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A comparative analysis of the profile and treatment outcomes of tuberculosis patients managed at the community and primary health care facilities in Botswana

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ARTICLE INFO	A B S T R A C T
Keywords: Direct observation therapy Treatment cure Perception of service	Background: Successful treatment of Tuberculosis (TB) is necessary for mitigating and averting millions of deaths annually. This study compared the profiles and measured the association between patients, health system-related factors, and TB treatment outcomes of patients managed through the community tuberculosis care model with those managed in primary health care settings. <i>Methods:</i> A retrospective multicenter cross-sectional study was conducted in six districts in Botswana. Patient's records were reviewed using a data extraction sheet, and data not captured on registers were obtained using a
	structured questionnaire. <i>Results:</i> Three hundred and twenty-four TB patients were sampled. Most participants (84 %; n = 273) were receiving community-based DOT. Patients with moderate TB knowledge (OR 5.3,955 CI 1.01–27.7), good perception of TB care (OR 11, 95 % CI 1.29–94.0), were more likely to enroll for community DOT and achieve treatment cure. Those in businesses (OR 3.85 95 %CI 1.10–22.6), always had treatment available (OR 3.66, 95 % CI 1.12–11.4), never drank alcohol (OR 2.11, 95 %CI 1.06–4.19), used their vehicle (OR 2.11.95 %CI 0.99–4.48) were likely to enroll for community DOT.
	<i>Conclusion:</i> A patient-specific education program and continuous improvement practices to increase patient TB knowledge and satisfaction should be implemented at all levels to improve treatment outcomes.

1. Introduction

Tuberculosis (TB) remains one of the top infectious diseases globally with an estimated 10.6 million people falling ill with TB worldwide in 2021[1]. The disease burden varied substantially among countries, with a global average of approximately 137 cases per 100 000 population. The TB incidence rate increased by 3.6 % between 2020 and 2021, reversing a decline of approximately 2 % per year for most of the past two decades. Countries in the World Health Organization (WHO) African region had the highest TB incidence rates, accounting for 23 % of the global TB burden[1]. The African Region had the highest TB/HIV coremorbidities exceeding 50 % in some areas of southern Africa[1]. The estimated number of deaths from TB increased between 2019 and 2021, reversing years of decline between 2005 and 2019 with 1.6 million people dying from TB, inclusive of 187 000 people with HIV in 2021[1].

Botswana remains enlisted in the 2021–2025 30 high TB/HIV burden countries[2], with an estimated incidence rate of 235/100,000, TB-related death rate of 32/100 000 among the HIV negatives, 50/100 000 among the HIV-positive, and treatment coverage of 39 % in 2021 [3]. The overall treatment success rate for the new and relapse cases was 78 %, with 76 % among HIV-coinfected patients[3]. Strong policies and supportive structures, increased research and innovation, integrated patient-centered treatment and prevention are the focal points of the Botswana national tuberculosis control program strategic plan of 2018–2023[4]. Through implementation of these strategies, the TB incidence was expected to drop to 234 per 100,000 in 2020 and 198 per

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Abbreviations: CHW, Community health worker; DOT, Directly Observed Therapy; CBDOT, Community Based Directly Observed Therapy; FBDOT, Facility Based Directly Observed Therapy; OR, Odds Ratio; AOR, Adjusted Odds Ratio; CI, Confidence Interval; IRB, Institutional Review Board; TB, Tuberculosis; WHO, World Health Organization.

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100,000 in 2022 [4]. Additionally, it was projected that mortality rates for HIV-negative TB patients will drop to 16 per 100,000 in 2020, while TB/HIV death rates were predicted to drop to 32 per 100,000. Treatment success and treatment coverage of \geq 90 percent were also anticipated by 2020[4]. However, all these targets have not been achieved.

The community TB Care (CTBC) initiative, an integrated patientcentered treatment and prevention strategy was introduced in Botswana in 2004 as a response to the significant rise in the incidence and burden of TB as a consequence of the HIV/AIDS epidemic in the country[5]. However, this approach was met with only limited success; cases have continued to increase with detection rates and treatment success rates declining rapidly and remaining below national and global targets, thus resulting in increased healthcare expenditure and poor quality of life for the victims[6]. Therefore, this study aims to compare profiles of TB patients managed through the community Tuberculosis care model with those managed in primary healthcare settings and measure the association between the patients, health system-related factors, and TB treatment outcomes with a view to proposing sustainable, effective strategic solutions to strengthen the program.

