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# Routine Opt-Out HIV Testing in Jails: Findings from Two Prospective Controlled Trials

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Routine Opt-Out HIV Testing in Jails: Findings from Two Prospective Controlled Trials

A Thesis Submitted to the

Yale University School of Medicine

in Partial Fulfillment of the Requirements for the

Degree of Doctor of Medicine

by

Ravi R Kavasery

2010

ROUTINE OPT-OUT HIV TESTING IN JAILS: FINDINGS FROM TWO PROSPECTIVE CONTROLLED TRIALS. Ravi Kavasery, Duncan Maru, Joshua Cornman-Homonoff, Laurie Sylla, David Smith, and Frederick Altice. Section of Infectious Diseases, Department of Internal Medicine, Yale University, School of Medicine, New Haven, CT.

**Background:** Tens of millions of Americans enter jails annually. The Centers for Disease Control and Prevention now recommends routine HIV testing in prisons and jails. The logistics for performing routine HIV testing within jails, however, remains controversial.

**Specific Aims:**

- 1) To simulate and explore the feasibility of future implementation of a routine opt-out HIV testing protocol using rapid testing methods in the often-chaotic jail setting.
- 2) To evaluate the optimal time to perform routine HIV testing among inmates who are competent to consent to testing, in a manner that not only maximizes public health but also attends to the safety and health status of individual inmates.

**Methods:** Two prospective, controlled trials of routine opt-out HIV testing were conducted among 323 newly incarcerated female inmates in Connecticut's only women's jail (during August and September 2007) and 298 newly incarcerated male inmates in an urban men's jail in New Haven, Connecticut (during March and April 2008). Sequential entrants at both facilities were assigned to be offered routine opt-out HIV testing at one of three points after incarceration: immediate (same day), early (next day), or delayed (7 days). The primary outcome was the proportion of individuals in each group consenting to testing.

**Results:** In the women's trial, routine opt-out HIV testing was significantly highest (73%) among the early testing group compared to 55% for immediate and 50% for 7 days post-entry groups. Other factors significantly ( $p=0.01$ ) associated with being HIV tested were younger age and low likelihood of early release from jail based on bond value or type of charge for which women were arrested. In the men's trial routine opt-out HIV testing was significantly higher for the early (53%: AOR=2.6; 95% CI=1.5 to 4.7) and immediate (45%: AOR=2.3; 95% CI=1.3 to 4.0) testing groups compared to the delayed (33%) testing group. The immediate and early testing groups, however, did not significantly differ ( $p=0.67$ ). In multivariate analyses, factors significantly associated with routine opt-out HIV testing were assignment to the 'early' testing group ( $p=0.0003$ ) and low (bond  $\geq$ \$5,000, immigration or federal charges or pre-sentencing  $>30$  days) likelihood of early release ( $p=0.04$ ). Two male subjects received preliminary positive results and one of them was subsequently confirmed HIV seropositive.

**Conclusions:** In both correctional facilities, routine opt-out HIV testing in a jail setting was feasible, with highest rates of testing if performed within 24 hours of incarceration. Lower testing rates were seen with immediate testing, where there is a high prevalence of

inability or unwillingness to test, and with delayed testing, where attrition from jail increases with each passing day.

*Trial Registration:* [ClinicalTrials.gov](http://clinicaltrials.gov) NCT00624247  
<http://clinicaltrials.gov/ct2/show/NCT00624247>

*The findings from these trials have been previously presented at the 46<sup>th</sup> Annual Meeting of the Infectious Diseases Society of America in Washington, DC in October 2008. In addition, findings from both trials were previously published as companion pieces in PLoS One in November 2009.*

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## **Table of Contents**

<b>1. Introduction</b>	<b>1</b>
<b>2. Statement of Purpose, Specific Hypotheses, Specific Aims</b>	<b>6</b>
<b>3. Methods</b>	<b>8</b>
<b>4. Results</b>	<b>14</b>
<b>5. Discussion</b>	<b>20</b>
<b>6. References</b>	<b>28</b>
<b>7. Figure References and Legends</b>	<b>31</b>
<b>8. Tables</b>	<b>39</b>

## **Introduction**

Over 2.3 million people, or one in every 100 American adults, are incarcerated and their initial interface with the correctional system is usually via jail.[1-2] The prevalence of HIV infection in the United States is also several-fold greater in correctional settings than in the general population.[3] One-quarter of HIV-infected individuals in the United States pass through a correctional facility every year and it is believed that anywhere from one third to one half of these persons are unaware of their HIV status.[4-6] Jails and prisons thus serve as important sites for HIV testing and treatment.[5, 7-9]

The Centers for Disease Control and Prevention (CDC) recently recommended implementing routine opt-out HIV testing in all healthcare settings, including jails, acknowledging that HIV testing guided by risk factor assessment alone misses many of those who are HIV-infected.[10] As recently as 2007, however, HIV testing practices continued to be largely based on the pretesting probability that a patient had identifiable risk factors.[11] Yet, approximately 50% of individuals who enter correctional settings do not know their HIV status and many with HIV infection do not have traditional risk-based behaviors for HIV.[9, 12] Therefore, enhanced HIV testing strategies in correctional settings remain a high priority.

The revised CDC recommendations call for routine testing in all clinical settings, the central goal being to maximize the number of persons who are aware of their HIV infection and receive care and prevention services. According to the CDC guidelines for routine testing, “HIV-negative results may be conveyed without direct personal contact between the patient and the health-care provider.” Only HIV positive results should be communicated confidentially through personal contact by a clinician, nurse, mid-level

practitioner, counselor, or other skilled staff. Furthermore, the guidelines state that prevention counseling should not be required as a part of HIV screening programs in health-care settings. [10]

Understanding the issues related to implementing routine opt-out HIV testing in jails presents both a challenge and an opportunity in correctional settings to expand access to HIV services to correctional inmates. [10, 13-14] Historically, performing HIV testing in jails has been difficult. Jails interact with a larger number of individuals at risk for HIV infection than do prisons; however, jails also pose unique logistical and health-related constraints for implementing widespread HIV screening programs. Jails differ from prisons in several important ways that impact HIV testing strategies: 1) jail populations have short periods of incarceration and high rates of turnover with many-fold greater admissions and discharges; 2) jails house individuals with higher rates of acute intoxication from psychoactive drugs, uncontrolled mental illness, and suicidal behavior; [15] and 3) the individuals who enter jails have higher recent risk behaviors for HIV than those in prisons. [16-17] Given these considerations, jails have been less well-equipped to implement screening, prevention, and treatment programs to address patients with or at risk for HIV/AIDS.

Recent advances in testing diagnostics, however, have created promising opportunities for screening in jail settings. The development of the OraQuick rapid HIV-1 antibody test, for example, allows for the prompt delivery of preliminary positive and definitively negative results within twenty minutes. [18] Recent cost-benefit analyses also support expanded HIV screening in all settings, especially in sites where the prevalence of HIV exceeds 1%; [19-20] the prevalence of HIV in jails in the Northeast exceeds that

amount several-fold and would likely yield the highest number of unidentified HIV-infected individuals.

Current HIV testing practices in U.S. jails are highly variable. Nearly one-fifth of jails report no official HIV testing protocol, [21] and as few as 21.6% of jail inmates were HIV tested after admission.[22] Surveys conducted by the CDC and the National Institute of Justice, report that only 4% of jails provide HIV testing upon inmate request and only 2% offer routine HIV testing on admission; none of those surveyed mandated HIV testing of incoming inmates.[23]

Experience with rapid HIV testing in jail settings is limited.[24-25] To date, only two such studies have been published. One study, conducted among female inmates during intake at the Cook County Jail, consisted of approaching detainees in the corner of a large room, in open view of security officers and fellow inmates, and offering them rapid HIV testing. Among this group, 30% were found to be ineligible; however, ineligibility was not systematically defined. Additionally, and perhaps as a result of requiring inmates to consent in a public setting, less than half of those approached were willing to accept testing.[24] A more recent study was conducted at the Rhode Island Department of Corrections Jail, a facility where routine HIV testing has been in place for over 15 years.[25] Although 95% of participants accepted rapid HIV testing, 87% reported they had been previously HIV tested at this facility during a prior incarceration. Moreover, the time after incarceration was not provided, suggesting that inmates may have been longer term inmates and we were not told how many were ineligible for HIV testing at all. Given these circumstances, concerns remain whether the results of the Rhode Island study can be generalized to other correctional settings. In addition to these

studies, the CDC has funded four Jail Demonstration Projects in Florida, Louisiana, New York and Wisconsin, encompassing more than 23 jails in those states. The program, which offers voluntary rapid HIV testing based on referral, has conducted over 33,000 tests and found that 1.1% of individuals were positive, 70% of whom were previously unknown cases of HIV.[26]

