

## Delayed entry into HIV medical care after HIV diagnosis: Risk factors and research methods

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Timely linkage to HIV medical care has the potential to improve individual health outcomes and prevent secondary HIV transmission. Recent research found that estimates of delayed care entry varied by study design, with higher estimates among studies using only HIV case surveillance data. In this analysis, we compared the prevalence and risk factors for care delay using data from two studies with different designs conducted in New York City. The Medical Monitoring Project (MMP) used a retrospective design to estimate historical delay among persons currently receiving care, while the Never in Care (NIC) study used a prospective design to estimate current delay status among persons who were care-naïve at baseline. Of 513 MMP subjects in 2007–2008, 23% had delayed care entry greater than three months after diagnosis. Independent risk factors for care delay were earlier year of diagnosis and testing positive in a nonmedical environment. Of 28 NIC subjects in 2008–2010, over half had tested positive in a nonmedical environment. The primary-stated reasons for delay were the same in both studies: denial of HIV status and lack of perceived need for medical care. The strengths and weaknesses of surveillance only, prospective, and retrospective study designs with respect to investigating this issue are explored. Future studies and interventions should be mindful of the common selection biases and measurement limitations with each design. A triangulation of estimates from varying designs is suggested for accurately measuring care linkage efforts over time.

**Keywords:** HIV/AIDS; medical care; initiation; linkage; delay

### Introduction

Timely linkage to HIV medical care following HIV diagnosis is necessary to monitor clinical status of HIV disease progression and to derive maximal benefit from antiretroviral therapy (ART) and other interventions (Metsch et al., 2008). Presentation for and retention in care is a precondition for initiation of and adherence to ART, which reduces risk of secondary transmission because of suppressed HIV viral load (VL) (Quinn et al., 2000). On a population scale, a universal “test and treat” approach has the potential to reduce the scope of the HIV epidemic (Dodd, Garnett, & Hallett, 2010). For these reasons, the US National HIV/AIDS Strategy establishes a benchmark that 85% of persons be linked to care within three months of diagnosis (Holtgrave, 2010). However, a recent meta-analysis found that 28% of persons had delayed entering care more than three months after diagnosis (Marks, Gardner, Craw, & Crepaz, 2010).

Broadly, three study designs have been used to investigate delayed care entry: surveillance-based, retrospective, and prospective. Surveillance-based studies use HIV clinical test reports (usually CD4 cell counts or VL tests) as proxy indicators for care

entry. One such study found that care delayers in New York City (NYC) were more likely to be injection drug users (IDU) and diagnosed in non-medical environments (Torian, Wiewel, Liu, Sackoff, & Frieden, 2008). Retrospective studies investigate historical care delay among persons currently in care; one example is the HIV Cost and Services Utilization Study, among the first to identify the racial disparities in care linkage (Shapiro et al., 1999). Finally, prospective studies investigate the population who are care-naïve at baseline. This is the least commonly used design, often because study recruitment is complicated by subjects’ lack of connection to services (Molitor et al., 2006). One prospective study in Alabama found that scheduling lag for the first care visit increased the likelihood of delayed care (Mugavero et al., 2007).

Choice of study design can influence outcomes in important ways. Higher estimates of delayed care entry have been found in surveillance studies (Marks et al., 2010), for example, in part because surveillance test records may not always be accurate indicators of clinical evaluations (Christopoulos, Das, & Colfax, 2011). Retrospective studies, often nested within large-scale studies of those receiving care, may

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underestimate delay by excluding the care-naive and those who have died (Shapiro et al., 1999). Our objective was to study the prevalence and correlates of delayed care entry through the lens of study design. We examined the sociodemographic and psychosocial factors associated with delay using data from two studies with different designs conducted in NYC. Finally, we qualitatively assessed the strengths and weaknesses of all three designs.

## Methods

### *Medical Monitoring Project (MMP) procedures*

Medical Monitoring Project is a cross-sectional, multi-stage cluster designed study of adults receiving HIV medical care. Its background and methods have been described (McNaghten et al., 2007). MMP used a probability-proportional-to-size sampling design with three selection stages. First, health jurisdictions in the US (states and cities) were randomly selected as target areas based on their underlying AIDS prevalence; NYC was among those selected. Second, HIV medical facilities in NYC were randomly selected to participate, with facility selection probability a function of HIV patient caseload. Laboratory tests (CD4 cell count and VL) and supplemental data from HIV surveillance were used to identify facilities, which were then contacted to determine their caseload. Of 489 facilities identified and confirmed for the 2007 and 2008 study cycles, 34 were selected, with 25 and 21 participating in 2007 and 2008, respectively. Third, patients within participating facilities were randomly selected, with 800 patients selected in 2007 and 752 in 2008. MMP field staff then worked with facility staff to contact and recruit selected patients into the study.

