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

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

**Measure Title**: IF a patient has rheumatoid arthritis, THEN functional status should be assessed using a standardized measure at least once yearly

**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**: Click here to enter a date

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| **Instructions**  *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.*   * Respond to all questions as instructed with answers immediately following the question. 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. * Maximum of 10 pages (*incudes 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 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:   * Health outcome: [**3**](#Note3) a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior. * 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.   **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 U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **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

Health outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Functional Status

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Assessment of a patient-reported outcome (PRO) relating to functional status

Structure: Click here to name the structure

Other: Click here to name what is being measured

The proposed measure is a *process* measure that requires collection of a key health outcome (*functional status*) using a validated measure to record a standardized score. Collecting this outcome measure in routine clinical care is supported by American College of Rheumatology (ACR) guidelines (e.g. *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*).

RA is a chronic autoimmune disorder often characterized by progressive joint destruction and multisystem involvement. It affects approximately 1.3 million Americans and affects women disproportionately (*Helmick CG et al., Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part I. Am J Public Health. 2012 Mar;102(3):426-33*). There is no cure; consequently, the goal of treatment is to slow the progression of the disease and thereby delay or prevent joint destruction, relieve pain, and maintain functional capacity. Functional status assessment is essential to determining whether a key treatment goal (maintaining functional capacity) is being met.

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**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**1a.2.** **Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.**

**1a.2.1.** **State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).**

*Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.*

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**intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measure**

**1a.3.****Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes**. Include all the steps between the measure focus and the health outcome.

Measuring physical function is recommended in RA treatment guidelines because it is a necessary step in prognosis assessment, which guides the choice of disease-modifying (DMARD) medications; and at regular intervals to assess response to therapy and guide the decision to change DMARD medication, as illustrated by the following diagrams:

Physical function assessment => prognosis => choice of DMARD medication

*and*

DMARD treatment => physical function assessment => decision to change DMARD medication.

**1a.3.1.** **What is the source of the systematic review of the body of evidence that supports the performance measure?**

Clinical Practice Guideline recommendation – ***complete sections*** [***1a.4***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

Other – ***complete section*** [***1a.8***](#Section1a8)

*Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.*

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**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

**1a.4.1.** **Guideline citation** (*including date*) and **URL for guideline** (*if available online*):

There is general consensus by experts and strong agreement across RA guidelines from various countries, that persistent or worsening impairment in physical function necessitate a change in therapy (DMARD medications). Guidelines also consistently recommend assessing prognostic factors of RA, which includes a measure of physical function, and to consider the presence of poor prognostic factors when making treatment decisions about DMARD medications. This provides a rationale for the quality measure of measuring physical function periodically.

American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the management of rheumatoid arthritis: 2002 Update. Arthritis Rheum. 2002 Feb;46(2):328-46.

Saag K, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. Arthritis Rheum 2008;59(6):762-84.

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 2012;64(5):625-39.

Stoffer MA, Smolen JS, Woolf A, et al. Development of patient-centred standards of care for rheumatoid arthritis in Europe: the eumusc.net project. Ann Rheum Dis. 2013 Aug 6.

Smolen JS, Landewé R, Breedveld FC et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update. Ann Rheum Dis. 2014 Mar 1;73(3):492-509.

Smolen JF, Aletaha D et al. Treating rheumatoid arthritis to target: recommendations of an international task force. *Ann Rheum Dis* 2010 69: 631-637

van Hulst LT, Fransen J, den Broeder AA, et al. Development of quality indicators for monitoring of the disease course in rheumatoid arthritis. Ann Rheum Dis. 2009 Dec;68(12):1805-10. (Netherland’s Scientific Institute on the Quality of Health Care)

Bykerk VP, Akhavan P, Hazlewood GS. Canadian Rheumatology Association Recommendations for Pharmacological Management of Rheumatoid Arthritis with Traditional and Biologic Disease-modifying Antirheumatic Drugs. J Rheumatol 2011;38(11).

National Institute for Clinical Excellence (NICE). Rheumatoid arthritis: The management of rheumatoid arthritis in adults: NICE clinical guidance 2009;79 [Internet. Accessed February 18, 2014]. Available from: <http://www.nice.org.uk/nicemedia/pdf/CG79NICEguideline.pdf>.