None of the aforementioned studies adequately addresses the screening of inmates for psychological distress, intoxication, and withdrawal prior to conducting widespread HIV testing. A major challenge to implementing a routine HIV testing protocol in jails is determining the optimal time to test, taking into account an inmate's ability to consent to testing and his or her level of psychological distress. Because the incarcerated experience high rates of suicidal behavior, mental illness, acute intoxication, and withdrawal, they might not be competent to consent to HIV testing or to receive a positive HIV test result, even though these same individuals might also be at highest risk for infection.[21, 25] Therefore, when choosing the appropriate time to screen inmates for HIV, testing must be performed in a manner that not only maximizes public health, but also attends to the safety and health status of individual inmates. It is well documented that inmates are more likely to experience mental distress and present at a higher risk for committing suicide within the first 48 hours of incarceration.[15, 27-29] A ten-year study of deaths in the Chicago Cook County jail found that suicides were the third leading cause of death among inmates, following heart and cerebrovascular disease.[30] In addition, studies of jail populations at time of admission show that acute symptoms of serious mental illnesses requiring treatment are present in about 6% of males and 15% of females at booking.[31-32]

Prisoners might be too distressed at their time of admission to consider the consequences of being HIV tested. In particular, distressed individuals might not be prepared to receive a positive HIV test result. Furthermore, recently incarcerated prisoners might be intoxicated or experiencing symptoms of withdrawal, thereby preventing them from providing informed consent. The challenge with postponing testing is that many individuals experience very short stays in jail, with about 1/3 leaving within 48 hours, followed by further attrition daily for the first week. Therefore, every day that testing is delayed a greater number of inmates will leave jail without being tested. Although several authors have acknowledged the importance of screening jail inmates for mental status and suicide risk before conducting widespread HIV testing, no literature exists evaluating the tradeoffs between early versus late testing with regard to individual health needs and public health benefit.

The CDC has identified several major issues that must be addressed when developing model routine HIV testing strategies in jails. These include: 1) **choosing the timing of testing after jail entry**; 2) marketing and advertising of services; 3) manner in which testing is presented to inmates; 4) testing protocols; 5) methods of informing those tested of their results; 6) confidentiality of results; 7) HIV counseling associated with testing; and 8) administrative and implementation issues.[33]

## **Statement of Purpose, Specific Hypotheses, Specific Aims**

### *Statement of Purpose*

To evaluate the optimal time to conduct routine opt-out HIV testing of newly incarcerated male and female jail inmates in a manner that maximized the number of individuals capable of consenting and willing to be tested.

### *Specific Hypotheses*

1. A higher proportion of inmates approached for testing the night of intake will be deemed incompetent to consent to testing (using the standardized MacArthur Competence Assessment Tool) compared to those inmates approached in the days after intake.
2. A higher proportion of inmates approached for testing the night of intake will present at a higher risk for suicidal ideation and psychological distress (according to the nursing staff's mental health assessments and the standardized K6 psychological distress scale) compared to those inmates approached in the days after intake.
3. A higher proportion of inmates approached for testing the night of intake will not receive HIV testing (because they are either deemed incompetent or choose not to provide consent for testing) compared to inmates approached on subsequent days.
4. A significant portion of individuals assigned to being approached for HIV testing on Day 7 will leave the facility prior to Day 7 and will miss the opportunity to be tested.
5. Correctional medical and custodial staff will express resistance to implementing

widespread routine HIV testing in jail settings.

*Specific Aims*

1. To simulate and explore the feasibility of future implementation of a routine opt-out HIV testing protocol using rapid testing methods in the often-chaotic jail setting;
2. To determine the ability of subjects to pass a competency assessment in order to consent to routine HIV testing at varying times after entry into jail
3. To examine the acceptability among jail inmates of a routine HIV testing protocol using rapid HIV testing methods;
4. To evaluate the optimal time to perform routine HIV testing among inmates who are competent to consent to testing, in a manner that not only maximizes public health but also attends to the safety and health status of individual inmates.
5. To assess the attitudes toward future widespread implementation of a routine rapid HIV testing protocol by correctional, medical, and custodial staff
6. To assess the feasibility of implementing routine HIV testing in jails at different time points during and after entry processing from a systems operations perspective

## **Methods**

### *Ethics Statement*

These trials were approved by the Institutional Review Board at Yale University and by the Connecticut Department of Correction Research Committee.

### *Design Overview*

These two prospective, controlled trials were conducted among female and male inmates in two Connecticut jails from 2007 to 2008. Over a 5-week period starting August 22, 2007, all 323 consecutive, newly incarcerated female inmates at York Correctional Institution were offered routine opt-out HIV testing after being sequentially assigned to one of three study arms upon admission to the facility: 1) ‘immediate’ (during a mandatory initial medical screen the night of admission); 2) ‘early’ (during a required physical exam the following evening); or 3) ‘delayed’ (7 days after arrival to the facility). The same study design was used for all 298 consecutive, newly incarcerated male inmates at New Haven Community Correctional Center from March 25, 2008 to April 16, 2008.

Decisions about timing for routine opt-out HIV testing were based upon previous surveys of correctional and medical professionals as well as from experts in the field of HIV testing in correctional settings. These three time points were chosen to coincide with other routine healthcare activities at the jail in order to simulate the future implementation of a routine opt-out HIV testing protocol.

When designing the study protocol, review of the scientific literature suggested that not only do men and women have different attitudes toward HIV testing in jail or in

general, but they are also likely to present with different rates of mental illness and substance withdrawal that could potentially affect the primary outcome. Additionally, the policymaking process is largely made independently for male and female jails. Therefore, the men's and women's trials were intended as separate studies with separate analyses. Although the primary outcome was the same for both trials, the primary outcome was assessed independently for the male and female jails.

### *Setting and Participants*

The women's trial was conducted at York Correctional Institution in Niantic, Connecticut, the state's sole correctional facility for women. Intake involves both sentenced and pre-trial detainees. The average daily census is 1641 inmates. Testing for pregnancy, opioids, tuberculosis and acute medical conditions is routinely conducted. Inmates maintained on or experiencing opioid withdrawal symptoms are provided a methadone taper. The evening following admission, a routine physical examination, including Papanicolaou smear and phlebotomy, occurs in all new inmates remaining within the facility. [12]

The men's trial was conducted at the New Haven Community Correctional Center (NHCCC) in New Haven, Connecticut, an urban men's jail that houses primarily unsentenced detainees as well as those serving sentences  $\leq 1$  year. The facility's average daily census is 919 individuals.

At both the men's and women's study sites, similar to other jails, a brief, standardized medical and psychiatric assessment is routinely conducted on all inmates, including medical, sexual, and drug-use histories immediately upon arrival. Voluntary HIV testing

is available by medical referral or by self-request and often involves being placed on a waiting list. Current policy in Connecticut requires that in the absence of an emergent clinical indication, inmates must be beyond the three month “window period” from their last HIV risk behavior to receive an HIV antibody test. Newly confirmed HIV positive test results are reported to the Connecticut Department of Public Health as part of the state’s mandatory reporting system.

As part of this study, all newly incarcerated inmates were sequentially approached for competency and HIV testing and sequentially assigned to one of the three study groups. Eligibility to be HIV tested required demonstration of competency by: 1) clinician-confirmed ability to demonstrate knowledge of the risks, benefits, and consequences of HIV testing in accordance with the MacArthur Competence Assessment Tool for Clinical Research [MacCAT-CR][34]; and 2) no self-reported suicidal ideation or evidence of mental instability.

### *Intervention*

For each testing group, the inmate was approached with the following scripted statement: “As part of your regular medical care, HIV testing can now be done using an oral swab that you swipe across your gums. You can receive your results after 20 minutes. Would you like to be tested at this time?” If the inmate responded affirmatively, he or she was instructed to self-administer the oral HIV test by the clinical staff in the ‘immediate’ and ‘early’ test groups as part of routine clinical activities in order to simulate how routine opt-out HIV testing would be performed if not embedded within a complicated research study. On day 7, research personnel oversaw the verbal consent

and self-administration procedures using the same process. All subjects were instructed that HIV results require minimal waiting. Anyone not wanting to know HIV test results was not swabbed. If the inmate agreed to be swabbed and tested, he or she *subsequently* met with a research assistant who discussed two written informed consents – one for study participation and one for HIV testing (legislatively mandated). Inmates who initially agreed to be swabbed but refused to provide both written consents did not have their HIV swabs tested and these specimens were immediately discarded. These individuals, along with anyone not wanting testing were informed voluntary HIV testing was available through self-referral from an HIV counselor. Those who self-identified as being HIV-infected were not swabbed.