2. Methods

2.1. Study design and setting

This retrospective multicenter cross-sectional study was conducted in six health districts in Botswana (Boteti, Kweneng west, Kweneng East, Southern, Moshupa and Lobatse).

2.2. Selection of study population

The study population included drug-susceptible pulmonary TB Patients aged 18 years and above upon diagnosis. Diagnosed in selected PHC facilities between 1st January to December 31st, 2019. TB Patients who did not complete treatment duration and those with missing outcomes were excluded.

2.3. Sampling

A multistage sampling strategy was used. In the first step, districts were divided into two categories that represented the nation's low- and high-performing successful treatment outcomes. Three districts in each category were then chosen at random. High performing districts included the Boteti district (89 % success rate), Kweneng West (87 %), and Southern (76 %). The three low performing districts sampled were Kweneng East, Moshupa, and Lobatse (respectively with 65 %, 57 %, and 51 % treatment success rates) [7].Two villages from each district were randomly selected with all TB facilities chosen for data collection. At a patient level, all smear-positive pulmonary TB patients registered within the selected facilities were eligible.

2.4. Data collection procedure

A data extraction sheet was utilized to examine 472 patient records and gather clinical data.

Variables measured: Treatment outcomes, Diabetes mellitus status, HIV status.

Following exclusions, 324 participants included in the study were located using their address and contacts from the facility registers. A self-administered structured questionnaire was then utilized to retrospectively gather data not found on the registers.

Variables measured: The questionnaire had two parts, the first part consisted of demographic questions like age, gender, marital status, educational level, employment status, smoking status, alcohol drinking status, distance to the facility, mode of transport, psychosocial support, medication availability, and stigma. Second part had knowledge, stigma, and perceptions of service questions.

2.5. Outcome measures

Treatment cure and treatment completion.

2.6. Statistical analysis plan

Data were analyzed using STATA software version 14.0. Descriptive analysis was employed to describe characteristics of TB patients using frequencies, proportions, and numerical summary measures. The strength of the association between the predictor and outcome variables was assessed using bivariate and multivariate logistic regression. Variables with a p-value < 0.25 in the bivariable analysis were entered into the multivariable analysis. A crude and adjusted odds ratio (OR) with a corresponding 95 % confidence interval (CI) were computed and reported. Statistical significance was declared at p-value < 0.05.

Ethical approval

The study obtained ethical approval from the Biomedical Research and Ethics Committee of the University of KwaZulu-Natal in South Africa dated March 03, 2022 (Protocol reference number: BREC/ 00003225/2021) and the Botswana Health Research and Development Division dated December 16, 2021 (reference number: HPDME 13/18/ 1) before the study was conducted. Permission was obtained from each study site.

Informed consent

The consent form was read and signed by study participants who could read, and those who couldn't were allowed to bring a trusted relative or close friend to read and explain it to them while the investigator documented the process. The consent form gave contact information for the researcher, supervisor, and the research ethics committees that approved the study as well as a detailed description of the study purpose. The anonymity and confidentiality of the data collected were always assured.

3. Results

Three hundred and twenty-four pulmonary TB patients were enrolled in this study. Most of the participants were receiving community-based direct observation therapy (CBDOT 84 %; n = 273) with sixteen percent(n = 51) receiving facility-based direct observation therapy (FBDOT). (Fig. S1).

The study population had a mean age of 40 years (Standard deviation (SD):16.8) and a median age of 43.65 years (IQR: 30-53 years). There was no statistical difference (P = 0.653) between the mean ages for patients who were on CBDOT (Mean 43.45, SD:16.53) and FBDOT (Mean 44.71, SD:18.59). (Table S1).

Males made up more than half of the respondents in both cohorts; CBDOT (58.6 %; n = 160) and the FBDOT (52.9 %; n = 27), both of which showed comparable marital status results, with married people making up the largest population (92.7 %; n = 253 and 86.3 %; 44 respectively) and divorced patients making up the smallest population (1.8 %; n = 5 and 0 %, respectively). Secondary education also dominated the educational spectrum, accounting for 54.6 % (n = 149) of those on CBDOT and 54.9 % (n = 28) of those receiving FBDOT. Similar numbers were seen across all employment status categories, with more than 50 % of participants in both community (55.7 %; n = 152) and facility-based DOT (58.8 %; n = 30) being unemployed.

