Identifying Contextual Determinants of Problems in Tuberculosis Care Provision in South Africa: A Theory-Generating Case Study

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Research Article

Keywords: Tuberculosis, health systems strengthening, primary healthcare, person-centred care, context

Posted Date: January 25th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-152411/v1

Abstract

Background

Despite progress towards meeting End TB strategy targets for reducing tuberculosis (TB) incidence and deaths by 2035, South Africa remains among the top ten high-burden tuberculosis countries globally. A large challenge lies in how policies to improve detection, diagnosis and treatment completion interact with social and structural drivers of TB. Detailed understanding and theoretical development of the contextual determinants of problems in TB care is required for developing effective interventions. This article reports findings from the pre-implementation phase of a study of TB care in South Africa, contributing to ASSET - a broader five-year research programme developing and evaluating health system strengthening interventions in sub-Saharan Africa. The study aimed to develop hypothetical propositions regarding the contextual determinants of problems in TB care to inform intervention development to reduce TB deaths and incidence whilst ensuring the delivery of quality integrated, respectful person-centred care.

Methods

Theory-building case study design using the Context and Implementation of Complex Interventions (CICI) framework to identify contextual determinants of problems in TB care. Between February and November 2019, we used mixed methods in six public-sector primary healthcare facilities and one public sector hospital serving impoverished urban and rural communities in the Amajuba district of KwaZulu-Natal province, South Africa. Qualitative data included stakeholder interviews, observations and documentary analysis. Quantitative data included routine data on sputum testing and TB deaths. Data were inductively analysed and mapped onto the seven CICI contextual domains.

Results

Delayed diagnosis was caused by interactions between fragmented healthcare provision; limited resources; verticalised care provision; poor TB screening, sputum collection and record-keeping. One nurse responsible for TB care, limited integration with other conditions, and policy focus on treatment adherence contributed to staff stress and limited focus on patients' psychosocial needs. Patients were lost to follow up due to discontinuity of information, poverty, employment restrictions and limited support for treatment side-effects. Infection control measures appeared to be compromised by efforts to integrate care.

Conclusion

Interventions are required that strengthen early detection, diagnosis, treatment initiation and completion. TB policy needs to promote person-centred support for healthcare professionals and patients through the TB treatment pathway.

Background

Despite substantial progress and renewed political commitment to its eradication, 1.4 million deaths during 2019 makes tuberculosis (TB) the highest source of global infectious disease mortality before the COVID-19 pandemic (1). The End TB Strategy established a key set of targets during the 2014 World Health Assembly, committing countries to achieve a 95% reduction in TB deaths and a 90% reduction in TB incidence (compared with 2015 levels) by 2035 (2). South Africa, long a high burden country, has made important strides in this direction; its TB incidence rate decreased from 981 per 100 000 population in 2010 to 567 per 100 000 population in 2017, alongside increased efforts to scale-up antiretroviral treatment (ART) (3). The proportion of patients lost to follow-up declined from 19% in 1997 to 7% in 2017, and the rate of new TB patients who successfully completed treatment rose from 61% in 2001 to 85% in 2017 (3). Nonetheless, the country's TB epidemic continues to impose a substantial burden on its health system and people – South Africa's 2019 TB incidence rate of 615 per 100 000 population is exceptionally high compared against the global average of 130 per 100 000 (1). The 58% prevalence of HIV among TB incident cases is much higher than the global average of 8%, and the 71% treatment success for new and relapse TB cases in 2018 was substantially lower than the global average of 85%, partly due to the high case fatality rate (1). In addition to being among the top ten high-burden TB countries, South Africa has been designated one of the 20 countries where there is an overlap in high burdens of TB, multi-drug resistant tuberculosis (MDR-TB) and TB-HIV coinfection (1). In 2016 TB was the leading cause

of death in people living with HIV and the single leading cause of death overall, contributing 7% of all deaths (4). In 2018, the annual incidence of MDR-TB was 19 per 100 000, with an estimated 3.4% (2.5–4.3) of all new cases, and 7.1% (4.8–9.5) previously treated cases (1). These figures are especially troubling given that approximately 160 000 people with known active TB are lost to follow-up (5). MDR-TB poses a disproportionate burden on the South African TB budget (11% of total) because of the cost of medications used to treat MDR, including bedaqualine which South Africa has chosen to rollout widely (1).

There are many reasons for the country's protracted battle with TB. Its public health sector underperforms in the implementation of national TB management guidelines, compared to targets. In 2018/9, provincial TB screening rates (patients asked about TB symptoms) for patients aged 5 years and above ranged from 47–98%, with only two of the nine provinces reaching the 90% target. TB sputum testing for symptomatic patients over 5 years ranged from 36–99%, with just over half of all districts meeting the 90% target (5). Although there are valid concerns regarding these figures (5), research confirms substantial losses during all steps of the TB cascade (screening, testing, diagnosis, linkage to care, retention to care) indicating multiple health system failures (6). These include poorly organised and understaffed primary healthcare facilities, poor communication of test results, negative staff attitudes towards TB (7), poor integration of HIV and TB services, medication stock-outs, and inadequate information technology, infrastructure, data capture and monitoring systems (8). Low levels of TB knowledge among service users (9), lack of patient empowerment (10), high levels of psychosocial distress (9), dual stigma with HIV (7), food shortages and the high socioeconomic costs associated with TB treatment due to attending clinic appointments and missing work (11, 12), further impacts on care-seeking and adherence. South Africa's large socioeconomic inequities are well-known, and together with HIV, have led to TB flourishing among vulnerable populations who live in poverty, in high-density areas.

The COVID-19 pandemic has only added to the country's TB woes. As with many essential services across the continent, the focus on COVID-19 was accompanied by a rerouting of resources from TB programmes to address COVID-19, dramatic reductions in TB case detection and treatment completion, leading some to warn that we risked greater losses from TB than from COVID-19 itself (1, 13). Further, COVID-19 shares many symptoms with TB, increasing complexity of diagnosis, has competed for scarce mask and GeneXpert resources, and is associated with a more than two-fold risk of death especially during active disease (14).

Despite extensive documentation of TB programme failures, there has been little theoretical development of how contextual features of healthcare systems interact to produce poor service delivery and poor outcomes for patients. We conducted a case study to explore these relationships and generate theoretical propositions to inform development of a health system strengthening intervention to improve TB care delivery. It forms part of a broader five-year research programme (ASSET) with pre-implementation, intervention development, and pilot and evaluation phases, closely aligned with the Sustainable Development Goal of Universal Health Coverage, conducted across four countries - Ethiopia, Sierra Leone, South Africa, and Zimbabwe (15). ASSET has an overall aim of developing and evaluating effective and sustainable health system strengthening interventions that support the translation of evidence-based practices that promote equitable person-centred care into routine health services. Our recent scoping review found little evidence of person-centred care interventions being deployed for people with tuberculosis, (16) which require an attempt to incorporate shared decision-making and understanding of the individual's psychosocial dimensions over time, alongside biomedical symptomology. This article reports findings from the pre-implementation phase of one of the ASSET work packages as a starting point to address these gaps, providing the theoretical basis for developing health systems strengthening interventions to strengthen person-centred TB care so as to improve key TB outcomes in South Africa.

Methods

The study aimed to develop hypothetical propositions regarding the contextual determinants of problems in TB care in South Africa. To do so we devised a theory-building case study design (17) using mixed methods, comprising stakeholder interviews, observations of TB care, documentary review of national TB guidelines and policies and routinely available data. To ensure coherence and wider theoretical generalisablity of findings across pre-implementation, intervention development and evaluation phases, we adopted the Context and Implementation of Complex Interventions (CICI) framework. (18) CICI is a determinant and evaluation framework comprising three dimensions – context, implementation and setting - which interact with one another and with the intervention. For the pre-implementation phase we focused on CICI's seven contextual domains as a means for

developing hypothetical propositions on the contextual determinants of problems in the delivery of TB care, including: geographical, epidemiological, socio-cultural, socio-economic, ethical, legal and the political domain.

Study Setting

The setting was six public- sector primary healthcare (PHC) facilities or clinics and one public sector hospital serving impoverished urban and rural communities in the Amajuba District of KwaZulu-Natal province, South Africa (see Table 1). In 2017, 7.4% of all deaths in KwaZulu-Natal were due to TB (19), with a high case fatality rate of 11% (20), and in Amajuba TB represented the highest cause of death (19). Three PHC facilities and the hospital outpatient department were initially selected for inclusion and data collection conducted in February 2019. We completed additional data collection in November 2019 in two of these PHC facilities, as well as an additional three facilities, at the request of the health department to assess screening processes and practices in greater detail.

