**National Quality Forum—Measure Testing (subcriteria 2a2, 2b2-2b7)**

**Measure Number** (*if previously endorsed*)**:** Click here to enter NQF number

**Measure Title**: Rheumatoid Arthritis: Disease Modifying Anti Rheumatic Drug (DMARD) Therapy

**Date of Submission**: Click here to enter a date

**Type of Measure:**

|  |  |
| --- | --- |
| Composite – ***STOP – use composite testing form*** | Outcome (*including PRO-PM*) |
| Cost/resource | Process |
| Efficiency | Structure |

|  |
| --- |
| **Instructions**   * Measures must be tested for all the data sources and levels of analyses that are specified. ***If there is more than one set of data specifications or more than one level of analysis, contact NQF staff*** about how to present all the testing information in one form. * **For all measures, sections 1, 2a2, 2b2, 2b3, and 2b5 must be completed.** * **For outcome and resource use measures**, section **2b4** also must be completed. * If specified for **multiple data sources/sets of specificaitons** (e.g., claims and EHRs), section **2b6** also must be completed. * Respond to all questions as instructed with answers immediately following the question. All information on testing to demonstrate meeting the subcriteria for reliability (2a2) and validity (2b2-2b6) must be in this form. An appendix for *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Maximum of 20 pages (*incuding questions/instructions;* minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.*** * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| --- |
| **Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF’s evaluation criteria for testing.**  **2a2.** **Reliability testing** [**10**](#Note10) demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For **PRO-PMs and composite performance measures**, reliability should be demonstrated for the computed performance score.  **2b2.** **Validity testing** [**11**](#Note11) demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For **PRO-PMs and composite performance measures**, validity should be demonstrated for the computed performance score.    **2b3.** Exclusions are supported by the clinical evidence; otherwise, they are supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion; [**12**](#Note12)  **AND**  If patient preference (e.g., informed decisionmaking) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately). [**13**](#Note13)  **2b4.** **For outcome measures and other measures when indicated** (e.g., resource use):   * **an evidence-based risk-adjustment strategy** (e.g., risk models, risk stratification) is specified; is based on patient factors that influence the measured outcome (but not factors related to disparities in care or the quality of care) and are present at start of care; [**14**](#Note14)**,**[**15**](#Note15) and has demonstrated adequate discrimination and calibration   **OR**   * rationale/data support no risk adjustment/ stratification.   **2b5.** Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for **identification of statistically significant and practically/clinically meaningful** [**16**](#Note16) **differences in performance**;  **OR**  there is evidence of overall less-than-optimal performance.  **2b6.** **If multiple data sources/methods are specified, there is demonstration they produce comparable results**.  **2b7.** For **eMeasures, composites, and PRO-PMs** (or other measures susceptible to missing data),analyses identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias.  **Notes**  **10.** Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).  **11.** Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality.  **12.** Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.  **13.** Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.  **14.** Risk factors that influence outcomes should not be specified as exclusions.  **15.** Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care, such as race, socioeconomic status, or gender (e.g., poorer treatment outcomes of African American men with prostate cancer or inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than to adjust out the differences.  **16.** With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers. |

**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.23*)** | **Measure Tested with Data From:** |
| abstracted from paper record | abstracted from paper record |
| administrative claims | administrative claims |
| clinical database/registry | clinical database/registry |
| abstracted from electronic health record | abstracted from electronic health record |
| eMeasure (HQMF) implemented in EHRs | eMeasure (HQMF) implemented in EHRs |
| other: Click here to describe | 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*).

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

**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.26*)** | **Measure Tested at Level of:** |
| individual clinician | individual clinician |
| group/practice | group/practice |
| hospital/facility/agency | hospital/facility/agency |
| health plan | health plan |
| other: Click here to describe | other: Click here to describe |

**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 two testing sites that were geographically dispersed, included racial/ethnically diverse patient populations, and that used different electronic health record systems for collection of RA disease activity measures. We have summarized the geographic location and characteristics of the sites in Table 1 below.

