constrain their practice.

Another gap in the research is that patients' subjectivities and voices were absent in our data. Deepening patient-centered practice in research and policy implementation must consider tensions, contradictions and congruencies between different "people's" narratives in the health system to truly understand how human elements of the health system may impact policy implementation in practice.

Conclusion and Recommendations

This paper sought to investigate PHC nurses' experiences of diagnosing TB since the implementation of GeneXpert policy in their practice. This was done to understand the barriers that limit implementation of TB diagnostic policy in nurses' practice. An investigation into nurses' experiences through an analysis of discourse and practice offer important lessons for people-centered health systems in TB diagnostic policy implementation.

Findings from this study reflect a series of contradictions and tensions that nurses have to navigate in the process of diagnosis and care for patients presenting in the TB room. Paradoxes between nurses' talk and their practices are consequences of these contradictions. Nurses' experiences of policy implementation are situated within the nexus between policy frameworks (including instructions, targeted outcomes and outputs, directives) and the organizational aspects of the health system at service delivery level (including contexts, management, communication, administration). This study found that, for nurses, broader systemic factors within health systems organizational contexts can both support and undermine people-centred care.

The primary health care (PHC) approach, the patient rights charter and the ideologies underpinning TB policies support people-centeredness in health care delivery (Kironde & Kahirimbanyib, 2002; Van Lerberghe, 2008; WHO, 2003). This is also reflected in nurses' discourse as their narratives about their interactions with patients in their practice showed a deepened concern for patient care in their implementation practices. However, observing nurses' practices and their narratives revealed that TB targets, highly bureaucratized, routinized and heavy administration, and autocratic approaches to communication and engagement with nurses undermine their capacities to be responsive to the needs and complex realities of individual patients. Although the institutionalization of performance-driven culture yields concrete benefits for patients, health workers and the organization system (Dye *et al.,* 2006; Dye & Williams, 2008; Lönnroth, *et al.,* 2010), nurses in this study were critical of the extent to which management prioritizes targets, bureaucracy and administration over dignity, responsiveness and humanity in the process of diagnostics care in TB policy implementation.

Drawing on people-centred scientific approaches and foregrounding the humanity of nurses in their organizational and social systemic policy contexts can strengthen health systems implementation. Findings from this study reflect the significance of research, policy

and management to think beyond the solutions to policy implementation that only focuses on the hardware aspects of health systems. A focus on the human and relational elements of policy implementation within the health system is essential for advancing responsiveness and people-centeredness (Sheikh & Porter, 2010; Gilson *et al*., 2011). There is a need for increased awareness of the capacity to be intentional and deliberative in policy implementation processes for acknowledging the human qualities of the health system. This requires focussing attention on nurses' perspectives of the process of care instead of merely focusing on targets, paperwork and bureaucracy (Lomas, 2012; Michel, Waelli, Allen, & Minvielle, 2017; Street, 1992). Furthermore, strengthening communication and engagement with nurses may be critical in implementing policy in health systems (Arabi, Rafii, Cheraghi, & Ghiyasvandian, 2014; Escott, & Walley, 2005; Haines, Kuruvilla, & Borchert, 2004; Parvin *et al.,* 2017). Moreover, successful implementation further demands augmenting nurses' contributions in the policy implementation process. There is a need for public health officials and different levels of management to provide opportunities for nurses to share their voices, input and prowess in the policy process. Future research and policy efforts must seek to actualize the contributions of low level health workers in relation to perspectives from and frameworks of policy makers and higher levels of management. At the same time, the humanity of actors and bureaucrats of the health system and their responses to the complex lived experiences of patients, must be acknowledged to deepen people-centric practices for better policy implementation.

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Conflict of interest

No conflict of interest has been declared by the authors.

Part D: Appendices

Appendix 1: Questionnaire/data capture instrument(s)

Semi structured interview schedule

Main interview question:

Tell me about how it is to diagnose a patient in practice?

Tell me about how you are finding the process of patient diagnosis with GeneXpert. Start by when you first heard about GeneXpert and how it is up until now?

Probing questions:

Tell me about your facility from when you started working in the TB room? How did you find the process of diagnosing patients at first? Has it changed? If so, how?

What is difficult/challenging for you? What do you find easy and meaningful?