TB care provision in Amajuba is governed by National TB guidelines and protocols (25). In brief, patients with symptoms are required to present to primary care for evaluation which should include testing for TB in those with a cough of more than two week's duration, and of any duration if known to be HIV positive. Such passive case detection is augmented by routinely asking all attendees about four cardinal symptoms of TB (cough, weight loss, fever, night sweats). Screening at clinic level is supposed to take place in 'vital signs' rooms where patients' folders are reviewed, and basic measurements like blood pressure performed, usually by Enrolled Nurses (ENs) or Enrolled Nursing Assistants (ENAs). Professional Nurses (PNs) review screening results in consulting rooms. Screening questions are also deployed by community care workers, in KwaZulu-Natal known as Community Caregivers (CCGs), during household visits as part of ward-based outreach teams. Patients who screen positive are required to produce a sputum sample of around 5mL of sputum, which is sent to a hospital-based laboratory for GeneXpert testing which shows whether or not TB is present and indicates rifampicin resistance. Production of a good quality sample is notoriously difficult; vigorous coughing is needed to produce sufficient sputum rather than saliva. Early morning samples have been preferred, leading to many patients being asked to take bottles home for collection. Provision for diagnosis using a chest-x-ray, cultures and LPA (Line Probe Assays) by a doctor is made for patients unable to produce sputum or for smear-negative patients with persistent symptoms.

Treatment must be provided by the public sector and is the standard DOTS (Directly observed treatment short course) six months' short course, with a two-month intensive phase comprising four medications (rifampicin, isoniazid, pyrazinamide, ethambutol) provided as a fixed dose combination (RHZE), and four months continuation phase using rifampicin and isoniazid. Sputa are collected at pre-defined intervals to determine whether the intensive phase needs to be extended to three months and to classify treatment outcome. Transfer of patients from the verticalised TB service to the Integrated Chronic Condition service is encouraged after two weeks, once the patient is deemed non-infectious (24).

Treatment of MDR-TB changed dramatically in 2018 from prolonged (two years) therapy comprising at least one year of daily streptomycin to shorter injection-free treatment with bedaquiline (26). Although not officially a requirement, MDR patients are often admitted for initiation of treatment. Those with drug-sensitive TB may be admitted if clinically warranted.

Study population, sampling and recruitment

Primary healthcare facility staff

We recruited facility managers to inform our understanding of the organisation of TB care; and purposively sampled nurses, doctors, counsellors and community caregivers who were treating patients at each of the primary care facilities in the selected district to be interviewed and/or observed. We also recruited nurses who were not routinely seeing TB patients as well as a private sector general practitioner and one traditional healer to understand their perspectives about the organisation of TB care, and of TB and the management of it.

Patients

To be eligible for interview, patients diagnosed with TB needed to have taken treatment for at least one month, in order to be able to inform us about their experience of care. Eligible patients who arrived at the facility on each day of data collection were consecutively sampled. Nurses identified eligible patients and informed the research team who then approached the patient about participation in individual interviews.

In the second stage of data collection, patients who screened positive for TB symptoms ('presumptive TB') were also interviewed after vital signs' assessment. Nurses informed patients about the research, and if the patient was willing, notified the researcher who approached the individual about participating in a short interview. Informed consent was taken and interviews were audio-recorded.

Other stakeholders: Other key stakeholders were identified and purposively sampled to obtain a broader range of perspectives of service delivery, including researchers working for the Desmond Tutu Tuberculosis Centre (https://blogs.sun.ac.za/dttc/), TB managers at district and provincial level, and members of TB Proof, a NGO which started representing health workers with occupational TB and which now represents the views of people living with and surviving TB more generally (http://www.tbproof.org/who-we-are/).

Data Collection

Individual interviews

In the first stage of data collection, we conducted five manager interviews; two provincial and district TB manager interviews; and individual interviews with eight clinical staff (two community caregivers, three doctors, three nurses), one traditional healer, 20 with patients with TB (see Table 2); and three members of TB NGOs, totalling 20 hours and generating 244 pages of transcripts. Within the second stage of data collection we conducted nine interviews with patients with presumptive TB.

Interviews were semi-structured and carried out in the language most appropriate to each participant (isiZulu = 29; English = 19), audio recorded, translated and transcribed in English. Once informed consent had been obtained, the researcher checked the participant was willing for the interview to be audio-recorded, explaining the reasons for doing so. Participants were reassured that neither the transcript of the interview nor the handwritten notes would contain any personal identifying information and that nobody would listen to the audio-recording or read the notes, except for members of the research team involved in transcribing and/or analysing the data.

Individual interviews with patients elicited stories (27) of patients' journeys through the TB care pathway from the point where they first noticed symptoms through to treatment and followed up topics as they arose. Patients who screened positive for TB were briefly interviewed to elicit their understanding of the screening questions, instructions for providing sputum testing and next steps for their care.

Interviews with nurses, counsellors, community caregivers and doctors explored the provision of TB care, implementation of infection control measures, and solutions for strengthening TB care. Interviews with provincial managers and stakeholders explored current services and interventions to support people with TB, interventions to reduce TB infection and address pyschological needs of patients with TB, and perspectives on required interventions to improve service delivery at a system wide, organisational and individual facility level.

Healthcare facility observations

Within each primary healthcare facility we carried out periods of direct, non-participant observations within non-clinical areas to understand the organisation and process of TB care including patient flows, TB screening and testing, infection control measures and data capturing processes. This enabled us to understand how facilities operationalised policies for managing patients with TB alongside other patients, how and where patients were screened, triaged and then seen within each facility, instructions for providing sputum samples, the use of infection control masks, how the physical design of each facility affected the ability to control the spread of infection, and how staff were allocated to treat TB alongside other conditions. We recorded contemporaneous written field notes of their observations using a semi-structured observation guide (Additional File 1).

Documentary and routine data review

Table 1 provides details of policy and guidelines reviewed to identify best practices for TB screening, testing, diagnosis, treatment initiation, infection control and follow-up of patients against which we compared observations of TB care delivery. TB mortality figures per health facility were reviewed for April 2018 - March 2019 to focus efforts on PHC facilities experiencing highest burdens. An internal report of TB mortality in Amajuba, based on routine data from the electronic data system, provided further analysis of mortality burden as a proxy for health system outcomes (20). Routine TB-related indicators from the District Health Information System (facility-level data) and from the Electronic Medical Record system (individual-level data) were summarised for the four preceding reporting quarters, in order to identify data system and clinical care bottlenecks.

Data Analysis

In order to generate hypothetical propositions on the contextual determinants of problems in TB care delivery, we identified relationships between CICI domains and across macro-contextual features (e.g. national and international healthcare policy, discourses, infra-structural relations, socio-economic factors), meso-contextual features (i.e. organisation of TB care at a primary healthcare facility level), and micro-contextual features (i.e. patients' and clinician's behaviour). We drew on Braun and Clarke's thematic analysis as a 'contextualist' method (28), examining how macro-contextual features shaped meso and micro (or vice versa), thereby tracing a thread between specific perspectives or observations to the broader social historical context in which they were manifested (see Fig. 1). Rather than necessarily developing higher-order themes within the discrete datasets, this approach required treating each participant report or observation as a potential contextual feature which we then explored within and across contextual levels and across data types to develop and test emerging theories (29), for example how reported implementation of infection control measures matched recommended practice within TB guidelines as well as our observations within the facility. This iterative approach enabled us to transition from the particularities of Amajuba as a single case to theoretical explanations of how different contextual determinants applicable in other South Africa settings may shape the patterns we observed, facilitating generalisable inferences and predictions on what kinds of intervention components are needed to tackle different contextual determinants of problems in TB care.

All interviews were inductively coded for features using NVivo software. This provided detailed staff, manager and stakeholder perspectives of the process and content of TB care in facilities; and for patients, pathways to care, and experiences of living with and managing TB. Initially four researchers (RC, AD, JM, AvR) coded two of the same interviews and compared these to identify and resolve differences. The facilities were then divided between these research members, with the coding of features checked by JM. A constant comparison approach was adopted, working iteratively between data obtained from different interviewees within and between facilities to test out categories, including searching for disconfirming cases (30). First order codes were then analysed to consider if they could be developed into higher order codes to better facilitate understanding of emerging relationships between contextual features. Field notes were analysed to provide a detailed description of the process and content involved in provision of TB care, including screening, testing, data capture and infection control measures.

Data synthesis within CICI framework

As the analysis developed we mapped contextual features onto the seven contextual domains of the CICI Framework. Any feature which did not readily map onto a domain was discussed and assigned to a domain or an additional domain added. We then analysed the mapped domains in light of emerging theories to generate hypothetical propositions which specified the contextual determinants of problems in delivering effective person-centred TB care. Finally, we hypothesised which intervention components and implementation strategies would logically tackle those determinants. Throughout analysis, we held regular meetings between all project team members and the district health department to review findings, discuss emerging theories on the relationship between features and contextual domains, and later develop hypothetical propositions and intervention components.

