Proposed measure = 
$$\left(\frac{\text{HIV diagnoses in year X}}{\{\text{HIV prevalence in year}[X-1] \times [1-\% \text{ of PLWH aware of diagnosis in year}(X-1)]\}}\right) \times 100^{-1}$$

TABLE 1. Annual HIV Diagnoses in Context of Previous Year Prevalence of Undiagnosed HIV Seropositivity

Year	New HIV Diagnoses*	Prevalence†	% of PLWH Aware of Diagnosis,‡ %	X/Undiagnosed HIV Seropositivity in Year (X-1), %
2012	45,287	_	_	27.7
2011	44,040	1,200,300	86.4	26.1
2010	45,136	1,181,300	85.7	25.9
2009	46,971	1,161,800	85.0	26.0
2008	_	1,142,700	84.2	_

<sup>\*</sup>Estimated by Centers for Disease Control and Prevention (see Ref. 3) and adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting.

PLWH, persons living with HIV.

strategies to reach an increasing proportion of undiagnosed PLWH. If we can achieve these steps, then we will continue our progress toward realizing the National HIV/AIDS Strategy goal regarding serostatus awareness for PLWH.

### Robert A. Bonacci, MPH\*† David R. Holtgrave, PhD‡

\*Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

†MPH Program, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

‡Department of Health, Behavior, and Society, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

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# Comparing HIV Case Detection in Prison During Opt-In vs. Opt-Out Testing Policies

To the Editors:

#### **INTRODUCTION**

Routine HIV screening in health care settings, including prisons and jails, is recommended by the US Centers for Disease Control and Prevention to enhance the detection of HIV infection.<sup>1,2</sup>

The parent study was supported by the National Institute of Mental Health, National Institutes of Health (NIH), Grant R01 MH079720-01A1; this analysis was supported by NIH Grant R01 Al116384 and by the University of North Carolina at Chapel Hill Center for AIDS Research (CFAR), an NIH funded program, P30 AI 50410. D.A.W. was supported in part by K24 DA037101, and C.E.G. was supported in part by K24 HD069204. The remaining authors have no funding or conflicts of interest to disclose.

A centerpiece of this strategy is opt-out HIV screening whereby patients are informed that testing will be conducted unless they decline the test. Although incarceration is considered an opportunity to detect HIV and initiate or restart HIV care,<sup>3–6</sup> there are few data describing the performance of an opt-out testing policy in prisons, where HIV prevalence is several-fold that found in the general population.<sup>3</sup>

In November 2008, the North Carolina Department of Public Safety (NCDPS) Division of Adult Correction changed its HIV screening policy for incoming inmates from opt-in to opt-out testing. At the time of the policy change, we were conducting a HIV seroprevalence study among incoming prisoners. The co-occurrence of the change in policy and our seroprevalence study provided a natural experiment to assess the impact of the testing policy on HIV case detection of both newly diagnosed and previously diagnosed cases.

#### **METHODS**

This study was approved by the University of North Carolina Institutional Review Board, the NCDPS Human Subjects Review Committee, and the Office of Human Research Protections at the US Department of Health and Human Services (DHHS).

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<sup>†</sup>Estimated by Centers for Disease Control and Prevention (see Ref. 4) using back-calculation on HIV data for persons aged ≥13 years and adjusted to account for reporting delays, missing transmission category, and incomplete reporting.

<sup>‡</sup>Estimated by Centers for Disease Control and Prevention (see Ref. 4) and adjusted for reporting delays, deaths, and incomplete reporting.

#### **Study Population and Setting**

All sentenced individuals entering the NCDPS between June 2008 and April 2009 were studied. Entering inmates underwent HIV screening within 2 weeks of prison entry. Before the change in policy (June 1 to October 31, 2008), HIV testing was offered under opt-in conditions, wherein a prison nurse conducted pretest counseling and asked inmates if they wanted to be tested. After the policy change (November 1, 2008 to April 15, 2009), HIV testing was provided in an opt-out manner, in which inmates were informed that they would be tested for HIV unless they declined testing.