What does GeneXpert mean to you? How does mean in your practice?

How do you see your role in relation to the GeneXpert Policy?

How would you describe your relationships in the facility? The relationship with the lab, the relationships with your colleagues, the relationships with the facility managers? Who else do you have relationships with? Why are these people important/not important to you?

What more or what else can you tell me about diagnosing TB in your facility?

Appendix 2: Consent forms and participant information forms – Nurses

University of Cape Town
School of Public Health and Family Medicine

Health workers' experiences of the implementation of molecular diagnostics for TB in South Africa: Xpert MTB/RIF

Dear Health Worker,

1. **Invitation and Purpose**
   You are invited to take part in this study which explores health workers' experiences of the implementation of molecular diagnostics for TB in South Africa: Xpert MTB/RIF. I am a student researcher from the School of Public Health and Family Medicine at the University of Cape Town. This project is undertaken to fulfil the conditions of being awarded a master's degree.

2. **Background**
   This study focuses on health workers' experiences with the implementation and operation GeneXpert, TB diagnostic technology. GeneXpert is a fairly new technology that has been implemented in SA health system approximately 5 years ago (in some facilities longer than others) and it is important to assess to understand the success, challenges and the factors that bring about these. It is thus the purpose of this study to evaluate the implementation of GeneXpert and it aims to do this through obtaining narratives from health workers' about their experiences of the implementation of GeneXpert. This area of research is important because it will contribute meaningfully to the growing literature of TB and the implementation of new TB diagnostics such as GeneXpert. It is further important because it will assist in uncovering successes and challenges of implementation generally and seek to develop strategies for such challenges and learn from successes to strengthen implementation in this area. More essentially, it will contribute to knowledge about health systems strengthening from the perspective of health workers and facility managers.

3. **Procedures**

- If you decide to take part in this study I will interview you and some of the staff of your facility about your and their experiences of the implementation of Xpert MTB/RIF molecular diagnostics for TB in your facility. I will ask you to share your experiences of when you first heard that Xpert MTB/RIF molecular diagnostics for TB will be implemented in your facility and how it is up until now. I will also ask you about your experiences of different areas within your facility. By interviewing you I hope to find out what it is like to work with GeneXpert and what you think about the technology and how it is working in your facility.
- The interviews should take about an hour; however, you are free to speak to me for shorter or longer periods.

- Participating in this study is voluntary. You are free to end the interview at any time with no penalty or any other consequences.
- In addition to the interviews, I would also like to engage as an active observer in your facility. This will be on request of your permission and the duration of the observation will occur simultaneously with interviews. This will mean that I will engage with and partake in informal discussion with staff, observe to understand processes and take notes of observations.

4. **Benefits**

- This study seeks to contribute effectively to the improvement of the implementation of TB diagnostics in South Africa primary health care facilities and to strengthen TB diagnostics with the broader objective of reducing the incidence and prevalence of TB in SA.
- This study aims to contribute meaningfully to the evidence base in the area of the implementation of GeneXpert thus expanding our knowledge and understanding of GeneXpert and its implementation in SA.
- Health workers and facility managers will be focus of this study, thus giving voice to your interpretations and experiences of GeneXpert and its implementation. There is very little research done on health workers' and facility managers' experiences at primary health care level in this field. Thus by taking part in this study, you will be able to share insights on your experiences and how these experiences influence the 'actual' implementation and operation of GeneXpert in your facility. You will therefore have an opportunity to express concerns, challenges and strategies for success that may inform policy, implementation guidelines and future research.
- To find feasible solutions to assist health workers and facility managers working in PHC and gage success strategies to strengthen implementation and TB care in their facilities.

5. **Risks, Discomforts & Inconveniences**

- This study poses a low risk of harm to you.
- Speaking about your experiences may potentially bring up sensitive issues and could potentially be emotionally distressing. However, you will decide what you would like to discuss in the interview and you will not be obligated to speak about anything you do not feel comfortable speaking about. Under no circumstances will your identity or that of the facility be revealed in any presentation of findings (see section on Privacy and Confidentiality below).
- You might be inconvenienced by having to give an hour of your time (this may be during lunch time or during any other free time that you may have). You can decide on any time that is most suitable to you.
- Taking part in this study or refusing to take part in this study/withdrawing from the study will not influence your current or future employment at this facility.

