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“I do not do what is said to be done”: Practice of directly observed therapy (DOT) for drug-resistant tuberculosis in the face of consistent tinkering – a qualitative study exploring healthcare providers’ perspectives in Ethiopia

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Keywords:	Tuberculosis < INFECTIOUS DISEASES, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Public health < INFECTIOUS DISEASES
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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	6,7
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	7
3. Occupation	What was their occupation at the time of the study?	7
4. Gender	Was the researcher male or female?	7
5. Experience and training	What experience or training did the researcher have?	7
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	N/A
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	N/A
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Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	5,7
<i>Participant selection</i>		
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12. Sample size	How many participants were in the study?	5

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<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	6
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	N/A
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	8
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	5,6
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	5
20. Field notes	Were field notes made during and/or after the inter view or focus group?	5
21. Duration	What was the duration of the inter views or focus group?	5
22. Data saturation	Was data saturation discussed?	5
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	N/A
Domain 3: analysis and findings		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	7
25. Description of the coding tree	Did authors provide a description of the coding tree?	N/A
26. Derivation of themes	Were themes identified in advance or derived from the data?	7
27. Software	What software, if applicable, was used to manage the data?	N/A
28. Participant checking	Did participants provide feedback on the findings?	N/A
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Results (9-13)
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Results
31. Clarity of major themes	Were major themes clearly presented in the findings?	Results (9-13)
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Discussion (13-16)

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Bridging the gap between policy and practice: a qualitative analysis of providers' field experiences tinkering with directly observed therapy in patients with drug-resistant tuberculosis in Addis Ababa, Ethiopia

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3 **Bridging the gap between policy and practice: a qualitative analysis of providers' field experiences**
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5 **tinkering with directly observed therapy in patients with drug-resistant tuberculosis in Addis**
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7 **Ababa, Ethiopia**
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ABSTRACT

Objectives: Drug-resistant tuberculosis (DR-TB) is one of the major public health threats in low-income countries such as Ethiopia. It is intertwined with larger socioeconomic and political factors that complicate its management and control. Whether directly observed therapy (DOT) is serving its purpose – better patient adherence and treatment outcome – still remains a debatable issue. To contribute to this discussion, the present study explored health workers' field experiences tinkering with directly observed therapy in patients with drug-resistant tuberculosis in Addis Ababa, Ethiopia.

Design: A qualitative study using in-depth interviews and focus group discussion.

Setting: Ten public healthcare facilities: eight health centres at Addis Ababa Health Bureau level and two TB specialised hospitals at the Federal Health Bureau level in Ethiopia

Participants: 18 healthcare providers working with DR-TB patients.

Results: Three findings emerged from the analysis. Firstly, the purpose of DOT is to ensure that patients go to healthcare facilities and swallow pills under the observance of a healthcare provider. Thus, its rigid application could lead to the emergence of more DR-TB. Secondly, DOT should be tinkered with and its practice improved by incorporating much counselling and health education, with more flexibility towards, and attentiveness of, patient context. Thirdly, there exists a family-like patient-provider relationship, and providers do understand their patients and empathise with them to provide better healthcare services.

Conclusion: If rigidly implemented, DOT could lead to more DR-TB – a problem DOT was invented to resolve. Front-line healthcare providers are sensitive to the tragic experiences of DR-TB patients and empathise with them. Thus, they do not strictly implement DOT and are willing to take any blame resulting from tinkering with it. It is high time to shape the practice of DOT for DR-TB patients, with meaningful contributions from front-line healthcare providers.

Strengths and limitations of the study

- The use of a qualitative methodology was suitable to explore experiences on DOT
- The use of two qualitative data collection methods (IDI and FGD) provided a comprehensive description of concepts.
- Inclusion of study participants from both primary- and tertiary-level health care facilities augmented the scope and depth of the study
- Thematic analysis and an inductive approach to coding facilitated the generation of in-depth accounts of health workers' perceptions and experiences.
- It was not possible to collect data outside of work hours, and this might have affected chances of having longer discussions with participants

