Efficacy of a Process Improvement Intervention on Delivery of HIV Services to Offenders: A Multisite Trial

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The National Institute on Drug Abuse launched the Criminal Justice Drug Abuse Treatment Studies, Phase 2 in 2008, under a cooperative agreement with multiple research organizations and a coordinating center. The purpose was to test implementation strategies for health-related interventions for offenders incarcerated in prisons and jails or supervised by probation and parole agencies. The research centers designed the protocols and conducted the trials. The HIV Services and Treatment Implementation in Corrections (HIV-STIC) study evaluated implementation strategies in HIV/AIDS prevention—education, testing, and treatment.

Inmates and other offenders are at high risk for HIV infection, and the rate of confirmed AIDS cases among state and federal prisoners has been about 2.4 times the rate in the general US population.\(^1\)\(^2\) In 2009, the Centers for Disease Control and Prevention released practice guidelines for managing HIV risk among offenders in correctional systems; they called for HIV testing, prevention programming, and discharge planning for seropositive inmates.\(^3\) Although many correctional facilities offer HIV testing, prevention, and antiretroviral medication services, studies have demonstrated that many gaps remain in delivering effective HIV services.\(^4\) Furthermore, although inmates identified as HIV positive are provided with antiretroviral therapy (ART) by correctional facilities, gaps in access to medications when inmates are released to the community are common and can have catastrophic consequences for offenders and collateral contacts.\(^7\)\(^8\)

For the HIV-STIC study, we found helpful ideas in the model of implementation research developed by Proctor et al.\(^9\)\(^10\) They (and other theorists) propose that experimental testing has identified many effective public health interventions, so that now the pressing need is to test implementation strategies to achieve successful use of those interventions in organizations.

Another important concept is service penetration to recipients (the number of eligible persons who use a service as a proportion of the total number of persons eligible for the service).\(^10\)\(^11\) Effective HIV prevention models for correctional populations have been identified,\(^12\)\(^13\) but transferring these programs from carefully controlled trials into real-world practice is difficult,\(^14\)\(^15\) and few studies have tested the implementation processes in field settings.\(^14\)\(^16\)

Quality improvement strategies have become common in health care systems. The Network for the Improvement of Addiction Treatment (NIATx)\(^17\) trains coaches to help local agency change teams learn how to try out and assess new organizational processes for targeted improvements such as improved patient retention in treatment.\(^18\)\(^19\)

HIV continues to be a major public health problem (even though research has established the efficacy of HIV testing, prevention practices, and ART) because these services have not been adequately implemented for high-risk populations. We sought to expand the new field of implementation science to evidence-based HIV services for a very high-risk population: offenders in correctional facilities or recently released from such facilities. We also tested a NIATx model modified for the implementation of HIV services in prisons and jails.

Nine research centers cooperated in planning and conducting the research. Our long-term goal was improved health services for an at-risk population: offenders under correctional supervision. Specifically, we aimed to more effectively implement improvements in HIV services for preventing, detecting, and treating HIV. Our primary hypothesis was that, compared to the control condition facilities, proportionally more offenders in our experimental condition facilities (where staff were exposed to the modified NIATx model) would receive improved delivery of HIV services.

**METHODS**

The HIV-STIC study consisted of 14 cluster-randomized trials in which one correctional facility was assigned to the experimental condition (training in HIV services and coaching in...
a modified NIATx model) and the other was assigned to the control condition (HIV training only). Multilevel hierarchical linear modeling is ordinarily used to analyze cluster-randomized trials. However, this method requires (1) individual-level data and (2) measurement of data on a common dependent variable; HIV-STIC could meet neither of these requirements. In accordance with institutional review board agreements, correctional staff provided us with records of delivery of HIV services to offenders in aggregate form, without individual-level data. We knew that different correctional organizations would choose different types of HIV service improvement outcomes for their experiments.

