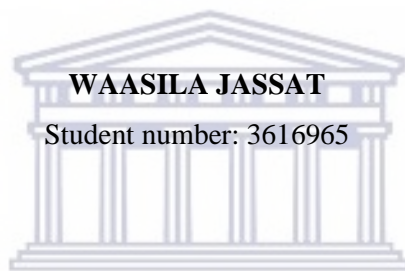


**THE DECENTRALISED DRUG-RESISTANT TB PROGRAMME IN
SOUTH AFRICA: FROM POLICY TO IMPLEMENTATION**



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KEYWORDS

Drug-Resistant TB

Decentralisation

Policy implementation

Policy analysis triangle

Case study

KwaZulu-Natal Province

Western Cape Province

Actors

Content

Context

Process



DECLARATION

I declare that *The decentralised drug-resistant TB programme in South Africa: from policy to implementation* is my own work, that it has not been submitted before for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged as complete references.

Full name: Waasila Jassat



Signed:

Date: 1 December 2022



ABSTRACT

South Africa is one of the high burden countries for drug-resistant tuberculosis (DR-TB) globally. A policy supporting decentralised DR-TB treatment provision was introduced in 2011 but to date implementation has been suboptimal with variable coverage and quality. This thesis opens the ‘black box’ explaining sub-national policy implementation of DR-TB decentralisation in two provinces of South Africa, Western Cape and KwaZulu-Natal. The thesis is grounded in the field of policy analysis and adopts the methodological approach of a qualitative multiple case study, comparing 15 embedded district and subdistrict cases in the two provinces, through data collected in 94 in-depth interviews, document reviews, and observations. Applying Walt and Gilson’s Policy Analysis Triangle framework, the case studies of DR-TB in the two provinces revealed how aspects of actors’ engagement with the policy instrument, influenced by organisational dynamics and the wider context, resulted in varying effectiveness of policy implementation. Implementation was shaped by actor interpretations of policy, the emergence of champions and resisters, and the effects of actor networks, as well as by the specific change strategies they employed. Policy implementation was also affected by funding and resource constraints, insufficient integration of DR-TB in the district health system and lack of buy in from managers in many districts. Increasing coverage to new, inadequately capacitated DR-TB initiating sites, without institutionalising clinical governance and improvement strategies, resulted in compromised quality of care. Based on the findings, a set of 13 actor-centred propositions on implementation are put forward, as follows. Actors make sense of policy, and this framing is expressed as support or resistance to policy. They create shared meaning and act as networks. Their shared resolve translates into absorptive capacity, and when combined with supportive contexts, enables readiness for change. Their emergent and dynamic expressions of agency influence their actions and strategies for implementation. District managers play a key role in oversight of implementation and vertical programme implementation that bypasses core health system structures will face challenges. Similarly, policy instruments (content) and implementation (change) strategies need to go beyond narrow technical interventions (such as DR-TB guidelines and training), and embrace broader goals, such as quality improvement, patient-centred care and health systems strengthening. A theory of policy implementation is proposed, asserting that implementation of complex and often ambiguously defined technical interventions, unfolding within a complex system context, requires a range of coordinated implementation strategies across multiple levels; and furthermore, results in a dynamic interplay between individuals and organisations, that itself shapes the implementation process. New advances in diagnosis and treatment to address the growing burden of DR-TB in South Africa will have little impact unless implementation dynamics are better understood, and attention paid to individual and organisational processes of adopting and integrating complex care strategies.

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DEDICATION

This thesis is dedicated to
the many heroes who battle the scourge of drug-resistant TB in South Africa,
most notably Dr Iqbal Masters who succumbed to COVID-19 in 2021,
who was described to me as ‘the messiah of MDR-TB’.



ACRONYMS

ART	Antiretroviral Therapy
BCH	Brooklyn Chest Hospital
CEO	Chief Executive Officer
CHC	Community Health Centre
CoCT	City of Cape Town
CoSH	Church of Scotland Hospital
CoE	Centre of Excellence
DMT	District Management Team
DOT	Directly Observed Therapy
DR-TB	Drug-Resistant Tuberculosis
DS-TB	Drug-Sensitive Tuberculosis
ECG	Electrocardiogram
HAST	HIV, AIDS, STI and TB
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
KDH	King Dinizulu Hospital
KZN	KwaZulu-Natal Province
LMIC	Low and Middle-Income Countries
LTFU	Loss to Follow-Up
MDR-TB	Multi-Drug Resistant Tuberculosis
MDT	Multi-Disciplinary Team
MRC	Medical Research Council
MSF	Médecins Sans Frontières
NDoH	National Department of Health
NGO	Non-Governmental Organisation
NIMDR	Nurse-Initiated Management of Drug-Resistant TB
OPD	Outpatient Department
PHC	Primary Health Care
PWDR-TB	People with Drug-Resistant TB
PLWH	People Living with HIV
SDC	Sub-District MDR-TB Coordinator
SMO	Senior Medical Officer
TB	Tuberculosis
XDR-TB	Extensively Drug-Resistant Tuberculosis
WC	Western Cape Province
WHO	World Health Organization

DEFINITIONS

Implementation:	The constellation of processes intended to get an intervention into use within an organisation.
Policy analysis:	Focus on content of reform, the processes of policy-making, the behaviour of actors in formulating and implementing policy and the context within which policies are implemented.
Implementation science:	The scientific inquiry into questions concerning implementation – the act of carrying policies, programmes, or individual practices into effect.
Quality of care:	Care that is safe, timely, effective, efficient, equitable, and patient-centred.
Effectiveness:	The extent to which planned outcomes, goals, or objectives are achieved as a result of an activity, strategy, intervention, or initiative intended to achieve the desired effect, under ordinary circumstances.
Coverage:	The extent to which people in need actually receive important health interventions.
Multi-Drug Resistant TB:	Resistance of Mycobacterium tuberculosis strains to at least isoniazid and rifampicin, the cornerstone medicines for the treatment of TB.
Decentralisation:	In the context of the drug-resistant TB programme, the movement of services in the health department away from a single centre to other locations.
Black box of implementation:	The ‘black box’ that addresses the questions of how policies can meet their intent, in order to understand how implementation worked, or did not work within the context.

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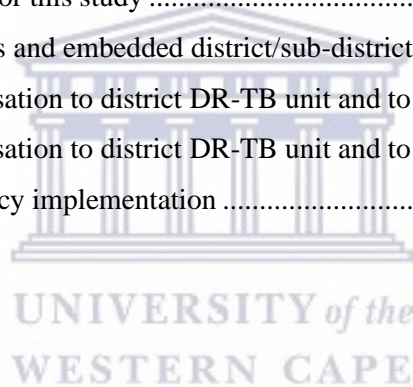


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CHAPTER 1. INTRODUCTION

Despite evidence-based health policies, many countries fail to deliver accessible, quality health services that result in good health outcomes. In the two decades post-Apartheid, South Africa has developed progressive, human rights-based legislation and health policy informed by evidence. However, health outcomes still lag behind those of countries with similar income and health expenditure (Mayosi & Benatar, 2014). In South Africa as elsewhere, health system reforms have insufficiently considered the factors affecting implementation (Walt & Gilson, 1994). Analysing policy implementation can open the ‘black box’ that may explain why and how health policies achieve their intent or not (Parashar et al., 2020).

The black box of implementation referred to throughout this thesis, addresses the questions of how policies can meet their intent, and describes the relationship between the intervention and context. In an adaptation of Easton’s (1965) systems model of policy-making, Buse et al. (2012) provide an approach to simplifying the complexities of political decision-making and to understanding its key universal components. The systems model highlights *inputs* (demands for change and support for action to address the demands) that feed into policy-making to produce *outputs* (the decisions and policies of government), and the linkages between them. Government decision-making that mediates inputs and outputs is considered the black box of policy-making.

This thesis explores the phenomenon of policy implementation through the lens of a complex programmatic strategy, namely, decentralisation of drug-resistant tuberculosis (DR-TB) treatment in the quasi-federal health system of South Africa. The thesis is grounded in the field of policy analysis and adopts the methodological approach of a qualitative case study.

This introductory chapter provides the background, rationale, and purpose of the research, highlighting contributions to understanding both DR-TB programming and the policy implementation gap more generally. The chapter starts by introducing the field of health policy implementation and then introduces the DR-TB programme as the lens for exploring policy implementation. The DR-TB burden in South Africa, the status of the programme, and challenges in DR-TB services, are detailed. Next, key events and evidence that have shaped the development of the national DR-TB decentralisation policy are outlined, with a descriptive account of the factors over the preceding decades that have informed the process of agenda setting and policy formulation. This formed the policy context for the implementation that followed, the focus of this thesis. The study settings of the Western Cape (WC) and KwaZulu-Natal (KZN) and the rationale for their selection are then described. Thereafter, the problem statement, research purpose, and aims and objectives of the research are outlined. The chapter concludes with an overview of the remaining chapters in this thesis.

1.1 HEALTH POLICY IMPLEMENTATION

The public policy process is divided into four main stages according to the stages heuristic framework: agenda setting, policy formulation, policy implementation, and policy evaluation (Brewer & deLeon, 1983). In health policy, agenda setting is the stage during which a health challenge or need comes to the attention of decision-makers. In the formulation stage, decision-making bodies design and enact policies in formal policy statements, law, or regulation. In the implementation stage, governments or other providers carry out these policies, and in the evaluation stage, impact is assessed. These stages are not linear and demarcations between them are blurred in practice (Sabatier, 2007). The implementation stage is widely recognised as a central challenge in the health policy process (Gilson et al., 2018) and a key preoccupation in the field of health policy and systems research (Bennett et al., 2018).

Implementation is defined as the “constellation of processes intended to get an intervention into use within an organisation” (Damschroder et al., 2009, p. 3) or the “act of carrying policies, programmes, or individual practices into effect” (Peters et al., 2013b, p. 1). It requires a “deliberately initiated attempt to introduce new, or modify existing, patterns of action in health care” (May et al., 2016, p. 3). Policy implementation therefore involves interventions that are institutionally sanctioned, formally defined, consciously planned, and intended to lead to a changed outcome.

Fixen et al. (2005; 2009) further divide policy implementation into six phases. The first phase, exploration and adoption, involves developing a strategy based on the policy ‘instrument’ (e.g. decentralised care). In the installation stage, goals are developed, funding secured, and the organisation adapted as required, such as recruiting additional staff. The phase of initial implementation that follows entails the complex process of organisational change. Full operation is achieved when the intervention is integrated into routine operations. The innovation and sustainability stages focus on activities throughout the life cycle of the intervention, such as programme adaptation to improve service.

Despite evidence of a policy’s efficacy and affordability, there can be significant variation in its effective implementation (Peters et al., 2013a). Looking inside the black box of implementation can reveal the sources of this variation and unpack the mechanisms that inform changes in outcomes (Parashar et al., 2020). Implementation research is the scientific inquiry into questions concerning implementation, and focuses on the gap between policy objectives and actual implementation (Hill & Hupe, 2002). It mobilises theories and methods to better understand what, why, and how interventions work in ‘real-world’ settings in order to improve policy and programme delivery (Ridde, 2016).

This thesis draws on a number of different frameworks and approaches for understanding the dynamics of implementation in the broader fields of implementation science and policy implementation research, spanning different disciplines, research traditions, and theoretical perspectives (Damschroder et al., 2009). Using implementation research approaches to understand implementation gaps often entails a specific focus or tracer through which the broader system phenomena can be understood (Gilson et al., 2018). In this research, the tracer phenomenon is the case of the DR-TB programme in South Africa, specifically the implementation of the DR-TB Decentralisation Policy Framework of 2011 (NDoH, 2011).

1.2 DRUG-RESISTANT TB (DR-TB)

DR-TB has emerged as a public health crisis due to decades of poorly performing TB programmes and inadequate drug development.

There are two pathways by which people contract DR-TB. Primary resistance results from infection with a drug-resistant strain, and secondary or acquired resistance from inadequate treatment of drug-sensitive (DS)-TB. The World Health Organization (WHO) classifies DR-TB into five categories, based on drug susceptibility testing (WHO, 2021):

- isoniazid-resistant TB: resistant to isoniazid and susceptible to rifampicin
- rifampicin-resistant TB (RR-TB): resistant to rifampicin and susceptible to isoniazid, regardless of resistance to other drugs
- multi-drug resistant TB (MDR-TB): resistant to isoniazid and rifampicin
- pre-extensively drug-resistant TB (pre-XDR-TB): resistant to rifampicin and any fluoroquinolone (a class of second-line anti-TB drug)
- extensively drug-resistant TB (XDR-TB): resistant to rifampicin, plus any fluoroquinolone, plus at least one of the drugs, bedaquiline or linezolid.

The WHO Global TB Report (2021) reports that globally, DR-TB continues to increase, particularly in 30 ‘high burden’ countries. In 2020, among 2.1 million people with confirmed TB tested for resistance, 157 817 cases of MDR/RR-TB and 25 584 cases of pre-XDR-TB or XDR-TB were detected. Treatment initiation remains suboptimal and in 2020, 150 510 people with MDR/RR-TB and 22 050 with pre-XDR/XDR-TB were enrolled on treatment. It has been estimated that of all the cases that commenced treatment in 2018, the treatment success rate was 59% for MDR/RR-TB and 52% for XDR-TB.

The COVID-19 pandemic has had a significant impact on DR-TB, setting the programme back decades (Monedero-Recuero et al., 2021; WHO, 2021; Tiberi et al., 2022). Between 2019 and 2020, globally there was an 18% decline in the total number of TB case notifications, 21% decline in TB preventive treatment, reduced access to treatment, 1 million more TB deaths, and a drop in global TB spending

from US\$5.8 billion to US\$5.3 billion. The DR-TB programme has seen a 22% decline in DR-TB case notifications and a 15% decline in the number of people with DR-TB (PWDR-TB) enrolled onto treatment (WHO, 2021). Targets set by the 2018 United Nations High-Level Meeting on the fight against TB, the Sustainable Development Goals, and the End TB Strategy are unlikely to be met (Monedero-Recuero et al., 2021).

1.2.1 Burden of DR-TB in South Africa

South Africa is one of 30 high burden countries that account for the majority of incident MDR-TB cases globally and has the second largest incidence of notified MDR/RR-TB cases in the world (after countries of the former Soviet Union). South Africa is also one of 10 countries that account for about 70% of the global gap between the estimated incidence of DR-TB each year and the number of people enrolled in treatment (WHO, 2021).

TB resistance surveys conducted across South Africa showed an increase in the rate of rifampicin resistance from 3.4% in 2001–2002 (Weyer et al., 2007) to 4.6% in 2012–2014 (NICD, 2016). According to the WHO Global TB Report (2021), it is estimated that in 2021, approximately 1.8% of new TB cases and 6.7% of previously treated TB cases in South Africa had MDR-TB. Only 8,804 (65%) of MDR-TB and 1,429 (57%) XDR-TB cases diagnosed in 2018 in South Africa started treatment, often with considerable delays. Of the 2018 cohort of RR-TB cases, among the patients with recorded outcomes, the RR-TB treatment success rate was 49%, falling short of the WHO target of 75%. In 2020, due to disruptions in screening and care caused by COVID-19, only 6,784 MDR-TB cases were diagnosed, down from 13,005 in 2019.

DR-TB is of particular concern in South Africa where the overlap of the TB and Human Immunodeficiency Virus (HIV) epidemics have resulted in one of the world's highest burdens of DS-TB, DR-TB, and TB-HIV co-infection. In 2020, 7.8 million South Africans were living with HIV (UNAIDS, 2020) and 57% of people with DR-TB (PWDR-TB) were HIV-co-infected (WHO, 2021). TB is the leading cause of mortality in people living with HIV (PLWH) (WHO, 2021). Socio-economic conditions, including overcrowded informal housing, migrant labour, and inequitable health services have fuelled transmission of both HIV and TB (WHO, 2014).

1.2.2 The South African DR-TB programme

In the 1980s, reports emerged of resistance to isoniazid, rifampicin, and streptomycin, core drugs used in TB regimens (Cox et al., 2017). Nevertheless, the management of DR-TB in South Africa remained firmly focused on DS-TB and implementing the DOTS (Directly Observed Treatment, Short-course) strategy adopted by WHO in 1996. DOTS, advocated as the most effective strategy available for containing the TB epidemic, had five key components, including government commitment; case

detection; standardised treatment regimen of six to eight months with directly observed treatment for at least the initial two months; regular uninterrupted supply of anti-TB drugs; and a standardised recording and reporting system (WHO, 2011). In the 1990s, informally developed clinical treatment guidelines for DR-TB were being used that employed individualised treatment regimens based on resistance testing (Cox et al., 2017). By the late 1990s, the growing burden of DR-TB was beginning to be recognised and the urgent need to address it was highlighted by local TB experts and international non-governmental organisations (NGO). In 1999, the National TB Programme introduced the first national guidelines for the treatment of MDR-TB (DOTS-Plus), providing for either individualised or standardised treatment regimens.

However, the South African Government expressly stated that the priority remained strengthened implementation of the overall national TB programme, and the MDR-TB guidelines of June 1999 noted that, “There is no point using scarce health care resources for the treatment of MDR tuberculosis while neglecting to properly implement the National Tuberculosis Control Programme, since most cases of MDR tuberculosis arise as a result of a poorly applied Tuberculosis Control Programme” (NDoH, 1999 p. 2).

An XDR-TB outbreak in 2005 in Tugela Ferry in the KwaZulu-Natal province, and the release of the revised WHO DR-TB treatment guidelines in 2006, prompted revision of the national DR-TB guidelines, relying principally on standardised treatment. From 2008, the guidelines recommended that the sub-set of people with MDR-TB already exposed to second-line TB drugs, people with pre-XDR-TB, and XDR-TB be treated with an individualised drug regimen based on drug-sensitivity testing for each person. Standardised treatment regimens were given to PWDR-TB in the absence of individual drug-sensitivity testing, and in practice, were more commonly used across South Africa as second-line testing was not widely available (Cox et al., 2017).

In line with WHO guidelines, the policy in South Africa was to hospitalise PWDR-TB for the initial six months of the ‘intensive phase’ of treatment until they were no longer infectious, and to allow for daily injections and close monitoring for adverse events. Following discharge, and for the remaining 18 months or longer of treatment, they were expected to return for monthly outpatient visits to the same institution (Loveday et al., 2012). The rationale for these guidelines was to ensure that patients who were treated with complex DR-TB regimens would be managed and monitored for side-effects by experts, ensuring treatment adherence and limiting community transmission. Prior to 2000, only a limited number of specialised hospitals were treating MDR-TB. Around 2000, one DR-TB centre of excellence (CoE) was established in each province, usually in an urban setting. Community-based models were limited to linking patients diagnosed with DR-TB to specialised care, and for contact tracing and tracking patients in their communities who had been lost to follow-up.

In 2011, a national policy for decentralised DR-TB treatment was adopted (NDoH, 2011). Programme improvements were also enabled by new diagnostic tests including the ‘line probe assay’ in 2007, followed by GeneXpert in 2012 (Erasmus et al., 2011). In the years that followed, new and repurposed drugs for the treatment of DR-TB and shorter treatment regimens were introduced (NDoH, 2015). South Africa pursued an aggressive strategy to address DR-TB, in 2012 implementing compassionate use access programmes to bedaquiline and delamanid that had shown great promise, and then formally rolling out these drugs in the national DR-TB programme in 2015. Injection-free regimens were adopted in 2017 and shortened regimens of 9–12 months in 2019.

However, despite bold policy advances with the introduction of effective diagnostic and treatment strategies and with improving access to care through decentralisation, implementation of these policies has been a challenge (Cox et al., 2017). A review of the DR-TB programme by the National Department of Health (NDoH) and WHO in 2015 revealed that decentralisation has been slow and varied across provinces (NDoH/WHO, 2016). Health systems challenges continue to impact the implementation of the policy (Loveday et al., 2014) and weak health systems compromise DR-TB prevention and care (Iacobini et al., 2020; Cox et al., 2019). As a result, despite decentralised care improving treatment initiation, treatment outcomes remain poor with high loss to follow-up (LTFU) and early mortality (Cox et al., 2014; Loveday et al., 2015).

The next sections describe the challenges faced in the DR-TB programme and the history, events, and stakeholders involved in agenda setting and formulation of the decentralisation policy. This serves to provide essential historical context for the further exploration of the dynamics of implementation of the policy.

1.2.3 DR-TB as a complex health challenge

Before 2011, DR-TB was far more difficult to treat than DS-TB, requiring lengthy, complex, low-efficacy treatment regimens, costly second-line drugs, and provision of treatment in specialised centres (Cox et al., 2017; Kendall et al., 2019). The DR-TB care pathway had to provide for early diagnosis at primary health care (PHC) level, referral to DR-TB treatment centres, provision of daily treatment including injections, monitoring and management for adverse events, and high levels of adherence throughout a 24-month period (Brust et al., 2012).

There were significant gaps throughout the DR-TB care cascade, which resulted in many patients remaining undiagnosed and untreated, contributing to ongoing transmission of DR-TB (Cox et al., 2019). In studies conducted between 2005 and 2009, treatment initiation delays of up to 16 weeks were reported due to bed shortages, long waiting lists, and unwillingness of PWDR-TB to be hospitalised for

long periods (Wallengren et al., 2011; MSF, 2011; Nardell et al., 2010). These delays resulted in high initial LTFU, with a study in 2011 showing that only 63% of newly diagnosed PWDR-TB initiated treatment (Ebonwu et al., 2013). In Tugela Ferry between 2005 and 2007, 40% of PWDR-TB died before treatment initiation (Gandhi et al., 2010). A 2014 study of the treatment journey of PWDR-TB highlighted a multitude of health system bottlenecks, including a six-week delay to receive culture results, a month's delay for hospital admission due to an inpatient bed shortage, incomplete treatment regimens as a result of drug stock-outs, and delayed antiretroviral therapy (ART) initiation (Padayatchi et al., 2014).

For PWDR-TB who were started on treatment, treatment adherence was suboptimal, and many failed to complete treatment. DR-TB treatment was difficult to tolerate due to high pill burdens, long treatment duration, and frequent drug-related adverse events (Loveday et al., 2015). PWDR-TB were also not adequately supported and not informed about the duration of therapy or inpatient hospitalisation (Farley et al., 2011). Patients discontinued drugs when side-effects were intolerable, when they felt better, or when they believed treatment was futile as they failed to achieve a cure (Isaakidis et al., 2013). Other factors associated with poor adherence included younger age, male gender, HIV co-infection, previous DR-TB treatment, and substance abuse (Gajee et al., 2016). As a result of poor retention in care, PWDR-TB remained infectious for prolonged periods, increasing the risk of transmission (WHO, 2014).

HIV co-infection further complicated DR-TB treatment due to lack of integrated services and added health system costs (Farley et al., 2014). HIV co-infection introduces multiple additional challenges with DR-TB diagnosis, ART and DR-TB treatment interactions and poorer adherence (WHO, 2014; Singh et al., 2020), more rapid disease progression, and poorer outcomes (Brust et al. 2010; Farley et al. 2011; Chem et al., 2019).

Early mortality in the first weeks after DR-TB treatment initiation was considerable. Analysis of cases in the national Electronic DR-TB Register (EDRWeb) from 2012 to 2014 found that 44% of the DR-TB deaths occurred within the first three months of the 24 months of treatment (Schnippel et al., 2017). DR-TB treatment success rates in South Africa, while slowly rising, remained around 50% and well below global norms (WHO, 2021).

Globally, poor DR-TB treatment outcomes were reported to be related to providers, health system factors, and PWDR-TB (WHO, 2014).

- a. Providers: inappropriate treatment by health care providers (inappropriate or absent guidelines, poor training of physicians and nurses, suboptimal education of patients, poor management of adverse drug reactions, no monitoring of treatment, poorly organised or funded TB prevention and care programmes)

- b. Health system factors: inadequate drug supply (poor quality medicines, stock-outs, poor storage conditions, wrong dose or combination)
- c. People with DR-TB: inadequate drug intake or treatment response by PWDR-TB (social barriers, lack of information on treatment adherence, adverse effects, HIV, diabetes, undernutrition, malabsorption, substance abuse, psychiatric conditions).

Similar weaknesses have been reported in studies in South Africa. Studies documented inadequate DR-TB treatment and care by health care workers (HCWs). Doctors and nurses had insufficient knowledge and did not comply with DR-TB guidelines, for example not taking sputum samples for microscopy and subsequent culture, leading to diagnostic delay. Besides delays in diagnosis and treatment, inadequate treatment regimens, and poor treatment monitoring resulted in poor outcomes (Loveday et al., 2008). Negative HCW attitudes and limited resources with which to trace persons LTFU contributed to this (Loveday et al., 2014). Lack of support from HCWs to ensure treatment adherence in the face of overburdened clinics and the stigma attached to DR-TB was an added challenge (Cox et al., 2017).

A key additional health system factor was the centralisation of DR-TB care in CoEs that resulted in specialised centres becoming overwhelmed, with long waiting lists and bed shortages, and patients facing significant barriers to accessing care. Limited beds and long waiting lists delayed treatment initiation by two to three months. After discharge, there were insufficient resources to properly monitor all PWDR-TB for adverse events and to ensure adherence in those living far from the central hospital. Some patients had to be discharged before the end of the intensive phase to hospitals that had no capacity or resources for managing DR-TB, resulting in poor continuity of care, high LTFU, and poor treatment outcomes.

The centralised DR-TB programme was also costlier and diverted resources from national TB prevention and care (Dhedha et al., 2017). Pooran et al. (2013) estimated that the per patient cost of XDR-TB was four times greater than MDR-TB and 103 times greater than DS-TB. Despite DR-TB comprising only 2% of the case burden, it consumed 32% of the national TB budget in 2011. Drugs and hospitalisation were responsible for 71% of the MDR-TB and 92% of XDR-TB costs.

Finally, PWDR-TB faced catastrophic economic and social costs being isolated in hospitals, often far from home (Ramma et al., 2015; Wingfield et al., 2014). Some patients travelled up to 500 km to the central hospital and did not have funds for the monthly, arduous trips (Padayatchi et al., 2008). PWDR-TB were unable to work during lengthy therapy and household income was significantly reduced (van den Hof et al., 2016). While PWDR-TB were eligible for disability grants, there were often delays in accessing the grants, and they were insufficient to support them and their families (Cox et al., 2017). Many patients were required to have directly observed therapy (DOT) daily at the PHC clinic, which

was suggested to actually compromise adherence as patients incurred transport costs, were unable to attend work or school, and experienced discrimination from HCWs and community members (Dhedha et al., 2017).

These historical programmatic challenges were significant factors in shaping the later implementation of the DR-TB decentralised care policy.

1.3 THE IMPETUS FOR POLICY CHANGE

The need to address the challenges in the DR-TB programme drove a national policy response. Figure 1 below summarises the timeline of policy formulation, suggesting five key phases leading up to and influencing development of the DR-TB decentralisation policy of 2011.

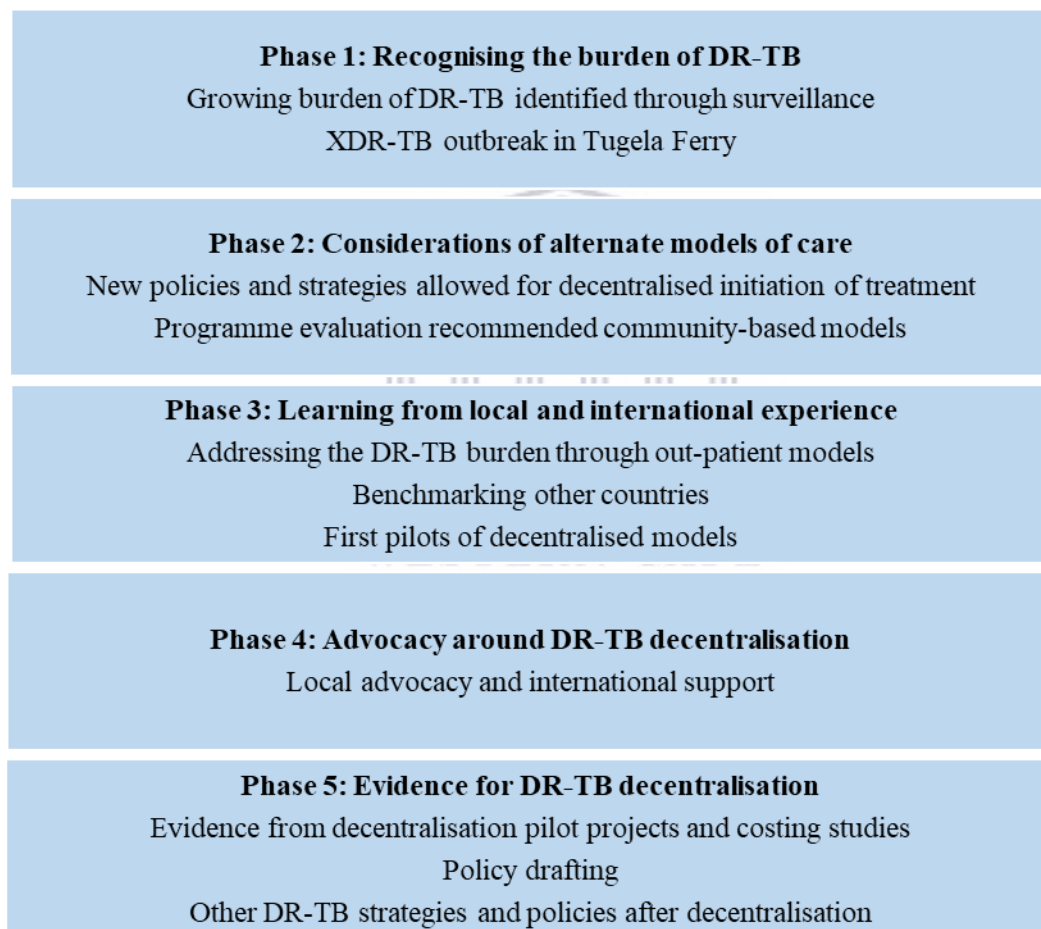


Figure 1: Phases that led to the formulation of the 2011 decentralised DR-TB policy

1.3.1 Recognising the burden of DR-TB

The first national TB resistance survey was conducted by the South African Medical Research Council (MRC) between 2001 and 2002, detecting DR-TB in 3% of people tested. In 2004, the South African government declared TB a national emergency and adopted a crisis plan with the goal of raising political commitment for the TB crisis and securing resources for TB prevention and care.

In October 2005, an outbreak of XDR-TB occurred in Tugela Ferry, a rural hospital in KZN Province, during which 39% of people with TB were reported to have MDR-TB and 6% XDR-TB. XDR-TB was rapidly and almost uniformly fatal, and all the patients identified were found to be HIV-positive (Ghandi et al., 2006). Nosocomial re-infection was frequently the source of drug-resistant disease, and the causal strain of the outbreak was found to be responsible for cases of DR-TB stretching back to 1994, and cases of XDR-TB since 2001.

This event caused a global sensation and created renewed attention to DR-TB throughout South Africa, prompting the NDoH to take ownership of the programme. In 2006, technical advisors seconded by WHO, conducted a review of laboratory data from the National Health Laboratory Service to work out the proportion of PWDR-TB (Wallengren et al., 2011). While the world was focused on XDR-TB reported from Tugela Ferry, the results showed that DR-TB was a much broader problem across South Africa than previously believed. The huge burden of undiagnosed DR-TB would not have been possible to manage with the specialised hospital capacity that existed at the time, suggesting community-based treatment as a measure for addressing the problem. There was also increasing evidence of the large burden of community transmission, with much more primary DR-TB being identified than acquired infection in patients who had received prior TB treatment. The report also touched on the origins of the DR-TB problem, suggesting that it was partly due to poor treatment of TB (there were anecdotal reports of a rural KZN site using a three-day per week TB regimen) and use of fluoroquinolones in PLWH who had diarrhoea, creating resistance.

1.3.2 Considerations for alternate models of DR-TB care

With the growing recognition of the burden of DR-TB in South Africa, many reports highlighted the need for adopting new approaches to DR-TB treatment. Service pressures played a part in the growing calls for new models. The CoEs had insufficient beds, experienced lengthy waiting times for DR-TB beds, and reported on the huge costs of long periods of hospitalisation. Waiting lists were reduced by decanting patients to other hospitals for the continuation phase of their DR-TB treatment. Despite this, PWDR-TB still waited for up to three months to access a CoE bed. Indicating growing public health concerns, in July 2008, a provincial High Court ruled it legal to forcibly isolate people with XDR-TB, provoking a rise in protests and violence in hospitals. Community-based treatment became recognised as a strategy that could help ease some of these tensions.

The HIV & AIDS and STI Strategic Plan for South Africa, 2007–2011 (SANAC, 2007) and the Tuberculosis Strategic Plan for South Africa, 2007–2011 (NDoH, 2007a), made explicit the goal of providing people with TB easy access to effective, efficient, and high-quality diagnostic, treatment, and care services; and addressing MDR- and XDR-TB. In June 2007, the draft Policy Guidelines for the

Management of Drug Resistant Tuberculosis in South Africa were released, acknowledging for the first time that non-availability of beds should prompt DR-TB units to ensure patients were initiated at local hospitals but with DR-TB units still responsible for their care (NDoH, 2007b). An article published in the *Lancet* around this time (Basu et al., 2007) concluded that “to develop and implement parallel community-based programmes could prevent nearly half of XDR-TB cases, even in a resource-limited setting.”

In August 2007, a rapid appraisal of community-based DR-TB care conducted for the NDoH, cautioned of “... a risk that adapting a standard ‘one size fits all’ approach to community-based MDR-TB programme management has the potential to rapidly erode capacity in districts or provinces struggling with high MDR burdens” (Bellis, 2007, p. 7). It offered a number of recommendations around community-based services (Box 1).

Box 1: Recommendations from rapid appraisal of community-based DR-TB care

1. The existing MDR bed system is operating at close to maximum capacity and requires an intervention (capital build and/or community support) to maximise effective use of beds.
2. Community-based MDR Support Teams have been shown to be effective (in SA and other countries) but will require additional funding to be properly staffed. Their role should include supporting contact tracing and community education for all TB patients about completing a course of treatment.
3. Community-based MDR Support Teams should be integrated into the District Hospital to create an effective interface with hospital clinicians and MDR specialist centres.
4. Only programmes that meet or are showing consistent progress to meet the DOTS strategy targets should be allowed to undertake community-based MDR schemes. This should be via a documented accreditation process to be undertaken by provincial Departments of Health supported by the National TB Programme.
5. Policy guidelines for drug-resistant TB should be strengthened with a separate section on HR requirements and the importance of the use of multi-functional teams for community-based schemes.

1.3.3 Learning from local and international experience

As an alternative to prolonged hospitalisation, varying decentralised models began to be piloted globally, including community-based care in Peru, prison/hospital combination in Russia, combined hospital/community approach in Lesotho, and home-based care in Uganda. These models employed combinations of shorter hospitalisation and home-based DR-TB management where patients were visited by a nurse for the administration of injectable drugs and supervision of oral medications. The

NDoH and provinces began benchmarking exercises with these countries to learn from their experiences, and sent clinicians to Latvia for DR-TB training. Development partners funded the KZN Province and the uMzinyathi district staff to visit Lesotho to benchmark their community-based treatment. Following this visit, uMzinyathi district implemented a pilot project with treatment initiated at Greytown Hospital and ambulatory care provided by mobile, nurse-led teams visiting PWDR-TB at their homes. In the meantime, in the WC Province, Médecins Sans Frontières (MSF) were supporting HIV services in Khayelitsha, and in June 2008, began implementing a pilot programme for the provision of decentralised DR-TB care and treatment at 11 PHC clinics.

1.3.4 Advocacy around DR-TB decentralisation

Adding to the growing call for community-based care models, in about 2008 public health activists, NGOs, and members of the scientific community began advocating for the decentralisation of DR-TB. At the first TB Conference in Durban in June 2008, there was still significant resistance to decentralised DR-TB care, and decentralised DR-TB did not feature in the official conference programme. However, at the International AIDS Society Conference in Cape Town in July 2009, MSF ran a satellite symposium on decentralised DR-TB care with speakers including local implementers. By the second TB Conference in Durban in June 2010, MSF had around eight oral presentations describing aspects of decentralised DR-TB care in Khayelitsha, and these were generally well received.

In October 2008, the national MDR-TB guidelines were still in draft format and at that point did not contain any reference to decentralisation. The then AIDS Law Project (now Section 27), Treatment Action Campaign (TAC), and AIDS and Rights Alliance for Southern Africa (ARASA) submitted comments on the publicly released draft, highlighting problems with forced hospital admission, and discussing the need for home-based care, citing both pilot projects in Tugela Ferry and Khayelitsha. In April 2009, a ministerial meeting of MDR-/XDR-TB high burden countries was held in Beijing aiming to scale up DR-TB management and develop national five-year strategic plans that promoted universal access to DR-TB treatment. The meeting resolved that either hospital-based or community-based outpatient care models may be used depending on the setting.

1.3.5 Evidence for DR-TB decentralisation

Signalling a new phase in the policy process, in 2009 the new NDoH DR-TB Director, brought together a group of TB experts to start writing the policy for DR-TB decentralisation. As they embarked on the policy-writing process, policy-makers were able to consider the emerging evidence from the two pilot projects before it had appeared in the scientific literature. The experience of these pilot projects revealed that decentralisation was feasible and improved access to care.

MSF supported the City of Cape Town's (CoCT) 2007 model used in Khayelitsha, integrating DR-TB management into PHC. The model was implemented incrementally by MSF and CoCT, and included HCW training and support, PHC treatment under care of medical officers, routine monitoring, and patient counselling and home-based support. PWDR-TB were only hospitalised if clinically unstable. Rapid diagnosis, treatment close to the people's homes, and improved tracing contributed to earlier treatment initiation. However, treatment outcomes remained below those reported from other studies (Cox et al., 2014).

In KZN, decentralised care was piloted in 2008 in four district hospitals across the province, where patients were initially hospitalised and then followed up monthly as outpatients. Decentralised sites utilised mobile injection teams and local PHC clinics to administer injectable treatment, to counsel and educate patients and their families, and to follow up patients who missed appointments. A study reported a reduced time to treatment initiation to a matter of days, lower LTFU, and higher culture conversion at decentralised sites compared to the central hospital. However, there was higher mortality at decentralised sites (Loveday et al., 2012).

A pilot programme in Hlabisa sub-district of KZN revealed that community-based treatment for DR-TB was both feasible and safe in rural South Africa. Median time to sputum conversion was shorter for community-based management than hospital management (Heller et al., 2010). Treatment outcomes in short stay inpatient then home-based care was similar to long stay inpatient care in DR-TB facilities. Integrated, home-based treatment for DR-TB and HIV achieved good treatment outcomes, with lower LTFU, with only 9% of PWDR-TB requiring escalation of care and 6% who died (Brust et al., 2012).

Community-based models used nurses, community health workers, or family members to directly observe treatment at home or in the PHC clinic, and employed a mix of interventions, including support groups, social assistance, routine home visits, and clinician support. Community-based care was reported in a systematic review to be more effective than hospitalised models of care, providing improved access to diagnostic and treatment services, resulting in improved treatment adherence and lower LTFU, shorter time to treatment initiation, improved treatment success, and enhancing support to PWDR-TB and their families (Williams et al., 2016). Community-based treatment enabled patients to reintegrate into family, social, and work life (Seung et al., 2015).

A cohort study in Uganda reported decentralised treatment to be more acceptable to PWDR-TB, families, communities, and HCWs (Horter et al., 2014). Furthermore, it was perceived as safe, it facilitated psychosocial support, and it allowed patients time to be able to work and earn an income. In rural KZN, care closer to home was easier to access, convenient, allowed family support, and eliminated long and costly trips to a centralised hospital (Loveday et al., 2015).

Contrary to the belief that decentralisation may increase transmission of drug-resistant strains, community-based care models in eSwatini resulted in earlier treatment initiation and less need for infectious PWDR-TB to travel on public transport to distant DR-TB central hospitals, as well as lower risk of nosocomial infections while hospitalised (Kershberger et al., 2019).

A number of costing studies also demonstrated the cost savings and cost-effectiveness of decentralised DR-TB care and community-based services in South Africa due to reduced hospitalisation (Pooran et al., 2013; Schnippel et al., 2013).

In summary, the impetus for the DR-TB policy change can be framed by the Kingdom's 'three policy streams' of agenda setting as an interplay of the disease (problem), prevailing political forces (politics), and evidence showing programme alternatives (policy alternatives) (Kingdon, 1984). Government response was driven by the high disease burden, patients refusing to be admitted for lengthy periods, resource challenges and bed shortages in central DR-TB hospitals, as well as by the Tugela Ferry XDR-TB outbreak, which served as a focusing event. In addition, growing attention by activists, the mass media, and humanitarian organisations, resulted in pressure on policy-makers to act. Research evidence showed effective implementation of decentralisation in pilot sites (Sallie & Douglas, 2017).

As a result, the government engaged stakeholders to develop proposals around decentralisation of DR-TB care and treatment. The Global Fund committed resources for establishing 45 DR-TB treatment units, the National TB Programme committed over US\$200 million to the DR-TB programme, and a series of DR-TB treatment guidelines were issued (Churchyard et al., 2014). In 2011, WHO recommended that "patients with multidrug-resistant tuberculosis should be treated using mainly ambulatory care" (WHO, 2011, p. 26).

1.3.6 MDR-TB decentralised policy framework

The Multi-Drug-Resistant Tuberculosis: A Policy Framework on Decentralised and Deinstitutionalised Management for South Africa, launched in August 2011, shifted the paradigm from an institution-based model to a decentralised care model. The policy proposed transferring responsibility for the treatment of PWDR-TB to lower levels of the health care system (decentralisation) and reducing the length of hospitalisation for those who required admission (deinstitutionalisation) (NDoH, 2011). The policy stipulated that "all MDR-TB smear-negative, TB culture-positive patients be started on [outpatient] treatment. MDR-TB patients without extensive disease, [who are] stable [and] smear-positive should be admitted until two negative smear microscopy results are received. Only very sick MDR-TB [patients] with extensive disease and XDR-TB patients will be admitted until they have two consecutive TB culture negative results" (NDoH, 2011, p. 2).

The decentralisation policy described four levels of care for PWDR-TB, including initial admission or initiation at a CoE or a decentralised DR-TB unit, ongoing treatment at satellite PHC facilities, as well as home- or community-based services (Figure 2). Patients would initiate treatment at district level DR-TB units, then be referred to the closest PHC facility for DOT, injectable treatment, and monitoring of side-effects and adherence. XDR-TB, paediatric, and patients with complications would continue to be treated at centralised, provincial CoEs.

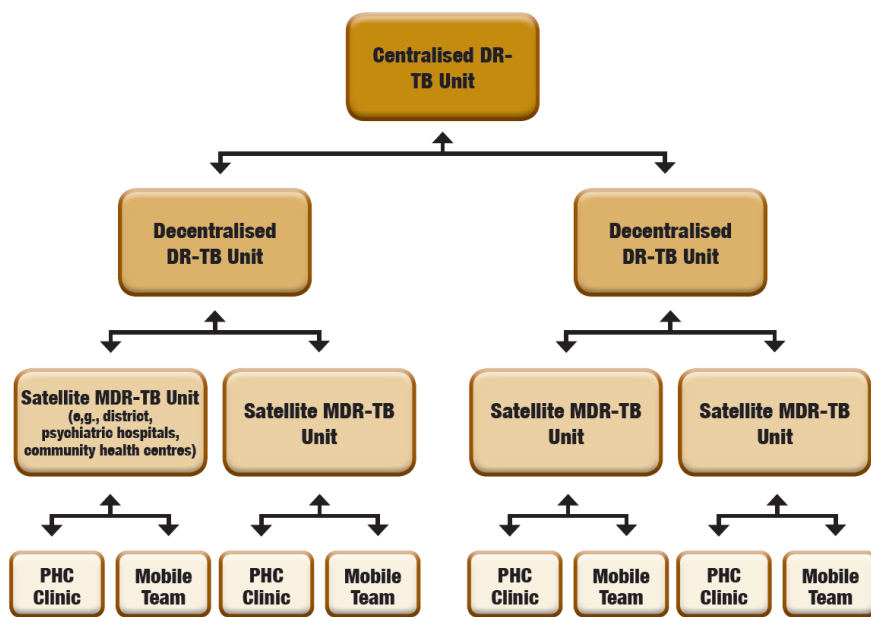


Figure 2: Units of care in the decentralised management of DR-TB

Source: NDoH, 2011, p. 19

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Each province would be required to establish a number of DR-TB units, depending on the burden of disease and geographic access issues. These could be whole DR-TB hospitals, or wards in provincial or district hospitals. It was intended that every district would establish at least one DR-TB initiation site. The policy also detailed the organisational and human resource requirements; and expected functions of each level of operations.

Following a national review of decentralised DR-TB care in South Africa (NDoH, 2018), an updated policy framework was released in May 2019, Multi-Drug-Resistant Tuberculosis: A Policy Framework on Decentralised and Deinstitutionalised management for South Africa (NDoH, 2019a). To reduce confusion associated with role definition and referral, the revised policy defined two types of DR-TB services, facilities that initiate DR-TB treatment and facilities that do not initiate but provide clinical follow-up, monthly refill of medicines, and monthly laboratory monitoring. The treatment initiation site could be managed by a medical officer, a clinical associate, or a clinical nurse practitioner. The revised

policy also clarified the provision of outreach services, a full-time on-site clinician initiator not being a requirement for DR-TB treatment initiation at these facilities.

The revised policy defined the modalities of DR-TB care, as either admission, ambulatory care, or home-based/community care. The previous NDoH policy dictated that PWDR-TB be hospitalised in centralised DR-TB units until they had two consecutive negative TB cultures taken at least 30 days apart. The revised policy stipulated that all stable RR/MDR-TB patients in fair to good general condition be started on ambulatory treatment regardless of their bacteriological status.

The initial target to establish at least one treatment initiation site per district was achieved in 2015. The target of the revised policy was to achieve at least one DR-TB treatment initiation site per sub-district.

The revised decentralisation policy of 2019 also explicitly advocated for a patient-centred approach, namely, that the treatment modality (ambulatory care, hospital admission, or community-based care) be dictated by the patient's needs (NDoH, 2019a). This is in line with the WHO TB strategy for ending TB, which places patient-centred care as a central pillar for achieving improved TB outcomes. Patient-centred care is about treating a person receiving healthcare with dignity and respect and involving them in all decisions about their health (WHO, 2014). Effective treatment is influenced by individual, economic, health system and social factors, which can be addressed through social support, including informational, emotional, companionship and material support (WHO, 2014).

1.4 PROBLEM STATEMENT

South Africa is one of the high burden countries for DR-TB globally (WHO, 2021). Many people with DR-TB are not detected early, a large proportion of those diagnosed do not receive treatment, and of those who are treated, treatment outcomes are poor (Cox et al., 2017). A policy supporting decentralised DR-TB treatment provision was introduced in 2011, but to date implementation has been suboptimal with variable coverage and quality of decentralised services, and suboptimal treatment outcomes (NDoH/WHO, 2016). WC has the largest number of DR-TB treatment initiation sites, while KZN has the least decentralised DR-TB services in the country (NDoH, 2019a). Poor treatment outcomes have been reported in WC (Cox et al., 2014) and KZN (Loveday et al., 2015) where decentralisation was first implemented. Health systems challenges continue to impact the implementation of the policy (Cox et al., 2017; Leavitt et al., 2021; Vanleeuw et al., 2020).

A number of advances in diagnosis and treatment have been introduced over the past 10 years to address the growing burden of DR-TB in South Africa (NDoH, 2018). However, these much needed technologies will have little impact unless the health system and service delivery capacity also improve (Cox et al., 2013; Padayatchi, et al., 2014), and unless attention is paid to individual and organisational

processes of adopting and integrating complex care strategies. Researchers have described health systems barriers, but have not examined the dynamics of DR-TB care implementation. It is important to understand what informs successful implementation, to improve the way new interventions are implemented in the DR-TB programme. This remains a key knowledge gap in the field, reflecting a wider lack of understanding.

While researchers have pointed to the recurring systems barriers to implementing health policy, there remain major gaps in understanding the implementation process itself. Early reviews mapping the evidence-base on policy implementation in low and middle-income countries (LMIC) settings, concluded that the body of literature was relatively small, fragmented, and of limited depth (Erasmus et al., 2014). Policy research examined content, but neglected the actors involved in policy reform, processes of implementing change, and the context within which policy is developed (Walt & Gilson, 1994). Gilson and Raphaely (2008) provide a critique of the body of policy implementation research that existed at the time. The field was regarded as still in its infancy and dominated by authors from the global North. Policy studies focused on policy development rather than implementation, and on national perspectives rather than sub-national implementation. Implementation studies seldom drew on conceptual frameworks and relevant theory to underpin their analysis. There was little detail on research design and methodology, and most studies were descriptive, with few attempting to provide an explicit, explanatory focus. Reflexivity on the part of researchers and analysis of their own institutional power, resources, and positions was absent or limited. Other papers have also suggested that policy research paid insufficient attention to politics, process, and power, and how the “exercise of power by those upon whom action depends influences implementation of policies, programmes, and interventions” (Gilson et al., 2014, p. 52).

In recent years a growing body of literature has addressed these weaknesses. Still, little research has been done to understand the dynamic interplay between individuals and the organisation within which they work, and how that interplay influences change processes, particularly in LMICs. There is a need for research that explains why, with adequate investment in health, good policy fails to be implemented well.

1.5 RESEARCH PURPOSE

This PhD thesis critically examines health policy and implementation through the lens of the DR-TB programme, to understand how the decentralisation policy of 2011 was variably implemented, and the factors explaining this at sub-national level in South Africa. Studying two provinces with high TB burdens and distinct programme trajectories (WC highly decentralised and KZN least decentralised), enabled an exploration of why implementation of DR-TB decentralisation varied, by considering the interplay between processes, actors, and context of health policy implementation. The purpose of this

research is to contribute to understanding the barriers and facilitators to effective implementation of quality, decentralised DR-TB services. It seeks to inform improvements in planning and management of the DR-TB programme, as well as open the implementation black box, contributing to a broader understanding of the policy-implementation gap and how to bridge this gap.

1.6 RESEARCH AIMS AND OBJECTIVES

The research aimed to explore the implementation of the decentralised DR-TB programme and examine the factors explaining the differences in programme implementation in two South African provinces, Western Cape (WC) and KwaZulu-Natal (KZN).

The study objectives were as follows:

1. To describe DR-TB policy implementation models that emerged and their programmatic outcomes
2. To explore key characteristics of the DR-TB policy content, including its complexity, the evidence on which it was based, how it was framed and detailed in policy documents, and how it was interpreted by implementing actors
3. To identify the policy actors both inside and outside the health system involved in DR-TB policy implementation, and to examine their power, agency, and influence on the programme
4. To describe the policy chronology, and the processes adopted for planning, scale, sequence, and timing of implementation, as well as for local adaptation
5. To describe the contextual factors at national, sub-national and local levels that acted as implementation barriers or facilitators

1.7 OVERVIEW OF STUDY SETTING

WC and KZN Provinces have the highest burden DR-TB and account for around half of the MDR-TB and XDR-TB cases in South Africa (NDoH, 2019a). These provinces have a long history of decentralised DR-TB services and provided early lessons from the implementation of pilot programmes from 2007–2010. They implemented decentralised care very differently, with WC achieving 100% coverage through PHC and outreach models shortly after the policy was launched, while KZN achieved 44% of sub-districts with an initiation site by 2019. Treatment success for the 2017 MDR-TB treatment cohort was 55% in WC and 63% in KZN, compared to the national average of 60% (Dlamini et al., 2020).

1.7.1 Western Cape

In WC, a decentralised treatment programme was implemented in Khayelitsha which reduced delays to treatment initiation and improved treatment success (Cox et al., 2015). WC had one centralised site (Brooklyn Chest Hospital) and five decentralised sites (Brewelskloof Hospital, Sonstraal Hospital, ID

Hospital, Harry Comay/Nelspoort Hospital, and DP Marais Hospital). By 2019, 406 health facilities (predominantly clinics and mobile units rather than hospitals) in the province were able to initiate DR-TB treatment in rural areas, largely through outreach models.

WC Province covers an area of 129,462 km² (SA Government, 2017) and has a population of 7.1 million (StatsSA, 2021). It is the fourth largest province in South Africa by surface area, and also ranks fourth in terms of population size. WC is divided into six health districts (one urban metropolitan CoCT, and five rural districts), and is further sub-divided into 24 sub-districts. CoCT Metro is home to 66% of the people in the province (WC, 2021).

There are significant differences in resourcing and geographic access challenges between the urban CoCT metropolitan district and the rural districts. Transport routes are good in the urban metropolitan district and it is estimated that most residents have access to a health clinic within 3–5 km of their homes. Rural districts are less densely populated, have more limited coverage and access to health facilities, and poorer transport routes and networks. The WC Province as a whole has historically been better resourced and managed than other provinces, and in the urban CoCT metro district, there are a higher number of health facilities per capita than in many other districts around the country. The 2016 Demographic Health Survey (NDoH/StatsSA/SAMRC/ICF, 2016) reported the following indicators of health care access and utilisation: 32% medical insurance coverage; the source of outpatient health care in the past month was 30% government hospital, 20% government clinic, and 44% private provider; and 23% of women reported having serious problems in accessing health care. The employment rate amongst men aged 15–49 years was 60%; and 46% of WC residents were in the highest quintile of wealth and 3% in the lowest.

1.7.2 KwaZulu-Natal

Ambulatory second-line treatment was first introduced in uMzinyathi district, the setting of the XDR-TB outbreak in Tugela Ferry, which was followed by the implementation of four decentralised DR-TB sites in district hospitals between 2008 and 2011. These decentralised models resulted in early treatment initiation and adherence being much improved (Brust et al., 2012; Loveday et al., 2012). KZN had one centralised site (King Dinizulu Hospital) and four decentralised sites (Greytown Hospital, Murchison Hospital, Catherine Boothe Hospital, and Manguzi Hospital) before the policy in 2011. By 2019, KZN had 42 initiating sites, with 19 sub-districts (44%) having a DR-TB site.

KZN has the highest burden of HIV and TB in the country, with 80% TB/HIV co-infection. The province also has the highest burden of DR-TB, with all 11 districts in the province reporting proportions of resistance above the national average (NDoH, 2019a).

KZN Province covers an area of 94,361 km² (SA Government, 2017) and has a population of 11.5 million (StatsSA, 2021), with 88% served by public health services (KZN, 2021). It is the third smallest and the second most populous province in the country. KZN is divided into 11 health districts (one urban metropolitan, eThekweni Metro, and 10 rural districts) and further sub-divided into 43 sub-districts.

Similar to WC, in KZN there are differences in resourcing and geographic challenges between urban and rural districts. Transport routes are good in the metropolitan and it is estimated that all residents have access to a health clinic within 3–5 km of their homes. KZN has a number of rural districts that are among the poorest and least developed in South Africa. Rural districts are less densely populated, have more limited coverage and access to health facilities, and poorer transport routes and networks. KZN continues to have unacceptably high percentages of households with no access to piped water and electricity (KZN, 2021). The 2016 Demographic Health Survey (NDoH/StatsSA/SAMRC/ICF, 2016) reported the following indicators of health care access and utilisation: 12% medical insurance coverage; the source of outpatient health care in the past month was 18% government hospital, 63% government clinic, and 18% private provider; and 40% of women reported having serious problems in accessing health care. The employment rate amongst men aged 15–49 years was 42%; and 15% of KZN residents were in the highest quintile of wealth and 26% in the lowest.

In choosing these two provinces, the thesis allowed for an exploration of DR-TB decentralisation as a complex problem. Despite implementation being executed so effectively in one province (WC), this did not necessarily translate into improvements in disease outcomes. This suggests that the effectiveness of decentralised care depended on the heterogeneity of the TB epidemic in each setting, nuances of implementation approaches, actors involved and pre-existing health system infrastructure, amongst other factors.

1.8 OUTLINE OF THE THESIS

This thesis is organised into 11 chapters and structured in the following manner: Chapter 2 discusses the literature in relation to the implementation of the DR-TB decentralisation policy and describes the frameworks and theories that informed the conceptual framework chosen for this study. Chapter 3 details the qualitative case study research design and data collection methods used in this thesis. Chapters 4 to 9 outline the findings of the thesis, and Chapter 10 synthesises and discusses these findings and provides recommendations.

The results chapters tell the same story from different lenses, inevitably with some repetition but told from a different perspective.

Chapter 4 describes the divergent policy implementation trajectories that unfolded in the two provinces, resulting in the emergence of a number of different models of DR-TB care.

Chapter 5 begins to explain the implementation differences, by exploring the ways in which the policy provided room for competing ideas and interpretations on the intent and meaning of the policy and its likely benefits.

Chapter 6 maps the actors that influenced health policy implementation at national, provincial, district, and facility level and examines the dynamics, namely the tensions and contestations between these different actors, and the ways in which they exerted influence (power) on the implementation of the DR-TB decentralisation policy as individuals and as networks.

Chapter 7 describes the process of DR-TB policy implementation and particularly focuses on strategies for policy dissemination, as well as ownership of policy.

Chapter 8 details the funding flows and resource allocation for managing DR-TB at newly established decentralised and satellite sites and how this impacted service delivery.

Chapter 9 describes the consequences of decentralisation, and the compromise of quality of care that resulted from trying to increase the coverage of DR-TB initiating sites.

In the final, discussion chapter (Chapter 10), I discuss what the findings offer for understanding the constellation of factors that shape policy implementation. I also outline the main conclusions and limitations of the research and offer recommendations for practice and further research.

CHAPTER 2. LITERATURE REVIEW

2.1 INTRODUCTION

This chapter discusses the empirical literature on implementation gaps and challenges in implementing DR-TB decentralisation in South Africa and globally. Given the centrality of the South African experience to the global evidence-base, these bodies of literature are presented together in an integrated fashion. The chapter also examines the policy-implementation gap as a general phenomenon and provides a summary of the history and challenges of conducting implementation research. It then reviews literature focused on the frameworks and constructs that are theorised to influence policy implementation, and outlines the conceptual framework chosen for this study. The core organising framework adopted in this thesis is the health policy analysis triangle of Walt and Gilson (1994). I also draw on frameworks in the field of implementation science including those of May (2013), Damschroder et al. (2009) and Greenhalgh et al. (2004). Other theoretical approaches at the intersection of implementation domains, including systems thinking, complexity theory, actor network theory, distributed leadership, organisational climate, and street-level bureaucracy, were utilised for a detailed exploration of factors influencing policy implementation. Combining the merits of multiple theoretical approaches offers a more complete understanding and explanation of implementation (Nilsen et al., 2013).

2.2 EMPIRICAL LITERATURE ON IMPLEMENTATION OF DR-TB POLICY

The introduction chapter summarised the evidence base on the design and development of decentralised DR-TB policy, nationally and globally. This section reviews what we know about the performance, and enablers and constraints to the performance of decentralised models. Overall, decentralisation was implemented to varying degrees across South Africa, and while it resulted in earlier treatment initiation and reduced programmatic costs, many studies revealed that treatment outcomes remained suboptimal.

2.2.1 Evidence on performance of decentralised DR-TB care

2.2.1.1 Coverage

At the time that the policy was launched in 2011, there were 17 DR-TB units in South Africa, with the goal of reaching one DR-TB initiating site per district. Decentralisation was initially sluggish and by 2013, 56% of PWDR-TB were still treated at a central DR-TB hospital (Cox et al., 2017). Nevertheless, by November 2015, an NDoH/WHO national DR-TB programme review reported that while 578 DR-TB units had been established, with at least one unit in each of South Africa's 52 districts, coverage of decentralised sites was inconsistent (NDoH/WHO, 2016). Different models of decentralisation had emerged, due to interpretations of the policy, district health systems contexts, capacity, and readiness to implement decentralised care (Cox et al., 2015). By 2019, coverage had risen to 658 DR-TB units, although with considerable variation in the degree and speed of decentralisation between provinces

(Gray et al., 2020). Even globally, despite evidence of decentralisation being recognised as an effective strategy, implementation was suboptimal. For example, hospitalisation remained compulsory in nine out of 29 high burden TB countries surveyed in 2017 (MSF, 2017).

2.2.1.2 DR-TB treatment cascade indicators

Since the launch of the DR-TB decentralisation policy in 2011, a mixed picture of programme performance has emerged from studies evaluating policy implementation. Table 1 summarises studies in South Africa and elsewhere comparing community-based or decentralised care to specialised hospital-based care.

Studies have universally pointed to the effectiveness of decentralised DR-TB care in improving case detection, reducing delays in treatment initiation, and reducing programme costs. Studies from KZN and WC reported that decentralising DR-TB services from CoEs to decentralised hospitals or community clinics reduced lengthy specialised hospital stays, and freed beds and resources for patients with complications with fewer treatment options (Gilbert et al., 2015; Cox & Ford, 2013). Community-based treatment addressed patients' needs, provided easier access to care closer to home, and eliminated long and expensive travel to central hospitals (Loveday et al., 2015).

