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**Brief Measure Information**

**CBE #:** 3210e

**Corresponding Measures:**

**Measure Title:** HIV Viral Suppression

**Measure Steward:** Health Resources and Services Administration - HIV/AIDS Bureau

**sp.02. Brief Description of Measure:** Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first three months of the measurement period, with an eligible encounter in the first eight months of the measurement period, who have a last HIV viral load test has result of less than 200 copies/mL during the measurement period.

**1b.01. Developer Rationale:** HIV is a communicable infection that leads to a progressive disease with a long asymptomatic period. Approximately 40,000 persons in the United States are newly infected with HIV each year (Centers for Disease Control and Prevention, 2021, p. 51). Without treatment, most persons develop acquired immunodeficiency syndrome (AIDS) within 10 years of HIV infection.

HIV viral suppression is a long-standing priority outcome among the HIV community in the United States and around the world. The National HIV/AIDS Strategy for the United States from 2022-2025, developed by the White House Office of National AIDS Policy with input from the HIV community across the United States, prioritizes increasing HIV viral suppression rates to 95% (The White House 2020). The DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents defines viral suppression as a viral load below the lower limits of detection in its guidelines on virologic failure, and it defines viral suppression as a viral load of less than 200 copies/mL as part of its guidelines for the use of antiretroviral therapy to prevent HIV transmission (Panel on Antiretroviral Guidelines for Adults and Adolescents 2022).

Antiretroviral therapy (ART) delays the progression to AIDS and increases the length of survival. ART reduces HIV-associated morbidity and mortality by maximally inhibiting HIV replication to achieve viral suppression (Hogg et al 2001; Lundgren et al., 2015). ART has also been shown to reduce transmission of HIV (Rodger et al 2019). Studies show disparities in rates of viral suppression by race and ethnicity among MSM and among women, with Black and Hispanic or Latino/a study participants

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having lower rates of viral suppression than White participants (Buchacz et al. 2020; Buchacz et al. 2018; Geter et al. 2018). This measure will help providers direct their attention and quality improvement efforts towards improving HIV viral suppression rates.

**CITATIONS:**

Buchacz, K., Armon, C., Palella, F. J., Novak, R. M., Fuhrer, J., Tedaldi, E., . . . Investigators, H. O. S. H. (2020). *The HIV Outpatient Study-25 Years of HIV Patient Care and Epidemiologic Research*. *Open Forum Infect Dis*, 7(5), ofaa123. <https://doi.org/10.1093/ofid/ofaa123>

Buchacz, K., Armon, C., Tedaldi, E., Palella, F. J., Novak, R. M., Ward, D., . . . Investigators, H. O. S. (2018). *Disparities in HIV Viral Load Suppression by Race/Ethnicity Among Men Who Have Sex with Men in the HIV Outpatient Study*. *AIDS Res Hum Retroviruses*, 34(4), 357-364. <https://doi.org/10.1089/AID.2017.0162>

Centers for Disease Control and Prevention (2021). *HIV Surveillance Report, 2019*. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>

Geter, A., Sutton, M. Y., Armon, C., Durham, M. D., Palella, F. J., Tedaldi, E., . . . Investigators, H. O. S. (2018). *Trends of racial and ethnic disparities in virologic suppression among women in the HIV Outpatient Study, USA, 2010-2015*. *PLoS One*, 13(1), e0189973. <https://doi.org/10.1371/journal.pone.0189973>

Hogg, R. S., Yip, B., Chan, K. J., Wood, E., Craib, K. J., O'Shaughnessy, M. V., & Montaner, J. S. (2001). *Rates of disease progression by baseline CD4 cell count and viral load after initiating triple-drug therapy*. *JAMA*, 286(20), 2568-2577. <https://doi.org/10.1001/jama.286.20.2568>

Lundgren, J. D., Babiker, A. G., Gordin, F., Emery, S., Grund, B., Sharma, S., . . . Group, I. S. S. (2015a). *Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection*. *N Engl J Med*, 373(9), 795-807. <https://doi.org/10.1056/NEJMoa1506816>

Panel on Antiretroviral Guidelines for Adults and Adolescents. "Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV." Washington, DC: U.S. Department of Health and Human Services, 2022. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf> Updated September 21, 2022.

Rodger, A. J., Cambiano, V., Bruun, T., Vernazza, P., Collins, S., Degen, O., . . . Group, P. S. (2019). *Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results*

## Measure Worksheet (MEW-PA-Maint)

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<p><i>of a multicentre, prospective, observational study. Lancet, 393(10189), 2428-2438. <a href="https://doi.org/10.1016/S0140-6736(19)30418-0">https://doi.org/10.1016/S0140-6736(19)30418-0</a></i></p> <p><i>The White House. (2021). National HIV/AIDS Strategy for the United States 2022–2025. <a href="https://files.hiv.gov/s3fs-public/NHAS-2022-2025.pdf">https://files.hiv.gov/s3fs-public/NHAS-2022-2025.pdf</a></i></p>
<p><b>sp.12. Numerator Statement:</b> Patients with a last HIV viral load test result of less than 200 copies/ml during the measurement period.</p> <p><b>sp.14. Denominator Statement:</b> All patients, regardless of age, diagnosed with HIV prior to or during the first three months of the measurement period with at least one eligible encounter in the first eight months of the measurement period.</p> <p><b>sp.16. Denominator Exclusions:</b> Not applicable.</p>
<p><b>Measure Type:</b> Outcome</p> <p><b>sp.28. Data Source:</b> Electronic Health Records</p> <p><b>sp.07. Level of Analysis:</b> Clinician: Individual</p>
<p><b>IF Endorsement Maintenance—Original Endorsement Date:</b> July 2017</p> <p><b>Most Recent Endorsement Date:</b> July 2017</p>
<p><b>IF this measure is included in a composite, Composite#/title:</b> N/A</p> <p><b>IF this measure is paired/grouped, CBE#/title:</b> N/A</p> <p><b>sp.03. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?</b> N/A</p>
<p><b>Staff Assessment: Maintenance of Endorsement</b></p> <p>To maintain endorsement, endorsed measures are evaluated periodically to ensure that the measure still meets the endorsement criteria (“maintenance”). The emphasis for maintaining endorsement is focused on how effective the measure is</p>

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for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.
<b>Criterion 1: Importance to Measure and Report</b>
<b>1a. Evidence</b>
<p><b>Maintenance measures—less emphasis on evidence unless there is new information or a change in evidence since the prior evaluation.</b></p> <p><b>1a. Evidence.</b> The evidence requirements for a <b>health outcome</b> measure include providing empirical data that demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service; if these data are not available, data demonstrating wide variation in performance can be used, assuming the data are from a robust number of providers and the results are not subject to systematic bias. For measures derived from a patient report, the evidence also should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.</p>
<p><b>The developer provides the following description for this measure:</b></p> <ul style="list-style-type: none"> <li>This is a maintenance outcome measure at the individual clinician level that calculates the percentage of patients, regardless of age, diagnosed with HIV prior to or during the first three months of the measurement period, with an eligible encounter in the first eight months of the measurement period, who have a last HIV viral load test result of less than 200 copies/mL during the measurement period.</li> <li>The developer provides a <u>logic model</u> showing the continuum of care for HIV. The model depicts structural inputs (HIV specialty clinicians, diagnostic laboratories, antiretroviral therapy (ART)) linked with expected activities/processes (conduct HIV viral load tests; initiate and manage ART). The anticipated output of the activities is adherence to ART, which is linked with the short-term outcome of HIV viral suppression (the measure focus), which leads to long-term outcomes of improved health and reduced rates of HIV transmission.</li> </ul> <p>This is an update to the prior logic model, which depicted a linear chain beginning with diagnosis with HIV to accessing medical care, retention in care, prescription of ART, and finally viral suppression as the outcome.</p>
<p><b>Summary of prior review in 2017</b></p> <ul style="list-style-type: none"> <li>The developer provided multiple guidelines for the administration of antiretroviral therapy and viral load monitoring</li> </ul>

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<p>intervals for adults, adolescents, and pregnant women.</p> <ul style="list-style-type: none"> <li>• The developer provided sufficient evidence demonstrating that antiretroviral therapy and viral suppression reduce morbidity and mortality associated with HIV.</li> <li>• Summary of feedback from standing committee: Standing committee members agreed there is significant evidence that HIV viral load is linked with several clinically relevant outcomes, including disease progression and incidence of opportunistic infections. No member reported knowing of new studies that contradicted the evidence base.</li> <li>• Performance data at the time showed additional room for improvement in the measure as specified. However, the committee suggested that with improvements in ART and assays to measure viral load, developers should consider lower cutoffs in the future (e.g., less than 20 copies/mL or undetectable instead of 200 copies/mL).</li> </ul>
<p><b>Changes to evidence from the last review</b></p> <p><input type="checkbox"/> The developer attests that there have been no changes in the evidence since the measure was last evaluated.</p> <p><input checked="" type="checkbox"/> The developer provided updated evidence for this measure:</p> <ul style="list-style-type: none"> <li>• Developer submits that HIV viral suppression continues to be a priority among the HIV community and cited <i>the National HIV/AIDS Strategy for the United States 2022-2025</i> as prioritizing raising HIV viral suppression rates to 95%.</li> <li>• Developer provides more recent evidence that ART reduces transmission of HIV (Rodger et al. 2019), and that individual healthcare providers can explain a significant amount of variation in viral suppression rates (Meyers et al 2019).</li> </ul>
<p><b>Question for the Standing Committee:</b></p> <ul style="list-style-type: none"> <li>• <i>Is there at least one thing that the provider can do to achieve a change in the measure results?</i></li> <li>• <i>Does the target population value the measured outcome and find it meaningful?</i></li> <li>• <i>Does the evidence support changing the viral suppression cutoff level to a level lower than 200 copies/mL?</i></li> </ul>
<p><b>Guidance From the Evidence Algorithm</b></p> <p>Outcome measure (Box 1) → sufficient evidence of relationship between healthcare actions and measured health outcome (Box 2) → PASS</p> <p><b>Preliminary rating for evidence:</b>   <input checked="" type="checkbox"/> <b>Pass</b>   <input type="checkbox"/> <b>No Pass</b></p>
<p><b>1b. <u>Gap in Care/Opportunity for Improvement</u> and <u>Disparities</u></b></p>
<p><b>Maintenance measures—increased emphasis on gap and variation</b></p>

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**1b. Performance Gap.** The performance gap requirements include demonstrating quality problems and opportunity for improvement.

The developer provided measure performance scores at the clinician level for the performance period from January 1, 2021, to Dec 31 2021, for all clinicians and among those with at least 11 denominator eligible patients. The subgroup of 47 clinicians had a mean of 85.2% suppression and SD of 10.9.

Table 1b.02. Distribution of the measure performance scores in the clinician samples

Sample	Clinicians	Patients	Mean	SD	Min	p10	p20	p30	p40	p50	p60	p70	p80	p90	Max	IQR
All clinicians	187	3,056	72.3	33.3	0.0	0.0	50	66.1	77.5	85.2	93.2	100	100	100	100	50
Clinicians with 11+ patients	47	2,995	85.2	10.9	46.2	70	79.3	81.7	83.9	87.9	90.8	91.5	94.5	95.2	100	12.4

Notes: SD=Standard deviation, Min=minimum, Max=maximum, p=percentile, IQR=interquartile range  
 These data reflect Ryan White HIV/AIDS Program patients, and thus reflect a sample of patients with higher rates of viral suppression than the national population of people with HIV (HRSA 2022, CDC 2020).

**Disparities**

Disparities data for HIV viral suppression are presented at the clinician level among the sample of 47 clinicians with at least 11 patients (2,995 patients) for the measure performance period from January 1, 2021, to December 31, 2021.

The mean performance score among patients under 50 years of age was significantly lower than among patients 50 and older (82.4 vs. 87.7%; p=0.05). No other difference in mean score was significant; however, the difference by race approached significance with Black patients having a lower mean score for viral suppression than white patients (79.7 vs. 86.7; p=0.06).

Developer notes higher variation in performance scores for Black patients (SD = 21.2) and patients with IDU (22.6) compared with other strata, indicating possible differences in care for these groups; however, higher variance in patients with IDU may be attributed to the small sample size.

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<b>Table 1b.04. Measure performance rates by population groups (age, HIV transmission, race and ethnicity)</b>																
Patient Group	Clinicians	Patients	Mean	Std dev	Min	10%	20%	30%	40%	50%	60%	70%	80%	90%	Max	IQR
AGE<50	47	1,472	82.4	12.5	40.0	68.7	75.0	76.4	80.2	82.7	86.9	88.5	91.8	100.0	100.0	14.6
AGE>=50	47	1,523	87.7	13.0	50.0	67.9	81.9	84.2	89.7	90.6	94.1	95.4	100.0	100.0	100.0	13.3
MSM	41	1,218	84.7	13.2	50.0	66.7	71.4	81.0	85.7	88.9	90.0	92.9	95.8	100.0	100.0	15.1
IDU	40	234	82.2	22.6	0.0	50.0	66.7	74.1	84.1	90.1	100.0	100.0	100.0	100.0	100.0	31.4
Other transmission	41	992	87.8	13.6	50.0	66.7	78.6	85.7	90.9	93.1	93.8	95.2	100.0	100.0	100.0	11.0
Black	47	1,351	79.7	21.2	0.0	60.0	73.2	78.9	81.6	85.7	88.5	90.2	92.6	94.8	100.0	15.1
White	47	1,520	86.7	12.4	50.0	66.7	75.0	82.7	87.0	90.9	92.7	95.3	99.3	100.0	100.0	20.3
Not Hispanic or Latino	47	2,559	84.7	11.9	50.0	65.9	78.9	80.9	84.7	87.1	90.0	92.4	94.4	96.1	100.0	12.9
Hispanic or Latino	36	429	89.7	19.1	0.0	77.5	84.6	88.2	93.8	99.1	100.0	100.0	100.0	100.0	100.0	13.2
<p>Notes: Results are for clinicians with ≥11 patients eligible for the denominator.            SD=standard deviation, p=percentile, min=minimum, max=maximum, IQR=interquartile range</p>																
<p><b>Questions for the Standing Committee:</b></p> <ul style="list-style-type: none"> <li>• <i>Is there a gap in care that warrants a national performance measure?</i></li> </ul>																
<p><b>Preliminary rating for opportunity for improvement:</b>  <input type="checkbox"/> High   <input checked="" type="checkbox"/> Moderate   <input type="checkbox"/> Low   <input type="checkbox"/> Insufficient</p>																
<p><b>Criteria 2: Scientific Acceptability of Measure Properties</b></p>																
<p><b>Complex measure evaluated by the Scientific Methods Panel (SMP)?</b>   <input type="checkbox"/> Yes   <input checked="" type="checkbox"/> No</p>																
<p><b>Evaluators:</b> Staff/Laura Aume</p>																
<p><b>2a. Reliability: <u>Specifications</u> and <u>Testing</u></b></p>																

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<p><b>For maintenance measures—no change in emphasis—specifications should be evaluated the same as with new measures.</b></p>
<p><b>2a1. Specifications</b> require the measure, as specified, to produce consistent (i.e., reliable) and credible (i.e., valid) results about the quality of care when implemented.</p> <ul style="list-style-type: none"> <li>The submitted measure specifications are clear and precise.</li> </ul>
<p><b>For maintenance measures—less emphasis if no new testing data are provided.</b></p>
<p><b>2a2. Reliability testing</b> demonstrates whether the measure data elements are repeatable and producing the same results a high proportion of the time when assessed in the same population during the same time period, and/or whether the measure score is precise enough to distinguish differences in performance across providers.</p>
<p><b>Specifications:</b></p> <ul style="list-style-type: none"> <li>Have the measure specifications changed since the last review? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No           <ul style="list-style-type: none"> <li>The previous denominator did not limit the eligible encounter to the first 8 months. This allows for time for patients who 1) change providers to re-establish viral suppression and obtain viral load test, which is recommended quarterly; or 2) are newly diagnosed to take HIV medications long enough to achieve viral suppression .</li> <li>The previous denominator did not limit the timing of the HIV diagnosis. The denominator criteria require an HIV diagnosis to occur within or prior to the first 3 months of the measurement period to allow enough time for newly diagnosed, ART-naïve patients to achieve initial suppression, which can take up to 26 weeks (Saag et al., 2020).</li> </ul> </li> <li>Measure specifications are clear and precise.</li> <li>eCQMs were specified using the latest industry-accepted eCQM technical specifications: HQMF, QDM, CQL, and value sets vetted through the National Library of Medicine’s (NLM) Value Set Authority Center (VSAC).</li> </ul>
<p><b>Reliability Testing:</b></p> <ul style="list-style-type: none"> <li>Did the developer conduct new reliability testing? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No           <ul style="list-style-type: none"> <li>The previous submission included reliability data from chart abstracted data. New reliability testing was conducted at the Accountable Entity level using EHR data.</li> </ul> </li> <li>Updated reliability testing conducted at the Accountable Entity Level:           <ul style="list-style-type: none"> <li>Methods: Signal-to-noise (beta-binomial method) shows a range in reliability from 62.8% to 100% with a median of 94%. Less than 5% of the clinicians have a reliability less than 70% and over 50% of the clinicians have a reliability greater than 90%.</li> </ul> </li> </ul>