Meta-analysis is a type of multilevel hierarchical linear modeling analysis that uses summary statistics instead of individual data and combines somewhat different types of outcomes to express effect sizes, such as odds ratios (ORs). When individual-level data are not available, the intraclass correlation cannot be computed. However, in meta-analytic multilevel analysis, cluster effects are assessed from measures of heterogeneity among the effect sizes of the experiments. In prospective meta-analysis, planning is done before the experiments begin to ensure that they have similar interventions and outcomes.

**Samples and Settings**

Each research center recruited either 1 pair of correctional (prison or jail) facilities to form 1 cluster-randomized trial or 2 pairs of facilities to form 2 independent cluster-randomized trials. Facilities were eligible to form a pair if they were roughly equivalent in (1) population size, (2) custody classification level (minimum or medium security), and (3) identified HIV service needs and problems to be addressed. We excluded maximum security prisons because inmates had much longer sentences and lower release rates, greater restrictions on movement, and more limited access to services. Centers that intended to improve connection to community care for HIV-positive inmates upon release partnered with community agencies. Although some correctional facilities contracted with or referred clients to multiple HIV service providers, for the experiment we selected only 1 HIV service provider partner for data collection. Our preference was to engage community HIV service programs that (1) served the largest number of offenders, (2) had demonstrated a collaborative disposition in working with the correctional partner and the research center, (3) had provided HIV services to correctional partner clients, either under contract or through referral, and (4) were not too distant from the correctional facility.

The regions where facilities were located were New England (4 jails), Mid-Atlantic (4 work-release facilities linking to community health providers and 2 jails with contracted service providers), East North Central (2 state correctional facilities), East South Central (2 state correctional facilities with 2 community health providers), Mountain (2 county detention facilities and 4 state correctional facilities), Pacific (4 state corrections centers), and Offshore Commonwealth (2 prisons and 2 community providers of HIV treatment).

Administrators of the correctional facilities and the HIV community services organizations agreed that pertinent staff would be available to participate in the HIV-STIC study. These were HIV counselors, prison medical staff, substance abuse treatment staff, and community HIV services staff. We invited certain staff members in the facilities randomly assigned to the experimental condition to participate in the study as members of local change teams (LCTs). Each research center administered informed consent procedures according to its respective institutional review board’s requirements.

Following the baseline training of the staff participants, we randomized correctional sites through a probabilistic random assignment function (RANUNI) in SAS version 9.2 (SAS Institute Inc, Cary, NC) to the experimental or control condition. Reports from senior staff and NIATx coaches and our observations indicated that conditions were followed as randomized.

**Objectives**

A senior administrator (executive sponsor) in the correctional agency ensured that within each experiment the experimental and control facilities would share the same primary goal, specifically to improve the delivery of the same kind of HIV service to the inmates. Records and observations showed that within each experiment, both experimental and control conditions focused on the same primary goal of HIV service improvement. Between experiments, centers selected different improvement goals, as allowed by the protocol.

Table 1 presents the primary outcomes for delivery of HIV services in the experiments. In addition to the main goal, stated in general terms, it also lists the specific criterion of success. For example, in experiment 5.1, success was operationalized as the number of discharged inmates who ever received HIV prevention education and the total or base as the number of inmates who were discharged during the same period. The operationalized outcomes were in records collected by the staff, who provided aggregated totals of the outcomes to the researchers. For some experiments, senior correctional staff held a strong opinion that 2 primary goals were important; these goals were weighted equally as goal 1a and goal 1b.

**Local Change Teams**

The executive sponsor appointed a senior administrator in the experimental condition facility (facility sponsor) to oversee LCT activity in the facility. Together they organized an LCT of a few staff persons and appointed 1 person with strong leadership, communication, and delegation skills as team leader. In the experimental condition, the LCT used the NIATx approach, which begins with walking through the service delivery to see it from the service recipient’s point of view and to detect difficulties. Next, the teams used rapid plan–do–study–act cycles: identify specific problems and generate solutions (plan), try out new processes (do), measure and assess the outcomes (study), and implement the solution or make additional changes (act). LCTs repeated the cycle for any other problems discovered. Teams executed plans for solving each problem 1 at a time, recorded and reviewed results data, and, at the end of each cycle, decided whether to adopt, adapt, or abandon that plan.