**Table 1. Geographic location, site characteristics and data sources used for rheumatoid arthritis disease activity quality measure.**

|  |  |  |
| --- | --- | --- |
| 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. | *Epic-based electronic health record.* Structured fields within the electronic record were queried. |
| **Southeastern** United States | Large community health system that serves both a *rural and urban* population in a statewide geographic region. The rheumatology clinics register over 20,000 visits annually. | *Cerner-based electronic health record*. Structured fields within the electronic record were queried |

**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 in the Northeastern and Southeastern health systems 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 each site. The number of patients in the testing projects are included in Table 2 below.

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

|  |  |  |  |
| --- | --- | --- | --- |
| Site | Total E-measure Population  (N) | Random Sample for Front-end EHR review  (N) | Sex  (% female) |
| Northeastern site | 1542 | 81 | 74% |
| Southeastern site |  | 81 |  |

**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 validity testing studies that involved a front-end electronic health record chart abstraction, a simple random sample of the eligible denominator population from the automated report generated by the e-measure was created for the sites (see Table 2 for details). The characteristics of the random sample were similar to the denominator population.

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**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.

**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.

**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 into the “substantial” category. Validity testing results are discussed in more detail below.

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**2b2. VALIDITY TESTING**

**2b2.1. 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*)

**2b2.2. 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 3 different aspects of validity that are relevant to the proposed measure. These include: 1) Validity of the performance measure score, obtained through comparison of automated e-measure data compared to a front-end total EHR data abstraction and 2) Validity of critical data elements, and 3) Systematic assessment of face validity using the ACR’s quality measure development process.

**1. Performance measure score validity**. 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. From the population in which the e-measure was applied, we created a simple random sample for front-end abstraction. For the characteristics of sampled patients, please see Table 2 above.

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.

**2. Critical data element validity.**

**For the QDM data element “Diagnosis: Rheumatoid Arthritis”** front-end chart review found disagreement in 11.7% of cases compared to the automated report. These instances resulted from the provider improperly coding the patient’s diagnosis as RA, when in fact the patient had another diagnosis. These data are consistent with the scientific literature in which the validity of case definitions for RA using related automated algorithms have been examined (*Chung CP, A systematic review of validated methods for identifying patients with rheumatoid arthritis using administrative or claims data. Vaccine. 2013 Dec 30;31 Suppl 10:K41-61; Carroll RJ et al. Portability of an algorithm to identify rheumatoid arthritis in electronic health records. J Am Med Inform Assoc. 2012 Jun;19(e1):e162-9*; *Liao KP, Electronic medical records for discovery research in rheumatoid arthritis. Arthritis Care Res. 2010 Aug;62(8):1120-7*). Conclusions from this literature are that algorithms, such as the one used here, in which more than one code for RA is required, including a diagnosis from a rheumatologist, have good sensitivity and specificity.

**3. 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 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 DMARD 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 | 1 | 13 | 14 | 7.14% |

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.

**2b2.3. What were the statistical results from validity testing**? (*e.g., correlation; t-test*)

**1. Performance measure score validity results**

Sample Size: 162

Kappa Overall, Range, % Agreement: .67, (.44, .89), 95.1%

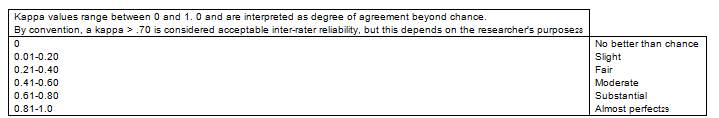
Kappa, Range, % Agreement Denominator: 1.00, (1.0, 1.0), 100%

Kappa, Range, % Agreement Numerator: .67, (.44, .89), 95.1%

Kappa, Range, % Agreement Exceptions: 1.00 (1.0, 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



**2. Critical data element validity.** Please see above section for details of validity testing results.

**3. Systematic assessment of face validity**.

**Table 3. Data from the American College of Rheumatology’s Rheumatoid Arthritis Quality Measures Project Expert Panel Rating Process for Disease Activity 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 | 1 | 13 | 14 | 7.14% |

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.

