

Understanding People Who Have Never Received HIV Medical Care: A Population-Based Approach

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SYNOPSIS

A substantial number of people living with human immunodeficiency virus (HIV) have never received HIV medical care despite the benefits of early entry to care. The United States has no population-based system that can be used to estimate the number of people who have never received HIV care or to monitor the reasons that care is delayed. Although local efforts to describe unmet need and barriers to care have been informative, nationally representative data are needed to increase the number of people who enter care soon after diagnosis.

Legal requirements to report all CD4 counts and all HIV viral load levels (indicators of HIV care) in most states now make national estimates of both care entry and non-entry feasible. The Centers for Disease Control and Prevention (CDC) and five state and local health department jurisdictions are testing and evaluating methods for a standardized supplemental HIV surveillance system to characterize HIV-infected people across the U.S. who have not entered HIV care after their diagnosis. This article reviews the context, rationale, and potential contributions of a nationally representative surveillance system to monitor delays in receiving HIV care, and provides data from the formative phase of the CDC pilot project.

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Entering medical care soon after diagnosis is essential if people living with human immunodeficiency virus (HIV) are to benefit from life-prolonging HIV care. The early initiation of antiretroviral therapy may reduce treatment-related complications, improve immune function, and, along with prophylaxis for opportunistic infections, reduce HIV-related morbidity and mortality.¹⁻¹⁵ Early HIV medical care also provides additional opportunities for prevention counseling, which may reduce further HIV transmission.^{2,15,16} Despite the advantages of early care and a publicly funded system designed to improve access to HIV care,¹⁷ a substantial number of HIV-infected people are not receiving HIV care. Using national HIV/acquired immunodeficiency syndrome (AIDS) surveillance data through 2001, Fleming et al. estimated that approximately 33% of people who were aware of their HIV serostatus were not receiving ongoing HIV medical care.¹⁸

The HIV-prevention strategic plan of the Centers for Disease Control and Prevention (CDC) aims to increase the proportion of people who enter HIV medical care within three months after learning their diagnosis from 50% to 80%.^{19,20} However, the United States has no population-based system that can be used to estimate the number of people who have never received HIV care or that can be used to monitor the reasons that care is delayed. Such information would be useful to program planners in determining the resources needed to provide services to all HIV-infected people and in designing strategies to overcome barriers to HIV care.

The Never in Care (NIC) pilot project, a population-based supplement to the national surveillance system, was conceived to enumerate and describe people in the U.S. who have a diagnosis of HIV infection but who have never received HIV medical care. We review the history of efforts to quantify unmet need for HIV care, explain how the NIC project builds on these efforts, provide data from the formative phase of the pilot project, and describe the contributions that the NIC project, as a supplemental system, could potentially make to a comprehensive national HIV/AIDS surveillance system.

EFFORTS TO QUANTIFY UNMET NEED FOR HIV CARE

Requirements for assessment of unmet need

Administered by the Health Resources and Services Administration (HRSA), the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act provides services to more than 500,000 people living with HIV infection in the U.S. The federal government allocates more than \$2.1 billion annually for Ryan White CARE

Act programs, which provide primary medical care, medications, and support services for people who would otherwise not have access. The Ryan White CARE Act was first enacted by Congress in 1990 and has been reauthorized three times—in 1996, 2000, and 2006. During this time, HRSA has expanded the requirements for reporting met and unmet need.

The Ryan White CARE Act Amendments of 2000 directed HRSA grantees to assess the needs of people living with HIV/AIDS, particularly those from disproportionately affected and historically underserved populations who are aware of their serostatus but who have yet to receive HIV-related health services.²¹ In 2003, HRSA introduced a framework developed by the University of California, San Francisco, for grantees to use to estimate met and unmet need. The framework called for the integration of two types of data: (1) data on a jurisdiction's population of HIV-infected people who are aware of their infection and (2) data on the number of HIV-infected people receiving care, based on laboratory reports of CD4 T-lymphocyte count and HIV viral load or the prescription of antiretroviral medications.²² Beginning in 2005, receipt of federal funding through the Ryan White CARE Act required an assessment of HIV medical care utilization.

