# Research

# Staff training and ambulatory tuberculosis treatment outcomes: a cluster randomized controlled trial in South Africa

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**Objective** To assess whether adding a training intervention for clinic staff to the usual DOTS strategy (the internationally recommended control strategy for tuberculosis (TB)) would affect the outcomes of TB treatment in primary care clinics with treatment success rates below 70%.

**Methods** A cluster randomized controlled trial was conducted from July 1996 to July 2000 in nurse-managed ambulatory primary care clinics in Cape Town, South Africa. Clinics with successful TB treatment completion rates of less than 70% and annual adult pulmonary TB loads of more than 40 patients per year were randomly assigned to either the intervention ($n = 12$) or control ($n = 12$) groups. All clinics completed follow-up. Treatment outcomes were measured in cohorts of adult, pulmonary TB patients before the intervention ($n = 1200$) and 9 months following the training ($n = 1177$). The intervention comprised an 18-hour experiential, participatory in-service training programme for clinic staff delivered by nurse facilitators and focusing on patient centredness, critical reflection on practice, and quality improvement. The main outcome measure was successful treatment, defined as patients who were cured and those who had completed tuberculosis treatment.

**Findings** The estimated effect of the intervention was an increase in successful treatment rates of 4.8% (95% confidence interval (CI): −5.5% to 15.2%) and in bacteriological cure rates of 10.4% (CI: −1.2% to 22%). A treatment effect of 10% was envisaged, based on the views of policy-makers on the minimum effect size for large-scale implementation.

**Conclusion** This is the first evidence from a randomized controlled trial on the effects of experiential, participatory training on TB outcomes in primary care facilities in a developing country. Such training did not appear to improve TB outcomes. However, the results were inconclusive and further studies are required.

**Keywords** Tuberculosis, Pulmonary/therapy; Health personnel/education; Directly observed therapy; Treatment outcome; Patient compliance; Inservice training; Patient-centered care; Ambulatory care; Randomized controlled trials; Cluster analysis; South Africa (*source: MeSH, NLM*).

**Mots clés** Tuberculose pulmonaire/thérapeutique; Personnel sanitaire/enseignement; Thérapie sous observation directe; Evaluation résultats traitement; Observance prescription; Stage; Soins centrés patient; Soins ambulatoires; Essai clinique randomisé; Sondage en grappes; Afrique du Sud (*source: MeSH, INSERM*).

**Palabras clave** Tuberculosis pulmonar/terapia; Personal de salud/educación; Resultado del tratamiento; Terapia por observación directa; Cooperación del paciente; Capacitación en servicio; Atención dirigida al paciente; Cuidados ambulatorios; Ensayos controlados aleatorios; Análisis por conglomerados; Sudáfrica (*fuente: DeCS, BIREME*).

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## Introduction

Tuberculosis (TB) is a major contributor to the disease burden in developing countries (*1–4*), including South Africa (*5*), where it is exacerbated by the epidemic of human immunodeficiency virus (HIV) (*6–8*). The implementation of DOTS — the internationally recommended strategy for the control of TB (*9, 10*) — in South Africa since 1996 has improved drug availability, bacteriological diagnosis and programme monitoring. South Africa uses the 6-month (8 months for re-treatment patients) multi-drug regimen that includes rifampicin. Treatment is taken under the direct observation of another person such as a health-care provider or a lay volunteer (*11*). TB care in the public sector generally covers the poorest areas and is provided free of charge to patients (*5*). Nevertheless, cure rates in South Africa remain at 65% (*5*), and are therefore insufficient to control or reverse the epidemic.

Previous studies have suggested that the failure of the TB control programme in South Africa to achieve its treatment outcome targets is multifaceted (*12–14*) (Fig. 1). Poor quality of care, resulting from rigid clinic routines; poorly motivated staff; and inadequate provider–patient relations, all contribute to poor adherence to treatment (*12, 15*). Similar problems have been reported elsewhere (*16–20*). However, there is little rigorous evidence of the effects of interventions that aim to improve the way in which health workers care for TB patients (*21, 22*).

To address these problems, a short in-service training programme for primary care clinic staff caring for TB patients was developed. We report here the findings of a cluster randomized controlled trial conducted to evaluate the impact of the programme on the outcomes of TB treatment (*23*).

The objective of the present study was to assess whether the addition to the DOTS strategy of an experiential, participatory training intervention for clinic staff would improve

treatment outcomes, when compared to those achieved with DOTS alone, in TB patients attending clinics with low rates for the successful treatment of TB (< 70%) in South Africa.

Our study hypothesis was that training would have a positive impact on patient adherence and treatment outcomes through better provider–client relations and improvements in the organization of TB care. The approach was pragmatic: we tested an intervention that could be realistically implemented in public sector facilities in South Africa and in countries with similar health-care delivery systems, and that examined key outcomes of TB control programmes (*24–26*).

