



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Washington, D.C. 20201

SEP -9 2008

The Honorable Henry A. Waxman  
Chairman, Committee on Oversight and  
Government Reform  
U.S. House of Representatives  
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your follow-up letters regarding the Centers for Disease Control and Prevention's (CDC) "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings" (*2006 Revised Recommendations*). CDC and the Health Resources and Services Administration (HRSA) have collaborated to address your questions regarding estimates of the number of new HIV infections that will be identified through the *2006 Revised Recommendations*, the increased demand for services, and how newly diagnosed individuals will be linked to prevention and care services. Responses to these questions are enclosed. Please excuse the delay of this response.

As you know, the *2006 Revised Recommendations* are intended to help the estimated 250,000 to 300,000 HIV-infected Americans who are unaware of their infection to learn their HIV status and access life-saving treatment and prevention services. The recommendations are based on best practices, and are intended to comply fully with the ethical principles of informed consent and the changing landscape of prevention and treatment options for persons living with HIV.

Thank you for your interest in this important health issue.

Sincerely,

Julie Louise Gerberding, M.D., M.P.H.  
Director  
Centers for Disease Control  
and Prevention

Elizabeth M. Duke, Ph.D.  
Administrator  
Health Resources and  
Services Administration

Enclosure

**Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA) Responses to the December 20, 2007, Letter From Representative Henry A. Waxman, Chairman, Committee on Oversight and Government Reform**

*1. Provide an estimate of the number of people who will be identified as HIV positive annually under the new guidelines, incorporating estimates based on both CDC and non-CDC funded efforts.*

At this time, CDC has insufficient data on which to base an estimate of how many HIV-infected persons might be identified by non-CDC funded efforts. However, systems are in place to obtain this information in the future. Our principal source of HIV/AIDS diagnosis data, CDC's HIV/AIDS Reporting System, collects information on facility of diagnosis. Using data from this system, CDC will be able to assess trends in diagnoses from health care settings in States with mature HIV surveillance systems. Because of differences in adoption of confidential name-based HIV surveillance and reporting delays from the States, national figures are not yet available.

In an effort to support implementation of the recommendations, CDC has provided supplemental funds to areas with a high burden of AIDS; this funding is aimed at expanding HIV testing in communities disproportionately affected by HIV/AIDS. The 23 jurisdictions that received these funds expect to identify a total of more than 20,000 additional HIV-infected persons. CDC has encouraged these programs to seek third-party reimbursement when possible, reserving CDC funds to underwrite costs of testing for uninsured persons. For example, New York and California have announced explicit policies for Medicaid reimbursement for HIV screening.

Thus, these 20,000 persons represent a minimum estimate of the number of newly identified HIV cases based on CDC and non-CDC funded efforts. Estimates from the Indian Health Service (IHS) and the Veterans Affairs (Appendix 1) are not explicit regarding the number of cases that will be identified per year, but specify a range of 7,500 to 30,000 for the total number of beneficiaries with undiagnosed HIV infection.

Other sources of data provide some indication of the yield of screening programs. Several analyses of the results of HIV screening in health care settings have been reported in the literature, at CDC's December 2007 National HIV Prevention Conference, and at the 2008 Conference on Retroviruses and Opportunistic Infections (See Table below). These suggest a median yield of 1 percent from HIV screening programs, with a wide range depending upon venue and geographic location.

Setting	Number of Projects	Total Tested	Number of New HIV Positive	% Positive	Median % Positive	Range
Emergency Departments	13	64,552	639	0.99%	1.04%	0.27%-1.93%
Primary Care	5	7,233	22	0.30%	0.17%	0.05%-0.95%
Hospital/Ambulatory	5	103,233	967	0.94%	1.73%	0.34%-3.67%
HIV/STD Clinics	4	5,634	85	1.51%	4.61%	0.39%-11.41%
Prisons	4	10,279	219	2.13%	0.95%	0.0%-3.63%
Mental Health Clinics	1	588	23	3.91%		
<b>Total</b>		<b>191,519</b>	<b>1,955</b>	<b>1.02%</b>	<b>1.02%</b>	<b>0.0%-11.41%</b>

Using local funds, several jurisdictions, notably New York City, Washington DC, Oakland, and Los Angeles, California have undertaken major initiatives to increase HIV screening in health care settings. Early results from these efforts indicate the number of HIV-infected persons identified in multiple health care settings has more than doubled; however, these efforts have not been accompanied by systematic data collection.