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<ul style="list-style-type: none"> <li>○ Split-half results               <ul style="list-style-type: none"> <li>▪ Spearman rank-order correlation of 96.7%</li> <li>▪ Spearman-Brown correlation of 98.3%</li> </ul> </li> <li>○ Test-retest results show an ICC of 93.2%</li> <li>○ Bootstrap resampling was also performed. Median values for each method are:               <ul style="list-style-type: none"> <li>▪ Spearman rank-order correlation: 97.5%</li> <li>▪ Spearman-Brown correlation: 98.7%</li> <li>▪ ICC: 94.8%</li> </ul> </li> </ul>
<p><b>Questions for the Standing Committee regarding reliability:</b></p> <ul style="list-style-type: none"> <li>• <i>Do you have any concerns that the measure cannot be consistently implemented (i.e., are the measure specifications adequate)?</i></li> </ul>
<p><b>Guidance From the Reliability Algorithm</b></p> <p>Precise specifications (Box 1) -&gt; Empirical testing reliability conducted (Box 2) -&gt; Reliability testing conducted with computer measure scores (Box 4) -&gt; Appropriate methods (Box 5) -&gt; Moderate (Box 6)</p> <p>The highest possible rating is high.</p>
<p><b>Preliminary rating for reliability:</b> <input type="checkbox"/> High <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Low <input type="checkbox"/> Insufficient</p>
<p><b>2b. Validity: <u>Validity Testing</u>; <u>Exclusions</u>; <u>Risk Adjustment</u>; <u>Meaningful Differences</u>; <u>Comparability</u>; <u>Missing Data</u></b></p>
<p><b>For maintenance measures—less emphasis if no new testing data are provided</b></p> <p><b>2b2. Validity testing</b> should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality.</p> <p><b>2b2-2b6. Potential threats to validity</b> should be assessed/addressed.</p>
<p><b>Validity Testing</b></p> <ul style="list-style-type: none"> <li>• Did the developer conduct new validity testing? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</li> <li>• Validity testing conducted at the Patient/Encounter Level:           <ul style="list-style-type: none"> <li>○ The developer assessed agreement between electronic health record (EHR) data extracted from structured fields and manually abstracted data from the medical record (“gold-standard”).</li> <li>○ The developer randomly selected 20 records in seven sites (140 total).</li> <li>○ The chance-corrected agreement (Gwet’s AC1) was used to assess agreement.</li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>○ Among the nine (9) data elements assessed, agreement was high except for HIV diagnosis date, although upon review the difference did not affect inclusion in the denominator.</li> <li>• Validity testing conducted at the Accountable-Entity Level:           <ul style="list-style-type: none"> <li>○ The developer assessed differences across “known groups” (age and HIV transmission category).</li> <li>○ The effect size was computed using Cohen’s d statistic</li> <li>○ There was a moderate effect of both age and HIV transmission category consistent with expectation (based on the literature).</li> <li>○ The developer also assessed face validity through structured interviews with seven clinicians and a poll of the Technical Expert Panel (TEP).</li> <li>○ Six of seven (86%) agreed that the measure can distinguish good from poor quality.</li> </ul> </li> </ul>
	<ul style="list-style-type: none"> <li>• Feasibility testing was conducted at seven test sites, which included four different EHR systems.</li> <li>• The Feasibility Scorecard indicated that the following data elements have issues with accuracy (note: these data elements were not available at one or more sites, and as a result scored low on accuracy as well. Neither is required to calculate the measure score):           <ul style="list-style-type: none"> <li>○ “Encounter Performed: Home Healthcare Services”</li> <li>○ "Encounter, Performed: Outpatient Consultation"</li> </ul> </li> <li>• Data elements tested:           <ul style="list-style-type: none"> <li>○ "Diagnosis: HIV"</li> <li>○ "Encounter, Performed: Face-to-Face Interaction"</li> <li>○ "Encounter, Performed: Office Visit"</li> <li>○ "Encounter, Performed: Outpatient Consultation"</li> <li>○ "Encounter, Performed: Preventive Care - Established Office Visit, 0 to 17"</li> <li>○ "Encounter, Performed: Preventive Care Services - Established Office Visit, 18 and Up"</li> <li>○ "Encounter, Performed: Preventive Care Services-Initial Office Visit, 18 and Up"</li> <li>○ "Encounter, Performed: Preventive Care- Initial Office Visit, 0 to 17"</li> <li>○ "Encounter, Performed: Telehealth Services"</li> <li>○ "Encounter, Performed: Telephone Visits"</li> <li>○ "Encounter Performed: Annual Wellness Visit"</li> <li>○ "Encounter Performed: Home Healthcare Services"</li> <li>○ "Encounter Performed: Preventive Care Services Other"</li> <li>○ "Laboratory Test, Performed: HIV Viral Load"</li> <li>○ "Patient Characteristic Ethnicity: Ethnicity"</li> <li>○ "Patient Characteristic Payer: Payer"</li> <li>○ "Patient Characteristic Race: Race"</li> <li>○ "Patient Characteristic Sex: ONC Administrative Sex"</li> </ul> </li> </ul>

## Measure Worksheet (MEW-PA-Maint)

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<b>Exclusions</b> <ul style="list-style-type: none"> <li>The measure does not use exclusions.</li> </ul>
<b>Risk Adjustment</b> <ul style="list-style-type: none"> <li>The measure is not risk-adjusted or stratified.</li> </ul>
<b>Meaningful Differences</b> <ul style="list-style-type: none"> <li>The developer calculated measure performance rates for 47 clinicians with at least 11 patients in the denominator.</li> <li>Of the 47 clinicians, 13 (28% of all clinicians in the sample) were statistically better than the sample average, and 2 clinicians (4.3%) were worse than the sample average.</li> <li>Rates ranged from 46.2% (minimum) to 100.0% (maximum).</li> </ul>
<b>Missing Data</b> <ul style="list-style-type: none"> <li>No data elements used in calculated measure scores had substantial rates of missing values.</li> </ul>
<b>Comparability</b> <ul style="list-style-type: none"> <li>The measure only uses one set of specifications for this measure.</li> </ul>
<b>Questions for the Standing Committee regarding validity:</b> <ul style="list-style-type: none"> <li><i>Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk adjustment approach, etc.)?</i></li> <li><i>Are the accuracy issues that are captured in the Feasibility Scorecard substantial enough to impact the validity of these data elements?</i></li> </ul>
<b>Guidance From the Validity Algorithm</b> All threats assessed (Box 1) -> Empirical validity testing conducted on the measure as specified (Box 2) -> Validity testing conducted with computer measure scores (Box 5) -> Appropriate methods (Box 6) -> Moderate (Box 7)  The highest possible rating is high.
<b>Preliminary rating for validity:</b> <input type="checkbox"/> High <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Low <input type="checkbox"/> Insufficient
<b>Criterion 3. Feasibility</b>
<b>Maintenance measures—no change in emphasis—implementation issues may be more prominent</b> <b>3. Feasibility</b> is the extent to which the specifications, including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.
<ul style="list-style-type: none"> <li>This measure is generated or collected by and used by health care personnel during the provision of care.</li> </ul>

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<ul style="list-style-type: none"> <li>All data elements are in defined fields in electronic claims.</li> <li>There are no fees or licenses required for usage of this measure.</li> </ul>
<ul style="list-style-type: none"> <li>Using a simulated data set, the submission demonstrates that the evaluation of 100 percent of the measure logic can be automated.</li> <li>The required data elements are widely available in electronic health data. The two encounter type data elements that were missing from test sites ("Encounter Performed: Home Healthcare Services" and "Encounter, Performed: Outpatient Consultation") are (1) not required for measure score calculation, given the availability of other eligible encounter types and (2) only missing because they are not applicable to the test sites. "Diagnosis: HIV" was not available in a structured data field at two of the seven test sites, although both collect this information in unstructured formats. One of these sites already has a plan in place to change workflows to capture this information in a structured field. Given the large share of test sites that captured this information or expect to do so in the future, measure data element feasibility is moderate.</li> </ul>
<p><b>Questions for the Standing Committee:</b></p> <ul style="list-style-type: none"> <li><i>Are the required data elements routinely generated and used during care delivery?</i></li> <li><i>Are the required data elements available in electronic form (e.g., EHR or other electronic sources)?</i></li> <li><i>Is the data collection strategy ready to be put into operational use?</i></li> <li><i>For data elements assessed to have feasibility issues, does the developer present a credible, near-term path to electronic collection?</i></li> </ul>
<p><b>Preliminary rating for feasibility:</b>   <input type="checkbox"/> High   <input checked="" type="checkbox"/> Moderate   <input type="checkbox"/> Low   <input type="checkbox"/> Insufficient</p>
<b>Criterion 4: Use and Usability</b>
<p><b>Maintenance measures—increased emphasis—much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences</b></p>
<p><b>4a. Use (4a1. <u>Accountability and Transparency</u>; 4a2. <u>Feedback on measure</u>)</b></p>
<p><b>4a. Use</b> evaluates the extent to which audiences (e.g., consumers, purchasers, providers, and policymakers) use or could use performance results for both accountability and performance improvement activities.</p> <p><b>4a.1. Accountability and Transparency.</b> Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If they are not in use at the time of initial endorsement, then a credible plan for implementation within the specified time frames is provided.</p>

<b>Content</b>			
<b>Current uses of the measure</b>			
Publicly reported?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	
Current use in an accountability program?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> UNCLEAR
Planned use in an accountability program?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
<b>Accountability program details</b>			
<ul style="list-style-type: none"> <li>• HRSA plans to submit this measure for use as a clinician-level measure in the CMS Merit Based Incentive Program (MIPS) program. HRSA will submit the measure to the 2023 Measures Under Consideration (MUC) list by April 30, 2023.</li> </ul>			
<p><b>4a.2. Feedback on the measure provided by those being measured or others.</b> Three criteria demonstrate feedback: (1) Those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; (2) Those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; and (3) This feedback has been considered when changes are incorporated into the measure.</p>			
<p><b>Questions for the Standing Committee:</b></p> <ul style="list-style-type: none"> <li>• <i>How have (or can) the performance results be used to further the goal of high quality, efficient healthcare?</i></li> <li>• <i>How has the measure been vetted in real-world settings by those being measured or others?</i></li> </ul>			
<p><b>Preliminary rating for Use:</b>    <input type="checkbox"/> <b>Pass</b>    <input checked="" type="checkbox"/> <b>No Pass</b></p>			
<p><b>RATIONALE:</b> Endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement, in addition to demonstrating performance improvement. The committee should consider if the rationale for no current use provided by the developer is acceptable.</p>			
<b>4b. Usability (4b1. Improvement; 4b2. Benefits of measure)</b>			
<p><b>4b. Usability</b> evaluates the extent to which audiences (e.g., consumers, purchasers, providers, and policymakers) use or could use performance results for both accountability and performance improvement activities.</p>			
<p><b>4b.1 Improvement.</b> Progress toward achieving the goal of high quality, efficient healthcare for individuals or populations is demonstrated.</p>			

Content
<p><b>Improvement results</b></p> <ul style="list-style-type: none"> <li>This measure is not currently in use as an eCQM in a quality improvement program. Data to support progress on improvement were not provided.</li> </ul>
<p><b>4b2. Benefits versus harms.</b> The benefits of the performance measure in facilitating progress toward achieving high quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).</p>
<p><b>Unexpected findings (positive or negative) during implementation</b></p> <ul style="list-style-type: none"> <li>Measure has not yet been implemented.</li> </ul>
<p><b>Potential harms</b></p> <ul style="list-style-type: none"> <li>Information on potential harms was not provided by the developer.</li> </ul>
<p><b>Additional Feedback:</b></p> <ul style="list-style-type: none"> <li>N/A</li> </ul>
<p><b>Questions for the Standing Committee:</b></p> <ul style="list-style-type: none"> <li><i>How can the performance results be used to further the goal of high quality, efficient healthcare?</i></li> <li><i>Do the benefits of the measure outweigh any potential unintended consequences?</i></li> </ul>
<p><b>Preliminary rating for Usability and Use:</b> <input type="checkbox"/> High <input type="checkbox"/> Moderate <input type="checkbox"/> Low <input checked="" type="checkbox"/> Insufficient</p> <p><b>RATIONALE:</b> Data to support progress on improvement and information on potential harms were not provided.</p>
<p><b>Criterion 5: Related and Competing Measures</b></p>
<p><b><u>Related Measures</u></b></p> <ul style="list-style-type: none"> <li>3209e: HIV Medical Visit Frequency</li> <li>3211e: Prescription of HIV Antiretroviral Therapy</li> <li>0409: HIV/AIDS: Sexually Transmitted Diseases- Screening for Chlamydia, Gonorrhea, and Syphilis (CQM only)</li> <li>2080: Gap in HIV medical visits (CQM only)</li> <li>0405: HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis (CQM only)</li> </ul>
<p><b>Harmonization</b></p>

## Measure Worksheet (MEW-PA-Maint)

**Content**

- The denominator population for this measure differs slightly from three related measures—3209e, 3211e, and 0409—with respect to the timing of the patient’s HIV diagnosis and eligible encounter, and these differences are due to the specific timing required for measuring viral suppression. This measure’s population is limited to patients diagnosed no earlier than three months into the performance period to allow sufficient time for a clinician to work with a newly diagnosed patient to achieve viral suppression.
- Eligible encounters are limited to those occurring within the first eight months of the measurement period to ensure that clinicians had enough time left in the year to work with new patients to achieve viral suppression.
- The measure also differs from the denominator population for 0409 with respect to the patient’s age because viral suppression is a relevant clinical outcome for all patients with HIV, regardless of age, while 0409 focuses on older patients who may be sexually active.

## QUALITY MEASURE SUBMISSION FORM

Version: 1.0; Generated: 13 April 2023

### Introduction

Thank you for your interest in submitting a measure to Battelle for possible endorsement.

**What criteria are used to evaluate measures?** Measures are evaluated on standardized criteria: importance to measure and report, scientific acceptability of measure properties, feasibility, usability and use, and related and competing measures. For your measure to be evaluated against these measure evaluation criteria, you must complete the measure submission form.

**Why do I have to complete a form?** Due to the volume and/or complexity of proposed measures, Battelle provides measure information to committee reviewers in a standardized format to facilitate their evaluation of whether the measure meets the measure evaluation criteria. This form allows the measure steward to present information demonstrating that the proposed measure meets endorsement criteria.

**What is on the form?** The information requested in this form is directly related to the measure evaluation criteria.

**Can't I just submit our files for consideration?** No. Measures must be submitted through the online form to be considered for the Spring 2023 cycle. Requested information should be entered directly into this form and as well as any necessary or required attachments.

**Can I submit additional details and materials?** Additional materials will be considered only as supplemental. Do NOT rely on material provided in an appendix to provide measure specifications or to demonstrate meeting the criteria. The core information needed to evaluate the measure should be provided in the appropriate submission form fields and required attachments. Please contact [PQMsupport@battelle.org](mailto:PQMsupport@battelle.org) regarding questions about submitting supplemental materials.

**What do I do first?** If you have started a new submission by answering five qualifying questions, you may proceed to the "Previous Submission Information" tab to continue with your submission. The "Conditions" tab will list the conditions that must be met before your proposed measures may be considered and evaluated for suitability as endorsed voluntary consensus standards. You are asked to acknowledge reading and accepting the conditions.





**Can I make changes to a form once I have submitted it?** No. Once you submit your measure, you will NOT be able to return to this submission form to make further revisions. You will need to contact project staff.

**What if I need additional help?** Please contact the project staff at [PQMsupport@battelle.org](mailto:PQMsupport@battelle.org) if you have questions regarding the information requested or submitting supplemental materials.

**NOTE: All measure submissions should be 508-compliant. Refer to the Checklist for Developer 508 Guidelines (PDF) to ensure all guidelines apply to all parts of your submission, including all fields and attachments used within the measure submission form.**

Please email us at [PQMsupport@battelle.org](mailto:PQMsupport@battelle.org) if you experience technical difficulties using the online submission form.

Thank you for your interest in submitting measures to Battelle.

## Previous Submission Information (1 – 4)

**1) Select whether this measure was previously submitted to the prior consensus-based entity (the National Quality Forum [NQF]) and given an identifying number.**

- Previously submitted to NQF
- New measure, never submitted.

**2) Provide the measure number of the previously submitted measure.**

3210e

**3) If the measure has an electronic clinical quality measure (eCQM) version, provide the measure number of the previously submitted measure.**

3210e

**4) If this eCQM has a registry version, provide the measure numbers of the previously submitted measure.**

2082

## Conditions (1 - 2)

**Several conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards. If any of the conditions are not met, the measure will not be accepted for consideration.**

- A. A Measure Steward Agreement is signed or the steward is a government organization. (All non-government organizations must sign a Measure Steward Agreement.) For more information about completing a Measure Steward Agreement, please go to: [Endorsement | Partnership for Quality Measurement \(p4qm.org\)](https://p4qm.org) and follow the instructions.
- B. The measure owner/steward verifies there is an identified responsible entity and a process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every three years.
- C. The intended use of the measure includes both accountability applications (including public reporting) and performance improvement to achieve high-quality, efficient healthcare.
- D. The measure is fully specified and tested for reliability and validity.
- E. The measure developer/steward attests that harmonization with related measures and issues with competing measures have been considered and addressed, as appropriate.
- F. The requested measure submission information is complete and responsive to the questions so that all the information needed to evaluate all criteria is provided.

### **1) Check if either of the following apply.**

- Proprietary measure or components (e.g., risk model, codes)
- Proprietary measure or components with fees
- None of the above

### **2) Check the box below to agree to the conditions listed above.**

- I have read and accept the conditions as specified above

**Specifications: Maintenance Update (spma.01 - spma.02)**

**spma.01) Indicate whether there are changes to the specifications since the last updates/submission. If yes, update the specifications in the Measure Specifications section of the Measure Submission Form, and explain your reasoning for the changes below.**

- No  
 Yes

**spma.02) Briefly describe any important changes to the measure specifications since the last measure update and provide a rationale.**

**For annual updates, please explain how the change in specifications affects the measure results. If a material change in specification is identified, data from re-testing of the measure with the new specifications is required for early maintenance review.**

*For example, specifications may have been updated based on suggestions from a previous measure endorsement review.*

Denominator criteria require the eligible encounter to occur within the first 8 months of the measurement period to allow enough time for the clinician to help the patient to achieve viral suppression before the end of the measurement period. The previous denominator did not limit the eligible encounter to the first 8 months. This allows for time for patients who 1) change providers to re-establish viral suppression and obtain viral load test, which is recommended quarterly; or 2) are newly diagnosed to take HIV medications long enough to achieve viral suppression. Denominator criteria also require an HIV diagnosis to occur within or prior to the first 3 months of the measurement period to allow enough time for newly diagnosed, ART-naïve patients to achieve initial suppression, which can take up to 26 weeks (Saag et al., 2020). The previous denominator did not limit the timing of the HIV diagnosis.

