# NATIONAL QUALITY FORUM

### Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

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| **NQF #:** 2082  **NQF Project:** Infectious Disease Project |
| (for Endorsement Maintenance Review)<br>**Original Endorsement Date:**  **Most Recent Endorsement Date:**  **Last Updated Date:** Sep 26, 2012 |

| BRIEF MEASURE INFORMATION |
|---|
| **De.1 Measure Title:** HIV viral load suppression |
| **Co.1.1 Measure Steward:** Health Resources and Services Administration - HIV/AIDS Bureau |
| **De.2 Brief Description of Measure:** Percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year<br><br>A medical visit is any visit in an outpatient/ambulatory care setting with a nurse practitioner, physician, and/or a physician assistant who provides comprehensive HIV care. |
| **2a1.1 Numerator Statement:**  Number of patients in the denominator with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year |
| **2a1.4 Denominator Statement:** Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the measurement year |
| **2a1.8 Denominator Exclusions:** There are no patient exclusions. |
| **1.1 Measure Type:** Outcome<br>**2a1. 25-26 Data Source:** Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Paper Medical Records<br>**2a1.33 Level of Analysis:** Clinician : Group/Practice, Facility<br><br>**1.2-1.4 Is this measure paired with another measure?** No<br><br>**De.3 If included in a composite, please identify the composite measure** (*title and NQF number if endorsed*):<br>Not applicable |

| STAFF NOTES  (*issues or questions regarding any criteria*) |
|---|
| Comments on Conditions for Consideration: |
| Is the measure untested?  Yes☐  No☐   If untested, explain how it meets criteria for consideration for time-limited endorsement: |
| 1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*):<br>5. Similar/related endorsed or submitted measures (*check 5.1*):<br>Other Criteria: |
| Staff Reviewer Name(s): |

| 1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT |
|---|

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence.
*Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria)

**1a. High Impact:**        H☐ M☐ L☐ I☐
(*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

**De.4 Subject/Topic Areas** (*Check all the areas that apply*):   Infectious Diseases : Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS)
**De.5 Cross Cutting Areas** (*Check all the areas that apply*):   Health and Functional Status, Population Health, Prevention

**1a.1 Demonstrated High Impact Aspect of Healthcare:**  A leading cause of morbidity/mortality, High resource use, Patient/societal consequences of poor quality, Severity of illness

**1a.2 If "Other," please describe:**

**1a.3 Summary of Evidence of High Impact** (*Provide epidemiologic or resource use data*):
Human immunodeficiency virus (HIV) is a communicable infection that leads to a progressive disease with a long asymptomatic period. Approximately 50,000 persons in the United States are newly infected with HIV each year. Without treatment, most persons develop acquired immunodeficiency syndrome (AIDS) within 10 years of HIV infection. Antiretroviral therapy delays this progression and increases the length of survival.

Antiretroviral therapy (ART) reduces HIV-associated morbidity and mortality by maximally inhibiting HIV replication (as defined by achieving and maintaining plasma HIV RNA (viral load) below levels detectable by commercially available assays). Durable viral suppression improves immune function and quality of life, lowers the risk of both AIDS-defining and non-AIDS-defining complications, and prolongs life (1-12). Emerging evidence also suggests that additional benefits of ART-induced viral load suppression include a reduction in HIV-associated inflammation and possibly its associated complications (13-18).

Measures of viral replication are known to predict HIV disease progression.  Among untreated HIV-infected individuals, time to clinical progression and mortality is fastest in those with greater viral loads (19). This finding is confirmed across the wide spectrum of HIV-infected patient populations such as injection drug users (IDUs) (20), women (21), and individuals with hemophilia (22). Several studies have shown the prognostic value of pretherapy viral load for predicting post-therapy response (23-24).  Once therapy has been initiated, failure to achieve viral suppression (25-27) and viral load at the time of treatment failure (28) are predictive of clinical disease progression.

ART has also been shown to reduce transmission of HIV. The risk of sexual HIV transmission is highly correlated with HIV viral load in the blood (29) and genital secretions (30-31) of the infected individual, and ART reduces HIV blood viral load (32) as well as HIV viral shedding in potentially infectious body fluids including semen (33-34), cervicovaginal secretions (35), and anorectal secretions (36). A recent randomized controlled trial of sero-discordant heterosexual couples documented a 96% reduction in transmission from treated persons to their partners (37), and observational studies are consistent with these findings (29,31,38).

**1a.4 Citations for Evidence of High Impact cited in 1a.3:**  1. HIV Trialists´ Collaborative Group. Zidovudine, didanosine, and zalcitabine in the treatment of HIV infection: meta-analyses of the randomised evidence. Lancet. Jun 12 1999; 353(9169):2014-2025.
2.        Hammer SM, Squires KE, Hughes MD, et al. A controlled trial of two nucleoside analogues plus indinavir in persons with human immunodeficiency virus infection and CD4 cell counts of 200 per cubic millimeter or less. AIDS Clinical Trials Group 320 Study Team. N Engl J Med. Sep 11 1997; 337(11):725-733.
3.        Zolopa A, Andersen J, Powderly W, et al. Early antiretroviral therapy reduces AIDS progression/death in individuals with acute opportunistic infections: a multicenter randomized strategy trial. PLoS One. 2009; 4(5):e5575.
4.        Mocroft A, Vella S, Benfield TL, et al. Changing patterns of mortality across Europe in patients infected with HIV-1. EuroS IDA Study Group. Lancet. Nov 28 1998; 352(9142):1725-1730.
5.        Hogg RS, Yip B, Chan KJ, et al. Rates of disease progression by baseline CD4 cell count and viral load after initiating

triple-drug therapy. JAMA. Nov 28 2001; 286(20):2568-2577.

6. Sterne JA, May M, Costagliola D, et al. Timing of initiation of antiretroviral therapy in AIDS-free HIV-1-infected patients: a collaborative analysis of 18 HIV cohort studies. Lancet. Apr 18 2009; 373(9672):1352-1363.

7. Baker JV, Peng G, Rapkin J, et al. CD4+ count and risk of non-AIDS diseases following initial treatment for HIV infection. AIDS. Apr 23 2008; 22(7):841-848.

8. Palella FJ, Jr., Deloria-Knoll M, Chmiel JS, et al. Survival benefit of initiating antiretroviral therapy in HIV-infected persons in different CD4+ cell strata. Ann Intern Med. Apr 15 2003; 138(8):620-626.

9. Cain LE, Logan R, Robins JM, et al. When to initiate combined antiretroviral therapy to reduce mortality and AIDS-defining illness in HIV-infected persons in developed countries: an observational study. Ann Intern Med. Apr 19 2011; 154(8):509-515.

10. Severe P, Juste MA, Ambroise A, et al. Early versus standard antiretroviral therapy for HIV-infected adults in Haiti. N Engl J Med. Jul 15 2010; 363(3):257-265.

11. Kitahata MM, Gange SJ, Abraham AG, et al. Effect of early versus deferred antiretroviral therapy for HIV on survival. N Engl J Med. Apr 30 2009; 360(18):1815-1826.

12. Writing Committee of the CASCADE Collaboration. Timing of HAART initiation and clinical outcomes in human immunodeficiency virus type 1 seroconverters. Arch Intern Med. Sep 26 2011; 171(17):1560-1569.

13. Atta MG, Gallant JE, Rahman MH, et al. Antiretroviral therapy in the treatment of HIV-associated nephropathy. Nephrol Dial Transplant. Oct 2006; 21(10):2809-2813.

14. Schwartz EJ, Szczech LA, Ross MJ, Klotman ME, Winston JA, Klotman PE. Highly active antiretroviral therapy and the epidemic of HIV+ end-stage renal disease. J Am Soc Nephrol. Aug 2005; 16(8):2412-2420.

15. Kalayjian RC, Franceschini N, Gupta SK, et al. Suppression of HIV-1 replication by antiretroviral therapy improves renal function in persons with low CD4 cell counts and chronic kidney disease. AIDS. Feb 19 2008; 22(4):481-487.

16. Calmy A, Gayet-Ageron A, Montecucco F, et al. HIV increases markers of cardiovascular risk: results from a randomized, treatment interruption trial. AIDS. May 15 2009; 23(8):929-939.

17. Kuller LH, Tracy R, Belloso W, et al. Inflammatory and coagulation biomarkers and mortality in patients with HIV infection. PLoS Med. Oct 21 2008; 5(10):e203.

18. Torriani FJ, Komarow L, Parker RA, et al. Endothelial function in human immunodeficiency virus-infected antiretroviral-naive subjects before and after starting potent antiretroviral therapy: The ACTG (AIDS Clinical Trials Group) Study 5152s. J Am Coll Cardiol. Aug 12 2008; 52(7):569-576.

19. Mellors JW, Rinaldo CR, Jr., Gupta P, White RM, Todd JA, Kingsley LA. Prognosis in HIV-1 infection predicted by the quantity of virus in plasma. Science. May 24 1996; 272(5265):1167-1170.

20. Vlahov D, Graham N, Hoover D, et al. Prognostic indicators for AIDS and infectious disease death in HIV-infected injection drug users: plasma viral load and CD4+ cell count. JAMA. Jan 7 1998; 279(1):35-40.

21. Anastos K, Kalish LA, Hessol N, et al. The relative value of CD4 cell count and quantitative HIV-1 RNA in predicting survival in HIV-1-infected women: results of the women´s interagency HIV study. AIDS. Sep 10 1999; 13(13):1717-1726.

22. O´Brien TR, Blattner WA, Waters D, et al. Serum HIV-1 RNA levels and time to development of AIDS in the Multicenter Hemophilia Cohort Study. JAMA. Jul 10 1996; 276(2):105-110.

23. Egger M, May M, Chene G, et al. Prognosis of HIV-1-infected patients starting highly active antiretroviral therapy: a collaborative analysis of prospective studies. Lancet. Jul 13 2002; 360(9327):119-129.

24. Anastos K, Barron Y, Cohen MH, et al. The prognostic importance of changes in CD4+ cell count and HIV-1 RNA level in women after initiating highly active antiretroviral therapy. Ann Intern Med. Feb 17 2004; 140(4):256-264.

