NATIONAL QUALITY FORUM

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Click to go to the link. ALT + LEFT ARROW to return

Purple text represents the responses from measure developers.

Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF #: 2522

Corresponding Measures:

De.2. Measure Title: Rheumatoid Arthritis: Tuberculosis Screening

Co.1.1. Measure Steward: American College of Rheumatology

De.3. Brief Description of Measure: Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis who have documentation of a tuberculosis (TB) screening performed within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).

1b.1. Developer Rationale: It is well-documented that biologic disease-modifying drugs (DMARDs) increase the risk of reactivation of latent tuberculosis (TB) infection. Data regarding the risk of TB from biologic DMARDs has accumulated for the last 20 years from clinical trials, post-marketing surveillance, and large registries. TB testing in RA patients receiving biologic DMARDs is an important patient safety measure and recommended as standard of care by the American College of Rheumatology. Because latent tuberculosis is treatable, while TB reactivation can lead to death or significant morbidity, universal screening is a cornerstone of safe, high quality care in RA.

Singh JA, Furst DE, Bharat A, Curtis JR. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2012 May;64(5):625-39.

S.4. Numerator Statement: Any record of TB testing documented or performed (PPD, IFN-gamma release assays, or other appropriate method) in the medical record in the 12 months preceding the biologic DMARD prescription.

S.6. Denominator Statement: Patients 18 years and older with a diagnosis of rheumatoid arthritis who are seen for at least one face-to-face encounter for RA who are newly started on biologic therapy during the measurement period.

S.8. Denominator Exclusions: N/A

De.1. Measure Type: Process

S.17. Data Source: Electronic Health Records, Registry Data

S.20. Level of Analysis: Clinician : Group/Practice, Clinician : Individual

IF Endorsement Maintenance – Original Endorsement Date: Most Recent Endorsement Date:

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. **IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?** N/A

Preliminary Analysis: New Measure

Criteria 1: Importance to Measure and Report

1a. Evidence

1a. Evidence. The evidence requirements for a *structure, process or intermediate outcome* measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

- **Systematic Review of the evidence specific to this measure?** ☒ **Yes** ☐ **No**
- **Quality, Quantity and Consistency of evidence provided?** ☒ **Yes** ☐ **No**
- **Evidence graded?** ☒ **Yes** ☐ **No**

Evidence Summary

- Brief background: This is a measure of patients 18+ with rheumatoid arthritis who have a tuberculosis screening within 6 months prior to receiving a first course of a biologic DMARD.
- Developer provided a logic model describing the relationship between TB risk, screening, identifying latent TB, treatment of latent TB, decreased risk of TB activation when on biologic DMARDs, and optimization of RA outcomes such as avoidance of TB sequelae due to therapy.
- Latent or active TB infection are contraindications to starting or resuming biologic DMARD therapy (which can reactive latent TB, leading to significant morbidity and mortality)
- Guidelines recommend routine TB screening to identify latent infections regardless of presence of risk factors, as the standard of care.

Questions for the Committee:

- What is the relationship of this measure to patient outcomes?
- How strong is the evidence for this relationship?
- Is the evidence directly applicable to the process of care being measured?

Guidance from the Evidence Algorithm

Process measure based on SR and grading of body of evidence (box 3) Y -> Specifics on QQC not provided (box 4) -> Guideline: GRADE – strong (box 6) -> Moderate

Preliminary rating for evidence: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

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

- The developer provided data for care provided from 2014 through 2017. Performance at the earliest dates was 47.45%; by 2017 performance improved to a mean of 58.85% with a standard deviation of 26.34%.
- The developer states that optical clinical performance should be 100%.

Disparities

- The RISE registry has limited data on social risk factors, however, available data suggest gaps in TB testing among patients with RA initiating biologic DMARDs, and studies demonstrate that African-Americans and immigrant populations in the United States are disproportionately affected by tuberculosis.
- The developer states that performance should be 100% regardless of social risk factors.

Questions for the Committee:

- Is there a gap in care that warrants a national performance measure?
- Are you aware of evidence that disparities exist in this area of healthcare?

Preliminary rating for opportunity for improvement: ☐ High ☒ Moderate ☐ Low ☐ Insufficient

Committee Pre-evaluation Comments:
Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence to Support Measure Focus: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures –are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission?

- I know of no new studies that would change the evidence for this measure.
- Measure is TB screening (by any currently used method) within 6 months of starting biologic therapy (although would argue that pts who are previously known to have been treated for TB or latent TB need to be excluded and pts who are receiving rituximab should also be excluded). Note the practices participating in RISE are often solo or small practice groups. Does not reflect larger multispecialty group practice.
- Strong evidence supporting this process measure, given high risks with TB and DMARD, this process measure is important to outcome, with overall rating of Moderate
- Evidence for this has ben extrapolated indirectly from directives from CDC in patients with immunosuppressed states such as leukemia, lymphoma, diabetes and HIV. The data is quite relevant to patients with autoimmune diseases. I am not aware of any new studies in this area.
- The evidence supports the process being measured (whether the patient had a TB screening within 12 months of starting DMARD treatment). It applies directly. The outcome is to not reactivate latent TB and it has a direct impact on the treatment outcomes.

1b. Performance Gap: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

- The performance gap in care is significant due to the serious safety issues if the TB screening is not completed before biologic drugs are prescribed and the patient has latent TB.
- Current performance gap was demonstrated, but suspect there may be under reporting. OK to have this as a national performance measure but for most patients receiving medication through insurance this is essentially required anyway. Surprised they found disparities in racial groups. This should be standard across all races.

- even with improvement in scores from 2014 to 2017, there still exist substantial opportunity for improvement; limited, but evidence that disparities exist
- Last data available is from 2017 that demonstrates significant gap in application of the measure in the clinical setting. The higher risk of active TB and TB reactivation exists in minority populations - African americans and Hispanics as well as low socio-economic groups who inherently may have poor access to care and inconsistent follow up thus skewing the performance data. Additionally as there is limitations to the utility of the screening tests for TB exposure and patients with prior exposure cannot be screened routinely with lab tests they may also negatively impact the performance measure if it is not adjusted for prior exposure.
- Less than optimal perforamnce. 2017 58.85% with a standard deviation of 26.34% (really high) and should be close to 100%. Documentation indicates that African-Americans and immagrant populations are disproportinately affected by TB. Evidence was not provided to support the statement.

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications **and** Testing

2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability Missing Data

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if 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 enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing 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. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Complex measure evaluated by Scientific Methods Panel? ☐ **Yes** ☒ **No**

Evaluators: NQF Staff

Evaluation of Reliability and Validity:

- Note that the measure developer has pooled the data for individual and practice level performance to perform their analyses, and therefore the measure has not been tested to specifications. Measures must be tested to specifications, meaning separate reliability analyses conducted for each level of analysis. In this case, separate analyses for clinician: individual and clinician: group/practice.
- This measure previously was submitted as an eMeasure and received Approval for Trial Use. Due to challenges in implementing the eMeasure, the developer is submitting this as a new non-eMeasure. It should be considered as a registry-based new measure.
- The measure has score and data element level reliability testing (signal to noise). The measure has score level validity testing using interrater reliability, as well as high face validity results. NQF staff assess the testing as moderate.

Questions for the Committee regarding reliability:

- Should developer set a minimum number of cases in the specifications to ensure reliability?
- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- Committee should discuss the implications of the reliability testing and the need to perform analyses according to specifications.

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The staff is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Preliminary rating for reliability: ☐ **High** ☐ **Moderate** ☐ **Low** ☒ **Insufficient**

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Rationale

- **The measure developer has pooled the data for individual and practice level performance to perform their analyses, and therefore the measure has not been tested to specifications.**
- **Measures must be tested to specifications, meaning separate reliability analyses conducted for each level of analysis.**
- **In this case, separate analyses for clinician: individual and clinician: group/practice. The measure has therefore been scored as insufficient.**

Evaluation A: Scientific Acceptability

Measure Number: 2522

Measure Title: Rheumatoid Arthritis: Tuberculosis Screening

Type of measure:

☒ **Process** ☐ **Process: Appropriate Use** ☐ **Structure** ☐ **Efficiency** ☐ **Cost/Resource Use**

☐ **Outcome** ☐ **Outcome: PRO-PM** ☐ **Outcome: Intermediate Clinical Outcome** ☐ **Composite**

Data Source:

☐ **Claims** ☐ **Electronic Health Data** ☒ **Electronic Health Records** ☐ **Management Data**

☐ **Assessment Data** ☐ **Paper Medical Records** ☐ **Instrument-Based Data** ☒ **Registry Data**

☐ **Enrollment Data** ☐ **Other**

Level of Analysis:

☒ **Clinician: Group/Practice** ☒ **Clinician: Individual** ☐ **Facility** ☐ **Health Plan**

☐ **Population: Community, County or City** ☐ **Population: Regional and State**

☐ **Integrated Delivery System** ☐ **Other**

Measure is:

☒ **New** ☐ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

NOTE: This measure was previously submitted as an eMeasure for Trial Use Approval. Due to challenges in implementing the eMeasure, the developer is submitting this as a new non-eMeasure.

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☒ **Yes** ☐ **No**

   Submission document: "MIF_xxxx" document, items S.1-S.22

   NOTE*: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.*

2. **Briefly summarize any concerns about the measure specifications.**

   None

RELIABILITY: TESTING

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level** ☒ **Measure score** ☒ **Data element** ☐ **Neither**
4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure** ☒ **Yes** ☐ **No**
5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of patient-level data conducted?

   ☐ **Yes** ☐ **No**

6. **Assess the method(s) used for reliability testing**

   Submission document: Testing attachment, section 2a2.2

   - Developer conducted signal to noise testing from outpatient rheumatology clinics participating in the RISE registry
   - Data elements were extracted from EHRs using computer programing
   - The measure developer has pooled the data for individual and practice level performance to perform their analyses, and therefore the measure has not been tested to specifications.
   - Measures must be tested to specifications, meaning separate reliability analyses conducted for each level of analysis.
   - In this case, separate analyses for clinician: individual and clinician: group/practice. The measure has therefore been scored as insufficient.

7. **Assess the results of reliability testing**

   Submission document: Testing attachment, section 2a2.3

   - Mean reliability 0.77, median 0.95. Scores range from 0.12-1.00. Developer suggests extreme outliers may be influenced by small case volume, and could be addressed by flagging/surpressing sites with very few cases.

QUESTION FOR COMMITTEE:

- Should developer set a minimum number of cases in the specifications to ensure reliability?

