Community-based MDR-TB management: task-shifting to community treatment supporters in Eswatini

by

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Declaration

I declare that the thesis I hereby submit for the PhD (Development Studies) degree at the University of the Free State is my own independent work and that I have not previously submitted it at another university. I furthermore cede copyright of the thesis in favour of the University of the Free State.

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Dr Ernest Peresu

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Acronyms and abbreviations

AIDS	Acquired immunodeficiency syndrome
APE	*Agente polivalentes elementares* (Elementary multipurpose agent)
APEASE	Acceptability, practicability, effectiveness, affordability, side-effects and equity
ART	Antiretroviral therapy
BCW	Behaviour Change Wheel
CBD	Community-based distribution
CBRHA	Community-based reproductive health agent
CHW	Community health worker
COM-B	Capability, Opportunity and Motivation Model of Behaviour
CP	Continuation phase
CTS	Community treatment supporter
CSO	Central Statistical Office
DOT	Directly observed treatment
DOTS	Directly observed treatment, short course
DR-TB	Drug-resistant tuberculosis
DST	Drug sensitivity testing
EEC	Eswatini Ethics Committee
ENC	Eswatini Nurses Council
FCHV	Female community health volunteer
HCW	Healthcare worker
HEW	Health extension worker
HIV	Human immunodeficiency virus
HRH	Human resources for health
ICER	Incremental cost-effectiveness ratio
IP	Intensive phase
IPC	Infection prevention and control
ISTC	International Standards for Tuberculosis Care
KAP	Knowledge, attitudes and practices
LHW	Lay health worker
LMIC	Low- and middle-income country
MDG	Millennium Development Goal

MDR-TB	Multidrug-resistant tuberculosis
MEPD	Ministry of Economic Planning and Development (Eswatini)
MOH	Ministry of Health (Eswatini)
MSF	Médecins Sans Frontières
NDS	National Development Strategy
NGO	Non-governmental organisation
NTCP	National Tuberculosis Control Programme (Eswatini)
PEP	Post-exposure prophylaxis
PHC	Primary health care
PHU	Public health unit
PLHA	People living with HIV/AIDS
RHM	Rural health motivator
SDG	Sustainable Development Goal
SEC	Scientific and Ethics Committee (Eswatini)
SPSS	Statistical Package for the Social Sciences
TB	Tuberculosis
TBA	Traditional birth attendant
TWG	Technical Working Group
TDF	Theoretical domains framework
UHC	Universal health coverage
UN	United Nations
US$	United States dollar
VHT	Village health team
VHW	Village health worker
WHO	World Health Organization
ZAR	South African rand

Summary

In Eswatini, the control of multidrug-resistant tuberculosis (MDR-TB) is renascent, not merely as a result of the enormous burden of the disease, but also as a consequence of its symbiotic relationship with poverty and development. So critical is the problem of TB that the country declared the epidemic a national disaster. The Eswatini National TB Control Programme (NTCP) adopted the WHO ambulatory clinic-based care model for managing MDR-TB in three of the country's four regions. Although substantial strides have been achieved in decentralising MDR-TB care, current progress does not meet ambitious national and global TB control and development targets. Access to MDR-TB treatment has been limited, particularly in rural areas, in part, by the reliance on nurse-led care in health facilities that are typically distant and geographically inaccessible from patients' homes, and often characterised by lack of frontline human resources for health (HRH).

In the remaining predominantly rural Shiselweni region, in 2008, Médecins Sans Frontières (MSF) established a novel patient-centred community-based MDR-TB management strategy based on task-shifting within the existing NTCP. The strategy aimed to expand access to MDR-TB treatment, address the dearth in HRH and improve treatment outcomes. The central tenet of this strategy is based on the task-shifting of directly observed therapy (DOT) and intramuscular MDR-TB injection administration – traditionally restricted to professional nurses – to incentivised and narrowly-trained lay health workers (LHWs), referred to as community treatment supporters (CTSs). Instead of making trips to the nearest clinic, this model of care allows patients to receive DOT and daily injections from incentivised CTSs in their (the patients') homes. MDR-TB patients receive financial and nutritional support to overcome the various socio-economic barriers they face in getting uninterrupted access to MDR-TB treatment.

The Capability, Opportunity, and Motivation Model of Behaviour (COM-B model) was used to understand the underpinnings of task-shifting to CTSs within the community-based MDR-TB management strategy. The study explored the knowledge, attitudes and practices of CTSs, and the acceptability of the task-shifting practice within the

community-based MDR-TB model of care to key national- and local-level stakeholders, including policymakers, service providers and patients. The study went further to evaluate the cost-effectiveness of the community-based MDR-TB model of care compared to a routine clinic-based strategy within the established NTCP. The study selected and applied appropriate research methods – qualitative, quantitative and economic evaluation – to explore each of the research questions and fulfil the research objectives. Data was collected in May 2017 among a purposive sample of patients, CTSs and key stakeholders through face-to-face interviews, focus group discussion and data abstraction from medical records.

Through the lens of the COM-B model, findings from the present research demonstrated that, as a component of community-based MDR-TB management, task-shifting can expand access to, and use of, MDR-TB services, address professional HRH deficits, improve treatment outcomes and is acceptable to most stakeholders, albeit with some apprehension. The results lend an economic justification for scaling up the community-based strategy in MDR-TB control. Based on findings from this study, the strategy can become a key accessory in bringing TB-related national, End TB Strategy and Sustainable Development Goal (SDG) targets within reach for Eswatini and other resource-limited countries. However, for the community-based MDR-TB management to succeed, the task-shifting practice should be embedded in a set of accredited training and certification, appropriate regulation, adequate supervision, and referral systems that support the delivery of MDR-TB care by CTSs.

Chapter 1: Introduction

1.1 Background

The control of tuberculosis (TB) is a high priority on the international public health agenda. That recognition is partly attributed to the disease being considered as an important cause and consequence of underdevelopment and poverty, a link that is well captured in the United Nations' (UN) Sustainable Development Goals (SDGs) (UN, 2015; Carter, Glaziou, Lönnroth, Siroka, Floyd, Weil et al., 2018). Despite notable progress recently, TB is still a major infectious cause of death globally and disproportionately affects disadvantaged segments of society. In 2018, the World Health Organization (WHO) reported that there were an estimated 10 million new TB cases and 1.5 million TB-related deaths globally (WHO, 2019a). Similarly**,** Eswatini (formerly Swaziland) has one of the highest TB notification rates in the world, primarily driven by the high prevalence of human immunodeficiency virus (HIV) (Ministry of Health [MOH], 2014a). So critical is the problem of TB that in 2011 the government declared the epidemic a national disaster (MOH, 2014a).

Over the past few years, there has been an escalation of a new public health threat – multidrug-resistant TB (MDR-TB) – that is undermining recent successes in TB control. Simply put, MDR-TB is defined as strains of TB resistant to the two most effective first-line anti-TB drugs, isoniazid and rifampicin. The current MDR-TB treatment regimens are more costly and associated with side effects and substantially worse outcomes over the two-year period of treatment compared to drug-sensitive TB (WHO, 2018a). The inclusion of a daily injection in the first eight months of treatment further complicates the management of MDR-TB. In 2019, the WHO approved the use of a shorter fully-oral MDR-TB treatment regimen (9 to 12 months) in certain circumstances (WHO, 2019b). The shortened regimen is only recommended for MDR-TB patients that have never received and are not – or are unlikely to be – resistant to second-line TB drugs (based on drug sensitivity testing). The Eswatini National TB Control Programme (NTCP) has piloted the shortened regimen in a few facilities and has indicated the intention to expand to the rest of the country.

The 2019 WHO global TB report estimated an incidence of close to 484 000 cases of MDR-TB in 2018, with the disease accounting for over 230 000 deaths in the same year (WHO, 2019a). Eswatini is currently ranked fourth in MDR-TB incidence in the world (WHO, 2019a). In 2018, an estimated 509 patients were notified to have confirmed drug-resistant (DR-TB) compared to 110 DR-TB patients in 2007 (MOH, 2019); that is more than a quadruple increase over a decade. Despite the burden appearing to be comparatively small, MDR-TB presents a disproportionate risk to prospects of TB control in a country that is also experiencing a huge HIV epidemic (Kerschberger, Telnov, Yano, Cox, Zabsonre, Kabore et al., 2018; MOH, 2019). The country has seen a surge in the proportion of MDR-TB among new TB cases from 0.9% to 8.6% between 1995 and 2018 (Sanchez-Padilla, Dlamini, Ascorra, Rüsch-Gerdes, Tefera, Calain et al., 2012; WHO, 2019a). The WHO (2019) reported the proportion of MDR-TB in previously treated cases of TB to be 18.0% in Eswatini. There is growing evidence that inappropriate or inadequate management of drug-susceptible TB and primary transmission of MDR-TB are both major drivers of the MDR-TB epidemic (Shah, Auld, Brust, Mathema, Ismail, Moodley et al., 2017).

Attention to MDR-TB control is renascent, not merely as a result of the enormous burden of the disease, but also as a result of its link with poverty and development. A considerable proportion of the rural population in Eswatini face significant barriers in accessing MDR-TB treatment (Turashvili, Becher, Kerschberger, Jouquet, Browne, Haye et al., 2014). Access to MDR-TB services has remained logistically challenging with patients having to overcome transport-related treatment barriers when trying to access distant primary health care (PHC) facilities (Root & Whiteside, 2013; Sibbald, 2013; Dlamini-Simelane & Moyer, 2017). The clinics typically lack adequate numbers of frontline human resources for health (HRH)[1] (Dlamini-Simelane & Moyer, 2017). The deficit in frontline HRH is felt in nearly every facet of public health in Eswatini, including in antiretroviral therapy (ART) for HIV (Dlamini-Simelane & Moyer, 2017).

Inadequate numbers of professional HRH remains an important challenge for Eswatini and sub-Saharan Africa as a whole throughout history. Of the 57 countries

[1] Frontline HRH in this setting refers to health personnel who are usually the community's first port of call for accessing TB control services.

with critical HRH shortages, 36 are in sub-Saharan Africa (WHO, 2018b). In 2018, Eswatini reported to have just 1.40 midwives, nurses and physicians per 1 000 population, falling short of the WHO recommended 2.28 healthcare workers (HCWs) per 1 000 population (WHO, 2018b). Even this masks the extent of the problem, as professional HCWs are likely to be positioned mostly in urban areas and not in hard-to-reach-and-stay rural areas. Essentially, in most developing countries, professional HRH are either in short supply and/or poorly distributed. Other challenges facing the NTCP includes the lack of adequate social support important for MDR-TB patients to cope and remain in care (MOH, 2014a; Turashvili et al., 2014).

In Eswatini, the NTCP is responsible for the programmatic management of MDR-TB that includes the organisation and delivery of healthcare services to diagnose and cure all forms of TB. Decentralisation of MDR-TB care, which is an integral part of the NTCP, is important in improving treatment access, adherence and outcomes. To this end, the NTCP recognises ambulatory[2] clinic-based care as the recommended model of MDR-TB care. The NTCP has implemented this model of care in three of the country's four regions – Lubombo, Hhohho and Manzini. The MDR-TB treatment regimen comprising of a daily injection for the first eight months and, in particular, the reliance on nurse-led care in directly observed therapy (DOT)[3] supervision and intramuscular MDR-TB injection administration has rendered the provision of clinic-based care problematic. Patients – even if very sick – and their caregivers travel daily to the nearest clinic to receive DOT and MDR-TB injectable medicine from a professional nurse.

Although substantial strides have been made in decentralising MDR-TB care in Eswatini, widespread accessibility of treatment has lagged (Turashvili et al., 2014; MOH, 2019). The current progress in MDR-TB control does not meet the ambitious national and global TB control and development targets. For example, in 2019, the rate of cure for MDR-TB was 72% (2016 cohort), below the WHO target of 75% or higher (Falzon, Mirzayev, Wares, Baena, Zignol, Linh et al., 2015; MOH, 2019;

[2] Ambulatory care in MDR-TB management refers to medical care that includes consultation, diagnosis, treatment, intervention procedures and follow-up provided on an outpatient basis closer to where patients reside or work. Under clinic-based care, patients travel to their nearest PHC clinic daily to receive DOT and intramuscular injections from a nurse.

[3] DOT involves a patient taking standard medication under guided supervision from a HCW or trained caregiver (WHO, 1999).

WHO, 2019a). In 2017, the NTCP estimated that respectively 26% and 10% of MDR-TB patients were lost-to-follow-up or died before the end of their two-year treatment duration (MOH, 2019). Difficulties in optimising adherence and treatment outcomes are attributed to unaddressed socio-economic factors and physical barriers presented by the MDR-TB treatment armamentarium that requires patients to visit a public clinic daily to receive injectable medicines (MOH, 2014a; Turashvili et al., 2014). Besides having to endure the negative effects of stigma, MDR-TB patients incur considerable transport costs travelling to the often distant, geographically inaccessible and inadequately resourced PHC clinics (Thomas, Shanmugam, Malaisamy, Ovung, Suresh & Subbaraman et al., 2016). The rapid roll-out of ambulatory care has revealed substantial gaps in adequate numbers of frontline HRH and left many patients facing challenges in accessing the appropriate type of care that MDR-TB management requires (Turashvili et al., 2014).

To expand access to MDR-TB care, in 2008, with permission from the MOH, Médecins Sans Frontières (MSF) established novel community-based programmatic management of MDR-TB in the Shiselweni region within the NTCP (Turashvili et al., 2014). The unique and central tenet of this multifaceted strategy is the task-shifting of DOT and intramuscular MDR-TB injection administration – traditionally restricted to professional nurses – to trained LHWs, referred to as community treatment supporters (CTSs)[4]. Instead of making trips to the nearest clinic, this model of care allows MDR-TB patients to receive DOT and daily injections from CTSs in their (the patients') homes. MDR-TB patients and their CTSs receive social support packages[5] to overcome the various socio-economic barriers they face in getting uninterrupted access to MDR-TB treatment.

The SDGs have highlighted the high levels of poverty and related public health challenges, including the TB epidemic, confronting the world (UN, 2015). The limited access to MDR-TB care and deficit of frontline HRH is a major bottleneck in

[4] Task-shifting refers to the delegation of specific tasks to HCWs with shorter narrowly-tailored skills-based training and fewer qualifications (WHO, 2008).

[5] Patients and their CTSs receive social support packages comprising of financial and material incentives to enhance adherence to MDR-TB treatment. CTSs also team up with community MDR-TB nurses and social workers to form a support system for the patients. Key components of the support consists of health education, individual and small group counselling, and emotional support to patients and their families in day-to-day life situations.

Eswatini's ability to implement and leverage evidence-based interventions aimed at achieving MDR-TB control targets outlined in the Eswatini National TB Strategic Plan (MOH, 2014b), WHO's End TB Strategy (WHO, 2015) and UN's SDGs (UN, 2015). Understanding the routes by which poverty influences disease progression and eventual MDR-TB treatment outcomes is crucial in breaking the vicious TB-poverty cycle.

1.2 MDR-TB and development

Despite global advances in the technology to diagnose MDR-TB and the wide availability of its treatment, the disease represents an unprecedented health and development dilemma (UN, 2015; WHO, 2015). The determinants of MDR-TB are primarily rooted in socio-economic and health factors (Hargreaves, Boccia, Evans, Adato, Petticrew & Porter, 2011; UN, 2015; WHO, 2015; Carter et al., 2018; Migliori & Garcia-Basteiro, 2018). The symbiotic relationship between MDR-TB and poverty is well described in literature and is evident in the global distribution of the disease (Hargreaves et al., 2011; Carter et al., 2018; Migliori & Garcia-Basteiro, 2018; WHO, 2019a). Of the 30 countries carrying the highest burden of the MDR-TB globally, a majority are low- and middle-income countries (LMICs) located in all regions across the world (WHO, 2019a). On its own, MDR-TB is certainly the epitome of a social, economic and developmental challenge (UN, 2015; WHO, 2015; Carter et al., 2018).

Poverty and its consequences, such as malnutrition and overcrowding, increase the likelihood of MDR-TB infection, as do HIV, diabetes and smoking, among other factors (WHO, 2018a). Apart from being a possible consequence of poverty, MDR-TB also creates and accelerates poverty. Lack of access to PHC facilities including MDR-TB services is common in poor communities (MOH, 2014a; Turashvili et al., 2014). The poor often lack adequate access to uninterrupted MDR-TB services for reasons comprising of shortages of frontline HRH and poverty itself. Illness, in general, often places huge economic pressure on patients and their families, and MDR-TB is no exception (WHO, 2015). MDR-TB places an enormous adverse economic cost on patients and their households, locking generations into a cycle of poverty (WHO, 2015; Carter et al., 2018; Migliori & Garcia-Basteiro, 2018). Absence of PHC facilities to diagnose or treat patients means a longer delay between the

onset of MDR-TB and ultimate cure. This perpetuates deterioration in health, ongoing spread of the disease and catastrophic[6] medical costs which further worsen poverty (Gler, Podewils, Munez, Galipot, Quelapio & Tupasi, 2012; Tanimura, Jaramillo, Weil, Raviglione & Lönnroth, 2014; Migliori & Garcia-Basteiro, 2018).

The barriers to access to MDR-TB services and shortage of HRH in the often distant PHC clinics in Eswatini are a critical gap that constrains the achievement of health and development goals. For Eswatini, national and global MDR-TB control and development targets remain elusive at the current treatment success rates (MOH, 2019). This is despite the existence of alternative strategies of decentralised MDR-TB care in the country. Task-shifting has been suggested as a key strategy to expand access to care and alleviate the HRH crisis confronting most healthcare settings in developing countries (WHO, 2008; Tsolekile, Puoane, Schneider, Levitt & Steyn, 2014; Kerschberger et al., 2019). The link between TB and development suggests that a health intervention such as the task-shifting of community-based MDR-TB treatment to CTSs holds the potential to improve not only the health of people, but also their individual wealth and welfare.

1.2.1 Eswatini National Development Strategy

In 1999, Eswatini launched the National Development Strategy (NDS), 2022 Vision, to provide a guide for the formulation of development plans and equitable allocation of resources (Ministry of Economic Planning and Development [MEPD], 1999). Underlying the vision is the focus on critical dimensions of quality of life, mainly poverty elimination, employment creation, gender equality, social integration and environmental protection that are crucially linked to health, education and other aspects of human resource development.

The NDS focuses among others on: 1) strengthening the control, prevention and treatment of TB and HIV; 2) strengthening the training and deployment of community-based rural health motivators (RHMs) who link communities with the health system; 3) promoting community participation and involvement in the

[6] Catastrophic costs refers to the total cost of TB treatment exceeding 20% of the annual income of the household, and it represents the financial burden experienced by TB-affected households (WHO, 2015).

planning, implementation, monitoring and evaluation of health issues; and 4) improving and expanding comprehensive PHC programmes (MEPD, 1999).

1.2.2 End TB Strategy and Sustainable Development Goals

For Eswatini and the rest of the world, the year 2015 marked the transition from the Millennium Development Goals (MDGs) strategy to the SDGs. Global TB targets were established as part the WHO's End TB Strategy (2016- 2035) and the UN's SDGs (2016-2030) to guide TB control and the development agenda worldwide (UN, 2015; WHO, 2015). One of the 17 SDGs is to 'Ensure healthy lives and promote well-being for all at all ages', under which a target was set to 'End the epidemics of AIDS, TB, malaria and neglected tropical diseases, and combat hepatitis, water-borne diseases and other communicable diseases' (UN, 2015). In line with this SDG, the WHO outlined the End TB Strategy covering the period 2016-2035. The SDGs and the End TB Strategy are profoundly aligned by their common ambitious target to eliminate TB rather than reduce the global TB epidemic by 2030 (the SDG end date) and 2035 (the End TB target date) (UN, 2015; WHO, 2015).

The End TB Strategy outlines targets (for 2030 and 2035) and milestones (for 2020 and 2025) to achieve in reducing TB incidence and deaths. The main targets in the End TB Strategy are a 90% and 95% reduction in TB deaths by 2030 (compared with 2015) and 2035, respectively; and parallel reductions in the TB incidence rate (new cases per 100 000 population per year) of respectively, 80% and 90% (WHO, 2015). The milestones set for 2025 are a 75% reduction in TB deaths and a 20% reduction in the TB incidence rate (WHO, 2015). The Strategy also comprises of a 2020 milestone that no TB-affected households are burdened with catastrophic costs due to TB illness (WHO, 2015). From a conceptual perspective, the Strategy recognises TB as a dual socio-economic and infectious disease problem and calls for strategies that combine biomedical, public health and socio-economic interventions to control the disease (WHO, 2015).

1.2.3 Global Plan to End TB 2016 - 2020

In line with the End TB Strategy, the Stop TB Partnership launched the Global Plan to outline actions and resources needed during the initial five years (2016-2020) to support the end of the global TB epidemic by 2030 (Stop TB Partnership, 2015). The primary aim of the Global Plan is to expand the reach and quality of medical management of TB. The Global Plan set out 90-(90)-90 targets that provide a baseline for measuring progress. The 90-(90)-90 targets are outlined below:

Target 1 Reach 90% of all people with TB and enrol them into appropriate care.

Target 2 Reach at least 90% of the most vulnerable and underserved at-risk populations who are often unable to access health services or suffer particularly catastrophic costs associated with TB.

Target 3 Achieve at least 90% treatment success for all people diagnosed with all forms of TB through affordable and quality treatment, support and follow-up (Stop TB Partnership, 2015).

1.2.4 National TB Strategic Plan (2015-2019)

The MOH developed the National TB Strategic Plan (2015-2019) with the overall goal to effectively guide all TB control activities in the country. The National TB Strategic Plan is aligned within the framework of the NDS, End TB Strategy and SDGs, and outlines the following objectives relating to MDR-TB control:

1. Strengthening community DR-TB management, care and support.
2. Increasing access to treatment for all MDR-TB cases by 2019.
3. Ensuring that 75% of MDR-TB cases are treated successfully by 2019 (MOH, 2014b).

In a nutshell, the targets of National TB Strategic Plan could not be achieved without parallel progress in meeting the NDS, the End TB Strategy and SDGs.

1.3 Contextualising the delivery of MDR-TB care in Eswatini

The NTCP adopted the WHO ambulatory clinic-based MDR-TB care model in three of the country's four regions (Lubombo, Manzini and Hhohho), and the community-based approach in the remaining Shiselweni region. Patients with MDR-TB are diagnosed and managed according to the national MDR-TB treatment guidelines on an ambulatory basis (MOH, 2014a). Ambulatory care can either be clinic-based (patient travels to the clinic to receive DOT and injections from a HCW) or community-based (patient receives DOT and injections in their homes from a CTS). Patients are diagnosed and enrolled into care at a few designated decentralised MDR-TB treating facilities in the country's four regions by professional HCWs – doctors, nurses, and psychologists, among others – exclusively dedicated to the TB treatment programme.

Patients with presumptive MDR-TB are commenced on a standardised treatment regimen that lasts for 24 months. The treatment regimen comprises of an eight-month intensive phase (IP) based on one injectable and four oral drugs followed by a 16-month continuation phase (CP) with the same drugs less the injectable. Inpatient care is only indicated for patients that are clinically unstable. The patient's MDR-TB treatment record and register are maintained at the MDR-TB treating facility and the patient is issued with a DOT booklet. The extent of decentralisation and tailoring to local conditions, which varies considerably between the two models of MDR-TB management, is unpacked below (see also Chapter 6: Table 1).

1.3.1 Clinic-based MDR-TB care model

Treatment is provided on an inpatient basis at least until the patient is clinically stable and thereafter continued on an outpatient basis if adequate treatment and infection prevention and control (IPC) measures in the home and transport to the nearest clinic are assured (MOH, 2014a). Discharged MDR-TB patients often make long and costly morning trips to receive DOT and their daily injections five days per week from professional HCWs at the closest PHC clinic during the IP. A CTS supervises DOT for the evening dose daily during the IP. In this context, a CTS is a lay family or community member who receives narrowly-tailored one-day training on

MDR-TB, medications, adverse effects and DOT. A CTS can have up to a maximum of three MDR-TB patients under their care. CTSs are supervised once every month by community MDR-TB nurses. CTSs and MDR-TB patients in the Lubombo, Manzini and Hhohho regions did not receive any financial incentives or food support at the time of the study.

1.3.2 Community-based MDR-TB care model in the Shiselweni region

The principal components of the community-based management of MDR-TB treatment strategy include the task-shifting of both DOT and MDR-TB injection administration responsibilities to incentivised CTSs and also provision of a package of financial and nutritional support to MDR-TB patients (MSF, 2013; Turashvili, 2014). Under this model of care, patients are enrolled in MDR-TB care at three MDR-TB treating facilities in the region and then transferred to community-based care. Patients requiring admission are hospitalised for an initial and relatively short stay in the MDR-TB ward at Nhlangano Rural Health Centre.

Patients are discharged for community-based care as soon as they tolerate MDR-TB treatment and IPC measures in their households are assessed. Patients remain in their homes during the treatment period without travelling long distances and spending long hours in clinics daily waiting for care. Patients receive a monthly supply of their oral and injection-based medicines during outpatient review visits at the MDR-TB treating facility. Administration of injections in the patients' homes by CTSs is considered critical during the IP of MDR-TB treatment, when patients are likely to be unwell and unable to complete the required daily trips to seek care at their nearest clinic.

1.3.3 Selection and recruitment of CTSs

With the help of the patient, the community MDR-TB nurse identifies a lay neighbour who is willing to be trained on DOT and injection administration and support the patient throughout the treatment duration. The CTS is a neighbour who is acceptable to the patient and serves this role as family members are considered to be prone to

coercion and manipulation by the patient. A CTS is an individual from the community who meets the profile outlined in Box 1.

Box 1: Profile of a community treatment supporter

- Should preferably be an existing community health worker (CHW) who may already have received some training on TB and HIV
- Is chosen by or is acceptable to the patient and his or her family
- Is active and not too old to work
- Is available throughout the day and night to support the patient
- Respects the patient's confidentiality
- Has a stable living situation near the patient to perform twice-daily DOT
- Is literate
- Is motivated to support the MDR-TB patient for the full length of the treatment

Source: MSF (2013)

1.3.4 Training and supervision of CTSs

CTSs are typically recruited and trained to focus solely on MDR-TB. The training, coordinated by community MDR-TB nurses, comprises of on-the-job learning that is followed by a 3-5 days theoretical workshop at a later stage. During the first component of the training, CTSs practice safe injection techniques on an orange fruit before progressing to their recruited client. Considerable emphasis is placed on the delicate skill of drawing the right dose of the injectable drug using a disposable syringe, TB IPC, DOT and waste disposal. To start administering MDR-TB injections on their own, CTSs complete at least three observed injections assessed by a community MDR-TB nurse. CTSs receive a backpack with a MSF logo to keep the patients' medical supplies together with a sharps container for safe disposal of used medical supplies. When full, the sharps disposal containers are returned to the MDR-TB treating facility for incineration. Given the risk of needlestick injuries, newly recruited CTSs are routinely informed of the patient's HIV status and trained on the procedure to get timely post-exposure prophylaxis (PEP) following occupational exposure to HIV.

Newly recruited CTSs wait for up to a month to attend the theoretical component of the training in groups of ten. The second component of the training focuses primarily on theoretical themes relating to MDR-TB epidemiology, transmission, diagnosis, DOT, safe injection handling and adverse drug reactions, CTS's responsibilities including patient confidentiality and procedures for patient referral to community MDR-TB nurses and other MDR-TB team members. CTSs are also trained in TB contact screening procedures using a checklist. The training is conducted by members of the formal health services, mainly community MDR-TB nurses through classroom instruction, group work and open discussions. A variety of materials are used for training, including MDR-TB participant manuals, trainer manuals, DOT cards and record-keeping tools.

Although the training workshop uses pre- and post-training assessments, there are no certificates or any formal form of accreditation issued to CTSs on completion of the training. Each CTS receives ongoing supervisory visits from and at the discretion of the community MDR-TB nurse, to re-evaluate their skills and on-the-job training needs. In some instances, supervision is carried out by mobile phone communication if needed. Thus, community MDR-TB nurses provide the most obvious link between CTSs and the formal healthcare system. Community MDR-TB nurses also collect and report service statistics to the MDR-TB experts meeting at the main rural health centre on a monthly basis.

1.3.5 Tasks shifted to community treatment supporters

MDR-TB care provided by CTSs ranges from brief to intensive face-to-face daily interactions with patients in their (the patients') homes over the span of treatment. CTSs observe patients ingesting medication, administer MDR-TB injections and record this on a card that is reviewed by nurses and doctors during the monthly outpatient clinical follow-up. Each CTS is responsible for no more than two MDR-TB patients. Although CTSs are typically recruited and trained to focus on MDR-TB, they also play an important role in adherence support to HIV co-infected MDR-TB patients on ART. Core clinical decisions such as initiation, variation and monitoring of MDR-TB treatment and progress are left to formal facility-based HCWs. Box 2 illustrates the roles of CTSs.

Box 2: Roles of community treatment supporters

- DOT and injection administration
- Identifying and promptly reporting missed doses, possible side effects and medication running out to the community MDR-TB nurse using a mobile phone
- Accompanying the patient to all medical consultations
- ART adherence support
- Assisting the patient in producing monthly sputum samples
- Receiving the monthly drug kit and verifying that it is correct
- Screening household contacts for TB and referring them for diagnosis
- Providing education, counselling and emotional support to patients and their families

Source: MSF (2013)

1.3.6 Treatment support components

To compensate for their time and effort in supporting MDR-TB patients, CTSs receive a monetary incentive of ZAR500 (= US$33.54 [exchange rate on 23/11/2017]) per month during the IP. Due to their close proximity to the patients, CTSs mainly incur out-of-pocket travel costs accompanying their patient for the monthly outpatient review by the MDR-TB management team or in cases of emergency (MSF, 2013). With the cost of public transport to PHC facilities for monthly medical reviews identified as a major barrier to treatment access, MDR-TB patients receive a monthly financial incentive of ZAR700 (= US$46.98 [exchange rate on 23/11/2017]) to cater for travel expenses for their follow-up visits at the MDR-TB treating unit. Patients also receive counselling and food packs to improve treatment adherence. Psychosocial support is considered to be a key element of the community-based MDR-TB treatment armamentarium (MSF, 2013).

1.3.7 Infection prevention and control

The community-based strategy implemented a hierarchy of MDR-TB IPC and other adjunctive hand hygiene interventions to reduce the risk of transmission of infections between patients, CTSs and household members. Box 3 outlines the inter-connected

household IPC measures that community MDR-TB nurses and CTSs are meant to ensure are implemented.

Box 3: Household infection prevention and control measures

Early identification of vulnerable or infectious contacts:

- Screening household contacts for TB
- Carrying out home assessments prior to initiation of treatment or discharge from hospital to determine crowding, ventilation and the vulnerabilities of family members

Reducing the risk of transmission:

- Teaching patients and household members on proper cough etiquette: covering a cough with a bent elbow or tissue and disposing tissue into a bin
- Providing surgical facemasks to patients to wear in closed environments
- Minimising contact by separating the MDR-TB patient from household members in the home and, if practical, having the patient sleep in a separate room
- Building an additional single-room if there is no separate room to accommodate the patient
- Improving ventilation in the home (keeping doors and windows open during warm weather and adding additional windows in the patient's room)
- Providing N95 respirators to and educating CTSs on proper wearing of facemasks during contact with patients
- Ensuring adequate supply of soap and clean water for the CTS to wash hands
- Providing a puncture resistant sharps container for disposal of needle and syringes after administering an injection
- Education of CTSs on the procedure for accessing HIV PEP following needlestick injury

Source: MSF (2013)

The management of MDR-TB in Eswatini is on the cusp of a transformative change, with the NTCP considering adopting and extending the community-based MDR-TB management model of care to the remaining three regions (Eswatini Tuberculosis Technical Working Group [TWG], 2017). Scaling-up the community-based model of care requires an understanding of the clinical skills CTSs possess, opinions of key

stakeholders including patients themselves, and the cost-effectiveness of the strategy, none of which has been empirically investigated in Eswatini. Therefore, as far as could be ascertained, this is the first study to report on how task-shifting in this multifaceted patient-centred community-based MDR-TB programme can be a key accessory to increase access to MDR-TB services, address frontline HRH shortages, and contribute to the achievement of the national and global TB control and development targets critical for TB elimination.

1.4 Problem statement

Albeit informally, task-shifting of community-based MDR-TB management to LHWs has been practised in the Shiselweni region for more than a decade. Highly differentiated clinical tasks such as MDR-TB injection administration were delegated to CTSs whose scope of practice elsewhere did not conventionally include these responsibilities. Although the global opinion on task-shifting has changed recently, the MOH has been slow in formalising the strategy due to considerable institutional resistance to the expansion of the approach in the country (Dambisya & Matinhure, 2012; Rustagi, Manjate, Gloyd, John-Stewart, Micek, Gimbel et al., 2015; TWG, 2017; Baine, Kasangaki & Baine, 2018). Besides informal arrangements that allowed task-shifting, there is no overarching national policy or regulatory framework on the strategy in the context of the MDR-TB care or wider healthcare services. Consequently, some aspects of the task-shifting of MDR-TB care to CTSs are in violation of the country's current health and professional regulations, restricting the extent to which the strategy can be implemented and coordinated effectively at the national level (TWG, 2017).

A myriad of misconceptions on the concept of task-shifting exist (TWG, 2017). Wider discourses and debates among key stakeholders regarding the impact of task-shifting clinical tasks to CTSs on acceptability, patient safety, quality of care and feasibility have been extensive (TWG, 2017). However, there is a dearth of sound and timely context-specific empirical evidence to thoroughly understand the strategy and inform these discussions. Recommendations about the strategy have largely relied on expert opinion and programme reports.

Apart from that, patients' perspectives on the task-shifting strategy are not known. Patient care experiences often remain at the periphery during programme evaluation. There is also a gap in understanding key stakeholders' opinions and notions of the acceptability of task-shifting clinical tasks to CTSs, and if there are any discordant views across stakeholder groups. There is also a need for more evidence on the cost-effectiveness of the community-based strategy. Lastly, little is known on how the incorporation of CTSs in MDR-TB care could contribute to the achievement of national and global TB control and development targets.

1.5 Theoretical framework to assess task-shifting of community-based MDR-TB management

The present study considered the Capability, Opportunity, and Motivation Model of Behaviour (COM-B model) as its theoretical foundation to understand the underpinnings of task-shifting to CTSs within the community-based MDR-TB management strategy (see Figure 1).

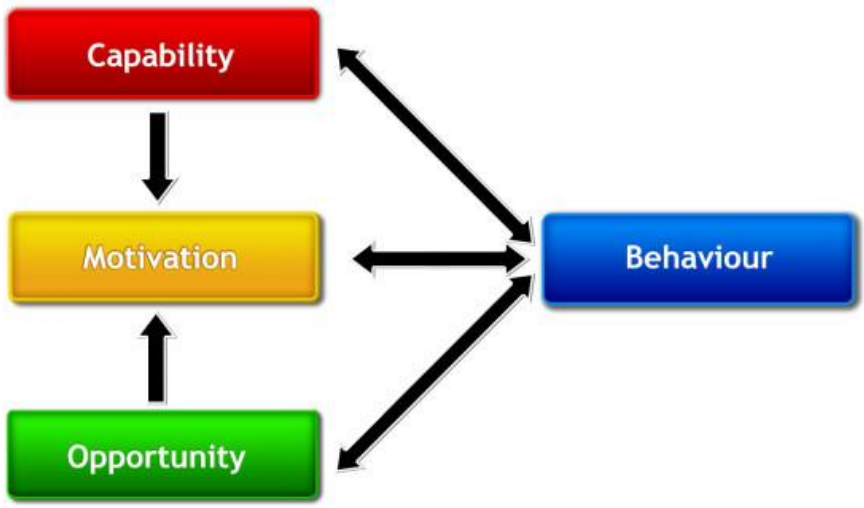


Figure 1: The COM-B system - a framework for understanding behaviour
Adapted from Michie, van Stralen and West (2011)

At its core, the COM-B model proposed by Michie, van Stralen and West (2011) theorises how three essential elements, namely capability, opportunity and motivation interact for a particular behaviour or intervention to occur. Capability

refers to the psychological or physical capacity an individual requires to engage in the intervention, and consists of reasoning, knowledge and skills. Opportunity includes all physical and social factors such as resources, and environmental and organisational context that exist outside the individual that shape or prompt the behaviour. Motivation refers to all brain processes that drive the desire to perform the behaviour and includes automatic (emotion) or reflective (beliefs, intentions) processes.

In addition to the COM-B model, behavioural experts developed the Theoretical Domains Framework (TDF) that builds on the constructs described in the COM-B model by simplifying a number of theories of behaviour change into 14 domains (Cane, O'Connor & Michie, 2012). These validated domains comprise of individual-level factors such as knowledge and skills (e.g. CTSs' knowledge of providing community-based MDR-TB services), social factors (e.g. social support), and environment and resource influences (e.g. task-shifting policies and regulation).

The COM-B model occupies the centre of the Behaviour Change Wheel (BCW), a handy tool primarily useful for developing health interventions (see Figure 2).

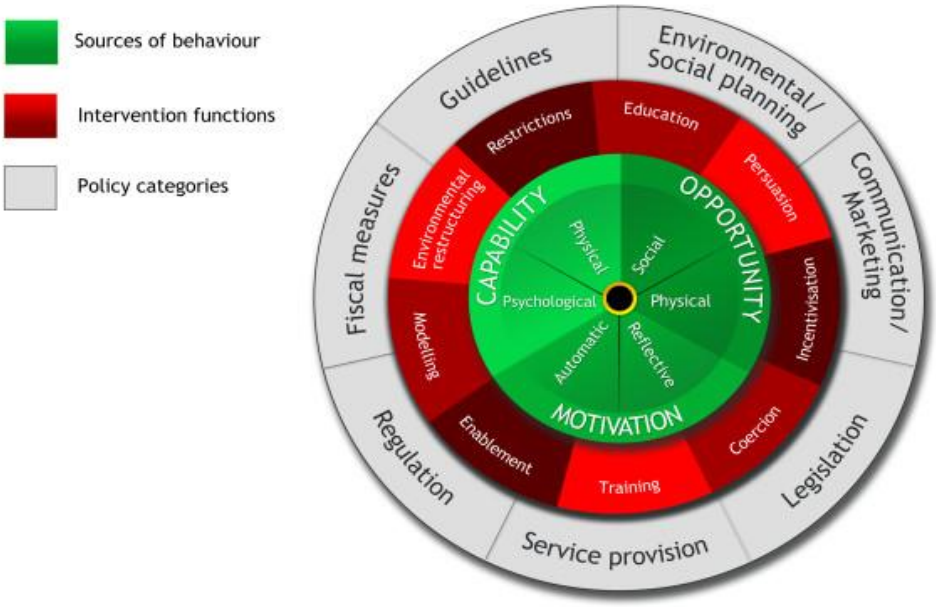


Figure 2: The Behaviour Change Wheel

Adapted from Michie et al. (2011)

The BCW theorises that the assessment of an intervention should include critical multilevel evaluation of the behaviour at the individual, interpersonal and system levels (Michie et al., 2011). The BCW has been successfully applied to a range of public health interventions in a number of contexts at both individual and organisational levels, including long-term hearing aid use (Barker, Atkins & de Lusignan, 2016), vaccination during pandemic flu outbreaks (Rubinstein, Marcu, Yardley & Michie, 2015) and treatment of diabetes (Murphy, Byrne, Zarabzadeh, Corrigan, Fahey & Smith, 2017). In the BCW, each of the three COM-B elements is connected to intervention functions and policy categories that form the second and outer layer of the wheel. Intervention functions relate to possible alternatives to address gaps in the COM-B model components, while policy categories focus on decision or legislative or service provision, undertaken by authorities that facilitate the implementation of the intervention.

Looking beyond the BCW, Michie, Atkins and West (2015) suggest that interventions are implemented within a social context and should be assessed based on six measures whose acronym is APEASE (acceptability, practicability, effectiveness, affordability, side-effects and equity). Table 1 provides a description of the APEASE criteria.

Table 1: The APEASE criteria

Criterion	Description	Example of question to answer
Affordability	An intervention is implemented within an acceptable budget to all beneficiaries	Can an intervention be delivered on budget at the scale intended?
Practicability	An intervention is delivered and implemented as planned	Is it feasible to implement an intervention as designed within the planned setting and human resources?
Effectiveness and cost-effectiveness	Effectiveness is the benefit of using an intervention to address a particular health problem under normal conditions. Cost-effectiveness ratio is the health benefits relative to costs of different interventions	How effective and cost-effective is an intervention in achieving intended results in the target population?

Criterion	Description	Example of question to answer
Acceptability	The extent to which an intervention is viewed to be appropriate by key stakeholders	What are the opinions of the different national- and local-level stakeholders including patients themselves?
Side-effects	The unwanted or unintended results of an intervention.	What are the unintended adverse or safety issues or effects?
Equity	An intervention may lessen or widen disparities between various potential beneficiaries.	How far does an intervention advantage some groups over others?

Source: Michie, Atkins and West (2014)

The design of the present study was therefore influenced by the thinking and framing behind the COM-B model in assessing the task-shifting of community-based MDR-TB management to CTSs in the Shiselweni region. To obtain an even more granular understanding, the TDF was used as the basis for evaluating the task-shifting of community-based MDR-TB management to CTSs in this context. The combined use of the COM-B model and the TDF provides provided a systematic method to consider and evaluate a wide range of factors in assessing task-shifting within the community-based MDR-TB management strategy. In applying the APEASE criteria, this study considered the most applicable subset of measures (acceptability, effectiveness, affordability and side effects) in its design.

The theoretical foundation that informed the present study considers individual-level factors as its methodological starting point and pays attention to individual-level factors such as knowledge and skills, attitudes and perceptions. In addition, it recognises a broad range of influences that exist outside the individual that may facilitate or impede implementation of the task-shifting strategy such as professional norms and standards, the policy and regulatory environment, and organisational context. However, on the basis of its exploratory approach, the current study only sought to conceptualise task-shifting through the COM-B model lens and was not intended to test, build or validate the constructs thereof regarding task-shifting.

1.6 Research questions

The study seeks to answer the following questions:

1) What is the level of knowledge, attitudes and practices (KAP) of CTSs in community-based MDR-TB management?
2) How do MDR-TB patients experience MDR-TB injection administration by CTSs? `
3) To what extent is the community-based MDR-TB management strategy acceptable to key stakeholders?
4) Is the community-based MDR-TB management model based on task-shifting of DOT and MDR-TB injection administration to CTSs in the Shiselweni region more cost-effective from a societal perspective compared to the clinic-based approach in the Lubombo region?

1.7 Aim and objectives

The main aim of this study was to assess the task-shifting of DOT and MDR-TB injection administration to CTSs within the existing infrastructure of the NTCP in the Shiselweni region of Eswatini.

The specific objectives of this study were to assess the:

1) KAP of CTSs on community-based MDR-TB management.
2) MDR-TB patients' satisfaction with the task-shifting strategy.
3) Acceptability of the task-shifting strategy to key stakeholders.
4) Cost-effectiveness of the community-based MDR-TB model of care in the Shiselweni region compared to the clinic-based strategy in the Lubombo region.

1.8 Rationale

The NTCP is currently considering expanding the task-shifting of DOT and MDR-TB injection administration to CTSs within the community-based model of care to the Manzini, Hhohho and Lubombo regions. With patient-centred care remaining the mainstay of the End TB Strategy, a key question, therefore, is whether the community-based MDR-TB management established in the Shiselweni region is acceptable, feasible and cost-effective. Despite gaining prominence on the global policy agenda, evidence is lacking on the acceptability and cost-effectiveness of

task-shifting to LHWs without a formal training background, specifically for tasks of a clinical and curative nature. Furthermore, assessment of community-based MDR-TB services has often been restricted to clinical outcomes without accounting for patients' satisfaction with care received.