25. O´Brien WA, Hartigan PM, Martin D, et al. Changes in plasma HIV-1 RNA and CD4+ lymphocyte counts and the risk of progression to AIDS. Veterans Affairs Cooperative Study Group on AIDS. N Engl J Med. Feb 15 1996; 334(7):426-431.

26. Hughes MD, Johnson VA, Hirsch MS, et al. Monitoring plasma HIV-1 RNA levels in addition to CD4+ lymphocyte count improves assessment of antiretroviral therapeutic response. ACTG 241 Protocol Virology Substudy Team. Ann Intern Med. Jun 15 1997; 126(12):929-938.

27. Chene G, Sterne JA, May M, et al. Prognostic importance of initial response in HIV-1 infected patients starting potent antiretroviral therapy: analysis of prospective studies. Lancet. Aug 30 2003; 362(9385):679-686.

28. Deeks SG, Gange SJ, Kitahata MM, et al. Trends in multidrug treatment failure and subsequent mortality among antiretroviral therapy-experienced patients with HIV infection in North America. Clin Infect Dis. Nov 15 2009; 49(10):1582-1590.

29. Quinn TC, Wawer MJ, Sewankambo N, et al. for the Rakai Project Study Group. Viral Load and heterosexual transmission of human immunodeficiency virus type-1. NEJM 2000;342:921-929.

30. Chakraborty H., Sen, PK, Helms, RW, et.al. Viral burden in genital secretions determines male-to-female sexual

transmission of HIV-1: a probabilistic empiric model. AIDS, 2001 Mar 30;15(5):621-7.

31.      Baeten JM, Kahle E, Lingappa JR, et al, Partners in Prevention HSV/HIV Transmission Study Team. Genital HIV-1 RNA predicts risk of heterosexual HIV-1 transmission.Sci Transl Med. 2011 Apr 6;3(77):77ra29.

32.      Gulick RM, Mellors JW, Havlir D, et al. Treatment with indinavir, zidovudine, and lamivudine in adults with human immunodeficiency virus infection and prior antiretroviral therapy. N Engl J Med. 1997 Sep 11;337(11):734-9.

33.      Zhang H, Dornadula G, Beumont M, et al. Human immunodeficiency virus type 1 on the semen of men receiving highly active antiretroviral therapy. N Engl J Med 1998;339:1803-1809.

34.      Vernazza PL, Troiani L, Flepp MJ, et al, The Swiss HIV Cohort Study. Potent antiretroviral treatment of HIV-infection results in suppression of the seminal shedding of HIV. AIDS. 2000 Jan 28;14(2):117-21.

35.      Cu-Uvin S, Caliendo AM, Reinert S, et al. Effect of highly active antiretroviral therapy on cervicovaginal HIV-1 RNA. AIDS. 2000 Mar 10;14(4):415-21.

36.      Kotler DP, Shimada T, Snow G, et al. Effect of combination antiretroviral therapy upon rectal mucosal HIV RNA burden and mononuclear cell apoptosis. AIDS. 1998 Apr 16;12(6):597-604.

37.      Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. Aug 11 2011;365(6):493-505.

38.      Hughes JP, Baeten JM, Lingappa JR, et al. Determinants of Per-Coital-Act HIV-1 Infectivity Among African HIV-1-Serodiscordant Couples. J Infect Dis. Feb 2012;205(3):358-365.

**1b. Opportunity for Improvement:  H☐ M☐ L☐ I☐**
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

**1b.1** Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
Sustained viral load suppression is directly related to reduction in disease progression and to reduction in potential for transmission of infection.  Among persons in care, sustained viral load suppression represents the cumulative effect of prescribed therapy, ongoing monitoring, and patient adherence.  The proposed measure will direct providers' attention and quality improvement efforts towards this important outcome.

**1b.2** Summary of Data Demonstrating Performance Gap *(Variation or overall less than optimal performance across providers)*:
[*For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]

•      Data from CDC's Medical Monitoring Project (MMP) representing persons receiving HIV medical care indicate that, in 2009, 89% of adults aged >=18 years in had been prescribed ART.  Of these, 77% had a suppressed viral load at their most recent test (1).  Data from the same that same system also indicate that, among all persons in care, only 72% achieved viral load suppression (2).

•      In an analysis of surveillance data from King County, Washington, Dombrowski et al. found that among persons with at least one viral load reported in 2009, 65% had undetectable viral load at the time of last report (3).  Among persons with at least one viral load reported in 2009, those engaged in continuous care were more likely to have virologic suppression [69 vs. 58%, OR 1.56 (95% CI 1.34–1.81)] and had a lower mean viral load (14 158 vs. 29 623, P < 0.001) than those not engaged in continuous care.

•      From the  Kaiser Permanente's HIV Challenge, the HIV Initiative (HIVI) 2011 year end report (4):

   o      Of all members with known HIV infection and on anti-retroviral therapy, 94.5% achieved viral suppression in 2009 (*NQF measure #407)

   o      Of all HIV+ patients in Kaiser Permanente in 2009, 69% achieved viral suppression, pointing to the need for further improvements across the spectrum of care that culminates in viral load suppression.

**1b.3** Citations for Data on Performance Gap: [*For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]

1.      CDC. Vital Signs: HIV Prevention Through Care and Treatment — United States.  MMWR 2011; 60(47);1618-1623.

2.      Skarbinski J, Johnson C, Frazier E, Beer L, Valverde E, Heffelfinger J.  Nationally Representative Estimates of the Number of HIV-infected Adults who Received Medical Care, Were Prescribed Antiretroviral Therapy, and Achieved Viral Suppression in the United States, Medical Monitoring Project — 2009 Data Collection Cycle.  Presented at the 19th Annual Conference on Retroviruses and Opportunistic Infections (CROI), held in Seattle, WA, March 5-8, 2012; Session 40, abstract # 138

3.      Dombrowski J, Kent JB, Buskin SE, Stekler JD, Golden MR.  Population-based metrics for the timing of HIV diagnosis,

engagement in HIV care, and virologic suppression.  AIDS 2012; 26 (1): 77-86.
4.          Kaiser Permanente and The Permanente Foundation.  Year-End Report, 2011—HIV Interregional Initiative.  Available at: http://info.kp.org/communitybenefit/html/our_work/global/hivchallenge/images/HIV_Challenge_PDFs/HIV%20Interregional%20Initiative-2011%20Year%20End%20Report%2001192012-for%20HIV%20Challenge%20toolkit.pdf; Accessed June 5, 2012.

**1b.4** Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]
•          Data from CDC's  Medical Monitoring Project indicate that, among persons prescribed ART, 79% (95% CI: 76-82%) of men, but only 71%  (95% CI: 68-75%) of women prescribed ART achieved viral load suppression (defined as their most recent HIV viral load test indicating <=200 copies/mL); 84% (95% CI: 80-87%) of whites, but only 70%  (95% CI: 66-74%) of Blacks/African-Americans prescribed ART achieved viral load suppression (defined as their most recent HIV viral load test indicating <=200 copies/mL); older individuals (persons in the 45-54 and 55 or older categories) achieved higher levels of viral load suppression than those in the 25 to 34 age range: 85% (95% CI: 82-87%) for persons 55 years of age or older, and 79 % (95% CI: 75-82%) for persons 45-54 years, versus 69%  (95% CI: 64-75%) for persons between the ages of 25 and 34 (1).
•          MMP data also indicate that, among all persons in care (both those on ART and those not), viral load suppression is significantly less likely among persons 18-29 years of age (56%, versus 79% among those over 50); non-Hispanic Blacks (64%, versus 80% among Whites); persons with less than a high school education (66%, versus 75% among those with some post-high school education); and individuals living at or below the federal poverty line (64%, versus 77% among those whose family incomes exceed the federal poverty level) (2).
•          In an analysis of laboratory and clinical outcomes for patients with HIV infection who were part of the CPCRA (Terry Beirn Community Programs for Clinical Research on AIDS) FIRST (Flexible Initial Retrovirus Suppressive Therapies) trial, Giordano et al. found that, independent of their assigned trial arm, African American enrollees were less likely than White enrollees to have an HIV RNA level less than 50 copies per milliliter at follow-up visits (3).  In a repeated measures analysis, African American enrollees had lower odds of viral suppression compared to white enrollees (OR 0.48, 95% CI 0.40, 0.58; p<0.001). The odds of viral suppression were not different for Latino enrollees compared to white enrollees (OR 0.85, 95% CI 0.67, 1.08; p=0.19).

**1b.5** Citations for Data on Disparities Cited in 1b.4: [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
1.          CDC. Vital Signs: HIV Prevention Through Care and Treatment — United States.  MMWR 2011; 60(47);1618-1623.
2.          Skarbinski J, Johnson C, Frazier E, Beer L, Valverde E, Heffelfinger J.  Nationally Representative Estimates of the Number of HIV-infected Adults who Received Medical Care, Were Prescribed Antiretroviral Therapy, and Achieved Viral Suppression in the United States, Medical Monitoring Project — 2009 Data Collection Cycle.  Presented at the 19th Annual Conference on Retroviruses and Opportunistic Infections (CROI), held in Seattle, WA, March 5-8, 2012; Session 40, abstract # 138
3.          Giordano TP, Bartsch G, Zhang Y, Tedaldi E, Absalon J, Mannheimer S, Thomas A, MacArthur RD.  Disparities in outcomes for African American and Latino subjects in the Flexible Initial Retrovirus Suppressive Therapies (FIRST) trial.  AIDS Patient Care STDS. 2010 May; 24(5):287-95.

**1c. Evidence** (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome?   Yes☐  No☐     __If not a health outcome__, rate the body of evidence.

Quantity:  H☐ M☐ L☐ I☐    Quality:  H☐ M☐ L☐ I☐    Consistency:  H☐ M☐ L☐  I☐

| Quantity | Quality | Consistency | Does the measure pass subcriterion1c? |
|---|---|---|---|
| M-H | M-H | M-H | Yes☐ |
| L | M-H | M | Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise **No**☐ |
| M-H | L | M-H | Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise **No**☐ |
| L-M-H | L-M-H | L | No ☐ |
| **Health outcome** – rationale supports relationship to at least one healthcare structure, process, intervention, or service | | **Does the measure pass subcriterion1c?** Yes☐ IF rationale supports relationship | |

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable
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**1c.1 Structure-Process-Outcome Relationship** *(Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome)*:
This measure assesses the proportion of patients with suppressed viral load which reflects the proportion of patients on effective therapy. Effective therapy reduces HIV-associated morbidity and mortality and reduces transmission of HIV. The mechanism through with antiretroviral treatment (ART) slows disease progression and prevents transmission is suppressed viral load.