6. **Privacy and Confidentiality**

- Interviews will take place in a private space. In the event that we have no other option but to conduct the interview in a public space, it will be ensured that the interviewee (yourself or other staff members) and the interviewer (myself) are alone and that the space is secure.
- Any information you share is strictly confidential. You will remain anonymous throughout the research process and to ensure anonymity, your identity and the identity of your facility will be masked with pseudo names in all writings and reports on the research. Explicit characteristics of the facility will not be mentioned (for examples, the exact location of the facility or specific attributes of the facility that will make it identifiable).You have the right to request that any information you have shared be omitted from the study and future reports.
- In addition, all observations and participation in the facility will be recorded through note taking. Notes will be hand written in a personal journal that will be locked up after the research process and will only be accessed during the analysis phases of the research project.

- This conversation will be recorded and a digital recording device will be used to record the interview. This is only for the purposes of the research. You have the option to choose at any time during the interview when the recording device should be switched off. Recorded material will be transcribed.
- All soft copy transcriptions will be stored on specific password protected hard drive and sky drive folders. Hard copies of transcriptions will be stored in hard cover folders and stored in a locked drawer in an office at UCT. These documents that will strictly only be accessed by the researchers, supervisors and transcribers of this project.
- The findings of this research paper may be published in an academic journal, newspaper article or other modes of mass communication.
- All audio-recordings and transcriptions will be destroyed approximately 5 years after the research has been accepted to be published in an academic journal.

7. **Contact details**

If you have questions, concerns, or complaints about the study please contact Lance Louskieter on 0837390528 or lsklan001@myuct.ac.za, Dr. Chris Colvin at the School of Public Health and Family Medicine, University of Cape Town (UCT) at coldvine@gmail.com.

Alternatively, you may contact the ethics committee that approved the study if you have any ethical concerns or questions about your rights or welfare as a research participant at the following information:

University of Cape Town, Faculty of Health Sciences

Human Research Ethics Committee

Telephone: (021) 406 6338

Email: shurette.thoma@uct.ac.za

INFORMED CONSENT FORM FOR PARTICIPANTS
University of Cape Town
School of Public Health and Family Medicine

Health workers' experiences of the implementation of molecular diagnostics for TB in South Africa: Xpert MTB/RIF

Signatures

{Participant's name}_____ has been informed of the nature and purpose of the procedures described above including any risks involved in its performance. He or she has been given time to ask any questions and these questions have been answered to the best of the investigator's ability. A signed copy of this consent form has been made available to the participant.

_____ _____
Investigator's Signature Date

I have been informed about this research study and understand its purpose, possible benefits, risks, and discomforts. I agree to take part in this research as a subject. I know that I am free to withdraw this consent and quit this project at any time, and that doing so will not cause me any penalty or loss of benefits that I would otherwise be entitled to enjoy. I am aware that the interview will be audio recorded and that I can ask for the audio recording device to be switched off at any given time of the duration of the interview. I am further aware that the research will be written up in the form of a master's research project and may be published in an academic journal.

_____ _____
Participant's Signature Date

Appendix 3: Consent Forms And Participant Information Forms - Facility Managers

University of Cape Town
School of Public Health and Family Medicine

Health workers' experiences of the implementation of molecular diagnostics for TB in South Africa: Xpert MTB/RIF

Dear Facility Manager,

1. **Invitation and Purpose**
   You are invited to take part in this study which explores health workers' experiences of the implementation of molecular diagnostics for TB in South Africa: Xpert MTB/RIF. I am a student researcher from the School of Public Health and Family Medicine at the University of Cape Town. This project is undertaken to fulfil the conditions of being awarded a master's degree.

2. **Background**
   This study focuses on health workers' experiences with the implementation and operation GeneXpert, TB diagnostic technology. GeneXpert is a fairly new technology that has been implemented in SA health system approximately 5 years ago (in some facilities longer than others) and it is important to assess to understand the success, challenges and the factors that bring about these. It is thus the purpose of this study to evaluate the implementation of GeneXpert and it aims to do this through obtaining narratives from health workers' about their experiences of the implementation of GeneXpert. This area of research is important because it will contribute meaningfully to the growing literature of TB and the implementation of new TB diagnostics such as GeneXpert. It is further important because it will assist in uncovering successes and challenges of implementation generally and seek to develop strategies for such challenges and learn from successes to strengthen implementation in this area. More essentially, it will contribute to knowledge about health systems strengthening from the perspective of health workers and facility managers.