MMP eligibility criteria were current HIV infection, adulthood, and receipt of care in the selected medical facility between January and April of the cycle calendar year. Data were collected in two annual, discrete data collection cycles (2007 and 2008), and the datasets were then merged. Patients could be selected and participate in both cycles, but duplicates ( $n=15$ ), determined by self-report and matching on identifiers, were removed from the merged data-set. Subjects received \$40 public transit cards for their time. Study protocols were approved by the institutional review boards of the DOHMH and participating facilities.

### *Never in Care (NIC) study procedures*

Never in Care is a prospective cohort study in five jurisdictions with one baseline subject encounter and

follow-up through surveillance records to assess care entry over time. Only baseline data are presented here. Its background and methods have been described (Fagan, Bertolli, & McNaghten, 2010). NIC first used surveillance data for initial sampling. Newly diagnosed persons in the NYC HIV surveillance registry were followed up for three months to assess their care entry status, using the proxy of having a CD4 or VL test result in a month subsequent to the diagnosis month. It is standard to order these tests upon initiation of care, and only physicians may order them. Persons with no such test for three months within their diagnosis were entered onto a sampling frame from which a random sample was drawn. Persons on that sample were contacted and asked to participate in the study. Sampling occurred on a monthly basis between March 2008 and August 2010, representing individuals diagnosed from January 2006 to June 2010.

NIC eligibility criteria were HIV diagnosis for at least three months, non-receipt of HIV medical care, adulthood, and NYC residence. When surveillance data obtained after the initial sampling indicated care entry, persons were reclassified as ineligible and removed from the sample (i.e., care entry at any time before interview was a final exclusion criterion for baseline interview). Study subjects who were interviewed received \$25–\$50 for their time. Study protocols were approved by the DOHMH institutional review board.

### *Measures*

MMP and NIC both involved a standardized, structured interview administered by trained field staff in private settings. Sociodemographic and behavioral risk questions were worded similarly in the two studies. For three variables (location of the diagnostic HIV-positive test, reason for testing, and reasons for delayed care entry), we combined response options with overlapping themes into composite categories for analysis. Several of the structured “reasons for delayed care entry” response options were worded slightly differently, and while subjects in both studies were invited to provide more than one response, NIC subjects were more likely to.

For NIC, the main outcome (delayed care entry) was an eligibility criterion. For MMP, delay was calculated with self-reported dates of HIV diagnosis (month and year) and first care (month and year). If the difference was greater than three months, persons were categorized as delayers. Sixty subjects were missing data on month and year of diagnosis or care entry and 19 were missing only month of diagnosis or care entry. Delay status could not be

calculated for the former, but we extrapolate care delay among the latter for persons entering care in a year subsequent to the diagnosis year.

### Statistical analysis

First, we estimated the prevalence and risk factors for care delay in the MMP sample, using chi-square tests to determine statistically significant differences and logistic regression to estimate odds ratios (OR) and confidence intervals (CIs). Differences between those with missing data on delay status were compared to those with complete data. To determine factors independently associated with care delay, we entered all variables significant in bivariate analysis (at  $p < 0.10$ ) into a multiple logistic regression model with backwards elimination of non-significant (at  $p < 0.05$ ) variables. Finally, we generated descriptive statistics for the NIC sample and compared them to the MMP subsample who delayed on the main sociodemographic, risk factor, and psychosocial variables. Analysis was conducted in SAS 9.2 (SAS Institutes, Cary, NC).

### Results

For MMP, of the 800 persons selected in 2007, 279 (35%) completed the study; of 752 persons selected in 2008, 249 (33%) completed the study, yielding an analytic sample of 234 when duplicates were removed. Complete data on care delay status were available for 434 of the 513 total subjects, and data were extrapolated for 19 others, for an analytic sample of 453. Subjects with missing delay data were more likely to be diagnosed before 1996 (9.8% vs. 2.2%;  $p < 0.01$ ) and to identify as heterosexual (91.5% vs. 85.0%;  $p < 0.02$ ).

As Table 1 shows, 72% were male, most were black (42%) or Hispanic (36%), and nearly three quarters (72%) were under the age of 40 at HIV diagnosis. Most were diagnosed after the introduction of highly-active ART (HAART) in 1996 (59%). Nearly a quarter (22%) were born in a foreign country, and 53% had some college education. Half (48%) identified as heterosexual, and 19% had ever injected illicit drugs. Over half (51%) had their first HIV-positive test in a nonmedical environment; the leading reasons for that test were perceived high risk (31%), illness (24%), or a routine offer by a medical provider (23%).