**1a.4.2.** **Identify guideline recommendation number and/or page number** and **quote verbatim, the specific guideline recommendation**.

American College of Rheumatology Guideline (2002): “The management of RA is an iterative process, and patients should be periodically reassessed for … limitation of function. Baseline evaluation of disease activity and damage in patients with rheumatoid arthritis [should include evaluation of] functional status or quality of life assessments using standardized questionnaires.”

American College of Rheumatology Guideline (2008): “Through a modified Delphi process, the CEP selected the following as the most clinically important markers of poor prognosis: functional limitation (e.g., HAQ Disability Index), …. For the purposes of selecting therapies, physicians should consider the presence of these prognostic factors at the time of the treatment decision.”

American College of Rheumatology Guideline (2012 update of the 2008 guidelines): “Poor prognosis is defined as: Presence of 1 or more of the following features: functional limitation (e.g., HAQ DI or similar valid tools), …” . The recommended algorithm for choosing DMARD treatment is based on the presence or absence of poor prognosis.

EULAR Guideline (2010, 2013): “People with RA should be fully assessed for … function at diagnosis; [this] assessment should also be done annually”

European working group, recommendation 2: “A large array of data has confirmed the value of reaching stringent remission not only with regard to signs and symptoms of RA, but also with regard to achieving maximal functional improvement and halting progression of structural damage; thus good outcomes in terms of physical function and structural changes are implicitly included in targeting good clinical outcome.”

Treat to Target recommendations (Smolen Ann Rheum Dis 2010): “ Structural changes and functional impairment should be considered when making clinical decisions, in addition to assessing composite measures of disease activity. This item reiterates the importance of using composite measures of disease activity, but indicates that other aspects such as functional impairment and joint damage, which are governed by the degree of disease activity, also have to be considered. … In addition to joint damage, continuing impairment of physical function despite achievement of the targeted disease activity level may also necessitate a therapeutic change (category IV)…”

Netherland’s Scientific Institute on the Quality of Health Care: “A rheumatologist or a specialised nurse in rheumatology should measure functional impairment yearly with the HAQ in an RA patient.”

Canadian Guidelines, Recommendation 2: The presence of the following poor prognostic features should be assessed at baseline and considered when making treatment decisions: … functional limitation, high number of swollen and tender joints, …. (Level II, Strength B)

UK guidelines (NICE):

* “1. Guidance. The following guidance is based on the best available evidence.
* 1.5 Monitoring rheumatoid arthritis
* 1.5.1.4 Offer people with RA an annual review to:
  + assess disease activity and damage, and measure functional ability (using, for example, the Health Assessment Questionnaire [HAQ])”

**1a.4.3.** **Grade assigned to the quoted recommendation with definition of the grade:**

No grade has been assigned to this recommendation in the American College of Rheumatology guidelines.

Treat to target recommendations (Smolen et al. Ann Rheum Dis 2010): Level IV, defined as:

Ia—evidence for meta-analysis of randomised controlled trials

Ib—evidence from at least one randomised controlled trial

IIa—evidence from at lease one controlled study without randomisation

IIb—evidence from at lease one other type of quasi-experimental study

III—evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-control studies

IV—evidence from expert committee reports or opinions or clinical experience of respected authorities, or both

Canadian guidelines (Bykerk 2011): (Level II, Strength B). Defined as

Levels of Evidence

I Meta-analyses, systematic reviews of RCT, or individual RCT

II Meta-analysis, systematic reviews of observational studies (cohort/case control studies), or individual observational studies

III Nonanalytic studies, e.g., case reports, case series

IV Expert opinion

Strength of Recommendation

A Strong recommendation: Direct level I evidence

B Moderate recommendation: Direct level II evidence or extrapolated level I evidence

C Weak recommendation: Direct level III evidence or extrapolated level II evidence

