Improving tuberculosis therapy completion after jail: translation of research to practice

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Abstract

Inmates have high rates of latent tuberculosis infection (LTBI), but inmates are often released early and do not complete therapy in the community. This study evaluated the translation of results from a randomized trial to improve therapy completion to usual care in a county jail using Rogers’ Diffusion of Innovation theory. Inmates who received a single education in the randomized trial in 1998–1999 (study group) were compared to inmates educated by Jail Discharge Planners in 2002–2003 (usual care group). Outcomes were rates of completion of a visit to the TB clinic and completion of therapy. Subjects in the usual care group were significantly less likely to go to clinic in the 30-day period after release (relative risk 0.84, 95% confidence interval 0.75–0.95). The transfer of an educational protocol did not achieve results seen under study conditions, mostly because of implementation fidelity. The educational session in the usual care period for 81.0% of inmates took 5 min, as compared to 10–15 min during the randomized trial. Differences in personnel administering the protocol, training, high turnover and time available may also account for lower rates seen. Practical clinical trials should focus on the context of care as well as the intervention and should have participation by those who will be implementing results.

Introduction

Recent declines in active tuberculosis (TB) in the US have been attributed to improvement in TB control activities, including identification and treatment of persons with latent TB infection (LTBI) (McKenna et al., 1998). However, progress in TB control has been disproportionately distributed among socioeconomic and ethnic groups, and has resulted in calls for targeted activities aimed at those considered most at risk (Centers for Disease Control and Prevention, 1995, 1999a). The high TB prevalence in correctional facilities has been well documented (Centers for Disease Control and Prevention, 1993, 1996, 1999b; Hutton et al., 1993). Inmates have many of the risk factors associated with TB, such as coming from racial and ethnic minorities (Jones et al., 1999; Beck et al., 2002) including foreign-born persons (Cantwell et al., 1994; McKenna et al., 1995), having overlaps with low-income and homeless populations (Zolopa et al., 1994; Centers for Disease Control and Prevention, 1995; Barnes et al., 1996; Harlow, 1998), having high rates of injection drug use associated with HIV infection (Bureau of Justice Statistics, 1995), and having limited access to health care (Glaser and Greifinger, 1993; Pelletier et al., 1993; Hammett and Harrold, 1994; Wilcock...
et al., 1996; Bock et al., 1998; Mitnick et al., 1998). In the San Francisco City and County jails, our study team reported a 26.9% prevalence rate for LTBI (Tulsky et al., 1998) and jails in other urban settings have similar rates (Bellin et al., 1993; Pelletier et al., 1993; Wilcock et al., 1996).

While jails have been identified as a site for treating persons with LTBI, completion of treatment has not been successful (Lobato et al., 2003). This is primarily because inmates are frequently released before completing a several-month course of standard therapy and have low rates of completing therapy in the community (Nolan et al., 1997; Tulsky et al., 1998). An observational study in 1996 in the San Francisco Jail demonstrated that under a system of usual care that included counseling by jail clinicians at the time of diagnosis, only 3% of those released while still on therapy completed a visit to the Public Health TB Clinic for free follow-up care (Tulsky et al., 1998). Reasons for low completion rates are complex, including characteristics of the inmates themselves, such as foreign birth and unstable housing, and characteristics of the system overall, including the nature of the jail, circumstances of release from jail, and post-release barriers of long clinic waiting times and transportation costs (White et al., 2002; Duong et al., 2003; Lobato et al., 2003).

The conceptual model guiding our efforts to improve completion of therapy, in observational studies and in a subsequent randomized trial, was the framework of Green and Kreuter (Green and Kreuter, 1999), suited to this problem because of its comprehensive approach. This educational framework takes into account the multiple factors that shape health status of a population, both within the individual and in the sociopolitical environment (Green and Kreuter, 1999). The components of the model applied in our work included factors originally presented in the Health Belief Model (Becker, 1974) as explanations for protective health behaviors: predisposing, reinforcing and enabling factors. Among the predisposing factors are health beliefs, attitudes and knowledge, which have predictive value for some preventive and short-term health actions (Sackett, 1976). Health beliefs, including culturally based beliefs about TB, are important predictors of adherence, as are sociodemographic variables such as age and gender (Centers for Disease Control and Prevention, 1999b) and health attitudes, although the presence of competing attitudes or demands may diminish the influence of health attitudes on behaviors (Morisky, 1990), as might be seen in a population released from jail.

