



METRICS AND EVALUATION MEASURES FOR MONITORING THE IMPLEMENTATION OF ROUTINE HIV TESTING IN THE U.S.

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BACKGROUND AND INTRODUCTION

In 2006, the Centers for Disease Control and Prevention (CDC) recommended routine, opt-out HIV testing for all persons aged 13-64 and pregnant women in clinical settings in the U.S.[1]. CDC estimates that 21% of persons infected with HIV are unaware of their infection[2]. The purpose of these recommendations are to improve detection of HIV in order to identify persons who are infected but unaware of their infection and to link infected persons to care earlier. In the years following the recommendations, a number of program models for implementing opt-out testing have been identified and much of the work to scale-up HIV testing has concentrated on program development and policy issues related to routinizing testing. Now, three years after the recommendations and increased implementation of routine testing, questions remain about how to evaluate testing programs and the metrics that should be used to identify the progress of programs including identifying infected individuals, linking them to care, getting them into care earlier and measuring retention in care.

As part of a series of meetings on maximizing opportunities for HIV diagnosis and prevention, which began with a roundtable discussion of policies related to and models for routine testing programs[3], the Forum organized a roundtable discussion of metrics and evaluation measures for monitoring the implementation of routine HIV testing in the U.S. The roundtable follows discussions that took place at the November 2008 National Summit on HIV Diagnosis, Prevention and Access to Care [4] and brought together a panel to discuss the metrics needed to assess expansion of HIV testing and efforts to link individuals to care since the 2006 CDC recommendations.



The objectives for this roundtable were:

1. To identify the metrics and measurements needed to evaluate and monitor the implementation of routine HIV testing.
2. To build a framework that will allow improvements at the program and system level to maximize impact of routine HIV testing
3. To recommend a set of metrics that can be employed across a variety of clinical settings that reflect testing rates, entrance into care and stage of disease at time of diagnosis.
4. To see where gaps in information exist and what can be done to improve information exchange.

A discussion of the different metrics needed to best identify the success of expanding HIV testing must acknowledge the wide variety of systems involved in HIV screening in the U.S.-including individual clinics (private and public) or emergency departments, hospitals and large hospital systems, managed care organizations, local and state health departments, and federal agencies such as CDC. Key to the success of identifying metrics that would be measurable across a wide array of systems such as these is identifying the common elements of information collected by systems, as well as the need for and the ability to calculate such measures.

NUMBERS OF PERSONS TESTED

National Perspective: The Centers for Disease Control and Prevention

CDC uses a number of different data resources to understand the impact of HIV at individual and community levels. In 2006, the CDC issued recommendations to implement HIV screening as a part of routine medical care for all individuals aged 13-64[1]. Data collection sources such as the National Health Interview Survey (NHIS), HIV surveillance systems, and HIV Counseling and Testing System (CTS) provide insight to HIV testing practices, incidence and prevalence of HIV, information about testing sites, and access to medical care and treatment.

Examples of Sources for Collecting Number of Tested Data

- National Health Interview Survey (NHIS)
- Behavior Risk Factor Surveillance Survey (BRFSS)
- Youth Risk Behavior Surveillance System (YRBSS)
- HIV Counseling and Testing System (CTS)
- National Ambulatory Medical Care Survey
- National Hospital Ambulatory Medical Care Survey
- Claims data
- Health Research & Educational Trust Surveys

Source of HIV Tests and Positive Tests

- 40% of adults age 18-64 have been tested
- 18 million adults age 18-64 tested annually in U.S.

	HIV tests*	HIV+ tests**
Private doctor/HMO	53%	17%
Hospital, ED, Outpatient	18%	27%
Community clinic (public)	5%	21%
HIV counseling/testing	5%	9%
Correctional facility	0.4%	5%
STD clinic	0.1%	6%
Drug treatment clinic	0.4%	2%

*National Health Interview Survey, 2006

**Suppl. to HIV/AIDS surveillance, 2000-2003

Adapted from: Centers for Disease Control and Prevention

National Health Interview Survey

The National Health Interview Survey (NHIS) is an annual cross-sectional multistage probability survey based on sampling of households [5]. NHIS provides valuable data on a broad range of health measures including HIV testing practices. Respondents are asked questions related to HIV testing habits including questions about having ever been tested for HIV and last month and year of an HIV test[6]. The findings from the CDC-led analysis showed that during 2002-2006, the percent of persons reporting ever having tested for HIV and having tested in the preceding 12 months remained constant at 40% and 10%, respectively. This suggests some respondents have been tested more than once during the same period, while a greater proportion did not seek HIV testing or remain untested. Data from the 2007 NHIS indicate an increase in the number of persons ever tested from 39.9% in 2005 to 41.3% in 2007; those who reported being tested in the last 12 months increased from 10.4% in 2005 to 10.7% in 2007[7]. A potential limitation of the NHIS data is the possibility of underreporting of testing due to recall bias. Respondents were asked to recall information over a 12-month period. Additionally, because the NHIS is a household survey, homeless, incarcerated, and others not living in a household are not included in the survey. Despite the limitations, the analysis is an indication of early progress in HIV testing since the 2006 recommendations.

