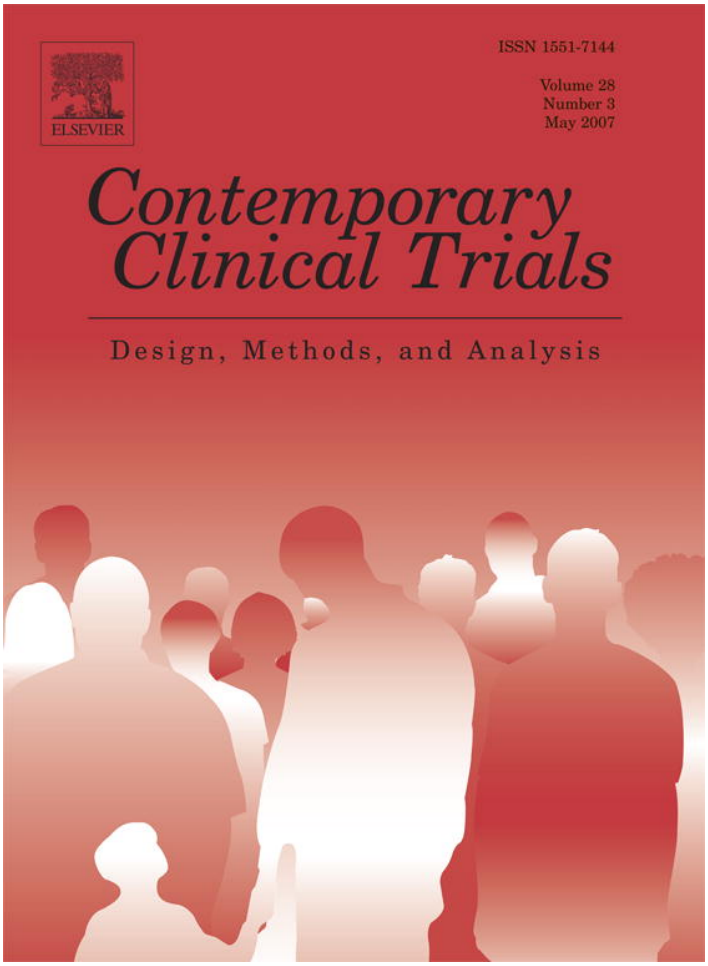

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# Factors associated with loss to follow-up in a large tuberculosis treatment trial (TBTC Study 22)

Donna Sepulveda Conwell [a,*], Ann Mosher [b], Awal Khan [c], Jan Tapy [d], Laurie Sandman [e], Andrew Vernon [c], C. Robert Horsburgh Jr. [f]
the Tuberculosis Trials Consortium (TBTC)

[a] *Veterans Affairs Medical Center, Washington, DC, USA*
[b] *Veterans Affairs Medical Center and Duke University Medical Center, Durham, NC, USA*
[c] *Centers for Disease Control and Prevention, Atlanta, GA, USA*
[d] *Department of Public Health, Denver Health and Hospitals, Denver, CO, USA*
[e] *Bellevue Hospital, NYU School of Medicine, New York, NY, USA*
[f] *Boston University School of Public Health, Boston, MA, USA*

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**Abstract**

*Introduction:* Loss to follow-up in clinical trials compromises achievement of study goals. We evaluated factors associated with loss to follow-up after completion of treatment phase in a large tuberculosis treatment trial (TBTC/USPHS Study 22) in the U.S. and Canada.
*Methods:* Patients who were lost to follow-up were compared to those who reached a study end-point or successfully completed follow-up. A generalized estimating equation model was used to combine patient-specific and site-specific factors.
*Results:* Of 1075 patients enrolled, 965 (89.8%) reached a study end-point, died, or completed the 2 year post-treatment follow-up phase, and 110 (10.2%) did not. Multivariate analysis showed the following factors to be independently associated with loss to follow-up: birth outside USA/Canada (OR 2.07, 95% CI 1.25–3.40, $p=0.005$), history of homelessness (OR 1.94, 95% CI 1.00–3.80, $p=0.05$), enrollment at a health department (OR 2.71, 95% CI 1.27–5.79, $p=0.010$), and use of any kind of incentive (cash/cash equivalent) during treatment phase (OR 3.04, 95% CI 1.73–5.33 $p=0.0001$).
*Conclusions:* Cultural or linguistic factors and lack of stable housing contribute to loss to follow-up. Attention to these factors could improve long-term retention in clinical trials. Enrollment at a health department and use of incentives during treatment phase may be markers for other factors leading to loss to follow-up.