A cost-effectiveness analysis from a societal perspective is needed to inform policymakers and programme managers in choosing an intervention that could be considered for scaling-up. The perspective is the point of view considered when choosing the type of costs and health benefits to include in a cost-effectiveness analysis (Drummond, Sculpher, Claxton, Stoddart & Torrance, 2015). Typical viewpoints are those of the health system (provider), patient or society. The societal perspective is the broadest and reflects an aggregate of all costs and benefits that affects the society as a whole, including those of the health system and patient. Decisions on what approaches to implement have largely been based on costs to the health system. Costs incurred by MDR-TB patients and their caregivers have often been overlooked, despite such costs being substantial. The overall societal costs, and not just the health system costs, were considered in assessing the costs and benefits of the community-based MDR-TB management strategy. Such evidence is required to support policy development, planning and budgeting processes at the national level.

1.9 Significance of the study

The process of scaling up the community-based model of MDR-TB care relies on a better understanding of the strategy as implemented in the Shiselweni region. The findings of this study will inform the development of a guiding and supportive national authoritative framework for the task-shifting of MDR-TB treatment to CTSs. Results from this study will also be used to inform recommendations to national and regional health administrators in the development of MDR-TB treatment guidelines, action plans and policies.

The study highlights whether or not the incorporation of LHWs in MDR-TB care could contribute to the achievement of national and global TB control and development targets. The findings of this study are of interest not just in Eswatini, but to other

resource-constrained countries where access to MDR-TB is a growing problem. As such, apart from the documented lessons from this assessment being shared widely, the study extends the present literature on the task-shifting of MDR-TB injection administration to CTSs in resource-limited settings like Eswatini.

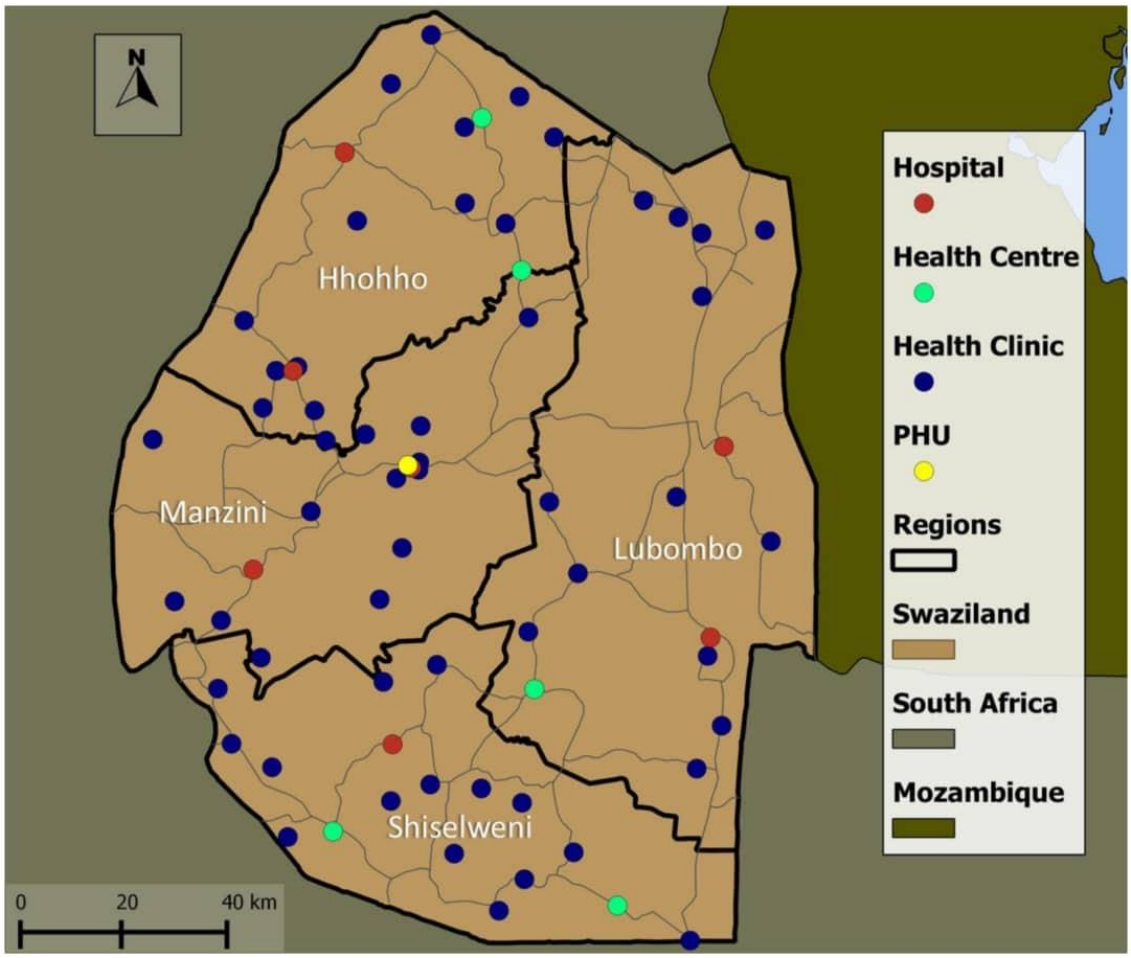
1.10 Study methods

The following section provides a concise overview of the general methodology employed in this study. The study drew on the COM-B model and TDF, and selected and applied appropriate research methods – qualitative, quantitative, mixed methods and economic evaluation – to explore each of the research questions and fulfil the research objectives. The individual articles (Chapters 3, 4, 5 and 6) contain a more detailed account of the methods applied.

1.101 Design and setting

The research followed a cross-sectional design. Figure 3 illustrates the geographical setting of the study – the Shiselweni and Lubombo regions of Eswatini.

Eswatini is a small land-locked country in Southern Africa with an estimated population of close to 1.1 million (Central Statistical Office [CSO], 2017). It is bordered in the north, south and west by South Africa and in the east by Mozambique. Eswatini has four administrative regions: Lubombo, Manzini, Hhohho and Shiselweni. These regions are further subdivided into 55 *tikundlas* (constituencies) and 360 chiefdoms and towns which share a similar SiSwati language and culture (CSO, 2017). With approximately 58.9% of the population living under the poverty line, Eswatini is classified as a LMIC (World Bank, 2019).



PHU: Public health unit

Figure 3: Map of Eswatini reflecting the study setting and health facilities

Source: MOH (2014a)

The study was conducted in the Shiselweni and Lubombo regions of Eswatini that form part of the country's four administrative regions. The study regions are predominantly rural and are characterised by low socio-economic indicators, with high rates of unemployment, child mortality and undernutrition, and life expectancy below 50 years (CSO, 2017; World Bank, 2019). MDR-TB prevalence across the two regions illustrates negligible dissimilarity in distribution (MOH, 2019). Transport facilities in rural areas are mostly poor, unreliable and expensive, with many non-paved roads. In the Lubombo region, over 48% of the population are unemployed compared to 62% in the Shiselweni region (CSO, 2017). With literacy rates of over 88%, there is relative parity in education across the two regions. Eswatini is facing a critical shortage of HCWs with a density of 1.40 nursing professionals per 1 000 population which is well below the WHO acceptable threshold of 2.28 nursing

professionals per 1 000 population (WHO, 2018b). The shortage also applies to other categories of skilled HCWs.

The Shiselweni region, with an estimated population of 204 111 in 2017 (CSO, 2017), has one hospital in Hlatikhulu and two large health centres in Nhlangano and Matsanjeni. These three main health facilities in the Shiselweni region support 18 smaller PHC clinics that collectively form part of the regional health network managed by the MOH. MDR-TB patients requiring hospitalisation are admitted at Nhlangano Rural Health Centre. The Lubombo region has an estimated population of about 212 531 and a health facility to population ratio of about 1 per 4 500 (CSO, 2017). Health facilities involved in MDR-TB care in the Lubombo region comprise of a mission hospital and a rural health centre that relate closely to the National TB Hospital in Manzini, the country's referral hospital for all forms of TB. DOT and outpatient injection administration is accessible at all the PHC facilities in the region.

1.10.2 Instrument development and pretesting

The study information sheets, informed consent forms and questionnaires were formulated in English before being translated into the local language (siSwati) by an experienced and qualified siSwati Grade 12 teacher (Appendix 1). The COM-B model and TDF guide informed the development of questionnaires and interview questions were formulated based on literature review. Prior to commencing data collection, all preliminary questionnaires and interview schedules were pre-tested on a total of 15 CTSs and MDR-TB patients who had provided or received MDR-TB injection more than 12 months prior to the study (exclusion criterion for participating in the study) to assess whether or not all questions were appropriate and understood by respondents. The information from the pre-testing was used to revise and improve the formulation of the questionnaires, interview schedule and focus group discussion (FGD) guide. An electronic data abstraction tool was developed to review medical records and collect data on costs and treatment outcomes of MDR-TB patients in the Shiselweni and Lubombo regions (Appendix 1.5).

1.10.3 Participants and sampling

Although theoretically it is possible to use a statistical formula to estimate the sample sizes, this study utilised the 'rule of thumb' method (Neuman, 2020). According to Neuman (2020), small populations of less than 1 000 would require large sampling ratios to achieve high accuracy. Given that the target population administering (n = 124) and receiving (n = 124) DOT and MDR-TB injections in the community-based management of MDR-TB implemented by MSF in the Shiselweni region is small, the entire population was included in the study to enhance accuracy. Table 2 shows the study participants and data sources utilised in this study.

Table 2: Study participants, sampling and data sources

Objective	Population group	No. of respondents	Population size	Inclusion criteria	Exclusion criteria	Instrument
Determining the KAP of CTSs on MDR-TB management	CTSs	82	124	Administered MDR-TB injections in the last 12 months	<1 month of injection administration experience	Questionnaire Appendix 1.1 Observation checklist Appendix 1.2
Determining MDR-TB patients' level of satisfaction with the task-shifting approach	MDR-TB patients	78	124	>1 month on injection therapy by a CTS	Severely ill and < 18 years of age	Questionnaire Appendix 1.3
Determining the acceptability of the task-shifting approach to key stakeholders	Policymakers, donor NGOs, professional regulatory institution, nursing academia, civil society and professional HCWs	10		Based on their leadership positions and/or programmatic significance		FGD guide Appendix 1.4
	CTSs	82	124	Administered MDR-TB injections in the last 12 months	<1 month of injection administration experience	Questionnaire Appendix 1.1

Objective	Population group	No. of respondents	Population size	Inclusion criteria	Exclusion criteria	Instrument
Determining health system, patient and caregiver costs during MDR-TB treatment	MDR-TB patients (Shiselweni and Lubombo regions) and their CTSs/caregivers	156	238	>1 month on injection therapy by a CTS	Severely ill and < 18 years of age	Questionnaire Appendix 1.3 Electronic medical records abstraction tool Appendix 1.5

CTSs: community treatment supporters; focus group discussion; HCWs: healthcare workers; KAP: knowledge, attitudes and practices; NGOs: non-governmental organisations

1.10.4 Recruitment of study participants

Three research assistants experienced in data collection and not involved in MDR-TB care were recruited for the study. The researcher held a two-day training workshop for the research assistants to update their MDR-TB knowledge and IPC practices, reviewing and mastering the content of the data collection instruments, and the procedure to obtain voluntary informed consent from respondents. The research assistants were stationed in private rooms within the MDR-TB treating health facilities.

All MDR-TB patients coming for their monthly review at the MDR-TB treating facility in the company of their CTS were approached by the community MDR-TB nurse and recruited into the survey. Before referral to the trained research assistants for more detailed information, MDR-TB nurses requested eligible MDR-TB patients and their accompanying CTS to participate in the study voluntarily at the end of consultation. Patients and CTSs consenting to participate in the study were accompanied to a separate room to be interviewed by a research assistant.

1.10.5 Data collection and analysis

Data was collected in May 2017 among a purposive sample of patients, CTSs and key stakeholders through face-to-face interviews, focus group discussion and data abstraction from medical records. The interviews were conducted at the health facilities that offered MDR-TB patient monthly medical reviews in the Shiselweni and Lubombo regions. The FGD was conducted in a hotel conference room to allow for private conversation without interruption. Data sources for costs and effectiveness of the community-based MDR-TB management strategy included primary usage data abstracted from patient medical records, central medical stores, expenditure and programme reports, vehicle logbooks, and face-to-face interviews with staff from the MOH and MSF. A detailed description of the data analysis employed is described in the respective articles (Chapters 3, 4, 5, and 6).

1.10.6 Ethical considerations

The carrying out of research relating to the use of human subjects revolves around issues of informed consent, duty of care, beneficence and “no harm” (World Medical Association, 2013). The following standards of ethics were employed to balance the tensions between risk and benefit that could arise from the study.

- **Authorisation and ethical clearance.** Ethical approval was obtained from the Health Sciences Research Ethics Committee (IRB00006240), University of Free State (Appendix 2.1) and the Eswatini Scientific and Ethics Committee (SEC) (Appendix 2.2). Authorisation of the study was granted by the NTCP (Appendix 3.1) and MSF (Appendix 3.2).
- **Confidentiality.** To ensure the maintenance of the participants’ confidentiality, no respondents’ names or other personal identifying information were collected on the questionnaires. Categorised values for age and time engaged in position for key stakeholders and CTSs were collected instead of specific values to enhance the anonymity of respondents. Completed questionnaires were safely secured in a locked cabinet in an office only accessible by the researcher. Access to data in the study database was restricted through the use of a password.
- **Privacy.** To ensure privacy and minimum interruption, interviews were carried out in private spaces within the health centres.
- **Informed consent.** MDR-TB patients and CTSs or other accompanying caregivers were requested to take part in the interview at the end of their consultation visit to ensure that they did not link participation in the study with their care or job security. Written informed consent was obtained from all participants prior to their participation. The research assistants presented the study information sheet and informed consent form attached to every questionnaire (Appendix 1.1, 1.3 and 1.4) to potential participants to read, and then answer any residual questions. Participants who agreed to take part in the study were provided with a copy of the study information sheet and informed consent form. In the case of less literate MDR-TB patients, the research assistants read and explained the consent form aloud in the local language (siSwati). The purpose of the study, its data-gathering procedures,

risks and benefits, the proposed duration of the interview, and the issue of confidentiality and data security were explained to the participants. They were informed that participation in the study was voluntary and of their right to withdraw if they were not comfortable in responding to any of the issues raised during the interview. Every participant was required to confirm understanding of the contents of the study information sheet and informed consent form prior to signing a copy confirming informed consent and voluntary participation in the study. Verbal informed consent was obtained from all key stakeholders prior to their participation in the FGD.

- **Sharing of recorded data and results of the research:** Recorded data was shared with the study promoters in anonymous form to advise analysis. The results of the research were reported in an aggregate form such that no individual patients, CTSs or stakeholders could be identified. The results of the research were also shared with MSF, the NTCP and the SEC. The research findings were also disseminated to patients and CTSs at research feedback meetings in the Shiselweni and Lubombo region. Findings were further submitted for publication in academic journal articles.
- **Beneficence.** There were no immediate or direct benefits that respondents received for participating in the study. No rewards were offered to induce participation. Participants who experienced discomfort during the interviews were given the option of discontinuing participation permanently without any penalty or prejudice. The interviewers received training on basic counselling to help them in identifying and initiating referrals for respondents who may have needed to see a psychologist. MDR-TB patients were assured that their participation or non-participation and responses would not affect their treatment care plan. CTS were assured that their participation or non-participation in the study was not linked to their continued engagement in the MDR-TB care programme. Research assistants were trained on IPC protocols during their interaction with participating MDR-TB patients.

1.11 Chapter outline

Chapter 2 reviews the literature on task-shifting and community-based MDR-TB management.

Reader's orientation to the thesis

In fulfilment of the regulations of the University of the Free State, the current research is presented in the form of four articles. Despite being based on a single study, each article (here presented as a chapter) has been submitted in a journal specific style for publication/peer review and should be considered independently. Two of the four articles have already been published, while the remainder are in the peer-review process.

Chapters 3 to 6 are the main results sections comprising of published and submitted research articles. The contents of each chapter are outlined below:

- The first article (Chapter 3) – *'Knowledge, attitudes and practices of community treatment supporters administering multidrug-resistant tuberculosis injections: a cross-sectional study in rural Eswatini (formerly Swaziland)'* – assessed CTSs' KAP regarding community-based MDR-TB management. The manuscript has been submitted to the *Journal of Infections in Developing Countries*.
- The second article (Chapter 4) – *'Patient satisfaction with multidrug-resistant tuberculosis injection administration by community treatment supporters: a cross-sectional study in rural Eswatini'* – reports MDR-TB patients' level of satisfaction with receiving community-based MDR-TB care from CTSs. This article was published in the *African Journal of Primary Health Care & Family Medicine,* 12(1), a2257.
- The third article (Chapter 5) – *'Task-shifting directly observed treatment and multidrug-resistant tuberculosis injection administration to lay health workers: stakeholder perceptions in rural Eswatini'* – assessed the perceptions of task-shifting DOT supervision and administration of intramuscular MDR-TB injections to LHWs by multiple stakeholders including representatives from the

MOH, donor organisations, professional regulatory institutions, nursing academia, civil society, HCWs and CTSs. This article has been published by *BMC Human Resources for Health*.

- The fourth article (Chapter 6) – *'Cost-effectiveness of ambulatory clinic- and home-based multidrug-resistant tuberculosis management models in Eswatini'* – compared the cost-effectiveness of the community-based management of MDR-TB in patients' homes using CTSs in the Shiselweni region to the clinic-based model of care in the Lubombo region. The manuscript has been submitted to *BMC Infectious Diseases*.

Chapter 7 contains the discussion summarising the interpretation and evaluation of the main findings of the thesis, suggested priority research areas and research limitations. This chapter also provides future perspectives regarding community-based MDR-TB management prior to providing concluding remarks. Important additional materials [i.e. the patient consent letters, interview schedules, electronic data abstraction tool (Appendix 1), ethical clearance letters (Appendix 2), and authorisation letters (Appendix 3)] are presented as appendices.

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Chapter 2: Literature review

This chapter reviews the prominent literature on the concept of task-shifting including characterising the task-shifting process, identifying the main trends, benefits and risks of, and enabling conditions for, the strategy. The chapter further provides a brief synopsis of the relevant literature on the definitions and key concepts of CHWs and their role in community-based MDR-TB management programmes. The review concludes by exploring the cost-effectiveness of community-based MDR-TB management and social protection measures for MDR-TB patients and their households.

2.1 Task-shifting

Globally, task-shifting has been widely endorsed as a remedy to increase access to healthcare services and address professional HRH shortages (WHO, 2008). Task-shifting is considered to be:

> "[t]he rational re-distribution of tasks among health workforce teams. Specific tasks are moved, where appropriate, from highly qualified health workers to health workers who have fewer qualifications in order to make more efficient use of the available human resources for health." (WHO, 2008: 81)

Tasks are reassigned or transferred to existing or new lower cadres of trained HCWs whose scope of practice originally did not include these roles (WHO, 2008; Gilbert, 2013; Crowley & Mayers, 2015). This lower cadre of workers is usually more conveniently and willingly available, and ideally receive shorter and narrowly-customised specific skills-based training and appropriate supervision (WHO, 2007; Kredo, Adeniyi, Bateganya & Pienaar, 2014).

Task-shifting is becoming more commonly referred to as task-sharing, a change aimed at highlighting that tasks are not taken away from one category of HCWs and given to another, but rather that an additional range of health workers who can deliver services is expanded (WHO, 2017). With task-sharing, identified tasks are expanded to other cadres while the usual health service providers retain the

responsibilities. Task-sharing is used to underscore the partial or entire performance of the entire clinical task among teams of different levels of HCWs. Task-shifting and task-sharing approaches reflect a similar intention to include HCWs who ordinarily lack competencies to deliver specific tasks in order to increase access to health care services (WHO, 2017).

Task-shifting can occur in diverse forms, ranging from shifting tasks from professional HCWs to patients and their caregivers, to machines, and to other HCWs. The WHO recognises the following four types of task-shifting (see Figure 1):

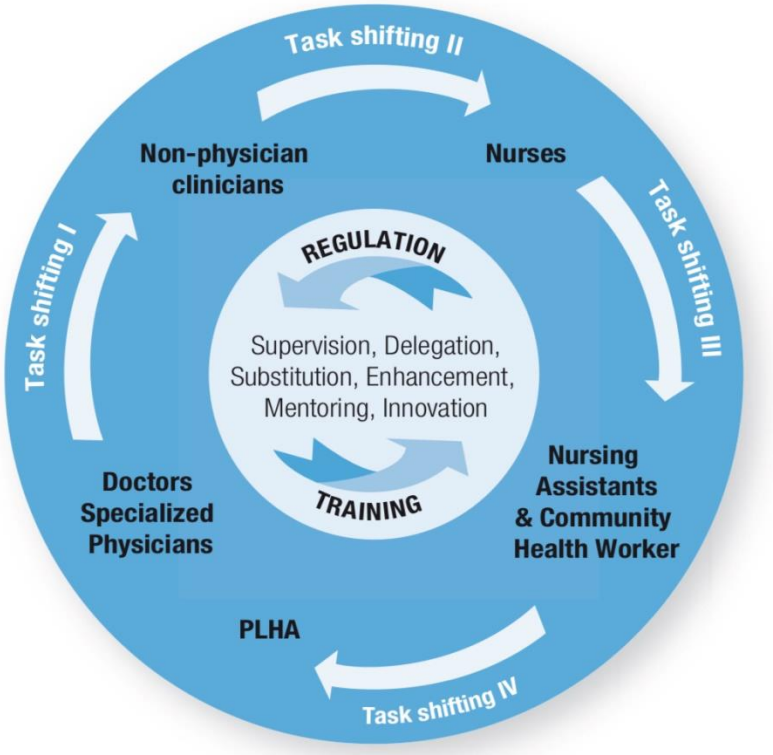

Figure 1: The four types of task-shifting in HIV care recommended by the World Health Organization

Source: WHO (2007: 4)

Based on this process of task-shifting HIV services, the scope of practice of HCWs in the first three levels – non-physician clinicians, nurses and midwives, and CHWs – is expanded to cover some roles of senior cadres. Box 1 illustrates the broad categorisation of the task-shifting practice.

Box 1: Types of task-shifting in HIV care

1. Type I: clinical tasks are shifted from doctors to non-physician clinicians (clinical officers, medical assistants).
2. Type II: clinical tasks are delegated from non-physician clinicians to nurses.
3. Type III: non-clinical tasks are shifted from nurses to nursing assistants and LHWs. These roles include counselling, point-of-care testing, adherence support, defaulter tracing and medication refill.
4. Type IV: certain aspects of care are delegated from LHWs to people living with HIV for self-management.

Source: WHO (2008: 81)

Task-shifting has been practised in many forms and for many functions across sub-Saharan Africa for decades (WHO, 2008; Crowley & Mayers, 2015; Mundeva, Snyder, Ngilangwa & Kaida, 2018). There is also substantial evidence of the increasing use of this practice in a number of high-income countries (Maier & Aiken, 2016; Taylor, Henshall, Goodwin & Kenyon, 2018). In Eswatini, the task-shifting practice is not a new concept, particularly in TB control (Kliner, Mamvura, Ndwandwe, Busulwa, Welfare, Richardson et al., 2015). Owing to the growing TB treatment access burden, task-shifting has become a reality in the management of all forms of TB. A number of studies and programme reports in Eswatini have described successes achieved through task-shifting, including a fall in the number of TB treatment defaulters (Turashvili et al., 2014; Kliner et al., 2015) and increased long-term retention in HIV care (Root & Whiteside, 2013).

Despite task-shifting being permissible, the country does not have an official policy framework to regulate the practice. Existing NTCP strategic plans and MDR-TB treatment guidelines only provide for task-shifting of certain professional nurses' responsibilities such as DOT supervision and TB treatment defaulter tracing to family members, neighbours or former TB patients as part of their guiding principles. Task-shifting is well described in contexts of HIV care, with the WHO providing limited or no comprehensive guidelines for its adoption in other disease conditions (WHO, 2008). Although the task-shifting of clinical tasks of a curative nature (injection administration) to LHWs is novel in MDR-TB control, in extant literature, such

innovations are not entirely new especially in developing countries (Malarcher, Meirik, Lebetkin, Shah, Spieler & Stanback, 2011; Glenton, Colvin, Carlsen, Swartz, Lewin, Noyes et al., 2013). The section below provides an overview of the global experience in task-shifting injection administration to LHWs.

2.2 Trends and acceptability of task-shifting injection administration to lay health workers

The history of public health in rural and resource-limited settings is filled with empirical evidence demonstrating the successful simplification and substitution of clinic-based management of serious neonatal and childhood infections by home-based treatment using CHWs (India – Bang, Bang, Stoll, Baitule, Reddy & Deshmukh, 2005; Bangladesh – Baqui, Arifeen, Williams, Ahmed, Mannan, Rahman et al., 2009; Nepal – Khanal, Sharma, Vijay Singh, Dawson, Houston, Khadka et al., 2011; Global – Glenton et al., 2013). Compared to a number of other costly treatments, such task-shifting approaches have been important in reducing neonatal mortality (Bang et al., 2005; Baqui et al., 2009; Khanal et al., 2011; Glenton et al., 2013). Domiciliary delivery of injectable-based contraception by CHWs is another example of such effective innovations (Mozambique – Jacinto, Mobaracaly, Ustáb, Bique, Blazer, Weidert et al., 2016; Ethiopia – Weidert, Gessessew, Bell, Godefay & Prata, 2017; Burkina Faso and Uganda – MacLachlan, Atuyambe, Millogo, Guiella, Yaro, Kasasa et al., 2018; global – Malarcher et al., 2011). The use of injectable-based medication by non-HCWs has also long been practised by diabetic patients in self-administration of insulin medication (Gerada, Mengistu, Demessie, Fantahun & Gebrekirstos, 2017).

Numerous studies over the past two decades have provided important insights into the safety, acceptability and feasibility of using LHWs to administer injections (Bang et al., 2005; Baqui et al., 2009; Glenton et al., 2013; Jacinto et al., 2016; Weidert et al., 2017; MacLachlan et al., 2018). Table 1 summarises the experiences of injection clients, CHWs, professional facility-based HCWs and/or programme managers on community-based provision of injections by LHWs in resource-limited settings. In most instances, the CHWs were already trained in other community health activities

prior to the pilot study, and the tasks of administering injectable medicines were added to their existing responsibilities.

Table 1: Summary of reviewed studies utilising CHWs to provide injections

Source (setting)	N	Study location	Study design	Population and study period	Intervention	Main outcome
India: Bang, Bang, Stoll, Baitule, Reddy and Deshmukh (2005)	5 796	39 villages in Gadchiroli	Controlled field trial	VHWs 1996 to 2003	Identifying sepsis and administering intramuscular injection and an oral antibiotic	VHWs were effective in treating neonatal sepsis and reducing case fatality. Gave unnecessary treatment to 4.7% of treated neonates
Uganda: Stanback, Mbonye and Bekiita (2007)	945 (I: 449; C: 328)	Health units in Nakasongola district	Non-randomised community trial	CHWs March to November 2004	Compared the safety and quality of contraceptive injections by CHWs and clinic-based nurses	Trained CHWs provided safe and acceptable contraceptive injections
Bangladesh: Baqui, Arifeen, Williams, Ahmed, Mannan, Rahman et al. (2009)	8474	Rural northeast Bangladesh	Cluster randomised controlled trial	CHWs 2004 to 2005	Diagnosis of severe disease in neonates and treating with injectable antibiotics.	Home treatment of very severe disease in neonates by CHWs was effective and acceptable
Nepal: Khanal, Sharma, Vijay Singh, Dawson, Houston, Khadka et al. (2011)	1 526	Village Development Committees in Morang district	Longitudinal study	CHWs 2005 to 2007	Identifying and treating possible severe bacterial infection in neonates and young infants	CHWs successfully diagnosed and administered appropriate antibiotic injection treatment
Uganda: Krueger, Akol, Wamala and Brunie (2011)		Bugiri and Busia districts	Case study	CHWs 2008 to 2009	Case study of community-based distribution of contraceptive injection by CHWs	Clients preferred initiating and continuing contraceptive injections from CHWs compared to facility-based health service points

Source (setting)	N	Study location	Study design	Population and study period	Intervention	Main outcome
Ethiopia: Prata, Gessessew, Cartwright and Fraser (2011)	1 062 (I: 622; C: 440)	Rural region of Ethiopia	Prospective intervention study	CBRHAs and HEWs 2008 to 2009	Injectable contraceptives administered by CBRHAs and HEWs at health units	Provision of injectable contraceptives by CBRHAs provided safe and acceptable injectable contraceptives, similar to HEWs at health units. Clients of CBRHAs reported a high contraceptive continuation rate
Nepal: Coffey, Sharma, Gargi, Neupane, Dawson and Pradhan (2012)	45	Village Development Committees in Morang district	Intervention study	FCHVs 2009	FCHVs managing sick new-borns at home using oral and prefilled injection antibiotics	Administration of antibiotic injections by FCHVs was highly satisfactory and acceptable to caretakers of sick young infants and was associated with a high treatment completion rate. FCHVs were concerned about the potential risk of liability in case of adverse events
Madagascar: Hoke, Wheeler, Lynd, Green, Razafindravony, Rasamihajamanana et al. (2012)	61	Anosy and Alaotora Mangoro regions	Cross-sectional study	CBD agents 2007	Provision of injectable contraceptives by CBD agents	CBD agents were competent in provision of injectable contraceptives. Clients were satisfied, had high re-injection rates and few reported side effects

Source (setting)	N	Study location	Study design	Population and study period	Intervention	Main outcome
Zambia: Chin-Quee, Bratt, Malkin, Nduna, Otterness, Jumbe et al. (2013)	40	Mumbwa and Luangwa districts	Cross-sectional study	CHWs 2009 to 2011	CHWs providing injectable contraceptives	Provision of injectable contraceptives by CHWs was safe, acceptable, and feasible
Kenya: Olawo, Bashir, Solomon, Stanback, Ndugga and Malonza (2013)	31	Tharaka district	Cohort study	CHWs 2009 to 2010	CHWs providing injectable contraceptives	Injectable contraception provision by CHWs was safe, acceptable, and feasible
Mozambique: Jacinto, Mobaracaly, Ustáb, Bique, Blazer, Weidert et al. (2016)	1 432	Chiure and Montepuez districts	Longitudinal study	TBAs and APEs 2014 to 2015	Community-based administration of injectable contraceptives	Provision of injectable contraceptives by TBAs and APEs was safe, effective, and acceptable
Ethiopia: Weidert, Gessessew, Bell, Godefay and Prata (2017)	8 604	Central and southern zones of Tigray	Prospective intervention study	CHWs 2011 to 2014	Combination of community-based distribution of injectable contraceptives with social marketing	CHWs improved access and reduced barriers to injectable contraceptives
Burkina Faso and Uganda: MacLachlan, Atuyambe, Millogo, Guiella, Yaro, Kasasa et al. (2018)		4 regions in Burkina Faso and 6 districts in Uganda	Longitudinal study	VHTs and facility-based health workers 2015 to 2017	Injection-based contraceptives delivered by facility-based health workers and VHTs	Uptake of injectable contraceptives was superior with VHTs compared with facility-based provision

APE: *agente polivalentes elementares* (elementary multipurpose agent); C: control; CBD: community-based distribution; CBRHA: community-based reproductive health agent; CHW: community health worker; FCHV: female community health volunteer; HEW: health extension worker; I: intervention; N: number ; TBA: traditional birth attendant; VHW: village health worker; VHT: village health team

The safety and acceptability of using LHWs to provide injections in hard-to-reach rural areas is consistent across the included studies and concordant with conclusions from two systematic reviews assessing perceptions of CHW programmes for newborn health (Glenton et al., 2013) and family planning (Malarcher et al., 2011). There is sound evidence that community-based interventions that utilise trained LHWs in injection administration are an effective platform for extending healthcare delivery, improving health-seeking behaviour and optimising treatment outcomes (Bang et al., 2005; Baqui et al., 2009; Stanback, Mbonye & Bekiita, 2007; Khanal et al., 2011; Malarcher et al., 2011).

2.3 Potential risks and benefits of task-shifting

Whilst task-shifting may be inevitable in the context of patients staying in hard-to-reach areas without healthcare facilities in their vicinity, in many ways, the strategy is challenging to implement. The successful scale up of healthcare services in resource-limited settings is firmly rooted on decentralisation of care to PHC facilities and communities, nearer to patients for whom treatment may be inaccessible (Sharp, Riches, Mims, Ntshalintshali, McConalogue, Southworth et al., 2020). Although decentralisation theoretically enables more patients to access care, it also involves patients receiving care in settings with fewer resources and from different care providers, often with lesser training (WHO, 2008; Kredo et al., 2014; Crowley & Mayers, 2015). Consequently, this has raised a unique set of questions and varied views about task-shifting among stakeholders (Dambisya & Matinhure, 2012; Rustagii et al., 2015; Baine et al., 2018).

Crowley and Mayers (2015), in an exhaustive overview of the scientific evidence on task-shifting trends in HIV treatment in Africa, critically reviewed and appraised the longstanding and contradicting attitudes towards task-shifting (Table 2).

Table 2: Arguments for and against task-shifting

Arguments for task-shifting	Arguments against task-shifting
Rational distribution of tasks in care teams. New cadres perform additional tasks (e.g. defaulter tracing), which will improve the quality of patient care.	Delegation of tasks to already overburdened health workers.
Expanded roles lead to empowerment.	Lowering the required level of competence promotes deprofessionalisation.
Job creation and career progression.	No job description, performance framework or increase in remuneration.
Increased community access to basic health care and improved community engagement. Efficiency of services improves patient satisfaction.	A decrease in quality of care. Infringement of the rights of the community to receive care from skilled health workers.
Increased cost effectiveness (increasing the number of services provided at a given quality and cost). Alleviate skill-mix imbalances.	Decisions are based on economic and budget constraints rather than on actual health worker shortages. Hidden costs associated with training and supervision.
Only a basic level of training, focused on specific skills, is needed. Some tasks require only focused training.	Comprehensive care requires advanced education, professionalism and ethics. Roles and tasks are continually evolving, requiring ongoing training.
A task-oriented approach improves efficiency of care.	A task-oriented approach causes fragmentation of care.
Ethical responsibility to adapt to the needs of the community and provide equitable access to health care.	Ethical responsibility to protect the community and HCWs from harm.

Adapted from Crowley and Mayers (2015)

Based on vivid examples in practice, task-shifting is documented as cost-effective in an HIV intervention in Zambia (Simbaya & Moyer, 2013), to increase patient satisfaction in Eswatini (Peresu, Heunis, Kigozi & De Graeve, 2020) and Ethiopia (Asfaw, Dominis, Palen, Wong, Bekele, Kebede et al., 2014), and to be acceptable to HCWs in Mozambique (Rustagi et al., 2015). In Kenya, an improvement in quality of HIV care was attributed to task-shifting (Rabkin, Lamb, Osakwe, Mwangi, El-Sadr & Michaels-Strasser, 2017).

Those in favour of task-shifting view the strategy as a solution to the dual burden of limited access to healthcare services and shortage of professional HRH in the seldom accessible clinics in resource-constrained settings. In Kenya (Ong'ang'o, Mwachari, Kipruto & Karanja, 2014) and Eswatini (Peresu et al., 2020), inclusion of lay people in service provision through task-shifting improved the acceptance of medical services by the affected population. In the Kenyan study, the role of CHWs in improving TB treatment adherence was valued and accepted by both healthcare facility personnel and the community. A systematic review of the effectiveness of

using CHWs in the prevention and treatment of TB found that community-based platforms empowered communities to participate in addressing their own problems and enhanced trust that is essential in maximising adherence to lengthy TB treatment regimens (Arshad, Salam, Lassi, Das, Naqvi & Bhutta, 2014). Community-based interventions also raise community awareness about TB that is crucial in changing attitudes and stigma towards patients (Sommerland, Wouters, Mitchell, Ngicho, Redwood, Masquillier et al., 2017).

Critics have argued that task-shifting overlooks ethical, patient safety and quality of care constraints associated with delegating tasks to lesser-trained non-traditional cadres (Dambisya & Matinhure, 2012; Crowley & Mayers, 2015; Rustagi et al., 2015; Baine et al., 2018). In previous studies on task-shifting in Uganda and Mozambique, the delegation of clinical care and curative tasks to CHWs beyond the more traditional clinic-based setting was perceived to result in unclear lines of accountability, inadequate supportive supervision and tension between expanding the quantity and assuring the quality of healthcare service provision (Dambisya & Matinhure, 2012; Crowley & Mayers, 2015; Rustagi et al., 2015; Baine et al., 2018).

Similarly, in Eswatini, stakeholders were not familiar with the skills LHWs possessed and voiced fears regarding issues of accountability and medical liability due to malpractice concerns about CTSs overstepping their responsibilities resulting in harm to MDR-TB patients (TWG, 2017). Some studies have argued that task-shifting has come to be seen as a ‘magic bullet’ that is uncritically promoted at the expense of training more and retaining professional HCWs (Munga, Kilima, Mutalemwa, Kisoka & Malecela, 2012; Baine et al., 2018).

2.4 Acceptability of task-shifting to professional healthcare workers

Besides improving access to care, expanding the roles of LHWs through task-shifting may be viewed by professional HCWs as lessening their burden of tasks (Crowley & Mayers, 2015). In Mozambique, clinicians were more likely to support task-shifting than policymakers and programme managers (Rustagi et al., 2015). Studies have reported that frontline HCWs with higher levels of education are more likely to accept

task-shifting if they view the roles delegated from them to lower cadres to be repetitive and less attractive (WHO, 2012).

In South Africa, some HCWs expressed concern over the encroachment upon their professional boundaries when their tasks are performed by LHWs (Gilbert, 2013). By delegating their roles to lower cadres, some professional HCWs argue that the practice de-professionalises their profession (Gilbert, 2013). These findings are consistent with those of another study conducted in South Africa; Schneider, Hlophe and Van Rensburg (2008) reported that nurses objected to the idea of LHWs dressing in uniforms in an effort to preserve professional boundaries. Previous studies (Lanktree, Corluka, Cohen & Larocque, 2014; Zuber, McCarthy, Verani, Msidi & Johnson, 2014) and the WHO (2008) have suggested that the long-term success of task-shifting hinges on investment in policy, regulation, pre-service education, financial commitment, reorganisation of health teams, clear scopes of practice, recognition and simplified guidelines.

2.5 Policy and regulatory environment

Although global opinions and policies about task-shifting have evolved over the years, the legal status of the strategy differs widely across countries. In many countries, changes in front-line practice often precede policy development. Previous research has identified a dearth of policies and regulations as a potential barrier to task-shifting (Dambisya & Matinhure, 2012; Baine & Kasangaki, 2014; Rustagi et al., 2015). In the absence of a policy, there is no legal indemnity for CHWs if they practice outside of their scope of work. A Ugandan study on task-shifting, highlighted the need for clear policy and guidelines to regulate task-shifting and protect those who carry out delegated tasks (Dambisya & Matinhure, 2012). Thus, a conducive and enabling policy environment is likely to make task-shifting successful and sustainable, as LHWs who assume added tasks and patients receiving their services will feel protected.

The importance of a conducive policy and regulatory environment to support task-shifting cannot be overstated. Professional practice regulations are drawn from policy decisions approved by legislature. Regulatory frameworks are typically useful

in ensuring adherence to a minimum set of practice standards, in particular, legal, quality of work and ethical issues related to CHWs in their expanded new roles (Crowley & Mayers, 2015; Mundeva et al., 2018). Where lower cadres perform the work of more senior personnel, clear regulation frameworks that set out their scope of practice, standards of training and codes of conduct should be in place (Mundeva et al., 2018). CHWs are expected to undertake new roles and deliver services within the context of these established standards and practices. LHWs in Kenya felt proud of their work if they were supervised, supported and linked to a recognised body in the process of service delivery to the community (Ochieng, Akunja, Edwards, Mombo, Marende & Kaseje, 2014). Thereupon, in Malawi, without appropriate training, a supportive environment and clearly defined roles, LHWs felt confused about their responsibilities (Smith, Deveridge, Berman, Negin, Mwambene, Chingaipe et al., 2014).

Box 2 summarises some of the questions that policymakers should consider when developing a task-shifting policy to ensure a seamless integration of LHWs into the public health system in practice.

Box 2: Aspects to be addressed by a task-shifting policy

- Who can delegate tasks, what responsibilities can be delegated, and what are the reasons for task-shifting (e.g., to expand the reach of services, to fill gaps of professional HRH)?
- Who can undertake the tasks, what setting can it be undertaken, and under what circumstances (e.g., skills, type of patients, context)?
- How are the roles performed (e.g., any guidelines or procedures)?
- What training is required, who will conduct the training, and how will it be conducted?
- How will competence be assessed and certified?
- What are the arrangements for ongoing training?

Source: Baine and Kasangaki (2014)

The development of enabling policies to support task-shifting should be a product of extensive consultation and consensus building with a wide range of stakeholders –

policymakers, regulatory institutions, professional bodies, implementing partners, and communities themselves (WHO, 2008; Baine & Kasangaki, 2014; Baine et al., 2018). A WHO-commissioned study on task-shifting identified the need for full and open consultation that engages the broad range of stakeholders at the country level for the successful implementation of task-shifting (WHO, 2008). Opinions of stakeholders on task-shifting may be influenced by the extent to which they are engaged. For example, in the 1970s, the regulatory body of the Medical and Nursing Council of Malawi refused to recognise the functions of the newly government-created CHWs due to inadequate consultation (WHO, 2008). However, following proper consultation, the same council approved the expansion of the scope of practice of non-physician clinicians and nurses to prescribe ART. Elsewhere, in Ethiopia, prior consultation with the regulatory bodies paved way for the successful establishment of CHWs within the civil service (WHO, 2008).

2.6 Training and competency assessment

A recent study in Uganda revealed that most health policymakers and managers considered task-shifting to be unacceptable as they questioned the competency of the lower cadres, especially in circumstances where there is inadequate support and supervision (Baine et al., 2018). The apprehension expressed by policymakers and managers is similar to that from two studies conducted in Mozambique (Rustagi et al., 2015) and Zambia (Ferrinho, Sidat, Goma & Dussault, 2012). In both studies, task-shifting was perceived to expose staff, management and patients to risks, even though the fear was mostly centred on lack of necessary resources and a supportive environment.

For task-shifting to succeed as a viable solution for improving healthcare coverage, the WHO recommends the establishment of competency-based training, accreditation and certification programmes for the newly 'skilled-up' CHWs (WHO, 2008). Recent studies suggest the need to engage professional bodies and training institutions in the development and delivery of teaching resources for the new cadres (Crowley & Mayers, 2015). A lack of standardised training and certification processes for LHWs may pose challenges in integrating them into formal public health systems due, in part, to a general lack of understanding among key

stakeholders about the skills these new cadres possess (Crowley & Mayers, 2015; Rustagi et al., 2015). Competency-based education and training can facilitate understanding among stakeholders on how the role of CHWs fits into the clinical care workflow and provides assurance that they have completed a standardised set of essential competencies linked to their new roles. Ultimately, undergoing a more standardised training, certification and accreditation process may also help broaden employment and career opportunities for CHWs due to the possible transferability of their basic skill set among settings (Dambisya & Matinhure, 2012; Crowley & Mayers, 2015).

2.7 Supervision support

In Kenya, lack of sufficient mentoring and clinical supervision was a major limitation to the delivery of quality services by CHWs (Selke, Kimaiyo, Sidle, Vedanthan, Tierney, Shen et al., 2014). Unfortunately, in most instances in Africa, the HCWs with the necessary knowledge and skills vital for supportive supervision are already experiencing heavy work overloads (Crowley & Mayers, 2015). Consequently, in countries such as Tanzania (Munga et al., 2012), Malawi (Smith et al., 2014) and Uganda (Baine & Kasangaki, 2014) tasks were often delegated to lower cadres without appropriate supportive supervision. Obstacles that often undermine adequate supervision stem from multiple levels of the health system, ranging from poor coordination, increasing supervision workload, limited professional development for supervisors, insufficient time for other non-supervision activities, lack of motivation, and logistical issues to travel to patients' homes (Rowe, Onikpo, Lama & Deming, 2010; Hill, Dumbaugh, Benton, Kallander, Strachan, ten Asbroek et al., 2014).

