Assessment of patient preference in allocation and observation of anti-tuberculosis medication in three districts in Tanzania

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Background: The new tuberculosis (TB) treatment in Tanzania contains rifampicin for six months. Direct observation of drug intake at the health facility for this period is not feasible.

Methods: Patients and health staff in three districts were interviewed to assess the burden of the current treatment strategy, and opinions on a proposed new strategy where patients are able to choose the place of treatment and the treatment supervisor, and receive treatment as a daily combination tablet.

Results: The study included 343 patients in 42 facilities. Daily collection of drugs was perceived as burdensome irrespective of distance needed to travel. Eighty percent of patients viewed medication taken at home or at a closer health facility as an improvement in TB-services. The proposed new treatment strategy was rated favorably by 85% of patients and 75% of health staff. Fifty-three percent of patients would opt for home-based treatment, and 75% would choose a family member or the spouse as treatment supporter.

Conclusion: Home-based supervision of TB treatment with fewer drugs is an expressed preference of TB patients in Tanzania. Such a strategy is now being assessed in a pilot study. If effective and feasible, the strategy will contribute to an improved TB control strategy.

Introduction
Tuberculosis (TB) is one of the leading causes of death in the United Republic of Tanzania (WHO 2006a). The case load of TB (all forms) in Tanzania was 39,847 in 1995 and increased to 64,200 in 2005 (WHO 2007). This increase is largely attributed to the ongoing HIV-epidemic in the country. Currently, the World Health Organization (WHO) estimates the incidence of TB (all forms) to be 342 per 100,000 population (WHO 2007). The estimated prevalence of HIV in the adult population (15–49 years) is 7% (TACAIDS et al 2005). The cornerstone of TB control is Directly Observed Therapy Short course (DOTS), which comprises of diagnosis by sputum microscopy and therapy with a 6–8 months drug regimen (WHO 2003). With rifampicin being part of the drug regimen during the initial two months (the intensive phase), it is recommended that the taking of treatment is observed to prevent selection of rifampicin-resistant strains of Mycobacterium Tuberculosis due to nonadherence. After this time, in the continuation phase, the regimen does, in general, not include rifampicin and treatment is collected on a monthly basis and taken by the patient unsupervised.

Conventionally, following recommendations of the WHO and the International Union against Tuberculosis and Lung Disease, observation of drug intake is done at the treatment center by health staff (WHO 2003). This implies that the patient has to report each day to the facility and that health staff has to attend daily to these patients in addition to other duties.
In 2006, the initial drug regimen for new TB patients in Tanzania was changed to include rifampicin also in the continuation phase because studies suggested that such a regimen was more effective in situations with a high prevalence of HIV-infection like in Tanzania (Johnson et al 1997; El-Sadr et al 2001; Korenromp et al 2003). This new regimen asks for a strict adherence, preferably by direct observation of drug intake. Having patient coming to a treatment facility and staff attending to them on a daily basis for 6 months puts an enormous stress on both sides and its feasibility is questionable.

It was therefore pertinent for the National Tuberculosis and Leprosy Programme (NTLP) of Tanzania to rethink its strategy of allocating and supervising TB treatment. The new strategy should be able to maintain adequate observation of treatment intake, should not increase the already high work load of health facilities, and be acceptable for the TB patients and the community at large.

The strategy for treatment allocation and observation that was designed has three components. First, all identified TB patients will be given the choice between home-based treatment supervision and health facility-based supervision. Second, patients who opt for home-based supervision can identify their own treatment supporter. Third, all four drugs of the intensive phase will be given as a single fixed-dose combination tablet (4FDC).

To assess whether such a strategy was acceptable for TB patients and health staff, the NTLP conducted an assessment in three representative districts in Tanzania. Both patients and health staff were interviewed to ascertain their views on the current DOTS strategy, their suggestions for improving their TB treatment, and their opinion on the proposed new strategy. The current manuscript describes the outcomes of this assessment.

Methods
The study was carried out in three geographically representative districts of Tanzania in 2004. Two rural districts were selected (Korogwe and Mbarali), and one urban district (Nyamagana). The study districts were chosen for convenience based on being representative for a rural setting an urban setting. Within the districts there was no sampling but all TB treatment centres (42) were included. Within the centres, all the patients who were on treatment were included as well as the attending health staff. The health staff included clinical officers, nurses/dispensers, attendants, and TB-coordinators. Three study teams of trained researchers who were assisted by local TB-coordinators known in the area carried out semi-structured interviews.

The questionnaires were designed in close collaboration with all stakeholders involved to assure that the questions were relevant and feasible. It was piloted in a sample of TB patients in Dar es Salaam, Tanzania. Unclear questions were rephrased. The narrative accounts of the interviewees were translated and analysed using qualitative software (MAX QDA). For most questions, multiple answers were possible. All data were entered in a central database at Ifakara centre, Tanzania. Different responses to the questions were tallied. No formal statistical analyses were performed.

