

## Community vs. facility-based directly observed treatment for tuberculosis in Tanzania's Kilimanjaro Region

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### SUMMARY

**SETTING:** Kilimanjaro Region, northern Tanzania.

**OBJECTIVE:** To assess the effect of the introduction of the patient-centred tuberculosis treatment (PCT) approach—which allows tuberculosis (TB) patients to choose between community and facility-based directly observed treatment (DOT)—on treatment outcomes, and to analyse factors that contribute to opting for community DOT.

**DESIGN:** Retrospective analysis of treatment outcomes of TB patients registered in the Kilimanjaro Region in 2007, differentiating between patients under community vs. facility-based DOT and taking into account demographic factors, disease classification, TB diagnosis and human immunodeficiency virus (HIV) status.

**RESULTS:** Data from 2769 TB patients were analysed. Treatment success rates were respectively 81% and 70% in patients under community vs. facility-based DOT ( $P <$

0.001). Cure rates were respectively 73% and 72% in smear-positive pulmonary TB patients under community vs. facility-based DOT ( $P = 0.62$ ). Women, children, patients residing in districts other than Hai, patients with newly diagnosed TB and patients with smear-negative pulmonary TB were most likely to be under community DOT.

**CONCLUSION:** The PCT approach was shown to be effective in terms of treatment outcomes. Treatment success rates were higher in patients who opted for community DOT than in patients who chose facility-based DOT (all cases), and were similar in smear-positive pulmonary TB patients under community or facility-based DOT.

**KEY WORDS:** tuberculosis; patient-centred treatment; community DOT; facility-based DOT; treatment outcome

DIRECTLY OBSERVED TREATMENT (DOT), promoted by the World Health Organization (WHO) as one of the elements of the DOTS strategy, is considered to be an important strategy for improving adherence to tuberculosis (TB) treatment.<sup>1</sup> In Tanzania, one of the 22 countries with the highest burden of TB,<sup>2</sup> patients used to receive daily DOT at the health care facility (facility-based DOT) during the first 2 months of treatment, and were then moved to self-administered treatment in the continuation phase of treatment. In 2006, a 6-month regimen containing rifampicin (RMP) throughout treatment was introduced. The use of RMP, one of the cornerstones of current TB treatment,<sup>3</sup> required daily DOT during the full course of treatment. This, coupled with an increasing TB incidence and insufficient human resources for health care, made facility-based DOT un-

manageable.<sup>4</sup> Randomised controlled trials have been conducted in rural and urban Tanzanian districts to evaluate the efficacy of community DOT (DOT provided by a community member) compared to facility-based DOT.<sup>4,5</sup> Results showed that, at least in an experimental setting, community DOT is as effective as facility-based DOT, and that sputum conversion rates and treatment outcomes were similar. Moreover, community DOT was found to be readily accepted by the community.<sup>6</sup> Results from these studies encouraged the Tanzanian Ministry of Health and Social Welfare to implement community DOT in the National TB and Leprosy Programme (NTLP).

In 2007, the so-called patient-centred TB treatment (PCT) approach was adopted. This allows TB patients to choose where their daily treatment is supervised and by whom, i.e., to choose between facility-based and community DOT.<sup>7</sup> Community DOT in the PCT approach involves the identification of a treatment

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supporter who is usually a family member or spouse. The treatment supporter is oriented in how to provide DOT and how to support the patient. The patient and the treatment supporter are supposed to visit the health care facility once a week during the intensive phase of treatment and once every 2 weeks during the continuation phase, to collect drugs and report problems.<sup>7</sup> The PCT approach has been used in Tanzania for over 2 years. Facility-based DOT has become less popular among patients, and is mainly used by in-patients (personal communication with TB and leprosy coordinators).

The present study aimed to evaluate the effect of the PCT approach on treatment outcomes in TB patients from the Kilimanjaro Region in 2007. Treatment outcomes were compared between patients who opted for community DOT and those who chose facility-based DOT. An analysis was made of the entire cohort of TB patients, and of the subgroup of patients with newly diagnosed sputum smear-positive TB.