CDC has devised plans to use existing surveys for monitoring and evaluating the adoption of the *CDC Revised Recommendations*.

The Assessment of HIV Testing in Clinical Settings (AHITS) is an 18-month (September 2007-March 2009) project directed by CDC through a contract with a private vendor. AHITS will: 1) determine the extent to which HIV testing is conducted in health care settings and HIV-infected individuals are identified; and 2) assess programmatic activities supported by CDC's testing initiative to promote HIV testing in health care settings, identify barriers to these activities and the strategies used to address them. The project will first establish baseline data for HIV testing at the national level before the release of the *CDC Revised Recommendations* in September 2006 using existing national data sources (outlined below) to quantify HIV testing in the United States and in CDC-funded State and municipal jurisdictions. The project will also provide CDC grantees programmatic activities to promote HIV testing in clinical settings. In-depth qualitative analysis will be conducted in six health department jurisdictions.

CDC will also utilize the following surveys of testing behavior. These surveys do not ask about test results, so they will yield information about changes in testing, but not new HIV diagnoses:

- The National Health Interview Survey (NHIS) is a nationally representative, household-based probability sample of the U.S. population conducted by the National Center for Health Statistics (NCHS). The NHIS conducts annual interviews to estimate the number of persons ever tested for HIV, the number tested in the last 12 months, and the location of testing. These surveys provide a consistent and

reproducible measure to monitor changes in testing rates and testing venue. Rates of HIV testing have remained relatively unchanged from 2000 to 2005, with modest increases in testing rates for white and racial and ethnic minority females<sup>1</sup>, perhaps a result of CDC's prior recommendations for universal testing of pregnant women. Results from the 2007 survey should be available for analysis in mid-2008.

- The Behavioral Risk Factor Surveillance System (BRFSS), conducted by the CDC, is an ongoing, State-based, random-digit-dialed telephone survey of the U.S. civilian and non-institutionalized population over age 18 years. State data from BRFSS are combined to produce national estimates. BRFSS has included questions about HIV testing since 1988, including month, year, and location of last test. Data from 2005-2006 are currently being analyzed to provide baseline information; 2007 data, representative of the first year after the *CDC Revised Recommendations* were issued, will be available for analysis in June 2008.
- The National Survey of Family Growth (NSFG), also conducted by NCHS, is a household survey of persons aged 15-44 years which provides national estimates of factors related to family life, pregnancy, and reproductive health. NSFG also includes questions about HIV testing; survey results from 2006-2008 will be released in 2009.

Two additional NCHS surveys, the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS), are national surveys designed to provide objective, reliable information about the provision and use of ambulatory medical care services in the United States. NAMCS findings are based on a sample of visits to non-Federally employed physicians who are primarily engaged in direct patient care. Data are collected from the physicians, rather than from patients, to provide an analytic base that expands information collected through other NCHS surveys. The survey also provides data on the demographic characteristics of patients and services provided, including information on diagnostic procedures. NHAMCS findings are based on a national sample of visits to the emergency departments and outpatient departments of non-institutional general and short-stay hospitals, exclusive of Federal, military, and Veterans Administration hospitals. Hospital staff completes Patient Record forms for a systematic random sample of patient visits during a randomly assigned 4-week reporting period. Data obtained includes demographic characteristics of patients, expected source(s) of payment, physicians' diagnoses, and diagnostic/screening services. Both surveys included information on HIV serology on the patient record form until 2006. The most recent data from 2004 revealed

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<sup>1</sup> Osterman J, et al, Trends in HIV Testing and Differences Between Planned and Actual Testing in the United States, 2000-2005. *Arch Intern Med.* 2007;167(19):2128-2135.

that HIV serology was performed during less than 0.5 percent of visits by persons age 15-64.<sup>2</sup> Data on HIV serology was not collected for the 2007-2008 survey cycle, but will be restored with the 2-year cycle beginning 2009. Baseline data on outpatient HIV testing available through 2006 will be compared with data gathered in the 2009-2010 cycle.