## Methods

### Setting

The study was undertaken in nurse-managed municipal primary health clinics that provided care to TB patients in Cape Town, South Africa. These clinics manage more than 90% of ambulatory TB treatment in the city. Many of the clinics are based in low-income, periurban townships. All had good access to diagnostic and referral facilities and drug supplies.
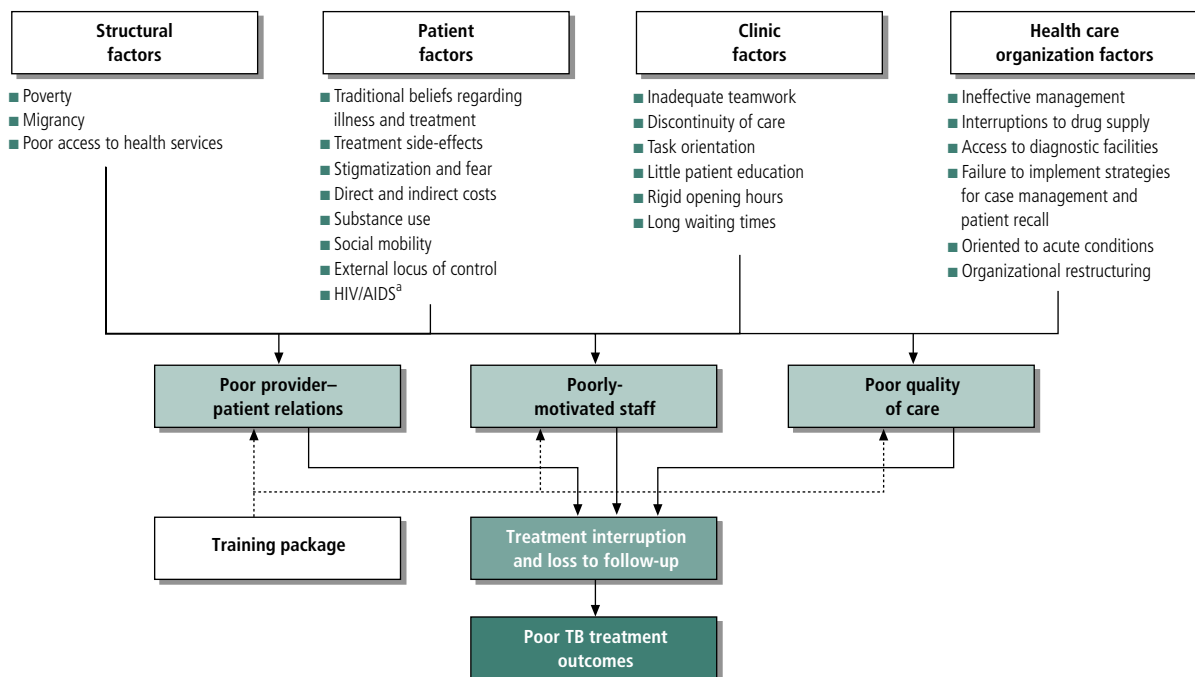
### Ethics and consent

Study approval was granted by the Medical Research Council of South Africa and health department managers in Cape Town. The facilitators met the staff of each clinic allocated to the intervention group to discuss the programme and to seek their consent for participation. One clinic allocated to the intervention group refused the intervention, but was analysed on an intention-to-treat basis.

### Clinic recruitment

Primary care clinics had to meet the following entry criteria for participation in the trial.

Fig. 1. **Factors affecting outcomes of tuberculosis (TB) control programmes in South Africa**



a HIV/AIDS = Human immunodeficiency virus/acquired immunodeficiency syndrome.

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- The overall successful treatment completion rate for all adult patients with smear-positive pulmonary TB was less than 70% in the year preceding the trial (1997). This ensured that only clinics with poor treatment outcomes were entered into the trial. Fifty-nine of the 90 municipal clinics were eligible under this criterion, accounting for 82% of the annual total load of adult, smear-positive pulmonary TB patients in Cape Town.
- The adult smear-positive pulmonary TB load was more than 40 patients per year, so as to ensure that the sample size of 50 patients per clinic could be achieved.
- The clinic had not acted as a pilot site for this or for other similar interventions in the 3 years preceding the study.
- The clinic offered the standard package of ambulatory TB care. This excluded services offered in prisons, inpatient facilities and mobile clinics.

Thirty-nine of the 90 primary care clinics in Cape Town were eligible for entry into the trial (Fig. 2).

## Patient recruitment

Eligible TB patients were adults (over 14 years), with Ziehl–Nielson sputum-smear- positive pulmonary TB, who started a new course of TB treatment during the course of the study. The trial focused on patients with smear-positive pulmonary TB as this is the key target group for the DOTS strategy (*11*).

The following patients were excluded:

- those who had transferred in from another health facility after the first 2 weeks of treatment;
- patients with recurrent TB who had already been in the trial; and
- patients in whom there was evidence of multidrug-resistant TB.