In addition to information on testing habits, the survey includes a question about testing locations (i.e. emergency departments, private doctor, STD clinic). According to the 2006 NHIS, 76% of those tested report having had an HIV test in health-care settings. Data from the 2003 Supplement to HIV/AIDS Surveillance suggest that approximately 65% of HIV-infected persons learned of their HIV infection status through testing in health-care settings[7].

In 2007, the CDC funded expanded testing programs in 26 different jurisdictions, with a major focus on promoting testing in clinical settings [8]. In the first year, 21 jurisdictions



reported approximately 450,000 persons tested. Of those tested, approximately 4,000 people were newly diagnosed with HIV[7]. Each jurisdiction collected information from all test takers including general demographic information (e.g. year of birth, race and ethnicity, age), self-reported HIV status, testing date, testing technology, test result, and site type. Healthcare providers collected additional information from HIV-positive testers on referral, entry to care, risk (exposure), and incidence related questions (i.e., history previous HIV-negative tests and antiretroviral therapy). Data on risk and incidence related questions were collected for surveillance purposes.

Managed Care/Large Health Care Systems

As of July 2007, there were 602 Health Maintenance Organizations (HMOs) and nearly 1,300 health insurance plans[9]. Great variability exists in the number of health plans represented in each state and the status of a plan (non-profit versus for-profit plan) which is dependent on individual state laws.

An ongoing issue for datasets coming from managed care organizations is that data on HIV testing and identifying patients at risk are limited. Some companies and organizations cite confidentiality and legal issues as reasons for not collecting data, making it very difficult to assess HIV testing for the various plans[10]. Furthermore, no data exist on the consistency of coverage or reimbursement rates. The introduction of new Healthcare Effectiveness Data and Information Set (HEDIS) measures by the National Committee on Quality Assurance (NCQA) can change the way this information is collected. While HIV screening is not a HEDIS measure, it has the potential of providing quantitative data and solving some of the challenges of reporting data on HIV screening among insurance companies[10]. For hospital specific measures, another approach to obtaining data on HIV reporting and testing rates is creating a measure for the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Information on testing patterns in hospital settings will also be available from national surveys including the National Hospital Ambulatory Medical Care Survey[11]. Additionally, public reporting of the stage of disease at time of diagnosis is another critical measurement needed to understand the disease's impact in the United States[10].

Even though some companies are studying testing rates across their programs, simply providing this information will not be enough. Quality improvement measures are necessary to evaluate the effect of HIV testing in managed care plans. In addition, creating or modifying current organizational guidelines for HIV testing will also aid in obtaining additional information, and improving quality of care. For example, Kaiser Permanente created new HIV testing guidelines that are an expansion of the U.S. Preventive Services Task Force (USPSTF) recommendations on HIV testing [10, 10]. Recently, CMS proposed including national coverage of HIV testing as a covered benefit under preventative health

services[12]. Like the USPSTF, insurance plan policies tend to follow the coverage formularies of CMS.

Kaiser Permanente Profile

- 2nd largest provider of HIV care in the U.S.
- More than 9 million members across the U.S. (2/3 in CA)
- Greater than 18,000 active HIV-infected patients
- Slightly more than 200 HIV-infected patients \leq 19 years old
- Greater than 100,000 HIV patient-years in the system
- Mortality is significantly less (1.6%) than the national average (3.4%)

Source: Kaiser Permanente

For Kaiser Permanente and other HMOs, the number of patients who are living with HIV is increasing. In the modern era of HIV treatment, Kaiser Permanente's approach to HIV care is multi-disciplinary, including HIV specialists, case managers, allied healthcare providers, social workers, health educators, mental health support and regional coordinators for larger regions. In 2005, Kaiser Permanente introduced an HIV Quality Improvement Program aimed at achieving the highest quality of care possible[10]. The emphasis is on viral control and prevention of opportunistic infections and co-morbidities through these four mechanisms: (1) improving HIV testing and case identification, (2) getting patients into care and remaining in care, (3) aiming for maximal viral control and improved CD4 counts, and (4) preventing short and long-term toxicities. The program should lead to longer patient survival, greater patient satisfaction and from an economic standpoint, greater efficiencies in retention in care. The program has a variety of measures, some of which will be HEDIS measures.

The two measures under the "Diagnosing HIV" category (testing for HIV among patients diagnosed with STD and determining the percentage of new HIV diagnoses who met AIDS criteria) are not currently HEDIS measures but could be beneficial in the assessment of primary care. If these measures do become HEDIS measures, they will have the potential to make HIV testing more routine in clinical settings and hold insurance plans and hospitals accountable for it.

HIV testing rates have increased over time for Kaiser Permanente. Prenatal testing and HIV testing of women during routine medical care contributed significantly to the increase in HIV testing rates; but only approximately 20% of the total Kaiser Permanente patient population has ever been tested for HIV[10].

Despite the successes in HIV testing, a variety of challenges remain. Regional variation may not accurately describe local issues and testing patterns. Lack of appropriate systems and support is another key challenge to the success of testing.



Implementation of organizational and support systems are critical to ensure that individuals are being tested, linked to care, and most importantly, remaining in care. Fortunately, integrated healthcare systems have the ability to diagnose and link a high percentage of clients to medical care.