Because of HRSA's requirement that its grantees estimate unmet need, some jurisdictions have a rich source of local data that characterize HIV-infected people who are not receiving HIV care. In addition, HRSA's Special Projects of National Significance Outreach Initiative, designed to refine and evaluate strategies to help underserved HIV-infected people access care, has provided additional data on unmet need.²³ Several other studies have added to the knowledge base about unmet need and barriers to HIV care, including the HIV Cost and Services Utilization Study, a nationally representative survey of adults living with HIV receiving care in the U.S.²⁴⁻³⁸

Limitations of current data

The framework used by HRSA grantees to estimate need provides an operational definition of unmet need and allows HRSA grantees flexibility in choosing the method that is most suitable for their local laboratory reporting data. However, differing methods may limit jurisdictional comparisons of the levels of unmet need: that is, data may be more comparable within a jurisdiction than among multiple jurisdictions (especially with regard to subpopulations or trends over time).^{38,39} Although local efforts to describe unmet need and barriers to care have been informative, nationally representative data are needed to increase the number of people who enter care soon after diagnosis.

Research, including the national HIV Cost and

Services Utilization Study described previously, has been primarily retrospective (i.e., focused on people who delayed HIV care after they had entered care). Descriptions of unmet need have tended to focus on people who made fewer than the recommended number of primary care visits or who were not prescribed antiretroviral therapy despite clinical indications. Few studies have described people who have never received HIV care, and these few studies were not population-based.⁴⁰

Historically, the capacity to describe unmet need by the use of surveillance data (per the HRSA-recommended framework) has been limited by the existence of laws requiring laboratories to report results of CD4 and HIV viral load tests ordered as part of HIV medical care. However, HIV surveillance reporting requirements have evolved. In 1999, CDC recommended the national reporting of HIV diagnoses.⁴¹ In 2001, the Council of State and Territorial Epidemiologists (CSTE) urged all states to improve HIV surveillance by reporting CD4 cell counts and HIV viral load.⁴² By 2004, laws in all 50 states mandated the reporting of HIV diagnoses, CD4 cell counts, and HIV viral load results.⁴³ However, the specific values of CD4 cell counts and HIV viral load required to be reported differed by jurisdiction.⁴² For example, some states required only the reporting of CD4 cell counts and viral loads below or above a specified threshold (i.e., for CD4 counts, those potentially predictive of AIDS; for viral loads, detectable virus).

The use of CD4 cell counts and HIV viral load to estimate met and unmet need for HIV medical care necessitates the reporting of all CD4 or all HIV viral load test results, without restriction to specific values. Unless all CD4 or all HIV viral load test results are required to be reported, the presence or absence of that information is not a meaningful indicator of HIV care or the absence of HIV care.⁴³

Shifts in federal policy and changes in state reporting requirements have increased the availability of data that can be used to estimate unmet need. According to the CSTE, as of 2008, 36 of the 50 states required reporting of all CD4 cell counts or all HIV viral loads, regardless of the specific values. Table 1 details state reporting requirements. As more states have removed restrictions on reportable values of CD4 cell counts and HIV viral load, the capacity to characterize unmet need by the use of routinely collected surveillance data has increased. Systematically reporting all HIV diagnoses, CD4 cell counts, and HIV viral loads is a critical step in establishing standardized national population data that can be used to estimate unmet need.

THE NEVER IN CARE PROJECT

How the NIC project builds on efforts to quantify unmet need

The NIC project builds on recent shifts in policy and HIV reporting regulations that enhance the feasibility of using standardized methods for characterizing people who have never received HIV care. The purpose of the NIC pilot project is to test and evaluate methods for a supplemental HIV surveillance system to describe a particular aspect of unmet need, specifically delayed entry into HIV care. The NIC pilot is focused on HIV-infected people who received an HIV diagnosis three to 15 months before the date of selection and have never received HIV care.

Eligibility was restricted to those more recently diagnosed, because formative work indicated that project staff would be more successful in contacting these people for interviews using the available contact information, which was collected at the time of diagnosis. Although those who have never received HIV care do not represent the entire population considered by HRSA to have unmet need for HIV services,²² this population was chosen as the focus of the NIC project because there is less information about it, the population can be clearly defined, and the definition can be applied consistently across jurisdictions. A focus on HIV-infected people who have not entered HIV care allows for rigorous testing of case identification and data collection methods and provides a foundation for broadening case definitions to include not only people who have never received HIV care, but also people who have received HIV care but who are not currently in care. The NIC pilot uses HIV/AIDS surveillance data to identify the population of interest, a strategy that has the advantage of being population-based and that has been proven to be one of the most promising strategies among those promoted by HRSA's framework for assessing unmet need.⁴⁴

The design of the NIC pilot addresses recommendations from the Institute of Medicine (IOM) report "Measuring What Matters: Allocation, Planning and Quality Assessment for the Ryan White CARE Act," which urges collaboration between HRSA and CDC and other agencies to estimate the number of people who have a diagnosis of HIV infection but who are not in care,⁴⁵ at least for the subpopulation of people who have never received care. After methods have been validated for characterizing people who have never received care, adjustments in the methods might be made to include people who are not receiving care consistently or as often as recommended.