3. **Procedures**

- If you decide to take part in this study I will interview you and some of the staff of your facility about your and their experiences of the implementation of Xpert MTB/RIF molecular diagnostics for TB in your facility. I will ask you to share your experiences of when you first heard that Xpert MTB/RIF molecular diagnostics for TB will be implemented in your facility and how it is up until now. I will also ask you about your experiences of different areas within your facility. By interviewing you I hope to find out what it is like to work with GeneXpert and what you think about the technology and how it is working in your facility.

- The interviews should take about an hour; however, you are free to speak to me for shorter or longer periods.
- Participating in this study is voluntary. You are free to end the interview at any time with no penalty or any other consequences.
- In addition to the interviews, I would also like to engage as an active observer in your facility. This will be on request of your permission and the duration of the observation will occur simultaneously with interviews. This will mean that I will engage with and partake in informal discussion with staff, observe to understand processes and take notes of observations.

4. **Benefits**

- This study seeks to contribute effectively to the improvement of the implementation of TB diagnostics in South Africa primary health care facilities and to strengthen TB diagnostics with the broader objective of reducing the incidence and prevalence of TB in SA.
- This study aims to contribute meaningfully to the evidence base in the area of the implementation of GeneXpert thus expanding our knowledge and understanding of GeneXpert and its implementation in SA.
- Health workers and facility managers will be focus of this study, thus giving voice to your interpretations and experiences of GeneXpert and its implementation. There is very little research done on health workers' and facility managers' experiences at primary health care level in this field. Thus by taking part in this study, you will be able to share insights on your experiences and how these experiences influence the 'actual' implementation and operation of GeneXpert in your facility. You will therefore have an opportunity to express concerns, challenges and strategies for success that may inform policy, implementation guidelines and future research.
- To find feasible solutions to assist health workers and facility managers working in PHC and gage success strategies to strengthen implementation and TB care in their facilities.

5. **Risks, Discomforts & Inconveniences**

- This study poses a low risk of harm to you.
- Speaking about your experiences may potentially bring up sensitive issues and could potentially be emotionally distressing. However, you will decide what you would like to discuss in the interview and you will not be obligated to speak about anything you do not feel comfortable speaking about. Under no circumstances will your identity or that of the facility be revealed in any presentation of findings (see section on Privacy and Confidentiality below).
- You might be inconvenienced by having to give an hour of your time (this may be during lunch time or during any other free time that you may have). You can decide on any time that is most suitable to you.
- Taking part in this study or refusing to take part in this study/withdrawing from the study will not influence your current or future employment at this facility.

6. **Privacy and Confidentiality**

- Interviews will take place in a private space. In the event that we have no other option but to conduct the interview in a public space, it will be ensured that the interviewee (yourself or other staff members) and the interviewer (myself) are alone and that the space is secure.
- The participants will be known to the researcher and thus anonymity cannot be fully guaranteed throughout the research process. However, the researcher will ensure that participants remain anonymous in the writings and reports of the research process to protect the identity of participants as far as possible. The researcher will do this by masking your identity and the identity of your facility with pseudo names (for example, Participant A or Facility X) in all writings and reports on the research. Explicit characteristics of the facility will not be mentioned (for examples, the exact location of the facility or specific attributes of

the facility that will make it identifiable).You have the right to request that any information you have shared be omitted from the study and future reports.

- Information you share and all data generated in this study will be treated with confidentiality.
- All observations and participation in the facility will be recorded through note taking. Notes will be hand written in a personal journal that will be locked up after the research process and will only be accessed during the analysis phases of the research project.
- This conversation will be recorded and a digital recording device will be used to record the interview. This is only for the purposes of the research. You have the option to choose at any time during the interview when the recording device should be switched off. Recorded material will be transcribed.
- All soft copy transcriptions will be stored on specific password protected hard drive and sky drive folders. Hard copies of transcriptions will be stored in hard cover folders and stored in a locked drawer in an office at UCT. These documents that will strictly only be accessed by the researchers, supervisors and transcribers of this project.
- The findings of this research paper may be published in an academic journal, newspaper article or other modes of mass communication.
- All audio-recordings and transcriptions will be destroyed approximately 5 years after the research has been accepted to be published in an academic journal.