**2b2.4. 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?*)

**E-measure validity testing**. The kappa statistic of 0.67 for overall performance indicates substantial agreement between the automated report and the front-end chart abstraction. Individual data elements were found to be highly reliable.

**Systematic assessment of validity**. 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.

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**2b3. EXCLUSIONS ANALYSIS**

**NA**  **no exclusions — *skip to section*** [***2b4***](#section2b4)

**2b3.1. 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*)

The current measure adds e-specifications to an NQF-endorsed measure (DMARD use in RA, stewarded by the National Committee for Quality Assurance). Exclusions of the current measure are consistent with those in previous versions of this measure that are currently widely used and accepted in the U.S. health care system. Exclusions are based on the scientific literature and include:

1) Pregnancy, Active. This is clinically justified for a number of reasons. These include that most DMARDs are either frankly teratogenic (e.g. methotrexate, leflunomide) or are inadequately studied in pregnant women, and that many individuals with RA may experience lower levels of disease activity during pregnancy and therefore may not require drug therapy. In addition, even in the case of active disease, women may reasonably decide to minimize medication use to reduce potential harm to the fetus (*Makol A. Rheumatoid arthritis and pregnancy: safety considerations in pharmacological management. Drugs. 2011 Oct 22;71(15):1973-87*).

2) HIV, Active. This is clinically justified since the safety of immunosuppressive drugs is inadequately studied in individuals with HIV/AIDS.

3) Rheumatoid Arthritis, inactive. This is clinically justified and based on clinical guidelines (*Singh J 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*). The course of RA is variable, and some patients may achieve remission off of drug therapy.

To identify these exclusions, an automated query was generated to identify:

Patients Aged 18 and older -> Patients with Diagnosis, RA -> Patients with two or more encounters during the measurement period –> Patients with a diagnosis Pregnancy, Active and/or HIV, Active, and/or Rheumatoid Arthritis, Inactive. *Running this query did not reveal any patients who met this exclusion criterion in our testing sites*.

These exclusions are expected to be relatively uncommon based on available scientific literature, but are included to increase both the scientific and face validity of the DMARD measure. For example, in a national sample of Medicare fee-for-service enrollees with rheumatoid arthritis, **HIV/AIDS** was only identified in 6 individuals among a cohort of over 20,000 patients with RA (*Yazdany J et al. Glucocorticoid monotherapy among Medicare beneficiaries with rheumatoid arthritis. Arthritis Care & Research, in press*). In addition, because the mean age of individuals with RA in the United States is currently 67 years and expected to rise as our population ages (*Helmick CG, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part I. Arthritis Rheum. 2008 Jan;58(1):15-25*), **pregnancy** exclusions are expected to be present but not common.

Although precise population-based estimates are not available, studies to date suggest that up to 10% of individuals with RA may achieve a **drug-free remission** over the course of their disease (*van der Woude D. Sustained drug-free remission in rheumatoid arthritis after DAS-driven or non-DAS-driven therapy: a comparison of two cohort studies. Rheumatology (Oxford). 2012 Jun;51(6):1120-8*).

**2b3.2. 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*)

See response above, including data from testing sites and also national benchmark data on these exclusions.

**2b3.3. 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*)

These exclusions are expected to be present, but not common. They are clinically justified and lend scientific and face validity to the measure. Members of our Expert Panels felt strongly that these exclusions should be included to increase acceptability of the DMARD measure among practicing clinicians.