The development of a standardized education, combining education to increase knowledge and counseling to improve attitudes, increased the rate of visit to the TB Clinic from 3 to 24% (White et al., 1998). In 1998–1999, a larger randomized trial demonstrated that repeated educations of inmates every 2 weeks while in jail increased the rate of both completion of a follow-up visit and completion of therapy after release, as compared to a separate, single education at diagnosis or an incentive provided at the time of clinic visit (White et al., 2002).

While these results were promising, incorporating results of the randomized trial into the usual care in the jail presented logistical difficulties, in part because of the nature of the jail system. As short-term facilities, persons are housed in jail pre-trial and during trial proceedings, as well as for sentences usually up to 1 year in length. Unlike health care settings, date of release is sometimes unknown. Precipitous releases, such as directly from court, transfers to other facilities, and releases during evening and night hours make discharge planning and pre-release counseling difficult. Moreover, time and resource limitations faced by most jurisdictions preclude multiple counseling sessions for inmates with LTBI. Therefore a separate, single education using study materials and methods was added to the usual care of counseling by clinicians at the time of diagnosis. Jail Health Services Discharge Planners agreed to add this separate educational session for inmates with LTBI to their usual workload, which included plans for post-release housing, program placement and arranging with the jail pharmacy that medications for chronic conditions be placed in the property of inmates about to be released. The goal of the study reported here was to evaluate the translation of research results to the usual clinical practice in the jail.
Theoretical framework

Roger’s Diffusion of Innovation theory has been used extensively in the last 20 years to understand the process of transferring new knowledge gained in research into clinical practice (Rogers, 1983, 1995). This theory provides the framework for the current study and its interpretation. The stages presented in the framework (knowledge, persuasion, decision to adopt an innovation, implementation and confirmation) represent a non-linear pathway toward change in practice. Rogers further proposes specific attributes of innovations that are important in whether practice change is ultimately adopted and successfully implemented: relative advantage, compatibility, complexity, trialability and observability (Rogers, 1995). Relative advantage is the degree to which the innovation is thought to be better than usual care; compatibility is the degree to which the innovation is compatible with existing values; complexity refers to whether the innovation is difficult to understand or implement; trialability is whether the innovation can be implemented on a limited or trial basis; and observability is whether the result of the innovation is apparent. A further consideration in the ultimate success of the translation of research to practice is fidelity or how close the practice innovation, once implemented, matches the methods and intent of the research protocol (Dusenbury and Hansen, 2004), and the organizational context in which the innovation is implemented (Kaluzny, 1974; Dobbins, et al., 2002; Sanson-Fisher, 2004).

For this study, new research knowledge, the influence of education and counseling on post-release behavior, constitutes an innovation consistent with Rogers’ description of a new preventive health care practice. The dissemination of research, which occurs during the knowledge stage, can be viewed in this context as the analysis, interpretation, presentation and publication of the findings of the clinical trial (White et al., 2002). Participation of the Director of Jail Health Services as a co-investigator in all the studies and involvement of Jail Health Services personnel during the studies facilitated the decision to adopt the innovation to usual care. This study reports on the initial implementation of the study protocol for education and counseling, with a goal of assessing success of its implementation to usual care in the jail in terms of patient outcomes, with consideration of the barriers and enablers of change in practice in the jail setting.

Methods

Aims

The primary aim was to compare rates of first visit to the TB clinic after release from jail, as well as completion of therapy, in inmates with LTBI who participated in a randomized trial versus inmates who were counseled and educated using the same protocol, but delivered by jail health workers. A second aim of the study was to examine the nature of the educational sessions, and to describe characteristics of the protocol that was adopted by jail personnel.

Design

This study used descriptive cohort methods and was approved by the University of California, San Francisco Committee on Human Research.