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

☐ **No**

☐ **Not applicable** (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☐ **Not applicable** (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):

    ☐ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

    ☐ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has not been conducted)

    ☐ **Low** (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

    ☒ **Insufficient** (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**

    - The measure developer has pooled the data for individual and practice level performance to perform their analyses, and therefore the measure has not been tested to specifications.
    - Measures must be tested to specifications, meaning separate reliability analyses conducted for each level of analysis.
    - In this case, separate analyses for clinician: individual and clinician: group/practice. The measure has therefore been scored as insufficient.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. **Please describe any concerns you have with measure exclusions.**

    Submission document: Testing attachment, section 2b2.

    - N/A – no exclusions

13. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

    Submission document: Testing attachment, section 2b4.

    - The average performance in 2017 was 58.85%; developer states that the drop in average success from prior assessments likely reflects both changing demographics and a shift from non-EHR-based measure versions used in the past. Performance should be 100%.

14. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**
    Submission document: Testing attachment, section 2b5.

    - N/A

15. **Please describe any concerns you have regarding missing data.**

    Submission document: Testing attachment, section 2b6.

- Developer states there is no missing data in the registry. Developer found a prevalence of 3% of missing data when testing eCQM version; which informed decision to move measure based on abstracted data from EHR, with no missing data.
- Developer states that if a data element is missing, indicates the provider did not perform expected action, not that the data itself is missing.

16. **Risk Adjustment**

16a. **Risk-adjustment method** ☒ **None** ☐ **Statistical model** ☐ **Stratification**

16b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☐ Yes ☐ No ☒ Not applicable

16c. **Social risk adjustment:**

16c.1 Are social risk factors included in risk model? ☐ Yes ☐ No ☒ Not applicable

16c.2 Conceptual rationale for social risk factors included? ☐ Yes ☐ No

16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☐ No

16d.**Risk adjustment summary:**

16d.1 All of the risk-adjustment variables present at the start of care? ☐ Yes ☐ No

16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No

16d.3 Is the risk adjustment approach appropriately developed and assessed? ☐ Yes ☐ No

16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☐ Yes ☐ No

16d.5.Appropriate risk-adjustment strategy included in the measure? ☐ Yes ☐ No

16e**. Assess the risk-adjustment approach**

N/A

VALIDITY: TESTING

17. **Validity testing level:** ☐ **Measure score** ☐ **Data element** ☒ **Both**

18. **Method of establishing validity of the measure score:**

☒ **Face validity**

☐ **Empirical validity testing of the measure score**

☐ **N/A (score-level testing not conducted)**

19. **Assess the method(s) for establishing validity**

Submission document: Testing attachment, section 2b2.2

- Data element level validity: comparison of automated eMeasure data compared to front-end total EHR data abstraction (inter-rater), and validation performed during RISE registry onboarding/yearly audit process.
    - Developer notes this is functionally a registry measure, that cannot be reproduced, but can be assessed through iterative work between practices, registry tech vendor, and data analytic centers.
    - RISE dashboard allows providers to evaluate against registry average.
- Yearly audits conducted to verify accuracy of the patient data extracted from the EHR systems of a random sample of participating practices
- Face validity testing during measure development process.

20. **Assess the results(s) for establishing validity**

    Submission document: Testing attachment, section 2b2.3

    - 2018 registry manual audit of 2017 data found 97.99% success rate (correct responses).
    - Median face validity score was 9; median feasibility score was 8.5. All 14 raters had a validity score greater than or equal to 7. Public comments and input from committees and the Board of ACR was also collected.

21. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

    Submission document: Testing attachment, section 2b1.

    ☒ **Yes**

    ☐ **No**

    ☐ **Not applicable** (score-level testing was not performed)

22. **Was the method described and appropriate for assessing the accuracy of ALL critical data elements?** *NOTE that data element validation from the literature is acceptable.*

    Submission document*: Testing attachment, section 2b1.*

    ☒ **Yes**

    ☐ **No**

    ☐ **Not applicable** (data element testing was not performed)

23. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

    ☐ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

    ☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

    ☐ **Low** (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were not assessed OR if testing methods/results are not adequate)

    ☐ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level is required; if not conducted, should rate as INSUFFICIENT.)

24. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability-Specifications: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- There are concerns about the reliability and may be insufficient in that the methodology doesn't meet NQF guidelines.
- Reporting seems quite low -- surprisingly so in the RISE registry. Is there a way to exclude pts who have previously received treatment for TB or latent TB (we would not typically retest this group). How will they assess patients receiving concurrent treatment for latent TB

- According to NQF criteria, the data must meet specification requirements and pooling of individual and group data does not meet testing to specifications, therefore this does not meet reliability requirements
- Reliability has not been specified previosuly for this measure. Current use of steroids will imapct the reliabilty of the test in the clinical setting.
- The testing was lacking and did not test the measure to specifications. For this to be considered a valid and reliable measure, it needs to be tested according to specifications. I'm also concerned that the measure did not work out as an eMeasure and is now being switched to a non-eMeasure. There is no evidence yet that the measure is able to be consistenly implemented. Not ready for inclusion as a recommended measure.

2a2. Reliability - Testing: Do you have any concerns about the reliability of the measure?

- It may need a different level of testing to meet the specifications.
- Significant false positive rate on Quantiferon gold testing which requires re-testing/confirmation testing with either PPD or TBSpot. The latter two tests are often not collected using structured data fields. May be difficult to abstract data.
- see 2a1- •According to NQF criteria, the data must meet specification requirements and pooling of individual and group data does not meet testing to specifications, therefore this does not meet reliability requirement
- As mentioned above, the test may not be measured appropriately in patients who are on steroids at the time of testing
- Yes. Results were pooled versus standardized testing process. Not tested according to measure specifications.

2b1. Validity -Testing: Do you have any concerns with the testing results?

- The validity testing seems to be adequate.
- As above. False positive rate for Quantiferon gold, so often follow up testing needed if positive.
- no, agree with moderate score
- No
- If implemented according to specifications I do not have concerns with the validity of the measure specifications nor the results

2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data)2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure?

- There is no evidence of missing data in the proposed registry.
- Missing data may well be more related to data collection than substandard care. PPD and TB spot often not collected in structured data. Social factors are not well recorded in RISE to evaluate the disparities question.
- no missing data, no threats to validity
- 2b5. RISE registry allows for comparisons across different participating facilities. Results are generally comparable. 2b6 - I would think that missing data - defined here as data not available due to lack of proper documentation and unavailability of scanned or paper resuls will impact validity. RISE does not have missing data but not all facilities participate in RISE.
- Was developed as an eMeasure so does not include logical data sources such as claims and paper medical records. Because individual providers and provider groups were merged, can't differentiate measure results according to the measure specifications. The measure was not implemented according to specifications so it would be hard to determine what the results say about quality.

2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment)2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure?2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- Risk adjustment doesn't apply. However, in future there may be a need to collect data about social issues, such as migrant status or race.
- Missing data may well be more related to data collection than substandard care. PPD and TB spot often not collected in structured data. Social factors are not well recorded in RISE to evaluate the disparities question.
- no exclusions, no risk adjustment
- 2b2 - no exclusions. 2b3 - No risk adjustment needed
- There are no exclusions and the measure developer indicates the rate should be at 100%.

Criterion 3. Feasibility

3. Feasibility 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.

- Data elements generated during routine care; all data elements in defined fields in electronic sources
- This was an eCQM, is now being submitted as a paper-based measure: “ACR made a conscious decision to move away from an eCQM in order to provide the most flexible route to electronic health record data-based measurement and avoid forcing individual practitioners to change their workflow and documentation to satisfy requirements for HQMF specifications. The ACR will continue to monitor developments in coding and HQMF specifications to determine if the updates would provide the necessary flexibility to make this measure an eCQM.”
- Tb testing data not always systematically collected as structured data
- No fees or licensing required

Questions for the Committee:

- Are the required data elements routinely generated and used during care delivery?
- Is the data collection strategy ready to be put into operational use?

Preliminary rating for feasibility: ☐ High ☒ Moderate ☐ Low ☐ Insufficient

RATIONALE:

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

3. Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?

- By using the RISE registry, the measurement data collection strategy seems feasible.
- Missing data may well be more related to data collection than substandard care. PPD and TB spot often not collected in structured data. Social factors are not well recorded in RISE to evaluate the disparities question.
- data is available in EHR and registry; only challenge is that TB testing info may not be in structured field
- PPD results are often scanned in or written into the clinical note which may be hard to extrapolate while measuring TB testing.

- No significant concerns with feasibility since transitioning to a non emeasure. Registry data may be more problematic in some states.

Criterion 4: Usability and Use

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. 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 not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☒ **Yes** ☐ **No**

Current use in an accountability program? ☒ **Yes** ☐ **No** ☐ **UNCLEAR**

OR

Planned use in an accountability program? ☒ **Yes** ☐ **No**

Accountability program details

- MIPS
- RISE Registry – internal QI and external benchmarking

4a.2. Feedback on the measure by those being measured or others. 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; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- Providers have access to results via registry (updated monthly), can contact ACR or registry vendor staff with issues and questions

Additional Feedback:

N/A

Questions for the Committee:

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- Performance rates are decreasing over time (worse results). Developer suggests early positive results may be skewed by early adopter phenomenon and later results are more reflective of a more generalizable group of US rheumatology practices as participation rates have more than doubled.
- Tb screening rates are consistently low.

4b2. Benefits vs. harms. 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).

Unexpected findings (positive or negative) during implementation

- Providers were documenting measure data elements in free text/nonstandard formats, creating challenges in reporting.
- No negative or unintended consequences found for patients.

Potential harms

- None listed

Additional Feedback:

Questions for the Committee:

- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability and use: ☐ High ☒ Moderate ☐ Low ☐ Insufficient

Committee Pre-evaluation Comments:
Criteria 4: Usability and Use

4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided?4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as assistance with interpreting the measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- Users have been given ample opportunity to provide feedback.
- ACR is giving feedback to users of RISE. Many providers (most providers) do not participate in RISE. Rituximab is a safer agent in regards TB reactivation -- many providers do not routinely screen prior to rituximab.
- pass for Use (data reported and given to providers)
- Not all rheumatology practices have access or participate in the RISE registry. While individual organizations may or may not be using this measure as a performance measure for their practice, this data is largely unavailable to practices
- Very little feedback on the measure. The developer referred back to the registry.

4b1. Usability – Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations?4b2. Usability – Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.

- With some issues over time, there will need to be work on the improvement. However, there do not seem to be harms or unintended consequences to the measure.
- No major harms except added level of documentation and cost of testing.
- agree with moderate score and explanation of why preliminary data was better than subsequent data
- There is no unforseeable negative consequence of this testing
- Results were documented in free text boxes which made data harder to collect.

Criterion 5: Related and Competing Measures

Related or competing measures

N/A

Harmonization

N/a

Committee Pre-evaluation Comments: Criterion 5:
Related and Competing Measures

5. Related and Competing: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?

- There are no related or competing measures.
- None to my knowledge.
- None
- No
- No related or competing measures.