*Keywords:* Loss to follow-up; Tuberculosis; Retention in clinical trials; Attrition in clinical trials

## 1. Background

Successful completion of clinical trials depends on satisfactory recruitment and retention of study participants. Even with successful recruitment and treatment adherence, retention of an adequate number of participants to the end of

* Corresponding author. Infectious Diseases Section (151B), Veterans Affairs Medical Center, 50 Irving Street, NW, Washington, DC 20422, USA.
*E-mail address:* donna.sepulveda@med.va.gov (D.S. Conwell).

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study follow-up is essential for generation of valid results. Participant attrition at any stage of a clinical trial has the potential to compromise the achievement of study goals [1–3]. It threatens the internal validity and representativeness of study results [3,4]. More importantly, attrition is a potential source of bias in clinical trials [2,5,6]. Lost participants may be different from those retained with respect to the outcomes being studied. The greater the loss to follow-up, the less certain one can be that the study outcomes are representative of the entire study population. The bias this introduces can work in two directions [7]. Lost participants may be either sicker or healthier than those retained for follow-up. The effect of such a bias would be to spuriously increase or decrease the frequency of negative study outcomes.

In addition, the duration of a trial may need to be extended if there is substantial loss to follow-up to achieve the sample size needed for statistical power. Thus, responding to participant loss can consume considerable effort, time and money [8,9]. It is vital that factors which act as barriers to study completion be identified early. Appropriate interventions can then be developed to prevent loss of participants.

Published literature places greater emphasis on recruitment and adherence with study treatment than on retention, even in clinical trials with extended follow-up periods after participants have completed treatment. However, long term studies are more likely to lose participants [1,2]. Among reported barriers to participant retention are work and family demands, lack of transportation or distance to the clinic, frequent study visits, negative staff attitudes, other medical conditions, fear of study drug risks or side effects, lack of knowledge about the study, younger age, weak relationship with study staff, and life events [1,3,4,10–17]. There is a lack of research that focuses on retaining clinical trial participants after they have completed treatment and until they have completed the follow-up phase of the study. Additional studies that focus on retention in both the treatment and follow-up phases of clinical trials are needed.

Retention strategies from a broad range of studies included family involvement, incentives, and shorter office visits. Retention rates were reported to be higher in participants who felt they were helping others to "find a cure," or had a commitment to or "bonding" with the study [1,11–13,18]. The relationship between the study staff and participant was also thought to be significant. Other characteristics or actions reportedly associated with retention included efforts and communication by research staff with participants, spending time with the participant, and consistent contact with study personnel [1,11,12,14]. To identify factors associated with loss to follow-up, we studied the post-treatment phase of a large tuberculosis treatment trial in North America. In part, this was done using the framework of Ickovics and Meisler [19], who proposed that factors affecting adherence and retention in AIDS clinical trials could be placed in the following categories: (1) patient characteristics, (2) treatment regimen, (3) patient–provider relationship, (4) clinical setting, and (5) disease severity.

