

HAB HIV Core Clinical Performance Measures for Adult/Adolescent Clients: Group 1

Performance Me	easure: ARV Therapy for Pregnant	OPR-Related Measure: Yes			
Women	www.hrsa.gov/performancereview/measures.htm				
Percentage of pre	egnant women with HIV infection who a	re prescribed antiretroviral therapy			
Numerator:	Number of HIV-infected pregnant women who were prescribed antiretroviral therapy during the 2nd and 3 rd trimester				
Denominator:	Number of HIV-infected pregnant women who had a medical visit with a provider with prescribing privileges ¹ , i.e. MD, PA, NP at least once in the measurement year				
Patient Exclusions:	 Patients whose pregnancy is terminated Pregnant patients who are in the 1st trimester and newly enrolled in care during last three months of the measurement year 				
Data Element:	1. Is the client HIV-infected? (Y/N) a. If yes, is the client female? (Y/N) i. If yes, was she pregnant during the reporting period? (Y/N) 1. If yes, was she on antiretroviral therapy during this reporting period? (Y/N)				
Data Sources:	 Ryan White Program Data Report, Section 5, Item 53 may provide data useful in establishing a baseline for this performance measure Electronic Medical Record/Electronic Health Record CAREWare, Lab Tracker, or other electronic data base Medical record data abstraction by grantee of a sample of records 				
National Goals, Targets, or Benchmarks for Comparison:	None available at this time.				
Outcome Measures for Consideration:	 Rate of perinatal transmission in the measurement year Number of events of perinatal transmission in the measurement year 				
1					

Basis for Selection and Placement in Group 1:

Treatment recommendations for pregnant women infected with HIV-1 have been based on the belief that therapies of known benefit to women should not be withheld during pregnancy unless there are known adverse effects on the mother, fetus, or infant and unless these adverse effects outweigh the benefit to the woman. Antiretroviral therapy can reduce perinatal HIV-1 transmission by nearly 70%.²

Measure reflects important aspect of care that significantly impacts survival, mortality and hinders transmission. Data collection is currently feasible and measure has a strong evidence base supporting the use.

US Public Health Service Guidelines:

Health-care providers considering the use of antiretroviral agents for HIV-1 infected women during pregnancy must take into account two separate but related issues:



- Antiretroviral treatment of maternal HIV-1 infection, and
- Antiretroviral chemoprophylaxis to reduce the risk for perinatal HIV-1 transmission

The benefits of antiretroviral therapy for a pregnant woman must be weighed against the risk of adverse events to the woman, fetus, and newborn. Although ZDV chemoprophylaxis alone has substantially reduced the risk for perinatal transmission, antiretroviral monotherapy is now considered suboptimal for treatment of HIV-1 infection, and combination drug regimens are considered the standard of care for therapy. Initial evaluation of an infected pregnant woman should include an assessment of HIV-1 disease status and recommendations regarding antiretroviral treatment or alteration of her current antiretroviral regimen.

This assessment should include the following:

- Evaluation of the degree of existing immunodeficiency determined by CD4 T-cell count,
- Risk for disease progression as determined by the level of plasma RNA,
- History of prior or current antiretroviral therapy,
- Gestational age, and
- Supportive care needs.

Decisions regarding initiation of therapy should be the same for women who are not currently receiving antiretroviral therapy and for women who are not pregnant, with the additional consideration of the potential impact of such therapy on the fetus and infant.

Further, use of ZDV alone should not be denied to a woman who wishes to minimize exposure of the fetus to other antiretroviral drugs and therefore, after counseling, chooses to receive only ZDV during pregnancy to reduce the risk for perinatal transmission.¹

References/Notes:

¹A "provider with prescribing privileges" is a health care professional who is certified in their jurisdiction to prescribe ARV therapy.

²Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States (http://aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf)



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				www.hrsa.gov/performancereview/measures.htm			
Percentage of clients with HIV infection who had 2 or more CD4 T-cell counts performed in the							
measurement year							
Numerator:	Number of HIV-infected clients who had 2 or more CD4 T-cell counts performed at least						
Numerator.	3 months apart during the measurement year						
Denominator:	Number of HIV-infected clients who had a medical visit with a provider with prescribing						
Denominator:	privileges ¹ , i.e. MD, PA, NP at least once in the measurement year						
Patient Exclusions:	Patients newly enrolled in care during last six months of the year						
	1. Is the clien	t HIV-infe	ected? (Y/	N)			
Data Element:	a. If yes, did the client have a CD4 count test conducted during the						
Data Element.	reporting period? (Y/N)						
		a. If yes,	, list the q	uarters of th	nese tests		
	Electronic Medical Record/Electronic Health Record						
Data Sources:	CAREWare, Lab Tracker, or other electronic data base						
Data Sources:	HIVQUAL reports on this measure for grantee under review						
	 Medical record data abstraction by grantee of a sample of records 						
	IHI Goal: 90% ²						
National Goals,	National HIVQUAL Data: ³						
Targets, or	Tradional III v QUI	2003	2004	2005	2006		
Benchmarks	Top 10%	87.2%	87.7%	90.3%	87.5%		
for	Top 25%	74.2%	78.0%	76.6%	78.8%		
Comparison	Median*						
F	Median* 61.0% 62.7% 63.9% 62.5% *from HAB data base						
	Rate of opportunistic infections in the measurement year						
Outcome	 Rate of clients with progression to AIDS in the measurement year Montality rates 					ent vear	
Measures for						, ,	
Consideration	morality rates						
	ı						

Basis for Selection and Placement in Group 1:

The CD4 T-cell count plays a vital role in determining the staging of HIV disease and indicating the need for prophylaxis against opportunistic infections. It continues to be used in decisions regarding initiation or adjustment of antiretroviral treatment.

The most recent CD4 T-cell count is the strongest predictor of subsequent disease progression and survival, according to clinical trials and cohort studies data on patients receiving antiretroviral therapy.⁴

Measure reflects important aspects of care that significantly impacts survival and mortality. Data collection is currently feasible and measure has a strong evidence base supporting the use.

US Public Health Service Guidelines:

"In general, CD4 T-cell count should be determined every three to six months to (1) determine when to start antiretroviral in patients who do not meet the criteria for initiation; (2) assess immunologic response to



antiretroviral therapy; and (3) assess the need for initiating chemoprophylaxis for opportunistic infections." ³

References/Notes:

Guidelines state that CD4 T-cell counts should be measured at least every 3-4 months depending on the stage of the disease. The timeframe of 6 months was determined by clinical expert consensus for the purpose of this measure, but can and should be measured at more frequent intervals if needed.

¹A "provider with prescribing privileges" is a health care professional who is certified in their jurisdiction to prescribe ARV therapy.

²IHI Measure reads, "Percent of Patients/Clients with a CD4 Count Test in the Past <u>4</u> Months" (http://www.ihi.org/IHI/Topics/HIVAIDS/HIVDiseaseGeneral/Measures/Percentof+patientswithaCD4counttestinthepast4months.htm)

³National HIVQUAL data looks at the percent of clients who have a CD4 T-cell count done every <u>four</u> months, not every six months.

(http://www.hivguidelines.org/admin/files/qoc/hivqual/proj%20info/HQNatlAggScrs3Yrs.pdf)

⁴Panel on Antiretroviral Guidelines for Adult and Adolescents. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. Department of Health and Human Services. December 1, 2007; 1-143. Available at http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed December 12, 2007.



