

Randomized Controlled Trial of Interventions to Improve Follow-up for Latent Tuberculosis Infection After Release From Jail

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Background: Adherence to treatment of persons with latent tuberculosis infection after release from jail has been poor.

Methods: A randomized controlled trial was conducted at the San Francisco City and County Jail, San Francisco, Calif. Subjects undergoing therapy for latent tuberculosis infection who spoke either English or Spanish were randomly allocated to receive education every 2 weeks while in jail; an incentive if they went to the San Francisco County Tuberculosis Clinic within 1 month of release; or usual care. The main outcome measures were completion of a visit to the tuberculosis clinic within 1 month of release and completion of therapy.

Results: Of 558 inmates enrolled, 325 were released before completion of therapy. Subjects in either intervention group were significantly more likely to complete a first visit than were control subjects (education group, 37%; in-

centive group, 37%; and controls, 24%) (adjusted odds ratio based on pooled results for the education and incentive groups, 1.85; 95% confidence interval, 1.04-3.28; $P=.02$). Those in the education group were twice as likely to complete therapy compared with controls (adjusted odds ratio, 2.2; 95% confidence interval, 1.04-4.72; $P=.04$). Of those who went to the tuberculosis clinic after release, subjects in the education group were more likely to complete therapy (education group, 65% [24/37]; incentive group, 33% [14/42]; and control group, 48% [12/25]; $P=.02$).

Conclusions: Education or the promise of an incentive improved initial follow-up. Education was superior to an incentive for the completion of therapy. Fairly modest strategies provided in jail can improve adherence. Further links between jail health services and community care should be explored.

Arch Intern Med. 2002;162:1044-1050

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TREATMENT OF persons with latent tuberculosis (TB) infection (LTBI) to prevent progression to disease is a critical component of TB control efforts in the United States.^{1,2} The highest risk for progression is among the recently infected³; among immigrants from countries with high rates of TB, in particular within the first 5 years following immigration^{4,5}; among intravenous injection drug users^{6,7}; and among persons with clinical conditions such as the human immunodeficiency virus.⁸

Correctional facilities have disproportionate numbers of persons with characteristics associated with developing active TB.⁹ Inmates are likely to come from racial and ethnic communities, be members of low-income or homeless populations,^{1,10-12} have high rates of injection drug use associated with human immunodeficiency virus infection, and have limited ac-

cess to health care.¹³⁻¹⁶ Jails are the initial intake points for incarceration; persons arrested, awaiting or on trial, and serving sentences up to 1 year are housed in jails for relatively short periods and then return to the community.¹⁶ In the San Francisco City and County Jail, 27% of inmates during routine screening had LTBI. Most treated for LTBI (81%) were Latino persons and foreign-born, with a median of 3 years since immigration.¹⁷

Treatment of LTBI has been based on clinical trials of isoniazid in the 1950s and 1960s, indicating effectiveness in preventing progression to disease, 3 with evidence of increased efficacy based on length of treatment and adherence to the treatment regimen.^{18,19} Poor adherence, defined as taking isoniazid for 3 months or less, has been associated with a 6-fold increase in risk for subsequent disease compared with completing more than 3 months of treatment.²⁰

PARTICIPANTS AND METHODS

RESEARCH DESIGN

A randomized controlled trial was designed to study the effects of 2 interventions given to inmates in the San Francisco City and County Jail. The 2 interventions were as follows: (1) education, provided every 2 weeks while in jail; or (2) the promise of an incentive (\$25 equivalent in food or transportation vouchers) provided at the first visit to the TB Clinic. A third (control) group received neither intervention. The 2 study outcomes were as follows: (1) the first visit to the TB Clinic within 1 month after release from jail and (2) completion of a full course of therapy. The study design was approved by the institutional review board of The University of California, San Francisco.