Sample

The sample was comprised of two cohorts of inmates who received education in the jail and were released before completion of therapy. The first cohort came from our randomized trial in 1998–1999 of inmates who were diagnosed with LTBI, started on treatment and educated about TB prevention, then consented to be in the study. Subjects in the trial were randomized to one of three groups (single education, multiple educations and incentive). The cohort for this analysis was the group receiving the single education and released from jail before treatment completion. For the purpose of this report, this is called the study group. The second was the cohort of inmates with LTBI in 2002–2003, who received a single education by Jail Discharge Planners and were released from jail before treatment completion. For the purpose of this report, these subjects are called the usual care
group. The origin and flow of the two cohorts are shown on Figure 1.

**Procedures**

As part of regular jail health care, inmates identified with LTBI were prescribed therapy and briefly counseled by jail clinicians about completing care after release. Lists were generated each day of inmates who were prescribed therapy, using the jail electronic medical record. This method of identification of potential subjects was used during the randomized trial and done in the same way for the usual care period.

During the randomized trial period, the Project Director (E. M.) gave research assistants structured training on the educational intervention. This training included a class on TB based on educational material that was made into a brochure that would be given to inmates; practice educating each other in an office setting; observation of the Project Director with an inmate; the Project Director observing them with an inmate; and repeat of this process every 6 months.

**Study Group**

- On INH N=777
- Missed / ineligible by study criteria N=129
- Educated and approached for consent N=648
- Refused N=90
- Enrolled and randomized N=558
- Randomized to single education group N=188
- Sent to other facility (n=51) / Off INH (n=19) / Finished INH in jail (n=14)
- Released on INH N=104

**Usual Care Group**

- On INH N=379
- Missed, released N=157
- Educated N=222
- Randomized to other groups N=370
- Sent to other facility (n=15) / Off INH (n=11) / Finished INH in jail (n=32)
- Released on INH N=164

**Fig. 1.** Flow chart of inmates with LTBI for two cohorts: during the randomized trial (study group) and in the usual care period (usual care group). INH = isoniazid.
During enrollment, inmates who were eligible to be approached for the education (English or Spanish speakers, not under special security) were brought to an interview or other private room within a short time after diagnosis and prescription of therapy. Research assistants provided education, including questions at the end to confirm understanding, for 10–15 min prior to asking about study participation. Those who gave informed consent were then interviewed and randomized to one of the three study arms; the single education group, which is the sample for this analysis, received no further contact from study personnel until they either did or did not complete a clinic visit within 30 days after release. Thirty days was selected because those who miss more than one month in the first three months of therapy need to restart therapy (American Thoracic Society, Centers for Disease Control and Prevention, 2000). After the 30-day point, attempts were made to find and interview all subjects in the community. Record review at the TB Clinic completed the procedures, to determine if any came to clinic at a later date, and to ascertain completion of therapy for LTBI. Additional descriptions of the randomized trial procedures are available in detail elsewhere (Menendez et al., 2001; White et al., 2002), including educational methods and the brochure (Duong et al., 2003).

During the usual care period, the same Project Director (E. M.) gave Discharge Planners the same structured training on the educational intervention as described above. Repeat training was planned for 6-month intervals. Because of employee turnover, however, each Discharge Planner was educated only once. Following training, the Project Director daily faxed the list of inmates who were prescribed therapy for LTBI to Discharge Planners, who had other job duties and made efforts to meet with inmates within their work schedules. They then met with inmates to provide education and completed information afterward on the nature of each session. There was no supervision or observation of the sessions provided by Discharge Planners except during the training period. Research assistants conducted record review at the TB Clinic to determine if any subjects came to clinic at a later date and to ascertain completion of therapy for LTBI.

Data

Data available for both periods included the following: age, gender, ethnicity, length of incarceration, preferred language and whether born in the US or elsewhere as surrogate measures for cultural differences. Information from the TB Clinic was available for both periods for those who made a visit and had a record started, and included date of visit, final status of completion of therapy and reasons for not completing therapy. Information from the usual care period, gathered for the second aim of the study, included the date of the education, the length of the education, the number of inmates educated during the session and whether the brochure was given to the inmate.