D Consensus recommendation: Expert opinion based on very limited evidence

NR Recommendations are not linked to evidence

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

There is good evidence (Grade B) that functional status measures predict long-term outcomes in rheumatoid arthritis and are responsiveness to treatment changes (Grade A). Physical function, measured as a patient-reported outcome (PRO) using validated questionnaires such as the Health Assessment Questionnaire, has consistently been identified as a significant predictor of future clinically important outcomes in people with RA1, with poorer physical function being associated with increased risk of work disability2-6, joint replacement surgery7 and mortality.8-17

1. Maska L, Anderson J, Michaud K. Measures of functional status and quality of life in rheumatoid arthritis: Health Assessment Questionnaire Disability Index (HAQ), Modified Health Assessment Questionnaire (MHAQ), Multidimensional Health Assessment Questionnaire (MDHAQ), Health Assessment Questionnaire II (HAQ-II), Improved Health Assessment Questionnaire (Improved HAQ), and Rheumatoid Arthritis Quality of Life (RAQoL). Arthritis Care Res (Hoboken). 2011 Nov;63 Suppl 11:S4-13.

2. Callahan LF, Bloch DA, Pincus T. Identification of work disability in rheumatoid arthritis: Physical, radiographic and laboratory variables do not add explanatory power to demographic and functional variables. J Clin Epidemiol 1992;45:127-38

3. Wolfe F, Hawley DJ: The longterm outcomes of rheumatoid arthritis: Work disability: A prospective 18 year study of 823 patients. J Rheumatol 1998;25:2108-17.

4. Lacaille D, Sheps S, Spinelli JJ, Chalmers A, Esdaile JM. Identification of modifiable work-related factors that influence the risk of work disability in rheumatoid arthritis. Arthritis Rheum 2004;51:843-52.

5. Eberhardt K, Larsson B-M, Nived K, Lindqvist E. Work Disability in Rheumatoid Arthritis – Development Over 15 Years and Evaluation of Predictive Factors Over Time. J Rheumatol 2006; 34(3):481-487

6. Burton W, Morrison A, Maclean R, Rudolph R. Systematic review of studies in productivity loss due to rheumatoid arthritis. Occup Med (Lond) 2006;56:18-27.

7. Wolfe f, Zwillich SH. The Long-Term Outcomes of Rheumatoid Arthritis: A 23-Year Prospective, Longitudinal Study of Total Joint Replacement and Its Predictors in 1,600 Patients with Rheumatoid Arthritis. Arthritis Rheum 1998;41(6):1072-82

8. Pincus T, Callahan LF, Sale WG, Brooks AL, Payne LE, Vaughn WK: Severe functional declines, work disability, and increased mortality in seventy-five rheumatoid arthritis patients studied over nine years. Arthritis Rheum 1984;27:864-72.

9. Wolfe F, Kleinheksel SM, Cathey MA, Hawley DJ, Spitz PW, Fries JF: The clinical value of the Stanford health assessment questionnaire functional disability Index in patients with rheumatoid arthritis. J Rheumatol 1988;15:1480-8.

10. Kazis LE, Anderson JJ, Meenan RF. Health status as a predictor of mortality in rheumatoid arthritis: a five-year study. J Rheumatol 1990;17:609-13.

11. Leigh JP, Fries JF: Mortality predictors among 263 patients with rheumatoid arthritis. J Rheumatol 1991;18:1307- 12.

12. Pincus T, Brooks RH, Callahan LF: Prediction of long-term mortality in patients with rheumatoid arthritis according to simple questionnaire and joint count measures. Ann Intern Med 1994;120:26-34.

13. Wolfe F, Mitchell DM, Sibley JT, Fries JF, Bloch DA, Williams CA, et al. The mortality of rheumatoid arthritis. Arthritis Rheum 1994;37:481-94.

14. Callahan LF, Cordray DS, Wells G, Pincus T: Formal education and five-year mortality in rheumatoid arthritis: Mediation by helplessness scale scores. Arthritis Care Res 1996;9:463-72.

15. Callahan LF, Pincus T, Huston JW III, Brooks RH, Nance EP Jr, Kaye JJ: Measures of activity and damage in rheumatoid arthritis: Depiction of changes and prediction of mortality over five years. Arthritis Care Res 1997;10:381- 94.

16. Soderlin MK, Nieminen P, Hakala M: Functional status predicts mortality in a community based rheumatoid arthritis population. J Rheumatol 1998;25:1895-9.