## METHODS

### *Setting*

The Kilimanjaro Region is situated in northern Tanzania. It covers an area of 13 309 km<sup>2</sup> and has a population of over 1.3 million.<sup>8</sup> The region is divided into six districts, one urban (Moshi Urban) and five rural (Moshi Rural, Mwanga, Same, Rombo, Hai). The region hosts one of the four national referral hospitals, in Moshi Urban, and the national TB referral hospital, in Hai. The region also has one governmental regional hospital, in Moshi Urban, and several hospitals and health centres in the districts. The NTLP is integrated into the existing primary health care system.<sup>7</sup> One regional and six district TB and Leprosy Coordinators (RTLC and DTLCs) are responsible for managing the NTLP at the regional and district levels of the Kilimanjaro Region.

### *Methods*

The 2007 TB registers from all districts of the Kilimanjaro Region were used as data sources. Apart from demographic data (sex, age and district of residence), data were collected on TB classification (new case, relapse, failure, transfer in, return after default and other, as defined by the WHO<sup>1</sup>) and diagnosis (smear-positive pulmonary, smear-negative pulmonary or extra-pulmonary TB), human immunodeficiency virus (HIV) status, type of DOT (community or facility-based) and treatment outcome. Treatment outcomes were described in terms of treatment success (cured and completed treatment) and unfavourable outcomes (failure, defaulter, death, transferred out and lost to follow-up), in line with WHO definitions.<sup>1</sup>

The study was approved by the Institutional Review Board of the Kilimanjaro Christian Medical Centre, Moshi, Tanzania. Informed consent was not ob-

tained from participants as it was a retrospective study in which no individual patient details were used.

Data analysis was performed using SPSS version 16.0.1 (Statistical Package for the Social Sciences, Chicago, IL, USA) for Windows 2007 (MicroSoft, Redmond, WA, USA,  $\chi^2$  tests were used to compare proportions. Univariate and multivariate logistic regression analyses were performed to analyse factors that contributed to the choice of community vs. facility-based DOT, and to analyse the effect of the chosen type of DOT on treatment outcomes. Finally, unfavourable treatment outcomes were analysed for association with type of DOT (univariate analysis).

Odds ratios (ORs), defined as the probability of occurrence over non-occurrence, with values greater than one indicating a greater probability of occurrence as compared to the reference group (indicated by 1 in the tables), and 95% confidence intervals (95%CI) were calculated and are provided in the tables.

## RESULTS

### *Patient characteristics*

A total of 2769 TB patients were registered. The case notification rate of new and retreatment cases ( $n = 2449$ ) was 178 per 100 000 population; 63% ( $n = 1749$ ) of the patients were male and 11% ( $n = 308$ ) were children aged <15 years (Table 1). The median age of the adults was 35 years (interquartile range [IQR] 26–47). Moshi Urban, Moshi Rural and Hai Districts covered 76% of the patient load. Eighty-three per cent ( $n = 2312$ ) of the patients were new TB cases, 4% ( $n = 115$ ) were relapse cases, 1% ( $n = 22$ ) treatment failures or returning after default and 12% ( $n = 320$ ) were transferred in or not otherwise defined. Forty-one per cent ( $n = 1126$ ) of patients were diagnosed with smear-positive pulmonary TB, 75% of whom ( $n = 840$ ) were new cases; 39% ( $n = 1075$ ) had smear-negative pulmonary TB and 21% ( $n = 568$ ) extra-pulmonary TB (smear results not known). HIV status was not known in 36% ( $n = 994$ ) of patients; 31% ( $n = 847$ ) were HIV-positive and 34% ( $n = 928$ ) HIV-negative. Significantly more female than male patients were HIV-positive (39% vs. 26%, OR 1.83, 95%CI 1.54–2.16).