SAMPLE

The target population was jail inmates who were screened by jail medical personnel and determined to have LTBI, eligible for and agreed to begin therapy in jail, and released into the community while still undergoing therapy. Those who went to prison or who remained in custody for the duration of therapy were not the focus of this study, because they received the entire course of medication during incarceration. However, because the release date and destination were unknown at study enrollment, all consecutive eligible inmates were approached for recruitment and informed consent, many of whom were ultimately not eligible for the final analytic sample. Sample size calculations indicated that 86 subjects in each study group would provide sufficient power (≥ 0.8) to detect a 20% difference in adherence, based on previous work^{17,22} in the jail, between either intervention group and the control group at $\alpha = .05$.

Inmates who did not speak Spanish or English or who were determined by sheriff's personnel to be violent or by Jail Health Services' mental health staff to have serious psychiatric illness were excluded from the study. Also excluded were known human immunodeficiency virus-positive inmates under the care of the Forensic AIDS [Acquired Immunodeficiency Syndrome] Project. These inmates receive a different treatment for LTBI in jail and intensive follow-up in the community after release, including additional incentives to continue care.

STANDARD TB SCREENING AND CARE IN JAIL AND AFTER RELEASE

All decisions on screening, medication prescription or discontinuation, and monitoring of inmates in jail were made

by jail medical personnel. During the study, the course of therapy provided was 6 months of isoniazid,²³ and therapy was observed directly.

We reviewed jail electronic medical records daily and provided standard information to inmates who began therapy for LTBI. This session, under an agreement with Jail Health Services, became the usual care for the duration of the study. Research assistants conducted this one-to-one session based on Centers for Disease Control and Prevention guidelines²⁴ in English or Spanish, according to inmate preference. The information focused on LTBI, therapy, adverse effects, availability of free care after release, and location of, transportation to, and hours of the TB Clinic. The message concluded with encouragement that completing therapy could eliminate future risk, with interaction to confirm understanding. Research assistants were bilingual and bicultural Spanish speakers, without formal health care education, trained by the project director (E.M.). Once this information was provided to each inmate, jail pharmacy personnel prepared a 1-month supply of isoniazid to put in his or her personal belongings at release.

Medication continuation and discontinuation, method of therapy administration, and completion of therapy for inmates who went to the TB Clinic after release were determined by TB Clinic clinicians.

STUDY PROTOCOL

Following the informational session provided to all inmates (usual care), the research assistant determined study eligibility, described the study, and obtained informed consent. As part of the consent process, inmates were told that if they completed isoniazid therapy in jail, if isoniazid was discontinued, or if they were not released to the community, they would no longer be participants in the study. Enrolled inmates provided baseline data and postrelease contact information to research assistants using a structured interview in English or Spanish.

Subjects were then randomized, using ordered sealed envelopes containing allocation determined by a random numbers table, into 1 of the 3 study groups: education, incentive, or control. Inmates in the education group were told they would be visited every 2 weeks for the duration of their jail stay, to reinforce the initial information and message of the first session. Inmates in the incentive group were told they would have no further contact with study personnel in jail and that they would be able to choose a \$25 equivalent in food or transportation vouchers if they went to the TB Clinic within 1 month of release. Inmates in the

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Few studies have focused on inmates and the unique issues of treatment started in jail with the need for completion in the community. Nolan et al²¹ reported poor results from an integrated screening program in a Seattle, Wash, jail combined with community-based directly observed therapy for LTBI, in which 40.1% were lost to follow-up at release from jail and only 49.7% completed therapy despite intensive case management. In an initial study¹⁷ in the San Francisco City and County Jail, less than 3% of inmates released from jail went to the San Fran-

cisco County Tuberculosis Clinic (TB Clinic) after being counseled once in jail, at the time of medication prescription. In a clinical trial²² in which a consistent single educational session was provided to all inmates after prescription of therapy for LTBI, the rate was increased to 23.3% in the education group and 25.8% in a group promised a \$5 incentive in addition to the education. This study builds on the scientific evidence to measure the effect of education or incentives on initial follow-up and completion of care among inmates released to the community.

control group were told they would have no further contact with study personnel in jail.