**1c.2-3 Type of Evidence** *(Check all that apply)*:
Clinical Practice Guideline

**1c.4 Directness of Evidence to the Specified Measure** *(State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population)*:
Effective treatment reduces HIV-associated morbidity and mortality and reduces transmission of HIV. The mechanism for the impact of treatment is viral load suppression.
The Department of Health and Human Services (HHS) Guidelines for use of antiretroviral agents in HIV-infected adults and adolescents state that: "The primary goal of antiretroviral therapy (ART) is to reduce HIV-associated morbidity and mortality. This goal is best accomplished by using effective ART to maximally inhibit HIV replication, as defined by achieving and maintaining plasma HIV RNA (viral load) below levels detectable by commercially available assays. Durable viral suppression improves immune function and quality of life, lowers the risk of both AIDS-defining and non-AIDS-defining complications, and prolongs life. Based on emerging evidence, additional benefits of ART include a reduction in HIV-associated inflammation and possibly its associated complications."

Multiple studies demonstrate that viral load suppression is associated with slowing disease progression. Analysis of 18 trials that included more than 5,000 participants with viral load monitoring showed a significant association between a decrease in plasma viremia and improved clinical outcome (1). Viral load testing serves as a surrogate marker for treatment response and can be useful in predicting clinical progression (2-4). As a result, the Department of Health and Human Services (HHS) Guidelines include a recommendation for measuring viral load at baseline and on a regular basis because viral load is the most important predictor of response to therapy. This recommendation is graded AI.  The review of the evidence focuses on the evidence for the treatment and prevention recommendations.

**1c.5 Quantity of Studies in the Body of Evidence** *(Total number of studies, not articles)*:  The HHS Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents contain recommendations for treatment to reduce HIV-associated morbidity and mortality, and recommendations for treatment to reduce transmission of HIV. The treatment recommendations are based on 6 analyses of randomized controlled trials (one of which is a meta-analysis of 9 RCTs), and 8 analyses of observational studies (several of which are collaborations of cohort studies) (5-18). The prevention recommendations are based on 1 randomized controlled trial and 3 observational studies, 3 ecological analyses, 1 meta-analysis of observational studies (19-25).

The HHS Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection highlight that antiretroviral (ARV) treatment has "been associated with enhanced survival, reduction in opportunistic infections (OIs) and other complications of HIV infection, improved growth and neurocognitive function, and improved quality of life in children. In the United States and the United Kingdom, significant declines (81%–93%) in mortality have been reported in HIV-infected children between 1994 and 2006, concomitant with increased use of highly active combination regimens; significant declines in HIV-related morbidity and hospitalizations in children have been observed in the United States and Europe over the same time period."

**1c.6 Quality of Body of Evidence** (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events)*:  1. Body of evidence used for recommendations on treatment to reduce HIV-associated disease and death:
As a whole, the quality of the randomized controlled trials was high. Intervention and control groups had similar baseline characteristics and retention rates were high. The observational studies were large (several analyses represented collaborations of

cohorts) and used advanced statistical methods to minimize the bias and confounder that arise when observational data are used to answer questions about when to initiate treatment. Nonetheless, unmeasured confounders may affect these analyses. For most studies, outcomes were progression to AIDS and mortality. Exceptions were disease progression (7), AIDS and non AIDS related conditions (17), and severe bacterial infections, pulmonary TB, WHO Stage 4 disease, and death (18).

2. Body of evidence used for recommendations on treatment to reduce transmission:
One randomized controlled trial of discordant heterosexual couples of high quality (18); 3 observational studies demonstrating a decreased rate of HIV transmission among serodiscordant heterosexual couples (19-21), 3 ecological analyses of communities with relatively high concentrations of men who have sex with men and IDU (22-24), and 1 meta-analysis of observational studies (25), considered together as being of moderate quality.

1c.7 **Consistency of Results across Studies** *(Summarize the consistency of the magnitude and direction of the effect):* 1. Effect on disease progression by pre-treatment CD4 count
Studies or persons with pre-treatment CD4 cell counts <350 cells/mm3 show consistent impact of treatment on disease progression and death. These studies include 4 RCTs and 6 observational studies (4-14) with consistent findings and narrow confidence intervals with the exception of one study with a higher hazard ratio and wide CI (4.0, 1.6-9.8) likely due to small number of events (14).

Studies of persons with pre-treatment CD4 cell counts of 350-500 cells/mm3 show a statistically significant impact on disease progression/death and consistent magnitude of impact with hazard ratios ranging from 1.3-1.7 and narrow confidence intervals. One study found a higher hazard ratio which was associated with a wide confidence interval (HR 4.3, CI 10-22.2) (17). Five studies, one RCT and 4 cohorts, were used to examine mortality as the outcome. Two of the cohort studies showed a lower risk of death among those initiating treatment at 350-500 CD4 cells/mm3 (16, 18). Hazard ratios were consistent and confidence intervals were narrow ([1.69, 1.26-2.26] and [0.51, 0.33-0.80]).

Among 3 observational studies of patients with pre-treatment CD4 cell counts >500 cells/mm3 (6,11,12), 2 showed no impact on progression to AIDS or death and one showed a significant impact on death (15). On the whole, results were generally consistent within categories, and impact of treatment decreased as pre-treatment CD4 count increased (<350, 350-500 and 500+ cells/mm3).

2. Effect on transmission
A large RCT of sero-discordant heterosexual couples documented 96% reduction in risk of transmission (HR 0.11 95% CI 0.04-0.32) for the treatment group compared with the deferred treatment group (18). Three observational studies show an association between plasma HIV1-RNA and heterosexual transmission of HIV (19-21).

Quinn et al (20): In a community-based study of 15,127 persons 415 discordant couples were followed for up to 30 months. Among couples in which the initially seronegative partner seroconverted, the mean serum HIV-1 RNA of the HIV-1-postive partner was significantly higher than that of the HIV-1-positive partner in couples in which the initially seronegative partner remained seronegative (90,254 copies/ml vs 38,029 copies/ml). The rate of transmission was zero among the 51 couples in which the HIV-1-postive partner had undetectable serum levels or levels<1500 copies/ml. The rate of transmission increased to 2.2 per 100 person years with serum RNA levels<3500 copies/ml and reached a maximum of 23 per 100 persons years with 50,000 or more copies/ml.

Hughes et al (21): Used data from a randomized clinical trial of HSV-2 suppressive therapy for prevention of HIV-1. No effect of HIV-2 suppressive therapy was observed. 3927 discordant couples were followed for up to 24 months. A total of 86 linked transmission events were observed. Each ten-fold increase in plasma HIV-1 RNA increased the per-act risk of transmission by factor of 2.9.

A meta-analysis of observational studies showed an overall 92% reduction in transmission in serodiscordant heterosexual couples (25). Among 5 studies that included couples in which the HIV-seropositive partner used antiviral therapy, overall transmission risk was 0.46 (0.01-10.9)/100 person years. Two of these studies stratified results by viral load and there were no episodes of transmission from persons with undetectable viral load. Among 10 studies that included seropositive persons not receiving treatment with 9998 person years follow up, the transmission rate was 5.64 (3.28-9.70) per 100 person years.

**1c.8 Net Benefit** *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
Benefits: Having suppressed viral load is associated with improved health outcomes.
Harm: There is no perceived harms associate with receiving a HIV viral load test.
Cost: Cost associated with a HIV viral load test.

**1c.9 Grading of Strength/Quality of the Body of Evidence.** Has the body of evidence been graded? Yes

**1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:** The panel members that contributed to the Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents as well as the panel members' disclosures can be found in the guidelines available at http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf.

The panel members that contributed to the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection as well as the panel members' disclosures can be found at http://aidsinfo.nih.gov/contentfiles/PedFinancialDisclosures2011.pdf.

**1c.11 System Used for Grading the Body of Evidence:** Other

**1c.12 If other, identify and describe the grading scale with definitions:** Recommendations in these guidelines are based upon scientific evidence and expert opinion. Each recommended statement is rated with a letter of A, B, or C that represents the strength of the recommendation and with a numeral I, II, or III that represents the quality of the evidence.

Strength of Recommendation:
A: Strong recommendation for the statement
B: Moderate recommendation for the statement
C: Optional recommendation for the statement

Quality of Evidence for Recommendation:
I: One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II: One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes
III: Expert opinion