BACKGROUND

The global health community has long faced issues interconnected with socioeconomic and political determinants of health.¹⁻⁶ Tuberculosis (TB) is a major infectious disease and a health security threat that the global health community has been struggling to eliminate.⁷ It causes around 10 million people to fall ill and 1.6 million to die every year.⁸ Drug-resistant TB (DR-TB) is a major public health threat and a critical challenge in the prevention and control of TB in many countries.⁹⁻¹¹ The problem is considerably more complex in sub-Saharan African countries where resources are scarce and political situations are unstable.¹²⁻¹⁷ The WHO 2018 Global TB Report¹⁸ showed that TB remains a leading cause of death in Africa. The continent accounts for a quarter of new TB cases and TB deaths worldwide, with 2.5 million people falling ill and 417,000 people dying from TB annually.¹⁸

The WHO, passing the ambitious End TB Strategy, envisions a world free of TB - zero deaths, disease and suffering due to TB by 2035.¹⁹ Previous attempts to eradicate TB gave a lesson that a more comprehensive and patient-centred approach is needed to reach such a goal. Pursuant to the 1993's

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3 declaration of TB by WHO as a global health emergency, WHO announced the Directly Observed
4 Therapy Short-course (DOTS) – a brand name for the WHO’s recommended strategy for TB control by
5 which all countries with a TB problem were to abide. The WHO launched the DOTS in 1995 and it
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7 “became the new mantra. This was what countries needed to integrate into their primary health
8 systems – it was to be the toolkit of their national control programmes”.²⁰ The strategy was composed
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10 of five distinct elements: political commitment; microscopy services; drug supplies; surveillance and
11 monitoring systems; the use of short-course regimens; and direct observation of treatment.^{21 22}
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13 However, this TB control strategy had a limitation: it did not take any account of DR-TB and, since the
14 problem of drug resistance in TB is often linked with poor implementation of DOTS, this rather
15 aggravated the conditions for multidrug-resistant (MDR) TB.²³ In order to address this gap, DOTS-Plus
16 was built upon the five elements of the DOTS strategy, taking into account the use of second-line anti-
17 TB drugs in MDR-TB endemic settings and thereby aiming to prevent the further development and
18 spread of MDR-TB.^{24 25} There are controversies surrounding the feasibility²⁶⁻²⁸ and effectiveness^{29 30} of
19 DOTS-plus, especially in resource-limited countries. In addition to psychosocial and economic
20 consequences resulting from an approx. two-year treatment course,³⁰ other challenges in
21 implementing DOTS-Plus include the need for more advanced diagnostic tools³¹ and the incidence of
22 adverse events associated with anti-MDR-TB drugs.³²

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42 The goal of creating a world free of TB relies on, among other measures, ensuring direct
43 observation of drug swallowing – Directly Observed Therapy (DOT). The strict implementation of DOT,
44 especially in sub-Saharan Africa and other resource-limited high-TB burden countries, renders itself
45 vulnerable to critical questions that relate to, for example, human rights and ethics.³³ In Ethiopia, a
46 country in the horn of Africa with over 100 million population, the national TB program³⁴ complies with
47 the global TB treatment strategy and therefore, there is no alternative TB treatment strategy to DOT.
48 According to the WHO 2018 report,¹⁸ TB treatment coverage in Ethiopia is 68%, which is minimum
49 even to accommodate the current DOT needs. The estimated percentage of MDR/RR TB cases is
50 significantly higher in previously treated cases [14% (6.7–25)] than new cases [2.7% (1.6–4.1)], which
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3 indicates that management of TB treatment under DOT is problematic in the country. There were 680
4 MDR/RR-TB and four XDR-TB laboratory-confirmed cases in the country in 2017¹⁸ while many more
5 were presumably left undiagnosed due to limited availability of healthcare services. Whether DOT is
6 serving its purpose – better patient adherence to TB treatment and thereby increased treatment
7 outcome – remains a debatable issue. Thus, this study aimed to explore healthcare providers'
8 perceptions on DOT and their experiences of tinkering with it in the context of DR-TB – “a major threat
9 to public health”.³⁵