There is a consensus among social scientists that supervision is a key enabler for improving the performance of CHWs, with numerous studies linking certain supervision practices such as audit with feedback and improved CHW compliance to clinical guidelines (Bosch-Capblanch & Garner, 2008; Kok, Vallières, Tulloch, Kumar, Kea, Karuga et al., 2018). Previous research has shown that CHWs are prompted to change their practice when provided with feedback indicating that their clinical performance does not match expectation (Hill et al., 2014; Kok et al., 2018).

When provided adequately, supervision can help in setting clear expectations; offer motivation, training and job satisfaction; monitor performance; model appropriate practices; and engender skills in problem-solving (Kok, Kane, Tulloch, Ormel, Theobald, Dieleman et al., 2015; Kok et al., 2018).

2.8 Compensation for community health workers

Despite strong research evidence demonstrating the effectiveness of CHWs in performing delegated tasks of professional HCWs, CHWs hardly receive appropriate recognition and status (Gilbert, 2013). In recent times, researchers have examined the package of incentives that influence the motivation and performance of CHWs (Agarwal, Anaba, Abuya, Kintu, Casseus, Hossain et al., 2019; Ormel, Kok, Kane, Ahmed, Chikaphupha, Rashid et al., 2019). Both monetary and non-monetary incentives, individually and in combination, have consistently been found to be associated with improved CHW motivation (Daniels, Odendaal, Nkonki, Hongoro, Colvin & Lewin, 2014; Agarwal et al., 2019; Ormel et al., 2019). Monetary incentives vary from monthly remuneration for those formally employed to allowances for volunteers. Non-monetary incentives comprise of uniforms, backpacks, free and preferential medical treatment, and availability of new career paths (Kok, Dieleman, Taegtmeyer, Broerse, Kane, Ormel et al., 2015; Agarwal et al, 2019).

Some of the disquiets about task-shifting are foremost grounded in apprehensions about possible exploitation of CHWs (Mundeva et al., 2018). In some settings, CHWs are compensated for their services and integrated into the formal health system, while in other countries, they work on a voluntary basis at the community level (Crowley & Mayers, 2015; Mundeva et al., 2018). The recent WHO guidelines on CHW programme support acknowledge the need for CHWs to be compensated for their services (WHO, 2018). Yet others have questioned the effectiveness of monetary incentives, arguing that compensation may erode the spirit of volunteerism or undermine the commitment and relationships CHWs have with their communities (Scott & Shanker, 2010; Schuster, de Sousa O, Rivera, Olson, Pinault, Young et al., 2016). CHWs are also at an increased likelihood of experiencing other unfair employment practices comprising of inadequate training and poorly explained roles, causing tension with higher-trained HCWs (Mundeva et al., 2018).

The provision of incentives alone does not always guarantee improved performance of CHWs as expected. Collectively, studies over time have explicitly outlined a number of enabling factors that are also essential for improving the performance of CHWs (Lehmann & Sanders, 2007; Kok et al., 2015; Ormel et al., 2019). Availability of resources such as medical supplies, adequate supportive-oriented supervision with constructive feedback, ongoing training, and career development opportunities are some of the identified job enablers (Hill et al., 2014; Crowley & Mayers, 2015; Kok et al., 2015). Several other authors have lent support to this, also demonstrating that in instances where one of these job enablers is perceived to be absent or suboptimal, the performance of CHWs is often impeded (Mpembeni, Bhatnagar, LeFevre, Chitama, Urassa, Kilewo et al., 2015; Naimoli, Perry, Townsend, Frymus & McCaffery, 2015; Ormel et al., 2019). In Malawi, regular peer-based support for the newly 'skilled-up' cadres and their mentors was found to be a key contributory factor for the success of task-shifting (Sodhi, Banda, Kathyola, Joshua, M., Richardson, Mah et al., 2014).

The growing momentum to achieve ambitious global health initiatives through task-shifting, including those linked to the SDGs, has notably been credited with the resurgence of the important role CHWs play. The next section provides a definition of CHWs and their contribution to improve access to basic health services within communities.

2.9 Community health workers

The concept of CHWs was universally endorsed during the Alma Ata[7] conference in 1978 (WHO, 1978; Lehmann & Sanders, 2007). The compelling view of universal health coverage (UHC) that emerged from the declaration, now prominent and embedded in the SDGs, sought to leverage and integrate CHWs into healthcare systems. Article VII.7 of the Alma Ata Declaration defined the role for CHWs explicitly by stating that:

[7] The Alma Ata conference concluded with the issuing of a declaration that provided global recognition to the concept of primary health care as the lynchpin for achieving universal health coverage. The declaration asserted that PHC is *'the first level of contact of individuals, the family and community with the national health system bringing healthcare as close as possible to where people live and work, and constitutes the first element of a continuing healthcare process'* (WHO, 1978).

> "For many developing countries, the most realistic solution for attaining total population coverage with essential health care is to employ community health workers who can be trained in a short time to perform specific tasks. They may be required to carry out a wide range of health care activities, or, alternatively, their functions may be restricted to certain aspects of health care, the total range being provided by a team of health workers, each performing a specific group of tasks." (WHO, 1978: 62)

Viewed from the global perspective, CHWs are defined as follows:

> "Any health workers carrying out functions related to health care delivery; trained in some way in the context of the intervention, and having no formal professional or paraprofessional certificate or degree in tertiary education." (Lewin, Munabi-Babigumira, Glenton, Daniels, Bosch-Capblanch, van Wyk et al., 2010: 2)

The vast array of names – e.g. community health agent in Ethiopia, community health promoter in Zambia, community health volunteer in Malawi, community treatment supporter in Eswatini and village health worker in various countries – that CHWs operate under makes it difficult to provide a precise definition, and reflects the fluctuating nature and width of their scope of work (Lehmann & Sanders, 2007). The health conditions that CHWs play a role in controlling also reflect a very diverse spectrum, from HIV prevention to distribution of contraceptives, malaria prevention to management of childhood illnesses.

The shared attributes across CHWs, irrespective of nomenclature or disease intervention is that they are:

- members of the communities where they work,
- selected by the communities,
- answerable to the communities for their activities,
- supported by the health system, but not necessarily a part of its organisation, and
- have shorter training than professional HCWs (Lehmann & Sanders, 2007; Tulenko, Mgedal, Afzal, Frymus, Oshin, Pate et al., 2013).

Moreover, in contrast to professional HCWs, there is notable variation in the content and length of CHWs' training. For instance, in some countries, CHWs only receive informal training conducted outside traditional training (Lehmann & Sanders, 2007). The quick turnaround in training make CHWs an attractive short-term solution for shortages in professional HRH and improving access to PHC services (Lehmann & Sanders, 2007; Matsuzaka, Wainberg, Norcini Pala, Hoffmann, Coimbra, Braga et al., 2017).

In extant literature, CHWs are often delegated with less complex roles while they refer those with more complex needs to facility-based professional HCWs with clinical expertise (Lehmann & Sanders, 2007). In some settings, CHWs provide education and support to patients with chronic health conditions, while others see CHWs as coordinators without any direct care responsibility. In most care models, CHWs are assigned to specific populations such as individuals with MDR-TB or HIV and to specific programmatic goals such as reducing infant mortality (Glenton et al., 2013; Root & Whiteside, 2013; Daru, Matji, AlMossawi, Chakraborty & Kak, 2018; Kerschberger et al., 2019). Lehmann and Sanders (2007) in a WHO-commissioned extensive systematic review distinguished two types of CHWs – generalists and specialists. Unlike generalist CHWs, specialist CHWs are typically recruited and trained to focus on a particular health issue related to a specific condition such as HIV/AIDS, TB, maternal and child health, family planning, or malaria (Lehmann & Sanders, 2007).

In recent times, CHWs have featured prominently in the public health response to pandemics. Drawing from lessons learnt in tackling HIV and TB epidemics in communities rather than in hospitals, more recently, CHWs have been mobilised in the fight against the COVID-19 pandemic in South Africa (Ballard, Bancroft, Nesbit, Johnson, Holeman, Foth et al., 2020; David & Mash, 2020). CHWs were trained to perform door-to-door screening of COVID-19 using a symptom screening questionnaire, temperature checks and referring eligible suspected COVID-19 cases for testing at a local mobile testing centre. CHWs have also been mobilised in previous Ebola outbreaks in Guinea, Liberia, and Sierra Leone, undertaking multiple roles including health education and awareness, countering stigma and performing contact tracing (Miller, Milsom, Johnson, Bedford, Kapeu, Diallo et al., 2018).

Treatment models that utilise CHW-driven delivery platforms have been shown to increase treatment adherence in diverse settings (setting – Malarcher et al., 2011; setting – Root & Whiteside, 2013; setting – Kliner et al., 2015). CHWs leverage on their understanding of local issues (shared language, culture, geographic location or health condition) and strong connection with community members (Lehmann & Sanders, 2007). In doing so, they play a unique intermediary role between formal health services and communities they serve. CHWs are usually the community's first port of call on health-related issues They thus extend the reach of healthcare services where professional HCWs are scarce (Lehmann & Sanders, 2007).

CHWs have delivered health services throughout Eswatini for decades. Large-scale task-shifting in the country can be traced back over four decades. In 1976, the MOH introduced a new cadre of CHWs referred to as rural health motivators (RHMs) to address some of the PHC gaps. RHMs perform a number of tasks including health education and awareness; advising the community on hygiene, nutrition, and infant mortality matters; being the first port of contact in case of illness; and referring sick individuals to clinics (Geldsetzer, Vaikath, De Neve, Bossert, Sibandze & Bärnighausen et al., 2017; Walker, Burtscher, Myeni, Kerschberger, Schausberger, Rusch et al., 2020). The emergency of HIV epidemic in the late 1990s changed the country's public health landscape, with RHMs undertaking HIV- and TB-related responsibilities. However, the introduction of parallel CHW groups supported by non-governmental organisations (NGOs), marginalised the role of RHMs in responding to HIV/TB (Walker et al., 2020).

Consequently, the national RHM programme reported several challenges that included high levels of attrition and overall poor coverage (Geldsetzer et al., 2017; Walker et al., 2020). Researchers concur that the poor performance of this intervention was not entirely a consequence of the failure of the concept of CHWs, but rather a result of intervention design factors comprising, in part, of lack of ongoing training, supportive supervision, monetary incentives and logistical support (Geldsetzer et al., 2017; Walker et al., 2020).

2.9.1 Global experience in the role of CHWs in community-based MDR-TB management

Access to MDR-TB services has often been undermined by inadequate decentralisation of services and a critical shortage of HRH, leading to heightened impetus for task-shifting within NTCPs (Mitnick, Bayona, Palacios, Shin, Furin, Alcántara et al., 2003, Shin, Furin, Bayona, Mate, Kim & Farmer, 2004; Seung, Omatayo, Keshavjee, Furin, Farmer & Satti, 2009; Daru et al, 2018; Kerschberger et al., 2019). CHWs have played a central role in the success of community-based MDR-TB strategies (Daru et al, 2018; Kerschberger et al., 2019). The general structure and design of the community-based MDR-TB model implemented in the Shiselweni region is comparable to that established in other settings where the experience has been reported (see Table 3).

Table 3: Summary of established community-based MDR-TB management programmes

Country	Peru	Lesotho	Bangladesh	Eswatini (study setting)
Place of MDR-TB care provision	Patient's home or a closer convenient location	Patient's home	Patient's home	Patient's home
DOT provider	CHW	CHW or nurse	CHW	CTS
MDR-TB injection provider	Nurse	Nurse	Nurse	CTS
Frequency of DOT provision to MDR-TB patients	6 days/week; twice daily	6 days/week; twice daily	Every day; once daily	Every day; twice daily
Number of patients per DOT provider	Up to 4 patients	Up to 3 patients	Up to 2 patients	Up to 2 patients
Incentives for DOT provider	Monthly monetary incentive	Monthly monetary incentive	Monthly monetary incentive, mobile phone airtime top-up, fixed amount for transporting patient and specimen	Monthly financial incentives during the IP only
Training for DOT provider	1-day training on TB, drugs, adverse effects and DOT	1-day training on TB, drugs, adverse effects, DOT, psychological support; periodic refresher workshops	1-day training on TB, drugs, adverse effects, DOT, psychological support; periodic refresher workshops	2 weeks long practical and 3-5 days of theoretical training
Supervisors of DOT providers	Health promoters working with a nurse from the nearest clinic	DOT coordinator and nurse from the nearest clinic	Nurses from nearest clinic	Community MDR-TB nurse
Role of professional nurses	TB screening, manage side effects, monitor adherence and laboratory tests, keep medical records, supervision of health promoters and CHWs.	TB screening, manage side effects, monitor adherence and laboratory tests, keep medical records, supervision of CHWs	Managing patients at the hospital and playing a supportive role at the nearest clinic	Mentoring and supervising CHWs administering DOT and injections, monitor side effects, provide health education and advise on household IPC
Incentives or enablers provided to MDR-TB patients	Negligible (few patients got support for transport to the nearest clinic; About 10% of patients received food and temporary housing)	Biweekly food packages; free transport to the clinic	Monthly financial support for food and transport costs	Monthly financial support and food packages

Country	Peru	Lesotho	Bangladesh	Eswatini (study setting)
Extent of community-based MDR-TB care	Nearly the whole country	The whole country	Almost one-third of the country	One-quarter of the country
Community IPC measures	N95 respirators issued to all MDR-TB care providers	N95 respirators issued to all MDR-TB care providers	Assessment of household IPC; Monthly supply of disposable N-95 masks to CHW and contacts	Environmental control interventions aimed at improving natural ventilation such as the structural addition of windows on the existing patient's room or in some instances, construction of a new one-roomed house for the patient to sleep alone; Monthly supply of N-95 respirators to CTSs and surgical masks to MDR-TB patients

CHW: community health worker; CP: continuation phase; CTS: community treatment supporter; DOT: directly observed therapy; IP: intensive phase; IPC: infection prevention and control

Source: Mitnick et al. (2003), Shin et al. (2004), Seung et al. (2009), Satti et al. (2012), Turashvili et al. (2014), Daru et al. (2018)

The models vary in the extent of responsibilities delegated to CHWs; from making them operate as a central part of the treatment delivery team to involving them as DOT supervisors or health education providers. A key variable in the descriptions of the four countries' programmes is the level of interaction between CHWs and MDR-TB patients, specifically, the extent of tasks delegated to CHWs, location of service provision, and frequency and length of interaction. The notable difference is that in the Shiselweni region alone, the tasks delegated to lay community members extended beyond provision of DOT to include clinical tasks such as intramuscular injection administration. The incentives and enablers provided to CHWs and MDR-TB patients also varied greatly across reported studies. The programmes provided a wide range of support to MDR-TB patients ranging from nothing to nutritional and financial assistance over the duration of the treatment.

2.10 Cost-effectiveness of community-based MDR-TB management

The WHO in a conditional recommendation supports the adoption of community-based MDR-TB management as the default model of care rather than models principally centred on hospitalisation (WHO, 2014). This recommendation is subject to reasonable IPC measures in the home, stable clinical state of the patient, availability of DOT treatment support to enhance treatment adherence, and accessibility of a healthcare facility to manage patients who require hospitalised care (WHO, 2014).

It is now well established from systematic reviews that community-based models of MDR-TB care are cost-effective and result in similar or superior treatment outcomes compared to hospital-based management of MDR-TB (Fitzpatrick & Floyd, 2012; Floyd, Hutubessy, Kliiman, Centis, Khurieva, Jakobowiak et al., 2012; Bassili, Fitzpatrick, Qadeer, Fatima, Floyd & Jaramillo, 2016; Loveday, Wallengren, Reddy, Besada, Brust, Voce et al., 2018). In an extensive review of three economic evaluations undertaken in Peru, the Philippines, Estonia and Tomsk Oblast in the Russian Federation, community-based management of MDR-TB was less costly and, therefore, more cost-effective compared to hospital-based care (Fitzpatrick & Floyd, 2012). Recently, in a cost-effectiveness analysis of various models of community-based care, a study in KwaZulu-Natal, South Africa, reported that the

mobile model of care utilising nurses to provide MDR-TB care including provision of injections in the patients' homes was more cost-effective than care in either a decentralised or centralised setting (Loveday et al., 2018). These findings lend support to the WHO recommendation for adopting community-based care as a preferable alternative for resource-limited countries with a high MDR-TB burden (WHO, 2014). However, the outpatient models of care considered in the reported studies utilised professional nurses rather than LHWs to administer MDR-TB injections.

2.11 Social protection mechanisms for MDR-TB patients

With poverty and food insecurity both recognised as causes and consequences of TB, addressing these wider socio-economic issues today is as important in the management of the disease as ever (WHO, 2013). Yet, very few programmes use economic interventions to directly address this relationship (Hargreaves et al., 2011). Even though TB programmes in most LMICs provide free diagnosis and treatment of MDR-TB, patients incur considerable out-of-pocket costs when accessing treatment.

Studies in South Africa have documented that patients and their caregivers experience substantial out-of-pocket costs in accessing MDR-TB care, in particular, high non-medical costs driven by frequent travel to hospitals and PHC facilities for review and collection of medication (Ramma, Cox, Wilkinson, Foster, Cunnama, Vassall et al., 2015). The economic costs to patients and their caregivers also include indirect costs from longer periods of hospitalisation and loss of income during visits to the clinics for care (Ramma et al., 2015). Combined together, patients and their households may bear catastrophic health care costs as a result of MDR-TB. Such costs represent a barrier to MDR-TB access, adherence and consequently treatment completion (Tanimura et al., 2014; Tupasi, Garfin, Kurbatova, Mangan, Orillaza-Chi, Naval et al., 2016; Thomas et al., 2016). To address this, there is general national and global commitment to eliminate these catastrophic costs by expanding patient-centred care approaches that reduce time spent seeking MDR-TB services and social protection mechanisms to alleviate loss of income during illness (Ramma et al., 2015; WHO, 2015).

Summary

The preceding literature review has provided an understanding of task-shifting as an optimum alternative solution to increase access to health care services and address acute shortage of HRH that has been used in diverse settings on a routine basis for decades. The review examined the process of task-shifting by considering its risks and benefits. More precisely, the discussion identified factors that may facilitate or impede task-shifting, and highlighted the consequences of the strategy for the health system, HCWs and patients themselves.

Furthermore, the review identified the paucity of studies assessing task-shifting of specifically MDR-TB injection administration to LHWs, a gap addressed by the present study. Attention was also drawn to the concept of CHWs and the global experience of their role in community-based MDR-TB management. The review concluded by providing an overview of the cost-effectiveness of community-based MDR-TB management and the social protection mechanisms that enhance the capacity of patients and their households to protect themselves against catastrophic costs of MDR-TB illness.

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Chapter 3: Knowledge, attitudes and practices of community treatment supporters administering multidrug-resistant tuberculosis injections: a cross-sectional study in Shiselweni, Swaziland

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Structure

3.1 Abstract

Background: Expansion of frontline human resources for health through task-shifting of directly observed treatment (DOT) and intramuscular injections for

multidrug-resistant tuberculosis (MDR-TB) from professional nurses to trained and incentivised community treatment supporters (CTSs) is a novel approach to extend MDR-TB services and improve patient retention in care and treatment outcomes. This study assessed knowledge levels, attitudes and practice patterns of CTSs that may facilitate or impede the delivery of quality community-based MDR-TB care including administration of injections in the Shiselweni region.

Methods: A cross-sectional interviewer-administered survey among a purposive sample of 82 CTSs providing DOT and administering intramuscular injections to MDR-TB patients was conducted in May 2017. Observations to verify CTSs' self-reported community-based MDR-TB management practices were also undertaken in the patients' homes.

Results: Out of 82 respondents, 78 (95.1%) were female, with 33 (40.2%) in the over 50 years age group. Half (n = 41; 50.0%) of the respondents had low literacy skills (primary education or lower). Over one-tenth (n = 12; 14.6%) had not attended an MDR-TB training workshop. Overall, 71.9% and 28.1% of the CTSs had good (≥ 70.0%) and moderate (40.0% - 69.9%) knowledge scores respectively. The mean attitude score of CTSs was 93.5 % (± 9.9 %), ranging from 55.6% to 100% of appropriate responses. A majority of respondents (75.6%) reported good community-based MDR-TB practices that were largely verified through observation. A binomial regression analysis revealed that duration administering intramuscular injections, MDR-TB training, knowledge and attitudes had no statistically significant association with good community-based MDR-TB management practices.

Conclusions: The study results indicate that there is the need for ongoing in-service training programmes to reinforce awareness, address gaps in current knowledge and dispel misperceptions and potentially stigmatising attitude regarding community-based MDR-TB management. Despite the limited literacy and numeracy skills of most CTSs, trained lay community members can be an option to complement an overstretched health workforce in providing DOT supervision and highly differentiated clinical tasks such as safe administration of MDR-TB injections at the community level.

Keywords: MDR-TB, Swaziland, Community treatment supporters, Task shifting, Human resources for health, Directly observed treatment, Injection administration

3.2 Background

Tuberculosis (TB) in Swaziland and the world at large is a complex public health issue confronting families, healthcare professionals and non-professionals, government officials and patients themselves. Like many countries in southern Africa, Swaziland had a high estimated TB incidence rate of 280 TB cases per 100 000 population in 2015 [1]. In 2016, Swaziland had the third highest TB mortality in the world. Over the past few years, there has been an escalation of a new threat – multidrug-resistant TB (MDR-TB) – that is showing no sign of receding and is undermining recent successes in TB control. MDR-TB is defined as strains of TB resistant to the two most effective first-line anti-TB drugs, isoniazid and rifampicin [2].

The WHO Global TB Report estimated an incidence of close to 490 000 cases of MDR-TB in 2016, with the disease accounting for over 240 000 deaths [1]. In 2016, Swaziland had an estimated MDR-TB incidence rate of 49 cases per 100 000 population, the second highest incidence in the world [1, 3]. MDR-TB is often a consequence of inappropriate or interrupted treatment of drug-susceptible TB. A drug-susceptibility study performed in the country in 2009 revealed the proportion of MDR-TB in new and previously treated cases of TB to be 7.7% and 33.8% respectively [4].

The control of TB has been highlighted as a priority in the post-2015 global TB strategy (the End TB Strategy) and the Sustainable Development Goals (SDGs) agendas [2, 5]. In 2015, Swaziland reported a 56% treatment success rate for MDR-TB patients (2011 cohort), that is, well below the 2015 WHO target of 75% or higher [3, 6]. The country's National TB Control Programme (NTCP) reported a concerning state of MDR-TB estimating that respectively 26% of MDR-TB patients were lost-to-follow-up and 10% died before the end of their two year treatment in 2014 [7].

Community-based interventions such as directly observed treatment (DOT) involving a patient taking standard TB medication under guided supervision from a lay

community or family member have been widely endorsed globally as a remedy for frontline human resources for health (HRH) shortages and for increasing access to TB services [8, 9]. However, the emergence of MDR-TB for which the standardised therapeutic regimen is complex, prolonged and includes a daily injectable for the first eight months of treatment has rendered DOT by lay community members difficult. The NTCP has limited the use of shorter MDR-TB treatment regimens (9 months instead of the usual 2 years) to a few pilot PHC facilities in the country.

The goal to increase accessibility of primary health care (PHC) services has widely been promoted since the WHO's breakthrough Alma Ata Declaration in 1978 [10]. This long-standing mission of universal health coverage (UHC) continues to be at the core of interventions to achieve SDGs targets by 2030. The WHO identified the health workforce as one of the six critical building blocks of a well-functioning health system [11]. Implicitly, a shortage of frontline TB HRH will result in weakened health systems and subsequently in suboptimal community-based management of MDR-TB. Frontline TB HRH in this setting refers to health personnel who are usually the community's first port of call for accessing the NTCP.

The rural areas in Swaziland carry a disproportionately high burden of MDR-TB and have PHC clinics that are often far away and geographically inaccessible from the patient's home, and are typically also characterised by a lack of frontline TB HRH [12–15]. As a coping mechanism to address the prevailing healthcare access and HRH challenges in the predominantly rural Shiselweni region, in 2008, Médecins Sans Frontières (MSF) established a community-based MDR-TB treatment model based on task-shifting within the existing NTCP [12]. In this context, task-shifting refers primarily to the transfer of DOT and MDR-TB injection administration responsibilities traditionally restricted to professional nurses, to trained lay community members.

In this model of care, MDR-TB patients discharged from the MDR-TB inpatient hospital are linked to a lay community member, referred to as a community treatment supporter (CTS), of their choice from their locality. Instead of making trips to the nearest clinic, this model of care allows MDR-TB patients to receive their daily injections and DOT from CTSs in their (the patients') homes. CTSs are typically

recruited and trained to focus solely on MDR-TB. On inception, newly recruited CTSs receive hands-on demonstrations, mentored practice and routine follow-up on TB infection prevention and control (IPC), DOT, and injection administration by a community MDR-TB nurse. Thereafter, they start supervising DOT and administering injections while awaiting to attend a standardised 3-5 days long training workshop to reinforce their competencies related to community-based MDR-TB management. There are no certificates or any formal form of accreditation given to CTSs on completion of the training. They receive a stipend of ZAR500 (= US$33.54 [Exchange rate on 23/11/2017]) per month during the eight-month long injection phase of their patient's treatment.

The expansion of frontline HRH through task-shifting of community-based MDR-TB management to CTS in the Shiselweni region has generated divergent views regarding the contribution of CTSs to treatment outcomes and quality of care [12, 16]. Although a majority of national TB Technical Working Group (TWG) members view task-shifting of community-based MDR-TB care to CTSs as an indispensable component of increasing access to TB services, a considerable group was critical about some of the perceived features of community health workers (CHWs) [16]. In particular, questions arose regarding CTSs' relatively narrow-focused training, perceived incompetency, lack of quality assurance and uncertainty about the sustainability of the MSF strategy.

While there is strong evidence in recent literature discourses suggesting that community-based interventions utilising trained lay community members are an effective platform for extending healthcare delivery, and improving retention of patients in care and health outcomes, various studies globally have also revealed that frontline health personnel do not always have sufficient knowledge or the appropriate positive attitude; and do not demonstrate acceptable practices concerning the prevention and treatment of MDR-TB [17–22]. However, these studies mainly focused on professional frontline HRH such as medical doctors and nurses in health facilities and do not reflect the knowledge, attitudes and practices (KAP) of CHWs on MDR-TB management.

For the community-based MDR-TB programme in the Shiselweni region, a KAP analysis would help to highlight the knowledge levels, attitudes and practice patterns that may facilitate or impede the delivery of quality care by CTSs. To the authors' knowledge, no studies to date have assessed these key elements in this context. We conducted a comprehensive assessment of the KAP of CTSs in the community-based MDR-TB management programme in the Shiselweni region. The study was part of a larger research project to assess the task-shifting of MDR-TB care from professional nurses to incentivised CTSs in the Shiselweni region of Swaziland.

3.3 Methods

3.3.1 Setting and design

The Shiselweni region, with an estimated population of 204 111 in 2017, has one hospital in Hlatikulu and two health centres in Nhlangano and Matsanjeni [23]. These three main health facilities support 18 smaller PHC clinics that form part of the regional health network managed by the Ministry of Health (MOH). TB inpatient wards for the region are available at Nhlangano Health Centre. Patients diagnosed with MDR-TB nominate a neighbour to be trained and assigned to supervise DOT and administer intramuscular injections daily in the community. There are no educational requirements for CTS recruitment. MDR-TB patients in the company of their CTSs visit one of the three main health facilities monthly for their outpatient treatment monitoring and review.

A cross-sectional survey using an interviewer-administered structured questionnaire was conducted among incentivised CTSs providing DOT and administering injections to MDR-TB patients in the Shiselweni region in May 2017. Direct observation of CTSs supervising DOT and administering intramuscular injections in the MDR-TB patients' homes was conducted and recorded on a structured checklist.

3.3.2 Sampling

A purposive sample of 82 CTSs providing injection administration to MDR-TB patients in the Shiselweni region was considered for the interviewer-administered

survey. The inclusion criteria were having at least one month experience and currently administering MDR-TB injections. There were no refusals to participate in the survey.

From a list of the 82 CTSs that participated in the interviewer-administered survey, 20 were selected using a stratified sampling method to verify self-reported practices by direct observation. The sampling frame (list of CTSs) for each stratum was obtained from the register of CTSs at each MDR-TB treating facility. Within each stratum, participants were selected through proportionate random sampling to reach a target sample size for each facility – Matsanjeni Health Centre (10), Nhlangano Health Centre (6) and Hlatikhulu Hospital (4). All CTSs that were approached agreed to be observed while administering DOT and MDR-TB injections to their patient.

3.3.3 Instrument development

Data was collected in May 2017 using a newly developed structured questionnaire. The questionnaire was developed based on literature review and CTS training materials and job descriptions [17, 19–21, 24]. The questionnaire consisted of 64 items, with six measuring CTSs' demographic details (i.e. sex, age, training and length of service); 25 examining their knowledge about MDR-TB, DOT and injection administration; 21 assessing their attitudes towards MDR-TB; and 12 measuring their practices in community-based MDR-TB management. The content validity of the questionnaire was assessed by expert opinion. Internal reliability of the KAP scale was assessed by measuring the Cronbach's alpha. The internal reliability of the KAP scale was found to be acceptable and had a satisfactory discriminating power with subscale Cronbach's alpha co-efficient for knowledge, attitude and practice of 0.72, 0.68 and 0.62 respectively [25–29].

To improve reliability, the questions were translated from English to siSwati by an experienced siSwati Grade 12 teacher. The final questionnaire was availed in both English and siSwati. The instrument was pretested for practicality among 10 CTSs who were no longer administering MDR-TB injections. They were excluded in the main study since it focused on CTSs who were currently administering injections to MDR-TB patients.

A structured observation checklist for verifying CTSs' self-reported community-based MDR-TB management practices was developed based on a schedule used by community MDR-TB nurses in supervising CTSs and literature review [30–33]. The checklist comprised of 27 items recording CTSs' TB IPC, DOT, and injection administration practices.

3.3.4 Measures

The questionnaire collected socio-demographic details including age, gender, level of education, duration administering injections, on-the-job training and attendance of MDR-TB training as shown in Table 1. There were 25 knowledge-related questions that examined the definition of MDR-TB, its aetiology, transmission, main symptoms, diagnosis, treatment, safe injection handling, and IPC as shown in Table 2. Respondents were asked to choose the best response on a given statement on a scale that ranged from 1 ("yes"), to 2 ("unsure"), and 3 ("no"). Responses to knowledge questions were assigned a score of 1 for correct or appropriate and 0 for incorrect, inappropriate or uncertain responses.

Attitudes towards community-based MDR-TB management were assessed on a 5-point Likert-type scale. Participants were asked to indicate the extent to which they agreed or disagreed with given statements by choosing either strongly agree (5 points), agree (4 points), unsure (3 points), disagree (2 points) and strongly disagree (1 point) on the scale as shown in Table 3. CTS's self-reported practices regarding MDR-TB were assessed based on responses to 12 questions checking whether or not they were involved in patient and community MDR-TB education and awareness; implementation of administrative, environmental and personal protection TB IPC measures; DOT; and safe injection handling procedures, as shown in Table 4. The self-reported practices were verified by carrying out observations in a sample of 20 CTSs using a structured observation checklist, as shown in Table 5.

3.3.5 Participant recruitment and data collection

CTSs accompanying their MDR-TB patients for their monthly review at the three MDR-TB treating facilities were informed about the research (interviews and observations) by the community MDR-TB nurse at the end of their consultation. The CTS was then referred to a trained male or female research assistant stationed in a private room within the MDR-TB unit at the health centre. Three research assistants experienced in data collection were recruited for the study. Respondents had the option to choose between a male or female interviewer. The research assistants explained the research purpose, its data-gathering procedures, risks and benefits, and the expected duration of the interview to the potential participant. All eligible respondents that were approached agreed to participate in the interviews. For the observation visits, the first author accompanied community MDR-TB nurses during their routine supervisory visits to MDR-TB patients' residences and verified CTSs' self-reported MDR-TB practices using the structured observation checklist.

Participation in the study was voluntary and respondents were assured that their participation or non-participation in the study was not linked to their job security. No incentives or rewards were offered for participating in the research. To ensure the maintenance of respondents' confidentiality, no names or other personal identifying information was collected on the questionnaires and findings were reported anonymously using aggregate analysis. Written and verbal informed consent was sought from all participants (CTSs and MDR-TB patients) prior to their participation in the interviews and observations respectively.

3.3.6 Analysis

Data was captured and cleaned in Epi Info 7 before being exported to Stata Version 14 for analysis. Descriptive statistics such as means, frequencies and percentages were used to summarise the data. Total KAP scores on each of the scales were obtained from the composite scores and converted into percentages. Knowledge scores were classified as poor (≤ 39.9%), moderate (40.0% - 69.9%) and good (≥ 70.0%). Attitude scores below a cut-off level of 80% were classified as negative whereas greater than or equal to 80% were considered as positive towards MDR-TB.

Respondents with practice scale scores < 75 and ≥ 75% were considered as having poor and good community-based MDR-TB management practices, respectively. Three relatively similar studies investigating TB IPC and occupational exposure among healthcare workers (HCWs) in South Africa, Lesotho and Ethiopia were used to inform cut-off points for good levels of MDR-TB KAP [17, 24, 34]. Results from direct observation on CTSs' MDR-TB practices were expressed as percentages.

Binomial logistic regression analysis was used to establish factors that were significantly associated with good community-based MDR-TB management practices. The model included socio-demographic factors, knowledge about and attitudes towards MDR-TB as independent variables. The odds ratios (OR) were calculated to estimate the strength of association between the independent variables and CTSs' MDR-TB practices. The level of statistical significance was considered at p value < 0.05 and 95% confidence interval (CI).

3.3.7 Ethical clearance and authorisation

Ethical approval was obtained from the Scientific and Ethics Committee of Swaziland and the Health Sciences Research Ethics Committee (IRB00006240), University of Free State. Authorisation of the study was granted by the NTCP and MSF.

3.4 Results

Table 1 presents a summary of the demographic characteristics of the study sample. Of the total of 82 study participants, a majority (95.1 %) were female and 33 (40.2 %) were older than 50 years. In terms of education, half (n = 41; 50.0 %) of the respondents had low literacy and numeracy skills (primary education or lower), while the other half had adequate literacy and numeracy skills since they had secondary or higher education.

The length of service of respondents administering MDR-TB injections ranged from 1 to 8 months, with a mean duration of 5.8 months. While all CTSs reported to have received the prerequisite hands-on demonstrations, mentored practice and supervision on TB IPC, DOT and injection administration from a community MDR-TB

nurse, more than one-tenth (n = 12; 14.6 %), comprised of newly recruited CTSs had not attended the 3-5 day long training workshop in the 12 months prior to the study.

Table 1: Socio-demographic characteristics

	N = 82 (%)
Sex	
Male	4 (4.9)
Female	78 (95.1)
Age group	
≤ 30 years	10 (12.2)
31-40 years	21 (25.6)
41-49 years	18 (22.0)
≥ 50 years	33 (40.2)
Education level	
Primary school or lower	41 (50.0)
Secondary school or higher	41 (50.0)
Months administering MDR-TB injections	
1-4 months	17 (20.7)
> 4 months	65 (79.3)
Attended MDR-TB training workshop in the past 12 months	
Yes	70 (85.4)
No	12 (14.6)
Received MDR-TB on-the-job training in the past 12 months	
Yes	82 (100.0)
No	0 (0)

3.4.1 Assessment of CTSs' MDR-TB knowledge

The mean knowledge score for the respondents was 70.8% (standard deviation [SD]: ± 8.0%) with correct responses ranging from 40.2% to 88.2%. Overall, 71.9% and 28.1% of the CTSs had good or moderate scores on the knowledge scale respectively. However, poor knowledge was apparent in responses to some individual questions relating to the definition of MDR-TB, treatment, and safe injection handling, as shown in Table 2.

Less than two-thirds (n = 48; 58.5%) of the respondents correctly defined MDR-TB as strains of TB resistant to at least isoniazid and rifampicin. Two in every five respondents chose the following incorrect responses: people who sleep in the same room are not close TB contacts (n = 36; 43.9%); and swabbing before injections will minimise the pain during injection (n = 36; 43.9%). Almost half (n = 39; 47.6%) incorrectly answered that MDR-TB is best diagnosed from a chest X-ray. Over four-fifths also chose the following incorrect response: MDR-TB is best treated with following drug combination: rifampicin, amikacin and levofloxacin only (n = 71; 86.6%). Only one-third (n = 28; 34.2%) correctly responded that kanamycin is the drug that is used for injection during the intensive phase.

More than 9 in every 10 (n = 76; 92.7%) of the CTSs were aware that recapping of used needles can cause needlestick injuries. However, more than 4 in every 10 (n = 33; 40.2%) of the respondents did not know that taking antiretroviral drugs as post-exposure prophylaxis (PEP) reduces the likelihood of human immunodeficiency virus (HIV) infection following needlestick injuries.

Table 2: CTSs' knowledge about MDR-TB

CTSs knowledge items (correct response)	Correct response n (%)
MDR-TB are strains of TB resistant to at least isoniazid and rifampicin (yes)	48 (58.5)
MDR-TB is contagious (yes)	81 (98.8)
A CTS providing care to a patient with MDR-TB may develop MDR-TB (yes)	79 (96.3)
People who sleep in the same room are not close TB contacts (no)	36 (43.9)
Babies under two years are close TB contacts of their parents, or anyone who looks after them (yes)	79 (96.3)
A person can get MDR-TB from shaking hands with someone with MDR-TB (no)	61 (74.4)
A person with HIV is more likely to develop MDR-TB (yes)	79 (96.3)
Opening windows can help in preventing the spread of MDR-TB (yes)	82 (100)
Wearing a N95 respirator can reduce the risk of transmission of MDR-TB (yes)	79 (96.3)
All people with MDR-TB infection have visible symptoms (no)	68 (82.9)
Coughing is the most common symptom of MDR-TB (yes)	53 (64.6)
MDR-TB is best diagnosed from a chest X-ray (no)	39 (47.6)
The correct way of assessing MDR-TB treatment outcome is through sputum culture (yes)	79 (96.3)
MDR-TB can be cured (yes)	80 (97.6)
General antibiotics given at the health centre can cure MDR-TB (no)	73 (89.0)
MDR-TB is best treated with the following drug combination: rifampicin, kanamycin and levofloxacin only (no)	11 (13.4)
The standard length of injection treatment for a newly diagnosed case of MDR-TB is eight months (yes)	76 (92.7)

CTSs knowledge items (correct response)	Correct response n (%)
Kanamycin is the drug that is used for injection during the intensive phase (yes)	28 (34.2)
The duration of treatment for MDR-TB is between 18 to 24 months (yes)	77 (93.9)
Sometimes people with MDR-TB do not get better because they do not take their medication (yes)	80 (97.6)
Medications with visible contamination or breaches of integrity (e.g. cracks, leaks) should be discarded (yes)	79 (96.3)
Swabbing before injections will minimise the pain during injection (no)	36 (43.9)
Recapping of used needles can cause needlestick injuries (yes)	76 (92.7)
Taking antiretroviral drugs as post-exposure prophylaxis (PEP) can reduce the rate of infection in healthcare workers exposed to HIV through needlestick injuries (yes)	49 (59.7)
An infection or boil on the injection site is a side effect related to the injection that should be reported to the community MDR-TB nurse (yes)	73 (89.0)

3.4.2 Attitudes

The mean attitude score of the CTSs was 93.5 % (± 9.9 %), ranging from 55.6% to 100% of appropriate responses. Overall, a large majority of respondents (n = 71; 86.6%) reported positive attitude regarding community-based MDR-TB management. Almost all of the respondents concurred that increasing community awareness about MDR-TB (n = 77; 93.9%), wearing a N95 respirator (n = 81; 98.8%), encouraging adequate ventilation in the patient home (n = 80; 97.6%), practising hand hygiene before and after direct patient contact (n = 79; 96.3%, and safe injection handling practices (n = 80; 97.6%) were important interventions in preventing transmission of MDR-TB and minimising risk of adverse events, as shown in Table 3.

Despite these positive attitudes, just more than a quarter (n = 21; 25.6%) of CTSs thought MDR-TB was not a major public health threat in Swaziland. Only two-thirds (n = 56; 68.3%) of the respondents felt that they had enough information about community-based MDR-TB management. Almost nine in every ten (n = 71; 86.6%) of the respondents were worried about acquiring MDR-TB during their engagement as CTSs, while a large majority (n = 77; 93.9%) believed it was difficult for patients with MDR-TB to understand the need to continue taking medication after they start feeling better.

Table 3: CTSs' attitude towards MDR-TB

CTSs' attitude items	Concur n (%)	Unsure n (%)	Differ n (%)
Awareness			
MDR-TB is a major public health threat in Swaziland	61 (74.4)	0 (0)	21 (25.6)
I feel awareness of MDR-TB in my community is adequate	58 (70.7)	0 (0)	24 (29.3)
Community awareness about MDR-TB is important in the control of the disease	77 (93.9)	2 (2.4)	3 (3.7)
Training			
I understand the importance of attending regular training on TB prevention	82 (100)	0 (0)	0 (0)
I have enough information about community MDR-TB management	56 (68.3)	1 (1.2)	25 (30.5)
Patient education			
It is my responsibility to teach patients about TB prevention	77 (93.9)	2 (2.4)	3 (3.7)
Infection prevention and control			
Patients with known MDR-TB should be separated from HIV patients	57 (69.5)	3 (3.7)	26.8)
Washing my hands before and after direct patient contact is a necessary part of my work	79 (96.3)	1 (1.2)	2 (2.4)
I encourage adequate ventilation in the patient's home, regardless of weather conditions	80 (97.6)	1 (1.2)	1 (1.2)
I use a N95 respirator even though it may be uncomfortable	81 (98.8)	0 (0)	1 (1.2)
Risk of acquiring MDR-TB			
I worry about acquiring active MDR-TB disease while at work	71 (86.6)	0 (0)	11 (13.4)
I think I have a very low risk of acquiring MDR-TB from my patient	63 (76.8)	1 (1.2)	18 (22.0)
I believe following safe injection practices can help reduce the risk of infectious adverse events in healthcare providers	80 (97.6)	2 (2.4)	0 (0)
Adherence			
I think it is difficult for patients with MDR-TB to understand they need to continue taking medication after they start feeling better	77 (93.9)	4 (4.9)	1 (1.2)
I consider interrupted MDR-TB treatment course to be a possible cause of worsening of symptoms	80 (97.6)	1 (1.2)	1 (1.2)
I believe taking traditional medicine makes the treatment of MDR-TB difficult	37 (45.1)	1 (1.2)	44 (53.7)
Compassion and stigma			
I feel I should show compassion to my MDR-TB patient	80 (97.6)	2 (2.4)	0 (0)
MDR-TB patients are to blame for their own condition	29 (35.4)	3 (3.7)	50 (61.0)
I feel MDR-TB patients are confronted with significant social stigma surrounding the disease	49 (59.8)	5 (6.1)	28 (34.2)
My MDR-TB patient may not want other people to know that he/she has TB	60 (73.2)	3 (3.7)	19 (23.2)

CTSs' attitude items	Concur n (%)	Unsure n (%)	Differ n (%)
Supervision			
My supervisor is easily accessible when I need help in managing my MDR-TB patient	80 (97.6)	0 (0)	2 (2.4)

3.4.3 Practices

The mean practice score of CTSs was 83.9% (± 11.81%), ranging from 46.7% to 100% of good practice responses. Overall, a majority of respondents (n = 62; 75.6%) reported good practices regarding implementation of TB IPC measures, DOT and safe injection handling procedures as shown in Table 4. Observations of CTSs providing DOT and administering intramuscular injections revealed strong supporting evidence of these good practices in community-based MDR-TB management (see Table 5). Three-quarters (n = 61; 74.4%) of the respondents reported having a copy of and frequently referring to the CTS MDR-TB training manual when performing their tasks. Those without the manual had only received on-the-job training and not yet attended a workshop on MDR-TB management. However, only 67.1% (n = 55) frequently provided information on MDR-TB to patients and the community.