17. Sokka T, Hakkinen A, Krishnan E, Hannonen P: Similar prediction of mortality by the health assessment questionnaire in patients with rheumatoid arthritis and the general population. Ann Rheum Dis 2004;63:494-497.

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

Yes **→ *complete section*** [***1a.7***](#Section1a7)

No **x**  **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

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**1a.5.** **UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

**1a.5.1.** **Recommendation citation** (*including date*) and **URL for recommendation** (*if available online*):

**1a.5.2.** **Identify recommendation number and/or page number** and **quote verbatim, the specific recommendation**.

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**:

**1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: the* *grading system for the evidence should be reported in section 1a.7.*)

**1a.5.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.5.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1.** **Citation** (*including date*) and **URL** (*if available online*):

Evidence pertaining to functional status assessment is provided above. Here we also discuss the body of ***evidence supporting the PROs recommended for this purpose in the current measure (HAQII, MDHAQ, PROMIS measures)***. Scientific evidence regarding available measures was summarized in a recent *systematic review examining the criterion validity, construct validity, predictive validity and ability to detect change of functional status assessments in rheumatoid arthritis*, including 2 of those recommended in the proposed measure (HAQ II and MDHAQ).1 Evidence grading for the additional recommended measures, PROMIS PF-10, PROMIS PF-20, and PROMIS CAT, were obtained from publications by investigators collaborating with the National Institutes of Health in the PROMIS initiative.2-5

Members of the ACR’s RA Quality Measures Project Work Group reviewed the scientific literature on available measures and surveyed experts in the field (Patricia Katz PhD (Professor of Medicine at UCSF), Jim Fries MD (Professor Emeritus at Stanford), Peter Tugwell (Director for Global Health, University of Ottawa), Vibeke Strand MD (Clinical Professor at Stanford), Ted Pincus MD (Clinical Professor at NYU) to determine which available functional status measures have high quality evidence supporting their measurement properties and are feasible to use in clinical practice. These measures were proposed to an Expert Panel using the RAND Appropriateness Method (for details and ratings, please see Measure Testing forms under this submission). Mean panel ratings indicated excellent validity. Key references for the final measures are provided below.

1. Maska L, Anderson J, Michaud K. Measures of functional status and quality of life in rheumatoid arthritis: Health Assessment Questionnaire Disability Index (HAQ), Modified Health Assessment Questionnaire (MHAQ), Multidimensional Health Assessment Questionnaire (**MDHAQ**), Health Assessment Questionnaire II (**HAQ-II**), Improved Health Assessment Questionnaire (Improved HAQ), and Rheumatoid Arthritis Quality of Life (RAQoL). Arthritis Care Res (Hoboken). 2011 Nov;63 Suppl 11:S4-13.

2. Hays RD, Spritzer KL, Fries JF et al. Responsiveness and minimally important difference for the Patient-Reported Outcomes Measurement Information System (**PROMIS**) 20-item physical functioning short form in a prospective observational study of rheumatoid arthritis. Ann Rheum Dis. 2013 Oct 4.

3. Fries JF, Krishnan E, Rose M, et al. Improved responsiveness and reduced sample size requirements of **PROMIS** physical function scales with item response theory. Arthritis Res Ther. 2011;13(5):R147. doi: 10.1186/ar3461.

4. Fries J, Rose M, Krishnan E. The **PROMIS** of better outcome assessment: responsiveness, floor and ceiling effects, and Internet administration. J Rheumatol. 2011 Aug;38(8):1759-64.

5. Bjorner JB, Rose M, Gandek B et al. Method of administration of **PROMIS** scales did not significantly impact score level, reliability, or validity. J Clin Epidemiol. 2014 Jan;67(1):108-13.