Overall, 105 (23.2%) delayed care entry at least three months after their diagnosis. Risk factors for delay were transgender identity ( $p = 0.04$ ), aged 18–29 at diagnosis ( $p < 0.01$ ), diagnosis before HAART

availability ( $p < 0.01$ ), birthplace in the US or Puerto Rico ( $p < 0.01$ ), history of injection drug use ( $p < 0.01$ ), receiving the first HIV-positive test in a nonmedical environment ( $p = 0.04$ ), and testing for reasons other than perceived high risk ( $p < 0.01$ ). In multivariate analysis (data not shown), each subsequent HIV diagnosis year was associated with decreased likelihood of care delay (adjusted OR: 0.90; 95% CI: 0.86–0.93), while HIV testing in a nonmedical environment was associated with increased likelihood of delay (adjusted OR: 1.69; 95% CI: 1.06–2.70).

For NIC, 1664 cases were selected, of whom 293 were successfully contacted to participate. Of the 293, 97 (33%) self-reported they were in care, 16 (6%) were not previously informed of their HIV status, 104 (36%) refused to participate, 6 (2%) were not NYC residents, 19 (7%) were diagnosed with HIV before the study period, and 23 (8%) were ineligible for other reasons. The remaining 28 (10%) were eligible and completed the study. Most subjects were male (64%), black (68%), or Hispanic (32%), and half were under the age of 40 at diagnosis. More than a third of subjects had been born in a foreign country (39%), and 29% had some college education. Two-thirds (68%) identified as heterosexual, and 7% had ever injected illicit drugs. Over half (54%) had their HIV-positive diagnostic test in a nonmedical environment; the leading reasons for that test were routine offer (57%) and perceived high risk (29%).

The most commonly cited reasons for delayed care entry in MMP (Table 2) were not wanting to think about being HIV-positive (39%) or feeling good and not perceiving a need to enter care (17%). Other responses included difficulties finding or accessing care (9%), disbelief of their test result (8%), and current drinking or drug use (7%). In NIC, the most common reasons were not wanting to think about being HIV-positive (71%), feeling good and not perceive a need to enter care (68%), and not wanting to discuss their HIV result (54%). Additionally, 39% did not believe their test result, 36% did not have health insurance, and 29% had difficulties finding or accessing care.

### Discussion

Delayed entry into HIV medical care is a persistent problem, and may only escalate if HIV testing campaigns are not coupled with similar efforts for care linkage and retention (Mayer, 2011). From the MMP study, we found that nearly one-quarter of persons currently in care had delayed, consistent

Table 1. Factors associated with delayed entry into HIV medical care after HIV diagnosis, from the MMP study (2007–2008) and NIC study (2008–2010), New York City.