The typical LCT had 5 members at the start of the project, 2 left during the project, 3 joined after the start of the project, and 6 remained at the end. Examples of reasons for staff movement out of LCTs were transfer to another facility and retirement and for joining an ongoing project were having needed skills and replacing lost staff.
<table>
<thead>
<tr>
<th>Research Center, Experiment</th>
<th>Main Goal</th>
<th>Goal 1a</th>
<th>Goal 1b</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Criterion of Success, No.</td>
<td>Total or Base, No.</td>
</tr>
<tr>
<td>3.1 Prevention</td>
<td>Inmates who received the prevention intervention</td>
<td>Inmates who could have received the prevention intervention</td>
<td>...</td>
</tr>
<tr>
<td>4.1 Linkage of inmates discharged on ART to ART in community</td>
<td>Inmates for whom ART was scheduled with community HIV treatment</td>
<td>Inmates discharged on ART</td>
<td>...</td>
</tr>
<tr>
<td>4.2 Linkage of inmates discharged on ART to ART in community</td>
<td>Inmates for whom ART was scheduled with community HIV treatment</td>
<td>Inmates discharged on ART</td>
<td>...</td>
</tr>
<tr>
<td>5.1 Prevention</td>
<td>Discharged inmates who ever received prevention education</td>
<td>Inmates discharged</td>
<td>...</td>
</tr>
<tr>
<td>5.2 Prevention</td>
<td>Discharged inmates who ever received prevention education</td>
<td>Inmates discharged</td>
<td>...</td>
</tr>
<tr>
<td>6.1 Linkage of inmates discharged on ART to ART in community</td>
<td>Inmates on ART who had contact with community HIV treatment</td>
<td>Inmates on ART who were scheduled to receive community HIV treatment</td>
<td>...</td>
</tr>
<tr>
<td>7.1 Linkage of inmates discharged on ART to ART in community</td>
<td>Inmates on ART who had contact with community HIV treatment</td>
<td>Inmates on ART who were scheduled to receive community HIV treatment</td>
<td>...</td>
</tr>
<tr>
<td>8.1 Prevention</td>
<td>Inmates contacted by other inmates trained in dissemination of HIV education</td>
<td>Inmates targeted for HIV education dissemination by inmates</td>
<td>...</td>
</tr>
<tr>
<td>8.2 Prevention</td>
<td>Inmates contacted by other inmates trained in dissemination of HIV education</td>
<td>Inmates targeted for HIV education dissemination by inmates</td>
<td>...</td>
</tr>
<tr>
<td>9.1 HIV testing</td>
<td>Admitted inmates who were tested for HIV</td>
<td>Admitted inmates</td>
<td>...</td>
</tr>
<tr>
<td>9.2 HIV testing</td>
<td>Admitted inmates who were tested for HIV</td>
<td>Admitted inmates</td>
<td>...</td>
</tr>
<tr>
<td>10.1 Linkage of inmates discharged on ART to ART in community</td>
<td>Inmates on ART who were scheduled to receive community HIV treatment</td>
<td>HIV-positive inmates discharged</td>
<td>Inmates on ART who had contact with community HIV treatment</td>
</tr>
<tr>
<td>10.2 Linkage of inmates discharged on ART to ART in community</td>
<td>Inmates on ART who were scheduled to receive community HIV treatment</td>
<td>HIV-positive inmates discharged</td>
<td>Inmates on ART who had contact with community HIV treatment</td>
</tr>
<tr>
<td>11.1 Linkage of inmates discharged on ART to ART in community</td>
<td>Inmates on ART who were scheduled to receive community HIV treatment</td>
<td>HIV-positive inmates discharged</td>
<td>Inmates who refilled ART prescription after release</td>
</tr>
</tbody>
</table>