20 METHODS

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23 The study employed a qualitative methodology as the aim of the study was to explore perceptions and
24 experiences. Hence, data were collected through in-depth interviews (IDIs) and focus group discussion
25 (FGD), using interview and FGD guides developed by all authors (box 1). A total of 18 participants were
26 purposively selected from eight healthcare centres at Addis Ababa Health Bureau level and two TB
27 specialised hospitals at the Federal Health Bureau level in Ethiopia. The two TB specialised hospitals
28 were the only health facilities in the Addis Ababa that that provide specialised DR-TB diagnosis and
29 care services. The remaining eight healthcare centres were located at varying distances in Addis
30 Ababa, which allowed for potentially different participant characteristics and perceptions. The
31 participants were approached directly, face-to-face after obtaining verbal approval from medical
32 directors at each healthcare facility. Participants were healthcare providers who are currently
33 employed in a healthcare facility, took university or college education in health-related discipline, had
34 worked and/or is working with DR-TB patients, and showed their willingness to participate by signing
35 an informed consent form. Healthcare providers who provide direct DR-TB services at TB clinic,
36 laboratory unit or pharmacy unit were considered eligible. The number of participants was determined
37 by the level of data saturation.^{36 37} The interview was piloted on a clinical nurse to determine the clarity
38 of the questions and to gain experience in conducting an IDI. None of the information from the
39 pretesting was used for the study. Eighteen IDIs were conducted, followed by one FGD consisting of
40 five individual members selected from the in-depth interviews based on their willingness and
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availability to participate. On average, each IDI took 45-55 minutes and the FGD lasted three hours. Based on consent from participants, all IDIs and the FGD were audio-recorded, with the exception of one participant who preferred that the interviewer takes notes, instead of recording the interview.

Box 1: Summary of the IDI and FGD guides and probes

Summary of the IDI guide and probes

Working in DR-TB care and treatment

- How do you describe your work in general?
- What do you think are your important roles/responsibilities in connection with working with DR-TB patients?
- In your opinion, and based on your experience, what do DR-TB patients need or expect from healthcare providers?

Practicing DOT

- How would you define DOT, both objectively and subjectively?
- How do you practice DOT in connection with DR-TB care and treatment?
- What does it mean to be flexible in providing medical care?

Patient-provider relations

- How do you describe the relationship between patients and healthcare practitioners in general?
- Have you ever imagined yourself being a DR-TB patient? If so, how did that feel?
- What are the challenges DR-TB patients face?
- What does it mean to understand a patient?
- What does it take to understand a DR-TB patient?

Summary of the FGD guide and probes

Practicing DOT

- How would you define DOT?
- How do you practice DOT in connection with DR-TB care and treatment?

- What does it mean to rigidly apply DOT? Are there any strong or weak sides of that?
- What makes the practice of DOT better?

Patient-provider relations

- How do you describe the relationship between patients and healthcare practitioners in general?
- What does it mean to understand a patient?

Data were collected between August and October 2017. The participants themselves decided the place and time to conduct the IDIs and FGD and thus, data were collected in their workplace. The language of communication with the participants was Amharic, which is the working language in the selected healthcare facilities and the mother tongue of the data collector (KMM). As to the impression of the data collector (KMM), the absence of language and cultural barriers helped to build rapport with participants, thereby helping them express themselves more comfortably and openly.³⁸ Moreover, the data collector (KMM) reported that the FGD was very lively and the participants were highly concerned about the topic that they wanted to hold a three-hour discussion, refusing to take a break in between.

In order to ensure anonymity and confidentiality, the participants' names were replaced by pseudonyms. The data collector (KMM) kept the audio files in safe storage, where none other could access, and deleted them at the end of the study.

Data management and analysis

We used an inductive approach to analyse the data. Data analysis started during fieldwork so as to identify concepts and gaps early and to continuously explore them in depth throughout the data collection process. We used Braun and Clark's reflexive thematic analysis framework, which involves six phases of analysis – familiarization, initial coding, theme construction, reviewing themes, defining themes and producing the report.³⁹ We analysed the data manually using MS word. The first author (KMM) openly coded the data line-by-line to identify concepts and to build themes. Trustworthiness -

credibility, transferability, dependability, confirmability - was ensured through different ways. The participants were selected based on criteria to ensure that they provide relevant and credible information. All authors were engaged with the data and contributed meaningfully throughout the data analysis. Confirmability was demonstrated by identifying themes and using illustrative quotes.

The data collector (KMM) is a male who studied social work and international community health. During the study period, he was a student taking the master's programme (MPhil) in International Community Health at the University of Oslo, Norway. He received trainings in qualitative research methods and interview techniques and has a special interest in critical perspectives in global health.