7. **Contact details**

If you have questions, concerns, or complaints about the study please contact Lance Louskieter on 0837390528 or lsklan001@myuct.ac.za, Dr. Chris Colvin at the School of Public Health and Family Medicine, University of Cape Town (UCT) at coldvine@gmail.com.

Alternatively, you may contact the ethics committee that approved the study if you have any ethical concerns or questions about your rights or welfare as a research participant at the following information:

University of Cape Town, Faculty of Health Sciences

Human Research Ethics Committee

Telephone: (021) 406 6338

Email: shurette.thoma@uct.ac.za

Signatures

{Facility Manager's name}_____ has been informed of the nature and purpose of the procedures described above including any risks involved in its performance. He or she has been given time to ask any questions and these questions have been answered to the best of the investigator's ability. A signed copy of this consent form has been made available to the participant.

_____ _____

Investigator's Signature Date

I have been informed about this research study and understand its purpose, possible benefits, risks, and discomforts. I agree to take part in this research as a subject. I know that I am free to withdraw this consent and quit this project at any time, and that doing so will not cause me any penalty or loss of benefits that I would otherwise be entitled to enjoy. I am aware that the interview will be audio recorded and that I can ask for the audio recording device to be switched off at any given time of the duration of the interview. I am further aware that the research will be written up in the form of a master's research project and may be published in an academic journal.

_____ _____

Facility Manager's Signature Date

Appendix 4: Research Study Poster for Facility

University of Cape Town
School of Public Health and Family Medicine

Health workers' experiences of the implementation of molecular diagnostics for TB in South Africa: Xpert MTB/RIF

Dear Patients attending facility X,

A study which explores health workers' experiences of the implementation of molecular diagnostics for TB in South Africa: Xpert MTB/RIF, is taking place in this facility. As part of the study, an observation component will take place where the researcher may observe health workers' interactions with patients. The nature of the observation is to assess the interactions and relationships of health workers with patients to better understand their actions and behaviours. I am a student researcher from the School of Public Health and Family Medicine at the University of Cape Town. This project is undertaken to fulfil the conditions of being awarded a master's degree. Thank you for your time in reading this notice.

This poster serves to notify and inform you of the nature and purpose of the study and how your privacy and confidentiality and that of the facility will be protected. It will also provide the contact details of the researcher and the contact details of the UCT Faculty of Health Sciences Research Ethics Committee who have approved this study.

Background

This study focuses on health workers' experiences with the implementation GeneXpert, TB diagnostic technology. GeneXpert is a fairly new technology that has been implemented in SA health system approximately 5 years ago (in some facilities longer than others) and it is important to assess to understand the success, challenges and the factors that bring about these. It is thus the purpose of this study to understand the implementation of GeneXpert and it aims to do this through obtaining narratives from health workers' about their experiences of the implementation of GeneXpert. This area of research is important because it will contribute meaningfully to the growing literature of TB and the implementation of new TB diagnostics such as GeneXpert. It is further important because it

will assist in uncovering successes and challenges of implementation in nursing practice and seek to develop strategies for such challenges and learn from successes to strengthen implementation in this area. More essentially, it will contribute to knowledge about health systems strengthening from the perspective of health workers and facility managers.

Benefits

- This study seeks to contribute effectively to the improvement of the implementation of TB diagnostics in South Africa primary health care facilities and to strengthen TB diagnostics with the broader objective of reducing the incidence and prevalence of TB in SA.
- This study aims to contribute meaningfully to the evidence base in the area of the implementation of GeneXpert thus expanding knowledge and understanding of GeneXpert and its implementation in SA.
- Health workers and facility managers will be focus of this study, thus giving voice to their interpretations and experiences of GeneXpert and its implementation. There is very little research done on health workers' and facility managers' experiences at primary health care level in this field. Thus through observing their interactions with you, I hope to gain insights on their experiences and how their experiences influence the 'actual' implementation and operation of GeneXpert in this facility.
- This study also seeks to find feasible solutions to assist health workers and facility managers working in PHC and gage success strategies to strengthen implementation and TB care in their facilities.