## 2. Methods

The Tuberculosis Trials Consortium (TBTC) recently concluded TBTC/USPHS Study 22. Our retrospective analysis looked at factors affecting retention in this multi-center, randomized, open label Phase III clinical trial that compared the efficacy and safety of once-weekly directly observed therapy (DOT) using rifapentine and isoniazid (INH) with those of standard twice-weekly DOT using rifampin (RIF) and INH, during the last 4 months of a six-month tuberculosis treatment regimen. Eligibility for Study 22 included successful completion of a standard 2 month induction regimen. Once enrolled, subjects were followed for 4 months of study phase therapy plus 24 months of follow-up phase.

Trial methods have been reported elsewhere [20]. In brief, between April 1995 and November 1998, Study 22 enrolled 1075 patients (1004 HIV negative and 71 HIV positive). At study entry, information was collected on patient demographic and other characteristics. Patients were seen monthly during the four-month treatment phase. They were seen during follow-up phase at months 3, 6, 9, 12, 18 and 24 following completion of treatment. Study 22 included subjects from diverse populations throughout the United States and Canada. The primary study endpoints were failure (evidence of recurrent tuberculosis disease during treatment), or relapse after treatment.

In August 2000, a questionnaire was distributed to 26 of the 29 sites that had participated in Study 22. Three sites were not queried (they were no longer part of the TBTC and had only 2% of total enrollment). The questionnaire collected data on: (1) clinical setting characteristics (e.g., medical care services, waiting time for DOT, treatment and follow-up visits, parking availability, type and frequency of patient/staff contact); (2) patient–provider characteristics (e.g., consistency of staff responsible for study visits, time spent at visits, provision of other assistance, availability of bilingual staff and social workers); and (3) use of incentives/enablers (e.g., cash incentives, vouchers, and completion bonuses). Responses to the clinical setting and patient–provider characteristics were assessed on a 5-point Likert Scale.

Because responses were found to be heavily skewed or clustered, we combined the less frequent and more cohesive responses to create dichotomized variables for analysis ("usually" or "always" versus "rarely" or "never"). The relationship between the selected clinical and patient–provider characteristics, defined by dichotomized variables, were assessed for both treatment and follow-up phases where applicable. Responses were received from study staff at all 26 sites. An enrollment "site affiliation" variable, created from the site survey, indicated where most of the patients were enrolled. The site affiliation variable has two levels; health departments and "non-health departments" (university or public hospitals, Veterans Affairs medical centers/hospitals, private clinics). Clinical setting characteristics, patient–provider characteristics, and use of incentives/enablers were assessed as two-level categorical variables.

We conducted chi-square or Fisher's exact tests to determine the association between each factor and follow-up status (completed or lost). Statistical significance was defined as $p<0.05$. In analyzing the combined data (patient and site-specific), we used a generalized estimation equation (GEE) model in PROC GENMOD. This allowed us to control for the effect of clustering in site-specific data. All variables with $P<0.15$ were entered into the model and a stepwise elimination procedure was used to arrive at the final model. Variables were selected for retention based on both Odds Ratios (OR) and confidence intervals (CI), and the model was reconstructed after each single elimination to examine whether there was modification of the OR of the remaining variables by the variable that was removed. "Availability of a social worker" was not able to be retained in the same model with "enrollment site" because of collinearity. Data analyses were performed using SAS 8.12 (SAS Institute, Cary, NC).

Additionally, we performed a retrospective analysis of the Study 22 database to identify factors associated with loss to follow-up. Participation in Study 22 was designed to last for a total of 28 months (4 months of treatment, followed by 24 months of follow-up). We analyzed demographic and disease characteristics, other social factors, and trial characteristics. "Being foreign-born" was defined as having a birthplace outside the U.S. or Canada. Race/ethnicity was classified as non-Hispanic white versus all other groups. Other social factors included history (in the 5 years prior to study entry) of being homeless for ≥6 months, being unemployed for ≥1 year, illicit drug use, alcohol use of ≥1 drink a day, and incarceration for ≥1 month. Disease characteristics included being ≥10% below ideal body weight at tuberculosis diagnosis, having cavitation on chest X-ray at diagnosis or enrollment (at 2-months after starting tuberculosis treatment), having a positive sputum culture for *Mycobacterium tuberculosis* after two months of induction therapy, and having more than one tuberculosis symptom within the first two months of therapy. Trial characteristics included the treatment arm to which the patient was randomized. Persons who reached a primary end-point, died, or completed the final follow-up period study visit were considered as having completed the trial (retained); those who did not were considered lost to follow-up.

