

~ Standard Example ~

Peer-Reviewed Journal Article Requirement

Section 101(c)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires submission of new measures for publication in applicable specialty-appropriate, peer-reviewed journals prior to implementing in the Merit-based Incentive Payment System (MIPS). These measures will be submitted by the Centers for Medicare & Medicaid Services (CMS), to a journal(s), before including any new measure in the MIPS Quality Measures List under MIPS. The measure submitter shall provide the required information for article submission under the MACRA per the CMS Call for MIPS Quality Measures submission process.

Stakeholders submitting measures for consideration through the MIPS Call for Quality Measures must complete the required information by the Annual Call for Measures deadline. Some of the information requested below may be listed in specific fields in the Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT); however, to ensure that CMS has all of the necessary information and avoid delays in the evaluation of your submission, please fully complete this form as an attached Word document. The information in MERIT must be consistent with the example measure information below, including the following, but not limited to:

- **Measure Title:** HIV Screening
- **National Quality Strategy (NQS) Domain:** Community/Population Health
- **Meaningful Measure Area (MMA):** Preventive Care

Measure Steward: Centers for Disease Control and Prevention

Measure Developer: Mathematica Policy Research

Description: Percentage of patients 15-65 years of age who have been tested for human immunodeficiency virus (HIV).

I. Statement

- **Background (Why is this measure important?).** This measure is designed to promote higher implementation levels of existing HIV screening guidelines and recommendations, including the U.S. Preventive Services Task Force (USPSTF) recommendation that clinicians screen for HIV infection in all adolescents and adults ages 15 to 65. In the United States, an estimated 1.2 million people are living with human immunodeficiency virus (HIV), a serious, communicable infection that, if untreated, leads to illness and premature death (CDC 2016). In 2014, approximately 37,600 persons in the United States were newly infected with HIV (CDC 2017). If identified, persons living with HIV can use antiretroviral therapy (ART) to achieve a suppressed viral load (a very low level of the virus), allowing them a near-normal life expectancy. Unfortunately, too many people living with HIV are undiagnosed and unaware of their status. At the end of

- ✓ Please refer to resources such as the CMS Program-Specific Measure Needs and Priorities posted on the [CMS Pre-Rulemaking website](#) for more information regarding these domains.

- ✓ Please choose the appropriate NQS domain from the following list:
 - Effective Clinical Care
 - Communication and Care Coordination
 - Patient Safety
 - Person and Caregiver-Centered Experience and Outcomes
 - Efficiency and Cost Reduction
 - Community/Population Health
- ✓ Please choose the appropriate [Meaningful Measure Area](#) from the following list:
 - Healthcare-associated Infections
 - Preventable Healthcare Harm
 - Care is Personalized and Aligned with Patient's Goals
 - End of Life Care According to Preferences
 - Patient's Experience of Care
 - Functional Outcomes
 - Medication Management
 - Admissions and Readmissions to Hospitals
 - Transfer of Health Information and Interoperability
 - Preventive Care
 - Management of Chronic Conditions
 - Prevention, Treatment, and Management of Mental Health
 - Prevention and Treatment of Opioid and Substance Use Disorders
 - Risk Adjusted Mortality
 - Equity of Care
 - Community Engagement
 - Appropriate Use of Healthcare
 - Patient Focused Episode of Care
 - Risk Adjusted Total Cost of Care

2013, 13 percent, or about 161,200, of those infected with HIV were undiagnosed, and almost 23 percent of the people who were diagnosed had a Stage 3 (AIDS) classification at the time of diagnosis (CDC 2016).

Targeted testing on the basis of risk behaviors fails to identify many people who are HIV infected (Klein 2003; Alpert 1996; Chen 1998). A substantial number of persons, including many of those who are infected, do not perceive themselves to be at risk for HIV, or do not disclose their risk factors (Nunn et al. 2011; Pringle et al. 2013). Routine HIV testing lessens the stigma associated with an assessment of risk behaviors (Irwin 1996; Copenhagen 2006). More patients agree to be tested for HIV when testing is offered routinely to everyone without requiring a risk assessment (Fincher-Mergi 2002; CDC 2005a). Diagnostic testing in health care settings continues to be the mechanism by which nearly half of new HIV infections are identified (CDC 2006).

National goals emphasize the importance of increasing the percentage of HIV-infected persons who are diagnosed, stay in medical care, and achieve viral suppression. More specifically, with respect to HIV testing, progress has been defined by, and is tracked against, the following indicator:

- Increase the percentage of people living with HIV who know their serostatus to at least 90 percent.