Table 1. CD4 and HIV viral load reporting requirements as of December 2008: 50 U.S. states, Puerto Rico, and the District of Columbia^a

State/territory	CD4 count, cells/ μ L		HIV viral load	
	Lab reporting required	Reportable level	Lab reporting required	Reportable level
Jurisdictions requiring reporting of all CD4 or all HIV viral load levels, regardless of specific values				
Alaska	Yes	All values	Yes	Any result
Arkansas	Yes	All values	Yes	Any result
California	Yes	All values	Yes	Any result
Colorado	Yes	<500	Yes	Any result
Connecticut	Yes	<200 or <14%	Yes	Any result
Delaware	Yes	All values	Yes	Any result
District of Columbia	Yes	All values	Yes	Any result
Florida	Yes	All values	Yes	Any result
Georgia	Yes	All values	Yes	Any result
Hawaii	Yes	All values	Yes	Any result
Indiana	Yes	All values	Yes	Any result
Iowa	Yes	All values	Yes	Any result
Kansas	Yes	<500 or <29%	Yes	Any result
Kentucky	Yes	All values	Yes	Detectable
Louisiana	Yes	All values	Yes	Any result
Maine	Yes	All values	Yes	Any result
Maryland	Yes	All values	Yes	Any result
Michigan	Yes	All values	Yes	Any result
Mississippi	Yes	All values	Yes	Any result
Missouri	Yes	All values	Yes	Any result
Nebraska	Yes	<800	Yes	Any result
New Hampshire	Yes	All values	Yes	Any result
New Jersey	Yes	<200 or <14%	Yes	Any result
New Mexico	Yes	<200 or <14%	Yes	Any result
New York	Yes	All values	Yes	Any result
North Dakota	Yes	All values	Yes	Any result
Oklahoma	Yes	<500	Yes	Any result
Oregon	Yes	All values	Yes	Any result
Puerto Rico	Yes	All values	Yes	Any result
Rhode Island	Yes	<200 or <14%	Yes	Any result
South Carolina	Yes	All values	Yes	Any result
Utah	Yes	All values	Yes	Any result
Vermont	Yes	<200 or <14%	Yes	Any result
Virginia	Yes	All values	Yes	Any result
Washington	Yes	All values	Yes	Any result
West Virginia	Yes	All values	Yes	Any result
Wisconsin	Yes	<200 or <14%	Yes	Any result
Wyoming	Yes	All values	Yes	Any result
Jurisdictions requiring reporting of CD4 and HIV viral load levels within a specified range of values				
Alabama	Yes	<200	No	NA
Arizona	Yes	<200 or <14%	Yes	Detectable
Idaho	Yes	<200 or <14%	Yes	Detectable
Illinois	Yes	<200 or <14%	Yes	Not specified
Massachusetts	Yes	<200 or <14%	No	NA
Minnesota	Yes	<200	Yes	Detectable
Montana	No	NA	Yes	Detectable
Nevada	Yes	<500	Yes	Detectable
North Carolina	Yes	<200	Yes	Detectable
Ohio	Yes	<200	Yes	Detectable
Pennsylvania ^b	Yes	<200 or <14%	Yes	Detectable
South Dakota	Yes	<200	No	NA
Tennessee	Yes	<200	Yes	Detectable
Texas	Yes	<200 or <14%	Yes	Detectable

^aCouncil of State and Territorial Epidemiologists HIV Surveillance Assessment

^bAlthough state law in Pennsylvania does not require reporting of all CD4 or all HIV viral load values, city law in Philadelphia does, making Philadelphia eligible to participate in the Never in Care project.

HIV = human immunodeficiency virus

μ L = micrograms/liter

NA = not applicable

Description of the pilot project and findings from formative work

CDC is funding five state and local health department jurisdictions to implement the NIC pilot from September 2005 through September 2010 to test and evaluate methods to identify, locate, and interview people reported as HIV infected three to 15 months previously, who have never received HIV medical care. Through an objective review process, Indiana, New Jersey, Washington State, New York City, and Philadelphia were selected to participate in the pilot.