Self-reported environmental IPC practices were well applied, with almost all (n = 80; 97.6%) CTSs indicating that cross ventilation was implemented in the room their MDR-TB patient slept. This was confirmed by the observation that all windows for patients' rooms were open. In most homes visited, MSF had optimised simple natural ventilation by renovating or even building MDR-TB patients a one-roomed house with sufficiently sized and appropriately sited windows.

A majority of respondents reported wearing a N95 disposable respirator when attending to an MDR-TB patient (n = 79; 96.3%). However, none of the MDR-TB patients visited was observed wearing a surgical mask due to lack of supplies. Nevertheless, these patients were observed practising proper methods of good cough hygiene. In addition, the DOT card indicated that patients had disclosed their MDR-TB status to their families and all household members had been screened for the disease.

A majority (n = 12; 60.0%) of patients were observed swallowing their MDR-TB medication in the presence of the CTS. However, the DOT card revealed that all CTSs consistently administered injections and oral medications daily without failure, also on the day of the observation visit. A total of 20 CTSs were observed administering intramuscular injections to MDR-TB patients in their (the patients') homes. In all observations, checking for sterility and expiry of syringes, needles and vials; breakage of ampoule using a small cotton pad as barrier to minimise injury of fingers; and the correct dosage, site and technique of injection was noted. No re-use of disposable syringes and recapping of needles was observed.

All CTSs observed had enough stock of syringes and needles to last up to at least the next appointment date at the MDR-TB PHC facility. Based on observation, all needles and syringes were disposed intact immediately in a puncture-resistant sharps container, corresponding with the self-reported practice. Despite all CTSs self-reporting performance of hand hygiene before and after patient contact, the observations found conflicting evidence. A fifth (n = 4; 20.0%) of the CTSs did not perform hand hygiene after patient contact. All CTSs documented DOT and the injection procedure in the patient's MDR-TB DOT card immediately after completing injection administration.

Nine respondents (11.0%) reported having sustained a needlestick injury during practice. Of these, only two needlestick injuries were reported and PEP was not recommended. Reasons for not reporting included that the needlestick injury occurred before administering the injection (n = 4); perceived low risk of infection from the injury (n = 1); lack of awareness about the need to take PEP (n = 1); and fears about losing one's job as a CTS (n = 1).

Table 4: Self-reported CTSs' community-based MDR-TB practices

	n	%
MDR-TB training manual		
Do you have a CTS MDR-TB training manual? (yes)	61	74.4
How often do you refer to the CTS MDR-TB training manual? (always/frequently)	58	70.7
Community MDR-TB education and awareness		
Are you personally involved in educating patients or communities about MDR-TB? (yes)	62	75.6
How often do you provide information on MDR-TB? (always/frequently)	55	67.1
	n	**%**
Environmental IPC		

	n	%
How often is cross ventilation implemented in the room your MDR-TB patient sleeps? (always/frequently)	80	97.6
Administrative IPC		
Are there enough supplies such as soap and clean water to wash your hands at patient homes? (Yes)	81	98.8
How often do you wash your hands before and after direct contact with an MDR-TB patient? (always/frequently)	80	97.6
How often do you wash your hands before and after direct contact with an MDR-TB patient? (always/frequently)	82	100
Personal Protective Equipment		
How often do you wear a N95 disposable respirator when attending to an MDR-TB patient? (always/frequently)	79	96.3
Safe injection handling practices		
How often do you use a clean needle and syringe to draw up and administer medication? (always/frequently)	82	100
How often do you use a clean needle and syringe to draw up and administer medication? (always/frequently)	82	100
How often do you immediately place needles and syringes in a sharps disposal container after administering an injection? (always/frequently)	82	100

Table 5: Community-based MDR-TB practices observed at patients' homes

Checklist Item	Yes	
	n	%
MDR-TB education and awareness		
CTS MDR-TB training manual available	15	75.0
Patient disclosed MDR-TB status to his/her family	20	100
All household members have been screened for MDR-TB	20	100
DOT		
Patient swallowed MDR-TB medicine in the presence of the CTS	12	60.0
From the patient card, the CTS provided all injections and oral drugs	20	100
Infection control		
Patient sleeps alone in a separate room	20	100
Patient's room has windows	20	100
Windows in patient's room open	20	100
CTS wearing N95 respirator	20	100
Patient wearing surgical mask	0	0
Adequate supply of soap and clean water to wash hands	20	100
Safe injection handling technique		
Hands washed before procedure	20	100
New single needle and single syringe used	20	100
Vial checked for content, dose, and expiration date	20	100
Syringe filled with contents of the vial	20	100
Air expelled from syringe	20	100
Careful disposal of the drawing up needle from syringe and replacement with a fresh one	20	100
Exact site for injection located	20	100
Injection site disinfected with alcohol preparation pad	20	100
Patient told to relax the muscle	18	90.0
Needle inserted swiftly at an angle of 90 degrees	20	100
Aspirated briefly to ensure the needle is not sited in a blood vessel	18	90.0
All contents of the syringe injected slowly (less painful)	20	100
Injection site gently pressed with a clean cotton ball	20	100
Needle and syringe disposed intact in a puncture-resistant sharps container	20	100
Hands washed after procedure	16	80.0
Information recorded on patient's card and other data collection forms	20	100

3.4.4 Predictors of good community-based MDR-TB management practice

A bivariate logistic regression analysis (Table 6) was performed to describe the effects of age, level of education, duration administering injections, MDR-TB training, knowledge and attitudes on good community-based MDR-TB management practice. In the analysis, the individual socio-demographic variables, knowledge and attitudes had no significant association with good community-based MDR-TB management practice. A binomial logistic regression analysis was performed to identify factors contributing most to the likelihood of having good community-based MDR-TB management practices. Socio-demographic factors i.e. duration administering injections and having attended MDR-TB training were included as potential predictor variables in the equation. MDR-TB knowledge and attitude were also considered as potential explanatory variables for community-based MDR-TB management practice.

The Box-Tidwell test was applied to test for linearity of the logit assumption. All continuous independent variables entered into the regression model were linearly related to the logit of the dependent variable. A few outliers with no high leverage or influential data points were detected. Given that the unusual values were not a result of data entry errors, they were kept in the analysis. The logistic regression model was not statistically significant, $\chi 2\ (4) = 4.37$, $p > 0.05$ and explained 4.8% (Nagelkerke R2) of the variance in the tendency in the dependent variable. The Hosmer and Lemeshow test showed that the model was a good fit, $\chi 2\ (6) = 7.88$, $p > 0.05$. The model correctly classified 86.6% of cases. Sensitivity and specificity was 96.7% and 15.0% respectively. The positive predictive value was calculated to be 77.9% and the negative predictive value was 60.0%. Regression analysis revealed that after controlling for other variables in the model, none of the predictor variables were statistically significant.

Table 6: Bivariate and binomial logistic regression predicting community-based MDR-TB management practice among CTSs

Variables	Practice		COR (95% CI)	P value	AOR (95% CI)	p value
	Good n (%)	Poor n (%)				
Age category						
≤ 30 (Ref)	6 (66.7)	3 (33.3)				
31-40	17 (81.0)	4 (19.0)	2.13 (0.36-12.38)	0.40		
41-50	14 (73.7)	5 (26.3)	1.40 (0.25-7.83)	0.70		
>50	25 (75.8)	8 (24.2)	1.56 (0.32-7.73)	0.58		
Education level						
Primary school or lower (Ref)	30 (73.2)	11 (26.8)				
Secondary school or higher	32 (78.0)	9 (22.0)	1.30 (0.47-3.59)	0.61		
Duration administering MDR-TB injections						
1-4 months (Ref)	10 (58.8)	7 (41.2)				
> 4 months	52 (80.0)	13 (20.0)	2.8 (0.89-8.77)	0.077	2.04 (0.38-11.12)	0.41
Attended MDR-TB training workshop						
Yes (Ref)	55 (78.6)	15 (21.4)				
No	7 (58.3)	5 (41.7)	0.38 (0.11-1.38)	0.14	0.21 (0.03-1.49)	0.12
Knowledge						
Moderate (Ref)	19 (82.6)	4 (17.4)				
Good	43 (72.9)	16 (27.1)	0.57 (0.17-1.92)	0.36	0.60 (0.17-2.16)	0.43
Attitude						
Positive (Ref)	32 (80.0)	8 (20.0)				
Negative	30 (71.4)	12 (28.6)	0.63 (0.22-1.74)	0.37	0.60 (0.21-1.76)	0.36

COR: crude odds ratio; AOR: adjusted odds ratio; Ref: reference

3.5 Discussion

Successful MDR-TB treatment outcomes in the Shiselweni region hinge on appropriate DOT supervision, and safe and correct administration of intramuscular injections by CTSs. Thus, CTSs' KAP regarding community-based MDR-TB management is indispensable for optimum TB control. However, in the absence of a national policy and country-specific experience on task-shifting in Swaziland, critics contend that it is unsafe for non-clinically trained lay community members to administer intramuscular injections to MDR-TB patients. Given the paucity of previously published research examining the KAP of CTSs in providing DOT and administering MDR-TB injections in the Shiselweni region and elsewhere, the outcomes of this research have wider policy and programmatic implication in other similarly resource limited and high MDR-TB prevalence settings.

Consistent with previous studies, all CTSs reported satisfactory knowledge regarding basic questions on MDR-TB aetiology, transmission, main symptoms, diagnosis, and infection control [17, 24, 34, 35]. High knowledge scores demonstrated by CTSs are likely to translate to MDR-TB patients and/or their families also being knowledgeable on these subjects. This is plausible considering the significant association between patients' knowledge about TB and its treatment and adherence to medication [31].

However, although all CTSs in the present study had received a series of ongoing hands-on demonstrations and in-service training on injection administration, there were some important gaps in their training. More than one-tenth (14.6%) of CTSs had not attended an MDR-TB training workshop that focused primarily on theoretical themes relating to the definition of MDR-TB, diagnosis, treatment, TB IPC and safe injection handling. CTSs, as frontline HCWs, are intrinsically linked to the success of community-based MDR-TB management through their involvement in household IPC, patient support, DOT supervision and injection administration. As such, it is imperative that CTSs are adequately educated and trained to effectively participate in and comprehend the fundamentals of community-based MDR-TB management.

Half of the respondents incorrectly defined MDR-TB and a substantial majority of CTSs (86.6%) were not aware of the combination of medication used to treat MDR-

TB. Similar results were found among HCWs in other countries [18, 21, 22, 24]. The incorrect responses could be accounted for, in part, by the small proportion of CTSs that had not attended the standardised MDR-TB training workshop in this study. These results underscore the importance of timeous and continuous provision of appropriately tailored educational initiatives with lay conceptualisations and, where possible, translated into the local language used in treating MDR-TB. This will help CTSs recognise adverse effects, seek timely referral of the patient to the decentralised MDR-TB PHC facility, and encourage adherence to treatment plans.

Overall, the study documented a high percentage of respondents (93.9%) concurring that it is difficult for patients with MDR-TB to understand the need to continue taking medication after they start feeling better. The finding corroborates results from previous studies in Tanzania [37] and South Africa [36], in which 'feeling better' was cited among reasons for both TB and MDR-TB patients to discontinue treatment. Given that MDR-TB treatment is prolonged (typically 18-24 months) and associated with adverse drug events, this finding underlines the importance of emphasising continuation of treatment even when patients feel better.

Similar to findings reported in previous studies among professional HCWs, most CTSs in the current study (86.6%) perceived themselves to have a high occupational risk of acquiring MDR-TB infection [34, 38]. This result is significant considering the findings from Swaziland [38], Uganda [39] and Russia [22] that HCWs' perceived threat of acquiring TB infection at work was heightened when environmental IPC measures were inadequate. This was indeed the case in the current study where none of the patients visited in their homes were observed wearing surgical masks. Thus, the need for training in community MDR-TB IPC in order to improve their KAP, both in the beginning and during the course of their work as CTSs, cannot be overemphasised.

In the current study, CTSs were found to generally have good understanding of and maintain good practice in implementing administrative TB IPC principles. Several previous studies focusing on HCWs in other developing countries reported similar findings [17, 24, 34]. These findings differ substantially with the low TB IPC

knowledge scores and practices reported among HCWs in Swaziland [38], Lesotho [18] and Russia [22].

Observation visits noted a good correspondence between self-reported and actual practice – a majority of MDR-TB patients had disclosed their MDR-TB condition to family members, slept alone in a separate room and all household members had been screened for TB. These findings may be considered as strong evidence of the positive effect of CTSs educating patients and increasing community awareness about MDR-TB.

However, the high overall good scores masked substantial gaps in some aspects of CTSs' MDR-TB knowledge and attitudes. For example, in this study, more than half of the respondents incorrectly answered that people who sleep in the same room are not close TB contacts (56.1%) and taking antiretroviral drugs as post-exposure prophylaxis (PEP) does not reduce the rate of infection in HCWs exposed to HIV through needlestick injuries (40.3%). The findings highlighted salient erroneous beliefs, with just more than one-quarter (25.6%) of the CTSs incorrectly believing that MDR-TB was not a major public health threat in Swaziland. As reported in other studies, negative CTSs' attitudes and erroneous beliefs could adversely influence patients' behaviours in relation to accessing MDR-TB services [40–42].

Despite displaying these responses, surprisingly, about one-quarter (25.6%) of the CTSs reported not being involved in patient education about MDR-TB. These finding are similar to those reported among HCWs in Lesotho [18]. Programme managers could develop tailor-made standard operating procedures aided by a supportive approach to supervision to guide CTSs in their scope of practice as a way of ensuring that CTSs fulfil all their community-based health-related functions. An improvement in the formal financial incentives may also be considered as a way of motivating CTSs to devote time and amplify their present commitment to their work.

Frontline HCWs such as CTSs and family members are at a disproportionate risk of acquiring MDR-TB infection from their daily direct contact with patients. Community TB transmission is frequently eclipsed by the attention placed on nosocomial transmission, even though in high prevalence areas, MDR-TB is often spread in

household and community settings [43–45]. With regard to the practice of implementing environmental IPC measures to reduce household MDR-TB transmission, all respondents maintained that they advise households to apply cross ventilation in the room the MDR-TB patient slept.

Despite the study being carried out during winter, the 20 MDR-TB patients' rooms observed all had adequate windows and doors that were open, mirroring recent observations of an Indian study evaluating TB infection control interventions among households of MDR-TB patients [46]. This is higher compared to observations in studies in Ethiopian (89.2%) and South African (69.0%) hospitals [47,48]. However, the difference may be partially explained by the limited alternatives for environmental control measures in rural households that are often restricted to opening windows and doors, while in hospital settings, other options such as air cleaning filters or ultra violet germicidal irradiation may be available.

In this study, most participants were aware of the importance of wearing a protective mask in reducing the risk of MDR-TB transmission when in contact with a patient. Virtually all participants reported receiving a consistent supply of N95 respirators and also wearing them despite the discomfort. The level of adherence to IPC guidelines by CTSs in this study was higher than that reported among HCWs in Lesotho and South Africa [17, 18, 24]. The higher compliance with use of protective masks by CTSs observed in this study could be due to the frequent and daily direct physical contact with and exposure to MDR-TB patients compared to mere observation in DOT for drug sensitive TB treatment.

During observation visits to the 20 households, CTSs consistently wore respirators, while none of the MDR-TB patients wore surgical masks in their homes due to lack of supply. Similar findings were reported from a study on TB IPC in PHC facilities in South Africa [24]. When worn by patients, surgical masks are an adjunct measure in TB IPC akin to other administrative and environmental controls such as cough etiquette and simple natural ventilation. In the context of this study setting, surgical masks are necessary to compliment the currently available IPC measures. As such, a consideration should be made to provide MDR-TB patients with an adequate supply of surgical masks to wear, particularly, during the intensive treatment phase.

The observations conducted, albeit limited in number, found the overall intramuscular injection practices of CTSs providing care to MDR-TB patients in their (patients') homes to be safe and highly satisfactory. These findings were comparable to results reported among professional HCWs in a large Indian hospital [49] and CHWs administering injectable contraceptives [50, 51]. Implicitly, despite their lower basic literacy and numeracy skills relative to professional HCWs, with appropriate training and supervision, CTSs were competent enough to administer safe MDR-TB injections.

Noteworthy and in line with established international standards, CTSs were observed to correctly assemble medication, alcohol swabs, syringes, needles, and sharps disposal container; explain the procedure and relax the patient before the injection; locate the site using landmarks; clean the area with an alcohol swab; apply the right injection technique; discard sharps in a puncture-proof sharps disposal container; dispose used supplies; and document the procedure in the patient's DOT card [30–32, 52].

Nevertheless, of concern was the finding of higher self-reported basic hand hygiene practice than observed practice – similar to other studies [34, 53]. While all CTSs were observed to perform hand hygiene before administering injections, one-fifth did not wash hands after contact with their patient. Moreover, in this study, CTSs were observed to use plain non-antimicrobial soap for hand washing, contrary to alcohol-based hand antiseptics recommended by the national TB IPC guidelines [54]. Possible explanations for the disparity between IPC guidelines and actual implementation of effective hand hygiene practices include inadequate training, lack of enough supply of hand hygiene products, and limited clean flowing water [34, 53, 54].

Drawing from recommendations from previous research globally, key strategies in this setting include the reinforcement of educational initiatives with written reminders for CTSs to recognise hand hygiene opportunities as well as the availability and use of low cost alcohol based hand rub to interrupt the cross-contamination chain [34, 53, 55, 56].

With the task-shifting of injection administration to lay HCWs being a relatively new concept, as far as could be established, there were no studies in extant literature describing needlestick injuries among this frontline cadre. Needlestick injuries among HCWs can be considered as a cardinal indication of unsafe injection handling practices. Encouragingly, the prevalence of needlestick injuries among CTSs in this study was low (11.0%) compared to that reported for professional HCWs in Kenya (19.0%) and Nigeria (51.0%) [57, 58]. Needlestick injuries are among the most common occupational hazards that CTSs are exposed to during their work and carry the potential likelihood of transmission of blood borne pathogens such as HIV. However, with the reporting of needlestick injuries being purely voluntary, the scale of these incidents among CTSs could not be accurately established and therefore the actual prevalence of sharps injuries remains unclear.

As also reported in previous studies, the few CTSs who recounted having experienced an accidental needlestick injury did not report the incident because the needles that caused injury were not used on patients, perceived low risk of HIV infection, job security fears and lack of knowledge on the importance of taking PEP [57, 59]. The implications for programme managers and community MDR-TB nurses is the need to reinforce training of frontline CHWs (CTSs) on the various elements of standard precautions on injection safety, particularly, the immediate reporting of occupational injuries, and commencement of PEP. There is need to further explore and identify barriers to reporting needlestick injuries among CTSs to enable provision of PEP to occupationally exposed HCWs.

Although treatment adherence cannot be attributed to one single factor, the onus for patients' adherence is often on CHWs who have the strategic role of ensuring access to TB services, and promptly detecting and reporting treatment default [56]. This study revealed that CTSs invariably administered injections and oral medications daily thereby optimising their patients' adherence to MDR-TB treatment plans. This finding is consistent with previous studies that have demonstrated that patients who receive TB care and support from CHWs were likely to adhere to treatment and achieve cure [60, 61].

In the current study, binomial regression analysis revealed that there was no statistically significant correlation between individual socio-demographic variables, knowledge and attitudes and good community-based MDR-TB management practice. This is in converse to findings from research conducted in South Africa and Ethiopia that identified knowledge as a predictor of good TB infection control practices [24, 62]. Taken together, these findings raise questions about the adequacy, design, content and methods of delivering MDR-TB related information to CTSs in ways that improve their knowledge and attitudes and changes their practice patterns for the better. A comprehensive approach to MDR-TB education aimed not only at imparting appropriate job skills, but also an adequate knowledge base to influence CTSs practice patterns is required.

3.5.1 Limitations

Findings of this study should be interpreted with caution because of the small sample size (n = 82), and future research with a sufficiently larger sample would be required to widen the range of possible data and obtain a better picture from regression analysis. The high proportion of CTS with good community-based MDR-TB management scores in this study could also be creating a high ceiling effect, concealing potential variation and differences between respondents. The highly skewed practice scores, typically lacking a normal distribution pattern, reduce the chances of obtaining significant predictors.

With this study mostly founded on self-reported practice and compliance, the tendency of survey respondents to present themselves in the most socially desirable manner poses a serious concern. However, consistent with the overall thrust of this study, structured observations of CTS administering MDR-TB injections were undertaken to complement survey responses and partly circumvent this tendency. Even so, the observed CTSs could possibly have altered certain facets of their behaviour, particularly as a result of their awareness of being studied by the first author who was a medical doctor (Hawthorne effect).

Although verification of self-reported practice was limited to 20 CTSs, the observations yielded valuable insights by giving the researchers access to the

context and meaning surrounding CTSs' self-reported KAP and what they actually practice in community-based MDR-TB management. Furthermore, the effect of social desirability bias associated with self-reports and observations was also countered by assuring the respondents of the maintenance of confidentiality of the information gathered during the interviews. Respondents were assured that no names or other personal identifying information would be collected during the interviews and that observations and findings would be reported anonymously using aggregate analysis. They were also assured that the outcomes of the observations were for research purposes only and would not affect their job security or incentives in any way.

Although administrative and environmental TB IPC were observed to be adequately implemented, the present study did not examine the role of MDR-TB patients in ensuring TB IPC measures are consistently implemented in their households. Evidence from research carried out in rural South Africa has shown that knowledge and acceptability of patient-specific IPC standards is key to TB patients' adherence in implementing these measures within household and community settings [63].

Despite results from this cross-sectional research not being easy to generalise, the study's presentation of contextualised data regarding the task-shifting of DOT and MDR-TB intramuscular injection administration to CTSs in the Shiselweni region offers unique insights into this novel practice.

3.6 Conclusion

The overall knowledge, attitudes and actual practice of community-based MDR-TB management demonstrated by CTSs in this study in Shiselweni, Swaziland appeared, in most respects, similar or superior to that reported in previous research among both lay and professional HCWs. Trained lay community members can complement an overstretched health workforce by competently providing satisfactory DOT supervision and highly differentiated clinical tasks such as safe administration of MDR-TB injections at community level.

However, the good KAP scores on community-based MDR-TB management reported in this study does not mean that the provision of optimum care by CTSs could not be improved. In light of the limited literacy and numeracy skills of a majority of CTSs, ongoing in-service training programmes to reinforce awareness, address gaps in current knowledge and dispel misperceptions regarding community-based MDR-TB management should be emphasised. Administering a lengthy course of MDR-TB tablets and injections is not straightforward and requires programme managers to consider providing regular supportive supervision and an improvement in the financial incentives as a way of motivating CTSs to fulfil their delegated tasks.

The lack of a positive significant association between socio-demographic factors such as CTS's training and experience together with knowledge and attitudes and good community-based MDR-TB management practices calls for further research exploring the reasons for the absence of a relationship. This is imperative considering that it is these relationships that could be used as a foundation to build interventions to enhance the performance of CTSs upon.

List of abbreviations

TB: Tuberculosis; MDR-TB: multidrug-resistant tuberculosis; CTS: community treatment supporter; DOT: directly observed treatment; WHO: World Health Organization; PHC: primary health care; IPC: infection prevention and control

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3.8 Authors' contributions

EP participated in the conception and design of the study, acquisition of data, performed the statistical analysis and drafted the manuscript.

CH, NGK and DD gave advice in the design of the study, the interpretation of the results, and participated in the revision of the article for important intellectual content.

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Chapter 4: Patient satisfaction with directly observed treatment and multidrug-resistant tuberculosis injection administration by lay health workers in rural Eswatini

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Structure

4.1 Abstract

Background: The human resources for health crisis in rural Eswatini led to a novel community-based multidrug-resistant tuberculosis (MDR-TB) treatment strategy based on task-shifting; i.e. delegation of directly observed treatment (DOT) and administration of MDR-TB injections, traditionally restricted to professional nurses, to lay community treatment supporters (CTSs).

Aim: This study assessed the level of patient satisfaction with receiving community-based MDR-TB care from a CTS.

Setting: The study was conducted at three MDR-TB-treating facilities in the mostly rural Shiselweni region.

Methods: A cross-sectional survey of a purposive sample of 78 patients receiving DOT and intramuscular MDR-TB injections from CTSs was carried out in 2017. Descriptive statistics and regressions were calculated.

Results: A high overall general patient satisfaction score for receiving community-based MDR-TB care from a CTS was observed. Adherence counselling, confidentiality, provider selection and treatment costs significantly ($p < 0.05$) influenced satisfaction. A large majority ($n = 62$; 79.5%) of patients indicated that they would likely recommend their significant others to receive MDR-TB care from a CTS. Respondents identified the need to provide CTSs with adequate training, regular supervision, and sufficient incentives, and also to broaden the scope of their services.

Conclusions: This study observed that task-shifting of DOT and MDR-TB injection administration to CTSs was supported from a patient perspective. However, adherence counselling, confidentiality, provider selection and treatment costs should be taken into account in community-based MDR-TB care programming. Further to the patients, community-based TB care could be enhanced by improving CTSs' training, supervision, incentives and broadening the scope of their services.

Keywords: Community treatment supporter, human resources for health, task-shifting, multidrug-resistant tuberculosis, injection administration

4.2 Introduction

Tuberculosis (TB) is a major public health concern and remains one of the most devastating diseases in the world. Although global TB incidence has been declining for the past few years, a new threat has emerged - multidrug resistant-TB (MDR-TB)

- that is showing no signs of receding and is undermining progress in TB control. MDR-TB is defined as strains of TB not susceptible to two of the most potent first-line drugs, isoniazid and rifampicin.[1] Interrupted treatment of drug-sensitive TB is an important factor in the development of acquired drug resistance.[2] In 2017, the World Health Organization (WHO) reported the proportion of MDR-TB in new and previously treated cases of TB in Eswatini to be 6.8% and 16.0% respectively.[1] The country's treatment success rate among MDR-TB cases remained at 68% (2015 cohort) and below the 2015 WHO target of 75% or higher.[3–5] So serious is the problem of TB in Eswatini that already in 2011 the government declared the epidemic a national disaster.

In response, the Eswatini Ministry of Health developed the National TB Strategic Plan (2015-2019)[6] that is aligned within the framework of the End TB Strategy[7] and the Sustainable Development Goals (SDGs)[8]. The Plan aims to strengthen community drug-resistant TB management, increase access to treatment and ensure that 75% or more MDR-TB cases are treated successfully.[6]

In Eswatini, the standardised therapeutic regimen for MDR-TB consists of toxic, complex and expensive second line anti-TB drugs that include a daily injectable for the first eight months and treatment that takes up to 24 months to complete.[9] The National TB Control Programme (NTCP) is in the process of scaling up the use of the WHO-recommended shorter MDR-TB treatment regimens (nine months instead of the usual two years) across the whole country. MDR-TB patients typically make daily visits to the closest PHC facility to receive directly observed treatment (DOT) and their injection from a professional nurse. DOT is a strategy recommended by the WHO that involves a health worker supervising TB patients as they take each dose of their standardised medication.[10]

In Eswatini, rural areas carry a disproportionately high burden of MDR-TB. In addition, PHC facilities are often distant and geographically inaccessible from patients' homes, and are also frequently characterised by lack of front-line TB human resources for health (HRH).[11–14] In this context, front-line TB HRH refers to healthcare workers who are generally the community's first level of contact within a PHC system for accessing TB services. In order to address the prevailing MDR-TB treatment access and HRH challenges in the predominantly rural Shiselweni region,

in 2008, Médecins Sans Frontières (MSF) established a novel patient-centred community-based MDR-TB treatment strategy based on task-shifting within the existing NTCP. In this context, task-shifting refers primarily to the transfer of DOT and MDR-TB injection administration responsibilities traditionally restricted to professional nurses, to trained lay community members. In extant literature, the task-shifting of highly differentiated clinical tasks such as injection administration to LHWs has been limited to the delivery of contraceptives and injectable antibiotics in home-based management of new-born infections in rural and low-resource settings.[15,16]

Under this model of care, MDR-TB patients discharged from the MDR-TB treating hospital are linked to a lay community member (not a family member) of their choice from their neighbourhood, referred to as a community treatment supporter (CTS). This strategy allows MDR-TB patients to receive DOT and their daily injections from CTSs in their (the patients') homes without having to make daily trips to the nearest clinic. The selected neighbour must have sufficient literacy skills to be able to read the training manual in English and document administered injections. On inception, newly recruited CTSs receive hands-on demonstrations, mentored practice and theoretical training that focuses primarily on MDR-TB epidemiology, transmission, diagnosis, treatment/strategies (DOT), safe injection handling and adverse drug reactions. In addition, due to the potential risk of contracting HIV infection from needlestick injuries, newly recruited CTSs are routinely informed of the patient's HIV status prior to undergoing training. The CTS's responsibilities include patient confidentiality and procedures for patient referral to community MDR-TB nurses and other MDR-TB team members.

CTSs are directly supported by a team of professional healthcare workers made up of a doctor, community MDR-TB nurse, psychologist and social worker. Each CTS receives ongoing supervisory visits from and at the discretion of the community MDR-TB nurse, to re-evaluate their skills and on-the-job training needs. CTSs accompany their MDR-TB patients to the main health facilities for their monthly outpatient treatment review or unscheduled visits, in the case of worsening health condition. Although CTSs are typically recruited and trained to focus solely on MDR-TB, they are also important adjuncts in the provision of adherence support to human immunodeficiency virus (HIV) co-infected MDR-TB patients on antiretroviral therapy.

Core clinical decisions related to the MDR-TB treatment are taken by formal facility-based professional healthcare workers. Local administration of DOT and intra-muscular injections by a CTS was introduced to reduce some of the social and financial difficulties frequently faced by patients in accessing the often more distant centralised clinic-based MDR-TB treatment services.[14]

Despite the decade-long implementation of the task-shifting strategy in the Shiselweni region, the Ministry of Health is yet to officially endorse the strategy. Existing NTCP strategic plans and MDR-TB treatment guidelines only provide for task-shifting of certain professional nurses' responsibilities such as DOT supervision and TB treatment defaulter tracing to LHWs. Professional bodies in Eswatini have voiced ethical concerns about standards of care and safety risks for both patients and CTSs ranging from potential errors in dosing to transmission of infections through unsafe injection handling and inappropriate community MDR-TB infection prevention and control practices.[17] These fears were heightened by the increased recognition of the role community transmission played in the publicised outbreak of extensively drug resistant TB in the neighbouring KwaZulu-Natal province of South Africa.[18]

Authorities have also raised questions regarding the sensitive nature of aspects of care delegated to lay community members, in particular, whether the CTSs respect patients' confidential medical information.[17] This is important given the stigma that surrounds the disease. Despite many years of public health education, MDR-TB is presumed to be incurable.[19,20] CTSs learn about the medical condition and may view the intimate anatomy of patients as they administer and coordinate care. The CTS-patient encounter also takes place in the home setting which is often not conducive for maintaining privacy and confidentiality.

Assessment of community-based MDR-TB services, specifically the task-shifting of care to CTSs, has often been restricted to clinical outcomes without accounting for patients' satisfaction with health services received. There is strong evidence that patient satisfaction with health care services received can instrumentally affect treatment uptake, adherence and retention in TB care.[21–25] The need to incorporate the patients' perspective of TB care received is emphasised in the International

Standards for Tuberculosis Care (ISTC)[25] and the Compendium of Best Practice Guidelines of the International Union Against Tuberculosis and Lung Disease (The Union).[26] Drawing from a myriad of existing WHO recommendations, the ISTC and The Union support the call for a patient-centred approach based on the patient's needs and mutual respect between the patient and the healthcare service provider. By administering DOT and MDR-TB injections, CTSs perform a critical public health responsibility that carries a high level of obligation to the community and the individual MDR-TB patient. Thus, as frontline HRH in the provision of MDR-TB care, the interaction of CTSs with patients may considerably influence treatment outcomes.

Patient satisfaction with TB care refers to the match between the patient's prior expectations of care and subsequent perception of services actually received.[19,20] Patient satisfaction may be seen to centre on the fulfilment of the following expectations: reasonable waiting time for care, respectful and considerate interaction with healthcare providers, accurate diagnosis and optimism of a good prognosis, continuity and coordination of care, affordability and the professional competence of service providers.[21,22,27,28]

Despite the recognition of the importance of determining levels of patient satisfaction as a measure of the quality of TB services,[21,22] no study to date has evaluated patients satisfaction with receiving DOT and intramuscular MDR-TB injections from CTSs in the Shiselweni region. In view of the growing global experience of the potential role of patient satisfaction in optimising clinical outcomes, particularly with respect to TB services, this study was conducted to assess the level of patients' satisfaction and their perceptions of the different dimensions of MDR-TB care delegated from professional nurses to CTSs in a rural region of Eswatini. Results will help in formulating recommendations to optimise the task-shifting approach in community-based MDR-TB management in resource-limited settings and contribute to the achievement of various MDR-TB control targets as outlined in the national TB Strategic Plan, End TB Strategy and SDGs.

4.3 Methods

4.3.1 Study setting and design

The predominantly rural Shiselweni region is one of the four regions of Eswatini. With an estimated population of 204 111 in 2017,[29] the region has one hospital and two health centres supporting 18 smaller outlying PHC clinics. In May 2017, a cross-sectional study was conducted among MDR-TB patients receiving or who had received DOT and intra-muscular MDR-TB injections from a CTS in the Shiselweni region using a structured interviewer-administered questionnaire.

4.3.2 Sampling method

The study population consisted of 124 MDR-TB patients enrolled at any of the three MDR-TB treating healthcare facilities in the Shiselweni region and receiving or who had received DOT and intramuscular injections from a CTS in the 12 months (to reduce recall bias) preceding May 2017. A purposive sample of 78 out of the study population was selected for the survey. A total of 46 MDR-TB patients from the study population that did not meet the inclusion criteria were excluded from participation. The study excluded 26 patients younger than 18 years and seven participants that were too ill and hospitalised at the time of the study from participation.

Due to practical constraints, this study also excluded the participation of two MDR-TB patients who had profound deafness from medication toxicity who could have provided diverse and instructive opinions about their level of satisfaction with the task-shifting community-based MDR-TB care to CTSs. The difficulty in comprehension could have undermined the potential deaf participants' ability to give an informed consent, participate voluntarily and interact with researchers in the study. In addition, 11 MDR-TB patients who had been under the care of a CTS for less than a month were not included as they may not have had enough experience to rate the services received from a CTS. There were no refusals to participate in the survey.

4.3.3 Instrument development and data gathering

Given the paucity of an adequately tested appropriate tool to measure MDR-TB patient satisfaction with receiving DOT and intramuscular injections from CTSs, a newly-developed questionnaire based on literature review, CTS training materials and job descriptions was used.[21,22,25,30] The content validity of the questionnaire was assessed by expert opinion. The internal reliability of the satisfaction scales was also examined, considering Cronbach's alpha coefficients of 0.7 or higher as acceptable.

The questionnaire consisted of items measuring socio-demographic characteristics of MDR-TB patients including sex, age, marital status, educational level, employment status, source of income, duration of MDR-TB treatment, distance between place of residence and nearest PHC facility, and types of transportation to the facility. Patient satisfaction with nine dimensions of MDR-TB care delegated to CTSs was measured using single five-point Likert-scale items with responses ranging from “strongly disagree” to “strongly agree” and coded in values from 1 to 5. Both negatively- and positively-worded questions were included to minimise response bias. The questionnaire was forward-translated from English to siSwati and back-translated to English before being pre-tested for face validity and understanding in a convenience sample of ten previous MDR-TB patients who were excluded in the main study. The information from the pre-testing was used to revise and improve the clarity of the questions.

Trained interviewers conducted face-to-face interviews in either siSwati or English with patients attending one of the three rural health centres in the Shiselweni region. MDR-TB patients visiting these facilities for their monthly review in May 2017 were informed by the community MDR-TB nurse about the research at the end of their consultation. Participation in the study was voluntary and patients were assured that non-participation would not compromise their MDR-TB care in any way. No incentives or tokens of appreciation were provided. To reduce the effect of social desirability bias associated with self-reported satisfaction, participants were assured of the maintenance of confidentiality of the information gathered during the interviews. They were informed that no names or other personal identifying information would be collected during the interviews and that the findings would be reported anonymously using aggregate analysis. They were also assured that the

outcomes of the study were for research purposes only and would not affect their care and support in any way.

Once a respondent agreed to participate, the trained interviewers explained the purpose of the research, data-gathering procedures, risks and benefits, and the expected duration of the interview. Written informed consent was obtained from all study participants before the interviews were conducted.

4.3.4 Measures

Satisfaction with dimensions of MDR-TB services from CTSs. The questionnaire was divided into nine subscales covering satisfaction with dimensions of MDR-TB care and services received from CTSs. The breadth of measurement covered the following domains: 1) satisfaction with MDR-TB services availability and convenience (3 items): 2) provider-patient communication (4 items); 3) provider attitude, respect and compassion (5 items); 4) stigma (1 item); 5) health education (5 items); 6) adherence counselling (1 item); 7) confidentiality (1 item); 8) provider selection (1 item); and 9) treatment cost (1 item).

General patient satisfaction. One global rating question regarding the primary outcome, general satisfaction with receiving DOT and intramuscular MDR-TB injections from a CTS was included. Another question enquiring about willingness to recommend a close family member or friend with MDR-TB to receive DOT and intramuscular MDR-TB injections from a CTS was also added as a proxy for general satisfaction with services provided by CTSs. To aid in the interpretation of the quantitative findings, an open-ended question “What can be done to improve community-based MDR-TB care services rendered by the CTS?” was also included.

4.3.5 Data analysis

Data from the questionnaire was double entered into Epi Info 7 and exported to Stata (Version 13.1) for analysis. Standard descriptive statistics were used to summarise socio-demographic variables. Mean scores were calculated for each dimension of MDR-TB care as a composite measure of satisfaction using each of the items under

the subscale indicator. Also, the mean score for the general satisfaction question was calculated.

Regression analysis was used to assess and compare the effect of socio-demographic variables on the general patient satisfaction score. Ordinal regression models were used to predict the regression coefficients for the mean general satisfaction score for each of the nine dimensions of MDR-TB services provided by CTSs. P-values of less than 0.05 were considered to be statistically significant. Individual participant responses to the open-ended question "What can be done to improve the services rendered by the CTSs?" were reviewed, coded and manually assigned to key themes. Using thematic analysis, common ideas and emerging patterns in the responses from the data were identified and analysed.

4.3.6 Ethical clearance and authorisation

Ethical approval was obtained from the Scientific and Ethics Committee of Eswatini (IRB00006240) and the Health Sciences Research Ethics Committee, University of Free State (UFS-HSD2016/1489). The study was authorised by the Eswatini NTCP and MSF. No personal identifying information was collected and findings were reported anonymously using aggregate analysis.

4.4 Results

Half of the participants (n = 39; 50.0%) were aged between 31 and 40 years (Table 1). Almost nine in every ten of the participants (n = 69; 88.5%) had received DOT and MDR-TB injections from a CTS for at least four months. Almost two-thirds (n = 47; 65.3%) were not married and more than half (n = 43; 55.1%) had low literacy and numeracy skills (primary education or lower). Most of the MDR-TB patients interviewed (n = 65; 83.3%) were not employed. More than three-quarters of patients interviewed (n = 67; 85.9%) had an estimated monthly household income of less than ZAR1000 (= US$74.07 [exchange rate on 31/05/2017]). Most patients (n = 42; 53.8%) lived more than 20 kilometres from the nearest PHC facility. A large majority (n = 75; 93.6%) relied on public transport to travel to the nearest health care facility.

Table 1: Socio-demographic characteristics of survey respondents

Characteristics	N = 78 (%)
Sex	
Male	43 (55.1)
Female	35 (44.9)
Age group (years)	
< 30	20 (25.6)
30-39	39 (50.0)
40-49	7 (9.0)
≥ 50	12 (15.4)
Marital status	
Married	27 (34.6)
Unmarried	51 (65.4)
Education level	
Primary school or lower	43 (55.1)
Secondary school or higher	35 (44.9)
Employment	
Employed	13 (16.7)
Unemployed	65 (83.3)
Estimated monthly household income (ZAR)[a]	
0-1000	67 (85.9)
1001-10000	11 (14.1)
> 10000	0 (0.0)
Duration on MDR-TB injections from CTS	
1-4 months	9 (11.5)
> 4 months	69 (88.5)
Distance to nearest clinic	
< 5 km	5 (6.4)
5-10 km	10 (12.8)
11-20 km	21 (26.9)
> 20 km	42 (53.8)
Transportation to clinic	
Bus/taxi	73 (93.6)
Drive/ride from family member	3 (3.8)
Walk/bicycle	2 (2.6)

[a]ZAR, South African Rand (local currency); US$1 = ZAR14.91 [exchange rate on 23/05/2017] Receipt of ART was a criterion for admission to the community-based models for patients co-infected with HIV

The overall mean score of general patient satisfaction for receiving DOT and intramuscular MDR-TB injections from a CTS was 4.4 (standard deviation: 1.0).

Table 2 illustrates patient socio-demographic factors influencing mean general patients' satisfaction scores. All socio-demographic factors were considered as predictor variables in the adjusted model. The study revealed no significant association between mean general satisfaction score and the other patient socio-demographic characteristics.

Table 2: Adjusted coefficients for mean general satisfaction and patient socio-demographic characteristics

Characteristics	N	Mean (SD)	P-value	Adjusted			P-value
	78	4.4 (1.0)		β	95% CI		
Respondents' sex							
Male (reference)	43	4.4 (1.0)	0.8053				
Female	35	4.4 (1.0)		0.12	-0.83	1.08	0.804
Age group (years)							
< 30 (reference)	20	4.2 (1.2)	0.2403				
30-39	39	4.4 (1.0)		0.38	-0.71	1.48	0.493
40-49	7	4.3 (1.1)		0.05	-1.65	1.67	0.995
≥ 50	12	4.9 (0.3)		2.04	-0.18	4.26	0.072
Marital status							
Married (reference)	27	4.6 (0.9)	0.2849				
Unmarried	51	4.4 (1.1)		0.58	-0.48	1.64	0.282
Education level							
Primary school or lower (reference)	43	4.6 (0.8)	0.378				
Secondary school or higher	35	4.3 (1.2)		-0.43	-1.38	0.52	0.374
Employment							
Employed	13	4.2 (1.2)	0.7422				
Unemployed	65	4.5 (1.0)		-0.23	-1.51	1.06	0.728
Estimated monthly household income (ZAR)[a]							
0-1000 (reference)	67	4.4 (1.0)	0.9579				
1001-10000	11	4.4 (1.1)		0.04	-1.37	1.45	0.956
Duration on MDR-TB injections from CTS							
1-4 months (reference)	9	4.7 (0.7)	0.51				

Characteristics	N	Mean (SD)	P-value	Adjusted			P-value
	78	**4.4 (1.0)**		**β**	**95% CI**		
> 4 months	69	4.4 (1.0)		-0.54	-2.17	1.09	0.516
Distance to nearest clinic							
< 5 km (reference)	5	4.4 (0.9)					
5-10 km	10	4.3 (1.1)	0.91	-0.07	-2.14	2.00	0.945
11-20 km	21	4.5 (1.0)		0.38	-1.54	2.30	0.699
> 20 km	42	4.4 (1.1)		0.35	-1.46	2.15	0.707
Transportation to clinic							
Bus/taxi	73	4.5 (1.0)					
Drive/ride from family member (reference)	3	2.5 (1.5)	0.04	-3.58	-6.47	-0.69	0.015
Walk/bicycle	2	4.5 (1.0)		2.72	0.37	5.08	0.023

[a]ZAR, South African Rand (local currency); US$1 =ZAR14.91 [exchange rate on 23/05/2017].