Patient and public involvement

Patients and the public were not involved in the design or planning of the study.

RESULTS

This study included 18 participants (table 1). Findings pertaining to the themes developed from the qualitative data are presented below with thick descriptions – detailed descriptions and interpretations - and illustrative quotes. Three broad themes emerged from the analysis.

Table 1: Demographic characteristics of study participants

Name	Sex	Profession/title
(anonymized)		
P1	Female	Clinical nurse
P2	Female	Clinical nurse
P3	Female	Lab technologist
P4	Male	Health officer
P5	Male	Health Officer

P6	Male	Clinical nurse
P7	Male	Health Officer
P8	Female	Clinical nurse
P9	Male	Clinical nurse
P10	Female	Clinical nurse
P11	Male	Clinical nurse
P12	Male	Clinical nurse
P13	Female	Clinical nurse
P14	Female	Health Officer
P15	Male	Clinical nurse
P16	Male	Clinical nurse
P17	Male	Lab technologist
P18	Male	Clinical nurse

Defining DOT

This theme discusses healthcare providers' understanding of what DOT is. For the participants, DOT is merely a medical supervision routine in which TB patients swallow pills with the attendance of a healthcare provider: *"DOT tells you to go to patients, make them open their mouth and make sure that they swallow the pills."* (P13, FGD); *"DOT means the patient goes to the health worker until the day he/she finishes the drugs."* (P7, IDI). For the healthcare providers, practicing DOT as it is means nothing more than to see, and make sure, that patients swallow pills. The centre of focus is "swallowing pills", not patient situation. Due to this, the participants said, there is no counselling in practicing DOT: *"DOT doesn't have counselling. DOT and counselling are two different things."* (P13, FGD). Unlike

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3 defining DOT that seemed to be easy, however, the participants stated that evaluating whether DOT
4 is effective or not is a difficult task. Notwithstanding the rigidity of DOT and the unpleasant experiences
5 it could inflict upon patients, as the participants noted, DOT has benefits both to individual patients
6 and to the community where they live in: *“There are of course some careless patients who must come
7 to us and take their drugs here. For example, if such patients take pills at home, they don’t keep the
8 right time and dosage. So in such cases, I support DOT.” (P4, FGD); “the patient has an obligation to
9 come daily to the healthcare centre. If the patient refuses to come and quits treatment, who is going
10 to be the looser. It is our community.” (P5, FGD).* However, on the other hand, some participants during
11 the FGD argued that if rigidly implemented, DOT could lead to more DR-TB – a problem which DOT was
12 invented to fight: *“...I think DOT is one cause for the spread of drug resistant TB.” (P6, FGD). “This (DOT
13 being one possible cause for the spread of DR-TB) is true. DR-TB patients are aggressive and sensitive
14 due to drug side effects and other reasons. So if you treat your patient according to the DOT principle,
15 like by saying ‘take these pills, open your mouth and swallow them’, you make things worse.” (P13,
16 FGD)”. Another participant who said that focusing on the DOT task creates a problem echoed this
17 argument: *“Patients miss the day when they will finish their drugs and no longer come to us daily. So
18 health workers should be flexible on this. For example, if your patient says ‘I am not coming tomorrow
19 because I have a funeral to attend’, then you have to give tomorrow’s dose for the patient to take it at
20 home. But if you say ‘DOT, DOT’ and be stubborn, the patient will disappear.” (P8, FGD).* There was
21 consensus, through both verbal and nonverbal cues, among participants during the FGD that the rigid
22 application of DOT could lead to more drug resistance in tuberculosis; that focusing on pill-swallowing
23 burdens patients, pushes them away from TB treatments and makes things worse. Being the most
24 striking result to emerge from the data, this finding, instead of leading to the conclusion that DOT is
25 one of the causes of DR-TB, renders an indication that there is a need to improve the practice of DOT
26 in Ethiopia, so that it serves the purpose it was invented for.*