Procedure

As the researcher, I will be present in the patient waiting areas and other areas that the facility manager gave me permission to be present in. In these areas I will observe and engage with health workers in their day to day operations and activities associated with the TB diagnostic technologies with a primary focus on GeneXpert. I will take notes with a note book and pen.

I will only be engaging and having conversations with the health workers directly and observing their actions, interactions and relationships. I will only be observing patients and not interact with them. You are free to request from the researcher not to be observed at all.

Privacy and Confidentiality

Any information gathered from this study is strictly confidential. You will remain anonymous in the writings and reports of the research and to ensure anonymity, your identity and the identity of the facility will be masked with pseudo names in all writings and reports on the research. Explicit characteristics of the facility and its patients will not be mentioned (for examples, the exact location of the facility or specific attributes of the facility that will make patients and it identifiable).

Contact details

For more information or if you have queries about the information presented in the poster, you may contact the researcher/s at the following details:

Name (Student Researcher): Lance Louskieter
Cell: 0837390528
Email: lsklan001@myuct.ac.za

Name (Supervisor): Associate Professor Chris Colvin
Email: coldvine@gmail.com.

Alternatively, you may contact the ethics committee that approved the study if you have any ethical concerns or questions about your rights or welfare as a research participant at the following information:

University of Cape Town, Faculty of Health Sciences
Human Research Ethics Committee

Telephone: (021) 406 6338
Email: shurette.thoma@uct.ac.za

Appendix 5: Information Sheet and Informed Consent Form for Facility Meeting Attendees

University of Cape Town
School of Public Health and Family Medicine

Health workers' experiences of the implementation of molecular diagnostics for TB in South Africa: Xpert MTB/RIF

Dear Facility Meeting Attendee,

A study which explores health workers' experiences of the implementation of molecular diagnostics for TB in South Africa: Xpert MTB/RIF, is taking place in this facility. As part of the study, an observation component will take place where the researcher will be attending meetings held at facility X and taking minutes.

1. **Invitation and Purpose**
   You are invited to take part in this study which explores health workers' experiences of the implementation of molecular diagnostics for TB in South Africa: Xpert MTB/RIF. I am a student researcher from the School of Public Health and Family Medicine at the University of Cape Town. This project is undertaken to fulfil the conditions of being awarded a master's degree.

2. **Background**
   This study focuses on health workers' experiences with the implementation of GeneXpert, TB diagnostic technology. GeneXpert is a fairly new technology that has been implemented in SA health system approximately 5 years ago (in some facilities longer than others) and it is important to assess to understand the success, challenges and the factors that bring about these. It is thus the purpose of this study to understand the implementation of GeneXpert and it aims to do this through obtaining narratives from health workers' about their experiences of the implementation of GeneXpert. This area of research is important because it will contribute meaningfully to the growing literature of TB and the implementation of new TB diagnostics such as GeneXpert. It is further important because it will assist in uncovering successes and challenges of implementation in your practice and seek to develop strategies for such

challenges and learn from successes to strengthen implementation in this area. More essentially, it will contribute to knowledge about health systems strengthening from the perspective of health workers and facility managers.

3. **Procedures**

- As the researcher, I will be present in the facility meetings that the facility manager gave me permission to be present in. In these a\meetings I will observe and take minutes of information and discussions associated with the implementation of the TB diagnostic technologies with a primary focus on GeneXpert. I will take meetings with a note book and pen or my computer or Ipad.
- I will not be interrupting any part of the meeting and will not be actively engaging in the meetings.

4. **Benefits**

- This study seeks to contribute effectively to the improvement of the implementation of TB diagnostics in South Africa primary health care facilities and to strengthen TB diagnostics with the broader objective of reducing the incidence and prevalence of TB in SA.
- This study aims to contribute meaningfully to the evidence base in the area of the implementation of GeneXpert thus expanding our knowledge and understanding of GeneXpert and its implementation in SA.
- Health workers and facility managers will be focus of this study, thus giving voice to your interpretations and experiences of GeneXpert and its implementation. There is very little research done on health workers' and facility managers' experiences at primary health care level in this field. Thus by taking part in this study, you will be able to share insights on your experiences and how these experiences influence the 'actual' implementation and operation of GeneXpert in your facility. You will therefore have an opportunity to express concerns, challenges and strategies for success that may inform policy, implementation guidelines and future research.
- To find feasible solutions to assist health workers and facility managers working in PHC and gage success strategies to strengthen implementation and TB care in their facilities.