Ethical Considerations

The key ethical principles of voluntary and informed participation, confidentiality and safety of participants were used in all researcher and participant interactions. Written consent for interviews was obtained from all stakeholders, facility managers, clinicians and patients. Facility managers provided consent for observations of non-clinical areas. All participants were provided

with written information about the research, informed that their participation was voluntary and that they could withdraw from participation at any time. Patients were typically approached after their consultation and interviews were conducted in outdoor areas with researchers wearing a mask where possible.

Results

The findings from the pre-implementation phase are structured into two sections. Firstly, we provide a map of the TB care pathway in Amajuba. Secondly, using the CICI framework, we report findings of the contextual determinants of problems in the delivery of TB care.

TB care pathway in Amajuba

Figure 2 provides a process map of TB care in Amajuba which is also broadly representative of TB care in South Africa. It illustrates the complexity of this process and how successful screening, testing, diagnosis and treatment is reliant on a multitude of inter-related actions being effectively coordinated as part of a functioning system. The pathway depends on people with symptoms being identified or presenting at PHC facilities. Screening tools need to be effectively deployed to identify patients with presumptive TB, and patients need to understand how, and be able, to provide a sputum sample that is testable at a laboratory. Positive test results need to be returned to facilities in a timely fashion to initiate patients on treatment, requiring efficient communication channels, accurate documentation and facility staff being able to easily contact patients. Patients starting treatment need to adhere to medication through to completion to avoid relapse, requiring regular visits to the facility. Taken together this reveals numerous points of vulnerability to providing effective TB care.

Contextual determinants of problems in the delivery of TB care

Table 3 reports how contextual features from our analysis mapped onto the seven CICI framework contextual domains and how each domain has a bearing on the organisation, delivery and access to TB care. Quotations from interviewees are used which illustrate the particular contextual feature. We identified several features of PHC facilities which we felt were not accurately reflected in any of the CICI domains and therefore added an eighth dimension – institutional context - to make clear features that articulate organisational practices which we might then link to other features within other domains.

Table 4 shows how features mapped onto problems in delivery of TB care, as well as determinants, hypothetical propositions about the relationship between contextual determinants and problems, and potential intervention components and implementation strategies to tackle determinants. High TB case fatality rates framed these problems which we categorised into four themes: delayed diagnosis, limited support for staff and patients psychosocial needs, patients lost to follow-up after diagnosis, and inadequate infection control.

Delayed diagnosis at community and facility level

Patients reported a range of referral pathways (Figure 2) from the point of noticing symptoms to diagnosis and treatment initiation, in one case involving three doctors, (including private doctors) over a two-month period before being diagnosed with MDR-TB. Fragmented data recording and sharing underpinned such delays which was also reflected in delays retrieving sputum test results from laboratories, leading to loss of follow up or delayed diagnosis and treatment. Within facilities, there was typically one room dedicated for TB patients and care provided by one professional nurse. Ideal Clinic policy requires that nurses screen patients for TB in vital signs rooms, asking four questions: ‘Do you have a cough?’; ‘Do you have a fever?’; ‘Have you lost weight?’; and ‘Are you sweating a lot at night?’ However, we observed wide variation in TB screening practices, taking place within and outside vital signs rooms and inconsistent questioning of patients, sometimes only occurring if patients showed signs or symptoms. Within some facilities, data recording of patients screened was incomplete and inaccurate, including discrepancies between numbers of patients observed and recorded; and missing screening data for chronic condition patients. Instructions to provide sputum at home or in the clinic varied both within and between clinics, with some patients asked to revisit the clinic with the sample. However, patients screening positive for TB were not recorded in a TB register until they returned their sputum. Patients also reported being confused about how to provide sputum, how much sputum to produce and when and where to return the sample. Only two facilities reported that they supervised sputum collection. This was reflected in high rejection rates of

sputum samples. For the period of January to August 2019, the two main reasons for rejected samples in the district were insufficient specimen (44%) and leaked specimens (30%).

Other issues causing delays were patients having a preference for private doctors, accessing traditional healers as a first point of contact and delayed presentation to public sector health services. Several staff reported that patients provided incorrect addresses citing privacy concerns including not wanting to be seen attending their local clinic or having CCGs follow them up in their homes.

Limited support for psychosocial needs of staff and patients

Patients reported how key aspects of their life had been lost since being diagnosed with TB, including control of their body, mental state, professional role, social contact and personal relationships. These different forms of loss can be seen to represent a 'loss of self' (31) as patients struggled to adjust to the changes in their lives, highlighting a need to provide psychosocial support from the point of diagnosis through to treatment completion. However, both staff and patients frequently presented care as having a biomedical focus on treatment adherence, with limited discussion of the psychosocial support patients may require or how to continue with everyday activities that are important to patients.

The loss of social contact and personal relationships arising from patients choosing to self-isolate during the early weeks of their treatment was intimately connected to a moral incentive not to infect others. For some this created a stigmatising element to their relationships, with friends or relatives distancing themselves from the diagnosed patient. Stigmatisation and fear of being infected shaped how some staff reported being stressed about providing TB care, and in one facility we observed staff visibly recoiling at the suggestion that they might need to take on this role. An exception to this was one nurse whose expressed commitment to caring for individuals living with TB functioned to articulate the otherwise wider stigmatisation and marginalisation of this group: '*You know if people are sick with TB, nobody loves them. Nobody likes them. Nobody wants anything to do with them. I said, if they cannot be loved by anyone, why can't I love them. That is what keeps me here each and every day. Just to give my love to them. To understand them and to love them, and to attend to their needs.'* (TB nurse)

Patients lost to follow-up after diagnosis or end of treatment initiation phase

An important contextual feature shaping the ability of patients to adhere to treatment and for facilities in following patients through to treatment completion is the level of unemployment, at 39.1% in 2014 (32). A large proportion of the community live in high-density housing, which is likely to increase the risk of TB transmission. Patients and clinicians reported difficulties in attending facilities to collect treatment (and therefore medication adherence) because transport costs are required. Many patients are daily paid workers within manufacturing industries with working conditions which restrict their ability to flexibly attend clinic appointments. Related to this are working migration patterns, with some patients working away from home and then returning to collect medication, potentially creating discontinuities in treatment, made worse if patients provide the wrong address or move without informing the facility.

The reported focus of consultations on ensuring patients were adherent to medication was set against little evidence of patients being supported to deal with medication side-effects either through expressions of empathy or provision of medication to assist with them.

Inadequate infection control alongside policy to minimise TB stigma

A particular challenge for minimising the stigma surrounding TB is the subtle interaction with the need to take appropriate infection control measures. Integration of HIV care into chronic care services has helped reduce stigma in South African primary care (33, 34). Ideal Clinic policy builds on this by extending this arrangement to those with TB, after the intensive phase of treatment has been completed. While these patients should be non-infectious, in practice we observed patients with TB at various stages of treatment sitting with others attending for other chronic conditions. We also noted inconsistent use of masks by nurses and patients, potentially revealing spaces where the tension between infection control and stigma creates individual uncertainty about what measures are appropriate and should be taken to reduce infection.

Primary care facility infrastructure did not help minimise the spread of TB, including long corridors with few windows. We observed patients with TB sat close by other patients including pregnant women and children, and clinical staff reported the difficulties in maintaining appropriate infection control measures. In contrast, at the hospital site, dedicated to treating both drug-sensitive and MDR-TB, patients sat in open air waiting areas, masks were routinely worn in all inpatient wards and outpatient consultation rooms, and a team of staff deployed to treat the range of patients requiring care.

Discussion

Achieving WHO End TB strategy targets (2) urgently requires interventions that strengthen the healthcare system to better identify, test and diagnose people with TB and to support them to successfully complete the TB treatment pathway. Our findings highlight that to do so requires careful consideration of how different contextual features interact to produce different problems in the delivery of TB care. We have provided hypothetical propositions, and recommendations for potential intervention components and implementation strategies to facilitate this process, pinpointing relationships between policy, the infrastructural organisation of primary healthcare, and discourse at a macro-contextual level; the operationalisation of policy within primary care at a meso-level; and how these contextual conditions come to be manifested at a micro-level where patients seek and receive care.

There is a pressing need to improve systems of TB screening, testing, data capture as well as developing interventions that function to destigmatise TB within communities. Patients frequently present to services some time after onset of symptoms and may have multiple contacts over weeks or months before receiving a diagnosis. Fragmented service provision and under-resourced public services reinforce these delays undermining data sharing, referrals, and efficient screening and testing procedures. Within clinics, we identified variable quality in TB screening, sputum testing and data capture, and patients were unclear about how to provide sputa samples. Strengthening patient education and systems for screening and testing within public facilities are required to reduce delays to diagnosis and treatment, supporting similar findings in previous research (6-8). Although some determinants such as poverty and distribution of employment are societal challenges that require systemic intervention over decades, recognition of these difficulties highlights the need to ensure patients taking TB medication have access to food (10), as well as the potential of inter-sectoral collaboration between health and industry to support employees to attend facilities in different locations (35).