Tinkering and augmenting DOT

Participants in this study emphasised the need to tinker, to compromise and improvise – a medical practice the result of which is an augmented, better DOT practice. The participants argued that it is important to be sensitive to the situation at hand and tinker with care accordingly, instead of committing oneself to rigidly follow DOT: *“What I normally do is what my mind tells me. So I just follow my gut feeling. I do not do what is said to be done.”* (P2, FGD). The healthcare providers see DOT as a treatment strategy that lacks counselling component and therefore, argue that DOT needs to be tinkered with: *“We cannot implement DOT as it is. We give counselling and health education first. So we do not have patients who hide pills, go to the woods and throw them.”* (P14, IDI). All participants agreed with the statement that good counselling and health education to both DR-TB patients and their relatives should accompany DOT in order to increase its effectiveness. Good counselling, according to the participants, will not only make the practice of DOT more beneficial, but also help to reduce severe psychological consequences amongst DR-TB patients who suffer from both the disease and its exhaustive treatment: *“imagine how unbearable it is for DR-TB patients to commute to healthcare centres for two years. They wish to die than live like this.”* (P4, IDI); *“I had one MDR-TB patient. One day he came to me, looking hopeless and with a very sad face, and said ‘for the last three days, I have not taken any of those pills you gave me. I have given up and I am ready to die.’ This guy fathers two children and has many responsibilities. After much counselling and support from his relatives, it is good that he resumed treatment”* (P6, IDI). It is known that DOT is invented to increase adherence of TB patients to TB treatment and thereby prevent any possible complications. However, the participants noted that DR-TB patients experience treatment fatigue and, as a result, choose to face the consequences of non-adherence. Performing mundane, everyday healthcare tasks, the healthcare providers see the need to negotiate care; to focus on the needs and challenges of the patient whom, after all, the very existence of healthcare is to serve. Therefore, sometimes, healthcare providers give patients the right dosage of DR-TB drugs for them to keep and take at home. Arguing for a patient-centred and understanding-based approach, the participants also mentioned that they are willing to take any blame resulting from flexibly implementing DOT: *“Health workers are blamed*

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3 *for giving patients drugs to take them at home instead of here in front of us. But patients come daily*
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5 *to us and we have to understand that this is tiresome for them. We need to be careful about how we*
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7 *implement DOT. It should not be like a¹“command post” (laughter). Many people who live in this area*
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9 *have low socioeconomic status and it is unfair to make them come every day and take drugs, even*
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11 *though that is what the health authorities tell us to do. So you need to communicate with your patients*
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13 *and understand each other. This is how I have helped many patients to recover. Medication is not a*
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15 *military command, it is rather about an understanding between the patient and the healthcare*
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17 *provider.” (P2, IDI).*
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20 21 22 “We are family”

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24 In addition to defining what DOT for them is, and alluding to ways in which the practice of DOT
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26 could be improved, the participants reflected on the degree of relationships they have with their
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28 patients. Elaborating this, they reported that they understand their patients’ situations, see them as
29
30 friends and families and give them their best. They indicated that the kind of relationship that exists is
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32 more than that of between a healthcare provider and a patient: *“These patients do not take the drugs*
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34 *because they like them. When I treat my patients, I always imagine myself as a patient. I do my very*
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36 *best, especially on counselling. There was an old lady in the age of 50’s who was one of my MDR-TB*
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38 *patients. She didn’t not want to follow treatment properly. ...One day, I took off my white coat, sat with*
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40 *her, held her hands and said ‘so now, be my mother and listen to what I am saying.’ She was happy to*
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42 *hear that and said ‘ok my daughter’. So I told her in a way she could understand me, and finally she*
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44 *agreed and said ‘God bless you my daughter’. We are family. So we need to understand our patients*
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46 *and give them good counselling.” (P2, IDI).* All participants mentioned the importance of understanding
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48 DR-TB patients in order to increase treatment effectiveness. The inquiry to know to what extent the
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50 health workers understand their patients started with an exploration of their empathy for their
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57 ¹The word “command post” was used to refer to a government body that oversees the state of emergency
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59 that was on effect from October 2016 to August 2017 public protest against the government. Freedom of public
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speech, gatherings, access for media, etc were restricted. Using the word “command post” was common by the
public whenever reference to the military force was made.