Ethical approval for the study was obtained from the Institutional Review Board of the National Institute for Medical Research. All participants provided verbal consent to participate in the study.

Results
All 42 health facilities agreed to participate, as well all registered patients and health staff in the facilities. The study included all 343 patients who were receiving TB treatment at the health facilities, and 90 health care workers. Two hundred patients (58%) were in the intensive phase and 143 (42%) in the continuation phase of anti-TB treatment. At the time of the study, patients on the intensive phase reported to the health facility daily for DOT, while those on the continuation phase collected their drugs once a month. Of the health care workers, 41 (46%) were senior (Regional or District TB and Leprosy Coordinator [R/DTLC] or Clinical Officer [CO]), and 49 (54%) were junior (nurse or dispenser). Not all patients answered all the questions because the semi-structured nature of the questionnaire gave this opportunity.

Appraisal of the current health facility-based DOT system
Of the 200 patients who collected their medication daily, 164 (82%) lived within 5 kilometres of the health facility, and 36 (18%) lived more than 5 kilometres away from the nearest health facility. In the only urban district 99% of the patients in the intensive phase were living within 5 kilometres from the nearest health facility. The common mode of transport to the health facility was by walking, and by bus or car.

Information on the appraisal of the current health facility-based DOT strategy was obtained from 193 (97%) of the patient in the intensive phase. The daily travel to the health facility was seen as a burden by 58% of the patients living within 5 kilometres of the health facility, and 72% of the patient living further way. Reasons for this burden were
the distance, the generally poor health of the patients, and problems in finding or financing transport (Table 1).

Reasons for not finding the daily travel to the health facility a burden were close distance, the possibility of transport, the wish to be cured, and the responsibility felt towards the health worker. Most health worker shared the view of the patients that daily DOT at the health facility is a burden for the patient.

“Because my body hurts I have no strength. I get very tired when I walk, although I am living nearby. I take a long time to reach the center. As you can see, my condition is not good.”

(35-year-old male)

### Table 1: Appraisal of the current DOT strategy

|                                      | Patients       | Health workers |
|--------------------------------------|----------------|----------------|
|                                      | <5 km          | >5 km          | CO/RTLC        | Nurse          |
|                                      | N = 161        | N = 32         | N = 41         | N = 49         |
| HF-DOT is a burden                   | 93 (57.8)      | 23 (71.9)      | 32 (78.0)      | 31 (63.3)      |
| Daily walk difficult                 | 37 (39.8)      | 5 (21.7)       | 16 (47.1)      | 21 (63.6)      |
| Long distance to HF                  | 66 (71.0)      | 17 (73.9)      | 26 (76.5)      | 27 (81.8)      |
| Weakness/poor health                 | 49 (52.7)      | 6 (26.1)       | 16 (47.1)      | 15 (45.5)      |
| Too much pain                        | 28 (30.1)      | 4 (17.4)       | 13 (38.2)      | 6 (18.2)       |
| Financial/Transport problems         | 17 (18.3)      | 8 (34.8)       | 7 (17.1)       | 14 (28.6)      |
| No child care                        | 3 (3.2)        | 4 (17.4)       |                |                |
| HF-DOT is not a burden               | 68 (42.2)      | 9 (71.9)       | 7 (17.1)       | 14 (28.6)      |
| Live close to HF                     | 39 (60.9)      | 1 (10)         |                |                |
| Want to be cured                     | 17 (26.6)      |                |                |                |
| No transport problems                | 8 (12.5)       | 6 (60)         |                |                |
| Important to see health worker       | 7 (10.9)       | 1 (10)         |                |                |
| Feel responsible                     | 7 (10.9)       | 1 (10)         |                |                |
| Other                                 |                |                |                |                |

Notes: *In the intensive phase of treatment (daily drug collection); All numbers are n (%).