#### *Outcomes and Follow-up*

Oral swab testing was conducted onsite using the OraQuick ADVANCE<sup>®</sup> rapid HIV-1 antibody test [sensitivity: 99.3% (98.4-99.7), specificity: 99.8% (99.6-99.9)].[18, 35] The primary outcome, assessed independently for the male and female jails, was the proportion of individuals in each assigned group that provided verbal consent to be swabbed for HIV testing.

Individuals were not swabbed for HIV testing if they were physically not available (e.g., released from jail, at court, attorney visits, too ill), were deemed medically incompetent to provide consent, or opted out of HIV testing. The primary outcome, using a public health perspective, was analyzed using an intention-to-treat (ITT) approach and included all inmates admitted to the jail during the study period, as assigned. The intention-to-treat analysis assessed whether an inmate was swabbed, regardless of

whether he or she subsequently agreed to take part in the research protocol. Any subject for whom swab results were missing was deemed “failure to swab” in the analysis; however, there were no missing data in the final database. A secondary outcome, to assess individual acceptability of HIV testing, was the proportion of inmates who agreed to HIV testing among those still under correctional supervision at the time that testing was offered.

Pre-test counseling was not provided. Subjects who received a preliminary positive test result were immediately referred for phlebotomy for confirmatory testing with Western blot. Certified HIV counselors provided preliminary-positive post-test counseling and confirmatory results; study staff delivered negative results.

As an additional secondary analysis, inmates deemed competent to receive testing who provided written consent were asked about previous HIV testing experiences, attitudes toward HIV testing in jail settings and were also administered a series of standardized instruments: Clinical Opiate Withdrawal Scale [COWS], [36] Clinical Institute Withdrawal Assessment of Alcohol Scale [CIWA-Ar], [37] and the Kessler 6-Item Psychological Distress Scale (K6).[38]

To determine if the three testing groups in each trial differed with regard to social and demographic characteristics, the Connecticut Department of Correction (CTDOC) database was queried to abstract demographic characteristics [age and race (defined by CTDOC)], type of charge and bond value. No unique identifiers were provided. Low likelihood of early release was defined as a bond value  $\geq$ \$5,000, sentencing > 30 days, immigration or federal charges, or no bond allowed. High HIV-risk charges were considered to be any charges directly related to prostitution or drugs.

*Statistical Analysis*

The primary outcome was the proportion of individuals in each testing group who were orally swabbed and provided verbal consent to receive rapid HIV testing. Using two-sided Chi-Square tests for assessing three pair-wise differences between the different study arms and applying Bonferroni's correction (i.e.,  $\alpha=0.0166$  for each comparison), we sought to collect 97 patients in each arm to achieve 80% power to detect a 22% difference between arms given a baseline uptake of 60%. Comparisons of demographic, correctional and refusal characteristics were conducted using two-sided Chi-Square tests ( $\alpha=0.05$ ).

After calculating the bivariate associations with the primary outcome, a multiple logistic regression model was developed to predict the likelihood of being swabbed using the available subject characteristic variables. The Akaike information criterion (AIC) was used to assess model fit; lower AIC values indicate a better balance of parsimony and explanation of variance. In conjunction with AIC, a p-value of 0.30 was used to enter and leave the model. The optimal model was chosen as the convergence of the forward and backward models, with consideration of parsimony and plausibility. The two-sided Wald's test ( $\alpha=0.05$ ) was used to assess significance of each of the variables. All statistical analyses were conducted using SAS, version 9.1.3 (SAS Institute).

## Results

### *Women's Trial*

The baseline characteristics of the study population for the women's trial are shown in Table 1. During the study period, 323 newly incarcerated women were sequentially assigned to the following testing groups: 'immediate' (N=108, the night of admission), 'early' (N=108, the following evening), and 'delayed' (N=107, 7 days later). The three study groups did not differ significantly with respect to any of the social and demographic characteristics assessed.

The disposition of individuals approached for routine opt-out HIV testing in this trial is illustrated in Figure 1. Overall, 192 (59%) of 323 inmates assigned to testing groups provided verbal consent to be swabbed for HIV testing. For the primary outcome, 79 (73%) of those offered 'early' testing, received an HIV test, compared to 59 (55%) assigned to the 'immediate' and 54 (50%) assigned to the 'delayed' testing groups (Figure 2). The early testing group was significantly more likely to be tested than both the immediate group (OR=2.3; 95% CI=1.3-4.0; p=0.007) and the delayed group (OR=2.7; 95% CI=1.5-4.7; p=0.0007). The proportion swabbed in the immediate and delayed testing groups, however, did not differ (OR=1.2; 95% CI=0.7-2.0; p=0.54). To assess the individual acceptability of HIV testing, 268 subjects were physically present within the jail at the three time points when routine opt-out testing was made available (see Figure 2). Acceptability was highest for the early testing group (N=79/91, 87%), compared to 76% (N=54/71) in the delayed and 56% (N=59/106) in the immediate testing group (p<0.05 for all comparisons).

Stratified by testing group, the reasons that inmates were not swabbed are depicted in Table 2. In the ‘immediate’ group (N=108), 12 (11%) were medically incompetent to consent, compared with only 4 (4%) in each of the ‘early’ (N=108) and ‘delayed’ (N=107) testing groups. This difference was significant (OR=3.2; 95% CI=1.3-8.2;  $p=0.009$ ; not depicted in Table 2). In the ‘delayed’ testing group, 36 (34%) did not appear for testing compared with 4 (4%) in the ‘immediate’ and 17 (16%) in the ‘early’ testing groups (OR comparing delayed to other: 4.7; 95% CI: 2.6-8.6;  $p=0.000001$ ; not depicted in Table 2). The most common reasons for failing to be available for testing included being released from the facility (either paid bond or released from court), appearing in court that day, or rarely, logistical barriers within the jail setting that prevented movement within the facility. Among the 54 competent subjects who declined testing, 27 (54%) stated they did not perceive themselves at risk, 10 (19%) declared they were already HIV-infected (all were confirmed by medical record review), and 8 (15%) stated they were too tired, fearful of testing, or experiencing withdrawal.

Figure 3 demonstrates the attrition-decay curve from this jail expressed over time. The median duration of incarceration was 28 days; among the 323 subjects approached, 90 (28%) were no longer incarcerated after 7 days, 118 (37%) after 14 days, and 247 (76%) at 90 days after admission. The highest attrition rate was within the first 24 hours with 11% (n=34) leaving the facility during this time. These individuals, compared to those who were released at later times, trended toward having less opiate-positive urine test results (11% vs. 26%,  $p=0.06$ ) and were less likely to be jailed for sex- or drug-related charges (11% vs. 26%,  $p=0.06$ ). They were also significantly less likely to have been previously incarcerated (43% vs. 66%,  $p=0.009$ ). Bivariate and multivariate

analyses were conducted to determine predictors associated with being swabbed for HIV testing (Table 3). In the bivariate analysis, assignment to the ‘early’ testing group, younger age, low-likelihood of release, high HIV-risk charges, and being Hispanic were associated with being swabbed for HIV testing. In the multivariate analysis, assignment to the ‘early’ testing group ( $p<0.001$ ), younger age ( $p=0.01$ ), and low likelihood of release ( $p=0.01$ ) remained significantly associated with being swabbed for HIV testing.

Of the 192 individuals who were swabbed, 151 (79%) provided written consent to complete the entire study. Two additional participants failed to pass the MacArthur Competence Assessment Tool, leaving 149 (79%) individuals eligible to be HIV tested. Of these, 147 (99%) were HIV-negative and two had a preliminary-positive test result; both results were false-positive after obtaining confirmatory Western Blot testing. Thus, none of the 149 people tested were diagnosed as being HIV-infected. Two negative test results (one from the ‘immediate’ and one from the ‘early’ testing groups) were not delivered due to the inmate having left the facility.

Among the 149 subjects HIV-tested subjects that underwent standardized screening, 11 (7%) exhibited moderate or severe opioid withdrawal symptoms: three (7%) from ‘immediate’, eight (15%) from ‘early’ group, and none from the ‘delayed’ testing group. Ten (7%) individuals were deemed to have increased risk for alcohol withdrawal symptoms: three (7%) from ‘immediate’, seven (13%) from ‘early’, and none from the ‘delayed’ testing group. In addition, 50 (34%) of the 149 tested subjects had evidence of serious mental illness using the K6 psychological distress scale score: 11 (24%) from ‘immediate’, 22 (42%) from ‘early’, and 17 (33%) from the ‘delayed’ testing group. Nearly all (89%) of these 149 subjects self-reported having been HIV tested previously,

but only 32% reported testing within the previous year. The most recent HIV testing had occurred previously at a community organization (n=32, 21%), hospital (n=30, 20%), or correctional facility (n=29, 19%).