The pre-intervention treatment rates for each clinic were established using a cohort of the 50 most recent consecutive eligible patients attending that clinic for treatment initiation, whose treatment was completed before December 1998. The outcome of training was assessed, starting 2 weeks after each clinic had completed the training intervention, using a similar cohort of 50 sequential patients from each clinic.

## Sample size

The sample size of 24 clinics and 50 patients per clinic pre- and post-intervention was chosen to enable the detection of a 10% difference in successful treatment rate between the intervention and control groups, with power of 80% at a significance level of 5%, assuming an intra-cluster correlation coefficient of 0.05. The intra-cluster correlation coefficient was calculated using specially collected data on TB treatment outcomes from potential study sites. The selection of a 10% difference as the envisaged treatment effect was based on discussions with policy-makers regarding the minimum effect size required for large-scale implementation of the intervention.

## Stratification and randomization

Clinics were the unit of randomization and analysis because the intervention was directed towards clinic teams rather than individual staff. Eligible clinics were stratified according to the number of TB patients treated in the previous year as there was some evidence that clinic size was inversely related to treatment outcomes (*27*). This approach ensured a balance in the size of

Fig. 2. **Trial profile**
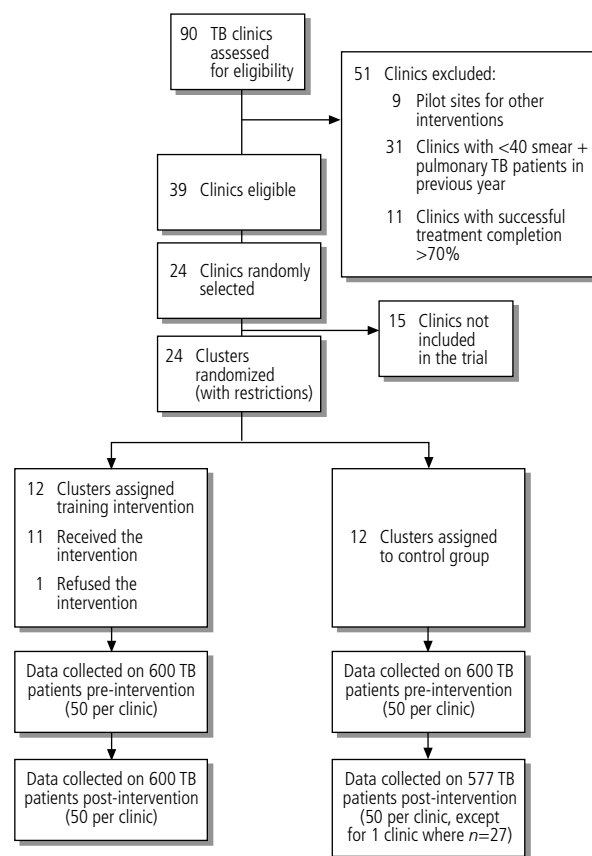


TB = Tuberculosis.

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the clinics randomly allocated to each group (*28*) and the generalizability of the findings across clinics in Cape Town.

All of four eligible large clinics (> 200 smear-positive cases per year) were included in the study. Random samples of 10 of 16 medium-sized clinics (> 111 and < 200 smear-positive cases per year) and 10 of 19 small clinics (> 40 and < 110 smear-positive cases per year) were drawn from separate opaque containers by an individual unconnected with the study or the health services, under the direct observation of the statistician. This ensured a self-weighted sample of these two groups of clinics in the trial. The 24 clinics included in the trial were then randomized within each stratum to either the intervention or control group. Restrictions were applied to ensure that all municipalities were represented so as to maximize generalizability of the findings across the metropolitan area and to improve the likelihood of participation by municipal health departments. The clinics were also allocated in such a way that no health service area manager was responsible for clinics in both arms of the trial, in order to reduce the potential for contamination between the intervention and control clinics. The 24 clinics accounted for 45% of the annual TB patient load in Cape Town (*27*).

## Definition of outcome measures

The principal study outcome, "successful treatment", was defined according to International Union Against Tuberculosis and Lung Disease/WHO criteria as patients who were cured and those who had completed treatment (*23*). "Cure" applied to patients who had had a pre-treatment sputum smear that was positive, who had received 6 months of treatment (8 months

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for re-treatment patients), and who had a negative second smear after 2–3 months of treatment and a negative smear result at the end of treatment.

"Treatment completed" applied to patients who had a positive pre-treatment smear and had completed the full course of treatment, but had either no smear result at the end of 2 months and a negative end-of-treatment result; or had negative results at the end of 2 months and no end-of-treatment result. Patients with a positive smear or culture result at the end of treatment were considered to be "treatment failures", whereas "treatment interrupters" were patients who had stopped taking their treatment for 8 or more weeks in the course of the treatment period. Other outcomes were: transfer to another health facility, or death, due to TB or other causes, while receiving treatment. The laboratory staff who undertook the smear microscopy were unaware of the group to which the clinics had been allocated.