Analysis

Descriptive data on each cohort were compared using univariate analyses to assess comparability between the two time periods. For Aim 1, rates of completion of first visit and completion of therapy for LTBI were calculated and compared between groups. Final logistic regression analyses were done to estimate relative risk of completion in the usual care group as compared to the study group, with 95% confidence intervals, controlling for other variables influencing the two outcomes. For Aim 2, summary descriptive data on the nature of the educational sessions were analyzed by whether the subject did or did not complete a visit or therapy. Final logistic regression analyses were done to examine characteristics of the educational session that were associated with completion. For all analyses, $\alpha$ was set at 0.1 for inclusion in a multiple regression, with $\alpha = 0.05$ for final determination of statistical significance. Analyses were done using SPSS (version 11.0, Chicago, IL).

Results

The two cohorts differed in important ways (Figure 1). First, in the study group, the 129 who were missed for consent included both those who were ineligible for participation because of language and security reasons ($n = 31, 4.0\%$), and those who were
missed because they were released or sent to another facility before they could be approached (n = 98, 12.6%). By contrast, a higher proportion of inmates were missed for education in the usual care period because they were released or sent to other facilities (n = 157, 41.4%). Second, a lower proportion of inmates was sent to other facilities after education in the usual care group (n = 15, 6.8%) as compared to those sent to other facilities in the study group (n = 51, 27.1%). Third, the study group did not include inmates who refused participation (n = 90, 13.9%), while the inmates in the usual care group included those who might have refused participation.

**Aim 1**

Table I shows the demographic characteristics available for the 104 subjects released on isoniazid in the study group and 164 subjects released on isoniazid in the usual care group. Subjects in the usual care group were in jail significantly longer than those in the study group, which may be explained by the differences in procedures of the randomized trial and the Discharge Planners as described earlier. Subjects in the usual care group were found for education later in their jail stay, therefore selecting for persons who were likely to remain in jail longer. By contrast, subjects in the study group were found early in their stay in jail and, therefore, the proportion of persons released very soon is higher in this cohort. Likewise, the time from isoniazid prescription to education, another indication of the longer time before education in the usual care period, was significantly longer for the usual care group.

Results showing whether released inmates came to clinic to continue therapy for LTBI (within 30 days after release or any time after release) and whether they completed therapy are shown on Table II. Subjects who were in the usual care group were significantly less likely to go to clinic, whether

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Study group [N = 104 (%)]</th>
<th>Usual care group [N = 164 (%)]</th>
<th>Total [N = 268 (%)]</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>95 (91.3)</td>
<td>149 (90.9)</td>
<td>244 (91.0)</td>
<td>0.891</td>
</tr>
<tr>
<td>female</td>
<td>9 (8.7)</td>
<td>15 (9.1)</td>
<td>24 (9.0)</td>
<td></td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latino</td>
<td>63 (60.6)</td>
<td>110 (69.2)</td>
<td>173 (65.8)</td>
<td>0.004</td>
</tr>
<tr>
<td>black</td>
<td>20 (19.2)</td>
<td>26 (16.4)</td>
<td>46 (17.5)</td>
<td></td>
</tr>
<tr>
<td>white</td>
<td>6 (5.8)</td>
<td>13 (8.2)</td>
<td>19 (7.2)</td>
<td></td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>5 (4.8)</td>
<td>10 (6.3)</td>
<td>15 (5.7)</td>
<td></td>
</tr>
<tr>
<td>other, mixed</td>
<td>10 (9.6)</td>
<td>0 (0.0)</td>
<td>10 (3.8)</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td>0.444</td>
</tr>
<tr>
<td>mean</td>
<td>30.5</td>
<td>31.4</td>
<td>31.1</td>
<td></td>
</tr>
<tr>
<td>median</td>
<td>29.7</td>
<td>29.0</td>
<td>29.4</td>
<td></td>
</tr>
<tr>
<td>Born outside US</td>
<td></td>
<td></td>
<td></td>
<td>0.728</td>
</tr>
<tr>
<td>mean</td>
<td>67 (66.3)</td>
<td>87 (68.5)</td>
<td>154 (67.5)</td>
<td></td>
</tr>
<tr>
<td>median</td>
<td>29.7</td>
<td>30.4</td>
<td>29.9</td>
<td></td>
</tr>
<tr>
<td>Time in jail on isoniazid</td>
<td></td>
<td></td>
<td></td>
<td>0.045</td>
</tr>
<tr>
<td>mean (days)</td>
<td>51.0</td>
<td>61.7</td>
<td>57.5</td>
<td></td>
</tr>
<tr>
<td>median (days)</td>
<td>36.0</td>
<td>47.5</td>
<td>43.0</td>
<td></td>
</tr>
<tr>
<td>Time, isoniazid start to education</td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>mean (days)</td>
<td>3.2</td>
<td>10.4</td>
<td>7.6</td>
<td></td>
</tr>
<tr>
<td>median (days)</td>
<td>2.5</td>
<td>9.0</td>
<td>7.0</td>
<td></td>
</tr>
</tbody>
</table>