#### **Data Sources and Linkage**

To determine whether HIV cases were detected or missed by prison system screening, we linked individual-level records from the prison system's HIV test (referred to hereafter as the Prison Test) and the HIV test we conducted to assess seroprevalence (referred to hereafter as the Study Test), which used excess blood from mandatory syphilis testing. We also determined whether incoming prisoners had been previously diagnosed with HIV, documented by NC DHHS record.

These testing and diagnosis data were integrated into a single database of all sentenced prisoners during the study period. Before populating the database with results from the Study Test, prisoner identifiers were removed.

#### **Statistical Considerations**

The primary goal of the analysis was to estimate the difference across opt-in and opt-out testing policies in the annual number of cases detected by the prison system.

Accordingly, we estimated the risk difference (RD) in case detection across testing policies, RD = probability (case detection|opt-out) - probability (case detection|opt-in). We then multiplied the estimated RD by an estimate of the annual number of HIV cases entering the prison system to estimate the annual difference in the number of cases detected under opt-out as compared with opt-in testing.

We also assessed the potential influence on our results of confounding

and of missing HIV status data (ie, those missing a Prison HIV Test, Study HIV Test, and with no record of a state diagnosis) using, respectively, multivariable regression models and both multiple imputation and a series of deterministic sensitivity analyses. The primary data analyses were conducted using SAS version 9.2 (Cary, NC). A full description of sensitivity analyses methods are available by request to the corresponding author.

#### **RESULTS**

During the study period, 23,373 sentenced prisoners (10,756 during optin and 12,617 during opt-out) entered the NCDPS (Fig. 1). A Study HIV Test was available for 94.7% (n = 22,134) of all incoming prisoners (opt-in: 96.0%, opt-out: 93.6%, P < 0.001). Of the 94.7%, 320 were HIV seropositive. Among the 5.3% (n = 1239) of inmates who were missing a Study HIV Test, 48 cases were identified by the Prison Test and state record (n = 36) or by state record alone (n = 12). Of the 368 total HIV cases, there were 177 during opt-in and 191 during opt-out, resulting in respective HIV prevalence estimates of 1.7% (95% CI: 1.5 to 1.9) and 1.5% (95% CI: 1.3 to 1.8); these estimates were not statistically different (P = 0.34).

## HIV Screening and Probability of Case Detection Under Opt-In and Opt-Out Conditions

The proportion of entering inmates receiving an HIV test during opt-in, 58.8%, and during opt-out testing, 95.2%, differed significantly (P <0.001). The estimated probability of detecting a case among those without a previous diagnosis was 0.2 (2/10) and 0.4 (4/10), P = 0.63, during opt-in andopt-out testing, respectively. Given the low number of HIV cases (n = 20) that entered prison without record of a previous diagnosis, the remaining analyses examined case detection regardless of previous diagnosis. The proportion of cases detected by the prison system, irrespective of previous diagnosis, was 0.76 (134/177) during opt-in and 0.90 (172/191) during opt-out, resulting in an estimated RD of 0.14 (95% CI: 0.07 to 0.22), based on analyses of records without missing HIV status data. Standardizing

the number of HIV cases during the study period to account for 25,000 annual entrants [25,000 annual prison entrants  $\times$  (368 HIV cases/22,892 prison entrants)], results in an estimated 402 HIV-positive annual entrants. With 402 HIV-positive inmates entering the prison system annually, opt-out testing would have detected 56 (=  $402 \times 0.14$ ) additional HIV cases as compared with opt-in.

Adjusting for confounding and for missing HIV status data had only a modest influence on our findings, resulting in between 53 and 80 additional annual HIV cases detected under opt-out vs. opt-in.