Achieving this national benchmark will require substantially improving the levels at which guideline-concordant HIV testing is provided and practiced in health care settings and by clinicians, clinics, and health systems. This quality measure will support and possibly incentivize efforts to implement these necessary improvements to practice quality (CDC 2015).

References

- Alpert, P.L., J. Shuter, M.G. DeShaw, M.P. Webber, and R.S. Klein. "Factors Associated with Unrecognized HIV-1 Infection in an Inner-City Emergency Department." *Annals of Emergency Medicine*, vol. 28, 1996, pp.159–164.
- Centers for Disease Control (CDC). "HIV Prevalence, Unrecognized Infection, and HIV Testing Among Men Who Have Sex with Men—Five U.S. Cities, June 2004–April 2005." *Morbidity and Mortality Weekly Report*, vol. 54, 2005, pp. 597–601.
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- Chen, Z., B. Branson, A. Ballenger, and T.A. Peterman. "Risk Assessment to Improve Targeting of HIV Counseling and Testing Services for STD Clinic Patients." *Sexually Transmitted Diseases*, vol. 25, 1998, pp. 539–543.
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- Nunn, A., Zaller, N., Cornwall, A., Mayer, K., Moore, E., Dickman, A., Beckwith, C., Kwakwa, H. "Low Perceived Risk and High HIV Prevalence Among a

Predominantly African American Population Participating in Philadelphia's Rapid HIV Testing Program." *AIDS Patient Care STDS*, vol. 25, no. 4, 2011; pp. 229–235. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068868/>. Accessed June 30, 2017.

Pringle, K., Merchant, R., Clark, M. "Is Self-Perceived HIV Risk Congruent with Reported HIV Risk Among Traditionally Lower HIV Risk and Prevalence Adult Emergency Department Patients? Implications for HIV Testing." *AIDS Patient Care STDS*, vol. 27, no. 10, 2013. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3837562/>. Accessed June 30, 2017.

- **Environmental scan (Are there existing measures in this area?).** We are not aware of any related or competing measures. There are numerous measures pertaining to care of patients with HIV. There are a few measures pertaining to HIV testing for specific populations (for example, pregnant women), but they are not in use in federal programs or currently endorsed by NQF.

II. Gap Analysis

- **Provide evidence for the measure (What are the gaps and opportunities to improve care?).** HIV testing is essential for improving the health of people living with HIV and helping to prevent new infections. CDC and the USPSTF recommend that all adolescents and adults get tested at least once for HIV as part of their routine medical care, and that gay and bisexual men and members of other populations at high risk get tested more frequently. While testing rates have steadily increased, CDC estimates that one in eight Americans living with HIV remain unaware of their infection (CDC 2014).

Overall, National Health Interview Survey (NHIS) data from 2015 suggest that only 38.6 percent of adults ages 18 and older have ever been tested for HIV (excluding testing performed during blood donations) (CDC 2016). Meanwhile, a recently published analysis of data from the National Youth Risk Behavior Survey (YRBS) and Behavioral Risk Factor Surveillance System (BRFSS) showed that only 22 percent of high school students and 33 percent of young adults ages 18 to 24 who had ever had sexual intercourse reported that they had been tested for HIV at any time in the past (Van Handel et al. 2016). Finally, data from the National Survey of Family Growth, 2011–2013, indicate that only 19 percent of persons between the ages of 15 and 44 had been tested for HIV in the past year, including 22 percent of females and 16 percent of

✓ Please review for competing quality measures. If a **similar measure** is identified, provide a rationale to justify the selection of the submitted quality measure over the current quality measure.

✓ In this section, explain the gap between actual healthcare and ideal healthcare and how this quality measure will assist in closing the gap. Provide statistical data supporting the **existence of a gap** in healthcare which may include average performance rates, ratios, and performance range.

males (Copen et al. 2015). Given that all of these survey estimates are based on self-reported data, and that some people may erroneously assume they have been tested for HIV as part of routine preventive care, the true percentage of persons in the United States who have ever been tested for HIV is likely to be lower than these survey results suggest.

Analyses of administrative claims data offer more evidence to support that HIV testing in general, and routine HIV screening in accordance with CDC and USPSTF recommendations in particular, is likely rare. In an analysis of 2012 outpatient medical visits captured by the Truven Marketscan database, 89,242 of 2,069,536 patients (4.3 percent) with Medicaid coverage had at least one HIV test, and 850 (1.0 percent) of those tested received a new HIV diagnosis. Among 27,206,804 patients with commercial insurance, 757,646 (2.8 percent) had at least one HIV test, and 5,884 (0.8 percent) of those tested received a new HIV diagnosis (Dietz et al. 2015). This analysis of claims offers little evidence that routine HIV screening was being widely implemented during outpatient medical visits in 2012.