**1c.13 Grade Assigned to the Body of Evidence:** AI-AIII

**1c.14 Summary of Controversy/Contradictory Evidence:** Not applicable

**1c.15 Citations for Evidence other than Guidelines** *(Guidelines addressed below)*:
1.	Murray JS, Elashoff MR, Iacono-Connors LC, et al. The use of plasma HIV RNA as a study endpoint in efficacy trials of antiretroviral drugs. AIDS. 1999;13(7):797-804.
2.	Hughes MD, Johnson VA, Hirsch MS, et al. Monitoring plasma HIV-1 RNA levels in addition to CD4+ lymphocytecount improves assessment of antiretroviral therapeutic response. ACTG 241 Protocol Virology Substudy Team. Ann Intern Med. 1997;126(12):929-938 929-938.
3.	Marschner IC, Collier AC, Coombs RW, et al. Use of changes in plasma levels of human immunodeficiency virus type 1 RNA to assess the clinical benefit of antiretroviral therapy. J Infect Dis. 1998;177(1):40-47.
4.	Thiebaut R, Morlat P, Jacqmin-Gadda H, et al. Clinical progression of HIV-1 infection according to the viral response during the first year of antiretroviral treatment. Groupe d´Epidemiologie du SIDA en Aquitaine (GECSA). AIDS.2000;14(8):971-978.
5.	HIV Trialists´ Collaborative Group. Zidovudine, didanosine, and zalcitabine in the treatment of HIV infection: meta-analyses of the randomised evidence. Lancet. Jun 12 1999;353(9169):2014-2025.
6.	Hammer SM, Squires KE, Hughes MD, et al. A controlled trial of two nucleoside analogues plus indinavir in persons with human immunodeficiency virus infection and CD4 cell counts of 200 per cubic millimeter or less. AIDS Clinical Trials Group 320 Study Team. N Engl J Med. Sep 11 1997;337(11):725-733.
7.	Zolopa A, Andersen J, Powderly W, et al. Early antiretroviral therapy reduces AIDS progression/death in individuals with

acute opportunistic infections: a multicenter randomized strategy trial. PLoS One. 2009;4(5):e5575.
8.     Mocroft A, Vella S, Benfield TL, et al. Changing patterns of mortality across Europe in patients infected with HIV-1. EuroSIDA Study Group. Lancet. Nov 28 1998;352(9142):1725-1730.
9.     Hogg RS, Yip B, Chan KJ, et al. Rates of disease progression by baseline CD4 cell count and viral load after initiating triple-drug therapy. JAMA. Nov 28 2001;286(20):2568-2577.
10.    Sterne JA, May M, Costagliola D, et al. Timing of initiation of antiretroviral therapy in AIDS-free HIV-1-infected patients: a collaborative analysis of 18 HIV cohort studies. Lancet. Apr 18 2009;373(9672):1352-1363.
11.    Baker JV, Peng G, Rapkin J, et al. CD4+ count and risk of non-AIDS diseases following initial treatment for HIV infection. AIDS. Apr 23 2008;22(7):841-848.
12.    Palella FJ, Jr., Deloria-Knoll M, Chmiel JS, et al. Survival benefit of initiating antiretroviral therapy in HIV-infected persons in different CD4+ cell strata. Ann Intern Med. Apr 15 2003;138(8):620-626.
13.    Cain LE, Logan R, Robins JM, et al. When to initiate combined antiretroviral therapy to reduce mortality and AIDS-defining illness in HIV-infected persons in developed countries: an observational study. Ann Intern Med. Apr 19 2011;154(8):509-515.
14.    Severe P, Juste MA, Ambroise A, et al. Early versus standard antiretroviral therapy for HIV-infected adults in Haiti. N Engl J Med. Jul 15 2010;363(3):257-265.
15.    Kitahata MM, Gange SJ, Abraham AG, et al. Effect of early versus deferred antiretroviral therapy for HIV on survival. N Engl J Med. Apr 30 2009;360(18):1815-1826.
16.    Writing Committee of the CASCADE Collaboration. Timing of HAART initiation and clinical outcomes in human immunodeficiency virus type 1 seroconverters. Arch Intern Med. Sep 26 2011;171(17):1560-1569.
17.    Emery S, Neuhaus JA, Phillips AN, et al. Major clinical outcomes in antiretroviral therapy (ART)-naive participants and in those not receiving ART at baseline in the SMART study. J Infect Dis. Apr 15 2008;197(8):1133-1144.
18.    Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. Aug 11 2011;365(6):493-505.
19.    Baeten JM, Kahle E, Lingappa JR, et al. Genital HIV-1 RNA predicts risk of heterosexual HIV-1 transmission. Sci Transl Med. Apr 6 2011;3(77):77ra29.
20.    Hughes JP, Baeten JM, Lingappa JR, et al. Determinants of Per-Coital-Act HIV-1 Infectivity Among African HIV-1-Serodiscordant Couples. J Infect Dis. Feb 2012;205(3):358-365.
21.    Quinn TC, Wawer MJ, Sewankambo N, et al. Viral load and heterosexual transmission of human immunodeficiency virus type 1. Rakai Project Study Group. N Engl J Med. Mar 30 2000;342(13):921-929.
22.    Das M, Chu PL, Santos GM, et al. Decreases in community viral load are accompanied by reductions in new HIV infections in San Francisco. PLoS One. 2010;5(6):e11068.
23.    Montaner JS, Lima VD, Barrios R, et al. Association of highly active antiretroviral therapy coverage, population viral load, and yearly new HIV diagnoses in British Columbia, Canada: a population-based study. Lancet. Aug 14 2010;376(9740):532-539.
24.    Porco TC, Martin JN, Page-Shafer KA, et al. Decline in HIV infectivity following the introduction of highly active antiretroviral therapy. AIDS. Jan 2 2004;18(1):81-88.
25.    Attia S, Egger M, Muller M, Zwahlen M, Low N. Sexual transmission of HIV according to viral load and antiretroviral therapy: systematic review and meta-analysis. AIDS. Jul 17 2009;23(11):1397-1404.

**1c.16** Quote verbatim, the specific guideline recommendation (*Including guideline # and/or page #*):
HHS Adolescent/adult guidelines:
ART has reduced HIV-related morbidity and mortality8-11 and has reduced perinatal12 and behavior-associated transmission of HIV.13-17 HIV suppression with ART may also decrease inflammation and immune activation thought to contribute to higher rates of cardiovascular and other end-organ damage reported in HIV-infected
Cohorts.

8.     Mocroft A, Vella S, Benfield TL, et al. Changing patterns of mortality across Europe in patients infected with HIV-1.EuroSIDA Study Group. Lancet. Nov 28 1998;352(9142):1725-1730.
9.     Palella FJ, Jr., Delaney KM, Moorman AC, et al. Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection. HIV Outpatient Study Investigators. N Engl J Med. Mar 26 1998;338(13):853-860.
10.    Vittinghoff E, Scheer S, O´Malley P, Colfax G, Holmberg SD, Buchbinder SP. Combination antiretroviral therapy and recent declines in AIDS incidence and mortality. J Infect Dis. Mar 1999;179(3):717-720.
11.    ART CC AC. Life expectancy of individuals on combination antiretroviral therapy in high-income countries: a collaborative analysis of 14 cohort studies. Lancet. Jul 26 2008;372(9635):293-299.

12.     Mofenson LM, Lambert JS, Stiehm ER, et al. Risk factors for perinatal transmission of human immunodeficiency virus type 1 in women treated with zidovudine. Pediatric AIDS Clinical Trials Group Study 185 Team. N Engl J Med. Aug 5 1999;341(6):385-393.

13.     Wood E, Kerr T, Marshall BD, et al. Longitudinal community plasma HIV-1 RNA concentrations and incidence of HIV-1 among injecting drug users: prospective cohort study. BMJ. 2009;338:b1649.

14.     Quinn TC, Wawer MJ, Sewankambo N, et al. Viral load and heterosexual transmission of human immunodeficiency virus type 1. Rakai Project Study Group. N Engl J Med. Mar 30 2000;342(13):921-929.

15.     Dieffenbach CW, Fauci AS. Universal voluntary testing and treatment for prevention of HIV transmission. JAMA. Jun 10 2009;301(22):2380-2382.

16.     Montaner JS, Hogg R, Wood E, et al. The case for expanding access to highly active antiretroviral therapy to curb the growth of the HIV epidemic. Lancet. Aug 5 2006;368(9534):531-536.

17.     Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. Aug 11 2011;365(6):493-505.

Antiretroviral therapy (ART) is recommended for all HIV-infected individuals. The strength of this recommendation varies on the basis of pretreatment CD4 cell count:
• CD4 count <350 cells/mm3 (AI)
• CD4 count 350 to 500 cells/mm3 (AII)
• CD4 count >500 cells/mm3 (BIII)

Regardless of CD4 count, initiation of ART is strongly recommended for individuals with the following conditions:
• Pregnancy (AI) (see perinatal guidelines for more detailed discussion)
• History of an AIDS-defining illness (AI)
• HIV-associated nephropathy (HIVAN) (AII)
• HIV/hepatitis B virus (HBV) coinfection (AII)

Effective ART also has been shown to prevent transmission of HIV from an infected individual to a sexual partner; therefore, ART should be offered to patients who are at risk of transmitting HIV to sexual partners (AI [heterosexuals] or AIII [other transmission risk groups]; see text for discussion).

Patients starting ART should be willing and able to commit to treatment and should understand the benefits and risks of therapy and the importance of adherence (AIII). Patients may choose to postpone therapy, and providers, on a case-by case basis, may elect to defer therapy on the basis of clinical and/or psychosocial factors. [Page E-1]

Optimal viral suppression is generally defined as a viral load persistently below the level of detection (<20– 75 copies/mL, depending on the assay used). However, isolated "blips" (viral loads transiently detectable at low levels, typically <400 copies/mL) are not uncommon in successfully treated patients and are not thought to represent viral replication or to predict virologic failure.5 In addition, low-level positive viral load results (typically <200 copies/mL) appear to be more common with some viral load assays than others, and there is no definitive evidence that patients with viral loads quantified as <200 copies/mL using these assays are at increased risk for virologic failure.6-8 For the purposes of clinical trials the AIDS Clinical Trials Group (ACTG) currently defines virologic failure as a confirmed viral load >200 copies/mL, which eliminates most cases of apparent viremia caused by blips or assay variability.9 This definition may also be useful in clinical practice. [Page C-6]

5.      Havlir DV, Bassett R, Levitan D, et al. Prevalence and predictive value of intermittent viremia with combination hiv therapy. JAMA. 2001;286(2):171-179.

6.      Damond F, Roquebert B, Benard A, et al. Human immunodeficiency virus type 1 (HIV-1) plasma load discrepancies between the Roche COBAS AMPLICOR HIV-1 MONITOR Version 1.5 and the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 assays. J Clin Microbiol. 2007;45(10):3436-3438.

7.      Gatanaga H, Tsukada K, Honda H, et al. Detection of HIV type 1 load by the Roche Cobas TaqMan assay in patients with viral loads previously undetectable by the Roche Cobas Amplicor Monitor. Clin Infect Dis. 2009;48(2):260-262.

8.      Willig JH, Nevin CR, Raper JL, et al. Cost ramifications of increased reporting of detectable plasma HIV-1 RNA levels by the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 version 1.0 viral load test. J Acquir Immune Defic Syndr. 2010;54(4):442-444.