### *Men's Trial*

The baseline characteristics of the study population from the men's trial appear in Table 4. The 298 newly incarcerated men were sequentially assigned to the following testing groups: 'immediate' (N=103, the night of admission), 'early' (N=98, the following evening), and 'delayed' (N=97, 7 days later). The three study groups did not differ significantly with respect to any of the social and demographic characteristics assessed.

The disposition of individuals approached for routine opt-out HIV testing in this trial is illustrated in Figure 4. Overall, 130 (44%) of 298 inmates assigned to testing groups provided verbal consent to be swabbed for routine opt-out HIV testing. Among those assigned to early testing, 52 (53%) accepted HIV testing versus 46 (45%) in the immediate and 32 (33%) for 7 days post-entry groups (Figure 5). Compared to the delayed testing group, the early (OR=2.6; 95% CI=1.5 to 4.7; p=0.001) and immediate (OR=2.3; 95% CI=1.3 to 4.0; p=0.01) testing groups were significantly more likely to be swabbed for HIV testing. The immediate and early testing groups did not differ with regard to the primary outcome (p=0.67).

There were differences between these two groups, however, in rates of acceptance among those actually physically available and medically competent to be approached for testing. Of the 226 subjects that were physically present in the jail at each of the three

time points, acceptability was highest for the early testing group (N=52/74, 70%), compared to 45% (N=46/103) and 65% (N=32/49) in the immediate and delayed testing groups, respectively (see Figure 5).

Stratified by testing group assignment, the reasons that inmates were not swabbed are depicted in Figure 6. In the immediate group, 5 (10% of those not swabbed in that group) were medically incompetent or did not have the capacity to consent, compared with none in the 'early' and in the 'delayed' testing groups. In the 'delayed' testing group, 48 (75% of those not tested) were no longer available for testing compared with none in the 'immediate' and 24 (57% of those not tested) in the 'early' groups. Among the 77 competent subjects who declined testing, 18 (23%) stated they were not interested in general, 15 (19%) did not perceive themselves to be at risk, 12 (16%) self-reported they were already HIV-infected (confirmed by medical record review), and 11 (14%) stated they were recently tested.

Figure 7 demonstrates the time to release from the facility. The median duration of incarceration at the facility was 34 days. Among the 298 subjects approached, 51 (17%) were released within the first 24 hours following admission, 81 (29%) were no longer incarcerated after 7 days, 107 (36%) after 14 days, and 142 (48%) were already released at 30 days. Individuals released within the first 24 hours following admission were less likely to have been incarcerated previously: 33 (65%) versus 211 (85%) ( $p=0.0005$ ); the two groups did not vary on any other characteristics.

Bivariate and multivariate analyses were conducted to determine predictors associated with being swabbed for routine opt-out HIV testing (Table 5). In the bivariate analysis, assignment to the 'immediate' or 'early' testing groups was associated with

being swabbed for HIV testing. In the multivariate analysis, however, only assignment to the ‘early’ testing group ( $p=0.0003$ ) and low likelihood of release ( $p=0.04$ ) were significantly associated with being swabbed for HIV testing.

Of the 144 individuals swabbed, 130 (90%) provided written consent to complete the entire study. Of these, 128 (98.5%) were HIV-negative and 2 (1.5%) had a preliminary positive test result; one was a false-positive and the other was confirmed using Western Blot testing. The one confirmed negative test occurred in the “immediate testing group”. Both individuals who tested preliminary positive were incarcerated at seven days and both received their confirmatory test results. Based on the 12 confirmed individuals known to be HIV-infected and the one newly diagnosed subject in this study, the minimum HIV prevalence for this facility is 13/298 (4.4%).

Among the 130 HIV-tested subjects who underwent standardized screening, 15 (12%) exhibited moderate or severe opioid withdrawal symptoms: 6 (13%) from ‘immediate’, 4 (8%) from ‘early’ group, and 5 (16%) from the ‘delayed’ testing group. Only 3 (2%) individuals were deemed to have increased risk for alcohol withdrawal symptoms: 1 (2%) from ‘immediate’, 2 (4%) from ‘early’, and none from the ‘delayed’ testing group. In addition, 17 (13%) of the 130 tested subjects had evidence of serious mental illness using the K6 psychological distress scale score: 5 (11%) from ‘immediate’, 9 (17%) from ‘early’, and 3 (9%) from the ‘delayed’ testing group.

## Discussion

To our knowledge, these represent the first prospective, controlled trials of routine opt-out HIV testing among inmates in any jail setting, a population that typically experiences high rates of psychological distress, rapid turnover, and both acute intoxication and withdrawal upon admission. Previously, voluntary testing had been shown to have limited uptake rates; one multicenter study tested only 6% of ~550,000 jail detainees using voluntary testing methods. [39] One observational study conducted recently in a Rhode Island jail demonstrated markedly higher rates of acceptability of testing compared to that found in our study. [25] The likely explanation for this difference is that mandatory HIV testing of prisoners has been in place in that state for nearly 20 years. As such, nearly all (88%) subjects had previously been tested within that setting and the authors themselves suggest that HIV testing was no longer considered as an emotional or “charged” issue. It can therefore be expected that acceptance of routine opt-out HIV testing will increase with time as the stigma and unfamiliarity with testing decreases among correctional staff and inmates. Additionally, a 4-site, CDC funded study demonstrated that rapid, voluntary HIV testing is feasible and identified many new people living with HIV. However, inmates often were tested days to weeks after incarceration, thereby potentially missing a large number of high risk individuals who were released prior to testing.[39] New initiatives examining HIV testing strategies in jails are now underway.[26]

Our results have two major public health implications. First, routine opt-out HIV testing in jails is feasible, whether provided immediately upon intake or a day or week later. The operational details of our program should provide guidance to jails

implementing routine opt-out HIV testing. The characteristics of the available jail population vary over time such that delays in testing result both in reduced likelihood of testing but also missing the important opportunity to HIV test those who have never interfaced with the correctional environment.

Second, our results suggest that testing within the first 24 hours after entry increases the number of individuals who receive HIV testing. This is likely due to optimizing the balance between allowing time for psychological and medical stabilization of the individual and expeditiously providing testing prior to individuals leaving the facility. The magnitude of these effects are of significant public health importance, in that 73% of those women approached the evening after admission were swabbed for HIV testing, compared to 55% and 50% of those approached immediately or seven days post-entry, respectively. This benefit was seen despite the fact that 11% of female inmates at this facility were released within the first 24 hours.

Likewise, the primary outcome from the men's trial demonstrated that offering routine opt-out HIV testing to male inmates in this urban jail within the first 24 hours of admission resulted in the highest likelihood of being HIV tested (53%). This suggests that routine opt-out HIV testing in jails should be offered as early in the intake process as possible. To balance the competing factors of risk of release with inmate willingness to accept testing, it may be beneficial to offer routine opt-out HIV testing at intake and again at a subsequent medical appointment within 24 hours if the inmate is not tested the night of intake.

The proportion of individuals choosing to opt out of testing the night of admission was high in both the women's and men's studies (32% and 50%, respectively). Inmates

in both trials were also considerably more willing to accept testing when offered the day after entry. Of the 268 women physically present in the facility at the time they were offered, 87% of those approached the evening after admission verbally consented to testing, compared to 56% and 75% of those in the immediate and delayed testing groups, respectively. Similarly, in the men's trial, among inmates physically present in the jail at the time of testing, 55% of those approached in the immediate group opted out, versus 30% in the early group. The attrition rate due to inmates quickly bonding out, however, resulted in the equalization of swabbing rates between these two groups. In contrast to the women's jail, the trial among male inmates was conducted at an urban facility with more daily admissions and a higher rate of release within the first twenty-four hours. These dynamics of increased attrition in the men's jail may account for the lost benefit of waiting until the day following entry to maximize uptake of HIV testing.

Testing inmates on the day of incarceration may be less optimal because these individuals are distraught from being arrested and tired from remaining in court or in a holding cell all day. The substantial increase in willingness to test 24 hours after admission may reflect acceptance of being incarcerated, in addition to having had a night of sleep. Though unclear from these data, acceptability among women decreased after remaining in the jail after 7 days, perhaps explained by the impact of peer pressure and/or recognition of potential stigma from HIV testing. Despite acceptability being slightly lower among those women approached for testing one week post-entry, a higher proportion consented than found in voluntary HIV testing programs in other correctional settings.[39-40]

In the women's trial, the most common reasons for not being swabbed for HIV testing included early release from the facility (presumably due to posting bond), failing to demonstrate medical competency to consent to testing, and choosing not to be HIV tested. On multivariate analysis, additional factors significantly associated with receiving HIV testing were younger age (conferring a 7% decrease in the likelihood of testing for every ten years of increasing age) and having bond set above \$5,000 (conferring nearly a 2-fold reduced likelihood of being released). Ability or willingness to test was particularly important for testing in the 'immediate' group. Although almost a third of individuals assigned to 'immediate' testing refused testing (Figure 2), only 7% of those approached one day later chose to opt-out. Those assigned to the 'immediate' testing group were also 3-times more likely than either of the other groups to be medically or psychologically unable to consent to testing. One potential explanation for the higher rate of testing in the 'early' testing group, particularly compared to the immediate group, is that women may have gotten some rest, been initiated on medication-assisted protocols to treat opioid or alcohol withdrawal, or had become resigned to being in jail.