Performance Measure: HAART				OPR-Related Measure: Yes www.hrsa.gov/performancereview/measures.htm			
Percentage of clients with AIDS who are prescribed HAART							
Numerator:	Number of clients with AIDS who were prescribed a HAART regimen ¹ within the measurement year						
Denominator:	 Number of clients who: have a diagnosis of AIDS (history of a CD4 T-cell count below 200 cells/mm³ or other AIDS-defining condition²), and had at least one medical visit with a provider with prescribing privileges³, i.e. MD, PA, NP in the measurement year. 						
Patient Exclusions:	1. Patients newly enrolled in care during last three months of the measurement year						
Data Element:	Is the client diagnosed with CDC-defined AIDS? (Y/N) a. If yes, was the client prescribed HAART during the reporting period? (Y/N)						
Data Sources:	 Ryan White Program Data Report, Section 2, Items 26 and 31 may provide data useful in establishing a baseline for this performance measure Electronic Medical Record/Electronic Health Record CAREWare, Lab Tracker, or other electronic data base. HIVQUAL reports on this measure for grantee under review Medical record data abstraction by grantee of a sample of records 						
National Goals, Targets, or Benchmarks for Comparison	IHI Goal: 90% CDC and HIVRN data consistent that 80% of those in care "eligible for ARVs" on tx. This includes CD4<350 and not just AIDS. S,6						
Outcome Measures for Consideration:	 Rate of opportunistic infections in the measurement year Rate of HIV-related hospitalizations in the measurement year Mortality rates 						

Basis for Selection and Placement in Group 1:

"Randomized clinical trials provide strong evidence of improved survival and reduced disease progression by treating symptomatic patients and patients with CD4 T-cells <200 cells/mm³."

Measure reflects important aspect of care that significantly impacts survival, mortality and hinders transmission. Data collection is currently feasible and measure has a strong evidence base supporting the use.



US Public Health Service Guidelines:

"Antiretroviral therapy is recommended for all patients with history of an AIDS-defining illness or severe symptoms of HIV infection regardless of CD4 T-cell count." ¹⁰

References/Notes:

¹Many authorities recommend two baseline CD4 T-cell measurements before decisions are made to initiate antiretroviral therapy because of wide variations in results. The test should be repeated yet a third time if discordant results are seen. The optimal time to initiate antiretroviral therapy among asymptomatic patients with CD4 T-cell counts >200 cells/mm³ is unknown. This measure focuses strictly on the subset of patients for whom antiretroviral therapy is unequivocally recommended—those with a CD4 T-cell count below 200 cells/mm³ or history of another AIDS-defining condition. Asymptomatic patients with CD4 T-cell counts of 201–350 cells/mm³ should be offered treatment. For asymptomatic patients with CD4 T-cell of >350 cells/mm³ and plasma HIV RNA >100,000 copies/ml most experienced clinicians defer therapy but some clinicians may consider initiating treatment. (See reference 8 below)

²AIDS Defining conditions are noted in CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992;41(no. RR-17). (http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm)

³A "provider with prescribing privileges" is a health care professional who is certified in their jurisdiction to prescribe ARV therapy.

⁴IHI Measure reads, "Percent of Patients with Appropriate ARV Therapy Management" http://www.ihi.org/IHI/Topics/HIVAIDS/HIVDiseaseGeneral/Measures/PercentofPatientswithAppropriateA RVTherapyManagement.htm)

⁵ Gebo, JAIDS January 2005, vol. 38, pp. 96-103.

⁶ Teshale Abstract #167, CROI 2005.

⁷ The National HIVQUAL data may not be directly comparable due to varying exclusions. Indicator definitions can be accessed at http://www.hivguidelines.org/Content.aspx?PageID=53.

8http://www.hivguidelines.org/admin/files/qoc/hivqual/proj%20info/HQNatlAggScrs3Yrs.pdf

⁹"HAART, CD4<200"

(http://www.hivguidelines.org/admin/files/qoc/hivqual/proj%20info/HQNatlAggScrs3Yrs.pdf)

¹⁰Panel on Antiretroviral Guidelines for Adult and Adolescents. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. Department of Health and Human Services. December 1, 2007; p. 9. Available at http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed December 12, 2007.