### Table 2: Suggestions for simplifying treatment

|                                      | Patients       | Health Workers |
|--------------------------------------|----------------|----------------|
|                                      | All            | Intensive phase| Continuation phase| CO/RTLC| Nurse |
|                                      | N = 231        | N = 140        | N = 91           | N = 41 | N = 50 |
| Provide treatment at home            | 115 (49.6)     | 79 (56.4)      | 36 (39.6)        | 13 (31.7) | 16 (32.0) |
| Provide treatment closer to home     | 65 (28.1)      | 31 (22.1)      | 34 (37.4)        | 11 (26.8) | 17 (34.0) |
| Improve services                     | 54 (23.4)      | 29 (20.7)      | 25 (27.5)        | 10 (24.4) | 5 (10.0)  |
| Shorten treatment/fewer drugs        | 27 (11.7)      | 21 (15.0)      | 6 (6.6)          | 12 (29.3) | 14 (28.0) |
| More HF providing diagnostics        | 23 (10.0)      | 8 (5.7)        | 15 (16.5)        | 11 (26.8) | 8 (16.0)  |
| Involve relatives/communities        |                |                |                  | 12 (29.3) | 11 (22.0) |
| Health education                     |                |                |                  | 6 (14.6)  | 7 (14.0)  |
| Improve transport                    | 16 (6.9)       | 11 (7.9)       | 5 (5.5)          | 5 (12.2)  | 4 (8.0)   |
| No change needed                     |                |                |                  | 2 (4.9)   | 2 (4.0)   |

Notes: All numbers are n (%).
and the provision of health education. Four health workers did not see a reason to change the current DOT system.

“If we could be given monthly drugs and have them from home, it would help reduce transport costs. It will also help us patients to complete the dose because even when we do not have money for transport, we will have the drugs at home. The family will have money for its expenditure because the money, which was being used as a bus fare, will now be used for the family.”
(31-year-old female)

Views on patient-centred treatment (PCT)
The patients were thoroughly explained that PCT consisted of having the opportunity to choose where and by whom their TB treatment was supervised. It was also made clear that regular returns to the health facility for check-up, sputum examinations, and drug collection were still needed, and that with home-based supervision a good record keeping had to be performed. To ensure that the concept was understood well, the patients had to explain the system back to the interviewer.

Patient-centred treatment was considered ‘very good’ or ‘good’ by 79% of the patients, 86% of the COs and RTLCs, and 76% of the nurses (Table 3). PCT was rated as not good by 10% of the patients, 7% of the COs and RTLCs, and 14% of the nurses.

Most of the patients and all but one health care workers gave reasons for their rating of PCT (Table 3). Reasons for a positive attitude of patients towards PCT included that it would reduce the tiresome daily travel, that there was more time to rest, and that it would make treatment more convenient. Health workers gave similar reasons for a positive attitude toward PCT, but included also the possible reduction of overcrowding and workload at the health facilities.

“We like the approach very much. It will help us to get more rest, less fare, and it will make us get time to sleep after swallowing drugs.”
(40-year-old male)

Reasons for a negative attitude of patients toward PCT included the notion that home treatment in general was not preferred due to lack of expertise, the opinion that observation of treatment in a health facility would be more reliable, and the believe that home-based treatment would lead to nonadherence (Table 3). Health workers reported a wide range of possible disadvantages of PCT of which the main were the difficulty in managing the strategy, the fear that an inappropriate supporter would be chosen, nonadherence, and improper storage of drugs.

“The supporter may fail to understand how to give drugs to the patient. Also he may not understand the side effects of the drug. So the home-centred strategy is not good. At the hospital there is good supervision hence it is good for the patient to take the drugs in health facilities.”
(Clinical Officer male)

Place of supervision and type of supporter
A small majority (53%) of both patients in the intensive phase and in the continuation phase would opt for home-based DOT when they had a choice (Table 4). This choice was not influenced by sex, age, marital status, or level of education. Even a considerable proportion of patients living within 5 kilometres of the health facility would choose home-based DOT if given a choice.

Reasons of patients to choose for home-based DOT included the treatment being less disruptive to their lives, time to rest, less costs, and the opportunity to keep working. A choice for health-facility based DOT was made because of the notion that treatment would be better, it was more convenient, and the believe that home-based treatment was in general not good.
Patient preferences for TB treatment

"As a businessman, instead of going to the health facility to collect drugs, I will be able to continue with my business.”
(30-year-old male)

The type of supporter for home-based DOT would be for the large majority of patients (74%) either a spouse or a family member (Table 4). This did not differ much by sex of the patient. Divorced men would opt for a family member, while this was less outspoken for divorced women. From the interviews it became clear that the choice for treatment supporter was driven by a close relationship, feelings of trust and helpful experiences in the past.

"I would choose my younger brother because he is the one who brings me to the hospital when I am sick and he loves helping me. When I am tired he may come to collect drugs for me.”
(32-year-old male)

The main role for supporters according to the patients would be to collect drugs, to encourage the drug taking, and to prepare food. Other tasks mentioned were the provision of support, to give feedback to the health worker, and help in the household.

Views on home-based drug taking
Patients who would choose home-based DOT did not see major problems in taking their daily medication and were aware of the need of a good compliance. From the point of both the patients and the health staff, proof a regular drug intake should be through a formal confirmation by the supporter, a visible improvement in patient’s health, or submission of empty packs or filled records on patient’s treatment card.