*2. Provide an analysis of increased demand for HIV/AIDS services within Medicaid, Medicare, the Indian Health Service, and the Veterans Administration (VA) system.*

An analysis of increased demand for HIV/AIDS services by payor source requires an estimate of the insurance status of the more than 20,000 HIV-positive individuals who will be identified annually as a result of the *CDC Revised Recommendations*. The estimate of persons tested as a result of the CDC funded initiative - at least 20,000 - was used as a minimum floor for the following analysis. Estimates of insurance status can be extrapolated from previous HIV-related studies and annual program data collected by the Ryan White HIV/AIDS Program.

The U.S. Census Bureau's 2006 Report on *Income, Poverty and Health Insurance Coverage in the United States: 2006* provides estimates on the percentage of the people with health care insurance coverage by type.<sup>3</sup> In 2006, an estimated 67.9 percent of people in the general civilian population had private health insurance, 13.6 percent were Medicare enrollees, 12.9 percent were Medicaid recipients, and 3.6 percent received health care through the military. The estimated percent of people with no insurance coverage was 15.8 percent in 2006. However, insurance status among people living with HIV/AIDS differs from that of the general population.

Findings from the HIV Cost and Services Utilization Study (HCSUS, 1998), the only nationally representative study of people with HIV/AIDS in care, provides an estimate of the insurance status of patients. In a 1998 paper, the HCSUS study group estimated that 19 percent of the HIV-positive patients in care were covered under Medicare with or without other insurance, 32 percent had private insurance, 29 percent were Medicaid enrollees, and 20 percent were uninsured.<sup>4</sup> More recent data from the HIV Research Network (HIVRN), a non-representative multi-state study of HIV clinical sites, found that among the more than 14,000 HIV-infected patients in the study, 16 percent had private insurance, 34 percent were Medicaid enrollees, 17 percent were covered by Medicare, and 28 percent were uninsured. Insurance status was unknown for 5 percent of the patients in the study.<sup>5</sup>

Additional data on the insurance status of HIV-positive patients is available from the Ryan White HIV/AIDS Program Annual Data Report (RDR). Each year, Ryan White HIV/AIDS Program Funded Grantees and their service providers report on the number and socio-demographic characteristics of the clients served in their organizations. As seen in the table below, insurance

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<sup>2</sup> McCaig LF, Nawar EN. National Hospital Ambulatory Medical Care Survey: 2004 emergency department summary. Advance data from vital and health statistics; no 372. Hyattsville, MD: National Center for Health Statistics. 2006.

<sup>3</sup> DeNavas-Walt C, Proctor, BD, Smith J, U.S. Census Bureau. Current Populations Reports, P60-233, *Income, Poverty, and Health Insurance Coverage in the United States: 2006*, U.S. Government Printing Office, Washington, DC, 2007.

<sup>4</sup> Bozzette SA, Berry S, et al. Care of HIV Infected Adults in the United States. *JAMA* 339 (26): 1897, 1998.

<sup>5</sup> Fleishman JA, Gebo KA, et al. Hospital and Outpatient Health Services Utilization Among HIV-Infected Adults in Care 2000-2002. *Medical Care* 43 (9 suppl):III-40, 2005.

status of clients served by the Ryan White HIV/AIDS Program Funded Organizations has remained constant over the 5-year period, 2002-2006.

**Ryan White HIV/AIDS Program  
Health Insurance Coverage Status of HIV-Positive Clients Served, 2002-2006**

<b>Health Insurance Coverage Status</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>
Private	11%	10%	11%	11%	11%
Medicare	11%	10%	10%	11%	12%
Medicaid	36%	36%	35%	35%	35%
Other public	9%	9%	9%	8%	8%
No insurance	32%	33%	32%	32%	32%
Other	2%	2%	3%	3%	3%

On average, 11 percent of clients served by these Organizations have private insurance, 11 percent are Medicare recipients, 35 percent are Medicaid enrollees, 8 percent are covered through other public programs including State-funded insurance plans, military health care (TRICARE), State Children’s Insurance Program (SCHIP), IHS, and Veterans Administration (VA), 32 percent of clients served by Ryan White HIV/AIDS Program Funded Organizations were uninsured, and 3 percent reported other sources of insurance. As expected, the percentage of uninsured HIV-positive persons receiving services is higher in Ryan White HIV/AIDS Program Funded Organizations than reported in the cited studies.