The NIC pilot adheres to the confidentiality and security protections required for all HIV surveillance data. Pilot areas adhere to local regulations pertaining to locating and contacting NIC-eligible participants. People eligible for NIC are located and contacted by using information from the HIV/AIDS Reporting System (HARS) database or through physicians, HIV testing centers, or case management service providers. State laws and regulations protect surveillance information, limit the uses of data for purposes not related to public health, and impose criminal penalties for the inappropriate disclosure of surveillance data.⁴⁶ Each project area has been granted a Certificate of Confidentiality, which protects the NIC data held by the state or city health department from subpoena. At the federal level, surveillance data are held under the Federal Assurance of Confidentiality, which protects data held by CDC from subpoena.⁴⁷

To determine eligibility for the NIC project, pilot project areas use local HIV/AIDS case and HIV laboratory databases and, if available, supplemental databases (e.g., Ryan White Title I, Ryan White Title II, and the AIDS Drug Assistance Program). The NIC pilot criteria for identifying people who have never entered care include people who have had a diagnosis of HIV infection reported in one of the five pilot areas, are at least 90 days post-diagnosis, and have had no CD4 or HIV viral load results reported to the relevant pilot area's HIV/AIDS surveillance system. Applying these criteria by using HIV/AIDS surveillance data potentially identifies the population of HIV-infected people whose diagnosis was made during a specified eligibility period and who met the criteria for "never in care." This population serves as a sampling frame from which to select eligible people to be approached for interview.

Contact is initiated with people selected. During the formative phase of the project, the pilot project areas conducted a trial run of sampling frame construction by identifying people who met the NIC eligibility criteria among those diagnosed between November 2005 and December 2006. These estimates represent the best available data from HARS and associated labora-

tory databases, before verification of never-in-care status required by the NIC project protocol. Among the 10,090 people who were diagnosed during this 12-month period and reported to HIV/AIDS surveillance systems in these areas by February 28, 2007, 2,119 (21%) had not entered care as of December 31, 2007.

Across the pilot project areas, the percentage of people diagnosed in the 12-month period who met the NIC project definition ranged from 20% to 25%. Table 2 shows that people who met the NIC project definition were more likely to be younger, African American, and Hispanic than those diagnosed in the same period for whom there was evidence of care entry.

Percentages of people never in care derived from HARS and associated laboratory data alone are likely overestimates, because of CD4 and viral load reporting delays and because some people without evidence of care entry should not be included. As mentioned, the NIC protocol requires verification of never-in-care status. Verification is accomplished through (1) review of incoming CD4 and HIV viral load results; (2) investigation into other events, such as death or change of residence (which are associated with not having a reported CD4 or HIV viral load result, but

Table 2. People diagnosed with HIV from November 2005 to December 2006 and reported to HIV surveillance by February 2007 in Indiana, Philadelphia, New Jersey, New York City, and Washington State

Variable	NIC eligible ^a N	In care N	Unadjusted odds ratio (95% CI)
Age (in years)			
18–34	883	2,872	1.3 (1.2, 1.4)
≥35	1,236	5,102	Ref.
Race			
Black (non-Hispanic)	1,068	3,434	1.8 (1.6, 2.1)
Hispanic	488	1,680	1.7 (1.5, 2.0)
White (non-Hispanic)	387	2,259	Ref.
Other	43	196	1.3 (0.9, 1.8)
Gender			
Male	1,535	5,733	1.0 (0.9, 1.2)
Female	584	2,241	Ref.

^aRefers to people who have had a diagnosis of HIV infection reported in one of the five pilot areas, are at least 90 days post-diagnosis, and have had no CD4 or HIV viral load results reported to the relevant pilot area's HIV/AIDS surveillance system

HIV = human immunodeficiency virus

NIC = Never in Care

CI = confidence interval

Ref. = referent group

AIDS = acquired immunodeficiency syndrome

nonetheless render a person ineligible to be counted as never in care in the jurisdiction); and (3) review of HIV counseling, testing, and partner services records containing information on whether linkage to care was successful. Those remaining eligible after this initial screening process are approached for participation and asked additional screening questions, including questions about entry to care. NIC pilot methods for identifying and interviewing eligible people have been described in more detail elsewhere.⁴⁸

All five pilot areas administer a 30-minute structured interview to those determined to be eligible to describe the following: demographic characteristics, barriers to and facilitators of HIV medical care, met and unmet need for HIV-related ancillary services, social support, HIV testing history, and possible modes of exposure to HIV. Blood is collected by fingerstick and tested by a central laboratory to assess CD4 cell count and HIV viral load. In addition, four of the pilot areas (Indiana, New York City, Philadelphia, and Washington State) are conducting a 60-minute qualitative interview to allow participants to respond in their own words rather than selecting from investigator-defined responses to questions about health-care utilization, illness perception, stigma, and access to HIV information.