## 3. Results

Of the 1075 patients enrolled in Study 22, 965 (89.8%) completed follow-up, met a study endpoint, or died, and 110 (10.2%) were lost to follow-up. Median age of the study patients was 53 years (IQR: 33–53 years); 810 (75%) were men and 265 (25%) were women.

Univariate analysis of the relationship between patient-specific factors and being lost to follow-up is shown in Table 1. Only the two patient-specific factors found to be significantly associated with loss appear in the table. Being unemployed ≥1 year and having tuberculosis symptoms for >1 month were associated, but with marginal significance ($p=0.09$ and $p=0.08$, respectively). Other patient-specific characteristics that were similarly distributed among those retained and

Table 1
Univariate analysis of patient-specific characteristics associated with loss to follow-up in the post-treatment phase of a tuberculosis treatment trial

| Characteristics | | Completed $N=965$ (%) | Lost $N=110$ (%) | Odds ratio (95% CI)[+] | $P$ value |
|---|---|---|---|---|---|
| *Demographic characteristics* | | | | | |
| Birth place | Foreign countries ($n=372$) | 320 (86.0) | 52 (14.0) | 1.81 (1.21–2.69) | 0.003 |
| | USA or Canada ($n=703$) | 645 (91.7) | 58 (8.3) | | |
| *Social factors* | | | | | |
| History of homelessness | Yes ($n=211$) | 180 (85.3) | 31 (14.7) | 1.71 (1.10–2.67) | 0.02 |
| (≥6 months) | No ($n=864$) | 785 (90.9) | 79 (9.1) | | |

[+]95% CI=95% confidence intervals.

those lost were: age greater than 50 years; gender; race; education less than 12th grade; history of illicit drug use; history of alcohol use; history of incarceration; ≥10% ideal body weight at tuberculosis diagnosis; cavitary disease at baseline/time of tuberculosis diagnosis and/or after 2 months of treatment; positive sputum culture at 2 months; Karnofsky score (a clinical score that measures patient performance of activities of daily living) below 80; HIV infection; and treatment arm.

Univariate analysis of the relationship between site-specific factors and loss is shown in Table 2. Only those site-specific factors found to be significantly associated with loss to follow-up are shown in the table. Having primary care available at the same site as tuberculosis care and an appointment required for DOT clinic visits were associated with loss, but with marginal significance ($p=0.12$ and $p=0.10$, respectively). Site-specific characteristics that were similarly distributed among those who completed and those lost were: waiting time for treatment phase study visits; waiting time for follow-up phase visits; appointment reminders sent to study subject; study personnel helped with other needs; any kind of incentive/enabler (cash/cash equivalent) in follow-up; and completion bonus available in treatment or follow-up phase.

The results of multivariate analysis of patient-specific and site-specific factors are shown in Table 3. Only four variables (2 patient-specific and 2 site-specific) were found to be significantly associated with loss to follow-up. When

Table 2
Univariate analysis of site-specific characteristics associated with loss to follow-up in the post-treatment phase of a tuberculosis treatment trial