### *Patient factors related to the choice of community vs. facility-based DOT*

The characteristics of patients under community vs. facility-based DOT are summarised in Table 1. A total of 1646 patients (59%) opted for community DOT. Compared to patients under facility-based DOT, patients under community DOT were more likely to be female, aged <15 years or HIV-positive, and were less likely to be registered in Hai District, to be diagnosed with smear-positive pulmonary TB or to be a retreatment case (univariate analysis). Multivariate logistic regression analysis showed an independent

**Table 1** Characteristics of the total cohort of patients and of patients under community vs. facility-based DOT

	Total cohort (N = 2769) n	Patients under community DOT (n = 1646) n (row %)	Patients under facility-based DOT (n = 1123) n (row %)	Unadjusted OR (95%CI)*	Adjusted OR (95%CI)†
<b>Sex</b>					
Male	1749	990 (57)	759 (43)	1	1
Female	1020	656 (64)	364 (36)	1.4 (1.2–1.6)	1.3 (1.1–1.6)
<b>Age, years</b>					
>14	2461	1442 (59)	1019 (41)	1	1
0–14	308	204 (66)	104 (34)	1.4 (1.1–1.8)	1.4 (1.0–1.9)
<b>Districts</b>					
Hai	681	146 (21)	535 (79)	1	1
Moshi Urban	893	465 (52)	428 (48)	4.0 (3.2–5.0)	3.7 (2.9–4.7)
Moshi Rural	535	477 (89)	58 (11)	30.1 (21.7–41.9)	33.9 (23.9–48.1)
Rombo	256	222 (87)	34 (13)	23.9 (16.0–35.9)	30.2 (19.6–46.7)
Same	238	198 (83)	40 (17)	18.1 (12.3–26.8)	20.5 (13.7–30.7)
Mwanga	166	138 (83)	28 (17)	18.1 (11.6–28.2)	20.2 (12.6–32.5)
<b>TB classification</b>					
New	2312	1426 (62)	886 (38)	1	1
Retreatment	137	25 (18)	112 (82)	0.1 (0.1–0.2)	0.1 (0.1–0.2)
Other/transferred in	320	195 (61)	125 (39)	1.0 (0.8–1.2)	0.7 (0.5–0.8)
<b>TB diagnosis</b>					
Smear-positive PTB	1126	589 (52)	537 (48)	1	1
Smear-negative PTB	1075	719 (67)	356 (33)	1.8 (1.6–2.2)	1.3 (1.0–1.6)
EPTB	568	338 (60)	230 (40)	1.3 (1.1–1.6)	0.9 (0.7–1.1)
<b>HIV status</b>					
Seronegative	928	534 (58)	394 (42)	1	1
Seropositive	847	531 (63)	316 (37)	1.2 (1.0–1.5)	1.1 (0.9–1.4)
Unknown	994	581 (58)	413 (42)	1.0 (0.9–1.2)	1.1 (0.9–1.4)

\*Univariate (unadjusted) ORs and 95%CIs were calculated for patients under community DOT vs. those under facility-based DOT; the reference category was community DOT.

†Multivariate (adjusted) ORs and 95%CIs were calculated for patients under community DOT vs. those under facility-based DOT; the reference category was community DOT.

DOT = directly observed treatment; OR = odds ratio; CI = confidence interval; TB = tuberculosis; PTB = pulmonary TB; EPTB = extra-pulmonary TB; HIV = human immunodeficiency virus.

association of female sex, being a child, residing in any district other than Hai, having newly diagnosed TB and having smear-negative pulmonary TB with opting for community DOT (Table 1).

**Patient factors that contributed to treatment success**  
The overall treatment success rate was 77% ( $n/N = 2128/2769$ ); 30% ( $n = 835$ ) of patients were cured and 47% ( $n = 1293$ ) completed treatment.

As shown in Table 2, treatment success was more likely in patients under community DOT than in those under facility-based DOT (81% vs. 70%), in patients with smear-positive pulmonary TB, and in patients who were HIV-negative (univariate analysis). These factors were also independently associated with treatment success in a multivariate regression model (Table 2). In Same and Moshi Rural Districts, treatment success rates were high in comparison to Hai District, but the difference disappeared in the multivariate regression model. Sex, age and treatment classification (new or retreatment) were not significantly associated with treatment outcome.

#### *Effect of type of DOT on treatment success in smear-positive pulmonary TB cases*

Of 1126 patients with smear-positive pulmonary TB, 815 (72%) were cured and 97 (9%) completed treat-

ment. Cure rates did not differ significantly between patients who opted for community DOT and those who opted for facility-based DOT (73% and 72%, respectively; OR 1.1, 95%CI 0.8–1.4). In smear-positive pulmonary TB patients for whom sputum smear results after 2 and 5 months of treatment were documented (66% and 63%, respectively), no significant differences in smear conversion rates between patients under community and those under facility-based DOT were found (respectively 95% and 97% after 2 months, and 99.5% and 99.5% after 5 months).