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 06/12/2019

- **No NQF Members have submitted support/non-support choices as of this date.**

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

TB_Evidence_Form_Final.docx,TB_Evidence_Form_2019_FINAL.docx

1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

1a. Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 2522

Measure Title: Rheumatoid Arthritis: Tuberculosis Screening

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:

Date of Submission: 4/1/2019

1a.1.This is a measure of: (*should be consistent with type of measure entered in De.1*)

Outcome

☐ Outcome:

☐ Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)

☐ Intermediate clinical outcome (*e.g., lab value*):

☒ Process: Tuberculosis screening prior to initiating newly prescribed biologic DMARD therapy for patients with RA.

☐ Appropriate use measure:

☐ Structure:

☐ Composite:

1a.2 LOGIC MODEL Diagram or 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.

This is a patient safety measure pertaining to commonly used therapies (specific biologic DMARDs) in rheumatoid arthritis. Administrative data suggest that over 1 in 4 individuals with RA receive biologic DMARDs (*Zhang J, Xie F, Delzell E, et al. Trends in the Use of Biologic Therapies among Rheumatoid Arthritis*

Patients Enrolled in the U.S. Medicare Program. Arthritis care & research. Jun 10, 2013). Over 1.3 million individuals in the United States have RA (*Helmick CG, Felson DT, Lawrence RC, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part I. Arthritis and rheumatism. Jan 2008;58(1):15-25*); therefore, this measure is expected to apply to over 300,000 Americans with RA. Biologic therapies can reactivate latent tuberculosis, leading to significant morbidity and even mortality.

The path between the *process* of care and *adverse health outcomes* is illustrated below:

TB risk → TB screening prior to initiating biologic DMARD therapy → Identification of latent Tb, which can be reactivated by immunosuppressive therapies, such as DMARDs → Treatment of latent Tb → Decreased risk of TB reactivation or worsening of active TB when initiating biologic DMARD therapy → Optimize RA outcomes by avoiding serious adverse events, such Tb reactivation

1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

****RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) ****

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

1a.3. SYSTEMATIC REVIEW(S) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the <u>systematic review of the body of evidence</u> 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. (IOM)

☒ 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

The 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis reviewed the literature and, based upon the absence of new data, the voting panel re-endorsed the recommendations previously published in the 2008 recommendations and in the 2012 update. Singh, et al, 2016, page 14: "The panel endorsed the recommendations previously published in the 2008 recommendations and in the 2012 update to be included in the 2015 recommendations (Table 3 and Figure 6). The panel indicated that in the absence of significant new knowledge, development of an alternate recommendation was not warranted with one exception: the Voting Panel recommended that the same TB screening algorithm as described for biologics should be followed for patients receiving tofacitinib." Therefore, we have provided all relevant reference citations and recommendations below:

Singh J et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis*. Arthritis Rheumatol. 2016 Dec;68(1):1-26*).

Singh, et al., 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. AC&R 2012;64(5):625-639. The following recommendations are all Level C Evidence, except for initiation of biologic agents in patients being treated for latent tuberculosis infection (LTBI), where the Level of Evidence is B

Saag, et al., American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. AC&R 2008;59(6):762-784: (**Grades not assigned to these recommendations)

Source of Systematic Review: • **Title** • **Author** • **Date** • **Citation, including page number** • **URL**	• American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. • Singh, et al • 2008 • AC&R 2008;59(6):762-784 • http://rheumatoidarthritis.semarthritisrheumatism.com/Content/PDFs/RR-2008-Guidelines.pdf
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	• In Table 2: "Latent TB infection prior to initiation of latent TB treatment, or active TB disease prior to completing a standard regiment of anti-TB therapy" were "contraindications to starting or resuming therapy with … biologic DMARDs in RA patients" • Page 776: "The TFP recommended routine TB screening to identify latent TB infection in patients being considered for therapy with biologic agents (Figure 4). The evidence for TB testing is based on a documented higher incidence of TB following anti-TNF-alpha therapy (references 117, 122). To begin, the TFP recommended that clinicians should ask all RA patients being considered for biologic DMARD therapy about their potential risk factors for TB infection (see below) and, irrespective of prior BCG vaccination, should use a TB skin test as a diagnostic aid to assess the patient's probability of latent TB infection (Figure 4)." • Page 776: "These ACR recommendations defer the decision to initiate anti-TB therapy to physicians possessing sufficient expertise in TB management. In general, patients with latent TB infection should begin preventive therapy before starting their anti-TNF-alpha therapy (Reference 248). The CDC suggests that the preferred regimen for management of latent TB infection is a 9-month course of daily isoniazid (Reference 245). The CDC also suggests delaying anti-TNF-alpha therapy until isoniazid treatment has been initiated but does not specify an optimal time period of delay (Reference 249). Observational studies suggest anti-TNF-alpha therapy can be safely started 1 month after starting isoniazid treatment (Reference 250,251). The British Thoracic Society also has provided recommendations on this issue (Reference 252). Treatment with isoniazid does not eliminate all cases of anti-TNF-alpha –associated TB, and clinicians should remain vigilant for active TB in any anti-TNF_–treated patient in whom constitutional or chronic respiratory symptoms develop during anti-TNF-alpha therapy."
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	Grades not assigned to these recommendations

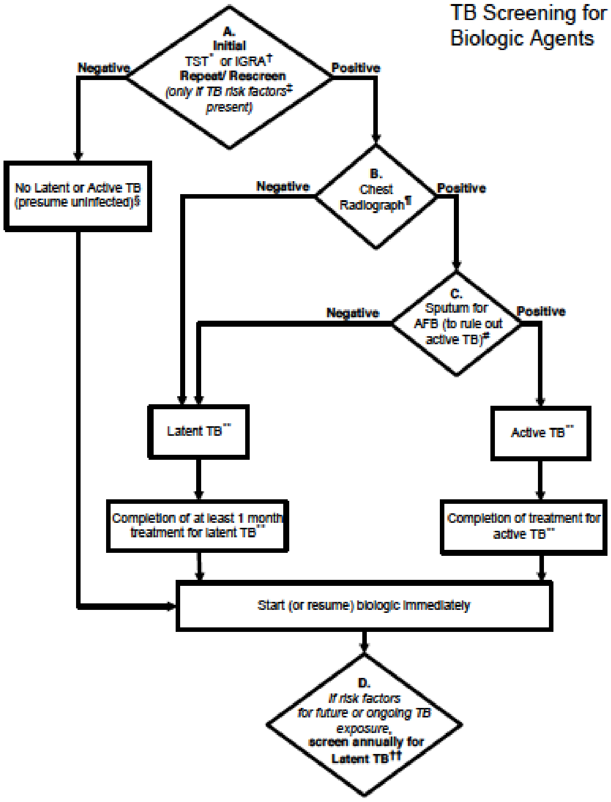
Provide all other grades and definitions from the evidence grading system	N/A
Grade assigned to the **recommendation** with definition of the grade	N/A
Provide all other grades and definitions from the recommendation grading system	N/A
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	N/A
Estimates of benefit and consistency across studies	N/A
What harms were identified?	N/A

<table>
<tr>
<td>Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?</td>
<td>

Singh, et al., AC&R 2012;64(5):625-639: This is an update to the 2008 ACR RA treatment Guidelines. The following recommendations are all Level C Evidence, except for initiation of biologic agents in patients being treated for LTBI, where Level of Evidence is B

- Page 634: “The panel recommends screening to identify LTBI in all RA patients being considered for therapy with biologic agents, regardless of the presence of risk factors for LTBI (diamond A of Figure 3) (Reference 14). It recommends that clinicians assess the patient’s medical history to identify risk factors for TB (specified by the CDC) (Table 2).”
- Figure 3 illustrates the recommendations for TB screening methods
- Page 636: “If the RA patient has active or latent TB based on the test results, the panel recommends appropriate antitubercular treatment and consideration of referral to a specialist. Treatment with biologic agents can be initiated or resumed after 1 month of latent TB treatment with antitubercular medications and after completion of the treatment of active TB, as applicable (Figure 3; below).”

Figure 3. Recommendations for TB Screening methods.


TB Screening for Biologic Agents
A. Initial TST* or IGRA† Repeat/ Rescreen (only if TB risk factors‡ present)
Negative
Positive
No Latent or Active TB (presume uninfected)§
B. Chest Radiograph¶
Negative
Positive
C. Sputum for AFB (to rule out active TB)#
Negative
Positive
Latent TB**
Active TB**
Completion of at least 1 month treatment for latent TB**
Completion of treatment for active TB**
Start (or resume) biologic immediately
D. If risk factors for future or ongoing TB exposure, screen annually for Latent TB††

- Page 638: “Because these recommendations were heavily informed by CDC guidance and minimal additional information was found in the broader literature search, our TB screening and vaccination recommendations are concordant with the CDC recommendations.”

The recommendations are all Level C Evidence, except for initiation of biologic agents in patients being treated for LTBI, which are Level of Evidence B. The strength of evidence was assigned using methods from the American College of Cardiology (*Hunt SA, et al. ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2005;112:e154–235*). The evidence was rated by an Expert Panel using the RAND Appropriateness Method, which requires median ratings of 7-9 and no disagreement; Tb screening recommendations had high agreement. From the guideline, “Level C

</td>
</tr>
</table>

	evidence often denoted a circumstance where medical literature addressed the general topic under discussion but it did not address the specific clinical situations or scenarios reviewed by the panel. Since many recommendations had multiple components (in most cases, multiple medication options), a range is sometimes provided for the level of evidence; for others, the level of evidence is provided following each recommendation." Definitions for this grading scheme: Level A. If data are derived from multiple randomized clinical trials or metanalyses. Level B. If data are derived from a single randomized trial or non-randomized studies. Level C. If recommendation is based on consensus opinion of experts, case studies, or standard-of-care

1a.4 OTHER SOURCE OF EVIDENCE

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

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

1a.4.2 What process was used to identify the evidence?

1a.4.3. Provide the citation(s) for the evidence.

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

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

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

It is well-documented that biologic disease-modifying drugs (DMARDs) increase the risk of reactivation of latent tuberculosis (TB) infection. Data regarding the risk of TB from biologic DMARDs has accumulated for the last 20 years from clinical trials, post-marketing surveillance, and large registries. TB testing in RA patients receiving biologic DMARDs is an important patient safety measure and recommended as standard of care by the American College of Rheumatology. Because latent tuberculosis is treatable, while TB reactivation can lead to death or significant morbidity, universal screening is a cornerstone of safe, high quality care in RA.