**CITATIONS:**

*Saag, M. S., Gandhi, R. T., Hoy, J. F., Landovitz, R. J., Thompson, M. A., Sax, P. E., . . . Volberding, P. A. (2020). Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults: 2020 Recommendations of the International Antiviral Society-USA Panel. JAMA, 324(16), 1651-1669. <https://doi.org/10.1001/jama.2020.17025>*

## Measure Specifications (sp.01 - sp.32)

### sp.01) Provide the measure title.

*Measure titles should be concise yet convey who and what is being measured.*  
HIV Viral Suppression

### sp.02) Provide a brief description of the measure.

*Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).*

Percentage of patients, regardless of age, diagnosed with HIV prior to or during the first three months of the measurement period, with an eligible encounter in the first eight months of the measurement period, who have a last HIV viral load test has result of less than 200 copies/mL during the measurement period.

### sp.03) Provide a rationale for why this measure must be reported with other measures to appropriately interpret results.

N/A

### sp.04) Check all the clinical condition/topic areas that apply to your measure, below.

- Behavioral Health
- Behavioral Health: Alcohol, Substance Use/Abuse
- Behavioral Health: Anxiety
- Behavioral Health: Attention Deficit Hyperactivity Disorder (ADHD)
- Behavioral Health: Bipolar Disorder
- Behavioral Health: Depression
- Behavioral Health: Domestic Violence
- Behavioral Health: Other Serious Mental Illness
- Behavioral Health: Post-Traumatic Stress Disorder (PTSD)
- Behavioral Health: Schizophrenia
- Behavioral Health: Suicide
- Cancer
- Cancer: Bladder
- Cancer: Breast
- Cancer: Colorectal
- Cancer: Gynecologic
- Cancer: Hematologic

- Cancer: Liver
- Cancer: Lung, Esophageal
- Cancer: Prostate
- Cancer: Renal
- Cancer: Skin
- Cancer: Thyroid
- Cardiovascular
- Cardiovascular: Arrhythmia
- Cardiovascular: Congestive Heart Failure
- Cardiovascular: Coronary Artery Disease
- Cardiovascular: Coronary Artery Disease (AMI)
- Cardiovascular: Coronary Artery Disease (PCI)
- Cardiovascular: Hyperlipidemia
- Cardiovascular: Hypertension
- Cardiovascular: Secondary Prevention
- Critical Care
- Critical Care: Assisted Ventilation
- Critical Care: Intensive Monitoring
- Dental
- Dental: Caries
- Dental: Tooth Loss
- Ears, Nose, Throat (ENT)
- Ears, Nose, Throat (ENT): Ear Infection
- Ears, Nose, Throat (ENT): Hearing
- Ears, Nose, Throat (ENT): Pharyngitis
- Ears, Nose, Throat (ENT): Tonsillitis
- Endocrine
- Endocrine: Calcium and Metabolic Bone Disorders
- Endocrine: Diabetes
- Endocrine: Female and Male Endocrine Disorders
- Endocrine: Hypothalamic-Pituitary Disorders
- Endocrine: Thyroid Disorders
- Eye Care
- Eye Care: Age-related macular degeneration (AMD)
- Eye Care: Cataracts
- Eye Care: Diabetic retinopathy
- Eye Care: Glaucoma
- Gastrointestinal (GI)
- Gastrointestinal (GI): Constipation
- Gastrointestinal (GI): Gall Bladder Disease

- Gastrointestinal (GI): Gastroenteritis
- Gastrointestinal (GI): Gastro-Esophageal Reflux Disease (GERD)
- Gastrointestinal (GI): Hemorrhoids
- Gastrointestinal (GI): Hernia
- Gastrointestinal (GI): Inflammatory Bowel Disease
- Gastrointestinal (GI): Irritable Bowel Syndrome
- Gastrointestinal (GI): Peptic Ulcer
- Genitourinary (GU)
- Genitourinary (GU): Benign Prostatic Hyperplasia
- Genitourinary (GU): Erectile Dysfunction/Premature Ejaculation
- Genitourinary (GU): Incontinence/pelvic floor disorders
- Genitourinary (GU): Prostatitis
- Genitourinary (GU): Urinary Tract Infection (UTI)
- Gynecology (GYN)
- Gynecology (GYN): Abnormal bleeding
- Gynecology (GYN): Endometriosis
- Gynecology (GYN): Infections
- Gynecology (GYN): Menopause
- Gynecology (GYN): Pelvic Pain
- Gynecology (GYN): Uterine fibroids
- Infectious Diseases (ID)
- Infectious Diseases (ID): HIV/AIDS
- Infectious Diseases (ID): Influenza
- Infectious Diseases (ID): Lyme Disease
- Infectious Diseases (ID): Meningococcal Disease
- Infectious Diseases (ID): Pneumonia and respiratory infections
- Infectious Diseases (ID): Sepsis
- Infectious Diseases (ID): Sexually Transmitted
- Infectious Diseases (ID): Tuberculosis
- Liver
- Liver: Viral Hepatitis
- Musculoskeletal
- Musculoskeletal: Falls and Traumatic Injury
- Musculoskeletal: Gout
- Musculoskeletal: Joint Surgery
- Musculoskeletal: Low Back Pain
- Musculoskeletal: Osteoarthritis
- Musculoskeletal: Osteoporosis
- Musculoskeletal: Rheumatoid Arthritis
- Neurology

- Neurology: Alzheimer's Disease
- Neurology: Autism
- Neurology: Brain Injury
- Neurology: Epilepsy
- Neurology: Migraine
- Neurology: Parkinson's Disease
- Neurology: Spinal Cord Injury
- Neurology: Stroke/Transient Ischemic Attack (TIA)
- Other (please specify here: )
- Palliative Care and End-of-Life Care
- Palliative Care and End-of-Life Care: Advanced Directives
- Palliative Care and End-of-Life Care: Amyotrophic Lateral Sclerosis (ALS)
- Palliative Care and End-of-Life Care: Hospice Management
- Palliative Care and End-of-Life Care: Inappropriate use of acute care services
- Palliative Care and End-of-Life Care: Pain Management
- Perinatal Health
- Perinatal Health: Labor and Delivery
- Perinatal Health: Newborn Care
- Perinatal Health: Post-Partum Care
- Perinatal Health: Preconception Care
- Perinatal Health: Prenatal Care
- Renal
- Renal: Acute Kidney Injury
- Renal: Chronic Kidney Disease (CKD)
- Renal: End Stage Renal Disease (ESRD)
- Renal: Infections
- Reproductive Health
- Reproductive Health: Family planning and contraception
- Reproductive Health: Infertility
- Reproductive Health: Male reproductive health
- Respiratory
- Respiratory: Acute Bronchitis
- Respiratory: Allergy
- Respiratory: Asthma
- Respiratory: Chronic Obstructive Pulmonary Disease (COPD)
- Respiratory: Dyspnea
- Respiratory: Pneumonia
- Respiratory: Sleep Apnea
- Surgery
- Surgery: Cardiac Surgery



- Surgery: Colorectal
- Surgery: Neurosurgery / Spinal
- Surgery: Orthopedic
- Surgery: Orthopedic Hip/Pelvic Fractures
- Surgery: Pediatric
- Surgery: Perioperative and Anesthesia
- Surgery: Plastic
- Surgery: Thoracic Surgery
- Surgery: Trauma
- Surgery: Vascular Surgery

**sp.05) Check all the non-condition specific measure domain areas that apply to your measure, below.**

- Access to Care
- Care Coordination
- Care Coordination: Readmissions
- Care Coordination: Transitions of Care
- Disparities Sensitive
- Health and Functional Status
- Health and Functional Status: Change
- Health and Functional Status: Nutrition
- Health and Functional Status: Obesity
- Health and Functional Status: Physical Activity
- Health and Functional Status: Quality of Life
- Health and Functional Status: Total Health
- Immunization
- Other (please specify here: )
- Person-and Family-Centered Care: Person-and Family-Centered Care
- Person-and Family-Centered Care: Workforce
- Primary Prevention
- Primary Prevention: Nutrition
- Primary Prevention: Tobacco Use
- Safety
- Safety: Complications
- Safety: Healthcare Associated Infections
- Safety: Medication
- Safety: Overuse
- Screening

**sp.06) Select one or more target population categories.**

*Select only those target populations which can be stratified in the reporting of the measure's result.*

- Adults (Age >= 18)
- Children (Age < 18)
- Elderly (Age >= 65)
- Populations at Risk: Dual eligible beneficiaries of Medicare and Medicaid
- Populations at Risk: Individuals with multiple chronic conditions
- Populations at Risk: Veterans
- Women

**sp.07) Select the levels of analysis that apply to your measure.**

*Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.*

- Accountable Care Organization
- Clinician: Group/Practice
- Clinician: Individual
- Facility
- Health Plan
- Integrated Delivery System
- Other (please specify here: )
- Population: Community, County or City
- Population: Regional and State

**sp.08) Indicate the care settings that apply to your measure.**

*Check ONLY the settings for which the measure is SPECIFIED and TESTED.*

- Ambulatory Care
- Behavioral Health
- Home Care
- Inpatient/Hospital
- Other (please specify here: )
- Outpatient Services
- Post-Acute Care

**sp.09) Provide a Uniform Resource Locator (URL) link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials.**

*Do not enter a URL linking to a home page or to general information. If no URL is available, indicate "none available".*

None available

**sp.10) Indicate whether Health Quality Measure Format (HQMF) specifications are attached.**

*Attach the zipped output from the measure authoring tool (MAT) for eCQMs - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications).*

- HQMF specifications are attached.
- HQMF specifications are NOT attached (Please explain).

**sp.11) Attach the simulated testing attachment.**

*All eCQMs require a simulated testing attachment to confirm that the HTML output from Bonnie testing (or testing of some other simulated data set) includes 100% coverage of measured patient population testing, with pass/fail test cases for each sub-population. This can be submitted in the form of a screenshot.*

- Testing is attached
- Testing is NOT attached (please explain)

**sp.12) Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.**

*Attach an excel or csv file; if this poses an issue, contact staff at [PQMsupport@battelle.org](mailto:PQMsupport@battelle.org). Provide descriptors for any codes. Use one file with multiple worksheets, if needed.*

- Available in attached Excel or csv file
- No data dictionary/code table – all information provided in the submission form

For the question below: state the outcome/process being measured. Calculations of the risk-adjusted outcome measures should be described in sp.22.

**sp.13) State the numerator.**

*Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome).*

*DO NOT include the rationale for the measure.*

Patients with a last HIV viral load test result of less than 200 copies/ml during the measurement period

For the question below: describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in sp.22.

**sp.14) Provide details needed to calculate the numerator.**

*All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets.*

*Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.*

Codes for qualifying viral load tests are in the attached file (see also value sets in sp.12 and specifications in sp.10).

Measurement period is equivalent to a calendar year.

For the question below: state the target population for the outcome. Calculation of the risk-adjusted outcome should be described in sp.22.

**sp.15) State the denominator.**

*Brief, narrative description of the target population being measured.*

All patients, regardless of age, diagnosed with HIV prior to or during the first three months of the measurement period with at least one eligible encounter in the first eight months of the measurement period.

For the question below: describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in sp.22.

**sp.16) Provide details needed to calculate the denominator.**

*All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets.*

*Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.*

Codes identifying qualifying HIV diagnoses and eligible encounter codes are in the attached file (see also

value sets in sp.12 and specifications in sp.10).  
Patient age  
HIV diagnosis date

**sp.17) Describe the denominator exclusions.**

*Brief narrative description of exclusions from the target population.*

Not applicable.

**sp.18) Provide details needed to calculate the denominator exclusions.**

*All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.*

Not applicable.

**sp.19) Provide all information required to stratify the measure results, if necessary.**

*Include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate. Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format in the Data Dictionary field.*

Not applicable.

**sp.20) Is this measure adjusted for socioeconomic status (SES)?**

- Yes
- No

**sp.21) Select the risk adjustment type.**

*Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.*

- No risk adjustment or risk stratification
- Statistical risk model

- Stratification by risk category/subgroup (specify number of risk factors)
- Other approach to address risk factors (please specify here: )

**sp.22) Select the most relevant type of score.**

*Attachment: If available, please provide a sample report.*

- Categorical, e.g., yes/no
- Continuous variable, e.g. average
- Count
- Frequency Distribution
- Non-weighted score/composite/scale
- Other (please specify here: )
- Rate/proportion
- Ratio
- Weighted score/composite scale

**sp.23) Select the appropriate interpretation of the measure score.**

***Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score.***

- Better quality = Higher score
- Better quality = Lower score
- Better quality = Score within a defined interval
- Passing score defines better quality

**sp.24) Diagram or describe the calculation of the measure score as an ordered sequence of steps.**

*Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.*

Denominator

1. Identify patients with an eligible encounter in the first eight months of the measurement period
2. Retain all patients diagnosed with HIV during the first three months of the measurement period or any time prior.
3. Patients meeting these criteria are in the denominator.

Numerator

1. Identify denominator eligible patients with an HIV viral load test during the measurement period.
2. Identify the last HIV viral load test during the measurement period

3. If the last HIV viral load test value is less than 200 copies/mL and/or below the lower limit of detection, the patient is included in the numerator. If the last HIV viral load test value is greater than or equal to 200 copies/mL, the patient is not included in the numerator.

**sp.25) Attach a copy of the instrument (e.g. survey, tool, questionnaire, scale) used as a data source for your measure, if available.**

- Copy of instrument is attached.  
 Copy of instrument is NOT attached (please explain).

The measure utilizes structured fields from electronic health record (EHR) data.

**sp.26) Indicate the responder for your instrument.**

- Patient  
 Family or other caregiver  
 Clinician  
 Other (specify)

N/A this is not a survey-based measure.

**sp.27) If measure testing is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.**

*Examples of samples used for testing:*

- *Testing may be conducted on a sample of the accountable entities (e.g., hospital, physician). The analytic unit specified for the particular measure (e.g., physician, hospital, home health agency) determines the sampling strategy for scientific acceptability testing.*
- *The sample should represent the variety of entities whose performance will be measured. The samples used for reliability and validity testing often have limited generalizability because measured entities volunteer to participate. Ideally, however, all types of entities whose performance will be measured should be included in reliability and validity testing.*
- *The sample should include adequate numbers of units of measurement and adequate numbers of patients to answer the specific reliability or validity question with the chosen statistical method.*
- *When possible, units of measurement and patients within units should be randomly selected.*

We recruited clinicians from 7 test sites that provide clinical care to patients with HIV and receive funding from the Ryan White HIV/AIDS Program. The characteristics of the test sites are listed below.

These sites represented different regions, covering both urban and rural areas and using different EHR systems to ensure the generalizability of findings. All clinicians that have at least 11 patients eligible for the measure denominator are included in the analysis for a total of 47 clinicians and 2,995 patients. The patients included in the analysis are Ryan White HIV/AIDS Program recipients that had an eligible encounter within the measurement period (January 1, 2021 to December 31, 2021) for those 47 clinicians. As a part of reliability testing in order to add rigor to the limited number of unique clinicians, we also conducted bootstrap resampling. This approach was used to test the stability of the measure rates over 2,000 replications of the initial sample. Results from the bootstrap testing (section 2a.11) support the generalizability of the findings.

**Geographic region and urban/rural communities served**

1. Four Northeast; two Midwest; one South
2. Five urban; two combined urban and rural

**Clinic types**

3. Two hospital or university-based clinics
4. Four publicly funded community health centers
5. One other community-based service organization

**Electronic health record (EHR)**

6. eClinicalWorks (3)
7. EPIC (2)
8. NextGen (1)
9. Athena Health (1)

**sp.28) Identify whether and how proxy responses are allowed.**

Not applicable.

**sp.29) Survey/Patient-reported data.**

*Provide instructions for data collection and guidance on minimum response rate.  
Specify calculation of response rates to be reported with performance measure results.*

Not applicable.

**sp.30) Select only the data sources for which the measure is specified.**

- Assessment Data
- Claims
- Electronic Health Data
- Electronic Health Records
- Instrument-Based Data
- Management Data
- Other (please specify here: )
- Paper Medical Records



Registry Data

**sp.31) Identify the specific data source or data collection instrument.**

*For example, provide the name of the database, clinical registry, collection instrument, etc., and describe how data are collected.*

The measure is calculated based on structured data pulled from each submitter's electronic health record.

**sp.32) Provide the data collection instrument.**

- Available at measure-specific web page URL identified in sp.09
- Available in attached appendix in Question 1 of the Additional Section
- No data collection instrument provided

## Importance to Measure and Report: Maintenance of Endorsement (1ma.01)

**1ma.01) Indicate whether there is new evidence about the measure since the most recent maintenance evaluation. If yes, please briefly summarize the new evidence, and ensure you have updated entries in the Evidence section as needed.**

Yes

No

New evidence includes updated rates of annual HIV infection in the United States, which are now around 40,000 incident casers per year (Centers for Disease Control and Prevention, 2021, p. 51) and updated evidence on the ability of antiretroviral therapy to reduce transmission of HIV (Rodger et al 2019). There is also new research on disparities in rates of viral suppression by race, ethnicity, and gender Buchacz et al. 2020; Buchacz et al. 2018; Geter et al. 2018). These studies show disparities in rates of viral suppression by race and ethnicity among both men who have sex with men (MSM) and women, with Black and Hispanic or Latino/a study participants having lower rates of viral suppression than White participants.

There are also updated guidelines from the Department of Health and Human Services (DHHS) Panels on Antiretroviral Guidelines for Adults and Adolescents and Children Living with HIV on defining viral suppression. The relevant content from the guidelines is included below. The guidelines also indicate the HIV viral load should be monitored at least quarterly for both adult and pediatric patients. Note: the previous viral suppression measure was chart-abstracted, while this submission is an eCQM.

### **Adult guidelines:**

“The primary goal of antiretroviral therapy (ART) is to prevent HIV-associated morbidity and mortality. This goal is accomplished by using effective ART to achieve and maintain a plasma HIV-1 RNA (viral load) below the quantification limits of commercially available assays. Durable viral suppression improves immune function and overall quality of life, lowers the risk of both AIDS-defining and non-AIDS-defining complications, and allows persons with HIV to live a lifespan approaching that of persons without HIV.” (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2021, E-1).