For those in the incentive group who went to the TB Clinic within 1 month of release, clinic personnel contacted research assistants who met the subject at the clinic or arranged another time to meet. Research assistants then provided them the choice of a \$25 equivalent in food or transportation vouchers. Follow-up interviews among all released to the community were conducted with those who could be located. This interview occurred after the first outcome (visit to the TB Clinic 1 month after release) was ascertained.

DATA

At enrollment, structured interviews were used to gather sociodemographic information (age, sex, educational level, marital status, previous time in jail or prison, and employment before jail), ethnicity and culture (country of birth, time since immigration, and preferred language), health status (alcohol or other drug problem using the CAGE questions, modified to include other drugs and alcohol [CAGE is a questionnaire for alcoholism evaluation: C, Have you ever felt the need to cut down on your drinking? A, Have you ever felt annoyed by criticism of your drinking? G, Have you ever felt guilty about your drinking? E, Have you ever taken a drink {eye opener} first thing in the morning?],²⁵ and self-rated health using the Medical Outcomes Survey 5-point scale from poor to excellent²⁶), and health care information (having a regular place to go for health care, number of visits in the past 12 months, medical insurance, and history of treatment with isoniazid). Housing in the month before jail was asked about in detail and then dichotomized into stable (own apartment or house, hotel, or house or apartment of friends or relatives) vs unstable (park or street; car, truck, or van; shelter; or positive answer to “in the month before coming to jail, did you spend any night on the street or in a shelter, in other words, homeless?”). Medication and health care attitudes and intent to complete therapy were asked in a series of questions used in previous studies²⁷ among the homeless. The presence of social support, by family or friends, for adherence to therapy was asked in a series of questions with Likert scale responses from “absolutely yes” to “definitely no.”

Jail records were used to monitor isoniazid therapy, length of jail stay, and disposition to the community. We were unable to determine whether inmates had the 1-month supply of isoniazid at release, as the sheriff's personnel were not always able to put it in the inmate's property and there were no records of this.

Records from the TB Clinic were used to determine outcomes (first visit to the clinic within 1 month after release and completion of therapy for LTBI among those who went to the clinic), with a follow-up record review until determination of completion was made by TB Clinic clinicians. The first outcome was recorded “yes” if there was a clinic record indicating that the person had come to the clinic to see a clinician within the first month of release from jail. The second outcome was recorded “yes” if the clinician indicated completion of therapy in the medical record. Medical record review was performed by personnel who did not have access to study group assignment.

STATISTICAL ANALYSIS

Standard methods were used to examine the sample and the distribution of known and suspected predictors of adherence. Any variables disproportionately distributed by study group were identified for inclusion in subsequent regression analyses. Both outcomes were analyzed by intent to treat for the analytic sample of those released while still taking isoniazid. A conditional analysis was also performed on the second outcome, completion of therapy for LTBI, for the subset of those who made the first visit to the TB Clinic and in whom medications were not discontinued because of adverse effects.

An ordered categorical variable was made to describe time in the United States, with 3 categories: born in the United States; foreign birth, with longer than 5 years spent in the United States; and foreign birth, with 5 years or less spent in the United States. The dichotomy of foreign-born to longer than 5 years vs 5 years or less spent in the United States was based on the work of McKenna et al⁴ indicating the highest risk for conversion to active TB in the 5 years since immigration.

Group status and other covariates were tested against the 2 outcome measures using χ^2 and *t* tests or Mann-Whitney tests. Using significant variables from bivariate analyses ($\alpha = .10$), we built a separate logistic regression model for each outcome, to assess the effect of group status while adjusting for multiple covariates. For the categorical variable, time in the United States (born in the United States, immigration >5 years ago, and immigration ≤ 5 years ago), 2 indicator variables were created to assess the independent contribution of each of the 2 foreign-birth categories compared with the reference group, those born in the United States.²⁸ Final statistical models predicting the 2 outcomes were generated, with adjusted odds ratios and 95% confidence intervals.