| | Completed* $N=950$ (%) | Lost $N=104$ (%) | Odds ratio (95% CI)[+] | $P$-value |
|---|---|---|---|---|
| *Clinical setting characteristics* | | | | |
| Combine other appointments on same day as treatment visits | | | | |
| Usually/always ($n=586$) | 516 (88.1) | 70 (11.9) | 0.49 | 0.003 |
| Never/rarely ($n=399$) | 374 (93.7) | 25 (6.3) | (0.31–0.79) | |
| Convenient and minimal or no cost parking available | | | | |
| Usually/always ($n=890$) | 795 (89.3) | 95 (10.7) | 0.49 | 0.04 |
| Never/rarely ($n=164$) | 155 (94.5) | 9 (5.5) | (0.24–0.98) | |
| Appointment required for treatment phase and follow-up visits | | | | |
| Usually/always ($n=935$) | 836 (89.4) | 99 (10.6) | 0.37 | 0.03 |
| Never/rarely ($n=119$) | 114 (95.8) | 5 (4.2) | (0.15–0.93) | |
| Patients seen for tuberculosis-related urgent problems, same day | | | | |
| Yes ($n=808$) | 737 (91.2) | 71 (8.8) | 1.61 | 0.03 |
| No ($n=246$) | 213 (86.6) | 33 (13.4) | (1.04–2.50) | |
| Patient contacted | | | | |
| Weekly/bi-weekly/monthly ($n=344$) | 292 (84.9) | 52 (15.1) | 0.44 | 0.001 |
| Every 3–4 months ($n=710$) | 658 (92.7) | 52 (7.3) | (0.30–0.67) | |
| *Patient–provider characteristics* | | | | |
| Site affiliation for patient enrollment | | | | |
| A health department ($n=668$) | 583 (87.3) | 85 (12.7) | 2.93 | <0.0001 |
| Other (hospital/academic institution/VA hospital/private clinic, $n=359$) | 342 (95.3) | 17 (4.7) | (1.71–5.02) | |
| Subject saw the same person | | | | |
| Always ($n=338$) | 320 (94.7) | 18 (5.3) | 2.43 | 0.001 |
| Usually ($n=716$) | 630 (88.0) | 86 (12.0) | (1.43–4.10) | |
| Change in the person primarily responsible for the patient's care | | | | |
| Yes ($n=233$) | 198 (85.0) | 35 (15.0) | 1.93 | 0.003 |
| No ($n=821$) | 752 (91.6) | 69 (8.4) | (1.24–2.98) | |
| Social worker available | | | | |
| Usually/always ($n=616$) | 535 (86.8) | 81 (13.2) | 0.37 | <0.0001 |
| Never/rarely ($n=438$) | 415 (94.7) | 23 (5.3) | (0.23–0.59) | |
| *Incentives/enablers* | | | | |
| Any kind of incentive/enabler (cash/cash equivalent) in treatment phase | | | | |
| Yes ($n=922$) | 823 (89.3) | 99 (10.7) | 3.06 | 0.01 |
| No ($n=132$) | 127 (96.2) | 5 (3.8) | (1.22–7.65) | |

*Includes numbers from 26 of 29 sites.
[+]95% CI=95 % confidence intervals.

Table 3
Multivariate analysis of risk factors associated with increased loss to follow-up in the post-treatment phase of a tuberculosis treatment trial

| Risk factors | OR[+] | 95% CI[++] | *P* value |
|---|---|---|---|
| Birth outside USA/Canada | 2.07 | 1.25–3.40 | 0.005 |
| History of homelessness | 1.94 | 1.00–3.80 | 0.05 |
| Enrollment at a health department | 2.71 | 1.27–5.79 | 0.010 |
| Any kind of incentive during treatment phase | 3.04 | 1.73–5.33 | 0.0001 |

[+]OR = Odds ratio.
[++]95% CI = 95% Confidence interval.

patients who had met primary endpoints (failure or relapse) or died were excluded, the comparison between those who were lost and those who completed the entire follow-up period provided similar findings (results not shown).

## 4. Discussion

The overall prevalence of loss to follow-up in the large tuberculosis treatment trial known as Study 22 was 10.2% (110 out of 1075). This rate is substantial, particularly since patients were enrolled only upon successful completion of the standard two-month induction regimen and had therefore previously demonstrated adherent behavior. Retaining patients in subsequent follow-up for two years is challenging, since symptoms of tuberculosis usually abate after the first few weeks of treatment and no medical intervention is required unless symptoms recur and tuberculosis relapse is suspected.