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3 patients: *"I have one MDR-TB patient and giving her injection every day is by itself painful for me.*
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5 *Taking injection even for one day is not easy. When that girl comes and says 'when am I going to take*
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7 *out this mask?' I feel terrible. We know and share the pain of our patients (deep breath and eyes filled*
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9 *with tear)." (P9, IDI); "Whenever I give injection to the patients, I ask myself 'what if I were them?'"*
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11 *(P1, IDI). The healthcare providers reported that they have strong level of empathy and share their*
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13 *patients' pains. Not only do they know the patients' situation and empathise with them, but the*
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15 *participants also said that they feel the pain. Moreover, the participants stated that they face a*
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17 *dilemma in decision-making. In MDR/XDR-TB wards, admitted DR-TB patients are not allowed to freely*
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19 *go out into the community; they are strictly isolated. In a situation such as this, healthcare providers,*
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21 *since they are attentive to their patients' conditions and share their emotional sufferings, find it*
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23 *difficult to comply with the need to strictly isolate patients: "These patients who are admitted here*
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25 *miss the outside world. ...If you let them out, they will infect others. What can you do? This dilemma is*
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27 *aching." (P18, IDI). This, in addition to putting them in dilemma to make a decision on whether they*
28
29 *should permit patients to, say, go out and buy something, puts the healthcare providers in a stressful*
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31 *situation. However, they did not report whether this has a negative impact on their daily work. The*
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33 *finding here is rather different: looking at patients' suffering shapes the health workers' perception of*
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35 *DR-TB and the way they treat their patients, the effect of which is better and patient-centred*
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37 *treatment: "When you work on DR-TB, you realise that patients and healthcare providers are like*
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39 *families. So you have to work from the bottom of your heart." (P3, IDI).*
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47 DISCUSSION

48 Our findings indicate that the "definition" and "practice" of DOT could be discussed separately.
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50 Participants' understanding of DOT explored in the current study corroborates with the notion that
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52 DOT is merely a directly observed and supervised drug swallowing the application of which requires
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54 great caution.^{35 40 41} The definition of DOT provided by our participants as a medical practice whereby
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56 TB patients take their drugs with the attendance of a care provider, coincides with existing
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58 understandings of DOT. For example, the WHO mentions that DOT means "watching patients taking
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3 their medications"⁴² and, likewise, Ethiopia's national TB programme³⁴ states: "one of the most
4 important components of DOTS is the direct observation of treatment, which means that a health
5 worker must watch the patient taking each dose". On the other hand, our participants' understanding
6 of the practice of DOT in Ethiopia differs from that which the WHO recommends. The participants in
7 the current study asserted that DOT, unless compromised, does not have built-in flexibility and rigidly
8 focuses on pill-swallowing. As the purpose of DOT is to ensure that patients swallow drugs,⁴³⁻⁴⁵ it is
9 easy to overlook patient context unless the healthcare provider chooses to empathise with the patient
10 by, for exempling, posing such question: Who knows what the patient eats before swallowing the DR-
11 TB tablets? What if it is unacceptable for the patient to take the tablets on some days? How much
12 sacrifice does the patient pay to commute to a healthcare centre every morning? In the eyes of the
13 suffering patient, could adhering to DR-TB treatment be worse than death?

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28 On the contrary, the WHO indicates that sensitivity to patient needs and flexibility – for
29 example, in where the TB patient receives treatment – are integral parts of DOT practice.^{42,46} However,
30 the WHO⁴⁶ states that such flexibility is subject to some stipulations: 1) a treatment supporter or
31 observer, whom the national tuberculosis control programme (NTP) is responsible to train and
32 monitor, must be present when the TB patient takes the drugs; 2) "the drugs should remain with the
33 treatment supporter and be given to the patient only at the time of ingestion". Similarly, Ethiopia's
34 "national TB program recommends supervision of treatment to be made by a trained health worker,
35 Health extension worker or a trained TB treatment supporter".⁴⁷ This evidence shows that the burden
36 of TB treatment should not fall on the patient alone, but rather should be shared. However, sharing
37 this burden – for example, identifying and training treatment supporters for each patient to take
38 treatments at home, or ensuring family and community support to the TB patient – requires resources
39 that pose a challenge in resource-poor countries such as Ethiopia.^{34,48,49} In the same vein, the following
40 text from the national TB programme provides an insight into the challenges in DOT practice as
41 explored in the current study.

