**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 2523

**Measure Title**: Rheumatoid Arthritis: Assessment of Disease Activity

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 4/1/2019

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *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. * 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 Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

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

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the 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*): Click here to name the intermediate outcome

Process: Rheumatoid Arthritis: Assessment of Disease Activity (collection of outcome score)

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**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.

The proposed measure is a *process* measure that requires collection of a key *health outcome* using a standardized score. Collecting this outcome measure in routine clinical care is supported by American College of Rheumatology (ACR) guidelines (*Singh J et al.* 2015 American College of Rheumatology

Guideline for the Treatment of Rheumatoid Arthritis*. Arthritis Rheumatol. 2016 Dec;68(1):1-26*).

The ACR undertook an extensive multi-year project, involving systematic literature reviews, expert consensus ratings, and national surveys to reach consensus on which RA disease activity measures are valid, reliable, and responsive, and feasible to implement in routine clinical practice (*Anderson J et al., Rheumatoid arthritis disease activity measures: American College of Rheumatology recommendations for use in clinical practice. Arthritis Care Res (Hoboken). 2012 May;64(5):640-7*). This manuscript is included as a supplemental Appendix.

The ACR endorsed 6 RA disease activity measurement tools, which include overlapping core elements (Figure 1). All include a patient-reported component (PRO). No measure is currently a gold standard; there is good scientific evidence supporting each endorsed measure. Therefore, clinicians can select from a range of valid options appropriate to their practice settings and available resources. This novel approach to measurement has been extensively validated in RA over a period of several decades (*Anderson J et al., Rheumatoid arthritis disease activity measures: American College of Rheumatology recommendations for use in clinical practice. Arthritis Care Res (Hoboken). 2012 May;64(5):640-7)*.

**Figure 1. Core elements of American College of Rheumatology’s endorsed rheumatoid arthritis** Figure 1.  Core elements of American College of Rheumatology’s endorsed rheumatoid arthritis
The figure contains a Venn diagram of three potential sources of information used for the ACR-endorsed disease activity assessment tools: patient, lab and provider. Under patient is PAS, PAS-II, and RAPID3. At the intersection of lab and provider is DAS28 and SDAI. At the intersection of provider and patient is CDAI.

The 6 proposed outcome measures have cutpoints for low, moderate and high disease activity as well as disease remission to facilitate clinical decision-making. See Table 1.

**Table 1. Disease activity cutpoints for American College of Rheumatology–recommended disease activity measures.**

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| --- | --- | --- | --- | --- | --- |
|  | Range | Remission | Low | Moderate | High |
| DAS28 (ESR or CRP) | 0-9.4 | < 2.6 | ≥ 2.6 - < 3.2 | ≥ 3.2 - ≤ 5.1 | > 5.1 |
| CDAI | 0-76 | ≤ 2.8 | > 2.8 - 10.0 | > 10.0 - 22.0 | > 22.0 |
| SDAI | 0-86 | 0.0 - 3.3 | 3.4 - 11.0 | 11.1 - 26.0 | 26.1 - 86.0 |
| RAPID-3 | 0-10 | 0 - 1.0 | > 1.0 - 2.0 | > 2.0 - 4.0 | > 4.0 - 10 |
| PAS | 0-10 | 0.00 - 0.25 | 0.26 - 3.70 | 3.71 - 7.99 | 8.00 - 10.00 |
| PASII | 0-10 | 0.00 - 0.25 | 0.26 - 3.70 | 3.71 - 7.99 | 8.00 - 10.00 |

In order to assess how patients with rheumatoid arthritis (RA) are responding to therapy or whether they are reaching treatment goals, RA disease activity should be assessed using a validated instrument.

Step 1: Measure disease activity using validated instrument

Step 2: Review disease activity assessment with patient during office visit: is the patient in remission, low, medium (moderate) or high disease activity?

Step 3: If the patient has moderate or high disease activity, consider treatment modification with goal of remission/ low disease activity.

Step 4: At next office visit or 3-6 months after initiation/ change in medication, repeat Steps 1-3 until patient is in remission/ low disease activity or until patient is satisfied with their functional status (patient-reported outcome measure, a separate quality measure).

**Figure 2. Algorithm for using standardized disease activity measures to target therapy in rheumatoid arthritis.**  *From Smolen et al. Treating rheumatoid arthritis to target: recommendations of an international task force. Ann Rheum Dis 2010;69:631-637 Algorithm for treating rheumatoid arthritis (RA) to target based on the recommendations.*

Figure 2.  Algorithm for using standardized disease activity measures to target therapy in rheumatoid arthritis.
The figure shows the main targets for patients with active RA, remission and low disease activity. It notes that providers should adapt therapy according to disease activity, which should be assessed every 3-6 months. For patienst in remission or low disease activity, therapy should be adapted if that disease state is lost.