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**2b4. 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*** [***2b5***](#section2b5)***.***

**2b4.1. What method of controlling for differences in case mix is used?**

**No risk adjustment or stratification**

**Statistical risk model with** Click here to enter number of factors **risk factors**

**Stratification by** Click here to enter number of categories **risk categories**

**Other,** Click here to enter description

**2b4.2. If an outcome or resource use measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities**.

**2b4.3. Describe the conceptual/clinical and statistical methods and criteria used to select patient 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 and not related to disparities*)

**2b4.4. What were the statistical results of the analyses used to select risk factors?**

**2b4.5. 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*** [***2b4.9***](#question2b49)

**2b4.6. Statistical Risk Model Discrimination Statistics** (*e.g., c-statistic, R-squared*)**:**

**2b4.7. Statistical Risk Model Calibration Statistics** (*e.g., Hosmer-Lemeshow statistic*):

**2b4.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves**:

**2b4.9. Results of Risk Stratification Analysis**:

**2b4.10. 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*)

**2b4.11.** **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*)

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**2b5. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE**

**2b5.1. 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)*

Performance varied between sites. Performances ranged from 88-90% in sites that have established workflow to collect data on DMARD therapy.

Variation between providers, health plans and geographic regions have also been documented when this measure has been applied across the U.S. population (*Schmajuk G et al. Receipt of disease-modifying antirheumatic drugs among patients with rheumatoid arthritis in Medicare managed care plans. JAMA. 2011 Feb 2;305(5):480-6* and *Schmajuk G et al. Patterns of disease-modifying antirheumatic drug use in rheumatoid arthritis patients after 2002: a systematic review. Arthritis Care Res (Hoboken). 2013 Dec;65(12):1927-35*).

**2b5.2. 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*)

Data from the literature suggest that there is significant variation on DMARD use within the U.S. health care system. Schmajuk et al. (*JAMA. 2011 Feb 2;305(5):480-6*) describe that overall performance on the analogous HEDIS DMARD measure in the Medicare managed care population was 67% in 2008. The largest difference in performance was based on age, with older individuals being less likely to receive a DMARD. Blacks, those with low personal incomes, and those residing in zip codes with low socioeconomic status also had significantly lower DMARD use. In addition, performance varied widely by health plan, ranging from 16% to 87%. Additional studies, including a systematic review have also documented variation (*Schmajuk G, Solomon DH, Yazdany J. Patterns of disease-modifying antirheumatic drug use in rheumatoid arthritis patients after 2002: a systematic review. Arthritis Care Res (Hoboken). 2013 Dec;65(12):1927-35*). Available studies also demonstrate that variation is significantly less for those under the care of a rheumatologist. This is consistent with data from the ACR’s Rheumatology Clinical Registry, in which performance was 92.5% among participating rheumatologists in 2011 (*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. Arthritis Rheum, 2013 abstract supplement*).

**2b5.3. 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?*)

Application of this measure in the U.S. health care system for the last decade (2005-2014) suggests that DMARD use is a disparities-sensitive measure with significant variation across providers and health care settings; see above.

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**2b6. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS**

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

**Note***: This criterion is directed 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).* ***If comparability is not demonstrated, the different specifications should be submitted as separate measures.***

**2b6.1. Describe the method of testing conducted to demonstrate comparability of 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*)

**2b6.2. 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*)

**2b6.3. What is your interpretation of the results in terms of demonstrating comparability of 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*)

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**2b7. MISSING DATA ANALYSIS AND MINIMIZING BIAS**

**2b7.1. 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*)

In 5.6% of the patient sample, missing medication data (DMARD) were noted.

Because there is currently heterogeneity in the U.S. electronic health record systems in medication capture, we expect that missing medication data (DMARD) may be a problem in some settings. In one study, up to 15% of medications taken by patients were not captured by the electronic health record (*Orrico KB. Sources and types of discrepancies between electronic medical records and actual outpatient medication use. J Manag Care Pharm. 2008 Sep;14(7):626-31*). As medication reconciliation procedures improve, the extent of missing data will likely decrease over time. No specific procedures are recommended at this time to capture such missing data.

**2b7.2. 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*)

Not applicable – there were no missing data in our testing.

**2b7.3. 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*)

See above.