Our study identified specific tensions between two broad policy agendas that have very different underpinning assumptions and framings of what type of problem TB represents, shaping what practices healthcare professionals enact and therefore the care of patients. On the one hand, TB policy (2, 36) is predominantly orientated towards reducing the mortality and incidence of TB, which discursively frames the illness as a *population-based disease epidemic*, inherently placing TB screening, testing, diagnosis, treatment adherence and TB infection control measures at the heart of protocols and practice for healthcare facilities, healthcare workers, patients and communities. At the same time, there is recognition that this agenda is at odds with a person-centred view of TB care (2), which constructs the condition as an *individually-experienced social problem*, facilitating understanding of how TB has impacted on individual's participation in society and their associated psychological, emotional and mental health.

These different orientations are not necessarily mutually exclusive. However, our findings highlight how the global discourse of TB as epidemic can dominate clinical practice at the expense of the individual, seen in terms of patient's psychosocial problems not being elicited within consultations, but also the individual concerns of healthcare workers who may be the sole person responsible for TB care. The realities of operationalising these two agendas without one undermining the other requires multi-faceted and nuanced strategies for supporting healthcare workers and patients through the TB treatment pathway. Disease-specific policies and guidelines in low and middle-income countries (LMICs) have historically functioned to verticalise care of chronic illnesses (37, 38), and despite the promotion of integrated care within facilities, this institutionalised practice places responsibility for meeting TB targets in the hands of individual nurses. South Africa's Integrated Chronic Disease Management programme has also made progress in integrating primary care for HIV and NCDs, but TB care remains separate, partly due to the need to prevent transmission within facilities and report on TB treatment outcomes. Important interventions therefore lie in ensuring TB policy recognises the challenges clinicians face in providing TB care, identifying strategies for enabling the collective management of TB, training all staff to provide that care, and providing support for staff to manage anxieties about TB infection.

Such interventions broaden the scope of person-centred care to incorporate clinicians in addition to patients and their families, and in doing so, may function to facilitate more holistic care of individual patients. As well as integrating care for HIV, TB and non-communicable conditions, prioritising a focus on the relationship between psychosocial health and TB treatment adherence may be critical for supporting the emotional, social and mental health needs of patients as a mechanism to enhance treatment adherence. Evidence is already available which has demonstrated the links between stigma, depression, family and community support, and non-adherence for patients with TB (39-45). However, efforts to improve TB treatment outcomes have not prioritised identification and management of stigma and depression, and research in this area remains scarce and limited to MDR-TB or those hospitalised for treatment. Our recent scoping review (16) which identified a paucity of person-centric TB care being delivered across LMICs, found only two studies, both based in Nepal, which focused on psychosocial support of patients with MDR-TB (46, 47).

Interventions that orientate to the interaction between TB stigma and psychosocial health might be undermined by infection minimisation strategies that function to reinforce and perpetuate such stigma. South Africa introduced a TB infection control programme in 2007 (updated in 2012) with a structural review of healthcare facilities and TB infection control practices, as well as development of minimum standards for health facilities (48). However, while in most high-income countries it is standard practice to isolate people who are potentially infected with TB, in many LMICs this rarely happens and is often perceived to be discriminatory (46, 49). The boundaries between appropriate infection control measures and actions that function to reinforce TB stigma are therefore blurred and despite the availability of legislation, guidelines and policies, we found implementation of TB infection control is generally poor and adherence of health care workers is sub-optimal, echoing previous research (50-52). This has created an ethical paradox between attempts to minimise TB stigma and the implementation of infection control policies which have arguably led to indecision within healthcare facilities about what infection control measures are appropriate and consequentially the less than optimal practices we observed.

The range of factors that perpetuate the South African TB epidemic have been rendered all the more complex with the onset of the COVID-19 pandemic, which has already had dire consequences for TB care (53). Not only is little known about the incidence, risk and course of illness of COVID-19 in people with undiagnosed pulmonary, drug-resistant or complex TB presentations but COVID-19 shares many symptoms with TB, such as cough, fever, and shortness of breath, making differentiating between COVID-19 and TB challenging for healthcare workers. On the other hand, the normalisation of mask wearing and increased awareness around infection control practices has potential to destigmatise these measures for TB care in the longer term.

Strengths and Limitations

This study took place in one district in South Africa with a high burden of TB, limiting direct transferability of our findings to other parts of South Africa and other LMICs. However, by focusing on Amajuba as a theory-building case study (17) we have generated hypothetical propositions which trace a thread between global forces on the identification, diagnosis and treatment of TB and the actions of individual clinicians and patients who face the realities of managing TB in everyday life. In doing so we offer theoretical generalisability on the contextual determinants of TB that echo across LMICs with a high burden of TB, providing a foundation for developing interventions to tackle those determinants.

In setting out the domains and contextual determinants of TB care, we are conscious that the foundations of our findings lie in the situated perspectives of participants and our own observations of TB care. We are not claiming to have objectively established causal relationships between domains, TB care and rates of TB cases and fatalities. However, the breadth of data we have collected, the depth of analysis and triangulation across data types provide strong foundations for the hypothetical propositions we propose. Concrete intervention development work is now required, using the recommendations for intervention components and implementation strategies as a starting point for further development and specificity.

Our sample was limited by staff availability and according to which patients presented on the day of data collection and whom were willing to participate. Negotiating access to facilities to conduct fieldwork required numerous communications to build trust between district managers, facility staff and the research team, which in itself revealed the burden of accountability experienced by staff responsible for reducing TB morbidity and mortality within this district. Interviews and observations were sometimes

difficult to conduct in busy facility environments which limited our ability to purposively select patients and screening assessments.

Conclusions

Significant health systems strengthening interventions are required if WHO targets for TB are to be achieved in South Africa by 2035. To do so requires careful consideration of how different contextual determinants interact to produce problems in the delivery of TB care. Strengthening the quality and processes for screening, testing and diagnosing patients within primary healthcare facilities are essential but need to be supported by policy that resolves tensions between treating TB as a population-based epidemic and TB as an individually-experienced social problem. At the heart this are TB nurses who need to practise in a climate of stigma, infection control measures and accountability for ensuring patients complete the TB treatment pathway. Structuring TB care as a collective endeavour within facilities underpinned by a person-centred ethos of support for colleagues may help ensure the same principles are translated to supporting patients to manage not just the condition but their experience of TB.

Abbreviations

AFB - Acid-Fast Bacilli

ART - Antiretroviral Treatment

ARV - Antiretroviral

CCG – Community Caregiver

CHC – Community Health Centre

CICI - Context and Implementation of Complex Interventions (CICI) framework

DOTS - Directly Observed Treatment Short Course

EN – Enrolled Nurse

ENA – Enrolled Nurse Assistant

LMIC - Low and Middle-Income Countries

LPA - Line Probe Assays

MDR-TB - Multi-Drug Resistant Tuberculosis

OPD – Outpatient Department

PHC – Primary Healthcare

PN – Professional Nurse

TB – Tuberculosis

Declarations

Ethics approval and consent to participate: Ethics approval was obtained from University of Cape Town Human Research Ethics Committee (HREC 286/2018), the KwaZulu Natal's Biomedical Research Ethics Committee; King's College London Ethics Committee (LRS-19/20-21011) and the Provincial Research Ethics Committee of the KwaZulu Natal Department of Health. The study was registered with the South African National Health Research Database, (KZ_201811_031). Written consent for

interviews was obtained from all participants. Facility managers provided consent for observations of non-clinical areas. All participants were provided with written information about the research, informed that their participation was voluntary and that they could withdraw from participation at any time.

