**Measure Title**: Viral Load Supression

**1a.12** **LOGIC MODEL**

HIV

diagnosis

Linkage to medical care

Retention in medical care

Viral suppression

Prescription of HIV ART

Although the above diagram outlines the sequential septs of medical care that people living with HIV go through from initial diagnosis to achieving the goal of viral suppression. For some patients, this is a linear path with sustained viral suppression for many years. For other patients, there may be years between diagnosis and linkage. Yet still for others, retention in medical care is not consistent, which results in missed visits, no prescription for or adherence to HIV antiretroviral therapy (ART), and lack of viral suppression.

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process (e.g., intervention, or service).**

Regularly attending medical visits (retention) is paramount to monitoring patients health status, screenings, and laboratory values. Providers need this information to make an informed decision in order to prescribe HIV antiretroviral therapy (ART). 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. 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.

In 2011, the HIV community saw the emergence of the HIV care continuum.  This simple model outlines the sequential steps of medical care that people living with HIV go through from initial diagnosis to achieving the goal of viral suppression.  The steps include diagnosis, linkage to care, retention in care, receipt of HIV antiretroviral therapy and viral suppression.  This model has been incorporated into the National HIV/AIDS Strategy as it has focused all HIV prevention, care, and treatment efforts in the United States.  As outlined in the model, all though there are five different steps, each step is dependent upon each other.   For instance, you cannot become virally suppressed if you are not receiving HIV antiretroviral therapy or retained in medical care.

The most recent nationwide data from CDC dated 2014 estimates that although 86% of people living with HIV have been diagnosed, only 40% are engaged in care, 37% have been prescribed HIV antiretroviral therapy, and 30% have achieved viral suppression.

Right now, we are at a very special time and place.  Many states and large metropolitan areas across the United States have developed plans to end the HIV epidemic in the communities.  These jurisdictions have used the HIV care continuum and its steps as the framework by which they have developed their plans.

In closing, the measures we have put forth are in alignment with the HIV care continuum.  We see these measures as a suite – each important as individual measures, but work together as a suite to improve health outcomes for people living with HIV in the United States.

**1b.1. Briefly explain the rationale for this measure (e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)**

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 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). Viral suppression is a main goal of HIV treatment and an indicator of treatment success and reduction of potential HIV transmission. It is directly related to:

* Reduction in disease progression, incidence of opportunistic infections, the risk of both defining and non-AIDS- defining complications and the incidence and severity of chronic conditions.
* Reduction in the risk of transmitting HIV to a sexual or drug-using partner who does not have HIV.
* Improvement of immune function, quality of life, increase in time until development of AIDS increase in life expectancy. Being virally suppressed is good for an HIV-positive person’s overall health and preventing HIV infection from advancing to AIDS, the last stage of HIV infection.
* Durable viral suppression improves immune function and quality of life, prolongs life, lowers the risk of both AIDS-defining and non-AIDS-defining complications, and prolongs life. The proposed measure will direct providers’ attention and quality improvement efforts towards this important outcome.

**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

**1a.4.1. Guideline citation** (*including date*) and **URL for guideline** (*if available online*):

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, Accessed November 18, 2016: <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>

Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States, Accessed November 18, 2016

<https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/0>

International Advisory Panel on HIV Care Continuum Optimization (IAPAC). (2015). IAPAC Guidelines for Optimizing the HIV Care Continuum for Adults and Adolescents. Accessed November 18, 2016. <http://www.iapac.org/uploads/JIAPAC-IAPAC-Guidelines-for-Optimizing-the-HIV-Care-Continuum-Supplement-Nov-Dec-2015.pdf>

World Health Organization (WHO). (2016). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach. Accessed November 18, 2016: <http://apps.who.int/iris/bitstream/10665/208825/1/9789241549684_eng.pdf?ua=1>

Günthard HF, Saag MS, Benson CA, del Rio C, Eron JJ, Gallant JE, Hoy JF, Mugavero MJ, Sax PE, Thompson MA, Gandhi RT, Landovitz RJ, Smith DM, Jacobsen DM, Volberding PA. Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults 2016 Recommendations of the International Antiviral Society (IAS)–USA Panel. JAMA. 2016. <https://www.iasusa.org/content/antiretroviral-drugs-treatment-and-prevention-hiv-infection-adults-2016-recommendations>

**1a.4.2. Identify guideline recommendation number and/or page number** and **quote verbatim, the specific guideline recommendation**.

**Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents**

[Panel's Recommendations for Initiating Antiretroviral Therapy in Treatment-Naive Patients](https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/10/initiation-of-antiretroviral-therapy) (pE1)

Antiretroviral therapy (ART) is recommended for all HIV-infected individuals, regardless of CD4 T lymphocyte cell count, to reduce the morbidity and mortality associated with HIV infection (**AI**).

[Panel's Recommendations for Acute and Recent (Early) HIV Infection](https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/20/acute-and-recent--early--hiv-infection) (pI1)

* Antiretroviral therapy (ART) is recommended for all individuals with HIV-1 infection **(AI)** including those with early HIV-1 infection.
* Once initiated, the goal of ART is to suppress plasma HIV-1 RNA to undetectable levels **(AIII)**. Testing for plasma HIV-1 RNA levels, CD4 T lymphocyte counts, and toxicity monitoring should be performed as recommended for patients with chronic HIV-1 infection **(AII)**.

[Panel's Recommendations Regarding Virologic Failure of the Treatment-Experienced Patient](https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/15/virologic-failure) (pH1)

* The goal of treatment for ART-experienced patients with drug resistance who are experiencing virologic failure is to establish virologic suppression (i.e., HIV RNA below the lower limits of detection of currently used assays) **(AI)**.
* Discontinuing or briefly interrupting therapy may lead to a rapid increase in HIV RNA and a decrease in CD4 cell count and increases the risk of clinical progression. Therefore, this strategy is **not** recommended in the setting of virologic failure **(AI)**.

[Laboratory Testing, Plasma HIV-1 RNA (Viral Load) and CD4 Count Monitoring](https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/458/plasma-hiv-1-rna--viral-load--and-cd4-count-monitoring) (pC5)

* Viral load is the most important indicator of initial and sustained response to ART (AI) and should be measured in all HIV-infected patients at entry into care (AIII), at initiation of therapy (AIII), and on a regular basis thereafter. For those patients who choose to delay therapy, repeat viral load testing while not on ART is optional (CIII).
* Plasma viral load should be measured before initiation of ART and within 2 to 4 weeks but no later than 8 weeks after treatment initiation or modification (AIII). The purpose of the measurements is to confirm an adequate initial virologic response to ART, indicating appropriate regimen selection and patient adherence to therapy. Repeat viral load measurement should be performed at 4- to 8-week intervals until the level falls below the assay’s limit of detection (BIII).
* In virologically suppressed patients in whom ART was modified because of drug toxicity or for regimen simplification. Viral load measurement should be performed within 4 to 8 weeks after changing therapy (AIII). The purpose of viral load monitoring at this point is to confirm the effectiveness of the new regimen.
* In patients on a stable, suppressive ARV regimen. Viral load should be repeated every 3 to 4 months (AIII) or as clinically indicated to confirm continuous viral suppression. Clinicians may extend the interval to 6 months for adherent patients whose viral load has been suppressed for more than 2 years and whose clinical and immunologic status is stable (AIII).