"I will be ticking my treatment cards. My wife will confirm this. I will accompany my supporter often to the health facility for drug collection and you will be able to see how I progress.”
(42-year-old male)

Discussion
The current study showed that daily contact with a health facility to obtain TB treatment was seen as a burden by both the patients and the health staff. Fifty percent of the patients who found daily travel to the health facility a burden lived within 5 kilometres of the facility. It is therefore not surprising that patients mentioned the possibility to take their drugs at a nearer health facility or at home as a way to improve the current strategy of TB treatment delivery. This is in addition to the expressed wish of having fewer drugs and/or a shorter treatment period. These factors were also mentioned by the health workers as the most important factors for improvement the current TB treatment strategy.

Both patients and health workers had a positive attitude towards a strategy where the patients would be able to make the choice of the place of supervision and the supervisor. A large majority of patients, who would opt for home-based supervision, would opt for their spouse or a family member as their treatment supporter.

Studies in Nepal (Newell et al 2006), Swaziland (Wright et al 2004), Kenya (Kangangi et al 2003), Uganda (Adatu et al 2003), Malawi (Manders et al 2001), and Thailand (Akkslip et al 1999) showed that supervision of TB-treatment can be done outside the health facility without compromising treatment success rates. The study in Nepal reported that supervision at home by either a community health worker or a family member resulted in a proportion of successful treatment outcomes that was in line with the targets set by WHO (Newell et al 2006).

Within the TB-community, the discussion continues whether family members are suitable to supervise treatment. In a reaction to the publication of the Nepal study, Garner et al supported the use of family members as treatment supporters (Garner and Volmink 2006). They see the fact as whether these family members do actually observe treatment intake as immaterial. It is the communication between patient, supporter, and health staff, and the sharing of responsibility for treatment adherence that makes the intervention in Nepal successful according to the authors. On the other side of the debate, Frieden and Sbarbaro (2006) stated that TB patients in many countries have received suboptimal treatment because of the use of family members as treatment supporters. This statement is underscored by a study in the southern parts of Thailand, where 35% of the family members who acted as

| Preferred place of DOT | All patients | Male | Female |
|------------------------|-------------|------|--------|
| Home                   | 182 (53.1)  | 111  (53.9) | 71   (51.8) |
| Health facility        | 161 (46.9)  | 95   (46.1) | 66   (48.2) |

| Supporter at home     |                |      |        |
|-----------------------|----------------|------|--------|
| Spouse                | 51 (28.0)      | 36   (32.4) | 15   (21.1) |
| Family member         | 83 (45.6)      | 49   (44.1) | 34   (47.9) |
| Self                  | 18 (9.9)       | 10   (9.0)  | 8    (11.3)  |
| Health worker         | 12 (6.6)       | 6    (5.4)   | 6    (8.5)   |
| Other                 | 18 (9.9)       | 10   (9.0)  | 8    (11.3)  |

Notes: All numbers are n (%).
treatment supporter acknowledge not to consistently observe treatment intake by the patient, in comparison to 11% of the health staff at health facilities (Punggrassami et al 2002).

A large community randomized trial in South Africa showed that 59% of the TB patients who could choose their treatment supporter would opt for a family member (Thiam et al 2007). The remaining 41% chose either a health care worker at the health facility or within the community. Of the patients supervised by family members, 4% defaulted treatment compared to 8% of the patients supervised by health staff. Treatment success was achieved in 88% of the patients supervised by family members compared to 77% of the patients supervised by health staff.

Whether family members can be treatment supporters will not only depend on rates of default and treatment success, but also on cultural circumstances (Macq et al 2003). In a home-based treatment supervision study in Uganda, the treatment supervision was preferably done by a neighbour rather than a family member (Adatu et al 2003). This was to avoid uneasiness within the family if the relationship between patient and supporter was not congruent with hierarchical pattern commonly seen in Ugandan families. This example makes it clear that treatment delivery strategies and supervision strategies are context-specific and that the strategies have to be carefully assessed in each new setting.

The National Tuberculosis and Leprosy Programme of Tanzania is currently conducting a pilot study to assess the efficacy of the proposed new treatment allocation and supervision strategy in three districts other than those involved in the assessment of needs. The proposed strategy can be seen as patient-centered since it is the patient who decides on where and how of treatment supervision. Such a patient-centered approach fits within the universal TB-control as described in the Stop-TB strategy (2006b). This strategy focuses on DOTS expansion, addressing TB/HIV and multidrug-resistant TB, strengthening of health systems, engaging of all health care providers, empowerment of TB patients and communities, and enabling research. We realize that the empowerment of TB-patients and communities is far wider than home-based treatment and supervision by family members. However, the freedom of choice to the patients gives them more ownership of their own treatment and engages the patient in taking responsibility for their treatment. Both these factors can contribute to improving adherence to TB-treatment which is essential for treatment success.

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