Consent for publication: Not applicable

Availability of data and materials: The datasets generated and/or analysed during the current study are not publicly available due to data transcripts including personal participant information not suitable for sharing, but are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

Funding: This research was funded by the National Institute for Health Research (NIHR) Global Health Research Unit on Health System Strengthening in Sub-Saharan Africa, King's College London (GHRU 16/136/54) using UK aid from the UK Government to support global health research. The views expressed in this publication are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Authors' contributions: All authors contributed to the conceptualisation of the research and contributed to writing the manuscript and design of the research protocol. AvR, AD, RC, AA and JM collected, analysed and interpretated all data. JM drafted the manuscript and all co-authors edited and commented on revised drafts. All authors approved the final draft for submission. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Acknowledgements: We would like to thank all the provincial and district stakeholders, operational nurse managers, doctors, nurses, community health workers, traditional healers and most importantly the patients who participated in this study. The views expressed in this publication are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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Tables

Table 1: Characteristics of participating facilities

Site	Urban/Rural	Number of staff	Staff responsible for screening TB	Location of Sputum collection	TB care person	Monthly Average Number of patients*	Monthly Average TB screening
PHC Facility 1[a]	Rural	21	EN (Vital signs room)	Outside Area	1 PN	4279	Not available
PHC Facility 2 [a, b]	Rural	38 (17 CCGs)		Outside area	1 PN	4941	5000
PHC Facility 3 [a, b,*]	Urban	26	EN/ENA/PN (7 screening points)	Outside area	1 PN	8377	Not available
PHC Facility 4 [b]	Rural	20 (10 CCGs)	EN (Vital signs room)	Outside area	1 PN	4492	2000
PHC Facility 5 [b]	Rural	18 (25 CCGs)	EN (Vital signs room)	Outside area	1 PN	5387	4000
PHC Facility 6 [b]	Rural	20 (17 CCGs)	EN (Vital signs room)	Outside area	1 PN	4826	2000
Hospital 7 [a,*]	Rural	16	Referral only	No sputum collection. Receive referrals from PHC facilities	All staff	1772	Not available
Relevant local, national and international guidelines in use							
Ideal Clinic Policy (21)	Promotes integrated clinical services for all patients with a view that patients receive all care by one clinician.						
Practical Approach to Care Kit (PACK) guidelines (22)	PACK guidelines are clinical decision support tools, providing an evidence-based, comprehensive clinical approach to support the treatment of common symptoms, syndromes, diagnoses and conditions. The guides are designed for use in each consultation and starts with screening and a symptom-based approach, guides the diagnosis of common conditions, including priority chronic conditions and facilitates the routine care of the patient with one or several chronic conditions. PACK guides include PACK Child, Adolescent, Adult, Community and Home, thereby covering the life course and supporting all health workers in the primary care team.						
Adult Primary Care (APC) Guidelines (23)	APC guidelines are a comprehensive clinical tool for primary care of adults 18 years or older. The guidelines were developed using approved clinical policies and guidelines issued by the National Department of Health and is intended for use by health care practitioners. APC is being implemented as part of the Integrated Clinical services Management, a key focus within the Ideal Clinic.						
	The National Tuberculosis Management Guidelines provide South African department of Health's guidance for management of TB, guidance on the management of adverse drug events and anti-retroviral initiation for patients co-infected with HIV.						
	The National Infection Prevention Control guidelines for TB, MDR-TB and XDR-TB provide guidance for staff to minimise the risk of TB transmission in health settings. Infection control						

	measures should be established to reduce risk of TB transmission to both the general population and health care personnel.
National Tuberculosis Management Guidelines (24)	
National Infection Prevention Control Guideline for TB, MDR-TB and XDR-TB (25)	

[a] Facilities and hospital included in first stage of data collection.

[b] Facilities included in second stage of data collection.

*January 2018 to January 2019

PN – Professional Nurse

EN – Enrolled Nurse

ENA – Enrolled Nurse Assistant

CCG – Community Caregiver

Table 2: Characteristics of interviewed patients diagnosed with TB

Gender	Male	13
	Female	7
Time on treatment	>1 month, duration uncertain	2
	Less than 2 months	9
	2-8 months	6
	Post treatment	3
Retreatment	3 patients	
Place of diagnosis	Hospital	11
	Clinic	5
	General Practitioner	4
Type of TB	MDR-TB	6
	Drug sensitive	14

Table 3: Contextual Domains for Tuberculosis care

Contextual Domain	CICI Description	Contextual Feature	Excerpts
Epidemiological context	Distribution of disease/conditions, the attributable burden of disease as well as determinants of needs in human populations. Therefore, it also includes demographics.	*Meso (District/Facility/Hospital) level:* **High TB case fatality rates. >**11% for past four consecutive years. In 2017/8, 93% of those who died were registered as new cases (20). 79% died within the first three months of starting treatment. 75% died of pulmonary TB [21]. Between 2014-18, 71% of TB deaths were patients co-infected with HIV, 85% of whom were enrolled on anti-retroviral treatment (54).	'*We are having a high death rate, even with our drug sensitive TB there is a high death rate, but it also depends if the patient has been through a facility and missed out and also if you are having a high loss to follow up on the ARV* [Antiretroviral] *Programme you are going to see that type of issue.*' (TB Manager)
		Micro (Individual) level: **HIV and TB co-infection.** Many clinicians reported that TB patients are also co-infected with HIV. 71% of TB deaths were co-infected with HIV and has been started on anti-retroviral treatment (54).	*We have at least close to 65% of our patients are co-infected so we have to make sure that if they are on the TB programme that they need to be on ARVs also.' (TB Manager)*
Socio-economic context	Economic resources of a community and the access of a population to these resources. It also shows the relationship between an economy and its society.	*Macro (National and International) level:* **Unemployment and poverty.** Many TB patients come from households with low socio-economic status, where unemployment is rife and living conditions are sub-optimal which results in a high TB burden.	'O*ur patients most of them are not working. Sometimes they will report that they don't have food at home.'* (Facility Manager)
		Meso-level: **Electricity load-shedding.** Due to national electricity shortages, load shedding affects laboratories systems and therefore delays release of results and initiation of treatment.	*'Just an example from today, we don't have any blood results, or sputum results. So, there are quite a few sick patients that I took bloods on yesterday, and when I checked on the system today there are no results. I called the lab, they said there is load shedding, the system is down. So, I mean, if there's any correctable factors, I can't really*

			do it. Patients I need to start ARVs, I need results for. I can't do it, I don't have any results.' (Doctor)
		Micro-level: **Access to facility.** Patients described being unable to adhere to their TB treatment because of a lack of finances to travel to the facility. **Poor Nutrition**. Many patients report not having sufficient food/nutrition to take their treatment.	'*They start their treatment and promise they will be able to come whatever but eventually when they can't afford the taxi fees or the bus fare, that is when they start defaulting.'* (Facility Manager) *'I mean generally, we see quite a few patients coming in in extremely poor condition; malnourished in respiratory distress, oxygen dependent.'* (Doctor)
Political context	The distribution of power, assets and interests within a population, as well as the range of organisations involved, their interests and the formal and informal rules that govern interactions between them. The domain also comprises the health care system and the securing of its accessibility.	*Macro-level:* **The WHO End TB Strategy:** The strategy aims to end the global TB epidemic, with targets to reduce TB deaths by 95% and to cut new cases by 90% between 2015 and 2035, and to ensure that no family is burdened with catastrophic expenses due to TB (2). (https://www.who.int/tb/post2015_strategy/en/) **90-90-90 targets:** Mimicking the UNAIDS 90-90-90 targets, this is to screen 90% of all people with TB, as part of this approach to reach 90% of key populations (55) and to achieve at least 90% treatment success for all people diagnosed with TB (48). **Ideal Clinic Policy:** The Ideal Clinic policy encourages integrated clinical services for all patients including those with TB. Ideally a patient can receive all care by one clinician instead of multiple clinicians for e.g. TB treatment, ARV treatment administered by one clinician (56).	*'So, we are looking at 90-90-90. Screening 90% of patients and above, making sure 90% are initiated and 90% are sustained and compete their treatment, but we are far from that I think.'* (TB District Manager)
		Meso/micro-level: **Continued verticalized care**: Despite the implementation of Ideal Clinic policy, different clinicians are allocated to see patients with TB and HIV separately. They are considered	'*My challenge is here if there was someone doing the HIV programme they will just*

		specialists compared to other nurses who report lacking knowledge to manage TB patients.	*concentrate on the ARV programme, the person that is doing the TB programme will have to concentrate on that. In the Ideal Clinic situation if you walk into this stream, you will get everything done. But it doesn't work that way, I mean I have complaints from the TB co-ordinators in the facility that if they are not there, the patients are not seen to.'* (TB Manager)
Institutional context (Added to CICI domains)	Workforce arrangements, staff training, organisational rituals and patient flows.	Meso/micro-level: **Biomedical focus of care.** Patients and clinicians described that care for TB patients was primarily focused on the clinical aspect of ensuring the patients were adherent to treatment.	*'I didn't talk to any of the doctors or nurses who were treating me but also nobody ever asked me how I am feeling, how I am coping. The clinic focuses more on the biological. And not that they ask how treatment is going, their focus is the drugs and the drugs got in and you didn't vomit but they never actually ask how I was doing on treatment or how I was feeling in the process, so for me I feel like it was completely ignored.'(TB Proof member)*
		Ill-prepared for treatment side effects. Patients seemed ill prepared for the side effects they were experiencing and how to manage these.	'*We give them health education on how to take after they've taken treatment, they need to tick saying I've taken treatment today, and if they have not taken treatment, also tell them to indicate that they did not take treatment on the day. So, at the end of the course of treatment then we go back to cover for days they did not take treatment. Also we just give them*