Based on data from the cited studies and the Ryan White HIV/AIDS Program Data Reports, it is estimated that 11 to 16 percent of those newly diagnosed HIV-positive, as a result of CDC funded efforts to implement routine testing, will have private insurance. Eleven to 17 percent will be Medicare recipients, 29 to 35 percent will be Medicaid enrollees, 25 to 32 percent will have no insurance, and 3 to 8 percent have other types of insurance including State-funded insurance plans, military health care (TRICARE), SCHIP, IHS, and VA benefits. It is important to emphasize that these estimates are based, in part, on Ryan White HIV/AIDS Program data (the best data currently available) and may not provide a complete picture of the demand for HIV/AIDS services. The utility of Ryan White HIV/AIDS Program data is limited by **duplicated client counts**. Data as collected and reported by individual Ryan White-funded service providers are generally unduplicated. However, since an individual client may receive services from more than one provider, and because the data report does not currently include client-level data with unique identifying information, there is no way of knowing that the counts of individuals served by one provider are not also included in the counts of another service provider. Thus, aggregating the provider data to the national level results in duplicate client counts.

3. Provide an analysis of increased demand for Ryan White and AIDS Drug Assistance Program (ADAP) services and other HIV/AIDS services among people without insurance.

## **Estimate of the Demand for the AIDS Drug Assistance Program**

The CDC has estimated that at least 20,000 additional HIV-infected persons will learn their serostatus annually as a result of CDC funded efforts to implement the *Revised Recommendations*. CDC estimated that approximately two-thirds (66.67 percent) of those aware of their status are engaged in ongoing care.<sup>6</sup> This means that of the 20,000 newly diagnosed, approximately 13,334 would enter ongoing care. ADAP serves about 25 - 28 percent (or 3,333 – 3,733) of HIV-infected persons in ongoing care. ADAP provides coverage where insurance does not. The proportion of persons served by the ADAP program is consistent with the overall projections of uninsured persons living with HIV/AIDS in the U.S. The HIV Cost and Services Utilization Study (HCSUS), the only nationally representative study of people with HIV/AIDS in care, found that one fifth of these persons were uninsured. Analysis of data from the HIV Research Network (HIVRN), a multi-state study of HIV clinic sites, found that 28 percent of the 14,000 patients with HIV in the study were uninsured.

## **Estimate of the Demand for Ryan White HIV/AIDS Program and other HIV/AIDS services among people without insurance**

Several assumptions are used to estimate the increase demand for Ryan White HIV/AIDS Program and other HIV/AIDS services among people without insurance. These assumptions include:

- An estimated two-thirds of HIV-positive persons who learn their serostatus in 2008 will enter care. At least 20,000 persons are expected to learn of their infection as a result of CDC's funded efforts to implement the *Revised Recommendations*. Thus, at least 13,334 of the newly identified HIV-positive persons will enter care.
- Of those entering care, an estimated 25 to 28 percent (3,333 – 3,733) will be uninsured and may seek one or more services from the Ryan White HIV/AIDS Program and/or other safety net programs.

*4. Provide information regarding how newly identified HIV positive patients will be linked into care and treatment, including any variation among different health-care settings, and whether and how CDC will monitor the effectiveness of such linkage. Please include any guidelines that have been developed for specific health-care settings.*

CDC's principal source of HIV/AIDS diagnosis data, the HIV/AIDS Reporting System, can be used for monitoring linkage to care for HIV infected persons. In States with confidential name-based HIV surveillance, most laboratories report positive HIV tests, and also CD4 T-cell count and HIV viral load data. CDC monitors the number and proportion of patients with a CD4 count or viral load within 12 months of diagnosis as a surrogate marker for entry into care. These data