## Treatment regimens

All patients received their medication under the DOTS strategy, in which a second person, usually a nurse, was assigned to observe that each treatment dose was taken by the patient (11). New patients (i.e. those who had never before had any TB treatment) received weight-adjusted Rifater® (rifampicin, isoniazid, pyrazinamide) and ethambutol, five times per week during the intensive phase of 8–12 weeks. If they had a negative smear result after 8 weeks, they received Rifinah® (rifampicin and isoniazid) for the following 16 weeks. If their smear result was positive at 8 weeks, the intensive phase was continued to 12 weeks, after which they received Rifinah for 12 weeks. Smear-positive re-treatment patients received the same regimen as new smear-positive patients, with the addition of weight-adjusted streptomycin for the first 8 weeks. At the end of the third month, the pyrazinamide was discontinued.

## The intervention

The "clinic level" barriers to improving adherence to TB treatment included poor provider–patient relations; inadequate teamwork among providers; lack of audit; and little motivation to implement changes in practice (12, 29). The training intervention therefore focused on concentrating the attention of all primary care clinic staff on the central task of maintaining patients' participation in the TB treatment process, so as to improve treatment adherence and outcomes. The design of the intervention drew on a number of theoretical models: the theory of reasoned action (30), social learning theory (31)

and the theory of self-efficacy (32). It also utilized concepts and materials developed by the Health Workers for Change Project (33, 34). Further information on the intervention has been published elsewhere (35, 36). The intervention had the following aims:

- equipping clinic staff to understand the barriers to improving client relations (37);
- encouraging patient-centredness, including the provision of support to patients and sharing control of the consultation with them (38);
- empowering clinic staff to implement changes at their clinic; and
- continuous quality improvement, self-evaluation and critical reflection on practice.

The package was pilot-tested in two clinics where encouraging results were obtained in improving quality of care and adherence to TB treatment (35). Seven training modules were developed (Box 1), each constituting one training session. Primary care clinic staff met with the learning facilitators for one 3-hour session per week for 6 weeks. Each session was linked to the next, and the learning points reinforced, by requesting participants to complete some "homework" and reviewing this at the next session. The training used an experiential learning approach which encouraged participants to reflect on their experiences of caring for TB patients; explore problems in delivery of care; and develop an action plan for practice change (33, 39, 40). The training allowed some flexibility for responding to the specific needs of each clinic and therefore differed slightly between the clinics. TB patients were not directly involved in developing or delivering the intervention. However, research on consumer experiences of illness informed the design of the intervention (41).

Some follow-up inputs were provided in the 6 weeks following the final training session. These included meetings and telephone discussions between the facilitators and clinic staff. Further supervision was the responsibility of health service managers. Training began in February 1999 and was completed in October 1999.

The training was undertaken by two clinical nurse practitioners, both of whom had extensive experience of working with TB patients in primary care facilities. Between them, the facilitators were fluent in the three commonly spoken local languages. They were therefore able to conduct training in the preferred language of the clinic staff. The successful implementation of the training was verified, firstly, through training

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| Box 1. **The clinic training modules** |
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| **Session 1**   What would you like to know? Introduction of the project. Explanation of the training programme and how it will operate. Seeking consent from the health-care workers for their participation in the training process. |
| **Session 2**   Who am I? Self reflection to identify the factors that resulted in each staff member's choice to work at the clinic and how this choice affects the care provided to patients and attitudes towards both patients and colleagues. |
| **Session 3**   Looking ahead. Visualizing the ideal clinic. How does the clinic work now? What are the barriers to achieving the ideal clinic? |
| **Session 4**   A fresh look at how we work. Analysing client flow within the clinic — where are the problems? |
| **Session 5**   Making contact. Communication: how to understand the patient's experience of illness. |
| **Session 6**   A new journey. The way forward: using the output of the training to develop a plan for change in the clinic. Looking at ways of achieving the planned changes. |
| **Session 7**   Follow-up: what progress has been made since the final session? |

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debriefing meetings that discussed progress in each clinic and reviewed the programme for forthcoming sessions and, secondly, through observation of training sessions in half of the intervention clinics by a researcher.

The staff who attended the training sessions included professional and assistant nurses, doctors, health educators, clerical staff and community-based lay health workers associated with the clinic. The size of the group ranged from 4 to 20 participants. Training was successfully conducted in all but one clinic, which refused the intervention. In some clinics all staff attended whereas in others only staff who worked with TB patients volunteered to attend.

### Data collection

Cases were identified manually from non-computerized TB registers at 20 of the 24 participating clinics. These registers were completed routinely by the clinic staff and included the following data: patient name and clinic number; date of notification; patient origin (where referred from); gender; age; type of TB (e.g. pulmonary or extrapulmonary); sputum smear results at diagnosis and at 2 and 5 months after treatment initiation; and whether the patient was a new or a re-treatment case. A planned secondary measure of adherence to treatment (doses taken as a proportion of doses prescribed) could not be obtained as this information ceased to be collected routinely during the study. There were no other changes to the TB register during the study period.