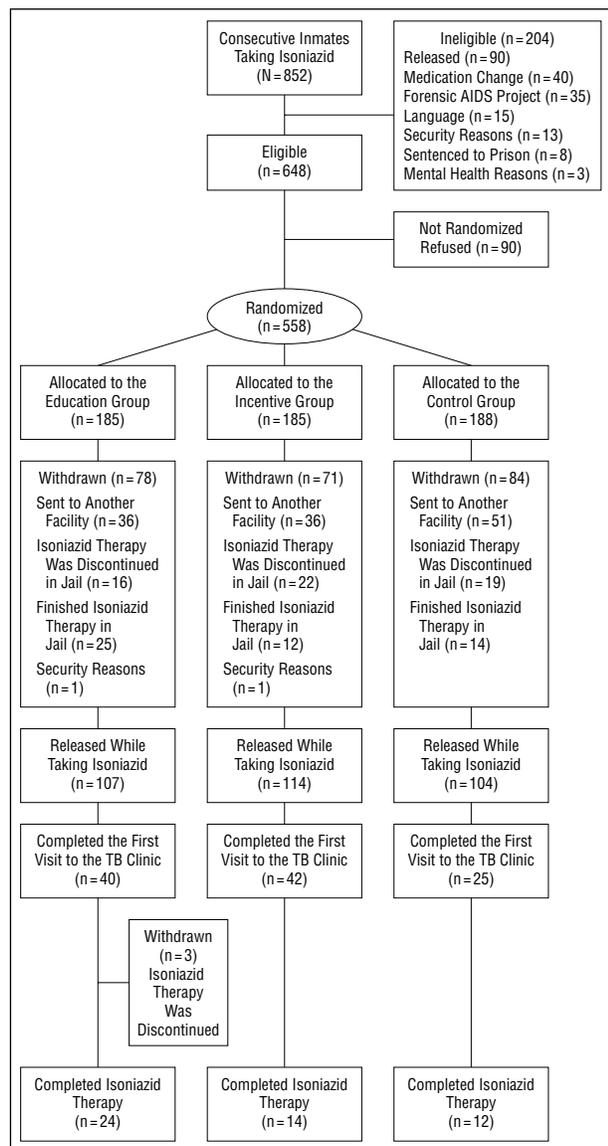
RESULTS

SAMPLE CHARACTERISTICS

Eligibility determination and recruitment from March 1, 1998, through May 31, 1999, and flow of subjects through the study are shown in the **Figure**. Of the 558 subjects enrolled, 510 continued to take isoniazid and 62 (12%) of these 510 finished therapy while in jail. Nearly three

quarters (325 [73%]) of the 448 who continued to take isoniazid in jail were released before completion, after an average of 48.6 days (median, 34 days) of a 6-month course of isoniazid. These 325 subjects composed the analytic sample for determining study outcomes. There were no significant differences in subjects by study group, in either the 558 enrolled or the 325 released from jail. Sample characteristics are shown in **Table 1**.

A problem with alcohol or other drugs was reported by 55% of subjects, but 81% answered yes to 1 or



Flow of study participants through the randomized controlled trial. AIDS indicates acquired immunodeficiency syndrome; TB Clinic, San Francisco County Tuberculosis Clinic, San Francisco, Calif.

more of the questions that composed the CAGE measure, modified to reflect a problem with alcohol or other drugs.²⁵ One third (33%) of the subjects reported that they would have support for taking isoniazid after release, from a spouse or steady partner, family, or friends. Nearly all subjects (98%) believed taking isoniazid was good, stated they would definitely go to the TB Clinic (84%), and reported they would definitely complete therapy for LTBI (81%).