It was clear that the high-risk women approached for testing in this trial had not been adequately reached with HIV testing services. While 89% of those who consented to study participation reported being previously tested for HIV, only 30% had received an HIV test within the last year, per CDC recommendations for high-risk individuals.

A major strength of the present study design was that it enabled us to accurately assess realistic acceptance for HIV testing in an ethical manner. Socially marginalized individuals, such as prisoners, may be leery about participating in research in coercive places like jails. [2, 41] We overcame this obstacle by asking jail-based clinicians to ask

individuals to provide verbal consent to be HIV tested before referring them to research personnel to obtain written consent for study participation. Thus, this trial simulated what routine opt-out HIV testing within a clinical encounter in jail might look like and avoids biasing participant response during the encounter. Indeed, approximately 22% of those female subjects who agreed to be swabbed for rapid HIV testing as part of routine intake procedures later refused to provide consent for study participation. In most cases, this was because of subjects' suspicion of being involved in research or because of the time involved in completing several interview instruments at a time when they were tired or did not feel well. The primary outcome of being swabbed for an HIV test, therefore, served as a better marker in this trial for acceptance of HIV testing than completion of the informed consent aspect of the study and thereby receiving an HIV test result.

In addition, a key factor contributing to the higher rate of routine opt-out HIV testing within the first 24 hours of admission was that the testing procedures were linked to a routine clinical activity (intake or physical exam) with clinical personnel. This policy, of linking routine opt-out HIV testing with routine clinical activities, makes logistical sense and should be considered when implementing testing in the future. It also helps to demonstrate to inmates that HIV testing is simply a component of comprehensive primary healthcare. Future observational and controlled studies should assess which staff members should perform testing and delivery of both positive and negative HIV test results during the chaotic post-entry period. Our study did not assess this fully; we utilized jail staff for intake, testing, and follow-up of positive HIV test results, while all our own research staff provided negative results.

Although both trials successfully demonstrated the feasibility of routine opt-out HIV testing in a jail, challenges remain to be addressed before routine opt-out HIV testing is implemented more widely in other jail settings. Daunting challenges remain to implement routine opt-out HIV testing upon intake at some of the largest and busiest jails. Several hundred people may be processed daily, with intake procedures taking place 24 hours a day.

One of the unresolved issues for routine opt-out HIV testing in jails is ensuring delivery of confirmatory HIV test results for those who test preliminarily-positive. In the women's trial, only two (0.6%) of the 323 women approached for testing received a preliminarily-positive test result that required a confirmatory blood draw, the results of which often require up to a week to receive. Similarly, in the men's trial, only one individual was released prior to receiving his negative test result, and both individuals who tested preliminarily positive were incarcerated at 7 days to receive their final test results. Although individuals in both trials were still incarcerated in the facility and therefore able to receive their confirmatory blood draw results a week later, there will be cases of release prior to receipt of results. Indeed, over one-quarter of the inmates in the women's trial were released within seven days of entry. Delivery of test results, particularly for individuals who have blood drawn for confirmatory testing, will prove difficult among this transient population. If routine opt-out HIV testing is to be broadly implemented in our nation's jails, however, delivery of test results will remain an important issue and requires further resolution. While we await more rapid, confirmatory testing technology, Western Blot testing remains the accepted standard. Logistical issues of providing results in the jail will therefore be incumbent on correctional

authorities to resolve, yet public health infrastructure must be maintained to address case finding and delivery of results to those who leave before HIV testing results are available.

As is typical of many urban jails in the United States, the study site for the men's trial houses a population with rapid turnover. Nearly a fifth of new admissions were released by the next day, with 29% no longer remaining in the facility within a week. This raises significant questions about the current policy in Connecticut of requiring HIV testing only on those inmates with at least 90 days since their last HIV risk behavior. Continuing such a policy would result in nearly three quarters of jail detainees being ineligible for HIV testing because they would already be released.

An additional important finding was in both the men's and women's trials, those having a low likelihood for release were more likely to consent to testing, regardless of group assignment. This suggests that, in jail systems with high volumes that preclude testing of all inmates at entry, triage systems could be useful in focusing initial testing efforts on those inmates for whom early release is more likely. While the men's study did diagnose one new individual with HIV, it likely missed many other high risk individuals who left the facility before being offered testing as part of their assigned testing group.

There are several important limitations of the present trials. Owing to logistical difficulties, we could not undertake a true randomized trial. This makes it possible that confounders, such as cohort effects from particular peer leaders' influence on testing uptake, biased our results (internal validity). Our large sample size and final effect size suggests, however, that the differences detected here were real. Additionally, since our trials were restricted to a single female and male correctional facility, the findings may

not be generalizable to other jail settings (external validity). Not all jails provide routine clinical assessments the day following admission, and others may not provide any routine healthcare services at all.[42] Furthermore, large, metropolitan correctional facilities experiencing many-fold higher daily admissions may face additional logistical challenges in implementing testing as part of intake procedures.

In conclusion, our study confirms that routine opt-out HIV testing in a jail setting is feasible and that early testing will likely result in the largest number of individuals being tested. This approach balances the medical and psychiatric instability seen among those immediately upon incarceration with the high attrition rate demonstrated by those tested 7 days later. Early testing also results in testing a larger proportion of those who have never been within the correctional system before and have previously received an HIV test. Such programs, if implemented properly, will result in identifying individuals with HIV who do not know they are infected and increase their likelihood of reducing their HIV risk behaviors and increasing their access to HIV treatment and prevention services. Notwithstanding the merits of answering the logistical question of when to HIV test, many other questions remain, including how to avoid repeat testing, costs associated with increased HIV testing and barriers associated with written informed consent.

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**Figure References**

*Figure 1. [Women's Trial] Disposition of Inmates Approached for HIV Testing*

*Figure 2. [Women's Trial] Rapid HIV Testing Swab Results by Assigned Testing Group*

*Figure 3: [Women's Trial] Time to Release Following Incarceration*

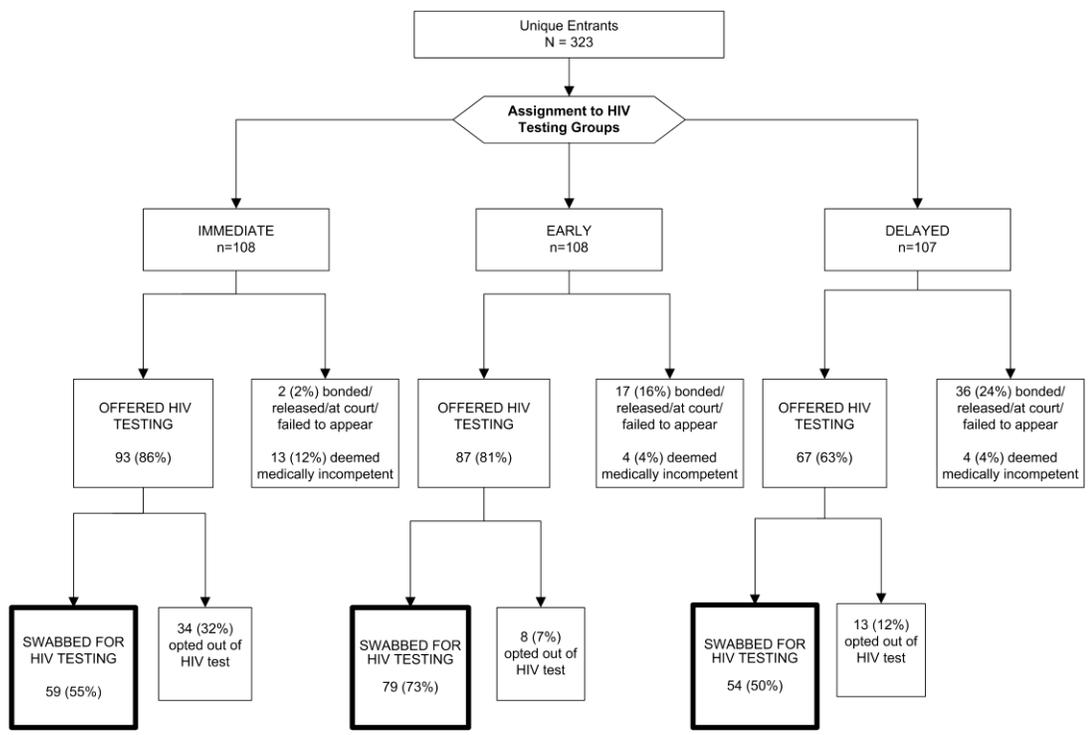
*Figure 4. [Men's Trial] Disposition of Inmates Approached for HIV Testing*