A Spearman correlation coefficient was computed to examine the relationship between mean scores of general satisfaction and satisfaction with nine specific measures of MDR-TB services provided by CTSs (Table 3). There was a weak correlation between treatment costs, r (78) = 0.27, p = 0.015 and general satisfaction. Overall, the weak but positive correlation between treatment costs and general satisfaction scores suggests that this dimension assesses factors other than the patient's general satisfaction.

Table 3: Correlation between mean general satisfaction score and satisfaction with other dimensions of MDR-TB care

Satisfaction scale	Mean score (SD)	Correlation coefficients (r)	P-value	R^2
Accessibility and convenience	4.62 (0.74)	0.05	0.649	0.04
Provider-patient communication	4.87 (0.37)	0.10	0.392	0.09
Provider attitude, respect and compassion	4.77 (0.52)	0.01	0.947	0.09
Health education	4.78 (0.78)	0.14	0.214	0.29
Adherence counselling	4.91 (0.40)	-0.02	0.864	0.06
Stigma	4.41 (1.16)	-0.01	0.909	0.01
Confidentiality	4.78 (0.49)	-0.10	0.376	0.12
Provider selection	4.82 (0.58)	0.17	0.134	0.04
Treatment costs	4.65 (1.03)	0.27	**0.015**	0.28

Ordinal regression models were used to predict regression coefficients for the mean general satisfaction score for each of the nine dimensions of MDR-TB services provided by CTSs (Table 4). All nine dimensions of MDR-TB services provided by CTSs were included as potential explanatory variables in the adjusted model. In the adjusted model, adherence counselling (p = 0.019), confidentiality (p = 0.026), provider selection (p = 0.037), and treatment costs (p = 0.014) significantly predicted mean general patient satisfaction.

Table 4: Adjusted and unadjusted ordinal regression coefficients for mean scores of patient's general satisfaction score by specific dimensions of MDR-TB care

Dimensions of MDR-TB care scores	Unadjusted		Adjusted		P-value
	β	SE	β	SE	
Accessibility and convenience	0.42	0.30	-1.14	0.72	0.116
Provider-patient communication	1.37	0.60	-0.81	1.69	0.633
Provider attitude, respect and compassion	1.06	0.47	1.67	1.25	0.178
Health education	0.61	0.32	0.56	0.36	0.126
Adherence counselling	1.17	0.67	5.03	2.14	0.019
Stigma	0.04	0.20	-0.04	0.35	0.912
Confidentiality	0.21	0.62	4.58	2.06	0.026
Provider selection	0.56	0.32	1.73	0.83	0.037
Treatment costs	0.41	0.18	0.60	0.24	0.014

Approximately four-fifths (n = 62; 79.5%) of the respondents indicated that they were likely to recommend their friends or family to receive DOT and MDR-TB injections from a CTS. More than half (n = 44; 56.4%) of the respondents suggested broadening of the scope of services provided by CTSs to include treatment of minor ailments or side effects of the medication such as nausea, vomiting and loss of appetite. More than one-third (n = 27; 34.6%) of the respondents identified the need to adequately train CTSs on respecting the privacy and confidentiality of their condition and medical information. Just more than a quarter (n = 20; 25.6%) of patients highlighted the need for regular supervision of and sufficient incentives for CTSs as ways of improving MDR-TB services.

4.5 Discussion

Previous studies evaluating community-based MDR-TB models of care have focused on clinical outcomes[31,32] without paying attention to patients' satisfaction. As far as could be ascertained, this is the first study to assess MDR-TB patients' views and the extent to which their perceptions of various aspects of care experiences provided by CTSs are associated with overall satisfaction with community-based MDR-TB treatment and care in the rural Shiselweni region. This study further contributes to the current national debate on task-shifting of DOT and injection administration to lay

community members by providing the patients' perspective and suggestions of ways to improve patient experiences in practice.

The overall mean score of self-reported general patient satisfaction in this study was fairly favourable, 4.4 based on a rating scale ranging from 1 (very low satisfaction) to 5 (very high satisfaction). There is a paucity of literature describing patients' perspectives on receiving MDR-TB treatment, with most researchers limiting their assessment to patient satisfaction with drug-sensitive TB services. Patient satisfaction is considered to be a highly desirable outcome measure of clinical care, influencing both treatment adherence and continuity of care. Findings from studies on levels of general satisfaction with community-based TB services conducted in various African settings in diverse geographical locations, albeit limited in number, have often been inconsistent.[21,22,24,30] The mixed results are not unexpected, since there are huge variations in how TB care is offered across different settings.

In studies conducted in South Africa[22] and Nigeria satisfaction[24], patients' socio-demographic characteristics such as age, gender and marital status have been reported to contribute significantly to patient satisfaction. Conversely, in this study patient characteristics were not significantly related to patient satisfaction, with the exception of the mode of transport. MDR-TB patients in this study also suggested the need to broaden the scope of services provided by CTSs to include treating of minor ailments and side effects of the medication. Taken together, these findings provide evidence that patients in poor rural settings face many barriers in accessing PHC such as transport limitations in reaching the distant and geographically inaccessible clinics.[12,14] This is significant in light of findings from a study in rural South Africa that reported time lost travelling for TB treatment as a potential cause of missed appointments and threat to treatment adherence and retention.[33] The findings from this study provide an impetus for policymakers to consider progressively increasing, where applicable, the geographical distribution of PHC facilities in rural areas. There is also need for more research to understand the extent to which transport limitations impede access to MDR-TB services in rural settings.

In this study, four dimensions of care experience – adherence counselling, confidentiality, provider selection and treatment costs – were found to significantly predict overall patient satisfaction. These findings could assist authorities in framing specific strategic interventions to improve patient satisfaction and strengthen patient-centred community-based MDR-TB care. It was rather surprising to find that the other dimensions of MDR-TB care provided by CTSs were not related to general patient satisfaction, because these aspects have been linked to satisfaction in prior studies.[21–24,27,30,34]

MDR-TB treatment regimens are lengthy with a high daily pill burden carrying frequent side-effects and requiring high levels of adherence to function optimally. Yet, the level of adherence to MDR-TB treatment varies significantly in different settings.[35–37] As such, adherence counselling is considered an integral component of a worthwhile care experience.[21,24] Consistent with results from previous research,[24] this study found adherence counselling to significantly influence patient satisfaction. These results suggest key targets to optimise the delivery of community-based MDR-TB care by CTSs. The WHO[38] and the Eswatini treatment guidelines[39] for drug-resistant TB recommend that health care workers should regularly assess, reinforce and support patient adherence to complex MDR-TB treatment plans due to its importance to successful treatment. Ongoing support for CTSs should recognise their critical role in adherence counselling and reinforce their training about the disease, treatment methods, common complications and skills essential to optimise adherence to care. On the basis of this finding, further research is needed to understand adherence counselling practices of CTSs that may guide the development of comprehensive MDR-TB treatment adherence interventions.

Findings from this study point to treatment costs as one of the dimensions of MDR-TB care that predicted general patient satisfaction. Although MDR-TB treatment is generally offered free of charge, a considerable share of the costs are incurred by patients and their households. MDR-TB patients are confronted with costs associated with visits to the health care facilities such as transport, food, and accommodation and loss of income due to inability to work. These costs impose a financial strain on patients and their households, potentially creating barriers to

treatment access and adherence, and increased treatment interruptions.[40,41] In the present study, a majority of patients were unemployed and reported a low monthly household income. One of the main milestones of the End TB strategy is that no families affected by TB face catastrophic costs by 2020.[6] As such, various levels and types of social protection support measures should be considered by policymakers to assist MDR-TB patients and their families. Future studies should assist policymakers in identifying, understanding and mitigating the effect of MDR-TB treatment on the financial status of patients and their families.

This study found that provider selection influenced general patient satisfaction. Perrault[42] established that patients who purposely participated in choosing their healthcare provider reported higher satisfaction. These patients often preferred to choose providers with whom they felt they shared some similarity. MDR-TB patients in this study context purposely selected a CTS of their choice from their neighbourhood. Thus the CTSs worked in the community they lived, typically sharing similar culture, language, religion, socio-economic status, and life experiences with their MDR-TB patients. The findings of the current study may suggest that provider selection empowered MDR-TB patients to play a significant involvement in their own care by participating in arguably one of the most key decisions - the initial nomination of a DOT and injection provider. This is important given recent calls by international bodies challenging national TB programmes to develop a broader interest in patient-centred care and systematically consider the perspectives of patients in the planning and provision of TB care.[25,26]

Prior to decentralisation of MDR-TB treatment, few people other than professional healthcare workers were de facto custodians of patients' health information, a situation that has changed with the task-shifting of clinical tasks to CTSs in the Shiselweni region. The observation of the confidentiality of patients' medical information is recognised as a central tenet in engendering patient satisfaction with TB care.[22] The present study found a link between overall satisfaction of MDR-TB patients and their perception of the maintenance of confidentiality as they interacted with CTSs. A breach of confidentiality can erode patients' trust in their healthcare provider and may have grave repercussions such as marital difficulties,

discrimination and loss of employment.[19,20] This observation is important in light of an assertion made by Dapaah and Senah[43] in a study carried out in rural Ghana on the socio-psychological trauma patients experience in accessing HIV services. The authors reported that patients were actually more worried about the social consequences of treatment than the medical outcomes of accessing care.

The task-shifting of DOT and intramuscular MDR-TB injections to lay healthcare workers in the Shiselweni region has so far gone ahead despite reservations and apprehensions from policymakers and NTCP functionaries.[17] Policymakers have raised ethical concerns related to the perceived inability of LHWs to observe the privacy and confidentiality of patients and also recognise and report MDR-TB treatment adverse events such as hearing loss. A substantial proportion of MDR-TB patients in this study recommended the need for adequate training on respecting patients' confidentiality, regular supervision and appropriate incentives for CTS. Implicitly, these suggestions potentially represent concerns from participants about CTSs' deficiencies in those aspects of care. Therefore, it is recommended that authorities consider formalising the task-shifting practice and facilitate the development of appropriate competency-based pre-service and on-the-job training, optimisation of supportive supervision of CTSs and active surveillance of treatment adverse events and breaches of confidentiality in the community-based MDR-TB treatment strategy. Future studies could examine ways to improve CTSs' respect for and maintenance of the confidentiality of patients' medical information.

In this study, almost four in every five of the respondents indicated that they were likely to recommend to their friends or family to receive community-based MDR-TB care from a CTS. This is significant in the context of scaling up the community-based programme implemented in the rural Shiselweni region. Without discounting the significance of other factors, the fact that MDR-TB patients would recommend to their significant others to receive care from a CTS is considered a valuable indicator of their personal experience of receiving services from a community-based healthcare provider.[44,45] The programme's reputation (or level of former or current patients' satisfaction) is likely to be the only information available to prospective MDR-TB patients or their care givers to help them choose a preferred provider or

model of care. Previous satisfaction is also important for former patients to return for further care to the same healthcare provider or programme in the future. The present study findings reveal new insights for programme managers and policymakers targeting new MDR-TB patients, retaining existing ones and generally increasing access to MDR-TB care.

4.5.1 Limitations

The use of patient perspectives to assess satisfaction with aspects of care by providers is not without problems. Tension exists regarding the subjective nature of patients' evaluation and questions have been raised as to whether their views truly represent the quality of care or the healthcare workers' interpersonal skills.[22] Patient satisfaction is considered to reflect the service dimension rather than the technical aspect of quality of care.[22] Participants' responses may also reflect socially desirable answers rather than their true views and experiences. With this study mostly founded on self-reported satisfaction, social desirability bias may have occurred. However, this was partially countered by assuring respondents of the anonymity of the questionnaires, that findings will be reported using aggregate analysis and that the outcomes of the study would not affect their care in any way.

The sample for this study was relatively small (n = 78) and participants were selected purposively. Small samples may be inadequate to provide reliable correlations. Furthermore, the strength of association between general patient satisfaction and the dimensions of care that were significant was weak. Although the current study included a number of possible underlying dimensions of care influencing satisfaction, future studies with a broadened spectrum of dimensions of care may explain some of the differences in patient satisfaction reported in this research. In addition, satisfaction with healthcare services cannot be adequately assessed without accounting for a patient's self-perceived health status. Literature suggests that the overall satisfaction rating is significantly influenced by the patient's severity of illness.[46,47] Although the present study excluded MDR-TB patients that were too ill or had profound deafness from medication toxicity, future studies on patient satisfaction

with the community-based MDR-TB model should include a measure of the participant's health status.

In spite of these limitations, the findings from this study provide valuable insights on how the services provided by CTSs are perceived by patients and what authorities may have to prioritise to improve patients' satisfaction.

4.6 Conclusion

The findings provide strong evidence that patients were satisfied with the task-shifting of DOT and MDR-TB injection administration to CTSs in the study area. The study also provided some insights into the four dimensions of care grounded in adherence counselling, confidentiality, provider selection and treatment costs that significantly influenced patients' general satisfaction. These aspects of MDR-TB care will need to be addressed in order to improve overall patient satisfaction. Provision of adequate training, regular supportive supervision, sufficient incentives and broadening of the scope of services offered by CTSs to include treatment of minor ailments were recommended as ways to optimise the delivery of community-based MDR-TB care.

The expansion of tasks delegated to LHWs to include administration of important injection medication has great potential. Evidence from this study suggests the need for policy and regulatory support to formalise the task-shifting practice; developing interventions for active surveillance of treatment adverse events; and improving patient experience of privacy and confidentiality. Future studies could further explore the barriers to and facilitators of the delivery of patient-centred MDR-TB care based on the task-shifting of clinical tasks to LHWs.

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4.8 Authors' contributions

EP conceptualised and designed the study, acquired data, performed the statistical analysis and drafted the manuscript.
CH, NGK and DD participated in the design of the study, the interpretation of the results and writing and revision of the article.

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Chapter 5: Task-shifting directly observed treatment and multidrug-resistant tuberculosis injection administration to lay health workers: stakeholder perceptions in rural Eswatini

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Structure

5.1 Abstract

Background

Eswatini is facing a critical shortage of human resources for health (HRH) and limited access to multidrug-resistant tuberculosis (MDR-TB) treatment in rural areas. This study assessed multiple stakeholders' perceptions of task-shifting directly observed treatment (DOT) supervision and administration of intramuscular MDR-TB injections to lay health workers (LHWs).

Methods

A mixed methods study comprising of a cross-sectional survey using a semi-structured questionnaire with community treatment supporters (CTSs) and a focus group discussion with key stakeholders including representatives from the Eswatini Ministry of Health (MOH), donor organisations, professional regulatory institutions, nursing academia, civil society and healthcare providers was conducted in May 2017. Descriptive statistics, thematic content analysis and data triangulation aided in the interpretation of results.

Results

A large majority of CTSs (n = 78; 95.1%) were female and 33 (40.2%) were older than 50 years. Most (n = 7; 70.0%) key stakeholders had over ten years of work experience in policy-making, advocacy in the fields of HRH and day-to-day practice in MDR-TB management. Task-shifting of MDR-TB injection administration was implemented without national policy guidance and regulation. Stakeholders viewed the strategy to be driven by the prevailing shortage of professional frontline HRH and limited access to MDR-TB treatment. Task-shifting was perceived to improve medication adherence, and reduce stigma and transport-related MDR-TB treatment access barriers. Front-line healthcare workers and implementing donor partners fully supported task-shifting. Policy-makers and other stakeholders accepted task-shifting conditionally due to fears of poor standards of care related to perceived

incompetence of CTSs. Appropriate compensation, adequate training and supervision, and non-financial incentives were suggested to retain CTSs. A holistic task-shifting policy and collaboration between the MOH, academia and nursing council in regulating the practice were recommended.

Conclusions

Stakeholders generally accepted the delegation of DOT supervision and administration of intramuscular MDR-TB injections to LHWs as a strategy to increase access to treatment, albeit with some apprehension. Findings from this study stress that task-shifting is not a panacea for HRH shortages, but a short-term solution that must form part of an overall simultaneous strategy to train, attract and retain adequate numbers of professional healthcare workers in Eswatini. To address some of the apprehension and ambivalence about expanding access to MDR-TB services through task-shifting, attention should be paid to important aspects such as competence-based training, certification and accreditation, adequate supportive on-the-job supervision, recognition, compensation, and expediting policy and regulatory support for LHWs.

Keywords: Eswatini, human resources for health, MDR-TB, community treatment supporter, directly observed treatment, injection administration

5.2 Background

Sub-Saharan Africa is facing the most serious shortage in human resources for health (HRH) in the world. Eswatini is among 57 countries classified as experiencing a critical professional healthcare worker shortage, with 1.40 midwives, nurses and physicians per 1000 population [1]. This is far below the benchmark of 2.28 healthcare workers per 1 000 population recommended for adequate coverage of essential health services [2]. In Eswatini, the rural areas carry a disproportionately high burden of multidrug-resistant tuberculosis (MDR-TB) and have primary healthcare (PHC) clinics that are often far and geographically inaccessible from the patient's home, and are typically also characterised by a lack of front-line TB HRH

[3-7]. Frontline TB HRH in this setting refers to health personnel who are usually the community's first port of call for accessing TB control services.

The control of TB has been highlighted as a priority in the Eswatini National TB Strategic Plan [8], the post-2015 global TB strategy (the End TB Strategy) [9] and the Sustainable Development Goals (SDGs) agendas [10]. In 2017, Eswatini reported a 68% treatment success rate for MDR-TB patients (2015 cohort), which was below the World Health Organization (WHO) target of 75% or higher [3, 11, 12]. The critical shortage of HRH and extent of the MDR-TB epidemic, particularly in rural areas, has seen the number of patients requiring access to MDR-TB treatment exceed the current capacity of the Eswatini Ministry of Health (MOH). The serious HRH scarcity impedes the country's ability to implement and leverage interventions aimed at achieving national and international MDR-TB control targets.

In order to address the prevailing professional frontline HRH and MDR-TB treatment access challenges in the predominantly rural Shiselweni region, Médecins Sans Frontières (MSF) established a novel patient-centred community-based MDR-TB treatment strategy in 2008 within the existing National Tuberculosis Control Programme (NTCP) [7]. The main feature of this model is the task-shifting of directly observed treatment (DOT) supervision and intramuscular MDR-TB injection administration responsibilities traditionally restricted to professional nurses to trained lay health workers (LHWs). DOT involves a patient taking standard medication under guided supervision from a healthcare worker or trained caregiver. Local supervision of DOT and administration of intra-muscular injections by a CTS was introduced to address some of the social and financial difficulties frequently faced by patients in accessing the often more distant centralised clinic-based MDR-TB treatment services [7].

In this model of care, MDR-TB patients discharged from the MDR-TB inpatient hospital are linked to a LHW, referred to as a community treatment supporter (CTS), of their own choice and from their locality. Community MDR-TB nurses facilitate the selection, recruitment and training of CTSs. The recruitment of CTSs, which starts as soon as the diagnosis of MDR-TB is made, involves the patient proposing possible

neighbours to the community MDR-TB nurse who then selects and contacts the most suitable candidate. The selected neighbour must have sufficient literacy skills to be able to read the community MDR-TB management training manual in English and document treatment [7]. In addition, the CTS should have a stable living accommodation near the patient to perform twice-daily DOT and administer injection-based medication; be available throughout the day and night to support the patient; and motivated to support the MDR-TB patient for the full length of the treatment.

The training of CTSs comprises of a 5-day theoretical workshop and on-the-job learning. The theoretical component of the training is conducted by community MDR-TB nurses through classroom instruction, group work and open discussions, and focuses primarily on themes relating to MDR-TB epidemiology, transmission, diagnosis, treatment/strategies (DOT), safe injection handling and adverse drug reactions. CTSs also learn about maintaining their patients' confidentiality during the pre-service training. The hands-on training covers the delicate skill of drawing the right dose of the injectable drug using a disposable syringe, TB infection prevention and control (IPC), DOT and waste disposal. CTSs practice safe injection techniques on an orange fruit before progressing to their recruited client.

Instead of making trips to the nearest clinic, this model of care allows MDR-TB patients to receive DOT and daily injections from CTSs in their (the patients') homes. CTSs accompany their MDR-TB patients to the main health facilities for their monthly outpatient treatment review or, in the case of worsening health condition, unscheduled visits. CTSs are also expected to identify and promptly report missed doses, possible side effects and medication running out to the community MDR-TB nurse using a mobile phone. CTSs assist the patient in producing sputum samples for monthly MDR-TB laboratory monitoring. In addition, they provide health education and emotional support to the patient and family. Due to the possible risk of HIV exposure from needlestick injuries, newly recruited CTSs are routinely informed of the patient's HIV status prior to undergoing training. They are also expected to support their patients in antiretroviral medication adherence.

CTSs are directly supervised by community MDR-TB nurses. Using mobile phones, CTSs are able to interact with and receive ‘just-in-time’ supervision support or technical assistance from their supervisors. The community MDR-TB nurses are supported by a team of facility-based professional healthcare workers made up of a doctor, psychologist and social worker. Core clinical decisions such as initiation, variation and monitoring of MDR-TB treatment and progress are taken by formal facility-based professional healthcare workers. CTSs receive a monetary incentive of ZAR500 (= US$33.54 [exchange rate on 23/11/2017]) per month – approximately five percent of the monthly salary community MDR-TB nurses received – during the eight-month long injection phase of their patient’s treatment. The monthly incentive is meant to cover out-of-pocket transport expenses CTSs incur when accompanying their patients for outpatient medical reviews. MSF has consistently sustained the provision of this financial incentive to CTSs since the inception of the task-shifting strategy.

Task-shifting has been widely endorsed globally as a remedy for increasing access to healthcare services and professional healthcare worker shortages. Task-shifting is defined as "the rational redistribution of tasks among health workforce teams," and the WHO added in global guidelines issued in 2008 that “specific tasks are moved, where appropriate, from highly qualified health care workers to health workers who have fewer qualifications in order to make more efficient use of the available HRH” [13]. More recently, the WHO provided the Global Strategy on Human Resources for Health: Workforce 2030 supporting the use of sustainable, contextually appropriate and cost-effective interventions to address the shortage of HRH particularly in resource limited settings [14]. The WHO global recommendations and guidelines on task-shifting and previous research have established that the long-term success of the strategy hinges on investment in policy, regulation, pre-service and ongoing education, accreditation and certification programmes, reorganisation of health teams, clear scopes of practice, remuneration and simplified guidelines [13, 15-19] .

Although the use of task-shifting as a strategy to expand access to health services is most notably credited with the resurgence of LHWs, the approach is accompanied by a unique set of benefits and challenges. Previous research has shown that task-

shifting can reduce overhead costs, expand access to care, improve patient experience and optimise programme effectiveness [15-17, 20-22]. However, important concerns remain over whether or not task-shifting to LHWs does not overlook issues related to patient safety and quality of care, accountability, medical liability (if adverse events arise), the ability of LHWs with limited levels of training to handle complex cases requiring clinical skills of a curative nature, and alignment with wide health system strengthening [17-20, 22].

Despite the existence of the task-shifting strategy for over a decade in the Shiselweni region, the MOH has not yet officially endorsed the strategy. In the absence of a national regulatory policy on task-shifting, MSF implemented the task-shifting strategy after informal permission was granted by the MOH. This raises questions about the perceptions of policy-makers on the task-shifting strategy and whether or not the practice has been implemented in compliance with the WHO recommendations and guidelines. The MOH and other professional bodies have raised ethical concerns about standards of care and safety risks for patients and the newly 'skilled-up' LHWs. As a result, there are fears that task-shifting community-based care to CTSs may create a two-tiered system of MDR-TB management, with “superior” and “inferior” tracks [23]. Existing NTCP strategic plans and MDR-TB treatment guidelines only provide for task-shifting of certain professional nurses’ responsibilities such as DOT supervision and TB treatment adherence support to family members, neighbours or former patients.

Although the Shiselweni region has relied largely on task-shifting in expanding MDR-TB treatment access for over a decade, surprisingly, the opinions about the practice of stakeholders in Eswatini are purely anecdotal, understudied and still to be empirically examined. It is still uncommon internationally for LHWs to administer injections to patients. As far as could be ascertained, this is the first study to assess multiple stakeholder perceptions of task-shifting of DOT supervision and administration of intramuscular MDR-TB injections to LHWs in Eswatini. In this study, the multiple stakeholders comprised of representatives from the MOH, donor organisations, professional regulatory institutions, nursing academia, civil society, professional healthcare providers and CTSs in Eswatini. This study elucidates some

of the factors that decision-makers should consider when expanding MDR-TB treatment access through task-shifting of DOT supervision and injection administration to LHWs in rural settings.

5.3 Methods

5.3.1 Setting and design

The Shiselweni region had an estimated population of 204 111 in 2017 [24]. The region has one referral hospital and two health centres supporting 18 smaller PHC clinics that form part of the regional health network managed by the MOH. The referral hospital provides specialised and general healthcare for the region, while the two health centres, each with an approximately 40-bed capacity, provide medical, surgical and maternal referral care, support and supervision of the PHC clinics. The PHC clinics provide outpatient services to the community and are usually staffed with nurses.

A mixed methods study comprising of a cross-sectional survey using a semi-structured questionnaire with CTSs and a focus group discussion (FGD) with key stakeholders was conducted simultaneously in May 2017. Patients' perspectives on task-shifting community-based MDR-TB care are analysed in another paper. Throughout this study, the term key stakeholder is used to refer to FGD participants. Data triangulation aided in the comparison and interpretation of the two sets of results.

5.3.2 Sampling

A purposive sample of 82 out of a study population of 114 CTSs enrolled in community-based MDR-TB management in the Shiselweni region was recruited for participation in the survey. Eligibility criteria required CTSs to have at least one month experience of administering DOT and MDR-TB injections. The study excluded 31 CTSs who had provided community-based MDR-TB care for less than a month and one late withdrawal due to an acute illness.

Participants for the FGD were purposively selected from across diverse national stakeholders based on their potential to generate rich perspectives on the task-shifting approach from the senior positions they occupied in policy-making and advocacy and experience in the fields of HRH and day-to-day practice in MDR-TB management. Participants were drawn from the MOH, donor organisations, professional regulatory institution, nursing academia, civil society and healthcare providers. Table 1 depicts the FGD participants. Representatives were invited to participate in the FGD in person and via telephone and email. All eligible respondents that were approached agreed to participate in the FGD.

Table 1: Summary description of FGD participants by level

Key stakeholder type	N = 10	Description
Ministry of Health	3	National-level officials working in healthcare system administration, policy-making, programme development or leadership
Donor partners	2	Individuals working as leaders or managers of international entities providing financial aid or serving as an MDR-TB treatment implementing partner
Professional regulatory institution	1	Representative from the Eswatini Nursing Council, an autonomous body that provides professional guidance and imposes conditions on the practice of nurses
Academia	1	Individual representing an institution providing formal training in nursing
Civil society	1	Non-governmental actors that participate and engage in public health advocacy and policy reform
Healthcare providers	2	Professionally trained medical doctors and nurses working in a health facility providing MDR-TB treatment

5.3.3 Instrument development and data collection

A semi-structured questionnaire for interviews with CTSs was developed based on literature review and CTS training materials and job descriptions [13-20, 22]. The questionnaire consisted of items measuring CTSs' demographic details and perceptions on different elements of task-shifting such as awareness, risks and

benefits, compensation, retention, and regulation. The content validity of the data collecting tool was assessed by expert opinion. The questionnaire was forward-translated from English to siSwati and back-translated to English before being pre-tested for face validity and understanding in a convenience sample of ten CTSs who were excluded in the main study. The information from the pre-testing was used to revise and improve the clarity of the questions.

CTSs accompanying their MDR-TB patients for their monthly review at the three MDR-TB treating facilities were informed about the research by the community MDR-TB nurse at the end of their consultation. The CTS was then referred to a trained research assistant stationed in a private room within the MDR-TB unit at the health centre. Three research assistants with previous experience in data collection were recruited for the study. The trained interviewers conducted face-to-face interviews in either siSwati or English with CTSs at one of the three rural health centres in the Shiselweni region. The interviews typically lasted between 30 and 45 minutes.

The FGD was organised topically to verify findings from the interviews with CTSs. The FGD followed a topic guide which included six open-ended exploratory questions (with probes) assessing the following areas: 1) awareness of task-shifting in community-based MDR-TB care, 2) potential risks and benefits of task-shifting, 3) opinion on whether CTSs should be compensated for the tasks they perform, 4) perception on what should be done to retain CTSs, 5) perspectives on the regulation of task-shifting, and 6) acceptability of task-shifting of community-based MDR-TB care to CTSs as a strategy to increase access to MDR-TB treatment.

The FGD was held in a hotel conference room to allow for private conversation without interruption. The first author and one research assistant who assumed the role of note-taker conducted the FGD. Key issues raised during the FGD were summarised on a flip chart to facilitate collective member checking. The researcher used member checking to clarify meanings and generate potentially more valid interpretations. The FGD lasted for an hour and was conducted in English, digitally recorded and transcribed verbatim by research assistants. The first author performed quality checks. A debriefing session between the first author and note-taker was

convened after the FGD. The notes served as supplementary documentation and also captured body language and other non-verbal cues used during the FGD.

The researcher visited the potential FGD participants in person two weeks prior, sent personalised invitations one week before and telephoned each stakeholder a day before the session to remind them. The interaction served to build relationships between the research team and the participants. The facilitator was flexible to adjust to the flow of the discussion, remain open to changes in the FGD guide, remain neutral, and politely enforce ground rules throughout the discussions in order to diplomatically level power dynamics in the FGD. Candid moderation supported by giving everyone a chance to be heard and discouraging participants to interrupt others while they are speaking was used to control dominant individuals.

Participation in the study was voluntary and no rewards were offered for participation. No personal identifying information was collected and findings were reported anonymously using aggregate analysis. Verbal informed consent was obtained from all participants prior to their participation in interviews and audio-recording of the FGD. Participants were informed of their right to discontinue participation permanently or withdraw consent to take part in the study at any point without reprisal. Anonymity of the ten participants in the FGD was achieved through allocation of a coding letter to individual respondent's data. During the FGD, each participant wore a small card (nametag) displaying their assigned letter. Any personal identifying information revealed during the FGD was removed during transcription. To ensure confidentiality, the digital audio recordings were kept under lock and key by the first author.

5.3.4 Data analysis

The data was first checked for completeness and consistency by the first author. Data from the questionnaire was double entered into Epi Info 7 and exported to Stata (Version 13.1) for analysis. Standard descriptive statistics were used to summarise the responses.

Qualitative data from the interviews and FGD were analysed using content analysis. First, two coders independently reviewed responses to each open-ended question, identified and grouped similar responses into sub-categories for a sample of ten participants. Second, the coders compared notes and resolved any differences that showed up on their initial sub-categorisation to ensure that they were independent, mutually exclusive and exhaustive. Third, the first author used the consolidated list of generic categories to independently apply coding to the data. The frequency of each of the established categories was calculated. Infrequent categories were collated to form the broader category 'other'. Fourth, the categories were then grouped under the emerging main themes. Data from the interviews with CTSs was compared with findings from FGD to add breadth and depth to stakeholder perceptions on task-shifting DOT and MDR-TB injection administration to LHWs. Triangulation aided in determining areas where stakeholder perspectives from the two sources were in agreement or in divergence.

5.3.5 Ethical clearance and study authorisation

Ethical approval was obtained from the Scientific and Ethics Committee of Eswatini and the University of the Free State's Health Sciences Research Ethics Committee (IRB00006240). Authorisation of the study was granted by the NTCP and MSF.

5.4 Results

In this section, we first give a description of the socio-demographic characteristics of the CTSs and FGD participants. We then report the responses given by the CTSs and compare it with reactions of the FGD participants. CTSs' and FGD participants' socio-demographic characteristics are described in Table 2. A large majority of CTSs (n = 78; 95.1%) were female and 33 (40.2%) were older than 50 years. Most (n = 7; 70.0%) key stakeholders had more than ten years of work experience.

Table 2: Socio-demographic characteristics of CTSs and key stakeholders

	CTSs	Key stakeholders
	N = 82 (%)	N = 10 (%)
Sex		
Male	4 (4.9)	6 (60.0)
Female	78 (95.1)	4 (40.0)
Age group		
≤ 30 years	10 (12.2)	1 (10.0)
31-40 years	21 (25.6)	2 (20.0)
41-49 years	18 (22.0)	4 (40.0)
≥ 50 years	33 (40.2)	3 (30.0)
Education level		
Primary school or lower	41 (50.0)	0 (0)
Secondary school or higher	41 (50.0)	10 (100.0)
Months administering MDR-TB injections		
1-4 months	17 (20.7)	
> 4 months	65 (79.3)	
Key stakeholder experience in position		
1-5 years		1 (10.0)
6-10 years		2 (20.0)
> 10 years		7 (70.0)

5.4.1 Level of awareness of task-shifting practices in Eswatini

A total of 78 (95.1%) CTSs considered MDR-TB to be a major public health challenge as shown in Table 3. Over four-fifths (n = 70; 85.4%) of the CTSs believed lay community members played an important role in MDR-TB care and the achievement of national and global TB targets. Most FGD participants identified the delegation of counselling, testing services and treatment adherence support to LHWs at PHC clinics offering antiretroviral treatment as examples of ongoing task-shifting practices in the country. There was apparent awareness among all key stakeholders of the task-shifting of community-based MDR-TB care to CTSs in the Shiselweni region.

Table 3: CTSs' awareness of task-shifting (n = 82)

Statement	n	%
MDR-TB is a major public health threat in Eswatini (yes)	78	95.1
Community members should play a role in MDR-TB care (yes)	70	85.4
Are you aware of any task-shifting of responsibilities from professional nurses to LHWs in relation to medical conditions other than MDR-TB in Eswatini (yes)	75	91.3
What type of CTS roles do you think is preferable		
Specialist (limited to DOT supervision and administering MDR-TB injections)	14	17.1
Generalist (providing MDR-TB and other PHC needs of the community)	68	82.9

A majority of CTSs (n = 68; 82.9%) expressed preference for a 'generalist' type of role with a broader mandate not solely limited to MDR-TB care. FGD participants indicated that the community often had a wide range of expectations that fell outside the prescribed responsibilities of CTSs.

> *"The community view CTSs as 'small' nurses. Some of the CTSs often tell me that they are approached by people looking for medicines to treat fever, diarrhoea or simple first aid."* [Participant D]

5.4.2 Potential risks and benefits of task-shifting

Table 4 illustrates potential risks and benefits of task-shifting community-based MDR-TB care identified by CTSs.

Table 4: Open-ended responses by CTSs regarding potential risks and benefits of task-shifting community-based MDR-TB care (n = 82)

	N (%)
Potential risks (n = 213)	
Compromised quality of care	60 (73.2)
Malpractice liability fears	40 (48.8)
Poor infection prevention and control	36 (43.9)
Inadequate training	20 (24.9)
Irregular supervision	18 (22.0)
	N (%)
Increased non-adherence to treatment	14 (17.1)
Poor retention of CTSs	10 (12.2)

Power conflict with community MDR-TB nurses	9 (11.0)
Other[a]	6 (7.3)
Potential strategies to mitigate the risks (n = 174)	
Appropriate training	69 (84.1)
Regular supportive supervision	40 (48.8)
Simplified instructions and job aids	31 (37.8)
Regulation	23 (28.0)
Improved availability of medical supplies	11 (13.4)
Potential benefits (n = 281)	
Increased MDR-TB treatment access	78 (95.1)
Reduced transport-related treatment access barriers	65 (79.3)
Improved adherence to MDR-TB treatment	63 (76.7)
Reduced stigma	32 (39.0)
Improved social status of CTSs	21 (25.6)
Reduced workload for community MDR-TB nurses	15 (18.3)
Increased pool of healthcare workers	7 (8.5)

[a]Other includes disintegrated healthcare system, uncertainty over long-term sustainability and reduced focus on training skilled healthcare workers.

CTSs cited suboptimal quality of care (n = 60; 73.2%), fears of malpractice litigation (n = 40; 48.8%) and poor IPC (n = 36; 43.9%) as some of the major risks associated with the task-shifting strategy in the Shiselweni region. Implicitly, these responses potentially represent CTSs' concerns about inadequacies in the pre-service training and ongoing supervision they receive. Not surprisingly, substantial proportions of CTSs suggested improved ongoing training (n = 69; 84.1%) and supervision (n = 40; 48.8%), and simplified instructions and job aids (n = 31; 37.8%) as potential strategies to mitigate the risks.

Similarly, key stakeholders representing policy-makers, professional regulatory bodies, academia and civil society in the FGD raised concerns about compromised standards of care and safety risks of shifting invasive clinical procedures such as intramuscular injection administration to LHWs. The absence of a standardised training curriculum for CTSs exacerbated the perceived fear of improper dosing, suboptimal management of adverse events, potential legal implications, transmission of infections through unsafe injection handling and inappropriate community MDR-TB IPC practices among stakeholders. Inadequate oversight and erratic supervision

by community MDR-TB nurses and lack of role clarity were other important risks discussed by FGD participants.

Nearly all CTSs (n = 78; 95.1%) cited increased access to MDR-TB treatment as the primary advantage of task-shifting. Task-shifting was thought to be helping patients overcome transport-related treatment access barriers (n = 65; 79.3%), improving medication adherence (n = 63; 76.7%) and reducing stigma (n = 32; 39.0%). These results were corroborated by findings from the FGD. Based on their experience of the role of LHWs in HIV programmes, FGD participants acknowledged the potential role of CTSs to facilitate efficient scale-up of MDR-TB treatment especially in rural and remote areas. By enabling the supervision of DOT and administration of MDR-TB injections in the patients' homes, the task-shifting strategy was perceived to improve patient adherence to treatment and reduce stigma associated with the disease. Furthermore, task-shifting was thought to be helping patients overcome common transport-related treatment access barriers such as long distance travels, cost of transportation and poor road infrastructure that often result in missed or delayed clinic appointments.

> *"Task-shifting is allowing MDR-TB patients to receive injections in their homes from CTSs instead of boarding a bus to the clinic daily. In this way, MDR-TB patients also avoid going to the clinic where some people with stigmatising attitudes may not be comfortable to sit in a clinic queue with them due to fear of getting the disease." [Participant H]*

There were numerous shared views among key stakeholders supporting the delegation of tasks to CTSs such as creating awareness about MDR-TB, referring suspected TB cases to the clinic, supervising DOT and reporting side effects to the community MDR-TB nurse.

5.4.3 Compensation and retention of CTSs

All CTSs reflected positively on the fact that they received a monetary incentive to cover their own transport when accompanying their MDR-TB patient for review at the nearest clinic. However, some FGD participants – frontline health workers, donor partners and civil society – perceived the monetary incentive to be too little and even in direct contravention of the country's employment laws. These participants argued that LHWs should be viewed as employees and not volunteers, and hence, should earn a monthly salary equivalent to or above the minimum wage. Conversely, the provision a monthly monetary incentive to CTSs as a general rule was challenged and viewed to be contrary to volunteerism by policy-makers, regulatory authorities and academia.

Over half (n = 44; 53.7%) of the CTSs surveyed suggested that they should be compensated because of their perceived high occupational risk of acquiring MDR-TB infection. Key stakeholders iterated that CTSs provided direct care to patients for long periods in the household setting often with poor IPC measures. Participants agreed that the retention of LHWs may be encouraged, or conversely, attenuated by the design and appropriateness of the compensation strategies. Alongside appropriate compensation, participants suggested competency-based pre-service and ongoing on-the-job training and adequate supervision, and provision of uniforms, badges and airtime for communicating with the facility based nurses. Some CTSs suggested that the community MDR-TB nurse who supervised their work should introduce them to the local chiefs and other community leadership for their work to be appreciated.

Almost one-third (n = 26; 31.7%) of the CTSs expressed dissatisfaction over the lack of permanent career opportunities in the public health system despite many months of service as entry level frontline healthcare workers, a suggestion that drew hesitant responses from MOH representatives in the FGD. The participants viewed LHWs as de facto volunteers whose integration into the hierarchy of the health system would be unsustainable.

"Incorporating CTSs into the public health system and payroll will not be sustainable. The resources are not enough considering the challenges we are facing to improve remuneration of trained doctors and nurses to stop them from leaving for greener pastures." [Participant G]

5.4.4 Regulation of task-shifting

Over a quarter of the CTSs (n = 23; 28.0%) indicated that regulatory support would provide a conducive and enabling environment for the task-shifting practice. Almost all FGD participants concurred with this view. Participants identified the need to optimise the standard and quality of care, mitigate potential malpractice liability fears for CTSs, and comply with WHO global recommendations and guidelines for task-shifting as major factors compelling the need to regulate delegation of community-based MDR-TB care to CTSs.

"Imagine what would happen if patients knew their rights and had the legal knowledge to approach courts and seek redress in case of adverse events due to injections administered by lay people. So regulation will set quality standards and protect CTSs to a certain extent." [Participant A]

Stakeholders agreed that the MOH should work closely with relevant professional institutions in developing a competency-based and accredited curriculum for CTS education that is aligned with the country's National Qualifications Framework. Participants urged the MOH to expedite the adoption of the task-shifting policy that will provide an enabling environment for regulation.

"Right now the only national policy on task-shifting is still in the draft phase since 2011. Unfortunately, similar to the WHO guidelines on task-shifting, this draft Task Shifting Implementation Framework which should be adopted is biased towards preventive rather than curative services. So delegation of injection administration to lay people may not be adequately covered." [Participant B]

5.4.5 Acceptability of task-shifting

Although generally positive, this question drew a broad range of conflicting opinions about task-shifting, largely stratified by the current job position and day-to-day sphere of practice of the key stakeholders. Table 5 presents some of the verbatim opinions. Most key stakeholders acknowledged that task-shifting in most geographically inaccessible rural areas of Eswatini was driven by necessity and the alternative to this practice would be no MDR-TB care at all.

Table 5: Selected participants' opinions on task-shifting community-based MDR-TB care to CTSs (n = 10)

Supporting views	Opposing views
Task-shifting is good for the patient especially those too ill or do not have transport money to travel daily to the clinic for injections. I see task-shifting of injection administration to patients' neighbours as an important part of the so-called patient-centred care. [Participant C]	*Instead of letting nurses continue throwing their roles to lay people, we should train more professional healthcare workers and ensure they don't leave for greener pastures.* [Participant F]
Most patients stay in villages that are difficult to reach with cars. With proper training, CTSs are the only people able to reach these patients. Otherwise rural patients will not get MDR-TB treatment at all. The just need proper guidelines and tools prepared in SiSwati (local language). [Participant D]	*The use of lay people to give injections is unethical but it is better than nothing. Do you think you can train CTSs to respect the confidentiality of the patient's medical problems in three days? Giving injections involves exposing and sometimes seeing the intimate anatomy of patients. This takes place in a home setting where there is no privacy. Let us adopt task-shifting, but at the same time, we should address the root causes for shortages in nurses.* [Participant B]
The delegation of tasks to community health workers is working in HIV. Of course, to use lay people to provide injections is complicated. So the MOH should speed-up the process of putting together a comprehensive policy to guide the use of LHWs. [Participant H]	*Task-shifting is the only solution though. But I still want to have a look at the curricula for training CTSs. I am convinced it's unsafe for the patients to receive injections from people other than nurses. Very soon patients will think they are receiving second-class care from CTSs.* [Participant A]

Supporting views	Opposing views
An adequate number of healthcare workers will always be scarce even if we build nursing schools in every region. The increase in MDR-TB cases makes the situation worse. However, task-shifting to CTSs in Shiselweni improved treatment adherence and MDR-TB treatment cure rates that are important in achieving targets set by the country, WHO and SDGs. [Participant I]	*In the short-term, we can use task-shifting. Is this approach a magic bullet for problems in our healthcare system? No! To me, this is just a half-baked hurried solution for the poor. A few things need to be done before scaling-up the use of CTSs to provide MDR-TB treatment. Besides, in case of a complication arising from poor injection practice by a CTS, how will the liability be adjudged? Is it the CTS; the trainer; the implementing organisation; or the MOH that is liable? Is the training effective enough to teach CTSs infection prevention and safe handling of injections?* [Participant J]

Frontline healthcare workers – doctors and nurses – and donor partners involved in MDR-TB treatment were almost unanimous in reporting positive experiences with CTSs taking care of patients enrolled at their MDR-TB treating facilities. Task-shifting was more acceptable to this group of stakeholders as they were directly confronted in their day-to-day practice by some of the barriers that limit patients from accessing MDR-TB treatment. These participants indicated that CTSs seemed to enjoy performing their tasks, were appreciated by patients and improved treatment adherence.