5. **Risks, Discomforts & Inconveniences**

- This study poses a low risk of harm to you.
- Under no circumstances will your identity or that of the facility be revealed in any presentation of findings (see section on Privacy and Confidentiality below).
- Taking part in this study or refusing to take part in this study/withdrawing from the study will not influence your current or future employment at this facility.

6. **Privacy and Confidentiality**

- The participants will be known to the researcher and thus anonymity cannot be fully guaranteed throughout the research process. However, the researcher will ensure that participants remain anonymous in the writings and reports of the research process to protect the identity of participants as far as possible. The researcher will do this by masking your identity and the identity of your facility with pseudo names (for example, Participant A or Facility X) in all writings and reports on the research. Explicit characteristics of the facility will not be mentioned (for examples, the exact location of the facility or specific attributes of the facility that will make it identifiable).You have the right to request that any information you have shared be omitted from the study and future reports.
- Information you share will be treated with confidentiality.
- All observations and participation in the facility will be recorded through note taking. Notes will be hand written in a personal journal that will be locked up after the research process and will only be accessed during the analysis phases of the research project.

- Hard copies of transcriptions and had written notes will be stored in hard cover folders and stored in a locked drawer in an office at UCT. These documents that will strictly only be accessed by the researchers, supervisors and transcribers of this project.
- The findings of this research paper may be published in an academic journal, newspaper article or other modes of mass communication.
- All audio-recordings, transcriptions and notes will be destroyed approximately 5 years after the research has been accepted to be published in an academic journal.

7. **Contact details**
   If you have questions, concerns, or complaints about the study please contact Lance Louskieter on 0837390528 or lsklan001@myuct.ac.za, Dr. Chris Colvin at the School of Public Health and Family Medicine, University of Cape Town (UCT) at coldvine@gmail.com.

   Alternatively, you may contact the ethics committee that approved the study if you have any ethical concerns or questions about your rights or welfare as a research participant at the following information:

   University of Cape Town, Faculty of Health Sciences

   Human Research Ethics Committee

   Telephone: (021) 406 6338

   Email: shurette.thoma@uct.ac.za

Signatures

{Participant's name}_____ has been informed of the nature and purpose of the procedures described above including any risks involved in its performance. He or she has been given time to ask any questions and these questions have been answered to the best of the investigator's ability. A signed copy of this consent form has been made available to the participant.

_____ _____
Investigator's Signature Date

I have been informed about this research study and understand its purpose, possible benefits, risks, and discomforts. I agree to take part in this research as a subject. I know that I am free to withdraw this consent and quit this project at any time, and that doing so will not cause me any penalty or loss of benefits that I would otherwise be entitled to enjoy. This means that I can decide to ask the researcher to stop the observation at any given time. I am aware that I will be observed as a meeting attendee in a meeting held at facility X and that I can request for information that I may share in the meeting to be withheld. I am further aware that the research will be written up in the form of a master's research project and may be published in an academic journal.

_____ _____
Meeting Attendee Signature Date

APPENDIX 6: LETTER OF APPROVAL FROM RESEARCH ETHICS COMMITTEES

CITY OF CAPE TOWN
ISIXEKO SASEKAPA
STAD KAAPSTAD

CITY HEALTH

Dr Hélène Visser
Manager: Specialised Health

T: 021 400 3981 **F:** 021 421 4894 **M:** 083 298 8718
E: Helene.Visser@capetown.gov.za

2016-04-13

Re: Research Request: Health Workers experiences of the implementation of molecular diagnostics for TB in South Africa (ID No: 10557)

Dear Mr Louskieter,

Your research has been approved as per your research request, but noting that for this fairly lengthy interview of staff, only Fridays after 3pm can be used.