Improved treatment success in decentralised care has been reported in systematic reviews and in studies in African countries (eSwatini, Tanzania, Uganda) and further afield (Indonesia and Bangladesh). However, studies in South Africa have suggested that while gains have been made in treatment initiation and culture conversion, there has not been a corresponding improvement in treatment outcomes. Most South African studies reported no improvement in treatment success, and higher LTFU and mortality with decentralised care (Cox et al., 2014; Loveday et al., 2012; Loveday et al., 2015; Evans et al., 2018; Berhanu et al., 2016; Hirasen et al., 2018). High mortality could be attributed to having more experienced clinicians at central sites with greater capacity for detecting and managing treatment failures (Kusmiati et al., 2020). Also, PWDR-TB with advanced disease at presentation may not receive the closer monitoring in decentralised sites that would be provided in a hospital or sub-acute care setting during the early treatment period (Hirasen et al., 2018). This may be related to rapid decentralisation to sites that have limited experience and capacity in managing DR-TB (Kasozi et al., 2020). It is evident that in South Africa, as is true elsewhere, the entire cascade of DR-TB care needs to improve, not just one or two elements (Talbot & Pai, 2019). Some have cautioned that a weak decentralised DR-TB programme could be more harmful and create further drug-resistance than can be managed (Padayatchi & Friedland, 2008).

Table 1: Summary of DR-TB empirical studies on treatment pathway, 1990–2018

Reference	Location, year	Findings on programme performance
Systematic review		
Weiss et al., 2014	10 studies in 6 countries (1990–2012)	Outcomes for community-based care similar to outcomes in previous reviews of hospital-based care.
Ho et al., 2017	8 studies in 6 countries (1995–2016)	Improved treatment success for decentralised versus centralised care, but less impact on deaths; decentralised models less costly than centralised models.
Williams et al., 2016	16 studies in 9 countries (2005–2015)	Higher treatment success rate in community-based treatment compared to hospital-based treatment.
South Africa		
Naidoo et al., 2017	SA (ETR.Net 2013 cohort)	In the decentralised care model (nationally), 16% of PWDR-TB did not access diagnosis; 10% did not return for results; 25% did not initiate treatment; and 22% did not complete treatment.
Schnippel et al., 2017	SA (EDRWeb 2012–2014 cohort)	Persistently high mortality in decentralised care, especially in first few weeks of treatment; earlier initiation associated with higher mortality risk.
Cox et al., 2014	Khayelitsha, WC (2005–2011)	Post-decentralisation, improved case detection, reduced treatment delay and improved survival in clinic-based care. However, treatment success remained poor and high LTFU.
Heller et al., 2010	Hlabisa, KZN, (2001–2008)	Reduced time to initiation, and smear and culture conversion in community-based versus hospitalised care.
Loveday et al., 2012	KZN (2008–2009)	Four decentralised hospitals compared to one CoE: higher proportion with culture conversion, shorter time to initiation but higher mortality in decentralised care.
Loveday et al., 2015	KZN (2008–2010)	Four community-based care models compared to one CoE: earlier treatment initiation, higher cure rate, lower LTFU, but higher mortality in community-based care.
Brust et al., 2012	Tugela Ferry, KZN (2008–2010)	In decentralised care, retention high (only 5% defaults, 93% of visits attended), favourable outcomes (77% cured/still on treatment, 82% undetectable viral load, 6% died). However, longer hospitalisation than expected (80 days vs. 2 weeks).

Bateman, 2018	uMzinyathi, KZN (2014)	Post-decentralisation, reduced time to treatment initiation from 2 months to 48 hours, and average inpatient stay 4–6 weeks, compared with 4 months before decentralisation.
Evans et al., 2018	Johannesburg, Gauteng (2011–2014)	In post-decentralisation cohort, reduced time to treatment initiation and pre-treatment mortality; LTFU remained high, no difference in treatment success or mortality.
Berhanu et al., 2016	Johannesburg, Gauteng (2013–2014)	In post-decentralisation cohort, reduced time to treatment initiation, but high rates of early mortality and LTFU.
Hirasen et al., 2018	Johannesburg, Gauteng (2013–2016)	Post-decentralisation, higher mortality and LTFU, particularly in first three months of treatment.
Other countries		
Kershberger et al., 2019	eSwatini (2008–2016)	Improved treatment initiation and reduced mortality, LTFU, treatment failure in community- versus clinic-based care.
Molla et al., 2017	Tanzania (2012–2015)	Increased treatment initiation, treatment success after ambulatory care introduced.
Kasozi et al., 2020	Uganda (2012–2017)	Post-decentralisation, increased enrolment on treatment and cure rate, treatment success sustained above global average.
Daru et al., 2018	Bangladesh (2012–2015)	Improved treatment enrolment, reduced delays in treatment initiation, improved adherence, higher cure rates, and lower mortality in community-based care.
Noerfitri et al., 2019	Indonesia (2018)	Reduced LTFU in decentralised care.
Kusmiati et al., 2020	Indonesia (2015–2016)	Lower LTFU and higher treatment success in PHC compared to hospitalised care.

Abbreviations: ETR.Net: Electronic TB Register; EDRWeb: Electronic DR Tuberculosis Register; LTFU: Loss to follow-up; CoE: DR-TB Centre of Excellence; SA: South Africa

2.2.1.3 Costs

DR-TB care is costly. One study estimated that the inpatient cost of treating MDR-TB was 40 times the cost of treating DS-TB in South Africa (Schnippel et al., 2013). A number of studies and systematic reviews showed that shifting to a model of decentralised, outpatient DR-treatment resulted in cost savings (Loveday et al., 2018; Ho et al., 2017; Bassili et al., 2013; van Rensberg, et al., 2019; Pooran et al., 2013). Shorter hospital stays reduced costs by 36%–42% resulting in a potential saving of US\$80 million annually (Sinanovic et al., 2015). Costs were 3–4.5 times lower in community-based

models even after controlling for duration of hospitalisation (Loveday et al., 2018). Drugs and tests remained the major cost drivers in decentralised models (Loveday et al., 2018).

People with TB are generally from a poor socio-economic class, therefore social protection should be a key strategy in TB programmes (WHO, 2014). Community-based treatment reduced household costs and prevented catastrophic expenditure (Loveday et al., 2018). However, despite diagnosis and treatment in the public sector being free, patients still incurred costs accessing care, and because they were unable to work.

2.2.2 Evidence on facilitators and barriers to performance

In order to explore the reasons for poor DR-TB treatment outcomes, the following section describes the provider, PWDR-TB, and health system factors associated with the performance of decentralised care.

2.2.2.1 Provider

Somewhat complicating decentralisation has been the considerable advances in DR-TB management, necessitating frequent updates to WHO and national DR-TB treatment guidelines (Gray et al., 2020). New drugs and regimen options with new side-effect profiles and interactions, have resulted in increasingly complex management algorithms, posing a threat to decentralised care in which non-specialists manage PWDR-TB.

Shortages of medical officers have led to task shifting being employed in decentralised models, with nurses increasingly at the frontline of challenges. Training, supervision, and support have been reported to be suboptimal in some settings (Vanleeuw et al., 2020). A study of nurses working in TB units in PHC clinics in the Eastern Cape Province, found that less than 40% were trained on DR-TB compared to 91% trained on HIV/AIDS. They had inadequate knowledge of drug side-effects and managing DR-TB contact persons, and were hampered by staff shortages and high staff turnover (Singh & Janse van Rensburg, 2017).

In decentralised sites new to implementing DR-TB treatment in rural South Africa, clinical management errors, inadequate monitoring of adverse events, and suboptimal treatment occurred in half of the cases reviewed (Florman et al., 2020). Common clinical errors included failure to recognise existing resistance, addition of a single drug to a failing regimen, and suboptimal dosage of second-line drugs (Jacobino et al., 2020). Despite treatment guidelines stating that ambulatory care be offered only to patients who were bacteriologically negative, in an urban cohort of ambulatory PWDR-TB, 25% were bacteriologically positive at the start of treatment (Hirasen et al., 2018). Another study reported that only half of all co-infected patients were on ART, and half of PWDR-TB were on second-line therapy (Pai & Temesgen, 2017). The 2015 NDoH/WHO review revealed inadequate treatment monitoring, and

in a sample of files reviewed, 29% of patients were not asked about adverse events and up to 90% missed treatment doses (NDoH/WHO, 2016). In a national clinical audit of 14 DR-TB facilities in 2019, infection prevention and control protocols were not universally implemented, 40% of PWDR-TB were not treated with appropriate treatment regimens, and documentation and management of adverse events continued to be poorly executed (NDoH, 2019b).

Barriers to retention in care stem from patients not being tested at initial contact, HCWs not adhering to testing algorithms, results not being available, and patients with positive results not being recalled (Naidoo et al., 2015). A KZN study revealed that while DOT was recommended in national guidelines, it was not well implemented, PWDR-TB self-administered treatment, and adherence was not monitored (Loveday et al., 2015). A study in KZN describing HCW challenges in DR-TB service delivery in a CoE, pointed to provider fatigue with commitment to follow national guidelines; and DOT was used as a supervisory rather than a supportive tool due to time and resource limitations (Daftary & Padayatchi, 2016).

Compounding these challenges was the fear of acquiring DR-TB. HCWs have a risk of developing DR-TB that is five-fold greater than the general population. Concerns about lack of access to personal protective equipment and compensation or danger allowance for working in a high-risk setting impact the provision of quality patient-centred care as well (Tudor et al., 2013).

2.2.2.2 People with drug-resistant TB

Studies have pointed to the benefits to PWDR-TB of bringing treatment closer to home through decentralised care, including reducing lengthy specialised hospital stays (Gilbert et al., 2015; Cox & Ford, 2013), eliminating long and expensive travel to central hospitals (Loveday et al., 2015), and thereby reducing household costs and preventing catastrophic expenditure (Loveday et al., 2018).

Despite this, studies evaluating decentralised models in South Africa still report high LTFU. WHO defines LTFU as patients who disengage from treatment for two consecutive months (WHO, 2014). LTFU and poor adherence places patients at risk of developing additional drug resistance, transmitting DR-TB to others, and treatment failure (Franke et al., 2008). A review showed poor patient engagement and high LTFU rates of PWDR-TB in South Africa (McNabb et al., 2021). In one South African study of ambulatory DR-TB care service, 54% of patients missed at least one and 40% missed three or more appointments (Gajee et al., 2016). Sixty percent of the first missed appointments occurred within the first three months after treatment initiation. PWDR-TB prone to missing follow-up appointments included those who were sicker and referred from inpatient care, those who were younger, and PLWH with low CD4 counts. Another study identified risk factors for LTFU as male sex, younger age, race, alcohol and substance abuse, unemployment, and unstable housing (McNabb et al., 2021).

The reasons for poor retention in care lie at several levels, related to disruptions in the treatment journey, complexity of coordination across levels of care, and ongoing costs of access/utilisation of care.

A study in KZN of patients' experiences in DR-TB care identified social and therapeutic complexities of treatment over four critical stages of DR-TB care: diagnosis, treatment initiation, discharge into the community, and treatment continuity (Daftary et al., 2021). Multiple visits for diagnosis and prolonged hospitalisation with little choice, resulted in disruptions to routine life, and many patients delayed starting treatment. Treatment was marked by systemic stigmatisation, isolation, and social disconnectedness; and side-effects prompted several patients to consider treatment discontinuation. Even after discharge and during ongoing treatment, PWDR-TB continued to experience stigma, social disruption, and deepening socio-economic challenges despite clinical recovery. Fragmented health care further added to the frustration: community social workers were unfamiliar with DR-TB; PHC clinics referred PWDR-TB back for specialised care for minor health issues; and due to insufficient monitoring, patients missed taking their medications.

Decentralisation is thought to improve retention due to treating PWDR-TB closer to home, however it adds complexity because it requires coordination and referral across multiple levels of care (Watermeyer et al., 2019). High LTFU is related to inadequate investment into community-based follow-up and support systems (Loveday et al., 2014; Loveday et al., 2015). As a result of poorly coordinated referral systems in the public sector, PWDR-TB continue to 'fall through the cracks' and many are LTFU. On the other hand, implementing strategies that addressed LTFU and adverse events positively influenced treatment success (Williams et al., 2016). For example, in Indonesia, LTFU was lower and treatment success higher, in a community-based model which emphasised the importance of health promotion and prevention, and education about disease, treatment, and side-effects (Kusmiati et al., 2020).

A study in KZN (Daftary & Padayatchi, 2016) describing the human resource and operational challenges in DR-TB service delivery pointed to worse stigma for DR-TB than for HIV, perpetuated within non-specialised facilities lacking familiarity and training in DR-TB. Interactions with HCWs displaying patronising attitudes in turn influenced patients' health-seeking behaviour.

Decentralisation does not do away completely with the costs of utilising care. Geospatial analysis reported that despite people with XDR-TB in KZN living a mean of 2.9 km to the nearest clinic and 17.6 km to the nearest hospital, their actual distance travelled to the diagnosing facility was a mean of 69 km (Kapwata et al., 2017). They travelled a mean of 1.2 hours and 80% used public transport (taxis, minivans, and buses) that were crowded and poorly ventilated, with poor quality of road networks. The

reasons suggested for PWDR-TB still facing long distance and travel time to health facilities were because they resided outside the district where they were tested, they opted to seek care where they were employed rather than where they resided, or they perceived urban hospitals to be better or to have shorter waiting times and queues. Barriers to accessing care impact on treatment initiation and retention, and greater transmission may occur during long travel on public transport.

Even before the 2011 policy, CoCT Metro had already implemented decentralisation to local clinics that were effective at treatment and providing patient support, and the urban setting resulted in shorter travel distance and time and therefore decreased treatment challenges and the chance of transmission during travel. Rural districts, on the other hand, had a reduced density of DR-TB hospitals, long distances between facilities, and lack of resources including experienced clinicians. A study comparing patient pathways, showed travel patterns consistent with a decentralised model in Cape Town, unlike the rural WC districts that had more centralised patterns of care (Hill et al., 2016). In a WC study analysing laboratory data from 2012–2015, PWDR-TB in rural districts travelled 30 times further, were more likely to be hospitalised, and had longer admission duration than those in urban Cape Town (Leavitt et al., 2021).

2.2.2.3 Health systems

Weak public health sectors in many high TB-burden countries have compromised their TB programmes (Iacobino et al., 2020; Cox et al., 2019). Successful implementation of TB programmes requires “strong leadership, political will, social mobilisation, adequate human and financial resources, and sustainable development of health care services” (Abdool Karim et al., 2009, p. 921). Atun et al. (2010) detailed the health system bottlenecks that have hampered TB prevention and care, related to health workforce shortages, inadequate financing, disrupted drug supply, lack of well-functioning information systems for surveillance, poor governance, and compromised service delivery.

Studies have suggested that DR-TB treatment outcomes correlate with broader health system performance (Loveday et al., 2013; 2014) and that gaps in implementation of the policy can be partly explained by major recurring barriers across each of the health systems building blocks (WHO, 2007), summarised in Table 2 below.

Table 2: Health systems challenges in implementation of DR-TB decentralisation

Health system factors	Study findings
Governance	Poor alignment of the policy with other policies and strategies (Loveday & Cox, 2017)

	<p>Implementation not operationalised in District Implementation Plans (Cox et al., 2017)</p> <p>Distinction between levels of care is unclear and poorly understood (NDoH/WHO, 2016)</p> <p>Poor district management capacity, insufficient provincial and district support (NDoH/WHO, 2016; Cox et al., 2017)</p>
Finance	<p>Implementation not costed (Cox et al., 2017)</p> <p>Inadequate funding for implementing policy directives (Downie & Angelo, 2015; Cox et al., 2017)</p>
Service delivery	<p>Models of care insufficiently adapted to different geographical and epidemiological settings (NDoH/WHO 2016)</p> <p>Lack of coordination, linkage to care, and referral between levels of care (Mekler, 2018)</p> <p>Fragmentation of care (Loveday et al., 2013)</p> <p>Inadequate integration of TB and HIV (Gilbert et al., 2015)</p> <p>Inadequate integration of DR-TB into existing services (Loveday et al., 2014)</p> <p>Lack of tracing of patients who do not return, poor quality of services (Naidoo et al., 2017)</p>
Information	<p>Vertical Electronic DR-TB Register, data bypasses districts affecting their ability to validate data; little ownership of data; poor quality of data (Cox et al., 2017)</p> <p>Recording and reporting systems poorly functional due to limited resources, such as laptops, connectivity, and human resources (NDoH/WHO, 2016)</p> <p>Poor recording of patient contact information (Naidoo et al., 2017)</p>
Drugs and diagnostics	<p>Stock-outs of TB drugs due to a combination of international drug shortages and domestic supply chain problems (Seunanden & Day, 2014)</p> <p>Challenges with medicine supply and diagnostic services (Loveday et al., 2013)</p>
Human resources	<p>Rapid staff turnover, gaps in training and support, resistance to take on additional workload (Cox et al., 2017)</p> <p>HCW capacity constraints (Loveday et al., 2013)</p> <p>Uncaring staff attitudes (Naidoo et al., 2017)</p> <p>HCW shortages, poor morale (Mekler, 2018)</p> <p>Inadequate support, low motivation, and ineffective mechanisms for accountability (Loveday et al., 2014)</p> <p>Provider fatigue with following national guidelines and direct treatment supervision (Daftary & Padayatchi, 2016)</p>

2.2.3 Evidence on implementation dynamics

The 2015 NDoH/WHO review of the decentralised DR-TB programme in South Africa found that coverage of decentralised sites was inconsistent, quality of services varied, and PWDR-TB still travelled long distances to treatment centres and experienced long waiting times to access services (NDoH/WHO, 2016). Different models of decentralisation had emerged due to interpretations of the policy, district health systems contexts, capacity, and readiness to implement decentralised care (Cox et al., 2017). The revised decentralisation framework of 2019 stated that, “Given the range of variation in disease burden, population density, infrastructure readiness and the introduction of new policies on PHC re-engineering, the decentralisation programme has not been implemented by provinces at the same pace” (NdoH, 2019a, p. 5).

A study comparing the first four decentralised sites in KZN to care in the CoE demonstrated different interpretations and implementation of decentralisation guidelines, with one model still involving long periods of hospitalisation due to HCW anxiety about community spread (Loveday et al., 2018). Another KZN study also reported durations of hospitalisation longer than the policy dictated (380 days versus 2 weeks), suggesting that it was difficult to change the long-standing practices of HCWs who were reluctant to discharge people who were culture-positive (Brust et al., 2012). Similarly, in rural WC districts decentralisation lagged, despite the models and evidence on community-based DR-TB care in the CoCT Metro (Leavitt et al., 2021). These studies all emphasised the importance of leadership and management support at district level for re-aligning and re-organising health service components, monitoring implementation, and ensuring buy-in of frontline staff (Loveday et al., 2014).

In a study evaluating implementation in 22 decentralised sites in four provinces, HCWs reported that DR-TB was introduced to their facilities with little warning or engagement, and added to the workload of TB clinicians (Vanleeuw et al., 2020). Many had no prior experience with PWDR-TB, causing fear and anxiety, they were offered little support and felt isolated. Audiology equipment was provided and HCWs were trained, but follow-up support was lacking from the district and province. HCWs also reported difficulty accessing referral services in the hospitals, including radiology, audiology, and transport. They attributed these challenges to a lack of integration of the vertical DR-TB programmes into existing TB, PHC, and other general health care services of the district health systems. Another South African study exploring the implementation of DR-TB decentralisation found that implementation strategies for effectively managing organisational change processes were not uniformly present across all districts (Kielmann et al., 2021).

Given the complexity and the challenges of decentralised DR-TB care, some have argued for a more careful approach to the ‘how’ of implementation. Decentralisation should be adapted for the local context (Brust et al., 2012). Centralised DR-TB programmes may work in low-prevalence settings, as

they concentrate the treatment of PWDR-TB in specialised settings, and appropriate standard of care is provided by specialised clinicians. High burden settings do not have sufficient bed capacity to hospitalise all new PWDR-TB, face high LTFU of patients if they are far from their families, and struggle to monitor and trace patients after discharge. Therefore, a fully decentralised model is appropriate in high burden, urban areas with existing infrastructure, including trained medical officers in clinics, and access to DR-TB hospitals for patients with complications (Sinanovic et al., 2015). Furthermore, in implementing decentralisation, the model selected (PHC versus home-based care) does not impact costs, as the factor that reduced costs was shorter hospitalisation (Sinanovic et al., 2015). It is also recommended that implementation be phased, starting with areas with highest DR-TB burden, and sites that display initiative and motivation, that are linked to DR-TB specialists, and have HCWs with expertise and interest (Padayatchi & Friedland, 2008).

It has been argued that in the past, National TB Programmes have focused more attention on treatment success than outcomes (Naidoo et al., 2017). The DR-TB burden has led to a “culture that strives towards quantity as opposed to quality of health care administered, often neglecting to implement even the most basic principles of care” (Padayatchi et al., 2014, p. 2115). Recommendations to decentralise require consideration of programme characteristics that lead to improved outcomes, including community engagement and education, community support for maintaining adherence, and careful consideration of aspects that can be safely decentralised.

In summary, the empirical literature review has revealed a wealth of evidence related to performance of decentralised models (‘what’), and some of the facilitators and barriers to implementation and improved programme outcomes (‘why’), but there is still very limited understanding of the ‘how’ of implementation/organisational change. This is key to thinking about future programme strengthening.

2.3 CONCEPTUAL REVIEW AND THEORETICAL FRAMEWORKS

2.3.1 The policy-implementation gap

Policy implementation is a complex and dynamic process that constantly shifts in content and emphasis (Brynard, 2009). Firstly, this process evolves in a broad political, social, and cultural context. Changes among the actors, the policy instruments, or the political, economic, or social dimensions of the policy process can affect implementation outcomes (Dossou et al., 2020). Health facilities are embedded in wider political and social contexts (Gilson et al., 2018), and the effectiveness of interventions can be reduced because of contextual factors which act against implementation (Durlak & DuPre, 2008).

Secondly, health policy implementation is a multi-level process (Van Damme et al., 2010), involving mechanisms at the macro-level (national level, also influenced by a wider national and international

context), meso-level (district health system and the organisational level, such as hospitals) and micro-level (individuals and groups within organisations or communities) (WHO, 2012).

Thirdly, implementation can be understood as influenced by the *hardware* (structural) and *software* (social) aspects of health systems (Sheikh et al., 2011; Atun et al., 2008; de Savigny et al., 2009). Hardware includes the structure, technology, and resourcing of the health system and covers organisational, policy, legal, and financing frameworks, as well as clinical and service delivery requirements. Software covers norms, traditions, values, roles, and procedures embedded within the system. Software can be tangible (structures, processes, and systems) or intangible (relationships, communication, values, and norms) (WHO, 2012). Social science is critical for understanding implementation barriers, as the ‘softer’ issues, such as leadership and management, effective teams and networks, and positive cultures and behaviours are the most important factors in whether innovations succeed or fail (Goodwin, 2019).

These broad factors account for significant variation in the effective delivery of interventions in diverse settings, despite evidence of their efficacy and affordability (Peters et al., 2013a). Looking inside the black box of implementation can reveal specific configurations and sources of variation in policy implementation (Parashar et al., 2020). This is critical for several reasons. As a first step it is important to differentiate between theory/programme failure (the theory behind the intervention did not address the problem) and implementation failure (implementation was incomplete or poorly designed even if the theory behind the intervention was correct) (Nilsen et al., 2013). Ineffective implementation can be the result of both faults in policy design and constraints in delivery.

Hudson identifies four broad contributors to policy failure, “overly optimistic expectations, implementation in dispersed governance, inadequate collaborative policymaking, and the vagaries of the political cycle” (Hudson et al., 2019). A systematic analysis of 32 case studies of injury prevention interventions from 24 countries, identified a diverse set of factors that influenced health policy implementation. These included the evidence-based intervention itself, the context setting, visibility of the issue being addressed, leadership, management and collaboration, funding, data, and capacity (Vincenten et al., 2019). Another study of private health care regulation in India, described a constellation of factors affecting implementation, starting with the lack of clarity in policy content, followed by the lack of coordination between the implementing agencies, human resource shortages, poor knowledge and lack of competency of frontline HCWs on the content and the implementation mechanics of the policy, and insufficient policy oversight from meso-levels of the health system (Putturaj et al., 2021). Trade-offs in implementation have been described between the objectives of efficiency and equity, and between extending coverage and maintaining quality (Marmor & Wendt, 2012).

Beyond the design of policy, barriers to implementation can occur at multiple levels of health care delivery (patient, provider, organisation, and policy level), and involve multiple actors in the health system and beyond (Damschroder et al., 2009; Hanson et al., 2003). Implementation can fail in settings with dispersed governance (Hudson et al., 2019). Policies formulated at national level face challenges in ensuring consistency in delivery at sub-national level, especially in the context of decentralised political authority (Norris et al., 2014). Even where governance is concentrated, implementation is still dependent on local context, and interventions that are successful in one setting but that may not be as effective elsewhere (Braithwaite et al., 2018).

Studies have suggested that processes are principally at fault, whether for planning, introducing, piloting, implementation support, or monitoring and providing feedback on innovations (Brooke-Sumner et al., 2019). The long time lag between implementation and outcomes, scientific uncertainty and contestations, and governmental silos also affect implementation (Brooke-Sumner et al., 2019). Securing resources for policy implementation in competitive resource allocation processes is challenging and is influenced by political power and the legitimacy of actors supporting the policy (Dossou et al., 2021).

At the frontline of delivery, a broad range of individual and organisational factors contribute to policy implementation, including organisational climate, openness to change, and actor relationships and competencies (Cresswell & Sheikh, 2013). Resistance to change may arise from micro-level factors, such as the personalities, attitudes, and behaviours of HCWs, their lack of understanding of potential benefits of the policy, high workload, resource constraints, and inadequate communication through health system structures (Brooke-Sumner et al., 2019). Resistance is further compounded by ‘change fatigue’ from frequent policy changes (Scott et al., 2014). These are enduring challenges in LMIC settings (Gilson et al., 2018).

2.3.2 Evolution of implementation research

Implementation research is the scientific inquiry into questions concerning implementation and focuses on the gap between policy objectives and actual implementation (Hill & Hupe, 2002). It mobilises theories and methods to better understand what, why, and how interventions work in ‘real-world’ settings in order to improve policy and programme delivery (Robson, 2002). There are a number of different frameworks and approaches for opening the black box of implementation from the broader fields of implementation science and policy implementation research, spanning different disciplines, research traditions and theoretical perspectives (Damschroder et al., 2009).

The research approach for understanding factors that influence policy implementation has evolved over the past four decades. Nilsen (2013) summarises the history of implementation research, starting with earlier studies that employed a top-down approach, which explored implementation success and failure from the perspective of central government or policy elites. In the early 1980s, second generation studies took a bottom-up approach, which recognised the influence of actors, particularly frontline staff (Hjern, 1982). ‘Street-level bureaucracy’ focused on actors’ discretionary decisions that could determine success or failure of policy (Lipsky, 1980). The third generation of policy implementation research authors reconciled the two approaches, shifting to address the effects of institutional and inter-organisational relationships and to capture the interaction between multiple actors at multiple levels (Hill & Hupe, 2002). The fourth generation acknowledged the complex nature of the policy implementation process. Factors that shape implementation are increasingly seen to be multi-faceted and multi-leveled, having multiple possible origins and potential solutions that vary by place and time (Sabatier & Jenkins-Smith, 1993). Grounded in sociology, public administration, organisational theory, public management research, economics, and political science studies, fourth generation studies of implementation stress the importance of rigorous research methodology using comparative qualitative multiple case studies (Gilson et al., 2018).

A prominent strand of implementation studies in health is that of *Implementation Science*, defined as “the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice” (Eccles & Mittman, 2006, p. 1). Implementation science as a field developed from the evidence-based medicine movement in the 1990s, drawing from quality improvement methodology and increasingly occupying centre stage in research on micro-level service delivery and clinical practice innovations. Mirroring norms of research in evidence-based medicine, such as randomised controlled trials, recent decades have seen a number of journals dedicated to reporting such studies. In recent years the field has incorporated theoretical and methodological approaches from social sciences (Nilsen et al., 2013) embracing interpretative approaches alongside positivist orientations.

Policy implementation research and implementation science both emphasise the importance of interdisciplinary research using a variety of research methodologies. Both fields have developed models and frameworks from within the field, while also borrowing theories, models, and frameworks from other fields (Nilsen et al., 2013). Authors in both fields have identified variables that can affect the success of implementation (Durlak & DuPre, 2008; Fixsen et al., 2005; Fixsen et al., 2009). Scholars have agreed that due to the complexity of implementation, a single theory may not be appropriate (Signe, 2017).

2.3.3 Conceptual frameworks for studying policy implementation

There are a number of conceptual frameworks for studying policy implementation. I have adopted the *health policy analysis triangle* as the overall organising framework for this research (Walt & Gilson, 1994). Grounded in a political economy perspective, this framework understands “policy and policy processes to be contested, involving multiple actors, with different concerns, interests and values, often in competition with each other and influenced by a range of contextual factors and also by, for example, the timing of policy change and the content – the forms and focus – of specific policies” (Gilson et al., 2018, p. 12). Power dynamics are a central consideration and actors are therefore placed at the centre of this framework, and the research assumes an actor-centric focus.

Other frameworks and models from implementation research and implementation science have offered me additional concepts for exploring the domains of the policy analysis triangle. Hill’s theory of implementation adds insights into characteristics of implementation organisations, in addition to the behaviour of frontline staff (Hill & Hupe, 2002). The distinction made by the Consolidated Framework for Implementation Research (CFIR) between the *outer* and *inner* setting, supports the analysis of multi-level implementation contexts (Damschroder et al., 2009). The Integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework considers that successful implementation is related to *facilitation*, which enables *recipients* within their particular *context* to adopt and apply the *innovation* by tailoring their intervention appropriately (Harvey & Kitson, 2016). I have also drawn on the conceptual model for considering the determinants of diffusion (Greenhalgh et al., 2004), in particular the notion of system readiness, and the *processes* for adoption and routinisation. May’s Normalisation Process Theory model explains implementation in complex adaptive systems, exploring how actors negotiate implementation of innovations within service delivery contexts through mechanisms, such as adaptation and collective action (May et al., 2016). I have included in the conceptual framework a consideration of policy *outputs* and *outcomes* (Pawson & Tilley, 1997).

2.3.3.1 Domains of implementation

Both policy implementation research and implementation science approaches recognise the inherent interdependency between key domains in the policy analysis triangle: the implementation object (policy in policy analysis and clinical practice in implementation science), implementers, strategies, and context. Below is a description of the constructs within these domains as they are understood and used in various frameworks and theories.

Implementation object: policy content or practice intervention

Policy-related interventions can be complex and multi-faceted, with many interacting components (Peters et al., 2013a). The policy content or intervention is the substance of the policy and can be embedded in legislation, policy documents, or guidelines (Walt et al., 2008). Features of the

intervention design that may influence implementation include, its relative advantage over current practice (Simmons et al., 2008; Nilsen et al., 2013), whether content is relevant for addressing persistent problems, is compatible with users' established values and norms (Simmons et al., 2008), and fits with existing views and practices (Pawson & Tilley, 1997). The nature and scale of the epidemiological problem (Coker et al., 2010) and the quality of evidence of the health problem and intervention (Pawson & Tilley, 1997) also have a bearing. The complexity of the intervention or policy determines whether it is easy to implement and understand, and informs the knowledge and technical support required (Nilsen et al., 2013). Another construct advanced by some authors is adaptability. Interventions can have *core components* (essential and indispensable elements of the intervention) and an *adaptable periphery* (adaptable elements and systems related to the intervention and organisation into which it is being implemented) (Fixsen et al., 2005). Achieving full and consistent implementation across different contexts while allowing for local sites to adapt policy as needed, remains a tension (Nilsen et al., 2013).

Context, setting or environment

Context is described as the characteristics of the setting in which implementation takes place (Pawson & Tilley, 1997) and generally, influences the implementation process beyond the control of the implementers (Nilsen et al., 2013). In the field of implementation science, contextual factors typically focus on health care settings (inner context), whereas the context for policy implementation analyses tend to examine the larger (outer) contexts (Nilsen et al., 2013). Inner context represents features of the workplace or organisation in which implementation takes place, including structural characteristics, networks, communication, and implementation climate (Pettigrew et al., 2001). Outer context includes the wider health system environment (Coker et al., 2010) and aspects of the policy environment in which policies are implemented, including the historical and socio-cultural context, global economic forces, societal and political pressures and interests, and government systems (Walt et al., 2008). There is no clear line between the inner and outer setting and the interface is dynamic (Damschroder et al., 2009).

Health systems as a contextual factor can be understood in terms of their building blocks (hardware): leadership and governance, financing, human resources, medicines, information, and service delivery (WHO, 2007). Health systems also encompass the interactions and interrelationships between the building blocks and between the various actors within the system (Frenk, 1994), the software being regarded as key to service delivery towards health improvement (Gilson, 2003).

An alternative approach to context is to distinguish between local (*micro*), organisational (*meso*), and external (*macro*) health system levels (Pawson & Tilley, 1997). The external health system level includes policy drivers and priorities, incentives, mandates, regulatory frameworks, and inter-organisational networks and relationships. The organisational level includes organisational priorities,

senior management support, culture, structures and systems, history of innovation and change, absorptive capacity, and learning networks. The local level includes formal and informal leadership support, culture, past experience of innovation and change, mechanisms of embedding change, evaluation processes, and the learning environment.

Individuals involved: actors, implementers or adopters

“Individuals have agency; they make choices and can wield power and influence on others with predictable or unpredictable consequences for implementation” (Damschroder et al., 2009, p. 5). As pointed out by Greenhalgh et al., “People are not passive recipients of innovations. Rather ... they seek innovations, experiment with them, evaluate them, find (or fail to find) meaning in them, develop feelings (positive or negative) about them, challenge them, worry about them, complain about them, 'work around' them, gain experience with them, modify them to fit particular tasks, and try to improve or redesign them” (Greenhalgh et al., 2004, p. 598).

Policy is shaped by different actor groupings. Walt identifies policy actors as the individuals, organisations or networks that formulate policy, both inside and outside the bureaucracy (Walt et al., 2008). This includes the policy elites (both national and international, interest groups, and media), policy-brokers or policy ‘entrepreneurs’ (who play a connecting role, linking people, ideas, and problems to solutions like civil society activists), actors who implement policies (managers, professionals, street-level bureaucrats), and those who benefit from or resist policies (citizens and users of services). Implementation actors have also been described as change agents, opinion leaders, boundary spanners, or champions (Rogers et al., 2005); as formally appointed internal implementation leaders and external change agents (Damschroder et al., 2009). Opinion leaders formally or informally influence the attitudes and beliefs of others in the organisation regarding the intervention. Formally appointed implementation leaders from within the organisation serve as coordinators, project managers, team leaders, or other similar roles. Champions are individuals who (often spontaneously) “dedicate themselves to supporting, marketing, and driving implementation, overcoming indifference or resistance that the intervention may provoke in an organisation” (Damschroder et al., 2009, p. 11). External change agents, often with professional training in the technical field relevant to the implementation object, are individuals affiliated with an outside entity that influences decision-making.

Actors may seek to influence implementation processes based on their motivation, beliefs, values, norms, and goals (Damschroder et al., 2009; Pawson & Tilley, 1997; Gilson et al., 2011). Actors also shape implementation by nature of their knowledge and belief about the intervention, self-efficacy, stage of change, and identification with the organisation (Damschroder et al., 2009). Attributes, such as tolerance of ambiguity, intellectual ability, competence, capacity, innovativeness, and learning style are

other personal influences (Damschroder et al., 2009), while collaboration and teamwork, existing networks, and power and authority are important relational influences (Pawson & Tilley, 1997).

Importantly, the lived experiences of policy actors, and their everyday interactions and power struggles, shape policy implementation (Long, 2001; Long & Liu, 2009). Power is at the heart of every health policy process (Pawson & Tilley, 1997; Erasmus & Gilson, 2008; Gilson & Raphaely, 2008) and an analysis of power “allows for a more nuanced understanding of the roles and influences of multiple actors in the policy process” (Lehmann & Gilson, 2012, p. 3). Micro-level practices of power of diverse frontline actors engaged in policy implementation help to explain the implementation gap (Hill, 2009; Lehmann & Gilson, 2012; Gilson et al., 2014). Power practices are subtle and exist beyond visible power structures that shape implementation (Parashar et al., 2021). Examples of sources of power for implementation support include personal and professional values, personal knowledge and skills, and personal motivation as well as professional roles within the health system, organisational coherence and resourcing, socio-cultural values, and the political and economic context (Gilson et al., 2014). It is therefore critical for policy implementation to examine agency, decisions, actions, and power dynamics of actors.

Power practices can impact on implementation both positively and negatively (Parashar et al., 2020). Lipsky (1980) describes implementation of policy as steered by street-level bureaucrats – frontline staff who rather than simply complying with organisational rules established by central actors, “routinely exercise power in their everyday decision-making to influence client access to services and resources” (Lehmann & Gilson, 2012, p. 2). Discretionary power reflects implementers’ efforts to adapt policies to local circumstances and to cope with control from above (Nilsen et al., 2013; Barrett, 2004). Health policy actors exercise their power and agency to engage in contestation, negotiation, and collaboration (Parashar et al., 2020). They make choices and can yield power and influence on others with predictable or unpredictable consequences for implementation (Damschroder et al., 2009). Researchers have described numerous examples of actors implementing practices of power at times in alignment with policy goals, and at other times contradicting them (Gilson, 2016).

Policy processes, strategies, and facilitation

Policy process as a domain of implementation has been explored in a number of ways, from the perspective of policy stages (agenda setting, policy formulation, policy implementation, and policy evaluation) to the dynamic and multiple different forms of interaction among policy actors (Gilson et al., 2012). Successful implementation requires an active change process aimed to achieve individual and organisational level implementation of the intervention as designed (Damschroder et al., 2009). These processes may be formally planned or spontaneous, conscious or subconscious, may not

necessarily occur sequentially, and often comprise related processes progressing simultaneously at multiple levels within the organisation (Damschroder et al., 2009).

Berlan et al. (2014) provide an understanding of ‘the bit in the middle’ – the diffusion phase of the policy process, bridging agenda setting and implementation. They identify seven distinct activities inherent in policy adoption: generation of policy alternatives, deliberation and/or consultation, advocacy, and lobbying for specific alternatives, negotiation of policy decisions, drafting or enacting policy, and guidance/influence on implementation development. The CFIR identifies four activities during the adoption/assimilation and implementation phases (planning, engaging, executing, reflection and evaluating) (Damschroder et al., 2009).

Implementation strategies, also referred to as implementation interventions, facilitators, or enablers, influence the implementation process in order to achieve desired changes in practice. A range of strategies that can be used to get interventions onto the policy agenda or to implementation, include data analysis and evidence-use, providing technical information, mobilising finance, strategic networking, and garnering political support to overcome potential opposition to proposed policy changes (Gilson et al., 2018). Another important strategy involves strengthening “decision-making processes by integrating actors responsible for financial decisions and programme implementation more closely into policy decision-making processes” (Gilson et al., 2018, p. 57). Normalization Process Theory identifies four determinants of embedding or normalising complex interventions in practice (coherence or sense-making, cognitive participation or engagement, collective action, and reflexive monitoring) (Murray et al., 2010).

Facilitation is positioned as the active ingredient of implementation (Harvey & Kitson, 2016). The difference between strategies and implementers is not always clear (Nilsen et al., 2013b). Actors, in their roles as change agents, boundary spanners, champions, and experts, can influence the implementation process and serve as helpful strategies in garnering support at the local level during implementation (Greenhalgh et al., 2004; Orgill et al., 2019).

Facilitating implementation is dependent on the nature of the evidence (content) and the influence of context (Harvey & Kitson, 2015). In a receptive context (in terms of its learning culture, leadership support, staff involvement and engagement) where the research evidence aligns closely with actors’ experience, practice, and local priorities, a simple approach to facilitation may be sufficient. Where the environment is “unreceptive to change and the evidence is disputed, more intensive facilitation is needed” to address the local and organisational barriers, requiring sophisticated “skills in negotiation, consensus development, and conflict management” (Harvey & Kitson, p. 124).

Implementation outcomes

Without performance information, there is no strong evidence with which to design or assess implementation of health care reforms (Marmor & Wendt, 2012). Policy implementation can be assessed at different levels, as intermediate outputs (impact on implementers) or outcomes (both health and societal impacts) (Nilsen et al., 2013). Outputs are generally administrative (e.g. the number of implementing sites), whereas comparable outcomes include improvements in health. Outcomes indicate success of implementation but are often difficult to attribute directly to determinants and outputs (Peters et al., 2013a).

In terms of outputs, it is possible to explore availability, coverage, implementation costs, sustainability, quality and fidelity (degree to which the intervention was implemented as it was designed) through description of implementation experiences. Actor analysis may provide some understanding of actors' perceptions of acceptability, appropriateness (fit or relevance of the intervention in the setting), and feasibility (extent to which the intervention can be carried out in a particular setting) of the policy. Inclusion of patient perspectives would be necessary to fully explore aspects such as accessibility and acceptability of services. The United Nations Committee on Economic, Social and Cultural Rights, specifies four elements in the right to health, namely availability, accessibility, acceptability and quality (AAAQ) (United Nations, 2000).

In terms of outcomes, the trade-off between expanding coverage and compromising quality of care may be explored through the views of the participants.

2.3.3.2 Theory at the intersection of domains

In this section I consider constructs that function at the intersection of the domains of implementation. The dynamic interplay between actors and the policy content, process/strategy, and context have been key to explaining implementation processes and gaps.

Sense-making: actors make sense of the innovation within their context

Underscoring the actor-centric nature of implementation is the observation that “programs do not work in and of themselves; they work through the reasoning of program subjects” (Pawson, 2010, p. 186). Health policy analysis seeks to explore *ideas* or the beliefs, perceptions, and policy assumptions of actors, as a phenomenon distinct from their material interests (Walt et al., 2008). Actors' ideas and perceptions can in and of themselves shape policy implementation. Implementation faces opposition if there is a gap between policy intentions and the assumptions of actors which results in divergent ideas about implementation (Beland & Ridde, 2016). On the other hand, a convergence between the core assumptions of actors and the policy, facilitates implementation.

Innovation-system fit represents the interplay between the innovation and the context within which it is embedded (Greenhalgh et al., 2004). Systems thinking explores the relationship between elements of the innovation and a dynamic environment characterised by uncertainty, unpredictability, and emergence (Renmans et al., 2017). In Complex Adaptive Systems, leaders adapt through self-organisation, attention to interdependencies (how the parts of the system fit together), and sense-making (the process by which people, individually and collectively, assign meaning to experience and link it to action) (Greenhalgh & Papoutsis, 2019). More generally, implementing actors attribute meaning to a complex intervention, make sense of its possibilities within their field of agency and establish communities of practice, mobilising their skills and resources towards collective action. In support of collective sense-making, leaders “nurture the collective meanings that shape group behaviour by working with the invisible norms and beliefs that shape actors’ conceptions of their interests and values” and by recognising actors’ positions and power (Gilson, 2016, p. 191).

Framing involves selecting aspects of an issue to make them more noticeable or meaningful for others, defined as *perspectives* or *positions* (Schon & Rein, 1994). Frames provide a scaffold for ideas, directing the way a problem is perceived and guiding action (Schon & Rein, 1994). The elements to be framed include the policy content, the identities and relationships of key actors, and the policy process itself (van Hulst & Yanow, 2016). Successful policy often relies on multiple frames and intentional ambiguity to appeal broadly to all actors in the policy formulation process (Marani et al., 2021). Ambiguity is inevitable and is most evident where high levels of discretion are exercised (such as in federal systems) (Signe, 2017). The level of ambiguity in an intervention will often determine the degree of implementation fidelity, success, and replicability across different settings (Matland, 1995). Policy controversies and contestation are characterised by conflicting frames among stakeholder groups with varying roles, interests, and channels of information (Marani et al., 2021; Schon and Rein, 1994).

Actors are embedded in relational and organisational contexts

Implementation processes are “interactions between *emergent expressions of agency* (i.e. the things that people do to make something happen, and the ways that they work with different components of a complex intervention to do so); and as *dynamic elements of context* (the social-structural and social-cognitive resources that people draw on to realize that agency)” (May, 2013, p. 1). The incorporation of a complex intervention within a social system depends on actors’ capacity to cooperate and coordinate their actions.

Considering embedded practices of power is critical to opening the implementation black box. Long’s Actor Interface Analysis allows an understanding of how the exercise of power between actors and with policy implementation processes, leads to renegotiated and reshaped policy outcomes (Long, 2001). *Actor lifeworlds* considers the multiplicity of lived realities of policy actors manifesting in everyday

politics and power practices (Parashar et al., 2021). Actor interfaces, shaped by the similar, intersecting or differing lifeworlds, are where power struggles, such as domination, control, collaboration, contestation, resistance, or negotiation amongst actors are located. This theory can be used to understand why, in similar contexts, the implementation and outcomes of policies unfold differently (Parashar et al., 2020).

Political and administrative settings and their histories and traditions govern the spread of formal power amongst actors and their responses to new policies and changes within the system (Gilson, 2016). Frontline and middle managers are particularly key, as they connect the operational core of an organisation with higher management levels. From this position, their leadership enables or constrains the interactions that sustain collective action toward shared goals and that support innovation and adaptation. Distributed leadership thus underpins the collective action necessary for implementation.

Complexity theory regards the relationships between individuals as more important than individual attributes, in influencing implementation (Braithwaite et al., 2018). Actor-network theory focuses on the way in which actors build and maintain networks and how these networks, in turn mould actors' interests and identities (Heeks & Stanforth, 2015). Connections between individuals may be strong or weak, formal or informal, tangible or intangible (Damschroder et al., 2009). Social networks and social capital are useful theories regarding the quality and the extent of relationships between individuals in creating shared vision, information sharing, and collective action in complex systems (Nilsen, 2015).

Another way to explain organisational influences on implementation processes is through theories of organisational culture and organisational climate (Gilson et al., 2014; Erasmus et al., 2017). There has been a growing interest in constructs, such as absorptive capacity and readiness for change (Nilsen et al., 2013). Change valence points to the organisational members' shared resolve, commitment, and confidence to implement an intervention (Weiner, 2009). With high organisational readiness for change, organisational members are more likely to value and initiate change, exert greater effort, exhibit greater persistence, and display more cooperative behaviour, resulting in more effective implementation (Damschroder et al., 2009).

Actors' role in implementing strategy, influenced by context

The difference between strategies and implementers is not always clear (Nilsen et al., 2013b). Actors can be seen as both implementers and a strategy that facilitates the implementation process (Nilsen et al., 2013). Facilitation is positioned by the i-PARIHS framework as the active ingredient of implementation, aligning the innovation within the local, organisational, and wider system context (Harvey & Kitson, 2016). Facilitation involves one or more individuals in the role of facilitator, applying a combination of improvement strategies to enable and support change.

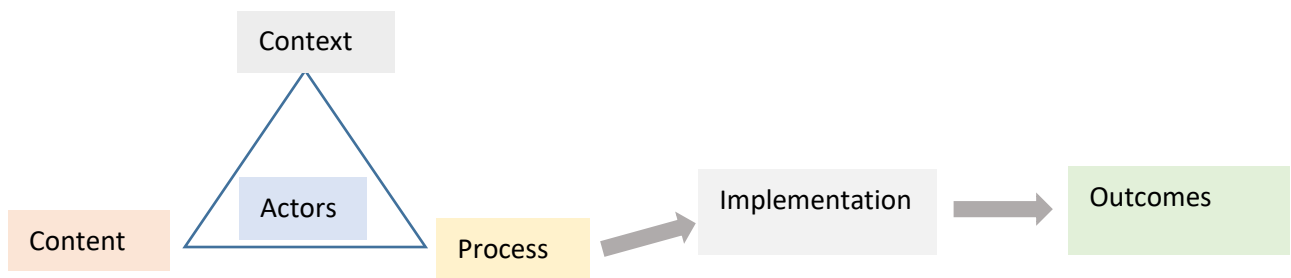
In complex interventions, there are often many actors involved in implementation processes and these potential drivers of change must be identified and their roles defined (Nilsen et al., 2013). Senior managers act as role models and make the decision to implement the intervention and mobilise resources, while middle managers are responsible for communicating and implementing change, and support organisational-level interventions (Guth & Macmillan, 1986; Nilsen et al., 2013).

Facilitation encompasses reflective, distributed learning through teams and networks, flexibility and adaptation, tailoring approaches to different needs, building relationships, and understanding and communicating practices. Leading change requires well-planned implementation strategies to give lower-level managers relevant information, also allowing opportunity for bottom-up inputs to key decisions. Effective communication through formal planned dissemination strategies that target particular audiences with appropriate messaging are a key part of successful implementation (Greenhalgh et al., 2004). Resources and managerial support are equally important (Orgill et al., 2019). Higher level managers need to take into account the structure and quality of actors' social networks (horizontal spreading peer influence and vertical for cascading information and formal decisions downwards). Leaders tailor their facilitation strategies for the particular issue, context, and with particular groups of actors (Harvey & Kitson, 2015). Working across different contextual levels and managing the interplay between evidence and context requires facilitators to function in a flexible and responsive way.

2.3.4 Conceptual framework

The conceptual framework guiding the research (Figure 3) brings together the domains and elements of implementation, drawing on theories from the fields of both *health policy and systems research* and *implementation science* outlined above.

The overall organising framework is the policy analysis triangle (Walt & Gilson, 1994), which depicts the domains of actors, policy content, the implementation process and context, and the interplay between those domains. A number of important constructs from the literature elaborate how each domain is explored. Implementation outputs, such as coverage by decentralised sites and fidelity, as well as programme outcomes, such as quality of care, are also considered. Finally, the framework considers constructs at the intersection of domains.



Content	Context	Actors	Process	Implementation Outputs	Programme Outcomes
Evidence	Outer:	Ideas	Decision-making	Acceptability	Quality of care
Relevance	Socio-cultural	Values	style	Appropriateness	Loss to follow-up
Relative advantage	Health systems	Motivation	Consultation	Feasibility	Mortality
Complexity	Pressures/interests	Knowledge	Communication	Fidelity (models)	Treatment success
Compatibility	Inner:	Self-efficacy	Managing actors	Coverage	
Adaptability	Structure	Power	Scale and timing		
	Networks	Authority	Tailoring		
	Organisational climate	Distributed leadership	Support		
			Facilitation		
			Adoption		

Intersecting theory

Innovation-system fit: complex adaptive systems

Sense-making, framing and ambiguity: actor interface analysis, actor lifeworlds

Actors as individuals and networks: actor network theory, social capital, organisational culture and climate

Absorptive capacity and readiness for change

Implementation facilitation as a process

Figure 3: Conceptual framework for this study

CHAPTER 3. METHODS

3.1 INTRODUCTION

This chapter describes the research design and data collection methods used in this thesis. Exploring the implementation of the DR-TB decentralisation policy required a flexible research approach and employed a qualitative case study design. The chapter begins by describing the epistemological assumptions that underpinned the research design to address the research aims and objectives. It then details the case study approach and the way that data sources were triangulated to analyse factors in early policy implementation. The chapter proceeds to detail the sampling of provinces and districts selected, as well as the key informants who were included. This is followed by a detailed account of the data collection methods and analytical approaches relating to semi-structured interviews with key informants, document reviews, and field observations of important DR-TB programme meetings. Finally, the chapter reflects on researcher positionality and ethical considerations.

3.2 RESEARCH STRATEGY AND DESIGN

3.2.1 Research strategy

The starting point for the research was the observation of variable DR-TB policy implementation at sub-national levels and an array of contextually bound factors apparently shaping this implementation. To better understand these different pathways and dynamics of implementation, the study deliberately took a holistic perspective on explaining implementation processes over time, while also seeking to understand similarities and differences through a comparative approach.

The research thus adopted a flexible explanatory strategy with exploratory and descriptive components. Exploratory and descriptive strategies are used when there is no single set of outcomes and examine ‘what’ and ‘how’ questions, while explanatory strategies are used to explain presumed causal links that are complex and begin to answer ‘why’ questions (Robson, 2002).

A multi-method, qualitative approach was employed, combining in-depth individual interviews and review of documents, supplemented by field observations. This allowed for the study of the research problem in its natural setting, eliciting multiple perspectives, and identifying different types of causal pathways and outcomes (Ozawa & Pongpirul, 2014; Peters et al., 2013b).

The research was located in a social constructivist paradigm, which involved an exploration of participants’ subjective accounts of implementation issues, formed through their interaction with others and through historical and organisational norms (Gilson et al., 2018). In trying to understand what influenced implementation of the policy, the research relied principally on different participants’

experiences and the meanings they brought to them, and to situate these within their specific workplace/organisational contexts (Denzin & Lincoln, 2011). Broad, general, and open-ended questions were thus posed to interviewees, so that they could share their experiences and interpretations of the research problem and construct their meanings of the situation. In developing lines of explanation from the case studies, it was necessary to inductively analyse the patterns of meaning, recognising that interpretations were shaped by my own experience and background, and required reflexivity (Creswell, 2013).

3.2.2 Case study design

In line with the research strategy, the research design was a comparative, explanatory case study with exploratory and descriptive components. The case was defined as sub-national implementation of DR-TB decentralisation policy in the WC and KZN Provinces of South Africa.

The case study method is well-suited to answering ‘how’ and ‘why’ questions in complex systems (Yin, 2018). First, it allows an in-depth investigation of the phenomenon in its real-life context (Yin, 2009), a “... contemporary bounded system (a case) over time, through detailed, in-depth data collection involving multiple sources of information” (Creswell, 2013, p. 97). Second, case studies facilitate the investigation of the interaction of multiple factors simultaneously. It is useful in the dynamic and complex landscape of health systems, where multiple, interacting variables act upon programme implementation and outcomes. Third, it prompts the researcher to draw on theory to explain how and why implementation varies between different settings by looking in detail at the inter-relationships and inner working of cases. Case studies can be considered theory building or theory affirming.

The second key feature of the research design was the comparative nature of the case study, with the units of comparison having both similar and contrasting replication logics as cases of implementation (see below) (Yin, 2018). According to Yin (1993), multiple case studies provide a better basis for theory building based on the comparison of cases, which can lead to a stronger theory than single case studies.

An explanatory multiple case study was the most appropriate strategy and design for the research into the implementation of the DR-TB decentralisation policy because it allowed an extensive and in-depth exploration of the perceptions of participants regarding the social phenomenon, which was the implementation of the policy. Given the aim to explore and explain implementation in a complex system: (1) exploratory and descriptive designs alone do not posit causal links; (2) fixed designs would rely on a priori hypothesis and closed ended methods that might miss key dynamics; and (3) experimentation might be relevant to studying micro-level strategies and specific phenomena but is not suited or feasible for whole system analyses.

Study designs and approaches that grapple with complexity, such as systems mapping approaches, capture features of complex systems, such as “multi-causality, indirect effects, uncertain boundaries of open systems, and multiple stakeholder perspectives” (Barbrook-Johnson & Penn, 2022, p. 17). These approaches are participatory and allow for a shared understanding of the problem and identification of potential solutions (De Savigny et al., 2017). Systems mapping approaches include systems dynamic modelling; network analysis; tools, such as causal loop diagramming; processes of enquiry, such as soft systems methodology; and visual representations, such as causal loop diagrams. It could be argued that these approaches would be relevant for this research, but application of these approaches was still nascent during the design phases of my research. Moreover, the open-ended exploratory-explanatory approach adopted provided the best opportunity to fully grasp the range of factors and multiple interfaces at stake in the policy, so as to obtain a whole system perspective.

3.3 SAMPLING AND DATA COLLECTION

3.3.1 Case selection and sampling

Selection of provincial cases

The two provinces selected for study, the WC and KZN are similar in that they have a relatively high population with also a high burden of DR-TB. They are different in terms of political control, health system structure, dynamics of health management at different levels, models of DR-TB service delivery, programme implementation performance, and programme outcomes. The cases selected thus have both ‘literal’ (based on similarity) and ‘theoretical’ (based on difference) replication logics (Rolf et al., 2008).

Selection of embedded cases (districts and facilities)

Embedded district/sub-district cases were selected for study in each province: six sub-districts/districts in the WC and nine districts in KZN (total of 15 embedded cases), and within these units, 13 hospitals and 10 PHC facilities (community health centres and clinics) were further sampled across the two provinces (Figure 4 and Table 3).

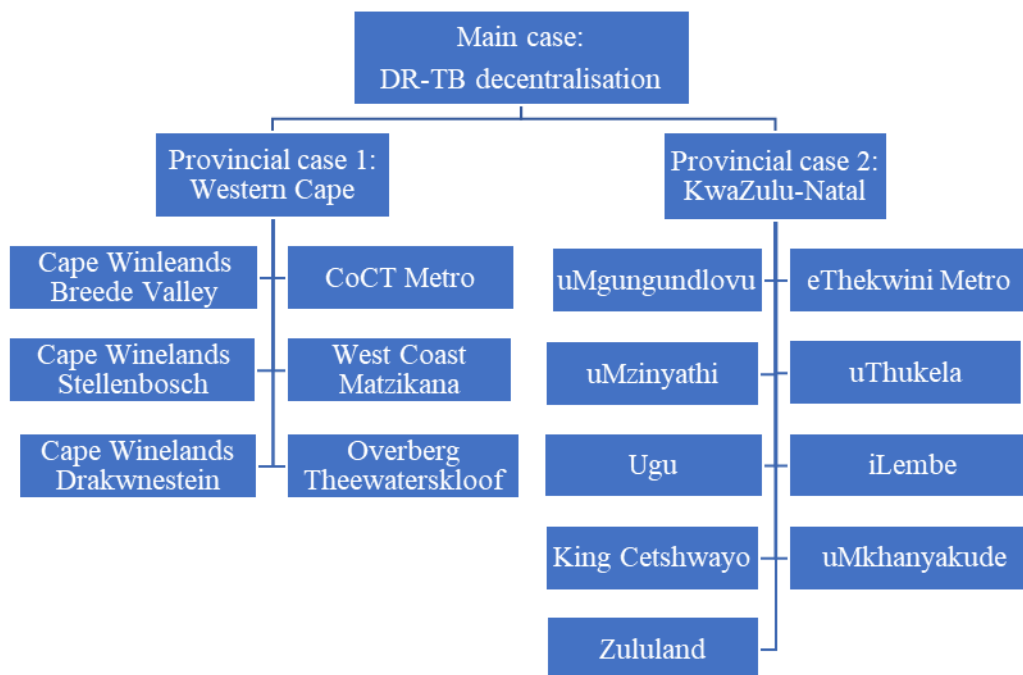


Figure 4: Selected provincial cases and embedded district/sub-district cases

These districts and facilities were selected in consultation with provincial TB managers. Sampling of the districts was purposive and guided by theory, to ensure variability. Maximum variation sampling took into account issues, such as rural/ urban setting, staff mix, patient load, and population groups served by clinics (Glaser & Strauss, 1967). Also considered were different models of DR-TB services and time periods of decentralisation in each province, and good and poor performers. This sampling strategy allowed for embedded cases to represent differences with respect to factors in the success/failure of DR-TB decentralisation, the main variable of interest, while remaining as similar as possible with regard to potential rival explanations, such as resourcing.

In districts like CoCT that decentralised all at once and achieved full coverage of all PHC facilities, the sampling was stratified to include one clinic per sub-district, while in KZN and rural WC, which phased decentralisation over time, sampling captured the range of models and facilities that were implemented in different time periods.

In the WC, one urban district (CoCT Metro) and five rural sub-districts (Cape Winelands Breede Valley, Cape Winelands Stellenbosch, Cape Winelands Drakenstein, West Coast Matzikana, and Overberg Theewaterskloof) were selected due to their high burden of DR-TB, their different service delivery models, and their time periods of implementation. The facilities included in the CoCT were the provincial CoE Brooklyn Chest Hospital (BCH) located in CoCT Metro, and four PHC clinics (one per sub-district). Facilities selected in Cape Winelands District were Brewelskloof DR-TB Hospital (serving both Cape Winelands and Overberg District) and three PHC facilities. In the West Coast,

Sonstraal DR-TB Hospital and one PHC clinic were selected. In Overberg, one PHC clinic was included.

Using the same criteria of variability, in KZN one urban district (eThekweni Metro) and eight rural districts (uMgungundlovu, uMzinyathi, uThukela, Ugu, iLemba, King Cetshwayo, uMkhanyakude, and Zululand) were selected. The facilities included in eThekweni Metro were King Dinizulu Hospital (KDH) the provincial CoE, one decentralised site, Don McKenzie DR-TB Hospital, and one PHC facility. For the rural district cases, the following DR-TB hospitals or units were included: Greytown DR-TB Hospital, Doris Goodwin DR-TB Hospital, Estcourt Hospital, Murchison Hospital, Montebello Hospital, Catherine Booth Hospital, Hlabisa Hospital, and Thula Sizwe DR-TB Hospital.