[**Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States**](https://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0)

[**https://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0**](https://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0)

Panel's Recommendations for HIV-Infected Pregnant Women Who Have Never Received Antiretroviral Drugs (pC27)

* All HIV-infected pregnant women should receive combination antiretroviral therapy (cART) to reduce the risk of perinatal transmission of HIV **(AI)**. The choice of regimen should take into account current adult treatment guidelines, what is known about the use of specific drugs in pregnancy, and the risk of teratogenicity (see [Table 6](https://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/487/table-6---what-to-start--initial-combination-regimens-for-antiretroviral-naive-pregnant-women) and [Table 7](https://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/489/table-7--antiretroviral-drug-use-in-pregnant-hiv-infected-women--pharmacokinetic-and-toxicity-data-in-human-pregnancy-and-recommendations-for-use-in-pregnancy)).
* Consideration should be given to initiating cART as soon as HIV is diagnosed during pregnancy; earlier viral suppression is associated with lower risk of transmission. This decision may be influenced by CD4 T lymphocyte count, HIV RNA levels, and maternal conditions (e.g., nausea and vomiting) **(AIII)**. The benefits of early cART must be weighed against potential fetal effects of drug exposure.

Panel's Recommendations Regarding Lack of Viral Suppression During Antepartum Care (p48)

* Because maternal antenatal viral load correlates with risk of perinatal transmission of HIV, suppression of HIV RNA to undetectable levels should be achieved as rapidly as possible **(AII)**.
* If an ultrasensitive HIV RNA assay indicates failure of viral suppression (after an adequate period of treatment):
	+ Assess adherence and resistance (if HIV RNA level is high enough for resistance testing) **(AII)**.
	+ Consult an HIV treatment expert and consider possible antiretroviral regimen modification **(AIII)**.
	+ Scheduled cesarean delivery is recommended for HIV-infected pregnant women who have HIV RNA levels >1,000 copies/mL near the time of delivery **(AII)**.

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* Where possible, jurisdictions should consider longitudinal cohort measurement of HIV service utilization and treatment outcomes to identify the means to maximize viral suppression through ensuring early access to ART and retention in care. (A IV) (p4)

World Health Organization:

* ARV drugs play a key role in HIV prevention. People taking ART who achieve optimal viral suppression are extremely unlikely to pass HIV to sexual partners. ARV drugs taken by people without HIV as PrEP or PEP are highly effective in preventing HIV acquisition. (p64)
* People starting treatment and carergivers should be informed that the first ART regimen offers the best opportunity for effective viral suppression, immune recovery and consequently clinical benefit and that successful ART requires all medications to be taken as prescribed. (p72)
* Access to ART should be the first priority for all age groups, and lack of testing for monitoring treatment response should not be a barrier to initiating ART. If viral load testing capacity is limited, it should be introduced in a phased approach. Examples of phased approaches include: …
	+ using viral load initially as a targeted test to confirm treatment failure;
	+ prioritizing viral load testing for pregnant and breastfeeding women, especially around the time of delivery, as sustained viral suppression is critical to prevention of transmission to the child, and documented high viral load at delivery is an indication for enhanced infant prophylaxis; (p134)

**Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults, 2016 Recommendations of the International Antiviral Society–USA Panel**

* HIV RNA level should be monitored every 4 to 6 weeks after treatment is initiated or changed until virus is undetectable (evidence rating AIa). (Box 5)
* After viral suppression is achieved, HIV RNA should be monitored every 3 months until suppressed for 1 year and at least every 6 months thereafter for adherent patients who remain clinically stable (evidence rating AIII). (Box 5)
* When virus has been suppressed for at least 2 years and CD4 cell count is persistently above 500/μL, repeat monitoring of CD4 cell count is not recommended unless virologic failure (evidence rating AIIa) or intercurrent immunosuppressive conditions occur or immunosuppressive treatments are initiated (evidence rating AIII). (Box 5)
* If the HIV RNA level remains above the limit of quantification by 24 weeks after starting new treatment or if rebound above 50 copies/mL occurs at any time, the assay should be repeated within 4 weeks to exclude impending virologic failure (evidence rating AIIa). (Box 5)
* For patients with persistent quantifiable HIV RNA between 50 and 200 copies/mL, reassessment for causes of virologic failure, evaluation again within 4 weeks, and close monitoring are recommended (evidence rating BIII). (Box 5)

**1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:**

**Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents and** [**Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States**](https://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0)

Basis for Recommendations

Recommendations in these guidelines are based upon scientific evidence and expert opinion. Each

recommended statement includes a letter (A, B, or C) that represents the strength of the recommendation and a Roman numeral (I, II, or III) that represents the quality of the evidence that supports the recommendation (see Table 2).