**1a.6.2.** **Citation and** **URL for methodology for evidence review and grading** (*if different from 1a.6.1*)**:**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE supporting the measure**

*If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.*

**1a.7.1.** **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?**

Maska et al reviewed the *criterion validity, construct validity, predictive validity and ability to detect change* of functional status assessments in rheumatoid arthritis, see above. The Table below summarizes key findings from this systematic review on the functional status measures referred to in this quality measure.

| FSA Tool | Criterion Validity | Construct Validity | Predictive Validity | Ability to Detect Change |
| --- | --- | --- | --- | --- |
| MDHAQ | The MDHAQ and HAQ have been shown to be highly correlated; however, average  MDHAQ scores have been shown to be 0.34 lower than HAQ scores. | MDHAQ scores correlate with the  Disease Activity Score in 28 joints (DAS28) at baseline (r = 0.51), although the change in MDHAQ over 12 months correlated less well with change in the DAS28 (r = 0.39). | MDHAQ scores were more significantly  associated with degree of morning stiffness than pain, fatigue, joint counts, and patient global. MDHAQ scores have also been shown to independently predict 10-year mortality among people with RA. | Variability of scores over time was not significantly different compared to variability of pain and patient global assessment scores (*P* < 0.13) in a  study of weekly self-assessment over 6 months. MDHAQ lacks a normal distribution at the lower end of the scale and may fail to detect  numerical improvement in scores despite clinical improvement in up to 4.4% of patients. |
| HAQ-II | The HAQ-II and HAQ are highly correlated (r = 0.92) with average HAQ-II scores shown to be only minimally lower (by 0.02–0.04) than HAQ scores. | The HAQ-II was designed using Rasch analysis and was found to measure disability over a longer scale than the HAQ, and has no nonfitting items and  no gaps between items. | HAQ-II values are correlated with clinical outcomes including pain, fatigue, patient’s and physician’s assessments of global disease severity, Disease Activity Score in 28 joints, erythrocyte sedimentation rate, joint counts, medical costs, joint replacement, and work disability, at levels similar to those of the HAQ and MHAQ. | HAQ-II lacks a normal distribution at values near 0 and may fail to  detect numerical improvement in scores despite clinical improvement in up to 5.8% of patients. |

**1a.7.2.** **Grade assigned for the quality of the quoted evidence with definition of the grade**:

Evidence has not been graded in this review. Evidence ratings for functional status assessment in RA are discussed above.

**1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.**

**1a.7.4.** **What is the time period covered by the body of evidence?**

The literature search included studies from 1962 through February 2009.

**QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1a.7.5.****How many and what type of study designs are included in the body of evidence**? (*e.g., 3 randomized controlled trials and 1 observational study*)

There is moderate evidence, based on > 2 high quality non-RCT studies which controlled for potential confounders with large, precise estimates of effect, with consistent results across studies, that the focus of the measure, physical function, is an intermediate clinical outcome leading to desired long term health outcomes in rheumatoid arthritis.

**1a.7.6.** **What is the overall quality of evidence across studies in the body of evidence**? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

There have been no trials that have randomized patients or practices to perform (versus not perform) functional status assessments in RA. Therefore, although there is widespread consensus based on national and international guidelines that this is key outcome measure in RA and should be part of routine clinical practice, it remains unknown whether the process of functional status assessment improves patient outcomes over time.

**ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE**

**1a.7.7.** **What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence**? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

No meta-analyses are available to provide estimates of benefit.

**1a.7.8.** **What harms were studied and how do they affect the net benefit (benefits over harms)?**

Although no study has found harm from performing functional status assessments, there is a literature enumerating the time burden to both patients and physicians for completing these PROs. For all of the measures, including the HAQ-II, MDHAQ, and PROMIS forms, the the respondent burden is <5 minutes and the administrative burden to score the measure is <1 minute (*Maska L, Anderson J, Michaud K. Measures of functional status and quality of life in rheumatoid arthritis: Health Assessment Questionnaire Disability Index (HAQ), Modified Health Assessment Questionnaire (MHAQ), Multidimensional Health Assessment Questionnaire (MDHAQ), Health Assessment Questionnaire II (HAQ-II), Improved Health Assessment Questionnaire (Improved HAQ), and Rheumatoid Arthritis Quality of Life (RAQoL). Arthritis Care Res (Hoboken). 2011 Nov;63 Suppl 11:S4-13*).

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**1a.7.9.** **If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.

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**1a.8 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.8.1** **What process was used to identify the evidence?**

**1a.8.2.** **Provide the citation and summary for each piece of evidence.**