|                       | MMP study ( <i>n</i> = 453) |      |                    |      |          |      | NIC study ( <i>n</i> = 28) |          |       |
|-----------------------|-----------------------------|------|--------------------|------|----------|------|----------------------------|----------|-------|
|                       | Total                       |      | Delayed care entry |      |          |      | Total                      |          |       |
|                       | <i>n</i>                    | %    | <i>n</i>           | %    | <i>p</i> | OR   | 95% CI                     | <i>n</i> | %     |
| Gender                |                             |      |                    |      | 0.04     |      |                            |          |       |
| Male                  | 324                         | 71.5 | 73                 | 69.5 |          | 1.00 |                            | 18       | 64.3  |
| Female                | 123                         | 27.2 | 28                 | 26.7 |          | 1.01 | 0.62–1.66                  | 10       | 35.7  |
| Transgender           | 6                           | 1.3  | 4                  | 3.8  |          | 6.87 | 1.23–38.25                 |          |       |
| Race                  |                             |      |                    |      | 0.41     |      |                            |          |       |
| Black                 | 191                         | 42.2 | 45                 | 42.9 |          | 1.62 | 0.80–3.27                  | 19       | 67.9  |
| Hispanic              | 165                         | 36.4 | 42                 | 40.0 |          | 1.79 | 0.88–3.65                  | 9        | 32.1  |
| White                 | 75                          | 16.7 | 12                 | 11.4 |          | 1.00 |                            | 0        | 0.0   |
| Other                 | 22                          | 4.9  | 6                  | 5.7  |          | 1.97 | 0.64–6.05                  | 0        | 0.0   |
| Age at HIV diagnosis  |                             |      |                    |      | <0.01    |      |                            |          |       |
| < 18                  | 6                           | 1.3  | 0                  | 0.0  |          | –    | –                          | 0        | 0.0   |
| 18–29                 | 129                         | 28.5 | 46                 | 43.8 |          | 1.00 |                            | 7        | 25.0  |
| 30–39                 | 193                         | 42.6 | 41                 | 39.1 |          | 0.49 | 0.30–0.80                  | 7        | 25.0  |
| 40–49                 | 100                         | 22.1 | 14                 | 13.3 |          | 0.29 | 0.15–0.57                  | 10       | 35.7  |
| 50 +                  | 25                          | 5.5  | 4                  | 3.8  |          | 0.34 | 0.11–1.06                  | 4        | 14.3  |
| Year of HIV diagnosis |                             |      |                    |      | <0.01    |      |                            |          |       |
| 1996 or earlier       | 185                         | 40.8 | 62                 | 59.1 |          | 2.64 | 1.69–4.12                  | 0        | 0.0   |
| 1997 or later         | 268                         | 59.2 | 43                 | 40.9 |          | 1.00 |                            | 28       | 100.0 |
| Birthplace            |                             |      |                    |      | <0.01    |      |                            |          |       |
| United States         | 310                         | 68.4 | 79                 | 75.2 |          | 2.54 | 1.32–4.88                  | 14       | 50.0  |
| Puerto Rico           | 42                          | 9.3  | 14                 | 13.3 |          | 3.71 | 1.54–8.94                  | 3        | 10.7  |
| Foreign-born          | 101                         | 22.3 | 12                 | 11.4 |          | 1.00 |                            | 11       | 39.3  |
| Education             |                             |      |                    |      | 0.49     |      |                            |          |       |
| No college            | 211                         | 46.6 | 52                 | 49.5 |          | 1.16 | 0.75–1.81                  | 20       | 71.4  |
| ≥ Some college        | 242                         | 53.4 | 53                 | 50.5 |          | 1.00 |                            | 8        | 28.6  |
| Sexual identity       |                             |      |                    |      | 0.11     |      |                            |          |       |
| Heterosexual          | 215                         | 47.5 | 57                 | 54.3 |          | 1.43 | 0.92–2.21                  | 19       | 67.9  |
| Gay/bisexual/other    | 238                         | 52.5 | 48                 | 45.7 |          | 1.00 |                            | 9        | 32.1  |
| Ever injected drugs   |                             |      |                    |      | <0.01    |      |                            |          |       |
| No                    | 365                         | 80.6 | 74                 | 70.5 |          | 1.00 |                            | 26       | 92.9  |
| Yes                   | 88                          | 19.4 | 31                 | 29.5 |          | 2.14 | 1.29–3.55                  | 2        | 7.1   |
| Testing location      |                             |      |                    |      | 0.04     |      |                            |          |       |
| Medical               | 220                         | 48.6 | 42                 | 40.0 |          | 1.00 |                            | 13       | 46.4  |
| Non-medical           | 233                         | 51.4 | 63                 | 60.0 |          | 1.57 | 1.01–2.45                  | 15       | 53.6  |
| Reason for testing    |                             |      |                    |      | <0.01    |      |                            |          |       |
| Illness               | 109                         | 24.1 | 35                 | 32.3 |          | 3.26 | 1.72–6.16                  | 0        | 0.0   |
| Perceived high risk   | 142                         | 31.4 | 18                 | 17.1 |          | 1.00 |                            | 8        | 28.6  |
| Routine offer         | 103                         | 22.7 | 26                 | 24.8 |          | 2.33 | 1.20–4.52                  | 16       | 57.1  |
| Just wanted to know   | 94                          | 20.8 | 25                 | 23.8 |          | 2.50 | 1.27–4.90                  | 2        | 7.1   |
| Other                 | 5                           | 1.1  | 1                  | 1.0  |          | 1.72 | 0.18–16.28                 | 2        | 7.1   |

Note: *p*-values were calculated using chi-square tests, odds ratios (OR), and 95% confidence intervals (CI) were estimated with bivariate logistic regression.

with previous estimates (Marks et al., 2010). Independent risk factors for delay were diagnostic year and a nonmedical testing environment. NIC subjects differed from care delayers in MMP with respect to many factors, but the primary psychosocial reasons for delay were the same for both studies.