Note: ART = antiretroviral therapy; ellipses = not applicable.
Study Phases
We held a stakeholder orientation meeting in each corrections agency to bring criminal justice participants and researchers together for an overview of the study protocol, deadlines, and staff time and effort commitment. The Bridging Group, a consulting firm, provided training on HIV services to likely staff participants. The first research center held its orientation meeting in February 2011 and the last in April 2012. Participant recruitment began about the time of the orientation meeting, but some new participants entered many months later if the strategies of the LCT required new members.

Collection of baseline survey data occurred soon after the orientation meeting. Randomization of facilities to the experimental or control condition was the next milestone. The intervention phase began at each experimental facility with an initial in-person meeting between the NIATx coach and the LCT to summarize the project, introduce NIATx concepts, and specify the key objectives of the implementation project. The implementation phase (typically 10 months) focused on the LCT carrying out the NIATx rapid-cycle testing activities.

Collection of HIV services records data covering all 14 experiments began with the first baseline months of HIV services records in January 2011, and collection of the final follow-up months of HIV services records ended in July 2013. Some corrections organizations joined HIV-STIC much later than others, so the onset and end of each phase varied substantially across the experiments.

Measures
To assess the experiment’s primary goal of delivering a specific HIV service to people under correctional supervision, we obtained records on the possible outcomes in each condition of the experiment: nS, the number to whom the intervention was successfully delivered; nF, the number who failed to receive the intervention; total N, the total (or targeted base). Thus, nS + nF = total N. The observed probability of success in the sample was nS/total N. The odds of success were nS/nF. Because the data were in the form of success, failure, total, we took the conventional approach of using the OR as the main effect size. The OR was the ratio of the odds of success with experimental treatment over the odds of success with the control treatment. For the statistical analysis we followed the standard practice of converting the OR to the log OR.

We considered 3 covariates in assessing whether the modified NIATx organizational process improvement interventions significantly improved the delivery of HIV services in this set of 14 cluster-randomized trials:

- Targeted outcome. If the general type of primary outcome (prevention, HIV testing, linkage of HIV-positive inmates to ART) chosen for each experiment was related to the effect size, that should be taken into account in interpreting the findings.
- Baseline effect size. This is the effect size comparing the experimental group to the control group prior to the intervention. If either experimental or control groups appeared to be significantly more successful at baseline, including that as a moderator variable should help us to understand the findings.
- Fidelity. If some of the actual interventions were poor and others were good approximations of the NIATx model, that should be included as a moderator variable.

As is standard practice, for the statistical analysis we added a conventional value of 0.5 to any number of successes exactly equal to zero (to avoid the impermissible operation of division by zero), and we used the logarithm of the OR (because that method makes that effect size symmetric around 0 and has sampling distributions that are closer to normality). We then converted the results back into OR form. We conducted a meta-analysis for a hypothesis test of the primary outcome, followed by a meta-analysis or a meta-regression in which we controlled for potential moderator variables. For those key analyses we used Comprehensive Meta-Analysis version 2.2.055 and the Metafor statistical package version 1.8-O in R statistical software version 3.0.1.

RESULTS
The data collected to measure the primary outcomes are presented in Table 2. The
number of inmates targeted for improved HIV services (total) varied greatly. Some criminal justice facilities had many inmates who had not been tested for HIV and many who had not received any HIV prevention intervention, but relatively few inmates who were HIV positive and in need of ART. In both the experimental and the control condition, the targeted total number for delivery of the HIV service and the number of inmates to whom that HIV service was successfully delivered enabled us to calculate the conventional effect size OR. We used random-effects statistical models.