9.      Ribaudo H, Lennox J, Currier J, et al. Virologic failure endpoint definition in clinical trials: Is using HIV-1 RNA threshold

<200 copies/mL better than <50 copies/mL? An analysis of ACTG studies. Paper presented at: 16th Conference on Retroviruses and Opportunistic Infections; February 8-11, 2009; Montreal, Canada. Abstract 580.

Virologic failure: The inability to achieve or maintain suppression of viral replication (to an HIV RNA level <200 copies/mL). [Page H-1]

HHS Pediatric guidelines:

Table 7. Indications for Initiation of Antiretroviral Therapy in HIV-Infected Children:
Age band: <12 months
Criteria for Therapy Initiation: Regardless of clinical symptoms, immune status, or viral load [Treat (AII)]

Age band: 1 to <5 years
Criteria for Therapy Initiation:
•        AIDS or significant HIV-related symptoms [Treat (AI*)]
•        CD4 percentage <25%, regardless of symptoms or HIV RNA level [Treat (AII) ]
•        Asymptomatic or mild symptoms and o CD4 percentage =25% and o HIV RNA =100,000 copies/mL [Treat (BII)]
•        Asymptomatic or mild symptoms and o CD4 percentage =25% and o HIV RNA <100,000 copies/mL [Consider Treatment (CIII)]

Age band: =5 years
Criteria for Therapy Initiation:
•        AIDS or significant HIV-related symptoms  [Treat (AI*)]
•        CD4 count =500 cells/mm3 [Treat; CD4 count <350 cells/mm3 (AI*); CD4 count 350–500 cells/mm3 (BII*)]
•        Asymptomatic or mild symptoms and CD4 count >500 cells/mm3 and  HIV RNA =100,000 copies/mL [Treat (BII*)]
•        Asymptomatic or mild symptoms and CD4 count >500 cells/mm3 and  HIV RNA <100,000 copies/mL [Consider Treatment (CIII)] [Page 38]

Laboratory Monitoring of Pediatric HIV Infection Before Initiation of Therapy (Updated August 11, 2011):
•        The age of the child must be considered when interpreting the risk of disease progression based on CD4 percentage or count and plasma HIV RNA level (AII).
•        For any given CD4 percentage or count, younger children, especially those in the first year of life, face higher risk of progression than do older children. In children younger than 5 years of age, CD4 percentage is preferred for monitoring immune status because of age-related changes in absolute CD4 count in this age group (AII).
•        CD4 percentage or count should be measured at the time of diagnosis of HIV infection and at least every 3-4 months thereafter (AIII).
•        Plasma HIV RNA should be measured to assess viral load at the time of diagnosis of HIV infection and at least every 3-4 months thereafter (AIII).
•        More frequent CD4 cell and plasma HIV RNA monitoring should be considered in children with suspected clinical, immunologic, or virologic deterioration or to confirm an abnormal value (AIII). [Page 19]

**1c.17 Clinical Practice Guideline Citation:**  Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. Section accessed June 29, 2012. [Pages C-6; H-1]

Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. August 11, 2011; pp 1-268. Available at http://aidsinfo.nih.gov/ContentFiles/lvguidelines/PediatricGuidelines.pdf.  Section accessed June 29, 2012.  [Pages 19; 38]

**1c.18 National Guideline Clearinghouse or other URL:**
http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf.;
http://aidsinfo.nih.gov/ContentFiles/lvguidelines/PediatricGuidelines.pdf

**1c.19 Grading of Strength of Guideline Recommendation.** Has the recommendation been graded?  Yes

**1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:**  Expert panel that developed the guidelines

**1c.21 System Used for Grading the Strength of Guideline Recommendation:**  Other

**1c.22 If other, identify and describe the grading scale with definitions:**  Recommendations in these guidelines are based upon scientific evidence and expert opinion. Each recommended statement is rated with a letter of A, B, or C that represents the strength of the recommendation and with a numeral I, II, or III that represents the quality of the evidence.

Strength of Recommendation:
A: Strong recommendation for the statement
B: Moderate recommendation for the statement
C: Optional recommendation for the statement

Quality of Evidence for Recommendation:
I: One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II: One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes
III: Expert opinion

**1c.23 Grade Assigned to the Recommendation:**  A-C

**1c.24 Rationale for Using this Guideline Over Others:**  1. For reducing progression to HIV-associated morbidity/mortality, by pre-treatment CD4 cell count:
•	CD4 <350 cells/mm3: A
•	CD4 350-500 cells/mm3: A
•	CD4 >500 cells/mm3: B

2. For preventing transmission: A

Pediatric guidelines:
Age band:  <12 months
Criteria for Therapy Initiation:  Regardless of clinical symptoms, immune status, or viral load [Treat (AII)]

Age band: 1 to <5 years
Criteria for Therapy Initiation:
•	AIDS or significant HIV-related symptoms [Treat (A)]
•	CD4 percentage <25%, regardless of symptoms or HIV RNA level [Treat (A) ]
•	Asymptomatic or mild symptoms and o CD4 percentage >=25% and o HIV RNA =100,000 copies/mL [Treat (B)]
•	Asymptomatic or mild symptoms and o CD4 percentage =25% and o HIV RNA <100,000 copies/mL [Consider Treatment (CI)]

Age band: >=5 years
Criteria for Therapy Initiation:
•	AIDS or significant HIV-related symptoms [Treat (A)]
•	CD4 count =500 cells/mm3 [Treat; CD4 count <350 cells/mm3 (A); CD4 count 350–500 cells/mm3 (B)]
•	Asymptomatic or mild symptoms and CD4 count >500 cells/mm3 and HIV RNA >=100,000 copies/mL [Treat (B)]
•	Asymptomatic or mild symptoms and CD4 count >500 cells/mm3 and HIV RNA <100,000 copies/mL [Consider Treatment (C)]

Rating of Recommendations:
A: Strong
B: Moderate
C: Optional

Based on the NQF descriptions for rating the evidence, what was the <u>developer's assessment</u> of the quantity, quality, and consistency of the body of evidence?
**1c.25** Quantity: Moderate    **1c.26** Quality: Moderate**1c.27** Consistency:  High
**1c.28** Attach evidence submission form:
**1c.29** Attach appendix for supplemental materials:

Was the threshold criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*)   Yes☐  No☐
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement),  it may be considered for continued endorsement and all criteria need to be evaluated.

## 2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. **(<u>evaluation criteria</u>)**
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field.  Supplemental materials may be referenced or attached in item 2.1. See <u>guidance on measure testing</u>.

**S.1 Measure Web Page** *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications  can be obtained)*. Do you have a web page where current detailed specifications for <u>this</u> measure can be obtained?  No

**S.2 If yes, provide web page URL:**

**2a. RELIABILITY. Precise Specifications and Reliability Testing:  H☐ M☐ L☐ I☐**

**2a1. Precise Measure Specifications**.  (*The measure specifications precise and unambiguous.*)

**2a1.1 Numerator Statement** *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
Number of patients in the denominator with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year

**2a1.2 Numerator Time Window** *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
The numerator time window is the measurement year.  The measurement year can be any consecutive 12-month period.

**2a1.3 Numerator Details** *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
To be included in the numerator, patients had a HIV viral load less than 200 copies/mL at the last HIV viral load test during the measurement year

**2a1.4 Denominator Statement** *(Brief, narrative description of the  target population being measured)*:
Number of patients, regardless of age, with a diagnosis of HIV with at least one medical visit in the measurement year

**2a1.5 Target Population Category** *(Check all the populations for which the measure is specified and tested if any)*:  Adult/Elderly Care, Children's Health, Special Healthcare Needs

**2a1.6 Denominator Time Window** *(The time period in which cases are eligible for inclusion)*:
The denominator time window is the measurement year.  The measurement year can be any consecutive 12-month period.

**2a1.7 Denominator Details** (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
To be included in the denominator, patients must meet all of the following conditions/events:
1.      Patients of any age during the measurement year
2.      Patients diagnosed with HIV during the first 3 months of the measurement year or prior to the measurement year
3.      Patients who had at least one medical visit during the measurement year

**2a1.8 Denominator Exclusions** *(Brief narrative description of exclusions from the target population)*:
There are no patient exclusions.

**2a1.9 Denominator Exclusion Details** *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
There are no patient exclusions.

**2a1.10 Stratification Details/Variables** *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses )*:
Not applicable

**2a1.11 Risk Adjustment Type** *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*:  No risk adjustment or risk stratification     **2a1.12 If "Other," please describe:**

**2a1.13 Statistical Risk Model and Variables** *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.)*:
Not applicable

**2a1.14-16 Detailed Risk Model Available at Web page URL** (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses.  Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

**2a1.17-18. Type of Score:**  Rate/proportion

**2a1.19 Interpretation of Score** *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*:  Better quality = Higher score

**2a1.20 Calculation Algorithm/Measure Logic** *(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*:
1.      Identify the individuals who satisfy all specific criteria for inclusion in the denominator:  1.) diagnosed with a HIV during the first 3 months of the measurement year or prior to the measurement year; and 2.) had at least one medical visit during the measurement year.  The individuals who met these criteria are the denominator population.
2.      Identify the individuals from the denominator population who meet the criterion for inclusion in the numerator:  had a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.
3.      Calculate the percentage by dividing the numerator population by the denominator population and multiply by 100.

**2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:**

Attachment
Viral_Load_Suppression_Measure_Logic_6-20-12.pdf

**2a1.24 Sampling (Survey) Methodology.** If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
Not applicable; not based on a sample.

**2a1.25 Data Source** (*Check all the sources for which the measure is specified and tested*). If other, please describe:
 Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Paper Medical Records

**2a1.26 Data Source/Data Collection Instrument** (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): Not applicable.

**2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:**

**2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:**
Attachment
Viral_load_measure_data_dictionary.pdf

**2a1.33 Level of Analysis** (*Check the levels of analysis for which the measure is specified and tested*): Clinician : Group/Practice, Facility

**2a1.34-35 Care Setting** (*Check all the settings for which the measure is specified and tested*): Ambulatory Care : Clinician Office/Clinic

**2a2. Reliability Testing.** (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.*)

**2a2.1 Data/Sample** (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):
We utilized the multisite HIV Research Network (HIVRN), a consortium of community and academic HIV providers care sites, linked by a centralized Data Coordinating Center (DCC).  The HIVRN has 18 participating treatment sites.  However, for this work, we included 9/18 sites.  Sites that exclusively used the ultrasensitive and b-DNA HIV viral load assays were included.   The sites are representative of both academic and community-based HIV care; of the 4 major geographic divisions of the U.S. of the demographic diversity of HIV infection across the U.S. and of the insurance status and coverage types typical of the population in care.  The measurement year included calendar year 2010.