“ART is recommended for all individuals with HIV to reduce the morbidity and mortality associated with HIV infection and to prevent HIV transmission to sexual partners and infants (AI). ART should be initiated as soon as possible after HIV diagnosis (AI).” (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2021, p. E-2).

“The guidelines and the AIDS Clinical Trials Group (ACTG) now define virologic failure as a confirmed viral load >200 copies/mL- a threshold that eliminates most cases of apparent viremia caused by viral load blips or assay variability.” (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2021, P. C-6).

“Individuals who are adherent to their ARV regimen and do not harbor resistance mutations to the component drugs can generally achieve suppression 8 to 24 weeks after ART initiation; rarely, in some

patients it may take longer.” (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2021, C-6).

**Pediatric guidelines:**

“Based on accumulated experience with currently available assays, the current definition of virologic suppression is a plasma viral load below the detection limit of the assay used (generally <20 to 75 copies/mL).” (Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV, 2020, p. D-5).

“The Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV finds value in continuing to perform viral load testing every 3 to 4 months to provide enhanced monitoring of adherence or disease progression among children and adolescents.” (D-3 of guideline)

**CITATIONS:**

*Buchacz, K., Armon, C., Palella, F. J., Novak, R. M., Fuhrer, J., Tedaldi, E., . . . Investigators, H. O. S. H. (2020). The HIV Outpatient Study-25 Years of HIV Patient Care and Epidemiologic Research. Open Forum Infect Dis, 7(5), ofaa123. <https://doi.org/10.1093/ofid/ofaa123>*

*Buchacz, K., Armon, C., Tedaldi, E., Palella, F. J., Novak, R. M., Ward, D., . . . Investigators, H. O. S. (2018). Disparities in HIV Viral Load Suppression by Race/Ethnicity Among Men Who Have Sex with Men in the HIV Outpatient Study. AIDS Res Hum Retroviruses, 34(4), 357-364. <https://doi.org/10.1089/AID.2017.0162>*

*Centers for Disease Control and Prevention (2021). HIV Surveillance Report, 2019. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>*

*Geter, A., Sutton, M. Y., Armon, C., Durham, M. D., Palella, F. J., Tedaldi, E., . . . Investigators, H. O. S. (2018). Trends of racial and ethnic disparities in virologic suppression among women in the HIV Outpatient Study, USA, 2010-2015. PLoS One, 13(1), e0189973. <https://doi.org/10.1371/journal.pone.0189973>*

*Panel on Antiretroviral Guidelines for Adults and Adolescents. “Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV.” Washington, DC: U.S. Department of Health and Human Services, 2022. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf>. Updated September 21, 2022.*

*Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection, 2022. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/pediatric-arv/guidelines-pediatric-arv.pdf>. Updated October 11, 2022.*

*Rodger, A. J., Cambiano, V., Bruun, T., Vernazza, P., Collins, S., Degen, O., . . . Group, P. S. (2019). Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. Lancet, 393(10189), 2428-2438. [https://doi.org/10.1016/S0140-6736\(19\)30418-0](https://doi.org/10.1016/S0140-6736(19)30418-0)*

## Importance to Measure and Report: Evidence (Complete for Outcome Measures) (1a.01 - 1a.03)

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

### Current Submission:

Updated evidence information here.

### Previous (Year) Submission:

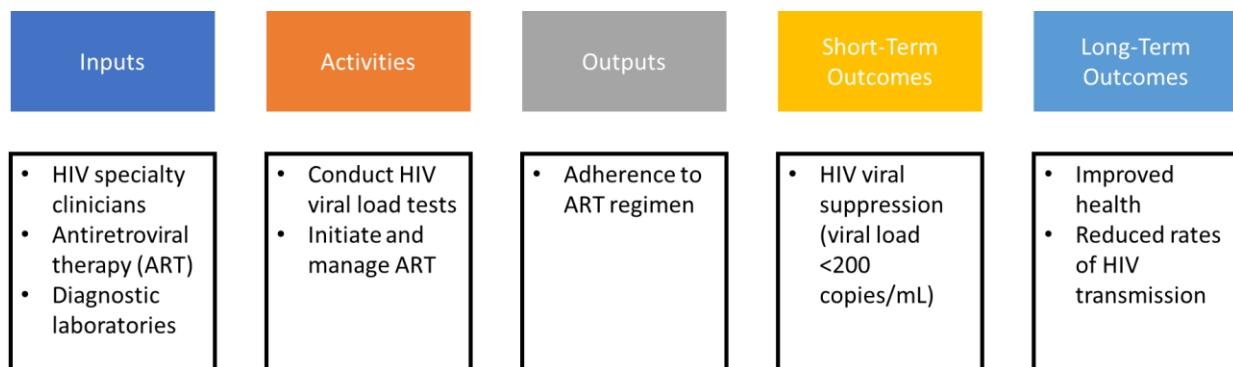
Evidence from the previous submission here.

### 1a.01) Provide a logic model.

*Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.*

Current Submission:

**Figure 1a.01 Logic Model**



The HIV "continuum of care" is the process of HIV testing, linkage to HIV care, initiation of ART, adherence to treatment, retention in care, and virologic suppression (Gardner et al 2011). Inputs to the process include HIV specialty clinicians, antiretroviral therapy (ART), and diagnostic laboratories. These inputs feed into the following activities: HIV specialty clinicians refer their patients to diagnostic laboratories, which conduct HIV viral load tests; and HIV specialty clinicians initiate and manage ART. These activities result in the output of patient adherence to their ART regimen (Meyers et al., 2019). This

output results in the short-term outcome of HIV viral suppression, defined as a viral load < 200 copies/mL (Byrd et al., 2019). This short-term outcome leads to the longer-term outcomes of improved health and reduced rates of HIV transmission (Cohen et al., 2011).

**ALT-TEXT:**

Figure 1a.01 shows the inputs, activities, outputs, short-term outcomes, and long-term outcomes involved in the “HIV continuum of care” that result in HIV viral suppression. The inputs include HIV specialty clinicians, antiretroviral therapy (ART), and diagnostic laboratories. The activities include conducting HIV viral load tests and initiating and managing ART, and the output is adherence to ART. The short-term outcomes are HIV viral suppression and the long-term outcomes are improved health and reduced rates of HIV transmission.

**CITATIONS:**

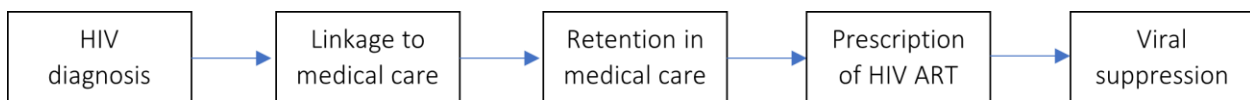
Byrd, K. K., Hou, J. G., Hazen, R., Kirkham, H., Suzuki, S., Clay, P. G., Bush, T., Camp, N. M., Weidle, P. J., Delpino, A., & Patient-Centered HIV Care Model Team (2019). Antiretroviral Adherence Level Necessary for HIV Viral Suppression Using Real-World Data. *Journal of acquired immune deficiency syndromes (1999)*, 82(3), 245–251. <https://doi.org/10.1097/QAI.0000000000002142>

Cohen, M. S., Chen, Y. Q., McCauley, M., Gamble, T., Hosseinipour, M. C., Kumarasamy, N., Hakim, J. G., Kumwenda, J., Grinsztejn, B., Pilotto, J. H., Godbole, S. V., Mehendale, S., Chariyalertsak, S., Santos, B. R., Mayer, K. H., Hoffman, I. F., Eshleman, S. H., Piwowar-Manning, E., Wang, L., Makhema, J., ... HPTN 052 Study Team (2011). Prevention of HIV-1 infection with early antiretroviral therapy. *The New England journal of medicine*, 365(6), 493–505. <https://doi.org/10.1056/NEJMoa1105243>

Gardner, E. M., McLees, M. P., Steiner, J. F., Del Rio, C., & Burman, W. J. (2011). The spectrum of engagement in HIV care and its relevance to test-and-treat strategies for prevention of HIV infection. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, 52(6), 793–800. <https://doi.org/10.1093/cid/ciq243>.

Meyers, D. J., Cole, M. B., Rahman, M., Lee, Y., Rogers, W., Gutman, R., & Wilson, I. B. (2019). The association of provider and practice factors with HIV antiretroviral therapy adherence. *AIDS (London, England)*, 33(13), 2081–2089. <https://doi.org/10.1097/QAD.0000000000002316>

Previous Submission:



Although the above diagram outlines the sequential steps 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.02) Provide evidence that the target population values the measured outcome, process, or structure and finds it meaningful.**

*Describe how and from whom input was obtained.*

Current Submission:

HIV viral suppression is a long-standing priority outcome among the HIV community in the United States and around the world. The National HIV/AIDS Strategy for the United States from 2022-2025, developed by the White House Office of National AIDS Policy with input from the HIV community across the United States, prioritizes increasing HIV viral suppression rates to 95%. This goal builds on the goal that was set forth by the United Nations AIDS Programme in 2014, in coordination with stakeholders, to achieve at least 90% suppression among all people receiving antiretroviral therapy worldwide (UNAIDS 2014).

**CITATIONS:**

*The White House. (2021). National HIV/AIDS Strategy for the United States 2022–2025. <https://files.hiv.gov/s3fs-public/NHAS-2022-2025.pdf>*

*UNAIDS. Geneva: UNAIDS. (2014). 90-90-90: an ambitious treatment target to help end the AIDS epidemic. [https://www.unaids.org/sites/default/files/media\\_asset/90-90-90\\_en.pdf](https://www.unaids.org/sites/default/files/media_asset/90-90-90_en.pdf)*

**1a.03) Provide empirical data demonstrating the relationship between the outcome (or PRO) and at least one healthcare structure, process, intervention, or service.**

Current Submission:

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 (Hogg et al 2001; Lundgren et al., 2015). ART has also been shown to reduce transmission of HIV (Rodger et al 2019). Prior analyses have shown that provider can explain a significant amount of variation in viral suppression among Medicaid enrollees (Meyers et al 2019). Further, interventions such as providers asking for self-reported ART adherence, the use of once-daily ART regimens, reminder devices, and education and counseling are all recommended strategies for improving ART adherence (Thompson et al. 2012).

**CITATIONS:**

*Hogg, R. S., Yip, B., Chan, K. J., Wood, E., Craib, K. J., O'Shaughnessy, M. V., & Montaner, J. S. (2001). Rates of disease progression by baseline CD4 cell count and viral load after initiating triple-drug therapy. *JAMA*, 286(20), 2568-2577. <https://doi.org/10.1001/jama.286.20.2568>*

*Lundgren, J. D., Babiker, A. G., Gordin, F., Emery, S., Grund, B., Sharma, S., . . . Group, I. S. S. (2015). Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection. *N Engl J Med*, 373(9), 795-807.*

<https://doi.org/10.1056/NEJMoa1506816>

Meyers, D. J., Cole, M. B., Rahman, M., Lee, Y., Rogers, W., Gutman, R., & Wilson, I. B. (2019). The association of provider and practice factors with HIV antiretroviral therapy adherence. *AIDS (London, England)*, 33(13), 2081–2089. <https://doi.org/10.1097/QAD.0000000000002316>

Rodger, A. J., Cambiano, V., Bruun, T., Vernazza, P., Collins, S., Degen, O., . . . Group, P. S. (2019). Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. *Lancet*, 393(10189), 2428-2438. [https://doi.org/10.1016/S0140-6736\(19\)30418-0](https://doi.org/10.1016/S0140-6736(19)30418-0)

Thompson, M. A., Mugavero, M. J., Amico, K. R., Cargill, V. A., Chang, L. W., Gross, R., Orrell, C., Altice, F. L., Bangsberg, D. R., Bartlett, J. G., Beckwith, C. G., Dowshen, N., Gordon, C. M., Horn, T., Kumar, P., Scott, J. D., Stirratt, M. J., Remien, R. H., Simoni, J. M., & Nachega, J. B. (2012). Guidelines for Improving Entry Into and Retention in Care and Antiretroviral Adherence for Persons With HIV: Evidence-Based Recommendations From an International Association of Physicians in AIDS Care Panel. *Annals of Internal Medicine*, 156(11), 817–833. <https://doi.org/10.7326/0003-4819-156-11-201206050-00419>

Previous Submission:

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.



## **Importance to Measure and Report: Evidence (Complete for Process Measures) (1a.03 - 1a.16)**

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

### **Current Submission:**

Updated evidence information here.

### **Previous (Year) Submission:**

Evidence from the previous submission here.

### **1a.01) Provide a logic model.**

*Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.*

### **1a.02) Select the type of source for the systematic review of the body of evidence that supports the performance measure.**

*A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data.*

- Clinical Practice Guideline recommendation (with evidence review)
- US Preventive Services Task Force Recommendation
- Other systematic review and grading of the body of evidence (e.g., Cochrane Collaboration, AHRQ Evidence Practice Center)
- Other (please specify here: )

If the evidence is not based on a systematic review, skip to the end of the section and do not complete the repeatable question group below. If you wish to include more than one systematic review, you may add additional tables to the relevant sections. Please follow the 508 Checklist for tables.

### **Evidence - Systematic Reviews Table (Repeatable)**

### **1a.03) Provide the title, author, date, citation (including page number) and URL for**

the systematic review.

**1a.04) Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the systematic review.**

**1a.05) Provide the grade assigned to the evidence associated with the recommendation and include the definition of the grade.**

**1a.06) Provide all other grades and definitions from the evidence grading system.**

**1a.07) Provide the grade assigned to the recommendation, with definition of the grade.**

**1a.08) Provide all other grades and definitions from the recommendation grading system.**

**1a.09) Detail the quantity (how many studies) and quality (the type of studies) of the evidence.**

**1a.10) Provide the estimates of benefit, and consistency across studies.**

**1a.11) Indicate what, if any, harms were identified in the study.**

**1a.12) Identify any new studies conducted since the systematic review, and indicate whether the new studies change the conclusions from the systematic review.**

## **Evidence**

**1a.13) If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, describe the evidence on which you are basing the performance measure.**

**1a.14) Briefly synthesize the evidence that supports the measure.**

**1a.15) Detail the process used to identify the evidence.**

**1a.16) Provide the citation(s) for the evidence.**

## Importance to Measure and Report: Gap in Care/Disparities (1b.01 - 1b.05)

### 1b.01) Briefly explain the rationale for this measure.

*Explain how the measure will improve the quality of care and list the benefits or improvements in quality envisioned by use of this measure.*

Current Submission:

HIV is a communicable infection that leads to a progressive disease with a long asymptomatic period. Approximately 40,000 persons in the United States are newly infected with HIV each year (Centers for Disease Control and Prevention, 2021, p. 51). Without treatment, most persons develop acquired immunodeficiency syndrome (AIDS) within 10 years of HIV infection.

HIV viral suppression is a long-standing priority outcome among the HIV community in the United States and around the world. The National HIV/AIDS Strategy for the United States from 2022-2025, developed by the White House Office of National AIDS Policy with input from the HIV community across the United States, prioritizes increasing HIV viral suppression rates to 95% (The White House 2020). The DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents defines viral suppression as a viral load below the lower limits of detection in its guidelines on virologic failure, and it defines viral suppression as a viral load of less than 200 copies/mL as part of its guidelines for the use of antiretroviral therapy to prevent HIV transmission (Panel on Antiretroviral Guidelines for Adults and Adolescents 2022).

Antiretroviral therapy (ART) delays the progression to AIDS and increases the length of survival. ART reduces HIV-associated morbidity and mortality by maximally inhibiting HIV replication to achieve viral suppression (Hogg et al 2001; Lundgren et al., 2015). ART has also been shown to reduce transmission of HIV (Rodger et al 2019). Studies show disparities in rates of viral suppression by race and ethnicity among MSM and among women, with Black and Hispanic or Latino/a study participants having lower rates of viral suppression than White participants (Buchacz et al. 2020; Buchacz et al. 2018; Geter et al. 2018). This measure will help providers direct their attention and quality improvement efforts towards improving HIV viral suppression rates.

#### CITATIONS:

*Buchacz, K., Armon, C., Palella, F. J., Novak, R. M., Fuhrer, J., Tedaldi, E., . . . Investigators, H. O. S. H. (2020). The HIV Outpatient Study-25 Years of HIV Patient Care and Epidemiologic Research. Open Forum Infect Dis, 7(5), ofaa123. <https://doi.org/10.1093/ofid/ofaa123>*

*Buchacz, K., Armon, C., Tedaldi, E., Palella, F. J., Novak, R. M., Ward, D., . . . Investigators, H. O. S. (2018). Disparities in HIV Viral Load Suppression by Race/Ethnicity Among Men Who Have Sex with Men in the HIV Outpatient Study. AIDS Res Hum Retroviruses, 34(4), 357-364. <https://doi.org/10.1089/AID.2017.0162>*

*Centers for Disease Control and Prevention (2021). HIV Surveillance Report, 2019. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>*

*Geter, A., Sutton, M. Y., Armon, C., Durham, M. D., Palella, F. J., Tedaldi, E., . . . Investigators, H. O. S. (2018). Trends of racial and ethnic disparities in virologic suppression among women in the HIV*

*Outpatient Study, USA, 2010-2015. PLoS One, 13(1), e0189973.*  
<https://doi.org/10.1371/journal.pone.0189973>

*Hogg, R. S., Yip, B., Chan, K. J., Wood, E., Craib, K. J., O'Shaughnessy, M. V., & Montaner, J. S. (2001). Rates of disease progression by baseline CD4 cell count and viral load after initiating triple-drug therapy. JAMA, 286(20), 2568-2577. <https://doi.org/10.1001/jama.286.20.2568>*

*Lundgren, J. D., Babiker, A. G., Gordin, F., Emery, S., Grund, B., Sharma, S., . . . Group, I. S. S. (2015a). Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection. N Engl J Med, 373(9), 795-807. <https://doi.org/10.1056/NEJMoa1506816>*

*Panel on Antiretroviral Guidelines for Adults and Adolescents. "Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV." Washington, DC: U.S. Department of Health and Human Services, 2022. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf> Updated September 21, 2022.*

*Rodger, A. J., Cambiano, V., Bruun, T., Vernazza, P., Collins, S., Degen, O., . . . Group, P. S. (2019). Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. Lancet, 393(10189), 2428-2438. [https://doi.org/10.1016/S0140-6736\(19\)30418-0](https://doi.org/10.1016/S0140-6736(19)30418-0)*

*The White House. (2021). National HIV/AIDS Strategy for the United States 2022–2025. <https://files.hiv.gov/s3fs-public/NHAS-2022-2025.pdf>*

Previous Submission:

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:

1. 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.
2. Reduction in the risk of transmitting HIV to a sexual or drug-using partner who does not have HIV.
3. 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.
4. 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.