For the four remaining clinics, TB data were sent directly to the municipal health department where they were entered into a central register. Data for these clinics were extracted at that level. The two field workers who extracted data from the TB registers were not blinded as to the clinic allocation, but were not involved in the design or implementation of the intervention or in the final analysis. Clinic staff were blinded as to which patients would be included in the cohorts whose outcomes would be assessed.

Missing information was sought in the first instance from the patient's clinic folder. Where clinic or municipal records were incomplete, the records of the central laboratory service were searched for the results of sputum smears. This central laboratory conducts sputum smears for all TB patients treated in primary care clinics in the Cape Town metropolitan area and

has rigorous quality controls. For quality assurance, a random sample of 10% of the sputum smear results held at clinics were verified against the laboratory database to confirm treatment outcomes. For the collection of data before the intervention, the first patient to enter the trial started treatment on 2 July 1996 and the last on 15 December 1998. For the collection of post-intervention data, the first patient started treatment on 6 April 1999 and the last patient on 6 July 2000. Post-intervention data collection was therefore initiated in some clinics while training was still taking place in others.

A parallel qualitative evaluation assessed the extent to which clinic staff carried out the activities advocated in the intervention.

### Statistical analysis

Analysis was by intention to treat and took into account the effects of clustering (42). The main analysis compared the outcomes of TB treatment of the 12 intervention and 12 control clinics before the intervention with those 9 months later (post-intervention). Data on individual patients were combined for each intervention and control clinic and the rates of successful treatment calculated for each clinic, and for previously planned subgroups (clinic stratum, gender, and whether the patient was new or attending for re-treatment). A two-way analysis of variance was used for the analysis of the differences between the pre- and post-intervention outcomes, with stratification and intervention as the two main effects. All analyses were planned a priori. All statistical tests were two sided and 95% confidence intervals (CI) were calculated for the effects of the intervention on various outcomes (28).

## Findings

### Data validity and collection

The clinic-based records were found to match the central laboratory-based records for 100% of the sampled records. Complete pre-intervention data on 50 sequential patients for each of the 24 clinics were successfully obtained. Post-intervention data for 50 patients were obtained for all but one clinic (Fig. 2). This clinic had enrolled only 27 eligible patients, possibly due to changes in the catchment area. One clinic allocated to the intervention group refused training, but data were collected on 50 pre-intervention and 50 post-intervention patients and analysed

Table 1. **Pre-intervention and post-intervention data on patient demographics and treatment category**

| | Pre-intervention | | | Post-intervention | | |
|---|---|---|---|---|---|---|
| | **Control clinics** | **Intervention clinics** | **Total** | **Control clinics** | **Intervention clinics** | **Total** |
| | **n (%)** | **n (%)** | **n (%)** | **n (%)** | **n (%)** | **n (%)** |
| **Total number of patients** | 600 | 600 | 1200 | 577 | 600 | 1177 |
| **Demographic data** | | | | | | |
| Mean age (years) | 35.2 (SD[a] = 11.44) | 34.5 (SD = 12.15) | 34.8 (SD = 11.80) | 35.5 (SD = 11.7) | 35.2 (SD = 12.1) | 35.4 (SD = 11.9) |
| Male | 388 (64.7) | 399 (66.5) | 787 (65.6) | 374 (64.8) | 393 (65.5) | 767 (65.2) |
| Female | 212 (35.3) | 201 (33.5) | 413 (34.4) | 203 (35.2) | 207 (34.5) | 410 (34.8) |
| **Patient category** | | | | | | |
| New patients | 385 (64.2) | 397 (66.2) | 782 (65.2) | 390 (67.6) | 391 (65.2) | 781 (66.4) |
| Re-treatment patients | 215 (35.8) | 203 (33.8) | 418 (34.8) | 187 (32.4) | 209 (34.8) | 396 (33.6) |

[a] SD = Standard deviation.

Table 2. **Pre-intervention and post-intervention data on patient treatment outcomes**