All of the patients in the HIVRN dataset have a diagnosis of HIV.  Patients were included, regardless of age, if they had at least one medical visit during the measurement year.  For calendar year 2010, 11,134 patients were included in the analysis.  The patient characteristics for calendar year 2010 are as follows.  The patient characteristics are representative of CDC surveillance data for people living with HIV in 2009 (Table 15a in http://www.cdc.gov/hiv/surveillance/resources/reports/2010report/index.htm).
            2010
Race/Ethnicity:
African American/Caribbean          46.87%
White, not Hispanic          28.34%
Hispanic 23.06%
Other     1.73%

Gender:
Male     69.99%

Female  29.26%
Transgender       0.75%

Age:
<18       2.11%
18-29    11.70%
30-49    56.98%
50+       29.21%

HIV Risk:
IV Drug Use       12.40%
Men Having Sex with Men 41.59%
Heterosexual Contact       39.44%
Vertical  2.60%
Blood     0.64%
Other/Unknown    3.33%

Insurance:
Private   18.01%
Medicaid          33.50%
Medicare          15.26%
Dual (Medicare and Medicaid)        1.74%
Uninsured         2.88%
Ryan White        26.70%
Other/Unknown   1.90%

Site Type:
Hospital-based    65.12%
Community-based          34.88%

**2a2.2 Analytic Method** *(Describe method of reliability testing & rationale)*:
Reliability was calculated according to the methods outlined in a technical report prepared by J.L. Adams for the National Committee for Quality Assurance  titled "The Reliability of Provider Profiling: A Tutorial" (RAND Corporation, TR-653-NCQA, 2009). In this context, reliability represents the ability of a measure to confidently distinguish the performance of one physician from another.  As discussed in the report: "Conceptually, it is the ratio of signal to noise. The signal in this case is the proportion of variability in measured performance that can be explained by real differences in performance. There are 3 main drivers of reliability; sample size, differences between physicians, and measurement error."
According to this approach, reliability is estimated with a beta-binomial model. The beta-binomial model is appropriate for measuring the reliability of pass/fail measures such as those proposed here. Reliability scores vary from 0.0 to 1.0, with a score of zero indicating that all variation is attributable to measurement error (noise, or individual accountable entity variance) whereas a reliability of 1.0 implies that all variation is caused by real difference in performance across accountable entities.
As discussed in the technical report, there is not a clear cut-off for minimum reliability level. Values above 0.7, however, are considered sufficient to see differences between some physicians (or clinics) and the mean, and values above 0.9 are considered sufficient to see differences between pairs of physicians (in this case clinics).
Clinic-specific reliability results for the "HIV viral load suppression" measure are detailed in the Table below. Clinic-specific reliability is consistently greater than 0.9, and thus can be considered to be very good. Clinic-specific reliability was also calculated for 2008 and 2009. Results were consistent with results from 2010 and are not shown here.

**2a2.3 Testing Results** *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Table 1: Clinic-Specific Reliability for Viral Suppression Measure – Year 2010
Between-clinic variance: 0.0066
Clinic     n          percent  Reliability

| | | | |
|---|---|---|---|
| A | 700 | 77.9 | 0.96 |
| B | 808 | 50.4 | 0.96 |
| C | 438 | 78.8 | 0.95 |
| D | 1586 | 69.9 | 0.98 |
| E | 1739 | 76.1 | 0.98 |
| F | 4116 | 72.4 | 0.99 |
| G | 1337 | 78.5 | 0.98 |
| Peds | 410 | 67.8 | 0.93 |

Median 0.97 (Range 0.93-0.99)

**2b. VALIDITY. Validity, Testing, <u>including all Threats to Validity</u>:** H☐ M☐ L☐ I☐

**2b1.1** Describe **how the measure specifications** *(measure focus, target population, and exclusions)* **are consistent with the evidence cited in support of the measure focus (***criterion 1c***) and identify any differences from the evidence:**
Studies show that lack of HIV viral load suppression leads to poorer health outcomes among people living with HIV. The measure specifications presented are consistent with the elements of HIV viral load suppression as descried in the studies.

**2b2. Validity Testing.** (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.*)

**2b2.1** **Data/Sample** *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
We utilized the multisite HIV Research Network (HIVRN), a consortium of community and academic HIV providers care sites, linked by a centralized Data Coordinating Center (DCC). The HIVRN has 18 participating treatment sites. However, for this work, we included 9/18 sites. Sites that exclusively used the ultrasensitive and b-DNA HIV viral load assays were included. The sites are representative of both academic and community-based HIV care; of the 4 major geographic divisions of the U.S. of the demographic diversity of HIV infection across the U.S. and of the insurance status and coverage types typical of the population in care. The measurement year included calendar years 2010.

All of the patients in the HIVRN dataset have a diagnosis of HIV. Patients were included, regardless of age, if they had at least one medical visit during the measurement year. For calendar year 2010, 11,134 patients were included in the analysis. The patient characteristics for calendar year 2010 are as follows. The patient characteristics are representative of CDC surveillance data for people living with HIV in 2009 (Table 15a in http://www.cdc.gov/hiv/surveillance/resources/reports/2010report/index.htm).
      2010
Race/Ethnicity:
African American/Caribbean     46.87%
White, not Hispanic     28.34%
Hispanic 23.06%
Other   1.73%

Gender:
Male   69.99%
Female  29.26%
Transgender     0.75%

Age:
<18     2.11%
18-29   11.70%
30-49   56.98%
50+    29.21%

HIV Risk:
IV Drug Use    12.40%
Men Having Sex with Men 41.59%
Heterosexual Contact    39.44%

Vertical  2.60%
Blood    0.64%
Other/Unknown   3.33%

Insurance:
Private   18.01%
Medicaid          33.50%
Medicare          15.26%
Dual (Medicare and Medicaid)        1.74%
Uninsured      2.88%
Ryan White      26.70%
Other/Unknown   1.90%

Site Type:
Hospital-based    65.12%
Community-based         34.88%

**2b2.2 Analytic Method** *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Face validity was established through a technical work group established for the development of the measures. The technical work group consisted of leading researchers and physicians in HIV retention, care, and treatment as well as governmental and non-governmental public health officials from across the country.  The technical work group used a modified Delphi process whereby experts presented the most current research to the work group members.  Often, the principle investigator of the study presented to the work group.  The work group members discussed each of the presentations and identified data elements for each measure.  The work group members voted on the domains for the proposed measures.  The vote was based on importance, feasibilityn use in quality improvement activities.  The votes were tallied and draft components of the measures were returned to the work group for additional voting via survey.  Consensus was reach when a simple majority agreed on the final set of measures.

Additional face validity was gained through a structured process of webinar presentations to a national audience of Ryan White Program providers.  The Ryan White providers were presented detailed information about each of the measures (e.g. work group process, numerator, demoninator, exclusions, etc.) via a webinar.  After receiving the detailed information about the measures, Ryan White providers were asked to implement the measures within their quality management program and provide feedback on the feasibility and usability of the measures.  Feedback was gathered during an additional webinar and written responses.

**2b2.3 Testing Results** *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)*:
This measure was found to be important, usable, and feasible by the technical work group overseeing the development of this measure and several others.  The technical work group considered 7 measures.  In total, 4 of the 7 measures were voted as the most import, feasible, and useable.  The Ryan White providers have also deemed the measures important, usable, and feasible.  Over 180 Ryan White providers from across the country have voluntary reported performance data for this measure at least once with 148 of those providers reporting performance data for 4 straight measurement periods.

**POTENTIAL THREATS TO VALIDITY**.  (*All potential threats to validity were appropriately tested with adequate results.*)

**2b3. Measure Exclusions.**  (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

**2b3.1 Data/Sample for analysis of exclusions** *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Not applicable.

**2b3.2 Analytic Method** (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)*:
Not applicable.

**2b3.3 Results** *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
Not applicable.

**2b4. Risk Adjustment Strategy.** (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

**2b4.1 Data/Sample** *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Not applicable.

**2b4.2 Analytic Method** (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)*:
Not applicable.

**2b4.3 Testing Results** (*Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata)*:
Not applicable.

**2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment:** Not applicable.

**2b5. Identification of Meaningful Differences in Performance.** (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

**2b5.1 Data/Sample** *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
We utilized the multisite HIV Research Network (HIVRN), a consortium of community and academic HIV providers care sites, linked by a centralized Data Coordinating Center (DCC). The HIVRN has 18 participating treatment sites. However, for this work, we included 9/18 sites. Sites that exclusively used the ultrasensitive and b-DNA HIV viral load assays were included. The sites are representative of both academic and community-based HIV care; of the 4 major geographic divisions of the U.S. of the demographic diversity of HIV infection across the U.S. and of the insurance status and coverage types typical of the population in care. The measurement year included calendar years 2010.
All of the patients in the HIVRN dataset have a diagnosis of HIV. Patients were included, regardless of age, if they had at least one medical visit during the measurement year. For calendar year 2010, 11,134 patients were included in the analysis. The patient characteristics for calendar year 2010 are as follows. The patient characteristics are representative of CDC surveillance data for people living with HIV in 2009 (Table 15a in http://www.cdc.gov/hiv/surveillance/resources/reports/2010report/index.htm).
            2010
Race/Ethnicity:
African American/Caribbean          46.87%
White, not Hispanic          28.34%
Hispanic 23.06%
Other    1.73%

Gender:
Male     69.99%
Female  29.26%
Transgender      0.75%

Age:
<18      2.11%
18-29    11.70%
30-49    56.98%

50+        29.21%

HIV Risk:
IV Drug Use        12.40%
Men having sex with Men   41.59%
Heterosexual Contact       39.44%
Vertical   2.60%
Blood      0.64%
Other/Unknown    3.33%

Insurance:
Private   18.01%
Medicaid          33.50%
Medicare          15.26%
Dual (Medicare and Medicaid)        1.74%
Uninsured        2.88%
Ryan White       26.70%
Other/Unknown   1.90%

Site Type:
Hospital-based    65.12%
Community-based           34.88%

**2b5.2 Analytic Method** *(Describe methods and rationale  to identify statistically significant and practically/meaningfully differences in performance)*:
We reported the mean, minimum, maximum, and percentile.