aData were missing on some characteristics for each cohort.
looking at the 30-day period after release (relative risk 0.84, 95% confidence interval 0.75–0.95) or any time after release (relative risk 0.79, 95% confidence interval 0.68–0.92). It should be noted, however, that for the study group, subjects were found for interview following the 30-day period. This likely served as an additional intervention, resulting in a ‘booster effect’ or reminder to subjects who had not gone to clinic and resulting in the subsequent visits to clinic (White et al., 2002). All subjects who went to clinic in the time after the 30-day mark had been found by study personnel for this interview prior to the date that they went to clinic; no additional subjects went to clinic without this interview. No such additional intervention was provided to inmates in the usual care period.

In examining the 30-day visit completion for both cohorts, other variables were associated with going to clinic. There was a high correlation between preferred language (English or Spanish), being Latino and birth outside the US, indicating that these characteristics described the same persons, about 65% of both cohorts. Subjects who preferred English were twice as likely to go to clinic (21%) as those who preferred Spanish (12%) (relative risk 1.8, 95% confidence interval 1.0–3.1, P = 0.045). Also, subjects who went to clinic had an average of 45 days on isoniazid in jail (median 30) as compared to those who did not (mean 60, median 47 days, P = 0.036). In logistic regression, neither variable remained significant, and subjects in the usual care period remained less likely to go to clinic (relative risk 0.37, 95% confidence interval 0.18–0.75, P = 0.006).

For subjects who made the visit within the first 30 days, no differences were seen in the average time between release and clinic visit (study group: mean 3.8, median 2 days; usual care group: mean 5.6, median 3 days). For subjects who went to clinic any time after release, average interval did not differ significantly for those in the study group (mean 30.1 days, median 3 days) as compared to subjects in the usual care group (mean 34.9 days, median 9 days).

Completion of therapy is also shown on Table II. The apparent difference between distributions of therapy outcomes in the two periods disappears when subjects who completed therapy were combined with subjects who had completed therapy previously. When summed, 50% of the study group and 52% of the usual care group completed therapy, which is within the range of outcomes seen at the TB Clinic among high-risk patients (White et al., 2003).

**Aim 2**

For Aim 2, Jail Discharge Planners recorded information on each educational session. Characteristics of the educational sessions are presented on Table III, by whether or not the released inmate went to the TB Clinic. Subjects who were born in the US were more likely to go to clinic than subjects