OUTCOMES

Completion of the First Visit to the TB Clinic

One third of the 325 subjects (107 [33%]) completed the first visit to the TB Clinic after release from jail. Rates of completing a first visit in the education group (37%) and the incentive group (37%), when pooled, were signifi-

Table 1. Characteristic of 325 Subjects Released From Jail, by Study Group*

Characteristic	Study Group		
	Education (n = 107)	Incentive (n = 114)	Control (n = 104)
Male sex	86	90	91
Age, median, y	29.5	28.5	29.7
Ethnicity†			
Latino	53	52	61
Black	20	26	19
White	6	4	6
Asian	3	9	5
Other or mixed	18	10	10
Foreign birth	66	64	67
Spanish language preferred	50	51	59
Married or partnered	35	27	39
Stable housing before jail	86	82	81
Education, median, y	11	11	10
Employed during the 3 mo before jail	58	49	61
In jail before	80	81	85
Alcohol or other drug problem	55	56	54
Regular place for health care	29	26	30
Any medical insurance	20	19	24
Received isoniazid before	24	25	19

*Data are given as percentage of subjects unless otherwise indicated.

†Percentages may not total 100 because of rounding.

cantly different from the rate in the control group (24%) ($P = .02$, χ^2 test).

Other variables significant in bivariate analyses predicting completion of a first visit were older age (mean, 33.4 vs 29.8 years) ($P = .10$), more years of education (mean, 10.5 vs 8.9 years) ($P = .001$), having unstable housing ($P = .02$), and being seen more often by a physician or nurse practitioner in the past 12 months (mean, 1.9 vs 1.2 times) ($P = .02$). Language preference (Spanish vs English) was highly correlated with being Latino (Cohen κ , 0.90, $P < .001$) and foreign birth (Cohen κ , 0.68, $P < .001$), and all were inversely associated with going to the TB Clinic. Language was chosen for inclusion in the model because it has support as a surrogate measure for acculturation, with validity as a measure of cultural integration²⁹ and relevance to health behaviors.³⁰ Time in the United States was strongly associated with going to the TB Clinic: 42% of those born in the United States, 39% of those foreign-born who immigrated more than 5 years before jail, and 12% of recent immigrants (≤ 5 years) completed the first visit ($P \leq .001$). The logistic regression model controlling for these covariates is presented in **Table 2**.

Number of Educational Sessions and Time in Jail. Subjects randomized into the education group understood that they would receive educational sessions every 2 weeks in jail. Nearly one third (32 [30%]) were released before any session occurred. The distribution of rates of completion of the first visit to the TB Clinic, by the number of educational sessions received, is shown in **Table 3**. Even among those who did not stay long enough to have the promised session, the rate of completion was 38% (12

Table 2. Characteristics Associated With Completion of the First Visit to the TB Clinic Among 325 Subjects Released From Jail, by Logistic Regression Analysis*

Characteristic	Adjusted Odds Ratio (95% Confidence Interval)	P Value
Study group (education or incentive vs control)	1.85 (1.04-3.28)	.04
Time in the United States		.006
Foreign-born		
≤5 y	0.34 (0.12-0.95)	.04
>5 y	1.28 (0.63-2.60)	.50
Born in the United States	Reference	...
Language (preferring English)	1.03 (0.49-2.17)	.94
Stable housing before jail	0.51 (0.26-1.00)	.05
Age	1.02 (0.99-1.06)	.15
Education (years completed)	1.05 (0.97-1.13)	.22
Visits to a physician or nurse practitioner in the past 12 mo	1.07 (0.96-1.19)	.22

*The TB Clinic was the San Francisco County Tuberculosis Clinic, San Francisco, Calif.

Table 3. Completion of the First Visit to the TB Clinic by the Number of Educational Sessions Provided, in 107 Subjects Randomized to the Education Group*

No. of Educational Sessions Provided	No. (%) of Subject Who Completed the First Visit to the TB Clinic
0 (n = 32)†	12 (38)
1 (n = 24)	10 (42)
2 (n = 17)	7 (41)
3 (n = 10)	3 (30)
≥4 (n = 24)	8 (33)
Total (n = 107)	40 (37)

*The TB Clinic was the San Francisco County Tuberculosis Clinic, San Francisco, Calif.