**1b.02) Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.**

*Include mean, std dev, min, max, interquartile range, and scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.*

We calculated the measure performance scores at the clinician level for the measure performance period from January 1, 2021, to December 31, 2021. The total sample included 187 unique clinicians and 3,056 patients, of which 47 clinicians had at least 11 patients—the minimum sample size requirement outlined in the CMS cell suppression policy. The data for these 47 clinicians included 2,995 unique patients. We provide the distribution of the measure performance scores for all clinicians and clinicians with at least 11 patients eligible for the denominator below. In the remainder of this document, we will focus on clinicians with at least 11 patients.

Table 1b.02. Distribution of the measure performance scores in the clinician samples

Sample	Clinicians	Patients	Mean	SD	Min	p10	p20	p30	p40	p50	p60	p70	p80	p90	Max	IQR
All clinicians	187	3,056	72.3	33.3	0.0	0.0	50	66.1	77.5	85.2	93.2	100	100	100	100	50
Clinicians with 11+ patients	47	2,995	85.2	10.9	46.2	70	79.3	81.7	83.9	87.9	90.8	91.5	94.5	95.2	100	12.4

Notes: SD=Standard deviation, Min=minimum, Max=maximum, p=percentile, IQR=interquartile range  
 These data reflect Ryan White HIV/AIDS Program patients, and thus reflect a sample of patients with higher rates of viral suppression than the national population of people with HIV (HRSA 2022, CDC 2020).

**ALT-TEXT:**

Table 1b.02 describes the distribution of the measure scores in the sample of all clinicians and clinicians with at least eleven patients. The table shows the number of clinicians and patients, and the mean, standard deviation, interquartile range and minimum and maximum scores on the measure, as well as the distribution of the measure scores by decile. The table shows that there’s an overall high performance on the measure but there is a substantial variation in the measure scores indicating the potential for further improvement. Overall, there was slightly more variation and the higher percentile scores in the sample of all clinicians.

**CITATIONS:**

*Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2021. (2022). [www.hab.hrsa.gov/data/data-reports](http://www.hab.hrsa.gov/data/data-reports).*

*Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2018. (2020). HIV Surveillance Supplemental Report; 25(2). <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-25-2.pdf>*

**1b.03) If no or limited performance data on the measure as specified is reported above, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement. Include citations.**

Not applicable

**1b.04) Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.**

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. For measures that show high levels of performance, i.e., “topped out”, disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

Data for this analysis are the same as the measure testing data (see section sp.27 for full details.) A total of 47 clinicians and 2,995 unique patients from 7 test sites are included in the analysis below. During testing, measure performance was stratified to assess whether there were disparities in viral suppression by patients’ age (< 50 years vs. >= 50 years), HIV transmission category (men who have sex with men [MSM], injection drug use [IDU], which includes both IDU and MSM and IDU, and Other transmission), race (White vs. Black), and ethnicity (Hispanic or Latino vs. not Hispanic or Latino). Table 1b.04 summarizes the results of the analysis.



**Table 1b.04. Measure performance rates by population groups (age, HIV transmission, race and ethnicity)**

Patient Group	Clinicians	Patients	Mean	Std dev	Min	10%	20%	30%	40%	50%	60%	70%	80%	90%	Max	IQR
AGE<50	47	1,472	82.4	12.5	40.0	68.7	75.0	76.4	80.2	82.7	86.9	88.5	91.8	100.0	100.0	14.6
AGE>=50	47	1,523	87.7	13.0	50.0	67.9	81.9	84.2	89.7	90.6	94.1	95.4	100.0	100.0	100.0	13.3
MSM	41	1,218	84.7	13.2	50.0	66.7	71.4	81.0	85.7	88.9	90.0	92.9	95.8	100.0	100.0	15.1
IDU	40	234	82.2	22.6	0.0	50.0	66.7	74.1	84.1	90.1	100.0	100.0	100.0	100.0	100.0	31.4
Other transmission	41	992	87.8	13.6	50.0	66.7	78.6	85.7	90.9	93.1	93.8	95.2	100.0	100.0	100.0	11.0
Black	47	1,351	79.7	21.2	0.0	60.0	73.2	78.9	81.6	85.7	88.5	90.2	92.6	94.8	100.0	15.1
White	47	1,520	86.7	12.4	50.0	66.7	75.0	82.7	87.0	90.9	92.7	95.3	99.3	100.0	100.0	20.3
Not Hispanic or Latino	47	2,559	84.7	11.9	50.0	65.9	78.9	80.9	84.7	87.1	90.0	92.4	94.4	96.1	100.0	12.9
Hispanic or Latino	36	429	89.7	19.1	0.0	77.5	84.6	88.2	93.8	99.1	100.0	100.0	100.0	100.0	100.0	13.2

Notes: Results are for clinicians with  $\geq 11$  patients eligible for the denominator.

SD=standard deviation, p=percentile, min=minimum, max=maximum, IQR=interquartile range

Across all clinicians, mean clinician-level performance rates varied by age, HIV transmission group, and race/ethnicity. Patients under age 50 had lower rates of viral suppression (mean= 82.4%) as compared to patients age 50 and older (mean=87.7%). The differences in the measure score by patients' ages were statistically significant ( $p=0.05$ ), which reflects the lower rates of HIV viral suppression among younger patients based on national surveillance data (HRSA 2022). Black patients had lower rates of viral suppression than white patients (79.7% vs. 86.7%), while non-Hispanic patients had lower rates of viral suppression than Hispanic patients (84.7% vs. 89.7%). Patients whose HIV transmission group is IDU had lower rates of suppression (82.2%) than those whose transmission group was MSM (84.7%) or other (87.8%). However, the differences in the measure scores by ethnicity ( $p=0.18$ ), race ( $p=0.06$ ), and HIV transmission group ( $p=0.42$ ) did not reach statistical significance at the  $p \leq 0.05$  level. We observed more variability in the clinician-level measure rates for Black patients (mean=79.7, SD=21.2) and IDU patients (mean=82.2, SD=22.6) relative to other strata. Larger variation in the measure rates for IDU patients can be attributed to the relatively small sample for that stratum, whereas variability in the measure rates for Black patients may reflect differences in care within this group of patients. Please refer to the 2b.02 for the interpretation.



**ALT-TEXT:**

Table 1b.04 describes the measure performance rate age, virus transmission model, race, and ethnicity.

The table shows the number of clinicians and patients, and the mean, standard deviation, interquartile range, and minimum and maximum scores on the measure, as well as the distribution of the measure scores by decile. The measure scores are shown separately for 1) patients less than 50 years of age, patients fifty years of age and older, 2) patients with MSM, IDU and other (i.e.: non-MSM/IDU) virus transmission model, 3) White and Black patients, and 4) Hispanic or Latino and not Hispanic or Latino patients. The mean measure scores are higher for patients fifty years of age and older, patients with non-IDU or MSM transmission methods, White patients and Hispanic or Latino patients.



**CITATIONS:**

*Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2021. (2022). <https://ryanwhite.hrsa.gov/data/reports>.*

**1b.05) If no or limited data on disparities from the measure as specified is reported above, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in above.**

Not applicable.

**Scientific Acceptability: Maintenance (2ma.01 - 2ma.04)**

**2ma.01) Indicate whether additional empirical reliability testing at the accountable entity level has been conducted. If yes, please provide results in the following section, Scientific Acceptability: Reliability - Testing. Include information on all testing conducted (prior testing as well as any new testing).**

*Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:*

**Current Submission:**

Updated testing information here.

**Previous Submission:**

Testing from the previous submission here.

Yes

No

**2ma.02) Indicate whether additional empirical validity testing at the accountable entity level has been conducted. If yes, please provide results in the following section, Scientific Acceptability: Validity - Testing. Include information on all testing conducted (prior testing as well as any new testing).**

*Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:*

**Current Submission:**

Updated testing information here.

**Previous Submission:**

Testing from the previous submission here.

Yes

No

**2ma.03) For outcome, patient-reported outcome, resource use, cost, and some process measures, risk adjustment/stratification may be conducted. Did you perform a risk adjustment or stratification analysis?**

- Yes
- No

**2ma.04) For maintenance measures in which risk adjustment/stratification has been performed, indicate whether additional risk adjustment testing has been conducted since the most recent maintenance evaluation. This may include updates to the risk adjustment analysis with additional clinical, demographic, and social risk factors.**

**Please update the Scientific Acceptability: Validity - Other Threats to Validity section.**

**Note: This section must be updated even if social risk factors are not included in the risk adjustment strategy.**

- Yes - Additional risk adjustment analysis is included
- No additional risk adjustment analysis included

## Scientific Acceptability: Reliability - Testing (2a.01 - 2a.12)

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 fields in the Scientific Acceptability sections of the Measure Submission Form.

- Measures must be tested for all the data sources and levels of analyses that are specified. If there is more than one set of data specifications or more than one level of analysis, contact Battelle staff at [PQMsupport@battelle.org](mailto:PQMsupport@battelle.org) about how to present all the testing information in one form.
- All required sections must be completed.
- For composites with outcome and resource use measures, Questions 2b.23-2b.37 (Risk Adjustment) also must be completed.
- If specified for multiple data sources/sets of specifications (e.g., claims and EHRs), Questions 2b.11-2b.13 also must be completed.
- An appendix for supplemental materials may be submitted (see Question 1 in the Additional section), but there is no guarantee it will be reviewed.
- Contact Battelle staff at [PQMsupport@battelle.org](mailto:PQMsupport@battelle.org) with any questions.
- For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for the [2021 Measure Evaluation Criteria and Guidance](#).

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet the evaluation criteria for testing.

2a. Reliability testing demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument-based measures (including PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure;

AND

If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

2b3. For outcome measures and other measures when indicated (e.g., resource use):

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; 14,15 and has demonstrated adequate discrimination and calibration

OR

- rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful 16 differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

2b6. Analyses identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias.

2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:

2c1. the component measures fit the quality construct and add value to the overall composite while achieving the related objective of parsimony to the extent possible; and

2c2. the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.

(if not conducted or results not adequate, justification must be submitted and accepted)

## **Definitions**

Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measure scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.

Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

Risk factors that influence outcomes should not be specified as exclusions.

With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of \$25 in cost for an episode of care (e.g., \$5,000 v. \$5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

**Current Submission:**

Updated testing information here.

**Previous (Year) Submission:**

Testing from the previous submission here.

**2a.01) Select only the data sources for which the measure is tested.**

- Assessment Data
- Claims
- Electronic Health Data
- Electronic Health Records
- Instrument-Based Data
- Management Data
- Other (please specify here: )
- Paper Medical Records
- Registry Data

**2a.02) If an existing dataset was used, identify the specific dataset.**

*The dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).*

**Current Submission:**

This submission relies on the patient-level EHR data from seven participating sites. Please refer to section sp.27 for more details about the sample.

**Previous Submission:**

This measure is a legacy electronic clinical quality measure (eCQM) – an NQF endorsed measure that has been respecified into eMeasures and is currently used in federal quality programs. Per NQF modified testing requirements for legacy eCQMs, the measure was tested in the Bonnie testing tool. Bonnie is designed to validate eCQM specifications (HQMF output and value sets) against the measure’s expected behavior for user-developed synthetic test patients.

The synthetic patient bundle used to test this measure was designed to simulate clinically relevant, realistic patient scenarios aligned with the target population for this measure. Full details on the Bonnie synthetic patient bundle used to test this measure are included in the Bonnie testing attachment.

For more information on Bonnie, please visit <https://bonnie.healthit.gov/>.

**2a.03) Provide the dates of the data used in testing.**

*Use the following format: “MM-DD-YYYY - MM-DD-YYYY”*

**Current Submission:**

01-01-2021 – 12-31-2021

**Previous Submission:**

The Bonnie test environment simulates the year 2012 as the measurement period.

**2a.04) Select the levels of analysis for which the measure is tested.**

*Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.*

- Accountable Care Organization
- Clinician: Group/Practice
- Clinician: Individual
- Facility
- Health Plan
- Integrated Delivery System
- Other (specify)
- Population: Community, County or City
- Population: Regional and State

**2a.05) List the measured entities included in the testing and analysis (by level of analysis and data source).**

*Identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample.*

**Current Submission:**

Seven test sites that are Ryan White HIV/AIDS Program recipients representing three regions (Northeast, South, and Midwest) provided the data for this measure. Of these seven sites, four test sites were publicly funded community health centers, two sites were hospital-based clinics, and one site represented a community-based service organization. The sites varied in EHR systems (eClinical Works, EPIC/OCHIN EPIC, NextGen, Athena Health). At these 7 test sites, a total of 47 clinicians were included in testing. These 47 clinicians had a total of 2,995 patients included in the measure denominator. Table 2a.05 breaks down the characteristics of the participating sites included in the beta testing of the measure.



Table 2a.05. Test site characteristics

Site	Provider type	Region	EHR	# of clinicians with 11+ patients	# of patients
Site 1	Publicly funded community health center	NE	eClinical Works	5	136
Site 2	Publicly funded community health center	NE	eClinical Works	3	157
Site 3	Hospital or university-based clinic	NE	EPIC	21	592
Site 4	Publicly funded community health center	SO	OCHIN EPIC	6	516
Site 5	Other community-based service organization	NE	NextGen	3	60
Site 6	Publicly funded community health center	MW	Athena Health	3	484
Site 7	Hospital or university-based clinic	MW	eClinical Works	6	1050

Notes: NE=Northeast, SO=South, MW=Midwest

**ALT-TEXT:**

Table 2a.05 provides characteristics of the seven test sites, including provider type, provider region, provider electronic health record system, as well as the number of clinicians (for clinicians with at least 11 patients) and patients in the sample the measure developer received from each provider.

**Previous Submission:**

Not applicable. The Bonnie synthetic patient bundle was used to test the measure.

**2a.06) Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.**

*If there is a minimum case count used for testing, that minimum must be reflected in the specifications.*

**Current Submission:**

The full analytic sample extracted from the EHR included 3,056 patients attributed to 187 clinicians within the measurement period from 7 sites that are Ryan White HIV/AIDS Program participants. This sample represents all patients with HIV that had any encounter during the measurement period. The measure is specified to require a minimum denominator of 11 patients during the measurement period, to follow the CMS cell size suppression policy stating that no cell can be reported that allows a value of 1 to 10 reported. The restricted sample, used for testing, includes 47 clinicians (25.1% of the initial number of clinicians) and 2,995 patients (98.0% of the initial number of patients). When limited to clinicians with 11 or more patients eligible for the denominator during the measurement period, the average (mean) clinician has an HIV Viral Suppression measure rate of 85.2%.

Out of the patients attributed to a clinician with at least 11 patients in the denominator:

1. 3% (88) patients were under the age of 25, and 97% (2,910) patients were over the age of 25.
2. 49% (1,472) patients were under the age of 50, and 51% (1,523) patients were over the age of 50.
3. Broken out by HIV transmission group, 41% (1,218) of patients' transmission group was men who have sex with men (MSM), 6% (186) of patients' transmission group was injection drug use (IDU; note that IDU included patients who had both MSM and IDU listed as their HIV transmission group), and 35% (1,015) of patients' transmission group was other, while 18% (551) of patients were missing information on HIV transmission group.
4. 25% (748) patients were cisgender women, 74% (2,232) patients were cisgender men, and 0.5% (15) patients were transgender women.

**Previous Submission:**

A test bundle of 34 patients was designed and built within the Bonnie testing tool to evaluate the measure logic. Information documented for each patient within the bundle include:

1. Patient name
2. Date of birth
3. Race
4. Ethnicity
5. Gender
6. Payer

Additional elements contained within the patient profiles as appropriate for testing against expected outcomes include:

7. Diagnosis
8. Laboratory tests and associated results
9. Encounters

The patient bundle's demographics were designed to mimic the HIV/AIDS population, specifically drawing from the patient characteristics collected via the Ryan White HIV/AIDS Program Services Report (RSR).

The breakdown of test bundle demographics for the 34 patients included (represented by number of patients/percentage of bundle): males 23/68%; females 11/32%; American Indian/Alaska Native 1/3%; Asian 1/3%; Black/African American 15/44%; Native Hawaiian/Pacific Islander 0/0%; White 9/26%; Hispanic/Latino 8/24%; younger than 13 1/3%; 13-17 years old 1/3%; 18-24 years old 2/6%; 25-34 years old 6/18%; 35-44 years old 6/18%; 45-54 years old 10/29%; 55-65 years old 6/18%; older than 65 2/6%.

Full details on the Bonnie synthetic patient bundle used to test this measure, including human-readable and QRDA Category 1 format documents for each synthetic patient record, are included in the Bonnie testing attachment.

**2a.07) If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing.**

**Current Submission:**

The same data are used for all clinician-level testing (reliability, concurrent validity, known group validity, and meaningful difference in performance), as described below.

**Reliability:** To assess reliability, we used the EHR data from each of seven sites covering the period between January 1, 2021, and December 31, 2021. For the reliability analysis (and all other clinician-level testing) we restricted the sample to clinicians who saw at least 11 patients during the measurement period.

**Data element validity:** To assess data element validity, we randomly selected a subset of 20 patient encounters (from the full EHR extract) in each of the seven sites, for a total of 140 encounters. For selected cases, site personnel manually abstracted data elements necessary for the measure calculation from each site's EHR. We then compared the manually abstracted and electronically extracted data to assess data element validity via agreement between the gold-standard source (manual abstraction) and the EHR extract.