**2b5.3 Results** *(Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
 Among the 9 sites (2 pediatric sites were combined due to small patient populations), the following data are reported for measurement year 2010.
Minimum          50.37%
Maximum          78.77%
Mean     72.20%
25th percentile    69.39%
50th percentile    74.29%
75th percentile    78.01%

**2b6. Comparability of Multiple Data Sources/Methods.** (*If specified for more than one data source, the various approaches result in comparable scores.*)

**2b6.1 Data/Sample** *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
This measure was not tested with multiple data sources.

**2b6.2 Analytic Method** *(Describe methods and rationale for  testing comparability of scores produced by the different data sources specified in the measure)*:
This measure was not tested with multiple data sources.

**2b6.3 Testing Results** *(Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted)*:
This measure was not tested with multiple data sources.

**2c. Disparities in Care:**   H ☐ M ☐ L ☐ I ☐  NA ☐ (*If applicable, the measure specifications allow identification of disparities.*)

**2c.1 If measure is stratified for disparities, provide stratified results** *(Scores by stratified categories/cohorts)*: The following are the results stratified by patient characteristics and site.
2010
Race/Ethnicity:
African American/Caribbean          67.16%
White, not Hispanic          78.84%
Hispanic 74.16%
Other     71.73%


Gender:
Male     74.22%
Female  67.56%
Transgender       65.06%


Age:
<18      78.30%
18-29    56.10%
30-49    71.19%
50+      80.20%


HIV Risk:
IV Drug Use       69.44%
Men Having Sex with Men 76.31%
Heterosexual Contact      69.39%
Vertical  75.43%
Blood     69.01%
Other/Unknown   62.53%


Insurance:
Private   76.21%
Medicaid          68.69%
Medicare          73.16%
Dual (Medicare and Medicaid)       81.96%
Uninsured         55.45%
Ryan White        74.87%
Other/Unknown   67.45%


Site Type:
Hospital-based   72.54%
Community-based          71.58%


Site:
A         77.86%
B         50.37%
C         78.77%
D         69.92%
E         76.14%
F         72.45%
G         78.46%
Pediatric Sites (combined) 67.80%


**2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please**

| explain: |
|---|
| Not applicable |

| **2.1-2.3** Supplemental Testing Methodology Information: |
|---|
| |

| Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met? (*Reliability and Validity must be rated moderate or high*) Yes☐ No☐ Provide rationale based on specific subcriteria: |
|---|
| If the Committee votes No, STOP |

## 3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (<u>evaluation criteria</u>)

**C.1** Intended Actual/Planned Use *(Check all the planned uses for which the measure is intended)*:  Public Health/Disease Surveillance, Public Reporting, Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

**3.1** Current Use *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*:  Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

**3a. Usefulness for Public Reporting:**  H☐ M☐ L☐ I☐
(*The measure is meaningful, understandable and useful for public reporting.*)

**3a.1. Use in Public Reporting - disclosure of performance results to the public at large** *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* <u>If not publicly reported in a national or community program</u>, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement:  [*For <u>Maintenance</u> – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]
The technical work group saw utility in publically reporting this data.
This measure may be used providers of HIV care and treatment.  It is currently used a performance measure for a national quality improvement project focused on retention in medical care among people living with HIV.  Access to the performance data collected by the national quality improvement project is available for participants enrolled in the project as well as available to the public on the project's website.

Additionally, upon endorsement, the measure developer will seek inclusion in Stage 3 of the Center for Medicare and Medicaid (CMS) Electronic Health Records (EHR) Incentive Programs (Meaningful Use) and Physician Quality Reporting System (PQRS).

The agencies within the U.S. Department of Health and Human Services (HHS) who provide funding for services for people living with HIV (e.g. CDC, CMS, HRSA, IHS, NIH, and SAMHSA) as well as the Office of HIV/AIDS and Infectious Disease Policy, U.S. Department of Veterans Affairs, HIV Medical Associate, Kaiser Permanente, and a subset of the HHS 12-cities participants have come together to develop a parsimonious set of seven performance measures and to reduce federal reporting requirements.  This measure has been put forward to fill the measurement gap for viral load suppression.  The implementation date for reporting will be established by the end of 2012.  This is important in the National HIV/AIDS Strategy as it calls for a reduction in viral load among gay and bisexual men and people of color.

**3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting**. <u>If usefulness was demonstrated</u> (e.g., focus group, cognitive testing), describe the data, method, and results**:** When reviewing the HIV Research Network data by sites, this measure is able to distinguish difference in performance across sites.  The top and bottom performing sites for this measure tended to consistently perform as either the top or bottom performer on other

measures.

This measure is currently being utilized in a national quality improvement project focused on retention in medical care among people living with HIV. As part of this national quality improvement project, Ryan White providers voluntarily agreed to submit data on 4 performance measures, including this measure, every two months. See data below. As each of the measurement periods closes, the performance data submitted by each site are aggregated and report to the project participants via webinar. (Anyone can access the live webinar and the archived webinars. Available at: http://www.incarecampaign.org) The project participants have reported that this measure is meaningful to the management of their HIV patient population and understandable by both providers and patients.

Measurement year: 10/1/2010-9/30/2011
Mean (Total Patients): 68.87% (126,381)
Sites Reporting: 187

Measurement year: 12/1/2010-11/30/2011
Mean (Total Patients): 69.25% (139,086)
Sites Reporting: 182

Measurement year: 2/1/2011-1/31/2012
Mean (Total Patients): 70.49% (142,230)
Sites Reporting: 186

Measurement year; 4/1/2011-3/31/2012
Mean (Total Patients): 71.20% (134,419)
Sites Reporting: 148

**3.2 Use for other Accountability Functions (payment, certification, accreditation).** If used in a public accountability program, provide name of program(s), locations, Web page URL(s): Not applicable

**3b. Usefulness for Quality Improvement: H☐ M☐ L☐ I☐**
(*The measure is meaningful, understandable and useful for quality improvement.*)

**3b.1. Use in QI.** If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[*For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].
This measure is currently used as a performance measure for a national quality improvement project focused on retention in medical care among people living with HIV. Along with submitting performance measure data, the Ryan White providers participating in the project are asked to select one or more of the four project performance measures and use it as the basis for a quality improvement project. The project collects improvement strategies tested by each of the participating Ryan White providers and shares the strategies during month webinars. The improvement strategies, performance data, archived webinars, list of participating Ryan White providers, and other materials can be found at www.incarecampaign.org/.

The agencies within the U.S. Department of Health and Human Services (HHS) who provide funding for services for people living with HIV (e.g. CDC, CMS, HRSA, IHS, NIH, and SAMHSA) as well as the Office of HIV/AIDS and Infectious Disease Policy, U.S. Department of Veterans Affairs, HIV Medical Associate, Kaiser Permanente, and a subset of the HHS 12-cities participants have come together to develop a parsimonious set of seven performance measures and to reduce federal reporting requirements. This measure has been put forward to fill the measurement gap for viral load suppression. The implementation date for reporting will be established by the end of 2012. This is important in the National HIV/AIDS Strategy as it calls for a reduction in viral load among gay and bisexual men and people of color.

**3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement.** If usefulness was demonstrated *(e.g., QI initiative),* describe the data, method and results:
The Ryan White providers who are employing this measure have reported that this measure is meaningful, understandable, and

useful for quality improvement activities. This measure is an outcome measure. This is the only outcome measure in HIV care and treatment. Studies have established a significant relationship between HIV viral load suppression and reduced patient morbidity and mortality as well as HIV transmission risk. Thus, this measure is central to any HIV care and treatment quality improvement program.

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

## 4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (**evaluation criteria**)

**4a.** Data Generated as a Byproduct of Care Processes: H☐ M☐ L☐ I☐

**4a.1-2 How are the data elements needed to compute measure scores generated?** *(Check all that apply).*
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition,
Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)

**4b. Electronic Sources:** H☐ M☐ L☐ I☐

**4b.1 Are the data elements needed for the measure as specified available electronically** *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*: ALL data elements in electronic health records (EHRs)

**4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:**

**4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences:** H☐ M☐ L☐ I☐

**4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:**
we are not aware of any inaccuracies, errors, or unintended consequences of measurement identified during testing and/or operational use.

**4d. Data Collection Strategy/Implementation:** H☐ M☐ L☐ I☐

**A.2 Please check if either of the following apply** (*regarding proprietary measures*):
**4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues** (*e.g., fees for use of proprietary measures*):
This measure is available for public use.

For the national quality improvement project, this measure had additional exclusions of patients who died, were incarcerated, or transferred care during the measurement year. From the feedback received from a subset of the Ryan White providers who participated in the national quality improvement project, we eliminated these exclusions. The main reason for the elimination of the incarceration and transferred exclusions was the inability to electronically code incarceration and transferred in either claims data or electronic health records. As for death, Ryan White providers and experts felt that there is sufficient reason for a patient to be virally suppressed at any point in time while alive.

The data used in this measure are readily available and used for other purposes such as payment, meeting reporting requirements for public funding, and disease surveillance. We used the data from 9 sites within the HIV Research Network. These sites have been reporting data to the HIV Research Network for a minimum of 5 years. The HIV Research Network puts forth effort to review for and correct missing or invalid data. We believe the variations in performance across the sites were related to performance and not differences in data availability.

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

## OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement?  Yes☐  No☐
Rationale:

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

## 5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

**5.1 If there are related measures** *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population)*, list the NQF # and title of all related and/or competing measures:
0407 : HIV/AIDS: HIV RNA Control After Six Months of Potent Antiretroviral Therapy

### 5a. Harmonization

**5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):**
Are the measure specifications completely harmonized?  No

**5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:**
We used the most current and available National Committee on Quality Assurance (NCQA) measure when we set out to draft this measure to achieve harmony.  We will continue to work closely with the NCQA to continue to harmonize the measures for the care and treatment of people living with HIV.