Non-smokers made up more than half of the respondents in both cohorts; CBDOT (62.6 %; n = 171) and FBDOT (54.9 %; n = 28). Moreover, less than half of the respondents in both cohorts reported to have never drank alcohol before (CBDOT 46.9 %; n = 128 and FBDOT 33.3 %; n = 17). More than 7/8(n = 250) of the CBDOT respondents travelled less than 5 km to access health facilities, with walking being

the most popular form of transportation (74 %; n = 202). Similar patterns were reported among individuals using FBDOT, where 92.2 % (n = 47) travelled less than 5 km and 72.5 % (n = 37) walked to access the health facility.

While FBDOT respondents primarily received counselling (49 %; n =25) and family and community support (41.2 %; n = 21), most CBDOT respondents (74.7 %; n = 204) reported receiving psychosocial support from the family and community. TB Medication all-time availability was reported by 97.1 % (n = 265) and 90.2 % (n = 46) among CBDOT and FBDOT respectively. Nearly half (46.2 %; n = 126) of the respondents in CBDOT had HIV with 1.5 % (n = 4) having diabetes as comorbid conditions. None of the FBDOT cohort's 37.5 % (n = 19) HIV positive members had diabetes mellitus. Poor TB knowledge was reported by half of the respondents in both CBDOT (50.5 %; n = 138) and FBDOT (51 %; n = 26) groups, while good knowledge was least common with 1.1 % (n = 3) and 5.9 % (n = 3), respectively. In both treatment approaches (CBDOT 60.1 %; n = 164 and FBDOT 52.9 %; n = 27), more than half of the patients experienced moderate stigma, whereas more than threequarters of CBDOT and FBDOT (82.1 %; n = 224 and 80.4 %; n = 41, respectively) reported having excellent service perceptions. Individuals receiving therapy under the community model had a higher chance of being cured (21.2 %; n = 58) than those receiving treatment in the facilities (15.7 %; n = 8). (Table S2).

3.1. Factors associated with TB treatment outcomes

3.1.1. Treatment cure versus treatment completion

On bivariate analysis, the study showed moderate TB knowledge (OR 1.72, 95 %CI 0.98–2.99, P < 0.05) to be positively associated with cure rate compared to treatment completion. Whilst divorced patients (OR 0.15, 95 % CI 0.21–1.00, P < 0.05), and diabetic (OR 0.24, 95 % CI 0.13–0.44, P = 0.00) were significantly less likely to be cured compared to treatment completion.

On multivariate analysis, moderate TB knowledge maintained a positive association with Treatment cure (AOR 1.86, 95 % CI 0.98–3.50, P = 0.05), good perception of service (AOR 3.72, 95 % CI 0.98–0, P = 0.02), an excellent perception of service (AOR 9.29, 95 % CI 0.-, P = 0.03) also indicated a positive significant association with treatment cure. CBDOT showed non-significant increased odds for treatment cure (AOR 1.09, 95 % CI 0.47–2.56) while patients with diabetes maintained a significantly less likelihood to be cured (AOR 0.23 95 % CI 0.12–0.42, P = 0.00) (Table S3).

3.1.2. Community DOT versus facility TB DOT

On bivariate analysis, patients who ran their businesses (OR 3.85, 95 % CI 1.10–22.6, P = 0.03), always had TB treatment available (OR 3.66, 95 % CI 1.12–11.4, P = 0.03), never drank alcohol (OR 2.11, 95 % CI 1.06–4.19, P = 0.03), those who used their vehicle to a treatment facility (OR 2.11, 95 % CI 0.99–4.48, P = 0.05), had good TB knowledge (OR 5.3,955 CI 1.01–27.7, P = 0.04) and Good perception of TB care,(OR 11.0, 95 % CI 1.29–94.0, P = 0.02) were significantly more likely to select CBDOT when compared with FBDOT.

Following multivariate analysis, patients who always had TB treatment available maintained a positive association to CBDOT enrollment (AOR 6.26, 95 % CI 1.70–22.9, P = 0.006). While patients with Diabetes comorbidity (AOR 0.23, 95 % CI 0.07–0.67, P = 0.00) and those who used taxis to a treatment center (AOR 0.07, 95 % CI 0.00–0.83, P0.03) showed a negative association to CBDOT compared to FBDOT. (Table S4).

4. Discussion

Successful treatment of TB has been instrumental in mitigating and averting millions of deaths annually. However, the TB program in Botswana faces several challenges that make the program less effective than expected, and thus, these factors result in not realizing the national and End TB treatment success targets [8]. We evaluated the TB treatment outcomes and predictors of treatment cure for patients managed through the community tuberculosis care model and those in primary health care settings, which is key to the performance of a National TB control program.