**Construct validity:** To assess validity of the measure using known-group validity method we stratified the sample by age (patients <50 years old vs. patients 50 years old or older) and HIV transmission group (IDU vs. non-IDU). For this analysis we used the EHR data from each of seven sites covering the period between January 1, 2021, and December 31, 2021, and we restricted the sample to clinicians who saw at least 11 patients during the measurement period.

**Face validity:** We solicited feedback on the measure's face validity from 7 clinicians via a semi-structured interview. We also conducted a formal poll during a meeting of the Technical Expert Panel (TEP) that was convened during the development of the HIV Viral Suppression measure. The TEP was comprised of clinicians, patient representatives, and other experts in EHR systems and HIV care.

**Exclusions:** Not applicable; this measure does not have exclusions.

**Risk adjustment:** Not applicable; this measure is not risk adjusted.

**Meaningful difference in performance:** To assess whether meaningful differences in the measure performance we restricted the sample to clinicians who saw at least 11 patients during the measurement period, using EHR data from each of seven sites covering the period between January 1, 2021, and December 31, 2021.

**Previous Submission:**

The Bonnie patient test deck was used to satisfy all testing requirements for this measure. The testing results are further supported by testing data for the chart-abstracted version of this measure collected through the Health Resources and Services Administration HIV/AIDS Bureau's Ryan White HIV/AIDS Program Services Report.

**2a.08) List the social risk factors that were available and analyzed.**

*For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.*

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.09 check patient or encounter-level data; in 2a.010 enter “see validity testing section of data elements”; and enter “N/A” for 2a.11 and 2a.12.

**Current Submission:**

We collected information on the following variables using data extracted from hospital EHR systems: age, sex, race, ethnicity, payer, and HIV transmission category. We examined disparities in the measure rates by age, race, ethnicity, and HIV transmission category. Section 1b.4 describes those results.

**Previous Submission:**

Patient sociodemographic variables considered in the analysis of the chart-abstracted version of this measure were included in the eCQM specifications and modeled in the Bonnie patient bundle. These variables included age, race, ethnicity, gender and payer.

**2a.09) Select the level of reliability testing conducted.**

Choose one or both levels.

- Patient or Encounter-Level (e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements)
- Accountable Entity Level (e.g., signal-to-noise analysis)

**2a.10) For each level of reliability testing checked above, describe the method of reliability testing and what it tests.**

*Describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used.*

**Current Submission:**

We tested reliability of the measure at the clinician level using three methods: signal-to-noise reliability, which tests the precision of the measure rates at the clinician level, and split-half and test-retest methods, which test the stability of the measure rates across clinicians.

The signal-to-noise method summarizes the proportion of the total variation in the clinician scores that is attributable to real underlying differences between clinicians (signal), in relation to random variation within each clinician (noise). Noise can be introduced by patient-level variability, which might include unmeasured patient characteristics, or by the lack of precision in the measure estimates because of a lack of sufficient patient sample size within clinicians (Deutsch et al 2012). The beta-binomial model is an appropriate framework for estimating reliability for the measure (Adams 2009). Reliability is calculated as the ratio of the variance between clinicians and the total variance (that is, the sum of the between-clinician and within-clinician variances) of the measure rates.

The resulting reliability statistic ranges from 0 to 1. If reliability is 0, there is no variation on the measure across clinicians, and all observed variation is because of random variation within a clinician. In this case, the lack of reliability suggests that the measure is not useful for distinguishing between clinicians with respect to that outcome. Conversely, if reliability is 1, all provider scores are free of random variation, and all variation represents real differences between clinicians in the measure result.

After we computed the signal and noise variance for providers in the sample, we determined the minimum denominator size necessary to reach the reliability of 0.7, which is commonly considered the threshold for acceptable reliability.

We used split-half and test-retest approaches to examine stability of the measure scores within the same clinicians. The split-half method involves comparing the measure scores for two independent samples of patients within the same provider. For this method, we randomly split the sample of patients within each clinician into two mutually exclusive samples with equal or nearly equal size, resulting in two samples that cover the same one-year period but with case volume the size of a measure that would be calculated with six months of data. **Thus, each clinician appeared in the sample twice, but with an entirely different set of patients.** Then, we estimated Spearman- and intraclass correlations between the measure rates within two samples. We also computed the Spearman-Brown correction to account for the attenuation of the Spearman correlation due to dividing the original sample of patients in two halves.

**Since split-half method can, under some conditions, over- or underestimate reliability because of capitalization on chance,** we also assessed stability of the measure scores using the test-retest method, which involves comparing the measure scores for the same clinicians computed in different samples of patients either within the same measurement period or two adjacent measurement periods. Since we only had one year of data, we opted to use bootstrap resampling to generate independent samples of patients within the same clinicians. The bootstrap method avoids biased sampling, maintains the original sample size, and allows estimation of confidence intervals for the reliability estimates. We drew 2,000 independent samples with replacement (stratified by the provider), maintaining the same number of beneficiaries for each provider as in the original sample, and grouped the samples into 1,000 pairs. These random samples from a given clinician are assumed to reflect an independent set of re-measurement of the HIV Viral Load Suppression rates for a clinician. Then, we estimated Spearman- and intraclass correlations between the measure rates within each pair and computed the mean and the 95percent confidence interval of the distribution of correlations from the 1,000 paired samples.

Spearman correlation captures the association between the ranks of clinicians in different realizations of the bootstrap samples. The intraclass correlation captures the degree of correlation and agreement between measurements and is represented as a ratio of the variance in the measure counts between providers over the sum of the variances between and within providers. Hence, the smaller the disagreement between the measure counts for each clinician in different samples, the larger the intraclass correlation coefficient. Correlation values range from 0 to 1; a value of 1 indicates perfect reliability, and a value of 0 means the measure is perfectly unreliable.

Following CMS's cell size suppression policy for reporting, all clinicians with fewer than 11 patients in the measurement period were excluded from calculations.

**CITATIONS:**

*Adams, J. L. (2009). The Reliability of Provider Profiling: A Tutorial.*

[https://www.rand.org/pubs/technical\\_reports/TR653.html](https://www.rand.org/pubs/technical_reports/TR653.html)

Deutsch, A., Smith, L., Gage, B., Kelleher, C., & Garfinkel, D. (2012). Patient-Reported Outcomes in Performance Measurement. [https://www.qualityforum.org/Projects/n-r/Patient-Reported\\_Outcomes/Commissioned\\_Paper\\_2.aspx](https://www.qualityforum.org/Projects/n-r/Patient-Reported_Outcomes/Commissioned_Paper_2.aspx)

**Previous Submission:**

Currently, there is no performance data available to test the eCQM. However, the chart-abstracted version of this measure has been in use in national quality reporting programs since as early as 2010.

The most recent reliability analysis of the chart-abstracted measure was confirmed 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.

**2a.11) For each level of reliability testing checked above, what were the statistical results from reliability testing?**

*For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis, more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, Measure Evaluation Criteria).*

**Current Submission:**

Table 2a.11-A summarizes the mean and range of the signal-to-noise reliability statistics for the HIV Viral Suppression measure, which was calculated separately for each clinician. The mean signal-to-noise reliability across all 47 clinicians with at least 11 patients eligible for the denominator was 0.90, with the standard deviation of 0.10, suggesting that the measure is highly reliable.

**Table 2a.11-A Signal to Noise Reliability of Clinician-level Measure Scores**

Sample	Clinicians	Min	Mean	SD	p5	p10	p25	p50	p75	p90	p95	Max
Clinicians >= 11 patients	47	0.628	0.90	0.10	0.70	0.75	0.85	0.94	0.98	0.99	1.00	1.00

Notes: Results are provided for clinicians with ≥11 patients eligible for the denominator (n = 47).

Min=minimum, SD=standard deviation, Max=maximum

**ALT-TEXT:**

Table 21.11-A provides results of the signal-to-noise reliability testing for clinicians with at least 11 patients eligible for the denominator. The table shows the number of clinicians, and the mean, standard deviation, minimum and maximum scores on the measure, as well as the measure scores for the 5th, 10th, 25th, 50th, 75th, 90th and 95th percentiles. Mean reliability in a sample was very high and measure scores for most clinicians in a sample were highly reliable.

Table 2a.11-B summarizes the Spearman rank-order correlation, Spearman-Brown correlation, and intra-class correlation for the split-half reliability statistics for the HIV Viral Suppression measure. All statistics exceeded the 0.9 threshold, indicating very high stability of the measure scores across independent samples of patients.

**Table 2a.11-B Split-Half Reliability of Clinician-level Measure Scores**

Sample	Spearman rank-order correlation	Spearman-Brown correction for the sample size attenuation	Intra-class correlation
Clinicians >= 11 patients	0.967	0.983	0.932

Notes: Results are provided for clinicians with ≥11 patients eligible for the denominator (n = 47)

**ALT-TEXT:**

Table 2a-11B provides the results of the split-half reliability for clinicians with at least 11 patients eligible for the denominator. Spearman correlation, Spearman correlation corrected for sample attenuation using Spearman-Brown correction, and intra-class correlations exceeded 0.9 indicating high split-half reliability of the measure.

Table 2a.11-C summarizes the mean and range of the Spearman rank-order correlation, Spearman-Brown correlation, and intra-class correlation for the test-retest reliability statistics for the HIV Viral Suppression measure, which were calculated using the bootstrap method in 1,000 pairs of bootstrap samples. In this analysis, the mean reliability statistics exceeded the 0.9 threshold, indicating very high stability of the measure scores across 1,000 pairs of patient samples.



**Table 2a.11-C Test-Retest Reliability of Clinician-level Measure Scores via the Bootstrap Resampling Method**

Sample	Statistical Method	Mean	Min	p5	p10	p25	p50	p75	p90	p95	Max
Clinicians >= 11 patients	Spearman rank- order correlation	0.973	0.897	0.951	0.959	0.967	0.975	0.981	0.985	0.987	0.993
Clinicians >= 11 patients	Spearman-Brown correction	0.986	0.945	0.975	0.979	0.983	0.987	0.990	0.993	0.993	0.997
Clinicians >= 11 patients	intra-class correlation	0.944	0.811	0.899	0.914	0.933	0.948	0.961	0.970	0.973	0.987

Notes: Results are provided for clinicians with  $\geq 11$  patients eligible for the denominator (n = 47)

Our findings regarding the minimum sample size for the measure indicate the median sample size per clinician necessary to reach signal-to-noise reliability of 0.7 in our sample was 7 patients. With a sample size of 10 patients, 75 percent of clinicians would reach the 0.7 threshold for signal-to-noise reliability. Therefore, assuming our findings are generalizable to the universe of reporting clinicians, our findings indicate that using the CMS cell suppression policy to set a minimum sample size of 11 patients would allow us to produce statistically valid comparisons between clinicians.

**ALT-TEXT:**

Table 2a.11-C shows the results for test-retest reliability of the measure scores estimated using bootstrap resampling for clinicians with at least 11 patients eligible for the denominator. The table shows mean, minimum, maximum and the percentile distribution of the Spearman correlations, Spearman correlations corrected for sample attenuation using Spearman-Brown correction, and intra-class correlations obtained in 1,000 pairs of samples generated using bootstrap. The mean reliability exceeded 0.9 for all three methods indicating high test-retest reliability of the measure.

**Previous Submission:**

Overall reliability scores (i.e., median of provider-level reliability [R\_median], minimum [R\_min], maximum [R\_max]) by year, and the overall variance between sites, are summarized below.

**Overall reliability scores by year, 2010-2014**

Year	% suppressed	Var_between	R_median	R_min	R_max
2010	60.6	0.051	0.983	0.290	1.000
2011	64.7	0.046	0.982	0.267	1.000
2012	69.9	0.038	0.979	0.338	1.000
2013	76.1	0.020	0.967	0.211	1.000
2014	80.3	0.013	0.954	0.092	1.000

Reliability scores varied across providers by year. The proportion of providers with reliability greater than or equal to 0.9, 0.8, and 0.7 are shown below.



Distribution of provider-level reliability scores by year, 2010-2014

Year	N	≥0.9 n (%)	≥0.8 n (%)	≥0.7 n (%)
2010	846	764 (90.3)	809 (95.6)	826 (97.6)
2011	811	721 (88.9)	766 (94.5)	786 (96.9)
2012	816	713 (87.4)	775 (95.0)	794 (97.3)
2013	823	657 (79.8)	738 (89.7)	772 (93.8)
2014	813	595 (73.2)	690 (84.9)	751 (92.4)

**2a.12) Interpret the results, in terms of how they demonstrate reliability.**

*(In other words, what do the results mean and what are the norms for the test conducted?)*

**Current Submission:**

The HIV Viral Suppression measure demonstrates high reliability in all three methods of testing indicating that the measure could be useful to distinguish a clinician’s performance from the sample mean and between any clinician pair. The results also indicate that the measure has good stability.

Although there is not a clear cut-off for the minimum signal-to-noise reliability level, reliability of 0.4 is often considered to be the lower limit of moderate reliability sufficient for public reporting (Schone, Hubbard and Jones, 2011), reliability above 0.7 is considered sufficient to see differences between physicians and the mean (Adams, 2009), and reliability above 0.9 is considered sufficient to see differences between any physician pair (National Quality Forum, 2013). According to our calculations, not only is the measure’s average reliability high, but most individual clinicians also have highly reliable scores.

The ICC captures the effect of the clinician on the patients’ outcomes and could be interpreted as the correlation in the outcome between two individuals randomly selected from the same clinician (Austin and Merlo, 2017). There are no standard values for acceptable reliability using ICC. A low ICC could not only reflect the low degree of agreement but also relate to the small number of subjects. Following Porteny and Watkins, we rely on the following interpretation: ICC values less than 0.5 are indicative of poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability, and values greater than 0.90 indicate excellent reliability. The ICCs exceeding 0.9 obtained from the split-half and test-retest testing methods indicate excellent reliability of the measures.

Finally, according to Cohen’s (Cohen, 1992) effect-size criteria, the Spearman correlations above 0.8 indicate a large effect size, thus also supporting the claim that the HIV Viral Load Suppression measure is highly reliable.

**CITATIONS:**

Adams JL. *The Reliability of Provider Profiling: A Tutorial*. Santa Monica, CA: RAND Corporation; 2009. [http://www.rand.org/pubs/technical\\_reports/TR653.html](http://www.rand.org/pubs/technical_reports/TR653.html). doi:10.7249/TR653

Austin, P. C., & Merlo, J. (2017). *Intermediate and advanced topics in multilevel logistic regression analysis*. *Statistics in Medicine*, 36(20), 3257–3277. <https://doi.org/10.1002/sim.7336>

Cohen, J. (1992). *A power primer*. *Psychological bulletin*, 112(1), 155.

Deutsch A, Smith L, Gage B, Kelleher C, Garfinkel D. (2012) *Patient-reported outcomes in performance measurement*. [https://www.qualityforum.org/Projects/n-r/Patient-Reported\\_Outcomes/Commissioned\\_Paper\\_2.aspx](https://www.qualityforum.org/Projects/n-r/Patient-Reported_Outcomes/Commissioned_Paper_2.aspx)

National Quality Forum. *Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties* (2011). <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70943>.

Portney LG, Watkins MP. *Foundations of clinical research: applications to practice*. New Jersey: Prentice Hall; 2000

Schone E, Hubbard M, Jones D. (2011). *Reporting period and reliability of AHRQ, CMS 30-day and HAC quality measures*. Memorandum submitted to the Centers for Medicare and Medicaid Services. <https://EconPapers.repec.org/RePEc:mpr:mprres:cab712bf5e324d0db15eca9c404f3eb2>.

#### **Previous Submission:**

There is no established cut-off for minimum reliability level. Values above 0.7 are considered sufficient to see differences between providers and the mean, and values above 0.9 are considered sufficient to see differences between pairs of providers (RAND Corporation, TR-653-NCQA, 2009).

Each year, the majority of provider-level reliability scores were greater than 0.9, and more than 90% of providers had reliability scores of 0.7 or greater. Therefore, the reliability of viral suppression can be considered to be sufficient to identify real differences in performance across providers. As previously mentioned, sample size is another driver of reliability and likely contributed to the lowest reliability scores (e.g., in 2014 site 8645 had a reliability of 0.21, and reported 3 of 4 patients with a medical visit were virally suppressed). However, median reliability was consistently over 0.95 during 2010-2014 and can help to support the conclusion that the reliability of this measure can be considered very good.

**Scientific Acceptability: Validity - Testing (2b.01 - 2b.04)****2b.01) Select the level of validity testing that was conducted.**

- Patient or Encounter-Level (data element validity must address ALL critical data elements)
- Accountable Entity Level (e.g., hospitals, clinicians)
- Empirical validity testing of the measure score
- Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)

**2b.02) For each level of testing checked above, describe the method of validity testing and what it tests.**

*Describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used.*

**Current Submission:**

We tested the data element validity, face validity (qualitative assessment of validity based on the experts' feedback), and measure score validity (construct validity) for all three eCQM.

**Data element validity.** This form of validity testing assesses whether the data elements, as obtained from the structured, extractable fields in the EHR, accurately reflect the care the patients received. We tested data element validity by examining agreement for measure data elements from two sources for a randomly selected set of patients:

1. EHR data extracted from the structured fields used by the eCQMs
2. Manually abstracted data from the entire medical record, including free-text note fields and scanned documents (considered the 'gold-standard')

We requested that the test sites pull the structured patient data from their EHRs through automated extraction algorithms and send us the data. To support this request, we provided sites with data dictionaries containing all of the data elements associated with the three measures, as well as the corresponding value sets. We then selected a random sample of medical record numbers from the EHR extract from each site (20 records per site for a total of 140 records across 7 sites) and ask the site staff to abstract the same data elements through a manual review of the patients' medical records. At all phases of the EHR extract and manual abstraction process we met with sites as needed to answer questions about the process.