The results of the critical null hypothesis test of the meta-analysis relating the primary outcome to the experimental versus control condition are summarized in the note at the bottom of Table 2. Our significance test at the .05 level led us to reject the null hypothesis of no difference between the experimental and control conditions, because the computed probability was .01. The point estimate for the log OR was 0.76 (95% confidence interval CI = 0.18, 1.33). Those statistics corresponded to a point estimate for the OR of 2.14 (95% CI = 1.20, 3.80). The conversion functions in Comprehensive Meta-Analysis software showed that the point estimate OR of 2.14 converted to a Cohen $d$ of 0.42, an effect size conventionally considered between small and medium.32

Statistics on the heterogeneity of the experimental results also appear in the note to Table 2. The $Q$ test result of $P<.001$ indicated that the studies probably did not share a common effect size, and an $I^2 = 94.5$ could be characterized as high heterogeneity.33 Therefore, we investigated 3 potential moderator variables.

First, we analyzed a categorical moderator variable, the main goal of the experiments, shown in Figure 1, which is a forest plot of the 14 experiments. As shown in the scale at the bottom, the effect size is the logarithm of the OR, and that provides its zero point as a convenient vertical reference line in the middle of the graph, with successful experiments displayed to the right of the zero point. The left column shows the labels for research centers and their experiment(s). The second column shows the main goal of each experiment, with the 5 HIV prevention experiments near the top, the 2 HIV-testing experiments just below that, and the 7 linkage to HIV treatment experiments at the bottom of the plot. Within each of those 3 separate goals, the experiments are sorted in descending order of their effect sizes. On the right is each log OR and its associated 95% CI. Below the 14 experiments, the RE model indicates random-effects model. The black diamond just above the scale at the bottom shows that the meta-analysis finding is to the right of, and does not overlap, the 0.00 point; thus the meta-analysis is statistically significant.

To the right of the diamond are the overall summary log OR and its associated 95% CI. The forest plot displays experiments with proportionately larger sample sizes having narrower CIs (e.g., 8.1 and 8.2) and experiments with smaller sample sizes with proportionately wider (uncertain) CIs (e.g., 4.1 and 4.2). In the actual moderator analysis, the log ORs were (1) prevention, 1.13 (95% CI = 0.05, 2.21; $P = .04$); (2) HIV testing, 0.16 (95% CI = −0.24, 0.57; $P = .43$); and (3) linkage to treatment, 0.70 (95% CI = −0.33, 1.74; $P = .18$). The results for HIV prevention did not include the zero log OR (i.e., no-difference point), indicating that HIV prevention mainly accounted for the significant overall null hypothesis test.

We also used meta-regressions to assess 2 interval-level variables as potential moderators. One covariate of interest was the effect size comparing the experimental to the control group prior to the intervention. In the matched pair of corrections facilities, we used random assignment to limit differences in the levels of the chosen HIV service delivery prior to the intervention. If the effect sizes at baseline seemed to have little or no relation to the effect sizes at follow-up (as intended), then the findings would be easy to interpret. However, if either the experimental or control group appeared to be significantly more successful at baseline, this effect should be estimated statistically in analyses after the critical test. The log OR at baseline showed that (as intended) this variable was not statistically significant (exact $P = .32$).

We assessed the fidelity of the actual LCT interventions to the NIATx model with an instrument constructed during this project. Four items rated structural components (e.g., a senior staff person able to bring resources to the change team). Six rated the process (i.e., plan, do, study, act). Eight (reverse coded) rated problems (e.g., the LCT’s meetings were too infrequent). A meta-regression that included the rating of fidelity to NIATx showed that the rating of fidelity was not even close to being a significant predictor (exact $P = .86$) of the effect sizes.