Singh JA, Furst DE, Bharat A, Curtis JR. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2012 May;64(5):625-39.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. *(This is required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, 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 (4b1) under Usability and Use.*

Data source: Performance among providers and practices participating in the Rheumatology Informatics System for Effectiveness (RISE) registry during the measurement periods

Average performance over time

Dates: July 1, 2014 through June 30, 2016

Practices: 49

2015 Q1: 47.56%

2015 Q2: 51.48%

2015 Q3: 61.23%

2015 Q4: 63.23%

2016 Q1: 66.17%

2016 Q2: 67.68%

2016 Q3: 69.58%

2016 Q4: 70.99%

Most recent performance

Dates: January 1, 2017 through December 31, 2017

Practices: 105

Setting: 73% group, 25% solo practitioner, 2% health system

Patients: 9,943

Mean: 58.85%

Standard Deviation: 26.34%

Min: 0.00%

Max: 100.00%

Interquartile Range: 34.40%

Deciles

10%: 16.09%

20%: 37.21%

30%: 48.66%

40%: 57.69%

50%: 65.06%

60%: 68.97%

70%: 76.18%

80%: 82.67%

90%: 88.47%

100%: 100.00%

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, 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.

N/A

1b.4. 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. *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) 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 (4b1) under Usability and Use.*

Relevant disparities data are not routinely and uniformly collected on all patients within the RISE registry.

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, 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 1b.4

This measure is not risk-adjusted and the RISE registry has limited data on social risk factors. Furthermore, optimal clinical performance for this measure should be 100%, regardless of social risk, as this measure reflects the minimum performance standard. Nevertheless, as part of RISE's ongoing efforts to expand and improve, the American College of Rheumatology is exploring ways to obtain better social risk data to appropriately monitor performance disparities going forward. While no studies have examined differences in TB testing by sociodemographic characteristics (race/ethnicity, sex, gender, disability status, socioeconomic status), available data suggest gaps in TB testing among patients with RA initiating biologic DMARDs, and studies demonstrate that African-Americans and immigrant populations in the United States are disproportionately affected by tuberculosis. Therefore, improvement in performance on this measure potentially has the greatest health impact on at-risk populations.

Jose A. Serpa, Larry D. Teeter, James M. Musser, and Edward A. Tuberculosis Disparity between US-born Blacks and Whites, Houston, Texas. Emerg Infect Dis. 2009 June; 15(6): 899–904.

Nahid P, Horne D, Jarlsberg LG et al. Racial Differences in Tuberculosis Infection in United States Communities: The Coronary Artery Risk Development in Young Adults Study. Clin Infect Dis. 2011 August 1; 53(3): 291–294.

Buskin SE, Gale JL, Weiss N, Nolan CM. Tuberculosis risk factors in adults in King County, Washington, 1988 through 1990. Am J Public Health. 1994 November; 84(11): 1750–1756.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ***Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

Musculoskeletal : Rheumatoid Arthritis

De.6. Non-Condition Specific*(check all the areas that apply):*

Safety : Medication

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

S.1. Measure-specific Web Page *(Provide a 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.)*

https://www.rheumatology.org/Portals/0/Files/TB-Screening-Measure.pdf

S.2a. **If this is an eMeasure**, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

Attachment **Attachment:** TB_Screen_Value_Sets_Updated_2018-03-30-636579260604748366.xls

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. **For maintenance of endorsement:** Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

Yes

S.3.2. **For maintenance of endorsement,** please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

Current HQMF specifications were insufficient to capture all the data elements required for measurement. Also, we have practices participating in the ACR´s RISE registry using more than 30 different electronic health record vendors. Based on member input, ACR made a conscious decision to provide the most flexible route to electronic health record data-based measurement and avoid forcing individual practitioners to change their workflow and documentation to satisfy requirements for HQMF specifications. Finally, as the majority of RISE participants are solo or small practices and unaffiliated with an academic or other institution, few have IT services sufficient to support modifications to their electronic health records to meet eCQM standards. For these reasons, we decided to change this from an eMeasure to a standard quality measure.

S.4. Numerator Statement *(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.*

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Any record of TB testing documented or performed (PPD, IFN-gamma release assays, or other appropriate method) in the medical record in the 12 months preceding the biologic DMARD prescription.

S.5. Numerator Details *(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 S.2b)*

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Acceptable TB tests include tuberculin skin test or laboratory tests for TB-specific peptide antigens, during the 12 month measurement period. A list of biologic DMARDs is provided below. Available procedure and drug codes that can be used identify both TB tests and biologic DMARDs are included in S.2b.

Biologic DMARDs:

- Adalimumab (Humira)
- Etanercept (Enbrel)
- Infliximab (Remicade)
- Abatacept (Orencia)
- Anakinra (Kineret)
- Rituximab (Rituxan)
- Certolizumab pegol (Cimzia)
- Tocilizumab (Actemra)
- Golimumab (Simponi)
- Tofacitinib (Xeljanz)
- Sarilumab (Kevzara)
- Infliximab-dyyb (Inflectra)
- Infliximab-abda (Renflexis)
- Infliximab-qbtx (Ixifi)
- Etanercept-szzs (Erelzi)
- Adalimumab-atto (Amjevita)
- Adalimumab-adbm (Cyltezo)

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

Patients 18 years and older with a diagnosis of rheumatoid arthritis who are seen for at least one face-to-face encounter for RA who are newly started on biologic therapy during the measurement period.

S.7. Denominator Details *(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 S.2b.)*

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

For the purposes of this measure, patients who are 'newly started on biologic therapy' are those who have been prescribed DMARD biologic therapy during the measurement period and who were not prescribed DMARD biologic therapy in the 12 months preceding the encounter where DMARD biologic therapy was newly started.

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

N/A

S.9. Denominator Exclusion Details *(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 S.2b.)*

N/A

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including 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 with at S.2b.)*

N/A

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

No risk adjustment or risk stratification

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

Better quality = Higher score

S.14. Calculation Algorithm/Measure Logic (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)*

Cases meeting target process/Target population

S.15. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

A random sample is obtained by assigning each patient a sequential number and then using a random number generator to select patients.

S.16. Survey/Patient-reported data *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*

Specify calculation of response rates to be reported with performance measure results.

N/A

S.17. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*

If other, please describe in S.18.

Electronic Health Records, Registry Data

S.18. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

Data source 1: electronic health records

Instrument: RA Measure Testing Data Collection Form

Data source 2: Rheumatology Informatics System for Effectiveness (RISE) Registry

Data collection: passive abstraction from EHR

S.19. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

Available in attached appendix at A.1

S.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*

Clinician : Group/Practice, Clinician : Individual

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Outpatient Services

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

N/A

2. Validity – See attached Measure Testing Submission Form

TB_Measure_Testing_Form_Final.docx,TB_measure_testing_form_January_2019_FINAL_Updated_4.3.2019-636912728579779370.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

No - This measure is not risk-adjusted

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** 2522
Measure Title: Rheumatoid Arthritis: Tuberculosis Screening
Date of Submission: 1/7/2019

Type of Measure:

☐ Outcome (*including PRO-PM*)	☐ Composite – ***STOP – use composite testing form***
☐ Intermediate Clinical Outcome	☐ Cost/resource
☒ Process *(including Appropriate Use)*	☐ Efficiency
☐ Structure	

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing,(e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for all the sources of data specified and intended for measure implementation.* ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

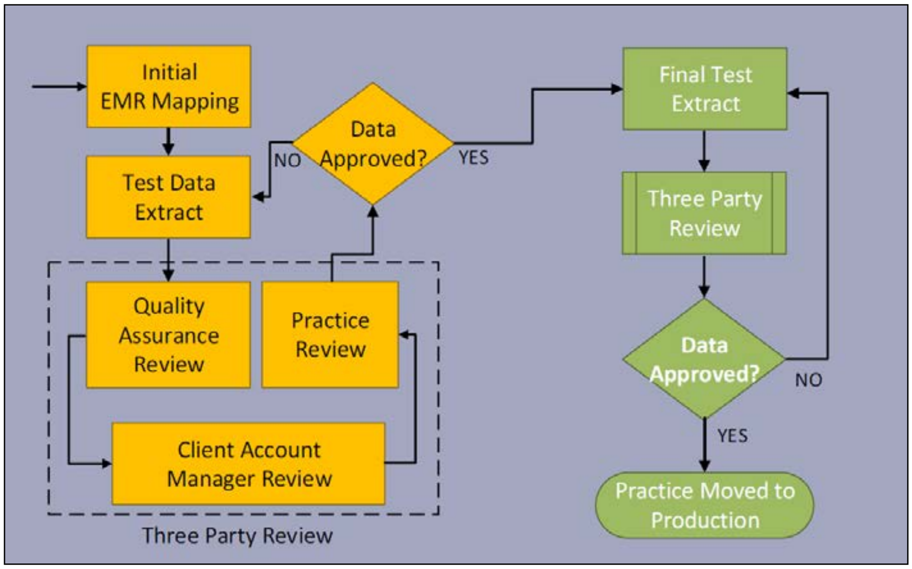
Measure Specified to Use Data From: **(*must be consistent with data sources entered in S.17*)**	**Measure Tested with Data From:**
☐ abstracted from paper record	☐ abstracted from paper record
☐ claims	☐ claims
☒ registry	☒ registry
☒ abstracted from electronic health record	☒ abstracted from electronic health record
☐ eMeasure (HQMF) implemented in EHRs	☐ eMeasure (HQMF) implemented in EHRs
☐ other:	☐ other:

1.2. 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*).

Registry data used for the most recent testing of this measure was collected through the ACR's Rheumatology Informatics System for Effectiveness (RISE) registry. RISE is a Qualified Clinical Data Registry (QCDR) that has been in operation since 2014. It was developed to serve as a tool for improving quality of care in rheumatology practices and a mechanism for providers to complete various federal reporting requirements for Medicare reimbursements. As of September 30, 2018, 218 practices across the United States with a total of nearly 1.5 million patients were fully connected to the RISE registry.

RISE uses proprietary computer programming to extract patient data from the EHR systems of participating providers. The data is then aggregated and used to calculate performance on a number of quality measures, including this measure. Practices that participate in RISE must complete an extensive data validation process, as seen in Figure 1, in order to be considered fully connected. During this process, practices work closely with RISE registry technical experts to gather the necessary information on the practice and identify where and how patient information, such as outcome measures, medications, laboratory results, diagnoses, etc., is stored in the provider's EHR. After the initial mapping to the various EHR fields is complete, the RISE team works with the practice to systematically extract and review test data via the RISE dashboard. The extracted data is used to calculate performance on each quality measure in RISE. The practice and registry technical experts then review the measure performance by drilling down into the patients included in and excluded from each step of the measure and the specific patient data used in the measure calculations. This allows the practices to confirm that each part of the measure calculation (denominator, numerator, exclusions and exceptions) does not include false negatives or positives and uses only accurate information. If any inaccuracies are discovered, the data extraction and mapping are refined and the review process begins again. This continues until the practice and the RISE team can validate that all the measure scores and patient data used to calculate the performance are accurate.