Policy-makers, and to a lesser extent, regulatory authorities and academia, were less likely to support the use of LHWs to administer intramuscular MDR-TB injections. These stakeholders were sceptical about the effectiveness of the once-off narrowly-tailored training provided to CTSs on assuming duties. It was thought that without ongoing continuous training, the knowledge and skills of CTSs delivering community-based MDR-TB care was likely to fall-off over time, raising further patient safety concerns. Regulatory authority and academia representatives expressed dissatisfaction about the increased attention paid to task-shifting as a panacea to the critical shortage of professional HRH in Eswatini, while neglecting long-standing challenges in training, recruitment and retention of professional healthcare workers, particularly in rural areas.

5.5 Discussion

This study not only extends the growing literature on task-shifting, but also contributes new insights critical for evidence-informed policy-making and practice regarding the delegation of DOT and highly differentiated clinical tasks such as administration of MDR-TB injection to LHWs in resource-limited settings like Eswatini. This study highlights considerable contextual differences that influence the perceptions on and acceptability of task-shifting DOT and MDR-TB injection administration to LHWs by stakeholders, and further illuminates substantial gaps in the current strategy that warrant attention. There was considerable support for and consensus among key stakeholders around the acceptability of task-shifting practices in community MDR-TB management, albeit with some reservations and apprehensions.

Consistent with results from previous studies, findings from this study highlight systemic concerns that may impede the task-shifting practice, including underinvestment in training, erratic supervision, lack of appropriate compensation, and absence of regulation of the practice [17-20, 22, 25, 26]. Nevertheless, findings from the interviews and FGDs identified the following conditions as important enablers for the acceptance and formalisation of the practice in Eswatini: adequate pre-service and continuous accredited training, appropriately tailored protocols and job aids, ongoing structured supportive supervision, recognition, compensation, and regulation [13, 15, 17-20, 22, 26].

Participants widely viewed LHWs as essential frontline HRH critical for the successful scaling-up of MDR-TB treatment access and achievement of MDR-TB control targets outlined in the National TB Strategic Plan, End TB Strategy and SDGs. In this study, a majority of participants preferred ‘generalist’ type of LHWs with a wider scope of practice and mandate aimed at providing contextually-appropriate integrated basic PHC needs of the community. These findings highlight the tension that exists between the current LHWs’ disease-specific scope of work and the community’s broad preventive and curative PHC healthcare needs and expectations [27]. LHWs could leverage on their physical accessibility and

understanding of local issues – shared language, culture and strong connection with community members – to extend the reach of healthcare services to remote settings where HRH are scarce [28, 29].

Similar to evidence from previous studies [26, 30, 31], CTSs preferred to be paid, but barring that, also appreciated non-monetary incentives. Nevertheless, policy-makers and regulatory authorities commented that providing these incentives may have subtle pitfalls of undermining the long-term sustainability of the task-shifting approach. Many of the recommendations proposed by CTSs and key stakeholders suggest that strong social networks, social cohesion and support systems at the community level that validate the roles and responsibilities of LHWs play an important role in improving their retention [26, 30, 31].

By delegating clinical tasks traditionally restricted to professional nurses to LHWs, the status and expectation of CTSs is likely to change and challenge traditional hierarchies [18, 22]. The retention of CTSs could be strengthened by paying attention to opportunities for their financial independence and social recognition [26, 30]. These factors coupled with inputs by the programme such as access to competency-based training and certification, supportive supervision, adequate logistical support, and opportunities for career progression and being integrated into the formal health system determine whether or not CTSs continue in their role [13, 22, 26, 30, 31]. This finding correlates favourably with the WHO's Global Strategy on Human Resources for Health 2030, that emphasizes the need to design appropriate strategies and incentives to retain LHWs and optimise workforce capacity [14]. Although this research limited its scope to assessing factors affecting retention of CTSs, the findings provide a base for future studies exploring potential influences of LHWs' attrition in Eswatini.

In this study, concerns about the clinical quality of care, patient safety and malpractice liability fears were cited as important reasons compelling the need to regulate task-shifting by both CTSs and key stakeholders, particularly from participants representing the MOH, professional regulatory bodies and training institutions. These results appear to validate similar disquiets expressed in

Mozambique [20] and Uganda [17-19]. Key stakeholders in the current study proposed that the MOH, professional regulatory bodies and training institutions work in close collaboration to create a supportive regulatory environment for task-shifting.

Similar to recommendations from global research on task-shifting, participants suggested a number of elements that could facilitate the regulation of task-shifting, broadly comprising of: 1) expediting the formalisation of the country's task-shifting policy that was still in the draft phase; 2) developing minimum requisite literacy and numeracy skills for CTSs; 3) standardising pre-service and ongoing curricula design; 4) clarifying roles and extent of scope-of-practice; and 5) establishing a supportive conducive environment including supervision and appropriate recognition [15, 25, 30, 32]. Implicitly, in this study, there was minimal compliance to the WHO recommendations and guidelines on task shifting that propose the need for consultation, national endorsement, an enabling regulatory framework and quality assurance mechanisms including standardised training, certification and regular supportive supervision important in optimising quality of care [13].

Frontline healthcare workers and donor partners that encountered MDR-TB patients in their day-to-day practice were more supportive of the task-shifting approach compared to policy-makers and other stakeholders. Those supportive of the strategy went beyond viewing task-shifting simplistically as a way of shifting responsibilities to cheaper and lower skilled LHWs. They justified task-shifting on various grounds including improved medication adherence, economic considerations and as an appropriate response to frontline TB HRH shortages, among others. This is consistent with results from previous studies [17, 20, 22].

Dissenters to the strategy described task-shifting with terms such as "unethical", "unsafe", "second-class care", and "a half-baked hurried solution for the poor" suggesting that the concept was not fully understood by all stakeholders. The divergent views on task-shifting resonate globally. Although frontline healthcare workers in South Africa [33], Mozambique [20] and Tanzania [34] were found to support task-shifting, policy-makers in Uganda [19] opposed it. Yet, it has been conclusively shown in Uganda that without adequate support and endorsement from

policy-makers, task-shifting may still occur but in a disorganised manner, potentially compromising the standard of care [19].

Some key stakeholders – professional regulatory authorities and academia – in this study believed that the task-shifting strategy was overshadowing long-standing challenges with training of new and retention of existing professional HRH, substantiating previous findings [19, 34]. In Tanzania, respondents viewed task-shifting as a short-term solution whilst the government considered more permanent and sustainable alternatives to address the shortage of healthcare workers [34].

5.5.1 Limitations of the study

With this study mostly founded on self-reported perceptions of task-shifting community-based MDR-TB care to LHWs, it is possible that participants' responses may reflect socially desirable answers rather than their true views and experiences of task-shifting. However, this was partially countered by assuring respondents of the anonymity of the questionnaires and FGD, that findings will be reported using aggregate analysis and that the outcomes of the study were not linked to CTSs' job security. Due to practical constraints, this study excluded the participation of family members and other caregivers who could have provided diverse and instructive opinions about task-shifting community-based MDR-TB care to CTSs. Future studies could seek to understand their opinions on the practice.

5.6 Conclusion

Taken together, stakeholders generally accepted the delegation of DOT supervision and administration of intramuscular MDR-TB injections to LHWs as a strategy to increase access to treatment, albeit with some apprehension. Findings from this study suggest that task-shifting is considered as an acceptable interim measure that can be implemented alongside other strategies to train, attract and retain adequate numbers of professional healthcare workers in Eswatini.

The absence of an explicit holistic policy guidance and sufficient support from policy-makers for task-shifting at national level undermine the acceptance and the potential for scaling-up the approach in Eswatini. To address some of the apprehension and ambivalence about expanding access to MDR-TB services through task-shifting, attention should be paid to important aspects such as competence-based training, certification and accreditation, adequate supportive on-the-job supervision, recognition, compensation, and expediting policy and regulatory support for LHWs. Future studies should explore the underlying reasons for the differences in opinions between policy-makers and professional healthcare workers and the extent to which this may undermine the successful formalisation of task-shifting community-based MDR-TB care to LHWs in Eswatini.

List of abbreviations

CTS: community treatment supporter; DOT: directly observed treatment; FGD: focus group discussion; HRH: human resources for health; LHW: lay health worker; MOH: Ministry of Health; MSF: Médecins Sans Frontières; MDR-TB: multidrug-resistant tuberculosis; NTCP: National Tuberculosis Control Programme; PHC: primary healthcare; SDG: Sustainable Development Goal; TB: Tuberculosis; WHO: World Health Organization

5.7 Acknowledgements

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5.8 Authors' contributions

EP participated in the conception and design of the study, acquisition of data, performed the statistical analysis and drafted the manuscript.

CH, NGK and DD gave advice in the design of the study, the interpretation of the results, and participated in the revision of the article for important intellectual content.

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Chapter 6: Cost-effectiveness of ambulatory clinic- and home-based multidrug-resistant tuberculosis management models in Eswatini

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Structure

6.1 Abstract

Background

We compared the cost-effectiveness of a home-based multidrug-resistant tuberculosis (MDR-TB) model of care, based on task-shifting of directly observed therapy (DOT) and MDR-TB injection administration to LHWs, to a routine clinic-based strategy within an established national TB programme in Eswatini.

Methods

Data on costs and effects of the two ambulatory models of MDR-TB care was collected using documentary data and interviews in the Lubombo and Shiselweni regions of Eswatini. Costs were assessed from a societal perspective in 2014 in US$ using standard methods. Cost-effectiveness was calculated as the cost per patient successfully treated.

Results

In the clinic-based and home-based models of care, respectively, a total of 96 and 106 MDR-TB patients were enrolled in 2014, with treatment success rates of 67.8% and 82.1%. Health system costs per patient treated were slightly lower in the home-based strategy (US$19 598) compared to the clinic-based model (US$20 007). The largest costs in both models were for inpatient care, administration of DOT and injectable treatment, and drugs. Costs incurred by patients and caregivers were considerably higher in the clinic-based model of care due to the higher direct travel costs to the nearest clinic to receive DOT and injections daily. In total, MDR patients in the clinic-based strategy incurred average costs of US$670 compared to US$275 for MDR-TB patients in the home-based model. MDR-TB patients in the home-based programme, where DOT and injections was provided in their homes, only incurred out-of-pocket travel expenses for monthly outpatient treatment monitoring visits averaging US$100. The cost per successfully treated patient was US$31 106 and US$24 157 in the clinic-based and home-based models of care, respectively. From a

societal perspective, the home-based care model generated a net cost saving per additional patient successfully treated.

Conclusion

The home-based strategy generated substantial health and economic benefits, particularly for patients, from a societal perspective and can be considered as a cost-effective alternative to expand and optimise MDR-TB control in resource-limited settings. Further research to understand the appropriate mix of treatment support components that are most important for optimal clinical and public health outcomes in the ambulatory home-based model of MDR-TB care is necessary.

Key words: Eswatini, cost-effectiveness, community treatment supporter, task-shifting, multidrug-resistant tuberculosis, ambulatory, clinic-based care, home-based care, directly observed therapy, injection administration

6.2 Background

The global strategy to control tuberculosis (TB) has been highlighted as a priority within the framework of the End TB Strategy and the Sustainable Development Goals (SDGs) agendas.[1,2] Nevertheless, multidrug-resistant TB (MDR-TB) treatment is accessible to only one-third of the estimated cases globally.[3] In Eswatini, access to MDR-TB care has remained limited, reflecting a range of interconnected issues including the widespread shortage of professional frontline healthcare workers, poor geographic accessibility of health facilities and high costs incurred by patients.[4–6] Unsurprisingly, in 2019, the country reported a suboptimal MDR-TB treatment success rate of 72% (2016 cohort) which was below the World Health Organization (WHO) target of 75% or higher.[3,7]

To reduce costs to the health system, expand treatment access and provide patient-centred care, the Eswatini National TB Control Programme (NTCP) adopted the WHO ambulatory clinic-based care model for managing MDR-TB in three of the country's four regions.[8] In the remaining region, MDR-TB care was delivered using a

novel patient-centred home-based treatment approach based on task-shifting of directly observed therapy (DOT) and intramuscular MDR-TB injection administration – traditionally restricted to professional nurses – to LHWs, referred to as community treatment supporters (CTSs).[4] Although the WHO has prioritised the use of shorter and fully oral MDR-TB treatment regimens (nine to 12 months instead of the usual two years), at least for the time being, the use of long injectable-containing regimens in settings with high rates of complex drug resistance like Eswatini persists.[5,9] Instead of making trips to the nearest clinic, this model of care allowed MDR-TB patients to receive DOT and daily injections during the first eight months of treatment from CTSs in their (the patients') homes.[6,10]

Previous economic evaluation studies have consistently demonstrated the cost-effectiveness of ambulatory models of care embedded within communities, closer to or in the patient's home, rather than hospitalised care.[11–13] Yet, to date no review on the cost-effectiveness of the ambulatory clinic- and home-based care models has been conducted in Eswatini. Cost-effectiveness data of the two ambulatory models are needed to assess whether the home-based strategy provides value for money, and if outcomes are favourable to assist policymakers in allocating resources and scaling-up optimal strategies. We conducted a comprehensive cost-effectiveness analysis of two models of MDR-TB care established in two regions of Eswatini from a societal perspective.

6.3 Methods

6.3.1 Study design and setting

We evaluated, firstly, the clinic-based approach implemented by the Ministry of Health (MOH) in the Lubombo region and, secondly, the home-based model adopted by Médecins Sans Frontières (MSF), in the Shiselweni region within the NTCP. The evaluation considered a cohort of patients enrolled in MDR-TB care between 1 January and 31 December 2014 over a two-year analytic horizon.

Lubombo and Shiselweni form part of the country's four administrative regions. The two regions have relatively similar socio-economic conditions.[14] The Shiselweni region has one referral hospital and two health centres that support 18 smaller primary health care (PHC) clinics that form part of the regional health network managed by the MOH. MDR-TB patients requiring inpatient care are hospitalised in the TB ward at one of the health centres. The Lubombo region has an estimated population of about 212 531 and a health facility to population ratio of about 1 per 4 500.[14] Health facilities involved in MDR-TB care in the Lubombo region comprise of a mission hospital and a rural health centre that relate closely to the National TB Hospital in Manzini, the country's referral hospital for all forms of TB. DOT and outpatient injection administration is accessible from all the PHC facilities in the region. The prevalence of MDR-TB across the two regions illustrates negligible dissimilarity in distribution.[5] HIV prevalence among the general population is estimated at 27.0%, with no significant geographic variation across the regions of the country.[5]

6.3.2 Alternative strategies

In Eswatini, patients receive the full standardised MDR-TB regimen on an ambulatory basis at their nearest outpatient health care facility. Ambulatory care can either be clinic-based (patient travels to the clinic five days per week to receive DOT and injections from a healthcare worker) or home-based (patient receives DOT and injections seven days per week in their homes from a CTS). The main components and activities of each of the alternative strategies are summarised in Table 1; detailed descriptions are available elsewhere.[6,10] The MDR-TB treatment regimen consisted of an eight-month intensive phase (IP) based on one injectable and four oral drugs followed by a 16-month continuation phase (CP) with the same drugs less the injectable. Besides the differences in some treatment support components, patients in both regions received the same clinical evaluation, diagnosis and treatment according to the national MDR-TB treatment guidelines.

Table 1: Comparison of alternative strategies

Treatment component	Clinic-based strategy	Home-based strategy
	Lubombo region, MOH	**Shiselweni region, MSF**
Hospital admission	For treatment initiation and often prolonged if patient's home is distant from nearest clinic, unstable clinical condition, unfavourable social and logistic conditions	Only if necessitated by clinical condition
Treatment component	**Clinic-based strategy**	**Home-based strategy**
	Lubombo region, MOH	**Shiselweni region, MSF**
Caregiver/treatment supporter	Family member	IP – CTS (neighbour) CP – family member
Training of treatment supporter	Routine training on DOT and household IPC	Training provided specifically to CTSs for injection administration, DOT and household IPC. Family member trained on DOT and household IPC
DOT supervisor	Nurse supervised morning DOT during IP Family caregiver supervised evening DOT during IP and CP	CTS in IP and option of family member during CP
Injection administration	Travels 5 days per week to nearest clinic for injection administration by a nurse during IP	Receives intramuscular injections 7 days per week from a CTS in their (patient's) home during IP.
Outpatient visits to health facility for review and collection of drugs	Monthly in company of a family member	IP – monthly in company of a CTS CP – monthly in company of a CTS/family member
Community supervision	Community MDR-TB nurses once a month during IP	Community MDR-TB nurses twice a month during IP and once a month during CP
Financial incentives	N/A	Patients received US$41/month during IP and US$8/month during CP CTS received US$58/month during IP
Food enablers	N/A	Patients received food packages valued at US$33 every month throughout treatment
Structural environmental household TB infection prevention and control measures	N/A	Environmental control interventions aimed at improving natural ventilation such as structural addition of windows in patient's room or in some instances, construction of a new one-roomed house for patient to sleep alone

MOH – Ministry of Health; MSF – Médecins Sans Frontières; DOT – directly observed therapy; N/A – not applicable; CP – continuation phase; CTS – community treatment supporter; IP – intensive phase; IPC – infection prevention and control; US$ – United States dollars

6.3.3 Cost and cost-effectiveness analysis

The study assessed costs from a societal perspective using current standards for cost-effectiveness analysis.[15] Broadly, costs were considered as health care system, patient and caregiver costs. All costs were expressed in year 2014 United States dollar currency.

6.3.4 Health system costs

For health systems costs, the average cost of each component of treatment was calculated by combining data on the quantity of resources used with the unit prices, with the exception of non-salary recurrent expenditure that was only available in aggregated form. Health system costs consisted of costs of inpatient stay, outpatient costs associated with laboratory and radiology tests; outpatient attendance; drugs and medical supplies (including for adverse effects), DOT and injection administration at the clinic or in the home; training and supervision visits of CTSs and overall programme management (including costs of structural adaptations to the patient's home). Unit costs for some health system resources were derived from a South African study.[16]

For all strategies, data sources included primary usage data abstracted from patient medical records, central medical stores, expenditure and programme reports, vehicle logbooks, and face-to-face interviews with staff from the MOH and MSF. Staff costs were estimated from standard salary and benefits scales for established positions obtained from the MOH. Capital costs for items such as buildings, vehicle and equipment were depreciated using standard recommended methods and a discount rate of 3%.[15] Joint costs were allocated based on the proportion of time the cost item was used for MDR-TB programme components and activities.

6.3.5 Patient and caregiver costs

Patient and caregiver costs were estimated using a survey among a purposive sample of 78 patients under each of the care models in May 2017. A validated

structured questionnaire was used to gather direct travel and indirect time costs associated with patient and caregiver visits to health facilities.[17] Patients were eligible to participate in the study if they were aged 18 years or older, had completed at least one month of MDR-TB treatment and were being treated at a health facility in the selected regions.

Trained interviewers conducted face-to-face interviews in either siSwati or English with participants attending the MDR-TB treating facilities for their monthly review in the two regions. All patients and their accompanying caregiver were approached at the end of their follow-up visit and referred to a trained interviewer stationed in a private room within the MDR-TB unit at the health centre. Participation in the study was voluntary and not linked to participants' care or job security. No incentives were offered to induce participation. Written informed consent was obtained from patients and their caregivers prior to participation in the interviews. To reduce recall bias, only costs related to the previous month were collected. Total MDR-TB treatment costs for patients were estimated by extrapolating the monthly costs according to standard recommended durations of the intensive and continuation phases: eight months and 16 months respectively. To calculate the opportunity cost of time, the number of hours lost was multiplied by the estimated hourly wage derived from the country's weekly minimum wage.[18]

6.3.6 Effectiveness and cost-effectiveness

Successful treatment rates were obtained from the standard recording and reporting system used by the NTCP which followed the International Union Against Tuberculosis and Lung Disease (IUATLD) guidelines.[19] The primary outcome measures were namely: 1) cured, 2) completed treatment, 3) died, 4) defaulted, 5) transferred out of the region, and 6) failed treatment. For each strategy, the average cost per patient successfully treated was calculated. For the cost-effectiveness analysis, the incremental cost per additional successfully treated patient associated with the home-based MDR-TB model of care in comparison to the clinic-based model was calculated.

6.3.7 Ethical clearance and authorisation

Ethical approval was obtained from the Scientific and Ethics Committee of Eswatini and the Health Sciences Research Ethics Committee (IRB00006240), University of Free State. Authorisation of the study was granted by the NTCP and MSF.

6.4 Results

6.4.1 Patient characteristics

In this study, a total of 202 MDR-TB patients' records were reviewed, 96 under the clinic-based strategy in the Lubombo region and 106 in the home-based care model in the Shiselweni region (Table 2). The mean age of MDR-TB patients in the clinic-based (34 years) and home-based model (35 years) was almost similar. Overall, a significant proportion of MDR-TB patients in the clinic-based approach (n = 74; 77.1%) and home-based strategy (n = 87; 82.1%) were unemployed. More than three-quarters of patients in each of the models of care had MDR-TB/human immunodeficiency virus (HIV) co-infection. A chi-square test showed no statistically significant difference between the socio-demographic characteristics of patients in the two regions; gender (p = 0.534), mean age (p = 0.584), employment status (p = 0.378), co-morbid chronic medical condition (p = 0.232) and HIV co-infection (p = 0.585).

Table 2: Socio-demographic and clinical characteristics of MDR-TB patients

Characteristics	Clinic-based strategy N = 96 (%)	Home-based strategy N = 106 (%)	P value
Female	42 (43.7)	51 (48.1)	0.534
Mean age (years)	34	35	0.584
Unemployed	74 (22.9)	87 (17.9)	0.378
Chronic medical condition/s	21 (21.9)	31 (29.2)	0.232
HIV-infected[a]	73 (76.0)	84 (79.2)	0.585

[a]MDR-TB and HIV services were integrated, and all MDR-TB/HIV co-infected patients were enrolled for antiretroviral treatment

6.4.2 Overall treatment details

The frequency of outpatient treatment monitoring visits, and DOT and injection administration at the clinic or in the home and supervision visits varied according to total duration of treatment, length of the injectable phase and number of inpatient hospitalisation days across the two models (Table 3).

Table 3: Frequency of treatment components for MDR-TB patients

Treatment component	Lubombo	Shiselweni
	Clinic-based strategy	Home-based strategy
	N = 96	N = 106
Duration of MDR-TB treatment (days)	600/594	641/620
Duration of intensive phase (days)	235/229	240/236
Duration of continuation phase (days)	364/357	419/408
Inpatient care (days)	41/25	23/18
Injections administered at clinic	142/138	N/A
Injections administered at home	N/A	216/210
Supervision visits by community MDR-TB nurse	23	32
Hospital OPD visits for treatment monitoring/collection of drugs	23	24
DOT supervision by family member	369/354	418/401

Data are mean/median; OPD – outpatient department; DOT – directly observed therapy

6.4.3 Health system costs

From a societal point of view, health system costs per patient treated were slightly lower in the home-based strategy (US$19 598) compared to clinic-based model (US$20 007) (Table 4). The largest costs in both models were for inpatient care, administration of DOT and injectable treatment, and drugs (approximately one-quarter of the total health system costs in each model). The total cost to provide the laboratory diagnostic and monitoring tests was US$480 per patient for the clinic-based model and US$1 881 per patient for the home-based strategy. The frequency

of laboratory tests varied in the two models and was lower in the clinic-based model than in the home-based strategy.

Table 4: Costs of managing MDR-TB patients from diagnosis to completion of treatment, alternative strategies

Cost component	Lubombo	Shiselweni
	Clinic-based strategy Cost US$ (%)	Home-based strategy Cost US$ (%)
Health system costs		
Inpatient care	6 414 (32)	3 663 (19)
Laboratory and radiology tests	480 (2)	1 881 (10)
Drugs	4 509 (23)	5 512 (28)
Hospital OPD treatment monitoring	2 056 (10)	2 007 (10)
Clinic DOT/injection administration visit	3 399 (17)	0 (0)
DOT and injection administration by CTS	0 (0)	2 379 (12)
DOT supervision by family member/CTS	1 478 (7)	1 670 (9)
Supervision by community MDR-TB nurse	446 (2)	621 (3)
Programme level costs	1 225 (6)	1 865 (10)
Total health system costs	*20 007 (100)*	*19 598 (100)*
Patient costs		
Transport expenses to hospital OPD visits	95 (14)	100 (36)
Cost of food during visit to hospital OPD visits	51 (8)	56 (20)
Transport expenses for DOT and injection administration visit	285 (43)	0 (0)
Time taken hospitalised	101 (15)	58 (21)
Time taken attending MDR-TB treatment monitoring	28 (4)	28 (10)
Time taken attending clinic for DOT/injections	110 (16)	0 (0)
Time taken receiving DOT/injections in the home	0 (0)	34 (12)
Total patient costs	*670 (100)*	*276 (100)*
Caregiver costs		
Time taken to attend training	1 (0)	11 (6)
Transport expenses accompanying patient to hospital OPD visits	95 (21)	100 (57)
Transport expenses accompanying patients to clinic for DOT and injection administration visits	285 (63)	0 (0)
Time taken accompanying patient to hospital OPD visits	7 (2)	7 (4)
Time taken accompanying patient to clinic for DOT and MDR-TB injections	44 (10)	0 (0)
Time taken to provide DOT supervision and injection administration	0 (0)	34 (20)
Time taken to provide DOT supervision	19 (4)	22 (13)
Total caregiver costs	*451 (100)*	*174 (100)*

Cost component	Lubombo	Shiselweni
	Clinic-based strategy Cost US$ (%)	Home-based strategy Cost US$ (%)
Total costs (health system, patient and caregiver costs)	*21 128*	*20 048*

Notes: All costs were adjusted to 2014 prices. OPD – outpatient department; DOT – directly observed therapy; CTS – community treatment supporter

6.4.4 Patient and caregiver costs

Costs incurred by patients and caregivers were considerably higher – more than double – in the clinic-based model of care due to the higher direct travel costs to the nearest clinic to receive DOT and injections daily. Travel costs accounted for about 43 percent and 63 percent of the total costs incurred by patients and caregivers in the clinic-based model, respectively (Table 4). In total, MDR patients in the clinic-based strategy incurred average costs of US$670 compared to US$275 for MDR-TB patients in the home-based model. MDR-TB patients in the home-based programme, where DOT and injections was provided in their homes, only incurred out-of-pocket travel expenses for monthly outpatient treatment monitoring visits averaging US$100. Opportunity costs of travel and treatment time for patients ranged from US$239 in the clinic-based model to US$120 in the home-based approach.

6.4.5 Treatment outcomes

The overall treatment success rate was higher in the home-based approach (82.1%) compared to the clinic-based model (67.8%), successfully treating nearly 15% more of the cases (Table 5).

Table 5: Treatment outcomes of MDR-TB patients in alternative strategies

Treatment outcome	Lubombo	Shiselweni
	Clinic-based strategy n (%)	Home-based strategy n (%)
Total number of patients in cohort	96 (100.0)	106 (100.0)
Number of patients cured	35 (36.5)	69 (65.1)
Number of patients completed treatment	30 (31.3)	18 (17.0)

Treatment outcome	Lubombo	Shiselweni
	Clinic-based strategy n (%)	Home-based strategy n (%)
Number of patients failed	7 (7.3)	6 (5.7)
Number of patients died	13 (13.5)	9 (8.5)
Number of patients defaulted	11 (11.5)	4 (3.8)
Total patients successfully treated[a]	65 (67.7)	87 (82.1)

[a]Treatment success is the proportion of patients in whom the treatment outcome was either cured or completed.

6.4.6 Cost-effectiveness

The cost per successfully treated patient was US$31 278 and US$24 488 in the clinic-based and home-based models of care, respectively (Table 5). From a societal perspective, the home-based care model in the Shiselweni region was a dominant alternative, leading to a lower cost and increased effectiveness per patient treated.

Table 6: Cost-effectiveness of the MDR-TB management strategies in 2014 US dollars

Treatment strategy	Success rate (%)	Cost per patient (US$)	Average cost per success (US$)	Incremental effect (%)	Incremental cost (US$)	ICER (US$)
Clinic-based strategy	67.7	21 128	31 278	14.4	-1 080	Negative
Home-based strategy	82.1	20 048	24 488			

ICER – incremental cost-effectiveness ratio

6.4.7 Sensitivity analysis

In one-way sensitivity analysis, the ICER was mildly sensitive to the rate at which costs were discounted and moderately sensitive to the assumption regarding increases in laboratory testing.

6.5 Discussion

As far as could be ascertained, this is the first study to evaluate the cost-effectiveness of an ambulatory approach using CTSs to administer DOT and MDR-TB injectable medicines in patients' homes. Our analysis indicates that the home-based strategy is less costly than, and considerably more cost-effective than the clinic-based MDR-TB model of care in a high HIV prevalence setting from a societal perspective. However, the programmatic implementation of the novel home-based model of care that relies on the task-shifting of highly differentiated clinical tasks such as injection administration to CTSs is not without challenges. Despite acceptability by MDR-TB patients, concerns about suboptimal quality of clinical care, patient safety and malpractice liability fears related to the use of LHWs have been expressed previously.[10,20]

Future research could explore how the different MDR-TB care strategies can be complementary and implemented together in the same setting. From a programmatic perspective, this would enable patients for whom one of the strategies is otherwise inappropriate to choose and move seamlessly between the different MDR-TB models of care based on their own needs and differing community contexts.

In both models, drug costs were a major contributor to the total health system costs. Drawing from WHO recommendations, the NTCP has stated its intention to expand the roll out of shorter-duration regimens contingent on patient preference, clinical judgement and results of drug susceptibility testing that will have substantial cost implications.[9,21] Shortened treatment regimens imply reduced periods of care requiring fewer drugs and laboratory tests, less visits to health facilities and ultimately reduced economic burden on households.

In the clinic-based strategy, MDR-TB patients and their caregivers incurred substantial direct out-of-pocket travel costs in addition to the associated indirect costs from lost time accessing daily injections at their nearest health facility. These costs are recognised barriers to treatment completion.[22,23] Patient direct out-of-pocket costs – from diagnosis to treatment and ultimately cure – are, in part, a

function of the structure of the public health system, with transport costs reflecting accessibility of MDR-TB services and distribution of health facilities. In the home-based model, patients collected their monthly supply of oral and injectable drugs during the outpatient treatment monitoring visit and CTSs administered the daily treatment in their (patients') homes, requiring no travel to the clinics for injections and limited supervisory visits by professional healthcare workers. Implicitly, the home-based approach may free up resources and allow professional healthcare workers to focus on other important healthcare tasks in TB control.

The serious downstream consequences of the catastrophic cost of illness for MDR-TB patients are well documented and comprise of non-adherence to care, treatment failure and increased risk of onward transmission of the disease in the community.[22,23] A disproportionately high proportion of patients in this study had no source of income. The End TB Strategy recognises social protection interventions as powerful tools for mitigating the catastrophic costs experienced by MDR-TB-affected households and optimising MDR-TB control indicators.[7] In the home-based strategy, patients received monthly incentives of US$74 and US$41 during the IP and CP, respectively. CTSs also received a monthly stipend of US$58 during the IP only. Although these cash transfer payments could not be included in the analysis from a societal point of view, they were still a cost burden for the health care system (US$1 718) and were substantial relative to the total costs incurred by patients and their caregivers.

Supplementing standard MDR-TB care with a mix of incentives may have been decisive in mitigating the catastrophic costs experienced by MDR-TB-affected households and optimised treatment success observed in the home-based strategy.[6,24] Our findings broadly insinuate the implementation of interventions to alleviate financial barriers to patients and accompanying further research evaluating the influence of these social protection packages on patient healthcare expenditures and treatment outcomes.

In this study, treatment success rate was higher in the home-based approach (82%) than clinic-based model (68%), comparing very well with the MDR-TB treatment

success rate of 56% recorded in 2018 globally.[3] These findings are consistent with recent evidence on the feasibility of ambulatory home-based care models.[13,25] Interestingly, treatment success rates from our study were superior or comparable to published outcomes from a similar setting in South Africa with a high prevalence of HIV.[13] In the South African context, some of the community-based care models used nurse-led mobile injection teams for daily DOT supervision and injection provision in patients' homes. These unexpected differences can possibly be attributed to the high HIV treatment uptake (n = 157; 100%) in the present study. Among MDR-TB patients co-infected with HIV, antiretroviral therapy is an important contributor of treatment success.[26]

A possible limitation was that we had no data on unit costs for some health system resources such as laboratory investigations in Eswatini where the two ambulatory models of care were implemented. However, the negligible variation in MDR-TB clinical practices, life expectancy, payment systems and discount rate enabled the geographic transferability of cost data reported by Pooran and colleagues in South Africa to the Eswatini context.[16] This analysis did not include the reduction in MDR-TB transmission, cost per death averted or increased productivity from treating patients since the scope of the excluded the assessment of other economic and public health benefit of MDR-TB control. A strength of this study includes the use of empirical cost data within the same socio-economic context under approved programme conditions rather than previously published estimates or projections.

6.6 Conclusion

Our study showed that the ambulatory home-based strategy generated substantial health and economic benefits, particularly for patients, from a societal perspective and can be considered as a cost-effective alternative to the clinic-based model of care. However, to support the scaling up of universal access to uninterrupted MDR-TB care in Eswatini and the achievement of national targets, the SDGs and post-2015 global heath targets, it is imperative for policymakers and programme managers to consider reorienting MDR-TB management by strengthening care in the community and replicating the conditions that may have contributed to its success in

the home-based strategy. More work remains to be done to better understand the appropriate mix of treatment support components that are most important for optimal clinical and public health outcomes in the ambulatory home-based model of MDR-TB care.

List of abbreviations

CP: continuation phase; CTS: community treatment supporter; DOT: directly observed therapy; HIV: human immunodeficiency virus; IP: intensive phase; IUATLD: International Union Against Tuberculosis and Lung Disease; MOH: Ministry of Health; MSF: Médecins Sans Frontières; MDR-TB: multidrug-resistant tuberculosis; NTCP: National Tuberculosis Control Programme; PHC: primary health care; SDG: Sustainable Development Goal; TB: tuberculosis; WHO: World Health Organization

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6.8 Authors' contributions

EP participated in the conception and design of the study, acquisition of data, performed the statistical analysis and drafted the manuscript.
DD, CH and NGK gave advice in the design of the study, the interpretation of the results, and participated in the revision of the article for important intellectual content.

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Chapter 7: Discussion, recommendations, limitations and conclusions

Despite the existence of the task-shifting of community-based MDR-TB management to CTSs for over a decade in the Shiselweni region, as far as could be ascertained, no study to date has evaluated the practice. This study aimed to gain a better understanding of the task-shifting practice and was informed by the COM-B model and TDF in assessing the KAP of CTSs, patients' satisfaction, acceptability to key stakeholders and cost-effectiveness of community-based MDR-TB management. Through the lens of the COM-B model, this section comprises a broader and more nuanced discussion of task-shifting within the community-based MDR-TB management strategy implemented in the Shiselweni region. Implications and key recommendations towards the development of task-shifting policies, guidelines and practice from findings of the present study are highlighted together with an overall assessment and future perspectives of delegating community-based MDR-TB management to CTSs. The chapter ends by summarising the conclusions from the present study.

7.1 Knowledge, attitudes and practices of CTSs on community-based MDR-TB management

The COM-B model was used to inform the assessment of whether or not CTSs had the 'capability' to provide satisfactory community-based MDR-TB services to their patients. Capability, as set out in the COM-B model, is demonstrated by individuals possessing the necessary skills and knowledge to perform a behaviour or intervention (Michie et al., 2011). This study found the KAP of CTSs to be fairly satisfactory, although important knowledge gaps and some poor attitudes and practices towards MDR-TB were evident. The generally good CTS knowledge levels were, however, permeated with misunderstandings of the definition and combination of drugs used to treat MDR-TB. Similar results were reported among HCWs in other Southern African countries such as Lesotho (Malangu & Adebanjo, 2015) and South Africa (Engelbrecht, Janse van Rensburg, Kigozi & van Rensburg, 2016).

Consistent with previous studies, MDR-TB-related attitudes among CTSs were found to vary, ranging from being supportive to harbouring misconceptions and erroneous and stigmatising opinions regarding individuals with the disease (Toczek, Cox, du Cros, Cooke & Ford, 2013; Buregyeya, Kasasa & Mitchell, 2016; Tupasi et al., 2016; Gugssa Boru, Shimels & Bilal, 2017). The discriminatory attitude identified among CTSs is reason for concern and contrary to professional discourses that view healthcare providers as caring, compassionate, concerned and motivated to assist patients (Kesbakhi, Rohani, Mohtashami & Nasiri, 2017; Lee & Kim, 2019). Previous studies have shown that healthcare providers' knowledge and attitudes towards TB play a significant role in influencing how they relate to and communicate with their patients during delivery of TB services (Toczek et al., 2013; Buregyeya et al., 2016; Tupasi et al., 2016). Patients' perception of negative attitudes among their treatment providers may increase the risk for non-utilisation of health services and the likelihood of treatment non-completion.

Evidence from this study revealed that CTSs had good self-reported practices in relation to community-based MDR-TB management, including safe handling of injections and adherence to IPC measures. The overall mean practice score was comparable to those reported in previous studies in Ethiopia (Tenna, Stenehjem, Margoles, Kacha, Blumberg & Kempker, 2013) and South Africa (Bhebhe, Van Rooyen & Steinberg, 2014). An important poor practice identified in this relates to CTSs not frequently educating patients or communities about MDR-TB. This is worrying considering that CTSs are the patients' major link with the formal health system (Lehmann & Sanders, 2007). Poor adherence to hand hygiene was observed among CTSs in this study, despite evidence that strict compliance with handwashing lowers the risk of cross-transmission of infection (Tenna et al., 2014; Kolude & Emmanuel, 2020). This observation is important considering the implicit educational and instructive influence – positive role modelling – that CTSs' IPC practices may have on their patients, the patients' families, and the community at large.

The good self-reported community-based MDR-TB management IPC practices were verified to be true during the observation visits undertaken in a sample of CTSs. Although all sampled CTSs were observed to wear N95 face masks while attending

to their patients, none of the patients wore surgical face masks due to lack of supplies. Reducing respiratory infection transmission at source by wearing a surgical face mask is a well-established adjunct control measure (Dharmadhikari, Mphahlele, Stoltz, Venter, Mathebula, Masotla et al., 2012). Infectious patients with cough or sneezing are commonly recommended to wear a face mask, and this applies to patients with airborne-transmitted disease like MDR-TB or droplet-transmitted viral infections like COVID-19 (Dharmadhikari et al., 2012; WHO, 2020). The lack of supplies for surgical face masks is a serious concern vis-à-vis the recent WHO COVID-19 protocols recommending the wearing of face masks in the community (WHO, 2020). A high level of compliance is required to maximise the effectiveness of universal wearing of face masks in the community, especially in situations where practising social distancing is not practical. In line with the WHO recommendation, programme managers should consider providing patients with a simple and cheap substitute to surgical face masks such as cloth face covers (WHO, 2020).

Despite questions regarding the use of KAP surveys in assessing competencies, results from this research underscore the need to continuously review the content of the training curricula and should be appropriately tailored to the CTSs' limited literacy and numeracy skills. As reported in the present study, in the task-shifting strategy, on-the-job practical training for CTSs on aspects of community MDR-TB management preceded the theoretical workshop. A substantial proportion of CTSs were already administering MDR-TB injections and providing other MDR-TB services even though they had not received the theoretical component of the training, suggesting the need to revise the instructional design of the CTSs' training. MDR-TB theory is an essential core of the key skills CTSs should possess. A perfect mix of theoretical knowledge and practical skills is important for holistic learning and enhancing a deeper understanding of the different concepts and domains of MDR-TB care (WHO, 2018a). Future studies should evaluate the extent to which the content of the curriculum, methods of delivery, and degree of experience of community MDR-TB nurses involved in CTSs' training and supervision influences CTSs' ability to acquire important skills crucial for task-shifting.

Converse to results from previous studies (Temesgen & Demissie, 2014; Buregyeya et al., 2016; Engelbrecht et al., 2016), this analysis found no significant association between community-based MDR-TB practice scores and knowledge, attitude and other independent socio-demographic predictors among CTSs.

7.2 Patient satisfaction with the task-shifting of community-based MDR-TB management

The use of behavioural theories – the COM-B model and the TDF – in this study improved the understanding of patients' attitudes as evaluative judgement (or reaction) to the MDR-TB care they received from CTSs (Michie, van Stralen & West, 2011; Cane, O'Connor & Michie, 2012). By defining patient satisfaction as an attitude, these theories highlight the multidimensional nature of, and various patient and health service variables that influence satisfaction. The current study found favourable levels of patient satisfaction with the task-shifting approach, reflecting the extent to which the community-based MDR-TB programme was perceived to address patients' needs. This finding is significant considering the strong evidence that patient satisfaction with healthcare services received can instrumentally affect treatment uptake, adherence and retention in TB care (Nezenega, Gacho & Tafere, 2013; Chimbindi, Bärnighausen & Newell, 2014).

In this study, four dimensions of the care experience – adherence counselling, confidentiality, provider selection and treatment costs – were found to significantly predict mean general patient satisfaction. CTSs should recognise their critical role in adherence counselling and should therefore reinforce their training about the disease, treatment methods, common complications and skills essential to optimise adherence to treatment. Non-adherence to MDR-TB medication can result in lengthy periods of infectiousness and increased chances for developing extensively drug-resistant TB (WHO, 2018b).

Patients also made recommendations that could act synergistically to enhance their experience in community-based MDR-TB management. Among the recommendations is the need for adequate training of CTSs on respecting the

privacy and confidentiality of their condition and medical information. This suggestion indirectly represents concerns from patients about CTSs' shortcomings in that important dimension of care. A breach of confidentiality can erode patients' trust in their CTSs and may result in treatment interruption (Isaakidis, Rangan, Pradhan, Ladomirska, Reid & Kielmann, 2013; Morris, Quezada, Bhat, Moser, Smith, Perez et al., 2013).

The task-shifting approach reduces the physical and social barriers, and distance between patients and MDR-TB service providers. However, studies have reported that if tasks related to care for stigmatised conditions such as TB and HIV are delegated to providers from the same neighbourhood as patients, this 'reduced distance' is a potential risk to the confidentiality and privacy of patients (Thomas et al., 2016). CTSs should build a relationship of mutual trust with their patients, prioritising a patient-centred approach that provides care that is respectful of individual patient preferences, needs and values (Aït-Khaled, Alarcón, Armengol, Bissell, Boillot & Caminero, 2010; TB CARE I, 2014).

Patients in the present study widely recommended regular supervision as a strategy to improve the performance of CTSs. Implicitly, supervision in the task-shifting approach, although considered a priority, may have been weak and requiring attention. After the initial training, a CTS's interface with the rest of the public health system is typically restricted to interaction with community MDR-TB nurses who supervise them. The supervisory interactions provide CTSs with an opportunity to discuss their patients' condition, problems encountered and learn MDR-TB care practice skills from community MDR-TB nurses (MSF, 2013; Hill et al., 2014; Kok et al., 2018). Importantly, on-the-job supervision and support builds on and enhances CTSs' knowledge, attitudes and ethical practice standards in order to increase quality of care by closely evaluating CTSs' interaction with their patients under day-to-day working conditions (Hill et al., 2014; Kok et al., 2018).

Anecdotally, consistently maintaining regular supportive supervision is difficult in this setting. As part of the present study's scope, the researcher visited and observed a substantial proportion of CTSs providing DOT and administering MDR-TB injections

in practice in patients' homes. Poor transportation was observed to be a shared challenge during these visits, and the researcher hardly came across any all-weather accessible roads, with some of the gravel roads certainly impassable during the rainy season. Thus, sustained and regular face-to-face supervision of CTSs in some of these remote rural settings is likely to remain an elusive goal. The COVID-19 outbreak has influenced the use of alternative strategies to ensure continued service delivery, such as online/telephonic/electronic platforms for patient management. These could be optimised by the NTCP to improve CTS supervision and support.