Table 3: Characteristics of selected district/sub-district embedded cases

District	Population (2021 mid-year estimate)*	MDR-TB incidence per 1,000 (2019)&,#	No of clinics†	No of hospitals	DR-TB referral hospitals&,#	No of DR-TB initiating sites (2019) &,#
WESTERN CAPE						
City of Cape Town	4 678 900	0.26	139	26	Brooklyn Chest (CoE) and DP Marais Hospital (Cape Town)	114
Cape Winelands	955 814	0.27	56	9	Breede Valley sub-district: Brewelskloof DR-TB hospital (Worcester)	16
					Stellenbosch sub-district: no TB hospital Referral: Sonstraal Hospital (Paarl, Cape Winelands)	16
					Drakenstein sub-district: no TB hospital Referral: Sonstraal Hospital (Paarl, Cape Winelands)	23
West Coast	469 496	0.31	29	11	Matzikana sub-district: no TB hospital Referral: Sonstraal and ID DR-TB Hospital (Paarl, Cape Winelands); Brooklyn Chest Hospital (CoCT)	16
Overberg	305 529	0.17	23	4	Theewaterskloof sub-district: no TB hospital Referral: Brewelskloof DR-TB Hospital (Worcester, Cape Winelands)	18
KWAZULU-NATAL						
eThekwini	4 009 589	0.42	135	27	King Dinizulu Hospital (CoE), Don Mckenzie DR-TB Hospital, and Charles James DR-TB Hospital (Durban)	16
uMgugundlovu	1 139 914	0.27	59	9	Doris Goodwin DR-TB Hospital (Pietermaritzburg)	1
uMzinyathi	564 089	0.19	57	5	Greytown DR-TB Hospital (Greytown)	3
uThukela	700 381	0.19	40	8	Estcourt District Hospital with DR-TB ward (Estcourt)	1
Ugu	804 452	0.33	55	5	Murchison District Hospital with DR-TB ward (Port Shepstone)	6
iLembe	695 717	0.41	36	6	Montebello District Hospital with DR-TB ward (Montebello)	3

King Cetshwayo	954 129	0.35	66	9	Catherine Boothe District Hospital with DR-TB unit (Amatikulu)	4
uMkhanyakude	687 989	0.37	60	5	Hlabisa District Hospital with DR-TB ward (Hlabisa) and Manguzi DR-TB Hospital (Manguzi)	4
Zululand	884 180	0.32	77	9	Thula Sizwe DR-TB Hospital (Ceza)	7

* StatsSA, 2021; [&] KZN DoH, 2019; [#] WC DoH, 2019; [†] NDoH, 2021



Sampling of participants

Sampling for in-depth interviews was purposive. Purposive or non-random sampling in qualitative research enables inclusion of respondents who meet the specific criteria for the study (WHO, 2012), in this case a maximum range of perspectives.

Participants approached for interviews were: DR-TB experts, clinicians or policy-makers at national, provincial, district, sub-district, and facility levels within the health service; and DR-TB experts in NGOs, research institutions, and laboratory services. In each health facility, where possible, two people were selected for in-depth interviews, one in a clinical role and one in management. The sampling strategy thus incorporated multiple perspectives on DR-TB programme, from clinicians, managers, policy-makers, and TB scientists and advocates, at each level of the health system, and at facility level, nurses, doctors, and managers. All participants approached consented to interviews.

In total 94 interviews were conducted, 10 at national level, 40 in KZN, and 44 in WC provinces, respectively. This included six policy-makers at national level, five programme managers at provincial level, 24 programme managers/coordinators at district/ sub-district level, 21 nurses, 17 doctors, 11 facility managers, and 10 TB researchers/technical experts (Table 4). Sampling was conducted until a point of saturation was achieved, that is, when no new information was produced from additional cases and interviews (Stebbins, 2001). There are various views on how many interviews are needed to achieve data saturation, some suggesting as few as three to five respondents, while others believing that case studies require as many as 30 respondents. The sample was not homogeneous in that there were actors at different levels with different functions and different viewpoints on decentralisation, so a larger number of cases were included and interviews conducted.

Table 4: Participants included in key informant interviews

	Programme		Facility			Researcher
	Managers	Coordinator	Manager	Doctor	Nurse	
NATIONAL	6					4
WESTERN CAPE	3					
City of Cape Town Metro	4	2				2
Brooklyn Chest Hospital			1	1		
Delft CHC			1	1	1	
Delft South Clinic			1		1	
Mzamohle Clinic			1		1	

Bloekombos Clinic					1	
Ikhwezi Clinic			1		1	
Cape Winelands district	2	1				
Brewelskloof Hospital				2	1	
Worcester CDC				1	1	
Groendal Clinic					1	
Kayamandi Clinic			1	1	2	
TC Newman CHC				1		
Overberg district	1	1				
Grabouw CDC					2	
West Coast district		1				
Sonstraal Hospital				1		
Lutzville Clinic					1	
KWAZULU-NATAL	2					4
eThekwini Metro	3	1				
King Dinizulu Hospital				1		
Don McKenzie Hospital				1		
Tongaat CHC					1	
uMzinyathi district		1				
Greytown TB Hospital				1	1	
uMgungundlovu district		1				
Doris Goodwin Hospital			1		1	
uThukela district		1				
Estcourt Hospital			1	1	1	
Ugu district		1				
Murchison Hospital				1	1	
iLembe district		1				
Montebello Hospital				1	1	
King Cetshwayo district		1				
Catherine Booth Hospital			1	1		
uMkhanyakude district		1				
Hlabisa Hospital			1	1	1	
Zululand district		1				
Thula Sizwe Hospital			1	1	1	
TOTAL	21	14	11	17	21	10

To access the sampled participants, I first obtained provincial and national authorisation through the online National Health Research Database (NHRD) portal, to visit facilities, and to conduct interviews and observations. I then emailed provincial managers to confirm the field visits and worked with provincial TB managers to select the sampled districts and hospitals, which served as gateways to the facilities. I emailed and telephoned facility managers to get their permission to visit the facility and then emailed and telephoned prospective participants who had been sampled to confirm interview dates and logistics.

3.3.2 Data collection

Interviews were conducted from March 2018 to February 2019, district and provincial meetings observed from October to November 2018, and the national programme review meeting observed after data collection had concluded in September 2019. Data analysis began in June 2019, but further analysis and thesis writing was put on hold during the period March 2020 to April 2021, when I was involved in South Africa's COVID-19 surveillance and response through my work at the National Institute for Communicable Diseases. Analysis and writing resumed and was concluded during the period April 2021 to June 2022.

Primary and secondary data sources were used.

Primary data collected for this study included the following:

Interviews using a semi-structured interview guide intended to enable guided conversations rather than structured queries, were used. Yes/no questions were avoided and the researcher found it best to employ broad, open-ended questions followed up with further probing questions, to allow participants to share their perspectives, broadly following a sequence of 'what', 'how' and 'why' questions. Informants were asked about the facts and their opinions, and were asked to propose their own insights into implementing the DR-TB policy. The questions posed were modified and refined to reflect lessons that emerged during data collection.

The draft interview guide is included as Appendix 1. Interview questions were drafted based on former knowledge of the policy and its implementation, and based on insights from document and literature review. All interviews were conducted by the candidate in English, except one where the participant responded in Afrikaans, in which the researcher is fluent. Interviews were conducted in person except for three interviews conducted on skype because the participants were located outside the country or were not available when the fieldwork to those provinces was conducted. All interviews took place in private offices. Four interviews were conducted with a group of participants because of limited time available, with the recognition that this may have limited the openness to sharing conflicting opinions. All interviews were audio recorded and then

transcribed verbatim into a Microsoft Word document by a trained transcriptionist, who signed a confidentiality agreement. No names were identified on the audio recordings or on the transcripts and participants were assigned an alpha-numeric identifier.

Observations of policy and programme meetings at national, provincial, and sub-district levels, was used. Meetings selected provided insights at national, provincial and district level, and allowed observation of routine meetings from both provinces. The researcher was a non-participant observer at the following meetings:

- Northern Tygerberg sub-district DR-TB multi-disciplinary meeting, 19 October 2018
- CoCT TB Clinical Forum, Cape Town, 9 November 2018
- KZN drug-resistant TB technical forum meeting, Durban, 16 November 2018
- NDoH DR-TB Decentralisation Summit, Johannesburg, 18–20 September 2019

Opportunistic non-participant field observation of health facility processes was conducted and informal conversations held with local health providers at each of the sampled health facilities. This method enabled the researcher to observe local factors in selected health facilities, and within programme management at various levels, which could explain variations in service delivery and programme implementation. Through these informal engagements, the researcher gained a richer understanding of processes of implementation and ‘software’ aspects of the health system, such as decision-making, authority, and micro-power of implementers and managers in the programme. Appendix 2 contains an observation checklist. Daily field notes and diaries were kept that recorded observed behaviour of participants, including body language, attitude, emotions, and facial expressions which were sometimes more revealing than the actual words spoken.

The secondary data collected included *document review* of 105 policy documents, Department of Health (DoH) plans and progress reports, National Treasury annual reports and budget statements, research reports and publications, presentations from government officials and researchers, evaluation reports, and donor agency reports. These were a comprehensive archive of all available documents related to the implementation of DR-TB decentralisation that the researcher was able to obtain from public sources, fellow researchers and participants who were interviewed. Where available, the researcher also reviewed minutes of meetings, reports by implementing organisations, circulars and memoranda containing timelines of implementation, information on actors involved, and strategies for promoting the implementation of policy. Documents relevant to the implementation of DR-TB decentralisation provided additional information that was used to supplement the data gathered from interviews. Data related to the objectives

of this study were extracted from these documents and captured in Microsoft Word, according to coded categories (referring to content, context, process, and actors).

Given the scale and breadth of data collection, an *audit trail* was important for keeping track of the data and maintaining a chain of evidence, including research logs, reflective journals, and cataloguing systems for facilities visited, meetings attended, interviews conducted, and documents reviewed. Keeping a research journal in which reflections of the data collection and emerging understandings were noted, enhanced the rigor and trustworthiness of the research, by including new observations not previously considered, new questions to explore in future interviews, and how additional sites were included in the sample which were deviations from the original research protocol. In this way, the researcher was able to constantly connect the data collection to the research questions posed in relation to the case study design chosen.

3.3.3 Data analysis

The data analysis entailed triangulating different sources of data and perspectives to develop a valid case study description (Creswell, 2013).

Interview transcripts, in the first phase of analysis, were read for content familiarity and to get a general idea of the major themes or ideas that emerged. The researcher captured notes of the understanding of the overall narrative before the coding process began. Next, the qualitative software Atlas Ti 4.2 was used to organise the data and each interview was extensively coded. Codes that formed a common idea were grouped into themes (Creswell, 2013). Finally, the codes and themes were reviewed and aggregated to key categories or overall themes related to the conceptual framework and research questions.

Three levels of thematic codes were developed during the course of analysis (WHO, 2012):

- a priori themes drawing on the interview guide: such as expected role in implementing policies, and actual experience of participating in policy implementation
- emergent issues arising from interviewees' responses: accounts of own actions in implementing policy, or not, and explanations of actions
- analytical themes based on patterning of emergent themes: reality judgements and value judgements (influencing actions)

Coded chunks of data were retrieved, organised into the overall theme of each results chapter, and iteratively written up to develop a narrative thread and ensure that the research questions were addressed.

Interview quotes were chosen that facilitated identification of patterns and comparison within and between cases. Identifiers for individuals and health facilities were anonymised, and individuals were categorised using analytically relevant identifiers including their function within the health system (policymaker, health manager, HCW, or NGO technical expert/ researcher), level of health system where they worked (national, provincial, district, facility), type of health care facility (CoE, decentralised hospital site, satellite site/clinic) and rural or urban setting of the workplace. Dimensions such as gender or race, while clearly salient to understanding wider social dynamics in a country such as South Africa, emerged as less relevant than analytic constructs such as professional and hierarchical positioning.

Documents and observations captured in field diaries were manually coded, and relevant sections of data retrieved, organised, and written up. Thematic codes included policy content, contextual factors related to health systems (hardware), information about actors, disputes, and non-compliance with policy prescriptions, and process data that enabled the construction of the chronology/timeline of policy implementation.

The *general approach to analysis* followed the case study analysis methodology. The embedded district and sub-district cases were analysed individually, and then together in two provincial case studies. The researcher employed ‘thick description’, interpreting observations by reference to contextual features. Provincial case timelines were compiled, followed by a cross-case analysis and considering findings in relation to theory and implications for implementation. These formed the inputs for the drafting of the cross-case chapters (WHO, 2012). Comparison and contrast within and across cases using pattern matching and analysis of congruence, supported development of general insights and conclusions that were considered to have sufficient universality to be analytically generalisable to other settings. High levels of congruency were found in each case, triangulating between interview data and insights from document review and observations of key programme meetings, further strengthening the development of patterns between cases.

In addition, several illustrative examples of challenges related to infrastructure (Chapter 8) and quality of care (Chapter 9) emerged from the data and were presented in the Results chapters, as embedded thematic (as opposed to geographical) cases of the consequences of DR-TB decentralisation in a number of sites.

During the analysis phase the researcher worked at several levels simultaneously, guided by Yin’s case study analytic strategy (Yin, 2018). First, utilising the theoretical propositions to guide the case study and point to relevant findings and explanations. Second, working on the data from the ground up in an inductive fashion to identify interesting clues that led to further data analysis. Third, developing a case description

that detailed the evidence in relation to context to further identify explanations to be analysed. Fourth, considering and examining likely rival explanations. Writing up the findings also applied the logic of literal and theoretical replication. Literal replication involved studying the cases in-depth and finding support for explanations in other cases. Theoretical replication involved in-depth study of additional cases, with the goal of interrogating alternate explanations to strengthen credibility and interpretive finesse of this research.

What emerged in the analysis as a key feature across all themes was the role, positioning and influence of actors, and the thesis therefore adopted an actor-centred focus.

3.4 CASE STUDY RIGOUR AND REFLECTIONS ON RESEARCHER POSITIONALITY

3.4.1 Validity/Trustworthiness

A review of policy analysis studies that adopt a case study design pointed to a number of analytical weaknesses, such as limited contextualisation of reported experiences or inadequate comparison and contrast of cases (Gilson & Raphaely, 2008). To address this, I employed four recommended ‘tests’ (Yin, 2009) to ensure rigour and research quality in the case studies, specifically to ensure accuracy of the data and lessen the potential of researcher bias.

Confirmability

To ensure that the data confirmed the general findings, I took appropriate measures during study design, data collection, and analysis. I made explicit the theory guiding the sample selection, data collection, analysis, and interpretation. I utilised multiple sources of evidence and established a chain of evidence (Yin, 2018). An audit trail linked data collection and case study findings to study participant responses (reflected in verbatim quotes) (Bloomberg & Volpe, 2008), indicating that the results were a valid representation of data. I conducted peer debriefing by sharing the preliminary case study findings for review by members of a Wellcome Trust-funded DR-TB research team and by fellow PhD students.

Dependability

To ensure that the research process was reliable, logical, and well documented, I took several measures during design and data collection. I developed a case study database as an audit trail, providing a full record of methods of data collection and analysis. Sampling included as many as possible of the factors that might influence the behaviour of the people central to the topic focus. I used multiple methods to construct the case studies, including document reviews, formal interviews, researcher observation, and informal discussion.

Credibility

To ensure that there was a match between participants' views and my reconstruction of them, I took the following measures during data analysis: I looked for patterns in data and across cases (pattern matching), considered explanations for experience analysed (explanation building), and used logic models to think through causal mechanisms. Transparency in the research procedures was crucial for establishing trustworthiness and credibility (Bloomberg & Volpe, 2008) and was maintained by having a study protocol and clear documentation of the research procedures and chain of evidence. Journaling allowed for introspection regarding the data collected. Triangulation of evidence was crucial (Yin, 2018) and I looked for patterns of convergence, comparing results across multiple sources of evidence, across methodological approaches, with theory. I considered negative or unique cases and explicitly sought out experiences that contradicted the main line of argument, to test that argument and refine it, both within and across cases. To ensure credibility (Yanow, 2000), I conducted informal reflective discussions on key lessons with programme stakeholders with varying perspectives. I tried to constantly be aware of any personal biases that might have impacted the research and ensured that these were mitigated.

Transferability

To ensure that the findings generated insights that were transferable to other settings, I took the following measures during analysis and reporting: for analytic generalisability, I aimed to derive broad insights from cases, rather than specific recommendations (Yin, 2009). Drawing on theory, I advanced a series of general propositions (outlined in the discussion chapter) on implementation of health programme interventions in complex systems that will be of interest to a broad range of stakeholders including policy-makers, programme managers, frontline HCWs, academics, activists, communities, and patients themselves. These propositions provide a heuristic for the design and implementation of the programme transferable beyond South Africa to other settings implementing decentralised DR-TB services, and to the implementation of other programmes, health care service quality improvement efforts, and policy recommendations.

3.4.2 Reflexivity

Doing qualitative research in which I engaged personally with the participants through interviews and observing meetings, meant that I became a part of, and shaped, the data collection process. As a result, my preconceived biases or assumptions could have influenced data collection or data analysis. As a researcher, I acknowledged my role in the research, and I was aware that I brought many things to the research, including my personal history, views of myself and others, and ethical and political judgements. My 'position' influenced the issues that I, as a researcher, chose to focus on and therefore the research questions asked.

Greater reflexivity involved an analysis of my own institutional power, resources and positions, and my role in defining the research agenda and generating knowledge (Walt et al., 2008). I was also aware that positionality can shift during the research process (Jootun et al., 2009). In striving for greater reflexivity, I tried to examine my own beliefs, judgments, and practices during the research process and how these may have influenced me, as continuous self-awareness informs credibility of research (Houghton et al., 2013).

I am a South African, and have been a health care provider, manager, and researcher focused on health system effectiveness for over 20 years. I understand the challenges in health programme implementation. I have developed particular understandings or biases around the strengths and weaknesses of the South African health system, and preconceived notions about performance of programmes, and of different provinces. Most specifically, I was contracted by WHO to coordinate the external review of the DR-TB programme in 2015. As a result, I developed relationships with national and provincial stakeholders who served as gatekeepers for approval, access, and data collection. I spearheaded writing of the report, which helped to open doors and provided me with some credibility and legitimacy when seeking approvals. However, some participants may have responded with perspectives that they believed authorities or the WHO would want to hear (social desirability bias). At meetings, I was introduced as an observer and did not participate in any way, separating my prior role as DR-TB programme evaluator and my role as PhD researcher.

I undertook to conduct this study because I had always had an interest in public health, and particularly the implementation of health programmes, and found that health policy and systems research provided the appropriate vehicle for expanding that interest. I needed a programme lens to understand the gap between policy and implementation, and the experience of leading the DR-TB review when I became familiar with the issues of implementing decentralisation, presented a natural opportunity for my research. In exploring the implementation of DR-TB decentralisation, I was therefore not an outsider who was neutral, as I had opinions about the best way to implement the programme gleaned from my leading the national review. I was also familiar with the context in the two study provinces, and with the TB and HIV programmes in South Africa, having worked on HIV/TB strengthening programmes for many years. This allowed me to draw on the knowledge and relationships gained, but I also had to consciously let go of preconceived ideas.

My study was nested within a multi-year DR-TB research project funded by the Wellcome Trust, and one of the co-investigators subsequently became a co-supervisor on my PhD. This allowed me to be a part of a broader community of inquiry involved in DR-TB research. The principle investigators are acknowledged

DR-TB experts in South Africa from universities, the national laboratory system, and the South African MRC, who contributed to the DR-TB policy and its implementation for many years. I am subject to being influenced by their biases. However, I believe that our policy research team combined both insiders and outsiders engaged in active discussions of findings during the phases of data collection and analysis, and therefore yielded a richer and more comprehensive understanding of the policy implementation process (Buse, 2008).

I tried to mitigate any potential biases that I brought to the research to ensure that these would not interfere with the research, through bracketing (Tufford & Newman, 2010). I kept a reflexive journal, writing copious notes before and during data collection and data analysis so that I could examine and reflect on my engagement with the data. I was also conscious about how I would be perceived by participants. I established rapport and ensured confidentiality and this resulted in most participants being open and candid, and even sharing strong and opposing opinions about policy and implementation. Some participants remained guarded and many asked to make comments off the record, indicating their willingness to share their feelings but not to be formally quoted. In the analysis phase I strived to maintain objectivity and present all data, not just what supported my view.

3.5 ETHICAL CONSIDERATIONS

I followed ethics review and clearance procedures to conduct the study from the UWC Biomedical Research Ethics Committee (BREC) (Appendix 5). I also obtained approval from the National Health Research Database (NHRD), at national level and the respective provincial health departments of WC and KZN (Appendix 6 and 7). I obtained permissions from provincial and district managers to conduct fieldwork and then confirmed authorisation from the facility manager to visit the facility and conduct interviews.

Informed consent: Written informed consent was obtained from all participants to conduct interviews and for audio-taping (see Appendix 3 for Participation Information Sheet and Appendix 4 for Consent Form). The informed consent form was provided to them prior to the interview by email if possible, but also shared again at the time of the interview, and participants were given time to read through it after it was discussed, and then make the decision to participate. The nature and purpose of the study, and potential risks and benefits were discussed. It was indicated that participation was voluntary with the right to withdraw at any stage; refusal to participate would not result in any penalties or adverse effects. Participants signed the informed consent form if they agreed to be interviewed and if they agreed for the interview to be audio recorded. The principles of informed consent were also adhered to in less structured observations.

Confidentiality: This was discussed with participants at each step in the research process. Interview transcripts and observations were coded to anonymise the data and names of participants, names of health facilities were not used, and an alphanumeric coding system identified the group to which the participants belonged but not the actual person. As far as possible I ensured that study participants were not exposed, and discussed with them the challenge of maintaining anonymity of informants who are national experts in a specific health programme like DR-TB where there are a few key individuals involved in policy-making, programme management, and in providing technical guidance (Saunders et al., 2014). Informed consent documents were kept in a locked file cabinet that was only accessible to me and stored separately from the data. Computer files were password protected and documents were stored in a DropBox cloud database and were encrypted. The data generated from this research will be kept for five years in secure access-controlled storage before destruction.

Information acquired through this study will be shared with all participants prior to public dissemination. I will consider how best to present findings in ways that balance confidentiality and give voice to those not usually heard. Results of the study will be published in accredited, peer reviewed journals. Furthermore, findings will be disseminated within appropriate structures in the health system and at conferences.

3.6 CHAPTER SUMMARY

This chapter detailed the multi-method case study research design and its appropriateness for addressing the research questions. I employed a case study design, appropriate for research of a contemporary phenomenon in a complex health system, characterised by changing and emergent experiences while the research is being conducted, and directly influenced by the context. The multiple case study design allowed for deeper explanation of the experience using a number of embedded cases. I defined the cases as the experience of actors at provincial, district, sub-district, and facility level in implementing the DR-TB decentralisation policy in the period 2007 to 2018. I explored these two provincial cases in 15 districts or sub-district in two provinces, each thus serving as an embedded case study. Furthermore, the selection of cases (districts and facilities) was detailed as well as the sampling strategy for selecting participants for interviews. Other methods of data collection and analysis were also summarised relating to document review and observations. Finally, a reflection on ensuring trustworthiness of the research was presented, as well as a description of the researcher positionality and how reflexivity was achieved.

CHAPTER 4. TIMELINES OF NATIONAL POLICY FORMULATION AND PROVINCIAL IMPLEMENTATION

4.1 INTRODUCTION

This chapter serves as an introduction to the results chapters. The findings presented in this and subsequent results chapters are informed by triangulated analyses from document reviews, field observations, and interviews with 94 participants, including national policy-makers, provincial programme managers, district/sub-district programme managers/coordinators, DR-TB nurses and doctors, facility managers, and TB researchers/technical experts.

The chapter begins with the timeline of implementation of the DR-TB decentralisation policy in the two provinces, constructed from interview and document review data, also suggesting the reasons why policy was adapted for the local context. The rest of the chapter provides a definition and description of decentralised sites and the models that emerged in the two provinces. The policy framing, actors, processes and contextual factors that shaped the implementation of the policy in the two provinces will be the subject of discussion in the chapters that follow.

4.2 PROVINCIAL IMPLEMENTATION TIMELINES AND EMERGENT MODELS OF CARE

A combination of surveillance, benchmarking from other countries, the development of pilot projects, programmatic research, and advocacy, led to the formulation and launch of the DR-TB decentralisation policy in 2011. Prior to the launch of the policy, in June 2010, to ensure provision of quality services, the NDoH developed a tool to assess readiness of health facilities before starting DR-TB decentralisation. Using DR-TB diagnosed caseload per district and/or sub-district, provincial TB programmes in consultation with health facility managers, hospital services directorates, and PHC services were required to identify proposed decentralised, satellite, PHC, and mobile DR-TB units. They then had to develop provincial plans for decentralisation of DR-TB. By 2015, all provinces were reported to have decentralised sites, reaching the policy target of one DR-TB treatment initiation site per district. Despite this, provinces differed significantly on the extent to which the decentralised management of DR-TB had being implemented.

The next sections describe the unfolding implementation in KZN and WC, the provincial models adopted, and local factors shaping implementation. Detailed accounts are provided because they demonstrate the micro-level decision-making and policy interpretations involved in implementing DR-TB policy at different levels of the health system. Broadly speaking, as the DR-TB burden increased, decentralisation in both provinces was inevitable, but the first years of implementation varied because each province had

different approaches, with varying pace, standardisation, and degree of verticalisation/integration. With time, a degree of harmonisation was achieved as most districts moved towards implementing a fully decentralised model to satellite sites. However, the initial approach resulted in differences in resourcing and this impacted quality of care, which is further described in Chapters 9 and 10.

4.2.1 Overview of implementation in KwaZulu-Natal

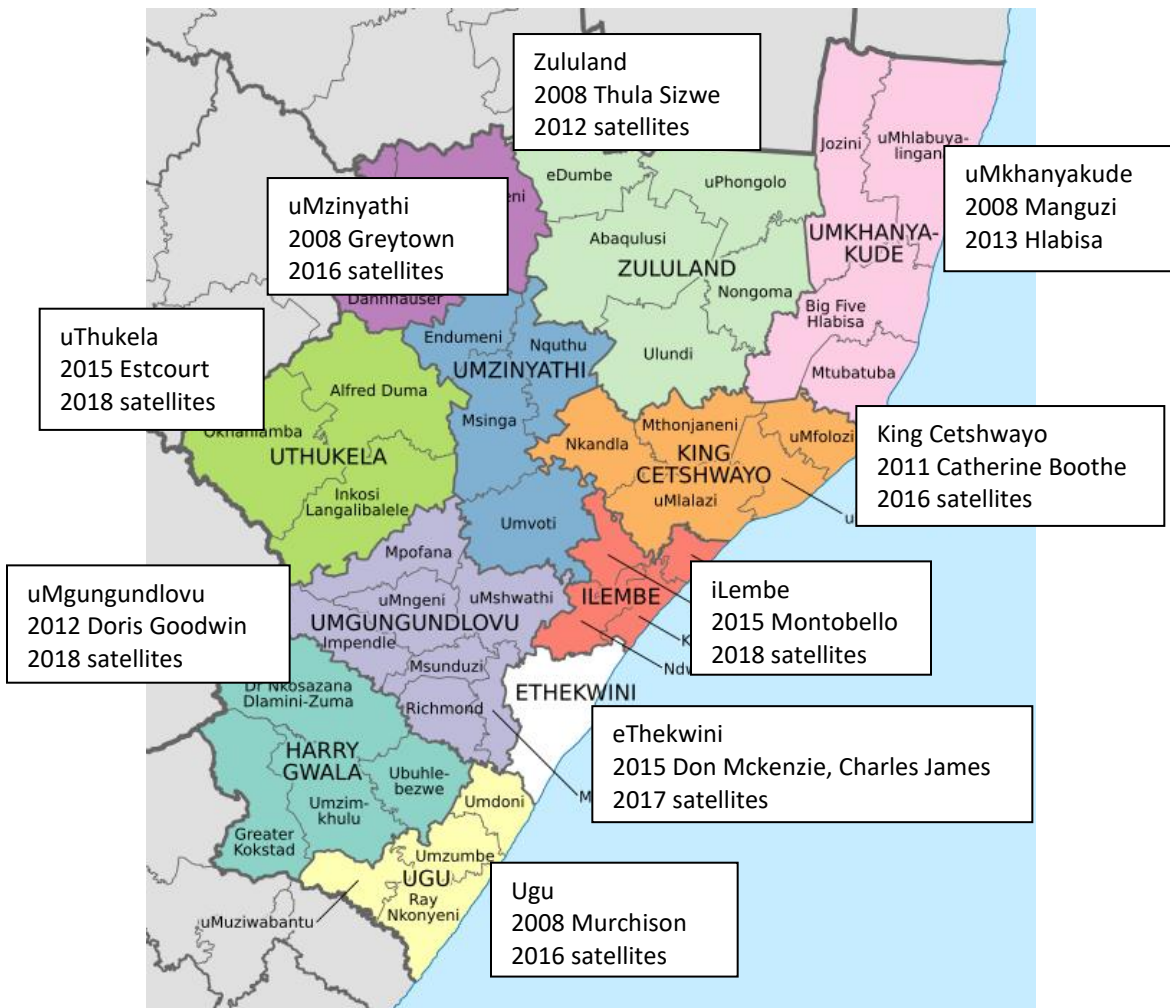


Figure 5: Timelines for decentralisation to district DR-TB unit and to satellite sites in KZN

4.2.1.1 Pre-decentralisation

Throughout the 1990s and 2000s, PWDR-TB were diagnosed and referred to KDH, the provincial CoE, for inpatient initiation until two cultures were negative. They were then referred back to the district referring site for ongoing treatment, while they returned to KDH for monthly monitoring. Bed shortages at KDH created a strain on the hospital and resulted in long waiting lists for admission, causing further transmission in the community. KDH began outpatient initiation in 2008 due to the huge patient load and waiting lists.

Poor continuity between KDH and the local hospitals or clinics resulted in patients who discontinued treatment not being picked up. It was then decided that it was better for PWDR-TB to be managed at a local level and they began being down-referred to sites in the district for the continuation phase. Down-referral was introduced in a phased manner within and between districts (Figure 4).

4.2.1.2 First district DR-TB units, 2008–2011

As indicated earlier, after the Tugela Ferry outbreak of XDR-TB in 2005, NGO supporting partners, the KZN provincial TB directorate, and the uMzinyathi district authorities established a decentralisation pilot project in Tugela Ferry, benchmarked on community-based treatment in Lesotho. Greytown Hospital was identified as an initiating DR-TB unit because it was under-utilised at the time. In their provincial decentralisation plan, the KZN authorities also identified four sites in other districts to begin decentralised care, namely, Manguzi (uMkhanyakude), Thula Sizwe (Zululand), Murchison (Ugu), and Catherine Boothe (King Cetshwayo) Hospitals. The Global Fund provided funding for building and upgrading DR-TB units in these sites.

Available capacity determined the choice of pilot project sites. Thula Sizwe was a TB hospital in Zululand that started admitting more PWDR-TB until the DS-TB section was closed down and it was formally designated as the district DR-TB site. Murchison was identified as a decentralised site for Ugu because of its location centrally along the travel routes, and because Port Shepstone Hospital in the town had no space to accommodate the unit. Catherine Boothe was selected as a decentralised site for King Cetshwayo district as it had sufficient space and low bed utilisation. A new DR-TB unit was erected linked to the district hospital as a complex.

4.2.1.3 Second wave of district DR-TB units, 2012–2015

A second wave of district DR-TB sites in KZN was established between 2012 and 2015, once the first sites had gained sufficient experience. Doris Goodwin, previously a SANTA (South Africa National TB Association) TB hospital in uMgungundlovu, was referring PWDR-TB to KDH for initiation and then serving as a stepdown facility. Due to their experience with DR-TB, the hospital was established as the decentralised site in 2012. In uMkhanyakude district, Hlabisa Hospital was earmarked in 2013 as a second site because of large patient volumes and the distance from Manguzi Hospital. eThekweni was served by the CoE, KDH, which was located within the district and because of this, the district was slow to further decentralise to other DR-TB units. In 2015, a new district clinical manager started the process of decentralisation in eThekweni. DR-TB units were established at Prince Mshiyeni and Clairwood Hospitals but they were “kicked out due to pressure from staff who didn’t want DR-TB” in their facilities (KZN urban

district manager). It was then that the old FOSA SANTA Hospital was emptied and converted into a DR-TB site. Patients were only admitted at FOSA after initiation, but were still followed up at KDH, and there continued to be waiting lists. When FOSA closed in 2015 due to issues with the lease, the doctors moved to Don Makenzie and Charles James Hospitals, both SANTA hospitals treating DS-TB. They first established outpatient DR-TB initiation programmes and by 2015 were formally established as DR-TB initiating sites. In 2015, Montobello Hospital was chosen as the site for iLembe because Stanger Hospital had no space for the park home donated by USAID. uThukela had not established a decentralised site and PWDR-TB from the district were referred to KDH for initiation and admission. Then, in 2014, patients started being admitting at Greytown Hospital in neighbouring uMzinyathi District because of the close proximity. The Greytown site began visiting and providing support to establish the DR-TB site at Estcourt Hospital in 2015.

4.2.1.4 Further decentralisation to satellite sites

Once these district DR-TB sites were established, PWDR-TB were referred from all clinics and hospitals in the district for initiation at the decentralised sites. However, these district DR-TB sites also began experiencing some bed shortages and capacity constraints and further decentralisation to satellite sites became necessary. The DR-TB sites adopted a phased approach in order to capacitate the satellite sites, which were largely district hospitals, but in some districts also included a few community health centres (CHCs). They first started down-referring patients to satellite sites for the continuation phase to continue monitoring and treatment, but they would still see patients for monitoring back at the district DR-TB site every month or less frequently in some settings. Then once the satellite site staff were capacitated, the district DR-TB site started preparing them to be an initiating site. They conducted readiness assessment and training, and in some districts support was offered via outreach visits, mentoring, and telephonic support from the district DR-TB site or from NGO mentors. Patients with complications were still referred to the district DR-TB site, but well patients were initiated at the satellite sites.

4.2.1.5 KwaZulu-Natal model of care

At the time of the research, patients who tested positive for DR-TB were identified by the clinic staff and referred to tracer teams, who contacted them telephonically or visited them in their homes, and then made arrangements for the patient to attend their nearest clinic where baseline investigations were done and the patient was counselled. Within 2–3 days, the patient was then sent to their DR-TB initiating site for initiation, possibly requiring admission. Once initiated, the referring clinics provided treatment and injections through injection teams, but throughout the intensive phase of treatment patients returned for outpatient follow-up to the district DR-TB site. If a patient was stable, had no complications, and no longer

infectious, they were down-referred to the referring clinic (satellite site) to be managed during the continuation phase. Outreach, tracer, or injection teams ensured linkage to care and treatment compliance. Some districts recruited linkage officers who assisted the TB coordinators. All KZN districts had TB coordinators and some also had sub-district TB coordinators.

KDH in Durban remained the provincial CoE, responsible for children, people with XDR-TB, and those with complications. Despite being a provincial specialist centre, KDH was the primary treatment centre for the central region in eThekweni that was not served by other decentralised DR-TB sites or satellite sites. KDH staff were also responsible for providing support to DR-TB sites throughout the province.

4.2.2 Overview of implementation in Western Cape

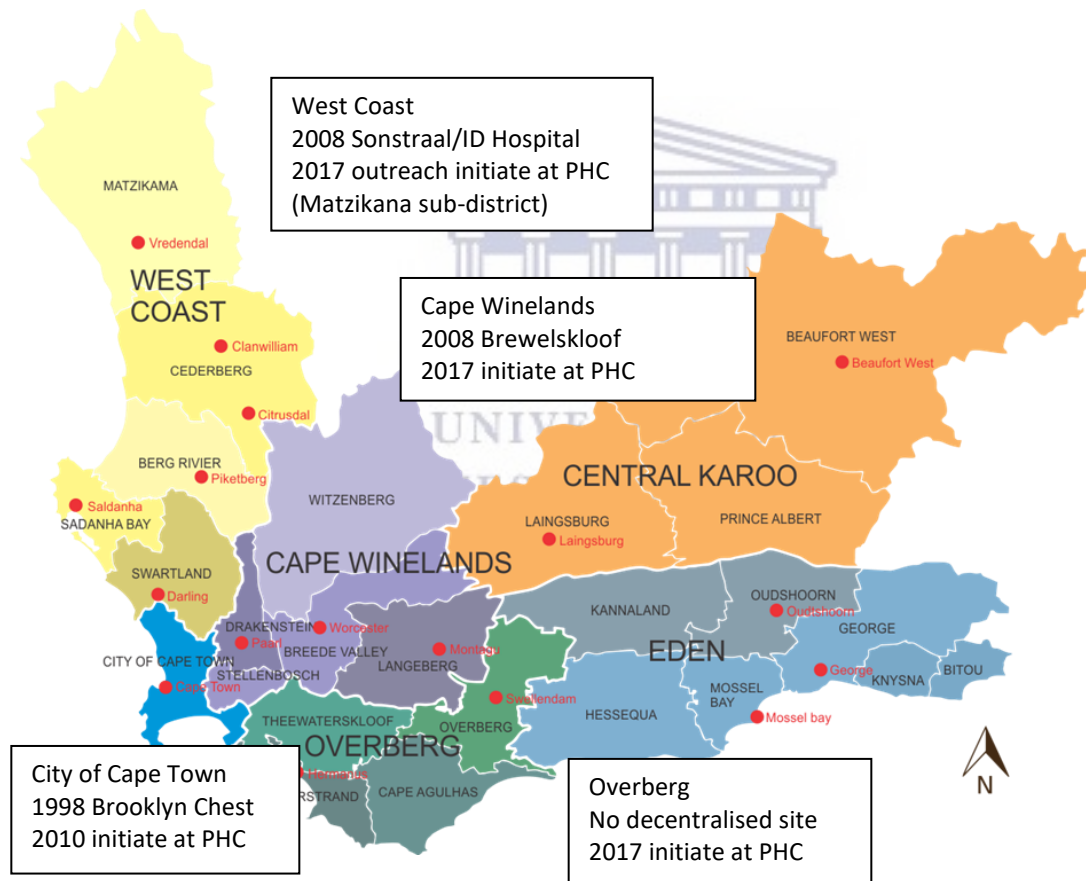


Figure 6: Timelines for decentralisation to district DR-TB unit and to satellite sites in WC

4.2.2.1 Pre-decentralisation

Throughout the 1990s and early 2000s, BCH was the only referral centre in the WC. From 2008, five DR-TB referral centres were established at Brewelskloof, Sonstraal, Nelspoort, DP Marais, and Harry Comay

Hospitals, at a time when other provinces still had just one CoE (Figure 5). PWDR-TB would be admitted at the CoE or DR-TB referral hospital for the intensive phase for six months and then discharged home. Outreach doctors would go out to the clinics to follow them up. In 2007, BCH established an outpatient DR-TB unit to allow ambulatory initiation of treatment and monthly follow-up at BCH. In time, nurses from the clinics would send the baseline workup to BCH, and they would fax scripts, and the patients would be initiated at the clinic.

Shortly thereafter, in 2008, MSF and the CoCT Health Department introduced the Khayelitsha pilot project for the provision of decentralised DR-TB care and treatment at PHC clinics. This pilot helped the CoCT and WC Province to learn important lessons about decentralisation of DR-TB care. These lessons shaped the WC's inputs into the drafts of national decentralisation policy, emphasising the role of PHC in decentralisation. In October 2010, the WC provincial TB technical task team was established, which developed the first draft of the WC decentralised DR-TB management plan, recommending two models of care, the first (urban model) based on the Khayelitsha programme and the second (rural model) based on the KZN model with mobile injection teams.

4.2.2.2 City of Cape Town model

Learning from the Khayelitsha pilot, by 2008, the TB manager in the CoCT began replicating the lessons of the MSF Khayelitsha pilot across other sub-districts. Even though the national model recommended decentralisation from the CoE to the regional/district hospital then to PHC satellite sites, the CoCT already had staff at PHC who were familiar with the programme and had developed expertise caring for PWDR-TB, therefore CoCT decentralised directly to PHC clinics. Patients could have ambulatory care and did not need to be hospitalised.

In a nurse-led doctor-supported model, PWDR-TB were initiated and managed throughout their treatment at the PHC clinic. They needed referral to community day centres to see a psychologist and social worker, and audiology was provided through a roving team in each sub-district. The clinics were supported by senior medical officers (SMO) and the MDR-TB professional nurse who coordinated the programme in each sub-district. CoCT did not adopt community-based treatment and did not employ injection teams.

The PHC clinic nurses diagnosed PWDR-TB, did the baseline workup and counselling, and then referred to the doctor. If there was an outreach rather than full-time doctor, the nurses started the patient with a telephonic script and the patient was seen by the doctor the next time they were visiting. Patients were started on treatment within a few days of submitting sputum, and returned daily to the clinic for DOT.

Doctors saw the patients monthly and those with complications were discussed with the sub-district SMO, multi-disciplinary DR-TB team or BCH specialists. Children under 5 years were initiated at Tygerberg Hospital or Red Cross Children's Hospital. People with XDR-TB were initially referred to BCH for initiation and then returned to the clinic to continue management. Later, patients also began to be initiated at the clinics.

4.2.2.3 Rural districts model

In Cape Winelands Breede Valley sub-district and the Overberg district, PWDR-TB were admitted at Brewelskloof Hospital for the intensive phase for 4–6 months until culture-negative, and when they were discharged home, the DR-TB doctors would do outreach to see them in the clinics. Similarly, in the Cape Winelands Drakenstein and Stellenbosch sub-district model, patients were initiated at Sonstraal Hospital, then discharged for daily DOT in clinics, and followed-up by Sonstraal doctors doing outreach. Mobile services provided injections at farms in some sub-districts. Clinic doctors were not involved in patient management in the rural districts. In the West Coast model, patients were referred to BCH for admission for intensive phase treatment. The patients would be discharged to their clinics and BCH doctors would do three-monthly outreach to monitor them. However, due to the burden of patients and insufficient beds, the CoE could no longer manage and outreach became less frequent. By 2008, BCH stopped doing outreach and patients were admitted at ID Hospital or Sonstraal Hospital. Family physicians had to take over coordinating and supporting DR-TB in the clinics and the CoEs only provided some outreach and telephonic support, which varied between districts.

In 2015, Brewelskloof Hospital clinicians began to build capacity at sub-district level for DR-TB care. They started with clinics that had done good baseline workups of patients, providing telephonic support to the doctors, and writing their scripts. The patients were initiated and attended daily for DOT at the satellite site. Brewelskloof Hospital doctors did monthly outreach visits to review all patients. Over time they reduced the frequency of outreach to quarterly visits and clinics started writing their own scripts, which were checked by the Brewelskloof Hospital doctors. The family physician assumed responsibility for the programme, trained other doctors, and developed a roster to visit peripheral clinics and provide outreach support. In Overberg, Brewelskloof Hospital began weaning support and they just telephonically reviewed scripts written by the clinics. In Overberg district, the challenge of receiving outreach support from Brewelskloof Hospital in the neighbouring Cape Winelands district, prompted the district to develop a decentralisation plan, to request more doctors, and to set up a pharmacy to have access to DR-TB drugs. They wanted to move towards having a DR-TB unit in Caledon Hospital and not having to refer to Brewelskloof Hospital. In Cape Winelands Drakenstein and Stellenbosch sub-districts, when Sonstraal

Hospital had capacity challenges and stopped doing outreach, the sub-districts took over management of DR-TB through family physicians who played a greater role in supporting the satellite sites. Medical officers were trained and started treating DR-TB in the satellite sites. In West Coast, there was no DR-TB site and no outreach provided by Sonstraal and ID Hospitals. The private GPs who did other general medical outreach did not have the capacity to manage DR-TB. Only one sub-district, Matzikana, had a DR-TB trained outreach doctor from Vredendal Hospital. The other sub-districts, Cederberg and Saldanha did not have a dedicated DR-TB outreach doctor. Local managers hoped that the West Coast district could establish a DR-TB unit in a district hospital in the future.

The next section summarises the different models adopted in the two provinces, and compares these to the models of decentralisation contained in the 2011 decentralisation policy.

4.3 MODELS OF DR-TB CARE THAT EMERGED

The intention of the National Framework for DR-TB Decentralisation was for each district to establish a decentralised site. Once there was coverage of every district, the province was expected to plan around how they would then develop decentralised sites in each sub-district. What emerged was a variety of different models, adapted to the local context, taking into account the burden of DR-TB, the history of decentralisation that had existed prior to the policy, the rural/urban nature of the district, and the resources available in that district: *“decentralisation in different areas looks different”* (WC NGO technical advisor). The Khayelitsha pilot model made more sense in an urban setting, where PWDR-TB were close to the clinic and could attend the PHC clinic daily for treatment, whereas the uMzinyathi pilot model suited a rural setting and required the use of community-based injection teams that traced, counselled, monitored, and delivered treatment at the patients’ homes. There was an acknowledgement at a national level that different models would be adopted based on the context in those districts.

As you know, South Africa is very different. The situation in KwaZulu-Natal is not the same as in the Western Cape ... The direction that needs to be taken was decentralisation. But of course this would have taken different shapes and different pace in the country, but there was a need to decentralise and to have different models. (WHO technical advisor)

4.3.1 Definition of decentralised site

The 2011 policy defined levels of care including: (a) a central site or CoE at a provincial level; (b) a decentralised DR-TB site that initiated patients in each district; and (c) a satellite site that managed patients after initiation. The staff that would be required for each 40-bed decentralised DR-TB unit that initiated DR-TB treatment included one doctor, 15 nurses, and one each of a pharmacist, social worker, dietician,

clinical psychologist, occupational therapist, physiotherapist, and data capturer for 10–20 patients; as well as one audiologist for 10–40 patients. These allied staff should be part-time staff giving 10%–20% of their time to PWDR-TB. Satellite sites which would not be initiating treatment according to the policy, would require one professional nurse for 20 patients and one community caregiver for 10 patients, with other staff, such as doctors and social workers being optional.

After the policy began to be implemented, the NDoH and those implementing the policy realised that these definitions were no longer applicable, as many satellite sites were supported to start initiating treatment and therefore could be deemed decentralised sites even though they did not meet the staffing and resource definitions contained in the policy.

The challenge is that the document remains stagnant for so long. So when it was written the definitions of decentralisation or the definitions of satellite site made sense in some ways but they don't any longer and the reason for that is really all satellite sites are now decentralised sites ... It might not always be part and parcel with what the guideline says specifically but a decentralised site I always defined it as not the Centre of Excellence but the site that is the provider of some level of nurse or doctor who could initiate treatment at that site. (NGO technical advisor)

Apart from the innovator pilot sites in uMzinyathi and Khayelitsha, when provinces decentralised DR-TB care, they did so to a DR-TB site in the district. The models that emerged ranged from centralised district hospital unit, district hospital units that initiated then down-referred to satellite sites, completely decentralised district models, sub-district models, decentralised sites at PHC facilities, decentralisation to PHC with outreach support from the DR-TB site, and even districts that had no decentralisation. Over time DR-TB hospital units down-referred to satellites, then satellites began initiating, and so a centralised model became a decentralised model, resulting in changing models of care in different places and over the period of implementation.

4.3.2 Centralised district model

In KZN, the first steps towards decentralisation in most districts was to move from the CoE to a decentralised DR-TB unit in a hospital, employing a centralised model, treating PWDR-TB at the hospital, and requiring them to return for follow-ups and monitoring in the intensive phase, without involving sub-district injection teams or PHC clinics. This was particularly evident in uThukela, iLembe, uMkhanyakude, Ugu, and uMgungundlovu. The DR-TB units employed tracer teams and sent them out to the entire district rather than have the sub-districts and PHC facilities take responsibility for tracing and community-based care.

It didn't take place the way it was set in the policy ... In actual fact, some of the decentralised sites kind of became mini centralised sites ... Why am I saying that is that if you are really decentralising you are a centre somewhere here, then beneath there, the decentralised site, there should be a sub-district, then under sub-district you'll have your satellite, I mean your clinics, then from the decentralised sites, when the patient has been admitted the patient will have to go to the sub-district ... then the sub-district has to link the patients to the facilities for follow-up and injection, because the injection teams, most of the time are at this level ... So what is happening now in other sites, you'll find that the injection teams are here [at the decentralised site] ... then let's say you've got four sub-districts. How are they going to cover all of these areas? (KZN provincial TB manager)

In WC rural districts, the care in the district DR-TB site was initially centralised, using a hospital model, and PHC facilities were not involved in managing or monitoring PWDR-TB. The DR-TB hospital would do ongoing patient monitoring at the hospital or provide outreach support to the PHC clinic.

4.3.3 District model with down-referral to satellite sites

District DR-TB hospital units then started to move towards down-referring patients once initiated, to their closest PHC facilities and to receive community-based injections. Patients were diagnosed at a PHC facility, baseline investigations done and they were then referred to the district DR-TB unit, where they were initiated and monitored monthly. After the intensive phase, they were down-referred to be managed at the satellite site. Once the satellite site became more confident and better trained and capacitated they would start to initiate. However, some hospitals preferred not to down-refer PWDR-TB with comorbidities and continued to monitor them at the district DR-TB hospital.

In other places they just send a patient away while he is on kanamycin, send a patient away while he is still on bedaquiline, they send the patient away during the intensive phase and then in our place we said no let the people first complete the intensive phase. Then we know that their adherence is good. They have gained weight. They have got insight to the programme ... we make sure that it is 6 months before we refer them to these (satellite) sites. Then the patients with the further coexisting comorbidities, such as diabetes we keep those for good. Epilepsy, we keep them for good. All those chronic conditions we won't down-refer those, we just keep them because we need to really monitor them. (KZN rural DR-TB unit doctor)

4.3.4 Decentralised district model

With time, district DR-TB units in the hospitals began to function in a decentralised way, implementing further decentralisation to satellite sites which were now initiating. The DR-TB unit no longer managed injection or tracer teams sending them out to the entire district, but these teams were established in sub-districts.

Previously we had a team at Murchison that was specifically for DR-TB tracing and they used to trace throughout the district. Since then we have managed to get more teams put into the sub-districts, each sub-district has its own tracer team. (KZN rural district TB coordinator)

The district DR-TB unit still served as overall support for satellite sites and for registering PWDR-TB and monitoring the programme. The DR-TB unit now served as a 'district CoE', seeing only patients who were sick or had complications and those requiring bedaquiline.

We are now devising what can be treated at the other clinics and what can be kept here and so we are becoming the King Dinizulu of Ugu and letting the other facilities manage their own patients ... we would get the more complicated patients. The patients who require bedaquiline, the patients who are very sick and the patients that cannot be kept at their facility they will get sent to us. (KZN rural DR-TB unit doctor)

However, with new regimens and particularly bedaquiline being introduced, there was a move to centralise DR-TB treatment again to the district DR-TB units and CoEs, because the satellite sites did not have the resources, like electrocardiograms (ECG) and capacity to initiate and monitor the patients, because permissions were required to use the drugs in order to control access, and because there was a need for pharmacovigilance with the new drug.

4.3.5 Decentralised sub-district model

In KZN, many believed that further decentralisation should occur to one site per sub-district in line with the policy, preferably a hospital or well-equipped CHC with required equipment and doctors. Decentralisation all the way to PHC would not be possible because of lack of availability of key resources.

No, we want to keep it at a sub-district level, the reason being is that we are looking at the rationalisation of the resources because if you further go down to PHC level you will need the ECG. Are we going to be able to have ECGs in all facilities? The answer is no, so it is better if it is decentralised up to the level of the mother [sub-district] hospital. (KZN provincial TB manager)

It would be difficult to capacitate every PHC clinic, ensuring new information reaches them and that they received training on new policies and guidelines. So it was a more rational approach to have a site at each sub-district with good transport to get patients to these sites. The other reason to adopt a sub-district access model was to capacitate the doctors in the sub-district hospital so that they could have expertise to support the other sub-district facilities that would be referring and being down-referred to. This ensured DR-TB expertise in every sub-district and not necessarily at every clinic.

We did do a decentralisation model per district which was requested from National ... initially the drive was to move to PHC but in Ugu district we decided that we are not going to rush into PHC but rather we are going to move to our district hospitals and community health care centres. The reason we decided that was because we wanted to capacitate our hospitals and CHCs so we have doctors available so they can provide support to the PHCs when they start initiating ... so that the burden won't still lie with Murchison hospital ... This would allow for holistic management of the DR-TB patient, because the normal referral pathway could be followed for DR-TB and their other medical conditions. (KZN rural district TB coordinator)

4.3.6 Decentralise to PHC

In CoCT, the decentralisation model adopted was aligned to the Khayelitsha pilot and involved decentralisation all the way down to PHC clinics where patients would be initiated, monitored, and complete their treatment. The CoCT had capacity at PHC level and had doctors who could support initiation of DR-TB, so did not need to first decentralise to a district DR-TB site in a regional hospital. In fact, they believed that it would be a burden on the regional hospital and would not really improve patient access to care if done the way the policy recommended.

Even though the initial plan spoke about decentralising to like a regional hospital ... If the original plan unfolded, instead of registering at Brooklyn Chest they would now be registering patients at GF Jooste but if we've already got a system in place in PHC and GF Jooste is congested why would we even go that route ... You've already got sufficient support and infrastructure in place between the PHC and the existing specialised centre. To introduce a secondary hospital just simply for the sake of accommodating a plan simply did not make sense. (WC urban district TB manager)

The City believed that its capacity at PHC level allowed it to skip the earlier phases intended by the policy and immediately go right down to PHC level, which was the ultimate intention of the policy.

If I remember the plan originally, I saw it in a step-wise fashion and the City was simply in a position that it could go to the last step ... it was able to decentralise to PHC quickly. I think at this stage that is what national would want anyway. (WC urban district TB manager)

Some DR-TB managers in KZN saw decentralisation down to PHC as reasonable in the next five years as they capacitated satellite sites to start initiating and managing treatment.

We are turning the corner. Really, we feel that when we are coping, we will make other facilities cope as well. Eventually we don't want to manage patients in the next five years in this facility. We want every facility to manage their patients. (KZN rural DR-TB unit manager)

The PHC decentralisation in KZN would have to be nurse-led supported by doctors that provided weekly visits because of the lack of doctors in most KZN rural clinics. However, they would still need to refer out for audiology and ECG.

eThekwini was able to develop initiation sites to cover all 18 PHC areas, usually in CHCs. In this way, not all clinics initiated treatment, but each PHC area has at least one site that could initiate. However, others argued that decentralisation should occur only down to CHC and not PHC level because PHC clinics were understaffed, underfunded, overburdened, and did not have infrastructure and space.

I also don't think we need to go down that far to that lower level. A lot of the clinics are understaffed and underfunded, you need expertise. They are already overburdened ... So, if you unpack it right to the bottom you will need training across the board, you will need support and I don't think it is going to be feasible to train to that lower level for MDR management. If you keep it at CHC, it is possible. (KZN CoE doctor)

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4.3.7 Decentralise to PHC with outreach

In rural WC, DR-TB managers believed the ideal model of decentralisation down to PHC required outreach support from the district DR-TB site because PHC clinics did not have capacitated doctors to manage DR-TB care. This ensured clinical governance. This model was more favourable for patients to access care closer to home. The outreach doctors would visit facilities, review all files to look at results of monitoring tests, and check that the prescribed regimens were correct.

(The ideal model) will be that when an MDR-TB ... will be diagnosed at a clinic. He will be initiated on treatment by the sister and the PHC doctor working together, being informed about the disease, building a relationship with the family to support, initiate that patient on treatment there and link them to care with the home-based carers and the community care workers at home ensuring that the patient is adherent on treatment at home. There is still support from the specialist in terms of MDR-TB, visiting the facilities and ensuring clinical governance is there ... I would like more available to do MDR outreach to support those areas much more where there are not skilled doctors due to changes of staff

or doctors at clinic level, where they can give more support to those patients and health care workers. So, only those that really need admission for a specific reason need to be admitted at the hospital. (WC rural district TB manager)

The clinics sent forms on all new patients to the doctors at the district DR-TB site who wrote the script, but when facilities were more confident, they wrote the scripts themselves and sent them to the district DR-TB hospital for approval.

In the beginning they still send me the form so that I have all of the information about the patient and then they write the script. Then they also send the script to me so that I can just see if they were correct. In the beginning I saw a lot of mistakes that I corrected for them and let them know that they can change it but now the more they are doing I don't change anything anymore for these specific sub-districts. Other sub-districts don't do any scripts, I do them all but I think it is a process and not all of the sub-districts are on the same level but it is fine. (WC rural DR-TB unit doctor)

Some argued for a telemedicine approach where medical officers or nurses telephoned DR-TB specialists to discuss the patients, who supported them to initiate treatment.

I would rather use a method of telemedicine ... All you have to do is phone a specialist ... it could be a nurse who has emailed a standard set of data. Someone phones and asks maybe a few more questions and then they clarify what should happen to that patient, which is kind of nurse initiation anyway but with a lot of support, so I think that could work. (NGO technical advisor)

4.3.8 Districts with no decentralised site

In rural WC there were still two districts that did not have DR-TB hospitals. They previously referred to DR-TB hospitals in neighbouring districts and relied on outreach and telephonic support provided from these hospitals. In the West Coast district, only one sub-district had a doctor that did DR-TB outreach, while the other sub-districts continued to refer to Sonstraal or ID DR-TB Hospitals. West Coast programme managers believed that they did need a DR-TB site in their own district to refer to and to support the PHC facilities.

I really don't know if it was money, staff or what but really Matzikama is one of our sub-districts with the highest MDR and TB and if we could have a hospital in the sub-district or near and the patients can be like from Monday to Friday there and then weekends, they can go home it will be great. (WC rural district HAST coordinator)

Overberg district also had no DR-TB hospital and previously referred PWDR-TB to Brewelskloof Hospital, which is situated in Cape Winelands district. The doctors from Brewelskloof Hospital provided outreach support but that has decreased in frequency and transitioned to telephonic approval of scripts. Overberg district would prefer having their own doctors capacitated to initiate patients in their facilities and explored having a DR-TB unit with a few beds in one district hospital, but that did not progress any further.

We have to use the Brewelskloof model for now but the long-term plan is to have ... at least a room within our main hospital which is Caledon. Hopefully, we will get there where we don't need to refer our patients to Brewelskloof unless it is really necessary. (WC rural district PHC manager)

4.4 CHAPTER SUMMARY

In summary, the way that decentralisation was implemented in KZN and WC varied between the provinces and also within the provinces between districts. In WC, CoCT adopted a model quite early of decentralising directly to PHC clinics, while rural districts maintained hospital-based models with down-referral and outreach support, then initiation in clinics much later. In KZN, each district established one DR-TB site within a hospital, some were established early after the policy and others within the following four years. Once each district had a DR-TB site, they began down-referral models to satellite sub-district sites (usually hospitals and some CHCs), then capacitated them to become initiating sites. Implementation was adapted to the specific context of the districts and provinces, and also reflected actor choices and interpretations of policy.

The remaining chapters explore these factors in more depth, namely, the varied perceptions of the meaning and intent of the policy (Chapter 5), the way that actors shaped implementation (Chapter 6), the process of implementation that required district ownership (Chapter 7), how resourcing influenced implementation (Chapter 8), and the trade-off between creating access to care and ensuring quality of care (Chapter 9).

CHAPTER 5. POLICY INTENT AND MEANING OF DECENTRALISATION

5.1 INTRODUCTION

The previous chapter showed the divergence of policy implementation across the two provinces, resulting in a number of different models of care being adopted. This chapter begins to explain the implementation differences, by unpacking the meaning and concept of decentralisation, exploring the ways in which the policy provided room for competing ideas and interpretations on the intent and meaning of the policy and its likely benefits. Decentralisation meant different things for different actors, and was executed in many different ways. Contesting arguments revealed the tensions that existed among policy-makers, experts, programme managers, and clinicians on whether DR-TB care needed to be specialised or generalised, nurse- or doctor-led, centralised or decentralised, institutionalised or ambulatory, and on whether directly observed versus patient empowered models of treatment delivery were preferable. Chapter 6 then explores how actors had different positioning, power, interests, and influence on implementation.

5.2 POLICY INTENT

The DR-TB Decentralisation Policy Framework stated that decentralised DR-TB treatment was more effective, socially acceptable to PWDR-TB, provided access closer to patients' homes, and reduced the burden on central hospitals for lengthy hospital stays. Participants expressed similar perceptions on the intent of the decentralisation policy that varied from achieving patient-centred care, to improving treatment outcomes, addressing waiting lists and bed shortages, and strengthening the DR-TB programme. This section spells out these different intents, which on the surface seemed aligned to each other and to the stated policy purpose.