*Figure 5. [Men's Trial] Rapid HIV Testing Swab Results by Assigned Testing Group*

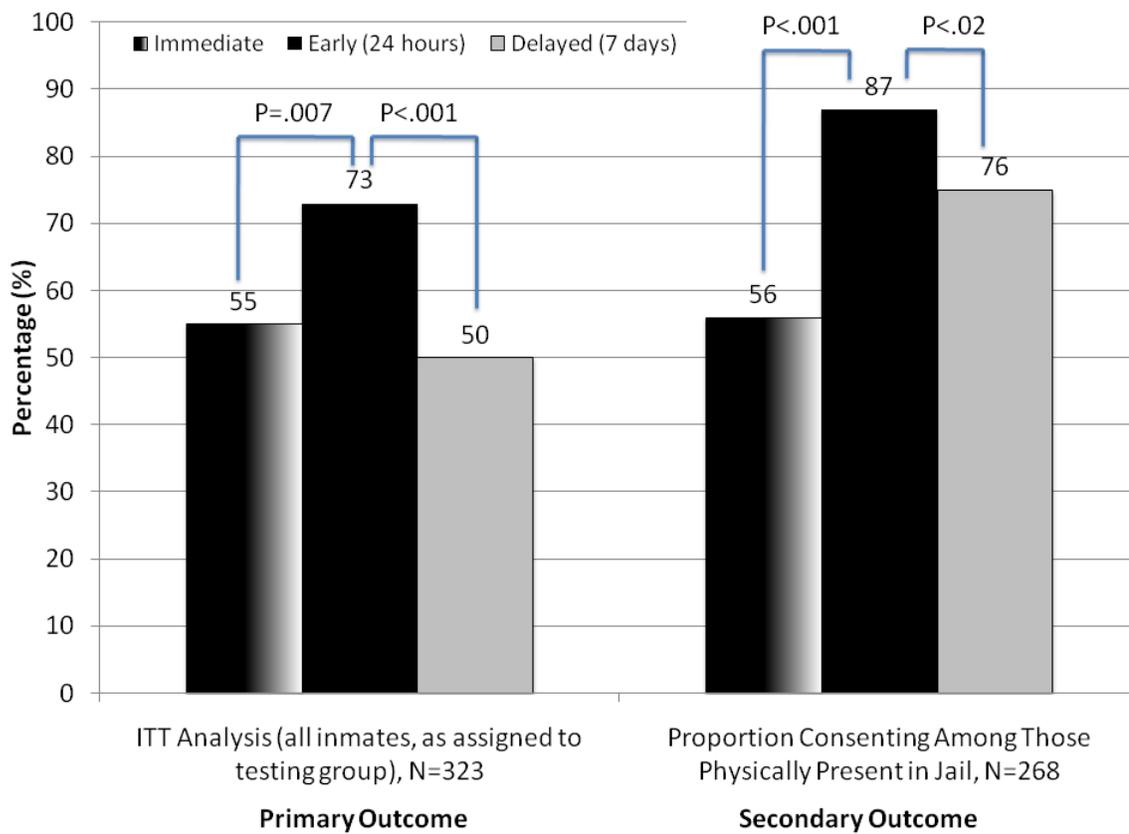
*Figure 6. [Men's Trial] Reasons Inmates were not Swabbed for HIV Testing*

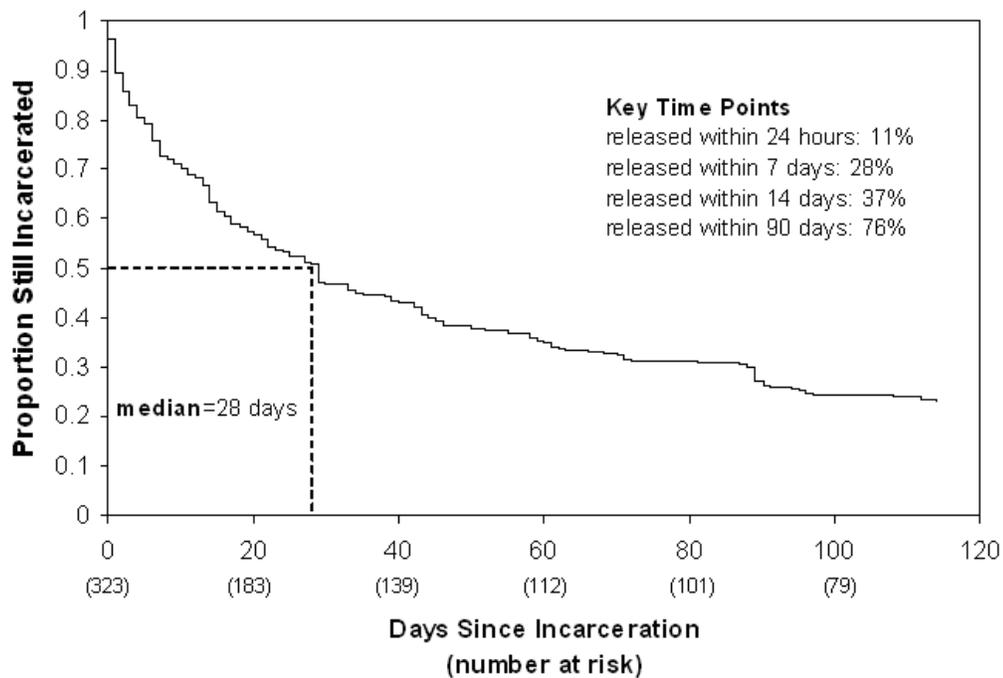
*Figure 7. [Men's Trial] Time to Release Following Incarceration*