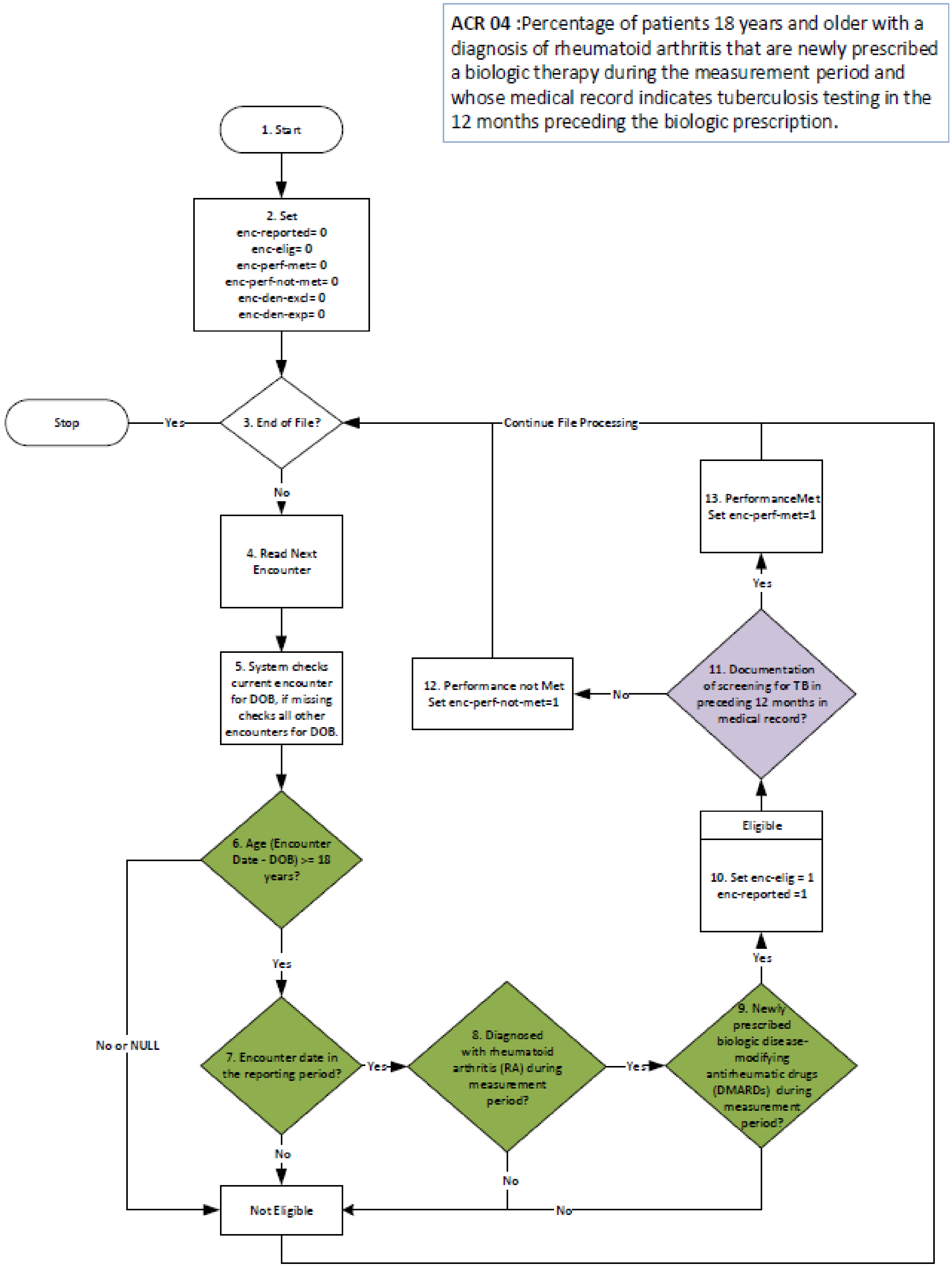
Figure 1. Custom mapping and data validation for RISE registry participants



Once practices are fully connected, they continue to monitor their data accuracy through the analytic dashboard. Additionally, a limited data set extracted from the registry data is shared with a third-party center for wider analytic purposes. This data analytic center is a highly regarded academic center experienced in working with EHR data. The center performs a variety of additional accuracy and validation checks on the limited data set.

For each measure incorporated into the RISE registry, the various data elements identified in the value set (including ICD-10, LOINC and CPT codes) and measure specifications are used to build a comprehensive data dictionary in order to identify the various data elements across the different EHRs at each practice. The data dictionary is then used as the basis for the XML programming code that runs against the registry data to calculate measure performance. The flowchart of the programming for the Rheumatoid Arthritis: Tuberculosis Screening measure can be seen in Figures 2a and 2b.

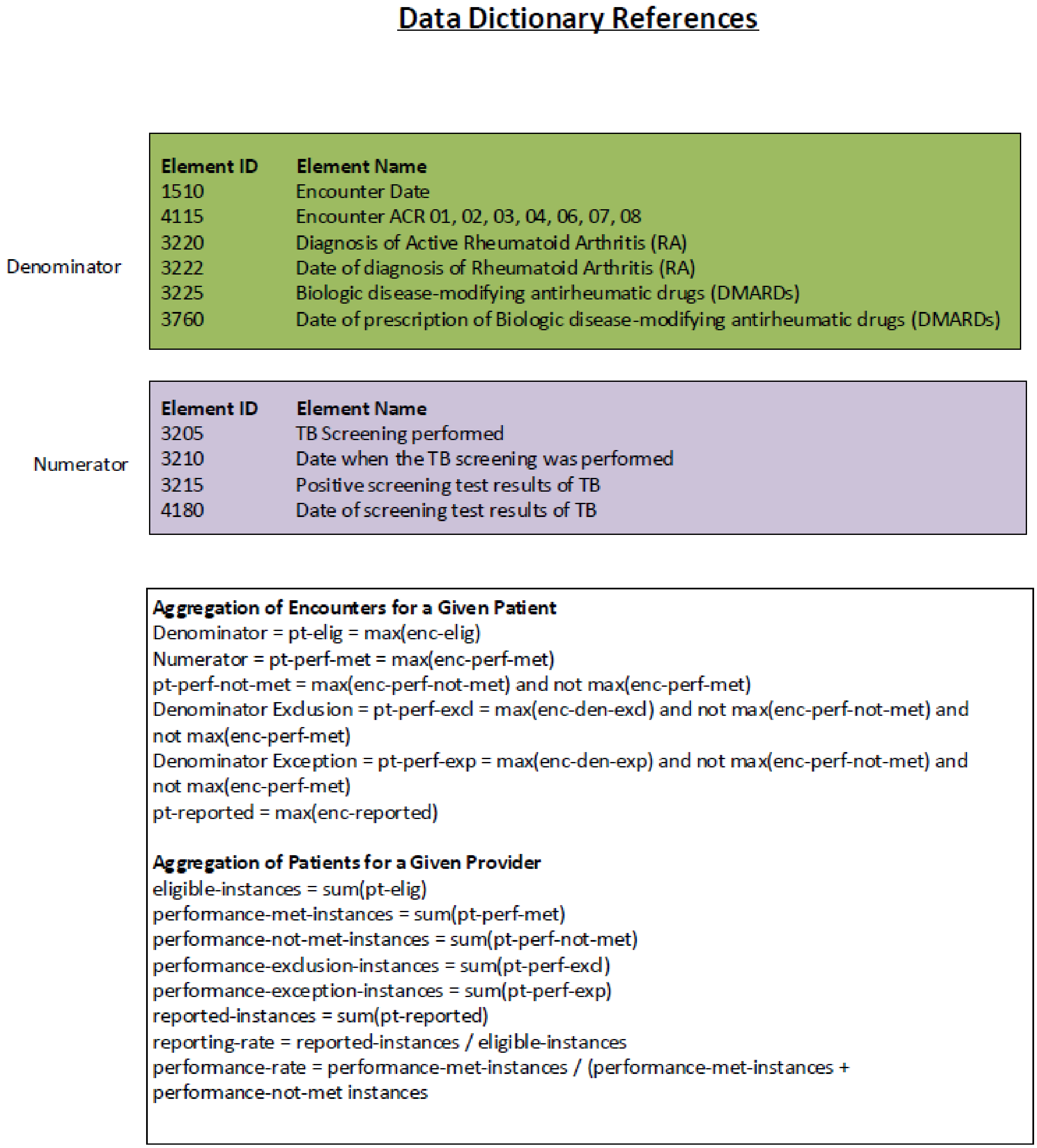
Figure 2a. Flowchart of calculation for the Rheumatoid Arthritis: Tuberculosis Screening measure



ACR 04 :Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis that are newly prescribed a biologic therapy during the measurement period and whose medical record indicates tuberculosis testing in the 12 months preceding the biologic prescription.

1. Start
2. Set
enc-reported= 0
enc-elig= 0
enc-perf-met= 0
enc-perf-not-met= 0
enc-den-excl= 0
enc-den-exp= 0
Stop
Yes
3. End of File?
Continue File Processing
No
4. Read Next Encounter
5. System checks current encounter for DOB, if missing checks all other encounters for DOB.
13. PerformanceMet Set enc-perf-met=1
Yes
12. Performance not Met Set enc-perf-not-met=1
No
11. Documentation of screening for TB in preceding 12 months in medical record?
Eligible
10. Set enc-elig = 1 enc-reported =1
6. Age (Encounter Date - DOB) >= 18 years?
Yes
No or NULL
Yes
7. Encounter date in the reporting period?
Yes
8. Diagnosed with rheumatoid arthritis (RA) during measurement period?
Yes
9. Newly prescribed biologic disease-modifying antirheumatic drugs (DMARDs) during measurement period?
No
No
No
Not Eligible

Figure 2b. Supplement to flowchart of calculation for the Rheumatoid Arthritis: Tuberculosis Screening measure



Data Dictionary References

Denominator

Element ID	Element Name
1510	Encounter Date
4115	Encounter ACR 01, 02, 03, 04, 06, 07, 08
3220	Diagnosis of Active Rheumatoid Arthritis (RA)
3222	Date of diagnosis of Rheumatoid Arthritis (RA)
3225	Biologic disease-modifying antirheumatic drugs (DMARDs)
3760	Date of prescription of Biologic disease-modifying antirheumatic drugs (DMARDs)

Numerator

Element ID	Element Name
3205	TB Screening performed
3210	Date when the TB screening was performed
3215	Positive screening test results of TB
4180	Date of screening test results of TB

Aggregation of Encounters for a Given Patient
Denominator = pt-elig = max(enc-elig)
Numerator = pt-perf-met = max(enc-perf-met)
pt-perf-not-met = max(enc-perf-not-met) and not max(enc-perf-met)
Denominator Exclusion = pt-perf-excl = max(enc-den-excl) and not max(enc-perf-not-met) and not max(enc-perf-met)
Denominator Exception = pt-perf-exp = max(enc-den-exp) and not max(enc-perf-not-met) and not max(enc-perf-met)
pt-reported = max(enc-reported)

Aggregation of Patients for a Given Provider
eligible-instances = sum(pt-elig)
performance-met-instances = sum(pt-perf-met)
performance-not-met-instances = sum(pt-perf-not-met)
performance-exclusion-instances = sum(pt-perf-excl)
performance-exception-instances = sum(pt-perf-exp)
reported-instances = sum(pt-reported)
reporting-rate = reported-instances / eligible-instances
performance-rate = performance-met-instances / (performance-met-instances + performance-not-met instances

1.3. What are the dates of the data used in testing? 1/2013 to 12/2013

1/2017 to 12/2017

1.4. What levels of analysis were tested? (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: **(*must be consistent with levels entered in item S.20*)**	**Measure Tested at Level of:**
☒ individual clinician	☒ individual clinician
☒ group/practice	☒ group/practice
☐ hospital/facility/agency	☐ hospital/facility/agency
☐ health plan	☐ health plan
☐ other:	☐ other:

1.5. How many and which measured entities were 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*)

We recruited one large testing site to examine the TB testing measure. We have summarized the geographic location and characteristics of the site in Table 1 below.