Similarly, CDC recently estimated the mean annual number of visits by males ages 18–39, and of HIV testing at those visits, using 2009–2012 National Ambulatory Medical Care Survey (NAMCS) and U.S. Census data (Hoover et al. 2016). The study showed that, overall, only 1.3 percent of males ages 18 to 39 were tested for HIV, based on an estimated 58.4 million annual visits to physician offices. The study also showed that with current HIV testing rates, most males would not be tested by the age of 39 and that a fourfold increase in HIV testing at visits to U.S. physicians' offices could achieve high HIV testing coverage of persons up to age 39.

References

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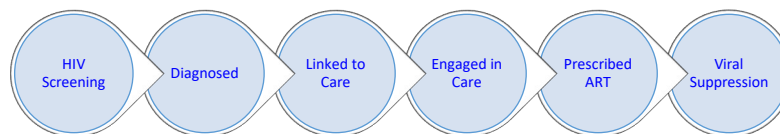
Dietz, P.M., M. Van Handel, H. Wang, P.J. Peters, J. Zhang, A. Viall et al. HIV Testing among Outpatients with Medicaid and Commercial Insurance. PLOS ONE, vol. 10, no. 12, 2015. e0144965.

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Hoover, K.W., C.E. Rose, and P.J. Peters. "Setting a Benchmark for HIV Testing at Visits to U.S. Physician Offices by Males." Available at <http://www.croiconference.org/sites/default/files/uploads/croi2016-abstract-book.pdf>. Presented at Conference for Retroviruses and Opportunistic Infections on February 24, 2016, Boston, MA.

Van Handel, M, L. Kann, E.O. Olsen, and P. Dietz. "HIV Testing Among US High School Students and Young Adults". Pediatrics, vol. 137, no. 2, 2016. doi: 10.1542/peds.2015-2700. Epub 2016 Jan 19.

- **Expected outcome (patient care/patient health improvements, cost savings).** As illustrated below, HIV screening ensures that more persons living with HIV are made aware of their infections and linked to clinical and prevention services. In 2014, approximately 37,600 persons in the United States were newly infected with HIV (CDC 2017). The CDC estimates that almost 13 percent of the people living with HIV infection in the United States are unaware of their infection (Centers for Disease Control and Prevention 2016). Antiretroviral therapy (ART) delays this progression and increases the length of survival, but it is most effective when initiated during the asymptomatic phase. It is estimated that on average, an HIV-infected person who is 25 years old and receives high quality health care will live another 38 years (Farnham 2013).



References

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, 2014." HIV Surveillance Supplemental Report, vol. 21, no. 4, 2016. Available at

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- [Recommendation for the Measure \(Is it based on a study, consensus opinion, USPSTF recommendation etc.?\)](#). The USPSTF recommends that clinicians screen for HIV infection in adolescents and adults ages 15 to 65. Younger adolescents and older adults who are at increased risk should also be screened (A Recommendation) (Moyer 2013).

Since 2006, CDC has recommended routine opt-out HIV screening (that is, the patient is notified that testing will be performed unless the patient declines) of adolescents and adults ages 13 to 64, and required health care facilities to perform HIV diagnostic testing of adolescents and adults with clinical signs or symptoms consistent with HIV infection (Centers for Disease Control and Prevention 2006).

References

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✓ This section should list the recommendations or guidelines that support the quality measure. Quality measures should reflect **current** guidelines.

III. Reliability/Validity

- What testing has been performed at the clinician level? Please provide testing results including the N value, correlation coefficient and any other pertinent information or values to be considered. We are currently using electronic health records (EHR) data from three clinician practices to test the measure's reliability and validity, as well as the sensitivity of measure scores to an alternative numerator specification. CDC tested the reliability and validity of a previous version of the measure using EHR data from five community health centers, which included data on 87,969 eligible patients and over 400,000 encounters. The previous version failed to obtain NQF endorsement because it included patients identified as HIV positive prior to the measurement period in the denominator. The current version of the measure excludes patients identified as HIV positive before the measure period from the denominator.