We calculated the raw agreement (percentage agreement) and the chance-corrected agreement (Gwet's AC1) between the two data sources. The interpretation of the AC1 statistic is the same as that of Cohen's Kappa, but AC1 is a more robust measure of interrater reliability. Kappa is sensitive to classification probabilities which in some cases lead to the low chance-corrected agreement despite the high observed agreement (the so-called Kappa paradox). This situation does not occur when using AC1 (Quarfoot and Levine 2016). Higher values for agreement statistics demonstrate that the structured EHR data used to calculate the measure have accuracy similar to looking at the medical record overall, including clinical notes, documents, and other fields that convey information about the patient but cannot be used to calculate eQMs. When the two measurements agree perfectly, the value of the agreement will be 1.0.

**Face validity:** We conducted clinician interviews with seven clinicians from the seven test sites. We developed an interview guide to solicit clinician perspectives on the utility and face validity of the measure. Specifically, we asked whether they thought measure scores could be used to accurately distinguish quality among providers. The evaluation of face validity was conducted through a semi-structured interview process. We also conducted a formal poll during a meeting of the Technical Expert Panel (TEP) that was convened during the development of the HIV Viral Suppression measure. The TEP was comprised of clinicians, patient representatives, and other experts in EHR systems and HIV care.

**Construct validity.** We assessed the differences in the measure rates by subgroups shown in the literature to have differences in rates of HIV viral suppression: transmission category (injection drug use [IDU] versus non-IDU) and age (younger than age 50 versus 50 or older). This approach, known-group validity, is a hypothesis-based testing that leverages hypotheses based on known differences in care to see if the same differences are reflected in the measure rates, thus providing evidence of the measure's validity. For each characteristic, we stratified the sample, calculated the measure rates, and computed the effect size using Cohen's *d* statistic. A higher absolute value of Cohen's *d* indicates a higher standardized difference between the two groups. NQF does not set specific thresholds for known-group validity; rather, the committee might consider collective evidence from all validity tests to adjudicate the measure.

**CITATIONS:**

Quarfoot, D., & Levine, R. A. (2016). *How Robust Are Multirater Interrater Reliability Indices to Changes in Frequency Distribution?* *The American Statistician*, 70(4), 373–384.

<https://doi.org/10.1080/00031305.2016.1141708>

**Previous Submission:**

The Bonnie testing environment was used to test the validity of the measure logic and data elements. For each Bonnie synthetic patient, an expected measure result was assigned to reflect the expected outcome of the measure given the specific patient scenario and associated data. The synthetic patients were run against the HQMF output loaded into Bonnie, which produces a measure outcome for each patient and evaluates it against the expected outcome. A patient is considered to pass Bonnie testing when the expected outcome matches the actual outcome, e.g. when a patient is expected to be in the numerator population and the computation of the synthetic patient data against the eQCM logic places the patient in the numerator.

In order to achieve a rigorous, clinically relevant test bundle, synthetic patients were designed following the below principles and test areas:

1. Clinical relevance. References cited within the chart abstracted measure specification were used to design clinically relevant, realistic patient profiles for the measure’s target population. This approach ensured the eCQM logic maintained alignment with the clinical intent of the chart abstracted measure.

100% logic coverage: The resulting bundle of synthetic patients collectively includes all data elements and conditions logic that are specified within the measure logic, including at least one patient evaluating against each measure population pathway. Fully testing the measure logic increases test rigor and mitigates risk of unexpected outcomes.

Edge case testing. Edge cases refer to those data elements that test the upper or lower boundary of measure logic conditions, e.g. a diagnosis starting on the latest qualifying date or an HIV viral load result equal to the highest qualifying value. Edge cases are designed to test each edge that exists within each measure population.

Negative testing. Negative testing involves use of test cases do not evaluate positively against measure logic, but are otherwise clinically relevant and realistic, e.g. scenarios where an HIV diagnosis was not documented or an HIV viral load was performed without a documented result. Negative testing further validates measure logic by accurately evaluating patients against expected outcomes and simulating the effect of missing data on measure results.

In addition to Bonnie testing, the measure specifications were reviewed independently by three eCQM experts to confirm the logic was syntactically correct, using appropriate and current versions of the eCQM standards and terminologies, and consistent with the intent of the chart-abstracted measure.

**2b.03) Provide the statistical results from validity testing.**

*Examples may include correlations or t-test results.*

**Current submission**

**Data element validity.** We found that the percent agreement between the EHR data and manual abstraction ranged from 75% to 100%, corresponding to a Gwet’s AC1 ranging from 0.68 to 1.00.

**Table 2b.03-A. Agreement Between Medical Records and Manual Abstraction (140 records collected from 7 sites)**

Data Element	Percent Agreement	Gwet’s AC1
HIV diagnosis date	75.0	0.68
Encounter 1 date	99.3	0.99
Encounter 1 type	99.3	0.99
Encounter 2 date	99.3	0.99
Encounter 1 type	99.3	0.99
Viral load 1 date	98.6	0.98

Data Element	Percent Agreement	Gwet's AC1
Viral load 1 value	98.6	0.98
Viral load 2 date	98.6	0.97
Viral load 2 value	100.0	1.00
Average across all elements	96.4	0.95

**ALT-TEXT:**

Table 2b.03-A shows the observed agreement expressed as percent agreement and the chance-corrected agreement computed using Gwet's AC1 statistic between the medical records and manual abstraction across 140 records collected from 7 sites. Results indicate very high observed and change-corrected (above 0.95) reliability for all data elements except for the HIV diagnosis date, for which the observed reliability was 0.75 and chance-corrected reliability was 0.68.

**Face validity.** We found that six of the seven clinicians interviewed (86%) agreed that the measure can distinguish good from poor quality of care.

**Construct validity.** Among patients attributed to clinicians with at least 11 patients, the mean rate of viral suppression was 82.4% for those under 50 as compared to 87.7% for those 50 years or older with an effect size of 0.415 using Cohen's D, indicating a moderate effect. The mean rate of viral suppression was 81.2% for those whose HIV transmission group was IDU as compared to 88.1% for those whose HIV transmission group was not IDU, with an effect size of 0.404 using Cohen's D, indicating a moderate effect.

**Table 2b.03-C. Known-group validity results for clinicians >= 11 patients eligible for denominator**

Patient sub-group	Mean Viral Suppression	S.D.	Cohen's D	t-test p-value
Age < 50 years	82.4	12.3	0.415 (results for comparison of age sub-groups)	0.047 (results for comparison of age sub-groups)
Age >= 50 years	87.7	13.0	*	*
Non-IDU HIV transmission category	88.1	8.5	0.404 (results for comparison of HIV transmission category subgroups)	0.085 (results for comparison of HIV transmission category subgroups)
IDU HIV transmission category	81.2	22.8	*	*

Notes: \* = Cell intentionally left empty; S.D. = standard deviation

**ALT-TEXT:**

Table 2b.03-C shows results for the known-group validity testing for clinicians with at least 11 patients eligible for the denominator. The table shows the mean viral suppression scores and standard

deviations, as well as Cohen's D statistics and p-values for the t-tests by groups. The results are provided separately for patients by age groups (less than 50 years of age, and 50 years and older), and patients with non-IDU and IDU HIV transmission category. The mean measure scores were higher for the patients 50 years and older and patients with non-IDU HIV transmission category.

**Previous Submission:**

Full details on Bonnie testing results are contained in the Bonnie testing attachment. The attachment includes a human-readable (HTML) summary document that lists each patient within the bundle and its passing status against expected measure outcomes. The attachment also includes a summary spreadsheet for the synthetic patient bundle which lists each patient, associated demographics, expected and actual measure population outcomes, and which portions of each measure population logic the patient meets expectations for.

**2b.04) Provide your interpretation of the results in terms of demonstrating validity. (i.e., what do the results mean and what are the norms for the test conducted?)****Current Submission:**

We tested validity of the measure using both qualitative (face validity) and quantitative methods (data element level: data element validity; measure score level: concurrent and known group validity). [add summary sentence or two stating the measure showed good evidence of data element validity and known group validity]

**Face validity.** Most respondents strongly agreed or agreed that the measure score is an accurate reflection of quality (4 out of 7 respondents) and that the measure score can be used to distinguish between good and poor quality of care (6 out of 7 respondents). Further, among the technical expert panel (TEP) convened for the development of this measure, 100% agreed that the measure was important and related to quality of care. These results demonstrate high face validity of the measure.

**Data element validity.** The AC1 values calculated through data element validity testing suggest high levels of agreement between the data extract generated from the EHR systems and the manually abstracted data. We observed the 96.4 percent average agreement across all data elements or higher for all data elements. The average chance-corrected agreement captured by the AC1 statistic was 95.2 percent. These statistics indicate very high data element validity. Observed agreement was very high (above 98 percent) for all data elements with the exception for the HIV diagnosis date, for which the observed agreement was 75 percent. As a sensitivity test, we compared the HIV diagnosis dates in both data sources (i.e., EHR and chart data). We found that in all cases, observed differences between the HIV diagnosis dates did not affect whether or not the patient would have been included in the denominator because all of the dates occurred prior to the measurement period.

**Known-group validity.** The differences in the measure rates between patient subgroups by age and HIV transmission category are consistent with the observed literature. We found that younger patients (age < 50 years) had had viral suppression rates 5.3 percentage points lower than older patients (age 50+ years). This is consistent with national Ryan White HIV/AIDS Program data from 2021 showing that individuals with HIV who are ages 15-19 and 20-24 have HIV viral suppression rates of 81.7 and 82.7%,

respectively, which is lower than individuals with HIV at older ages (e.g., ages 50-54 and 55-59 have HIV viral suppression rates of 91.1% and 92.5%, respectively) [Health Resources and Services Administration, 2021].

We also found that patients whose HIV transmission category was Injection Drug Use had viral suppression rates approximately 7 percentage point lower than patients in the non-IDU transmission category. This is also consistent with the literature indicating that viral suppression rates were about 6% lower in patients whose HIV transmission group was Injection Drug Use (IDU) using the most recent HIV viral load measure using data from eight HIV clinical cohorts across 1997 to 2015 (Nance et al, 2018). Thus, observed differences in the viral suppression rates observed in our sample are in line with the literature, providing evidence of measure validity.

**CITATIONS:**

*Health Resources and Services Administration (2022). Ryan White HIV/AIDS Program Annual Client-Level Data Report 2021. <http://www.hab.hrsa.gov/data/data-reports>.*

*Nance, R. M., Delaney, J. A. C., Simoni, J. M., Wilson, I. B., Mayer, K. H., Whitney, B. M., . . . Crane, H. M. (2018). HIV Viral Suppression Trends Over Time Among HIV-Infected Patients Receiving Care in the United States, 1997 to 2015: A Cohort Study. *Ann Intern Med*, 169(6), 376-384. <https://doi.org/10.7326/M17-2242>*

**Previous Submission:**

The results of measure logic testing through use of Bonnie provided confidence in the measure logic accurately representing the clinical intent and alignment with the chart abstracted measure.



## **Scientific Acceptability: Validity - Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data) (2b.05 - 2b.14)**

### **2b.05) Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified.**

*Describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided in Importance to Measure and Report: Gap in Care/Disparities.*

#### **Current Submission:**

To examine differences in performance, we calculated measure performance rates for 47 clinicians with at least 11 patients eligible for the denominator in the performance period. We excluded clinicians with fewer than 11 patients eligible for the denominator consistent with CMS's cell suppression policy, and also because the estimates for clinicians with fewer cases tend to be less reliable. Then, we computed a 95 percent confidence interval (95% CI) around each clinician's measure score and compared the 95% CI to the mean measure rate in our sample. If the confidence intervals did not overlap with the mean measure rate in a sample, clinician's performance was identified as significantly better or worse than the mean.

We also calculated the distributions of the measure rates to determine if the measure was "topped out." For the measure to be topped out, two conditions had to be met (Analysis of Topped-Out Measures 2014). First, the 75th performance percentile must be statistically indistinguishable (within two standard errors) from the 90th percentile. Second, the truncated coefficient of variation (TCV) (calculated by first removing the lower and upper 5th percentiles and then dividing the standard deviation by the mean of this truncated distribution) must be less than or equal to 0.10.

#### **CITATIONS:**

*Centers for Medicare & Medicaid Services. Analysis of Topped-Out Measures Finalized for the PY 2016 ESRD QIP. (2014). Updated June 19, 2014. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/AnalysisofTopped-OutMeasuresFinalizedforthePY2016ESRDQIP.pdf>.*

#### **Previous Submission:**

The chart-abstracted version of this measure has been in use since 2010. To examine meaningful differences in performance, we examined the distribution of the proportion of patients with viral suppression across providers, by year. Performance scores were broken into the bottom 10% and top 90% providers to better characterize the gaps that remain across providers. Moreover, performance scores were examined with respect to NHAS 2020 Indicator 6: increase the percentage of persons with diagnosed HIV infection who are virally suppressed to at least 80 percent.

### **2b.06) Describe the statistical results from testing the ability to identify**

**statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.**

*Examples may include number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined.*

**Current Submission:**

Based on the sample of 47 clinicians with at least 11 patients eligible for denominator, the HIV Viral Load Suppression measure rates in our sample ranged from 46.2% to 100.0% (with a median of 87.9% and an interquartile range of 80.6% and 93.0%). Thus, there is variation in measure scores across clinicians.

**Table 2b.06-A. Performance distribution of the HIV Viral Suppression measure rates**

Sample	Clinicians	Patients	Mean	SD	Min	p10	p25	p50	p75	p90	Max	IQR
Clinicians with 11+ patients	47	2,995	85.2	10.9	46.2	70.0	80.6	87.9	93.0	95.2	100.0	12.4

**ALT-TEXT:**

Table 2b.06-A shows the performance distribution of the measure scores for clinicians with at least 11 patients eligible for the denominator. The table shows the number of clinicians and patients for the sample of clinicians with at least 11 patients, as well as the mean, standard deviation, median, interquartile range and percentile distribution of the measure scores in the sample.

Of the 47 clinicians, 13 (28% of all clinicians in the sample) were statistically better, and 2 clinicians (4.3%) were worse than the sample average, which is conceptually equivalent to an “average-performing clinician” in a sample. Distribution of the performance categories shown in Table 2b.06-B suggests that improvement in the measure scores is possible for nearly three quarters of clinicians whose performance scores were either no different from the sample average (68.1%) or worse than the sample average (4.3%).

**Table 2b.06-B. Performance distribution of the HIV Viral Suppression measure rates relative to the sample average for clinicians with at least 11 patients eligible for the denominator**

Performance group	N and % of clinicians	Mean performance rate
Better than the sample average	13 (27.7%)	94.9%
No different than the sample average	32 (68.1%)	83.0%
Worse than the sample average	2 (4.3%)	56.9%
All Clinicians	47 (100.0%)	85.2%

**ALT-TEXT:**

Table 2b.06-B shows performance distribution of the HIV viral suppression measure scores relative to the sample average for clinicians with at least 11 patients eligible for the denominator. Out of 47 clinicians in the sample, 32 clinicians had measure scores that were not significantly different from the

sample average and 13 and 2 clinicians had measure scores that were, respectively, better and worse than the sample average.

The results of the topped-out analysis indicate that the measure has a truncated coefficient of variation (TCV) equal to 0.09, which meets criterion 2 (TCV<0.10), but does not meet criterion 1 (75th percentile within 2 standard errors of the 90th percentile), and thus the measure is not considered topped out.

**Table 2b.06-C. Topped out analysis of the HIV Viral Suppression measure rates.**

Measure	75 <sup>th</sup> pctl.	90 <sup>th</sup> pctl.	90 <sup>th</sup> – 75 <sup>th</sup> pctl.	2x S.D. of 90 <sup>th</sup> pctl.	Criterion 1 met?	TCV	Criterion 2 met?
HIV Viral Suppression	0.93	0.95	0.02	0.01	No	0.09	Yes

Notes: pctl= percentile, S.D= standard deviation, TCV= truncated coefficient of variation.

**ALT-TEXT:**

Table 2b.06-C shows results of the topped-out analysis of the measure scores. For the measure to be topped out, two criteria must be met. First, the the truncated coefficient of variation must be less than 0.10, and second, the 90th percentile on the measure score distribution must be indistinguishable from the 75th percentile. The table shows the results for both statistical analyses.

**Previous Submission:**

**% Patients with viral suppression across providers**

Year	Mean	SD	Median	10th %ile	90th %ile
2010	60.6	23.8	67.8	19.5	82.8
2011	64.7	22.1	71.4	31.9	84.9
2012	69.9	20.3	75.6	40.2	88.0
2013	76.1	17	80.7	57.1	90.2
2014	80.3	15.5	84.2	65.0	93.1

**Providers achieving ≥80% suppression**

Year	N	n	%
2010	846	145	17.1
2011	811	207	24.5
2012	816	277	32.7
2013	823	435	51.4
2014	813	530	65.2

**2b.07) Provide your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities.**

*In other words, what do the results mean in terms of statistical and meaningful*

*differences?*

**Current Submission:**

There was substantial variability in the measure rates across clinicians in our sample, and the measure was able to distinguish between clinicians with better and worse than average performance scores. As about 25 percent of clinicians had significantly better measure scores than the sample average, this indicates potential for performance improvement for nearly three quarters of clinicians in our sample whose measure scores were either worse than or not significantly different from the sample average. The measure is also not considered topped out based on testing. Further, these data reflect Ryan White HIV/AIDS Program patients, and thus reflect a sample of patients with higher rates of viral suppression than the national population of people with HIV (HRSA 2022, CDC 2020). It is likely that when this measure is applied to a broader population of patients with HIV, the performance scores are unlikely to be as high.

**CITATIONS:**

*Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2021. (2022). [www.hab.hrsa.gov/data/data-reports](http://www.hab.hrsa.gov/data/data-reports).*

*Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2018. (2020). HIV Surveillance Supplemental Report; 25(2). <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-25-2.pdf>*

**Previous Submission:**

The table above demonstrates meaningful variability across providers, allowing for the identification of meaningful differences across sites. Specifically, the measure is able to detect providers with better or worse than median performance scores. In 2014, the bottom 10% of providers had viral suppression rates of 65.0% or lower; the top 90% of providers had viral suppression rates of 93.1% or higher. While this gap appears to be narrowing over time, a meaningful difference of 28.1 percentage points remains, demonstrating the value of the measure in identifying sites based on poor performance relative to the top performers.