Table 1. Geographic location, site characteristics and data source used for Tuberculosis measure testing.

Geographic Location	Site Characteristics	Data Source
Northeast United States	Large health system serving a largely *rural* population of over 2.6 million over 44 counties. The rheumatology clinics have over 24,000 patient visits per year. Within this system, rheumatology clinical encounters were analyzed.	*Rheum-PACER (Patient Centric Electronic Redesign).* This electronic, web-based platform pulls data from the health system's separate EMR as well as a patient touchscreen questionnaire completed at the start of each rheumatology visit, and provides both clinical staff and patients access to outcome measures at the point of care.

For the signal-to-noise testing, we used data collected from outpatient rheumatology clinics that participate in the ACR's Rheumatology Informatics System for Effectiveness (RISE) registry. In the first quarter of 2017, 109 practices were fully connected to the RISE registry. The participating practices covered all regions of the country and represented a variety of practice settings: 28 solo practices, 77 group practices, two health systems, and two unknown settings. The practices used nearly 30 different EHR systems, including NextGen, eClinicalWorks, and Amazing Charts.

For testing purposes, the practices included in the signal-to-noise analysis were limited to those that were evaluated on measure performance from January 2017 through December 2017, which totaled 105. Of these 105, 26 (25%) practices were individual providers, while the other 79 (75%) were group practices or health systems. Given the high percentage of individual providers also classified as individual practices, the analysis covers both individual- and practice-level results.

1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

Data were analyzed at the individual patient level. *All* patients receiving care in rheumatology clinics at this site were eligible for the denominator population if they met inclusion criteria, including ≥2 encounters for RA, being over age 18 years, and meeting these criteria over the measurement period of January 2013-December 2013.

For the front-end chart abstraction, a *simple random sample* was constructed for analysis. The number of patients involved in the testing project is included in Table 2 below.

Table 2. Patient characteristics of individuals with rheumatoid arthritis, by site, for quality measure testing studies.

Site	Total E-measure Patient Population (N)	Random Sample for Front-end EHR review (N)	Sex (% female)
Northeastern site	87	66	69%

For the signal-to-noise testing, patients were included in the analysis if they were seen at one of the practices that met the practice inclusion criteria for Item 1.5 and if they met the patient inclusion criteria for the measure, including ≥2 encounters for RA, being over age 18 years, and meeting these criteria over the measurement period of January 2017 through December 2017. Across all sites, 9,943 patients met the inclusion criteria.

1.7. 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 reported below.

For reliability testing, as noted above, we used physicians/practices reporting in 2017.

1.8 What were 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.

We do not routinely and uniformly collect social risk factors on all patients for this measure. Furthermore, we do not anticipate that measure reliability and validity would be impacted by social risk factors because the measure is a process measure, and therefore not risk-adjusted, and completion of the process at the core of this measure is important for all patients, regardless of patients' social status. Finally, the measure has been tested and implemented with positive results without requiring social risk information, so we do not believe the analysis of social risk factors is required.

2a2. RELIABILITY TESTING

Note*: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)

☒ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)

☒ **Performance measure score** (e.g., *signal-to-noise analysis*)

2a2.2. For each level 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*)

Please see section "2b2. VALIDITY TESTING" for testing results.

For signal-to-noise testing, data elements for this quality measure were extracted for the RISE registry from EHRs using computer programming, and therefore by virtue of automation, this process is repeatable (reliable); this was further verified during data element validation (described below). Data from the RISE registry included the number of patients and number passing the measure for each practice. With this, we can calculate pass rate and sample size for each practice, and we can compare variability in measure performance between practices. Because reliability depends on pass rate and sample size, it varies between practices.

Psychometricians use a rule of thumb of 90 percent for drawing conclusions about individuals. (*Hays RD, Revicki D. Reliability and validity (including responsiveness). In: Fayers P, Hays R, eds. Assessing Quality of Life In Clinical Trials. New York: Oxford University Press; 2005.; Adams, John L., The Reliability of Provider Profiling: A Tutorial. Santa Monica, CA: RAND Corporation, 2009. https://www.rand.org/pubs/technical_reports/TR653.html.*) For binary measures, a tutorial by the RAND Corporation recommends fitting practices to a beta-binomial model. This can be done with the SAS Betabin macro (*Ian Wakeling - Qi Statistics. MACRO BETABIN Version 2.2 March 2005, www.qistatistics.co.uk*). This provides parameters a and b.

For the beta-binomial model, practice-to-practice variation = σ^2 = ab / ((a+b+1)*(a+b)^2).

Practice specific/measurement error for a binomial distribution = p*(1-p)/n; or when p = 1 or p = 0, substitute 3/n for p, by the rule of three.

Reliability = σ^2 / (σ^2 + p(1-p)/n), which represents the fraction of variance observed between practices not explained by practice specific variance.

2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

Please see section "2b2. VALIDITY TESTING" for testing results.

As noted above, because this is an e-measure, data is by definition reliable. The focus of testing was on data element and overall score validity. See more detailed information under validity below.

For the signal-to-noise testing, each practice has a reliability score for the measure. The distribution of these practice-level scores is reported in Table 2a below.

Table 2a. Reliability scores for the Rheumatoid Arthritis: Tuberculosis Screening measure among practices participating in the RISE registry, January 2017-December 2017.

Mean Reliability	**Min Reliability**	**1st Quartile Reliability**	**Median Reliability**	**3rd Quartile Reliability**	**Max Reliability**	**Proportion of lowest quartile performers with reliability ≥0.9**	**Proportion of middle 50% performers with reliability ≥0.9**	**Proportion of highest quartile performers with reliability ≥0.9**
0.77	0.12	0.48	0.95	0.98	1.00	0.50	0.73	0.56

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)

Data elements for this quality measure were extracted from EHRs using computer programming, and therefore by virtue of automation this process is repeatable (reliable); however, because data can be incorrect, testing focused on validity. Validity testing is outlined in detail below. Briefly, according to cutpoints that are commonly accepted (*Landis J, Koch G, The measurement of observer agreement for categorical data, Biometrics, 1977;33:159-174.)*, the overall Kappa in this study falls is excellent. Validity testing results are discussed in more detail below.

Based on standard interpretations of reliability, these findings support strong reliability of the measure result. For the few extreme outliers with poor reliability, the poor performance is likely due to small case volumes and can, if needed, be addressed by flagging or suppressing any measure results based on very few observations.

2b1. VALIDITY TESTING

2b1.1. What level of validity testing was conducted? (*may be one or both levels*)

☒ **Critical data elements** (*data element validity must address ALL critical data elements*)

☒ **Performance measure score**

☐ **Empirical validity testing**

☒ **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*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. 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)*

Below, we discuss 2 different aspects of validity that are relevant to the proposed measure. These include: 1) Validity of critical data elements, obtained through comparison of automated e-measure data compared to a front-end total EHR data abstraction, as well as the validation performed during the RISE registry onboarding and yearly audit processes, and 2) Systematic assessment of face validity using the ACR's quality measure development process. *Reviewers are referred to materials elsewhere in the application that discuss the scientific literature supporting extensive validity studies of the measurement tools themselves, including their content and construct validity, responsiveness and comparability.*

1. Validity of critical data elements. Data abstracted from randomly sampled patient records were used to calculate parallel forms reliability for the measure. Patient charts for abstraction were selected from visits for rheumatoid arthritis for adult patients with two or more face-to-face encounters for rheumatoid arthritis during the measurement period.

We examined whether EHR specifications and data exported electronically from the EHR were valid when compared to a front-end chart abstraction of the entire EHR by trained reviewers. Reviewers recorded relevant data elements using a structured data entry process. Overall performance rates using the automatically exported data as specified by the e-measure were compared to the front-end abstraction results by calculating a kappa coefficient, a statistical measure of inter-rater agreement.

As noted in section 1.2, this measure has been implemented in the ACR's RISE registry. RISE uses computer programming to extract data from the EHR systems of participating providers, analyze the data and provide feedback through an analytic dashboard on a provider's performance on this measure. Through the implementation process, providers must confirm that all data used to calculate the measure performance is accurate and valid. The dashboard is updated on a monthly basis and allows providers to track their performance over time. This allows providers to regularly assess the accuracy of their measure performance score. If providers discover any inconsistencies, they work directly with RISE registry technical experts to identify and correct the source of the issue.

While ACR is transparent about the specifications, this is functionally a registry measure, similar to STS' NQF-endorsed measures that cannot be reproduced by other entities, and thus the quality of the output (and the validity of normalized values) is performed through iterative work between the practices, the registry tech vendor and our third-party data analytic centers that review the data collected by the vendor during set-up of the practices and on a regular basis.

Furthermore, the RISE dashboard allows providers to see how their performance on each quality measure, including the Rheumatoid Arthritis: Tuberculosis Screening measure, compares to the average performance of all RISE providers. During the onboarding process, practices not only evaluate their own data to ensure that each element is accurate and valid; they also evaluate their performance against the registry average. Because all practices in RISE go through the same onboarding process, practices are able to verify that any difference in their measure performance as compared to the registry average is due to differences in quality of care.

The RISE registry also conducts yearly audits to verify the accuracy of the patient data extracted from the EHR systems of a random sample of participating practices. The most recent audit was conducted in 2018 on data from January 2017 to December 2017. Random sampling technique was used for a sample size of 13 TIN/NPI combinations. For each TIN/NPI sample, a minimum of 40-50 patients were reviewed for audit purposes. Providers reviewed and reported back on the accuracy of data for all reportable measures applicable to the patient, including data relevant to this measure.