More importantly, programme managers should be mindful of that supervisors – community MDR-TB nurses – are HCWs too, and require as much support, including supervision, as other front-line HCWs (Munga et al., 2012; Crowley & Mayers, 2015). It is critical not to neglect improving the competencies of community MDR-TB nurses tasked with supervising and providing mentorship to CTSs. As CTSs take up expanded clinical tasks, professional nurses' roles in MDR-TB management inevitably change. Community MDR-TB nurses are required to provide technical oversight to CTSs in their new roles. Implicitly, these changes result in the need to review and upgrade the skills set for community MDR-TB nurses to enable them to adequately fulfil their new roles. In most instances, supervisors are only equipped with technical knowledge and not adequate supervision and mentorship skills, implying a gap in the planning and conducting of supervision visits (Munga et al., 2012; Crowley & Mayers, 2015; Baine et al., 2018).

Programme managers should play an important role in monitoring the supervision of CTSs, recognising the evolving factors that affect supervision, and providing resources to address and remove obstacles to supervision. As supervisors, community MDR-TB nurses should have enough allocated time to regularly visit and support CTSs in performing MDR-TB roles. Managers could monitor supervision of CTSs by community MDR-TB nurses, for example, by tracking simple indicators such as the proportion of scheduled supervision visits that are completed. With digital technologies increasingly gaining attention in health care, mobile devices could become key accessories in bridging this gap in face-to-face supervision of

CTSs by community MDR-TB nurses (Falzon, Migliori, Jaramillo, Weyer, Joos, Raviglione et al., 2017).

In extant literature, remarkably, limited attention has been paid to understanding in depth why supportive supervision was perceived to be challenging in this setting. Several studies have investigated factors that influence the performance of CHWs, and while some have examined the challenges of CHWs more broadly, few have concentrated on supervision in detail (Agarwal et al., 2019; Ormel et al., 2019). Based on this gap in the literature and on findings from this study, future research should therefore prioritise investigating and identifying effective strategies to improve the frequency and quality of supervision by community MDR-TB nurses. Without supporting empirical evidence, it will remain challenging to recognise the pitfalls to avoid and effective approaches to replicate, and programme implementers will have to rely on experience and intuition.

Results from this study indicate that a majority of patients were likely to recommend to their friends or family to receive community-based MDR-TB care from a CTS. This finding is profound considering that patient satisfaction and recommendation of a provider are correlated factors (Tung & Chang, 2009). Recommendations from former patients is often the only information at the disposal of prospective MDR-TB patients or their caregivers when choosing a preferred provider.

Although the task-shifting strategy has been successful in improving patient satisfaction and treatment outcomes, its impact on patient safety has not been thoroughly assessed in this study setting (Peresu et al., 2020). By applying the APEASE criteria, this study showed that patients experienced adverse drug effects from the prolonged multiple MDR-TB medications they take. As reported by the current and other studies, some patients were observed to have experienced treatment adverse events including hearing loss as a result of the daily injectable medicine received during the IP of treatment (Seung et al., 2009; Satti et al., 2012). As such, CTSs are expected to be able to accurately and timely identify side effects that compromise patient safety and refer to the community MDR-TB nurses for further management. Timely recognition, communication and referral of patients with

adverse conditions beyond their competence for professional interventions is important in improving client comfort and treatment adherence (Agarwal et al., 2019). An efficient referral system to support CTSs providing MDR-TB services beyond the health care setting is therefore important, particularly, when this narrowly-trained cadre is perceived to be performing clinical procedures such as injection administration that are potentially harmful to patients.

7.3 Acceptability of task-shifting to key stakeholders

The BCW provided a useful framework to assess key stakeholders' views of task-shifting. The issue of whether or not task-shifting DOT and MDR-TB injection administration to CTSs was acceptable appeared to be an emotive issue among key stakeholders in this study. Albeit sometimes reluctantly, stakeholders broadly accepted that task-shifting MDR-TB care to CTSs bridged substantial gaps in MDR-TB treatment coverage and professional HCW shortages. The findings of the present study mirror wider discourses about task-shifting in the literature (Munga et al., 2012; Crowley & Mayers, 2015; Rustagi et al., 2015; Baine et al., 2018).

Stakeholders in the present study concurred that the task-shifting strategy was implemented on an ad hoc basis and further acknowledged that a major expansion of professional HCWs, particularly nurses, was unlikely to be realised in the short-term. The COM-B model provided insight in how to make task-shifting practices more acceptable to stakeholders through addressing the physical and social factors such as resources, and environmental and organisational context that CTSs perform their delegated roles (Michie, van Stralen & West, 2011). The task-shifting process can be facilitated by putting a conducive policy and regulatory environment, competency-based training, certification and accreditation, registration, and compensation in place (Munga et al., 2012; Crowley & Mayers, 2015; Rustagi et al., 2015; Baine et al., 2018).

7.3.1 Supportive policy environment

The present study revealed that policy development was lagging behind the current level of task-shifting MDR-TB care to CTSs. Consistent with results from other studies, the current lack of policy guidance to permit task-shifting has created concerns over CTSs' authority and indemnity in executing expanded MDR-TB clinical tasks in the community (Munga et al., 2012; Crowley & Mayers, 2015; Baine et al., 2018; Mundeva et al., 2018). MDR-TB patients were considered to be highly vulnerable demanding skilled care and stakeholders questioned the ability of CTSs with lower levels of training to manage complex situations such as adverse events (TWG, 2017). There is currently no clear articulation on which provider has ultimate accountability for the care delivered to MDR-TB patients. A permissive policy on task-shifting is not only essential in granting CTSs the authority and indemnity to administer injections, but also important in advocating for resources from the relevant government ministries and donors (Munga et al., 2012; Crowley & Mayers, 2015; Baine et al., 2018; Mundeva et al., 2018).

Findings from the present study suggest that the lack of sufficient involvement of key stakeholders in implementing the task-shifting strategy in the Shiselweni region potentially impedes an open, critical and transparent engagement about the approach. As a result of diverse opinions among stakeholders, CTSs were either viewed, incorrectly, as simply a source of cheap labour or, more constructively, as trained frontline HCWs actively participating in community-based MDR-TB management and expanding access to care. The disjuncture between practice and policy development in Eswatini is likely to persist unless there is increased attention to formalising task-shifting within the formal health system. Evidence from this study supports the use of the BCW to address the disjoint between stakeholders' views and the necessity of the task-shifting strategy (Michie et al., 2011). The BCW can be useful guide in establishing consensus and support for task-shifting with all relevant stakeholders by paying special consideration to barriers identified in this study such as the absence of a supportive task-shifting policy framework, the relatively weak stakeholder involvement, and the important inadequacies in the training of CTSs.

Similar results have been reported in Uganda (Baine and Kasangaki, 2014; Baine et al., 2018), Mozambique (Rustagi et al., 2015) and Tanzania (Munga et al., 2012).

7.3.2 Regulatory systems

Based on results from this study, the quality of MDR-TB care delivered through task-shifting will remain questionable unless the practice of CTSs is regulated and there is oversight over their training. The need to have an appropriate regulatory framework to safeguard the health and safety of MDR-TB patients by providing the scope of practice, training standards and codes of conduct for CTSs cannot be overemphasised (McCarthy et al., 2014; Crowley & Mayers, 2015; Baine et al., 2018; WHO, 2018a).

While the role of LHWs within MDR-TB management had increased, stakeholders questioned the long-term position of CTSs in the public health system. Policymakers from the MOH opposed the suggestion to fully integrate CTSs into the formal health system because the new CTSs' roles do not readily relate to the traditional public health delivery system and, most importantly, monetary incentives were viewed as unsustainable (Dambisya & Matinhure, 2012; Crowley & Mayers, 2015; Baine et al., 2018). Stakeholders in this study recommended that pre-service training and continuing educational support should be tied to accredited certification and registration to validate the competence of CTSs. Such accreditation will help the training of CTSs to be clearly understood by stakeholders outside direct provision of community-based MDR-TB care. This brings legitimacy to task-shifting and clarifies how the role of CTSs fit into the bigger context of the public health system (WHO, 2018a).

Traditionally, administration of medication including injections is a primary responsibility of professional nurses who fall under the Eswatini Nurses Council (ENC). The ENC is mandated by law to regulate the scope of practice of nurses including defining the necessary training requirements. However, the law is silent on which body controls the practice of LHWs. Stakeholders concurred that the MOH should work closely with relevant professional institutions in developing an enabling

environment for regulating the task-shifting practice. This would allow the MOH to provide oversight over the setting of standards for selection, pre-service education and on-the-job training, accreditation, mentorship and registration of CTSs. Regulation of the task-shifting practice can be used as the foundation to explicitly establish core competencies needed to perform the tasks, set practising norms and standards, outline career paths for CTSs and recognition of prior service as a requisite competency for other HCW training opportunities (Munga et al., 2012; Kok et al., 2015; WHO, 2018a).

However, some CTSs in the present study were opposed to the idea of formalising the certification and regulation process. Their fears could be attributed to perceived rigid and strict pre-selection, training and registration requirements that come with regulations that may act as barriers for them in practice (McCarthy et al., 2014; WHO, 2018a). Task-shifting inevitably leads to changes in the meaning of community MDR-TB nurses' responsibilities within the broader public health system (McCarthy et al., 2014; WHO, 2018a). Regulation of the task-shifting practice will reduce challenges related to role ambiguity created by changes in expanded clinical roles for CTSs as well as new supervisory responsibilities for community MDR-TB nurses.

7.3.3 Compensation of community treatment supporters

A majority of stakeholders in the present study, including patients, recognised that essential MDR-TB care cannot be delivered by CTSs on a voluntary basis. This finding is consistent with the universal consensus in literature, although often breached in practice, that recognises the importance of appropriately compensating CHWs for the services they provide (Daniels et al., 2014; Agarwal et al., 2019; Ormel et al., 2019). Although volunteers can make a valuable contribution in the short-term horizon, CTSs should receive an appropriate mix of monetary and non-monetary compensation, contingent on performance and proportionate with available resources in a sustainable way (Daniels et al., 2014; Agarwal et al., 2019; Ormel et al., 2019). The absence of compensation may have adverse effects on the

sustainability or scaling up of the task-shifting strategy (Mpembeni et al., 2015; Naimoli et al., 2015; Ormel et al., 2019).

Consistent with previous studies (WHO, 2008; Naimoli et al., 2015; Agarwal et al., 2019; Ormel et al., 2019), participants in this study suggested financial, material or non-material incentives as compensation for CTSs. While participants in this study suggested numerous financial and non-financial incentives as compensation for CTSs, it is still a conundrum as to which particular incentives or combinations thereof are important in retention of CTSs to execute MDR-TB roles.

7.4 Cost-effectiveness of community-based MDR-TB management

The BCW provided a framework for evaluating the two models of MDR-TB care implemented in Eswatini. According to the APEASE criteria that is an extension of the BCW, a cost-effectiveness analysis is necessary in making a decision about which intervention is most appropriate (Michie, Atkins & West, 2015). On account of sparse published experience on the community-based strategy, this is the first study to evaluate the cost-effectiveness of the community-based MDR-TB programme in Eswatini from a societal perspective. Results from the present study demonstrated that the community-based MDR-TB strategy is an affordable and cost-effective approach to optimise MDR-TB control in Eswatini. Similar findings were reported in South Africa (Loveday et al., 2018). However, in the South African study, MDR-TB injections were administered by mobile nurses instead of LHWs. In addition, the authors of that study excluded costs incurred by MDR-TB patients and their caregivers, despite evidence that such costs can be substantial (Ramma et al., 2015).

Even though MDR-TB treatment services are provided free of charge for patients in Eswatini, a substantial share of the costs fall on the patients and their caregivers. In the clinic-based model of care implemented in three of the country's four regions, the pathway to MDR-TB management is characterised by five times weekly visits by the patient and their caregiver to the clinic for DOT and injection administration during the IP. These visits to the clinic are associated with high out-of-pocket travel and

indirect income loss costs. In the present study, the community-based MDR-TB model of care more than halved the costs incurred by patients and their caregivers, compared to the clinic-based approach (US$450 for the community-based strategy compared to US$1 121 for the clinic-based model of care). The substantial costs incurred by patients and their caregivers represent a huge financial burden on MDR-TB patients to whom access to MDR-TB services is often a challenge (Ramma et al., 2015; WHO, 2015). A comprehensive understanding of these costs is essential in designing interventions to lessen the economic burden on patients as well as monitoring the country's progress in reaching zero catastrophic costs of MDR-TB illness.

7.5 Overall assessment of community-based MDR-TB management

A core component of the COM-B model, opportunity, provided a framework for understanding how social and environmental factors that are external to an individual facilitated the success of the community-based MDR-TB model of care. Among the priorities set out by the NTCP is to bring the provision of MDR-TB care as close as possible to patients who need treatment, improve treatment outcomes, and achieve national and global TB control and development targets. While decentralisation has improved access to clinic-based MDR-TB services, weaknesses in this model of care delivery have emerged as a major factor contributing to poor treatment outcomes in Eswatini (Turashvili et al., 2014; MOH, 2019). Findings from the current study suggest that a number of components of the community-based MDR-TB management strategy reflect a patient-centred approach in addressing the different needs of patients as also observed in other research (Aït-Khaled et al., 2010; TB CARE I, 2014; WHO, 2017). This study has demonstrated that community-based MDR-TB management eliminates the distance-to-clinic barrier, reduces transport costs for patients and their caregivers, and gives patients the autonomy to select their treatment supporter.

In addition, the community-based MDR-TB management strategy required less contact between patients and professional HCWs, freeing-up time for community MDR-TB nurses who in turn could support more patients and CTSs. A crucial

component in the community-based strategy could be regular one-on-one interaction and sustained social contacts between patients and their CTSs that addressed a broad range of psychosocial and treatment-related issues (Kerseburger et al., 2019). CTSs spend more time in the community with the patient, in line with the origins of the role (Lehmann & Sanders, 2007).

The End TB Strategy has positioned MDR-TB within the SDG agenda, calling for concerted actions beyond the traditional biomedical approach to strengthen MDR-TB control and, ultimately, help to eliminate the disease within the next decade (UN, 2015; WHO, 2015). Based on results from this study, the race to eliminate the MDR-TB epidemic by 2030 especially, but not exclusively, in resource-limited settings like Eswatini could be aided if community-based care is at the centre of the MDR-TB response. The task-shifting strategy paved the way for the community-based MDR-TB management to be feasible, and improved the reach and expansion of access to MDR-TB services to patients the NTCP has historically struggled to engage. CTSs played a critical role in the community-based management of MDR-TB; as the intermediary between patients and the NTCP, and facilitating the decentralisation of MDR-TB services.

By providing treatment in patients' homes, the community-based strategy eliminated idiosyncratic clinic-based MDR-TB care rituals such as costly daily visits to the often distant and geographically inaccessible clinics during the IP. Costs incurred by patients and their caregivers under the community-based MDR-TB model of care were typically 60 percent lower than those treated through the clinic-based model of care. The provision of financial and food support treatment enablers in the current study is coherent with the End TB Strategy's call for social protection interventions to mitigate the economic hardship faced by TB patients and their caregivers (Tanimura et al., 2014; WHO, 2015; Migliori & Garcia-Basteiro, 2018). Nonetheless, despite plausibility and consistency in literature, the actual impact of social protection measures and treatment adherence support enablers on MDR-TB outcomes in the Shiselweni region remains largely unknown.

In the present study, the treatment success rate was higher among patients under the community-based MDR-TB model of care compared with those treated through the clinic-based strategy, exceeding the WHO target of 75% (Falzon et al., 2015). Fewer patients were lost-to-follow-up or died from MDR-TB under the community-based model of care. Adverse treatment outcomes – including loss to follow-up - are the most disconcerting results in MDR-TB management and often a consequence of patients perceiving certain aspects of care (e.g. costly daily visits to distant and geographically inaccessible clinics) as unacceptable. The community-based MDR-TB management model of care implemented in the Shiselweni region can thus be considered to be a key accessory and alternative strategy to achieve important national and global TB control and development goals.

In summary, findings from the present study demonstrate the potential of the task-shifting strategy in expanding access to MDR-TB treatment and should inform planning for the development of analogous community-based MDR-TB models of care at scale in other geographical settings. However, scaling-up this community-based strategy is a complex and challenging process given the many factors that lie outside of the programme's control. It is important to acknowledge that this model of care was successful implemented on a limited scale under realistic conditions in one region of Eswatini, with intensive engagement and support from an NGO, MSF. Decision-makers should critically consider the landscape and all specific requirements that need to be met to achieve successful implementation on a large scale, typically under the MOH. Successful translation of this community-based model of MDR-TB care at scale will require a supportive policy framework, adequate political support, coordination and consensus among multiple stakeholders, appropriate management systems and financial resources.

7.6 Recommendations for an optimum community-based MDR-TB management strategy

Based on findings of the present study, Box 1 outlines the key recommendations that should be considered when task-shifting community-based MDR-TB management to CTSs.

Box 1: Recommendations for an optimum community-based MDR-TB management strategy

- National policy and legal frameworks should permit CTSs to provide community-based MDR-TB services
- Relevant key stakeholders – regulatory bodies, training institutions, civic society and clinicians, as well as patients themselves – should be carefully consulted in the preparation and implementation of task-shifting
- The MOH should work closely with appropriate professional regulatory institutions to provide oversight over the practice of CTSs
- Prior learning assessment and recognition framework for CTSs should be in place
- Competence-based training, accreditation and certification for CTSs should be implemented
- CTSs should receive pre-service training and adhere to safe injection handling and TB IPC protocols
- Short, repeated and regular ongoing training for CTSs should be carried out
- CTSs should receive both the theoretical and practical component of the training prior to commencing provision of MDR-TB services to patients
- Clear guidelines and protocols should be available to ensure CTSs are not expected to make individual clinical decisions
- Clear job descriptions for respectively CTSs and community MDR-TB nurses should guide their work
- Other professional HCWs should be informed about tasks and activities delegated to CTSs
- There should be sufficient levels of supervision and feedback taking into account the CTSs' competence, patients' needs, service settings and the tasks delegated
- Patients' households need to be assessed and comply with standard IPC measures
- A team consisting of professional HCWs should be in place and fully engaged in supervising, monitoring and supporting CTSs
- Protocols for timely communication, referral and management of adverse

treatment events need to be developed

- CTSs' training curriculum should prioritise important domains of care including adherence counselling, patient confidentiality issues and ways to reduce stigma
- CTSs should be fairly and appropriately compensated for their services and out-of-pocket costs associated with MDR-TB care
- Adequate social protection mechanisms such as cash transfers, food packages, transport incentives, and psychosocial support for MDR-TB patients need to be considered

7.7 Future perspectives

Drawing from recent WHO recommendations, the NTCP is currently prioritising all-oral shortened MDR-TB treatment regimens over injectable drugs. The new MDR-TB treatment protocols make clear that all-oral regimens based on drug-susceptibility testing should be the preferred alternative. The fully-oral regimens are also considerably easier to deliver as the COVID-19 pandemic continues to unfold. While the role of CTSs in delivering the new therapeutic approach was not examined in the present study, it is logical to presume that CTSs will remain an integral component in the expansion of socially acceptable and affordable MDR-TB services.

The COVID-19 pandemic has brought new challenges to community-based MDR-TB management. On the whole, the intersecting COVID-19, HIV and TB epidemics in countries like Eswatini with high TB/HIV co-infection rates is a well-founded concern (Alene, Wangdi & Clements, 2020; Tamuzi, Ayele, Shumba, Adetokunboh, Uwimana-Nicol, Haile et al., 2020). Both COVID-19 and MDR-TB diseases predominantly affect the lungs and transmission of infection primarily occurs via close contacts (Tamuzi et al., 2020). Although the precise impact of concomitant COVID-19 infection and MDR-TB is unknown, it has been suggested that MDR-TB patients who contract COVID-19 may experience severe complications including mortality, especially if MDR-TB treatment is interrupted (Liu, Yu, Fleming, Wang, Shen, Wang et al., 2020; Tamuzi et al., 2020). Importantly, COVID-19 is likely to require alternative approaches to DOT that limit face-to-face interactions between patients and their treatment supporters.

Maintaining uninterrupted adherence to treatment and access to MDR-TB services during the COVID-19 pandemic is critical for MDR-TB control. The use of digital technology to support video DOT is suggested as an intervention to navigate the limitations of in-person DOT (Falzon et al., 2017). In 2017, digital health platforms were recommended by the WHO Global Task Force on Digital Health for TB as an alternative for DOT supervision where possible (Falzon et al., 2017). Patients receive a monthly supply of drugs and use a smartphone with a WhatsApp Messenger to video call a facility-based nurse daily while taking their medication (Sekandi, Buregyeya, Zalwango, Dobbin, Atuyambe, Nakkonde. et al., 2020). The success of such innovative people-centred strategies call for the NTCP and other public health authorities to collaborate and work synergistically in responding to both diseases.

7.8 Limitations

The present study had a number of limitations.

- The sample size used was relatively small and a limited set of data was collected. As such, results from this study should be interpreted with caution. The study purposively selected all eligible patients and CTSs to expand the sample size. Future research should consider a sufficiently large sample.
- Recall bias may have occurred given the retrospective nature of the data collection process. To minimise recall bias, the study only considered CTSs and patients that had provided or received DOT and intramuscular injections under the community-based MDR-TB model of care in the 12 months preceding data collection.
- Participants' self-reported answers may have reflected social desirability bias rather than their true opinions and experiences of task-shifting. To counter this, respondents were assured of the confidentiality of the information collected, non-collection of names or other personal identifying information, anonymous reporting of findings using aggregate analysis, and that the outcomes of the research would not affect their job security or incentives in any way. In addition, structured observations of CTSs administering MDR-TB injections were undertaken to verify survey responses and partly circumvent

social desirability bias. The observation visits verified the self-reported practices to be true suggesting that social desirability bias was not a serious concern. The observations yielded valuable insights helping the researcher to understand the context and meaning surrounding the practice of CTSs.

- Patients who had hearing loss from medication toxicity where omitted from participating in this study due to practical constraints. The difficulty in comprehension could have undermined their ability to provide informed consent, participate voluntarily and interact with the interviewers. Inclusion of this group of patients could have elicited diverse and instructive opinions about their level of satisfaction with the task-shifting of community-based MDR-TB care to CTSs compared to those that had not experienced severe adverse effects of the treatment.
- The dearth in empirical studies on the delegation of clinical tasks such as injection administration to LHWs in community-based MDR-TB care presented a significant gap in the evidence to inform the design of the present study. However, the alternative of using evidence from the task-shifting of HIV treatment-related roles, and provision of injectable-based antibiotics and contraception to CHWs in LMICs provided a useful foundation for the present study to consider.
- The scope of the cost-effectiveness analysis excluded other economic and public health benefits of MDR-TB control such as the reduction in MDR-TB transmission, cost per death averted or increased productivity from treating patients. By relying on surrogate effectiveness endpoints, the assessment may have underestimated the cost-effectiveness of the community-based MDR-TB management model. Future studies should consider all the benefits of community-based MDR-TB control in the economic evaluation.
- The study followed a cross-sectional design and therefore causal inferences were not made. However, the study offers unique insights and understanding into the novel task-shifting practice by presenting contextualised data regarding the community-based MDR-TB management strategy in Eswatini.
- Due to time and logistical constrains, community and family members' perspectives were not included in the scope of the present study. Previous studies have shown that family members with raised TB awareness influence

the opinions of the community about TB, extent of community involvement in and support for TB patients, treatment-seeking behaviour and adherence (Datiko, Habte, Jerene & Suarez, 2019). Nevertheless, overall, this study attempted to gather the opinions of diverse stakeholders on task-shifting, including CTSs who might have shed light on the perspectives of family or community members as well since they interacted frequently. Future studies should, therefore, explore the community's level of understanding and acceptability of the community-based model of MDR-TB care.

7.9 Conclusions

Through the lens of the COM-B model, the current study demonstrated that, as a component of community-based MDR-TB management, task-shifting can expand uninterrupted access to, and use of, MDR-TB services, help to address professional HCW deficits in resource-limited settings, improve treatment outcomes, and is acceptable to most stakeholders including patients themselves. The results from the present study also lend an economic justification for adopting the community-based strategy in MDR-TB control. The task-shifting strategy within the community-based MDR-TB strategy can be a catalyst in bringing national, WHO and UN TB control and development targets within reach for Eswatini and other resource-limited countries.

However, the community-based MDR-TB management strategy requires a carefully planned process supported by the participation of all key stakeholders and clear task-shifting policy development to guide implementation. Considerable advocacy efforts are essential to effectively integrate the role of CTSs into the NTCP and addressing the apprehensions and ambivalence about expanding access to MDR-TB services through task-shifting. Similarly, for task-shifting to succeed, the strategy should be embedded in a set of accredited training and certification, appropriate regulation, adequate supervision, and referral systems that support the delivery of MDR-TB care by CTSs.

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Appendices

Appendix 1: Participant consent letters and interview schedules

Appendix 1.1: Knowledge, attitudes and practices of CTSs on MDR-TB management

Dear Sir/Madam

You are kindly invited to voluntarily take part in this research study. The study entails the following:

- Dr Ernest Peresu, a student at the University of Free State, South Africa is conducting research on the evaluation of the task-shifting of multidrug-resistant tuberculosis (MDR-TB) injection administration to community treatment supporters (CTSs) implemented in the Shiselweni region of Eswatini by Médecins Sans Frontières (MSF) from 2008 to date.
- All CTSs in the Shiselweni region have been selected to participate in this study. Your participation will help a lot in making this evaluation successful.
- If you agree to take part in the study, you will need to sign a consent form attached to this form and then complete a questionnaire about your knowledge, attitudes and practices on MDR-TB management. This will take no more than one hour.
- The study will be conducted over a period of four weeks at three rural health centres in the Shiselweni region.
- Your participation is entirely voluntary and you have the right to withdraw at any stage in the process without any penalty or prejudice regarding your work or continued engagement in the MDR-TB care programme.
- The responses you supply will be treated confidentially and will only be used for this study. Your name and identifying affiliations will be anonymised in the analysis and any resulting publications.
- The signed consent forms and completed questionnaires will be safely secured in a locked cabinet in an office only accessible by the principal researcher. Access to data in the study database will be restricted through the use of a password.
- There is no payment for taking part in this study. Participation or not will not affect your continued engagement in the MDR-TB care programme.
- We believe there are no known risks associated with this research study.

I,……....(Full name of CTS in block letters)

- have read and understood the Participant Information Sheet
- All the questions I had about the research have been satisfactorily answered.
- I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving reason.

Patient Signature……Date…….

If you have further questions about the study, you are welcome to contact Dr Ernest Peresu at 76026657 or e-mail address: eperesu@yahoo.com.
If you have any questions about the ethical conduct of this research please contact the Eswatini Ethics Committee at the following telephone number: 24042431.

Community-based MDR-TB Management: Task-shifting to Community Treatment Supporters in Swaziland

Lifomu lalongenela lucwaningo

Longenela lucwaningo

Uyamenywa kwekutsi ungenele lolucwaningo. Usengakancumi kungenela lolucwaningo, nati tinchazelo letimayelana nalolucwaningo.

- Dokotela Ernest Peresu benta lucwaningo lapho babuketa kuniketwa kwemijovo bagcugcutli nakulashwelwa iMDR TB lokuluhlelo lolwentiwa esifundzeni saseShiselweni kwentiwa yinkampani eMSF kusukela 2008 kutekube ngunamuhla.
- Bonkhe bagcugcuteli baseshiselweni bakhetsiwe kutsi bangenele lolucwaningo. Kungela lolucwaningo kutawusita kutsi lolucwaningo lube yimphumelelo.
- Nawuvuma kungela lolucwaningo, utawucelwa kutsi usayine lifomu lesivumelwano lelihlanganiswe kulelifomu lokutatisa kwalongenela lucwaningo. Utawubese ugcwalisa lifomu lelinemibuto ngelwati , kucabanga nalokwentiwako nakulashelwa iMDR-TB. Lelifomu litotsatsa emaminitsi langemashumi lamatsatfu.
- Lolucwaningo lotawutsatsa emaviki lasihlanu emitfolamphilo lemitsatfu leseShiselweni.
- Kubakulolucwaningo kungoba utikhetsele unalo lilungelo likuphuma kulolucwaningo noma kunini ngaphandle kwenkinga noma kubhadaliswa emsebentini nangekuchubeke usebente ekwelashweni iMDR- TB. Unalo lilungelo lokubuta futsi uphendvuleke mayelana nalelucwaningo.
- Nawuvuma kungenela lolucwaningo letimphendvulo lotawutisho titawugcinwa ngalokufihlakele tisetjentiswe ngulolucwaningo kuphela. libito lakho naloko lokungakhombisa wena ngeke kuvetwe nasekuchazwa noma sekukhishwa imiphumelo yalelucwaningo.
- Lamafomu esivumelwano kunye nemafomu emibito aakuhlala akhiyelwe ehhovisi lelivulwa ngulocwanikako kuphela. Kute lotawuvunyelwa kutsi abe nekufinyelela lakunalamafomu ngaphandle abe nesikhiya.
- Cela ucondze kutsi angeke ubhadalwe kuba kulolucwaningo. noma uyalingenela noma awulingeneli utochubeka ube ngumgcugcuteli.
- Kute likubi lokubhekekile noma lokungaba khona usangenele lolucwaningo.

Nawunemibuto leminye mayelana lolucwaningo wemukelekile kutsi utsintse Dokotela Ernest Peresu kunayi inombolo 7602 6657 noma umubhalele ku: eperesu@yahoo.com

Nawunemibuto mayelana nekuphepha nekuvumeleka kwalolucwaningo cela utsintse lihhovisi le Swaziland Ethics Committee kunayi inombolo: 2404 2431.

Mine.....(ligama lemgcugcuteli ngetinhlavu letinkhulu)
Ngifundzile ngacondza ngalolwatiso lalongenela lucwaningo.
yonkhe imibuto lebenginayo ngalolucwaningo imphendvulelile kahle.
Ngiyacondza kutsi kungenela lolucwaningo kuyimvuo yami futsi ngivumelekile kuyekela noma ngunini ngaphandle kwekuletsa sizatfu.

Sayina umgcugcuteli.....Lusuku.....

Sayina losebentela lucwaningo.....Lusuku.....

FOR OFFICIAL PURPOSES ONLY
Data Collector: _____
Date Collected: _____
Health Facility: _____

Please tick (✓) only one response that best answers the question. We would appreciate if you can answer all the questions as honestly as possible.

Maka (✓) *libhokisi lelicondzene nemphendvulo lekunetisako kulemibuto. Khetsa yinye imphendvulo ngaphandle nakushiwo kutsi tingaba tinengi. Yonkhe imibuto igcwaliswa ngekungativeti. Singajabula nawungayiphendvula yonkhe lemibuto ngekwetsembeka.*

1. GENERAL AND DEMOGRAPHIC QUESTIONS

1.1 How old are you?

Unamingakhi iminyaka?

Under 30 years *Phansi kwemashumi lamatsatfu*		31-40 years *Iminyaka leku 31-40*		41-50 years I*minyaka leku 41-50*		Over 50 years *Ngetulu kweminyaka lelishumi nesihlanu*	

1.2 What is your gender?
Ubulili buni?

Wesilisa/Male		Wesifazane/Female	

1.3 What is the highest level of education you have completed?
Esikolweni wagcina kabani?

Angifundzanga No school		Primary school		High school		*Unyuvesi/ekilishi* College/university		*Fundze kasebenta* Literacy classes only	

1.4 Are you employed?
Uyasebenta yini nyalo?

Yebo/Yes		*Cha*/No	

If yes please specify……..
Uma utsite yebo, sicela uchaze……..

1.5 Please answer the following regarding caregiver costs
Tindleko talonaka logulako

No.	*Umuco*	Statement	Amount
1.5.1	*Umholo wenyanga*	Daily income	
1.5.2	*Tindleko tekwekuhamba uma yehluke naleyo yalogulako*	Transport cost if different from patient	
1.5.3	*Inombolo yemalanga ekungaveli emsebentini kwenteela kupheketela logulako*	No. of days lost from work to accompany patient	
1.5.4	*Imali yemholo lephelele leyilahleke ngelilanga*	Amount of wages lost per day	

1.5 How many months have you been administering MDR-TB injections?

Tingakhi tinyanga solo ujovisa umjovo we MDR-TB?

	Tinyanga/months

1.6 In the past 12 months, have you attended training on MDR-TB?
Etinyangeni letilishumi nakuphili ukewaya kuyo fundze ngeMDR-TB?

Yebo/Yes		Go to question 1.6.1 Phendvula umbuto 1.6.1
Cha/No		Go to question 1.6.2

1.6.1 If you have attended training on MDR-TB, please indicate the topics that were covered:
Nangabe uke wangenela tifundziso taka MDR-TB, cela ukhetse letihloko letafundziswa:

	Kuvikela kutselelwana kweMDR-TB	MDR-TB infection control
	Kulashwa kwe MDR-TB	General MDR-TB management
		MDR-TB injection administration
	Lokunye (chaza) …… …….……..	Other (specify) …… …….. …….....

1.6.2 If you have not attended training on MDR-TB in the past 12 months, please indicate why:

Nawungakaze wayonfundza nge MDR-TB etinyangeni letilishumi nakubili letengcile, shano kutsi leni:

	Kufundza ngeMDR-TB akusebenti	Training on MDR-TB is not useful
	Kwakute lohlelo lokufundzisa nge MDR-TB lolwaluhleliwe	No MDR-TB trainings were organised
	Bekute sikhatsi lesanele sekufundziswa iMDR-TB	There was not enough time to attend MDR-TB training
	Bengite imali leyenele yekuyofundza ngeMDR-TB	You could not afford the cost of attending MDR-TB training
	Lokunye (chaza) …… …….....	Other (specify) …… ……

2. LWATI NGE MDR-TB/ MDR-TB KNOWLEDGE
Ngekubuka lokwatiko nge MDR-TB, khombisa kutsi lemisho ikahle: Yebo(Y) Anginasiciniseko (U) Cha (N)

Based on what you know about MDR-TB, please indicate whether the following statements are correct: Yes (Y); Unsure (U); and No (N).

No.	***Umuco***	**Statement**	**Y**	**U**	**N**
2.1	*MDR -TB legciwane lengilapheki nge liphilisi i isoniazid ne rifampicin*	MDR-TB are strains of TB resistant to at least isoniazid and rifampicin			
2.2	*MDR -TB itfolakala emoyeni*	MDR-TB is contagious			
2.3	*Umgcugcuteli lonaka umuntfu lone MDR-TB angabanayo iMDR -TB*	A CTS providing care to a patient with MDR-TB may develop MDR-TB			
2.4	*Bantfu labalala ekamelweni linye abasibo labangatselelana iTB*	People who sleep in the same room are not close TB contacts			
2.5	*Bantfwana labangaphansi kweminyaka lemibili angeke babatselele batali babo noma labo lababanakako iMDR-TB*	Babies under two years are close TB contacts of their parents, or anyone who looks after them			
2.6	*Umuntfu angayitfola iMDR-TB ngekuchawula lone MDR-TB*	A person can get MDR-TB from shaking hands with someone with			

		MDR-TB			
2.7	*Umuntfu lone HIV usematfubeni lamakhulu ekuba ne MDR-TB*	A person with HIV is more likely to develop MDR-TB			
2.8	*Kuvula emafasitelo kungasita kuvikela kwandzisa iMDR-TB*	Opening windows can help in preventing the spread of MDR-TB			
2.9	*Kufaka kwekuvikela emakhala iN95 kuyawehlisa ematfuba ekutfula iMDR-TB*	Wearing a N95 respirator can reduce the risk of transmission of MDR-TB			
2.10	*Bonkhe labane MDR -TB banetimphawu letibonakalako.*	All people with MDR-TB infection have visible symptoms			
2.11	*Kukwehlela ngulona phawu lolujwayelekile le MDR-TB.*	Coughing is the most common symptom of MDR-TB			
2.12	*MDR -TB itfolakala kahle esitfombeni sasegesini*	MDR-TB is best diagnosed from a chest X-ray			
2.13	*Indlela lekahle yekubona kuphumelela ekulashweni kwe MDR-TB kucwaninga sikhwehlela nekubuka kusebenta kwemaphalisi*	The correct way of assessing MDR-TB treatment outcome is through sputum culture and drug sensitivity testing (DST)			
2.14	*MDR-TB iyalapheka*	MDR-TB can be cured			
2.15	*Emaphilisi emjovo latfolakala emitfolaphilo angayelapha iMDR-TB*	General antibiotics given at the health centre can cure MDR-TB			
2.16	*IMDR-TB ilapheka kahle nganawa emaphilisi: irifampicin, amikacin and levofloxacin only*	MDR-TB is best treated with following drug combination: rifampicin, amikacin and levofloxacin only			
2.17	*Sikhatsi lesanele sekujovela iMDR-TB tinyanga letisiphohlongo*	The standard length of injection treatment for a newly diagnosed case of MDR-TB is 8 months			
2.18	*Umjovo i Amikacin nguwona usetjentiswa nawusacal kujovela iMDR TB*	Amikacin is the drug that is used for injection during the intensive phase			
2.19	*Sikhatsi sekulashelwa iMDR -TB singaba tinyanga letilishumi nesiphohlongo kuya kuletingemashumi lamabili nakune.*	The duration of treatment for MDR-TB is between 18 to 24 months			
2.20	*Kulesinye sikhatsi bantfu labalashelwa iMDR - TB ababincono ngoba abawanatsi emaphilisi abo*	Sometimes people with MDR-TB do not get better because they do not take their medication			
2.21	*Imitsi lenetikhomba tekufa noma kungcola lekutsite kufanelwe ilahlwe*	Medications with visible contamination or breaches of integrity (e.g. cracks, leaks) should be discarded			
2.22	*Kushikisha ungakajovi kuyabehlisa buhlungu nawujova*	Swabbing before injections will minimize the pain during injection			
2.23	*Kuvalwa kwetinyalitsi nawucedza kujova kungabanga kuhlatjwa tinyalitsi*	Recapping of used needles can cause needle-stick injuries			
2.24	*Kunatsa emaphilisi ekuvikela iHIV (PEP) kungawehlisa ematfuba ekutfola ligciwane le HIV nabahlatjwe yinyalitsi labasebenta esibhedlela*	Taking antiretroviral drugs as post-exposure prophylaxis (PEP) can reduce the rate of infection in health care workers exposed to HIV through needle-stick injuries			
2.25	*Ematfumba labekujovwa khona kufanelwe abikwe kunurse losebenta emmangweni lolapha iMDR-TB*	An infection or boil on the injection site is a side effect related to the injection that should be reported to the community MDR-TB nurse			

3. MDR-TB ATTITUDES

Please indicate how much you agree or disagree with each of the following statements. Strongly agree (SA); agree (A); unsure (U); disagree (D); or strongly disagree (SD).

Khetsa kutsi uvumelana nalemicu kangakanani. Kakhulu kakhulu (SA) Kakhulu (A) Angati kahle (U) Ngiyaphikisa (D) Ngiphikisa Kakhulu (SD)

No.	***Umuco***	**Statement**	**SA**	**A**	**U**	**D**	**SD**
3.1	*MDR-TB iyinkinga kutemimango kaNgwane*	MDR-TB a major public health threat in Swaziland					
3.2	*Ngiva ngatsi timfundziso teMDR TB emmangweni tanele*	I feel awareness of MDR-TB in my community is adequate					
3.3	*Kufundziswa kwalabalashelwa iMDR-TB nebantfu bommango kuze kuvikeleke kwandza kwe MDR-TB*	Community awareness about MDR-TB is important in the control of the disease					
3.4	*Ngiyacondza bumcoka bekungenela timfundziso tekuvikela iTB ngalokwejwayelekile*	I understand the importance of attending regular training on TB prevention					
3.5	*Nginelwati lolwanele ngekulashwa kwe MDR-TB emmnagweni*	I have enough information about community MDR-TB management					
3.6	*Ngumsebenti wami kufindzisa tigulane nge luvikelwa kweMDR-TB*	It is my responsibility to teach patients about TB prevention					
3.7	*Bantfu labalashelwa iMDR-TB kununa bahlukaniswe kulabaneHIV*	Patients with known MDR-TB should be separated from HIV patients					
3.8	*Kugeza tandla ngingakatsintsi sigulane noma sengicedzile kumcoka emebentini wami*	Washing my hands before and after direct patient contact is a necessary part of my work					
3.9	*Ngiyakhutsata kuvulwa kwemafasitelo nekungenisa lilanga emakhaya ngaphandle kwekubuka simo selitulu*	I encourage adequate ventilation and sunlight at the patient home, regardless of weather conditions					
3.10	*Ngiyayisebentisa imaskhi noma kungemnandzi*	I use a N95 respirator even though it may be uncomfortable					
3.11	*Ngiyakhatsateka ngekutfola iMDR-TB ngisasebenta*	I worry about acquiring active MDR-TB disease while at work					
3.12	*Ngicabanga ngisematfubeni lamacane ekutfola iMDR-TB kulenginakekelako*	I think I have a very low risk of acquiring MDR-TB from my patient					
3.13	*Ngiyakholelwa kutsi kusebentisa kahle kwemijovo kungehlisa ematfuba ekutfola kugula kulabasebenta ngetemphilo*	I believe following safe injection practices can help reduce the risk of infectious adverse events in healthcare providers					
3.14	*Ngicabanga kutsi kulukhuni kulabalashelwa iMDR-Tb kutsi bacondze kutsikufuna bachubeke nekunatsa emaphilisi kute babe ncono*	I think it is difficult for patients with MDR-TB to understand the need to continue taking medication after they start feeling better					
3.15	*Ngingasho kutsi kungacedzi noma kungatsi kahle emaphilisi eMDR-TB angenta timphawo tibe nguletinkhulu kakhulu*	I consider interrupted MDR-TB treatment course to be a possible cause of worsening of symptoms					
3.16	*Ngiyakholelwa kutsi kunatsa imitsi yesintfu noma lokunye kwenta kulashwa kweMDR – TB kubelukhuni*	I believe taking traditional or alternative medicine makes the treatment of MDR-TB difficult					
3.17	*Ngiyeva kufuna ngibeneluvelo kulengimelaphako lolashelwa iMDR-TB*	I feel I should show compassion to my MDR-TB patient					
3.18	*Labalashelwa iTB bangasoleka*	MDR-TB patients are to blame for					

	bona ngesimo sabo	their own condition					
3.19	*Ngiyacabanga labalashelwa iMDR-TB bayagcekwa kakhulu emimangweni ngale sifo*	I feel MDR-TB patients are confronted with significant social stigma surrounding the disease					
3.20	*Lengimsitako lolashelwa iMDR-TB angete afuna kutsu bantfu bati kutsi ine TB*	My MDR-TB patient may not want other people to know that they have TB					
3.21	*3.14 Longiphetse usheshe atfolakale nangidzinga lusito ekunakeni lolashelwa iMDR-TB*	My supervisor is easily accessible when I need help in managing my MDR-TB patient					

4. *LOKWENTIWA KA MDR-TB*/MDR-TB PRACTICES

4.1.1 Do you have a CTS MDR-TB training manual?
Unayo incwandzi yeMDR -TB yekufundzisa bagcugcuteli?

Yes *Yebo*		Go to question 4.1.2 *Phendvula umbuto 4.1.2*
No/*Cha*		Go to question 4.1.4 *Phendvula umbuto 4.1.4*

4.1.2 How often do you refer to the CTS MDR-TB training manual?

Uyisebentisa kangakanani lencwandzi yeMDR yekufundzisa bagcugcuteli.

Always *Sonkhe sikhatsi*		Frequently *Ngivamisile*		Rarely *Ngazo*		Never *Cha*	

4.2.1 Are you personally involved in educating patients or communities about MDR-TB?

Ngekwakho uyabafundzisa labalashelwa iTB noma emmangweni ngeMDR-TB?