- **Reliability Testing Results**

We assessed the reliability of the measure score using the signal-to-noise ratio (SNR) approach described by Adams (2009). The goal of these tests was to determine how well the measure scores distinguish between strong and poor performers based on true differences in clinician performance. Briefly, SNR methods assume that a patient's observed state, in Adam's approach, whether or not the patient was tested for HIV during the measurement period, reflects the combined effects of each patient's true state (signal) plus some overlying measurement error (noise). SNR methods use of a binomial or beta binomial function to estimate patient-level "true" scores. Analysts can then aggregate results at the clinician level to produce individual clinician-level "true" scores. SNR methods also use a binomial or beta binomial function to estimate clinician-level scores—that is, assuming that the clinician's score is a binomial random variable conditional on the true value that comes from the beta distribution (Adams 2009). In SNR analysis, reliability is measured as the ratio of the variance in clinician-level "true" scores to the variance in clinician-level actual observed scores (true score + error). An SNR indicates lower reliability when it is closer to zero and higher reliability when it is closer to one. Measures with reliability coefficients of 0.70 are generally considered adequately reliable (Nunnally and Bernstein 1994).

Using data extracted from three primary care clinics, we found the median reliability across all clinicians with at least 1 patient in the measure's denominator was 0.93, meaning that half of clinicians' scores had a reliability estimate of 0.93 or higher. We also calculated reliability

✓ The quality measure is required to be **fully tested** at the level of implementation in order to progress through the MUC process for MAP consideration. MIPS CQM and eCQM collection types require testing at the individual clinician level (may also be tested at the group level). Administrative Claims collection type may require a reliability threshold.

✓ In the reliability section, please include the N, correlation coefficient (signal-to-noise ratio), and any other pertinent information or values in a **table format**, if possible, so that the information can be readily available and easily inferred to support the reliability of the quality measure.

when limiting the population to physicians with a minimum number of eligible patients, and median reliability was 0.94 when we set the threshold to 10, 20, and 30 patients; at 50 patients, median reliability increased to 0.96. These results indicate high reliability and precision in clinician-level scores.

Table 1. Provider Reliability Scores by Number of Patients in the Provider's Denominator

Provider Type	Minimum Patients Per Provider in Denominator	Provider N	Average Reliability Coefficient
PCPs	1	281	0.93
PCPs	10-30	505	0.94
PCPs	50	264	0.96

- **Validity Testing Results, Clinician Sites**

At two of the three clinician practices,¹ we first extracted EHR data for all patients ages 15 to 65 who had an encounter with a clinician during the measurement period. We then completed chart abstraction on a random sample of 400 patients at the two testing sites. We calculated the minimum sample size needed to perform a validity analysis, and found it was necessary to abstract information from a minimum of 200 patient charts at each site. After we collected the data, we assessed the validity of the individual data elements by comparing the manually abstracted data to the data collected from the EHR extraction. We used both general agreement rates and Cohen's kappa coefficient to assess the agreement by individual data element and by overall score. The kappa statistic, which accounts for agreement occurring by chance as well as by intention, is generally a better indicator of data element validity than agreement rates alone.

Our data showed the agreement rates for the denominator and numerator were high, 98.3 and 92.5 percent respectively. The kappa statistic for the denominator was 0.66, suggesting moderate agreement between electronically extracted data and manually abstracted data, but showed excellent agreement (0.76) for the numerator. The agreement rate for the HIV diagnosis date—a key variable for accurately attributing patients to the denominator or numerator—was 95.3 percent, but the weighted kappa was only 0.57, suggesting moderate agreement. In most cases where the dates did not agree,

✓ Provide statistical data supporting the validity of the quality measure in a table format along with the level testing performed.

¹ We excluded the third site from the abstraction effort given the fact that a previous version of the measure was tested in multiple clinics and in recognition of resource constraints.

the abstractors identified older HIV diagnoses in the patients' records than were included in the electronic health record extract. This finding suggests that the measures might not accurately exclude all patients with HIV diagnoses prior to the measurement period, which may reduce a provider's score. Additionally, of the electronic records that showed no HIV test, manual abstractors found an HIV test in about 6% of the records, indicating that some over-testing may occur as a result of the disagreement between patient records.

For the earlier testing at community health centers, CDC's testing partner first extracted EHR data for all patients ages 15 to 65 who had at least one encounter in 2013. The organization then completed chart abstraction on a random sample of 300 patients. Based on the results of power calculation and greater concern about false negatives (type II errors) than false positives (type I errors), twice as many patients who "failed" the measure were sampled as those who "passed" it. As a result, through random selection, 100 patients who met the measure and 200 patients who did not meet the measure were pulled for chart review. Under this approach, the CDC only fully assessed numerator data element validity. CDC's testing partners examined denominator validity for charts that were selected, but the sampling approach didn't include charts of patients who weren't included in denominator. Consequently, the results address whether denominator elements are there when the measure says they are, but not whether they were there when the measure indicated they weren't (because the study didn't sample records that didn't meet the denominator).