### Risk factors for delay

In multivariate analysis, there were two independent risk factors for delay. First, each subsequent diagnostic year was associated with a 10% decreased likelihood of delay. This is consistent with a recent meta-analysis finding that estimates for delayed care entry were lower in studies collecting data after 2002

Table 2. Reasons for delayed HIV medical care after HIV diagnosis, from the MMP study (2007–2008) and NIC study (2008–2010), New York City.

|   | MMP study ( <i>n</i> = 105) |      | NIC study ( <i>n</i> = 28) |      |
|---|-----------------------------|------|----------------------------|------|
|   | <i>n</i>                    | %    | <i>n</i>                   | %    |
| Didn't want to think about being HIV-positive | 41                          | 39.1 | 20                         | 71.4 |
| Felt good, didn't need to go                  | 18                          | 17.2 | 19                         | 67.9 |
| Difficulties finding/accessing care           | 9                           | 8.6  | 8                          | 28.6 |
| Didn't believe HIV test result                | 8                           | 7.6  | 11                         | 39.3 |
| Didn't want to discuss HIV result             | 0                           | 0.0  | 15                         | 53.6 |
| Drinking or using drugs                       | 7                           | 6.7  | 1                          | 3.7  |
| Didn't have insurance                         | 5                           | 4.8  | 10                         | 35.7 |
| Incarcerated                                  | 5                           | 4.8  | 0                          | 0.0  |
| Moved out of town                             | 4                           | 3.8  | 0                          | 0.0  |
| Other   | 15                          | 14.3 | 16                         | 57.1 |

(Marks et al., 2010). This temporal trend may reflect increasing efforts in linking newly diagnosed persons to care (Craw et al., 2008; Purcell et al., 2007). NYC surveillance data suggest that care delay persists but is improving: 64% of persons diagnosed with HIV in 2003 had entered care within three months of diagnosis (Torian et al., 2008), but this climbed to 79% among those diagnosed in 2006–2008 (Bertolli et al., in press). However, the trend result may also reflect a bias in MMP (i.e., sampling subjects only in care), because persons who are care-naïve (more likely to be recently diagnosed) or have died (with differential attrition of care delayers through mortality) are excluded.

The second risk factor was testing in nonmedical environments, such as community-based organizations, health fairs, and other settings where HIV care is not provided. Our finding confirms the link between testing in medical settings and timely linkage to care (Torian et al., 2008; Zetola et al., 2009). Diagnostic testing in a medical environment benefits from the capacity to immediately establish care with newly diagnosed persons (Mugavero, Norton, & Saag, 2011). Therefore, novel testing strategies successful at identifying undiagnosed persons through social networks and at social venues require equally novel methods to link those newly diagnosed to care (Jenness et al., 2009).

Several differences emerged when comparing the NIC sample with the MMP subsample who delayed care. In NIC, we found a higher proportion who were black, older, foreign-born, less educated, heterosexual, and had never injected drugs. One reason for the differences may be that all NIC subjects were care-naïve and diagnosed in 2006 or later, whereas all MMP subjects were in care and only 9% were diagnosed in 2006 or later. Also, recruitment challenges in NIC resulted in a low response rate and a

sample that is unlikely to be representative, given the potential for selection bias. However, as suggested below, it is necessary to be mindful of potential recruitment bias at the study design stage.

#### *Psychosocial barriers to care*

Studies using surveillance or medical records as data sources are often unable to examine psychosocial barriers to care (Mkanta & Uphold, 2006). Our previous qualitative research identified such barriers as fear and denial of HIV status, distrust of medical providers, lack of perceived need for care, substance use, and competing life priorities (Jenness, Hanna, & Murrill, 2007). In both MMP and NIC, fear and denial of status and lack of perceived need for care were the two most common reasons for delaying. One notable difference between the studies was that a higher proportion of NIC subjects reported lack of insurance as a barrier (36% vs. 5%). The timeframe of study participation relative to the diagnosis date may bias findings like these, because newly diagnosed persons may not be aware of the insurance options available to persons with HIV (Godwin et al., 2011). Yet, these findings indicate the possible inadequacy of current HIV test counseling to eliminate perceived barriers to care entry.

#### *Assessment of study designs*

An important methodological question is how study design influences prevalence estimates of delayed care entry and risk factors for this outcome. In Table 3, we summarize the main features of surveillance, prospective, and retrospective study designs, and here we review the key differences between them.

Sampling for surveillance-only and the NIC prospective design is similar: a population-based

Table 3. Comparison of HIV surveillance, prospective (NIC), and retrospective (MMP) study designs to assess linkage to care.