5.2.1 Patient-centred care

Decentralisation of DR-TB care was in line with a growing move globally to ensure patient-centred care, treating a patient with dignity and respect and involving them in all decisions about their health (WHO, 2014). Effective TB treatment is influenced by support at the individual, economic, health system and social level (WHO, 2014). TB is associated with poverty and social isolation. Decentralisation brought care closer to PWDR-TB and reduced the need for hospitalisation so that they could remain with their families and continue their employment.

It was also to prevent, um the disjuncture within the family unit as well. Bring the services to the patient within the community, and at the end of the day once the patient is better, he can go back to work ... You're not breaking up that family, for one, what if it's the father of the family? What if it's the mother? And now you want to hospitalise that patient so, I think it was exclusively catered at

looking at the patient and doing what's in the best interest of the patient and also taking into consideration the family unit. Um to help that patient also ... get cured, he needs the family and the support of his family because the psychological impact of your disease has got a big outcome at the end of the day on how that patient is going to progress with disease. (WC provincial TB manager)

Hospitalisation for long periods in an urban hospital that was far-removed from home, meant families could not visit and patients felt isolated and abandoned. PWDR-TB were strongly against prolonged hospitalisations, and many refused admission or absconded.

The patients no longer wanted to be admitted. Other people just simply put it to us that they would rather die, they're not going to go into hospital. We had really extreme and unexpected strong reactions towards being admitted ... They [patients] are kind of lost because there is no easy transport. Their friends and family do not visit them and maybe they do visit them once but no more again and they feel abandoned, rejected, forgotten and they feel like they're going to die. (WC urban district manager)

In fact, so extreme was the resistance to being forcibly admitted, patients often did not return for treatment, resulting in many patients being lost to follow-up and dying.

A lot of the time patients were really locked against their will, and when they went to now clinics for continuation phase of treatment, we had a lot of problems. We used to lose patients, they would not come back because they'd be scared that they will be locked again ... Many people would just stop treatment, they died. (National TB manager)

With decentralisation, PWDR-TB would not have to lose their employment because of lengthy admissions and follow-ups at distant hospitals. In this way, they could resume their normal lives and employment, and this reduced the stigma of being sick.

MDR is not just about giving medicine ... It is a social disease ... Those who had a part-time job, if you admit them in hospital for long, they lose their jobs. When they go back there is no job. There is no way for them to recover, they remain sick. So, we tried to bring the treatment closer to the people. (KZN urban DR-TB unit doctor)

Improving access to DR-TB care allowed patients to avoid lengthy hospital admissions and follow-up care that incurred significant costs and lost time travelling to the provincial CoE.

You know money is a hell of a lot, it's a big thing for these patients, they don't have it ... because you know patients from Nqutu for example, they're two and a half hours away so for them to attend clinic

here ... (they) would go to Nqutu on a Tuesday, spend the night on a bench or on the floor, come here [district DR-TB site] on Wednesday, go back, spend Wednesday night at the hospital ... and only go home on Thursday, so it's two days away from home, sleeping on the bench or the cold floor or whatever. Spending the whole day in clinic on a bus, two and a half hours there, two and a half hours back. So now with this decentralising, it's spot on because they can just go to Nqutu and we follow them up every six months here just so we can do X-rays and see how they're doing. (KZN rural DR-TB unit nurse)

5.2.2 More effective treatment

The public health rationale for decentralising DR-TB care was that it would result in more effective treatment, with earlier treatment initiation, reduced transmission in communities, and improved treatment adherence. Research studies and NGO-led models showed that community-based treatment resulted in early treatment initiation because there were no delays in waiting for hospital beds, thereby reducing community transmission. In the past, patients waited at home for weeks and months due to long waiting lists for admission and remained an infection risk in the communities. Even when they were admitted, due to bed shortages, patients were sometimes discharged early before they 'smear converted', presenting another risk of transmitting resistant strains acquired in hospital. Since decentralisation, the time to initiation decreased from one month or more to within five to seven days in both WC and KZN, and waiting lists in hospitals were eliminated.

With new models of decentralisation, patients no longer had to be admitted for months, which had the impact of improving adherence.

When patients were interviewed, we discovered that it's a model that they like most because they can be with their families whilst they are on treatment in such a way that, to us it improved adherence to treatment and there were less defaulters. (KZN provincial TB manager)

Decentralisation therefore achieved two of the pillars of success in managing PWDR-TB, namely, initiating treatment early so that patients were no longer infectious, and improving treatment adherence.

5.2.3 Reduced load on hospitals

Prior to decentralisation, CoEs could not cope with the burden of DR-TB. Both KZN and WC experienced high patient volumes, insufficient hospital beds and long waiting lists. There were simply not enough beds to continue the central hospitalised model of care.

There were not enough beds to keep everybody in hospital. King Dinuzulu ... (had) say 150 beds, you had to be sick in hospital for six months ... so in one year you can treat 300 patients. However in KwaZulu-Natal in the lab there are 3 000 MDR-TB patients that were diagnosed ... I did a study where it showed there was an average of ... three months to wait for this bed and what happens is that the doctors here, they see, they have these like three months waiting list, everybody is screaming and shouting at the hospital, OK we can keep you for five months, ok for four months, ok for three months and then two months ... the people that were discharged that were culture-positive or even smear-positive was increasing and increasing and increasing. (KZN researcher)

Moving care out of hospitals was more cost-effective and allowed the hospitals to focus on sicker patients with complications.

I don't believe the treatment of TB is going to be beaten in hospitals ... I think the National Department's policy is, "treat as much as you can out there". Because hospitalising people is expensive, it costs us about R1 100 per patient per day and we are probably the cheapest because of our economic scale. So it is not a cheap business and drug-sensitive TB is a walk in the park financially, it is about R30 per month now. (WC CoE manager)

The burden of DR-TB was growing so rapidly, that building more hospitals would never be able to catch up with the need, notwithstanding the time and cost involved.

5.2.4 Improved linkage and HCW capacity

Decentralisation would result in strengthening the DR-TB programme, improving linkage and referral of patients, strengthening the capacity of HCWs at lower levels for managing DR-TB, and improving the quality of care.

With the previous centralised approach, the referral system between the CoE and local facilities was poor. PWDR-TB discharged from the CoE were not linked back to their PHC facilities, were unsupported between follow-up visits back to the CoE, and were often lost to follow-up.

Most of those clients were failing on treatment and the majority were also becoming lost to follow on treatment, mainly because there wasn't any coordinated structure in terms of the follow-up for the clients because the client would start treatment in our district ... goes down to Durban, starts treatment that side and they would discharge the client without informing us and the client will be found at home not knowing what to do ... and when the client is experiencing side-effects he just decides to stop with treatment as a result. (KZN rural district TB coordinator)

When discharged from the CoE after being initiated on treatment, PWDR-TB and their families had little knowledge about the disease.

As soon as you can walk, you can leave this hospital because I need your bed for another patient ... People were then discharged, they were still infectious and they are being discharged now home ... they have no idea, they don't know anything about MDR or infection control, the family doesn't know anything, there is no support or anything. (KZN researcher)

Interviewees shared that it would be easier to track and link patients to care and monitor them once they were managed at a district level, compared to being managed at a CoE. Local clinics were better able to do tracing, engage families, and address patients' challenges with treatment at a local level. Local clinics knew the communities well and developed trust with patients to ensure continuity of care.

You are a facility that knows the community, you know the geographical distribution, you know the ways of the cultures because each sub-district has their own way of existing. So, they are closer, you feel that you can trust somebody you are going to all the time instead of going to a doctor that you've only seen one time ... when we can't find a patient, we go to the clinics and we asked the clinics to please trace this person and bring them to us. (KZN rural DR-TB unit doctor)

Outpatient treatment was already adopted by CoEs and PWDR-TB were being sent home on treatment without DOT supporters and injection teams being in place. With decentralisation, the proper referral, linkage and outreach structures were put in place.

With decentralisation, there was also an opportunity for HCWs to improve their capacity to manage DR-TB and to therefore reduce the stigma amongst HCWs of treating DR-TB. Before decentralisation, patients who were discharged from CoEs would continue treatment at their local clinics and hospitals, where staff were not trained and confident in dealing with PWDR-TB. Decentralisation formalised the training for HCWs at lower levels and all nurses and doctors in new DR-TB units and satellites sites were trained on DR-TB management.

A long time ago MDR was treated as a big monster which was kept in King Dinizulu ... They were locked up, even health care professionals were not aware of MDR management let alone the caring of the patient ... To me one of the advantages of decentralisation was to impart knowledge to all health care workers in terms of management of MDR ... Those days if there was an MDR patient waiting for a bed at a central hospital, if that patient suffered from any other medical condition and needed attention from our normal hospitals, they would not admit them. So the decentralisation came with a

lot of information that changed the mindsets of more people than what we have imagined. (KZN urban district TB coordinator)

5.3 CONTESTATION AROUND DR-TB MODELS OF CARE

The perceived intentions of the policy did not seem to be in direct conflict. However, the translation of the perceived intents into practice resulted in districts taking very divergent approaches to implementation. These differences in approach related principally to whether policy was positioned primarily from the patient/family point of view or from the provider/system point of view; and what was believed to be the most effective clinical and public health approach to DR-TB.

5.3.1 Specialised versus generalised care

Many DR-TB experts and clinicians argued that managing PWDR-TB was complex, as they were often coinfecting with HIV and other diseases, DR-TB drug regimens were complex, and patients were likely to experience side-effects and drug interactions.

I had six clinicians in the training session ... They said we don't have the confidence to treat DR-TB patients. We are treating drug-sensitive TB patients out of a manual so now to do DR-TB patients ... the doctor does not know how to interpret this and interpret that, especially if it comes to liver functions and interactions with ARV drugs and all of those things you know that makes it complicated. I heard one of the doctors saying ... two years ago I was on campus and now you want me to treat the most complicated disease ... with comorbidities and added drugs and interactions. (WC provincial TB manager)

Some DR-TB experts proposed that the ideal model would be a mix, with specialised clinical expertise at a centralised site to initiate treatment, counsel patients, and prepare them for the duration of the treatment. After two weeks the patients would be referred to the PHC clinic to continue treatment. The patient should then still be monitored at the DR-TB site every three months. They also believed that DR-TB sites should be strengthened with more staff who could provide outreach rather than pushing DR-TB care to PHC.

The first thing is I would have a centralised facility where there were specialised doctors, not specialists, the doctors who treat DR-TB, and everybody would be admitted for two weeks. And in that two-week period, I would first of all confirm if this is MDR or XDR, start appropriate treatment, and have intensive counselling, because the treatment is shocking ... And also in that first two weeks, you can often detect early problems that are going to occur and do it properly. So if there's a kidney problem? Fix it up ... You know, then you send the patient home within a two-week period back to their clinic with a packet that said this is [person x's] drugs. (NGO technical advisor)

Others believed that all clinicians should be trained and confident to treat DR-TB at PHC level. This was done successfully for HIV and for DS-TB and, with experience, the PHC clinics would also be able to manage DR-TB treatment. Only patients with complications need referral to specialised DR-TB units. This would ensure patients did not experience delays and incur costs in accessing and initiating treatment early.

Because the more we have Centres of Excellence, the more we are centralising treatment and that is why TB is not moving anywhere. ARVs came from behind, they are treating treatment failures and using second-line regimens in the PHC. So why is TB still staying centralised? Why are we centralising? No, we don't need to centralise. Take DR-TB down there, they are already managing TB and let them treat it. The more they treat, the more they have the skill and the more they have the experience. The more you keep them away, the more they fear, so take it down there and let them do it. (NGO technical advisor)

5.3.2 Nurse- versus doctor-led model

The national policy framework also recommended the approach of nurse-initiated management of DR-TB (NIMDR). However, many DR-TB clinicians and managers, principally in the WC, expressed the belief that the treatment of DR-TB was too complex for nurses to manage. They argued that nursing approaches are protocol driven, and nurses may not be able to monitor patients adequately and make decisions about regimens and drug substitution. There was also a regular turnover of staffing especially in rural areas, making it difficult to build up sufficient capacity for managing DR-TB.

I think it is a pie in the sky idea ... They won't understand much of the new regimens. You also cannot expect a NIMDR nurse to make a decision on a dropping HB [haemoglobin] or interpreting a low blood count or deciding whether to stop or to continue with linezolid and all those toxic drugs. I think they are venturing into dangerous grounds. (WC rural DR-TB unit doctor)

I mean I don't want to be insulting towards nurses versus doctors, but nurses are very much protocol driven, doctors they don't just blindly follow. They're not going to blindly give a nine-month regimen if the patient is not suitable for a nine-month regimen. (WC NGO technical advisor)

However, in KZN a number of participants believed that with training, nurses could effectively treat DR-TB. There were not enough doctors available and there was no choice but to rely on nurses in many rural settings. Where nurses were trained, they were initiating DR-TB treatment independently and were believed to be competent, even if they did not initiate treatment in patients with complications. A study by

researchers from Johns Hopkins University (Farley et al., 2017), who supported the rollout and training of NIMDR, showed that nurses and doctors performed similarly in initiating DR-TB.

While most respondents believed that doctors should initiate DR-TB treatment, they did concede that ongoing monitoring and care could be done by a nurse.

My personal opinion on the matter is that the MDR drugs are so complex and difficult that I feel that initiation should happen with a doctor, but the long-term care can happen under a nurse practitioner, under the guidance of the doctor. (National manager)

The argument about nurse- versus doctor-led treatment aside, all agreed that nurses should be trained and become competent in DR-TB management, because they had an important role to play in diagnosing and working up the patient and in providing ongoing monitoring.

The nurses wash their hands from the DR-TB patients because the doctors were in charge of it. You do need to train the nurses and you do need to get them involved. You need to make it very clear that it is their baby not the doctor's baby. The monitoring, the engagement, the DOTS, the collection of specimens, it's got to be done by the nurses. It's only the treatment regimens and the choice, the assessments that I find you have to have a doctor for. The normal programme part of it, if you don't bring the nurses along you've lost it. Some nurses are remarkable the way they understand. They're just as good as doctors if not better. (WC urban district manager)

However, if nurses were to be involved in treating PWDR-TB, many DR-TB experts cautioned that they should at least be able to telephonically consult a doctor to initiate a patient.

There needs to be some consultation with doctors, even if it is a telephonic conversation so that I pick up the phone and I say, doctor so-and-so, I have got this patient in front of me, I've got this result, the doctor then asks a whole set of questions, I need to have been given a certain baseline results and then I need for him to say yes, it's fine, start this, start that, or don't. Remember that our nurses at a primary care level are not clinical nurse practitioners, they have basic training and often they have had no training in DR-TB. How can we want to make them mini doctors now? I think you know what, there is a scope of practice and I think there are certain skill levels ... I firmly believe we need a clinician input and support. (WC urban district TB manager)

5.3.3 Institutionalised versus ambulatory care

Before the decentralisation policy, there were concerns about initiating PWDR-TB as outpatients due to the risk of transmission in the community.

There was a lot of hype around whether you allow an MDR patient or XDR to be treated as an outpatient and initially there was a lot of resistance. You can't have an infectious person walking, you know outside there, you must isolate him. (KZN CoE doctor)

In reality, the CoEs were overwhelmed with large volumes of patients, shortage of beds, and long waiting lists, and despite national policy at the time to admit patients for the intensive phase, they had begun initiating them on treatment as outpatients.

At that time national said admit every patient until they culture convert ... What it did at our facility, it created a backlog ... you had patients that needed treatment that were waiting and we couldn't do anything ... So we decided we are going to do outpatient treatment, so patients that needed treatment were initiated as outpatients ... There was a need, it was out of the need that we did it. I think more than 60% of our patients were initiated as outpatients that was just to get them on treatment and we couldn't give them a bed. A lot of them were up and about, why make them wait. We also found that a lot of our patients didn't want to come here. They didn't want to stay here. You hear some sad stories of mothers leaving children with neighbours and coming here and then we ask them to stay six months which wasn't realistic. It wasn't practical so we did outpatient treatment. We gave them treatment, they went home. (KZN CoE doctor)

Employing a community-based model depended on the context. In urban areas, patients lived close to the PHC clinic and could come in daily, while in rural areas there was a role for community outreach by injection teams because patients had challenges accessing the clinics. In a number of KZN rural districts, such a community-based model was adopted. After short admission for initiation as an outpatient, dedicated community-based DR-TB teams would visit patients' homes, do contact tracing, administer injections and ensure adherence, and monitor patients and refer them if required. The patient would be required to visit the facility monthly for monitoring.

In urban areas, such as the CoCT, patients lived within a 3 km–5 km radius, so could come to the clinics daily, and home-based injection teams were considered not financially viable, especially in the light of the large patient volumes in urban areas. Facilities did rely on community health workers from NPOs and sub-district counsellors, who linked patients to care and traced persons LTFU. In rural WC districts, while there were no injection teams, community-based organisations assisted with home DOT and there were mobile clinics that went out to farm communities.

Despite the policy advocating for community-based care, some districts adopted an institutionalised model, decentralising to a district DR-TB unit, admitting patients for initiation and only discharging them after one to two months, once they had achieved culture or smear conversion. In this way, patients were counselled intensively to ensure good adherence, they were monitored for side-effects, and they were discharged when they were no longer infectious to the community.

I know that 2015 review they said that we shouldn't admit all of our patients ... but we would like to admit them just to see that they are adherent, any side-effects, adherence counselling, the social worker can see them, and the audiologist can see them. So that is why we prefer to admit them. (KZN rural DR-TB unit nurse)

Some argued that the model of institutionalised versus ambulatory care was less the issue than how well patients were counselled and prepared for treatment in either model.

Even today the challenge is you cannot say hospital-based or decentralised-based is better ... I feel that we have also moved from rushing to initiate people on treatment and not providing any counselling, not doing any home assessments. I mean when you look at a lot of our patients, the conditions they come from, to send a patient with MDR-TB who lives in one room with children. I don't think that is correct. (NGO technical advisor)

While the policy advocated for moving away from institutionalised models of care, there were still patients who needed to be admitted due to social problems. Many who were experienced in programme implementation advocated that patients who refused treatment, had defaulted, or who had drug addictions or safety issues, still be admitted for six months. Allowing them to be in the community without treatment was a community transmission risk and some proposed that there should be a policy that requires or enforces admission for these patients.

5.3.4 Decentralise to district hospitals versus de-institutionalise and provide care at PHC level

The decentralisation policy framework proposed one decentralised DR-TB unit per district to bring care closer to people, and to use this as a base for further decentralisation to sub-district satellite sites and for introducing community-based teams.

So the way I see the whole process we had the central hospital, one per province. Now, immediately having community structures and nothing in between would have been a problem ... you have got to align it with your general hospital services ... you should have some hospitals in each district and then from there, build your satellite sites which will be linked to the centralised sites ... Our first aim was to say even if we are not able to cover everywhere but at least as a starting point, every district should

have at least one of these decentralised sites in the country. So we have achieved that, each district has at least one decentralised site. (National TB manager)

Participants in KZN adopted this approach and set out to create access to treatment at DR-TB units at district hospitals rather than the provincial CoE. District DR-TB sites began to admit and manage PWDR-TB rather than just one provincial CoE, thus decreasing the load on the CoE.

Ok so I think it is basically allowing patients to access their treatment ... versus going to specialised facilities, such as King Dinizulu. Most patients are lost in the system. The hospitals can't cope with the burden of disease, so I think this just allows more access points for the patients which greatly assists them. (KZN rural DR-TB unit doctor)

One respondent pointed out that decentralisation was a general idea of shifting responsibility from the centre to the periphery, which did not have to automatically equate to de-institutionalisation, creating the space for the development of different models.

When you say this word decentralisation it's funny; everyone does have this not very different ... but different nuanced interpretation of it ... It would be amazing if my patients could just go to the next level down from my hospital. That would be decentralisation. It doesn't matter where as long as it's not just here. It's like this bottleneck ... So that is decentralisation in some ways ... it is moving it away from a central spot. (WC NGO technical advisor)

Using that understanding, decentralisation would not do away with hospital-based care, it would actually result in more hospitals establishing DR-TB sites, but at the same time strengthening the community-based services.

There's a huge difference in understanding ... It's about decentralising the care, meaning you still keep hospitals, actually increase the number of hospitals and then also you move treatment sites outside hospitals ... In KZN it was more about having structures that admit patients, the more hospitals there are, and a number of mobile units to visit patients who cannot reach the facilities. (National TB manager)

Some participants thus interpreted the model of decentralisation expressed in the policy framework as just decongesting and reducing pressure on the central hospitals, moving care to one level lower. They did not view the decentralisation to PHC as an intent of the policy, at least not in its initial implementation.

It was basically to get to release as much as possible the pressure from the big hospital and decentralise to minor hospitals ... At that time there wasn't much talk about really PHC yet. (WHO technical advisor)

Although de-institutionalisation was not initially included in the policy framework, it was added later in the policy formulation process because the WC experience in Khayelitsha provided evidence that PWDR-TB could be managed outside of a hospital setting, in PHC clinics. WC advocated through the National Health Council to explicitly include the term de-institutionalisation in the policy title and content.

The first draft that we circulated was saying decentralisation but then they actually insisted to say decentralisation and de-institutionalisation so that we do both at the same time ... Now to the Western Cape people, it was very easy to reach all your PHC because they have a system whereby doctors are treating all levels of care so it's very easy then to have all these people initiate care ... And when I presented this policy at the National Health Council ... the head of department from the Western Cape felt there must also be de-institutionalisation ... they insisted there was a need to ... initiate more in the community and few in the form of admission. (National TB manager)

Participants in the WC focused on what they believed to be the ultimate goal of the policy which was providing DR-TB treatment in all PHC facilities, foregoing the intermediate step of district DR-TB units, because they had the capacity at PHC.

The national model says specialist hospital, down to secondary hospital, down to district hospital, and from the district hospital outreach teams to primary care level, but because local authority and all in Cape Town had developed the expertise around managing TB anyway and the district hospitals, secondary hospitals on curative care, kinda it didn't make sense to use that national model in our context here and that's why we went straight from specialist hospital right down ... to primary care clinic level. (WC urban district TB manager)

5.3.5 Directly-observed treatment versus patient empowerment

There has been a long-standing debate in the TB field about whether people with TB have to be observed while taking their treatment or can self-administer their treatment. DOT was considered by some to be disrespectful and paternalistic, especially when all patients were expected to have DOT irrespective of their own circumstance or individual level of responsibility. Patients were not offered autonomy, and decisions were made for them.

The moment you are diagnosed as TB we assign you a lower intellect and that is just an unconscious thing. So, you've got TB so I must now think for you. I must make the decisions for you. (WC provincial TB manager)

The approach in the HIV programme was offered in contrast, where information was shared and patients were empowered through treatment literacy. People coinfecting with HIV and TB did not need to be seen every day to ensure their ART was taken, but they had to attend the clinic daily to observe their TB treatment.

Funnily enough we actually had patients on ART and TB treatment at the same time, but we can't trust you to swallow your TB pills, so you must still come to the clinics to swallow your TB pills, but it's ok to swallow your ART at home. (WC urban district TB manager)

DOT had consequences for patients who struggled to visit the clinic every day when they had to find work and earn an income. Even for the clinics and clinic staff, DOT was a burden, on the nurses' time and space required to accommodate the patients.

Research has documented the benefits of self-administered treatment (Mohr et al., 2018). Participants argued that as a consequence of decentralisation, PWDR-TB were now more educated, had become more empowered, and responsibility for their treatment was given back to them. In KZN using community-based models, patients were not expected to come to the clinic to do DOT. In CoCT, TB nurses took to bending the rules, pre-packing medication for patients to take at home because they understood the challenges of daily DOT at the clinic. CoCT participants noted that despite decentralisation for a few years in which daily DOT was implemented, there were still high rates of LTFU and poor outcomes, and adopted the strategy from the Khayelitsha model to pre-package medication to enable stable patients to self-administer treatment. Community health workers visited homes to talk to patients and their families, and to ensure support was in place, and would issue weekly or monthly supplies of medicines.

The argument against self-administered treatment was the danger that patients would not take their medicines properly or default. DR-TB treatment was not available in fixed dose combinations, and patients were found to take some pills and leave others out because of side-effects, which led to further and worse resistance. Daily DOT was also an opportunity for the TB nurse to monitor the patient for side-effects which could be quite severe. Experienced TB nurses and coordinators felt that they should not be lenient and allow self-administration before four to five months of treatment was completed, and even then, to give one- or two-weeks supply and not for a month.

In this area if they are on the long conventional (regimen), they must have daily DOT. Bedaquiline daily DOT is in the policy, shorter regimen daily DOT. I don't care if the patient is not on injectable, because of the adverse reactions, because the high doses of moxifloxacin and clofazimine has many side-effects, it is essential that you monitor the patient until there is a culture-negative and the adverse reactions have been sorted out ... and the patient is clinically well and he is adherent. It depends on the doctor and the nurse to make that decision, but I always say be lenient not before four or five months but then we give a week's supply and sometimes we give two-weeks supply but not a month.
(WC urban sub-district MDR-TB coordinator)

5.4 CHAPTER SUMMARY

There were differing perceptions from stakeholders of the policy purpose and intent, from addressing constrained bed capacity, to the need for patient-centred care, and adopting ambulatory and community-based care rather than hospitalised care, which would be more cost-effective. These multiple rationales were all articulated in the policy document and seem to be aligned towards the overall purpose of improving access to DR-TB care. However, the different core orientations and beliefs articulated and the space for different interpretations of policy (such as in the meaning of the term 'decentralisation') resulted in very different approaches and priorities in implementation. What emerged at district level depended in part on the way some discourses were able to assert dominance over others. How provinces, districts, and facilities chose to implement was subject to their own interpretation of the need for and the benefit of decentralisation, which challenge they perceived was greatest, which intervention offered most benefit, and what they believed about the evidence for the interventions.

This chapter has explored the perceptions of stakeholders about the policy's intent and also presented contestation about various approaches and models of DR-TB care. In so doing, it allows for a critical interrogation in the next chapter of the dynamics of actors and networks, exploring whose interests were dominating the discussion and how actors' positioning, power, and interest influenced implementation.

CHAPTER 6. POLICY AGENTS, CHAMPIONS, AND RESISTORS

6.1 INTRODUCTION

The previous chapters described the timelines of implementation, the models of DR-TB care that emerged, and the understanding of stakeholders regarding the meaning and intent of the decentralisation policy. This chapter first maps the actors that influenced health policy implementation at national, provincial, district, and facility level. It then examines the dynamics, namely the tensions and contestations between these different actors, and the ways in which they exerted influence (power) on the implementation of the DR-TB decentralisation policy as individuals and networks.

6.2 MAPPING DR-TB ACTORS

Table 5 presents a stakeholder analysis of the TB programme and health system actors influencing DR-TB implementation across multiple levels. The KZN and WC Provinces are contrasted, and the type of influence and support of actors is indicated as supportive and influential in driving implementation (green), minimally supportive or influential (orange), not supportive and able to exert resistance (blue), either supportive/influential or not (blue/green), and no support or influence (yellow).

The mapping revealed that in KZN, early implementation was supported and actively driven by the combination of an influential provincial TB manager, an innovator rural district uMzinyathi (with both a strong district manager and district TB coordinator), and technical support at provincial level through WHO and the MRC, and at the district level by a host of NGO partners including Philanjalo, Yale, Harvard, Partners in Health, the Italian Corporation, and University Research Co. (URC)/USAID. In the WC, implementation was influenced by an innovator sub-district (Khayelitsha) with a strong sub-district manager and NGO support (MSF), backed up by a proactive CoCT TB manager, sub-district managers, and MDR-TB coordinators. Systems dynamics were important in implementing DR-TB decentralisation, and in both provinces involved the actor combination of a TB programme champion, an innovator district or sub-district, and NGO technical support. In both provinces, clinicians at district DR-TB sites and satellite sites were either positive or negative influencers of implementation.

Table 5: Actors and their influence on implementation of DR-TB decentralisation in WC and KZN

National	External	Programme		Management		
	WHO	National TB programme manager		Minister of Health		
		DR-TB programme managers		National Treasury, Medicines, Labs		
Province	KZN			WC		
	External	Programme	Management	External	Programme	Management
	WHO	TB programme manager	Health MEC, management		TB programme manager	Health MEC, management
	MRC					
District Metro		eThekwini TB programme manager	eThekwini managers		CoCT TB programme manager	CoCT managers
District Rural	Philanjalo, Yale, Harvard, Partners in Health, Italian Corporation, URC/USAID	District TB programme coordinator	District manager		HAST managers	Rural district manager
Sub-district		TB programme coordinator		MSF	CoCT DR-TB coordinator	CoCT sub-district manager
Health facility		CoE clinicians			CoE clinicians	
		District DR-TB site clinicians	District DR-TB sites CEOs		District DR-TB site clinicians	District DR-TB sites CEOs
		Satellite site clinicians			Satellite site clinicians	

The sections which follow provide a description of the characteristics of actors and their networks that facilitated or impeded policy implementation; and an exploration of the factors shaping resistors and champions of implementation.

6.3 NATIONAL LEADERSHIP

Dr Aaron Motsoaledi, South Africa's Minister of Health from 2009 to 2019, was elected as the Chair of the Stop TB Partnership Coordinating Board in 2013. He was widely viewed as a bold and ambitious leader for TB, "Minister Motsoaledi's vision for a world free of TB, coupled with his deep personal commitment and inspiring political leadership across the African region and beyond make him the natural choice to take us forward at this critical time" (Executive Secretary of the Stop TB Partnership).¹ Managers at district and provincial level also regarded him as providing visionary leadership and commitment, serving as a strong advocate for TB policy, and a leader who would translate that commitment to programme change.

Our Health Minister just needs the numbers ... and you will find the money. I think that is the kind of vision that we probably need. When these challenges are rising, we need leaders who can dare to try something because on the ground we are faced with many challenges. (KZN rural DR-TB unit manager)

Others however were more muted in their appraisal, applauding his political will and advocacy for policy change, but did not see that translate into effective implementation.

It is great that we have a Minister of Health since 2009 that has been a strong advocate for TB. I still don't see the actions. It is great being an advocate but ... being an advocate and changing policy and introducing stuff, you don't necessarily see it playing out in the field. At least we have political will and that is majorly important. (WC rural DR-TB unit manager)

Political commitment by the Minister of Health was complemented by skilled and committed programme leadership for DR-TB. Dr Norbert Ndjeka was appointed as national DR-TB manager in 2008, having had prior experience in clinical DR-TB in Limpopo and conducting DR-TB training at URC. Appointing a DR-TB manager to specifically address the DR-TB issue was an important development and many believed that he enabled access to new policy and drugs. Dr Ndjeka was at the forefront of benchmarking DR-TB decentralisation programmes in other countries, learning lessons from pilot projects, then steering the development of the decentralisation policy by bringing stakeholders together to draft the policy. He was effective as a policy-broker in steering new policy for decentralisation and for new drugs and regimens, obtaining regulatory approvals for new drugs after successful compassionate use programmes.

¹ http://www.stoptb.org/news/stories/2013/ns13_044.asp

We're so lucky to actually have someone who engages and who gives a damn. He actually cares about it. Yeah like he really wants to make things happen and I think what a lot of us don't realise ... the pressure he is under on the other side to make things happen ... political pressures he has ... and yet still wants to make things happen. I think he has really pushed things forward in South Africa. (NGO technical advisor)

In terms of implementation, he had strong ownership, and hands-on coordination of the programme working through technical networks and within programme circles (provincial and district DR-TB managers and DR-TB clinicians), as well as leveraging NGOs.

Now the good thing about Norbert is that he spends a lot of his time out in the facilities and in the districts ... we have other managers who hardly ever go out ... I mean sitting here looking at data gives you context but without going out there you don't know how the implementation is unfolding, and calling people to meetings is not a very efficient way of managing, monitoring and coordinating. (National manager)

In facilitating implementation, it was important to get partners on board, create a clear shared vision, and navigate the concurrent nature of services, and this required soft skills in bringing people around to the vision.

The environment is complex and the only way to get things done is to be able to cajole, facilitate and know a little bit more than a few other people and be able to then use the evidence against them. (National manager)

Dr Ndjeka was the face of the DR-TB programme nationally. He commanded respect and worked well with colleagues at regional and global levels. He was well known and seen as an important global DR-TB expert, consulted even by WHO.

Norbert (Ndjeka) became as you know an international expert ... in his own right as the consequence of the progress we have made here. In fact, the WHO hardly ever takes a decision without asking us what we think, what we have done, and Norbert will participate in those meetings as a consequence of us trying out new things but responsibly. (National manager)

6.4 PROVINCIAL OWNERSHIP

National policy-makers were very clear that according to the National Health Act, the responsibility for implementation rested with the province and not with the NDoH.

I don't think anyone in their right mind can argue that the national department has to think about every implementation step. With implementation it is by province ... If you look at the National Health Act it doesn't say anywhere that the national department is responsible for implementation. We are responsible for policy, planning, monitoring and support. (National manager)

Support for the policy and efforts to drive its implementation differed amongst provincial TB programme officials and this explained some of the provincial variation in decentralisation.

You know the other provinces they have a lot of independence. I think that also the provincial person responsible for TB ... some were more pro-active than others ... about involving the different stakeholders and taking action ... [there were] highly committed staff who really moved things forward. (WHO technical advisor)

In KZN, the push for decentralisation came from the province because of bed shortages and high rates of LTFU. The previous provincial TB manager was considered by many participants to be a strong champion and driving force for DR-TB decentralisation. He worked across the province to support DR-TB surveillance, and embraced innovative pilot projects and research at Church of Scotland Hospital (COSH) with support from Yale University, but recognised the need for a systems approach to transition from an NGO-led pilot to a district-owned model.

Bruce (Margot) was also a key person you know ... I think some of the other provinces would have chased these researchers away but he didn't ... he embraced them, but [he said] you can't be at COSH you must come and be at Greytown ... which was a brilliant move because I think it [COSH] would have been possibly seen as a Yale facility. (KZN NGO technical advisor)

The provincial TB manager worked with MRC to learn lessons from the pilot, adopted tools, and obtained buy-in from districts for decentralisation to be scaled up to four other districts. In fact, the KZN efforts were seen to have sparked the strategy and policy for decentralisation.

That's when the South African DoH realised, it was more like the KZN TB co-ordinator who highlighted this issue and that we need to do something else, we needed a strategy. Then together the KZN DoH and the National DoH came up with the strategy of decentralisation. (KZN NGO technical advisor)

In contrast, the CoCT pilot was not supported by NDoH, and the WC provincial TB managers perceived the NDoH to be resistant to the Khayelitsha model. WC provincial managers were thus cautious in proceeding with decentralisation, despite the success of the pilot. As a result, the Khayelitsha pilot had to be discrete, as provincial actors, while supportive, were still unsure if the NDoH would approve.

There were a number of people at Province who were quite supportive, but they were kind of worried what National would think. So they didn't want to be so overtly against National you know ... It's kind of the same approach [of when] the antiretroviral treatment came ... let's just kind of do it under the table a bit. (WC NGO technical advisor)

There were also internal differences. The WC provincial TB manager who was in place at the time of the CoCT decentralisation, had differing views to the City TB manager around how implementation unfolded and what the priorities should have been. The province watched, supported and funded, while the City TB manager led in implementing decentralisation, pre-dating the policy. There was no decentralisation to other districts in the province. The WC Province actors were concerned about the fallout with NDoH on the one hand, and how they would scale one urban township model across a province where the context differed and where the support of NGOs was not as strong, on the other hand.

I think they (WC Province) were worried about the fallout with national before national agreed ... They were worried about if we succeeded ... how would they then do it elsewhere? ... Western Cape has always been very much involved with this thing of DR-TB ... but when we started with MSF wanting to go the decentralised way, the Western Cape didn't jump for joy. At that stage they said no hang on, hang on ... There was a bit of concern ... Because they were saying we can do it here in Khayelitsha because it's me and MSF but how are the other sub-districts going to do it? They didn't think the conditions in the other sub-districts without a partner could do it. (WC urban district manager)

6.5 DISTRICT-BASED NETWORKS

The experience and progress of implementing DR-TB decentralisation differed between the two provinces. Both started with pilot projects, in KZN at COSH in the rural uMzinyathi district, supported by NGO and research groups Yale University, Philanjalo, and the Italian Corporation; and in the WC in the urban sub-district of Khayelitsha, supported by MSF. However, in KZN the lessons from the rural pilot were scaled up by a network including the provincial TB manager, district manager, and district TB coordinator to one rural district, while other districts delayed implementation until two to five years later. In the WC, the urban pilot was scaled up by the City TB manager to all sub-districts in the CoCT, while there was very little decentralisation implemented in the rural districts until six years later, with little push for decentralisation from the province.

6.5.1 KZN innovator network for early implementation

In COSH, Tugela Ferry (uMzinyathi District), a strong network of actors that included the provincial TB manager, district manager, district TB coordinator, NGO partners (Philanjalo, Italian Corporation), and researchers (Yale University, University of KwaZulu-Natal), was credited with facilitating implementation of the decentralisation pilot project, building a common vision, learning lessons from the pilot study, facilitating ownership and buy-in across the district, and making resources available for scaling up. The district TB coordinator, who believed strongly in a community-based decentralised model, rather than establishing a CoE in the district, shaped and steered replication of the COSH pilot

in the uMzinyathi district. The district manager provided strategic leadership for decentralising care in the district, securing buy-in, and mobilising resources.

It was the district manager again, and the district management team, who took these mobiles ... and reorganised them and said you going to be injection teams and tracer teams. But it was him who did that ... in the beginning he even negotiated with the nurses ... because injections had to be given five days a week ... That was all the district management team, he was given no extra money, but he reoriented money within his district to make 16 ... or 21 mobile injection teams available. (KZN NGO technical advisor)

NGOs, such as the Italian Corporation, Philanjalo, Yale and Harvard Universities, who were supporting CoSH in Tugela Ferry where the XDR-TB outbreak had occurred, implemented the early pilot programme for community-based services, and funded benchmarking visits to Lesotho and attendance at TB conferences for the district and provincial team.

Clinical, research, and academic experts carry weight in policy discourse and had significant influence. In DR-TB decentralisation, the WHO technical expert and health systems researcher from the MRC, contributed to evidence that informed the policy and decentralised models adopted. The WHO consultant was a TB epidemiologist from Harvard University and had worked with Partners in Health. She was seconded to the KZN DoH to produce evidence of the DR-TB epidemic, and to put forward examples of successful decentralisation. The MRC researcher is credited as a ‘thought leader’ in decentralisation of DR-TB. She wrote up the Tugela Ferry pilot as a case study and produced evidence of the effectiveness of the pilot project. She supported the KZN TB manager, visiting districts, obtaining buy-in, and supporting them to replicate the Tugela Ferry pilot in uMzinyathi and other early districts. She also supported scaling up by developing or adapting tools from other settings and supporting the policy-writing process.

At that time, you know even the WHO was very weary of what we were doing because it had never been done globally before so we needed to learn lessons ... The MRC helped us to kind of learn the lessons and look at the outcomes, compare the outcomes whether they are treating the patients well and what are the challenges, are the patient even liking this to be treated closer to their homes and what not. So, after those results, we were confident that we can do this and expand to other districts. (KZN provincial TB manager)

6.5.2 Scale-up to other districts faltered

In contrast to the alliance established in uMzinyathi district, decentralisation to other districts faced challenges, starting from district managers whose support and commitment were not evident.

The other districts, nothing! ... So the other decentralised sites were given the exact same recipe, like these are the different components and we need to do different injection teams and blady blady blah but they just didn't do that. (KZN NGO technical advisor)

There were operational challenges, but decentralisation mostly faltered because of a lack of buy-in and resistance to decentralise not only on the part of district managers, but also from facility managers and clinicians at the hospitals.

That process of moving from King Dinizulu for example to Murchison ... That process was very start and stop. You would have meetings, you would have the provincial people come together and they would meet about a satellite site and then the matrons, the doctors or someone, district managers in that areas where they have agreed to the satellite site would push back. There was a lot of initial push back about helping a site become a decentralised site. There was everything, from the medical manager, the chief executive office whoever ... and a lot of the time it was nurses at many hospitals or from the district level management ... You would sometimes get really supportive TB programme managers and yet the hospital was completely unsupportive. Sometimes you have a really supportive hospital with no management support from the district ... I think the problems were different not only from province to province but also site to site within each province. (NGO technical advisor)

The facility and district managers in other districts expressed feeling excluded from policy-formulation and implementation processes. Without support from a network of actors – district and programme managers and DR-TB clinicians – working together with a common purpose, TB coordinators (often nurses) had less agency and were not able to navigate resistance from medical clinicians and secure buy-in for implementation.

So, that is where we started 2013, it was very difficult changing people's mindsets. Doctors are not easy to work with. I am not a doctor, I'm a nurse so getting doctors to do it was not easy ... We had King Dinizulu and I was waiting for them to come up with a strategy. I didn't want to dictate to them and also, we didn't have much support at the district office ... there were no doctors in the district office and then .. Dr S. joined ... He was interested in TB. He asked what were some of the challenges and then I said to him these are the problems then he said do a report for me. Then I took the guideline and I did a presentation and then I highlighted the challenges at King Dinizulu, the long waiting time, the congestion, not enough beds and not enough staff, yet we have this policy we need to implement this policy. Ok and then he asked me how and then I told him this is what we need to do. So, he came on board. We formed a district task team meeting with King Dinizulu. (KZN urban district TB coordinator)

In one instance, when two years of efforts had met with only resistance which could not be overcome, the intervention of the district manager was required, instructing the facility to decentralise.

Even within my own district, it was two years ago we did a facility audit and the medical manager outright said no we don't want MDR in our facility. They don't have a doctor that can be trained. They refused. We arrange training, they didn't send a doctor. They didn't send a nurse. They refused outright and it took us a lot to convince with my TB coordinator at district. It has taken us two years to convince them. We had to get the district manager involved to say no you will do MDR-TB because Murchison [district DR-TB site] can no longer take the burden of the programme. So now they have agreed. They are going to take the patients. (KZN rural DR-TB unit doctor)

6.5.3 eThekweni power and politics

South African provinces have urban metropolitan (city) districts and rural districts. Urban districts have clinics under municipal authority and clinics under district authority; and rural districts have clinics under district authority.

In eThekweni Metro, the municipal clinics diagnosed, then referred PWDR-TB for initiation to the DR-TB hospital, and later managed them during the continuation phase. This left a huge gap in initiation in some areas where there were only municipal clinics, leaving patients to be referred to district-managed facilities that were further away, or even to the CoE, which despite being a referral centre bore the load of managing the City's patients with no complications in the region in which it was located. The district authorities engaged municipal officials to begin decentralisation, but found them resistant to decentralise to their clinics. Reflecting the complexity of negotiations across spheres of government, the eThekweni municipal managers countered that there was no resistance, but offered reasons for the delay in implementing decentralisation, including the fear of transmission in the clinics, challenges with infrastructure and pharmacy, and lack of budget and resourcing for decentralised sites. District managers, in turn, indicated they did not believe there were challenges with infrastructure impeding decentralisation and cited an example of one identified municipal satellite site which served as a communicable diseases centre and had state of the art equipment for infection control, including extractor fans, ultraviolet lights and a sputum room.

The City admitted that they would have to eventually decentralise and that DR-TB was a responsibility for PHC but stated that the issue was "policy and plans" as they had not yet made an authoritative decision to decentralise.

I understand what the government wants to do... We take care of TB and HIV so eventually this thing will be decentralised to all facilities because MDR or drug-resistance is part of the PHC package, you can't divorce it. (KZN urban district TB coordinator)

The district managers on the other hand believed that rather than “policy and plans” it was about political jockeying between the City and district authorities. They found the municipal clinics willing but ascribed the delay to resistance from the municipal management.

The municipal clinics we went to...one facility, they welcomed us, they were very interested in this programme, but they were more scared of their managers... They wanted to start... They were really dying to be part of DR-TB... So, then the municipality manager refused... Province has gotten involved ... So, it is something which I think it is politics... it is not budget, it is not anything else. They have the doctors, they have a very willing team, they have a very strong team actually and DR-TB would do very well in their municipal clinics. (KZN NGO technical advisor)

6.5.4 WC innovator network for early implementation

In CoCT, the drive for decentralisation arose through collaboration between the MSF pilot and the Khayelitsha sub-district. MSF rolled out ART in Khayelitsha before it became national policy, and then realised they needed to address the DR-TB problem, so began decentralising DR-TB care. They established the first pilot model in 11 PHC clinics, working with the Khayelitsha sub-district manager, and generated many lessons about its effectiveness and optimum approaches for implementation. Their success lay in the fact that they forged ahead despite not having national support, bypassed difficulties and sidestepped challenges, such as acquiring and distributing bedaquiline before the NDoH started using it. Their approach was also to use evidence, through surveillance, to show effectiveness. MSF’s presence at conferences, organising sessions, presenting their experiences, and serving as patient advocates, shifted mindsets around decentralisation.

A strong sub-district manager in Khayelitsha was key as she claimed ownership of the pilot. She credited MSF as a strong vocal NGO with the resources and political influence required for the pilot to be implemented, but pointed out that the pilot would not have been successful without strong sub-district ownership.

I would never have attempted to do anything like this if I didn’t have the support of MSF. MSF, they are very competent and they do have the weight, the budget, the commitment and everything ... [but] MSF would not have been able to do this if we weren’t partnering with them. (WC urban district manager)

In partnering with the sub-district management, MSF allowed the City to claim the success as their own and present the pilot at conferences. This was crucial in leading to the City adopting these models and scaling up across the other sub-districts. Many lessons were learnt working with MSF around thinking about sustainability beyond NGO support, adopting what was feasible and affordable from their model.

The City TB manager learnt the lessons from the MSF pilots and replicated the model across the other sub-districts before the decentralisation policy was in place, and she was seen as a key champion for driving decentralisation in the CoCT.

If there wasn't a Judy Caldwell then probably nothing would have happened ... I think that it was just that we had a very proactive TB manager in the City of Cape Town that likes a challenge and just saw it as her responsibility to do what she did. (WC provincial TB manager)

The CoCT TB manager steered much of the early work around decentralisation, pre-dating the national policy, responding to the bed capacity issues. She led the change and was able to identify partners who would work with her and support her in achieving decentralisation to PHC clinics in the other CoCT sub-districts. She instituted many innovations, training, job aides, and new staff positions.

The CoCT TB manager believed in the model, was innovative, and pushed the boundaries as she navigated the city-province tensions. She recounted her motivations as follows:

There are some people that you can't shift irrespective and I will never forget, there was this one particular senior doctor in this sub-district who said, "if the rule says that, we don't break the rules and that's that" This patient I think was weighing like 30 something kilos, almost moribund and dying, and the doctor didn't want to break the rules to start DR-TB treatment because the policy said that and there were no beds available. I can't see that happening in front of me. I will break every rule in the book to help that patient rather than see that patient die because a rule says this ... we somehow managed to get someone to help this patient. And I think that's where we started evolving, putting pressure to 'ok maybe we need to start an outpatient service' and that, maybe we need to do this, and so at every step along the way, I had some tangible examples of where the system wasn't working and I fought their hand and my advocacy to change it ... So of course, you do need people who are prepared to push the boundaries, think out the box, do things differently, to learn the lessons. (WC urban district TB manager)

Strong managers at a sub-district level, including sub-district medical officers, supported the City TB manager and played a key role in facilitating implementation to other sub-districts.

6.5.5 WC rural districts' contrasting experience of decentralisation

In the WC, while the CoCT Metro had achieved early decentralisation to PHC pre-dating the policy since 2008, there was no push from the province to further decentralise to rural districts. The impetus to further decentralise in the rural districts came around 2015 from the districts themselves as a result of the growing burden of disease, large catchment areas with no DR-TB site, insufficient DR-TB clinicians in the district, and the distance and delays patients experienced in accessing care. As outlined in Chapter 4, DR-TB care was provided by referral DR-TB sites, but rural districts wanted to not have

to rely on outreach from the DR-TB site in another district and believed that they should manage their own patients. They started to push back against what they perceived as the DR-TB units holding on to the patients and resistance to decentralisation.

I understand also why he wants to check patients or keep care of the patients. I advocate for releasing the patient so that we look after them and their role is clear amongst us ... We don't want them to keep on telling us that we are the specialists, we must come and spend hours looking after your patients and all of that. They may have more reasons why they want to hang on to the patients, but we want to move away from that. (WC rural district HAST manager)

In the Drakenstein sub-district of the Cape Winelands district, the district pushed for decentralisation, and responsibility was handed to a family physician to take the lead, but she got very little support from the district and had to manage by herself.

No, they just gave instructions and said you have to do this and they will kind of support us but they didn't really realise that we would have to do it by ourselves ... Plus, we didn't even get proper training. I had to train myself and put out my feelers and made calls to Brooklyn Chest ... it takes one person, whether it is the family physician or a doctor, to say I will take this on and I will take the responsibility with the team and take it forward. (WC rural district family physician)

However, not all districts and sub-districts had strong clinical managers to support implementation and they experienced challenges in supporting new satellite sites. Other rural districts did not proceed with decentralisation as they had concerns that the experiences of the pilot projects in uMzinyathi and Khayelitsha would not easily translate to the rural WC context.

Then came the studies of Bruce Margot in KZN with the pickup vehicles, driving in very rural areas injection teams at homes. Now that makes a lot of sense if you see the terrain where they had to work. The other model was ... in Khayelitsha where they had money and resources put into an area where there is follow-up at homes and everything is done. We also thought that was a 'pie in the sky' because who is going to give that resources to us. And you can take a line and draw it around that area that they serviced, you can't do that here with the farming communities and migrant labour. So, we were struggling to understand decentralisation really and I think that is one of the reasons it was a problem for us, what does it mean for us in our context to decentralise? So, we didn't really do it at that stage. (WC rural district DR-TB unit manager)

6.6 PROFESSIONAL AND CLINICAL CHAMPIONS AND RESISTORS

The actors involved in implementation of the DR-TB programme had very polarised viewpoints and stances on implementing the policy when it was first released. Chief executive officers (CEO), medical managers and clinicians from the CoEs, DR-TB units, and proposed satellite sites, fell into either the

category of policy champions or resisters. However, the rationale and reasons behind their support or resistance were multifaceted.

6.6.1 Resisters

One group of resisters from all levels had concerns that decentralisation would result in increased transmission in communities and health facilities. A second group of predominantly experienced COE clinicians and managers had concerns about quality of care at lower levels. Another group, particularly facility managers and staff had concerns about inadequate infrastructure, resources, and staff capacity. A final group's resistance stemmed from the DR-TB site losing its headcount and budget if DR-TB was decentralised. The net effect of the resistance was that despite the policy and plans being in place to guide decentralisation, unwilling actors at lower levels could effectively block its implementation.

The bottom line is the provinces. The document is fine, our strategic policy is fine, but it can go right down to a CEO of a hospital who says I will not do this. And then the provincial HOD, there is nothing he can do about it. So it's the split between a good policy, and the implementation of the policy. (NGO researcher)

6.6.1.1 Fear of DR-TB transmission

At all levels, national, provincial, district, and facility, there were concerns that decentralisation would create a risk of transmission in communities. The National Health Council and some development partners were concerned about infectious people transmitting resistant strains in communities.

I do find it quite awkward from an ethical point of view that we're sending very dangerously sick people back into the communities who are not necessarily equipped to cope with that ... sending someone home to their family with MDR-TB or XDR condition and often if the families are not well-educated and not very knowledgeable presumably to some extent that does lead to transmission in communities and this thing kind of happened quite rapidly ... Not that I am necessarily in favour of keeping people in hospital for prolonged periods of time particularly against their will, but just in terms of the actual transmission dynamics of the epidemic I wasn't sure or very certain that this was a good policy. (National manager)

District and facility managers expressed similar concerns around risk of transmission in the community, and resisted becoming decentralised or satellite sites, due to concerns around infection control and transmission to other patients.

The facility manager just looked at us like do you want to kill all of us? ... You're going to let these DR-TB patients out into the community with their own drugs, responsible for their own treatment, you are going to kill us! She said do what you want but I'm taking no responsibility. (WC NGO technical advisor)

Staff in the hospitals and clinics were afraid of contracting DR-TB. They unionised and protested at some facilities about inadequate infection control and the lack of protection and surveillance for HCWs.

It is an infectious disease that is very dangerous. We have seen staff dying of MDR-TB, it is not a myth, it happens ... If you die you are done. Finished! You've left your family you were supporting ... A young doctor who when she got TB spine, she could not walk and she could not go to work and then ... there was no other support. This shocked a lot of other doctors ... there is no risk allowance, it is an infectious disease and if you go there you go at your own risk. (KZN urban DR-TB unit doctor)

As a result of these fears, clinicians actively shunned and denied treatment to PWDR-TB and tried to refer them to the DR-TB site even for minor ailments not related to DR-TB that could have been treated at the facility.

This whole thing of MDR being a stigma here as well in my hospital. If there is a patient in any of the other facilities diagnosed with MDR the patient is shoved in the corner of the ward and is left there until they come to Murchison. They come here dying. There is no oxygen. They are not on treatment for their oral thrush. So, they come on death's door. (KZN rural DR-TB unit doctor)

6.6.1.2 Concern for quality of care at lower levels

There was a perception of CoE clinicians and managers from both KZN and WC, that decentralised sites would not manage the patients well and that if specialists did not manage DR-TB, it was going to amplify drug resistance.

I don't trust those small units ... Things happen in those sites out there, people do their own thing if they feel that they don't want to use something ... you don't always follow the guidelines. You don't always have the guidelines in front of you ... The problem to keep it central is that it is taxing and it strains the central unit. We have been trying to unpack for a long time here but you can't unpack to places where you don't quite trust them or they don't have support. (KZN CoE doctor)

We didn't want to decentralise because we had a full understanding of all of our patients in the area on a name basis and we had good relationships with them. We knew what we were doing was the correct way of doing it in terms of treatment and follow-up. We didn't trust that anybody else outside could do the job ... with the same passion and correct treatment that we were doing ... It is one thing to compromise and the patient dies. It is another thing to compromise and the patient is now a treatment failure because now it becomes the health care providers problem again ... So why if there is a doctor and a hospital system that could manage the numbers of patients and you know you are giving the best clinical care and you're following up those patients, why would you risk that and give it to someone else that don't know TB very well or is going to change jobs in the next few months or years. (WC rural DR-TB unit manager)

People in the decentralised sites were frustrated by this attitude as it hampered their efforts to decentralise care, but they understood it was related to concerns about the quality of care. However, they also dealt with the reality that the facilities were overwhelmed and PWDR-TB needed to access care.

King Dinizulu did not want to let go of their hold on this whole programme. In some ways I do understand, you know when you look at statistics and you look at quality ... but on the other hand you cannot manage with the numbers and patients are dying and they are not getting the treatment that they require. There has to be some give and take. So, it took some time, it has taken me two years to get to the point where we are now. (KZN rural DR-TB unit doctor)

Even national managers understood that centralised facilities had the ability to halt implementation by resisting the release of their patients. An important focus of policy implementation was to work with clinical managers and clinicians to secure their commitment to the policy by building capacity so that there could be trust in the quality of care at lower levels.

You can create a policy that makes absolute sense on the basis of the evidence but if the individual managers or clinicians don't want to give up their patients, they are going to find every excuse in the book not to do it and the key question is how do you work with those managers to release their patients. If they're just giving up their patients with no safeguards in place ... he would say, for me if these patients are left out there, they are all going to die so I'm keeping them for as long as I can. (National TB manager)

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6.6.1.3 Inadequate infrastructure and resources

Doctors were resistant to establishing decentralised sites in their hospitals due to lack of equipment for monitoring, inadequate training and capacity, and the increased workload that would result. There were also challenges with infrastructure, insufficient space in the facilities, and inadequate infection control. Facilities complained that the equipment required for adequate DR-TB management was not available, including audiologists, audiometry, X-rays, GeneXpert, and drugs.

You need to have things like an audiologist. We are giving patients kanamycin. This hospital does not have an audiologist and we don't have a proper audio booth ... We don't have all of the necessary things that we need to manage MDR patients. This can be one of the issues around the implementation of decentralisation. The policy is good on paper, but you must have on the ground necessary tools to implement it. (KZN urban DR-TB unit doctor)

There was some resistance to start decentralisation because doctors had not been trained and did not feel confident that they could manage PWDR-TB with complications.

They said we don't have the confidence to treat DR-TB patients ... sometimes patients go home and go back because the doctor does not know how to interpret this and interpret that, especially if it comes to liver functions and interactions with ARV drugs and all of those things you know that makes it complicated. (WC provincial TB manager)

Another concern the managers and clinicians had was that of inadequate staffing, and the problem of retaining trained doctors and nurses, especially in rural areas. Also, adding DR-TB to PHC services would increase the workload of the health facility staff.

The other reason is the doctor working in the sub-district is doing six times more difficult complex work than any GP in private practice. We want that doctor in Robertson and Ceres to do anaesthetics. He must be very good in maternity care which GPs don't do anymore. GPs don't give anaesthetics anymore. We want them to treat complex HIV children. We also want them to manage all of the mental health complex clients that should be seen by psychiatrists. We want them to be boffins in chronic disease management. They must do the medical male circumcisions that has been politically put on our system. Now we want them to also do all of the MDR-TB work and the cost is that the patients in PHC do not get the doctor support service that they need. The patients have become much more complex in PHC because they are getting much older with more comorbidities. (WC rural DR-TB unit manager)

The risk of decentralising all the way to PHC and providing integrated care, would be poor quality of care because the staff were too overloaded.

They have no more staff, no more doctors but we just push all the time ... We are expecting too much. We don't want to work in silos. We want to give this integrated care ... the risk is going to be that we are not going to be good in anything but we can see most of the patients, but the system doesn't necessarily provide a good service. (WC rural DR-TB unit manager)

6.6.1.4 Management concerns of losing site designation

In some KZN sites, facility managers were resistant to decentralisation because if PWDR-TB were moved out of the DR-TB site to be treated at satellite sites, this would impact on their facility headcount and therefore reduce staffing and budgets. In some settings it was not just resistance but open sabotage of decentralisation, for example when facility managers refused to authorise the use of cars for outreach visits.

One of the issues of decentralisation is most of the so called well-known MDR-TB sites once they see that their numbers are going down because of decentralisation it is clear that they are not happy. You have well-known sites with the bed capacity of 100 beds. They have been full of patients, now you come and say send the patient home. You send the patient home and the bed occupation drops, it is under threat ... there are people who are going to challenge this decentralisation ...

and say no our bed capacity has dropped what is going to happen next? There's a lot of speculation around that they may close the hospital, that they may reduce the staff. Now they try to make sure that this does not happen ... I left because I was seen as a person who wanted to shut down the hospital. They started fighting in all directions. To go and visit a satellite site, for example I needed a vehicle to go, when they were aware of my roster that I was going to this place ... they will tell you that there is no vehicle because they don't want you to go there. They want decentralisation to fail. (KZN urban DR-TB unit doctor)

6.6.2 Champions

Champions of decentralisation included facility managers and clinicians, and their most important roles were serving as power-brokers and leading change.

6.6.2.1 Facility champions

Having a facility champion was key and many noted that it was important to have a clinical head of department or medical manager on board.

I think there was a doctor here ... he was everything. He was a medical manager ... So, what I understand is when the province offered this and King Dinizulu said that they wanted to decentralise he took it wholeheartedly with both hands. He went around and established the satellite units. (KZN rural DR-TB unit doctor)

However, even if the medical manager or lead clinician was resistant, they could be bypassed by other self-identified champions. This buy-in was facilitated through providing information about the need for decentralisation. As an NGO stakeholder in urban KZN noted:

The only place I faced a bit of resistance was in Prince Mshiyeni ... so when I started working with the doctor some nurses complained to him and he said that he was going to withdraw the permission ... He asked for the meeting, he called all of the management. He told me that he has not given permission to start. "I don't know why we are starting we need this, this and this" ... Then I told him, "would you mind if I addressed you directly?" I said, "Ok this is what I want from you as a medical manager, I want you to have leadership. I want you to have coordination." ... He went out and he never came back. The pharmacist took over the chairing and said, "Tell me what do you want." Then I laid out step-by-step what I want and then from there the sisters started understanding this is what we actually need to do. (KZN NGO technical advisor)

When facility managers and TB staff experienced challenges with referring PWDR-TB to central sites and realised the need for decentralisation, working collectively at facility level was key and they formed multi-disciplinary task teams, got hospital management support, worked with district TB coordinators, presented to the district, and got approval to establish decentralised sites.

We took it as a management decision because we have a committee in the facility that are responsible for the decision-making and monitoring of MDR-TB and the drug sensitive. So, we did a presentation seeing that we had a high congestion of our patients in outpatient facilities ... We were overburdened with resources and staffing. We were not coping ... The CEO, the medical manager, the pharmacy manager, the quality team, the operational management for MDR, an area manager, a senior manager, district TB coordinator, senior management from all of those components and the finance ... are part of this committee ... We do have a quarterly meeting with the district. So, we did a presentation. (KZN rural DR-TB unit manager)

These facility multi-disciplinary teams included hospital management, and developed plans that they presented to the district. Pressure was applied by the facility teams on the district and in turn by the district on the province.