		support, like taking treatment as expected.' (Nurse)
		Interviewee: Yes, they did tell me that there are changes that that I am going to experience but they didn't tell me specifically what are it that I am going to experience.'(Patient)
	Meso level:	
	Patient flow. Where previously TB patients were seen in 'park homes' (temporary structures used due to lack of formal infrastructure to accommodate patients outside the main clinic), with the implementation of Ideal Clinic they need to receive services within the clinic. Although this reduces stigmatising/discrimination it exposes other patients to TB as the TB room is positioned near consult rooms for patients with chronic illness and children.	'*It is a problem we are facing, because of the ideal, the streams, the Ideal says we must have three streams. All the time we used to take TB and do them in the park homes because there is enough ventilation there. So now they said those patients must come this side to be seen, because they said if we separate them we are discriminating the patients. Of which we are seeing it is a problem on our side because we were worrying because we have small babies, they are also sitting on the same area with these people, because there is no enough ventilation.*' (Facility Manager)
	Disorganised and unclear referral pathways. Numerous cases were reported where patients presented repeatedly at clinics and were not screened properly with diagnosis occurring months later in hospitals. Poor communication and lack of information continuity across services contributed to this situation resulting in delayed initiation of treatment.	
	Poor quality sputum collection. High sputum rejection rates; commonly insufficient specimens (40%) and leakage (34%) (January to August 2019).	*'I recently had an MDR case we were trying to follow who was diagnosed right in this clinic. The sister made arrangement for the patient to go to the hospital to be initiated, she got an ambulance and the patient was taken to hospital, was lost into the system in*

		the OPD [Outpatient Department]*, given treatment and sent back home. The patient was unwell and came back again and was sent to gate clinic now as she didn't come in an ambulance. They suspected her having TB, they took a GeneXpert and I don't know for some reason it came back negative but clinically they looked at her and they started her on TB treatment. She came back again not feeling well, so now they decide to send her to the TB doctor and then it was picked up, this was MDR patient. So, she was started on MDR treatment, so that was like about three weeks after.' (TB Manager)*
	Inconsistent TB screening. Quality of screening varied within and across facilities. Screening checklists inconsistently used, not all questions asked and questions asked from memory.	
	Medication shortages and TB/ART coordination. Doctors reported not having required medication and needing to prescribe contraindicated substitute	
		'Sometimes the lab will tell you the sputa is insufficient; the sputum is a poor quality. The results sometimes you find the sister is so busy, she can't even follow those patients because they have to repeat the sputa if the results came poor quality. I think we can conquer TB by that, if we call all those with poor quality to cough again.' (Facility Manager).
		'*We do have documents that we use but we don't carry them daily our document is our minds now.*' (Community caregiver)

			'Last year there was a shortage of, I think it was moxifloxacin [used for treatment of MDR-TB], *I think. So, we had to substitute a drug, basically which we can't really do. ARV wise, there is certain ARVs we can't give with the MDR treatment, because we need to substitute it, but then those drugs are out of stock. Then you basically need to switch someone to a different ARV regimen where that would actually be very detrimental to their health. Either because of contraindications such as anaemia. So, you need to get an anaemic patient medication that actually worsens anaemia, or because it can actually cause resistance of the HIV virus. So, this happens with the TB treatment, with the ARVs, with other medications. Potassium supplementation is out of stock at the moment.'* (Doctor)
Socio-cultural context	Explicit and implicit behaviour patterns, including their embodiment in symbols and artefacts; the essential core of culture consists of historically derived and selected ideas and values that are shared among members of a group. It not only refers to the conditions in which people are born, grow, live, work and age but also embraces the social roles a human being takes on as a family member, community member or citizen and the relationships inherent to these roles. Constructs such as knowledge, beliefs, conceptions, customs, institutions and any other capabilities and habits acquired by a group are covered by this domain.	*Micro-level:* **Providing incorrect addresses.** Facility staff reported that patients often provide incorrect addresses to the clinic, making it difficult for them to be followed up. Reasons stated were that patients preferred certain clinics and lied in order to receive treatment in their selected clinic. Sometimes the reason for selection is proximity to work and stigma (fear of being seen by neighbours in the local clinic) **Preference for doctors.** Clinicians report that patients often prefer to be seen by doctors and therefore community centres or hospitals are flooded with patients and most diagnosis occur at these levels.	*'Patients are defaulting their treatment. They do default, they give wrong addresses, even if you stress it is important to give the right address, but they do give the wrong address.* *Do you know why they give us wrong addresses is because they like to come to this clinic, they don't like to go to their respective clinics. It is because they know if they give the right address you are going to treat them and refer them to the nearest clinic.*

So, they like this clinic. That is why they give the wrong addresses.' (Facility manager)

Traditional healers. Patients commonly use traditional healers, who may in some cases be the first point of care before being screened at the clinic. Often this was reported as being significantly influenced by family members. According to several staff, patients often hide their use of traditional healers from clinicians.

'The other challenge is we have a CHC [Community Health Centre] *in* [name of hospital] *and then we have* [name] *hospital, patients like to be seen by a doctor, so they will flood these areas. If you look at* [name] *hospital, if you look at they are diagnosing 350 patients per quarter, you find in* [name of hospital] *which has a population of about 37000 that are diagnosing 150 patients, so they are flocking in to be seen by a doctor. The Community health centre has a doctor there, so they are flocking in to be seen, further if they want to start treatment there.' (*TB Manager)

Delayed care seeking. Clinicians described patients being afraid of diagnosis, with a tendency to present or take up referrals very late, sometimes even a month or two after providing sputum sample.

Self-isolation. Some patients reported that they self-isolated due to fear of infecting others.

Loss of sense of self. Patients frequently reported how key aspects of their lives had changed since diagnosis and commencing TB treatment. In each case, something had been lost, including:

- Control of the body - exhaustion, vomiting, joint pains, appetite, weight, bowel and bladder function, body odour.
- Mental state – *'I just couldn't control my actions, I felt like I was losing my mind.'*
- Professional role and income
- Social contact
- Personal relationships and intimacy
- Independence, burdening others

'Usually we ask, if you are really not sure what's happening. If someone is really the case is confusing you, you can't really figure out what's happening. They'll say no, and what I usually do is I'll ask the nurses to go and ask, because they are too scared to tell the doctor usually. They don't really willingly disclose herbal medication. If I can guess, it's because they scared you're going to be angry with them, I guess or instruct them to stop taking it. I think, which is what any doctor will tell you, please stop taking the herbal

			medication. They have quite strong faith in it.' (Doctor) '*People present very late, because they start getting sick and basically, they're told by the community, it's a very common thing that if you come to hospital you're going to die. So, hospital is almost a last resort. I work in casualty as well, after hours so I see that quite a lot. I mean people present extremely late. It's really within hours of dying.*' (Doctor) '*I usually sit alone because I do not want to spread TB to them.'* (Patient) *'It disrupted every part of my life'* (TB Proof representative, treated in 2012)
Ethical context	Reflections of morality, which encompasses beliefs, standards of conduct and principles that guide the behaviour of individuals and institutions.	*Meso-level:* **Hospitalisation of infectious patients.** Clinicians reported that they would hospitalise patients until their Acid-Fast Bacilli (AFB - test for TB bacteria) was negative for two consecutive months, indicating an ethical practice of protecting the wider community from infection. (NB was the standard test for TB before GeneXpert was introduced. It is still used widely to refer to a TB sputum test. AFBs are no longer completed, bur rather have been replaced by GeneXpert and LPA (Line-Probe Assay). Meso-level: **Difficulty implementing infection control measures**. Despite the need to implement infection control measures at facilities, clinicians report that these are not always practised. Micro level:	*'We admit, or we try and admit all patients, just to sort out all social issues and then within about a week we have the sputum results. So basically, there is a smear that says AFB either negative, which then tells us there's a low possibility of the patient actually be infectious to the community or relatives, and then we can think about discharging and treating as an outpatient, if the patient's condition permits it. Obviously if they're*

