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# Household members and health care workers as supervisors of tuberculosis treatment

## Membros familiares e profissionais de saúde na supervisão do tratamento da tuberculose

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### ABSTRACT

**OBJECTIVE:** To compare tuberculosis cure rates among patients supervised by household members or health care workers.

**METHODS:** Prospective cohort study of 171 patients treated by the program in Vitoria, Southeastern Brazil, from 2004 to 2007. Each patient was followed-up for six months until the end of the treatment. Of the patients studied, a household member supervised 59 patients and healthcare workers supervised 112 patients. Patients' sociodemographic and clinic data were analyzed. Differences between groups were assessed using chi-square test or Student's t-test. Significance level was set at 5%.

**RESULTS:** Most patients had smear positive, culture confirmed pulmonary tuberculosis. Two patients were HIV-positive. There were more illiterate patients in the healthcare-supervised group, in comparison to those supervised by their families ( $p=0.01$ ). All patients supervised by a household member were cured compared to 90% of the patients supervised by health care workers ( $p = 0.024$ ).

**CONCLUSIONS:** Successful tuberculosis treatment was more frequent when supervised by household members.

**DESCRIPTORS:** Tuberculosis, nursing. Homebound Persons. Family Nursing. Caregivers. Home Nursing. Medication Therapy Management. Treatment Outcome. Cohort Studies.

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## RESUMO

**OBJETIVO:** Comparar os resultados de cura por tuberculose entre pacientes supervisionados pelo membro familiar e pelo profissional de saúde.

**MÉTODOS:** Estudo de coorte prospectiva de 171 pacientes de Vitória, ES, no período de 2004 a 2007. Cada paciente foi acompanhado por seis meses até a finalização do tratamento. Dos pacientes estudados, 59 pacientes tratados eram supervisionados por um membro familiar e 112 pelos profissionais de saúde. Foram avaliados dados sociodemográficos e clínicos dos pacientes. Diferenças entre os grupos de estudo foram avaliadas utilizando o teste qui-quadrado ou teste t de Student ao nível de significância de 5%.

**RESULTADOS:** A maioria dos sujeitos do estudo apresentaram bacioscopia positiva e cultura confirmada para tuberculose. Dois pacientes tinham sorologia positiva para HIV. Um número maior de pacientes no grupo supervisionado por profissionais de saúde não eram alfabetizados, comparado com aqueles pacientes do grupo supervisionado por membros familiares ( $p = 0,01$ ). Todos os pacientes supervisionados por um familiar foram curados, frente a 90% dos pacientes supervisionados pelos profissionais de saúde ( $p=0,024$ ).

**CONCLUSÕES:** O sucesso do tratamento de tuberculose foi maior quando supervisionado por um familiar.

**DESCRITORES:** Tuberculose, enfermagem. Pacientes Domiciliares. Enfermagem Familiar. Cuidadores. Assistência Domiciliar. Conduta do Tratamento Medicamentoso. Resultado de Tratamento. Estudos de Coortes.

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## INTRODUCTION

Tuberculosis (TB) is a major public health problem in developing countries. Since standard short course chemotherapy for TB lasts six months and requires taking multiple drugs, patients frequently stop taking their medications before completion.<sup>7</sup> Thus, default is the biggest challenge in TB control due to the length and complexity of TB treatment.

Multiple strategies have been tried to promote adherence and reduce default, the most widely accepted of which is directly observed treatment (DOT).<sup>4,11</sup> Current technical manuals define DOT as direct supervision of medication ingestion by a treatment supporter who is acceptable and accountable to the patient and to the health system.<sup>4</sup>

The Directly Observed Therapy Short Course (DOTS), strategy advocated by the World Health Organization, includes five elements: supervised treatment by DOT, case detection by smear microscopy, regular provision of high quality drugs, an efficient system for registration of TB cases and for reporting treatment outcomes, and political commitment to TB control.<sup>17</sup> Supervised therapy where a designated treatment supervisor watches the patient swallow each dose of medications is a key component of DOTS. When default rates are high, many patients are not cured and are at risk for the development of acquired drug resistance.<sup>3,16</sup>

Identifying the most practical and cost-effective method of supervision that results in the highest cure rates is an important issue for the implementation of the DOT strategy. A study performed in Ceará, Northeastern Brazil, showed that a relationship based on respect and friendship between patients, their families and health care workers (HCW) was a key factor in promoting treatment completion as well as promoting active involvement of the patient's family members in anti-TB treatment.<sup>6</sup> In another study performed in Mexico, treatment completion and cure rates were similar in patients supervised by HCW and in those in self-administered treatment.<sup>15</sup>

A recent report by Okanurak et al<sup>13</sup> in Bangkok showed that treatment completion rates were significantly greater when treatment was supervised by a family member, compared to supervision by health professionals.<sup>13</sup> In a controlled trial in Nepal, treatment supervision by family members was as effective as treatment supervised by health professionals.<sup>12</sup> Although these results suggest that family members may be satisfactory treatment supervisors, there is still no agreement on the TB guidelines about the use of family members as treatment supervisors by TB control programs.