6.6.2.2 Doctors as power-brokers

Experienced DR-TB clinicians often served as power-brokers and mobilisers in influencing implementation. In KZN, the DR-TB clinicians in the DR-TB sites assumed ownership of DR-TB, more so than the district TB coordinators. They acted autonomously, without the impetus of the district or provincial pressure, they in many instances led the decentralisation of DR-TB, identifying the need, engaging with facilities, conducting training, and obtaining buy-in and supporting implementation. Doctors and nurses at early sites were champions for defining the model and producing lessons on how these sites could be established.

When you drive to Thula Sizwe, you will drive for four hours so the patient will have eight hours to and from Thula Sizwe so they were like no, this is not working. So, the doctor there started to say guys let us start seeing patients where the patients are. He started the decentralisation in each sub-district through his own will and had a bit of attitude but he would go there. Initially he would just go there and initiate patients there until some people had interest and joined him, mentored by him and then he left them to continue and then he will start another hospital. In some facilities some people were not used to that so you needed to push and make sure that you get the sub-district to come and benchmark kind of so that they kind of do things for themselves. (KZN provincial TB manager)

Doctors in hospitals saw the need for decentralisation and pushed the hospitals and districts to establish initiation sites.

I think maybe indirectly the push came from us because we were complaining that our patients are waiting just too long for beds and that was a concern because you keep a patient here and they are deteriorating and we have nothing. You can't help them. So that complaint was in every meeting.

The list was just too long. Patients have to wait for a month before they can start treatment. It is not fair. I think everyone was pushing in a sense. (KZN rural DR-TB unit doctor)

6.6.2.3 Ensuring sustainability

In some sites once the champion left, all efforts around decentralisation halted, which showed it was an individual championing the implementation rather than being driven systematically in a planned coordinated way by the district or the hospital. Strong champions have achieved much progress but without support from others, there is a risk of setting the programme back.

I think she [rural DR-TB unit doctor] is the pillar of MDR-TB in the district and my fear is that if she leaves, we will have a big challenge. Currently at Murchison she's the one that is running the programme. She's active in all of the training, she has really taken the forefront in managing the programme and monitoring the programme of MDR. It is just unfortunate that she doesn't have the support of all of the doctors. (KZN rural district TB coordinator)

Effective champions were those who capacitated others so that they would institutionalise the programme and ensure sustainability, so that they did not fall apart once the champion left. Many managers realised that they needed to put systems in place to ensure the interventions were sustainable beyond the individuals who instituted them.

The champions are important ... If something depends on me then I'm not a good champion. If I disappear the whole thing will collapse. I was a hopeless champion because I can't do things by myself; I have to put systems in place to do things. The point is I guess at that stage it was very much like it's the individual, but of course the individual plays an important role. (WC urban district manager)

6.7 THE ROLE OF TB COORDINATORS

In both provinces implementation was facilitated to varying degrees by a facilitator/coordinator of policy implementation, usually a TB programme coordinator. Their broad role and scope are described here, while their contribution to clinical governance is detailed in Chapter 9.

6.7.1 Rural Western Cape HAST coordinator

Rural WC districts had district HIV, AIDS, STI and TB (HAST) coordinators, whose role was to provide support to facilities doing monthly clinic visits, linking PWDR-TB to care, and data monitoring. The HAST managers had too many programmes to manage, being responsible for HIV, STI, DS-TB and DR-TB programmes, and they experienced challenges with transport and time for visiting facilities.

At the National Health Council, the minister insisted that we bring all of the HAST managers ... He wanted to know what you do every day because the programme has kind of clinically moved but the managers have not ... the problem is that most districts don't have an MDR coordinator,

they have a HAST coordinator who is doing a number of things and that is their argument and then they will tell you no they don't have transport and the number of kilometres they can travel every month it is limited. There is a whole range of implementation challenges which are real. I don't want to discount that. (National manager)

Rural districts opted to use allocated TB budgets to appoint a district person to do clinical governance rather than have dedicated DR-TB coordinators as in CoCT.

They are at liberty to take policy as received from province and look at how exactly they will operationalise that policy. So, for example like with the drug-resistant professional nurse, the province put a policy there, they maybe made funding available, but the chief director's office had a discussion with the directors and they thought they will utilise that funding in a different way, maybe not to appoint a professional nurse for the drug-resistant programme within every sub-district but maybe to appoint a person as in our case as a district post and not to do direct service delivery but to do clinical governance. So, they do have that leeway and that flexibility to do that. (WC rural district PHC manager)

6.7.2 KwaZulu-Natal TB coordinator

In KZN, DR-TB was coordinated by district TB coordinators who were professional nurses. Their role was coordination of both DS-TB and DR-TB programmes, and to ensure that guidelines were implemented and that the programme achieved its objectives through readiness assessments, training, and support visits. uMzinyathi first developed a position for sub-district TB coordinators and later, four other districts, uMgungundlovu, uMkhanyakude, Zululand, and eThekweni, also appointed sub-district TB coordinators or TB supervisors. It was considered an advantage that the TB coordinator role integrated both DS-TB and DR-TB and focused on HIV, as it was understood that you cannot separate the HIV and TB programmes. However, integration created a huge workload and different reporting lines.

Clinicians from the DR-TB sites reported that the TB coordinators needed to be more proactive in providing support, not just conducting training or visiting when there was a problem.

I think that the TB coordinators should be proactive. I think that it is very important of them as they are the facilitators ... You need a district coordinator to be aware of what is happening and to be informed all the time and to check frequently on the unit not just come when you call them when there's a problem. They should be there to see if everything is ok. They shouldn't just assume that so now we've trained them they know we are starting. (KZN rural DR-TB unit doctor)

6.7.3 City of Cape Town sub-district MDR-TB coordinator

In CoCT, while they had a HAST coordinator at the district, when the DR-TB programme was started they created a position for a dedicated sub-district MDR-TB coordinator (SDC) which was benchmarked on the MSF Khayelitsha pilot. The SDC was a professional nurse with both a clinical and programmatic function. They supported the clinics, conducted training and clinical audits, and held monthly programme meetings to ensure patients were linked to care and on correct treatment regimens. While a City (local government) employee, the SDC also supported and visited the district-authority facilities, and included then in DR-TB meetings and training. They also linked to the HAST programme and worked together regarding coinfecting patients.

6.8. EXTERNAL ACTORS

6.8.1 World Health Organization's approach evolved

WHO has been an important presence and influence in South Africa, guiding policy and programme implementation for HIV and TB, among other programmes. WHO's stance on decentralised DR-TB care has shifted over the years. Historically, WHO had a policy of centralised, institutionally-managed DR-TB care, and were cautious about decentralised care which had not been done before.

At that time, you know even the WHO was very weary of what we were doing because it had never been done globally before. (KZN provincial TB manager)

In fact, some saw WHO as 'resistant' and 'reluctant' because they (WHO) believed DR-TB required specialised management and could not be managed in decentralised sites.

They [WHO] were very resistant and reluctant ... The fears were that this was such a dreadful disease and we have got to treat it in a big hospital, we need specialists to do it ... decentralised sites won't be able to manage adverse events. (KZN NGO technical advisor)

WHO traditionally develop global policy and guidelines to guide country programmes. However, WHO never developed a policy on decentralisation and South Africa embarking on this approach flouted the conventional approach of WHO first developing policy and then countries adopting the policy.

I'm not aware of anywhere else in the world where decentralisation was done ... you know they've gone against this WHO policy ... Most of the developing countries would go with what WHO says, including South Africa ... Like, for example WHO would come up with guidelines, policy guidelines for the management of drug-sensitive TB or DR-TB. Then South Africa would take those guidelines and tweak it and adapt it for local conditions. I have never seen a WHO document for decentralisation. (KZN NGO technical advisor)

However, experts at WHO began to observe the lessons of development partners working in Peru and Lesotho and started bringing decentralisation and community-based care into the discourse in 2008. It

was interesting that they were seen to not be endorsing it but reflecting and sharing the experience from those countries. WHO then assisted South Africa through the policy-formulation process.

Partners in Health did something different and ... it worked and through their publications, WHO also started to talk about it around 2008/9, you know. Not really like endorsing it but saying that some people are doing it ... WHO didn't have a policy as such so they helped us, our policy. Yeah, we got WHO to come to our workshops and then we got a lot of help to get it developed. (National TB manager)

WHO then also supported the pilot projects.

So what happened then was that the WHO was then now allowing it to happen which made South Africa's National Department of Health ... say OK, WHO is happy with us experimenting in KwaZulu-Natal. (KZN NGO technical advisor)

WHO also provided more overt support through the technical assistance of a consultant who conducted surveillance and rapid reviews to generate evidence to support policy-formulation. However, the deployment of the consultant was not just for technical support but also to drive the agenda and ensure a strong response to the DR-TB crisis in South Africa.

WHO is also to assist the member states ... it was a way of changing or contributing to moving things from behind, that's why I've been deployed ... But it wasn't only the issue of technical assistance, it was an issue of moving an agenda forward in the country with something like a massive outbreak of XDR-TB and MDR-TB also linked to HIV, of course. (WHO technical advisor)

In 2015, WHO supported the NDoH with conducting a national DR-TB programme review, which produced insights into the implementation of the decentralisation policy.

6.8.2 Other actors supported implementation

A slew of other NGOs (national and international), private sector players, donors, and local research consortia supported implementation. Early on, NGOs, such as MSF presented at TB conferences on the decentralisation pilots, advocated for increased DR-TB funding, and started to turn opinion about decentralised care. Once the decentralisation policy was launched, NGOs supported its implementation. Donor support came from the Global Fund, which provided initial funding for infrastructure, a pharmaceutical company (Janssen) funded equipment like ECGs, and other funders procured laptops and KUDUwaves for decentralised sites, to support decentralisation.

Jhpiego (Johns Hopkins Program for International Education in Gynecology and Obstetrics) now known as JPS Africa, was contracted by the NDoH to support implementation of the DR-TB decentralisation programme. This included conducting readiness assessment, curriculum development,

NIMDR training for nurse-mentors, professional nurses, and other HCWs, and supporting high burden districts with programme strengthening. They then shifted to training regional training centre staff so that the training function could be absorbed by the provinces.

University Research Co. (URC) supported KZN and seven other provinces by funding a two-year mentoring programme for satellite and decentralised sites. Since 2019 as a district partner, through the USAID Tuberculosis South Africa Project, URC supported eThekweni with a mentoring model for implementing decentralisation down to CHCs. This has revealed many lessons for implementation while ensuring an approach built on strong clinical governance. Other district support partners, like the Centre for the AIDS Programme of Research in South Africa (CAPRISA), MatCH Research Unit, Mpilonhle, and Africa Health Research Institute (AHRI) implemented training, clinical mentoring, and provided implementation support. Local community-based organisations, like Red Cross and Hospice SA supported the facilities to conduct tracing and home visits.

6.9 CHAPTER SUMMARY

In summary, there were a number of actors who were important in implementing the decentralisation policy, with differing political influence at national, provincial, district, and facility level. At a national leadership level, the Minister of Health and DR-TB programme manager were strong advocates for DR-TB and for the decentralisation policy. Provincial ownership and influence was variable between the two provinces and dictated the progress of implementation. Most influential were networks of district actors that included district management, TB managers, and supportive NGOs. Programme coordinators at district and sub-district level had differing roles and varying levels of influence on effective programme implementation.

Interest groups working at the coalface influenced implementation most directly, either as resisters or champions. The motivation and beliefs of resisters were found to be nuanced. There were those who resisted decentralisation due to unfounded concerns about transmission of DR-TB in health facilities and communities, those who resisted rapid decentralisation because of concerns over quality of care, others who resisted due to lack of infrastructure, equipment, and trained staff, and those who resisted decentralisation due to the management impact of decreasing headcounts when shifting PWDR-TB out from central sites to the periphery.

External actors were strong advocates and developed evidence to inform policy, supported pilot projects that laid the groundwork for future scale up, evaluated the decentralised models, and funded and supported implementation.

The remaining chapters expand on this exploration of actors' influence to understand the implementation processes that engaged (or not) the wide variety of actors (Chapter 7), how resourcing influenced implementation (Chapter 8), and the trade-off between creating access to care and ensuring quality of care (Chapter 9).



CHAPTER 7. PROCESS OF POLICY IMPLEMENTATION: PLANNING AND ENSURING OWNERSHIP

7.1 INTRODUCTION

The previous chapters described the timelines of implementation, the models of DR-TB care that emerged, the understanding of policy-meaning and intent, the multiple actors involved, and the tensions between and contestation by stakeholder groups that influenced health policy implementation.

This chapter examines factors in the process of DR-TB policy implementation and the way these influenced policy outcomes in the two provinces. As indicated in Chapter 2, process factors include: (a) antecedents for implementation, such as piloting, operational planning for scale and timing, and tailoring and adapting policy; (b) supporting implementation, establishing communities of practice, and mobilising skills and resources towards collective action; and (c) consultation and communication, managing actors, and distributed leadership. This chapter specifically explores the role of pilot projects and benchmarking exercises; the process for determining needs; operationalising plans including training, mobilising necessary resources, and putting systems in place; as well as strategies of communication; mechanisms for adopting policy including who was/was not involved, and the manner in which actors were engaged; the subsequent processes of mobilising actor buy-in and support at all levels (including change management and fostering ownership); and the pivotal role of district players in all of the above.

7.2 PLANNING/ANTECEDENTS FOR IMPLEMENTATION

7.2.1 Piloting and benchmarking

Pilot projects and benchmarking exercises played an important role as catalysts not only for national policy development, but also to inform provincial implementation. In the WC, the MSF pilot in Khayelitsha local municipal clinics, provided training to local doctors in initiating DR-TB treatment at primary care level, and provided evidence that patients could be managed outside of the central hospital setting. The CoCT managers learnt these lessons and replicated them across other sub-districts.

Similarly, in KZN, after the XDR-TB outbreak in Tugela Ferry in 2005, with the huge burden of DR-TB and the long waiting list for beds at the CoE, the CoSH pilot supported by Philanjalo and Yale University adopted a model of community-based treatment utilising injection teams. Later, patients were admitted and initiated at Greytown Hospital which served as a decentralised DR-TB unit, rather than patients needing to be referred to KDH. The KZN provincial TB manager embraced this early work but saw the need to transition from an NGO-led pilot to a district-owned model. He worked with MRC researchers to learn lessons from the pilot and scale up in uMzinyathi and then to a further three

districts. Once decentralisation started, other district managers from Zululand and uThukela brought their CEOs and TB coordinators to benchmark the uMzinyathi model.

The pilot decentralisation projects in rural Tugela Ferry and urban Khayelitsha were initiated by NGOs, but provincial and local government decision-makers saw the value and impact of the pilots and worked to replicate the models. What was important was that pilot projects transitioned to local DoH ownership and scaled up.

MSF had experience in other countries that they brought to CoCT, and even in KZN, NGO partners encouraged the province and uMzinyathi district to learn from community-based treatment models developed by Partners in Health in Peru and Lesotho. Early benchmarking of experiences in Lesotho, Peru, Latvia, and former Soviet Union recognised the need to adapt lessons for the South African context with resource-constraints and high HIV prevalence.

7.2.2 Translating policy into plans

The first step in implementing the decentralisation policy was to formulate more detailed plans at national, provincial, and local levels. Implementation planning was widely recognised as a key, but an unevenly and inadequately fulfilled step in the policy process. Interviewees referenced the growing trend internationally to release all new policies with implementation plans, whereas in South Africa, policies were released with no business cases or implementation plans to accompany them. These implementation plans would have helped provinces and districts to think through how to operationalise and budget for the policy.

If you look at the NHS [National Health Service] in the United Kingdom and you look at their treatment guidelines. There is a standard treatment guideline but there is an ancillary document that goes with it which is its implementation plan and what is missing in South Africa is, generally I think we don't do poorly in terms of policy, quite often our policies blaze the path internationally, but we don't have the implementation plan and so basically with the MDR decentralisation I challenge you to show me the business case ... I challenge you to show me that there is a solid implementation plan owned by government. (National manager)

Frontline informants expressed that planning should have considered the reality on the ground and been developed from the ground up and not from the top down.

I'm sure there are forums where they address that but for me it is no use discussing those issues up there, you at ground level know the reality of things because they will never hear what the reality is ... So rather find out ... from ground level, what are your challenges and what are the things that we need to address and not just decide this is what we are going to do. I think that is also where we miss the mark. (WC urban clinic manager)

At provincial level in the WC, the CoCT developed a business plan to identify resources needed for implementation which included funding for extra professional nurses, SDCs, and data clerks. Districts and sub-districts used the broad provincial plan to develop their own local plans specifying clearly who would be responsible and how implementation would be operationalised. A sub-district HAST manager indicated that:

Our director called all of the districts together for a meeting and she wanted a plan on each sub-district ... She wanted to know who in each sub-district is the role players, who is going to take responsibility now and ... how are you are going to implement in your sub-district? (WC rural district HAST coordinator)

These local plans were coordinated by the sub-district managers and required broad engagement with all stakeholders including HAST coordinators, facility managers, pharmacists, TB nurses, and community-based services. The meetings covered practical aspects of policy implementation and detailed what the policy meant along the patient care pathway.

I started by having meetings with different role-players like the HAST coordinators were very important, the pharmacists and management ... the TB sisters ... We involved community-based services as well ... We compiled a plan, a key pathway of exactly what is going to happen from the minute they see an MDR-positive result. What do they do when they see that, how do they manage that patient? Where do they send the registration form? Who is going to see the patient and you know all of that, until the patient has started on treatment and within what period of time who would be like that patient to be started on treatment? As well as I drew up a guideline about all of the investigations that has to be done. (WC rural district family physician)

In KZN, implementation plans were developed by the province to identify which districts would decentralise first and which facilities would be DR-TB sites. Districts were then tasked with engaging relevant stakeholders and developing local plans with district and sub-district, facility and pharmacy managers, TB clinicians, and local NGO partners. However, district TB programme managers reported that planning was inadequate in the province and that some districts had no formal plan detailing the stages of policy implementation.

No there was no plan like that. It was a plan like, you ought to (decentralise). All of your patients will be initiated and you will be managing MDR ... you assess your facilities to see if they are ready and then you send the patient to them ...” There was no stipulated stages. (KZN rural district DR-TB unit manager)

In some districts the process of translating the national decentralisation policy and provincial plan for the context of that district simply did not happen. This process would have been useful in identifying the priority areas and facilities for decentralisation.

Yes, policy comes out and there is no real sitting down ... to understand it myself ... There was no real direction, it was just there is the policy and you need to decentralise, was there a plan? ... For me, it was their (province's) plan and nobody sat with me and said: "Ok this is where we need to be and ok this is your area, this is how many facilities you've got, use this and this to actually decide where, and looking at your area this is where you should perhaps target first and then that."
(KZN urban district TB coordinator)

7.2.3 Determining needs through readiness assessment

Developing and introducing operational plans described in the previous section required an understanding of the needs required by implementing sites. The decentralisation policy explicitly recommended a readiness assessment to be conducted to ensure all measures were in place for implementation. Readiness assessments were important for preparing the terrain for policy implementation.

You have to have these things in place. Your infection prevention and control measures must be adequate. You can't start with something in a PHC facility and that is not in place, what risks are you going to put your other health care patients into – see you have to take all these things into consideration, do the infrastructure assessment, do the facility assessment, do a readiness assessment and then, only if that is ready ... And once you have passed those tests then we can scale this up. (WC provincial TB manager)

A readiness tool was developed which focused not just on infrastructure, but also on the DR-TB burden, catchment population, staffing, equipment, laboratory, radiology, drug supply and storage, and willingness and buy-in from the hospital. District TB coordinators took the lead on conducting these readiness assessments, sometimes supported by development partners.

Addressing the gaps identified in the readiness assessment involved putting systems in place, including infrastructure improvements, staff training, and procuring drugs. This was complex and required management expertise.

But I suppose from my side I also didn't really understand the implications of a decentralised plan. You see the list of what is required and that looks fine on paper but to actually put those systems in place is complex. It needs some kind of management expertise. So for me if I look back I thought, oh well it is an easy process, but it's only when you then start seeing the data that you realise there is still a lot of work that still lies ahead for us to get that right. (WC provincial TB manager)

7.2.4 Training and capacity building

Training was an important vehicle for communicating the new policy and capacitating staff. A variety of training models were observed across provinces in urban and rural areas. The main training models that emerged included formal structured training courses developed in the CoCT and the KZN Province, unstructured training on the new policy in rural WC districts, and in-service training by TB coordinators for those who could not attend formal training. All agreed that regular structured training was a critical process of implementing DR-TB decentralisation.

If I had to put two or three things together to tell you what is important, training, training, and training ... You cannot have ad hoc training. You must have regular structured training. Everybody gets the same message and the same thing. (WC urban district TB manager)

A standardised three-day DR-TB training package was developed by CoCT, that included laboratory testing, drugs, and discussion of clinical cases. It took participants through operational and clinical matters in managing PWDR-TB at decentralised sites. This training became a part of the department training curriculum, and four to five courses were run per year to ensure all PHC clinic nurses and doctors were trained from all facilities. TB experts, local doctors, laboratory managers, and programme managers were invited to present. The SDCs also conducted routine in-service training when new regimens were introduced, and it was a requirement that all nurses attended these workplace skills training programmes. Many informants shared that it was important to include all clinic staff in the training, including enrolled nurses and clerks, and not just clinical staff.

The implementation of training in the rural WC districts was not as structured and detailed, and included explanation of laboratory testing and treatment regimens. Staff shortages and attrition were reported as a challenge and as a result not everyone could attend the training. Therefore, doctors or TB coordinators were sent to attend the training and they returned to cascade training to the nurses and doctors, but they acknowledged that this was not ideal.

In KZN, intensive training was done over the course of 18 months in all districts when the policy was launched. The province relied on partners, like JPS, CAPRISA, URC, Match, and Philanjalo to do the training, which included NIMDR training as well as training of doctors, social workers, and counsellors. There was a five-day training for implementers, and a three-day training for those not starting to implement immediately. The five-day training included five days in the classroom and five ancillary days at the CoE, being guided through the process of initiating treatment, after which participants were signed off as proficient to initiate. The district TB coordinators visited DR-TB units to conduct training for staff who were not able to attend training programmes.

In some districts it was noted that inadequate training was done for nurses and coverage of the formal training courses was uneven across districts.

What wasn't properly done from what I saw was the human resources. I don't know if there was a budget for training staff in the first place because most of the people were not trained especially the nurses ... I found that the nurses weren't really informed and they didn't understand the programme and they would have issues where they would say, "No, as nurses we don't do that. As nurses, we don't do this." Whereas if they were trained and they were made aware this is what the programme would require of them so it would be easy. (KZN rural DR-TB unit doctor)

Training focused only on DR-TB sites and not the other satellite clinics and hospitals that were referring patients and managing down-referrals. Also, training in KZN was only offered to clinicians. Most informants agreed that all facility staff, even those who were not dealing with DR-TB, needed to be trained and not just the DR-TB nurses and doctors, as a better skilled clinical team could help to reduce delayed diagnosis and late referrals. Also, because of staff attrition, especially in rural areas, repeat training programmes needed to be offered for new staff. Even after training, the clinical staff still required ongoing support and in-service training. Some informants reported that mentorship was lacking completely. A training and mentorship approach employed by an NGO supporting eThekweni was most effective to skill the team to begin implementing, and after two days of training, the staff were able to continue to call the mentor with questions until they felt confident.

Clinical and programme managers translated policies and plans into operational tools that would assist the nurses and doctors to translate guidelines into easy desktop references. Examples included, monitoring charts that guided clinicians on when and how often to do monitoring tests; dosing charts for adults and children; DR-TB wheels to ensure monthly sputa were done; registers that facilitated scheduling of patient follow-ups; referral forms to the CoE; patient education tools; adverse event forms; and consent forms. The CoCT also introduced a lever arch file with dividers to keep sputum results, blood results, audiology results, ECG results, home assessments, and the treatment script. The intention was to *"try and be as proactive as possible to support patients"* (WC urban district TB manager).

7.2.5 Forums for care coordination, monitoring, and review

An important aspect of the implementation process was having forums that guided implementation, reviewed progress, and shared feedback. National and provincial advisory committees were established to provide clinical guidance and also to review DR-TB treatment failures for further management. All districts held HAST quarterly review meetings that included programme and district management staff, to review programme performance and discuss cohort outcomes for each hospital. In COCT, weekly meetings were held to discuss patients with complications with the CoE doctors and other TB experts.

A quarterly TB clinical forum hosted by an NGO partner, Desmond Tutu TB Centre, allowed for difficult clinical cases and research to be presented. SDCs held a monthly multi-disciplinary team (MDT) forum with all of the SMOs, doctors, TB nurses, counsellors, and pharmacists, to guide facilities on ensuring that all PWDR-TB were on treatment, to assist with treatment regimens, and to discuss complex patient needs. In the WC rural districts, PHC meetings were held monthly with operational managers to discuss problems the clinics had, and information was fed back to the facility staff. KZN held a provincial DR-TB quarterly meeting with the CoE, and monthly teleconferences with the district TB coordinators to discuss decentralisation rollout to new sites and challenges experienced with training, resources, and so on. eThekweni City held a weekly clinical meeting focused on clinical governance, ensuring guideline compliance, sharing new policies and circulars, including new drugs and regimens being introduced. City facilities also held TB quality improvement meetings weekly.

7.2.6 Adapting policy to fit the context

Policy implementation theory recommends a hard core and ‘fuzzy’ fringe, which means a core of the policy that is uniform, while allowing room for adaptation and innovation at local levels. This links in part to the multiple meanings identified in Chapter 5, which created some scope for interpretation and recognising the fuzzy fringe. It also links to expressions of actor beliefs and interests explored in Chapter 6. When the decentralisation policy cascaded, there was a process of local assimilation and adaptation at provincial and district levels in both provinces to suit the context of the different districts in the province. One example was in the CoCT, that decentralised rapidly down to PHC and not to regional hospitals. CoCT also did not adopt NIMDR because they did not believe it was the correct approach. They also did not implement mobile teams because metro areas have PHC facilities in close proximity to patients, and they did not implement injection teams because implementing something that was regarded as unaffordable, just because it was in the policy, would be unsustainable. There was a “strong stance” taken by the WC that national policy be considered in the local context and adapted as required.

Western Cape has quite a strong stance around policy so if policy comes from national, Western Cape will look at its own context first ... they will look if for example the NIMDR sisters will it be successful, will it be helpful, can we implement it yes or no ... I think it is really working well with us with the implementation of new policies. (WC rural district HAST coordinator)

In KZN, it was argued that the rural Tugela Ferry model would not work for eThekweni and that the model would have to be adapted for an urban setting.

I don't think you can pull a rural model out and stick it in an urban area, it's not going to work, you're going to have to adapt it and I don't think it will be as well adapted ... So maybe the Khayelitsha model was probably a better model for an urban setting because patients should come to the clinic ... Tugela Ferry had a strong district health system and it was bolstered with all the

outside influences [NGO support]. Whereas you try to take that same model to a district that's not functioning effectively and things don't work, patients wouldn't pitch. (KZN CoE doctor)

A strong district management team (DMT) could navigate any changes or opposition to elements of the policy in order to adapt for the local needs.

You can proceed, you can implement things that work for you provided you have guidance from your district management and they are the ones that will actually help you to take a stand against policy and to develop something that works in your district ... but I think you need a strong management team in order to do that. Without a strong (district) management team people often don't oppose national policy and they expect it to be implemented as is, no questions asked. (KZN rural district TB coordinator)

7.2.7 Phased approach to implementation

There were extensive debates around the pace and sequence of implementation in both provinces. At every level people advocated for a phased or stepwise approach to implementing DR-TB decentralisation, *“as to not terrify the people with suddenly doing it all at once”* (WC NGO technical advisor), although there were differences in how that phasing would be done. The NDoH approach to stepwise implementation was to ensure that there was first a DR-TB site in every district, and once that was accomplished, a site in every sub-district was established. The MSF pilot used a staged process to decentralising from CoE inpatient care, to outpatient care, from sending the file to the CoE for scripts, to obtaining telephonic scripts, to treatment being initiated at PHC – all of which allowed people to progressively become confident in the abilities of PHC clinical staff. Transferring care of PWDR-TB to the PHC clinics was a stepwise process of familiarising and sensitising the clinical staff and capacitating them first.

Now ours has also been a stepwise approach. We didn't all of a sudden just say ok, now from tomorrow you are going to just start putting everyone on treatment ... We said, “Well ok, we are sending you patients but in order for you to manage these patients, let's teach you a little bit more.” (WC urban district TB manager)

In KZN districts, the satellite sites were already providing treatment and monitoring patients between visits to the DR-TB site, so the district DR-TB site worked with them to transition from satellite to initiating sites gradually as they got more experience and confidence managing PWDR-TB. *“Then as you see that they are comfortable doing the follow-ups and then they will become the initiating site.”* (KZN provincial TB manager). Another KZN district adopted phased implementation to start with one satellite and then move to others only when the first one was well trained and functioning. Some districts thought about phased implementation starting with district hospitals then CHC clinics then PHC clinics, due to the capacity that existed at different levels.

Another approach to phased implementation was implementing in small increments, starting with what was available, leveraging existing resources and capacity, and gradually scaling up. One district did not have inpatient infrastructure, and so started with outpatient treatment. Some sites started decentralised management of DR-TB even though staffing was not ideal. However, some cautioned against implementing without all the systems in place, citing an example of implementing the new shortened regimen without drug supply in place and training having been done, which resulted in the delivery of services suffering.

Sometimes, like with your short-term regimen, I felt they needed to make sure that all of the logistics were in place before they could ask us to start ... We were asked to start and we were not ready. In fact, we were supposed to start in January last year but we only started in June last year because of these challenges. We have been negotiating with district and head office to say we are not really ready in terms of first of all there was a shortage of clofazimine drug. Second, was the capacitation of the staff. Thirdly, how are the patients supposed to get their injections over the weekend and that was the problem ... Those were the challenges ... that was the gap after starting with the new regimen. (KZN rural DR-TB unit manager)

7.3 FOSTERING OWNERSHIP AND ACCOUNTABILITY

7.3.1 Engaging stakeholders

Another key process of implementation involved the mechanisms of communication and dissemination that engaged stakeholders from the national sphere to the frontline of service provision. In both provinces, provincial and district TB managers were important facilitators of this process. In WC, policy directives from NDoH were received by the Head of Department (HoD) of Health who devolved responsibility to the provincial TB programme manager, who formed a task force that included the CoCT, to develop an implementation framework. At the level below the HoD and the Deputy Director General, Chief Directors for Metro and Rural Districts were responsible for programme planning for urban and rural districts, and had the flexibility to adapt the policy to their respective contexts. CoCT had two district management platforms, the joint management structure where the City and DoH managers agreed on programme implementation; and the Health Management Team which consisted of City Health and sub-district managers, who approved any new policies to be implemented. The provincial TB manager conducted roadshows and workshops with districts on the new decentralisation policy, doing this jointly with the CoCT TB manager, to decide how implementation would fit the context in each district.

In KZN, new national directives were sent to the Health HoD, then shared with the provincial TB programme managers who cascaded to district managers. In some districts, the district TB coordinator took responsibility and engaged the district manager and sub-district TB coordinators, who cascaded

the policy to sub-districts. The engagements with the districts were in the form of a one-day orientation on the new policy, which allowed for an opportunity to look at how the policy needed to be adapted to the local context. Consultation between province and district was key in moving forward with implementing the policy.

7.3.2 Assigning responsibility for coordinating implementation

7.3.2.1 Decentralised DR-TB unit clinicians lead

Before decentralisation, DR-TB care was provided by the CoEs. There was generally one CoE in each province, and the NDoH DR-TB programme manager worked directly with the provincial TB manager and the clinicians in the CoE. Districts were not involved in DR-TB planning, reporting, and programme review. This was unlike DS-TB and other PHC programmes which were more integrated. So when decentralisation was implemented in the first KZN districts, the provincial programme manager described that the provincial and district managers and TB coordinators were all bypassed and national programme managers continued to work directly with DR-TB site clinicians.

When this was introduced in some other districts ... the national office was communicating directly with the decentralised sites, so you can imagine bypassing the sub-district, bypassing the district, by-passing the province, so that's what we're trying to currently address. (KZN provincial TB manager)

Even when further decentralisation was required from DR-TB sites to satellite sites, in some districts the DR-TB clinicians assumed the responsibility to push for decentralisation and deal with implementation. This proved challenging as the clinicians at the hospitals had no mandate or authority to engage with other facilities in the district, or to mobilise resources required for implementation.

If we have to deal with the managers from the other hospitals, you know they don't report to me. You only write them letters and advise them if they want to take it, they will take it, but if they don't want to, it is up to them. We used to have quarterly meetings here but eventually they died a natural death ... you'll send an invite and then no one pitches up here and it wastes your time preparing doing all those things ... I have no authority ... you can only say please come. (KZN rural DR-TB unit doctor)

It was also not sustainable for clinicians at the DR-TB site to drive decentralisation. These individuals took it upon themselves to down-refer to satellite sites, visiting them and building their capacity, but once these committed individuals left, decentralisation efforts abruptly ended. This resulted in frustration because DR-TB was being seen as a concern for one decentralised site that serves the district, whereas actually it should have been considered a district priority.

It is difficult because although the MDR unit is based at Murchison Hospital, the MDR programme is not a Murchison Hospital programme, it is a district programme. So, it has taken the district

some time to realise that no you are also responsible. It can't just be the responsibility of Murchison to be running around like headless chickens trying to sort out the problems. You also need to come and work because this programme is catering for the entire district not only the Murchison catchment area. It is the entire Ugu district. (KZN rural DR-TB unit doctor)

7.3.2.2 Programme managers lead

Decentralisation of DR-TB would result in a shift in ownership of the programme from the CoEs to the districts. As more districts began to decentralise, management and programme coordinators at district and sub-district level would have a bigger role to play, but an unanticipated concern emerged around the coordination of implementation by programme managers rather than district management. There was a sense in KZN, that responsibility for operationalising the policy was allocated to the district TB coordinators.

You know when national say decentralise, this is a decision that is taken at high level, now people on the ground need to execute and the province did make it clear that you can't expect the MEC to come and start decentralising ... the TB coordinator is there. They will tell you what to do and you on the ground would have to act ... The policy is on paper but someone needed to act. (KZN urban DR-TB unit doctor)

Early decentralisation in CoCT was driven almost entirely by the City TB manager. Even in one rural WC district, decentralisation was initially coordinated by the TB programme, from the provincial TB manager to the district HAST coordinator, but the district DR-TB site manager revealed that excluding district management would affect their ability to support implementation.

What was the communication channel for this thing to be implemented? ... The district manager was never included to ensure that this thing rolls out and they were not informed from ground level of the difficulty of getting things done ... It comes to Western Cape directorate, we channel it down to the TB directorate. So, this is the way to go, but the districts don't know that. They also don't care unless they are part of this thing and it is decided how we are going to use this policy, how is it implementable, is it possible on the ground level, what should be put in place first. (WC rural DR-TB unit manager)

District TB coordinators shared the difficulties of bearing responsibility for implementation themselves, and that implementation was easier when district management were included.

[Policy communication] was more through the programme ... It is a problem ... you will get a new policy from the province and for you to drive it, it just sits on our shoulders, but if it is communicated to the district manager it then becomes easier just to ensure that it moves at a pace. (KZN rural district TB coordinator)

A TB coordinator in a rural KZN district shared that TB coordinators found it difficult to engage new sites and required the district management team (DMT) support to push them to decentralise.

I mean obviously the satellite sites they won't take our word. So, if the district can come in they will be able to assist with a push to further decentralisation ... The decentralised site is the cornerstone ... But you've got to get the buy-in from the district and the province because without their push, they are the ones who really need to push the satellite sites to start initiating and to work together with decentralised sites. (KZN rural DR-TB unit manager)

As indicated in the previous chapter, TB coordinators could not navigate these challenges by themselves, as they were nurse managers and did not have authority over respected clinicians they encountered at the facilities. District management and especially medical managers in the district who were medical doctors were vital to overcoming the resistance faced at facilities.

You see another weakness in our system is, with due respect, we have a lot of nurses in leadership. And I find it's either culture or historical, I don't know what it is, but many doctors, they don't tend to take seriously what nurse managers say. And you need like another doctor or somebody at a level of that to go in there and say, "You know what, I understand this but this is how it should be done." ... The TB coordinators are wonderful staff, very capable, but they also need support from the district management team ... For moral authority. (KZN urban district manager)

7.3.2.3 District management team lead

In a decentralised health system, the DMT's involvement and support are critical, as only the district manager could instruct hospitals to implement and make resources available to support them. Some districts seemed not to take ownership of policy implementation as a result of TB being a vertical programme for so long rather than being embedded in a coherent system involving vertical coordination across levels (national to sub-district) and horizontal coordination between programme and line managers at operational level. It would have been important to include management structures at national, provincial, district, sub-district, and facility level, as well as programme coordinators at each level.

The extent to which districts took responsibility and ownership of the policy affected implementation and resulted in variable implementation between districts.

And the variability is partly because of where the drive for implementation is, where the ownership and accountability and leadership is, and some districts go and do it and they do it well and some are sitting with 10 years of waiting to fix infrastructure and they can't yet admit patients there because they don't have the ward ... So, you know that is a local implementation thing. (National manager)

TB coordinators shared that district and sub-district management buy-in was critical to support implementation.

Getting buy-in from management ... you will constantly be fighting to get things going. You need that buy-in, as soon as you get buy-in from your district management team and the sub-district management team, things tend to work much smoother. When you don't have buy-in from them, you will battle to get things going. (KZN rural district TB coordinator)

An important strategy to provide authority and achieve wider buy-in was having the district manager, district TB coordinator, and facility management attend initial meetings.

It must be very clear to the manager about what you intend to do and how it is going to be achieved and the outcome that is expected ... because managers need to divert resources ... You need a district (TB) coordinator to go with you. At the first meeting the district management must be there ... They need some planning with them to roll it out in the facility ... Key people, like management, need to be available in the first meeting, the pharmacist, the nursing services manager, the social worker, the dietician, the medical manager, the doctors, and nurses involved in TB must be in the meeting. Those key people must be there. (KZN NGO technical advisor)

At times when sites were not cooperating, it was only the district manager who could instruct facilities to implement.

The district management team must support what you are implementing otherwise nobody's going to listen to you. You must have the backing and the support of senior management ... There was one time where there was a deadlock at King Dinizulu and we were not moving anywhere and [district clinical manager] came with the district manager and the district manager said to them, "If you don't want to implement, please open that door, please leave now ... I am not here to ask for your permission, I'm here to say implement, this is where you are and this is where you need to be." (KZN urban district TB coordinator)

Besides having the authority to instruct facilities to implement, one of the most important reasons for DMTs to be responsible for coordinating, or at least to be involved in implementation, was that the DMT could direct resources for new policy.

I think it's important to have commitment in the district ... I think if a district management team doesn't see it as part of their core business, if they see it as parallel, it will just get reported to a TB programme or a DR programme, they are not going to take ownership for it when it comes time to allocate the resources for it, when it comes times to prioritise capital when purchasing ECGs or audiology machines. It's not going to happen. (WC urban district TB manager)

7.3.3 Change management

Participants reflected that it was difficult to embed new technologies especially in a conservative programme like DR-TB, where historically there has been resistance to change. Shifting people sometimes required a ‘maverick’ who challenged the existing status quo.

But you know some people are just quite conservative and there is due process to be followed and change is difficult, so it's a whole change management process really ... and sometimes you need a maverick. (WC urban district TB manager)

Readiness for change was more evident in settings where stakeholders on the ground realised that the current system could not cope, felt supported and capacitated through training, and had resources or early initiatives already in place. However, many other managers and clinicians were hesitant or resistant to decentralisation, so district TB coordinators and managers worked with those who were interested and open to change, and over time created a shift in mindset with regards to decentralisation.

It was very difficult changing people's mindsets ... What we did is that we worked with people that were willing. We took the low hanging fruit, we presented it to everybody and went around to all of the people and we found that with some of them it was going to take too much energy getting it going here, let us move on. And then we would get to the next place and people were open to change and you will work with them. That is how we got the thing going. (KZN urban district TB coordinator)

The provincial managers reflected on the slow pace of change, noting that changing mindsets of those who were not interested or resistant required many meetings and engagements.

So, the mindset that changes, but then again it is a lot of work. Sometimes you will come to the first meeting and there is no one who is interested. The second meeting ... The third meeting maybe you get one or two people who might even change their minds, some only change their minds after being trained, but you know you just have to work with them. (KZN provincial TB manager)

7.4 CHAPTER SUMMARY

In summary, the interplay of process factors had an influence on DR-TB policy implementation in both provinces. Early lessons from pilot projects and experience from other countries were adopted by the DoH and scaled up across the provinces. Implementation plans influenced the way the policy was implemented, but this was not done consistently in all districts. The operational factors that influenced implementation included, readiness assessments, structured training, and forums for guiding implementation. The CoCT's SDC monthly MDT meeting was a good example of innovation to ensure good policy implementation with a strong focus on quality. There were important examples of the way policy was adapted for different contexts, and was approached in a phased manner to allow capacity to develop for decentralisation.

It was important to engage stakeholders not just through training but to co-design the approach so that they could secure buy-in and support at all levels. Another important process factor was fostering ownership for the programme at all levels, but particularly involving DMTs which had the authority to instruct facilities to decentralise and held the purse strings to resource implementation.

The remaining chapters expand on how resourcing influences implementation (Chapter 8), and the trade-off between creating access to care and ensuring quality of care (Chapter 9).



CHAPTER 8. RESOURCING POLICY IMPLEMENTATION: UNFUNDED MANDATES?

8.1 INTRODUCTION

The previous chapters described the timelines of implementation, the models of DR-TB care that emerged, the understanding of policy meaning and intent, the tensions and contestation of stakeholder groups, and process factors that hampered or facilitated implementation of the DR-TB decentralisation policy.

This chapter focuses on funding and resourcing of policy implementation and draws on a review of National Treasury documents and interviews with national and provincial managers and TB experts. This chapter describes the nature of funding for DR-TB in South Africa's quasi-federal health system, explores the debates on where responsibility for funding DR-TB should lie, and considers health system capacity and constraints (human resources, infrastructure, etc.) in integrating a decentralised DR-TB programme through the district health system.

8.2 DR-TB, A HIGH COST AND RESOURCE-INTENSE PROGRAMME

The resources needed to manage the complex and long regimens for DR-TB are considerable: at the time of the research, once a patient was diagnosed, they first had to undergo a battery of baseline tests before they were initiated on DR-TB treatment. Treatment could then last up to two years with the long regimen, and needed to be directly observed in the clinic during the first few months of the intensive phase, and injectable treatment provided at patients' homes by injection teams. The patient then needed to be followed up monthly for monitoring, which included blood and sputum tests, audiometry, and ECGs. For the health system to manage PWDR-TB at decentralised sites according to the policy, it therefore required trained staff, equipment and diagnostic services, medicines, adequate infrastructure for in- and outpatients, community-based staff with means of transport, and the funding to achieve all these elements.

To reliably secure the resources, required first and foremost, a functional district health system. However, the South African health system was regarded as having long-standing systems weaknesses and as providing poor quality of care. It was believed by many experts that the health system needed to be sufficiently strengthened, otherwise new diagnostics and drugs would be ineffective. It was clearly articulated that rather than patients failing in their treatment, the health system was failing patients, through stock-outs, staffing unavailability, and inadequate monitoring and referral systems.

Normally when we look at TB we always say it's the patients fault, they are not taking their treatment ... But ... there are stock-outs in the pharmacy, the patient is waiting for the medication but it's not there because it's not in the pharmacy, or there's a public health strike and the nurses

are not there, or they lost the patient's file so now they can't find it, sorry you have to come back tomorrow. So it's actually the system failing the patient more than the patient is failing the system.
(KZN NGO technical advisor)

Implementing the new decentralisation policy required a proper understanding of the health care delivery systems and resources that would be needed.

I think in general people understood the concept or the rationale as to why you should decentralise, but I don't think people understood the systems that need to be in place for a decentralisation policy to be successful. You know the training and development of staff, the systems to ensure when there is loss to follow-ups how to trace them quickly and the fact that you are going to give daily injections now ... I think people did not understand it, so therefore those things weren't always done very well or maybe they just didn't have the resources. (WC provincial TB manager)

Establishing effective DR-TB management systems was costly in terms of clinician time on patient care and administration, bed costs, long admissions, equipment and monitoring required, community tracing, and treatment regimens.

The programme is very resource-intense if we had to do everything correctly, chase every contact [person], make sure there is patient support, especially because our numbers are quite high ... we need to do contact management, we need to do patient support, we need to make sure even in the community where patients stay there is proper infection prevention and control, we need to expand more and do more work at the community so that we can find people early and start them on treatment early. Our biggest problem here is transmission, transmission in our health facilities, getting our health facilities which were not built properly, especially the waiting area to be better ventilated, getting the facilities to properly screen the patients that come to them so that we can pick up TB quite early. (KZN provincial TB manager)

However, managers and clinicians tasked with implementing the policy felt that the province expected policy to be implemented but did not provide the resources required to support implementation.

The province comes with a policy and paper and they say, "Do 1,2,3", but they don't come with all of the necessary things that you need on the ground. (KZN urban DR-TB unit doctor)

8.3 FUNDING FOR DR-TB DECENTRALISATION

8.3.1 Mechanisms of TB funding

Health funding remains constrained in the South African public sector, due to shrinking gross domestic product (GDP) and stagnant allocation to health, and the quadruple burden of disease, including being one of the highest HIV and TB burden countries globally (Blecher, 2017). With many competing health priorities, there have been long-standing tensions between national policy-making geared towards the

latest evidence-based interventions and resource allocation to provinces which were considered to be chronically inadequate. Funding gaps (i.e. the difference between assessments by governments of funding needs for TB prevention, diagnosis, and treatment, and the actual amount of funds mobilised and made available) have persisted in detection and treatment of TB, both globally and in most countries with a high burden of disease (WHO, 2019). Globally, National TB Programmes reported a funding gap for TB of US\$1.3 billion (WHO, 2019). Despite growth in funding from domestic and international donor sources, many National TB Programmes are unable to mobilise all the funding required for full implementation of their national strategic plans (Floyd et al., 2013).

South Africa's response to TB has been funded by the NDoH through two key mechanisms: the direct equitable share allocations for health to each of the nine provinces; and conditional grants (Section 27, 2007) (Box 2).

Box 2. Description of funding allocations to provinces

Provinces receive the largest proportion of national revenue, as they are responsible for delivering services and implementing programmes. The equitable share budget is divided among the provinces on the basis of relative need and the different demographic and economic profiles of each province. It is meant to be redistributive so that the poorer provinces benefit more, but historical funding levels are also a key influence. Equitable share funds are unconditional, meaning that the provinces generally have complete discretion over how they distribute these funds to particular departments and programmes, provided they operate within the broad policy framework set by national government.

This is contrasted with conditional grants, which are given to provincial departments for spending on a particular objective or programme ('earmarked' funds). Conditional grants provide a way for the national government to monitor funding for national priorities and support these programmes – especially in provinces where priorities may be different from those set at a national level.

The Comprehensive HIV/AIDS Conditional Grant established in 2002, allowed government to prioritise funding to address the burden of HIV/AIDS (Section 27, 2007). In 2011/12, recognition of the burden of HIV and TB coinfection prompted the inclusion of a specific TB/HIV sub-programme in the conditional grant, which made up just 2% of the total grant (National Treasury, 2012). In 2016, the grant was expanded to include TB care and renamed the Comprehensive HIV, AIDS and TB conditional grant (National Treasury, 2016). To accommodate this, spending was expected to increase from ZAR16 billion in 2016/17 to ZAR22.9 billion in 2019/20, despite tight fiscal constraints and general budget reductions. However according to the National Strategic Plan 2017, the TB budget in the 2016/17–2019/20 medium-term expenditure framework still made up just 9% of total public budgets

for the HIV, TB, STI and social development sub-programme (SANAC, 2017). The allocated conditional grant included a dedicated ZAR200 million in 2017/18 and ZAR460 million in 2018/19, to equip provinces with the tools to implement the TB investment case recommendations (National Treasury, 2017). Then, in 2019, almost 15 years after the Tugela Ferry outbreak, a comprehensive TB component was introduced into the conditional grant to wholly fund the TB and DR-TB response (National Treasury, 2018). The reason cited by National Treasury was that TB, MDR and XDR are “key national priorities and require a country-wide coordinated response which is best achieved through a conditional grant” (Treasury, 2020, p. 745). Besides the need to ring-fence funding for an important health priority, the HIV conditional grant at ZAR20 billion in 2016, had grown too large to accommodate the TB budget, so the TB programme required a separate ring-fenced funding mechanism. The TB conditional grant, however, did not specify funding arrangements for the decentralisation policy (i.e. where the funds were to be allocated in the system).

8.3.2 Funding the DR-TB decentralisation policy

Prior to the Tugela Ferry outbreak, there was little coordinated government action for DR-TB. In response to the emerging DR-TB crisis, in 2007 the NDoH mobilised just over ZAR419 million (US\$56.7 million) from the Global Fund, to provide for improved detection and surveillance systems, and specialised inpatient DR-TB treatment hospitals in all provinces (National Treasury, 2008). In most provinces, DR-TB units were reported to have been built or upgraded using this funding.

When the government launched the 2011 DR-TB decentralisation policy, it did not commit a specific budget for decentralisation. A review of National Treasury annual reports and budget statements revealed that aside from Xpert rollout, which was reported as a budget priority in 2013 (National Treasury, 2013), there were no budgetary statements to support decentralisation of DR-TB when the policy was launched (National Treasury, 2011; 2012).

The sector had almost made no or very few budget bids for TB ... when MDR started we never really had a bid to say (what) this was going to cost ... we were asked to fund the Gene-Xpert. We were asked to fund the TB hospital build up ... we were never asked to fund the decentralisation programme. (National manager)

Provinces were asked to mobilise funds for the decentralisation policy from existing budgets for staff, injection teams, training, vehicles, equipment like ECGs, programme supplies like clinical stationery, and health education materials. Donors stepped in to support early implementation, funding equipment and training, as well as providing some prefabricated structures for outpatient departments (OPD) and DR-TB wards.

The funding envelope at provincial and district level was limited due to the competing priorities of other sectors, and within health, for other health priorities.

I don't think it is a lack of political will. Our department takes TB seriously ... It is a question of resources ... if you ask the ophthalmologist about cataracts, the back-log in cataracts ... he is going to say "it is far more important" ... If you ask someone in family planning, they are going to say the same. (WC CoE manager)

8.3.3 DR-TB decentralisation, an unfunded mandate

A key national manager acknowledged the challenge of implementing a policy without committing dedicated funding for it, stating that, "*it's very difficult to sell a dream without money ... but there's not been like proper budgets to support the entire decentralisation*" (National manager). For provinces, implementing a new policy without a specific budget was essentially seen as an 'unfunded mandate'.

So there are many unfunded mandates and provinces do find that a problem particularly in the current tough fiscal climate ... The whole increase in MDR was largely in a sense unfunded mandates because there was never any specific budget bid. (National manager)

Provinces differed in what they were able to do because they had to work with the resources they had or could mobilise.

What is seen as people do different things, is not exactly that, it's that people do what they can afford to do, given their circumstances, given their resources ... We didn't dedicate a budget for these activities ... and some provinces got their money, thank you to them, they moved. Others, they didn't really prioritise TB, they could not move the way we expected them, so it's been very difficult. (National TB manager)

Despite the initial investments from donors and provinces, decentralised sites thus struggled to mobilise funds to implement the policy. In particular, they experienced a challenge related to capital investments for infrastructure to enable them to cater for increased numbers of PWDR-TB and to improve infection control. Some DR-TB units expressed frustration after having made submissions, requests, and motivations for up to eight years, still waiting for infrastructure to be addressed.

8.3.4 Shifting budgets within provincial resource allocation

Some informants believed that providing DR-TB care, like all health services, was a funded mandate at the district level, and that it was up to provinces to shift the resources to where they would be required with decentralisation.

If you don't want something to work, you can always find reasons not to make it work and then you can use words like ... 'unfunded mandates' and those sorts of things. The issue is the Head of Health ... makes those decisions as to where the funding mandate is. MDR-TB according to the

essential drug programme is a disease that we treat, so how can it be an unfunded mandate? Ok when we change from the one medicine to another it is irrelevant. People don't run around and tell me when I introduce a new diabetic medicine that it is an unfunded mandate. As I say resistance to change, if you want to stop something you will find good reasons. (National manager)

Although not specifically earmarked for supporting decentralisation, provinces had a budget for DR-TB drugs, diagnostics, and outreach services through the conditional grant. However, when districts decentralised further to other satellite sites, budgets were not decentralised. National managers who set policy agreed that shifting services from central sites to decentralised sites did require a shift in resourcing to the periphery.

So basically if ... as a head of department, I've got money that falls on the hospital for the management of MDR-TB, but now I am wanting to send my patients to PHC, all I have to do is shift some of the money from the hospital level down to PHC that is a funded mandate. (National manager)

After decentralisation in KZN, the budget for DR-TB for the district was allocated completely to the decentralised DR-TB site. The DR-TB drugs budget was transferred from the district to the decentralised DR-TB units and drugs were sent by patient name from the decentralised unit to satellite sites. Laboratory costs were also catered for wherever the patient was treated. However, there was no shift in budget to new decentralised and satellite sites for staff, infrastructure, equipment, and other operational expenses.

As the patients move the drugs will move, as the patients move the labs will move, you know those are the two big ticket items. So, you might argue that they should be getting more human resources and that might be a fair comment but those are local decisions. (National manager)

In reality, it was difficult to move staff or the budget for those staff from specialist hospitals to districts, even though PWDR-TB were now being seen in district hospitals and PHC clinics.

So, the rationale for a management perspective is always the money follows the patient. That being said, when services are being decentralised the money must come from the centralised hospitals where the services have historically taken place and moved down to the PHC level and I'm answering you on a policy level now. However, those doctors are appointed on a fixed establishment of x rural hospital. You can't take them away and go put them in x district ... So, is the money following the patient in this sense? No, because they will retain those resources. But the thinking is good. The money should follow the patient. (WC rural district PHC manager)

Districts began to think about how the budgets would be further devolved to sub-districts, but there were risks associated with this, as was the case in one district that experienced a depletion of their budget when drugs were ordered at sub-district level for the first time.

It [budget] probably will be [shifted to sub-district] but at the moment it is not. So, when we started decentralising our patients, I think it was a year ago, we ordered drugs for your old regimen before we started with the injection-free regimen, we ordered drugs ... and we blew the budget for the quarter so that was a big challenge. We are going to do it via [district DR-TB hospital] until they have sorted out the budget at sub-district. (KZN rural district TB coordinator)

Managing this required further analysis around bed planning and anticipating the numbers of patients that would be managed at the decentralised DR-TB unit and the numbers that would be managed in sub-district satellite sites, as well as the complexity of care required for these patients.

8.3.5 Funding DR-TB using existing resources in the district health system

Many informants went further to argue that additional funds were not required to implement the DR-TB decentralisation policy, but that instead they should leverage the service delivery platform that already existed in the district health system. They believed these costs should have been absorbed by the treating hospital or clinic in the sub-district as it was required for managing their own patients.

Moving patients to lower levels, where there were already health care facilities with infection control measures, laboratories, information systems, and staff in place, only required policies for moving specific resources like drugs. Some implementing sites mobilised their own budgets for infrastructure once buy-in was obtained from the CEOs. Some even argued that districts did not require additional staff to implement DR-TB decentralisation, but needed to utilise the existing staff to manage the small number of additional patients they would see, and that these staff would only require specific DR-TB training.

I am a small facility. I'm only getting one [DR-TB] patient in a month. Why do you need more personnel to do that? It is because they don't appreciate how they work, they don't look at their workload and what is contributing to their workload. It is not DR-TB. One patient a month is not going to contribute anything significant to your workload and you cannot ask for additional resources to work with. We just need to give them the tools to work with. (KZN NGO technical advisor)

It was argued that equipment should be ordered by PHC and not through the DR-TB budgets, and while specialised DR-TB drugs were provided through the conditional grant by the province, other drugs in the DR-TB programme had been used in PHC for a long time.

Many managers identified the opportunity of leveraging HIV funding for the DR-TB programme where budgets were constrained.

If you look at the funding everything is HIV, all the research, all the funding, PEPFAR, UNAIDS etc. ... So, everybody focuses on HIV and then they forget about TB. So, we are like the forgotten sister ... So you sort of got to piggyback with HIV and try and bring TB with HIV ... It is very difficult to get funding for just TB or just for MDR, but if you have HIV on, people are more willing ... You know even with a budget that is allocated to us when we ask there's no money. We sort of have to do underhanded tactics. The HIV grant just sort of gets stuff done for us. (KZN rural DR-TB unit doctor)

Absorbing these patients in the districts required leadership, better planning, as well as innovation and the ability to integrate within existing services.

But I think we didn't always really need budgets to get things done. I think it just depends on the kind of leadership that we show, and the managers do they know which visions they want to implement. We don't need budget. I think within what we have it starts with good planning. (WC rural DR-TB unit manager)

8.3.6 Integrating decentralised DR-TB into a weak district health system

While it was argued that new policy be implemented within existing resources available in the district health system, some saw little spare capacity for coping with additional load.

I think we're living in an underfunded society as well and an under-resourced society. You are asking people to do more and sometimes you are asking them to do too much and sometimes the tools that have been created are really over the top and there's too much there and it is not practical and it is not going to get done. (KZN CoE doctor)

The district health system was strained and overburdened and not functioning optimally, with lack of capacity, management skills, information systems that interface between facilities, and inadequate patient follow-up. There were serious challenges with human resources including shortages of critical staff at PHC. Drug supply systems were already strained and there was a concern that the district health system would not cope with the additional load of expensive new DR-TB drugs that needed close monitoring and control.

We must not undermine these significant fiscal considerations. MDR-TB and XDR definitely is probably the most expensive disease [managed] with state medicine and so now you want to take commodities worth very high rand values and put them into a supply chain at PHC which is not designed to hold and account for stock of that magnitude ... we have 3 400 PHC clinics in South Africa. So now you want to have stock in all 3 400 PHC clinics in South Africa in case an MDR patient comes along. So just think about it, first of all making sure that you have enough stock,

making sure then that that stock does not expire, making sure that nobody steals it, are all complex issues ... So now you want to throw MDR onto an already stressed supply chain at a PHC level.
(National manager)

8.4 SPECIALISED SERVICES AND EQUIPMENT

Previously, CoEs were the only facilities managing PWDR-TB in the province, and with the introduction of this policy, newly established decentralised sites would be initiating and managing patients. They would require equipment, drugs, and staffing for diagnosis, monitoring, and treatment. In terms of monitoring, most important would be audiometry for patients who had been on ototoxic drugs to monitor for hearing loss, and ECGs to monitor patients started on bedaquiline which has rare cardiac side-effects (NDoH, 2011). The issue was not so much resource shortages, but the availability of resources at the lower levels of health care delivery that would now be expected to provide DR-TB services.

KZN opted to decentralise to district/regional hospitals initially, so it would be expected that these services and equipment would already exist at these hospitals. However, while some hospitals especially the ones with purpose-built DR-TB units had audiometry, other hospitals that established new DR-TB units did not have these resources dedicated to the unit. The required equipment was easier to obtain for the first wave of decentralised sites between 2007 and 2010, as the provinces received donor funding to procure ECGs and KUDUwaves for audiometry.

However, there were limited audiologists to conduct the hearing tests and usually there was just one for the entire hospital, who now also needed to service all the PWDR-TB being seen at the DR-TB unit. This resulted in a strain on existing staff, services, and equipment.

The audiologist is also having quite a difficult time. Because she is the only one for the whole hospital. She is not a designated TB audiologist and we have clinics on Monday, Tuesday, and Thursday, that requires her to be here most of the week ... All audiology patients get referred to her so she's struggling quite a bit as well. She has been fighting a losing battle with leaders at this hospital for audiology. She has been trying to either get someone to assist her here but like I said again they are having that issue with MDR ... maybe if they could at least send an audiologist to us here because we have a KUDUwave here, that is based here. (KZN rural DR-TB unit doctor)

Other decentralised sites that started later, after 2012, did not benefit from infrastructure and equipment paid by the initial Global Fund grants. They had no audiologists or audio booths and felt this compromised patient care and impacted the ability to implement the policy.