†Inmates were released before an educational session could be provided.

of 32 subjects). We examined, however, whether less time in jail, while not statistically significant ($P = .42$) in the overall analysis, could explain this observation. In a post hoc analysis, we compared subjects in all 3 groups who were in jail as long as those in the education group who did not go to any session. There were no statistically significant ($P = .59$) differences by study group, indicating that this observation may have been due to the proximity of the usual care to release.

Follow-up Effect. We observed an effect of the interview conducted in the community after release, after the first outcome had been ascertained. For subjects who had not completed a visit to the TB Clinic, this interview seemed to serve as a reminder. Completion rates were boosted nearly equally in each study group, to 48% in the education group, 46% in the incentive group, and 31% in the control group, following this interview.

Completion of Therapy for LTBI

For the intent-to-treat analysis of subjects released from jail, rates of completion were 23% (24/106) in the education group, 12% (14/113) in the incentive group, and

Table 4. Conditional Analysis of Characteristics Associated With Completion of Therapy Among 104 Subjects Who Went to the TB Clinic After Release From Jail and in Whom Isoniazid Was Not Discontinued, by Logistic Regression*

Characteristic	Adjusted Odds Ratio (95% Confidence Interval)	P Value
Study group		.01
Education	1.99 (0.63-6.22)	.24
Incentive	0.43 (0.14-1.31)	.14
Control	Reference	
Stable housing before jail	2.94 (1.01-8.58)	.05
Time in the United States		.44
Foreign-born		
≤5 y	2.81 (0.54-14.45)	.22
>5 y	1.37 (0.55-3.41)	.50
Born in the United States	Reference	...
Stated they would "definitely" complete isoniazid therapy	11.37 (1.12-115.81)	.04

*The TB Clinic was the San Francisco County Tuberculosis Clinic, San Francisco, Calif.

12% (12/103) in the control group. Medications were discontinued because of adverse effects in 3 subjects, all of whom were in the education group. Those in the education group were more than twice as likely to complete therapy as were those in the control group (adjusted odds ratio, 2.2; 95% confidence interval, 1.04-4.72; $P = .04$), whereas those in the incentive group did not differ from the controls (adjusted odds ratio, 1.07; 95% confidence interval, 0.47-2.40). No other variables were statistically significant ($\alpha = .05$) in predicting completion of therapy.

For the conditional analysis of the 104 subjects who went to the TB Clinic within 1 month and in whom medications were not discontinued, 50 (48%) completed isoniazid therapy, 65% (24/37) in the education group, 33% (14/42) in the incentive group, and 48% (12/25) in the control group. In a logistic regression model intervention, group overall remained statistically significant ($P = .01$) while controlling for the influence of variables identified in bivariate analyses (**Table 4**). Having stable housing before jail predicted completion of therapy (adjusted odds ratio, 2.94; 95% confidence interval, 1.01-8.58; $P = .05$), the opposite finding from that seen in predicting completion of the first outcome, first visit to the TB Clinic.

COMMENT

Substantial improvements can be made, in linking released inmates to postrelease care and in completion of therapy, with modest interventions conducted in the jail setting.^{17,22} Provision of standard education or the promise of an incentive significantly improved follow-up after release. In agreement with others,^{22,27,31-33} we found that an incentive influenced short-term outcomes, equal to the effect of education, but was less important in predicting therapy completion. Our finding that the influence of education persists over time is encouraging, and further work should focus on the role of a postrelease reinforcement, based on our anecdotal observation of a follow-up effect among nonadherent subjects.

Nolan et al²¹ concluded that TB screening of asymptomatic inmates is not a good use of funds for TB control because of poor completion of therapy in released inmates. Our completion rate among those who went to the TB Clinic within 1 month of release (48%) is remarkably similar to the overall completion rate among the non-randomized subjects in their intensive program to link inmates to appropriate community care (50%).²¹ Our conclusions, however, differ. The reality of the completion rates that are not as high as one would expect should not result in a conclusion to abandon initiation of treatment of LTBI in jail inmates.