### 5b. Competing Measure(s)

**5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures** *(e.g., a more valid or efficient way to measure quality);* **OR provide a rationale for the additive value of endorsing an additional measure.** *(Provide analyses when possible)*:
As presented, this HIV viral load suppression measure is responsive to the most recent U.S. Department of Health and Human Services guideline for HIV treatment by utilizing the definition of viral failure (>200 copies/mL) as the basis for the definition of HIV viral suppression.  Additionally, this measure captures the entire population of people living with HIV within facilities or clinics that are engaged or accessing medical care.  It does not apply any additional criteria such as needing to have a greater number of medical visits or be prescribed HIV antiretroviral therapy.  This is important as a greater emphasis is placed on community HIV viral load and the body of evidence of "treatment as prevention" grows.

## CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner):**  Health Resources and Services Administration - HIV/AIDS Bureau, 5600 Fisher Lane, Rockville, Maryland, 20857

Co.2 **Point of Contact:**  Marlene, Matosky, MPH, RN, mmatosky@hrsa.gov, 301-443-0798-

Co.3 **Measure Developer if different from Measure Steward:**  Health Resources and Services Administration - HIV/AIDS Bureau, 5600 Fisher Lane, Rockville, Maryland, 20857

Co.4 **Point of Contact:**  Marlene, Matosky, MPH, RN, mmatosky@hrsa.gov, 301-443-0798-

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

**Co.5 Submitter:** Marlene, Matosky, MPH, RN, mmatosky@hrsa.gov, 301-443-0798-, Health Resources and Services Administration - HIV/AIDS Bureau

**Co.6 Additional organizations that sponsored/participated in measure development:**
The Centers for Disease Control

**Co.7 Public Contact:** Marlene, Matosky, MPH, RN, mmatosky@hrsa.gov, 301-443-0798-, Health Resources and Services Administration - HIV/AIDS Bureau

## ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
**Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
The work group members determined the measure concepts, identified the data elements, voted on the final measures, and assessed the face validity of the measures.
Bruce Agins, NYS DOH AIDS Institute, New York, NY
Judy Bradford, Fenway Community Health, Boston, MA
John Brooks, CDC, Atlanta, GA
Karen Brudney, Columbia University, New York, NY
Laura Cheever, HRSA HAB, Rockville, MD
Nikki Cockern, Wayne State University,        Detroit, MI
Chinazo Cunningham, Montefiore Medical Center, New York, NY
William Cunningham, UCLA, Los Angeles, CA
Julie Dombrowski, University of Washington, Seattle, WA
Edward  Gardner, Denver Health, Denver, CO
Elvin Geng, UCSF, San Francisco, CA
Thomas  Giordano, Baylor College of Medicine, Houston, TX
Barb Gripshover, Cleveland ACT UP, Cleveland, OH
Deborah  Konkle Parker, University of Mississippi, Jackson, MS
Tim Long, Alliance Chicago, Chicago, IL
Cheryl Lynn-Besch, Louisiana State University, New Orleans, LA
Julio Marrero, COSSMA, San Juan, PR
Brian Montague, Brown University, Providence, RI
Karam  Mounzer, Philadelphia Fight, Philadelphia, PA
Michael   Mugavero, University of Alabama, Birmingham, AL
Sylvia Naar King, Wayne State University, Detroit, MI
Josiah Rich, Brown University, Providence, RI
Allan Rodriguez, Miami University, Miami, FL
Amy Sitapati, UCSD, San Diego, CA
Avnish Tripathi, University of South Carolina, Charleston, SC
Gregory Winstead, Christian Community Health Center,        Chicago, IL

**Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:**

Measure Developer/Steward Updates and Ongoing Maintenance
**Ad.3 Year the measure was first released:**
**Ad.4 Month and Year of most recent revision:**
**Ad.5 What is your frequency for review/update of this measure?**
**Ad.6 When is the next scheduled review/update for this measure?**

**Ad.7 Copyright statement:**

**Ad.8 Disclaimers:**

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable
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**Ad.9 Additional Information/Comments:**  It is our intention that this measure will be used in quality improvement in addition to public reporting.  As it is involved in quality improvement, it is not our intent that the performance goal will be 100%.  When we do set the performance goal, we will take into consideration appropriate reasons why the patient may not be able to meet the numerator criterion.

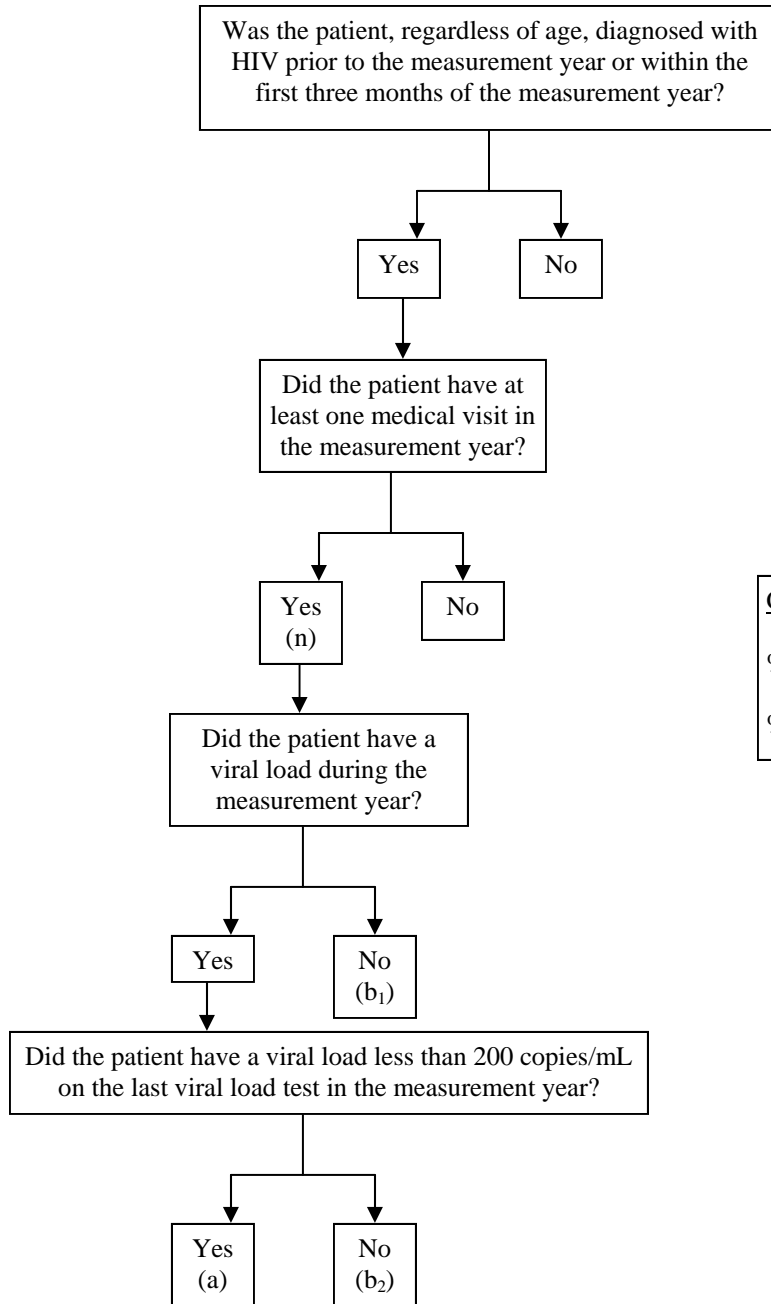**Date of Submission** (*MM/DD/YY*):  07/02/2012

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable
Created on: 09/26/2012 at 02:07 PM

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| VARIABLE DESCRIPTION | FORMAT TYPE | FIELD LENGTH | DEFINITION/ GUIDELINES |
|---|---|---|---|
| Date of Enrollment | Date | MM/15/YYYY | Date of patient's first HIV primary care visit at site. A fixed variable (does not change over time.) Report only month and year with the 15th day of the month. |
| Visit Date | Date | Date MM/DD/YYYY | Month, Day, Year |
| Primary Care Visit Type | Numeric | 1 | Please convert visit type to the associated numeric value. 1 = HIV primary care visit (NOTE: An HIV primary care visit is defined as "a visit with a medical provider – MD, DO, Fellow, Resident, PA, NP - in the HIV clinic") 2 = Nurse 3 = Social Worker 4 = Pharmacist 5 = Case Manager 6 = Nutritionist 8 = Other 0 = Specialty/non-HIV primary care visit type (examples include visits to a dentist, ob/gyn, hepatologist, etc.) 9 = Unknown |
| Date of HIV Diagnosis | Date | MM/01/YYYY | Date of patient's HIV diagnosis. *Note: Required for new patients; optional for existing patients.* Report month and year only using the 1st day of the month. *(Example: 04/01/1997)* If just the year is known, please code as the first of the year (01/01/1997). |
| Date of Viral Load Count | Date | MM/DD/YYYY | Record date of Viral load test. |
| Viral Load Count | Numeric | 11 | Record Viral load count for test date recorded in VLOADDT. Whole numbers only; no decimals. |
| Viral Load Method | Numeric | 1 | 1 = Ultra Sensitive 2 = Regular 3 = bDNA 4 = Nuclisens HIV-1 QT |

| | | | 9 = Unknown |
|---|---|---|---|

2a1.21 "Viral Load Suppression" Measure Logic Diagram and Calculation Logic

Was the patient, regardless of age, diagnosed with HIV prior to the measurement year or within the first three months of the measurement year?

Yes

No

Did the patient have at least one medical visit in the measurement year?

Yes
(n)

No

Did the patient have a viral load during the measurement year?

Yes

No
($b_1$)

Did the patient have a viral load less than 200 copies/mL on the last viral load test in the measurement year?

Yes
(a)

No
($b_2$)

Calculation:

% Patients with viral suppression = (a/n) x 100

% Patients absent viral suppression = ($b_1$ + $b_2$/n) x 100

Revised 6/20/2012