	Stigmatisation, stress and fear of TB amongst staff. Clinicians and managers expressed fear of TB and reluctance to be responsible for providing TB care. TB care in facilities was frequently seen as the sole responsibility of one nurse, leaving little support if the nurse was to contract TB symptoms.	*ill and they still need further inpatient treatment, we keep them here and discharge once they've stabilized. Otherwise anyone with AFB positive stays here until they have two negative AFBs, basically two months in a row.'* (Doctor working in MDR ward)
	Stigmatising experiences for patients. Some patients reported no stigma from relatives whilst others reported some stigma from friends seen through reduced interactions.	
	Staff and patients emphasised that many patients with HIV also have TB, indicating the potential for a dual stigma.	*'If you say wear enough masks you know each and every person will wear a mask. But they are not wearing them in the consultation. They will have it kept there but you will find it is just not worn.'* (TB Manager)
		'*It is difficult with TB because we are afraid, TB is a communicable disease. Sometimes I am afraid because I can get it. I am stress, I am stressed, If I can get it from working with patients. Even when I wake up in the morning, I am stressed. Why I am stressed because I have got in my house I have got my child, I have got two chronic, I have got my child who has diabetes and it is easier to get TB and my husband is also a chronic disease, so I am afraid if I am getting TB who is going to helping me, because me I am helping those patient.'* (TB nurse)
		'*My friends from school found out*

			from me or they heard me speaking at medical school about it. So I did feel stigmatised by them, because a lot of them just decreased their interactions with me. I heard rumours from others that maybe I had HIV and it really hurt.' (TB Survivor) '*They said HIV and TB are "best friends*"!' (Patient)
Legal context	Rules and regulations that have been established to protect a population's rights and societal interests.	*Macro level:* **Bureaucracy.** Tensions in lines of reporting between programme management and line management of clinical services. Clinics report to both, but their primary allegiance is to clinical services who are their direct managers and responsible for managing their performance. Patients seen privately need to be referred back to public health facilities for treatment.	'*You know we can't really go to a facility if we see something wrong, we have to report it to the operational manager. And we can't go and discipline that person. We probably take a report to the district office and then nothing really. I mean we are sitting with many challenges that are known about and there is nothing actually happening.'* (TB District Manager)
Geographical context	Broader physical environment, landscapes and resources, both natural and transformed by humans, available at a given location, including infrastructure at a given location, which could result in geographical isolation.	*Meso:* **Poor ventilation.** Clinic infrastructure limited ability to provide good ventilation with crowded corridors as waiting areas**.** *Micro:* **Employment demands**. Some patients are lost to follow up as they often come 'home' for treatment and then move back to the cities where they work once they feel better without obtaining a transfer letter to complete treatment. Manufacturing industries provide limited support for patients to attend scheduled appointments. Absence of communication between clinic and employer limits tracing, TB treatment initiation and completion.	*'There is not enough ventilation, that is why we become sick now and then, sick now and then. Because there is no ventilation in this clinic.'* (Facility manager) '*That is the other problem if they very ill they'll come home from Johannesburg, for instance They'll come home they'll be brought here, we'll do everything, we'll initiate the treatment. The next*

			thing they supposed to come back. We trace them even telephonically, 'oh no I'm in Johannesburg. I've gone back to work.' (Facility Manager) *'They don't get paid. I once had my husband's relative she was positive. So the sister told me, okay, could you please make sure so and so come. I also rang her to say she should come. So as I rang her, you know the answer she told me, I'll come on such and such a date. And I say no, why? Because you need to come by tomorrow. I rang her in the afternoon, you have to come tomorrow. Oh no, I have to go to work, you know that nobody is working here. So I don't know what is happening, how many people are having TB really in the industries because its so difficult.'*

Table 4 – Contextual determinants, hypothetical propositions and intervention components for tackling problems in TB care.

Problem	Contextual Domain: Level	Contextual Determinants	Evidence	Hypothetical Propositions	Recommendations for intervention components and implementation strategies
Delayed diagnosis at community and facility level	Epidemiological; institutional; political; socio-cultural: Macro, meso and micro	- Verticalised TB provision within facilities. - Inadequate screening of patients at community and facility level. - Inefficient referral pathways (private/clinic/hospital) -Lack of patient knowledge of how to provide sputum sample. - Poor documentation of TB presumptive patients. - Delays in test results being received by clinics or disclosed to patients. - Stigmatisation of TB shaping loss to follow-up, incorrect addresses, fear of diagnosis and treatment.	- One nurse dedicated to TB care. Reports that TB not managed by other clinicians. - Observations and patient reports identified inconsistent screening. Some patients reported accessing multiple public and private services before diagnosis. -Delayed diagnosis was reported due to poor sputum collection. High levels of rejected samples cause delays and patients are required to return to clinic. - Staff perceived patients being afraid of diagnosis and treatment, leading to delays in returning to clinic.	**Delayed diagnosis caused by interaction between:** ***Macro:*** Cultural stigmatisation of TB; vertical disease programmes; fragmented public and private healthcare provision; limited resources to support efficient and timely screening, testing and diagnosis; ***Meso:*** Inadequate screening of the community, poor sputum collection and test result turnaround, poor referral pathways and communication between contact points, community fears/stigmatisation of TB; and ***Micro:*** poor collection of sputum by nurses resulting in rejected samples and therefore delayed diagnosis.	**1.** Provide staff training to improve identification and management of patients. **2.** Strengthen screening and case finding at community and clinic level. **3.** Strengthen clinical practice and records of testing, diagnosis and treatment initiation at community and clinic level. **4.** Improve sputum collection at facilities and educate patients about providing sputum samples. **5.** Strengthen referral pathways within and between public and private sector. **6.** Educate communities about TB, potential for full recovery, importance of screening, need for support from families. **7.** Improve IT systems for data sharing between public and private sector.
Patients lost to follow up after	Socio-economic; institutional; geographical;	- Poverty restricting access to food leading to poor medication	- Staff and patients reported limited	**Patients are lost to follow up due to interaction between:**	**1.** Improve collaboration between industry

diagnosis or end of treatment initiation phase	socio-cultural: Macro, meso, micro	adherence and access to clinics. Patients working away from home leading to loss to follow-up and not completing treatment - Limited preparation for treatment side-effects, focus on educating patients about treatment adherence. - Clinics not able to contact patients leading to loss of follow-up and continuation of treatment	ability to access clinic. - Patients reported knowing very little about TB treatment side-effects and little support for psychosocial problems - Staff reported patients providing incorrect addresses (to avoid going to clinics near home or home visit from CCG)	***Macro:*** Cultural stigmatisation of TB, poverty, geographical distribution of employment opportunities, biomedical focus of care on treatment adherence; ***Meso:*** little preparation and support for treatment side-effects, inaccurate records of patient addresses, discontinuity of information across services, and ***Micro:*** poor access to nutrition and clinics, employment migration, avoidance of clinic.	and health sectors to adhere to TB medication. **2.** Increase financial support for TB patients to complete treatment phases. **3.** Educate/counsel patients around treatment side-effects and support through to completion. **4.** Strengthen resources to minimise medication stockouts. **5.** Strengthen information sharing between clinics when patients move for work
Limited support for psychosocial needs of staff and patients	Institutional; socio-cultural: Macro, meso, micro	- WHO policy emphasises TB as an epidemic that needs to be controlled through treatment adherence with limited focus on the support of the patient on this journey. - Verticalised TB care - TB Stigma/Fear of infection - Lack of training on TB management.	**-** Staff and patients reported the focus of TB care primarily on the clinical aspects of care and treatment adherence. Little support is offered psychologically or with management of side effects of the treatment. - One nurse usually allocated to see TB patients. There is a reluctance amongst staff for this role because of fear of infection.	**Macro** policy and discourse of TB as an epidemic shapes how staff are trained and clinical orientation towards TB screening, diagnosis and treatment adherence at a **meso-level**. Having only one nurse allocated to TB creates a stigmatised culture and emotional burden for TB nurse, limits support for staff to manage TB, as well as increasing exposure for allocated nurse to risk of infection. Clinical orientation regulates the form and content of patient contacts at a **micro-level**, limiting discussion about emotional and psychological problems for patients after starting treatment and may also be determinants of patient's non-adherence to treatment.	**1.** Strengthen knowledge of TB management and risk of infection for all staff at clinics. **2.** Develop TB policy to promote sharing responsibility of TB across all clinical staff. **3.** Provide psychosocial support for TB nurse to manage demands of role and fears of infection. **4.** Strengthen psychosocial support for TB patients during transition from intensive to continuation treatment. **5.** Strengthen support of TB patients discharged from hospital to community settings.