Overall, the automated calculation (EHR extract) for patients who were not screened for HIV performed almost equally to the manual review with the exception of calculations for four patients (Table 1). The automated calculation for patients who were screened for HIV was 100 percent accurate. The measure results are highly accurate representations of the information contained in patient's EHRs. False positives are likely to be exceedingly rare, and false negatives are unlikely to be so common that they fundamentally distort the picture of performance that emerges when measure results are calculated from the EHR.

Table 2. Agreement Between Automatically Determined and Manually Extracted Records of HIV Testing Among 300 Adults Ages 15 to 65: Community Health Centers

--		Manual Abstraction Calculation		Total	Sensitivity [SE] (95% CI)	Specificity [SE] (95% CI)	% Agreement [SE] (95% CI)	Kappa [SE] (95% CI)
		Met Numerator	Did Not Meet Numerator					
EHR Automated Calculation	Met the Numerator	100	0	100	0.96	1	98.6	0.97
	Did Not Meet the Numerator	4	196	200	[0.019] (0.92-0.99)	[0]	[0.68] (97.3-99.9)	[0.015] (0.94-0.99)
	Total	104	196	300	--	--	--	--

Note 1: Sensitivity and specificity were calculated considering the manually extracted records of HIV testing as the gold standard.
Note 2: CI = confidence interval; SE = standard error.

- **Alternative Numerator Specification**

We are testing an alternative measure specification that requires the presence of an HIV test result in the EHR to qualify a patient for inclusion in the provider's numerator. The default specification only requires the documentation that a test occurred, but it does not require the presence of a result. We are examining performance under this alternative specification, and also calculating reliability estimates for this specification using the same approach outlined above.

References

Adams, J. L. "The Reliability of Provider Profiling: A Tutorial." TR-653-NCQA. Santa Monica, CA: RAND Corporation, 2009.
Nunnally J. C., and Bernstein, I. H. Psychometric Theory, 3rd ed. New York: McGraw-Hill, 1994.

- [What were the minimum sample sizes used for reliability results?](#) Analysis of measure reliability is ongoing.

- **Other Information**

- [Is it risk adjusted? If so, how?](#) This measure is not risk adjusted.
- [What benchmarking information is available?](#) We have not studied or established any benchmarks for this measure.
- [Collection Type: Specify the data collection type.](#) eCQM.

IV. Endorsement

- [Provide NQF endorsement status \(and ID\) and/or other endorsing body \(If measure is only endorsed for paper records, please note endorsement for only the data source being submitted.\).](#) This measure is not currently NQF endorsed.

✓ **Collection Type:**
- Electronic clinical quality measures (eCQMs)
- MIPS clinical quality measures (MIPS CQMs) (*formerly referred to as "registry measures"*)
- Administrative claims measures (*collected solely by claims data*)

✓ Endorsement is not required but it is encouraged. If currently seeking endorsement, document what stage of the endorsement process the measure is in.

V. Summary

- [Alignment with CMS Meaningful Measures Initiative or MACRA \(if applicable\)](#). This measure falls into the Promote Effective Prevention and Treatment of Disease goal of CMS's Meaningful Measures Initiative, and the domain of Community/Population Health within MACRA.
- [Importance to MIPS or other CMS programs](#). This measure will incentivize clinicians to check whether their patients have been screened for HIV and to offer screening to those who have not. Higher levels of HIV screening will ensure that more people know their HIV status and are better empowered to protect their health. This will both improve clinical outcomes for patients with the disease and help to prevent future transmission.
- [Rationale: Use of measure for inclusion in program \(specialty society, regional collaborative, other\)](#). This measure has not yet been implemented in an existing program; however, we believe this measure would receive support as a meaningful and useful quality care concept. It is aligned with USPSTF and CDC guidelines for HIV screening and is consistent with CDC's goals for increasing HIV screening rates. Our testing results and the feedback we have received from experts indicate that the measure can be successfully implemented to assess clinicians' performance.
- [Public reporting \(if applicable\)](#). Because this measure has not been implemented yet, it is not publicly reported.
- [Preferable relevant Peer-Reviewed Journal for publication](#). We recommend submitting this measure to Clinical Infectious Diseases (first choice) or AIDS Care (second choice).

✓ Quality measures must be linked to existing and related cost measures and improvement activities, as applicable and feasible. MIPS quality measure stewards will be required to provide a rationale as to how they believe their measure correlates to other performance category measures and activities.