| Topic                  | HIV surveillance only   | Prospective (NIC)   | Retrospective (MMP)   |
|------------------------|---|---|---|
| Sampling & recruitment | Population-based sampling of diagnosed PLWHA possible based on standardized laboratory test reporting; no participant recruitment involved                            | Population-based sampling through HIV surveillance, with linkage status updated over time; participants recruited in window between HIV diagnosis and care entry  | Institutional probability proportional to size sampling, with population limited to persons in care at interview; recruitment at point of medical care  |
| Outcome measures       | Care linkage defined through presence of CD4 cell count or VL data; may not be accurate measure of true care entry; overlap between sampling and outcomes timeframes  | Care linkage defined through presence of CD4 cell count or VL data; care status confirmed through survey; linkage monitored over time through surveillance; overlap between recruitment and outcomes timeframes | Care linkage defined through historical diagnosis and care entry self-report; no overlap between recruitment and outcomes timeframes; underestimation of outcome through attrition of care delayers |
| Exposure measures      | Standard demographics, transmission risk, geography, and testing provider type; limited or no psychosocial barriers measures; overlap with outcome measures timeframe | Wide range of demographics and other measures, including psychosocial barriers to care; all measures overlap with outcome measures timeframe  | Several demographics and other measures, including psychosocial barriers to care; limited measures that overlap with the outcome measures timeframe   |
| Efficiency             | Analysis may be integrated into routine case surveillance activities  | Requires separate study design; population difficult to find and recruit in window period using surveillance-based data   | Can be integrated into any large study of HIV-positive persons, but relevance of delay data depends on recency of diagnoses   |
| Main strengths         | Population-based analysis; efficiency   | Population-based sampling; verified outcome measures; many exposure measures; adaptability  | Probabilistic sampling; verified outcome measures; efficient recruitment and adaptability   |
| Main weaknesses        | Unverified outcome measures; limited exposure measures  | Difficult recruitment; some barriers to care may be unknown to care-naïve participants; inefficient method  | Requires large sample; underestimation of outcome; no overlap between outcome and interview timeframe; limited overlap between exposure and outcome measures timeframes                             |

sampling frame of persons newly diagnosed with HIV who have not entered care is constructed based on laboratory and physician reports of diagnostic, CD4 cell count, and VL testing records. While no subject recruitment occurs in surveillance studies, prospective studies recruit potential subjects in the window period between delay status and care entry (Fagan et al., 2010). Other “prospective” designs that, similar to NIC, sample the care-naïve population include cross-sectional studies of groups at high risk for delay like IDU and longitudinal studies initiated at the time of HIV diagnosis to examine who fails to enter care (Bell et al., 2010; Giordano et al., 2005). In the retrospective design, sampling and recruitment occurs among those who are currently in care, with the goal of assessing historical delay patterns (Samet et al., 1998).

For the outcome, surveillance studies usually rely on CD4 or VL test reports as proxy indicators of care entry, because only clinicians order those tests and

they are routinely ordered upon care entry. Some surveillance studies also use secondary data, such as Ryan White program records, to refine outcome measurement (Meyerson, Klinkenberg, Perkins, & Laffoon, 2007). Persons without the proxy indicators within a defined interval (e.g., three months) are categorized as having delayed (Torian et al., 2008). The major limitation of surveillance studies is the uncertainty that this proxy is an accurate indicator of the true outcome, because ordering tests is neither a necessary nor a sufficient component of establishing care in all cases. The data may also be incomplete if there is underreporting. Surveillance studies may overestimate care delay because of these potentially inaccurate indicators (Bertolli et al., in press). In NIC, the outcome is initially defined through surveillance but then verified by self-report at interview. In the prospective design, the outcome is co-occurring with the sampling timeframe; in contrast, the outcome occurs before the sampling timeframe in the

retrospective design because the study sample is in care. This presents two problems for retrospective studies. First, they will underestimate delay if there is differential attrition through morbidity and mortality of persons who delayed. Second, there is a greater potential for misclassification of delay through misreported or missing care entry dates for persons with distal dates of diagnosis, as we found.

Exposure measures (i.e., risk factors) in surveillance studies are limited to those routinely collected in surveillance activities, such as demographic information and transmission risk. In contrast, because prospective and retrospective studies involve subject encounters, detailed measures may be collected, including psychosocial barriers to care. One difference, however, is that the timeframes of the exposure measures may not closely correspond to the timeframe of the outcome measure in the retrospective design because relevant exposure variables (e.g., substance use) tend to focus on recent history whereas the outcome may have occurred earlier. Again, there is a greater potential for recall bias for exposures measured in more distal time periods.

Finally, efficiency is an important consideration when comparing study designs. Surveillance studies are most efficient because they can be integrated into routine case surveillance activities. Prospective studies are least efficient because they require intensive recruitment of a target population that is often difficult to reach because they are not yet connected to services. In the California Bridge Project care linkage intervention, fewer than one-third of subjects were successfully linked and an average of 15 client contacts were required for those who were (Molitor et al., 2006). Successfully recruiting the care-naive depends on the quality of contact information available at sampling and the field staff's ability to track hard-to-reach populations in the window between the defined time points of delay and care entry. The retrospective design is often more efficient, since HIV-positive individuals may be recruited through ongoing medical services.