| 5.1 | Prevention  | 4.15 (1.35, 6.95) |
| 3.1 | Prevention  | 2.09 (1.83, 2.34) |
| 8.1 | Prevention  | 0.99 (0.57, 1.40) |
| 5.2 | Prevention  | 0.48 (0.13, 1.09) |
| 8.2 | Prevention  | −0.30 (−0.78, 0.18) |
| 9.2 | Testing     | 0.37 (0.23, 0.51) |
| 9.1 | Testing     | −0.04 (−0.18, 0.09) |
| 4.1 | Treatment   | 3.04 (−0.92, 7.01) |
| 10.1AB | Treatment | 1.83 (−1.25, 4.91) |
| 10.2AB | Treatment | 0.60 (−3.51, 4.71) |
| 6.1AB | Treatment  | 0.37 (−0.99, 1.74) |
| 7.1  | Treatment  | 0.34 (−3.35, 4.03) |
| 11.1AB | Treatment | 0.18 (−3.74, 4.11) |
| 4.2  | Treatment  | 0.00 (−5.54, 5.54) |

Note. Numbers in parentheses are 95% confidence intervals.

**Figure 1**—Forest plot of experiments sorted by main goal then by effect size in descending order: HIV Services and Treatment Implementation in Corrections, United States, 2011–2013.
We also examined how influential each experiment was on the overall results, performing diagnostic tests while removing 1 experiment at a time from the meta-analysis. We used the influence function in the Metafor package to conduct that procedure. The values of 2 statistics (rstudent = 3.17 and dfits = 1.96) indicated that experiment 3.1 had a significant influence on the overall results. We think that this degree of influence was a result of its large sample sizes, especially in the control condition.

**DISCUSSION**

In the correctional settings of our 14 cluster-randomized trials, addition of a modified NIATx change team approach doubled the odds of successful delivery of HIV services (point estimate for OR = 2.14). The HIV services under investigation were successfully delivered to 26% of the targeted inmates in the experimental condition and 16% in the control group.

**Strengths and Limitations**

Validity of our results was good (although not excellent) on 4 dimensions widely considered to be important. The study design (a prospective meta-analysis of cluster-randomized trials) reduced problems of internal validity. It is relatively unlikely that some factor other than the NIATx change team approach caused the improvement that we observed.

External validity was reasonably good. If we had had the luxury of drawing random samples of prisons and jails from across the United States, and if they had almost all agreed to carry out the experiments, the external validity would have been much stronger. However, the diversity of states and correctional facilities included suggests that the modified NIATx intervention was effective across variations in persons, settings, and treatment variables.

Field experiments encounter many potential threats to construct validity. A potential threat in our study was novelty and disruption effects, because “participants may respond unusually well to a novel innovation or unusually poorly to one that disrupts their routine.” Reports from the field suggested that a few members of the NIATx change teams found it new and interesting but that more staff limited their LCT participation to keep up with the routine duties of their work in the correctional organization. We do not know the net effect of these factors.

Statistical conclusion validity was also reasonably strong, considering that we conducted our experiments in the real world of prisons and jails and that the NIATx model is itself an intervention intended to be flexible and adaptive to the realities in the field. If the heterogeneity of the units is considered a threat to internal validity because it makes “detection of a relationship more difficult,” then this threat was not fatal to our study.

One of the post hoc tests of moderators was to examine the heterogeneity of effect sizes related to the 3 general HIV goals (prevention, testing, and linkage to ART). The experiments that had HIV prevention as their primary goal had a point estimate of the OR of 3.10, an effect size that would probably be considered of at least medium strength. That set of experiments had a 95% CI that was positive and excluded a no-difference point, suggesting that future research on a similar modified NIATx approach to increasing prevention will probably also find significant positive results. The experiments that had linkage to ART in the community as their primary goal had a point estimate OR of 2.02 (which corresponds to a Cohen d of 0.39, considered intermediate between a small and medium effect). However, those experiments had a lower limit of the 95% CI that included the no-difference point. It should be noted that although the prevention experiments had a combined total of 11 818 inmates, the linkage to ART experiments had a total of 1111, producing lower statistical power and a wider 95% CI.