We hypothesized that both patient and site-specific characteristics would be associated with loss to follow-up. Our analysis identified four factors that were independently associated with loss to follow-up: birth outside USA/Canada, history of homelessness, enrollment at a health department, and use of any kind of incentive (cash/or cash equivalent) during treatment phase.

There are several potential explanations for greater loss to follow-up among the foreign born. Inability or limited ability to speak English may lead to inadequate communication between health care provider and patient, with resulting limited communication of the importance of tuberculosis treatment. Even with good communication, cultural factors including health beliefs, values and social norms can be different among foreign born participants and have a large effect on retention. Legal status, particularly among those undocumented or illegally in the U.S., may also play a role in adherence with the follow-up schedule.

In North America, tuberculosis disproportionately affects medically and socially under-served populations, such as those who are unemployed, foreign-born, homeless and alcoholic. These factors can also present barriers to consistent participation in clinical trials. Homelessness can interfere directly with ability to keep follow-up appointments by limiting the ability of study personnel to maintain contact with the participant, and of the participant to receive reminders about scheduled visits. High rates of alcoholism, substance abuse and mental health problems are also associated with homelessness [21].

Our study also found that patients who were enrolled at health departments were more likely to be lost to follow-up. We hypothesize that health departments are markers for sites serving populations with high rates of poverty and unemployment, and that factors such as these are responsible for the loss to follow-up rather than enrollment at a health department *per se*. As suggested by others, study subjects with these characteristics may view research as suspicious, burdensome, and intrusive [22]. Such concerns offer an additional challenge to trial retention. The use of incentives during treatment phase was also associated with loss to follow-up in the post-treatment phase. It may seem that this finding is inconsistent with the literature that supports the idea of incentives having a salutary effect on retention. We hypothesize that persons enrolled in our study who did not receive treatment phase incentives were different in some unmeasured way from other participants and were, therefore, more likely to complete the follow-up phase.

We did not find that HIV co-infection or younger age was associated with loss to follow-up. However, the number of those HIV-infected was small. We were not able to assess the role of medical conditions other than HIV infection. In our study, younger age was defined as 50 or less, and median age was 53. This age was characteristic of tuberculosis in the United States between 1995 and 1998 [23]. In an earlier study that cited younger age as a barrier to retention, participants ranged in age from 21 to 50 and younger age was defined as 21–30 [17]. Thus, our study may not have had

enough younger subjects to allow detection of such an effect. We also did not find that a history of unemployment, alcohol, or other substance use were significantly associated with loss to follow-up. These factors, however, may be related to homelessness which was found to be associated with such loss.

Our study has several limitations. First, sites were queried retrospectively at only one point in time over a six-year study. Some sites experienced staffing changes, and site practices may have changed over the course of the study. Secondly, the analysis of many factors was based on site-level rather than patient-level data (i.e., an ecological analysis). The experience of individual patients (whether lost or not) in relation to site practices is unknown. Additional patient-level and prospective studies should be undertaken with both study personnel and individual patients, possibly at multiple time points during study. Third, there may be other factors (such as transportation or family responsibilities) not investigated in this study that patients considered important to their remaining in or dropping out of the trial.

Completion of follow-up in a clinical trial is essential to achieving trial objectives. This study identified several factors associated with loss of study patients that could potentially be modified. One such modification would be provision of better translation services and other culturally specific services to minimize loss among foreign-born study patients. Such culturally specific programs were recently reported to be associated with increased completion of treatment for latent tuberculosis [24]. Provision of housing and other support services for homeless persons might also decrease loss in clinical trials. More research is needed to define optimally effective and appropriate use of incentives in support of clinical trial retention [25], and to identify other specific measures to increase the retention of patients enrolled in health department settings.



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