2. Systematic assessment of face validity. Systematic assessment of face validity was performed using a multi-stakeholder expert panel that formally rated validity of the proposed measure using a scale based on the RAND Appropriateness Method. *Panelists participated in an open and transparent process in which they were specifically asked to address whether the scores obtained from the measure as specified will provide an accurate reflection of quality and can be used to distinguish good and poor quality*.

The American College of Rheumatology has worked for the last several years to develop a rigorous measure development process that leverages the considerable investment in producing guidelines and also input from stakeholders throughout the health care system in the area of rheumatoid arthritis (RA). *The following information is provided to place the Expert Panel ratings, used to assess face validity, in context*. The major elements of the measure development process are listed here. Reviewers are referred to materials in the supplemental appendix for further details.

- First, the ACR assembled a **Working Group** of 7 experts in RA, quality measurement, and health services research meeting its conflict of interest policies (requiring that a majority of group members, including the principal investigator, have no links to any company or commercial entity that makes a drug, device or product in the area of RA). The Work Group was tasked with drafting potential quality measures based on 2012 ACR Guidelines for the management of RA (*Singh JA, Furst DE, Bharat A et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2012 May;64(5):625-39*). Measures were drafted in an iterative fashion over a period of six months.
- Preliminary measures were presented to a separate multi-stakeholder **Expert Panel** of 16 for formal ratings. The group was comprised of patients with RA, practicing rheumatologists whose primary responsibility is patient care, an orthopedic surgeon nominated by the American Academy of Orthopedic Surgery, an Internal Medicine specialist nominated by the American College of Physicians, a member of the American Rheumatology Health Professional's Association, a payer representative (a Medical Director for a large public payer program), and methodological experts with expertise in quality measure development. For each measure, the panel was asked to review the scientific evidence and vote prior to meeting. These results were then presented to the panel and a facilitated discussion using initial ratings was undertaken during a meeting. Members voted again after deliberating. Results were analyzed according to the RAND Appropriateness Method (mean scores of 7-9 indicate good agreement if criteria for disagreement are absent; *see Brook RH. The RAND/UCLA appropriateness method. In: McCormick KA, Moore SR, Siegel RA, editors. Methodology perspectives. Rockville (MD): US Department of Health and Human Services; 1994. p. 59–70*). Panel ratings on the measure are provided below. Table 3 summarizes the results of the rating procedure. ***The median score for validity was 9 (indicating excellent validity).***

Table 3. Data from the American College of Rheumatology's Rheumatoid Arthritis Quality Measures Project Expert Panel Rating Process for Tuberculosis Screening Measure.[1,2]

Median score for validity	Median score for feasibility	# of raters with validity score ≤ 3	# of raters with validity score ≥ 7	# of raters total	% invalid (score ≤ 3)
9	8.5	0	14	14	0%

[1] *Panelists were provided with the following instructions*: "Your validity ratings should reflect whether you believe that the measure can be used to reflect the quality of care for RA. Questions to consider in determining your validity ratings should include:

a. Is there adequate scientific evidence or professional consensus to support the indicator?

b. Are there identifiable health benefits to patients who receive care specified by the indicator?

c. Based on your professional experience, would you consider providers with significantly higher rates of adherence to the indicator higher quality providers?

d. Are the majority of factors that determine adherence to the indicator under the control of the physician or health care system?"

[2] *Measure scale definitions*: For validity, 1=definitely NOT valid to 9=definitely valid; for feasibility, 1=definitely NOT feasible; 9=definitely feasible.

- In addition to the formal validity assessment by experts, additional vetting was performed in several ways. First, the ACR requested **public comment** on the measure, publicizing the comment period through email communication with ACR members and communicating with the leadership of other stakeholder groups. Public comments were reviewed and did not identify any additional issues concerns with the measure.
- Finally, the **ACR Quality Measures Subcommittee, ACR Quality of Care Committee** and **ACR Board of Directors** approved the measures.

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

1. Critical data element validity.

Sample Size: 66

Kappa Overall, Range, % Agreement: 1.00, 1.0 to 1.0, 100%

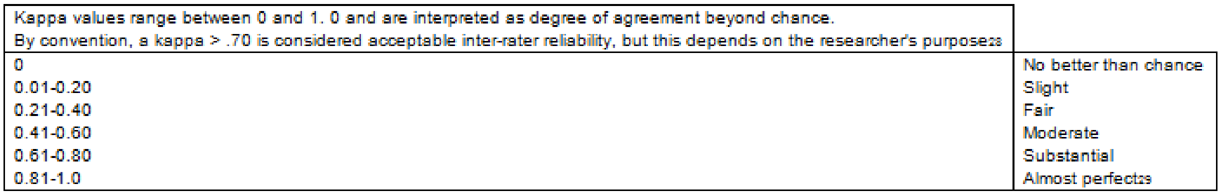
Kappa, Range, % Agreement Denominator: 1.00, 1 to 1, 100%

Kappa, Range, % Agreement Numerator: 1.00, 1 to 1, 100%

Kappa, Range, % Agreement Exceptions: **1.00** (1.0 to 1.0), 100%*

*100% agreement that there are no exceptions

Recommended guidelines for interpreting Kappa values from the National Quality Forum's Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties



Kappa values range between 0 and 1. 0 and are interpreted as degree of agreement beyond chance. By convention, a kappa > .70 is considered acceptable inter-rater reliability, but this depends on the researcher's purpose[28]	
0	No better than chance
0.01-0.20	Slight
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Substantial
0.81-1.0	Almost perfect[29]

Table 3a below contains the results from the registry audit conducted in 2018.

Table 3a. Results of RISE registry audit of data from January 2017-December 2017.

Number of NPI/TIN audited	**Number of Patients**	**Expected count of Responses**	**Number of Correct Responses**	**Number of Incorrect Responses**	**% Success**	**% Fail**
13	644	698	684	14	97.99%	2.01%

2. <u>Systematic assessment of face validity</u>.

Table 3. Data from the American College of Rheumatology's Rheumatoid Arthritis Quality Measures Project Expert Panel Rating Process for Tuberculosis Screening Measure.[1,2]

Median score for validity	Median score for feasibility	# of raters with validity score ≤ 3	# of raters with validity score ≥ 7	# of raters total	% invalid (score ≤ 3)
9	8.5	0	14	14	0%

[1] *Panelists were provided with the following instructions*: "Your validity ratings should reflect whether you believe that the measure can be used to reflect the quality of care for RA. Questions to consider in determining your validity ratings should include:

a. Is there adequate scientific evidence or professional consensus to support the indicator?

b. Are there identifiable health benefits to patients who receive care specified by the indicator?

c. Based on your professional experience, would you consider providers with significantly higher rates of adherence to the indicator higher quality providers?

d. Are the majority of factors that determine adherence to the indicator under the control of the physician or health care system?"

[2] *Measure scale definitions*: For validity, 1=definitely NOT valid to 9=definitely valid; for feasibility, 1=definitely NOT feasible; 9=definitely feasible.

2b1.4. What is 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?*)

<u>Critical data element validity.</u> The kappa statistic of 1.0 for overall performance indicates high agreement between the automated report and the front-end chart abstraction.

Manual audit validity testing results in a random sampling of practices indicated a very high (98%) accuracy.

<u>Systematic assessment of validity</u>. Ratings by a multi-stakeholder group in which the RAND/UCLA rating scale was applied found excellent validity of this measure, with a mean score of 9, and no disagreement.

2b2. EXCLUSIONS ANALYSIS

**NA ☒ no exclusions — *skip to section* **2b3

2b2.1. Describe the method of testing exclusions and what it tests (*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*)

2b2.2. What were 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*)

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., 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*)

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b4**.**

2b3.1. What method of controlling for differences in case mix is used?

☒ **No risk adjustment or stratification**

☐ **Statistical risk model with _risk factors**

☐ **Stratification by _risk categories**

☐ **Other,**

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) **Also discuss any "ordering" of risk factor inclusion**; for example, are social risk factors added after all clinical factors?

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

☐ **Published literature**

☐ **Internal data analysis**

☐ **Other (please describe)**

2b3.4a. What were the statistical results of the analyses used to select risk factors?

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

2b3.5. 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 controlling for differences in patient characteristics (case mix) below.

If stratified, skip to 2b3.9

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

2b3.9. Results of Risk Stratification Analysis:

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i*.e., what do the results mean and what are the norms for the test conducted*)

2b3.11. Optional Additional Testing for Risk Adjustment (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b4.1. 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 related to performance gap in 1b)*

Testing was performed in one large health system, which is a leader nationally in advancing patient safety. This health system has worked for over a decade to build systems to measure and improve quality of care in RA, and this is reflected in perfect performance (100%). There was therefore no statistical variation between providers at this site.

However, the proposed e-measure is analogous to the TB testing measure that has been part of the PQRS program since 2008. Data available from the ACR's Rheumatology Clinical Registry suggest variation between providers with performance improving over time (*Yazdany J et al. Uptake of the American College of Rheumatology's Rheumatology Clinical Registry (RCR): Quality Measure Summary Data. Annual Scientific Meeting. American College of Rheumatology. Reed Convention Center, Washington, DC. 27 October 2013. Arthritis Rheum abstract supplement*). Data from 2011 reveal performance of 73.6% among participating providers, increasing to 92.9% in 2012.

We also evaluated the variation in measure performance in 2017 among 105 RISE practices, representing 96.3% of all practices fully enrolled in RISE at the beginning of 2017.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., *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*)

National benchmarking data for this e-measure are currently not available. However, above we describe performance on the analogous PQRS measure as measured by the ACR's Rheumatology Clinical Registry.

Table 4. Variation in performance on Rheumatoid Arthritis: Tuberculosis Screening measure in the RISE registry, January 2017-December 2017.

Practices	Total Denominator	Mean Denominator	Denominator range	Total Numerator	Mean Numerator	Numerator Range	Average Practice Performance (%)	25th, 50th, 75th, 100th percentile
105	9943	94.70	6-535	6074	57.85	0-324	58.85%	43.75, 65.22, 78.15, 100

2b4.3. What is 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? (i*.e., what do the results mean in terms of statistical and meaningful differences?*)

See above.

The results demonstrate both wide variation and a continued need for improvement in performance overall given that the average performance in 2017 was 58.85%; the drop in average success from prior assessments likely reflects both changing demographics and a shift from non-EHR-based measure versions used in the past. Optimal clinical performance for this measure should be 100%, as this measure reflects an extremely important standard of care required to protect patients from potential reactivation of TB. An average measure score under 60% (and a 75th percentile of 78%) supports an ongoing opportunity for improvement in performance.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS

If only one set of specifications, this section can be skipped.