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<sup>6</sup> CDC, Fleming, P. L., et al., .HIV Prevalence in the United States, 2000., 9th Conference on Retroviruses and Opportunistic Infections, Oral Abstract, 2002

have been reported by age, race, sex, and transmission category in CDC's Supplemental Surveillance Reports.<sup>7</sup> Because facility of diagnosis is a routine data element collected during surveillance, this can be used to monitor the effectiveness of linkages from different health care settings. Using these markers, the New York City HIV Surveillance Program analyzed linkage to care by facility of diagnosis. They found that persons diagnosed at public or community-based sites were half as likely to enter care as were persons diagnosed in health care settings<sup>8</sup>. In addition, more than 80 percent of persons who received an HIV diagnosis in CDC's demonstration projects of HIV testing in health care settings were linked into care.

CDC has established a cooperative agreement with the HRSA-funded AIDS Education and Training Centers (AETCs), National Evaluation and Resource Centers at the University of California, San Francisco, and the University of Medicine and Dentistry of New Jersey to develop and pilot test an evaluation toolkit for health care providers. This toolkit will assess patient preferences, satisfaction and acceptance of opt-out HIV testing. Domains included in the patient instrument include patient perspectives on: reasons for accepting or declining an HIV test; pressure/coercion to take the test; confidentiality and privacy; satisfaction with the testing process; and stigma. The toolkit is designed to be used independently in a variety of health care settings, including hospitals, private primary care settings, and sexually transmitted disease (STD) clinics.

CDC has also established an agreement with the AETC National Clinicians Consultation Center, which hosts a "warmline" for clinician inquiries about the management of HIV-infected patients. Providers unfamiliar with HIV who encounter patients with a new HIV diagnosis can seek consultation from the warmline and referral to national databases of HIV specialists maintained by the HIV Medicine Association and the American Academy of HIV Medicine.

CDC is facilitating the development of implementation guidance for HIV screening in specific health care settings which include procedures for linkage to care. Each guidance module relies on contributions from practicing professionals who have experience with HIV screening in the relevant venue. Modules are under development for inpatient settings, community health centers, adult primary care settings, adolescent medicine and pediatrics, family planning, labor and delivery, STD clinics, substance abuse treatment centers, and correctional facilities. The web-based guidance module for Emergency Departments has been completed,<sup>9</sup> and those for community health centers and correctional facilities are in the final stages of review and public comment.

In addition to the care linkage activities cited above, HRSA and CDC have funded multi-site projects to develop, implement, and evaluate interventions to link and retain HIV-positive patients in medical care. The CDC funded Antiretroviral Treatment Access Study (ARTAS) and Antiretroviral Treatment Access Study . II (ARTAS II) evaluated a brief case management

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<sup>7</sup> Centers for Disease Control and Prevention. Reported CD4+ T-lymphocyte results for adults and adolescents with HIV/AIDS.33 states, 2005. HIV/AIDS Surveillance Supplemental Report 2005;11(No. 2). Available at: <http://www.cdc.gov/hiv/stats/hasrlink.htm>.

<sup>8</sup> L. Torian, E. Wiewel, D. Hanna, J. Sackoff. Risk factors for failure to initiate primary care after diagnosis of HIV, New York City: impact of transmission risk and site of initial diagnosis on successful transition to care. [Abstract THPDB03] 16th International AIDS Conference, Toronto, Canada.

<sup>9</sup> <http://www.edhivtestguide.org>



intervention to link newly diagnosed HIV-infected individuals to medical care.<sup>10 11</sup> Delivered in health departments and community-based organizations, the intervention includes up to 5 case management sessions over a 90-day period. Among the HIV-infected persons who participated in ARTAS-II, 79 percent had at least one visit with an HIV clinician within the first 6 months of enrollment in the program.

HRSA, through its Special Projects of National Significance Program, funded a national 5-year multi-site Targeted HIV and Intervention Model Development (Outreach Initiative) to engage and retain hard-to-reach HIV-positive populations in care.<sup>12</sup> Ten demonstration sites were funded to develop, implement and evaluate strategies to engage and retain underserved HIV-positive clients in HIV primary medical care. Strategies included outreach, motivational interventions, case management, and other ancillary services. Results from the initiative's multi-site evaluation found that program participants were half as likely to have a substantial gap (defined as 4 months or more) in primary care when they experienced 9 or more outreach program contacts with the first 3 months in these programs.<sup>13</sup> Cabral and colleagues suggest that these findings can be used to enhance the effectiveness of programs designed to link and retain HIV-positive patients in medical care.