Limited integration of TB with HIV and other NCDs	Institutional: Macro, meso, micro	- Verticalised TB care - Medication shortages potentially leading to prescribing contraindications.	- Despite Ideal Clinic policy, staff reported inconsistent integration of TB, HIV and other NCDs.	Verticalised care and medication shortages limit effective TB/ART coordination	**1.** Strengthen facilities capacity to integrate TB, HIV and chronic NCD care. **2.** Provide staff training on managing multi-morbidities. **3.** Promoting TB as 'everybody's business' (57)
Inadequate Infection Control alongside policy to minimise stigma	Institutional; socio-cultural: Macro, meso, micro	- Poorly ventilated clinics - Variable and less than adequate infection control measures within facilities. - Wearing masks not routinized and normalised within clinics.	- Despite being aware of infection control, observations identified that the main measure was to open windows and doors. Wearing of masks was mainly limited to TB consultation rooms. Some patients were observed wearing masks but often they were not properly fitted.	**Inadequate infection control caused by interaction between:** **Macro:** Ideal clinic policy aimed at destigmatising TB requiring TB patients not to be isolated from non-TB patients; **Meso:** Clinics implementing Ideal Clinic policy seating TB patients next to non-TB patients in waiting areas. Poorly designed clinics restricting ventilation; and **Micro:** lack of routinized use of masks results in higher rates of transmission of TB between patients in the clinic and exposes more staff to the infection.	**4.** Policy to clarify practice of infection control measures at clinic and community level, which do not also function to reinforce TB stigma. **5.** Develop health promotion messages to educate and normalise infection control and minimise stigma.
Limited access to care for patients with MDR-TB	Institutional; ethical: Meso	. Management of MDR TB centralised at hospital - PHC staff not equipped to manage MDR-TB	-According to clinicians, all MDR as well as some drug sensitive TB patients are hospitalised and initiated on treatment.	The centralisation of MDR-TB at hospitals limits access to treatment for patients with MDR-TB. This is a particular problem for those who are employed who cannot be hospitalised for extended periods. Prolonged hospital admissions increase	**1.** Strengthen support for MDR-TB patients discharged from hospital to community settings

	sense of isolation if far from home with no visitors.

Figures

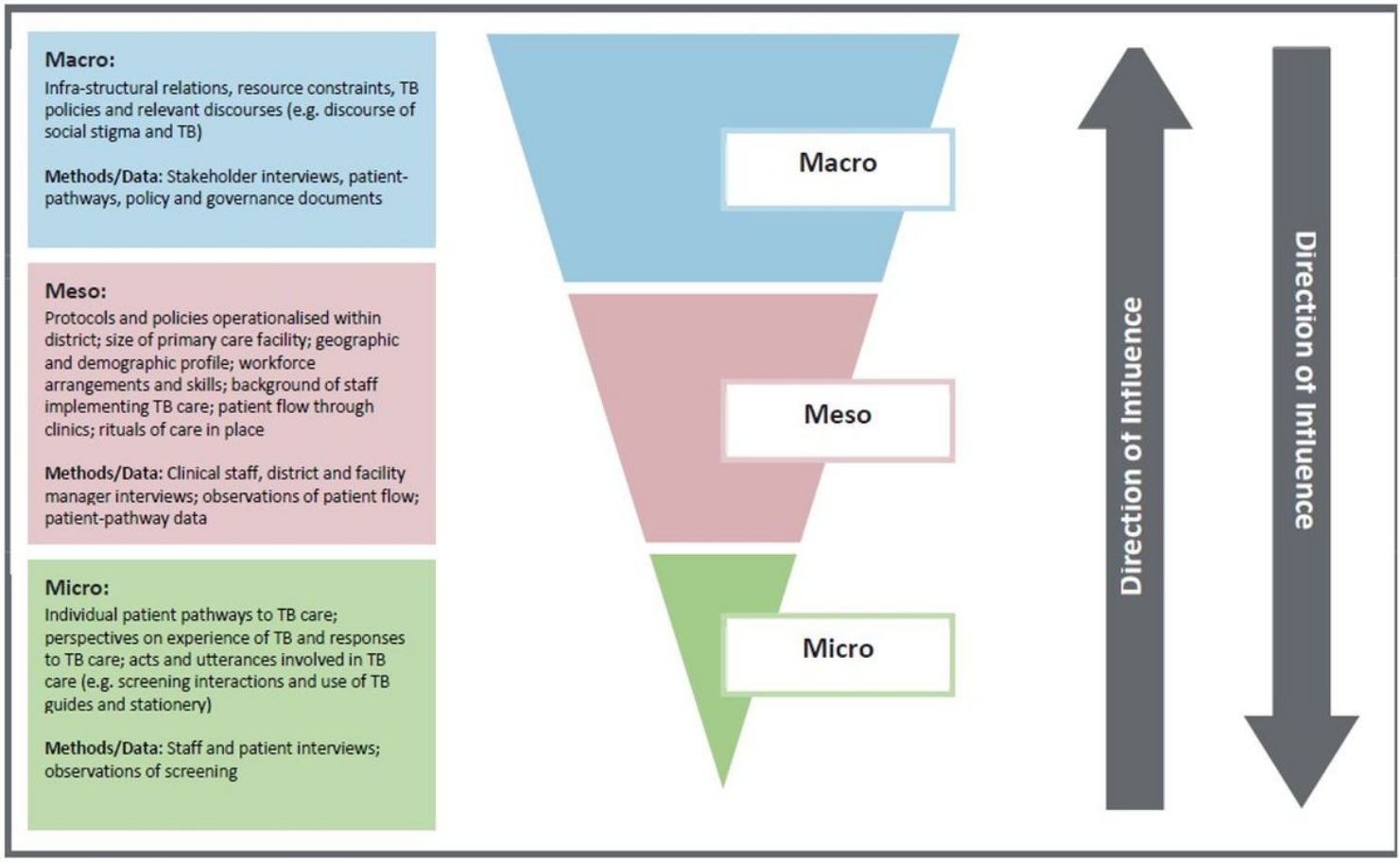

Figure 1

Contextual framework for investigating TB care in Amajuba district.

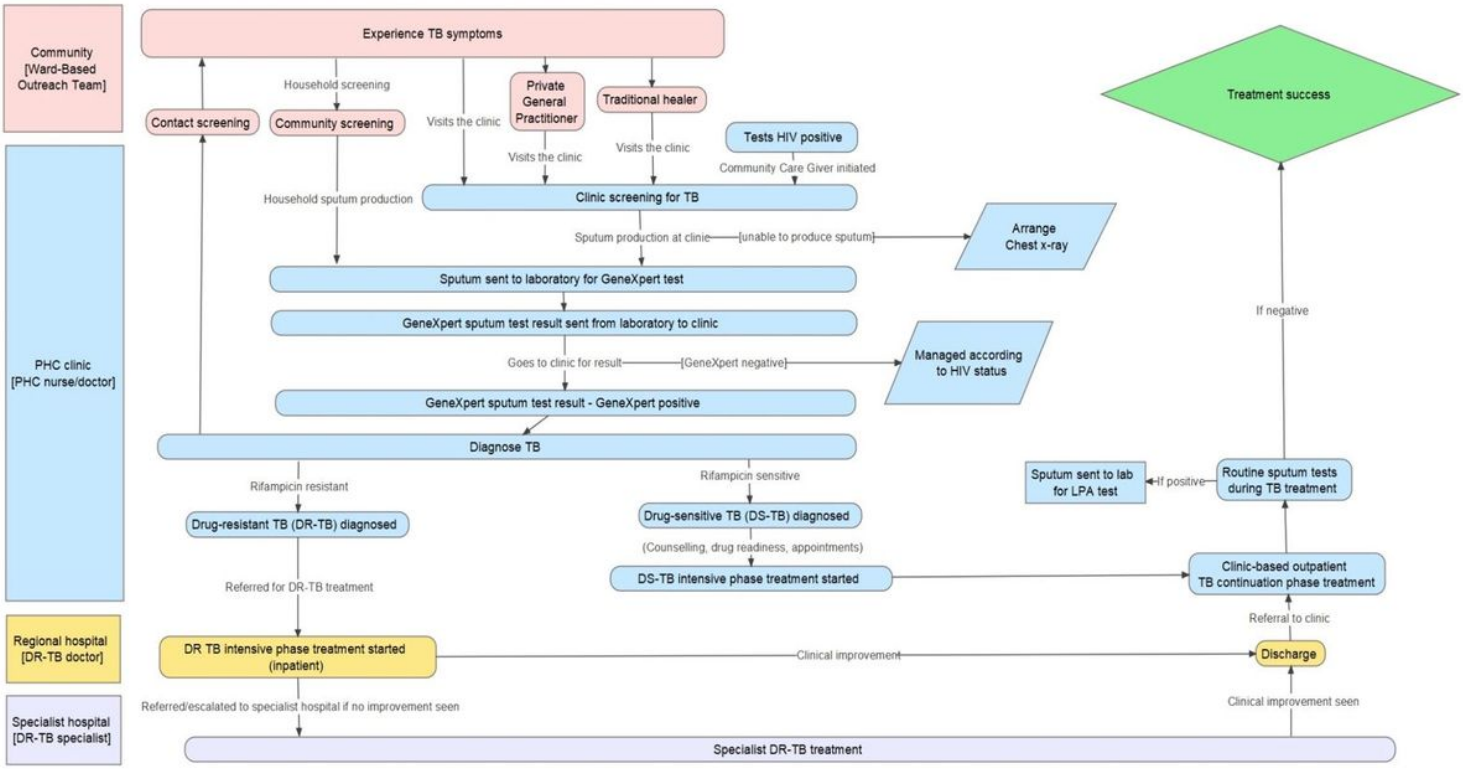

Figure 2

Process Map of TB Care.

Supplementary Files

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