Various efforts were recommended to improve quality measures in HIV testing in managed care or large health systems including:

- identifying areas that would benefit from quality improvement efforts
- repeating and tracking measures over time
- evaluating differences across health systems
- reconciling measures with other national measures (e.g., NCQA, HRSA, or AMA)
- developing national NCQA HIV testing quality measures

Discussion Points

Given the challenges that accompany the standardization of HIV screening and its measurement, numerous organizations, agencies, and foundations are providing financial and operational support for implementation of HIV screening. For example, the Veterans Administration is currently supporting HIV screening programs across the country and Congress most recently changed federal law with the elimination of the requirement for written informed consent for HIV testing and specific pre- and post-test counseling of VA patients[13]. Emergency room HIV testing programs are another example

where a case was made to conduct HIV testing in spite of perceived challenges and obstacles[14].

Differences exist in an institution's ability to measure HIV testing. Some may have the capacity to bring on extra staff to provide monthly updates on progress and areas of improvement. For example, the NYC Health and Hospitals Corporation hired a quality administrator to update departments, the CEO, and the NYC Department of Health and Mental Hygiene on testing initiatives on a monthly basis. This provided valuable information on the success and weaknesses of the program, data to support the increase or decrease of funding, and held individuals accountable for decreases in performance. Conversely, many institutions have financial constraints and have to rely on existing staff members to provide this information, which may be

problematic in an environment where the staff is already overburdened. Many lack resources, professional expertise, and infrastructure to track and provide information within their institution. All of these factors contribute to the variability among and capacity to conduct and monitor successful HIV testing initiatives.

Electronic medical records can be a useful tool in collecting information on HIV testing, linkage to care, and retention in care. In particular, electronic medical records could be a useful tool to monitor and measure things such as:

- testing rates on a more real-time basis
- test acceptability among patients
- number of missed opportunities before diagnosis and clinical parameters of patients at time of diagnosis
- number of HIV-infected persons linked to care.

The use of electronic medical records has its own challenges including lack of funding to implement and sustain systems and manpower to pull necessary data to evaluate HIV testing initiatives. Furthermore, there must be a standardization of entries in the electronic medical records or it could be prohibitively expensive to design individual queries to obtain information needed.

CDC Surveillance Case Definition for HIV Infection in Adults and Adolescents

- Stage 1: Laboratory confirmation of HIV infection and CD4 count $>500/\mu\text{L}$ or $>29\%$
- Stage 2: Laboratory confirmation of HIV infection and CD4 count $>200/\mu\text{L}$ and <500 or $>14\%$ and $<29\%$
- Stage 3: Laboratory confirmation of HIV infection and CD4 count $<200/\mu\text{L}$ or $<14\%$

Manufacturers of HIV test kits can provide information on the number of tests conducted with data on the number of test kits sold. However, the problem with test kit data is that it only provides the number of tests and not the actual number of persons tested. Whether continuing to put effort into examining the number of tests conducted



HIV Care Quality Measures 2005/2006 and 2007

Diagnosing HIV

- Testing for HIV among patients diagnosed with STD
- Determining % of new HIV diagnoses who met AIDS criteria (CD4 < 200/ μ L)

Getting Patients into Care

- Time until newly diagnosed KP HIV-infected members receive 1st CD4 count

Care Processes

- % of HIV-infected members seen at least twice annually (at least 60 days apart each visit)*
- % of HIV-infected members with CD4+ cell count performed at least once every 6 months*
- % of HIV-infected members with CD4 < 200/ μ L taking PCP prophylaxis*
- % of HIV-infected members with CD4 < 200/ μ L taking HAART (will increase to < 350)*

Care Results

- % of HIV-infected patients on HAART who have maximal viral control*
- % of HIV-infected patients on HAART with appropriate adherence

*--to be HEDIS measure

and the percent of populations tested depends on regional and population variability as well as need and available resources.

One of the major strategic goals at the CDC is monitoring those who are undiagnosed and getting them into care. Monitoring positivity rate also provides critical information on the success of the testing initiatives/programs, linkage to care rates, and need such as supportive services, outreach, and preventives services. However, with successful expansion of screening programs, positivity rates would be expected to decline (with more routine testing of lower risk persons) so such data need to be interpreted with caution.

STAGE OF DISEASE AT ENTRY INTO CARE

National HIV Surveillance

CDC collects information on the spectrum of morbidity and mortality through the National HIV Surveillance Program. Data collected through surveillance measures allow CDC to monitor first diagnosis, CD4 count, and viral load. Additionally the information collected allows CDC to estimate HIV incidence and monitor viral drug resistance. Information collected can be categorized by CDC surveillance case definition and allow for staging of disease, progression to AIDS, as well as follow-up through death and survival analyses. Surveillance information is also used to calculate life expectancies and disease prevalence estimates[15].

Case report forms include CD4 count closest to diagnosis, first CD4 count less than 200, and most recent viral load. Typically, when CD4 counts at time of diagnosis are analyzed and reported, a timeframe (e.g. within 3, 6 or 12 months of diagnosis) for reporting will be used to scale measures and present data. The timeframe for first CD4 counts is calculated based on date of HIV diagnosis

and date of (first) CD4 count. To be a true measure of CD4 "at diagnosis" it can be defined as first CD4 count within 3 months of diagnosis. Information on opportunistic infections can also be used to stage disease.