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<sup>10</sup> Gardner LI, Metsch LR, et al. Efficacy of a Brief Case Management Intervention to Link Recently Diagnosed HIV-infected Persons to Care. *AIDS*, 19(4):423-31, 2005.

<sup>11</sup> Craw JA, Gardner LI, et al. Brief Strengths-Based Case Management Promotes Entry into HIV Medical Care: Results of the Antiretroviral Treatment Access Study-II. *JAIDS*, 2008, Feb 14 [Epub ahead of print].

<sup>12</sup> Rajabiun S, Cabral H, et al. Program Design and Evaluation Strategies for the Special Projects of National Significance Outreach Initiative. *AIDS Patient Care and STDs*, 21 (Supplement 1): S-9, 2007.

<sup>13</sup> Cabral HJ, Tobias C, et al. Outreach Program Contacts: Do They Increase the Likelihood of Engagement and Retention in HIV Primary Care for Hard-to-Reach Patients? *AIDS Patient Care and STDs*, 21 (Supplement 1):S59-67, 2007.

## Appendix 1. Veterans Affairs (VA) and Indian Health Service (IHS) Estimates

Current Federal law mandates that all VA patients must provide written informed consent and receive pre-test counseling (documented in the medical record) in order to be tested for HIV. CDC and HRSA have heard from a number of providers that these requirements serve as a barrier to early diagnosis of HIV infection. In fact, in a study presented in 2006, researchers found that 55 percent of 3,760 veterans newly diagnosed with HIV had immunologic AIDS at the time of diagnosis.<sup>14</sup> VA does not have an official estimate of the number of undiagnosed HIV infected veterans, though the number could range from 7,500 to 30,000. The 7,500 estimate is based on the CDC's estimate that only 75 percent of HIV-infected persons in the U. S are aware of their serostatus (VA reported 22,638 HIV infected veterans in care in 2006). The larger estimate, 30,000, is derived from the assumption that approximately 1 percent of the 5.3 million veterans in care are infected with HIV. **[NOTE: BASED ON THE ASSUMPTION PROVIDED (I.E., 1 PERCENT INFECTED), THE UPPER-BOUND ESTIMATE WOULD BE \$53,000.]**

Currently IHS screens approximately 16,000 prenatal women for HIV each year, with the number increasing annually. Over the past 4 years, there have been an average of 222 (95 percent confidence interval 179, 264) new HIV/AIDS cases identified per year in IHS data, although few of those cases have been found as a result of current screening. Approximately 28 percent of new HIV cases per year have occurred in women between 15 and 45 years of age, the ages most likely to have been screened routinely. Assuming that a proportion of those cases occur in women identified as being at high risk and not found from routine screening, the 28 percent estimate should be considered an overestimate of HIV cases found through routine screening. Therefore, the estimated number of additional people with no high risk for HIV who might be detected through routine, universal screening that included men would most likely be similar to the number of women currently detected through routine prenatal screening, or 62±12 persons per year.

### Of note:

This is a very general estimate, the trends of HIV incidence and prevalence may show very different results if wider testing is implemented.

This estimate only pertains to IHS data, and is not an estimate of the American Indian/Alaska Native (AI/AN) population; many AI/AN patients are seen in non-IHS health facilities.

CDC and HRSA utilize CDC statistics at the State-level for data collection; however we do have the means to collect data at IHS facilities and potentially on a national level giving us important local data. There is anecdotal information that there may be a rising incidence in more rural areas to include Tribal lands within our own reporting system. Our national database is currently under development.

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<sup>14</sup> Gandhi N, Skanderson M, Gordon K, Concato J, Justice A. Delayed Presentation for HIV Care among Veterans: An Opportunity for Intervention. (Abstract 924) 13th Conference on Retroviruses and Opportunistic Infections; 5-8 February, 2006: Denver, CO.