We started initiating here and we opened the outpatient clinics. That was decentralisation, now we on the ground we have done what we were supposed to do, but you need to have things like an

audiologist. We are giving patients kanamycin; this hospital does not have an audiologist and we don't have a proper audio booth. We use a KUDUwave. We use a screening test, that is what we are using ... We don't have all of the necessary things that we need to manage MDR patients. This can be one of the issues around the implementation of decentralisation. The policy is good on paper, but you must have on-the-ground necessary tools to implement it. (KZN urban DR-TB unit doctor)

Similarly, with ECGs, they were available at all hospitals and there was capacity to interpret them. However, it became clear that dedicated ECGs were needed in the DR-TB unit. When DR-TB care started to be decentralised further, down-referring patients to satellite sites for ongoing treatment and monitoring, ECGs were not always available at this level, limiting their ability to start decentralising.

We are looking at other sites ... some of them don't have an ECG machine ... (they) could start but they don't have ECG machine ... Those are limitations ... A lot of the reasons why we can't initiate at a clinic level. (KZN CoE doctor)

Sometimes ECGs were available but the consumables for the machine were not. Patients then had to be referred to the closest hospital for ECGs, which resulted in delays and wasted time.

Regarding the equipment, the ECG is a stumbling block and that is the only problem that we have. In a lot of facilities all of them have access to an ECG but now we have realised that when they order the ECG paper, they are not finding the paper, so it is causing a delay, so now they are referring some patients ... When they send a patient, it takes them very long to do an ECG, it might take the whole day. At Cato Manor they send the patient to King Edward but he came back without an ECG, sent to King George but came back without an ECG, so those are two wasted days and this is a working patient. (KZN NGO technical advisor)

In the WC, particularly in CoCT, decentralising down to PHC was a challenge because resources like ECGs, audiologists, and audiometry equipment were not available at PHC level. However, this challenge was anticipated and the City managers made provisions for accessing these services at clinics. The CoE audiologist was previously doing all audiometry and was completely overwhelmed, so the WC Province provided CoCT with audiologists who covered two sub-districts each. The audiologists had a roster and visited clinics every two weeks where there were patients booked.

The rural WC districts, however did not have good access to audiometry and there was resistance to KUDUwaves travelling around to facilities. PWDR-TB were accessing care at local clinics but had to travel up to 200 km or wait up to three months for audiometry at referral hospitals.

Ok, so we've got a speech therapist employed. I think she has been here for about a month now and she is not an audiologist, but she is doing screening for us ... Before that, it was really terrible

because we then had to rely on Drakenstein, which obviously has a big burden of MDR themselves, so the waiting list for audiology screening was three months. So, imagine our patients then didn't get the screening that is required according to protocol, we had to wait three months to get a date. We were doing the best that we could but the patients were not getting their monthly screening. (KZN rural DR-TB unit doctor)

For monitoring patients on bedaquiline, the CoCT and rural WC districts did not have ECGs in PHC clinics and patients were referred to community day centres or hospitals, leaving the CoCT manager to reflect that PWDR-TB faced very significant challenges and barriers in accessing these tests.

What we expect out of the patients. And then we get upset when they default their treatment ... I need to send the patient to the CHC over there for the chest X-ray, say the patient needs an ECG, I don't have an ECG ... I need to send him to that place but then I still expect him to come here every day to swallow his pills. It just boggles my mind what we expect patients to do. (WC urban district TB manager)

8.5 HUMAN RESOURCES

Decentralising DR-TB care had implications on human resources, and participants noted the challenges related to allied health workers (psychologists, social workers, counsellors and pharmacists) as well as clinical staff including doctors and nurses. There were no explicit observations on challenges experienced by community health workers with decentralised care.

8.5.1 Allied health workers

KZN decentralised services to the hospital level first, which meant that there were social workers and psychologists employed within the hospital to whom PWDR-TB could be referred. However, one psychologist or social worker for the entire hospital was not adequate according to the staffing ratios in the decentralisation policy.

I think Province or National put very nice guidelines and policies, but it is sometimes very difficult to implement at ground level. Not every facility has that ability to do what is in the guidelines. If you look at the guidelines it says for every 20 patients, you should have a social worker. But we don't have that access and when we ask for that access they say it's not in our budget, but you've got it in the policy so why don't you create that (budget) for us. We make use of the general hospital social worker or the general hospital audiologist and even my pharmacy is now saying you need to give us a pharmacist from your budget because we cannot manage with MDR. (KZN rural DR-TB unit doctor)

In WC rural districts, there were psychologists at district level and mental health nurses at sub-district, and a social worker attached to the DR-TB hospital where patients would have to be referred. The CoCT previously had one social worker for the whole city who was overwhelmed. Patients were referred to community day centres to consult social workers and psychologists, but they had to travel a distance, it cost them money, and often they were not well enough to use public transport to get there. DR-TB clinicians and managers realised this was a big gap and that they were not able to support the patients who were at risk for serious mental ill-health.

When it comes to all of those other services, we really feel it needs to be there because we need to have a psychologist and we need to have a social worker which the City does not have because we are nowhere near being able to treat psychological things ... If you ask somebody, "how do you feel about this and whatever, where do you think you're going to be in five years' time", and this person says, "I don't care where I am," surely there's something going on. (WC urban sub-district MDR-TB coordinator)

In CoCT DR-TB counsellors were employed to support all the clinics in a sub-district, but one person was inadequate due to the huge geographical area they had to cover and the load of work on them to do tracing, recalls, home assessments, and so on.

We only have one MDR counsellor, she is doing Philippi and Mitchells Plain. Around here it is Weltevreden, Mzamomhle, Phumlani, Crossroads 1, Crossroads 2 which is in this area, five, and then she must also do Mitchells Plain and she's only one person. If we can maybe have two or three counsellors ... She checks if I'm struggling with any patients and then she will do our recalls ... She will go to their homes and she will do some talks. She will go and check where does the client stay, who does she stay with, how many people are in the house, and is there a support system in the house. Sometimes she can't reach the patient immediately due to her workload ... That is why sometimes she goes on weekends. (WC urban clinic nurse)

Counsellors alone were not adequate because the nature of counselling required for PWDR-TB was quite intense. They required support from social workers to address the social challenges and psychologists to support with mental health needs.

If we had funding, I would look at psychologists and social workers because I think that's a great gap in the system we have ... We have this generic facility counsellor, but they don't have that counselling skill that we require and they don't have the time to sit one-on-one with patients because they need to push numbers. So, even if we can get social workers to assist our patients, getting their IDs, getting everything sorted for them, and our psychologists getting everything to assist. (WC provincial TB manager)

Another human resource challenge in WC was that they had pharmacists at sub-district level, and only post-basic pharmacy assistants at PHC clinics. Those involved in the programme were concerned about how expensive and important drugs like bedaquiline would be controlled without pharmacists at the facility.

8.5.2 TB clinical staff

In both provinces, doctor and nurse shortages were a challenge in implementing the new policy. Staff attrition was a particular problem with TB nurses, who were recruited to NGOs where they were better paid and had better conditions of service. Working conditions were not ideal, HCWs were overwhelmed and absenteeism also compounded the staffing challenges. High turnover of clinical staff especially in rural areas, meant that when trained staff left, TB coordinators needed to identify and train new staff.

8.5.2.1 Doctors

In KZN, rural districts struggled to attract and retain doctors to work in DR-TB units. There was usually one trained DR-TB doctor at the DR-TB site, to support the entire district, and with a huge patient load to manage.

You know in a month I can see about 600 to 700 patients in my outpatients department and as the only doctor it is not possible because I've got to see to the outpatients, look after the ward patients, and it becomes very difficult. (KZN rural DR-TB unit doctor)

As a result, doctors were overwhelmed with the huge patient load, had no back up if they were sick or on leave, and as in one example, had to be called back from retirement because there were no other doctors available to take his place.

Yes, with us the doctor is not coping. He's the only doctor in this programme. If the doctor is not in, you cannot call another doctor in Nongoma. He's the only doctor who is trained here in Zululand to do this MDR. You can just imagine if he said next week I'm leaving what will happen with this institution? (KZN rural DR-TB unit manager)

When there were insufficient DR-TB doctors, other doctors in the hospital were co-opted to support the DR-TB site, but they were not adequately trained and struggle with managing complex patients.

Staffing is a little bit of a challenge here ... Staff are being co-opted from the other wards to work in MDR-TB and they don't seem to understand the programme properly. So you ask them why do you do this, why don't you follow the guidelines? They say no we are new here. We don't know much about how to manage this patient ... There are no dedicated staff to really focus on MDR-TB and ... the management of MDR-TB is completely different from the general management of TB in terms of managing the side-effects, managing the medication and other things. (KZN rural DR-TB unit doctor)

In WC, there was a difference between urban and rural districts. CoCT had doctors available at PHC level to manage PWDR-TB, some full-time on-site and others as sessional doctors who served a few clinics on a roster basis, and doctors were always available for telephonic consults with the TB nurses. The CoCT also allocated one SMO for two sub-districts to support the DR-TB programme. Initially these SMOs would initiate patients, but once clinic doctors were better capacitated, they would initiate patients independently with telephonic support from the SMOs and CoE doctors.

However, rural WC clinics did not have doctors trained in DR-TB. With decentralisation, the family physicians took responsibility in the Cape Winelands, Overberg were supported by Brewelskloof DR-TB Hospital, and West Coast had one doctor doing outreach to one sub-district, while the other sub-districts had to refer PWDR-TB to the DR-TB hospital.

8.5.2.2 Nurses

When new DR-TB and satellite sites started initiating treatment, the workload increased but staffing did not necessarily increase and the same HCWs needed to now also manage PWDR-TB. In some KZN hospitals, the DR-TB nurses were required to see patients in the ward, in the outpatient clinics, go out with injection teams, and also provide services in other departments of the hospital when they had staff shortages. The DR-TB programme required professional nurses, while in many DR-TB units only staff nurses were available.

You will find that the staff nurses that are allocated for TB programme are not that capacitated as compared to the professional nurses, so that is also a gap. I believe that if you want to win you need to put a person who will be in charge, a person that knows, and that person will be a professional nurse in the programme. I'm not saying that the staff nurses are not doing a great job, they are, but you know sometimes there is that lack of ownership and professionalism. (KZN rural DR-TB unit manager)

Besides the category of nursing, the TB nurse was quite specialised and needed to be trained, knowledgeable, and have compassion.

She must know the basics about MDR-TB and she must know about the side-effects ... She must know what to do, maybe not what to do herself and how to change medication that she must not do herself, but she must know to contact me or show the doctor or phone the doctor that used to come to the clinic or whatever. She must know what to do in case she sees this result ... A good TB nurse if they have compassion for the patients, because some of them do have and will actually walk an extra mile for the patients, and others don't. They must be knowledgeable about the TB field and the medication and things but they must also have compassion for the TB patients. (WC rural DR-TB unit doctor)

Unlike in other PHC clinical programmes, the DR-TB nurse needed to recognise complex drug side-effects, interactions and complications, and know how to act in response.

It depends on the nurse in the TB room, but some are definitely more competent than others. Someone will see the flag but won't even realise if they see a full blood count and now the HB [haemoglobin] drops from 10 to 6.5 and there's a flag that it's low ... It won't make any sense to them. Otherwise they will see it and react on it and phone. It's a concern but not only in the small clinics, it depends on who is in the clinic. (WC rural DR-TB unit doctor)

It is reasonable to place the primary responsibility for PWDR-TB on nurses, diagnosing, doing baseline tests, preparing the patients for initiation, and conducting monitoring tests, to provide the doctor with all the information required for treatment initiation and monthly review.

To get dedicated nursing staff in those rooms because a lot of what MDR is ... just making sure the bloods are done, that it is done on time, and having a good system in place so that you can check all of those little things, because a doctor is going to make decisions about the patient so we need all of that information. So, all the nurse has to do is to get the audiology report, get this report, do the bloods, and get the report of the bloods done according to protocol and then the doctor can make interpretations on what needs to happen when they get seen on a monthly basis. So, to strengthen the professional nurses within the clinics, that should be our focus and to give them adequate support ... We need adequate staff and adequately trained staff and then I think we can deliver a very good service especially with the new drugs and the shortened regimen. (WC rural district family physician)

The ideal would be to have dedicated trained professional nurses who managed the DR-TB programme, with support from doctors. However, all agreed that nurses needed doctor support, and could not manage PWDR-TB by themselves.

You do need to train the nurses and you do need to get them involved. You need to make it very clear that it is their baby not the doctor's baby. The monitoring, the engagement, the DOT, the collection of specimens, it's got to be done by the nurses. It's only the treatment regimens and the choice, the assessments that I find you have to have a doctor for ... Some nurses are remarkable the way they understand. They're just as good as doctors if not better, but that is not necessarily something that happens across the board and I think you need to be careful with that and how you do that with DR-TB. (WC urban district manager)

Having a dedicated DR-TB nurse ensured continuity of care and meant that the nurse was able to walk the journey with the patient, display empathy, and enable patients to develop trust in the nurses.

Not all of the clinics have TB sister always or a staff nurse that is dedicated to TB. So, everyone is doing it and that also causes a problem because the people trust the sister that they see every day on a regular basis. They know each other. They say, sister I don't have money this month for this, or this is a problem, so yes, they are more open to speak about their social problems. It is good to have a dedicated sister for TB but you don't have all over because of the shortage of staff. (WC rural district HAST coordinator)

Some argued that in PHC clinics, there was a need for nurse rotations so that all nurses get experience of all programmes.

We promote rotation so that everyone can have experience in different areas and that is the one reason, and the other reason is also that every area has its different challenges and one person if you are faced with those challenges year in and year out maybe you need a change of scenery. (WC urban clinic manager)

Other managers and experts believed that DR-TB nurses need to be specialised and have years of experience with the programme and should therefore not rotate.

If it was up to me, I would not have rotations in facilities. Once you find a good nurse, a good TB nurse, even though they say it's integration of services, but if you find a good TB nurse, you keep that person in the TB treatment. I know we don't want a crisis. But with TB it's such a different process. It's not just about the knowledge that you need to know about TB, it's also to have that compassion and treat the person differently. (WC provincial TB manager)

However, when there is just one dedicated TB nurse in a clinic, that nurse takes a huge burden in ensuring services are still delivered and there is little sustainability of care provided when the nurse is on leave or leaves the facility.

I think everyone must rotate because if that sister is not there and then the room stands still there and then no one knows what to do. (WC rural DR-TB unit nurse)

A reasonable solution offered by some was to have less frequent rotations of nurses in the TB room, keeping a DR-TB nurse for at least one year. Rotations of a year or two years allowed a nurse to treat a patient completing their two-year treatment, and allowed the nurse to become more confident so that they can train others. Another solution where resources permit, was to have one dedicated nurse and one that rotated through the TB room.

Ok, there is pros and cons on both because I love the idea of a dedicated TB nurse, but a week or two or three weeks that she is going on leave nothing happens and everything falls flat. That is the big negative but for the rest of the year, if she is there it usually went well. Where they are rotating, I really don't like that because it took about a year or more just to really know the field and how

to do it and what to do, so if they just know it and then there is someone new. That is terrible for me and so I don't like that. Most of the TB clinics are big enough I think for someone to be there always and for an extra person to rotate. I think that would be ideal because then there is that specific person that really knows the field and the other person that is rotating, so there is always that one that is always learning but she also knows quite a bit when that one lady goes on leave, something like that. But this whole rotation every time and no constant person, that is horrible.
(WC rural DR-TB unit doctor)

8.6 INFRASTRUCTURE

When the decentralisation policy was first launched, the NDoH obtained funding from the Global Fund for infrastructure, to establish DR-TB sites in all provinces. Some were upgraded units within hospitals, others were purpose-built DR-TB units or dedicated DR-TB hospitals. Despite these initial infrastructure upgrades, DR-TB sites in KZN still reported significant infrastructure challenges affecting the purpose-built DR-TB hospitals, the purpose-built DR-TB complexes linked to existing hospitals, and the DR-TB units established in district hospitals.

8.6.1 Case study 1: DR-TB hospital (Zululand)

In Zululand, Thula Sizwe was identified as a DR-TB hospital for the district. However, the old building used for inpatients was falling apart and was later replaced by temporary park homes. These park homes were not ideal, had insufficient beds (60 beds compared to 106 beds in the original unit), were poorly ventilated, and had poor temperature control.

Thula Sizwe was built with mud so now the mud has started to give up. It was just starting to fall apart. Have you seen the park homes? ... When it is hot they are sweating, when it is cold they are shivering as we have an open window policy ... We were told that it is a temporary structure because we were moving from that building. (KZN rural DR-TB unit manager)

8.6.2 Case study 2: Purpose-built DR-TB complex (King Cetshwayo)

In King Cetshwayo district, Catherine Boothe Hospital was identified for the development of a DR-TB complex linked to the district hospital. A new building was purpose-built with Global Fund funding. Despite being purpose-built, over the years it was found that it was not designed for the needs, with the OPD waiting area being exposed to the elements and inadequate for the patient numbers, and the unit lacking a pharmacy.

The infrastructure was not completely designed for the practice but it is better than most of the other institutions I have seen, especially our wards. They are quite fine ... our OPD is not well-suited for the kind of structure that we were supposed to be having with good ventilation and staff. We don't have a pharmacy on site. We still have to use the main pharmacy and our patients have to mingle with the other patients. (KZN rural DR-TB unit doctor)

8.6.3 Case study 3: Early DR-TB unit in a district hospital (Ugu)

Murchison Hospital was one of the first decentralised DR-TB sites established in KZN, serving Ugu district. There was no new infrastructure investment for the ward and OPD, so prefabricated and wooden temporary structures were used which lacked sufficient space and didn't allow for creating privacy and confidentiality during consultation and treatment. There were also inadequate toilets and water and electricity supply. When the hospital management motivated for Murchison Hospital to have a new DR-TB unit developed, it was intended that within two to three years a permanent unit would be built, but no progress has been made in 11 years, due to funding constraints and political interference.

I think our management motivated to have the MDR unit set up here with the district ... Their initial plan obviously was that within two to three years a permanent unit will be built but now this is like 11 years later we are still sitting with the original prefab buildings which we have been using. I mean if you look at our outpatients, it is wooden houses or Wendy houses. It hasn't moved anywhere ... We even had an occupational health report in terms of the poor ventilation, the enclosed space and the fact that we don't have proper resuscitation areas ... So, every year we sent a submission and as I've said finally they said yes. They are going to give it to us. The plans were drawn, we submitted a wish list of what we would like. It was accepted by [Provincial] Infrastructure Department, budget was allocated and then they told us "no sorry your budget has been taken for some other project. We will think about it maybe in the 2022/2023 financial year whether we are going to reallocate you the budget" ... Finances and I think there is lots of political involvement because we heard rumours that the money was taken to build some other hospital but it was politically motivated. So anyway we are a bit like ... how much longer can we wait in this place that is falling apart? (KZN rural DR-TB unit doctor)

8.6.4 Case study 4: Late DR-TB unit in a district hospital (uThukela)

uThukela was one of the last districts in KZN to establish a DR-TB unit in Estcourt Hospital, a district hospital. The OPD was a parkhome and consisted of two rooms where consultations and investigations were done. There was no sheltered waiting area and patients were exposed to the elements. For the hospital to serve as a DR-TB site, they required the necessary space and staff.

We practically have no space because this room is the audiology room, the next door is the room for vital signs, and then once the vital signs are done and then the patients will come for bloods and we move everything aside. We put the stretcher out for the ECGs and then we move it again, and then another patient will come for an ECG and then you move everything out again ... The only issue is the load that has been increasing ... We must establish it as a proper full facility because this is just two rooms basically and we are dealing with MDR. (KZN rural DR-TB unit doctor)

8.6.5 Case study 5: DR-TB outpatient department in a district hospital (iLembe)

iLembe was also one of the last districts in KZN to establish a DR-TB site. Montebello Hospital was selected because it had a TB ward, even though other hospitals were considered more suitable. However, the TB ward did not have adequate ventilation and ablution facilities. It was decided from the outset that Montebello Hospital would provide only an outpatient service and that patients who required admission would be transferred to KDH. A prefabricated structure was donated by USAID for the DR-TB OPD. It was small, not well ventilated, and did not have an adequate sheltered waiting area. The OPD also didn't have toilets and a cough booth.

The building of a new ward had been planned for a few years, with floor plans drawn and agreed, budget identified, but there were delays from the provincial Infrastructure Department.

There is budget to do it, but with infrastructure things it has to go via our provincial infrastructure. So, currently our district has done some floor plans and sent it to the provincial infrastructure because they wanted to know. Previously, they didn't approve of what we were thinking of doing but after some engagement with them and with the assistance of our provincial managers we were in agreement, but they just wanted to get a floor plan on how everything will be done and that has been submitted ... So, we are still waiting. There is budget. Province has provided budget for that, but we still need to follow procedures on the infrastructure side, so we are still waiting ... I think we submitted it two months ago because we have been working on it since last year. (KZN rural district TB coordinator)

In the meantime, the province had a short-term plan for minor renovations to the current wards including installing partitions and extractor fans. Funding had been identified, but province reported that the hospital had to initiate the process of tenders for the work to proceed. Province engaged the Infrastructure Department but there were many other facilities that required rebuilding, so there were not enough funds. A secondary plan was that the province had identified funding to build a new OPD.

We have tried to assist them, but you know at the provincial level there are things that you cannot do for the facility. There are things that they need to do for themselves. So, we have looked through their situation and have a short-term and a long-term plan for them ... So, for that we have lobbied for the conditional grant funding which has been available since the beginning of this financial year, but it needs them to actually start the process ... The tender processes has to come at that level which has been so much struggles especially because they have to do things right. Recently, I have asked our provincial infrastructure to assist them, but it is not moving at a pace that we wanted it to move. (KZN provincial TB manager)

8.6.6 Case study 6: City of Cape Town PHC clinics

When CoCT decentralised down to PHC, infection control was a challenge. There were no extractor fans and the clinics had to keep windows open to ensure adequate ventilation. To improve infection control, the CoCT faced challenges in securing funds, and there were long waiting periods for infrastructure upgrades.

There are no extractor fans. I remember when I came here, I asked them to do an assessment and they had this long report When they come with recommendations we have to cough up money and that is where the challenge comes From capital and then you put your name on the list and it might be like in five years' time when you are due for upgrades because there are other facilities within the sub-district that are already on the list for major upgrades or things like that. (WC urban clinic manager)

Another risk for infection control was the patient flow, with infectious people with TB and DR-TB not kept separate from other patients attending the clinics, and because there were long waiting times to be seen, there was greater risk of other patients being exposed to TB. Because engineering controls were inadequate, the administrative controls had to be employed, fast-tracking patients through the clinic, and patients wearing masks and staff wearing N95 respirators.

8.7 CHAPTER SUMMARY

In summary, funding flows and resource allocation for managing DR-TB at newly established decentralised and satellite sites were not determined before the policy was launched and this impacted service delivery. DR-TB was recognised as a resource-intensive/high-cost programme and there was a national shift towards ring-fenced funding, but informants expressed different views on its necessity. Differences in the capacity to shift funds and willingness to exercise decision space resulted in DR-TB service at district facilities being seen as an 'unfunded mandate'. As a result, decentralised sites experienced challenges with securing resources to manage PWDR-TB.

Limited availability and uneven distribution of resources in turn affected implementation. Lack of audiologists, audiometry, and ECGs resulted in poor monitoring of patients on DR-TB treatment; inadequate allied staff, like psychologists, social workers, and counsellors meant PWDR-TB could not be given the psychological support they required; the shortage and misdistribution of trained doctors and nurses impacted patient care; and infrastructure and infection control were not adequate for DR-TB.

DR-TB decentralisation can be regarded as a complex intervention requiring integration in a variably functioning system. The experiences described with resource allocation for policy implementation raises classic debates on integration versus vertical programmes, and serves to explain some of the

reasons why implementation of the DR-TB decentralisation policy was variable across the two provinces.

The remaining chapter describes the trade-off when decentralising from specialised DR-TB CoEs to decentralised DR-TB units, between creating access to care and ensuring quality of care (Chapter 9).



CHAPTER 9. THE COVERAGE-QUALITY TRADE-OFF OF DECENTRALISING

9.1 INTRODUCTION

The previous chapters showed how the DR-TB decentralisation policy favoured the achievement of coverage of decentralised sites in each district, which would address issues of access to care and reduce patient barriers, such as cost and transport; and provide patient-centred care closer to patients' homes. The chapters also described the political pressure to decentralise, with districts and provinces expected to report against targets for establishing new sites. Implementation proceeded even when all the necessary resources specified in the policy were not in place at decentralised sites. Against the context of existing health system challenges, coupled with introducing complicated DR-TB treatment in settings not fully capacitated and without all the necessary resources, this chapter describes the consequences of decentralisation, and the compromise of quality of care that resulted from trying to increase coverage of DR-TB initiating sites. It links the sentiments expressed in earlier chapters of policy intent (access to services), contestation by actors (concerns for quality), and resourcing (lack of staff, training, and equipment).

Many believed that over-hasty decentralisation from CoEs to lower-level units and satellite sites would impact quality of care. Some TB programme managers resisted pressures to increase the pace of decentralisation.

We have been nailed ... by the province and national, to say the pace that which we decentralising is not as what they expected. We've been saying that we will never ever decentralise at the expense of quality. (KZN rural district TB coordinator)

Many of the TB experts anticipated that decentralising too quickly would impact quality by not adequately building capacity among clinicians, and by not ensuring the health system was functional for delivering DR-TB care at lower levels. The following case studies reveal the consequences of decentralising DR-TB with inadequate resources, staffing, and training.

9.1.1 Case study: Poor quality of care at satellite sites in rural KZN (Zululand)

Zululand was one of the first districts to establish a DR-TB site at Thula Sizwe Hospital in 2011. Not long after, in 2012, an enthusiastic DR-TB medical manager at Thula Sizwe Hospital capacitated satellite sites to begin initiating PWDR-TB predominantly through a nurse-led model. Rollout of a number of satellite clinics was done rapidly instead of piloting to one site first while supporting the TB nurses until they were competent. The DR-TB medical manager had been mentoring the nurses but when he took a job elsewhere, that mentoring and support fell flat. The doctors that were trained left and other doctors were not interested in working in DR-TB, and as a result, patients were only being seen by NIMDR-trained nurses who themselves no longer received any mentoring. Poor care of PWDR-

TB by nurses in the satellite sites resulted in inadequate monitoring, and late identification and referral for complications like hearing loss.

Let me make an example, if a patient is having hearing loss, you can't just develop that overnight, there are some signs. If the nurse is injecting this patient daily, a patient cannot come to Thula Sizwe with total hearing loss in both ears. (KZN rural DR-TB unit manager)

Another example provided was of PWDR-TB with renal dysfunction, who were initiated at the satellite site despite the guidelines limiting nurses' scope to patients with no complications. The patients got worse and were referred very late to the DR-TB hospital.

Patients are developing complications out there. They are not sent here to the doctor, to manage them before it gets worse. Others they came with renal failure. When the doctor looks at their results, the doctor can say look this patient was initiated on treatment yet the U&E [kidney function test] of this patient did not allow it ... These people are trained. They are NIMDR-trained and others are NIMART-trained. You know that if the patient is having renal failure, you will not have to initiate these drugs. (KZN rural DR-TB unit manager)

When the new DR-TB medical manager started visiting the satellite clinics, he discovered that the nurses had been trained, but clinical treatment guidelines were not being followed. Nurses had to rely on telephonic consults with doctors at Thula Sizwe Hospital or KDH. Most TB clinicians and managers believed this was inadequate and that there should, in fact, be a doctor on-site at satellite units.

If this satellite programme was working well according to my view, there was going to be a doctor in that satellite who is attached to that clinic, who was assisting the nurses, because we as nurses we know how far we can go, and the doctor must come in there. (KZN rural DR-TB unit manager)

There were clear benefits to decentralising in managing the patient load and bringing care closer to patients, but without proper mentoring, local DR-TB clinicians and managers believed patients would have been better off waiting for care at the district DR-TB unit rather than being treated at poorly capacitated and supported satellite sites.

9.1.2 Case study: Hearing loss in rural KZN DR-TB unit (iLembe)

iLembe was one of the last districts to decentralise DR-TB and established a DR-TB site at Montebello Hospital in 2015. In 2016, a story broke in the media that 100 PWDR-TB treated at Montebello Hospital had developed hearing loss.

Do you remember when we had a scandal all over the newspapers? ... It was even on Xhosa FM that 100 patients are deaf here at Montebello ... Some of them had mild hearing loss which does need a hearing aid, but others had moderate and others had severe hearing loss. (KZN rural DR-TB unit nurse)

Montebello Hospital had inadequate infrastructure and was unable to admit PWDR-TB, referring them instead to KDH. Because they could not admit patients, when patients developed hearing impairment, they could not start them on bedaquiline. Aside from not being able to change PWDR-TB from ototoxic regimens containing injectables, there were also no baseline hearing tests being done during this period, because the KUDUwave was reportedly sent for calibration, without replacement equipment provided. TB clinicians thus continued to initiate patients without baseline hearing tests.

What happened was between 2015 and 2016, no baseline hearing tests were done before initiating patients on kanamycin because there was no KUDUwave to test patients before starting them on treatment ... We did have a KUDUwave but it was gone for calibration or something like that ... No plan was made (by the district). We just started initiating. (KZN rural DR-TB unit nurse)

In a conflicting report, the absence of audiometry was said to be due to the laptop used with the KUDUwave being stolen and not replaced.

At Montebello there was a problem with the audiology machine, there was a laptop that was donated that was supposed to be used by the audiologist because they were using KUDUwave and then that laptop got stolen and it was not replaced ... and she didn't have funds to buy a new laptop at that time. (KZN rural district TB coordinator)

The option of referral to Stanger Hospital, which had the equipment and audiologist, was also not pursued.

During that period ... not all patients had baseline audiometry done ... Sometimes you will find that a patient will go three or four months without any audio being done that is where we missed it. ... There was no other place to refer them to. We've got Stanger Hospital that has an audiologist and everything there, but if you look at the clinical notes, they were not being referred for audiology. (KZN rural district TB coordinator)

After the story went public, the health department responded, new audiometry equipment was supplied and all PWDR-TB began having baseline and follow-up audiology monitoring. It was clear that having a site not adequately established to deliver DR-TB care, resulted in significant morbidity to patients who did not receive effective care.

The following sections detail the main quality of care gaps that surfaced after decentralisation began to be implemented, and then contrasts the clinical governance interventions that were adopted across the two provinces, with varying effectiveness.

9.2 KEY QUALITY OF CARE CHALLENGES IN DECENTRALISED DR-TB CARE

There were two main quality of care challenges that were reported in newly established decentralised sites: (1) poor continuity of care; and (2) incorrect treatment, monitoring, and management of side-effects.

9.2.1 Poor continuity of care

Numerous gaps in the continuity of care were reported in interviews, starting with early diagnosis of PWDR-TB which required getting laboratory results in time, to community follow-up and contact tracing, to down and up-referral between different levels of care, which together negatively affected patient-centred care.

Inadequate systems for tracking laboratory results meant some clinics did not start DR-TB treatment on time.

It wasn't easy sorting out results quickly, like you discovered pre-XDRs three or four months later or something when you've had results for three months in the file, in the system, just because no one is tracking the patient. (KZN rural DR-TB unit doctor)

There were also challenges in linkage to care when PWDR-TB were down-referred to decentralised or satellite sites. Once diagnosed and referred for initiation of treatment, there was no follow-up to ensure a patient went to the site and started treatment. Many reported a disconnect between levels of care, between CoE and decentralised sites, decentralised sites and satellite sites, and satellite/decentralised sites and the community. The systems were set up and there were community caregivers or linking officers in place, but there were challenges with transport, and community-based services did not follow patients up at their homes.

A 13-year-old was diagnosed with rifampicin resistance, so the clinic made an appointment for the child to go to King Dinizulu because that is where all of the children are seen. They gave them an appointment date for the following week ... So, when the team went to go and screen the rest of the household, they found that the child hadn't been because they did not have bus fare. So if the team had not gone, they would not have known. (KZN urban district TB coordinator)

To effectively manage the burden of DR-TB, contact tracing and regular monitoring were critical, but resource shortages, including staff and transport, resulted in community-based services being ineffective in many areas.

The main challenge would be ... transport, you know, to go out and chase patients, that's still an outstanding problem. Like budgets have been given for the TB programme to purchase vehicles ... there's this big pool, now they've all disappeared. And you know you need actually, people to go in and follow-up patients. We need a whole cadre of staff. Somebody asked me, some funders, if we

have to make a difference what would we need. I said give us people who can go and immediately contact trace every contactable MDR patient, the way they do with Ebola and make sure that no one is left. (KZN urban district manager)

Some DR-TB doctors reported that PWDR-TB who were down-referred to satellite sites came back to the district decentralised site because they were not given information and no one responded to their questions. Patients felt they would have better patient-centred care and continuity of care at the CoE.

The problem is where you send patients there must be people managing these patients. You decentralise but where you open the site someone must be there to look after the patient. If there is no one you can't ... some patients were coming back ... You can ask those patients why they come back ... They will tell you that when I come here I see the doctor, I see the nurse, they talk to me, they ask questions they show me my results, but I went there and no one talks to me they just say take your pills and go ... When I'm consulting there at the clinic my computer is on. The patient sits. It is not much just to open the computer and say the sputum we took last month, this is the result, it is negative. It means that I am happy with it. Your viral load is low. It is fine, continue taking your ARVs. Just this conversation they are missing it ... They ask a lot of questions because it concerns their health. They are concerned, and if you send such a patient to other places they don't get all of the answers that they need. They get frustrated and they come back. I see them coming in and they say, "no don't send me there again, never send me again". (KZN urban DR-TB unit doctor)

9.2.2 Incorrect treatment

As a result of inadequate training and support to nurses and doctors, many PWDR-TB were not placed on correct regimens, monitored for side-effects, or treated effectively for treatment complications.

Senior DR-TB clinicians were concerned that nurses and doctors at satellite sites did not know or follow the treatment guidelines. As a result, in some satellite sites PWDR-TB were not optimally managed on the correct regimens.

It is scary what is happening to DR-TB patients. The regimens that they're on, they're still being managed by doctors and yet they're not on an optimum regimen. So I get that concern, I do, but that speaks to improving the preparation and improving the training that we give to people. (WC NGO technical advisor)

For PWDR-TB on new toxic drugs and drug regimens associated with many complications, monitoring for side-effects and managing abnormalities detected were critical. This required trained and experienced clinicians who understood the guidelines and knew how to identify and manage side-effects to treatment. Clinicians in newly established satellite sites who were not adequately trained and

supported, failed to follow guidelines for monitoring treatment, and this resulted in patients developing severe complications.

Some places we have unpacked to messed up ... who forgot to check a result and the patient goes into renal failure and dies, or some complication, ototoxicity because they have not been monitored, someone didn't check bloods, anaemia with the linezolid. It is happening everywhere. The more toxic drugs used, the more you are going to mess up here and there. (KZN CoE doctor)

9.3 CLINICAL GOVERNANCE INTERVENTIONS IMPLEMENTED VARIABLY

TB experts and managers affirmed the importance of clinical governance, and many made a purposeful effort to ensure decentralisation occurred slowly, while building capacity, empowering staff, and ensuring good quality of care.

You've got one good chance to cure the patients so it is decentralised there but I'm not sure that the clinical governance is there and the quality ... that is why in this area I firmly stand my ground to say we are going to do it slowly, over time, over years, we are going to build capacity so that the doctors don't feel like we have dumped something very complex on them. (WC rural DR-TB unit manager)

Clinical governance interventions adopted by the districts included assigning DR-TB programme coordinators/managers to support new sites, mentoring doctors and nurses at satellite sites, conducting quality of care audits, and establishing forums for coordinating clinical care. However, these interventions were implemented variably across districts in the two provinces and resulted in quality of care issues where they were not prioritised or less effective.

9.3.1 Programme coordination

The programme coordinators were described in Chapter 6 as actors involved in implementation. Here they are described in terms of their contribution to quality of DR-TB care. There were different approaches to assigning programme coordinators between and within provinces. WC rural districts had HAST coordinators responsible for all HIV, STI, DS-TB, and DR-TB activities, while at the other end of the spectrum CoCT appointed SDCs dedicated to DR-TB. KZN had district TB coordinators, while five of 11 districts also appointed sub-district TB coordinators/supervisors.

9.3.1.1 City of Cape Town sub-district DR-TB coordinator

In CoCT, the SDC was a professional nurse dedicated to the DR-TB programme, with both a clinical and programmatic function. They supported 10–15 clinics in the sub-district, visited larger facilities three to four times per month and smaller facilities twice per month, doing facility support visits, in-service training, and updating training for changes in the programme. They took responsibility for knowing the DR-TB cohort in the sub-district, ensuring that patients were linked to care, started on the

correct regimen, monitored and followed-up correctly, and persons LTFU traced. They also ensured monitoring sputa were done and patients were ‘converting’. They held monthly DR-TB programme meetings with all of the SMOs, doctors, TB nurses, and pharmacists in the sub-district. They also linked to the HAST programme and worked together regarding coinfecting patients.

The SDCs conducted folder reviews and monthly audits, providing recommendations to the facility on what needed to be addressed and arranging relevant in-service training. They engaged facility managers regarding challenges, ensuring the programme budget was spent efficiently, dealing with equipment and infrastructure needs, ensuring medicines availability, ensuring data was captured on the Electronic DR-TB Register, and monitoring the programme. At the monthly district managers meeting attended by SMOs, facility operational managers, and programme coordinators, they raised challenges and discussed resourcing and other needs. A CoE clinician commented positively on the value of SDCs:

It is the missing link because we know if we send a patient to a certain clinic where we know there is a coordinator, we know it is going to be done, whereas ... if a patient comes from an area where there isn't one, we know it is suspect. (WC CoE manager)

9.3.1.2 Rural Western Cape HAST coordinator and family physicians

Rural WC districts had district HAST coordinators, whose role was to provide support to facilities, doing monthly clinic visits, linking PWDR-TB to care, and data monitoring. The HAST managers were limited by the vast scope of their role, being responsible for HIV, STI, DS-TB, and DR-TB programmes.

The HAST coordinators, they do everything where HAST is concerned, the whole ART programme and the whole HIV programme including PMTCT and all of that, STI ... they've got all of those programmes that they need to coordinate and see that things are done. (WC urban MDR-TB sub-district coordinator)

9.3.1.3 KwaZulu-Natal district TB coordinators

In KZN, DR-TB was coordinated by district TB coordinators who were professional nurses managing both DS-TB and DR-TB programmes. Their role involved supporting readiness assessments, training and mentoring, distributing guidelines and stationery, adverse events reporting, monitoring programme performance, monthly/quarterly programme reporting, and conducting support visits to the facilities. The district TB coordinators also ensured surveillance was strengthened in hotspots and assisted in doing screening campaigns. They also had a role in clinical governance, tracking whether PWDR-TB were started on treatment, and conducting quarterly audits. They conducted monthly visits to the DR-TB units in their district, except in new decentralised or satellite sites they conducted intensive support visits weekly.

Five districts, uMzinyathi, uMgungundlovu, uMkhanyakude, Zululand, and eThekweni, appointed sub-district TB coordinators or TB supervisors, who had similar roles to the district coordinators but provided more operational support. They visited facilities weekly, reinforcing the latest guidelines, conducting training and mentoring, ensuring drug availability, ensuring good data recording in registers and on the Electronic DR-TB Register, and supervising outreach teams. They also played an important role in linking new patients to treatment, following-up laboratory alerts on new patients to ensure they presented at the facility and were initiated on treatment, even contacting the patients if needed.

Sub-district TB coordinators were responsible for both DS-TB and DR-TB and their role was therefore different to the SDCs in CoCT who were dedicated to DR-TB. It was seen as an advantage that the KZN TB coordinator role integrated both DS-TB and DR-TB, as it was understood that you cannot separate the programmes. However, integration created a huge workload and different reporting lines.

It is time consuming. There is a lot of work that is involved in managing MDR now. Basically, it is like running two separate programmes ... it becomes difficult to spread yourself ... You have different managers especially from national, you have a different manager for drug-resistant, you have a different manager for drug-susceptible TB and often they don't speak to each other. (KZN rural district TB coordinator)

9.3.2 Clinical outreach and support

Interviews pointed out that once-off training in DR-TB did not adequately prepare providers for the task. Ongoing systems of mentoring, oversight, and skilled back-up and support were key, but often inadequately developed. A number of different models of outreach and support appeared with varying effectiveness. However, some argued that support was provided variably between different districts because it was not clear whether it was a provincial or district responsibility.

So, you need to monitor and mentor. The problem is who does it? That is a problem and province need to control that I think or district, one of the two. (KZN CoE doctor)

9.3.2.1 City of Cape Town

When CoCT first decentralised DR-TB care to all PHC clinics in 2008, one SMO provided clinical support and did prescriptions for clinics across two sub-districts, but as the clinic doctors became more confident they relied less on the SMOs for prescribing treatment. They could discuss patients telephonically with doctors at BCH or at the Tuesday clinical specialist meetings. Over time, PHC doctors became comfortable with managing PWDR-TB and received support during monthly DR-TB multi-disciplinary meetings, and telephonically from SDCs and SMOs.

9.3.2.2 Rural Western Cape

In rural WC, the district DR-TB hospitals were responsible for outreach support to satellite sites, Brewelskloof Hospital for Cape Winelands Breede Valley sub-district and Overberg district; and Sonstraal Hospital for Cape Winelands Stellenbosch and Drakenstein sub-districts and West Coast district. Due to staff shortages, Sonstraal Hospital stopped outreach in 2014–2015, and family physicians had to take over this support. TB clinicians who required support telephonically contacted nurses from other clinics, the HAST coordinator, or the Sonstraal Hospital doctors. TB nurses in West Coast satellite sites only had one medical officer who provided outreach and whom that they could contact telephonically for advice. Decentralisation to poorly capacitated clinicians without the necessary support and outreach, resulted in poor care.

So, the outreach and support fell flat and Drakenstein and Stellenbosch family physicians has now taken over the clinical management of MDR-TB without any transfer of MDR skills in order to ensure that they do the right thing. My concern is that if they mess it up, I would say they used the patients as guinea pigs to see how decentralisation works because it was done too quickly and only the patient will pay the price. (WC rural DR-TB unit manager)

Family physicians in some districts were responsible for clinical governance and quality improvement for all programmes not just DR-TB, through training, mentoring, outreach, and support. Since 2015, most family physicians had been trained and identified to lead decentralised DR-TB. While this worked in some districts, not all districts and sub-districts had strong family physicians to support implementation and provide outreach support.

Drakenstein was faster on board because we have got a very good dedicated medical officer there Dr P, and then we have doctor Dr B, a very young doctor at Stellenbosch and she's has got all of the responsibility on her shoulders. She cannot do visits so she got her other doctors to support her, but they are battling. They are battling but they are on board already. (WC rural district HAST coordinator)

In Cape Winelands Breede Valley sub-district on the other hand, the Brewelskloof Hospital continued outreach and the DR-TB doctors provided more hands-on mentoring and support to satellite sites. They initially wrote scripts for them when a patient was initiated, then once the satellite site doctors were more confident, they would allow them to write the script which they just reviewed to see if correct.

What they do in the beginning they still send me the form so that I have all of the information about the patient and then we write the script. Then they send the script to me so that I can just see if they were correct. In the beginning I saw a lot of mistakes that I corrected for them and let them know that they can change it, but now the more they are doing I don't change anything anymore for these specific sub-districts. Other sub-districts don't do any scripts, I do them all, but I think it is a process and not all of the sub-districts are on the same level. (WC rural DR-TB unit doctor)

Brewelskloof Hospital's approach was to gradually strengthen the doctors at the satellite sites so that the outreach and support role could then transition from the DR-TB hospital to them.

In the meantime [we] try to strengthen the doctors on the outside more ... So, that is actually my main function that I want to do next year, to strengthen the doctor's abilities outside next year. I will also look at the nurses in the TB rooms, but mainly I want to strengthen the doctors so that they really know these new regimens, they really know how to follow them up so that they can be good support for the nurses in the TB room. So, that actually in the end the nurses will phone them and not me anymore. (WC rural DR-TB unit doctor)

9.3.2.3 KwaZulu-Natal

In the early phases of decentralisation from the CoE to district DR-TB units, KDH doctors played the role of providing mentorship, in-service training, and being available for telephonic support to new decentralised sites. However, the load on DR-TB doctors was substantial, to do their own clinical work at KDH, administrative programme responsibilities, and mentoring. CAPRISA, MSF, and other development partners had grants for programme support and provided new sites with mentoring support, however many of these grants have since ended.

Once further decentralisation occurred to satellite sites, doctors at the district DR-TB units provided telephonic support to the satellite sites. In Ugu, the doctor provided telephonic support and also developed a schedule for satellite site doctors and nurses to visit the DR-TB site for a week to observe and gain experience of outpatient and inpatient management of PWDR-TB.

We said that we will devise a schedule of when the doctor and nurse can maybe spend a week with us, spend time in the outpatients, in the initiations, learning to fill out the book, and what goes into the book. I know they know the bloods, but I want them to understand why we are doing it. I want them to spend some time with the patients in the ward and I want them to see this is what you need to look at. (KZN rural DR-TB unit doctor)

In Zululand, the satellite staff were sent to KDH to be capacitated to initiate DR-TB treatment, and they were thereafter mentored by the doctor from the district DR-TB site. The satellite staff could then continue to contact the doctors from the district DR-TB site or the CoE for telephonic support. However, when the district DR-TB doctor left Thula Sizwe Hospital, there was a long gap in support and mentoring, and the new DR-TB doctor who replaced him noted the concerning issues that had developed with quality of care.

In eThekweni, the DR-TB doctor from Don McKenzie, started visiting satellite sites to capacitate the nurses. The support was telephonic initially but he realised that he needed to visit the sites to assess their readiness and train and mentor the nurses.

I saw that there was a need for me to be in contact with people who receive our patients. So, when I go there I went to Kwa-Mashu I was planning to visit Pheonix and Tongaat to see how it is running ... they can phone me or they can phone King Dinizulu for advice. (KZN urban DR-TB unit doctor)

uMgungundlovu also planned to form a roving team of DR-TB clinicians who would visit the satellites to support them.

Our staff idea was that if we have less patients then we would be able to form a roving team whereby we will visit the clinics for capacitation as well and support, because that is what is needed and our doctors were actually willing to do that and maybe leave one doctor to be on the roving team to assist and support those clinics. (KZN rural DR-TB unit manager)

In eThekweni, the TB programme managers agreed that a roving team of doctors would be crucial to support the satellites. It was important that this be driven by the district management.

A roving team of doctors that actually go out to the people ... So if we can have some kind of thing like that with the PHCs, where ... TB hospitals can send doctors out and you know, help and support the nurses. Because the first six months of a patient's treatment can be quite complex for nurses to handle. Although the NIMDR nurses should be able to initiate stable patients. (KZN urban district manager)

A NGO that was providing support to the district, assigned a clinical mentor to the satellite sites who helped them to start initiating, and then provided ongoing mentorship and outreach support. The mentor's approach was to train and then mentor, then to be available for continued telephonic and on-site support. He saw the patients together with the nurse, until the nurse was proficient. He took the nurse through each of the register, clinical records, and prescription tools, demonstrated how to use them, and allowed the nurse to complete them while he supervised. When the mentor left, the nurse was confident to manage PWDR-TB independently and telephonic support calls became less frequent.

I have come to mentor you, all I need are the tools, ok let us start with the tools, these are the tools you will need. This one you are going to use as the register, I will show you how to fill it in, so this is going to be the patient's clinical record and this is going to be the prescription book. I will show you how you will complete it and where the doctor needs to complete it. And then this is the patient education tool and this is how you use it and when you use it. So, you first understand how to use the tools completely ... She will complete it herself ... We will take it page by page so that they understand up until the last page and then we will go through the register. We will then interpret

the result, so by the time I leave this nurse is able to do the next patient without me ... I've walked with her. I don't write anything for her. I just tell her what to write ... It is sustainable. I left in December and I have not gone back except for last week to check their performance. (KZN NGO technical advisor)

This was much more effective than nurses or doctors attending training for one week, then being expected to return to their clinic and start initiating patients on treatment.

They needed someone to hold their hand to walk them through it. You can't call a person to a classroom and then take them to another facility for a week and then tell them alright now go and initiate. (KZN urban district TB coordinator)

The mentor simplified DR-TB treatment for the satellite site clinicians so that they were not overwhelmed, and he trained them on-site while seeing a patient, so they didn't have to leave work to attend training. The district TB manager reflected on the success of this approach.

These decentralised sites were very slow in initiating ... The way he unpacks the programme, they don't need to go to training because he trains them on-site ... It is down to earth and after you have listened to that you want to go and initiate ... And it is like this thing is simple. Previously it was made to be like this huge overwhelming thing. Oh, how will I remember that? He simplifies the whole thing. (KZN urban district TB coordinator)

The district was looking into having the NGO clinical mentor train DR-TB doctors from other hospitals so that these DR-TB doctors could play the outreach and support role for satellites going forward.

Dr O is very good and I am trying to make recommendations that we get a doctor from Charles James, a doctor from Don McKenzie, and a doctor from the central hospital to go around with him to learn how to mentor. Not everyone knows how to mentor so then eventually when we get to the facilities initiating, they support the facilities. So, we haven't reached there yet. (KZN urban district TB coordinator)

Some make the distinction of mentoring versus audit as a way to support the facilities and improve quality of care. Audits find fault and criticism and demoralises the facility, whereas mentoring works with the staff to build their capacity.

We now need to look at quality issues which are in the programme. What are the gaps? So now it is an issue of dealing with quality ... It is not going to be an audit ... in the mentoring process you get to address the issues of quality so we can deal with it. People like saying I am going to audit, I wouldn't like it if anyone came to audit me ... I don't like going to the facility and saying that I am going to be auditing the facility. I would like to say that I have come to work with you, is there anything that you need us to deal with and then they would say I'm ok. Then I would say I'm

interested in looking at this, is it ok if I looked at it ... So that is how I look, I pick the files and then I sit with it. Mentorship is a better way of addressing the quality issues than the audit. The audit does not address quality issues. The audit finds faults and concentrates on faults, although it corrects it, but their approach has already demoralised the person. (KZN NGO technical advisor)

9.3.3 Quality of care audits

The CoCT developed a HAST audit tool in 2002 for annual audits of sampled folders at the clinics. The audit covered 12 service areas and became entrenched in the programme, providing a good proxy of the quality of care. Over the years the quality of care improved notably as feedback given after the audit had been addressed and corrected.

When we first did the audit, we found gaps, you didn't write the sputum conversion date down or second-line results were not in the folder, but through a process of feedback on the audit results, the changes in practice have been remarkable. (WC urban district TB manager)

The SDC conducted quarterly folder reviews and audits for all the facilities in their sub-district, following which the findings were discussed with the facility manager and TB nurse, and corrective action agreed and in-service training conducted.

The rural WC districts did annual HAST audits, coordinated by the HAST coordinator. They had intended to integrate the audit with family planning, women's health, and neonatal care. Brewelskloof Hospital, on the other hand, did not conduct an audit but reviewed every file when they visited the clinics. The purpose was not to audit quality of care in a sample of folders, but to check and ensure treatment and monitoring for each patient was correct.

We don't call it an audit. When I go out and see the patients, I see all of the patients with their files, with their results, with their ARV folder and everything and then I will look ... I've got a list, like I will look at what final diagnosis of the patients, because some people they will start on a GeneXpert, now is that LPA first-line, LPA second-line and if necessary first-line and maybe the second-line DST [drug-sensitivity testing], did they follow that up, so what is the final diagnosis of the patient? Is the regimen correctly prescribed for the final diagnosis? What is the patient's weight now and is the dosage still correct for that weight? So, I have a long list of things that I looked at. If the patient is HIV-positive what is the ARVs that he is on? If the patient is on bedaquiline then he cannot be on efavirenz, if he is maybe on linezolid he must not be on AZT ... so I look at all of those things also so I actually not really audit ... it is not just the difficult patients. I look at everyone. (WC rural DR-TB unit doctor)

In KZN, a provincial unit dealing with clinical support was responsible for audits across all programmes. The audits identified gaps and actions required to bridge the gaps. TB coordinators were

meant to conduct quarterly audits but provincial programme managers acknowledge that they were not regularly done and felt that the district medical manager should also be responsible.

A clinical audit hasn't been done very well so we are still lacking in that. It still needs to be strengthened ... I was thinking that the medical manager together with the TB coordinator, they should take control just to make sure that it (audit) is being done. (KZN provincial TB manager)

9.3.4 Forums for coordinating care, monitoring, and review

The forums for coordinating care were described in Chapter 7 as processes that facilitated implementation. Here they are described in terms of their effectiveness in supporting clinical governance. National and provincial advisory committees were established to provide clinical guidance and serve as a resource for clinicians and programme managers to discuss difficult clinical cases and for communication between the CoE, decentralised sites, pharmacy, and district, provincial, and national programme managers.

In the early phase of decentralisation in CoCT, CoE doctors and TB experts held weekly meetings to discuss patients who were complicated. In 2007, CoCT also established a quarterly TB clinical forum hosted by an NGO partner, Desmond Tutu TB Centre, where difficult clinical cases and research were presented. Each CoCT SDC also held a monthly MDT forum with all of the SMOs, doctors, TB nurses, counsellors, and pharmacists. This forum guided facilities on ensuring all PWDR-TB were on treatment, assisting with treatment regimens and discussing difficult cases, including psychosocial issues and persons LTFU. Each person attending had the opportunity to learn from the experience others had with similar patients or challenges. The doctors went through all scripts for new patients, and at the end the SDC sat with TB nurses to discuss issues identified at the audits and folder reviews, which they found to be supportive and geared for learning.

The other thing that we did have at sub-district level was to ensure the competence of the doctors, the senior medical officers, we created what we call clinical management meetings where we met once a month and all of the nurses and doctors treating DR-TB patients from the clinics in the sub-district, and it still continues they would have to come once a month and present their cases. So when they present their cases it's, "have you checked the mutations, what was second-line, what drugs have you prescribed, what was the audiology saying, what does this say ... hang on, this dose is too low so you have to change it to that" ... It is also an opportunity then to bring cases that they are struggling with to the meeting, so there is this kind of peer review process. (WC urban district TB manager)

In the WC rural districts, PHC meetings were held monthly with operational managers to discuss problems the clinics had, and information was fed back to the facility staff. All districts held HAST quarterly review meetings that included programme and district management staff, to review

programme performance. One district held a TB meeting monthly to discuss patients who were complex to manage as well as new protocols. However, there were no similar DR-TB clinical forums as was done in CoCT, and rural districts reported the lack of forums to obtain guidance on clinical matters.

In KZN, many DR-TB sites held weekly MDT meetings, during which each PWDR-TB was discussed with inputs from social workers, audiologists, physiotherapists, and dietitians. The districts also held quarterly HAST reviews, where programme performance was reviewed and cohort outcomes discussed for each hospital. There was a provincial DR-TB quarterly meeting with the CoE, but doctors from rural provinces reported that it was difficult to attend these meetings held in Durban because there were no additional doctors who could cover for them. The province also held monthly teleconferences with the TB coordinators to discuss decentralisation rollout to new sites, and challenges experienced with training, resources, and so on. eThekweni City held a weekly clinical meeting focused on clinical governance, ensuring guideline compliance, sharing new policies and circulars, including new drugs and regimens being introduced. City facilities also held TB quality improvement meetings weekly.

Table 6 summarises and contrasts the clinical governance interventions across and within the two provinces.

Table 6: Clinical governance interventions implemented in WC and KZN

Clinical governance aspect	CoCT	Rural WC	KZN
Programme coordination	Sub-district MDR-TB coordinator: dedicated to DR-TB programme	HAST coordinator: include HIV, STI, DS-TB, and DR-TB	District and/or sub-district TB coordinator: support DS-TB and DR-TB programmes
Clinical outreach and support	SMO support SDC BCH doctors	DR-TB site outreach Family physician focused on all health programmes Brewelskloof Hospital mentoring model	CoE, NGOs telephonic support DR-TB site clinician outreach Satellite TB nurses/doctors spend time at district DR-TB site or CoE NGO-mentoring model
Clinical audit	HAST annual audit SDC quarterly folder review	HAST annual audit Brewelskloof monthly folder review	TB coordinator quarterly audit

Forums for coordinating care	CoE meetings Quarterly TB clinical forum SDC monthly MDT meetings	District HAST quarterly review PHC monthly meetings	DR-TB site weekly MDT meeting District HAST quarterly review Provincial DR-TB quarterly meeting Monthly TB coordinators teleconferences eThekwini weekly TB meetings
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9.4 CHAPTER SUMMARY

In summary, this chapter highlighted the trade-offs of rapid decentralisation that resulted in compromised quality of care. It also described the different models of interventions employed for leading clinical governance, including programme coordination, outreach and support, clinical audits, and forums for coordinating care, and how the effectiveness of these approaches varied.

There were differences between the two provinces and between districts within each province in the way they implemented clinical governance interventions. Excellent examples stood out: (1) SDCs in CoCT focused only on DR-TB that coordinated, monitored, and supported the DR-TB programme; (2) a mentoring and outreach model in eThekwini Metro that provided on-site training and mentoring, and continuing support thereafter, and built competence and proficiency in satellite site staff; (3) a mentoring model in Brewelskloof Hospital that initially treated all patients, then over time weaned support to satellite sites when they were confident in managing patients; (4) monthly clinical record review done by CoCT SDCs and Brewelskloof DR-TB doctors, followed-up by in-service training and engagement with facility managers to implement improvements; and (5) the monthly MDT forum coordinated by SDC in CoCT that brought clinicians in the district together, reviewed each PWDR-TB, ensured all patients were initiated, were on the correct regimen, were followed-up adequately, and were traced if lost to follow-up.

CHAPTER 10. DISCUSSION

10.1 INTRODUCTION

Implementation research has grown in the past decade and offers many theories and frameworks for exploring the gaps in implementing health policy. However, this knowledge base tends to take a micro perspective on implementation, for example on uptake of guidelines in provider practice. This doctoral research took a multi-level systems approach to studying implementation. I adopted the heuristic of the policy analysis triangle (Walt & Gilson, 1994) – actors, content, context, and process – to map implementation domains, and a number of specific concepts and frameworks from the fields of policy analysis and implementation science to explore the individual domains. This broad approach to data collection and analysis, using a comparative case study of sub-national implementation, enabled me to open the proverbial black box (Buse et al., 2012) of DR-TB policy implementation. I have shown, firstly, how a variety of decentralisation models emerged, adapted to the specific context of the districts and provinces, taking into account the burden of DR-TB, the history of decentralisation that existed prior to the policy, and the rural/urban nature and the resources of districts; secondly, how implementation was shaped by actor interpretations of policy, the emergence of champions and resistors, and the effect of actor networks in different settings, as well as their strategies that facilitated or constrained implementation; thirdly, how funding and resource constraints affected policy implementation; and fourthly, how increasing coverage to new, inadequately capacitated DR-TB initiating sites compromised quality of care.

Taking further these findings, this chapter makes observations on the key factors that explain the variable DR-TB policy implementation and examines these against other experiences in the literature. These form the basis of a set of actor-centred ‘propositions on policy implementation’, that focus on the dynamic interplay of actors and other domains (context, processes, content). The propositions consider policy implementation as a continuum that spans the phases from actor engagement with policy, to assimilation, early action, and sustained implementation. Thirteen propositions are presented, followed by an integrated theory of health policy implementation that incorporates these propositions. I conclude with a discussion of research limitations and the implications of the findings for health policy theory, research, and practice.

10.2 PROPOSITIONS ON POLICY IMPLEMENTATION

Implementation of policy is shaped by the dynamic interfaces between actors, policy content, context, and processes of implementation. Unpacking these interfaces can enrich our understanding of variable implementation processes and outcomes. The following observations and associated propositions represent early steps in theory building which can be used for future theory testing) as they set forth

general preliminary assumptions about what factors lead to successful implementation and how these dimensions, components, and elements interact.

10.2.1 Actors framing and interpretations of policy

Framing and sense-making

Actors' differing perceptions of policy intent and the way they made sense of the DR-TB decentralisation policy content resulted in multiple interpretations of the policy. This led to policy conflict, or contestation over policy implementation, and the emergence of policy resisters and champions.

Starting with the policy intent, some actors believed the main goal was to provide patient-centred care; others believed providing treatment close to patients' homes would result in early initiation, improved linkage to care, and more effective treatment; while others believed the policy intended primarily to create DR-TB facilities at district level in order to reduce the load on the CoE and to improve DR-TB management capacity of hospitals, clinics, and HCWs. These perceptions revealed core underlying frames of actors, viewing the policy 'problem' and 'solution' primarily from the patient/family point of view or from the provider/system point of view; and what they believed to be the most effective clinical and public health approach to DR-TB.

Framing helps individuals make sense of ideas, shaping the way health challenges are perceived and subsequently guiding action (Schon & Rein, 1994). Interventions that resonate with the values and beliefs of those who would implement them, and result in coherence between individuals and organisations, are more likely to be adopted (McEvoy et al., 2014). Policy controversies and contestation result from conflicting frames among stakeholder groups with varying roles and interests (Cornelissen & Werner, 2014; Koon et al., 2016; Schon & Rein, 1994).