In 2001, DOT using household members as treatment supervisors was implemented in Vitoria, a large city in the Southeast of Brazil, one of the 23 countries with the highest global burden of TB. In a previous uncontrolled study, we reported high cure rates using domiciliary members as treatment supervisors.<sup>8</sup>

Due to the importance of identifying the most effective strategy for DOTS supervision, the present article aimed to compare default and cure rates among patients supervised by household members or HCW.

## METHODS

From November 2004 to March 2007, patients with newly diagnosed TB, who were treated at a university hospital and at a healthcare center in a surrounding poor neighborhood of Vitoria, were included in the study. In accordance with usual TB program procedures, before beginning anti-TB therapy patients chose whether their treatment would be supervised by a person living in their household (domiciliary supervisor) or a HCW.

All patients diagnosed as a new case were included in the study. Patients undergoing secondary TB treatment and re-entering after dropouts or relapses were excluded.

Among the 203 new patients with TB treated during the study, 32 refused to participate, most frequently due to lack of time. The study cohort included 171 patients: 59 patients chose a domiciliary supervisor and 112 elected treatment with a HCW supervisor.

Supervisors who were household members (domiciliary-supervised group) were trained by TB program staff to properly administer anti-TB drugs to the patient and to mark the patient's treatment card after each dose was administered. Drugs and treatment cards were supplied to the household supervisors every other week and were reviewed together by the supervisor and a TB program worker every other week.

Patients whose supervisors were HCW-supervised group attended the outpatient clinic daily for their medications. The supervising HCW administered their anti-TB drugs and marked their treatment cards. Patients who failed to attend clinic for scheduled follow-up visits were routinely traced and contacted by a HCW from the TB control program. In the HCW-supervised group, patients came to the outpatient clinic daily between 7 AM and 4 PM to receive their DOT. Each HCW supervisor supervised DOT daily for three patients on average during the study.

Patients in both groups were followed-up during monthly scheduled visits to the TB reference outpatient clinics over the six months of anti-TB treatment.

Sputum specimens were collected under routine TB program conditions before starting treatment and at the end of therapy. Sputum smears and cultures on Ogawa medium were done at the Mycobacteriology Laboratory of the *Universidade Federal do Espírito Santo*, the state TB reference laboratory, according to standard procedures.<sup>5</sup>

Failing to attend clinic for more than one month during treatment was defined as default. Treatment cure was defined as no clinical signs or symptoms of TB and/or having a negative sputum culture after receiving six months of anti-TB treatment.

For patient profiles, data on age, sex, education, chest radiographic findings, presentation of disease (pulmonary or extrapulmonary TB), HIV status, sputum smear and cultures results, supervisor type and treatment outcome were obtained from treatment records and the TB laboratory.

Data were entered and analyzed using STATA version 9 (StataCorp, College Station, TX). Differences between the groups were assessed by chi-square or Student's t-test, when appropriate. We calculated the relative risk (RR) for factors associated with default using bivariate analysis. P-values less than 0.05 were considered statistically significant.

The study protocol was approved by the institutional review board of the *Universidade Federal do Espírito Santo*.

## RESULTS

The baseline characteristics of the participants are listed in Table. The age and sex of patients in both groups were similar. As is typical in most TB programs worldwide<sup>a</sup> the majority of the patients treated for TB in our study (71%) were male. The age range of our patients was 18 to 54 years (mean 33 years), reflecting the young adult age group most commonly affected by TB in high burden countries. Most patients had smear positive, culture confirmed pulmonary TB. Although the patients in the domiciliary supervisor group had more culture positive confirmations than the patients supervised by HCW (RR=4.88; 95% CI:1.27;18.72), the HCW group had more patients with sputum smear grades of 2 to 3+ (67% vs. 52%, p=0.09).

Only two patients in either group were HIV-infected. More patients in the HCW supervisor group were illiterate compared to those supervised by household members (p = 0.01,  $\chi^2$  test for trend).

In the domiciliary supervisor group, 69.5% (41/59) of the supervisors were the patient's spouse, 24.4% (15/59)

<sup>a</sup> World Health Organization. Global tuberculosis control. (WHO Report 2004) [cited 2008 May 28]. Available from: <http://www.who.int/tb/publications/globalreport/2007/en/>

**Table.** Baseline characteristics of study patients stratified by type of supervision group. Vitória, Southeastern Brazil, 2004-2007.