Data collection is complicated by a variety of reporting laws that vary by state and jurisdiction. CDC tracks current HIV surveillance reporting laws. Currently, of 59 areas with HIV surveillance programs (50 states, 6 cities, DC, Virgin Islands, Puerto Rico), 32 areas report all CD4 counts. The remaining areas report only CD4 counts less than 200 or less than 14%. 42 areas report all viral loads. 11 areas report only detectable viral loads and 6 areas do not report viral loads currently.

From the HIV surveillance system, CDC is capable of monitoring metrics for staging of disease and access to care. Metrics for access to care can also be considered in two ways: entry into care and regular care. Metrics for entry into care assessed through surveillance information can be defined by a reported CD4 count or viral load within 3 months of diagnosis. Alternately, regular care can be defined as a patient receiving two test results (CD4 or viral load) within the past year. Since not all states require laboratory reporting to health departments and the collection of CD4 and viral load vary between states, the ability to assess regular care is limited by data collection and data completeness. Additional means for assessing access to care may be available through managed care or health systems data, such as office visit reporting and claims reporting of visits with associated diagnoses.

HIV surveillance case report forms require reporting a patient's first CD4 count, but historically not necessarily the first viral load test (instead requiring most recent viral load); however, the data collection system accommodated collection of any viral load and case report forms are currently undergoing revision. In theory, staging of disease should be a measure that CDC would be able to assess if all CD4 counts were reported. However, in order to assess entry into care,



CDC would need to ascertain all viral loads rather than only the most recent.

Previous limitations of the CDC surveillance program software, HARS (HIV/AIDS Reporting System,) prevented jurisdictions from storing all measures collected allowing a limit of 10 viral loads and 20 CD4 counts per patient. New software has been deployed which allows the collection of all test results and which will allow CDC to collect more complete CD4 and viral load data. While these changes will improve surveillance data collection, the problem of underreporting (from laboratories to health department surveillance programs) remains. CDC continues to see issues related to data incompleteness in the proportion of cases that are unstaged or not in care (or potentially in care but do not have a CD4 or viral load reported). The surveillance priorities for CDC will be getting the first CD4 and viral load reported for each patient. Some states continue to collect information on opportunistic infections but states facing large amounts of reported CD4 and viral load results may be more likely to not collect opportunistic infection information. For these reasons, CDC continues to rely mostly on CD4 counts for staging of disease.

One reason that the timeframe (3, 6 or 12 months within diagnosis) becomes so critical for assessing staging is that it is unknown whether viral loads reflect values that were collected before treatment has begun or during treatment (when viral levels would decrease.) Additionally, the limited data on antiretroviral use collected through surveillance programs may not be reliable or complete. While CDC is able to assess the stage of disease at diagnosis, limitations in the HIV surveillance system prevent CDC from being able to assess quality of care or treatment.

Louisiana’s Model for HIV Surveillance

Louisiana began name-based HIV reporting in 1993 and was one of the earlier states to adopt the process. In Louisiana, reporting of all CD4 and viral loads has taken place since 1999. The state began rapid testing in 2003 and is expanding rapid testing to regional public hospital facilities primarily through emergency departments, but also to community health centers and STD clinics. Louisiana has approximately 1,100

to 1,200 new HIV diagnoses per year and in 2008 had CD4 counts for 74% of new diagnoses. The majority of lab reports coming into the state health department are electronic. In 2008, 87% of CD4 counts and 85% of viral load results were reported electronically which can improve the completeness of reporting and reduce data errors[16]. Louisiana typically uses measures within 6 months of diagnosis for measuring entry into care and uses the date of the first CD4 or viral load as a proxy for the date of entry into care. An additional measure used by Louisiana to monitor the Ryan White program in the state is the percentage of persons enrolled in ADAP with an undetectable viral load within 12 months of enrollment.

The main metrics used by Louisiana to monitor the degree to which late diagnosis is occurring are AIDS within 30 days of diagnosis and AIDS within 6 months of diagnosis. Additional metrics monitored by the state health department are the percent of persons with CD4 counts less than 50, percent of persons with CD4 less than 200 and median CD4 count within 6 months of diagnosis. Of particular interest for monitoring the distribution of disease in the state are measures looking at median CD4 by gender, race/ethnicity, age group, region of residence, risk exposure and facility of diagnosis. The majority of AIDS cases in Louisiana are identified by CD4 count, however a very small percentage of cases are identified as persons having an opportunistic infection. In 2007 in Louisiana, 60% of newly diagnosed individuals had CD4 counts less than 350 at diagnosis and would therefore be considered treatment eligible.

Additional metrics that the state health department uses to monitor the epidemic include positivity rates over time and between subgroups, percent new positives vs. previous positives, shifts in facilities of diagnosis, deaths within 6 months of diagnosis, percent of persons living with HIV who did not have a CD4/viral load in a 12 month period and percent of persons receiving Ryan White Part B services who had two or more CD4 counts that were at least 90 days apart within in a 12 month period.

Discussion Points:

An important consideration in the collection of HIV surveillance data at the state and local level is the completeness of data. Requirements for laboratory reporting of CD4 counts and viral load data differ between states. Health Department surveillance systems must continually monitor the quality of reported data and be vigilant for any detrimental changes in reporting (such as underreporting of CD4 due to clinic personnel changes). Health department surveillance programs rely on longitudinal data on CD4 counts in order to provide unmet needs assessments and to complete applications for HRSA funding.