| | Pre-intervention | | | Post-intervention | | |
|---|---|---|---|---|---|---|
| | Control clinics | Intervention clinics | Total | Control clinics | Intervention clinics | Total |
| | *n* (%) | *n* (%) | *n* (%) | *n* (%) | *n* (%) | *n* (%) |
| **Overall treatment outcome** | | | | | | |
| Cured | 310 (51.6) | 259 (43.3) | 569 (47.4) | 270 (46.8) | 266 (44.3) | 536 (45.5) |
| Treatment completed | 39 (6.5) | 67 (11.1) | 106 (8.8) | 82 (14.2) | 94 (15.7) | 176 (15.0) |
| Treatment failure | 9 (1.5) | 10 (1.7) | 19 (1.6) | 6 (1.0) | 8 (1.3) | 14 (1.2) |
| Interrupted | 156 (26) | 193 (32.2) | 349 (29.1) | 140 (24.3) | 171 (28.5) | 311 (26.4) |
| Transferred | 65 (10.8) | 51 (8.5) | 116 (9.7) | 57 (9.9) | 45 (7.5) | 102 (8.7) |
| Died | 21 (3.5) | 20 (3.3) | 41 (3.4) | 22 (3.8) | 16 (2.7) | 38 (3.2) |
| **Treatment outcomes — new patients** | | | | | | |
| Cured | 223 (57.9) | 186 (46.9) | 409 (52.3) | 199 (51.0) | 192 (49.1) | 391 (50.1) |
| Treatment completed | 26 (6.8) | 45 (11.3) | 71 (9.1) | 62 (15.9) | 68 (17.4) | 130 (16.6) |
| Treatment failure | 5 (1.3) | 5 (1.3) | 10 (1.3) | 2 (0.5) | 4 (1.0) | 6 (0.8) |
| Interrupted | 84 (21.8) | 114 (28.7) | 198 (25.3) | 81 (20.8) | 92 (23.5) | 173 (22.2) |
| Transferred | 41 (10.6) | 34 (8.6) | 75 (9.6) | 35 (9.0) | 27 (6.9) | 62 (7.9) |
| Died | 6 (1.6) | 13 (3.3) | 19 (2.4) | 11 (2.8) | 8 (2.0) | 19 (2.4) |
| **Treatment outcomes — re-treatment patients** | | | | | | |
| Cured | 87 (40.5) | 73 (36.0) | 160 (38.3) | 71 (38.0) | 74 (35.4) | 145 (36.6) |
| Treatment completed | 13 (6.0) | 22 (10.8) | 35 (8.4) | 20 (10.7) | 26 (12.4) | 46 (11.6) |
| Treatment failure | 4 (1.2) | 5 (2.5) | 9 (2.2) | 4 (2.1) | 4 (1.9) | 8 (2.0) |
| Interrupted | 72 (33.5) | 79 (38.9) | 151 (36.1) | 59 (31.6) | 79 (37.8) | 138 (34.8) |
| Transferred | 24 (11.2) | 17 (8.4) | 41 (9.8) | 22 (11.8) | 18 (8.6) | 40 (10.1) |
| Died | 15 (7.0) | 7 (3.4) | 22 (5.3) | 11 (5.9) | 8 (3.8) | 19 (4.8) |

in the allocated group. The intra-cluster correlation coefficient for the main outcome (successful treatment completion) at the post-intervention time point was 0.034. This closely approximated to the coefficient of 0.05 used to plan the study.

### Comparability
Prior to the intervention, the clinics in the intervention and control groups were comparable with respect to patient category (new or re-treatment); treatment outcomes; age; and gender distribution (Table 1 and Table 2). The two groups were also comparable with respect to the type of supervision received by patients. 89.1% of patients in the clinics that received the intervention and 79.8% of those in the control group of clinics received clinic-supervised treatment.

### Outcomes
Over the study period the principal outcome measure — rates for successful completion of treatment — improved more in the clinics that received the intervention than in the control clinics (4.8%, 95% CI: –5.5% to 15.2%) (Table 3). The bacteriological cure rate improved by 2.5% in the intervention clinics following the intervention, while it decreased by 7.9% in the control clinics (difference = 10.4%, 95% CI: –1.2% to 22%). These differences were not statistically significant.

The estimated effect of the intervention on successful completion of treatment for new patients only was 6.9% (95% CI: –6% to 20%) and for re-treatment patients only was 4.1% (95% CI: –13.5% to 21.7%). No difference in the effect of the intervention in relation to clinic size was detected.

## Discussion
This study examined the effects on TB treatment outcomes of an experiential, participatory training programme for primary health clinic staff. Successful treatment rates and bacteriological cure rates improved marginally in the clinics that received the intervention when compared to the control clinics. However, these differences were not statistically significant and the findings of the trial are therefore inconclusive. Bias is unlikely to explain these results. The training programme was successfully implemented in 11 of the 12 intervention clinics. The intervention and control groups were similar before the intervention; the outcome measures were objective; the quality of the data was high; and follow-up was complete for all clinics and for 98% of individual patients. The data extractors were not involved in the design or implementation of the trial or in the data analysis and the laboratory staff were blinded to clinic allocation.

Contamination is unlikely because the clinics that received the intervention were not aware of the identity of the control clinics and there was little communication between management or staff, and even less staff movement, between clinics. Finally, the complexity of the intervention would make informal replication in another clinic very difficult.

