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

**Measure Number** (*if previously endorsed*)**:** 0422

**Measure Title**: Functional Status Change for patients with knee impairments

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

**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:

Patient-reported outcome (PRO): Functional status change for patients with knee impairments

*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: Click here to name the process

Structure: Click here to name the structure

Other: Click here to name what is being measured

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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.**

Improvement in functional status is a primary goal of physical therapy treatment for patients with knee impairments. FOTO (knee) patient reported outcome measure (PROM) was designed to measure change in functional status from the time of admission to rehabilitation to the time of discharge. It can also be used to monitor change during treatment. Information of patient reported function assists the clinician in developing the plan of care, evaluating effectiveness of the plan and directing changes in treatment, if needed. Aggregated risk-adjusted data from FOTO (knee) PROM can be used as a provider performance measure (PRO-PM) for clinicians and clinics. Information gleaned from provider performance can be used to target and improve quality of care.

**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.

NA

**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.*

*NA*

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

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

The use of this **HEALTH OUTCOME/PRO PERFORMANCE MEASURE** is supported by the

following clinical practice guidelines:

Logerstedt DS, Snyder-Mackler L, Ritter RC, Axe MJ, Orthopedic Section of the American Physical

Therapy Association. Knee pain and mobility impairments: meniscal and articular cartilage lesions. J

Orthop Sports Phys Ther. 2010 Jun;40(6):A1-A35. [144 references] [PubMed](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=20511698) External Web Site Policy

http://www.guideline.gov/content.aspx?id=25754#Section420

Logerstedt DS, Snyder-Mackler L, Ritter RC, Axe MJ, Godges JJ, Knee stability and movement coordination impairments: knee ligament sprain: Clinical Practice Guidelines Linked to the International Classification of Functioning, Disability, and Health from the Orthopaedic Section of the American Physical Therapy Association. J Orthop Sports Phys Ther. 2010 Apr;40(4):A1-A37. [175 references] http://www.guideline.gov/content.aspx?id=25755

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

Knee pain and mobility impairments: meniscal and articular cartilage lesions: “Clinicians should use a

validated patient-reported outcome measure, a general health questionnaire,

and a validated activity scale for patients with knee pain and mobility impairments. These tools are

useful for identifying a patient's baseline status relative to pain, function, and disability and for

monitoring changes in the patient's status throughout the course of treatment." P. 2

Knee stability and movement coordination impairments: knee ligament sprain: “Clinicians should use a validated patient-reported outcome measure with a general health questionnaire, along with a validated activity scale for patients with knee stability and movement coordination impairments. These tools are useful for identifying a patient's baseline status relative to pain, function, and disability and for monitoring changes in the patient's status throughout the course of treatment.” P.2, P. 21.

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

Knee pain and mobility impairments: meniscal and articular cartilage lesions: Grade of C=Weak evidence, a single level II study or a preponderance of level III and IV studies including statements of consensus by content experts support the recommendation.

Knee stability and movement coordination impairments: knee ligament sprain: There were two grades provided for this same recommendation within this document (Grades A and B). P. 2 states: Strong evidence, a preponderance of level I and/or level II studies support the recommendation. This must include at least 1 level I study. Although not stated explicitly, strong evidence is a Grade of A). Whereas, P.21 states Grade B. A single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation

**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.*)

| **Grades of Recommendation** | | **Strength of Evidence** |
| --- | --- | --- |
| **A** | Strong evidence | A preponderance of level I and/or level II studies support the recommendation. This must include at least 1 level I study |
| **B** | Moderate evidence | A single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation |
| **C** | Weak evidence | A single level II study or a preponderance of level III and IV studies including statements of consensus by content experts support the recommendation |
| **D** | Conflicting evidence | Higher-quality studies conducted on this topic disagree with respect to their conclusions. The recommendation is based on these conflicting studies |
| **E** | Theoretical/foundational evidence | A preponderance of evidence from animal or cadaver studies, from conceptual models/principles or from basic sciences/bench research support this conclusion |
| **F** | Expert opinion | Best practice based on the clinical experience of the guidelines development team |

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

URL’s are shown in *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 **→ *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)

Both Guidelines used expert consensus to weight the evidence from systematic reviews of the literature.

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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*):

NA

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

NA

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

NA

**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.*)

**NA**

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

**NA**

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

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

NA

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

NA

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

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

NA

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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.*

NA

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

NA

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

NA

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

NA

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**: Click here to enter date range

NA

**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*)

**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*)

**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*)

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

**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.**

The use of this performance measure is also supported by FOTO’s internal studies and data in 7 peer-reviewed papers which demonstrate that functional status change measured by the FOTO knee PROM is reliable, (Wang, [Hart, et al. 200](#_ENREF_2)9 efficient, precise, valid ([Hart, Mioduski et al. 200](#_ENREF_2) and responsive measure for patients receiving therapy for knee impairments.

Hart et al 2008 reported that the knee FS CAT measure used on average 7 questions to produce

precise estimates of FS that adequately covered the content range with negligible floor and ceiling effects. Estimates of function from the CAT were as precise as measures using all items. In addition Hart et al 2008 reported test information functions and standard errors supported FS measure precision. Change of 9 FS units (0-100 scale) represented minimal clinically important improvement, which 67% of patients obtained at discharge from rehabilitation.

Research showed that the knee CAT demonstrated negligible

item functioning in an adaptive test of functional status for patients with knee impairments who spoke English or Hebrew, was efficient to administer and functioned well in routine clinical application (Hart, Mioduski et al. 2005, Hart, Wang et al 2008, Wang, Hart et al 2009, Wang, Hart et al 2009, Hart DL, Deutscher D et al 2009, Deutscher D, Hart et al 2011, Deutscher D, Hart et al 2010). Additional, detailed testing results are presented in section 3a of this application.

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

Search of the literature in PubMed and FOTO internal study was used to identify the evidence.

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

References

Hart, D. L., Mioduski, J. E., & Stratford, P. W. (2005). Simulated computerized adaptive tests for

measuring functional status were efficient with good discriminant validity in patients with hip, knee, or

foot/ankle impairments. J Clin Epidemiol, 58(6), 629-638.

Hart, D.L., Wang, Y.C., Stratford, P. W., Mioduski, J. E.(2008) Computerized adaptive test for patients

with knee impairments produced valid and responsive measures of function. J Clin Epidemiol,61:1113

1124.

Hart DL, Deutscher D, Crane PK, Wang YC. Differential item functioning was negligible in an adaptive test of functional status for patients with knee impairments who spoke English or Hebrew. Qual Life Res. 2009;18(8):1067-83.

Deutscher D, Hart DL, Stratford PW, Dickstein R. Construct validation of a knee-specific functional status measure: a comparative study between the United States and Israel. Phys Ther. 2011;91(7):1072-84.

Deutscher D, Hart DL, Crane PK, Dickstein R. Cross-cultural differences in knee functional status outcomes in a polyglot society represented true disparities not biased by differential item functioning. Phys Ther. 2010 Dec;90(12):1730-42. PubMed PMID: 20947673.

Wang, Y. C., Hart, D.L., Stratford, P. W., Mioduski, J. E. (2009). Clinical interpretation of outcome

computerized adaptive test-Generated outcome measures in patients with knee impairments. APMR 90:

1340-1348.

Wang YC, Hart DL, Stratford PW, Mioduski JE. (2009) Clinical interpretation of a lower-extremity

functional scale-derived computerized adaptive test. Phys Ther. 89(9):957-68.