**Measure Title**: Prescription of HIV Antiretroviral Therapy

**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 form initial diagnosis to achieving the goal of viral suppression (also known as the HIV care continuum). 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 patient’s 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.

**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. HIV antiretroviral therapy delays this progression and increases the length of survival.

Current HIV treatment guidelines now recommend universal prescription of HIV antiretroviral therapy for sustained viral load suppression which in turn is directly related to reduction in disease progression and reduction in potential for transmission of HIV 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.

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.

**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 15, 2016: <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.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 15, 2016: <http://apps.who.int/iris/bitstream/10665/208825/1/9789241549684_eng.pdf?ua=1>

International Advisory Panel on HIV Care Continuum Optimization (IAPAC). (2015). IAPAC Guidelines for Optimizing the HIV Care Continuum for Adults and Adolescents. Accessed November 15, 2016. <http://www.iapac.org/uploads/JIAPAC-IAPAC-Guidelines-for-Optimizing-the-HIV-Care-Continuum-Supplement-Nov-Dec-2015.pdf>

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–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:

Initiation of Antiretroviral Therapy (page E-1)

* 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).
* ART is also recommended for HIV-infected individuals to prevent HIV transmission (AI).
* When initiating ART, it is important to educate patients regarding the benefits and considerations regarding ART, and to address strategies to optimize adherence. On a case-by-case basis, ART may be deferred because of clinical and/or psychosocial factors, but therapy should be initiated as soon as possible.

Considerations for Antiretroviral Use in Special Patient Populations: Acute and Recent (Early) HIV Infection (page I-1)

* Antiretroviral therapy (ART) is recommended for all individuals with HIV-1 infection (AI) including those with early HIV-1 infection.

HIV-Infected Adolescents and Young Adults (page I-8):

* ART is recommended for all HIV-infected individuals (AI) to reduce morbidity and mortality. Thus, ART is also recommended for ART-naive adolescents. However, before initiation of therapy, adolescents’ readiness and ability to adhere to therapy within their psychosocial context need to be carefully considered as partner of therapeutic decision making (AIII).

HIV-Infected Women (page I-20):

* Antiretroviral therapy (ART) is recommended for all HIV-infected women to improve their health and to reduce the risk of HIV transmission to HIV-uninfected sex partners (AI).

HIV/Hepatitis C Virus Coinfection (page J-6):

* Antiretroviral therapy (ART) may slow the progression of liver disease by preserving or restoring immune function and reducing HIV related immune activation and inflammation. For most HCV/HIV-coinfected patients, including those with cirrhosis, the benefits of ART outweigh concerns regarding drug-induced liver injury. Therefore, ART should be initiated in all HCV/HIV-coinfected patients, regardless of CD4 T lymphocyte (CD4) cell count (AI).

WHO:

4.3 When to start ART (page xxxi)

4.3.1 When to start ART in adults (>19 years old)

* ART should be initiated in all adults living with HIV, regardless of WHO clinical stage and at any CD4 cell count (strong recommendation, moderate-quality evidence).
* As a priority, ART should be initiated in all adults with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and adults with a CD4 count ≤350 cells/mm3 (strong recommendation, moderate-quality evidence).

4.3.2 When to start ART in pregnant and breastfeeding women

* ART should be initiated in all pregnant and breastfeeding women living with HIV, regardless of WHO clinical stage and at any CD4 cell count and continued lifelong (strong recommendation, moderate-quality evidence).

4.3.3 When to start HIV antiretroviral therapy in adolescents (10–19 years of age)

* ART should be initiated in all adolescents living with HIV, regardless of WHO clinical stage and at any CD4 cell count (conditional recommendation, low-quality evidence).
* As a priority, ART should be initiated in all adolescents with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and adolescents with a CD4 count ≤350 cells/mm3 (strong recommendation, moderate-quality evidence).

4.3.4 When to start HIV antiretroviral therapy in children younger than 10 years of age

* ART should be initiated in all children living with HIV, regardless of WHO clinical stage or at any CD4 cell count:
* Infants diagnosed in the first year of life (strong recommendation, moderate-quality evidence).
* Children living with HIV 1-year-old to less than 10 years old (conditional recommendation, low-quality evidence).
* As a priority, ART should be initiated in all children <2 years of age or children younger than 5 years of age with WHO clinical stage 3 or 4 or CD4 count ≤750 cells/mm³ or CD4 percentage <25% and children 5 years of age and older with WHO clinical stage 3 or 4 or CD4 count ≤350 cells/mm³ (strong recommendation, moderate-quality evidence).

4.3.5 Timing of HIV ANTIRETROVIRAL THERAPY for adults and children with TB

* ART should be started in all TB patients living with HIV regardless of CD4 count (strong recommendation, high-quality evidence).

International Advisory Panel on HIV Care Continuum Optimization (IAPAC):

Increasing HIV treatment coverage (page 3)

* The immediate offer of ART after HIV diagnosis, irrespective of CD4 count or clinical stage, is recommended. (AI)

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

Box 1. Recommendations for When to Start (page 193)

* Antiretroviral therapy (HIV ANTIRETROVIRAL THERAPY) is recommended for all viremic patients with established HIV infection, regardless of CD4 cell count (evidence rating AIa).
* Initiation of ART is recommended as soon as possible in the setting of acute HIV infection (evidence rating BIII).
* Planned discontinuation of early ART after a specific duration of treatment is not recommended outside a research setting (evidence rating AIa).
* Initiation of ART is recommended for individuals who have persistent undetectable viral load without ART but have declining CD4 cell counts (evidence rating BIII).

**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:

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.:

The strength of a recommendation can be either strong or conditional. 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 evidnce  |

**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***