Standard collection of disease activity outcomes in RA to facilitate a “treat to target” approach, where the target is disease remission or low disease activity, has been shown to improve clinical and radiographic outcomes (*Schipper LG et al. A tight control treatment strategy aiming for remission in early rheumatoid arthritis is more effective than usual care treatment in daily clinical practice: a study of two cohorts in the Dutch Rheumatoid Arthritis Monitoring registry. Ann Rheum Dis. 2012 Jun;71(6):845-50; Smolen JS et al. Treating rheumatoid arthritis to target: recommendations of an international task force. Ann Rheum Dis. 2010 Apr;69(4):631-7; Grigor C et al. Effect of a treatment strategy of tight control for rheumatoid arthritis (the TICORA study): a single-blind randomised*

*controlled trial. Lancet 2004;364:263–9.).*

**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.)

While not all recommended disease activity measure are derived from patient report, it is important to note that patients participated in creating the updated 2015 ACR Guideline for the Treatment of Rheumatoid Arthritis and supported the key principle of collecting disease activity.

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

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | * 2015 American College of Rheumatology * Guideline for the Treatment of Rheumatoid Arthritis * *Singh J et al.* * *2016 Dec* * *Arthritis Rheumatol.;68(1):1-26* * [**https://onlinelibrary.wiley.com/doi/epdf/10.1002/art.39480**](https://onlinelibrary.wiley.com/doi/epdf/10.1002/art.39480) |
| 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. | Disease activity measurement using an ACR-recommended measure should be performed in a majority of encounters for RA patients (16).†  † Any of the ACR recommended disease activity measures may be chosen, as described in Anderson J, Caplan L, Yazdany J, Robbins ML, Neogi T, Michaud K, et al. Rheumatoid arthritis disease activity measures: American College of Rheumatology recommendations for use in clinical practice. Arthritis Care Res (Hoboken) 2012; 64:640–7. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Collection of disease activity is a fundamental principle underlying all remaining guidelines (evidence for subsequent guidelines ranges from low to high). |
| Provide all other grades and definitions from the evidence grading system | We developed this guideline following the recently revised ACR guideline development process (<http://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines> ). This process includes the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology (available at [www.gradeworkinggroup.org](http://www.gradeworkinggroup.org))  Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008;336:924–6.  Andrews J, Guyatt G, Oxman AD, Alderson P, Dahm P, Falck-  Ytter Y, et al. GRADE guidelines: 14. Going from evidence to  recommendations: the significance and presentation of recom-  mendations. J Clin Epidemiol 2013;66:719–25.  Andrews JC, Schunemann HJ, Oxman AD, Pottie K, Meerpohl  JJ, Coello PA, et al. GRADE guidelines: 15. Going from evi-  dence to recommendation: determinants of a recommendation’s  direction and strength. J Clin Epidemiol 2013;66:726–35. |
| 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 |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | N/A |

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | * EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update * Smolen JS et al * Mar 2014 * Ann Rheum Dis; 73(3): 492–509 * [**https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3933074/**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3933074/) |
| 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. | Treatment should be aimed at reaching a target of remission or low disease activity in every patient.  Monitoring should be frequent in active disease (every 1–3 months); if there is no improvement by at most 3 months after the start of treatment or the target has not been reached by 6 months, therapy should be adjusted. |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Levels of evidence (LoE), grades of recommendations (GoR), strength of recommendation (SoR; = level of agreement), and % of votes for the respective items as worded, based on the recommendations of the Oxford Centre for Evidence-Based Medicine  Treatment should be aimed at reaching a target of remission or low disease activity in every patient. LoE:1a; GoR: A; SoR: 9.6±0.7; %: 100.  Monitoring should be frequent in active disease (every 1–3 months); if there is no improvement by at most 3 months after the start of treatment or the target has not been reached by 6 months, therapy should be adjusted. LoE:2b; GoR: B; SoR: 9.5±1.0; %: 100. |
| Provide all other grades and definitions from the evidence grading system | N/A |
| Grade assigned to the **recommendation** with definition of the grade | See above |
| Provide all other grades and definitions from the recommendation grading system | **Figure 3. Recommendations of the Oxford Centre for Evidence-Based Medicine for levels of evidence (LoE) and grades of recommendations (GoR)**  Figure 3. Recommendations of the Oxford Centre for Evidence-Based Medicine for levels of evidence (LoE) and grades of recommendations (GoR) 1a - Systematic review (with homogeneity) of RCTs 1b - Individual RCT (with narrow Confidence Interval) 1c - All or none (ie all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it) 2a - Systematic review (with homogeneity) of cohort studies 2b - Individual cohort study (including low quality RCT; e.g. <80% follow-up) 2c - "Outcomes" research or ecologic studies 3a - Systematic review (with homogeneity) of case-control studies 3b - Individual Case-Control study 4 - Case series (and poor quality cohort and case-control studies) 5 - Expert opinion or based on physiology, bench research or "first principles" |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Not reported |
| Estimates of benefit and consistency across studies | N/A |
| What harms were identified? | N/A |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | N/A |

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**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.**