Performance Measure: Medical Visits		OPR-Related Measure: Yes www.hrsa.gov/performancereview/measures.htm				
	Percentage of clients with HIV infection who had two or more medical visits in an HIV care setting in the measurement year					
Numerator:	Number of HIV-infected clients who had a medical visit with a provider with prescribing privileges ¹ , i.e. MD, PA, NP, in an HIV care setting ² two or more times at least 3 months apart during the measurement year					
Denominator:	Number of HIV-infected clients who had a medical visit with a provider with prescribing privileges at least once in the measurement year					
Patient Exclusions:	Patients newly enrolled in care during last six months of the year					
Data Element:	Is the client HIV-infected? (Y/N) a. Did the client have at least 2 medical visits in an HIV care setting during the reporting period? (Y/N) i. If yes, list the quarters of these visits					
Data Sources:	 Ryan White Program Data Report, Section 5, Items 42 and 43 may provide data useful in establishing a baseline for this performance measure Electronic Medical Record/Electronic Health Record CAREWare, Lab Tracker, or other electronic data base HIVQUAL reports on this measure for grantee under review Medical record data abstraction by grantee of a sample of records 					
National Goals, Targets, or Benchmarks for Comparison	None available at this time.					
Outcome Measures for Consideration	 Rate of HIV-related hospitalizat Rate of HIV-related emergency Rate of opportunistic infections Mortality rates 	room visits in the measurement year				

Basis for Selection and Placement in Group 1:

Clinicians should schedule routine monitoring visits at least every 4 months for all HIV-infected patients who are clinically stable.^{3,4}

Greater experience among primary care physicians in the care of persons with AIDS improves survival.⁵

Measure reflects important aspects of care that significantly impacts mortality. Data collection is currently feasible and measure has a strong evidence base supporting the use.

US Public Health Service Guidelines:

In general, patients with early-stage disease are seen at 3-month intervals to undergo routine medical evaluation and monitoring of CD4 T-cell count, viral load and CBC. During the initial evaluation more frequent visits are common because there is so much information to transmit. Visits should also be more frequent when therapy is introduced and when the CD4 T-cell count is <200 cells/mm³ because complications



are more likely.6

Multiple studies have demonstrated that better outcomes are achieved in patients cared for by a clinician with expertise. This has been shown in terms of mortality, rate of hospitalizations, compliance with guidelines, cost of care, and adherence to medications. The definition of expertise in these studies has varied, but most rely on the number of patients actively managed. Based on this observation, the Panel recommends HIV primary care by a clinician with at least 20 HIV-infected patients and preferably at least 50 HIV-infected patients. Many authoritative groups have combined the recommendation based on active patients, along with fulfilling ongoing CME requirements on HIV-related topics. ⁷

References/Notes:

Guidelines state that routine monitoring of HIV-infected patients should occur at least every 3-4 months depending on the stage of the disease. The timeframe of 6 months was determined by clinical expert consensus for the purpose of this measure, but CD4 T-cell counts can and should be measured at more frequent intervals if needed.

¹A "provider with prescribing privileges" is a health care professional who is certified in their jurisdiction to prescribe ARV therapy.

²An HIV care setting is one which received Ryan White HIV/AIDS Treatment Modernization Act of 2006 funding to provide HIV care and has a quality management program in place to monitor the quality of care addressing gaps in quality of HIV care.

³New York State Department of Health. Primary care approach to the HIV-infected patient. New York: New York State Department of Health; 2004. p. 8.

http://www.hivguideliens.org/Content.aspx?pageID=257[Accessed November 27, 2007].

⁴AETC National Resource Center. Clinical Manual for Management of the HIV-Infected Adult http://www.aidsetc.org/pdf/AETC-CM_071007.pdf [Accessed November 27, 2007].

⁵<u>Kitahata MM, Van Rompaey SE, Dillingham PW, Koepsell TD, Deyo RA, Dodge W, Wagner EH</u>. Primary care delivery is associated with greater physician experience and improved survival among persons with AIDS. J Gen Intern Med. 2003 Feb;18(2):157-8.

⁶Bartlett JG, Cheever LW, Johnson MP, Paauw DS [eds]. A Guide to Primary Care of People with HIV/AIDS. Rockville(MD): US Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau; 2004, p. 167. http://hab.hrsa.gov/tools/primarycareguide/. [Accessed November 27, 2007].

⁷Panel on Antiretroviral Guidelines for Adult and Adolescents. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. Department of Health and Human Services. December 1, 2007; 1-143. Available at http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed December 12, 2007.