AIDS at and within 6 Mos. of Diagnosis Louisiana, 2007			
	New Diagnoses	AIDS at Diagnosis	AIDS within 6 mos. of Diagnosis
Total	1,151	26%	34%
Female	353	22%	28%
Male	798	28%	37%
African American	830	25%	32%
Hispanic/Latino	54	41%	57%
White	247	26%	35%
<24	224	12%	17%
25-44	646	28%	35%
45+	281	34%	44%

Louisiana Office of Public Health, HIV/AIDS Program



One of the main challenges in choosing a metric for measuring late diagnosis and entry into care is choosing the timeframe (within 3, 6, or 12 months) to maximize comparability across data systems. CD4 counts are not necessarily the best indicator of the success of testing programs; expanding testing in some settings, like Emergency Departments, may identify more patients with longstanding disease and lower CD4 counts. Emergency Departments may only reach approximately 8% of eligible testing populations [17] and may tend to select symptomatic populations with low CD4 counts, but enhanced screening programs will reach people earlier. The consortium of Emergency Room Physicians providing HIV testing have published a set of recommendations for testing which recommend a set of measures for Emergency Departments that provide HIV screening[14]. One potential additional source of data to inform entry and retention into care is the Medical Monitoring Project (MMP) a representative sample of persons receiving care that includes information on retention in care and first diagnosis[18].

Other factors that may influence median CD4 counts among those newly diagnosed in different settings are reimbursement policies that don't cover CD4 testing at diagnosis (such as diagnosis taking place in hospital settings) and programs that detect acute infection. CD4 counts may be transiently lower among acutely infected individuals and thus lower the median CD4 count in spite of earlier detection. And while not widespread, underreporting of CD4 counts may exist for patients in clinical trials whose CD4 counts are collected under confidential patient ID and not reported to HIV surveillance programs.

Additional metrics will be needed to inform future interventions for reducing the epidemic. Standardized assessments and reporting will be critical for assessing progress of uptake and organizational comparability of models and efforts to develop standardized metrics (such as those developed by the consortium of Emergency Department HIV testing providers)[14]. Community level "Test and Treat" strategies combining universal testing with immediate use of antiretroviral therapy to prevent transmission have been described in the literature[19, 20]. In order to measure the success of such interventions, which rely on reducing transmission of HIV by reducing the viral load of potential transmitters through antiretroviral treatment, a different set of metrics will need to be developed. These metrics will serve to develop models for predicting the success of Test and Treat programs and the impact of these programs on controlling the epidemic.

ADDITIONAL INDICATORS AND MEASURES

A variety of databases and data sources are available to assess the outcome of healthcare in the United States. In addition to HEDIS measures[21], another data source is the Consumer Assessment of Healthcare Providers and Systems (CAHPS), which is a survey of patient experiences with ambulatory and facility-level care[22].

CD4 Count at Diagnosis Louisiana, 2007			
	Total	Females	Males
<50	155 (19%)	44 (17%)	111 (19%)
50-199	163 (20%)	39 (15%)	124 (22%)
200-349	177 (21%)	51 (20%)	126 (22%)
350-499	150 (18%)	54 (21%)	96 (17%)
500+	184 (22%)	71 (27%)	113 (20%)

Louisiana Office of Public Health, HIV/AIDS Program

The American Medical Association convened a meeting with representatives from the Physician Consortium for Performance Improvement, the National Committee for Quality Assurance, JCAHO, Health Resources and Services Administration, specialty societies (e.g., HIVMA, etc.) and others to develop the HIV/AIDS related clinical performance measures designed for individual quality improvement[23]. Measurements were brought to the National Quality Forum for endorsement and to the Ambulatory Care Quality Alliance (ACQA) which selects the performance measures. The merged efforts by the various organizations, specialty groups, and professional societies present opportunities to avoid redundancy, achieve a wide consensus among the different groups and specialties, provide one harmonized national measures set, and align physician and system level measures.

Opportunities for improvement exist and will help to close the gap in measuring care data. For example, the potential exists for improving provider and system levels measurements related to preventative services (e.g., PCP prophylaxis, screening for high risk behavior, etc.), management (e.g., CD4 monitoring, use of potent antiretrovirals, etc.) and intermediate outcomes (e.g. HIV viral load.) Various sources contribute to identifying the gaps in care including the HIVQUAL Project through the New York State Department of Health AIDS Institute, peer-reviewed literature, and integrated health system quality efforts.

EXAMPLES OF MEASURES

The measures can provide detail on what services healthcare providers are providing and system level gaps that are inhibiting providers from being able to deliver care. By identifying these gaps at the provider and system levels, institutions can then begin to address the issues.



Process for developing a measure:

1. Identify a topic
2. Identify guidelines and gaps in care
3. Define and review evidence-based measures
4. Public comment
5. Consider comments; revise measures as necessary
6. Portfolio of tools
7. Pilot test measures
8. Encourage use; national recognition (e.g., NQF, CMS)

Going forward, the next steps for the clinical performance measures are testing the feasibility in diverse settings (e.g. clinics, groups, providers,) developing formal requirement for reporting by various organizations, developing tools to help clinicians accomplish these measures, and developing additional measures as needed.