### Limitations

Our empirical analysis is subject to at least three limitations. First, the response rates for both studies were low, introducing potential selection bias. This bias is important to consider when formulating future interventions, because recruitment challenges may be similar. Second, 15% of MMP study subjects had missing data on either their HIV diagnosis or care entry date, and those with missing data were more likely to be older at the time of diagnosis and to identify as heterosexual. These were two factors

associated with delayed care entry in bivariate, but not multivariate, analysis. Recall of dates that occurred as much as two decades prior may be the underlying cause; targeting only the more recently diagnosed could be an approach for future studies. Finally, these data were collected through interviewer-administered surveys, which may introduce social desirability biases when reporting sensitive issues like injection drug use.

### Conclusions

Linkage and engagement into HIV medical care are key components of the National HIV/AIDS Strategy; meeting the strategy benchmarks will ultimately improve individual-level health outcomes and reduce population-level HIV transmission (Millett et al., 2010). The National Institutes of Health have recently funded several research studies on how best to expand the "test and treat" concept to include the continuum of health needs for persons living with HIV, from testing to linkage to long-term retention in care (Meyerson et al., 2007; Mugavero et al., 2011; Torian & Wiewel, 2011). Interventions that address this continuum will likely need to address the multiplicity of individuals' psychosocial and structural barriers to care. Future research on this issue, used to assess progress in meeting the national strategy objective, should continue to investigate how study design and measurement specification influence outcome estimates. In the end, a triangulation of estimates from varying designs will be necessary to evaluate our progress over time.

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### References

- Bell, C., Metsch, L.R., Vogenthaler, N., Cardenas, G., Rodriguez, A., Locascio, V., ... del Rio, C. (2010). Never in care: Characteristics of HIV-infected crack cocaine users in 2 US cities who have never been to outpatient HIV care. *Journal of Acquired Immune Deficiency Syndromes*, 54(4), 376–380.