Provider-level performance differences observed in the table above also underscore improvements in the proportion of patients with viral suppression in achieving 80% viral suppression. In 2014, of 813 providers, 530 (65.2%) had at least 80% of patients reach viral suppression. Additionally, the overall percentage of patients with viral suppression was 80.3%; however, given the large population that the RWHAP serves, even the poorest performing sites (e.g., bottom 10%) represent a substantial number of patients.

**2b.08) Describe the method of testing conducted to identify the extent and distribution of missing data (or non-response) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing**

**data minimizes bias.**

*Describe the steps—do not just name a method; what statistical analysis was used.*

**Current Submission:**

Missing data are not expected to be a threat to validity for the measure. Data elements required to calculate the performance rate are ones in which absence of data in a data field reflects the absence of an eligible data element. For example, if a patient does not have a lab visit, we interpret this to mean that the patient did not have an eligible lab visit, rather than that the information for that visit was missing. Encounter type and dates are also required for the measure calculation. Results on missing data elements used in testing are presented below in Section 2b.09.

**Previous Submission:**

The HQMF standard specifies that if data are unknown or missing, they shall fail the criterion. This constraint embodies the notion that absence of evidence is evidence of absence, i.e. data not present in a structured field from which the measure draws will not be considered for measure calculation. In certain cases, missing data may have no impact on the measure outcome for a given patient. For example, a data element used in a series of OR statements will not impact the measure outcome if another data element in the OR statement is present and meets all other defined constraints.

**2b.09) Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.**

*For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).*

**Current Submission:**

As noted in 2b.08, we do not expect missing data to be a threat to validity. No data elements used in calculating the measure scores had substantial rates of missing values.

0.1% (9) of the viral load tests had a performance date but missing viral load value. This represents a very small number of tests and includes instances where the test was performed but results were inconclusive.

0.1% (13) of the encounters had a performance date but were missing the encounter code to indicate type of encounter. This represents a very small number of the total encounters.

**Previous Submission:**

The Bonnie synthetic patient bundle includes scenarios for missing data elements, which are a form of negative testing. All Bonnie synthetic patients with missing data performed according to the HQMF standard specification and as expected.

**2b.10) Provide your interpretation of the results, in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.**

*In other words, what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis was conducted, justify the selected approach for missing data.*

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) OR to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eCQMs). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

**Current Submission:**

As noted in 2b.08, we do not expect missing data to be a threat to validity. As noted in 2b.09, no data elements used in calculating the measure scores had substantial rates of missing values.

**Previous Submission:**

Please see response for question 2b7.1 above. (2b7.1 which is now question 2b.08)

**2b.11) Indicate whether there is more than one set of specifications for this measure.**

- Yes, there is more than one set of specifications for this measure  
 No, there is only one set of specifications for this measure

**2b.12) Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications.**

*Describe the steps—do not just name a method. Indicate what statistical analysis was used.*

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**2b.13) Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.**

*Examples may include correlation, and/or rank order.*

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**2b.14) Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.**

*In other words, what do the results mean and what are the norms for the test conducted.*

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

## Scientific Acceptability: Validity - Other Threats to Validity (Exclusions, Risk Adjustment) (2b.15 - 2b.32)

### 2b.15) Indicate whether the measure uses exclusions.

- N/A or no exclusions
- Yes, the measure uses exclusions.

### 2b.16) Describe the method of testing exclusions and what was tested.

*Describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used?*

#### Current Submission:

Not applicable.

#### Previous Submission:

Not applicable.

### 2b.17) Provide the statistical results from testing exclusions.

*Include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores.*

#### Current Submission:

Not applicable.

#### Previous Submission:

Not applicable.

### 2b.18) Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

*In other words, the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion.*

#### Current Submission:

Not applicable.



**Previous Submission:**

Not applicable.

**2b.19) Check all methods used to address risk factors.**

- Statistical risk model with risk factors (specify number of risk factors)
- Stratification by risk category (specify number of categories)
- Other (please specify here: )
- No risk adjustment or stratification

**2b.20) If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.**

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**2b.21) If an outcome or resource use measure is not risk-adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (i.e., case mix) is not needed to achieve fair comparisons across measured entities.**

**Current Submission:**

The White House National HIV/AIDS Strategy for the United States calls for increasing the rate of viral suppression among people diagnosed with HIV to 95 percent by 2025, up from a baseline of 63 percent in 2017 (White House, 2021). Achieving this goal will require clinicians to focus on helping all of their patients achieve viral suppression, including those who may currently have lower rates due to particular sociodemographic factors. Risk adjusting this measure would not be consistent with achieving this goal. Further, as noted in the previous submission, the Ryan White HIV/AIDS Program is a public health, safety net program providing care to a high proportion of racial/ethnic minority, transgender, unstable housing, and low-income people with HIV. Many of people served by the Ryan White HIV/AIDS Program represent sociodemographic factors incorporated into risk adjustment models by many measure stewards. As a result, the Ryan White HIV/AIDS Program does not adjust for risk in its performance measures.

The Technical Expert Panel (TEP) that was convened as a part of the development of this measure did not achieve a consensus on the need for risk adjustment (50% in favor, 50% opposed); furthermore, the TEP did not have a consensus on whether it would be appropriate to adjust for patient-level

characteristics and were more in favor of adjusting for clinic or area-level factors, such as location within a Medicaid expansion state.

**CITATIONS:**

*The White House. (2021). National HIV/AIDS Strategy for the United States 2022–2025.*  
<https://files.hiv.gov/s3fs-public/NHAS-2022-2025.pdf>

**Previous Submission:**

The Ryan White HIV/AIDS Program provides a comprehensive system of care that includes primary medical care and essential support services for people living with HIV who are uninsured or underinsured. The Program works with cities, states, and local community-based organizations to provide HIV care and treatment services to more than half a million people each year. The Program reaches approximately 52% of all people diagnosed with HIV in the United States.

As indicated in data presented earlier, the Ryan White HIV/AIDS Program is a public health, safety net program providing care to a high proportion of racial/ethnic minority, transgender, unstable housing, and low income people living with HIV. Many of people served by the Ryan White HIV/AIDS Program represent sociodemographics factors incorporate in risk adjusting models by many measures' stewards. As a result, the Ryan White HIV/AIDS Program does not adjust for risk in its performance measures. Rather, it is a fundamental aspect of the Ryan White HIV/AIDS Program to identify disparities and work to improve quality of care for subpopulations. Additionally, this measure is not used for pay-for-performance, bonuses, or penalties.

**2b.22) Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.**

- Published literature
- Internal data analysis
- Other (please specify here: )

**2b.23) Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.**

*Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of  $p < 0.10$  or other statistical tests; correlation of  $x$  or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).*

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**2b.24) Detail the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.**

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**2b.25) Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.**

*Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.*

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**2b.26) Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used). Provide the statistical results from testing the approach to control for differences in patient characteristics (i.e., case mix) below. If stratified ONLY, enter “N/A” for questions about the statistical risk model discrimination and calibration statistics.**

*Validation testing should be conducted in a data set that is separate from the one used to develop the model.*

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**2b.27) Provide risk model discrimination statistics.**

*For example, provide c-statistics or R-squared values.*

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**2b.28) Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).**

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**2b.29) Provide the risk decile plots or calibration curves used in calibrating the statistical risk model.**

*The preferred file format is .png, but most image formats are acceptable.*

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**2b.30) Provide the results of the risk stratification analysis.**

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**2b.31) Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).**

*In other words, what do the results mean and what are the norms for the test conducted?*

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**2b.32) Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.**

*Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.*

**Current Submission:**

Not applicable.

**Previous Submission:**

Not applicable.

**Feasibility (3.01 - 3.07)****3.01) Check all methods below that are used to generate the data elements needed to compute the measure score.**

- Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)
- Coded by someone other than person obtaining original information (e.g., DRG, ICD-10 codes on claims)
- Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)
- Other (Please describe)

**3.02) Detail to what extent the specified data elements are available electronically in defined fields.**

*In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields. ALL data elements are in defined fields in electronic health records (EHRs)*

- ALL data elements are in defined fields in electronic claims
- ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)
- ALL data elements are in defined fields in a combination of electronic sources
- Some data elements are in defined fields in electronic sources
- No data elements are in defined fields in electronic sources
- Patient/family reported information (may be electronic or paper)

**3.03) If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using data elements not from electronic sources.****3.04) Describe any efforts to develop an eQCM.**

We have developed this measure as an eQCM, including developing the specification in the current standard, the Quality Data Model (QDM), and completing Bonnie testing with 100% passing and coverage.

**3.05) Complete and attach the eQCM-Feasibility-Scorecard.xls file.****3.06) Describe difficulties (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.**

With one exception, all data elements required for this measure were consistently available and captured accurately across all seven test sites. Two sites did not consistently capture HIV diagnoses and/or diagnosis dates in structured fields. One site did not capture any HIV diagnosis dates in structured fields, and the other only captured HIV diagnoses and diagnosis dates in structured fields for patients covered by the Ryan White HIV/AIDS Program. Of these two sites, one began a process of changing workflows to capture HIV diagnoses and diagnosis dates in structured fields as a result of participating in our testing efforts. Given the availability of this data element either currently or in the near term across nearly all of our test sites, we do not expect this data element to substantially affect the feasibility of this measure. Moreover, in sites where the diagnosis date is unavailable, the date associated with the diagnosis on the problem list should be sufficient to determine whether diagnosis occurred prior to the performance year.

*Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.*

**3.07) Detail any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm),**

*Attach the fee schedule here, if applicable.*

N/A

**Use (4a.01 – 4a.10)**

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.

Endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement, in addition to demonstrating performance improvement.

**4a.01) Check all current uses. For each current use checked, please provide:**

- **Name of program and sponsor**
- **URL**
- **Purpose**
- **Geographic area and number and percentage of accountable entities and patients included**
- **Level of measurement and setting**

- Public Reporting
- Public Health/Disease Surveillance
- Payment Program
- Regulatory and Accreditation Programs
- Professional Certification or Recognition Program
- Quality Improvement with Benchmarking (external benchmarking to multiple organizations)
- Quality Improvement (Internal to the specific organization)
- Not in use
- Use unknown
- Other (please specify here: )

**4a.02) Check all planned uses.**

- Public reporting
- Public Health/Disease Surveillance
- Payment Program
- Regulatory and Accreditation Program
- Professional Certification or Recognition Program
- Quality Improvement with Benchmarking (external benchmarking to multiple organizations)
- Quality Improvement (internal to the specific organization)
- Measure Currently in Use
- Other (please specify here: )



**4a.03) If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.**

*For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?*

A MIPS CQM version of this measure, Quality ID 338, is currently in use in MIPS. HRSA plans to replace the MIPS CQM version with the present eCQM.

**4a.04) If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.**

*A credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*

HRSA plans to submit this measure for use as a clinician-level measure in the CMS MIPS program. HRSA will submit the measure to the 2023 Measures Under Consideration (MUC) list by April 30, 2023.

**4a.05) Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.**

*Detail how many and which types of measured entities and/or others were included. If only a sample of measured entities were included, describe the full population and how the sample was selected.*

Throughout the testing process we provided clinical practices that participated in testing with measure specifications, data dictionaries, value sets, and fact sheets to assist them in generating datasets used for testing. This measure has not yet been implemented.

**4a.06) Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.**

N/A. Measure has not yet been implemented.

**4a.07) Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.**

N/A. Measure has not yet been implemented.

**4a.08) Summarize the feedback obtained from those being measured.**

N/A. Measure has not yet been implemented.

**4a.09) Summarize the feedback obtained from other users.**

N/A. Measure has not yet been implemented.

**4a.10) Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.**

N/A. Measure has not yet been implemented.

**Usability (4b.01 - 4b.03)**

**4b.01) You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included). If no improvement was demonstrated, provide an explanation. If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.**

This measure is not currently in use as an eQIM in a quality improvement program. During measure testing, clinicians at all seven test sites agreed that the measure could be used to improve quality of care at their practices. Several of these clinicians noted that their practices already track which patients have not achieved viral suppression, and they use these results to focus outreach efforts on those patients to help improve medication adherence and take other steps to help them achieve viral suppression. Some of the clinicians interviewed also said that scores on this measure could motivate low-scoring clinicians to focus on improving their viral suppression rates through actions such as improving their communication with patients and making sure they were tracking their patients' viral suppression. As noted above in 1a.01, helping patients achieve viral suppression improves patient health and reduces the risk of those patients transmitting HIV to others. HRSA HAB is considering these measures for use in CMS's Quality Payment Programs (QPP), in particular the Merit-based Incentive Payment System (MIPS), which would provide a financial incentive for clinicians to ensure their patients are virally suppressed.

**4b.02) Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.**

N/A. Measure has not yet been implemented.

**4b.03) Explain any unexpected benefits realized from implementation of this measure.**

N/A. Measure has not yet been implemented.

## Related and Competing (5.01 - 5.06)

If you are updating a maintenance measure submission for the first time in MIMS, please note that the previous related and competing data appearing in question 5.03 may need to be entered in to 5.01 and 5.02, if the measures are endorsed. Please review and update questions 5.01, 5.02, and 5.03 accordingly.

### **5.01) Search and select all endorsed related measures (conceptually, either same measure focus or target population) by going to the PQM website.**

*(Can search and select measures.)*

- 3209e: HIV Medical Visit Frequency
- 3211e: Prescription of HIV Antiretroviral Therapy
- 0409: HIV/AIDS: Sexually Transmitted Diseases- Screening for Chlamydia, Gonorrhea, and Syphilis (CQM only)
- 2080: Gap in HIV medical visits (CQM only)
- 0405: HIV/AIDS: Pneumocystis jiroveci pneumonia (PCP) Prophylaxis (CQM only)

### **5.02) Search and select all endorsed competing measures (conceptually, the measures have both the same measure focus or target population) by going to the PQM website.**

*(Can search and select measures.)*

None

### **5.03) If there are related or competing measures to this measure, but they are not endorsed, please indicate the measure title and steward.**

- 0410: HIV/AIDS: Sexually Transmitted Diseases - Syphilis Screening (NCQA, endorsement removed)
- 0411: HIV/AIDS: Other Infectious Diseases - Hepatitis B Screening (NCQA, endorsement removed)
- 0412: HIV/AIDS: Hepatitis B Vaccination (NCQA, endorsement removed)
- 0413: HIV/AIDS: Screening for High Risk Sexual Behaviors (NCQA, endorsement removed)
- 0414: HIV/AIDS: Other Infectious Diseases - Hepatitis C (NCQA, endorsement removed)
- 0415: HIV/AIDS: Screening for Injection Drug Use (NCQA, endorsement removed)

### **5.04) If this measure conceptually addresses EITHER the same measure focus OR the same target population as endorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.**

- Yes  
 No

**5.05) If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.**

The denominator population for this measure differs slightly from three related measures—3209e, 3211e, and 0409—with respect to the timing of the patient’s HIV diagnosis and eligible encounter, and these differences are due to the specific timing required for measuring viral suppression. We limit the population to patients diagnosed no earlier than three months into the performance period because our expert workgroup and the clinicians we interviewed during testing agreed that this allowed sufficient time for a clinician to work with a newly diagnosed patient to achieve viral suppression. Similarly, we limited eligible encounters to those occurring within the first eight months of the measurement period to ensure that clinicians had enough time left in the year to work with new patients to achieve viral suppression. Given that neither 3209e, 3211e, nor 0409 are currently in use in MIPS as eQMs, we do not expect these differences to meaningfully affect data collection burden. The measure also differs from the denominator population for 0409 with respect to the patient’s age because viral suppression is a relevant clinical outcome for all patients with HIV, regardless of age, while 0409 focuses on older patients who may be sexually active. Again, given that 0409 is not currently in use in MIPS as an eQm, we do not expect these differences to meaningfully affect data collection burden.

**5.06) Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.**

*Provide analyses when possible.*

N/A

**Additional (1 - 9)**

**1) Provide any supplemental materials, if needed, as an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be collated one file with a table of contents or bookmarks. If material pertains to a specific criterion, that should be indicated.**

- Available in attached file
- No appendix
- Available at measure-specific web page URL identified in sp.09

**2) List the workgroup/panel members' names and organizations.**

*Describe the members' role in measure development.*

The technical expert panel (TEP) is a multi-stakeholder group with expertise in HIV clinical care, quality measurement, electronic health records (EHR), and patient and family representatives. Members of the TEP are listed in the table below. The TEP was convened three times: 1) prior to testing to provide feedback on initial measure specifications, 2) after importance and feasibility testing and the public comment period to review results and make recommendations for updates to specifications and approaches to validity and reliability testing, and 3) after validity and reliability testing to review results and evaluate the measure against NQF criteria.

The names and affiliations of the technical expertise panel members are:

Laura Bachmann, CDC

Kathleen Brady, Department of Public Health, Philadelphia

Crystal Chapman Lambert, University of Alabama

Jonathan Colasanti, Grady Hospital; Emory University

Elizabeth DiNenno, CDC

Thomas Gift, CDC

Thomas Giordano, Harris County Hospital District (Houston, TX); Baylor College of Medicine

Travis Gossey, Weill Cornell Medical College

David Harvey, National Coalition of STD Directors (NCSD)

Michael Horberg, Kaiser Permanente

Sheila Salvant Valentine, CDC

Shannon Sims, Vizient, Inc

Michelle Van Handel, CDC

Abby Viall, CDC (embedded at CMS)

Andrea Weddle, HIV Medical Association

Patient Experience Representative

**3) Indicate the year the measure was first released.**

2017

**4) Indicate the month and year of the most recent revision.**

July 2017

**5) Indicate the frequency of review, or an update schedule, for this measure.**

N/A

**6) Indicate the next scheduled update or review of this measure.**

Spring 2023 (review of endorsement)

**7) Provide a copyright statement, if applicable. Otherwise, indicate “N/A”.**

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**9) Provide any additional information or comments, if applicable. Otherwise, indicate “N/A”.**

N/A