The following factors were significantly associated with selecting community-based TB DOT compared to facility DOT. Patients with moderate TB knowledge were likely to choose CBDOT with positively increased odds for treatment cure. This is consistent with studies in China [9] and Ethiopia [10] indicating that, patients with more TBrelated knowledge were less likely to have low medication adherence, thereby increasing the likelihood of successful treatment outcomes. Additionally, a study in Botswana has shown that having adequate TB knowledge was a predictor for CBDOT enrolment. The possible explanation could be that clients can make informed decisions about the selection of their preferred DOT option based on the knowledge they have about TB [11].

Increased overall patient perception and satisfaction was a significant predictor of CBDOT enrolment with a positive effect on TB treatment cure. This is consistent with studies conducted in Ethiopia [12] and South Africa [13] where higher patient satisfaction with the service was significantly associated with higher levels of adherence, thus increasing the chances of treatment cure. Additionally, a study in Botswana has shown that patient satisfaction was a predictor of adopting CBDOT [11]. Patients who ran their businesses were also significantly more likely to enrol in CBDOT compared to FBDOT. This finding was supported by studies in Ethiopia [14] and India [15]. A possible explanation could be that these patients are always engaged with their daily work thus, CBDOT is convenient for them.

Although not significant our study highlights that females were more likely to enrol for CBDOT. This is supported by a study in Peru, which revealed that facility-supervised treatment is insensitive to female needs because the layout of most health establishments limited privacy at the point of delivery of therapy. Moreover, facility treatment supervision also proved difficult for mothers with children, where arranging childcare was a barrier to accessing FBDOT [16].

Patients who experienced mild to moderate TB stigma were also likely to enrol on CBDOT. This is corroborated by a global communitybased survey showing that enhanced stigmatization of people with TB, particularly by healthcare workers contributes to treatment noncompletion [17], thus patients would resort to community DOT fearing facility stigmatization. On contrary, another study has revealed TB stigma as a potential barrier to home- and work-based direct observational therapy (DOT), given that the presence of TB nurses might mark a person as infected [18].

People who have strong family support though not significant, showed increased likelihood of treatment cure. This was in line with research conducted in Indonesia [19–21] which showed that strong family support can increase TB patients' compliance, hence raising cure rates. This could be explained that, family members frequently provide patients with psychological support, which lowers the likelihood of poor medication adherence resulting in improved TB treatment outcomes and program improvement [9].

Community DOT clients were also likely to achieve a cured outcome. This finding is consistent with the results of previous systematic reviews and *meta*-analyses [22–24] and other studies in Indonesia [25] and South Africa [26] where CBDOT was reported to improve treatment cure and reduce the mortality rate. One plausible reason is that in CBDOT, patients with tuberculosis take medications under the direct supervision of a treatment supporter at home or in their community, allow family support, and eliminate long and costly trips to a centralized primary health facility. This is likely to result in better treatment adherence hence, a better cure rate [27,26,24].

Across all spectrums of employment, patients were likely to be cured compared to the unemployed. This finding was supported by studies in Ethiopia [14] and India [15] indicating a lower likelihood of having successful TB outcomes among the unemployed and unskilled occupations than among the employed. This could be explained that the employed has a reliable socioeconomic status, which may influence treatment outcomes through its impact on improved nutrition, and thereby is associated with the increased strength of the immune system and improved clinical outcomes [28,29].

5. Limitations

Although due diligence was maintained to ensure the integrity of the study, findings of the study are influenced by several limitations. Information bias because of the nature of the study being a retrospective study, the validity of the information obtained by subjects' recall cannot be established with certainty. Our sample size for certain variables and facility based DOT was relatively small, and consequently the ability to detect statistical significance between examined associations was limited. Moreover, as a cross-sectional study, causal links could not be established due to the lack of temporal connection.

6. Conclusion

CBDOT has the potential to contribute to better treatment outcomes because of its convenience. TB knowledge and good perception of service have been identified as tools for promoting community DOT enrollment and treatment cure. Thus, a more intensive patient-specific education program should be implemented at community and health facility levels to improve people's knowledge of TB and its prevention as well as continuous improvement practices to increase patient satisfaction. In addition, the continual assessment of DOT performance using the WHO's recommended guidelines becomes pertinent.

CRediT authorship contribution statement

Sejie Gabalape Arnold: Conceptualization, Data curation, Investigation, Methodology, Project administration, Resources, Writing – original draft, Writing – review & editing. **Mahomed Ozayr Haroon:** Conceptualization, Supervision, Formal analysis, Validation, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jctube.2023.100400.

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