<table>
<thead>
<tr>
<th>Criteria for Completion</th>
<th>Study group</th>
<th>Usual care group</th>
<th>Total</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completion of first visit to clinic within 30 days of release</td>
<td>N = 104 (%)</td>
<td>N = 164 (%)</td>
<td>N = 268 (%)</td>
<td>0.002</td>
</tr>
<tr>
<td>any time after release</td>
<td>25 (24)</td>
<td>16 (10)</td>
<td>41 (15)</td>
<td>0.001</td>
</tr>
<tr>
<td>Final status at TB Clinic among those who went any time after release</td>
<td>N = 34 (%)</td>
<td>N = 25 (%)</td>
<td>N = 59 (%)</td>
<td>0.049</td>
</tr>
<tr>
<td>completed therapy</td>
<td>16 (47)</td>
<td>7 (28)</td>
<td>23 (39)</td>
<td>0.049</td>
</tr>
<tr>
<td>completed therapy previously</td>
<td>1 (3)</td>
<td>6 (24)</td>
<td>7 (12)</td>
<td>0.049</td>
</tr>
<tr>
<td>still on therapy</td>
<td>1 (3)</td>
<td>0 (0)</td>
<td>1 (2)</td>
<td>0.049</td>
</tr>
<tr>
<td>taken off—side-effects</td>
<td>3 (9)</td>
<td>0 (0)</td>
<td>3 (5)</td>
<td>0.049</td>
</tr>
<tr>
<td>moved, referred</td>
<td>0 (0)</td>
<td>1 (4)</td>
<td>1 (2)</td>
<td>0.049</td>
</tr>
<tr>
<td>self-stopped; lost to follow-up</td>
<td>13 (38)</td>
<td>11 (44)</td>
<td>24 (41)</td>
<td>0.049</td>
</tr>
</tbody>
</table>
born outside the US (23 versus 8%, odds ratio 2.8, 95% confidence interval 1.1–7.0, \( P = 0.023 \)). While this specific information on the educational session is only available for the usual care period, we estimate that, based on schedules and assignments of research assistants and discussions in weekly meetings, that on average the education took 10–15 min during the randomized trial. The educational session in the usual care period for 81.0% of inmates took 5 min and for 98.2% of inmates the session was no longer than 10 min.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Went to clinic [( N = 25 ) (%)]</th>
<th>Did not go to clinic [( N = 139 ) (%)]</th>
<th>Total [( N = 164 ) (%)]</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Language of educational session</td>
<td></td>
<td></td>
<td></td>
<td>0.468</td>
</tr>
<tr>
<td>Spanish</td>
<td>13 (12.3)</td>
<td>93 (87.7)</td>
<td>106 (100)</td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>11 (21.6)</td>
<td>40 (78.4)</td>
<td>51 (100)</td>
<td></td>
</tr>
<tr>
<td>Tagalog, data missing</td>
<td>1 (14.3)</td>
<td>6 (85.7)</td>
<td>7 (100)</td>
<td></td>
</tr>
<tr>
<td>No. of inmates in educational session</td>
<td></td>
<td></td>
<td></td>
<td>0.478</td>
</tr>
<tr>
<td>1</td>
<td>24 (16.3)</td>
<td>123 (83.7)</td>
<td>147 (100)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1 (9.1)</td>
<td>10 (90.9)</td>
<td>11 (100)</td>
<td></td>
</tr>
<tr>
<td>3–4</td>
<td>6 (100)</td>
<td>6 (100)</td>
<td>6 (100)</td>
<td></td>
</tr>
<tr>
<td>Time spent in educational session (min)</td>
<td></td>
<td></td>
<td></td>
<td>0.849</td>
</tr>
<tr>
<td>5</td>
<td>20 (15.4)</td>
<td>110 (84.6)</td>
<td>130 (100)</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>5 (16.7)</td>
<td>25 (83.3)</td>
<td>30 (100)</td>
<td></td>
</tr>
<tr>
<td>12–25</td>
<td>4 (100)</td>
<td>4 (100)</td>
<td>4 (100)</td>
<td></td>
</tr>
</tbody>
</table>

There is an inherent difficulty in comparing the results of a tightly controlled randomized trial to an analysis of usual care using observational data. Differences in timing of the education, and differential refusal rates suggest selection bias and complicate the comparison. Inmates who agreed to be in the randomized trial could have been more likely to go to clinic. The combined effects of the education, contact with the inmate after release and reimbursement for interviews could well have influenced subjects. Inmates in the usual care period were not informed about the study, as it was conducted by record review; they did not receive reimbursement, and may not have believed they could refuse education by Jail Discharge Planners. Completion of therapy, among those who made a first visit to the TB Clinic, however, was the same for both cohorts and was similar to the 55% found by Bandyopadhyay et al. in Connecticut (Bandyopadhyay et al., 2002). This seems to suggest that the cohorts were similar and that activities of the TB Clinic personnel to encourage completion of therapy after release were the same for each group. This confirms the role of reinforcing factors on health behavior change (Green and Kreuter, 1999), but suggests that there were other reasons for the differences in results seen.

Viewed within the framework of Diffusion of Innovation theory (Rogers, 1975), research evidence...
was adopted for usual care; organizational commitment was made to change practice to include educational sessions developed and tested in the randomized trial. The innovation was demonstrated in the same setting to have relative advantage over usual care, and was compatible with the goals and activities of Discharge Planners and Jail Health Services. The complexity of the protocol did not exceed the capabilities of Discharge Planners, who were adept at case management of patients with other complex medical conditions. The change in practice was instituted with a trial period during training. However, observability, the final attribute described by Rogers (Rogers, 1995) as important for successful implementation, was missing. While Discharge Planners were made aware of the differences in therapy completion rates found in observational studies and in the randomized trial, there was no ongoing mechanism for them to receive feedback on the impact of education. Whether or not inmates released from jail went to TB Clinic or completed therapy was neither monitored nor reported to jail health workers, except in the conduct of research. Observability in terms of completion rates may not be achievable in a setting where efforts in one setting lead to outcomes in another, as is the case here.