#### *Evaluation of unfavourable treatment outcomes*

A total of 256 (9%) patients died. In 0.2% ( $n = 5$ ), treatment failed, 0.4% ( $n = 11$ ) defaulted, 10% ( $n = 273$ ) were transferred out, and 3% ( $n = 96$ ) were lost to follow-up; 9% (148/1646) of the patients under community DOT and 10% (108/1123) of the patients under facility-based DOT died during treatment (OR 0.9, 95%CI 0.7–1.2). Thirteen per cent of HIV-positive patients (111/847) and 8% of HIV-negative patients and patients with unknown HIV status died (145/1922, OR 1.9, 95%CI 1.4–2.4). Six per cent of patients with smear-positive pulmonary TB (65/1126) and 12% of patients with smear-negative pulmonary TB or extra-pulmonary TB (191/1643) died (OR 0.5,

**Table 2** Characteristics of patients with successful and unfavourable treatment outcomes

	Treatment success* (n = 2128) n (row %)	Unfavourable outcome† (n = 641) n (row %)	Unadjusted OR (95%CI)‡	Adjusted OR (95%CI)§
DOT type				
Facility-based	791 (70)	332 (30)	1	1
Community	1337 (81)	309 (19)	1.8 (1.5–2.2)	1.8 (1.5–2.3)
Sex				
Male	1343 (77)	406 (23)	1	
Female	785 (77)	235 (23)	1.0 (0.9–1.2)	NS
Age, years				
>14	1883 (77)	578 (23)	1	
0–14	245 (79)	63 (21)	1.2 (0.9–1.6)	NS
District				
Hai	505 (74)	176 (26)	1	1
Moshi Urban	654 (73)	239 (27)	1.0 (0.8–1.2)	1.0 (0.8–1.3)
Moshi Rural	440 (82)	95 (18)	1.6 (1.2–2.1)	1.3 (0.9–1.8)
Rombo	194 (76)	62 (24)	1.1 (0.8–1.5)	0.8 (0.5–1.1)
Same	202 (85)	36 (15)	2.0 (1.3–2.9)	1.3 (0.9–2.0)
Mwanga	133 (80)	33 (20)	1.4 (0.9–2.1)	1.1 (0.7–1.8)
TB classification				
New	1779 (77)	533 (23)	1	
Retreatment	104 (76)	33 (24)	0.9 (0.6–1.4)	
Other/transferred in	245 (76)	75 (23)	1.0 (0.7–1.3)	NS
TB diagnosis				
Smear-positive PTB	912 (81)	214 (19)	1	1
Smear-negative PTB	813 (76)	262 (24)	0.7 (0.6–0.9)	0.7 (0.6–0.9)
EPTB	403 (71)	165 (29)	0.6 (0.5–0.7)	0.6 (0.5–0.7)
HIV status				
Seronegative	753 (81)	175 (19)	1	1
Seropositive	626 (74)	221 (26)	0.7 (0.5–0.8)	0.7 (0.5–0.9)
Unknown	749 (75)	245 (25)	0.7 (0.6–0.9)	0.7 (0.6–0.9)

\* Cured or treatment completed (WHO definitions<sup>2</sup>).† Treatment failures, defaulters, deaths, transferred out, or out of control (WHO definitions<sup>2</sup>).

‡ Univariate (unadjusted) ORs and 95% CIs were calculated for patients with successful treatment outcome vs. those with unfavourable treatment outcome; the reference category was successful treatment outcome.

§ Multivariate (adjusted) ORs and 95% CIs were calculated for patients with successful treatment outcome vs. those with unfavourable treatment outcomes; the reference category was successful treatment outcome. Only variables that were significant in univariate analysis have been included in the multivariate logistic regression analysis.

OR = odds ratio; CI = confidence interval; DOT = directly observed treatment; NS = not significant; TB = tuberculosis; PTB = pulmonary TB; EPTB = extra-pulmonary TB; HIV = human immunodeficiency virus.