The five pilot areas funded to implement the NIC pilot are also participating in the Medical Monitoring Project (MMP), a supplemental HIV surveillance system that collects data on people receiving HIV medical care in the U.S.⁴⁹ The MMP collects clinical and behavioral data from people receiving HIV medical care. If interview response rates are adequate, the five state and local health department jurisdictions participating in both the NIC project and the MMP should be able to assemble complementary descriptions of met and unmet need among people who are receiving HIV care and people who have never received care.

Potential contributions of national implementation of a never-in-care approach

If proven successful and implemented on a national scale, the NIC project could yield estimates of the number of HIV-infected people in the U.S. who have never accessed HIV care and could provide useful information for estimating the cost of addressing this unmet need. NIC project surveillance could be useful in developing and prioritizing strategies to increase the number of people who receive HIV care within three months of diagnosis. Such efforts are critical in addressing CDC's Advancing HIV Prevention goals of increasing access to HIV medical care and reducing HIV incidence.⁵⁰

In an effort to increase the number of people who

are aware of their HIV serostatus,⁵⁰ CDC recommended expanding HIV testing and screening to all health-care settings.⁵¹ CDC's efforts to encourage HIV testing in nonclinical settings⁵² and make it routine in medical settings have increased the demand for HIV care services,^{17,53} but the impact of expanded testing on entry to care is unclear. Representative data on the number and characteristics of HIV-infected people who have never entered care are needed to evaluate this impact and monitor trends.

Information from the NIC project may help describe health-care access and utilization among people of minority races/ethnicities. Health-care access and utilization are often linked to socioeconomic status and race. In its 2003 report, "Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care," the IOM described disparities in the quality of health care received by people of minority races/ethnicities.⁵⁴ The NIC project is designed to uncover experiences with the health-care system that may have acted as barriers to HIV care. Such information may be useful in addressing one of the goals of CDC's HIV prevention strategic plan—to reduce the "disparities, stigma, and discrimination" that people of minority races/ethnicities may experience when accessing HIV care.²⁰

Data on people who have never received HIV care may also provide further information for estimates of severity of need, on which HRSA bases decisions regarding allocation of Ryan White CARE Act funding for HIV-related care and support services.¹⁸ An expanded NIC project, used as a supplement to the national HIV/AIDS surveillance system, could serve as a critical tool for monitoring, evaluating, and improving initiatives so that all people with a diagnosis of HIV infection have the opportunity to initiate and continue care throughout all stages of disease.

The vision of a continuum of HIV prevention and treatment is incorporated throughout CDC's strategic plan for HIV prevention, recently extended through 2010.^{19,20} Achieving the benefits of prevention and treatment interventions requires optimizing each component of the continuum—from increasing the number of HIV-seronegative people who receive HIV-prevention services to increasing the numbers of people who are aware of their HIV serostatus, linking HIV-infected people to care, increasing the utilization of care and prevention services, and increasing adherence to prescribed therapies. The goals of CDC's strategic plan reflect the components of the continuum, and national HIV/AIDS surveillance activities are designed to monitor progress toward these goals: behavioral and incidence surveillance monitor progress in prevention,⁵⁵ case surveillance monitors the expansion of HIV testing

through reporting of new diagnoses,⁴³ and the MMP monitors care.⁴⁹ The strategic plan aims to increase the proportion of people who enter HIV medical care within three months after learning their diagnosis,²⁰ but a mechanism to measure progress toward this goal is lacking. The NIC project, as a supplement to HIV/AIDS surveillance, could address these gaps and be a standardized system for monitoring delayed care entry.

CONCLUSIONS

Information about people who have a diagnosis of HIV infection but who are not currently in care, especially people who have never received HIV care, is limited. A supplemental surveillance system to collect data on people who have never entered HIV care would be an essential tool for uncovering patterns of HIV care utilization. Understanding the various factors that influence health-care utilization is critical to developing strategies for improving access to care for all HIV-infected people. Methods developed for the NIC pilot may contribute to a more comprehensive national HIV/AIDS surveillance system.

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