Yes/Yebo		No/Cha	

4.2.2 How often do you provide information on MDR-TB?

Ulunika kanjani lwati ngeMDR-TB?

Always *Sonkhe sikhatsi*		Frequently *Njalo*		Rarely *Ngazo*		Never *Cha*	

4.3.1 How often is cross ventilation implemented in the room your MDR-TB patient sleeps?

Ngabe kungeniswa kwemoya lokwanele kuyentiwa egumbini lapho kulala lomlaphela iMDR-TB?

Yes Yebo		No Cha	

4.3.2 If no, have you raised your concerns about this with the community MDR-TB team?

Nangabe cha, uke wakuveta kulelicembu le MDR-TB emmangweni?

Yes		No	

Yebo		Cha	

4.4.1 How often do you wear a N95 disposable respirator when attending to an MDR-TB patient?

Uyifaka imaskhi iN95 nawuya esigulaneni sakho seMDR-TB?

Every time I am attending to an MDR-TB patient *Sonkhe sikhatsi nanginaka lolashwa iMDR-TB?*		Frequently *Njalo*		Rarely *Ngazo*		Never *Cha*	

4.5.1 Are there enough supplies such as soap and clean water to wash your hands at patient homes?

Ngabe emanti netinsipho enele kugeza tandla emakhaya alabalashwako?

Yes Yebo		No Cha	

4.5.2 Do you wash your hands before and after direct contact with an MDR-TB patient?

Uyatigeza tandla ungattsintsi nanawucedza kunaka lolashelwa iMDR-TB?

Yes Yebo		No Cha	

4.5.3 How often do you wash your hands before and after direct contact with an MDR-TB patient?

Utigeza kangakanani tandla ungakatsintsi nanawucedza kubona lolashelwa iMDR-TB?

Every time I am attending to an MDR-TB patient		Frequently		Rarely		Never	

4.6.1 How often do you use a clean needle and syringe to draw up and administer medication?

Uyisebentisa kangakanani inyalitsi lehlobile nemjovo kunika umjovo?

Every time I am attending to an MDR-TB patient		Frequently		Rarely		Never	

4.6.2 How often do you immediately place needles and syringes in a sharps disposal container after administering an injection?
Imijovo lesebentile netinyalitsi utibeka emgcomeni lolahla tinyalitsi ngekushesha?

Every time I am attending to an MDR-TB patient Sonkhe sikhatsi nangi naka lone MDR-TB		Frequently Kaningi		Rarely Angikavami		Never Angikwenti	

4.7.1 Have you ever sustained a needle stick injury during your practise as a CTS?
Wake wahlatjwa yinyalitsi usasebenta njengemgcugcuteli?

Yes	Yebo	No	Cha

4.7.2 Did you report the needle stick injury?
Wakubika kuhlatjwa yinyalithi?

Yes	Yebo	Go to question 4.7.3 Phendvula umbuto 4.7.3
No	cha	Go to question 4.7.4 Phendvula umbuto 4.7.4

4.7.3 Did you take on HIV PEP after sustaining the needle stick injury?
Wawanatsa emaphilisi ekuvikela iHIV PEP ekubeni uhlatjwe yinyalisi.

Yes	Yebo	
No	Cha	

4.7.4 What was your reason for not reporting needle stick injury? Please tick all that apply.
Kwaba yini sizatfu sakho sekungabiki kuhlatjwa yinyalitsi? Khetsa lovumelana nako.

Bengingeke ngicitse sikhatsi.	I could not spare the time
Bekungangihluphi.	I could not be bothered
Bekunematfuba lamancane ekutfola iHIV.	There was a very low risk of HIV transmission at the time
Lebekalashelwa iMDR-TB abete i HIV.	The MDR-TB patient you cared for at the time was HIV negative
Bengingati kufanele ngibike	Did not know I had to
Bengingati ngibike njani	Did not know how to
Bengesaba kutsi simo sengati lesikhomba kuba khina kweligciwane sitangilahlekisela umsebenti nje mgcugcuteli.	I was afraid a positive HIV test result would affect my career as a CTS
Lokunye (Chaza)…… ……..	Other (specify)…… ……..

5 LEVEL OF AWARENESS OF MDR-TB AND TASK-SHIFTING
LIZINGA LEKWATI NGE MDR-TB NEKUSHINTJWA KWEMISEBENTI KUSUKELA KULABO LABACECESHIWE

5.1 In your opinion, is MDR-TB a major public health threat in Swaziland?
Ngekubuka kwakho, i-MDR-TB iyingoti yini emphilweni yebantfu eSwatini?

Yes ☐ Unsure ☐ No ☐
Yebo ☐ Angati ☐ Cha ☐

5.2 Do you think community members should play a role in MDR-TB care?
Uma ucabanga, ummango unayo yini indzima lewungayidlala ekunakeni labo labane MDR-TB?

Yes ☐ Unsure ☐ No ☐
Yebo ☐ *Angati* ☐ *Cha* ☐

5.3 Are you aware of any task-shifting of responsibilities from professional nurses to community health workers in relation to medical conditions other than MDR-TB in Swaziland?
Ingabe unalo lwati ngekushintjwa kwemisebenti kusuka kubahlengikati labaceceshiwe kuye etisebentini temphilo temmango macondzana naletinye timo temphilo ngaphandle kwe MDR-TB eSwatini?

Yes ☐ Unsure ☐ No ☐
Yebo ☐ *Angati* ☐ *Cha* ☐

If yes, please give examples
Uma utsite yebo, sicela tibonelo
……
……
……

6 ROLES AND RESPONSIBILITIES OF COMMUNITY TREATMENT SUPPORTERS (CTSs)
IMISEBENTI NETINDZIMA TEBASEKELI BEKWELAPHA BEMMANGO (EMA CTS)

6.1 In your opinion, what type of CTS do you think is preferable?
Ngekubuka kwakho, nguyiphi inhlobo yemsekeli wekwelapha ummango lokunguyena uncono?

	Umsekeli wekwelapha loceceshwe ngemijovo yeMDR-TB neDOT		A specialist CTS (mainly for MDR-TB injections and DOT)
	Umsekeli loceceshwe ngetimo temphilo		A generalist CTS (DOT/HIV issues/other

	letehlukile njengeHIV/DOT/nalokunye lokuphatselene netemphilo emmangweni		health promotion roles in the community)

Please explain
Sicela uchaze

……
……
……

7 RISKS/BENEFITS OF USING CTSs IN MDR-TB INJECTION ADMINISTRATION
TINGOTI/NETINZUZO TEKUSEBENTISA BASEKELI BEKWELAPHA BEMMANGO EKUJOVELENI i-MDR-TB

7.1 In your opinion, what are the three greatest risks related to using CTSs in administering MDR-TB injections, if any?
Ngekubuka kwakho, yini tingoti letintsatfu letihambelana nekutsi basekeli bekwelapha ummango bajove ummango lone MDR-TB, uma ikhona?

……
……
……
……

7.2 In your opinion, what are the three greatest benefits related to using CTSs in administering MDR-TB injections, if any?
Ngekubuka kwakho, yini tinzuzo letintsatfu letihambelana nekutsi basekeli bekwelapha ummango bajove ummango lone MDR-TB, uma ikhona?

……
……
……
……

8 INCENTIVES AND COMPENSATION
IMBHADALO NEKUHOLA

8.1 In your opinion, do you think CTSs should be compensated for the tasks they perform in MDR-TB care?
Ngekubuka kwakho, basekeli bekwelapha ummango kumele bayitfole yini imbhadalo noma liholo ngemsebenti labawentako ekunakeni ummango macondzana ne MDR-TB?

Yes ☐ Unsure ☐ No ☐
Yebo ☐ Angati ☐ Cha ☐

Please explain your choice
Sicela uchaze

……
……
……
……

8.2 In your opinion, how should CTSs be compensated for the tasks they perform in MDR-TB care?
Ngekubuka kwakho, basekeli bekwelapha ummango kumele babhadalwe kanjani ngalomsebenti labawentako ekunakeni ummango macondzana ne MDR-TB?

……
……
……
……

9 RETENTION OF CTSs
KUGCINWA KWEBASEKELI BEKWELAPHA BEMMANGO
9.1 What do you think can be done to retain CTSs in MDR-TB care?
Ucabanga kutsi yini lengentiwa kugcina basekeli bekwelapha ummango macondzana ne MDR-TB?

……
……
……
……
……

10 POLICY REGULATION FOR TASK-SHIFTING
KULAWULWA KWEMIGOMO YEKUSHINTJWA KWEMISEBENTI KUSUKELA KULABO LABACECESHIWE

10.1 In your view, should task-shifting of professional nurses' responsibilities to CTSs in MDR-TB care be regulated?
Ngekubuka kwakho, kushintjwa kwemisebenti kusukela kubahlengikati labacecesheiwe kuye kubasekeli bekwelapha ummango ekunakeni iMDR-TB kwamele kube nemigomo yini?

Yes	☐	Unsure	☐	No	☐
Yebo	☐	Angati	☐	Cha	☐

Please explain your response
Sicela uchaze
……
……
……
……

10.2 In your view, who should regulate the practice of CTSs in MDR-TB care?
Ngekubuka kwakho, ngubani lekumele alawule imisebenti yebasekeli bekwelapha ummango ekunakeni i MDR-TB?
……
……

10.3 In your opinion, how can the practice of CTSs in MDR-TB care best be regulated?
Ngekubuka kwakho, nguyiphi indlela lekahle yekwelawula imisebenti yebasekeli bekwelapha ummango labanake i MDR-TB?
……
……
……
……

11 ACCEPTABILITY OF USING CTSs IN MDR-TB INJECTION ADMINISTRATION
KWEMUKELEKA KWEKUSEBENTISA BASEKELI NEKWELAPHA UMMANGO EKUJOVELENI I MDR-TB

11.1 In your own opinion, should the task-shifting of MDR-TB injection administration to CTSs be adopted as one of a range of strategies to increase access to MDR-TB treatment?
Ngekubuka kwakho, kushintjwa kwemsebenti kusuka kulabo labacecesheiwe kuye kubasekeli bekwelapha ummango ekujoveleni i MDR-TB kungaba yindlela yekukhulisa kutfololakala kwekwelapheka kwe MDR-TB?

Yes	☐	Unsure	☐	No	☐
Yebo	☐	Angati	☐	Cha	☐

Please explain your response
Sicela uchaze
……
……
……
……
……

Siyabonga sikhatsi sakho usagcwalisa lelifomu

Thank you for taking time to complete this questionnaire

Appendix 1.2: Community treatment supporter observation checklist

Checklist Item	Yes	No
1 MDR-TB education and awareness		
1.1 CTS MDR-TB training manual available		
1.2 Has patient disclosed MDR-TB status to his/her family?		
1.3 Have household members been screened for MDR-TB?		
2 DOT		
2.1 Did the patient swallow the MDR-TB medicine in the presence of the CTS?		
2.2 From the patient card, how many times has the CTS missed giving injections and oral drugs		
3 Infection control		
3.1 Does the patient sleep alone in a separate room?		
3.2 Does the room have windows?		
3.3 Windows in the patient's room open		
3.4 CTS wearing N95 respirator		
3.5 Patient wearing surgical mask		
3.6 Is there adequate supply of soap and clean water to wash hands		
4 Safe injection handling technique		
4.1 Hands washed before procedure		
4.2 New single needle and single syringe used		
4.3 Checks the vial for content, dose, and expiration date		
4.6 Fills syringe with contents of the vial		
4.7 Expels air from syringe		
4.8 Careful disposal of the drawing up needle from syringe and replace with a fresh one		
4.9 Locates the exact site for injection		
4.10 Disinfects the injection site with alcohol prep pad		
4.11 The patient is told to relax the muscle		
4.12 Inserts the needle swiftly at an angle of 90 degrees		
4.13 Aspirates briefly to ensure the needle is not sited in a blood vessel		
4.14 Injects all contents of the syringe slowly (less painful)		
4.15 Gently presses the injection site with a clean cotton ball		
4.16 Needle and syringe are disposed intact immediately in a puncture resistant sharps container		
4.17 Hands washed after procedure		
4.18 Records information on the patient's card and other data collection forms		

Appendix 1.3: MDR-TB patients' satisfaction with the task-shifting approach and costs incurred during treatment

Dear Sir/Madam

You are kindly invited to voluntarily take part in this research study. The study entails the following:

- Dr Ernest Peresu, a student at the University of Free State, South Africa is conducting research on the evaluation of the task-shifting of multi-drug resistant tuberculosis (MDR-TB) injection administration to community treatment supporters (CTSs) implemented in the Shiselweni region of Eswatini by Médecins Sans Frontières (MSF) from 2008 to date.
- All MDR-TB patients in the Shiselweni region have been selected to participate in this study. Your participation will help a lot in making this evaluation successful.
- If you agree to take part in the study, you will need to sign a consent form attached to this form and then answer interview questions. This will take no more than one hour.
- In the interview you will be asked about your perceptions and acceptability of the task-shifting approach and the costs that you and your family have incurred during MDR-TB treatment.
- The study will be conducted over a period of four weeks at three rural health centres in the Shiselweni region.
- Your participation is entirely voluntary and you have the right to withdraw at any stage in the process without any penalty or prejudice regarding your MDR-TB care.
- The responses you supply will be treated confidentially and will only be used for this study. Your name and identifying affiliations will be anonymised in the analysis and any resulting publications.
- The signed consent forms and completed interview schedule will be safely secured in a locked cabinet in an office only accessible by the principal researcher. Access to data in the study database will be restricted through the use of a password.
- There is no payment for taking part in this study. Participation or not will not affect your continued care and treatment plan.
- We believe there are no known risks associated with this research study.

I,……....(Full name of participant in block letters)

- have read and understood the Participant Information Sheet
- All the questions I had about the research have been satisfactorily answered.
- I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving reason.

Participant signature……Date…….

If you have further questions about the study, you are welcome to contact Dr Ernest Peresu at 76026657 or e-mail address: eperesu@yahoo.com.
If you have any questions about the ethical conduct of this research please contact the Eswatini Ethics Committee at the following telephone number: 24042431.

Imibono nekunetisako kwalabalashelwa MDR-TB ngekulashwa bolomakhaya kanye nelinani letimali labalisebentisako.

Sawubona

Uyacelwa kutsi ungenele lolucwaningo lolucuketse naku lokulandzelako:

- Dokotela Peresu ngumfundzi wasenyuvesi yase Free State eSouth Africa wenta lucwaningo mayelana nekulashwa kwe MDR-TB bolomakhaya (kujova) lokwentiwa efifundzeni sase ShiselwenikaNgwane luphiko lwaMSF kusukela 2008 kute kube ngunyalo.
- Bonkhe labalashelwa ligciwane leMDR- TB esifundzeni seShiselweni bakhetsiwe kutsi bangenele lolucwaningo.
- Kungenela lolucwaningo kutosita kuletsa timphendvulo letitosita ekulashweni kwetigulane teMDR-TB.
- Nawuvuma kungenela lolucwaningo utocelwa kutsi usayine lifomu lesivumelwano bese uphendvula lemibuto. Loku kutotsatsa imizuzu lengeke yengce lihora.
- Kulemibuto utobutwa ngemivo yakho kanye nekumukela kwakho lokulashwa bolomakhaya kunye nelizinga letimali lesetisebetile ekhaya usalashelwa iMDR-TB.
- Lolucwaningo litowentiwa emaviki lasihlanu kulemitfolamphilo lekhetsiwe lemitsatfu esifundzeni sase Shiselweni.
- Kungenela lolucwaningo kuyimvumo yakho, usengashiya ekhatsi noma kunini kute imitselela ngekushiya kute nalotakwehlulela usalashelwa MDR-TB.
- Timphendvulo takho tito bekwa ngalokufihlakele tisetjentiswe kulolucwaningo kuphela. Libito lakho nalokungabonakaliso wena kutawufsuswa nasekuchazwa lemiphumela.
- Emafomu esivumelwano kunye netimphendvulo talemibuto kutobekwa lakufihlakele khona kutohlakukhiywe kuvule umcwaningi yedwa.
- Kute liholo ekungeneleni lolucwaningo. Kuba kulolucwaningo ngeke kuphatamise kulashwa kwakho.
- Siyetsemba kute tingoti talolucwaningo.

Mine…….. Libito leliphelele ngabo feleba

- ngifundzile lesatiso salongenela lolucwaningo
- Imibuto Yonkhe ngelucwaningo iphendvulekile kahle
- Ngiyacondza kutsi kungenela lolucwaningo kungenca yekuvuma kwami futsi ngisengayekela ngaphandle kwesizatfu.

Kusayina umgcugcuteli:…….. Lusuku:……

Nawunemibuto leminye ngalolucwaningo, wemukelekile kutsintsa dokotela Ernest Peresu ku 7602 6657 noma ubhalele ku: eperesu@yahoo.com.
Nawunemibuto ngekutiphatsa kulolucwaningo tsintsana nelihhovisi le Eswatini Ethic Committee kunayi nombolo: 2404 2431.

MDR-TB Patient Satisfaction Survey Questionnaire

FOR OFFICIAL PURPOSES ONLY
Data Collector: _____

Date Collected: _____

Health Facility: _____

Maka (✓) *libhokisi lelicondzene nemphendvulo lekunetisako kulemibuto. Khetsa yinye imphendvulo ngaphandle nakushiwo kutsi tingaba tinengi. Yonkhe imibuto igcwaliswa ngekungativeti. Singajabula nawungayiphendvula yonkhe lemibuto ngekwetsembeka.*
Please place a tick (✓) in the box that best answers the question. Kindly make only one selection unless otherwise instructed. All questionnaires are completed anonymously. We would appreciate it if you answer all the questions and answer as honestly as possible.

1. GENERAL AND DEMOGRAPHIC QUESTIONS

1.1 *Khombisa bulili balogulako*
Please note the patient's gender

Mdvuna	Male	
Umsikati	Female	

1.2 *Iminyaka yakho mingakhi?*
What is your age?

Ngaphansi kwemashumi lamatsatfu	Under 30 years	
Ngaphansi kwemashumi lamane	31 - 40 years	
Ngaphansi kwemashumi lasihlanu	41 - 50 years	
Ngetulu kwemashumi lasihlanu	Over 50 years	

1.3 *Ushadile yini?*
What is your marital status?

Angikashadi	Single, never married	
Ngishadile	Married	
Washona lengitsandzana nako	Widowed	
Ngehlukana nalebengishade naye	Divorced	
Angihlali nalengishade naye	Separated	

1.4 *Wagcina kuphi esikolweni?*
What is the highest grade or level of school that you have completed?

Angifundzanga	No school	
Ngagcina ebangeni lemfica	Primary school	
Ngafika ebangeni lekugcina	High school	
Ngafika ekolishi/enyuvesi	College/university	
Ngafundzela kasebenta	Literacy classes only	

1.5 *Inesikhatsi lesingakanani ujovela iMDR-TB?*
How long have you been on MDR-TB treatment?

	1-4 tinyanga		1-4 months
	>4 tinyanga		>4 months

1.6 *Uwutfola kumgcugcuteli umjovo weMDR TB?*
Are you receiving MDR-TB injections from a CTS?

Yebo	Yes	
Cha	No	

1.7 *Sewujove sikhatsi lesingakanani umjovo we MDR-TB kumgcugcuteli?*
How long have you been receiving MDR-TB injections from a CTS?

	1-4 tinyanga		1-4 months
	>4 tinyanga		>4 months

1.8 *Uhlala khashane kangakanani nemtfolamphilo noma sibhedlela?*
How far do you live from the nearest health clinic or hospital?

Libanga lelingaphansi kwa 5km	Less than 5km	
Libanga lelingaba ngu 5 kuya ku 10km	5-10km	
Libanga lelingaba ngu 10-20km	10-20km	
Libanga lelingetulu kwa 20km	More than 20km	

1.9 *Luphi luhlobo lokuhamba lolisebentisako nawuya emtfolamphilo? (khetsa kulokusebentisa)*
What types of transportation do you use for making clinic trips? (check all that apply)

Uyashayela	Drive yourself	
Ugibela ibhansi	Take public bus	
Uhamba nemngani noma sihlobo	Get a ride from family member or friend	
Icasha itekisi	Take taxi	
Ngelibhayisikili	Bicycle	
Uhamba ngentinyawi	Walk	

1.10 *Uyasebenta yini nyalo?*
Are you currently employed?

Cha angisebenti	No, unemployed	
Yebo, sonkhe sikhatsi	Yes, full time	
Yebo, hhayi sonkhe sikhatsi	Yes, part time	
Yebo, ngiyatisebenta	Yes, self-employed	
Loukunye……	Other (specify)……	

1.11 *Usebenta ini nyalo?*
What is your current occupation?

Chaza	……..	Specify	……..

1.12 *Ngalokulinganisiwe ufika malini kuwe ngenyanga?*
On average how much money do you earn per month after deductions?

Chaza	……..	Specify	……..

1.13 *Unawo imtfombo wemali longena njalo njalo?*
Do you have a regular source of income?

Yebo	Yes	
Cha	No	

1.14 *Imali lobanayo uyitfola kuphi?*
What is the main source of your personal income?

Lebuya kahulumendi	Grant	
Liholo	Salary (monthly payment for formal employment	

Ngihola ngemahora lengiwasebentile	Wages (paid hourly or daily for formal employment	
Sincephetelo	Stipend	
Lophiwa yona	Remittance	
Ngiyatisebenta	Self-employment	
Angisebenti	Unemployment	
Lokunye……	Other (specify)……	

1.15 *Ungabekisa kutsi ngenyanga kakho kungena malini sewuhlanganise yonkhe imali loyitfolako (ubale konkhe nemitselo, netikweleti kunye neyalohlala naye/lotsatsandzana naye)?*
Could you please provide an estimate of your annual household income from all sources (before tax and other deductions and including your partner/spouse)?

Chaza	E……	Specify	E……

1.16 MDR-TB-related treatment costs

No.	*Umusho*	Statement	Amount (South African rands)
1.16.1	*Tindleko tekuvela emtfolamphilo*	Cost of consultation per visit	
1.16.2	*Inombolo yekuvela emtfolapmhilo noma esibhedlela enyangeni leyengcile*	No. of consultations with the clinic/health centre in last month	
1.16.3	*Tindleko tekutfola lusito lwetemphilo enyangeni leyengcile*	Total cost of consultation fees in last month	
1.16.4	*Sikhatsi lesiphelele lesitsatfwa kuya nekubuya emtfolamphilo noma esibhedlela*	Total time taken (to and from) per visit to clinic/health centre	
1.16.5	*Tindleko tekwekuhamba kuya emtfolamphilo noma esibhedlela*	Cost of transport per visit to the clinic/health centre	
1.16.6	*Tindleko tekwekuhamba enyangeni leyengcile*	Total cost of transport in last month	
1.16.7	*Tindleko tekuhlola kubapopoli enyangeni leyengcile*	Total cost of laboratory tests in past month	
1.16.8	*Tindleko tekuhlola ku X-ray enyangeni leyengcile*	Total cost of X-rays in past month	
1.16.9	*Tindleko letiphelele tekutsenga imitsi nemaphilisi enyangeni leyengcile*	Total cost of drugs purchased in past month	
1.16.10	*Inombolo yemalanga ekungayi esibhedlela enyangeni leyengcile ngenca yekuya emtfolamphilo noma kulaliswa esibhedlela*	Total no. of days lost from work in last month (consultations and hospitalisation)	
1.16.11	*Imali yemholo lephelele leyilahleke ngelilanga*	Total amount of wages lost per day	
1.16.12	*Letinye tindleko letihambelana nekwelapha i MDR-TB enyangeni leyengcile. Cacisa……..*	Other costs associated with MDR-TB treatment in past month Specify……	
	Tindleko talonaka logulako	Caregiver costs	
1.16.13	*Umholo wenyanga*	Monthly income	
1.16.14	*Tindleko tekwekuhamba uma yehluke naleyo yalogulako*	Transport cost if different from patient	
1.16.15	*Inombolo yemalanga ekungaveli emsebentini kwenteela kupheketela logulako*	No. of days lost from work to accompany patient	

1.16.16	*Imali yemholo lephelele leyilahleke ngelilanga*	Amount of wages lost per day	

2. Khetsa kutsi uyavumelana nalemici lelandzelako. Ngivumelana nayo kakhulu (NK); ngivumelana nayo (N); anginasiciniseko (A); angivumelani nayo (AN); angivumalani nayo impela (AI). Lokumayelana nemgcugcuteli wakho
Please indicate how much you agree or disagree with each of the following statements. Strongly agree (SA); agree (A); unsure (U); disagree (D); or strongly disagree (SD).
Concerning your community treatment supporter (CTS), he or she

No.	***Umusho***	**Statement**	SA/ NK	A/ N	U/ A	D/ AN	SD/ AI
2.1	*Uhlala sikhatsi lesanele nami*	Spends enough time with you					
2.2	*Tikhatsi tekungisita tikahle*	Has convenient hours for visiting you					
2.3	*Nasebusuku uyatfolakala nangidzinga lusito*	Is always available to help you when you need help at night					
2.4	*Lusito langinika lona lungululuhlobile kuwe*	Renders health services that are clear to you					
2.5	*Ngiyajabula indlela umgcugcuteli langisita ngayo*	Helps you in a way that pleases you					
2.6	*Uyakulalele ngalokucinisekile nakatokuvakashela*	Listens attentively to you during his/her visits					
2.7	*Ukhombisa kutsatseka ngaloku lokushooko*	Shows interest in what you have to say					
2.8	*Kumelula nekuphefumula ngetinkinga tami*	Makes it easy for you to tell him or her about your problems					
2.9	*Uyayibona imizwa yakho ikakhula nawukhatsatekile*	Notices your feelings, especially worried feelings you might have during their visit					
2.10	*Uneluvelo ngalenkinga lonayo kutemphilo*	Is interested in your health problem					
2.11	*Uyanaka tindzaba leticondzene nami*	Is interested in your personal situation					
2.12	*Uyemukela lotama kutentela kona usatilaphisa*	Appreciates what you do to take care of yourself					
2.13	*Uyangihloni nakanginaka*	Treats you with respect					
2.14	*Uyangisita nangetinkinga mayelana nekuphila kwami*	Helps in dealing with emotional problems related to your health status					
2.15	*Ukunika lwati lolwanele mayelana neMDR-TB*	Provides you with adequate information about MDR-TB					
2.16	*Ukunika lwati ngeMDR lotokhona kulicondza*	Gives you MDR-TB care information that you can understand					
2.17	*Ukuchazela kahle longakucondzi usalashelwa iMDR-TB*	Adequately explains what you don't understand regarding your MDR-TB care					
2.18	*Uyabuta kutsi unayo imibuto mayelana nekwelashwa kwakho*	Asks if you have any questions about your recommended treatment					
2.19	*Uyangatisa ngetifo letihlasela ummango wakitsi*	Talks to you about other health-related issues that affect your community such as HIV					

2.20	*Uyakukhutsata kutsi ulandzele luhlelo lwakho lwekutilaphisa*	Encourages you to follow-through with your treatment plan					
2.21	*Kunakekelwa ngumgcugcuteli ngabe kulusito yini ekwehleseni kwecwaywa kwebantfu labalashelwa iMDR –TB?*	Receiving care from a CTS in your community helps in reducing the stigma surrounding MDR-TB					
2.22	*Tiphepha tami tiyimfihlo kuyo*	Keeps your clinical information confidential					
2.23	*Ubona kutsi kutikhetsdsela umgcugcuteli kungasita kangakanani ekulashweni kweMDR-TB?*	The ability to choose your own CTS to provide MDR-TB care improves your satisfaction					
2.24	*Kutehlisa kangakanani tindleko kulashwa ngumgcugcuteli nawu lashelwa ligciwane leMDR-TB?*	Receiving injections from your CTS saves costs related to your MDR-TB treatment					

3.1 *Nawulashelwa I MDR- TB, kuncono kujovwa ngumuphi kulabalandzelako. Khetsa yinye imphehdvulo kuletilandzelako*
Concerning your MDR-TB injections, what would you prefer? Please choose one response.

Kujovwa ngumgcugcuteli lodvute	To get injected by a CTS from your locality	
Kujovwa ngunesi emtfolamphilo lodvutane	To get injected by a nurse at a clinic	
Kuyafanana	Indifferent	
Angati	Unsure	

3.2 *Kungenteka kutsi ucwayise umngani wakho noma sihlobo sakho kutsi sijove kumgcugcuteli nasilashelwa iMDR-TB?*
How likely or unlikely is it that you would recommend your friends/family to get their MDR-TB injections from a CTS?

Kungentaka	Likely	
Ngeke kwenteka	Unlikely	
Angati	Unsure	

3.3 *Lukwenetisa kangakanani lusito lwebagcugcuteli usalashelwa iMDR-TB?*
To what extent are you satisfied or dissatisfied with the MDR-TB care service you receive from your CTS? Would you say you are very satisfied, satisfied, unsure, dissatisfied or very dissatisfied?

Kakhulu ngalokwecile	Very satisfied	
Ngalokwecile	Satisfied	
Anginasiciniseko	Unsure	
Alungenetisi	Dissatisfied	
Alungenetisi kakhulu	Very dissatisfied	

4. *Yini lokungentiwa kwenta ncono lolusito lwebagcugcuteli?*
What can be done to improve the services rendered by the CTSs?
……
……
……
……

Siyabonga sikhatsi sakho usagcwalisa lelifomu
Thank you for taking time to complete this form

Appendix 1.4: Stakeholder perceptions on task-shifting directly observed treatment and multidrug-resistant tuberculosis injection administration to community treatment supporters

Dear Sir/Madam

You are kindly invited to voluntarily take part in this research study. The study entails the following:

- Dr Ernest Peresu, a student at the University of Free State, South Africa is conducting research on the evaluation of the task-shifting of multi-drug resistant tuberculosis (MDR-TB) injection administration to community treatment supporters (CTSs) implemented in the Shiselweni region of Eswatini by Médecins Sans Frontières (MSF) from 2008 to date.
- Your name has been purposively selected from a list of policymakers, NTCP managers, implementing partners, professional healthcare workers and CTSs. Your participation will help a lot in making this evaluation successful.
- If you agree to take part in the study, you will need to sign a consent form attached to this form and then complete a questionnaire about your perceptions and acceptability of the task-shifting approach. This will take no more than one hour.
- Your participation is entirely voluntary and you have the right to withdraw at any stage in the process without any penalty or prejudice regarding your MDR-TB care.
- The responses you supply will be treated confidentially and will only be used for this study. Your name and identifying affiliations will be anonymised in the analysis and any resulting publications.
- The signed consent forms and completed interview schedule will be safely secured in a locked cabinet in an office only accessible by the principal researcher. Access to data in the study database will be restricted through the use of a password.
- There is no payment for taking part in this study. Participation or not will not affect your continued care and treatment plan.
- We believe there are no known risks associated with this research study.

I,……(Full name of participant in block letters)

- have read and understood the Participant Information Sheet
- All the questions I had about the research have been satisfactorily answered.
- I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving reason.

Participant signature……Date…….

If you have further questions about the study, you are welcome to contact Dr Ernest Peresu at 76026657 or e-mail address: eperesu@yahoo.com.

If you have any questions about the ethical conduct of this research please contact the Eswatini Ethics Committee at the following telephone number: 24042431.

Stakeholder perceptions on task-shifting directly observed treatment and multidrug-resistant tuberculosis injection administration to community treatment supporters

Focus group discussion guide

(Expected time duration – 1 hour)
Welcome, verbal consent process and introduction
Focus group logistics, participant unique identifiers and ground rules

Focus group questions and probes

1. Is MDR-TB a major public health threat in Swaziland? Please explain your answer.

2. Do you think community members should play a role in MDR-TB care? Please explain your answer. Are you aware of any task-shifting of responsibilities from professional nurses to community health workers in relation to medical conditions other than MDR-TB in Swaziland? If yes, please give examples.

3. What type of CTS between generalist and specialist do you think is preferable? Please explain your answer.

4. What are the greatest risks related to using CTSs in administering MDR-TB injections? Probes may include the following risks:
   - Reduced quality of care
   - Drug resistance
   - High workload for CTSs
   - Insufficient clarity about tasks
   - Disintegrated health services
   - Lack of oversight
   - Lack of training
   - Increased loss-to-follow-up
   - Conflict with community MDR-TB nurses

5. What are the greatest benefits related to using CTSs in administering MDR-TB injections? Probes may include the following risks:
   - Increased MDR-TB treatment access
   - Improved quality of MDR-TB care
   - Reduced MDR-TB stigma
   - Reduced workload for community MDR-TB nurses
   - Improved patient follow-up
   - Increased skilled healthcare workers
   - Improved adherence to MDR-TB treatment

6. Do you think CTSs should be compensated for the tasks they perform in MDR-TB care? How should CTSs be compensated for the tasks they perform in MDR-TB care?

7. What do you think can be done to retain CTSs in MDR-TB care?

8. Should task-shifting of professional nurses' responsibilities to CTSs in MDR-TB care be regulated? Who should regulate the practice of CTSs in MDR-TB care? How can the practice of CTSs in MDR-TB care best be regulated?

9. Should the task-shifting of MDR-TB injection administration to CTSs be adopted as one of a range of strategies to increase access to MDR-TB treatment?

Thank you so much for your time and support.

Appendix 1.5: MDR-TB electronic medical records abstraction tool

MDR-TB registration number		
Medical information		
Diagnosis Date		
Treatment outcome		
Treatment outcome date		
HIV co-morbidity	**Yes/No**	
Health system resources utilised		
Element	**Quantity**	
	Intensive Phase	**Continuation Phase**
Doctor's consultation		
Psychologist consultation		
Counsellor		
Admission (days)		
Injection Admin Clinic/CTS		
Routine laboratory investigations		
Smear		
GeneXpert		
Culture + DST		
Culture		
CXR		
ECG		
Audiometry		
Electrolytes		
HbsAg		
HTC		
CD4 Count		
Viral load		
Pregnancy test		
SGOT/SGPT		
Chemistry		
Creatinine		
Urea		
K+		
FBC		
LFT		
Uric acid		
Total Bilirubin		
TSH		
CSF		
Biopsy		
CXR		

Other		
MDR-TB drugs prescribed		
Pyrazinamide		
Kanamycin 1 g vial		
Capreomycin 1 g		
Levofloxacin 250 mg		
Moxifloxacin		
Ethionamide 250 mg		
Prothionamide		
Cycloserine 250 mg		
Teridizone		
Ethambutol 400 mg		
PAS		
Clofazimine		
Amoxy-Clav		
Bedaquiline		
Linezolide		
High dose INH		
Pyridoxine		
CTX/Dapsone		
TDF/3TC/EFV		
TDF/3TC/NVP		
AZT/3TC		
EFV		
3TC		
LPV/r		
Other ARVs		
Other drugs prescribed		
Folate		
FeSO4		
ART		
Ondansetron		
Metoclopromide		
Plumby nut		
Slow K		
Mg Gluconate		
Levothyroxine		
Diclofenac gel		
Diclofenac		
Fluconazole		
VTs		
Paracetamol		
Brufen		
AMT		

Appendix 2: Ethics approval letters
Appendix 2.1: University of Free State Health Sciences Research Ethics Committee approval letter

UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

IRB nr 00006240
REC Reference nr 230408-011
IORG0005187
FWA00012784

30 November 2016

DR E PERESU
CENTRE FOR HEALTH SYSTEMS RESEARCH AND DEVELOPMENT
FACULTY OF HUMANITIES
UFS

Dear Dr E Peresu

HSREC 183/2016 (UFS-HSD2016/1489)
PROJECT TITLE: COMMUNITY BASED MDR-TB MANAGEMENT: TASK-SHIFTING TO COMMUNITY TREATMENT SUPPORTERS IN SWAZILAND

1. You are hereby kindly informed that, at the meeting held on 29 November 2016, the Health Sciences Research Ethics Committee (HSREC) approved the above project.
2. The Committee must be informed of any serious adverse event and/or termination of the study.
3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.
4. A progress report should be submitted within one year of approval and annually for long term studies.
5. A final report should be submitted at the completion of the study.
6. Kindly use the **HSREC NR** as reference in correspondence to the HSREC Secretariat.
7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services-(HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

Yours faithfully

.....
DR SM LE GRANGE
CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

Cc Prof JC Heunis

Health Sciences Research Ethics Committee
Office of the Dean: Health Sciences
T: +27 (0)51 401 7795/7794 | F: +27 (0)51 444 4359 | E: ethicsfhs@ufs.ac.za
Block D, Dean's Division, Room D104 | P.O. Box/Posbus 339 (Internal Post Box G40) | Bloemfontein 9300 | South Africa
www.ufs.ac.za

Appendix 2.2: Scientific and Ethics Committee of Eswatini approval letter

Research Protocol clearance certificate

Type of review	Expedited	X		Full Board			
Name of Organization	Dr PERESU (NTCP)						
Title of study	COMMUNITY BASED MDR-TB MANAGEMENTBIN THE SHISELWENI REGION OF SWAZILAND: ASSESSMENT OF TASK- SHIFTING TO COMMUNITY TREATMENT SUPPORTERS.						
Protocol version	Version 1						
Nature of protocol	New	X		Amendment			
List of study sites	NHLANGANO HEALTH CENTRE, HLATHIKHULU HEALTH CENTRE, MATSANJENI HEALTH CENTRE						
Name of Principal Investigator	DR ERNEST PERESU						
Names of Co- Investigators	N/A						
Names of steering committee members in the case of clinical trials	N/A						
Names of Data and Safety Committee members in the case of clinical trials	N/A						
Level of risk (Tick appropriate box)	Minimal			High			
	X						
Clearance status (Tick appropriate box)	Approved	X		Disapproved			
Clearance validity period	Start date	20/10/2016		End date	20/10/2017		
Signature of Chairperson							
Date of signing	20/10/2016						
Secretariat Contact Details	Name of contact officers	Ms Simangele Maseko					
	Email address	kaluamasi@gmail.com					
	Telephone no.	(00268) 24040865/24044905					

MINISTRY OF HEALTH
20 OCT 2016
HEALTH RESEARCH REVIEW BOARD
SWAZILAND

Approval Conditions

Ref.	Conditions	Indication of conditions (tick appropriate box)				
1	Implementation of approved version of protocol	✓				
2	Reporting of adverse events within 5 days of occurrence	✓				
3	Submission of progress reporting for multi-year studies	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5
		N/A	N/A	N/A	N/A	N/A
4	Submission of end of project report (Hard copy)	✓				
5	Submission of end of project report (Soft copy)	✓				
6	Submission of data sets	✓				

List of reviewed documents

Ref.	Documents	Reviewed documents (tick appropriate box)
1	Completed application form	✓
2	Cover letter	✓
3	Evidence of administrative permission to conduct the research by involved institutions/sites (where applicable)	✓
4	Detailed current resume or curriculum vitae of Principal Investigator/s including Principal investigators declaration	✓
5	Summary resume or biography for other investigator(s)	✓
6	Evidence of approval/rejection by other Ethics Committees, including comments and requested alterations to the protocol, where appropriate.	
7	Research protocol (see outline in Annex 1)	✓
8	Questionnaires and interview guides (with back-translated versions where applicable)	✓
9	Case report forms (CRFs), abstraction forms and other data collection tools	✓
10	Participant/subjects Information Statement(s) (where applicable)	✓
11	Informed consent form(s) including photographic and electronic media consent statements.	
12	Advertisements relevant to the study (where applicable)	
13	Source of funding and detailed budget breakdown including material and incentives to participants if applicable	
14	Notification form for adverse effects/events.	
15	Proof of payment	✓
16	Proof of insurance cover for research subjects in clinical trials or where applicable	
17	Any other special requirements should be stated, if applicable	None

Appendix 3: Authorisation letters
Appendix 3.1: National TB Control Programme authorisation letter

Tel: (+268 404 2431)
Fax: (+268 404 2092

MINISTRY OF HEALTH
P.O. BOX 5
MBABANE
SWAZILAND

THE KINGDOM OF SWAZILAND

31 MARCH 2016

Dr Rudolph Maziya
The Chairman
Scientific and Ethics Committee
Ministry of Health
Mbabane, Swaziland

Dear Sir

Letter of support: **COMMUNITY BASED MDR-TB MANAGEMENT IN THE SHISELWENI REGION OF SWAZILAND: REVIEW OF TASK-SHIFTING TO COMMUNITY TREATMENT SUPPORTERS**

This letter serves to confirm that the National TB Control Program (NTCP) is in support of the study to be conducted in collaboration with Dr Ernest Peresu who developed the study protocol together with the NTCP Programmatic Management of Drug-Resistant TB (PMDT) team.

The NTCP support of the proposed research is aligned to the TB National Strategic Plan (2015 – 2019) and the Swaziland National Health Research Agenda as it falls within the following priority: Effectiveness of existing interventions (Community models of TB care). As per the Ministry of Health Research Unit requirements for conducting research in Swaziland, the study team is reminded of the following conditions:

1. The NTCP must be provided with the final approved protocol and SEC approval letter and should be always informed of any protocol amendments
2. The Ministry of Health remain the custodians of the data and upon study completion, datasets and reports must be furnished to the Research Unit

The NTCP is in full support of the study as it has the potential to contribute significantly towards the global body of evidence for improving access to care for TB and DR-TB patients.

We trust this application will receive the Ethics Committee kind consideration.

Yours sincerely,

MINISTRY OF HEALTH
P.O. BOX 54
MANZINI M200
01 APR 2016
TB PROGRAM MANAGER
SWAZILAND

Dr Wellie Sikhondze

NTCP Technical Adviser and Research Coordinator

Appendix 3.2: Médecins Sans Frontières authorisation letter

MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

Office Mbabane
Lot No. 331,Sheffield Road
CJ Investments Building
Industrial Area, Mbabane
Address
Medecins Sans Frontieres
(Switzerlund)
P.O. Box 18, Eveni, H130
Tel: (+268) 2404 8307 / 2404 3405
Fax: (+268) 2404 7884

Mbabane, 27.07.2016

To Dr Debrah Vambe
National PMDT Technical Advisor
NTCP
Manzini, Swaziland

RE: Request by the NTCP to conduct research in the Shiselweni region

In accordance with the NTCP request to conduct research on the evaluation of task shifting of DRTB injections in the Shiselweni region by Dr Debrah Vambe and Dr Ernest Peresu, we inform you that MSF is supporting this initiative. MSF is willing to provide access to CTS provided that the participation of the CTS in the research follows international practice of confidentiality and voluntary participation. For other research related activities in MOH premises (e.g. access to DRTB patients, health records), we trust that the NTCP will grant access for the researchers.

We highlight the following matters before the start of the study:

- This research was not commissioned by MSF which should be stated in the information and consent forms which will be provided to study participants, and in any reports and publications originating from this research.
- Findings of this research, as well as opinions mentioned about community-based DRTB treatment do not necessarily reflect the opinions of MSF and therefore is not endorsed by MSF. This should be mentioned in any reports and publications originating from this research.
- MSF requests the researchers to provide access to the findings of this study. Notably, a copy of any reports, abstracts and publications.
- MSF will assess from case to case if access to sensitive and confidential financial information related to MSF activities can be shared.
- The researcher is not authorised to use, in advertising, publicity, promotional, research or sales literature, or otherwise, any of MSF`s name, or logo without the prior written consent of MSF.
- MSF will not provide HR, logistic or financial support for this study.

MEDECINS SANS FRONTIERS Swaziland

Medecins Sans Frontiers is a non-profit medical humanitarian organisation

We wish the NTCP and the researchers to succeed in this important study and hope that the study will achieve its objectives and support community-based DRTB care in Swaziland.

For further information and clarification, the researcher should contact the MSF research focal person (Bernhard Kerschberger; Email: msfch-nhlangano-research@geneva.msf.org Cell: (+268) 7815 1718)

Yours faithfully,

MEDECINS SANS FRONTIERES
Swaziland

Dr Serge Mathurin KABORE, MD, Msc/MPH
Head of Mission - MSF SWAZILAND