95%CI 0.3–0.6). All of the five patients who failed to respond to treatment had smear-positive pulmonary TB; two received community DOT and three facility-based DOT. Four had unknown HIV status and one was HIV-positive. Eight of the 11 defaulters were under community DOT. Forty-two per cent ( $n = 115$ ) of the 273 patients who were transferred out of the region chose community DOT and the remaining 58% ( $n = 158$ ) chose facility-based DOT. Thirty-six (38%) patients who were lost to follow-up but did not comply with the definition of defaulter ( $n = 96$ ) received community DOT and 63% ( $n = 60$ ) facility-based DOT.

## DISCUSSION

In this study, higher treatment success rates were observed in patients who opted for community DOT than in patients who opted for facility-based DOT; similar cure rates were found in smear-positive pulmonary TB patients under community or facility-based DOT. The results from this observational, non-experimental study confirm findings from earlier

studies that were conducted in experimental settings in Tanzania,<sup>4,5</sup> other sub-Saharan countries<sup>9–11</sup> and non-African countries,<sup>12–14</sup> in which community DOT provided by community health workers,<sup>13,14</sup> community volunteers<sup>4,9,12</sup> or family members<sup>5,10,11</sup> proved at least as effective as facility-based DOT. Such results encourage the involvement of the community in the delivery of supervised TB treatment, a strategy that is readily accepted by patients<sup>6,9,13,15</sup> and has been shown to be cost-effective.<sup>16–21</sup> In Tanzania, community DOT reduced the total cost of treating a TB patient by 35% compared to facility-based DOT.<sup>16</sup>

The fact that more patients under facility-based DOT were lost to follow-up than patients who chose community DOT suggests that community DOT does not increase the risk of patients being lost to NTLP control. This, however, will need to be reassessed in the years to come. Concerns have been raised that community DOT as prescribed by the PCT approach is applied increasingly less rigorously: patients are sent home without identification of a treatment supporter, opting for self-administered treatment instead (personal communication with RTLC and DTLCs).

The gradual shift from community DOT to self-administered treatment is not desirable in settings with insufficient resources to monitor treatment adherence.<sup>22</sup>

The present study revealed some factors that influence the choice of community or facility-based DOT. The most important of these was district of residence: facility-based DOT was more common in Hai District than in the other districts. This could be explained by the presence of the national TB referral hospital in Hai District, where it is the policy to admit patients during the first 2 months of TB treatment. Women and children were more likely than men to opt for community DOT. In the Kilimanjaro Region, women are the main caregivers for their children and families, and are occupied with looking after the home. Community DOT may therefore be perceived as interfering less with daily activities than facility-based DOT. Retreatment cases and patients with smear-positive TB were less likely to receive community DOT. As these cases are regarded as significant threats to public health, the policy for such patients may tend towards hospital admission and facility-based DOT rather than community DOT. Although the cornerstone of the PCT approach is the empowerment of patients to choose between community and facility-based DOT, external factors, such as district of residence, disease classification and physician's advice, also contribute to the decision. Except for smear positivity, none of the factors that contributed to the choice of type of DOT were independently associated with treatment outcome.

The data presented here should be interpreted with caution. Although the TB registers provided nearly complete data for most outcome parameters of this study, TB cases in the Kilimanjaro Region are still registered manually, and the data are therefore sensitive to errors in documentation and interpretation. The TB registers did not provide information about whether patients under facility-based DOT were in- or out-patients, and it was not documented whether in-patients continued to be under facility-based DOT throughout treatment or whether they shifted to community DOT at a later stage of treatment. Some in-patients may have been lost to follow-up after discharge, which could explain the relatively large proportion of patients under facility-based DOT who were lost to follow-up as compared to patients under community DOT. Finally, uncertainties about the correctness of TB diagnosis in cases of smear-negative TB, and the true value of 'completed treatment' as an internationally used indicator for treatment success, raise doubts about the usefulness of treatment outcomes in studies that evaluate community and facility-based DOT.

In conclusion, this study showed that, in terms of treatment outcomes, community DOT is at least as effective as facility-based DOT in a PCT strategy that allows patients to choose between the two.