Discussion Points:

The process for creating the clinical performance measures is lengthy. For every measure, there needs to be a numerator, denominator, and inclusion criteria as well as beta testing for the measure. One of the biggest challenges in creating measures for testing and screening efforts is defining the numerator and denominator and obtaining buy-in from testing sites to contribute uniform data. Lessons learned from the AMA collaboration showed the complexity of defining and testing measures created for indicators related to care. Data are available on CD4 count, stage of disease and entry into care, which makes defining measures somewhat less difficult. This is not the same for evaluating the number of persons tested. The definition of the cohort population is easily obtained when attempting to develop measures for testing. The creation of the denominator would include defining the patient population being served. For example, for health plans this may be an easier answer (i.e., those who are plan members) than for those who are in private practice. It cannot be assumed that a

provider thinks that every patient that comes to their practice is a part of their practice. In addition, a provider may offer HIV tests to different populations within his or her practice (e.g., all persons, all persons ages 18-64), which adds to the complexity of identifying the cohort.

Similar to the problem of defining the denominator, it is necessary to define those who are offered HIV testing and consider any possible exclusion criteria. If there are exclusions, what would the criteria for exclusion be? This is complicated by the tremendous variability among health plans, private practices, community health centers, and emergency rooms. Current efforts at the national level to tailor measures to groups or sub-groups of the patient population exist, however, there can be difficulty in determining this because there is no census based data to track some sub-groups (e.g. MSM.).

Level	Clinical Performance Measure	Measures Description
System and Physician	Medical Visits	Measures retention in care
System	HIV RNA Control for all patients on potent antiretrovirals	Overall success
System	Hepatitis B vaccination	Measures the success of delivery of all three doses

GAPS IN KNOWLEDGE AND UNINTENDED CONSEQUENCES OF TESTING PROGRAMS

Despite the advantages and accuracies of HIV testing technologies, there remain gaps in knowledge and unintended consequences in testing programs. In December 2005 and late 2007, the New York City Department of Health and Mental Hygiene experienced different instances of increased false positive reporting in their STD walk-in clinics which were described in the MMWR[24]. After each instance, once oral fluid rapid testing resumed, the NYC DOHMH introduced an alternative algorithm for HIV testing. After a patient received a rapid oral HIV test, the test was immediately followed with a finger-stick whole blood test. The goal of the alternative algorithm was to reduce the number of false positive oral fluid tests. This led to creating an alternative strategy for other sites, settings and locations. False positive test results are uncommon yet they do occur. Therefore, confirmatory testing should be performed to reduce the chances of giving a false positive result to a patient. A thorough review of procedures, testing algorithms, and quality assurance protocols are essential if a site is experiencing an increase in false-positive tests.

False negative results are another issue when discussing HIV testing gaps in knowledge. Like false positives, false negative results do occur, although rarely, and can pose a problem. The United States lags behind other nations in approved HIV testing technology. The Vironostika test, a first generation EIA being used by a large majority of public laboratories in



the United States through 2006, had the lowest sensitivity during seroconversion of any commercially available test. As a result, there were incidences of false negatives among persons with early infection. Subsequently, the Vironostika test was withdrawn from the market in 2007. Fourth generation HIV tests (antigen/antibody combination tests) are marketed in other developed countries and are expected the United States. Even with fourth generation tests or RNA screening, there will be false negative results in persons tested very soon after infection.

Discussion Points

Unfortunately, there is no perfect test for avoiding both false positive and negative results. The HIV diagnostic industry will continue to develop better tests until a new test becomes the “gold standard”. The issue of false positive tests, while a concern, can typically be resolved within a short period of time. False negatives may be a more difficult problem because they are unlikely to be detected.

Another area where limited research is available is in the area of unintended consequences related to routine HIV testing programs. Discrimination and stigma associated with being HIV-infected and discrimination and stigma associated with HIV testing are different but closely related that may undermine the progress of routinizing HIV testing and combating the epidemic. Continuous efforts need to be made to decrease the discrimination and stigma associated with both HIV diagnosis and HIV testing. Reducing stigma if HIV testing is made routine is an intended consequence of the 2006 CDC recommendations[1]. Unintended consequences do not necessarily have to have a negative outcome, and may include increasing HIV testing acceptability. Some benefits may be anticipated such as the potential for reducing stigma while others may not. Exit interviews and surveys will provide useful data to examine the myths and perceived issues of routine HIV testing from a patient’s perspective. Nonetheless, in order to determine the impact of the societal constructs have on HIV testing and screening programs, more research is necessary.

Sustainability of programs is another challenge of many of the HIV testing programs. Venues where special counselors and testers conduct HIV tests are more difficult to sustain. Gaps in resources needed including financial, workforce, and support from organization leaders all affect a program’s sustainability. Additional efforts are needed to examine the sustainability of current models and develop new models of integrating routine HIV testing in to the current medical model.

CAPACITY TO CARE FOR NEWLY DIAGNOSED INDIVIDUALS IDENTIFIED THROUGH INCREASED HIV TESTING

One of the key expected outcomes of increasing HIV testing through routine HIV testing programs will be the identification and entry into care of previously undiagnosed individuals. CDC estimates that 21% of persons living with HIV are infected but unaware of their infection, and an additional 25% of persons may be infected but not currently in care[25]. One concern about increasing diagnoses through routine testing is the care system’s capacity to provide care for the approximately 46% of HIV infected individuals not currently in care.