#### **DISCUSSION**

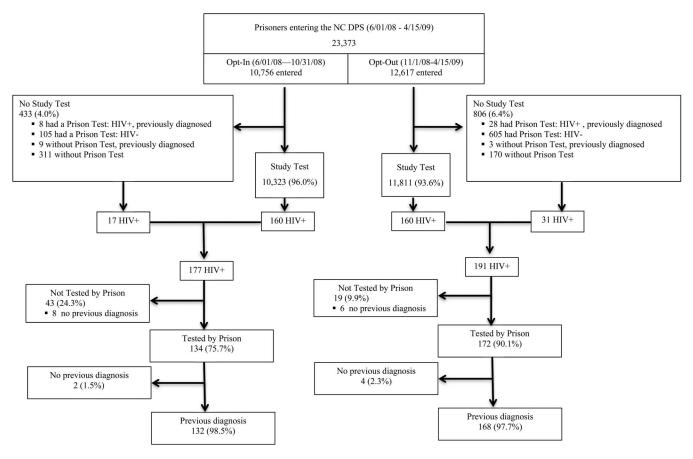
The adoption of opt-out HIV testing led to a sharp and large increase in the proportion of prisoners tested for HIV infection in this state prison system from nearly 60% to more than 95%. In addition, under opt-out testing, a greater proportion of HIV-infected individuals entering prison was tested compared with under opt-in. The dramatic increase in uptake of HIV testing with the adoption of opt-out testing mirrors that reported in the Washington state prison system<sup>8</sup> and is consistent with observations from sexually transmitted infection clinics. <sup>9–11</sup>

Expanded HIV testing of individuals at risk for HIV infection, as was observed with the shift to opt-out, is a linchpin in the strategy to contain the spread of the virus. We found that under opt-out testing, the probability of HIV case detection was approximately 15% higher than for opt-in testing. With an annual intake population of 25,000, opt-out would yield approximately 60 more cases than would have been discovered with opt-in testing. However, rather than representing new cases, the vast majority of HIV cases identified by the prison system were already known to the DHHS.

Although the primary intent of optout testing of prisoners is to reveal previously undetected cases of HIV, the adoption of an opt-out policy in this correctional setting produced a low yield as most of those detected with HIV were already known to the state. However, if the intent is to identify people in need for HIV care, then opt-out testing does provide benefit over opt-in testing. For those who test positive and entered aware of their HIV status, testing has an important

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Previous diagnosis, i.e. NC DHHS record indicating an HIV diagnosis prior to entering prison during the study period

**FIGURE 1.** Prison HIV testing among HIV+ prisoners entering the North Carolina state prison system under opt-in and opt-out testing policies, 2008–2009.

role in linking inmates into prison HIV care. Similarly, if tested individuals included those among the small minority in the state who were diagnosed previously but were unaware of their status or had never engaged in care previously, 12 testing would also prompt entry into care. The importance of identifying out-of-care HIVpositive individuals was highlighted in a systematic review of studies suggesting that once HIV-positive inmates are linked into prison HIV care, their rates of retention are much higher during incarceration (76%) than in the community (30%-40%). 13 With these benefits in mind, it is important that opt-out testing, which in prison is susceptible to being used without inmates' full knowledge, 14,15 be conducted in an informed and noncoercive manner.

This study has limitations. Although the Study Test was not available for 5% of inmates, we conducted

several sensitivity analyses, all of which suggested that missing data had little influence on our results. Additionally, for previously detected cases, the venue at which they first tested positive and whether they received their results were not known, and we could not determine the influence of knowing one's own serostatus on their testing decision; it is possible that people who knew themselves to be positive were more likely to decline the test under opt-in compared with opt-out, but still sought care. Similarly, data were not available on prisoners' linkage to and engagement in care after a positive HIV test during intake. Finally, the finding of few undetected HIV cases may not be generalizable to other correctional systems.16

In summary, the switch from optin to opt-out testing greatly increased the proportion of inmates tested for HIV, including those with HIV infection.

Although research is needed to understand the effects of opt-out HIV testing in other prison settings, our findings indicate that expanded HIV testing of prisoners may not lead to detection of large numbers of newly identified cases but can potentially be a tool for enlisting previously diagnosed inmates into care during their incarceration.

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for the scientific validity or accuracy of methodology, results, statistical analyses, or conclusions presented.

David L. Rosen, PhD, MD\*
David A. Wohl, MD\*
Carol E. Golin, MD\*†
Joseph Rigdon, PhD‡
Jeanine May, PhD†
Becky L. White, MD, MPH\*
Peter A. Leone, MD\*
Michael G. Hudgens, PhD‡
James Michael Bowling, PhD†

Departments of \*Medicine †Health Behavior ‡Biostatistics, University of North Carolina, Chapel Hill, NC

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