- Bertolli, J., Shouse, R.L., Beer, L., Valverde, E., Fagan, J.L., Jenness, S.M., ... Bolden, B. (in press). Using HIV surveillance data to monitor missed opportunities for linkage and engagement in HIV medical care. *Open AIDS Journal*.
- Christopoulos, K.A., Das, M., & Colfax, G.N. (2011). Linkage and retention in HIV care among men who have sex with men in the United States. *Clinical Infectious Diseases*, 52(Suppl. 2), S214–S222.
- Craw, J.A., Gardner, L.I., Marks, G., Rapp, R.C., Bosshart, J., Duffus, W.A., ... Schmitt, K. (2008). Brief strengths-based case management promotes entry into HIV medical care: Results of the antiretroviral treatment access study-II. *Journal of Acquired Immune Deficiency Syndromes*, 47(5), 597–606.
- Dodd, P.J., Garnett, G.P., & Hallett, T.B. (2010). Examining the promise of HIV elimination by 'test and treat' in hyperendemic settings. *AIDS*, 24(5), 729–735.
- Fagan, J.L., Bertolli, J., & McNaghten, A.D. (2010). Understanding people who have never received HIV medical care: A population-based approach. *Public Health Reports*, 125(4), 520–527.
- Giordano, T.P., Visnegarwala, F., White, A.C., Jr, Troisi, C.L., Frankowski, R.F., Hartman, C.M., & Grimes, R.M. (2005). Patients referred to an urban HIV clinic frequently fail to establish care: Factors predicting failure. *AIDS Care*, 17(6), 773–783.
- Godwin, N.C., Willig, J.H., Nevin, C.R., Lin, H.Y., Allison, J., Gaddis, K., ... Raper, J.L. (2011). Underutilization of the AIDS drug assistance program: Associated factors and policy implications. *Health Services Research*, 46(3), 982–995.
- Holtgrave, D.R. (2010). On the epidemiologic and economic importance of the National AIDS Strategy for the United States. *Journal of Acquired Immune Deficiency Syndromes*, 55(2), 139–142.
- Jenness, S.M., Hanna, D.B., & Murrill, C.S. (2007). Barriers to HIV medical care among adults newly diagnosed with HIV in New York City. In *National HIV prevention conference* [Abstract No. B-13-2], Atlanta, GA.
- Jenness, S.M., Murrill, C.S., Liu, K.L., Wendel, T., Begier, E., & Hagan, H. (2009). Missed opportunities for HIV testing among high-risk heterosexuals. *Sexually Transmitted Diseases*, 36(11), 704–710.
- Marks, G., Gardner, L.I., Craw, J., & Crepaz, N. (2010). Entry and retention in medical care among HIV-diagnosed persons: A meta-analysis. *AIDS*, 24(17), 2665–2678.
- Mayer, K.H. (2011). Introduction: Linkage, engagement, and retention in HIV care: Essential for optimal individual- and community-level outcomes in the era of highly active antiretroviral therapy. *Clinical Infectious Diseases*, 52(Suppl. 2), S205–S207.
- McNaghten, A.D., Wolfe, M.I., Onorato, I., Nakashima, A.K., Valdiserri, R.O., Mokotoff, E., ... Sullivan, P.S. (2007). Improving the representativeness of behavioral and clinical surveillance for persons with HIV in the United States: The rationale for developing a population-based approach. *PLoS One*, 2(6), e550.
- Metsch, L.R., Pereyra, M., Messinger, S., Del Rio, C., Strathdee, S.A., Anderson-Mahoney, P., ... Gardner, L. (2008). HIV transmission risk behaviors among HIV-infected persons who are successfully linked to care. *Clinical Infectious Diseases*, 47(4), 577–584.
- Meyerson, B.E., Klinkenberg, W.D., Perkins, D.R., & Laffoon, B.T. (2007). Who's in and who's out: Use of primary medical care among people living with HIV. *Am J Public Health*, 97(4), 744–749.
- Millett, G.A., Crowley, J.S., Koh, H., Valdiserri, R.O., Frieden, T., Dieffenbach, C.W., ... Fauci, A.S. (2010). A way forward: The national HIV/AIDS strategy and reducing HIV incidence in the United States. *Journal of Acquired Immune Deficiency Syndromes*, 55(Suppl. 2), S144–S147.
- Mkanta, W.N., & Uphold, C.R. (2006). Theoretical and methodological issues in conducting research related to health care utilization among individuals with HIV infection. *AIDS Patient Care STDS*, 20(4), 293–303.
- Molitor, F., Waltermeyer, J., Mendoza, M., Kuenneth, C., Aguirre, A., Brockmann, K., & Crump, C. (2006). Locating and linking to medical care HIV-positive persons without a history of care: Findings from the California Bridge Project. *AIDS Care*, 18(5), 456–459.
- Mugavero, M.J., Lin, H.Y., Allison, J.J., Willig, J.H., Chang, P.W., Marler, M., ... Saag, M.S. (2007). Failure to establish HIV care: Characterizing the "no show" phenomenon. *Clinical Infectious Diseases*, 45(1), 127–130.
- Mugavero, M.J., Norton, W.E., & Saag, M.S. (2011). Health care system and policy factors influencing engagement in HIV medical care: Piecing together the fragments of a fractured health care delivery system. *Clinical Infectious Diseases*, 52(Suppl. 2), S238–S246.
- Purcell, D.W., Latka, M.H., Metsch, L.R., Latkin, C.A., Gomez, C.A., Mizuno, Y., ... Borkowf, C.B. (2007). Results from a randomized controlled trial of a peer-mentoring intervention to reduce HIV transmission and increase access to care and adherence to HIV medications among HIV-seropositive injection drug users. *Journal of Acquired Immune Deficiency Syndromes*, 46(Suppl. 2), S35–S47.
- Quinn, T.C., Wawer, M.J., Sewankambo, N., Serwadda, D., Li, C., Wabwire-Mangen, F., ... Gray, R.H. (2000). Viral load and heterosexual transmission of human immunodeficiency virus type 1. Rakai Project Study Group. *New England Journal of Medicine*, 342(13), 921–929.
- Samet, J.H., Freedberg, K.A., Stein, M.D., Lewis, R., Savetsky, J., Sullivan, L., ... Hingson, R. (1998). Trillion virion delay: Time from testing positive for HIV to presentation for primary care. *Archives of Internal Medicine*, 158(7), 734–740.
- Shapiro, M.F., Morton, S.C., McCaffrey, D.F., Senterfitt, J.W., Fleishman, J.A., Perlman, J.F., ... Bozzette, S.A. (1999). Variations in the care of HIV-infected adults in the United States: Results from the HIV cost and services utilization study. *JAMA*, 281(24), 2305–2315.

- Torian, L.V., & Wiewel, E.W. (2011). Continuity of HIV-related medical care, New York City, 2005–2009: Do patients who initiate care stay in care? *AIDS Patient Care STDS*, 25(2), 79–88.
- Torian, L.V., Wiewel, E.W., Liu, K.L., Sackoff, J.E., & Frieden, T.R. (2008). Risk factors for delayed initiation of medical care after diagnosis of human immunodeficiency virus. *Archives of Internal Medicine*, 168(11), 1181–1187.
- Zetola, N.M., Bernstein, K., Ahrens, K., Marcus, J.L., Philip, S., Nieri, G., ... Klausner, J.D. (2009). Using surveillance data to monitor entry into care of newly diagnosed HIV-infected persons: San Francisco, 2006–2007. *BMC Public Health*, 9, 17.