Perhaps more importantly, the organizational context may have affected implementation fidelity. While training of study personnel and Discharge Planners was similar, study personnel were directly supervised to insure that the protocol was consistently administered. Research personnel were enthusiastic about the randomized trial, had no other job duties, and sought inmates with LTBI soon after diagnosis and prescription. By comparison, considerable turnover among Discharge Planners resulted in their being trained only once, although our intent was to repeat the training process with them every 6 months. Supervision of educations provided by Discharge Planners only occurred during the initial training. They had multiple job obligations in the jails, reflected by inmates’ longer stay in jail before they were seen for education. On average, the time spent in education during the usual care period was shorter. None of the subjects during the randomized trial were educated with other inmates present, whereas Discharge Planners sometimes provided education and counseling to more than one inmate with LTBI, and talked ‘through the bars’, rather than in a separate, private room. As a result, the practice adopted by the jails was different from that of the randomized trial. The lack of fidelity between the study protocol and the practice change implemented in the jail reflects the difficulties in adapting research to the real world setting. Castro et al. (Castro et al., 2004) point out, however, that there is an inherent tension between fidelity of implementation and program adaptation in order to meet the needs of those using research findings for practice, both of which are necessary for program effectiveness. In this study, Discharge Planners adapted the protocol to their job obligations and it is unknown which changes may have accounted for the differences in results seen. Studies that identify core elements in an evidence-based program, without which the program is unlikely to achieve desired outcomes, may be useful in easing this tension between fidelity and adaptation (Pentz, 2004).

Despite a growing body of evidence across a number of fields that fuels the call for evidence-based practice, there are consistent findings in health services research that clinical care does not mirror the scientific evidence (Hallfors and Godette, 2002; Grol and Wensing, 2004; Glasgow et al., 2004). Glasgow et al. (Glasgow et al., 2003) point out the gap between efficacy trials, in which research personnel follow a standardized protocol, and effectiveness studies, in which regular staff with competing priorities must implement an intervention. Acknowledging that behavioral interventions in particular are difficult to implement because of differences in training of personnel, quality control and standardization, they conclude that it should not be surprising when results of an intervention are efficacious in a tightly controlled randomized trial but cannot be replicated in a real-world setting. They call for more attention to external validity in efficacy trials, such as cost and time required for an intervention, qualifications of those delivering the intervention in the study protocol and of those who would be delivering it in a usual care setting, and organizational data (Glasgow et al., 2003). Sung
et al. (Sung et al., 2003) further suggest collaboration from the start with clinicians and the community anticipated to benefit from a study; collaboration with clinicians in the development of a protocol, with attention to and even testing of the attributes that promote adoption and implementation, can help us understand not only why and how an interventions works, but also how to encourage its adoption to practice (Pankratz et al., 2002). Developing relevant system measures can help the interpretation of results from a study protocol that is by design both too simple to represent all the relevant factors that influence an outcome and too complex to be useful in real practice (Brownson and Simoes, 1999; Glasgow et al., 2003). Such practical clinical trials are more likely to provide valid and reliable evidence of clinical effectiveness to inform clinicians and health policy decision makers (Tunis et al., 2003). Protocols found to be effective from these studies with both attention to external validity and close participation by real-world clinicians would more likely to be accepted and adopted for use in practice with fewer changes, thereby improving effectiveness.

Our studies of interventions to improve therapy completion for LTBI in jailed inmates have resulted in modest improvement following adoption in the usual care setting. Further gains may be realized by multiple strategies for intervention and study, at the individual and the system level. These successes, however, will not be effective in the real world without consideration of the context in which the findings will be applied. The ultimate improvement in therapy completion for LTBI will be achieved by carefully designed practical clinical trials combined with understanding and study of diffusion of research in the jail setting.

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