Performance Me	easure: PCP Prophy	ylaxis			ed Measure:	
Percentage of clie PCP prophylaxis	ents with HIV infect	ion and a (mm ³ who were prescribed
Numerator:	Number of HIV-infected clients with CD4 T-cell counts below 200 cells/mm ³ who were prescribed PCP prophylaxis					
Denominator:	 Number of HIV-infected clients who: had a medical visit with a provider with prescribing privileges¹, i.e. MD, PA, NP at least once in the measurement year, and had a CD4 T-cell count below 200 cells/mm³ 					
Patient Exclusions:	 Patients with CD4 T-cell counts below 200 cells/mm³ repeated within 3 months rose above 200 cells/mm³ Patients newly enrolled in care during last three months of the measurement year 					
Data Element:	1. Is the client HIV-infected? (Y/N) a. If yes, was the CD4 T-cell count <200 cells/mm ³ ? (Y/N) i. If yes, was PCP prophylaxis prescribed? (Y/N) 1. If no, was the CD4 count repeated within 3 months? (Y/N) a. If yes, did it remain below 200 cells/mm ³ ? (Y/N) i. If yes, was PCP prophylaxis prescribed? (Y/N)					
Data Sources:	 Electronic Medical Record/Electronic Health Record CAREWare, Lab Tracker, or other electronic data base HIVQUAL reports on this measure for grantee under review Medical record data abstraction by grantee of a sample of records 					
National Goals, Targets, or Benchmarks for Comparison:	IHI Goal: 95% ² National HIVQUA Top 10% Top 25% Median* *from HAB data base	AL Data ³ : 2003 100% 100% 93.3%	2004 100% 100% 90.9%	2005 100% 100% 92.3%	2006 100% 100% 94.4%	
Outcome Measures for Consideration:	 Rate of PCP in Mortality rates Cost savings 			ear		

Basis for Selection and Placement in Group 1:

Pneumocystis pneumonia (PCP) is the most common opportunistic infection in people with HIV. Without treatment, over 85% of people with HIV would eventually develop PCP. It is a major cause of mortality among persons with HIV infection, yet is almost entirely preventable and treatable. Pneumocystis almost always affects the lungs, causing a form of pneumonia. People with CD4 T-cell counts under 200 cells/mm³



are at greatest risk of developing PCP. The drugs now used to prevent and treat PCP include TMP/SMX, dapsone, pentamidine, and atovaquone.⁴

Before the widespread use of primary PCP prophylaxis and effective ART, PCP occurred in 70%--80% of patients with AIDS. The course of treated PCP was associated with a mortality rate of between 20% and 40% in persons with profound immunosuppression. Approximately 90% of cases occurred among patients with CD4 T-cell counts <200 cells/mm³. ⁵

Measure reflects important aspect of care that significantly impacts survival and mortality. Data collection is currently feasible and measure has a strong evidence base supporting the use.

US Public Health Service Guidelines:

HIV-infected adults and adolescents, including pregnant women and those on HAART, should receive chemoprophylaxis against PCP if they have a CD4 T-cell count <200 cells/mm³.⁶

References/Notes:

- ¹A "provider with prescribing privileges" is a health care professional who is certified in their jurisdiction to prescribe ARV therapy.
- ² IHI Measure reads, "Percent of Patients with a CD4 Cell Count Below 200 cells/mm³ Receiving Pneumocystis Carinii Pneumonia (PCP) Prophylaxis"
- ³(http://www.hivguidelines.org/admin/files/qoc/hivqual/proj%20info/HQNatlAggScrs3Yrs.pdf)
- 4 http://www.aidsinfonet.org/factsheet_detail.php?fsnumber=515
- ⁵ Centers for Disease Control and Prevention. Treating opportunistic infections among HIV-infected adults and adolescents: recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association/Infectious Diseases Society of America. MMWR 2004;53(No. RR-15) (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5315a1.htm)
- ⁶ Centers for Disease Control and Prevention. Guidelines for Preventing Opportunistic Infections Among HIV-Infected Persons 2002 Recommendations of the U.S. Public Health Service and the Infectious Diseases Society of America. MMWR 2002;51 (No. RR-8) (http://www.cdc.gov/mmwr/PDF/rr/rr5108.pdf or http://aidsinfo.nih.gov/ContentFiles/OlpreventionGL.pdf)