Rather, in this population with high rates of recidivism, linking jail health services to community care is critical to maximize the effect of resources used to screen and treat persons with LTBI inside and outside jail.

Results of this study do, however, provide strong evidence that the initiation of therapy for LTBI in jail must include strategies to ensure follow-up after release. Our findings that nearly one quarter of inmates had been taking isoniazid before and that three quarters were released after a median 34 days of therapy should raise serious questions about the value of starting therapy in jail without such strategies. New recommendations for short-course therapy may not solve the problem.² Rifampin and pyrazinamide, given daily for 2 months, may be too expensive for jail health care budgets, which must pay for the care and the close clinical monitoring of inmates without reimbursement from public or private insurance. In San Francisco, the cost of isoniazid is \$0.07 per day, compared with \$4.54 per day for the 2-drug regimen. Furthermore, on average, our subjects were released before a 2-month regimen could be completed, and close monitoring for adverse effects mandates postrelease care.³⁴ The recently revised recommendations for isoniazid therapy from 6 to 9 months² exacerbate the problem of follow-up.

Findings from this study differ from the literature in that few of the factors traditionally associated with non-adherence influenced the outcomes of this study. Such general factors include homelessness; substance abuse; lack of family or social support; migrant status; unemployment or low income; low education and minority status³⁵⁻⁴⁰, age and male sex,^{37,38} which have been inconsistent predictors^{36,37,40}, and specifically related to TB, no prior medication use, knowledge, and beliefs about medications, cultural factors, and limited access to care.^{38,41-48} Incarcerated persons share many of the factors identified as barriers, but in this study, time in the United States and stable housing were the only important additional predictors of adherence. Foreign-born subjects in the United States for 5 years or less, identified as being at highest risk for disease progression,^{4,5} were one third as likely to go to the clinic after release, but were just as likely to finish medication if they made the postrelease visit to the TB Clinic. This warrants further study to determine if those who are the least acculturated are initially lost to the system, but once engaged in care, follow through to completion.⁴¹ Another difference was that unstable housing predicted the first visit to the TB Clinic, while stable housing predicted therapy completion in those who went to the TB Clinic. The former may be explained by multiple messages regarding TB provided in homeless shelters and clinics serving the home-

less; the latter may reflect consistency with adherence literature,^{35,40} pointing to social support and additional resources among the stably housed.

Limitations to the study include selection for English- or Spanish-speaking inmates, to the exclusion of inmates who were non-English-speaking Asian/Pacific Islanders. Data from the city and county of San Francisco indicate that more than half treated for LTBI from 1997 to 1998 were Asian/Pacific Islanders (Masae Kawamura, MD, unpublished data, 1997-1998). In the jail, both groups have a high prevalence of LTBI (Asian/Pacific Islanders, 51.1%; and Latino persons, 26.7%). But only 5.2% of annual jail bookings in 1998 were Asian/Pacific Islanders, whereas Latino persons composed 17.7% of the bookings.⁴⁹ The multiple cultural and language groups implied in the category Asian/Pacific Islanders were beyond our scope and resources, although this is clearly a group that warrants further study. Subjects in this study are representative of inmates in the San Francisco City and County Jail with LTBI who speak English or Spanish, and the results are generalizable to areas with high immigration rates from Latin American countries. Based on extrapolation from 1993 to 1998 data, current estimates are that more than half of the persons with active TB in the United States are foreign-born⁵; addressing LTBI in foreign-born persons is a necessary corollary to other active TB control efforts and should be culturally appropriate and tailored to local needs.⁵⁰

Accepted for publication September 6, 2001.

This study was supported by grant R01 NR04456 from the National Institute of Nursing Research, National Institutes of Health, Bethesda, Md.

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