Policy instrument ambiguity

The deliberate ambiguity embedded in the DR-TB decentralisation policy instrument opened the way for divergent ideas to develop and for a multiplicity of frames to emerge. The DR-TB decentralisation policy framework articulated a number of goals the policy hoped to achieve, including reducing the load on central hospitals, improving access and providing patient-centred care, and improving retention and treatment outcomes. However, participants had a wide range of different perceptions of primary policy intent, based on their positioning and values. Given the political nature of policy formulation, goals laid down in policy documents will often be compromises, and therefore susceptible to multiple interpretations (Signe, 2017). Ambiguity is not only inevitable but can be intentional, to appeal to the range of actors involved in policy formulation (Signe, 2017). The degree of ambiguity will often

determine the likelihood of implementation success and replicability across different settings (Matland, 1995).

The framing of policy shaped subsequent action. Actors' divergent sense-making of the policy within complex adaptive systems, coupled with their dynamic policy strategies, ultimately influenced the scale and timing of implementation in different districts, as well as the characteristics of the decentralised models adopted. As a result of the differing frames, different approaches to decentralisation were favoured by actors (Parashar et al., 2020). There were important and very polarised positions around the details of policy content: whether DR-TB treatment required specialised expertise or could be provided by all clinicians at lower levels of the health system; whether complex DR-TB treatment needed to remain doctor-led versus a role for nurse-led treatment, especially in resource-constrained settings; whether some PWDR-TB still needed some aspect of hospitalisation for adequate treatment preparation and monitoring versus all patients being able to have ambulatory treatment; and whether ultimately decentralisation meant that all patients would in the future be diagnosed and managed at PHC clinics versus having a DR-TB initiation site in each-sub-district as an ideal middle ground to access and quality. These positions informed the models of care adopted in different settings.

Actors' engagement with the policy content influences implementation, depending on whether there is convergence or divergence between the ideas of key actors who formulated policy and those expected to implement the policy (Beland & Ridde, 2016). As a result of these diverging frames and contestation, when the decentralisation policy cascaded, there was a process of local assimilation and adaptation at provincial and district levels in both provinces. Some level of policy adaptation is acceptable, and policy implementation theory recommends a 'hard core' and 'fuzzy fringe', which means a core of the policy that is uniform, while allowing room for adaptation and innovation at local levels (Damschroder et al., 2009). Implementing actors should be allowed to translate and re-formulate policies through innovation and local adaptation. Successful implementation requires establishing meanings and framings of policy action that are acceptable to implementers rather than instructing them what to do (Lehmann & Gilson, 2012).

This suggests the following proposition:

Proposition 1. Actors' framing and sense-making of policy informs the strategy adopted and enables or constrains implementation, depending on the level of convergence or divergence of ideas.

10.2.2 Actor roles, networks, and expressions of power

Actor roles

Complex interventions typically engage many actors in the intervention process and these potential drivers of change must be identified, their roles defined and the power they exert understood (Nilsen et al., 2013). DR-TB decentralisation was shaped by policy elites, opinion leaders, entrepreneurs, change agents, formally appointed implementers, street-level bureaucrats, and champions (and resisters).

The South African Minister of Health provided political leadership and high-level support for the policy and was a prominent advocate even in international arenas. Professionals affiliated with outside entities, such as the researchers, technical experts from NGOs, and WHO, produced important evidence, and drove the policy-making agenda to ensure a strong response to the DR-TB crisis in South Africa. Policy ‘entrepreneurs’, like the NDoH DR-TB Director, the KZN TB manager and the CoCT Metro TB manager, played a connecting role, linking people, ideas, and problems to solutions. Opinion leaders with strong personalities, like the medical managers in Cape Winelands and eThekweni Metro were both professional experts and district managers who exerted formal and informal influences on the attitudes and beliefs of their colleagues with respect to implementing the policy. Formally appointed implementation leaders, such as the cadre of CoCT SDCs facilitated implementation of decentralisation amongst frontline actors or street-level bureaucrats, such as the health service managers, programme coordinators, and clinical professionals (doctors and nurses).

There were champions who enabled policy implementation at provincial/district level, such as those involved in the uMzinyathi (district manager and TB coordinator) and Khayelitsha pilot projects (sub-district manager and City TB manager). Other champions enabled implementation at local level, such as the experienced DR-TB doctors at district hospitals, serving as power-brokers and mobilisers in influencing implementation. Champions dedicate themselves to driving implementation and overcoming resistance that may arise in an organisation (Damschroder et al., 2009). Other studies have also described the utility of working with, and the impact of champions, in leading change (Brooke-Sumner et al., 2019).

Besides champions, this thesis also documented the emergence of policy resisters to decentralisation. However, this was not manifested in a simple, polarised expression of support or resistance and the reasonings behind resistant policy stances were often nuanced. One group of resisters was concerned that decentralisation would result in increased transmission in communities and health facilities. A second group of predominantly experienced CoE clinicians and managers had concerns about poorer quality of care at lower levels. Another group, particularly facility managers and staff, had concerns about inadequate infrastructure, resources, and staff capacity. A final group’s resistance stemmed from the DR-TB site losing its headcount and budget if DR-TB was decentralised. The nett effect of the

resistance was that despite the policy and plans being in place to guide decentralisation, unwilling actors at lower levels effectively blocked implementation.

Policy implementation tends to be intellectually and politically contentious, and the failure of collaborative efforts to establish a common ground between stakeholders, results in problems with implementation (Hudson et al., 2019). Understanding the politics of policy implementation and addressing conflict, resistance and cooperation, improves the chances of achieving policy objectives (Campos & Reich, 2019).

Expressions of power

Using the Veneklasen and Miller (2007) typology, the process of implementation in the two provinces was reshaped and renegotiated through four expressions of power. Authoritative power was evidenced by the uMzinyathi district manager and eThekweni medical manager who were able to secure management buy-in, resourcing, and facilitation of implementation ('power over'). The eThekweni district TB coordinator had little self-efficacy and agency to negotiate with medical managers and clinicians who were slow to implement, in contrast to the CoCT TB manager who navigated the implementation across the district very successfully ('power within'). Collective action in the pilot decentralisation sites allowed a broader scaling up of decentralisation, using district managers, TB coordinators and supportive provincial managers ('power with'). SDCs in CoCT sustained monthly meetings and supported clinics to ensure treatment initiation, patient retention, and good DR-TB outcomes, in contrast to TB coordinators in other districts who struggled to facilitate effective implementation ('power to').

Practices of power are often rooted in actors seeking to make the intervention 'fit' with their understandings and the nature of the local context. The cumulative effect was either facilitating or thinning down of the policy's intent. Actor interface analysis provided an understanding of different actors' interests and positioning in the implementation process (Long, 2001). These expressions of power translated to varying levels of decentralisation in four distinct interfaces: (1) between the NDoH and provinces who set out the policy to decentralise, and the districts that moved ahead or stalled implementation; (2) between district management who were responsible for supporting and resourcing implementation, and the district TB coordinators who were required to facilitate implementation; (3) between the older and newer generation of DR-TB experts at the CoEs and decentralised sites respectively; and (4) between decentralised sites and new satellite sites that supported or resisted decentralising care. In these interfaces, contestation and negotiation occurred overtly or subtly, but worked to shape policy implementation.

Actors have agency to influence implementation. Micro-level practices of power of frontline actors engaged in policy implementation help to explain the implementation gap (Hill & Hupe, 2009; Lehmann & Gilson, 2012; Gilson et al., 2014)). Actors' choices and the power and influence they wield on others have predictable or unpredictable consequences for implementation (Damschroder et al., 2009). However, as Veneklasen and Miller (2007, p. 39) argue, "power is both dynamic and multidimensional, changing according to context, circumstance and interest. Its expressions and forms can range from domination and resistance to collaboration and transformation."

Power practices can influence implementation both positively and negatively (Parashar et al., 2020). Power struggles, such as domination, control, collaboration, contestation, resistance, or negotiation amongst actors explain why, in similar contexts, the implementation and outcomes of policies unfolded differently (Parashar et al., 2020; Parashar et al., 2021). Researchers have described numerous examples of actors implementing practices of power at times in alignment with policy goals, and at other times contradicting them (Gilson, 2016). A study describing the role of power as a factor in implementation of a health service intervention in South Africa concluded that an analysis of power provides insights into implementation processes and is recommended in implementation research (Schneider et al., 2022). "A political analysis of the position, power and interest of the stakeholders involved in health policy implementation helps to understand their role in promoting, resisting, or blocking implementation, and the dynamics of their interactions" (Campos & Reich, 2019). A more relational and contextual understanding may inform more appropriate implementation strategies (Lehmann & Gilson, 2012). Considering embedded practices of power is critical to understanding the implementation black box. This suggests the following proposition:

Proposition 2. Actors play a variety of formal and informal roles and express agency and power in implementation. Actor expressions of power reshape and renegotiate policy intent and inform the process of policy implementation.

Actors as collaborators

Nodes of successful DR-TB decentralisation typically involved the actor combination of a TB programme champion, an innovator district or sub-district manager, and NGO technical support. In other districts, without support from a network of actors working together with a common purpose, TB coordinators (often nurses) had less agency and were not able to navigate resistance from medical experts and senior managers at proposed DR-TB sites to secure buy-in for implementation. Actors and networks were successful in influencing implementation by building a common vision, learning lessons from pilot studies, facilitating ownership and buy-in across the district, and making resources available for scaling up. Even at facility level, working collectively was key.

Complexity theory puts forward the importance of relationships between individuals over individual attributes, and the role of the collective in implementation (Braithwaite et al., 2018). Actor-network theory helps us to understand the way in which actors build and maintain networks and how the actors' interests and identities are translated during implementation processes (Heeks & Stanforth, 2015). Actors shape the implementation process through belonging to professional sub-cultures, communities of practices, and social networks that influence the way that ideas, knowledge, and learning spread (Nilsen et al., 2013). Managers connect the operational core of an organisation with higher management levels and enable the interactions among actors that sustain collective action towards innovation and adaptation.

This suggests the following proposition:

Proposition 3. Actor networks foster shared purpose and a common vision in steering implementation processes.

10.2.3 Change valence as key to adoption and implementation

Once we understand the positioning of actors and the development of actor networks, it is important to understand the dynamic expressions of these actors and network in terms of their capacity for action.

Participants reflected that it was difficult to embed new technologies especially in a conservative programme like DR-TB, where historically there had been resistance to change. Shifting people sometimes required a 'maverick' who challenged the existing status quo, such as the CoCT TB manager. Readiness for change was more evident in settings where stakeholders on the ground realised that the current system could not cope, felt supported and capacitated through training, and had resources or early initiatives already in place.

A study in three South African districts pointed to gaps in readiness to implement policy and suggested that different levels of readiness to decentralise DR-TB care were partly explained by the capacity of actors to adapt to ongoing challenges and new demands placed on a constrained health system (Kielmann et al., 2021). Another study suggested that the vision of managers, their perception of the policy and its instruments, the pressure to act, the perceived room for manoeuvre, and the level of trust were determinants of policy implementation (Dossou et al., 2020).

Theories of individual change have not sufficiently explored the dynamic interplay between individuals and the organisation within which they work, and how this influences individual or organisational behaviour change (Damschroder et al., 2009). Organisational context influences actors' commitment and capacity to act (Damschroder et al., 2009). While individual actors ultimately decide whether or

not to implement a practice or policy, they do not exist in a vacuum, and their decisions are influenced by other actors and factors considered part of the context (Nilsen et al., 2013).

Change valence helps to explore the organisational members' shared resolve to implement an intervention (change commitment) and their shared belief in their collective capability to do so (change efficacy) (Weiner, 2009). With high organisational readiness for change, actors are more likely to “initiate change, exert greater effort, exhibit greater persistence, and display more cooperative behaviour”, resulting in more effective implementation (Weiner, 2009, p. 1). Change valence is influenced by psychological and not just structural factors; and is situational depending on the content of the change and not just a general state of affairs depending on the context in an organisation.

This suggests the following proposition:

Proposition 4. The greater the actors value the innovation and feel confident to enable change, the more they will engage in the courses of action involved in implementation.

10.2.4 The role of implementation strategies

A range of implementation strategies were employed by provinces and districts, including scaling up pilot projects and benchmarking exercises with other districts and other countries, conducting needs and readiness assessment, developing operational plans, conducting training, mobilising necessary resources, and putting systems in place. Other important strategies were communication, engaging actors, leveraging networks, and mobilising actor buy-in and support at all levels. District players played a pivotal role in all of the above.

Many of these strategies were implemented variably and to different effect. While implementation planning was widely recognised as key, in practice it was unevenly and inadequately conducted for DR-TB decentralisation. In South Africa, policy is often released without accompanying business cases or implementation plans. These implementation plans would have helped actors to think through how to operationalise and budget for the policy. In some districts the process of translating the national and provincial decentralisation policy for the context of that district simply did not happen. This process would have been useful in identifying the priority areas and facilities for decentralisation. There were also significant differences between districts in relation to implementation support. Training was inconsistent, support from district and provincial coordinators was variable, and commitment to addressing resource constraints differed widely.

A South African study exploring the implementation of DR-TB decentralisation found that implementation strategies to manage organisational change processes were not uniformly present across all districts (Kielmann et al., 2021). The study also considered important strategy components, including

the ‘hardware’ of re-organising service delivery and addressing resource constraints; and the ‘software’ of multi-disciplinary team functionality, DR-TB integration within PHC services, and effective communication between different levels of the system. Others have identified the need for a streamlined process for planning, introducing, piloting, monitoring, and providing feedback on innovations, enabling cycles of implementation learning (Berwick, 1998). Ultimately, the incorporation of a complex intervention within a social system depends on actors’ capacity to cooperate and coordinate their actions. Their ability to adapt and develop strategies to implement policy directives speaks to their resilience and readiness for organisational change (Kielmann et al., 2021).

Leading change thus requires well-planned implementation strategies, engaging actors at all levels and allowing opportunity for bottom-up inputs to key decisions. In sum, process strategies include: (a) antecedents for implementation, such as piloting, operational planning for scale and timing, and tailoring and adapting policy; (b) supporting implementation, establishing communities of practice, and mobilising skills and resources towards collective action; and (c) consultation and communication, managing actors, and distributed leadership.

This suggests the following proposition:

Proposition 5. When implementation strategies are well-planned and engage actors at all levels, there is more likely to be effective management of organisational change processes.

Facilitation and implementation support as a key element of frontline implementation

Facilitation has been identified as a central facet of local adoption and implementation. DR-TB managers tailored their facilitation strategies for the particular issue, context, and with particular groups of actors. In receptive contexts, such as CoCT decentralising to PHC facilities, a simple approach to facilitation by the CoCT TB manager was sufficient. Where the environment was unreceptive to change and the evidence disputed, as was the case in eThekweni, more intensive facilitation by the district TB manager and medical manager was needed to address the local and organisational barriers. This required facilitators with sophisticated skills in negotiation, consensus development, and conflict management.

In CoCT, a decision was taken to recruit a cadre of SDCs to facilitate implementation, bridging the clinical and programmatic role in DR-TB in the sub-district. They acted across levels (sub-districts, health authorities) and spanned the different actors and professional disciplines, and they worked with individuals and teams across the sub-district, applying a combination of strategies to enable and support change. In contrast, TB coordinators in other districts had a different role and were less effective in facilitating change. The act of adopting facilitation as a strategy of policy implementation by the CoCT, was therefore an important driver of effective implementation.

The i-PARIHS framework posits that facilitation is the active element integrating the other three constructs, namely characteristics of the innovation and the recipients within their contextual setting (Harvey & Kitson, 2016). This requires a role (the facilitator) and a set of strategies and actions (the facilitation process) to enable implementation. Facilitation of implementation has been shown to be an effective element in a number of studies (Harvey & Kitson, 2016). At a local level, facilitation entails motivating individuals and the collective team to introduce the required changes. At an organisational level, it entails leadership and management support, aligning with priorities and strategies and the level of absorptive capacity (Harvey & Kitson, 2016). Implementation ‘facilitators’ or ‘entrepreneurs’ play a critical role not only in implementing programmes, but also in developing capacity for systems change (Franks & Bory, 2015).

To ensure policy intentions achieve the desired outcomes, there is growing recognition that the policy process requires a combination of policy preparation, tracking, supporting, and reviewing implementation (Hudson et al., 2019). During policy preparation, this involves guarding against faulty design and development of full implementation plans and ‘toolkits’ covering seven domains: planning, governance, stakeholder engagement, risks, monitoring, review and evaluation, resourcing and management strategy. During policy tracking, a central ‘delivery unit’ can track progress of policy implementation. Government appointed ‘implementation support centres’ and cadres of experienced and trusted ‘implementation brokers’ can offer support tailored to local contexts. Finally, implementation review considers the extent to which an intervention has helped to “secure policy legitimacy, develop stakeholder support, exhibit clarity of purpose, demonstrate a comprehension of complexity, sustain political support, and contribute to the wider attainment of policy objectives” (Hudson et al., 2019, p. 10).

This suggests the following proposition:

Proposition 6. The success or otherwise of local implementation depends on a facilitation process that supports and enables actors to adapt and adopt the innovation within their particular context.

10.2.5 The role of the health district

District ownership and distributed leadership

In a decentralised health system, the spheres of meso-level district management include overall ownership for policy implementation, leading change, coordinating actors, and allocating resources. This thesis detailed significant variability in district management involvement and support of DR-TB decentralisation and suggested that this was a key factor in shaping the way the policy was implemented in different settings.

The district manager of uMzinyathi District was a proactive supporter of implementation, formed effective networks, mobilised support, and committed resources for the programme, and this resulted in early progress in decentralising care in the district. However, in settings where DMTs were excluded, their support for implementation and resourcing of the new policy was limited. Underestimating the changes necessary in the district health system led to partial implementation, inadequate service delivery support, delays in re-allocation of resources, and poor integration of the DR-TB programme into existing PHC services. In a decentralised health system, the DMT's involvement and support are critical as only the district manager has the authority to engage stakeholders and instruct hospitals to implement. A prior study in uMzinyathi District confirmed how district level ownership and leadership enabled re-organisation and realignment of DR-TB services, translated into the provision of injection teams and staff at the DR-TB site, and interventions around patient literacy and home assessments in preparation for patient discharge (Loveday et al., 2014). Other studies have described the effect of leadership on the functioning of health system and the association of unsuccessful treatment outcomes when health systems are dysfunctional (Atun, 2012; Atun & Menabde, 2008).

In the revised decentralisation policy of 2019, while stating the importance of district and sub-district administrative and management responsibilities in ensuring effective DR-TB services, it detailed only the clinical/programmatic role of TB programme coordinators and was silent on district management roles (NDoH, 2019a).

Decentralised health systems create new challenges for political authority and ownership (Norris et al., 2014; Hudson et al., 2019). The district level is the key, but often neglected sphere in a decentralised health system (Scott et al., 2012). The example of eThekweni Metro's resistance to DR-TB decentralisation reflects the complexity of negotiations across spheres of government, and the conflict between provincial and municipal authorities. Implementing any new policy or reform thus demands more than instruction around a policy document. To understand these complexities, it is useful to consider the 'soft' issues of leadership and management (Goodwin, 2019). District managers do not simply administer and organise activities, they work with and through others across the whole health system, influencing commitment to new activities, aligning resources and organisational environments with policy goals, fostering effective networks and innovative solutions to steer the implementation of centrally driven policies (Gilson et al., 2014, Parashar et al., 2020). Distributed leadership is required with leaders located across different levels and positions within the health system, which underpins collective action for enabling health system change (Gilson, 2016).

This suggests the following proposition:

Proposition 7. In decentralised health systems, district management commitment and support are key to effective and sustained policy implementation.

Resource allocation for implementation

Resource availability for a given policy is constantly challenged in the competitive national resource allocation arena (Dossou et al., 2021). Access to available funding and resources, and commitment and allocation of resources are key actions for district managers and a precondition for successful implementation (Signe, 2017).

When the government launched the 2011 DR-TB decentralisation policy, it did not commit a specific budget for decentralisation and decentralised sites struggled to mobilise funds to implement the policy. It was up to provinces and districts to shift the resources to where they would be required with decentralisation. Absorbing DR-TB care into district health systems required leadership and planning, as well as innovation and the ability to integrate within existing services. Differences in the capacity to shift funds and willingness to exercise decision space resulted in DR-TB services at district facilities being seen as an ‘unfunded mandate’. As a result, decentralised sites experienced challenges with securing resources to manage PWDR-TB. Limited availability and uneven distribution of resources in turn affected implementation. Lack of audiologists and audiometry, and ECGs resulted in poor monitoring of patients on DR-TB treatment; inadequate allied staff like psychologists, social workers, and counsellors meant PWDR-TB could not be given the psychological support they required; the shortage and misdistribution of trained doctors and nurses impacted patient care; and infrastructure and infection control were not adequate for DR-TB. Other studies have also revealed that misguided provincial budget allocation constrained DR-TB decentralisation (Florman et al., 2020). Funding alone is not sufficient to ensure successful implementation, but it is critical for mobilising other aspects of the implementation strategy (Signe, 2017). Absence of staff, services, and other support functions will prevent successful implementation, and adequate resources in the right combinations must be made available for implementation to succeed (Dimitrakopoulos & Richardson, 2001).

This suggests the following proposition:

Proposition 8. Resource allocation by district health authorities is necessary for effective policy implementation.

Integration of vertical programmes into the district health system

The experience in this study of resource allocation for policy implementation raises classic debates on integrated versus vertical programmes and explains some of the reasons why implementation of the DR-TB decentralisation policy was variable across the two provinces. The level of decision space to transfer authority is crucial for promoting efficiency of services and allowing ownership and

accountability (Bossert, 1998). Furthermore, it enables flexibility to adapt policy to local needs of the community (Mekler, 2018; Roman et al., 2017). A KZN study reported how district managers integrated the new decentralised DR-TB vertical programme into the existing district health services resulting in a strengthened district health system (Loveday et al., 2014). In another study evaluating implementation amongst 22 decentralised sites in four provinces, HCWs reported difficulty accessing support services like radiology, audiology and transport, and attributed this to lack of integration of the vertical DR-TB programme into existing TB, PHC and other general health care services (Vanleeuw et al., 2020). The decentralisation of DR-TB has resulted in a vertical programme with its own goals, coordination, funding, information systems and lines of reporting and accountability. This vertical programme however, is expected to function in an established district health system, which is not primarily accountable to the DR-TB programme. The evidence is clear of the successful integration of the HIV programme with the TB programme, and within the district health system, but less effort has been made to integrate the DR-TB programme within the district health system (Vanleeuw et al., 2020). Insufficient integration of DR-TB services into TB and HIV programmes, and into the PHC service platform results in a lack of support from these services and affects treatment outcomes.

This suggests the following proposition:

Proposition 9. Successful implementation of complex interventions requires integration into functioning district health systems.

10.2.6 Including quality of care in implementation strategies

Models of clinical support and mentorship

This research found that DR-TB training was often once-off and did not adequately prepare providers for the task. Ongoing systems of mentoring, oversight and skilled back up and support were often inadequately developed. A number of different models of outreach and support emerged with varying effectiveness. Excellent examples of clinical governance interventions that stood out included (1) SDCs in CoCT that coordinated, monitored and supported the DR-TB programme; (2) a mentoring and outreach model in eThekweni Metro that provided on-site training and mentoring, and continuing support thereafter, and built competence and proficiency in satellite site staff; and (3) a mentoring model in Brewelshoof Hospital that transitioned from direct treatment of all patients, to overseeing prescriptions, then weaning off support when they were confident in the satellite sites capacity to manage patients. Others have suggested that integrating mentoring approaches is key, involving, for example, the district TB coordinator in lessons learnt to be rolled out to other areas (Florman et al., 2020).

Digital health solutions may complement on-site mentoring and support approaches and are increasingly promoted by WHO for health system strengthening (Gray et al., 2020). The utility of such tools has been demonstrated for health conditions that require HCWs to navigate of complex and frequently updated diagnostic and treatment algorithms and guidelines (Gray et al., 2020). In the context of DR-TB, digital health could support HCWs to initiate treatment using the correct regimen with correct doses, ensure appropriate adverse events monitoring, support decisions to modify treatment in response to adverse events or stock-outs, and manage drug–drug interactions, as has been done with ART. Digital tools could also potentially improve patient care and provide training for HCWs in decentralised settings. In India, e-platforms or web-based programmes providing support to frontline DR-TB clinicians by groups of expert clinicians, facilitated case management at satellite sites and ensured continuity of care (Dholakia & Mistry, 2018).

Building quality improvement into policy and implementation strategies

Implementation involves more than establishing a DR-TB site, training HCWs and making drugs and equipment available. Rapidly increasing coverage by DR-TB initiating sites without clear quality improvement strategies may result in poor quality of care, especially in poorly resourced and capacitated settings. Clinical governance interventions adopted by the districts included assigning DR-TB programme coordinators to support new sites, mentoring doctors and nurses at satellite sites, conducting quality of care audits and establishing forums for coordinating clinical care. However, these interventions were variably implemented across districts in the two provinces and where they were not prioritised or less effective, quality of care suffered. In the revised decentralisation policy of 2019, the importance of quality improvement strategies was explicitly stated, although the only strategies mentioned were training on adverse events monitoring and clinical audits (NDoH, 2019a).

Others have noted the threats to quality when moving care from specialised DR-TB hospitals to district hospitals in South Africa (Florman et al., 2020). DR-TB treatment models that embrace continuous quality improvement (CQI) approaches are associated with favourable treatment outcomes (Isaakidis et al., 2011). Studies from other LMIC settings confirm that training, mentoring, and supervision of frontline workers are essential to providing quality DR-TB care. In Uganda, decentralisation to community-based services resulted in improved treatment success rates because they focused not only on establishing decentralised services, but on a bundle of quality-related strategies, including: peer-to-peer mentorships and coaching, quality improvement methods, standard operating procedures, access to treatment monitoring investigations, management of TB drugs, strengthened data management and cohort reviews (Kasozi et al., 2020). In Tanzania, a national DR-TB continuous learning approach involving a standardised training package, on-the-job mentoring, and follow-up supervision, resulted in good patient treatment outcomes despite health system challenges (Lyakurwa et al., 2021). In Ethiopia, improved treatment success was achieved through a comprehensive programme strengthening

approach, including monthly mortality audits and continuing medical education sessions (Molla et al., 2017). A quality improvement project (QIP) in a rural South African hospital that focused on a poorly trained DR-TB clinical team, resulted in increases in the number of DR-TB-trained nurses, the proportion of patients that had body mass indexes recorded, dietician referrals, smear results available, and visual acuity tests and ECGs performed (Florman et al., 2020).

The tension between ‘quality of care’ (for example, safety and patient-centredness) and ‘efficiency’ (for example, access and equity) is common in health care. In the Canadian context, policy designers intentionally presented a broad notion of quality in service delivery reforms to reduce policy contestation, but competing frames and logics of implementers, resulted in frustration, leading to trade-offs, for example between quality and access to care (Marani et al., 2021). Busse et al. (2019) argue that consideration must be given to how quality is framed in policy documents, and also for how quality strategies in a given policy are explicitly packaged.

In an interesting case study in Pakistan, initial decentralised DR-TB gains were not sustained because the programme’s primary focus was on ‘materialities’ (materials, infrastructure, and technologies) and not on competencies (knowledge, skills, and processes) (Abbas et al., 2020). While clinics appeared to be well-managed, inconsistent staff role allocations, a lack of leadership and management, inadequate skill levels, and poor supervision and training were major limitations. There was ineffective patient-provider communication, and HCWs did not provide accurate information and respond to patients’ physical and mental health needs. The result was the prioritisation of material inputs, such as drug stocks and sputum sample collection at the expense of everything else. The study concluded that implementation failed to address the issue of treatment outcomes, but instead focused on process indicators, and that this narrow focus on measurable inputs, originates from priorities set at global and national levels and transmits to the micro-level. They argued for a DR-TB programme approach that does not focus only on what is relatively easy to measure (materialities) but rather on using quality and performance indicators, that may be hard to measure, but capture aspects of effective DR-TB care. Others have also commented on the DR-TB burden leading to a “culture that strives towards quantity as opposed to quality of healthcare administered, often neglecting to implement even the most basic principles of care” (Padayatchi et al., 2014, p. 2115).

This suggests the following proposition:

Proposition 10. Explicit quality improvement strategies are necessary for implementing complex health interventions and achieve improved health outcomes.

10.2.7 Including patient-centred care in implementation strategies

Implementation of the 2011 DR-TB decentralisation policy focussed on the mechanics of moving care from one level to another, in effect, decanting patients from the CoE to lower-level hospitals and clinics. This succeeded in initiating treatment earlier and treating PWDR-TB closer to their homes, but did not achieve improved retention and treatment outcomes or patient-centred care. One major inclusion in the revised decentralisation policy of 2019 was that of a patient-centred approach, namely, that the treatment modality (ambulatory care, hospital admission, community-based care) be dictated by the patient's needs (NDoH, 2019a). However, no further details of the strategy to achieve this were included in the revised policy.

WHO includes patient-centred care as a central pillar for achieving improved TB outcomes (WHO, 2014). These approaches prioritise autonomy and shared decision-making, in contrast with rigid treatment protocols that offer little patient choice (Horter et al., 2021). It has been argued that National TB Programmes have in the past focused more attention on programme success than on the specific needs of affected individuals (Horter et al., 2021). Unlike HIV, which promoted patient-centred approaches from the outset, TB management has historically utilised a biomedical approach where treatment was of primary importance, and social assistance was secondary (Kielmann et al., 2018; Daftary et al., 2016). Patient-centred approaches to care may overcome the failure of current approaches to combat TB (Dhedha et al., 2017; Padayatchi & Friedland, 2008).

Patient-centred approaches that consider the underlying social and structural factors that affect adherence to treatment need to include families, peers, and social networks (Kielmann et al., 2018). Social support services promote financial risk protection, improve access to and effectiveness of DR-TB prevention and treatment, and contribute to improving quality of life of patients (WHO, 2014). Recommendations to decentralise care therefore require considerations of programme characteristics associated with patient-centred care, including patient engagement and education, and patient and community support for maintaining adherence. When funding is limited to cover only the costs of TB drugs, for example, National TB Programmes neglect strategies that ensure treatment adherence, such as locally appropriate treatment support systems and financial support for patients (Khan & Coker, 2014).

Supporting adherence is critical and should involve peer support groups as well as individualised counselling and treatment literacy that is delivered by trained and paid lay health counsellors who continue to assess and understand the barriers to adherence and the most effective strategies for addressing them (Dhedha et al., 2017). Patient literacy should be emphasised at treatment initiation, and stronger linkages with social care organisations must be developed (Kielmann et al., 2018). Patient support services, including adherence counselling, treatment literacy, and socio-economic support need

to be continually emphasised and funded within DR-TB programmes (Kendall et al., 2019). Studies evaluating decentralisation of DR-TB in South Africa have concluded that investment in community-based follow-up and support systems should be prioritised to reduce LTFU (Berhanu et al., 2016; Andrews & Stout, 2015).

Experience in other countries implementing decentralisation has shown that a broader implementation focus on patient support reduces LTFU and improves treatment outcomes. In Uganda, PWDR-TB were provided with psychosocial and economic support, such as food and transport which serve as incentives and enablers to enhance nutritional status, patient adherence, and compliance (Kasozi et al., 2020). In Bangladesh, community-based services were strengthened, including counselling, support, psychiatric referrals, nutrition, provision of stipends, and vocational training (Daru et al., 2018). In eSwatini, a patient-centred approach (for example, food provision) supported treatment adherence in economically vulnerable patients. Providing a monthly supply of drugs resulted in patients not having to travel to the clinic for DOT and reduced out-of-pocket expenditure, ensuring less likelihood of treatment interruptions caused by health system failures, and making it easier for patients to complete therapy (Kershberger et al., 2019).

Socio-economic problems, including homelessness, unemployment and lack of food, are common among PWDR-TB and addressing these factors are important for successful DR-TB treatment. There is a need for DR-TB care to be coordinated with larger social and financial support services, and potentially alcohol and substance use treatment services (McNabb et al., 2021). Socio-economic interventions, such as provisions of ‘incentives’ (rewards that encourage patients to adhere to treatment, such as food packages), and ‘enablers’ (goods or services that make it easier for patients to adhere to treatment, such as transportation vouchers) are critical (Seung et al., 2015).

This suggests the following proposition:

Proposition 11. Policies will fail if they do not consider the socio-economic context of patients, and implementation strategies that focus on patient-centred care and adherence support, are more likely to be effective in improving outcomes.

10.2.8 Addressing health systems factors in implementation strategies

This study reports gaps in implementation of the DR-TB policy at every step of the patient pathway, including leadership, coordination, staffing, and resourcing implementation. Identifying health system barriers that may impact TB prevention and care is a part of routine TB programme planning (WHO, 2014). Decentralisation in Bangladesh required a systems strengthening approach with a focus on integrated service delivery, and involved obtaining national consensus and facilitating policy changes to redefine treatment approaches (Daru et al., 2018).

Weak public health sectors in many high TB-burden countries have compromised their TB programmes (Iacobino et al., 2020; Cox et al., 2019). Atun et al., (2010) detailed the health system bottlenecks that have hampered TB prevention and care, related to health workforce shortages, inadequate financing, disrupted drug supply, lack of well-functioning information systems for surveillance, poor governance, and compromised service delivery. Other studies have also suggested that implementation barriers can be partly explained by major recurring barriers across each of the health systems building blocks (Loveday et al., 2014; Loveday et al., 2013).

Historically, policy-makers have rushed to adopt medical or technological solutions in response to urgent health needs rather than long-term strategic interventions to strengthen health systems (Khan & Coker, 2014). However, it has been argued that these much needed improvements will have little impact unless the health system and service delivery are improved (Cox & Ford, 2013; Padayatchi et al., 2014). Experts caution that new health systems interventions require optimum system design (Atun et al., 2010) and need to be effectively implemented, and that the efficiency of the health care delivery system needs to be improved to achieve impact on national TB prevention and care efforts (Pai & Temesgen, 2017). The potential of these new interventions will only be fully realised if health system factors are addressed (Naidoo et al., 2015).

This suggests the following proposition:

Proposition 12. Successful implementation of policy requires recognising and addressing key health system bottlenecks.

I conclude the description of policy implementation with a summary proposition.

Implementation of complex and often ambiguously defined technical interventions, unfolding within a complex system context, requires a range of coordinated implementation strategies across multiple levels; and furthermore, results in a dynamic interplay between individuals and organisations, that itself shapes the implementation process.

10.3 SUMMARY

The findings showed the dynamic ways that policy implementation evolved in a complex adaptive system. Based on the findings, the propositions that explain policy implementation are summarised below (Table 7).

Table 7: Summary of findings and propositions

Summary findings	Propositions
FRAMING: Actors' framing of their perception of policy intent and the complexity and ambiguity of policy content, resulted in policy conflict, tensions, and contestations.	Proposition 1. Actors' framing and sense-making of policy informs the strategy adopted and enables or constrains implementation, depending on the level of convergence or divergence of ideas.
POWER: These tensions resulted in actors adopting supportive (champions, elites, opinion leaders, implementation leaders) or resistant stances and actions towards implementation.	Proposition 2. Actors play a variety of formal and informal roles and express agency and power in implementation. Actor expressions of power reshape and renegotiate policy intent and inform the process of policy implementation.
NETWORKS: Actors also organised into networks that facilitated or constrained implementation.	Proposition 3. Actor networks foster shared purpose and a common vision in steering implementation processes.
CHANGE VALENCE: It was difficult to embed new interventions in the DR-TB programme where actors had been resistant to change.	Proposition 4. The greater the actors value the innovation and feel confident to enable change, the more they will engage in the courses of action involved in implementation.
PLANNING: Actors enacted a range of activities, strategies, and processes that varied between provinces and resulted in varying implementation success.	Proposition 5. When implementation strategies are well planned and engage actors at all levels, there is more likely to be effective management of organisational change processes.
FACILITATION: Districts and provinces differed in the strategies adopted to support implementation. Depending on the receptiveness of the context, either a simple approach or more intensive facilitation was required.	Proposition 6. The success or otherwise of local implementation depends on a facilitation process that supports and enables actors to adapt and adopt the innovation within their particular context.
DISTRICT MANAGEMENT: The role of district management was key and if bypassed resulted in the inability to mobilise support and resources for policy.	Proposition 7. In decentralised health systems, district management commitment and support are key to effective and sustained policy implementation.
RESOURCING: The DR-TB decentralisation policy did not include a specific budget and decentralised sites struggled to mobilise funds to implement the policy.	Proposition 8. Resource allocation by district health authorities is necessary for effective policy implementation.

<p>INTEGRATION: In a decentralised health system, decision space for delegating authority and bypassing key district stakeholders, resulted in the perpetuation of vertical disease-focused programmes, rather than integration of the DR-TB programme into district health services.</p>	<p>Proposition 9. Successful implementation of complex interventions requires integration into functioning district health systems.</p>
<p>QUALITY: Implementation focused on the establishment of decentralised DR-TB sites and did little to enable quality implementation.</p>	<p>Proposition 10. Explicit quality improvement strategies are necessary for implementing complex health interventions and achieve improved health outcomes.</p>
<p>PATIENT-CENTRED: The choice to focus implementation on establishing DR-TB sites did not fully consider the social aspects that influence poor outcomes beyond providing treatment closer to patients' homes and reducing lengthy hospitalisation.</p>	<p>Proposition 11. Policies will fail if they do not consider the socio-economic context of patients, and implementation strategies that focus on patient-centred care and adherence support, are more likely to be effective in improving outcomes.</p>
<p>HEALTH SYSTEMS STRENGTHENING: The focus of implementation on the technical programme intervention did not at all consider the stressed health system within which new policy must be implemented.</p>	<p>Proposition 12. Successful implementation of policy requires recognising and addressing key health system bottlenecks.</p>
<p>Overall proposition. Implementation of complex and often ambiguously defined technical interventions, unfolding within a complex system context, requires a range of coordinated implementation strategies across multiple levels; and furthermore, results in a dynamic interplay between individuals and organisations, that itself shapes the implementation process.</p>	

10.4 INTEGRATED THEORY

This study identified the overarching domains that are important to the study of policy implementation and the key constructs and where they relate and intersect; and through a set of propositions, offers an expanded theory, summarising the factors that lead to effective implementation.

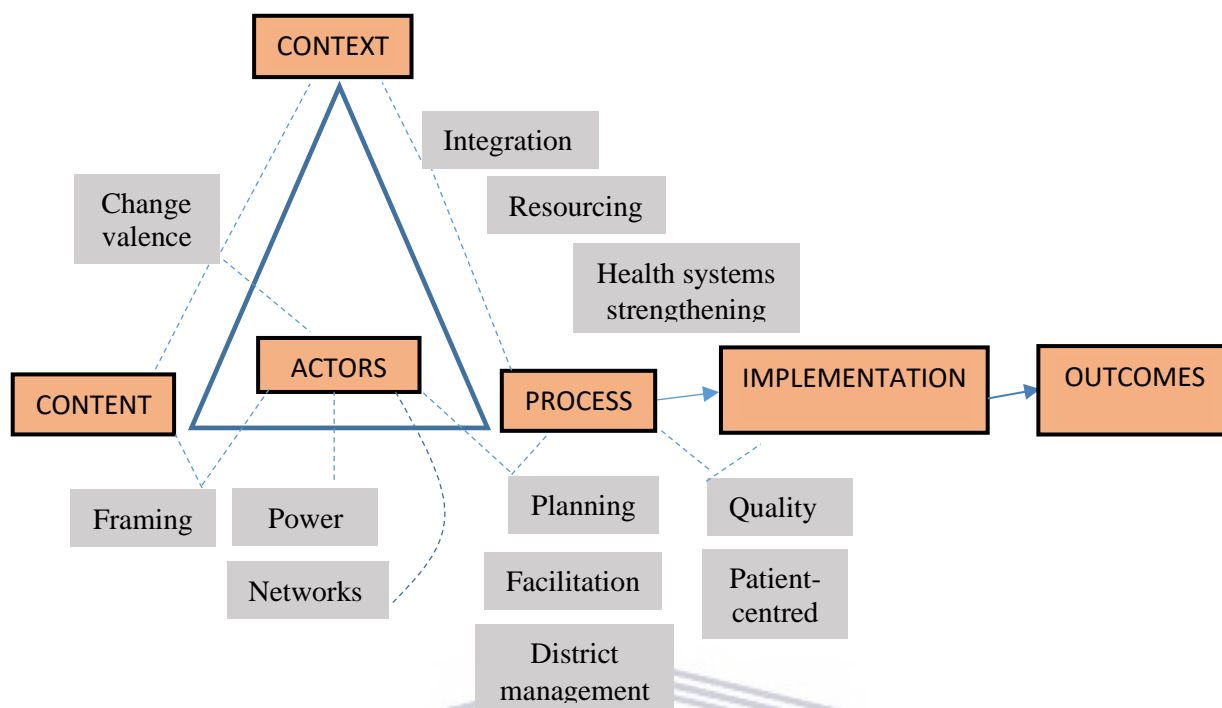


Figure 7: Integrated theory of policy implementation

The integrated theory for policy implementation is depicted in Figure 6 with orange boxes representing the policy domains, and grey boxes representing the dynamics and actions of the intersecting constructs. These intersecting constructs are linked through dashed lines to show the relationship between implementation domains. Together, implementation dynamics and actions shape the overall extent, fidelity, and quality with which policy is effectively implemented.

This theory integrates and extends several perspectives on domains that influence implementation, demonstrates the centrality of actors, and enriches our understanding of the many intersecting constructs that shape implementation. It is presented as a general theory that might be applied to analyses of programme implementation, in different policy arenas, and with varying levels of complexity. It synthesises and extends a number of conceptual frameworks, empirical research findings, and implementation knowledge and experiences into an integrative theory for researching, practicing, and evaluating policy implementation of complex health interventions.

10.5 CONCLUSIONS

The doctoral research set out to understand the reasons for the varied implementation of the DR-TB decentralisation policy in South Africa. Applying the policy analysis triangle framework and exploring intersecting implementation domains, the case studies of DR-TB decentralisation in WC and KZN

demonstrated that aspects of actors' engagement with the policy instrument, influenced by organisational dynamics and the wider context, and implementing varying effectiveness of policy strategies, helped to explain the policy implementation black box. This thesis positioned actors as key in this framework, and the conceptual framing adopted an actor-centric focus. It asserts that implementation of complex and oftentimes ambiguously defined technical interventions, unfolds within a complex system context, requires a range of coordinated implementation strategies across multiple levels, and results in a dynamic interplay between individuals and their organisation, that shapes implementation processes. This system context "creates opportunities and constraints and influences the dynamics and performance" of implementation over time (Emerson et al., 2012, p. 20).

Implementation is a multi-level process (Van Damme et al., 2010), and this thesis provided a deep exploration of the sub-national level including the meso-level (district health system and the organisational level, such as hospitals) and micro-level (individuals and groups within organisations or communities).

The research sought to overcome methodological weaknesses of prior studies (Gilson & Raphaely, 2008; Erasmus et al., 2014). Rigorous case study methodology, drawing on conceptual frameworks and relevant theory in the broader fields of implementation science and policy implementation research, spanning different disciplines, research traditions, and theoretical perspectives, underpinned the analysis. In this way, the thesis provides a better understand of what, why, and how DR-TB decentralisation works in the 'real world' in order to generate insights towards improving policy and programme delivery.

The study unpacked the mechanisms that shaped implementation, and looking inside this black box revealed sources of variation in policy implementation (Parashar et al., 2020). It provided a nuanced understanding of the gap between policy objectives and actual implementation, which is the purpose of implementation research (Hill & Hupe, 2002). It addressed issues of implementation failure due to incorrect theory behind the intervention or incomplete or poorly designed implementation strategies (Nilsen et al., 2013).

This thesis has detailed the dynamics of DR-TB care implementation beyond the recurring health systems barriers previously described in the literature. New advances in diagnosis and treatment to address the growing burden of DR-TB in South Africa will have little impact unless implementation dynamics are better understood (Cox & Ford, 2013; Padayatchi et al., 2014; Naidoo et al., 2015), and attention paid to individual and organisational processes of adopting and integrating complex care strategies.

10.6 LIMITATIONS

I selected DR-TB decentralisation as a case study for understanding policy implementation in the hope of strengthening decentralised DR-TB care, and also to inform other programme interventions. However, there are differences between health programmes in South Africa, in ideological underpinnings, burden of disease, advocacy of actors, funding, and efficiencies of service delivery. The findings from this case study may therefore not be directly generalisable to other programmes. Selecting two provinces with high TB burdens and different contexts and health systems challenges, may not also directly translate to the contexts in other provinces, and further limit generalisability. However, it may be argued that the same complexities in implementation exist in all health programmes and across all settings in South Africa, and there are similar service delivery challenges and similarly poor outcomes. Use of an in-depth qualitative case study design, involving a large number of interviews with actors across all levels of the health system, strengthened the validity the potential of this single case study to be analytically translatable to other issues and contexts.

In sampling participants for in-depth interviews, some key groups were omitted such as allied health care workers and community health workers, because it was believed that they were not critical informants on policy implementation. However, these perspectives may have been provided further insights, and their omission is a limitation of this study.

Another limitation is the timing of data collection, conducted during 2017 and 2018. There have been many changes and policies introduced to the DR-TB programme since then, such as new drugs and shortened regimens. These new technologies could improve programme delivery and outcomes: the new regimens are better tolerated, and since they are shorter, retention in care should be improved and health system dysfunction could play less of a part. However, I would argue that the implementation challenges identified in this study will continue to hamper DR-TB programme delivery if not addressed, even with the introduction of new drugs and diagnostics.

10.7 RECOMMENDATIONS FOR FUTURE RESEARCH AND PRACTICE

Further research is needed to better understand the patient perspectives of DR-TB decentralisation, as this study focused on actors within the health system involved in policy implementation and service delivery. Further research is also required to focus on identifying and addressing risk factors for poor patient engagement in DR-TB care (McNabb et al., 2021).

Future research could also utilise other research methodologies. This study primarily used a qualitative approach to address how and why implementation failed or succeeded. Supplementing this with quantitative methods, such as analysis of programme data at sub-district and district level, could more robustly establish whether the challenges encountered were accompanied by corresponding impacts on

treatment initiation, LTFU, treatment success, and mortality. As pointed out in the methodology chapter, the rapidly growing fields of systems mapping offers novel approaches to describing and evaluating complexity. An embedded research approach (De Savigny et al., 2017) would also add value to the study findings. This could include workshopping the findings of the study with the key actors at the meso- and micro-level in a reflective learning process, to inform future DR-TB programme strengthening. Reflective learning workshops with macro-level actors, primarily policy-makers at national level, could serve to embed lessons from this study that could inform future policy design, formulation, and implementation, for DR-TB and other programmes.

To complement the recommendations for further research, recommendations for practice are as follows:

- The policy formulation process should include stakeholder consultations and workshops to ensure bottom-up perspectives are considered and actors' inputs considered in policy design. Moreover, these consultations will also ensure actors' perceptions of the intent of the policy are aligned with the policy content, and will ensure that the policy content is aligned with evidence, local experiences, and the contexts where they will be implemented.
- Those responsible for policy-making at national levels, and with implementation at sub-national levels, should identify and engage early with the policy entrepreneurs, champions and opinion leaders, and actors and networks who can drive and facilitate implementation and enable change management.
- At meso- and micro-level, DMTs and district programme coordinators should have planned, well-formulated dissemination strategies, that include engagement through new policy roadshows with all district stakeholders present, in order to build shared meaning and vision for implementing the policy once released. It is not sufficient to email policy directives to programme coordinators instructing them to implement policy.
- All new policy should be accompanied by well-formulated business cases, implementation plans and 'toolkits', and standard operating procedures if required, as this will facilitate planning by the provinces and districts who are required to implement the policy. This planning process should identify and document possible resource constraints, involving staff, drugs, equipment, and so on, and the plans should specify and communicate how these resource constraints will be addressed ahead of the policy being communicated to provinces. If additional budget is required, medium-term expenditure framework (MTEF) planning with the National Treasury should ensure budget commitments. The plans should also document the supply chain requirements and capital investment for the new infrastructure. Not all policy will require additional budget, and in that case the implementation plan should suggest how existing resources should be redeployed or shifted to where they will be required.

- Contextual factors such as inequitable resource distribution between and within provinces should be considered when selecting the implementation approach and service delivery models, and conditional grant funding should be allocated towards poorly resourced areas.
- The DMT should be positioned as the key stakeholder in policy implementation, working closely in conjunction with the programme coordinator. Implementation plans should explicitly clarify authority, responsibility, and accountability mechanisms. In their local implementation plans and policy communications, the DMT should also make clear the delegation of authority to programme coordinators so that they do not face roadblocks in engaging with micro-level actors.
- The DR-TB and other programmes should learn the lessons from the HIV programme in South Africa and from other programme experiences in other countries, on how the programme could be better integrated into district health services. It is crucial for health authorities to strike the optimal balance in implementing vertical, technically intense programmes like DR-TB within an integrated service delivery platform.
- Quality of programme implementation and quality of care should be framed and built explicitly into the policy instrument, and more importantly, into implementation plans. Again, lessons may be learnt on the programme characteristics that enabled improved outcomes from DR-TB programmes in South Africa and other countries. These quality frames in all new policy should contain detail on how training, mentoring, and supportive supervision through a CQI approach are built into implementation.
- Policy-makers and policy opinion leaders should work together in the agenda setting phases, to ensure all policy instruments consider patient factors and are always patient-centred, and for DR-TB specifically, future policy should consider financial incentives and nutritional support. Future DR-TB programme efforts should also address strengthening community-based services, with patient literacy, peer counselling, and patient/family support to ensure retention in care and treatment completion.
- Finally, programme interventions alone will not be enough and broader transformation of the health system is critical. Whether the national health insurance is introduced as a new funding mechanism, Government needs to develop a strategy directed at improving resourcing in rural areas, strengthening linkage and referrals between levels, establishing information systems for tracking patients and outcomes, and overall health systems strengthening.

REFERENCES

Abbas, S., Kermode, M. and Kane, S. (2020). Strengthening the response to drug-resistant TB in Pakistan: a practice theory-informed approach. *Public Health Action*, 10(4): 147-156.

Abdool Karim, S.S., Churchyard, G.J., Karim, Q.A. and Lawn, S.D. (2009). HIV infection and tuberculosis in South Africa: an urgent need to escalate the public health response. *Lancet*, 374(9693): 921-933.

Andrews, J.R. and Stout, J.E. (2015). Treating multidrug-resistant tuberculosis in community settings: a wise investment. *The International Journal of Tuberculosis and Lung Disease*, 19(2): 127-127.

Atun, R. and Menabde, N. (2008). Health systems and systems thinking. Coker, R., Atun, R., McKee, M. (eds.), *Health systems and the challenge of communicable diseases: experiences from Europe and Latin America*. Maidenhead, Open University Press.

Atun, R., Weil, D.E., Eang, M.T. and Mwakyusa, D. (2010). Health-system strengthening and tuberculosis control. *Lancet*, 375(9732): 2169-2178.

Atun, R. (2012). Health systems, systems thinking and innovation. *Health Policy and Planning*, 27: iv4-iv8.

Barbrook-Johnson, P. and Penn, A.S. (2022). *Systems Mapping: How to build and use causal models of systems*. Switzerland: Palgrave Macmillan.

Barrett, S. (2004). Implementation studies: time for a revival? Personal reflections on 20 years of implementation studies. *Public Administration*, 82: 249-62.

Bassili, A., Fitzpatrick, C., Qadeer, E., Fatima, R., Floyd, K., Jaramillo, E. (2013). A systematic review of the effectiveness of hospital and ambulatory based management of multidrug-resistant tuberculosis. *The American Journal of Tropical Medicine and Hygiene*, 89(2): 271-280.

Basu, S., Andrews, J.R., Poolman, E.M., Gandhi, N.R., Shah, N.S., Moll, A., Moodley, P., Galvani, A.P. and Friedland, G.H. (2007). Prevention of nosocomial transmission of extensively drug-resistant tuberculosis in rural South African district hospitals: an epidemiological modelling study. *Lancet*, 370(9597): 1500-1507.

Bateman, C. (2015). Tugela Ferry's extensively drug-resistant tuberculosis – 10 years on. *South African Medical Journal*, 105(7): 517-520.

Béland, D. and Ridde, V. (2016). Ideas and policy implementation: Understanding the resistance against free health care in Africa. *Global Health Governance*, 10(3).

Bellis, K. (2007). Conduct a rapid appraisal for community-based drug resistant TB care. Report for the National Department of Health, August, 2007. Unpublished report.

Bennett, S., Frenk, J. and Mills, A. (2018). The evolution of the field of Health Policy and Systems Research and outstanding challenges. *Health Research Policy System*, 16(1): 1-6.

Berhanu, R., Schnippel, K., Mohr, E., Hirasen, K., Evans, D., Rosen, S. and Sanne, I. (2016). Early outcomes of decentralized care for rifampicin-resistant tuberculosis in Johannesburg, South Africa: an observational cohort study. *PLoS One*, 11(11): p.e0164974.

Berlan, D., Buse, K., Shiffman, J. and Tanaka, S. (2014). The bit in the middle: a synthesis of global health literature on policy formulation and adoption. *Health Policy and Planning*, 29(suppl_3): iii23-iii34.

Berwick, D.M. (1998). Developing and testing changes in delivery of care. *Annals of Internal Medicine*, 128: 651-6.

Blecher, M., Kollipara, A., Maharaj, Y., Mansvelder, A., Davén, J. and Gaarekwe, O. (2017). Health spending at a time of low economic growth and fiscal constraint. In: Padarath, A. and Barron, P. (eds.), *South African Health Review 2017*. Durban: Health Systems Trust: 25-39.

Bloomberg, L.D. and Volpe, M. (2008). *Completing your qualitative dissertation: A roadmap from beginning to end*. Thousand Oaks, CA: SAGE Publications, Inc.

Bossert, T. (1998). Analyzing the decentralization of health systems in developing countries: decision space, innovation and performance. *Social Science & Medicine*, 47(10): 1513-27.

Braithwaite, J., Churrua, K., Long, J.C., Ellis, L.A. and Herkes, J. (2018). When complexity science meets implementation science: a theoretical and empirical analysis of systems change. *BMC Medicine*, 16(1): 1-14.

Brewer, G. and deLeon, P. (1983). *The Foundations of Policy Analysis*. Monterey, CA: Brooks/Cole.

Brooke-Sumner, C., Petersen-Williams, P., Kruger, J., Mahomed, H. and Myers, B. (2019). 'Doing more with less': a qualitative investigation of perceptions of South African health service managers on implementation of health innovations. *Health Policy and Planning*, 34(2): 132-140.

Brust, J.C., Lygizos, M., Chaiyachati, K., Scott, M., van der Merwe, T.L., Moll, A.P., Li, X., Loveday, M., Bamber, S.A., Lalloo, U.G. and Friedland, G.H. (2011). Culture conversion among HIV co-infected multidrug-resistant tuberculosis patients in Tugela Ferry, South Africa. *PLoS One*, 6(1), e15841.

Brust, J.C., Shah, N.S., Scott, M., Chaiyachati, K., Lygizos, M., van der Merwe, T.L., Bamber, S., Radebe, Z., Loveday, M., Moll, A.P. and Margot, B. (2012). Integrated, home-based treatment for MDR-TB and HIV in rural South Africa: an alternate model of care [Perspectives]. *The International Journal of Tuberculosis and Lung Disease*, 16(8): 998-1004.

Brynard, P.A. (2009). Mapping the factors that influence policy implementation. *Journal of Public Administration*, 44(3): 557-577.

Buse, K. (2008). Addressing the theoretical, practical and ethical challenges inherent in prospective policy analysis. *Health Policy Plan*, 23(5): 351-360.

Buse, K., Mays, N. and Walt, G. (2012). *Making health policy*. UK: McGraw-Hill Education.

Busse, R., Klazinga, N., Panteli, D. and Quentin, W. (2019). *Improving Healthcare Quality in Europe: Characteristics, Effectiveness, and Implementation of Different Strategies*. Denmark: WHO Press.

Chem, E.D., Van Hout, M.C. and Hope, V. (2019). Treatment outcomes and antiretroviral uptake in multidrug-resistant tuberculosis and HIV co-infected patients in Sub Saharan Africa: a systematic review and meta-analysis. *BMC Infectious Diseases*, 19, 723.

Churchyard, G.J., Mametja, L.D., Mvusi, L., Ndjeka, N., Pillay, Y., Hesselning, A.C., Reid, A. and Babatunde, S. (2014). Tuberculosis control in South Africa: successes, challenges and recommendations: tuberculosis control – Progress towards the Millennium Development Goals. *South African Medical Journal*, 104(3): 244-248.

Coker, R., Balen, J., Mounier-Jack, S., Shigayeva, A., Lazarus, J.V., Rudge, J.W., Nail, N. and Atun, R. (2010). A conceptual and analytical approach to comparative analysis of country case studies: HIV and TB control programmes and health systems integration. *Health Policy Plan*, 25: i21–i31.

Cornelissen, J.P. and Werner, M.D. (2014). Putting framing in perspective: a review of framing and frame analysis across the management and organizational literature. *The Academy of Management Annals*, 8(1): 181-235.

Cox, H. and Ford, N. (2013). Decentralisation of multidrug-resistant-tuberculosis care and management. *Lancet Infectious Diseases*, 13(8): 644-646.

Cox, H., Hughes, J., Daniels, J., Azevedo, V., McDermid, C., Poolman, M., Boule, A., Goemaere, E. and Van Cutsem, G. (2014). Community-based treatment of drug-resistant tuberculosis in Khayelitsha, South Africa. *The International Journal of Tuberculosis and Lung Disease*, 18(4): 441-448.

Cox, H.S., Daniels, J.F., Muller, O., Nicol, M.P., Cox, V., van Cutsem, G., Moyo, S., De Azevedo, V. and Hughes, J. (2015). Impact of decentralized care and the Xpert MTB/RIF test on rifampicin-resistant tuberculosis treatment initiation in Khayelitsha, South Africa. *Open Forum Infectious Diseases*, 2(1): 1-7.

Cox, H., Dickson-Hall, L., Jassat, W., Moshabela, M., Kielmann, K., Grant, A., Nicol, M. et al. (2017). Drug-resistant tuberculosis in South Africa: history, progress and opportunities for achieving universal access to diagnosis and effective treatment. In: Padarath, A. and Barron, P. (eds.), *South African Health Review*. Durban: Health Systems Trust: 157-167.

Cox, V., Cox, H., Pai, M., Stillo, J., Citro, B. and Brigden, G. (2019). Health care gaps in the global burden of drug-resistant tuberculosis. *The International Journal of Tuberculosis and Lung Disease*, 23(2): 125-135.

Cresswell, K. and Sheikh, A. (2013). Organizational issues in the implementation and adoption of health information technology innovations: an interpretative review. *International Journal of Medical Informatics*, 82(5): e73-e86.

Creswell, J. (2013). *Qualitative Inquiry & Research Design: Choosing among five approaches* (3rd ed.). Thousand Oaks, CA: SAGE: 137-149.

Daftary, A. and Padayatchi, N. (2016). Provider perspectives on drug-resistant tuberculosis and human immunodeficiency virus care in South Africa: a qualitative case study. *The International Journal of Tuberculosis and Lung Disease*, 20(11):1483-1488.

Daftary, A., Mondal, S., Zelnick, J., Friedland, G., Seepamore, B., Boodhram, R., Amico, K.R., Padayatchi, N. and O'Donnell, M.R. (2021). Dynamic needs and challenges of people with drug-resistant tuberculosis and HIV in South Africa: a qualitative study. *Lancet Global Health*, 9(4): e479-e488.

Damschroder, L.J., Aron, D.C., Keith, R.E., Kirsh, S.R., Alexander, J.A. and Lowery, J.C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Science*, 4(1): 1-15.

Daru, P., Matji, R., AlMossawi, H.J., Chakraborty, K. and Kak, N. (2018). Decentralized, community-based treatment for drug-resistant tuberculosis: Bangladesh program experience. *Global Health: Science and Practice*, 6(3): 594-602.

De Savigny, D. and Adam T. (2009). *Systems thinking for health systems strengthening*. Geneva: World Health Organization.

De Savigny, D., Blanchet, K. and Adam, T. (2017). *Applied Systems Thinking for Health Systems Research: A Methodological Handbook*. United Kingdom: McGraw-Hill Education.

Denzin, N.K. and Lincoln, Y.S. (2011). Introduction: The discipline and practice of qualitative research. In: N.K. Denzin & Y.S. Lincoln (eds.), *The SAGE Handbook of Qualitative Research*. Thousand Oaks, CA: SAGE: 1-20.