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3 “During the initial phase of treatment, which always contains rifampicin, the patient must take
4 the drugs in front of the health worker who is responsible for verifying that the patient
5 swallows all of the prescribed drugs every day. If the patient lives, or can be housed, near a TB
6 clinic, he or she must attend every morning to take the drugs. If the patient lives near a health
7 post with staff that are trained and acknowledged to be capable by the TB clinic coordinator,
8 treatment can be delivered by this health post staff; the follow-up of the patient must continue
9 to be done by the TB clinic, and health post staff must be closely supervised.If directly
10 observed treatment cannot be provided on an out-patient basis, or if the condition of the
11 patient requires it, the patient should be hospitalized during the whole of the initial phase of
12 treatment, but this is quite costly.”³⁴

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26 The accounts of DOT that emerged from the findings show that rigidity in the practice of DOT
27 could serve against the very purpose DOT was invented to accomplish. This finding accords with what
28 Van Deun and Rieder⁴⁰ argue: “DOT when blindly and carelessly applied, for example obliging the
29 patient to attend a clinic daily just to be watched while swallowing his/her drugs, will often have the
30 opposite effect”. Moreover, our study coincides with, and responds to, a similar study conducted in
31 India, which questions the necessity of DOT as a pillar of DR-TB treatment and indicates the need to
32 further study the ‘validity’ of DOT in other settings.⁴⁵ On the contrary, the findings of the current study
33 do not support a systematic review of retrospective observational cohort studies⁴⁶ which indicates that
34 DOT might lead to MDR-TB treatment success. This difference could be, among other potential
35 explanations, due to the fact that the current study exclusively employed a qualitative approach to
36 explore subjective experiences.

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51 This study shows that the relationship between patients and healthcare providers is
52 comparable to that found in a family. As DR-TB is a chronic condition, healthcare providers and patients
53 spend longer periods together and as a result, disease and biography merge into each other. In relation
54 to this, we have also identified a high level of empathy characterising the way healthcare providers
55 communicate with, and treat, DR-TB patients. The participants argued that counselling and health
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3 education – which they believe are not part of the DOT strategy – are very important to provide
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5 effective treatment to DR-TB patients. This relates to the nurses in Peru who reported that emotional
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7 support and counselling to MDR-TB patients is necessary to cure them.⁵⁰ Due to the high level of
8
9 empathy, healthcare providers find it easy to understand their patients when they refuse to adhere to
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11 treatments. This finding contradicts the conventional treatment modality in which a significant space
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13 between the health professional and the patient exists. Such positive relationships explored in our
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15 study result in a better, patient-centred and flexible DOT practice. The findings are contrary to some
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17 literature^{33 51} which state that healthcare providers lose sight of patient context due to DOT. However,
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19 our study did not include DR-TB patients' perspectives and therefore, the findings cannot be
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21 extrapolated to patients. Nonetheless, the findings support evidence from previous studies^{43 49 52 53}
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23 which assert that the rigidity of DOT burdens patients, negatively affects patient adherence, and
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25 worries healthcare providers, thereby negatively affecting TB treatment and control.
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31 The healthcare providers in this study stated that they empathise with DR-TB patients and
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33 tinker with DOT to provide health service that they believe is patient-centred. This finding is in line
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35 with other studies^{45 54 55} that present healthcare practices in which healthcare providers do not strictly
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37 implement treatment guidelines. An effective DR-TB treatment, according to the participants, requires
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39 placing DOT in context and finding the most suitable arrangement that empowers the DR-TB patient.
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41 This reflects what Mol, et al.⁵⁶ mean by “perfect” care and “good” care: the perfect care is given
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43 “without considering the world in which the person lives” whereas the good care is “an arrangement
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45 of people and things that is a compromise”. Providing “perfect care” focuses on impeccably complying
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47 with guidelines whereas providing “good care” focuses on the patient. The results show that
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49 improvising medicine could happen due to different reasons. Firstly, healthcare providers tinker in the
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51 absence of enough resources and reading materials in place, including global and national DR-TB
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53 guidelines, to up-date and improve their clinical knowledge on DR-TB. Thus, improvisation becomes an
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55 ‘imposed’ practice; it becomes a must.^{57 58} Secondly, on the other hand, healthcare providers tinker
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57 because they object to the idea of accepting and venerating DOT as a pillar strategy. Regardless of the
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3 availability of resources, healthcare providers chose to place DR-TB patients at the centre of the entire
4 healthcare concept and accordingly adjust every action of care. Thus, the practice of tinkering becomes
5 an 'initiated' practice.⁵⁹ Rather than being the last option, tinkering is an important and a preferable
6 practice for a better treatment outcome. In fact, this is a good opportunity for the Ethiopian
7 government to elevate the fight against DR-TB, optimizing the healthcare providers' efforts and
8 enthusiasm for improved care. Resources on DR-TB, including training for healthcare providers, need
9 more attention from government and global partners more than ever to tackle this deadly disease.