The largest funders of HIV medical care in the US- Medicaid, Medicare, Ryan White and the Department of Veterans Affairs- cover the largest number of HIV patients in the country. Additional concerns exist about the ability of the national AIDS Drug Assistance Program (ADAP) to continue to provide HIV treatment for eligible individuals. In the past, state ADAPs have resorted to waiting lists and cost-containment measures (typically changing eligibility criteria or available formularies) to reduce the burden on the programs [26].

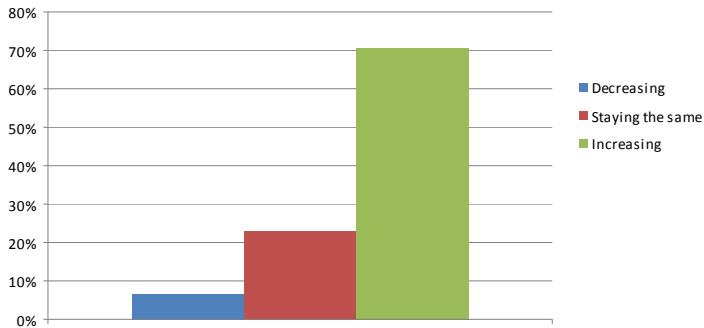
Potential increases in the number of newly diagnosed individuals through routine testing programs could be remedied by increases in authorizations for Ryan White or increased eligibility for Medicaid and Medicare, and

the demand on the federal programs depends largely on the characteristics of those individuals not currently in care that are unknown. In order to determine the need for federal services for HIV care, information about the unidentified and not-in-care populations (such as insurance status, eligibility for programs) would need to be known to assess the increasing demand.

A serious issue facing individuals newly diagnosed with HIV is the availability of HIV care and the aging HIV care workforce. More than 25 years into the epidemic, there are concerns that aging HIV care providers are quickly approaching retirement and that insufficient clinical resources will be available to replace the retiring workforce. Information about the capacity of Ryan White Part C Providers in the United States was assessed by a survey conducted by the HIVMA and HIV Forum in 2008[27]. Overall, 71% of providers indicated that the total numbers of new HIV patients seen by their clinics had increased in the last three years and the mean increase in new patients was approximately 30%. The HIVMA – HIV Forum survey, which was limited to Ryan White providers, can provide information about the potential impact of increasing numbers of newly diagnosed individuals on HIV care programs for the uninsured and underinsured.



How would you describe the trend in the TOTAL number of HIV patients served at your clinic over the past three years?



RECOMMENDATIONS

The recommendations for metrics to monitor the success of routine opt-out HIV testing programs can be divided into four types of measures:

1. Numbers of Persons Tested and Diagnosed
2. Stage of Disease at Time of Diagnosis
3. Entry into Care
4. Retention in Care

There was much discussion around the utility of the metrics for numbers of person tested and diagnosed. Determining the percent of persons tested for HIV will be necessary for clinics to identify the proportion of the population routine screening programs are reaching.

Discussions around the staging of disease at time of diagnosis centered on the need to define the best timeframe for measures based on laboratory results. The recommendation for ascertaining stage of disease is that the timeframe used “at diagnosis” include tests within 3 months. Additional measures for staging of disease will still be critical for disease monitoring by CDC and local surveillance programs and may include measures such as “late diagnosis” (Stage 3 within one year of diagnosis) or other measures. One important reason to include stage 3 (rather than only measures based on median CD4 count) as the main metric for measuring stage of disease

at diagnosis is to also include staging based on reported opportunistic infections.

The recommendations for measuring entry into care for surveillance programs is the percent of persons with a laboratory result (CD4 or viral load) within 3 months of diagnosis. Subsequently, recommendations for measuring retention in care are the reporting of two laboratory results, more than 90 days apart within a 12 month period. Forthcoming HEDIS measures on retention in care will include reports more than 60 days apart. While measures within 3 months are used to allow for adequate time for entry into care, a true quality measure of care could be access to care within 30 days.

A key component for the successful monitoring of the various metrics associated with testing will be the need to harmonize the measures (such as timeframes) within clinics and surveillance programs to provide consistency of measures across programs and for comparability.

Additionally, needs exist for ongoing, proactive monitoring of unintended consequences of routine HIV testing programs. Recommendations for such monitoring would include patient surveys at clinical sites to assess the effects of routine testing or large scale monitoring of reported unintended consequences through community/ advocacy services.

CDC’s current routine testing recommendation recommend repeat testing annually for persons at high risk for HIV but there will be a need for recommendations for the periodicity of repeat testing as the number of persons ever tested increases and routine testing becomes more “routine”.

Challenges exist with the implementation of quality measures and key recommendations from the group were to strengthen backend data systems to ensure the capacity to collect and analyze data and to reconvene expert panels (including the AMA, NCQA, CMS) to discuss deployment and collection of quality data indicators. Specific recommendations for improving quality measures include being able to better define the at-risk populations for the purposes of risk assessment and testing. Additional recommendations around indicators to measure who is providing care and who is paying for care would be useful for monitoring linkage to care from testing programs and the success of HIV care programs.