Table 2. Rating Scheme for Recommendations

|  |  |
| --- | --- |
| Strength of Recommendation | Quality of Evidence for Recommendation |
| **A:** Strong recommendation for the statement**B:** Moderate recommendation for the statement**C:** Optional recommendation for the statement | **I:** One or more randomized trials with clinical outcomes and/or validated laboratory endpoints**II:** One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes**III:** Expert opinion |

**International Advisory Panel on HIV Care Continuum Optimization; IAPAC Guidelines for Optimizing the HIV Care Continuum for Adults and Adolescents.**

Strong (A) = Almost all patients should receive the recommended course of action.

Moderate (B) = Most patients should receive the recommended course of action. However, other choices may be appropriate for some patients.

Optional (C) There may be consideration for this recommendation based on individual patient circumstances. Not recommended routinely.

Quality of the Body of Evidence and its Interpretation:

Excellent (I) = Randomized control trial (RCT) evidence without important limitations; overwhelming evidence from observational studies

High (II) = RCT evidence with important limitations; strong evidence from observational studies

Medium (III) = RCT evidence with critical limitations; observational study without important limitations

Low (IV) = Other evidence, including extrapolations from bench research, usual practice, expert opinion, consensus guidelines; observational study evidence with important or critical limitations

**World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection Recommendations for a public health approach - Second edition.**

Process of guideline development This edition of the guidelines was revised in accordance with procedures established by the WHO Guidelines Review Committee. New clinical and operational recommendations in the guidelines are based on the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach to reviewing evidence. Modelling, expert consultations and country case studies have all strongly informed the guidelines. The process has also identified key gaps in knowledge that will help to guide the future HIV research agenda. A strong recommendation is one for which there is confidence that the desirable effects of adherence to the recommendation clearly outweigh the undesirable effects. A conditional recommendation is one for which the Guideline Development Group concludes that the desirable effects of adherence to the recommendation probably outweigh the undesirable effects or are closely balanced, but the Groups are not confident about these trade-offs in all situations. At implementation, monitoring and rigorous evaluation is needed to address these uncertainties, which are likely to provide new evidence that may change the calculation of the balance of trade-offs and to suggest how to overcome any implementation challenges.

Quality of evidence Definition

Table 1.1. GRADE quality of evidence

|  |  |
| --- | --- |
| Quality of evidence  | Definition  |
| High  | We are very confident that the true effect lies close to that of the estimate of the effect  |
| Middle  | We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different  |
| Low  | Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect  |
| Very low  | We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect |

**Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults, 2016 Recommendations of the International Antiviral Society–USA Panel**

Table 1. Strength of Recommendation and Quality of Evidence Rating Scale

|  |  |
| --- | --- |
| Rating | Definition |
| Strength of recommendation |
| A | Strong support for the recommendation |
| B | Moderate support for the recommendation |
| C | Limited support for the recommendation |
| Quality of evidence |
| Ia | Evidence for > 1 randomized clinical trials published in the peer-reviewed literature |
| Ib | Evidence for > 1 randomized clinical trials presented in abstract form at peer-reviewed scientific meetings |
| IIa | Evidence from nonrandomized clinical trials or cohorts or case-control studies published in the peer-reviewed literature |
| IIb  | Evidence from nonrandomized clinical trials or cohorts or case-control studies published in the peer-reviewed scientific meeting |
| III | Recommendation based on panel’s analysis of the accumulated available evidence  |

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

All grade and definitions noted in 1a.4.3.

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

Citations noted in 1a.4.1.

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

X Yes **→ *complete section 1a.7***

☐ No **→ *report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7***