Figure 1. [Women’s Trial] Disposition of Inmates Approached for HIV Testing

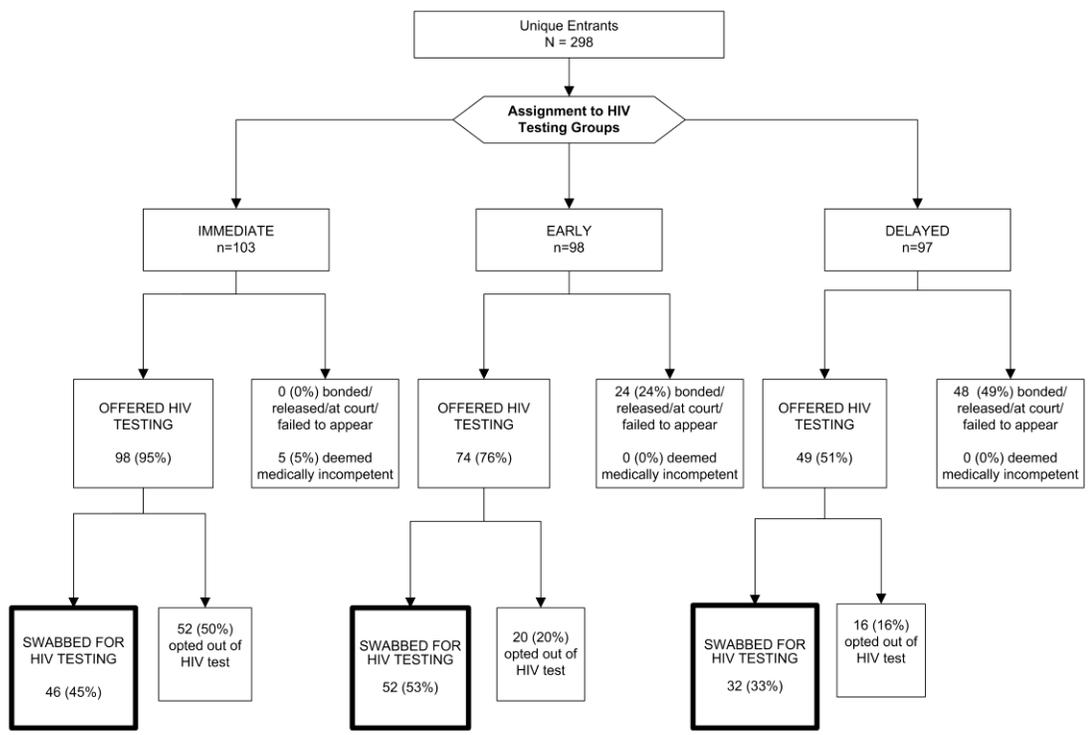


**Figure 2. [Women's Trial] Rapid HIV Testing Swab Results by Assigned Testing Group**

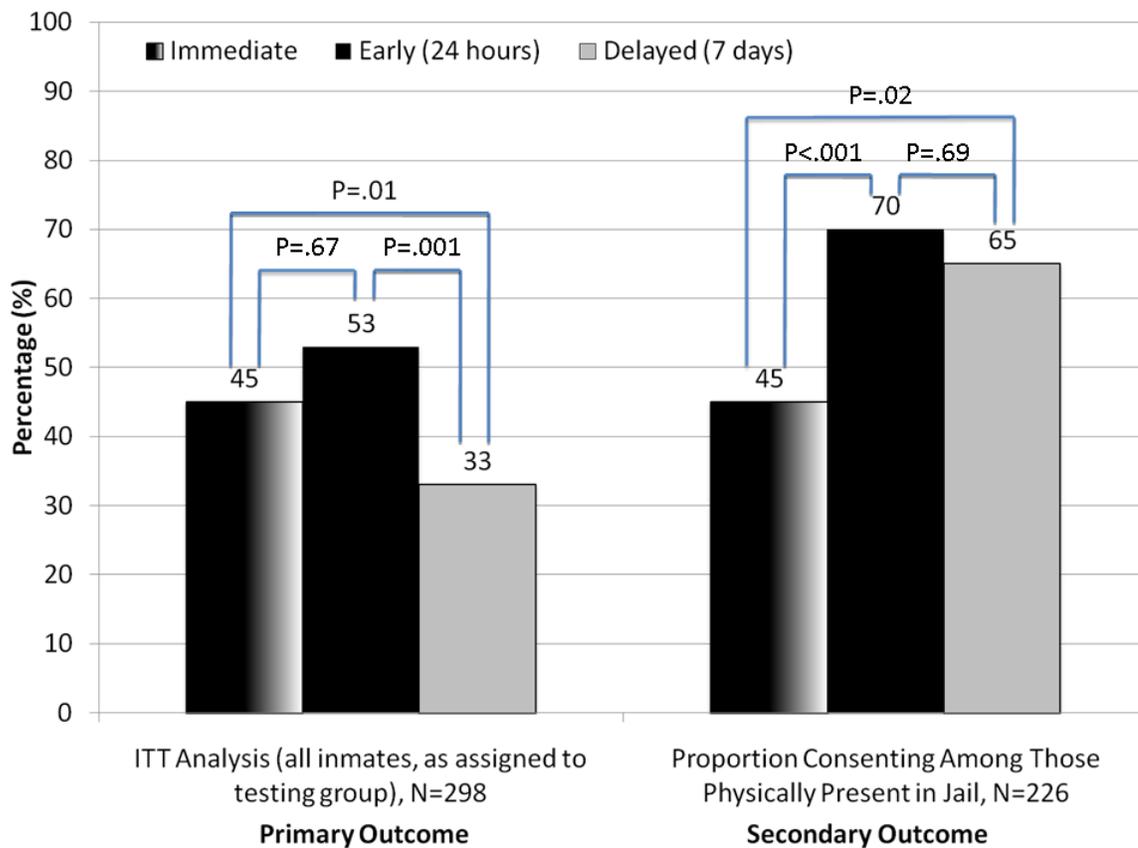


**Figure 3: [Women's Trial] Time to Release Following Incarceration**

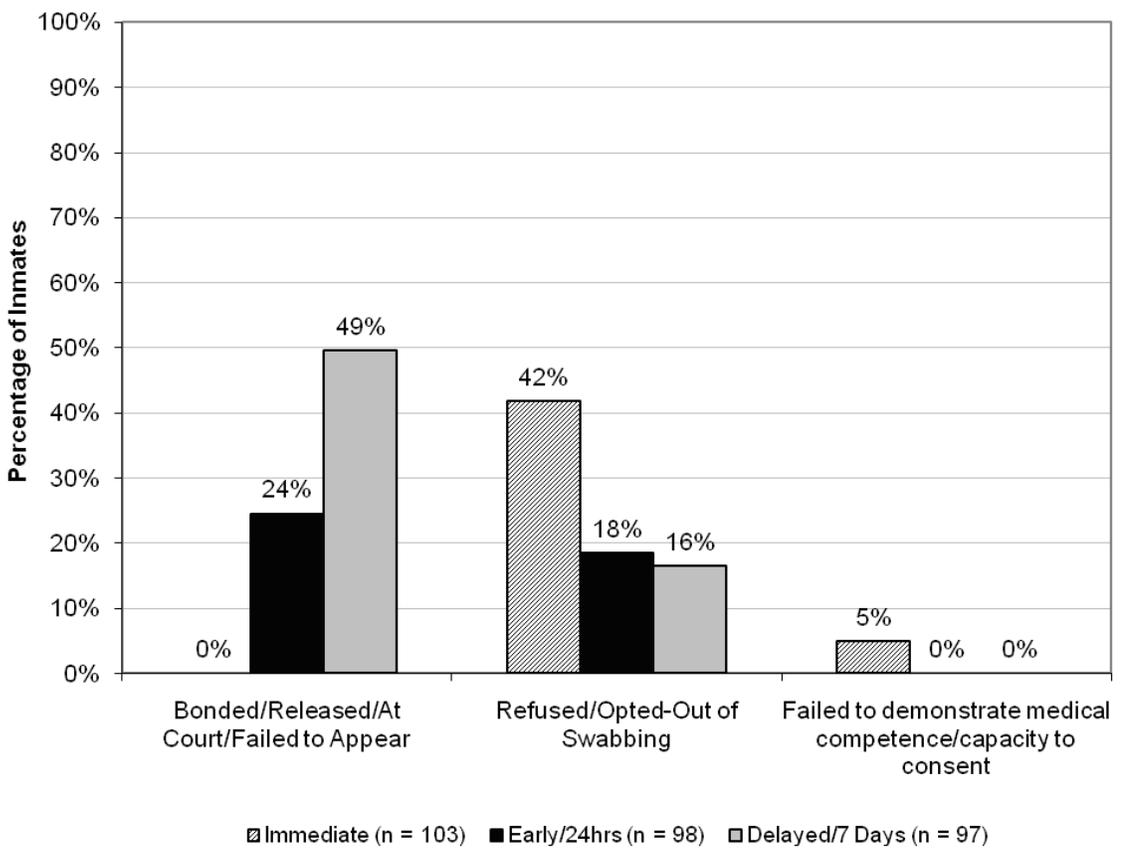
**Figure 4. [Men's Trial] Disposition of Inmates Approached for HIV Testing**

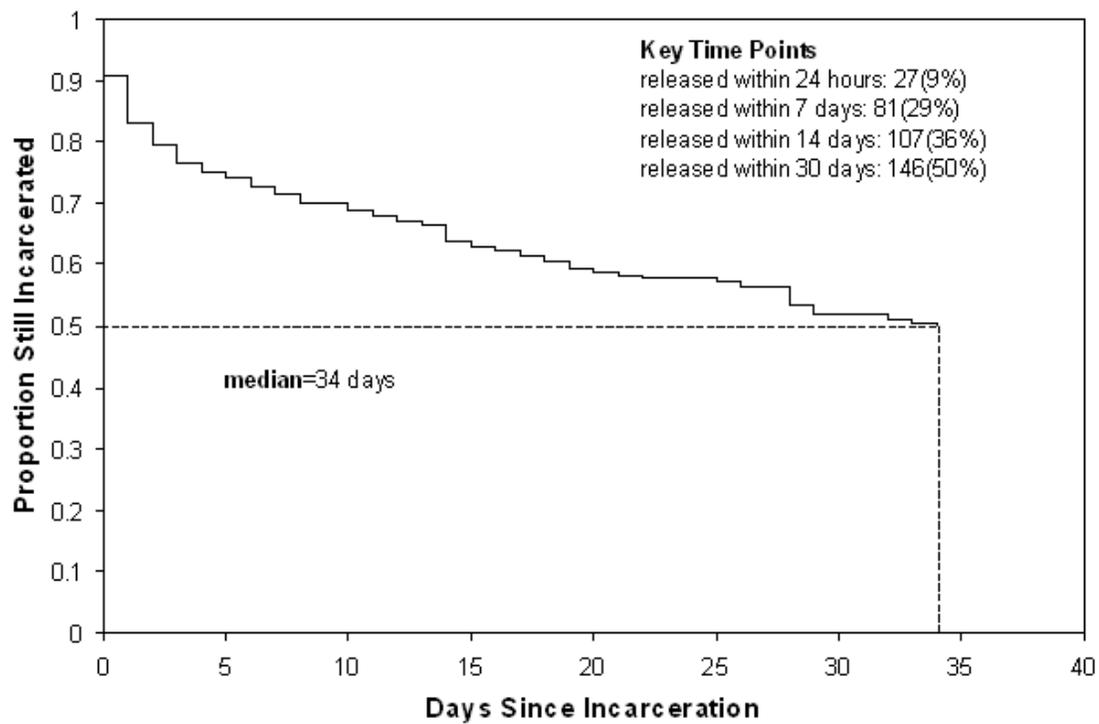


**Figure 5. [Men's Trial] Rapid HIV Testing Swab Results by Assigned Testing Group**



**Figure 6. [Men's Trial] Reasons Inmates were not Swabbed for HIV Testing**



**Figure 7. [Men's Trial] Time to Release Following Incarceration**

**Tables**

*Table 1. [Women's Trial] Baseline Characteristics of the Study Population (n=323)*