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## RÉSUMÉ

**CONTEXTE :** Région de Kilimanjaro, au nord de la Tanzanie.

**OBJECTIF :** Evaluer l'effet sur les résultats du traitement de l'introduction d'une approche du traitement de la tuberculose (TB) centré sur le patient, qui permet aux patients tuberculeux de choisir entre un traitement directement observé (DOT) basé sur la collectivité ou sur les services médicaux, et analyser les facteurs qui contribuent au choix d'un DOT basé sur la collectivité.

**SCHÉMA :** Analyse rétrospective des résultats du traitement TB enregistrés dans la région du Kilimanjaro en 2007 en faisant la différence entre les patients dont le DOT était basé sur la collectivité ou sur les services et en prenant en compte les facteurs démographiques, la classification de la maladie, le diagnostic de TB et le statut du virus de l'immunodéficience humaine.

**RÉSULTATS :** On a analysé les données de 2769 patients. Les taux de succès du traitement ont été respectivement de 81% et de 70% chez les patients dont le DOT était

basé sur la collectivité vs. sur les services médicaux ( $P < 0,001$ ). Les taux de guérison ont été respectivement de 73% et 72% chez les patients atteints de TB pulmonaire à bacilloscopie positive avec un DOT basé sur la collectivité vs. les services médicaux ( $P = 0,62$ ). Les plus susceptibles de recourir à un traitement DOT basé sur la collectivité sont les femmes, les enfants, les patients résidant dans les districts autres que Hai, et les patients dont la TB a été récemment diagnostiquée ou atteints d'une TB pulmonaire à baciloskopie négative.

**CONCLUSION :** L'approche du traitement de la TB centrée sur le patient s'avère efficace en termes de résultats du traitement. Les taux de succès du traitement sont plus élevés chez les patients qui ont opté pour un DOT basé sur la collectivité que chez ceux qui ont choisi le DOT basé sur les services médicaux (tous les cas), et ils sont similaires chez les patients atteints de TB pulmonaire à baciloskopie positive, que le DOT soit basé sur la collectivité ou sur les services de santé.

## RESUMEN

**MARCO DE REFERENCIA :** La región de Kilimanjaro al norte de Tanzania.

**OBJETIVO :** Evaluar el efecto sobre el desenlace terapéutico de una estrategia de tratamiento antituberculoso centrada en el paciente, gracias a la cual las personas pueden escoger entre el tratamiento directamente observado (DOT) en el establecimiento de salud o en la comunidad. También se analizaron los factores que contribuyen a optar por el tratamiento en la comunidad.

**MÉTODO :** Se llevó a cabo un análisis retrospectivo de los desenlaces terapéuticos de los pacientes tratados por tuberculosis (TB) en la región de Kilimanjaro en 2007 ; se estudiaron dos categorías : los pacientes tratados en la comunidad o en el centro de salud, tomando en consideración los factores demográficos, la clasificación de la enfermedad, el diagnóstico de TB y el estado con respecto al virus de la inmunodeficiencia humana.

**RESULTADOS :** Se analizaron datos de 2769 pacientes tuberculosos. La tasa de éxito fue de 81% en los pacien-

tes en DOT al nivel de la comunidad y 70% en los pacientes con DOT basado en el centro sanitario ( $P < 0,001$ ). Las tasas de curación de pacientes con TB pulmonar y baciloskopía positiva fueron 73% en el DOT comunitario y 72% en el DOT en el establecimiento sanitario ( $P = 0,62$ ). La probabilidad de optar por el DOT comunitario fue mayor en las mujeres, los niños, los pacientes que residían en distritos diferentes de Hai, los pacientes con un diagnóstico nuevo de TB y los pacientes con TB pulmonar y baciloskopía negativa.

**CONCLUSIÓN :** La estrategia de tratamiento centrada en el paciente demostró su eficacia en términos de desenlace terapéutico. Globalmente, todos los pacientes que optaron por el DOT comunitario lograron tasas de éxito superiores a las de los pacientes que escogieron el seguimiento institucional ; en todos los pacientes con TB pulmonar y baciloskopía positiva, las tasas de éxito fueron equivalentes con el seguimiento comunitario o institucional.