This evaluation was planned as a pragmatic effectiveness trial and the intervention was therefore designed to be realistic for system-wide implementation (*24*). A more intensive intervention, or more extensive tailoring of the intervention to the needs of specific clinics, might have produced larger improvements. However, we would argue that this would not be realistic

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Table 3. **Pre–post intervention comparisons of clinic-level outcomes for all patients (new and re-treatment)**

| Stratum | Group | Successful treatment completion (%) | | Difference in treatment completion rates (post-intervention minus pre-intervention) (%) | Estimate of mean (standard error) |
|---|---|---|---|---|---|
| | | Pre-intervention | Post-intervention | | |
| Small clinics | Intervention | 50 | 60 | 10 | 10.4 (4.9) |
| | | 50 | 82 | 32 | |
| | | 62 | 72 | 10 | |
| | | 48 | 46 | −2 | |
| | | 50 | 52 | 2 | |
| | Control | 58 | 62 | 4 | 0.6 (4.9) |
| | | 64 | 70 | 6 | |
| | | 66 | 64 | −2 | |
| | | 58 | 63 | 5 | |
| | | 78 | 68 | −10 | |
| Medium clinics | Intervention | 56 | 60 | 4 | −2.8 (4.9) |
| | | 66 | 66 | 0 | |
| | | 50 | 34 | −16 | |
| | | 50 | 66 | 16 | |
| | | 58 | 40 | −18 | |
| | Control | 42 | 60 | 18 | 5.6 (4.9) |
| | | 54 | 56 | 2 | |
| | | 72 | 64 | −8 | |
| | | 40 | 46 | 6 | |
| | | 42 | 52 | 10 | |
| Large clinics | Intervention | 58 | 74 | 16 | 15.0 (7.8) |
| | | 54 | 68 | 14 | |
| | Control | 56 | 66 | 10 | 2.0 (7.8) |
| | | 68 | 62 | −6 | |
| Pooled | Intervention | | | | 7.5 (0.2–14.9)[a] |
| | Control | | | | 2.7 (−4.6–10.0)[a] |
| Estimated intervention effect | | | | | 4.8 (−5.5–15.2)[a] |

[a] 95% confidence intervals.

for system-wide implementation in "real world" health-care settings. The decision not to recruit volunteer or highly-motivated clinics was appropriate to an "effectiveness" trial (*43*) as it allowed the evaluation of the intervention in a range of randomly selected clinics which more closely represented the real health system.

Our study hypothesis was that the training would have an impact on treatment adherence and treatment outcomes through better provider–client relations and improvements in the organization of TB care. We anticipated a virtuous spiral of reflection on practice; changes in work organization and practice; improved provider–patient relations; greater work satisfaction for providers of care; and increased self-generated motivation to improve practice. However, this spiral was not initiated in many of the participating clinics. A parallel qualitative evaluation (*44*) suggested that the intervention was well accepted by its recipients, who became more aware of the need to improve provider–patient relations and also made some changes in the organization of care. However, when compared with the findings of the pilot study, the changes in staff attitudes and practices

following the training were less marked and often did not translate into improved provider–patient relations. There are a number of reasons for these differences between the findings of the pilot study and the full-scale trial. Firstly, a highly motivated clinic manager was present at one of the pilot sites. This contrasted with the generally weak clinic and middle management in the trial intervention clinics. Secondly, the pilot sites happened to have fewer organizational problems than the clinics in the trial where poor team working and staff conflicts were common; task-oriented care was entrenched; and staff did not see themselves as having the agency to initiate workplace change.

Health service policy-makers and managers often assume that professional practice can be changed by training. However, few training programmes for providers in developing countries have been rigorously evaluated. The findings of this trial are inconclusive, but suggest that such training may not improve the outcomes of TB treatment. Systematic reviews of interventions to change professional practice indicate that most have modest effects, congruent with those found in this trial (*45*). We therefore recommend that researchers in other settings attempt

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to replicate this work, but with less ambitious goals in mind. Further research is also needed on the conditions under which training programmes might best change professional practice and the organization of care in these settings.

The alternative is to consider whether intensifying the intervention is a realistic goal in real-world settings. This would entail combining our training programme with interventions to address other barriers to clinic and organizational change. These include the shortage of experienced clinic and mid-level managers, and health system reform and restructuring, which have increased turnover of experienced staff and exacerbated uncertainty among those who remain (*46*).

## Conclusions

To our knowledge, this is the first randomized controlled trial to have evaluated staff training to improve primary-level TB care in a developing country. The intervention appears not to improve TB outcomes, possibly due to a range of health systems barriers that were not addressed by the training programme or due to other unknown or unmeasurable factors. The results therefore suggest that that such training may not be an effective use of public resources. However, given the many problems and the paucity of interventions to improve TB care in poor urban settlements, the possibility of an improvement of even 5% in treatment outcomes needs to be pursued. Larger studies are therefore required to examine this effect and to help ensure that scarce resources available for health care training are well spent (*47*). ■

## Résumé

### Formation du personnel et résultats du traitement ambulatoire antituberculeux : essai contrôlé et randomisé par grappes en Afrique du Sud

**Objectif** Évaluer si l'introduction, dans la stratégie DOTS (stratégie de lutte antituberculeuse internationalement recommandée) habituelle, d'une intervention de formation destinée au personnel clinique influerait sur les résultats du traitement antituberculeux délivré dans les dispensaires de soins de santé primaire qui obtiennent un taux de succès du traitement inférieur à 70 %.