Variable	Domiciliary supervisor (n =59)	Healthcare supervisor (n =112)	RR (95% CI)	P-value
Sex male – n (%)	39 (66)	80 (71)	0.85 (0.55;1.31)	0.47
Age – mean ± SD	34 (18.2)	33 (19.5)	-	0.55
Education– n (%)				
None	24 (41)	21(18.7)		0.01
Primary	20 (34)	45 (40.2)	-	
Middle	14 (24)	16 (14.3)		
Secondary or above	1 (2)	6 (5.4)		
No information	-	24 (21)		
HIV-infected – n (%)	-	2 (1.8)	_ <sup>a</sup>	0.55
Abnormal chest radiograph – n (%)	59 (100)	105 (93.7)	_ <sup>a</sup>	0.05
Confirmed TB – n (%)	59 (100)	112 (100)	_ <sup>a</sup>	-
Disease presentation				
Pulmonary TB – n (%)	59 (100)	98 (87.5)	_ <sup>a</sup>	0.003
Extrapulmonary TB – n (%)	-	14 (12.5)		
Smear positive – n (%)	46 (78)	85 (75.9)	1.08 (0.65;1.78)	0.76
Culture positive – n (%)	57 (90.6)	89 (79.5)	4.88 (1.27;18.72)	0.002

<sup>a</sup> Exact confidence levels not possible with zero count cells

were the mother and 5.1% (3/59) were other (father, brother, sister, grandmother). Of these supervisors, 56% (33/59) worked outside of the home.

All patients whose supervisors were household members were cured and 90% of those in the HCW supervisor group were cured, a statistically significant difference ( $p=0.024$ ,  $\chi^2$  test). Two patients in the HCW group died during the TB treatment.

## DISCUSSION

In a poor urban setting in Brazil, improved treatment outcomes can be achieved using household members as supervisors of TB treatment as shown in Maciel et al's study.<sup>8</sup> We found that cure rates equal or more than 90% were achieved during treatment supervised by both domiciliary and clinic-based HCW, which exceed the Brazilian national TB program target cure rate (85%). Our results confirm earlier studies from other program settings showing that household members are good DOT supervisors and can increase adherence and cure rates.<sup>1,10,12,18</sup>

Household members appear to be better treatment supervisors than HCW in some program settings since they may more effectively mobilize a network of family support around the patient's treatment than HCW can. The involvement of other household members may be decisive for treatment completion and cure.<sup>2,9</sup> Besides, household members know the patient well and are

invested in their care. HCW in TB programs are often overburdened by many duties, large patient numbers and limited transportation for outreach patients and treatment supervision.

Our study had some limitations. The non-randomized design, where patients chose their own type of supervisor, precludes definitive statements. Nevertheless, a non-randomized design was used because it more closely replicates program conditions where newly diagnosed TB patients participate in choosing their treatment supervisor. Patients with stronger home relationships and family resources may have elected to have a household member as a treatment supervisor. In our study, illiterate patients were more likely to select a HCW as their supervisor. Possibly, an illiterate patient also has uneducated family members, who can have difficulty in recognizing the medication and taking notes on the treatment cards, which are required for this strategy. The fact that the domiciliary supervisor group had approximately five times more patients with a confirmed positive culture can be explained because the requesting of a culture test is not universal for all patients in Brazil. The control program only recommends bacilloscopy and culture for diagnosis in those cases where a negative bacilloscopy is suspected of resulting from drug-resistance, extrapulmonary presentation, atypical micobacteria and treatment failure.<sup>b</sup> Our data show a greater number of patients with higher sputum smear grades (2 and 3+) in the HCW group, compared to the domiciliary supervisor

<sup>a</sup> Ministério da Saúde. Programa Nacional de Controle da tuberculose. Brasília: Ministério da Saúde; 2002.

group. This fact can be associated with the presentation of moderate and severe tuberculosis,<sup>14</sup> which could justify less culture requests by the tuberculosis control services.

Other unknown factors not included in this study could also influence the choice of supervisor and create bias, such as religion, distance to health service, type of work, drugs use and others. Among the strengths of our study are the program setting where it was developed, including patients representative of persons and

groups most affected by TB in high burden countries. Also, our study presented excellent participation and follow-up rates (95%).

The use of household members as supervisors frees up resources and HCW time for other important tasks in TB control. The feasibility and effectiveness of using household members as treatment supervisors may differ in different settings and cultures. The good results achieved with this strategy in our setting suggest that this strategy can be applied in TB programs in Brazil.

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