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19 One strength of this study was the use of a qualitative methodology to explore healthcare
20 providers' perspectives on the practice of DOT in DR-TB treatment in the study setting. By employing
21 two qualitative data collection methods (IDI and FGD), it attempted to provide a comprehensive
22 investigation of the topic. Recruiting participants from both primary- and tertiary-level health care
23 facilities contributed to having a wide perspective on the topic. The use of inductive coding facilitated
24 an in-depth understanding of the research question. Moreover, the data collector is from the same
25 cultural background as that of the participants' and the participants' working language is his mother
26 tongue, thereby making participants more open to discussions. This study has also limitations.
27 Following a qualitative approach, participants were purposively selected and there might be selection
28 bias as a result. In addition, data were collected during work hours and this might have limited chances
29 of having longer discussions and richer data.
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45 CONCLUSIONS

46 This study explored healthcare providers' perspectives on the daily practice of DOT and the
47 challenges therein. It has shown that there is a need to embrace tinkering in DR-TB treatment and
48 thereby enhance the practice of DOT among healthcare providers. If rigidly implemented, DOT could
49 lead to more DR-TB – a problem DOT was invented to fight. The findings have significant implications
50 for the rethinking of rigidly implementing guidelines. The findings of this research could be of interest
51 to scholars involved in challenging and questioning mainstream approaches to healthcare and in
52 echoing the voices of health workers, thus emphasising the need to incorporate their perspectives in
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3 designing healthcare guidelines and policies. It is high time to shape the practice of DOT for DR-TB
4 patients. More research drawing perspectives from disciplines such as medical ethics, human rights
5 and anthropology could further explore the challenges in integrating and implementing DOTS for DR-
6 TB within fragile healthcare systems wherein resources needed to ensure a patient-centred treatment
7 are limited. We suggest that more DOT training should be given to healthcare practitioners, in line with
8 their specific role in DR-TB care, to bring about positive changes to. The Ethiopian government needs
9 to strengthen its collaboration with global partners to leverage greater resources needed for the DR-
10 TB care and treatment program.

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23 that participated in this study, as well as the Addis Ababa City Administration Health Bureau.

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draft. All authors (KMM, CG and TM) reviewed the paper, provided comments and approved the final
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3 Data availability statement No data are available.
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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	6,7
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	7
3. Occupation	What was their occupation at the time of the study?	7
4. Gender	Was the researcher male or female?	7
5. Experience and training	What experience or training did the researcher have?	7
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	N/A
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	N/A
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	7
Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	5,7
<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	5
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	5
12. Sample size	How many participants were in the study?	5

13. Non-participation	How many people refused to participate or dropped out? Reasons?	N/A
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	6
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	N/A
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	8
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	5,6
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	5
20. Field notes	Were field notes made during and/or after the inter view or focus group?	5
21. Duration	What was the duration of the inter views or focus group?	5
22. Data saturation	Was data saturation discussed?	5
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	N/A
Domain 3: analysis and findings		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	7
25. Description of the coding tree	Did authors provide a description of the coding tree?	N/A
26. Derivation of themes	Were themes identified in advance or derived from the data?	7
27. Software	What software, if applicable, was used to manage the data?	N/A
28. Participant checking	Did participants provide feedback on the findings?	N/A
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Results (9-13)
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Results
31. Clarity of major themes	Were major themes clearly presented in the findings?	Results (9-13)
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Discussion (13-16)

Once you have completed this checklist, please save a copy and upload it as part of your submission. When requested to do so as part of the upload process, please select the file type: **Checklist**. You will NOT be able to proceed with

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