**Méthodes** Un essai contrôlé et randomisé par grappes a été mené de juillet 1996 à juillet 2000 dans des dispensaires de soins de santé primaires ambulatoires, gérés par des infirmières, à Cape Town, Afrique du Sud. Les dispensaires présentant un taux d'achèvement avec succès du traitement antituberculeux de moins de 70 % et une charge annuelle de tuberculose pulmonaire de plus de 40 malades par an ont été répartis au hasard entre le groupe d'intervention (n = 12) et le groupe témoin (n = 12). Le suivi a été mené à terme dans tous les dispensaires. Les résultats du traitement ont été mesurés sur des cohortes de patients adultes atteints de tuberculose pulmonaire avant l'intervention (n = 1200) et 9 mois après (n = 1177). L'intervention consistait en un programme de 18 h de formation en service participative

et empirique, délivré au personnel clinique par des moniteurs. Ce programme était axé sur la place centrale à donner au malade, sur la réflexion critique appliquée à la pratique et sur l'amélioration de la qualité. Le principal résultat mesuré était le succès du traitement, défini comme la guérison du malade et l'achèvement du traitement antituberculeux.

**Résultats** On a estimé que l'intervention s'était traduite par une augmentation du taux de succès du traitement de 4,8 % (intervalle de confiance à 95 % : - 5,5 % à 15,2 %) et du taux de guérison bactériologique de 10,4 % (intervalle de confiance : -1,2 % à 22 %). On a envisagé un effet de 10 % sur le traitement d'après le point de vue des décideurs politiques sur l'ampleur minimale de l'effet dans le cas d'une mise en œuvre à grande échelle.

**Conclusion** L'article présente les premières données d'un essai contrôlé et randomisé concernant les effets sur l'issue de la tuberculose d'une formation participative et empirique, délivrée dans les installations de soins de santé primaires d'un pays en développement. Cette formation n'a pas semblé améliorer l'issue de la tuberculose. Toutefois, les résultats n'étaient pas concluants et d'autres études sont nécessaires.

## Resumen

**Formación del personal y resultados del tratamiento ambulatorio de la tuberculosis: ensayo controlado aleatorizado por conglomerados en Sudáfrica**

**Objetivo** Determinar si una intervención de formación dirigida al personal de los dispensarios como complemento de la estrategia DOTS habitual (estrategia de lucha contra la TB recomendada internacionalmente) mejoraría los resultados del tratamiento de la tuberculosis en los dispensarios de atención primaria donde la tasa de tratamiento satisfactorio es inferior al 70%.

**Métodos** Entre julio de 1996 y julio de 2000 se realizó un ensayo controlado aleatorizado en ambulatorios de atención primaria gestionados por enfermeras de Ciudad del Cabo (Sudáfrica). Aquellos cuya tasa de tratamiento satisfactorio era inferior al 70% y cuya carga anual de adultos con tuberculosis pulmonar superaba la cifra de 40 pacientes al año fueron asignados de forma aleatoria a un grupo de intervención ($n = 12$) o a un grupo testigo ($n = 12$). Todos los dispensarios finalizaron el seguimiento. Se valoraron los resultados del tratamiento entre los grupos de adultos con tuberculosis pulmonar antes de la intervención ($n = 1200$) y nueve meses después de la formación ($n = 1177$). La intervención consistió en un programa experiencial de formación en el servicio basado en la participación, de 18 horas de duración. Impartida por

enfermeras, la formación giraba en torno a la atención centrada en el paciente, la reflexión crítica sobre la práctica y la mejora de la calidad. La variable de resultado principal fue el tratamiento satisfactorio, definido como la suma de los pacientes curados y los que habían terminado el tratamiento antituberculoso.

**Resultados** El efecto estimado de la intervención fue un aumento de un 4,8% de las tasas de tratamiento satisfactorio (intervalo de confianza del 95%: -5,5% a 15,2%) y de un 10,4% de las tasas de curación bacteriológica (intervalo de confianza: -1,2% a 22%). Considerando la opinión de las instancias normativas sobre el efecto mínimo para proceder a una implementación a gran escala, se perseguía un aumento de un 10%.

**Conclusión** Estos son los primeros datos obtenidos mediante un ensayo controlado aleatorizado sobre los efectos de una iniciativa de formación experiencial y participativa en los resultados del tratamiento de la tuberculosis en los establecimientos de atención primaria de un país en desarrollo. Aparentemente dicha formación no mejoró los resultados, pero los datos son inconcluyentes, por lo que es necesario realizar nuevos estudios.

Arabic

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