Dheda, K., Gumbo, T., Maartens, G., Dooley, K.E., McNerney, R., Murray, M., Furin, J., Nardell, E.A., London, L., Lessem, E. and Theron, G. (2017). The epidemiology, pathogenesis, transmission, diagnosis, and management of multidrug-resistant, extensively drug-resistant, and incurable tuberculosis. *The Lancet Respiratory Medicine*, 5(4): 291-360.

Dholakia, Y. and Mistry, N. (2018). Challenges and Opportunities for Programmatic Management of Drug Resistant TB in India. *SM Tropical Medicine Journal*, 3(1): 1017.

Dimitrakopoulos, D. and Richardson J. (2001). Implementing EU Public Policy. In: Richardson, J. (ed.), *European Union: Power and Policy-Making*. London: Routledge.

Dlamini, S., Ndjeka, N., Mvusi, L. and Massyn, M. (2020). Infectious Disease Control. In: Massyn, N., Day, C., Ndlovu, N. and Padayachee, T. (eds.), *District Health Barometer 2019/20*. Durban: Health Systems Trust.

Dossou, J.P., De Brouwere, V., Van Belle, S. and Marchal, B. (2020). Opening the ‘implementation black-box’ of the user fee exemption policy for caesarean section in Benin: a realist evaluation. *Health Policy and Planning*, 35(2): 153-166.

Dossou, J.P., Van Belle, S. and Marchal, B. (2021). Applying the realist evaluation approach to the complex process of policy implementation—The case of the user fee exemption policy for cesarean section in Benin. *Frontiers in Public Health*, 9: 553980.

Downie, R. and Angelo, S. (2015). *Counting the Cost of South Africa’s Health Burden*. Washington: Center for Strategic and International Studies.

Durlak, J.A. and DuPre, E.P. (2008). Implementation matters: A review of research on the influence of implementation on program outcomes and the factors affecting implementation. *American Journal of Community Psychology*, 41(3): 327-350.

Ebonwu, J.I., Tint, K.S. and Ihekweazu, C. (2011). Low treatment initiation rates among multidrug-resistant tuberculosis patients in Gauteng, South Africa. *The International Journal of Tuberculosis and Lung Disease*, 17(8): 1043-8

Eccles, M.P. and Mittman, B.S. (2006). Welcome to Implementation Science. Editorial. *Implementation Science*, 1(1).

Emerson, K., Nabatchi, T. and Balogh, S. (2012). An integrative framework for collaborative governance. *Journal of Public Administration Research and Theory*, 22(1): 1-29.

Erasmus, E. and Gilson, L. (2008). How to start thinking about investigating power in the organizational settings of policy implementation. *Health Policy Plan*, 23: 361–8.

Erasmus, L.K., Coetzee, G.J. and Stevens, W.S. (2011). Scale up of Xpert MTB/RIF from the national laboratory perspective: issues and challenges. *International Journal of Tuberculosis and Lung Disease*, 15(11 Suppl 3): S61.

Erasmus, E., Orgill, M., Schneider, H. and Gilson, L. (2014). Mapping the existing body of health policy implementation research in lower income settings: what is covered and what are the gaps? *Health Policy Plan*, 29: iii35–iii50.

Erasmus, E., Gilson, L., Govender, V. and Nkosi, M. (2017). Organisational culture and trust as influences over the implementation of equity-oriented policy in two South African case study hospitals. *International Journal for Equity in Health*, 16(1): 1-14.

Evans, D., Sineke, T., Schnippel, K., Berhanu, R., Govathson, C., Black, A., Long, L. and Rosen, S. (2018). Impact of Xpert MTB/RIF and decentralized care on linkage to care and drug-resistant tuberculosis treatment outcomes in Johannesburg, South Africa. *BMC Health Services Research*, 18(1): 1-12.

Farley, J.E., Ram, M., Pan, W., Waldman, S., Cassell, G.H., Chaisson, R.E., Weyer, K., Lancaster, J. and Van der Walt, M. (2011). Outcomes of multi-drug resistant tuberculosis (MDR-TB) among a cohort of South African patients with high HIV prevalence. *PLoS One*, 6(7): e20436.

Farley, J.E., Kelly, A.M., Reiser, K., Brown, M., Kub, J., Davis, J.G., Walshe, L. and Van der Walt, M. (2014). Development and evaluation of a pilot nurse case management model to address multidrug-resistant tuberculosis (MDR-TB) and HIV in South Africa. *PLoS One*, 9(11): e111702.

Farley, J.E., Ndjeka, N., Kelly, A.M., Whitehouse, E., Lachman, S., Budhathoki, C., Lowensen, K., Bergren, E., Mabuza, H., Mlandu, N. and Van Der Walt, M. (2017). Evaluation of a nurse practitioner-physician task-sharing model for multidrug-resistant tuberculosis in South Africa. *PLoS One*, 12(8): e0182780.

Fixsen, D.L., Naoom, S.F., Blase, K.A., Friedman, R.M., Wallace, F., Burns, B., Carter, W., Paulson, R., Schoenwald, S., Barwick, M. and Chambers, D. (2005). *Implementation Research: A Synthesis of the Literature*. Florida: University of South Florida.

Fixsen, D.L., Blasé, K.A., Naoom, S.F., and Wallace, F. (2009). Core Implementation Components. *Research on Social Work Practice*, 19(5): 531-540.

Florman, K., Hudson, J. and Loveday, M. (2020). Decentralisation of MDR-TB care in rural South Africa: Overcoming the challenges through quality improvement. *Clinical Infection in Practice*, 7: 100020.

Floyd, K., Fitzpatrick, C., Pantoja, A. and Raviglione, M. (2013). Domestic and donor financing for tuberculosis care and control in low-income and middle-income countries: an analysis of trends, 2002–11, and requirements to meet 2015 targets. *The Lancet Global Health*, 1(2): e105-e115.

Franke, M.F., Appleton, S.C., Bayona, J., Arteaga, F., Palacios, E., Llaro, K., Shin, S.S., Becerra, M.C., Murray, M.B. and Mitnick, C.D. (2008). Risk factors and mortality associated with default from multidrug-resistant tuberculosis treatment. *Clinical Infectious Diseases*, 46(12): 1844-1851.

Franks, R., and T. Bory. (2015). Who Supports the Successful Implementation and Sustainability of Evidence-Based Practices? Defining and Understanding the Roles of Intermediary and Purveyor Organisations. *New Directions for Child and Adolescent Development*, 149: 41-56.

Frenk, J. (1994). Dimensions of health system reform. *Health policy*, 27(1): 19-34.

Gajee, R., Schnippel, K., Mthupha, N., Muzah, B. and Berhanu, R.H. (2016). Missed appointments among rifampicin-resistant tuberculosis (RR-TB) patients at a decentralised RRTB outpatient clinic in Johannesburg, South Africa. *South African Medical Journal*, 106(9): 912-917.

Gandhi, N.R., Moll, A., Sturm, A.W., Pawinski, R., Govender, T., Lalloo, U., Zeller, K., Andrews, J. and Friedland, G. (2006). Extensively drug-resistant tuberculosis as a cause of death in patients co-infected with tuberculosis and HIV in a rural area of South Africa. *Lancet*, 368(9547): 1575-1580.

Gandhi, N.R., Shah, N.S., Andrews, J.R., Vella, V., Moll, A.P., Scott, M., Weissman, D., Marra, C., Lalloo, U.G. and Friedland, G.H. (2010). HIV coinfection in multidrug- and extensively drug-resistant tuberculosis results in high early mortality. *American Journal of Respiratory and Critical Care Medicine*, 181(1): 80-86.

Gilbert, J.A., Long, E.F., Brooks, R.P., Friedland, G.H., Moll, A.P., Townsend, J.P., Galvani, A.P. and Sheno, S.V. (2015). Integrating community-based interventions to reverse the convergent TB/HIV epidemics in rural South Africa. *PLoS One*, 10(5): e0126267.

Gilson, L. (2003). Trust and the development of health care as a social institution. *Social Science & Medicine*, 56(7): 1453-1468.

Gilson, L. and Raphaely, N. (2008). The terrain of health policy analysis in low and middle income countries: a review of published literature 1994–2007. *Health Policy Plan*, 23: 294-307.

Gilson, L., Hanson, K., Sheikh, K., Agyepong, I.A., Ssengooba, F. and Bennett, S. (2011). Building the field of health policy and systems research: social science matters. *PLoS Medicine*, 8(8): e1001079.

Gilson, L., Schneider, H. and Orgill, M. (2014). Practice and power: a review and interpretive synthesis focused on the exercise of discretionary power in policy implementation by front-line providers and managers. *Health Policy and Planning*, 29(suppl_3): iii51-iii69.

Gilson, L. (2016). Everyday politics and the leadership of health policy implementation. *Health Systems & Reform*, 2(3): 187-193.

Gilson, L., Orgill, M. and Shroff, Z.C. (2018). *A health policy analysis reader: the politics of policy change in low- and middle-income countries*. Geneva: World Health Organization.

Glaser, B. and Strauss, A. (1967). *The discovery of grounded theory: Strategies for qualitative research*. Chicago: Aldine.

Goodwin, N. (2019). Improving integrated care: can implementation science unlock the ‘black box’ of complexities? *International Journal of Integrated Care*, 19(3).

Gray, A.T., Boyles, T., Luedtke, S., Sossen, B., Birjovanu, G., Kostkova, P., Hughes, J. and Esmail, H. (2020). A threat to decentralised care for drug-resistant tuberculosis. *The Lancet Respiratory Medicine*, 8(10): 950-952.

Greenhalgh, T., Robert, G., Macfarlane, F., Bate, P. and Kyriakidou, O. (2004). Diffusion of innovations in service organizations: systematic review and recommendations. *The Milbank Quarterly*, 82(4): 581-629.

Greenhalgh, T. and Papoutsi, C. (2019). Spreading and scaling up innovation and improvement. *BMJ*, 365: 12068.

Guth, W.D. and Macmillan, I.C. (1986). Strategy implementation versus middle manager self-interest. *Strategic Management Journal*, 7: 313-327.

Hall, P. (2008). Systematic process analysis: when and how to use it. *European Political Science*, 7(3): 304-317.

Hanson, K., Ranson, M.K., Oliveira-Cruz, V. and Mills, A. (2003). Expanding access to priority health interventions: a framework for understanding the constraints to scaling-up. *Journal of International Development*, 15: 1-14.

Harvey, G. and Kitson, A. (2015). Translating evidence into healthcare policy and practice: single versus multi-faceted implementation strategies – is there a simple answer to a complex question? *International Journal of Health Policy and Management*, 4(3): 123.

Harvey, G. and Kitson, A. (2016). PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice. *Implementation Science*, 11:33.

Heeks, R. and Stanforth, C. (2015). Technological change in developing countries: opening the black box of process using actor–network theory. *Development Studies Research*, 2(1): 33-50.

Heller, T., Lessells, R.J., Wallrauch, C.G., Bärnighausen, T., Cooke, G.S., Mhlongo, L., Master, I. and Newell, M.L. (2010). Community-based treatment for multidrug-resistant tuberculosis in rural KwaZulu-Natal, South Africa. *The International Journal of Tuberculosis and Lung Disease*, 14(4): 420-426.

Hill, J., Dickson-Hall, L., Grant, A. D., Grundy, C., Black, J., Kielmann, K., Mlisana, K., Mitrani, L., Loveday, M., Moshabela, M., Le Roux, S., Jassat, W., Nicol, M. and Cox, H. (2020). Drug-resistant tuberculosis patient care journeys in South Africa: a pilot study using routine laboratory data. *The International Journal of Tuberculosis and Lung Disease*, 24(1): 83-91.

Hill, M. and Hupe, P. (2002). *Implementing public policy: Governance in theory and in practice*. London: SAGE.

Hill, M. and Hupe, P. (2009). *Implementing Public Policy*. (2nd Edition). London: SAGE.

Hirasen, K., Berhanu, R., Evans, D., Rosen, S., Sanne, I. and Long, L. (2018). High rates of death and loss to follow-up by 12 months of rifampicin resistant TB treatment in South Africa. *PLoS One*, 13(10): e0205463.

Hjern, B. (1982). Implementation research—the link gone missing. *Journal of Public Policy*, 2(3): 301-308.

Ho, J., Byrne, A.L., Linh, N.N., Jaramillo, E. and Fox, G.J. (2017). Decentralized care for multidrug-resistant tuberculosis: a systematic review and meta-analysis. *Bulletin of the World Health Organization*, 95(8): 584.

Horter, S., Stringer, B., Reynolds, L., Shoaib, M., Kasozi, S., Casas, E.C., Verputten, M. and du Cros, P. (2014). “Home is where the patient is”: a qualitative analysis of a patient-centred model of care for multi-drug resistant tuberculosis. *BMC Health Services Research*, 14(1): 1-8.

Horter, S., Daftary, A., Keam, T., Bernays, S., Bhanushali, K., Chavan, D., Denholm, J., Furin, J., Jaramillo, E., Khan, A. and Lin, Y.D. (2021). Person-centred care in TB. *The International Journal of Tuberculosis and Lung Disease*, 25(10): 784-787.

Houghton, C., Casey, D., Shaw, D. and Murphy, K. (2013). Rigour in qualitative case-study research. *Nurse Researcher*, 20(4).

Hudson, B., Hunter, D. and Peckham, S. (2019). Policy failure and the policy-implementation gap: can policy support programs help? *Policy Design and Practice*, 2(1): 1-14.

Iacobino, A., Fattorini, L. and Giannoni, F. (2020). Drug-resistant tuberculosis 2020: where we stand. *Applied Sciences*, 10(6): 2153.

Isaakidis, P., Cox, H.S., Varghese, B., Montaldo, C., Da Silva, E., Mansoor, H., Ladamirska, J., Sotgiu, G., Migliori, G.B., Pontali, E. and Saranchuk, P. (2011). Ambulatory multi-drug resistant tuberculosis treatment outcomes in a cohort of HIV-infected patients in a slum setting in Mumbai, India. *PLoS One*, 6(12): e28066.

Isaakidis, P., Rangan, S., Pradhan, A., Ladamirska, J., Reid, T. and Kielmann, K. (2013). ‘I cry every day’: experiences of patients co-infected with HIV and multidrug-resistant tuberculosis. *Tropical Medicine & International Health*, 18(9): 1128-1133.

Jootun, D., McGhee, G. and Marland, G.R. (2009). Reflexivity: promoting rigour in qualitative research. *Nursing Standard*, 23(23): 42-47.

Kapwata, T., Morris, N., Campbell, A., Mthiyane, T., Mpangase, P., Nelson, K.N., Allana, S., Brust, J.C., Moodley, P., Mlisana, K. and Gandhi, N.R. (2017). Spatial distribution of extensively drug-resistant tuberculosis (XDR TB) patients in KwaZulu-Natal, South Africa. *PLoS One*, 12(10): e0181797.

Kasozi, S., Kirirabwa, N.S., Kimuli, D., Luwaga, H., Kizito, E., Turyahabwe, S., Lukoye, D., Byaruhanga, R., Chen, L. and Suarez, P. (2020). Addressing the drug-resistant tuberculosis challenge through implementing a mixed model of care in Uganda. *PLoS One*, 15(12): e0244451.

Kendall, E.A., Sahu, S., Pai, M., Fox, G.J., Varaine, F., Cox, H., Cegielski, J.P., Mabote, L., Vassall, A. and Dowdy, D.W. (2019). What will it really take to eliminate drug-resistant tuberculosis? *The International Journal of Tuberculosis and Lung Disease*, 23(5): 535.

Kerschberger, B., Telnov, A., Yano, N., Cox, H., Zabsonre, I., Kabore, S.M., Vambe, D., Ngwenya, S., Rusch, B., Tombo, M.L. and Ciglenecki, I. (2019). Successful expansion of community-based drug-resistant TB care in rural Eswatini—a retrospective cohort study. *Tropical Medicine & International Health*, 24(10): 1243-1258.

Khan, M.S. and Coker, R.J. (2014). How to hinder tuberculosis control: five easy steps. *Lancet*, 384(9944): 646-648.

Kielmann, K., Vidal, N., Riekstina, V., Krutikov, M., van der Werf, M.J., Biraua, E., Duric, P. and Moore, D.A. (2018). "Treatment is of primary importance, and social assistance is secondary": A qualitative study on the organisation of tuberculosis (TB) care and patients' experience of starting and staying on TB treatment in Riga, Latvia. *PLoS One*, 13(10): e0203937.

Kielmann, K., Dickson-Hall, L., Jassat, W., Le Roux, S., Moshabela, M., Cox, H., Grant, A.D., Loveday, M., Hill, J., Nicol, M.P. and Mlisana, K. (2021). 'We had to manage what we had on hand, in whatever way we could': adaptive responses in policy for decentralized drug-resistant tuberculosis care in South Africa. *Health Policy and Planning*, 36(3): 249-259.

Kingdon, J. (1984). *Agendas, Alternatives, and Public Policies*. Boston: Little, Brown.

Koon, A.D., Hawkins, B. and Mayhew, S.H. (2016). Framing and the health policy process: a scoping review. *Health Policy and Planning*, 31(6): 801-816.

Kusmiati, T., Nugroho, N.P., Charisma, A.N. and Soedarsono, S. (2020). Drug-resistant tuberculosis treatment outcomes: A comparison between primary health care and hospital ambulatory treatment. *International Public Health Journal*, 12(2): 161-169.

KwaZulu-Natal Department of Health South Africa. (2019). KwaZulu-Natal Province Progress Report (unpublished). Presentation delivered at the DR-TB Decentralisation Summit, Johannesburg, 18–20 September 2019.

KwaZulu-Natal Department of Health South Africa. (2021). *2020/2021 Annual Report*. Pietermaritzburg: KZN Department of Health.

Leavitt, S.V., Jacobson, K.R., Ragan, E.J., Bor, J., Hughes, J., Bouton, T.C., Dolby, T., Warren, R.M. and Jenkins, H.E. (2021). Decentralized care for rifampicin-resistant tuberculosis, Western Cape, South Africa. *Emerging Infectious Diseases*, 27(3): 728.

Lehmann, U. and Gilson, L. (2012). Actor interfaces and practices of power in a community health worker programme: a South African study of unintended policy outcomes. *Health Policy Plan*, 28(4): 358-366.

Lipsky, M. (1980). *Street-level bureaucracy. Dilemmas of the individual in public services*. New York: Russel Sage Foundation.

Long, N. (2001). *Development Sociology: Actor Perspectives*. London: Routledge.

Long, N. and Liu, J. (2009). The centrality of actors and interfaces in the understanding of new ruralities: A Chinese case study. *Journal of Current Chinese Affairs*, 38(4): 63-84.

Loveday, M., Thomson, L., Chopra, M. and Ndlela, Z. (2008). A health systems assessment of the KwaZulu-Natal tuberculosis programme in the context of increasing drug resistance. *The International Journal of Tuberculosis and Lung Disease*, 12(9): 1042-1047.

Loveday, M., Wallengren, K., Voce, A., Margot, B., Reddy, T., Master, I., Brust, J., Chaiyachati, K. and Padayatchi, N. (2012). Comparing early treatment outcomes of MDR-TB in decentralised and centralised settings in KwaZulu-Natal, South Africa. *The International Journal of Tuberculosis and Lung Disease*, 16(2): 209-215.

Loveday, M., Padayatchi, N., Voce, A., Brust, J. and Wallengren, K. (2013). The treatment journey of a patient with multidrug-resistant tuberculosis in South Africa: is it patient-centred? [Notes from the field]. *The International Journal of Tuberculosis and Lung Disease*, 17(10): 56-59.

Loveday, M., Padayatchi, N., Wallengren, K., Roberts, J., Brust, J.C., Ngozo, J., Master, I. and Voce, A. (2014). Association between health systems performance and treatment outcomes in patients co-infected with MDR-TB and HIV in KwaZulu-Natal, South Africa: implications for TB programmes. *PLoS One*, 9(4): e94016.

Loveday, M., Wallengren, K., Brust, J., Roberts, J., Voce, A., Margot, B., Ngozo, J., Master, I., Cassell, G. and Padayatchi, N. (2015). Community-based care vs. centralised hospitalisation for MDR-TB patients, KwaZulu-Natal, South Africa. *The International Journal of Tuberculosis and Lung Disease*, 19(2): 163-171.

Loveday, M. and Cox, H. (2017). Carpe diem ('Seize the day'): building on the findings of the 2015 World Health Organization evaluation of the multi-drug resistant tuberculosis (MDR-TB) programme to make the most of shortened MDR-TB treatment in South Africa. *South African Medical Journal*, 107(3): 176-177.

Loveday, M., Wallengren, K., Reddy, T., Besada, D., Brust, J.C., Voce, A., Desai, H., Ngozo, J., Radebe, Z., Master, I. and Padayatchi, N. (2018). MDR-TB patients in KwaZulu-Natal, South Africa: Cost-effectiveness of 5 models of care. *PLoS One*, 13(4): e0196003.

Lyakurwa, D., Lyimo, J., Mulder, C., Pelzer, P.T., Koppelaar, I. and Heus, M. (2021). Assessment of training and mentoring for DR-TB care decentralization in Tanzania. *Human Resources for Health*, 19(1): 1-13.

Marani, H., Evans, J.M., Palmer, K.S., Brown, A., Martin, D. and Ivers, N.M. (2022). Divergent notions of "quality" in healthcare policy implementation: a framing perspective. *Journal of Health Organization and Management*, 36(1): 87-104.

Marmor, T. and Wendt, C. (2012). Conceptual frameworks for comparing healthcare politics and policy. *Health Policy*, 107(1): 11-20.

Matland, R.E. (1995). Synthesizing the implementation literature: The ambiguity-conflict model of policy implementation. *Journal of Public Administration Research and Theory*, 5(2): 145-174.

May, C. (2013). Towards a general theory of implementation. *Implementation Science*, 8(1): 1-14.

May, C.R., Johnson, M. and Finch, T. (2016). Implementation, context and complexity. *Implementation Science*, 11(1): 1-12.

Mayosi, B.M. and Benatar, S.R. (2014). Health and Health Care in South Africa — 20 Years after Mandela. *New England Journal of Medicine*, 371(14): 1344-1353.

McEvoy, R., Ballini, L., Maltoni, S., O'Donnell, C.A., Mair, F.S. and MacFarlane, A. (2014). A qualitative systematic review of studies using the normalization process theory to research implementation processes. *Implementation Science*, 9(1): 1-13.

McNabb, K.C., Bergman, A. and Farley, J.E. (2021). Risk factors for poor engagement in drug-resistant TB care in South Africa: a systematic review. *Public Health Action*, 11(3): 139-145.

Médecins Sans Frontières. (2011). *Scaling up diagnosis and treatment of drug-resistant tuberculosis in Khayelitsha, South Africa*. Cape Town: Médecins Sans Frontières. [Online]. Available: <http://www.msf.org.za/publication/scaling-diagnosisand-treatment-drug-resistant-tuberculosis-khayelitsha-south-africa>.

Médecins Sans Frontières & Stop TB Partnership. (2017). *Out of Step 2017 – TB policies in 29 countries: A survey of prevention, testing and treatment policies and practices*. Geneva: StopTB. [Online]. Available: http://www.stoptb.org/assets/documents/outofstep/UNOPS_out_of_step_2017_55_online.pdf.

Mekler, K.A. (2018). *Factors influencing the decentralisation of Multi-Drug Resistant Tuberculosis Care: A management perspective*. Unpublished Master's thesis. Cape Town: University of the Western Cape.

Mohr, E., Snyman, L., Mbakaz, Z., Caldwell, J., DeAzevedo, V., Kock, Y., Trivino Duran, L. and Venables, E. (2018). “Life continues”: Patient, health care and community care workers perspectives on self-administered treatment for rifampicin-resistant tuberculosis in Khayelitsha, South Africa. *PLoS One*, 13(9): e0203888.

Molla, Y., Jerene, D., Jemal, I., Nigussie, G., Kebede, T., Kassie, Y., Hiruy, N., Aschale, G., Habte, D., Gashu, Z. and Haile, Y.K. (2017). The experience of scaling up a decentralized, ambulatory model of care for management of multidrug-resistant tuberculosis in two regions of Ethiopia. *Journal of Clinical Tuberculosis and Other Mycobacterial Diseases*, 7: 28-33.

Monedero-Recueroc, I., Gegia, M., Wares, D., Chadha, S. and Mirzayev, F. (2021). Situational analysis of the 10 high drug resistant tuberculosis burden countries two years post-UNHLM

declaration: progress and setbacks in a changing landscape. *International Journal of Infectious Diseases*, 108: 557-567.

Moodley, P., Shah, N.S., Tayob, N., Connolly, C., Zetola, N., Gandhi, N., Friedland, G. and Sturm, A.W. (2011). Spread of extensively drug-resistant tuberculosis in KwaZulu-Natal province, South Africa. *PLoS One*, 6(5): e17513.

Murray, E., Treweek, S., Pope, C., MacFarlane, A., Ballini, L., Dowrick, C., Finch, T., Kennedy, A., Mair, F., O'Donnell, C., Ong, B.N., Rapley, T., Rogers, A. and May, C. (2010). Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Medicine*, 8(1): 1-11.

Naidoo, P., Van Niekerk, M., Du Toit, E., Beyers, N. and Leon, N. (2015). Pathways to multidrug-resistant tuberculosis diagnosis and treatment initiation: a qualitative comparison of patients' experiences in the era of rapid molecular diagnostic tests. *BMC Health Services Research*, 15(1): 1-13.

Naidoo, P., Theron, G., Rangaka, M.X., Chihota, V.N., Vaughan, L., Brey, Z.O. and Pillay, Y. (2017). The South African tuberculosis care cascade: estimated losses and methodological challenges. *The Journal of Infectious Diseases*, 216(suppl_7): S702-S713.

Nardell, E. and Dharmadhikari, A. (2010). Turning off the spigot: reducing drug-resistant tuberculosis transmission in resource-limited settings. *The International Journal of Tuberculosis and Lung Disease*, 14(10): 1233-1243.

National Department of Health South Africa. (1999). *The Management of Multidrug Resistant Tuberculosis*. Pretoria: NDoH.

National Department of Health South Africa. (2007a). *Tuberculosis Strategic Plan for South Africa, 2007-2011*. Pretoria: NDoH.

National Department of Health South Africa. (2007b). *Policy Guidelines for the Management of Drug Resistant Tuberculosis in South Africa*. Pretoria: NDoH.

National Department of Health South Africa. (2011). *A Policy Framework on Decentralised and Deinstitutionalised Management for South Africa*. Pretoria: NDoH.

National Department of Health South Africa. (2015). *Introduction of new drugs and drug regimens for the management of drug-resistant tuberculosis in South Africa: Policy framework. Version 1.1.* Pretoria: NDoH.

National Department of Health South Africa and the World Health Organization. (2016). *Towards Universal Health Coverage: Report of the evaluation of South Africa drug resistant TB programme and its implementation of the policy framework on decentralised and deinstitutionalised management of multidrug resistant TB.* Pretoria: NDoH and WHO.

National Department of Health South Africa. (2018). *Summary report on decentralised and deinstitutionalised management of multi-drug resistant tuberculosis services in South Africa.* Pretoria: NDoH.

National Department of Health South Africa, Statistics South Africa, South African Medical Research Council and ICF. (2019). *South Africa Demographic and Health Survey 2016.* Pretoria, South Africa, and Maryland, USA: NDoH, Stats SA, SAMRC, and ICF.

National Department of Health South Africa. (2019a). *A Policy Framework on Decentralised and Deinstitutionalised Management for South Africa.* Pretoria: NDoH.

National Department of Health South Africa. (2019b). *Drug resistant tuberculosis clinical audit report April 2018–March 2019.* Pretoria: NDoH.

National Department of Health South Africa. (2021). *National Master Facility List.* Pretoria: NDoH.

National Institute for Communicable Diseases. (2016). *South African Tuberculosis Drug Resistance Survey 2012–14.* Johannesburg: National Health Laboratory Service.

Nilsen, P., Ståhl, C., Roback, K. and Cairney, P. (2013). Never the twain shall meet? A comparison of implementation science and policy implementation research. *Implementation Science*, 8(1): 1-12.

Nilsen, P. (2015). Making sense of implementation theories, models, and frameworks. *Implementation Science*, 10(53).

Noerfitri, N., Sutiawan, R., Wahyono, T.Y.M. and Hartono, P.A. (2019). Influence of Decentralization and Type of Patient on Loss to Follow-Up among Multidrug-Resistant Tuberculosis

Patients in Indonesia from 2014 to 2015. *Kesmas: Jurnal Kesehatan Masyarakat Nasional*, 13(3): 105-111.

Norris, E., Kidson, M., Bouchal, P. and Rutter, J. (2014). *Doing Them Justice: Lessons from Four Cases of Policy Implementation*. London: Institute for Government.

Orgill, M., Gilson, L., Chitha, W., Michel, J., Erasmus, E., Marchal, B. and Harris, B. (2019). A qualitative study of the dissemination and diffusion of innovations: bottom up experiences of senior managers in three health districts in South Africa. *International Journal for Equity in Health*, 18(1): 1-15.

Ozawa, S. and Pongpirul, K. (2014). 10 best resources on... mixed methods research in health systems. *Health Policy and Planning*, 29(3): 323-327.

Padayatchi, N. and Friedland, G. (2008). Decentralised management of drug-resistant tuberculosis (MDR-and XDR-TB) in South Africa: an alternative model of care. *The International Journal of Tuberculosis and Lung Disease*, 12(8): 978-980.

Padayatchi, N., Loveday, M. and Naidu, N. (2014). Drug-resistant tuberculosis control in South Africa: scientific advances and health system strengthening are complementary. *Expert Opinion on Pharmacotherapy*, 15(15): 2113-2116.

Pai, M. and Temesgen, Z. (2017). Mind the gap: Time to address implementation gaps in tuberculosis diagnosis and treatment. *Journal of Clinical Tuberculosis and other Mycobacterial Diseases*, 6: 14-15.

Parashar, R., Gawde, N., Gupta, A. and Gilson, L. (2020). Unpacking the implementation blackbox using 'actor interface analysis': how did actor relations and practices of power influence delivery of a free entitlement health policy in India? *Health Policy and Planning*, 35(Supplement_2): ii74-ii83.

Parashar, R., Gawde, N. and Gilson, L. (2021). Application of "actor interface analysis" to examine practices of power in health policy implementation: an interpretive synthesis and guiding steps. *International Journal of Health Policy and Management*, 10(7): 430.

Pawson, R. and Tilley, N. (1997). *Realistic Evaluation*. London: SAGE.

- Pawson, R. (2010). Middle Range Theory and Program Theory Evaluation: From Provenance to Practice. In: Vaessen, J. and Leeuw, F.L. (eds.), *Mind the Gap Perspectives on Policy Evaluation and the Social Sciences*. New Brunswick, NJ: Routledge: 171-202.
- Peters, D.H., Tran, N.T. and Adam, T. (2013a). Implementation research in health: a practical guide. Geneva: Alliance for Health Systems Policy and Systems Research and World Health Organization.
- Peters, D.H., Adam, T., Alonge, O., Agyepong, I.A. and Tran, N. (2013b). Implementation research: what it is and how to do it. *BMJ*, 347: f6753
- Pettigrew, A.M., Woodman, R.W. and Cameron, K.S. (2001). Studying organizational change and development: Challenges for future research. *Academy of Management Journal*, 44(4): 697-713.
- Plsek, P. E. and Greenhalgh, T. (2001). The challenge of complexity in health care. *BMJ*, 323:625-8.
- Pooran, A., Pieterse, E., Davids, M., Theron, G. and Dheda, K. (2013). What is the cost of diagnosis and management of drug resistant tuberculosis in South Africa? *PLoS One*, 8(1): e54587.
- Putturaj, M., Bhojani, U., Rao, N.V. and Marchal, B. (2021). Decoding the black box of health policy implementation: A case of regulating private healthcare establishments in southern India. *National Medical Journal of India*, 34(2).
- Ramma, L., Cox, H., Wilkinson, L., Foster, N., Cunnam, L., Vassall, A. and Sinanovic, E. (2015). Patients' costs associated with seeking and accessing treatment for drug-resistant tuberculosis in South Africa. *The International Journal of Tuberculosis and Lung Disease*, 19(12): 1513-1519.
- Renmans, D., Holvoet, N. and Criel, B. (2017). Combining theory-driven evaluation and causal loop diagramming for opening the 'black box' of an intervention in the health sector: a case of performance-based financing in Western Uganda. *International Journal of Environmental Research and Public Health*, 14(9): 1007.
- Ridde, V. (2016). Need for more and better implementation science in global health. *BMJ Global Health*, 1(2): e000115.
- Robson, C. (2002). Real world research: a resource for social scientists and practitioner-researchers, (2nd Edition). Oxford: Blackwell Publishing.

Rogers, E.M. (2003). *Diffusion of Innovations* (5th Edition). New York: Free Press.

Rogers, E.M., Medina, U.E., Rivera, M.A. and Wiley, C.J. (2005). Complex adaptive systems and the diffusion of innovations. *The Public Sector Innovation Journal*, 10(3): 1-26.

Rolfe, B., Leshabari, S., Rutta, F. and Murray, S.F. (2008). The crisis in human resources for health care and the potential of a 'retired' workforce: case study of the independent midwifery sector in Tanzania. *Health Policy and Planning*, 23(2): 137-149.

Roman, T.E., Cleary, S. and McIntyre, D. (2017). Exploring the Functioning of Decision Space: A Review of the Available Health Systems Literature. *International Journal of Health Policy and Management*. 6(7): 365-376.

Sabatier, P.A. and Jenkins-Smith, H.C. (1993). Policy change and learning: an advocacy coalition approach. Boulder, Colo: Westview Press.

Sabatier, P.A. (2007). *Theories of the Policy Process*, Second Edition. New York: Routledge.

Salie, F. and Douglas, T.S. (2017). Towards understanding the drivers of policy change: a case study of infection control policies for multi-drug resistant tuberculosis in South Africa. *Health Research Policy and Systems*, 15(1): 1-11.

Saunders, B., Kitzinger, J. and Kitzinger, C. (2014). Anonymising interview data: Challenges and compromise in practice. *Qualitative Research*, 15(5): 616-632.

Schneider, H., Mukinda, F., Tabana, H. and George, A. (2022). Expressions of actor power in implementation: a qualitative case study of a health service intervention in South Africa. *BMC Health Services Research*, 22(1): 1-11.

Schnippel, K., Rosen, S., Shearer, K., Martinson, N., Long, L., Sanne, I. and Variava, E. (2013). Costs of inpatient treatment for multi-drug-resistant tuberculosis in South Africa. *Tropical Medicine & International Health*, 18(1): 109-116.

Schnippel, K., Firnhaber, C., Ndjeka, N., Conradie, F., Page-Shipp, L., Berhanu, R. and Sinanovic, E. (2017). Persistently high early mortality despite rapid diagnostics for drug-resistant tuberculosis cases in South Africa. *The International Journal of Tuberculosis and Lung Disease*, 21(10): 1106-1111.

Schon, D.A. and Rein, M. (1994). *Frame Reflection: Towards the Resolution of Intractable Policy Controversies*. New York: Basic Books.

Scott, V., Schaay, N., Olckers, P., Nqana, N., Lehmann, U. and Gilson, L. (2014). Exploring the nature of governance at the level of implementation for health system strengthening: the DIALHS experience. *Health Policy and Planning*, 29(suppl_2): ii59-ii70.

Section 27. (2007). Chapter 3 Budgeting for Health. In: Hassim, A., Heywood, M. and Berger, J. (eds.), *Health and Democracy*. Johannesburg: Section 27.

Seunanden, T. and Day, C. (2014). The extent and impact of TB stock-outs. In Padarath, A. and English, R. (eds.), *South African Health Review 2013/14*. Durban: Health Systems Trust: 173-8.

Seung, K.J., Keshavjee, S. and Rich, M.L. (2015). Multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis. *Cold Spring Harbor Perspectives in Medicine*, 5(9): a017863.

Sheikh, K., Gilson, L., Agyepong, I.A., Hanson, K., Ssengooba, F. and Bennett, S. (2011). Building the field of health policy and systems research: framing the questions. *PLoS Medicine*, 8(8): e1001073.

Signé, L. (2017). *Policy implementation. A synthesis of the study of policy implementation and the causes of policy failure*. Rabat: OCP Policy Center: PP-17/03.

Simmons, R., Fajans, P. and Ghiron, L. (2007). *Scaling up health service delivery: from pilot innovations to policies and programmes*. Geneva: World Health Organization.

Sinanovic, E., Ramma, L., Vassall, A., Azevedo, V., Wilkinson, L., Ndjeka, N., McCarthy, K., Churchyard, G. and Cox, H. (2015). Impact of reduced hospitalisation on the cost of treatment for drug-resistant tuberculosis in South Africa. *The International Journal of Tuberculosis and Lung Disease*, 19(2): 172-178.

Singh, A., Prasad, R., Balasubramanian, V. and Gupta, N. (2020). Drug-resistant tuberculosis and HIV infection: current perspectives. *HIV/AIDS Research and Palliative Care*, 12: 9-31.

Singh, V. and van Rensburg, E.S.J. (2017). The Knowledge of Nurses on the Management of Multidrug Resistant Tuberculosis at Primary Health Care Facilities: A Pilot Study. *Africa Journal of Nursing and Midwifery*, 19(3): 1-16.

South African Government. (2017). A complete guide to municipalities in South Africa. The Local Government Handbook of South Africa. Pretoria: SA Government.

South African National AIDS Council. (2007). *HIV & AIDS and STI Strategic Plan for South Africa 2007–2011*. Pretoria: NDoH

South African National AIDS Council. (2017). *South Africa's National Strategic Plan for HIV, TB and STIs 2017–2022*. Pretoria: NDoH

South African National Treasury. (2008). *Budget Review 2008. Division of Revenue*. Pretoria: National Treasury.

South African National Treasury. (2011). *Estimates of National Expenditure. Health Vote*. Pretoria: National Treasury.

South African National Treasury. (2012). *Medium Term Budget Policy Statement 2012*. Pretoria: National Treasury.

South African National Treasury. (2013). *Estimates of National Expenditure. Health Vote*. Pretoria: National Treasury.

South African National Treasury. (2016). *Estimates of National Expenditure. Health Vote*. Pretoria: National Treasury.

South African National Treasury. (2017). *Budget Review 2017. Division of Revenue*. Pretoria: National Treasury.

South African National Treasury. (2018). *Budget Review 2018. Division of Revenue*. Pretoria: National Treasury.

South African National Treasury. (2020). *Government Gazette: Part 2: Frameworks for Conditional Grants to Provinces*. Pretoria: National Treasury.

Statistics South Africa. (2021). *Statistical Release: Mid-year population estimates 2020*. Pretoria: Stats SA.

Stebbins, R.A. (2001). *Exploratory research in the social sciences*. Thousand Oaks, CA: SAGE.

Talbot, E.A. and Pai, M. (2019). Tackling drug-resistant tuberculosis: we need a critical synergy of product and process innovations. *The International Journal of Tuberculosis and Lung Disease*, 23(7): 774-782.

Tiberi, S., Utjesanovic, N., Galvin, J., Centis, R., D'Ambrosio, L., van den Boom, M., Zumla, A. and Migliori, G.B. (2022). Drug resistant TB – latest developments in epidemiology, diagnostics and management. *International Journal of Infectious Diseases*, S1201-9712(22)00165-5.

Tudor, C., Mphahlele, M., Van der Walt, M. and Farley, J.E. (2013). Health care workers' fears associated with working in multidrug- and or extensively-resistant tuberculosis wards in South Africa. *The International Journal of Tuberculosis and Lung Disease*, 17(10): 22-29.

Tufford, L. and Newman, P. (2010). Bracketing in qualitative research. *Qualitative Social Work*, 11(1): 80–96.

UNAIDS. (2020). *Country fact sheet South Africa*. Geneva: UNAIDS. [Online]. Available <https://www.unaids.org/en/regionscountries/countries/southafrica>.

UNAIDS. (2022). *Tuberculosis*. Geneva: UNAIDS. [Online]. Available <https://www.unaids.org/en/topic/tuberculosis>.

United Nations Committee on Economic, Social and Cultural Rights (CESCR) (2000). General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant), E/C.12/2000/4. Available at: <https://www.refworld.org/docid/4538838d0.html> [accessed 3 January 2023].

Van Damme, W., Pirard, M., Assefa, Y. and van Olmen, J. (2010). How can disease control programs contribute to health systems strengthening in sub-Saharan Africa? Which health systems for disease control. Antwerp: Institute of Tropical Medicine.

Van den Hof, S., Collins, D., Hafidz, F., Beyene, D., Tursynbayeva, A. and Tiemersma, E. (2016). The socioeconomic impact of multidrug resistant tuberculosis on patients: results from Ethiopia, Indonesia and Kazakhstan. *BMC Infectious Diseases*, 16(1): 1-14.

Van Hulst, M. and Yanow, D. (2016), From policy ‘frames’ to ‘framing’: theorizing a more dynamic, political approach. *The American Review of Public Administration*, 46(1): 92-112.

Van Rensburg, C., Berhanu, R., Hirasen, K., Evans, D., Rosen, S. and Long, L. (2019). Cost outcome analysis of decentralized care for drug-resistant tuberculosis in Johannesburg, South Africa. *PLoS One*, 14(6): e0217820.

Vanleeuw, L., Atkins, S., Zembe-Mkabile, W. and Loveday, M. (2020). Provider perspectives of the introduction and implementation of care for drug-resistant tuberculosis patients in district-level facilities in South Africa: a qualitative study. *BMJ open*, 10(2): p.e032591.

VeneKlasen, L. and Miller, V.A. (2007). *New Weave of Power, People & Politics: An Action Guide for Advocacy and Citizen Participation*. Oklahoma: World Neighbours.

Vincenten, J., MacKay, J.M., Schröder-Bäck, P., Schloemer, T. and Brand, H. (2019). Factors influencing implementation of evidence-based interventions in public health systems – a model. *Central European Journal of Public Health*, 27(3): 198-203.

Wallengren, K., Scano, F., Nunn, P., Margot, B., Buthelezi, S.S., Williams, B., Pym, A., Samuel, E.Y., Mirzayev, F., Nkhoma, W. and Mvusi, L. (2011). Drug-resistant tuberculosis, KwaZulu-Natal, South Africa, 2001–2007. *Emerging Infectious Diseases*, 17(10): 1913.

Walt, G. and Gilson, L. (1994). Reforming the health sector in developing countries: the central role of policy analysis. *Health Policy and Planning*, 9(4): 353-370.

Walt, G., Shiffman, J., Schneider, H., Murray, S.F., Brugha, R. and Gilson, L. (2008). ‘Doing’ health policy analysis: methodological and conceptual reflections and challenges. *Health Policy and Planning*, 23(5): 308-317.

Watermeyer, J., Penn, C., Scott, M. and Seabi, T. (2019). Bench, bed and beyond: Communication and responsibility in decentralised tuberculosis care. *Health SA Gesondheid*, 24(0).

Weiner, B.J. (2009). A theory of organizational readiness for change. *Implementation Science*, 4(1): 1-9.

Weiss, P., Chen, W., Cook, V.J. and Johnston, J.C. (2014). Treatment outcomes from community-based drug resistant tuberculosis treatment programs: a systematic review and meta-analysis. *BMC Infectious Diseases*, 14(1): 1-9.

Western Cape Department of Health South Africa. (2019). Western Cape Province Progress Report (unpublished). Presentation delivered at the DR-TB Decentralisation Summit, Johannesburg, 18–20 September 2019.

Western Cape Government. (2021). *Annual Report 2020–2021 Health*. Cape Town: WC Government.

Weyer, K., Brand, J., Lancaster, J., Levin, J. and Van der Walt, M. (2007). Determinants of multidrug-resistant tuberculosis in South Africa: results from a national survey. *South African Medical Journal*, 97(11): 1120-1128.

Williams, A.O., Makinde, O.A. and Ojo, M. (2016). Community-based management versus traditional hospitalization in treatment of drug-resistant tuberculosis: a systematic review and meta-analysis. *Global Health Research and Policy*, 1(1): 1-14.

Wingfield, T., Boccia, D., Tovar, M., Gavino, A., Zevallos, K., Montoya, R., Loennroth, K. and Evans, C.A. (2014). Defining catastrophic costs and comparing their importance for adverse tuberculosis outcome with multi-drug resistance: a prospective cohort study, Peru. *PLOS Medicine*, 11(7): p.e1001675.

World Health Organization. (2007). *Everybody's business: Strengthening health systems to improve health outcomes: WHO's framework for action*. Geneva: WHO.

World Health Organization. (2011). *Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis: 2011 Update*. Geneva: WHO.

World Health Organization. (2012). *Health policy and systems research: A methodology reader*. In: Gilson, L. (ed.). Geneva: WHO.

World Health Organization. (2014). *Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis: 2014 Update*. Geneva: WHO.

World Health Organization. (2019). *Global Tuberculosis Report 2019*. Geneva: WHO.

World Health Organization. (2021). *Global Tuberculosis Report 2021*. Geneva: WHO.

Yanow, D. (2000). *Conducting Interpretive Policy Analysis*. Newbury Park, CA: Sage.

Yin, R.K. (1993). *Applications of Case Study Research*. Thousand Oaks, CA: Sage.

Yin, R.K. (2003). *Case study Research Design and Methods*. 3rd Edition. Thousand Oaks, CA: Sage.

Yin, R.K. (2009). *Case study research: Design and methods*. 4th Edition. Thousand Oaks, CA, Sage.

Yin, R.K. (2018). *Case Study Research Design and Applications. Design and Methods*. 6th Edition. Thousand Oaks, CA: Sage.



Appendix 1: Draft interview guide: national informants

GENERAL:

1. Can you tell us in your own words what is meant by decentralisation of DR-TB?

POLICY FORMULATION:

1. What do you think motivated the idea to decentralise DR-TB in SA?
2. In your opinion, what were the main objectives intended by the decentralisation of DR-TB policy?
3. What issues and considerations necessitated and informed the design of the policy for decentralisation of DR-TB?
 - Epidemiological, e.g. disease burden, transmission
 - Economic, cost-effectiveness
 - Ethics and human rights questions
4. What were the expected outcomes in implementing the policy?
5. What were the steps followed in planning and designing the policy?
6. Who was consulted to develop the policy?
7. Who advised and assisted with the policy costing, funding allocation and financing flows which were linked to the decentralisation policy?
8. Who are the main role players involved in the policy design?
9. Was there senior support at different level of the health care system (national, provincial and district) for the decentralisation of DR-TB policy?
10. Were any other levels of government involved in the decentralisation process?
11. Were there any dynamics between the national and provincial expectation for decentralisation?
12. What is needed to ensure success of policy formulation?

POLICY IMPLEMENTATION:

1. Is there an implementation (operational) plan in each province?
2. Who are the main contributors, implementers, decision-makers, players and partners to implementation?
3. How has the implementation unfolded this far– reconstruct timelines, milestones, and progress?
4. What has been done to ensure that the implementation of decentralisation objectives are met?
5. What are the drivers, facilitators and barriers to implementation?
6. What has been the role of Xpert testing or other diagnostics in decentralisation?
7. How has the bedaquiline introduction / rollout been incorporated into the decentralisation strategy?
8. How do targets play a role in decentralisation? Eg: NSP targets
9. Which NGO funded stimulated / projects have contributed to / impacted upon this process?
10. What factors do you consider likely to hinder the success of the policy implementation?

11. What do you think is needed to ensure success of policy implementation?
12. What other resources have been necessary to ensure the successful implementation of the policy?
13. Describe the financing flows that are in place in order to ensure the successful implementation of the policy?
14. What are your comments about this process being an ‘unfunded mandate’?

HEALTH SYSTEM COMPONENTS:

1. In what way have policy directives been adapted to become context-specific models of care?
What influences these models of care?
2. How is quality ensured?
3. What lessons have been learnt thus far with regards to the decentralisation process?
4. What is needed to ensure success with decentralisation?



Draft interview guide: provincial informants

GENERAL:

1. Can you tell us in your own words what is meant by decentralisation of DR-TB?

POLICY FORMULATION:

1. What do you think motivated the idea to decentralise DR-TB in SA?
2. In your opinion, what were the main objectives intended by the decentralisation of DR-TB policy?
3. Who was consulted to develop the policy?
4. Was there senior support at different level of the health care system (national, provincial and district) for the decentralisation of DR-TB policy?
5. Were there any dynamics between the national and provincial expectation for decentralisation?

POLICY IMPLEMENTATION:

1. Is there an implementation (operational) plan?
2. Who are the main contributors, implementers, decision-makers, players and partners to implementation?
3. How has the implementation unfolded this far in your setting – reconstruct timelines, milestones, and progress?
4. What has been done to ensure that the implementation of decentralisation objectives are met?
5. What are the drivers, facilitators and barriers to implementation?
6. What has been the role of Xpert testing or other diagnostics in decentralisation?
7. How has the bedaquiline introduction/rollout been incorporated into the decentralisation strategy?
8. What are the different categories of staff involved in the implementation of the DR-TB policy – how are they organised and trained?
9. How does this decentralisation introduction and strategy affect the patients?
10. Do you think that decentralisation has had an impact on patient reliability or retention in care?
11. How do targets play a role in decentralisation? E.g.: NSP targets
12. Which NGO funded stimulated / projects have contributed to / impacted upon this process?
13. What factors do you consider likely to hinder the success of the policy implementation?
14. What do you think is needed to ensure success of policy implementation?
15. What other resources have been necessary to ensure the successful implementation of the policy?
16. Describe the financing flows that are in place in order to ensure the successful implementation of the policy?
17. What are your comments about this process being an ‘unfunded mandate’?

HEALTH SYSTEM COMPONENTS:

1. In what way have policy directives been adapted to become context-specific models of care?
What influences these models of care?
2. Can you describe the processes of facility reporting systems for DR-TB – give challenges?
3. How is quality ensured?
4. What lessons have been learnt thus far with regards to the decentralisation process?
5. What is needed to ensure success with decentralisation?



Draft interview guide: local informants

GENERAL:

1. Can you tell us in your own words what is meant by decentralisation of DR-TB?

POLICY IMPLEMENTATION:

1. How has the implementation unfolded this far in your setting – reconstruct timelines, milestones, and progress?
2. What are the drivers, facilitators, and barriers to implementation?
3. What are the different categories of staff involved in the implementation of the DR-TB policy – how are they organised and trained?
4. Do you think that decentralisation has had an impact on patient reliability or retention in care?
5. Which NGO funded stimulated/projects have contributed to/impacted upon this process?
6. What factors do you consider likely to hinder the success of the policy implementation?

HEALTH SYSTEM COMPONENTS:

1. Can you please describe how communication takes place between facilities?
2. In what way have policy directives been adapted to become context-specific models of care? What influences these models of care?
3. Can you describe the processes of facility reporting systems for DR-TB – give challenges?
4. How is quality ensured?
5. What lessons have been learnt thus far with regards to the decentralisation process?
6. What is needed to ensure success with decentralisation?

Appendix 2: Observation checklist

Observation category	Possible examples (and links to issues of power in policy implementation)
Physical objects related to policy	Posters: These might point to people who have power over implementation, e.g. the official or committee adjudicating patient complaints about poor service.
Objects not directly related to policy	Mission or strategy statements: These might reflect dominant discourses or construct key implementation relationships in a certain way, for example a discourse on cost-saving promoted by a powerful government department.
The organisation of workspaces and symbolic meanings attached to places	<p>Does the space intimidate, e.g. officials sitting on elevated platforms: This might affect the power balance between clients and officials and the uptake of services.</p> <p>Do people have particular associations with places, e.g. a negative name for the building where management is located: This might provide information about how staff members perceive the exercise of power by management.</p>
The routine organisation of daily tasks/the way people go about their jobs on a day-to-day basis	Routines in wards, e.g. starting times for consultations, the order in which patients are seen: This might provide information on who directs activity and is therefore able to exercise power in this way. It might provide information on how routine decisions are made and whether these always favour certain people, e.g. if decisions always accommodate the most senior nurses.
Organisational style: how people dress, talk to each other, etc.	Is the manager polite when speaking to nurses, but rude to other staff categories, such as clerks, e.g. someone being called 'sir', while first names are used for others: It might indicate who is accorded more status and behaviours, such as rudeness might represent practices of power, for example intimidating people.
Common language and conceptual categories	For example, staff of the same cadre are constructed as 'family' and patients as 'aggressive': Labels can have consequences for the interactions between actors, e.g. negative labels can discredit concerns of patients.
Encounters between clients and staff	How do staff members respond to requests for information? Do they give helpful information or are clients left in the dark? Are patients strategic about the information provided to bureaucrats in order to try and secure a positive outcome? Such exercises of power might affect the uptake of services or the relationships between providers and patients.

Source: Erasmus et al., 2008, p. 365

Appendix 3: Participant information sheet



UNIVERSITY OF THE WESTERN CAPE

Private Bag X 17, Bellville 7535, South Africa

Tel: +27 21-959 2809 Fax: 27 21-959 2872

E-mail: soph-comm@uwc.ac.za

INFORMATION SHEET

Project Title: The Decentralised Drug-Resistant TB Programme in South Africa: From Policy to Implementation

What is this study about?

This is a research project being conducted by Waasila Jassat at the University of the Western Cape. We are inviting you to participate in this research project because you are an expert who could provide insights around the implementation of the drug-resistant (DR)-TB programme. The purpose is to get a better understanding of what affects implementation to develop lessons for strengthening future implementation of DR-TB policy.

What will I be asked to do if I agree to participate?

You will be asked to provide responses to questions during interviews on your understanding, beliefs and perceptions about implementation challenges of the DR-TB programme. Interviews will be done in a location convenient for you, most likely your office or a room at your facility. We will only need about an hour of your time. A summary of the questions that you will be asked is included with this form.

Would my participation in this study be kept confidential?

The researchers undertake to protect your identity and the nature of your contribution. This research project involves making audio recordings of the interview with you. These recordings are made so that the researcher will be able to capture your words correctly and so that your contribution will be accurately analysed for this study. To ensure your anonymity, (1) the audio recording and transcription will be securely stored on a study computer, using password-protected computer files; (2) your name will not be included on the collected data; (3) a code will be placed on the collected data; (4) through the use of an identification key, the researcher will be able to link your survey to your identity; (5) only the researcher will have access to the identification key, the audio recordings and the transcripts; and (6) all data will be destroyed five years after completion of the research. To ensure your confidentiality, data will be stored in locked filing cabinets, using identification codes only on data forms. If we write a report or article about this research project, your identity will be protected.

What are the risks of this research?

There may be some risks from participating in this research study. All human interactions and talking about self or others carry some amount of risks. Interviews could cause minor discomfort, making you feel uncomfortable, fearful, embarrassed or fatigued. We will nevertheless minimise such risks and act promptly to assist you if you experience any discomfort, psychological or otherwise during the

process of your participation in this study. Where necessary, an appropriate referral will be made to a suitable professional for further assistance or intervention.

What are the benefits of this research?

This research is not designed to help you personally, but the results may help us learn more about why the DR-TB programme is not implemented well in South Africa. We hope that, in the future, other people might benefit from this study through improved understanding of barriers to implementing policy.

Do I have to be in this research and may I stop participating at any time?

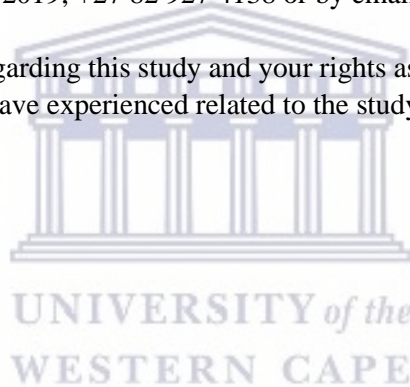
Your participation in this research is completely voluntary. You may choose not to take part at all. You may choose not to have the interview audio-taped. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate or if you stop participating at any time, you will not be penalised. Written permission from the health department or facility will be obtained and submitted to the UWC Biomedical Research Ethics Committee for record-keeping.

What if I have questions?

This research is being conducted by Waasila Jassat from the School of Public Health at the University of the Western Cape. If you have any questions about the research study itself, please contact Waasila Jassat at: PO Box 96228, Brixton, 2019; +27 82 927 4138 or by email at waasila@gmail.com.

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

Prof Helen Schneider
School of Public Health
Head of Department
University of the Western Cape
Private Bag X17
Bellville 7535
soph-comm@uwc.ac.za



Prof Rina Swartz
Acting Dean of the Faculty of Community and Health Sciences
University of the Western Cape
Private Bag X17
Bellville 7535
chs-deansoffice@uwc.ac.za

This research has been approved by the University of the Western Cape's Research Ethics Committee. (Reference Number: BM17/7/4)

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office
New Arts Building,
C-Block, Top Floor, Room 28
University of the Western Cape
Private Bag X17
Bellville 7535

Appendix 4: Participant consent form



UNIVERSITY OF THE WESTERN CAPE

Private Bag X 17, Bellville 7535, South Africa

Tel: +27 21-959 2809, Fax: 27 21-959 2872

E-mail: soph-comm@uwc.ac.za

CONSENT FORM

Title of Research Project: The Decentralised Drug-Resistant TB Programme in South Africa:
From Policy to Implementation

The study has been described to me in language that I understand. My questions about the study have been answered. I understand what my participation will involve and I agree to participate of my own choice and free will. I understand that my identity will not be disclosed to anyone. I understand that I may withdraw from the study at any time without giving a reason and without fear of negative consequences or loss of benefits.

- I agree to be audiotaped during my participation in this study
- I do not agree to be audiotaped during my participation in this study

Participant's name.....

Participant's signature.....

Date.....

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office

New Arts Building

C-Block, Top Floor, Room 28

University of the Western Cape

Private Bag X17

Bellville 7535

Appendix 5: Ethical approval letter from the University of the Western Cape



OFFICE OF THE DIRECTOR: RESEARCH RESEARCH AND INNOVATION DIVISION

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South Africa
T: +27 21 959 2988/2948
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E: research-ethics@uwc.ac.za
www.uwc.ac.za

14 September 2017

Ms W Jassat
School of Public Health
Faculty of Community and Health Sciences

Ethics Reference Number: BM17/7/4

Project Title: The decentralised drug-resistant TB programme in South Africa:
From policy to implementation.

Approval Period: 12 September 2017 – 12 September 2018

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

Please remember to submit a progress report in good time for annual renewal.

The Committee must be informed of any serious adverse event and/or termination of the study.

A handwritten signature in black ink, appearing to read 'Josias', is placed over a white rectangular stamp.

*Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape*

PROVISIONAL REC NUMBER -130416-050

Appendix 6: Research approval letter from KwaZulu-Natal Department of Health



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

Physical Address: 330 Langaibalele Street, Pietermaritzburg
Postal Address: Private Bag X9051
Tel: 033 395 2805/ 3189/ 3123 Fax: 033 394 3782
Email: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

DIRECTORATE:

Health Research & Knowledge
Management

HRKM Ref: 033/18
NHRD Ref: KZ_201801_034

Date: 8 February 2018

Dear Ms W. Jassat (University of the Western Cape)

Approval of research

1. The research proposal titled '**The decentralised drug-resistant TB programme in South Africa: From policy to implementation**' was reviewed by the KwaZulu-Natal Department of Health.

The proposal is hereby **approved** for research to be undertaken at the following hospitals:

Don McKenzie TB, Kind Dinuzulu, Montebello, Murchison, Doris Goodwin, Hlabisa, Manguzi, Greytown TB, Estcourt, Catherine Booth, Thulasizwe.

Selected clinics will also be included within eThekweni, iLembe, Ugu, UMgungundlovu, Umkhanyakude, Uthukela, King Cetshwayo, Zululand

2. You are requested to take note of the following:
 - a. Make the necessary arrangement with the identified facility before commencing with your research project.
 - b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.
3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Mr X. Xaba on 033-395 2805.

Yours Sincerely

Dr E Lutge

Chairperson, Health Research Committee

Date: 19/02/18

Fighting Disease, Fighting Poverty, Giving Hope

Appendix 7: Research approval letter from Western Cape Department of Health



Health impact Assessment
Sub-Directorate: Health Research

Health.Research@westerncape.gov.za
tel: +27 21 483 0866; fax: +27 21 483 9895
5th Floor, Norton Rose House, 8 Riebeeck Street, Cape Town, 8001
www.capegateway.gov.za

REFERENCE: WC_201801_027
ENQUIRIES: Dr Sabela Petros

University of Western Cape

Robert Sobukwe Road

Bellville

Cape Town

7535

For attention: Dr Waasila Jassat

Re: **The Decentralised Drug-Resistant TB Programme in South Africa: From Policy to Implementation.**

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact the following person to assist you with any further enquiries in accessing the following site:

Brooklyn Chest Hospital

Dr Julian Te Riele

021 508 7400

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. By being granted access to provincial health facilities, you are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of your project. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report

(Annexure 8) to the provincial Research Co-ordinator
(Health.Research@westerncape.gov.za).

4. The reference number above should be quoted in all future correspondence.

Yours sincerely

DR J EVANS

ACTING DIRECTOR: HEALTH IMPACT ASSESSMENT

DATE:

24/07/2018