	METRICS	NUMERATOR	DENOMINATOR	LEVEL
Numbers of Persons Tested and Diagnosed	Percent of persons tested for HIV in a given time period	Number of persons tested in a given time period	Total Numbers of Persons eligible for Testing in a given time period	Clinical
	Percent of Persons Ever Tested	Total number of persons ever tested for HIV	Total Number of Persons Ever Eligible for HIV Testing	Clinical
	Percent of New HIV Diagnoses	Number of new HIV Diagnoses in a given time period	Number of Persons Tested in a given time period	Clinical and Surveillance
Stage of Disease at Time of Diagnosis	Percent of Persons at Stage 3 within 3 months of diagnosis	Number of persons with CD4<200 or <14% or with opportunistic infection reported within 3 month of diagnosis in a given time period	Total Number of persons diagnosed with HIV in a given time period	Clinical and Surveillance
	Median CD4 count within 3 months of diagnosis			Clinical and Surveillance
Entry into Care	Percent of persons entering Care within 3 months of Diagnosis	Number of persons with a CD4 or viral load within 3 months of diagnosis in a given time period	Total Number of persons diagnosed with HIV in a given time period	Surveillance
Retention in Care	Percent of Persons having at least two laboratory results in a 12 month period at least 90 days apart	Number of persons with two or more laboratory results in a 12 month period at least 90 days apart in a given time period	Total Number of persons diagnosed with HIV in a given time period	Surveillance



APPENDIX A: ROUNDTABLE PARTICIPANTS

**Metrics and Evaluation Measures for Monitoring for the
Implementation of Routine HIV Testing Roundtable
Hyatt Crystal City Hotel
Arlington, VA
April 23, 2009
PARTICIPANT LIST**

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Linda Onaga, MPH

Forum for Collaborative HIV Research

Andrea Weddle, MSW

HIV Medicine Association



APPENDIX B: ROUNDTABLE AGENDA

Forum for Collaborative HIV Research
Maximizing Opportunities for HIV Diagnosis and Prevention in the U.S.A.
Metrics and Evaluation Measures for Monitoring the Implementation of Routine HIV Testing in the U.S.
Hyatt Regency Crystal City
2799 Jefferson Davis Highway
Arlington, Virginia, USA 22202

Agenda

April 23, 2009

8:00 - 9:00

BREAKFAST

9:00 - 9:30

Welcome and Introductions**Goals and Objectives of Roundtable:**

1. To identify the metrics and measurements needed to evaluate and monitor the implementation of routine HIV testing.
2. To build a framework that will allow improvements at the program and system level to maximize the impact of routine HIV testing.
3. To recommend a set of metrics that can be employed across a variety of clinical settings that reflect testing rates, entrance into care and stage of disease at time of diagnosis.
4. To see where gaps in information exist and what can be done to improve information exchange.

Michael Horberg
Ben Hauschild
Veronica Miller

9:30 - 10:30

SESSION 1-Numbers of Persons Tested**Goal:**

1. To find ways to standardize how information on numbers of persons tested is collected across the various testing programs.
2. To find ways to incorporate monitoring into programs that are not currently monitoring numbers tested, positivity rates, and other measures.

National data on numbers of persons tested

HIV Testing in managed care or large health systems

Moderator:
Bernie Branson

Presenters:
Bernie Branson
Michael Horberg

Discussants:
Chris Aldridge

10:30-10:45

BREAK

10:45 -12:15

SESSION 2-Stage of Disease at Entry into Care**Goal:**

1. To determine how disease stage is monitored in currently ongoing programs.
2. To find mechanisms for standardizing collection of this information across programs to allow evaluation at a national level.

National data on stage of disease at diagnosis

CD4 count at time of entry into care-data from local settings

Linkage to and retention in care in clinical settings

Moderator:
Veronica Miller

Presenters:
Irene Hall
Debbie Wendell

Discussants:
Rich Rothman
Heidi Bossley



12:15 - 1:00

LUNCH

1:00-2:15

SESSION 3 - Additional Indicators and Measures

Goals:

1. To review and discuss additional information necessary for comprehensive evaluation of testing implementation.
2. To discuss the feasibility and operational issues around quality measures.

Quality performance measures/quality indicators

Acceptability of routine HIV testing

Moderator:
Judith Feinberg

Presenters:
Judith Aberg

Discussants:
Leo Hurley

2:15 - 3:15

SESSION 4-Gaps in Knowledge

Goal:

1. To identify gaps in knowledge that impede routine testing and identify research questions that will help guide the further implementation of routine, opt-out testing.

False positive tests

Unintended consequences of routine HIV testing programs

HRSA capacity to care for newly diagnosed individuals identified through increased HIV testing

Moderator:
Ben Hauschild

Presenters:
Bernie Branson

Discussants:
Andrea Weddle
Yogesh Choudhri

3:15-3:30

BREAK

3:30-4:15

SESSION 5 - Recommendations/Discussion

Goal:

1. To review and synthesize recommendations from the roundtable and to discuss additional considerations for evaluating routine HIV testing.
2. To List recommended measure for evaluating implementation of routine HIV testing.

Moderators:
Michael Horberg and
Veronica Miller

4:15-4:30

Summing Up

Michael Horberg
Veronica Miller



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