Mitchells Plain Sub District:
Contact People

Mrs S Elloker (Sub District Manager)
Tel: (021) 391-5012/ 084 222 1478
Mrs N Nqana (Head: PHC & Programmes)
Tel: (021) 391-0175/ 084 2221489

Please note the following:

1. All individual patient information obtained must be kept confidential.
2. Access to the clinics and its patients must be arranged with the relevant Managers such that normal activities are not disrupted.
3. A copy of the final report must be sent to the City Health Head Office, P O Box 2815 Cape Town 8001, within 6 months of its completion and feedback must also be given to the clinics involved.
4. Your project has been given an ID Number (10557). Please use this in any future correspondence with us.
5. No monetary incentives to be paid to clients on the City Health premises.

Thank you for your co-operation and please contact me if you require any further information or assistance.

Yours sincerely

DR G H VISSER
MANAGER: SPECIALISED HEALTH

cc. Mrs Elloker & Ms Nqana
Dr Jennings

APPENDIX 7: INSTRUCTIONS FOR AUTHOR OF JOURNAL WHOSE FORMAT HAS BEEN USED

JOURNAL: SOCIAL SCIENCE & MEDICINE

DESCRIPTION

Social Science & Medicine provides an international and interdisciplinary forum for the dissemination of social science research on health. We publish original research articles (both empirical and theoretical), reviews, position papers and commentaries on health issues, to inform current research, policy and practice in all areas of common interest to social scientists, health practitioners, and policy makers. The journal publishes material relevant to any aspect of health from a wide range of social science disciplines (anthropology, economics, epidemiology, geography, policy, psychology, and sociology), and material relevant to the social sciences from any of the professions concerned with physical and mental health, health care, clinical practice, and health policy and organization. We encourage material which is of general interest to an international readership.

The journal publishes the following types of contribution:

1) Peer-reviewed original research articles and critical or analytical reviews in any area of social science research relevant to health. These papers may be up to 8,000 words including abstract, tables, and references as well as the main text. Papers below this limit are preferred.

2) Peer-reviewed short reports of research findings on topical issues or published articles of between 2000 and 4000 words.

3) Submitted or invited commentaries and responses debating, and published alongside, selected articles.

4) Special Issues bringing together collections of papers on a particular theme, and usually guest edited.

Please see our Guide for Authors for information on article submission.

AUDIENCE

Social scientists (e.g. medical anthropologists, health economists, social epidemiologists, medical geographers, health policy analysts, health psychologists, medical sociologists) interested in health, illness, and health care; and health-related policy makers and health care professionals (e.g. dentists, epidemiologists, health educators, lawyers, managers, nurses, midwives, pharmacists,

physicians, public health practitioners, psychiatrists, surgeons) interested in the contribution of the social sciences.

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GUIDE FOR AUTHORS

Your Paper Your Way

We now differentiate between the requirements for new and revised submissions. You may choose to submit your manuscript as a single Word or PDF file to be used in the refereeing process. Only when your paper is at the revision stage, will you be requested to put your paper in to a 'correct format' for acceptance and provide the items required for the publication of your article.

To find out more, please visit the Preparation section below.

INTRODUCTION

Click here for guidelines on Special Issues.

Click here for guidelines on Qualitative methods.

Social Science & Medicine provides an international and interdisciplinary forum for the dissemination of social science research on health. We publish original research articles (both empirical and theoretical), reviews, position papers and commentaries on health issues, to inform current research, policy and practice in all areas of common interest to social scientists, health practitioners, and policy makers. The journal publishes material relevant to any aspect of health and healthcare from a wide range of social science disciplines (anthropology, economics, epidemiology, geography, policy, psychology, and sociology), and material relevant to the social sciences from any of the professions concerned with physical and mental health, health care, clinical practice, and health policy and the organization of healthcare. We encourage material which is of general interest to an international readership.

Journal Policies

The journal publishes the following types of contribution:

1) Peer-reviewed original research articles and critical analytical reviews in any area of social science research relevant to health and healthcare. These papers may be up to 8000 words including abstract, tables, figures, references and (printed) appendices as well as the main text. Papers below this limit are preferred.

2) Systematic reviews and literature reviews of up to 15000 words including abstract, tables, figures, references and (printed) appendices as well as the main text.

3) Peer-reviewed short communications of findings on topical issues or published articles of between 2000 and 4000 words.

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