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 eMeasures). 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.***

2b5.1. 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; what statistical analysis was used*)

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i*.e., what do the results mean and what are the norms for the test conducted*)

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to 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 nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

Identification of missing data was included as part of the earlier critical data element validity testing described in section 2b1.

With the RISE registry, there is no missing data. As described in section 1.2, during the implementation process, providers work with the registry's technical experts to review the data elements necessary for measure performance calculations and direct the technical team on how to find those data elements in the practice's EHR system. The technical team is them able to extract the necessary data from both structured and unstructured fields. This ensures that accurate measure performance can be calculated no matter how the information is documented (in free text or as a scanned pdf).

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)

During the critical data element validity testing, missing data were encountered in 3% of patient records when testing this measure. In one instance, TB testing was performed but it was not recorded in a structured data field. This informed the ACR's decision to move the measure designation from a true eCQM to a measure based-upon data abstracted from the EHR.

As noted above, the data abstraction approach ensures there is no missing data. See 2b6.3.

2b6.3. What is 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 nonresponders) and how the specified handling of missing data minimizes bias**?** (i*.e., 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, provide rationale for the selected approach for missing data*)

We expect that most practices will have a significant amount of missing data if similar workflows are not put into place. For example, it is not uncommon for TB testing to occur at a clinic or facility that differs from the clinic starting the biologic drug. In this case, TB test results may appear as scanned documents or free text in a clinical note. An automated report from the electronic record that draws information from structured fields such as laboratory results or immunizations will therefore underestimate performance.

Because of the method of data mining used to calculate measure performance in the RISE registry, the absence of a necessary data element, such as a lab test, a medication or a disease activity assessment, is not indicative of missing data. Rather, it indicates that the provider did not perform the expected action.

3. Feasibility

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.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

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-9 codes on claims)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

ALL data elements are in defined fields in a combination of electronic sources

3b.2. 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 other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

As noted in S.3.2., the ACR made a conscious decision to move away from an eCQM in order to provide the most flexible route to electronic health record data-based measurement and avoid forcing individual practitioners to change their workflow and documentation to satisfy requirements for HQMF specifications. The ACR will continue to monitor developments in coding and HQMF specifications to determine if the updates would provide the necessary flexibility to make this measure an eCQM.

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment: RA_Feasibility_Survey_Responses_-_Data_Element_Scores-635291966727341423.xls

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. 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.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

TB testing data is sometimes not systematically collected in electronic health records as structured data. For example, TB testing results may reside in a scanned form sent from an outside facility, or may be recorded as free text in a clinical note, often based on patient self-report. Integrated health systems may have structured fields for immunizations and therefore easily accessible information on PPD testing. Interferon-release assays appearing as laboratory results in the electronic record are retrievable, but scanned outside laboratories may not be. As evidenced in our electronic measure testing, sites committed to patient safety have developed workflows to systematically incorporate this information in a structured field in the electronic health record. Implementation of this e-measure may require workflow changes for practices that do not record this information in a consistent way.

3c.2. Describe 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)*.

N/A

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

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 not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-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 performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
Public Reporting Regulatory and Accreditation Programs	Payment Program MIPS https://qpp.cms.gov/mips/overview Quality Improvement (external benchmarking to organizations) RISE Registry http://www.riseregistry.org Quality Improvement (Internal to the specific organization) RISE Registry http://www.riseregistry.org

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

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

Program: Merit-based Incentive Payment System
Sponsor: Centers for Medicare and Medicaid Services
Purpose: MIPS was designed to tie payments to quality and cost-efficient care, drive improvement in care processes and health outcomes, increase the use of healthcare information, and reduce the cost of care.
Geographic area: United States
Number and percentage of entities and patients: Per the most recent numbers provided by CMS*, approximately 3,550 rheumatologists across the country (and 100% of their patients) are eligible for MIPS reporting
Level of measurement: provider or practice, depending on whether they report as an individual or group
Setting: Non-hospital-based rheumatology practices enrolled in Medicare the exceed the low-volume threshold
* Page 374: https://www.govinfo.gov/content/pkg/FR-2017-11-16/pdf/2017-24067.pdf
Program: The Rheumatology Informatics System for Effectiveness (RISE) registry
Sponsor: American College of Rheumatology
Purpose: To help prepare rheumatologists for the significant challenges of a rapidly changing healthcare environment, including adapting to new payment and delivery models, meeting evolving certification requirements, and using EHR data to assess quality of care.
Geographic area: United States
Number of entities and patients: As of January 3, 2019, 937 rheumatology providers participated in RISE, representing 1,787,394 patients
Level of measurement: provider and practice
Setting: Solo practice, single-specialty group practice, multi-specialty group practice

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*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.*)

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

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.

For information on feedback from those being measured during measure development, please refer to the validity testing in section 2.

For implementation, those being measure are deeply involved in the process. Measure performance is shared with rheumatology providers via the ACR's RISE registry. Participating providers work closely with the registry technology vendor to ensure data is being extracted from their EHR correctly and portrayed accurately via the registry's analytic dashboard. Through the RISE dashboard, providers are able to see their individual overall performance on the measure, their practice's overall performance on the measure, and the average performance of all RISE users on the measure. Each provider is also able to drill down into their measure performance to see the patients who qualify for the denominator and the numerator. Furthermore, providers have direct access to the human readable measure specifications in the dashboard. If they have any questions or concerns about how the measure is being calculated or the specifications in general, they are able to contact both ACR staff and the registry technology vendor staff directly. This allows providers the ability to confirm the accuracy of their measure performance, review how their own practices impact their measure performance, and get any questions on measure interpretation answered directly by the measure owner.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

The analytic dashboard for all RISE providers is updated every month following the most recent data extraction. All providers have constant access to their analytic dashboard to review the measure specifications and their measure performance. ACR and vendor staff are available during regular business hours to answer their questions over the phone or via e-mail.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

RISE users communicate directly with the registry technology vendor and ACR staff over the phone and via e-mail.

4a2.2.2. Summarize the feedback obtained from those being measured.

When communicating with staff, they have said that this and the other measures included in the registry to be very helpful in understanding the quality of care they provide patients. When a provider first joins the RISE registry, most often they note that they expected higher performance on their measures. However, through their work with the registry technology vendor and the analytic dashboard, they are able to see an objective analysis of their data and realize that they are not providing as high of quality care as they assumed. The other most common feedback received on this measure is focused on ways to identify the various data elements in the measure. For example, a provider may use a different tool than approved for use in the measure or document a lab result in a different way than expected.

4a2.2.3. Summarize the feedback obtained from other users

As far as we are aware, this measure as specified has only been implemented in the RISE registry until recently. This measure was previously used by RISE participants for PQRS reporting. However, when CMS transitioned to MIPS, they denied inclusion of this measure as a QCDR measure because they said it was too similar to a QPP measure. We have since updated the QPP measure for the 2019 reporting year to conform to the requirements of this measure. Because of this, we have not received feedback from other entities. However, we will have the opportunity to begin doing so in 2020.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

As noted, RISE providers have direct communication with the registry vendor and ACR staff. They are able to ask questions and share concerns directly with the ACR and receive prompt feedback. As needed, ACR staff are able to take questions and concerns to a team of rheumatology volunteers with expertise in quality measurement. Feedback from ACR and the quality measure experts is then used to improve the guidance on quality measure implementation for both the registry technology vendor and the provider.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b 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, what are the reasons? 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.

The decrease in performance over time reflects persistent low performance of routine Tb screening. The prior increasing performance likely reflected an early adopter phenomenon, where early RISE adopters were more likely to have systems in place to collect a range of data elements, including Tb screening and had the benefit of quarterly measure results reporting to help that initial group improve performance over time. The over doubling of the number of practices in RISE between the two time periods (50 to 105), many in response to the MACRA legislation, probably reflects a more generalizable group of US rheumatology practices. The variation in results indicates continued need for assessing performance on this measure, especially as more practices continue to join RISE.

4b2. Unintended Consequences

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).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

As noted in S.3.2, we found that many providers were documenting key aspects of the measure data elements in free text or other non-standardized formats. Only a portion of providers have laboratory data and/or prescription data integrated into their outpatient electronic health record, further complicating the ability to pull HQMF-formatted specifications.

We are unaware of any negative or unintended impacts on patients due to measurement.

4b2.2. Please explain any unexpected benefits from implementation of this measure.

We received positive feedback from several participating providers. This included both the benefits of better understanding provider variation within practices as well as identification of higher-risk patients such as those with frequent disease flares.

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

No

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Attachment **Attachment:** Appendix-635291751849315969.xlsx

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): American College of Rheumtology

Co.2 Point of Contact: Rachel, Myslinski, rmyslinski@rheumatology.org, 404-633-3777-824

Co.3 Measure Developer if different from Measure Steward: American College of Rheumtology

Co.4 Point of Contact: Rachel, Myslinski, rmyslinski@rheumatology.org, 404-633--

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members’ names and organizations. Describe the members’ role in measure development.

Jinoos Yazdany, MD, MPH

University of California San Francisco

Mark Robbins, MD

Harvard Vanguard Medical Associates

Sonali Parekh Desai, MD

Diane V. Lacaille, MD, FRCPC, MHSc

Arthritis Research Center Canada

Gabby Schmajuk, MD

University of California San Francisco

Eric Newman, MD

Geisinger Medical Center

Jasvinder Singh, MD

University of Alabama Birmingham

Tuhina Neogi, MD

Boston University

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 **Year the measure was first released:**

Ad.3 **Month and Year of most recent revision:**

Ad.4 **What is your frequency for review/update of this measure?**

Ad.5 **When is the next scheduled review/update for this measure?**

Ad.6 **Copyright statement:** Copyright (c) 2013, American College of Rheumatology

Ad.7 **Disclaimers:** All materials are subject to copyrights owned by the College. The College hereby provides limited permission for the user to reproduce, retransmit or reprint for such user´s own personal use (and for such personal use only) part or all of any document as long as the copyright notice and permission notice contained in such document or portion thereof is included in such reproduction, retransmission or reprinting. All other reproduction, retransmission, or reprinting of all or part of any document is expressly prohibited, unless the College has expressly granted its prior written consent to so reproduce, retransmit, or reprint the material. All other rights reserved.

CPT(R) contained in the Measure specifications is copyright 2004-2013 American Medical Association.

LOINC(R) copyright 2004-2012 Regenstrief Institute, Inc.

This material contains SNOMED Clinical Terms(R) (SNOMED CT[R]) copyright 2004-2012 International Health Terminology Standards Development Organisation.

ICD-10 copyright 2012 World Health Organization. All Rights Reserved.

Due to technical limitations, registered trademarks are indicated by (R) or [R] and unregistered trademarks are indicated by (TM) or [TM].

Ad.8 **Additional Information/Comments:**