Only 2 experiments had HIV testing as their primary goal, both of them conducted by the same research center. The point estimate OR was 1.18, which would probably be considered a very small effect. The 95% CI included the no-effect point. A possible reason for the lack of success was staff dissatisfaction: some staff expressed concerns about being asked to do change team work in addition to their regular duties without receiving compensation or extra help.

**Conclusions**

Our study provides an important step toward reducing the spread of HIV among offenders and in the communities to which inmates return. Our study was a rare effort to apply NIATx-type process improvement services in correctional settings. Little was known about effective strategies for implementing this service improvement model in jails or prisons or in probation or parole settings. Future implementation studies that target correctional settings should consider conducting a preimplementation pilot study to identify potential problems (e.g., the staff dissatisfaction encountered by 1 research center).

Our study was part of efforts in the relatively new field of implementation science, focused here on health-related interventions for offenders under correctional supervision. We hope that other researchers will advance these efforts to improve the quality of services for at-risk and HIV-positive offenders and strengthen the measurement and assessment of the impact of these services. The next step to advance these efforts is for practitioners and researchers to engage in conceptual development and in pilot testing to strengthen our modified NIATx approach, particularly to improve the effect sizes that we found for linkage to ART in the community and for HIV testing in prisons and jails.

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**Contributors**

F. S. Pearson was part of the team that designed the study. He conceptualized and conducted the statistical analysis, wrote the Results section, and integrated all sections of the article. M. S. Shaber wrote the introduction and reviewed and edited drafts of the article. R. Dembo
helped develop the linkage to the antiretroviral component of the study and cowrote the Discussion and “Conclusions” sections. G. d. M. Vega-Debién cowrote the sections on staff attrition, recruitment and follow-up, and the experimental interventions. J. Pankow cowrote the sections on the locations where data were collected, participants’ characteristics and enrollment process, randomization of sites, and consent procedures. J. L. Duvall cowrote the sections on the locations where data were collected. S. Belenko provided general analytic guidance and edited drafts of the article. L. K. Frisman developed the measure of fidelity, reviewed the fidelity data from the research centers, and reviewed the article. C. A. Visher provided general analytic guidance and edited drafts of the article. M. Pich analyzed which objectives and outcomes sites focused on and how they were measured. Y. Patterson helped design the fidelity measure, performed quality control on the fidelity data, and reviewed drafts of the article.

Acknowledgments
This study was funded under a cooperative agreement with the US Department of Health and Human Services, the National Institute on Drug Abuse (NIDA); the Substance Abuse and Mental Health Services Administration, and the Bureau of Justice Assistance: We gratefully acknowledge the collaborative contributions by NIDA; the Coordinating Center, AMAR International Inc; and the research centers participating in the Criminal Justice Drug Abuse Treatment Studies (CJ-DATS). The research centers were Arizona State University and Maricopa County Adult Probation (grant U01DA025307); University of Connecticut and the Connecticut Department of Correction (grant U01DA016194); University of Delaware, Delaware Department of Correction, and Christiana Care HIV Wellness Program (grant U01DA016230); Friends Research Institute (grant U01DA025233) and Maryland Department of Public Safety Correctional Services’ Division of Parole and Probation, University of Kentucky and Kentucky Department of Corrections (grant U01DA016205); National Development and Research Institutes Inc and Colorado Department of Corrections (grant U01DA016209); Rhode Island Hospital–Brown University, University of Rhode Island, University of Puerto Rico, Rhode Island Department of Children, Youth and Families, and Rhode Island and Puerto Rico Departments of Corrections (grant U01DA016191); Texas Christian University and Illinois and Virginia Departments of Corrections (grant U01DA016190); Temple University and Pennsylvania Department of Corrections (grant U01DA025284); and University of California at Los Angeles and Washington State Department of Corrections (grant U01DA016211).

Note. The contents are solely the responsibility of the authors and do not necessarily represent the views of the Department of Health and Human Services, NIDA, or other CJ-DATS parties.

Human Participant Protection
Each research center that participated in this multisite trial received protocol approval from its institutional review board.

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