*Table 2. [Women's Trial] Reasons Inmates were not Swabbed for HIV Testing*

*Table 3. [Women's Trial] Bivariable and Multivariable Predictors of Receipt of Swab*

*Table 4: [Men's Trial] Baseline Characteristics of the Study Population (n=298)*

*Table 5. [Men's Trial] Bivariable and Multivariable Predictors of Receipt of Swab*

**Table 1: [Women's Trial] Baseline Characteristics of the Study Population (n=323)**

Characteristics	Subcategory	Value (%)
Age (mean years; SD)		33.6 (9.8)
Length of Current Incarceration (median days; IQR)		28 (7-94)
Race	Hispanic	53 (16)
	Black	104 (32)
	White/Other	166 (51)
Education	High School Graduate	201 (62%)
	Not a High School Graduate	122 (38%)
Likelihood of Early Release*	High	115 (36)
	Low	208 (64)
Type of Charge	Drug- or Prostitution-Related	81 (25)
	Not Drug- or Prostitution-Related	242 (75)
Previous Incarcerations	Never Incarcerated	117 (36)
	Incarcerated Previously	206 (64)
	Mean Number of Previous Incarcerations (N; SD)	1.9 (2.4)
Medical Insurance	Yes	120 (37)
	No	203 (63)
Urine Toxicology	Negative for Opiates	242 (75)
	Positive for Opiates	81 (25)

\* High: any charges directly related to prostitution or drugs.

Low: bond value  $\geq$  \$5000, bond sentencing > 30 days, immigration or federal charges, or no bond

**Table 2. [Women's Trial] Reasons Inmates were not Swabbed for HIV Testing**

Reason	Immediate Group (49 not swabbed of 108)	Early Group (29 not swabbed of 108)	Delayed Group (53 not swabbed of 107)
Bonded/Released/At Court, n (%)	4 (8)	17 (59)	36 (68)
Refused/Declined Swab or Study Participation, n (%)	33 (67)	8 (27)	13 (24)
Medically Incompetent/Failed MacArthur, n (%)	12 (25)	4 (14)	4 (8)

**Table 3. [Women's Trial] Bivariable and Multivariable Predictors of Receipt of Swab**

	<i>Uptake Rates, n (%)</i>	<i>Bivariable OR (95% CI)</i>	<i>Bivariable p-value</i>	<i>Multivariable OR (95% CI)</i>	<i>Multivariable p-value</i>
Assigned day 0*	59 (55)	1.2 (0.7 to 2)	0.54	1.2 (0.7 to 2.1)	0.51
Assigned day 1*	79 (73)	2.7 (1.5 to 4.7)	0.0007	<b>2.7 (1.5 to 5)</b>	<b>0.0009</b>
Assigned day 7*	54 (50)	--Referrent--	--	--Referrent--	--
Age (yrs) at Entry**	--	0.7 (0.6 to 0.9)	0.01	<b>0.7 (0.6 to 0.9)</b>	<b>0.01</b>
Low Likelihood of Release	133 (64)	1.7 (1.1 to 2.7)	0.03	<b>1.9 (1.1 to 3.1)</b>	<b>0.01</b>
High Likelihood of Release	59 (51)	--Referrent--	--	--Referrent--	--
High HIV-Risk Offense	56 (69)	1.7 (1 to 3)	0.04	1.7 (1 to 3)	0.07
Low HIV-Risk Offense	136 (56)	--Referrent--	--	--Referrent--	--
Black	55 (53)	0.7 (0.4 to 1.1)	0.10	0.7 (0.4 to 1.2)	0.17
Hispanic	40 (75)	2.4 (1.2 to 4.7)	0.01	2 (1 to 4.1)	0.07
White/Other	97 (58)	--Referrent--	--	--Referrent--	--
Previous Incarceration	125 (61)	1.2 (0.7 to 1.8)	0.55	-Out of Model-	--
No Previous Incarceration	67 (57)	--Referrent--	--	-Out of Model-	--
Urine Opiate(+)	51 (63)	1.2 (0.7 to 2)	0.46	-Out of Model-	--
Urine Opiate(-)	141(58)	--Referrent--	--	-Out of Model-	--
High School Graduate	118 (59)	0.92 (0.6 to 1.5)	0.73	-Out of Model-	--
Not High School Graduate	74 (61)	--Referrent--	--	-Out of Model-	--
Has Medical Insurance	66 (55)	0.7 (0.5 to 1.2)	0.21	-Out of Model-	--
No Medical Insurance	126 (62)	--Referrent--	--	-Out of Model-	--

\*OR Comparing day 1 or day 7, respectively to day 0.

\*\*The calculated OR represents the added likelihood conferred by every 10 years of age

**Table 4: [Men's Trial] Baseline Characteristics of the Study Population (n=298)**

Characteristics	Subcategory	Value (%)
Age (mean years; SD)		35 (11)
Ethnicity	Hispanic	56 (19)
	Black	104 (35)
	White/Other	138 (46)
High School Graduate	Yes	193 (65)
	No	105 (35)
Length of Current Incarceration (median days; IQR)		28 (4-36)
High Likelihood of Early Release*	Yes	122 (41)
	No	176 (59)
Drug- or Prostitution-Related Offense	Yes	46 (15)
	No	252 (85)
Previous History of Incarceration	Yes	244 (82)
	No	54 (18)
Has Medical Insurance	Yes	276 (93)
	No	22 (7)

\* High: any charges directly related to prostitution or drugs.

Low: bond value  $\geq$  \$5000, bond sentencing > 30 days, immigration or federal charges, or no bond

**Table 5. [Men's Trial] Bivariable and Multivariable Predictors of Receipt of Swab**

	<i>Uptake Rates, n (%)</i>	<i>Bivariable OR (95% CI)</i>	<i>Bivariable p-value</i>	<i>Multivariable OR (95% CI)</i>	<i>Multivariable p-value</i>
Assigned day 0*	55 (53)	2.3 (1.26 to 4)	0.01	2.4 (1.4 to 4.3)	0.00
Assigned day 1*	56 (57)	2.6 (1.5 to 4.7)	0.0013	<b>3.0 (1.7 to 5.6)</b>	<b>0.0003</b>
Assigned day 7*	33 (34)	--Referrent--	--	--Referrent--	--
Low Likelihood of Release	52 (43)	0.7 (0.5 to 1.1)	0.10	<b>0.1 (0.1 to 0.7)</b>	<b>0.04</b>
High Likelihood of Release	92 (52)	--Referrent--	--	--Referrent--	--
High School Graduate	88 (46)	0.74 (0.5 to 1.2)	0.20	0.8 (0.5 to 1.2)	0.21
Not High School Graduate	56 (53)	--Referrent--	--	--Referrent--	--
Has Medical Insurance	131 (47)	1.6 (0.7 to 3.9)	0.30	2 (0.8 to 5.1)	0.15
No Medical Insurance	13 (59)	--Referrent--	--	--Referrent--	--
Age (years) at Entry**	--	0.9 (0.72 to 1.12)	0.32	-Out of Model-	--
Low HIV-Risk Offense	18 (39)	--Referrent--	--	-Out of Model-	--
High HIV-Risk Offense	126 (50)	0.7 (0.4 to 1.3)	0.18	-Out of Model-	--
White/Other	49 (47)	--Referrent--	--	-Out of Model-	--
Black	29 (52)	1 (0.6 to 1.5)	0.73	-Out of Model-	--
Hispanic	66 (48)	1.2 (0.7 to 2.2)	0.58	-Out of Model-	--
No Previous Incarceration	23 (43)	--Referrent--	--	-Out of Model-	--
Previous Incarceration	121 (50)	1.4 (0.8 to 2.5)	0.35	-Out of Model-	--

\*OR Comparing day 1 or day 7, respectively to day 0.

\*\*The calculated OR represents the added likelihood conferred by every 10 years of age