



# Guidance for Using PROMIS Measures with People with Multiple Sclerosis

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|       |  |    |
|-------|--|----|
| 1.0   | Introduction .....   | 4  |
| 2.0   | Fatigue and Physical Function in People with MS .....  | 5  |
| 2.1   | Uses for PROMIS MS Measures .....  | 5  |
| 2.2   | Fatigue Measure Details.....   | 6  |
| 2.3   | Physical Function Measure Details .....  | 6  |
| 3.0   | Why Use PROMIS?.....   | 7  |
| 4.0   | Access Paper and Digital PROMIS MS Measures .....  | 8  |
| 4.1   | Paper Administration .....   | 8  |
| 4.2   | Digital Administration in English .....  | 9  |
| 4.3   | Digital Administration of a Translation.....   | 10 |
| 4.4   | Epic PROMIS CAT Application .....  | 11 |
| 4.5   | Comparing the Assessment Center API and HealthMeasures Electronic Administration<br>Permissions for Adding Measures to Digital Platforms ..... | 12 |
| 5.0   | Implementation in Digital Administration Platforms .....   | 14 |
| 5.1   | Guidance for Information Technology Team .....   | 14 |
| 5.1.1 | Correct Appearance of Items .....  | 15 |
| 5.1.2 | Report Scores.....   | 15 |
| 5.1.3 | Create Management Reports for Clinical Care .....  | 15 |
| 5.2   | Guidance for Clinic Staff .....  | 16 |
| 5.2.1 | Before the Office/Virtual Visit .....  | 16 |
| 5.2.2 | At the Office Visit .....  | 16 |
| 5.2.3 | After the Office Visit.....  | 17 |
| 5.2.4 | Best Practices in Administration .....   | 17 |
| 6.0   | Calculate Scores.....  | 18 |
| 6.1   | Handling Missing Data .....  | 18 |
| 6.1.1 | Form-level Missing Data.....   | 18 |
| 6.1.2 | Item-level Missing Data.....   | 18 |
| 6.2   | Handling Multiple Responses on a Paper Form .....  | 18 |
| 6.3   | Score Translations .....   | 18 |
| 6.4   | Preferred Scoring Instructions – Response Pattern Scoring.....   | 19 |
| 6.4.1 | Description.....   | 19 |
| 6.4.2 | Minimum Responses .....  | 19 |
| 6.4.3 | Response Pattern Scoring within an Administration Platform .....   | 19 |



|       |  |    |
|-------|--|----|
| 6.4.4 | Response Pattern Scoring via the HealthMeasures Scoring Service .....                | 19 |
| 6.4.5 | Response Pattern Scoring via the Assessment Center API .....                         | 20 |
| 6.5   | Manual Scoring Instructions – Convert Raw Summed Scores to T-scores with Tables .... | 21 |
| 7.0   | Interpret Scores.....  | 24 |
| 7.1   | T-score.....   | 24 |
| 7.2   | Standard Error .....   | 24 |
| 7.3   | Direction of Scores (Higher Scores = More) .....                                     | 24 |
| 7.4   | Score Range .....  | 25 |
| 7.5   | Reference Population .....   | 25 |
| 7.6   | Reliability .....  | 25 |
| 7.7   | Score Cut Points.....  | 25 |
| 7.8   | Comparing Scores .....   | 26 |
| 7.9   | Change Scores .....  | 26 |
| 7.10  | Discussing PROMIS MS Measure Scores with an Individual Patient .....                 | 26 |
| 8.0   | Publishing PROMIS Data .....   | 27 |
| 8.1   | Reporting Scores .....   | 27 |
| 9.0   | PROMIS MS Measure Development.....   | 28 |
| 9.1   | Development of PROMISnq PFMS 15a .....   | 28 |
| 9.1.1 | Source of Items .....  | 28 |
| 9.1.2 | Item Content .....   | 28 |
| 9.1.3 | Score .....  | 29 |
| 9.1.4 | Primary Reference for Measure .....  | 29 |
| 9.2   | Development of PROMIS FatigueMS 8a.....  | 30 |
| 9.2.1 | Source of Items .....  | 30 |
| 9.2.2 | Item Content .....   | 30 |
| 9.2.3 | Score .....  | 30 |
| 9.2.4 | Primary Reference for Measure .....  | 30 |
| 10.0  | References.....  | 31 |
| 11.0  | Acknowledgements.....  | 32 |

## 1.0 Introduction

This *Guidance for Using PROMIS Measures with People with Multiple Sclerosis* includes information on:

- PROMIS measures for people with Multiple Sclerosis (MS)
- Accessing measures for paper or digital administration
- Implementation guidance for information technology teams
- Implementation guidance for clinical staff
- Scoring instructions
- Guidance for interpreting scores
- Overview of measure development methodology

For more information about PROMIS measures, see [www.HealthMeasures.net/PROMIS](http://www.HealthMeasures.net/PROMIS).

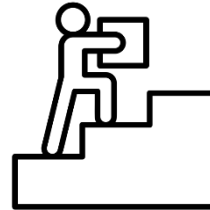
## 2.0 Fatigue and Physical Function in People with MS

Multiple sclerosis (MS) is a chronic disease that affects the central nervous system. It causes a range of neurological symptoms and functional disability. Two patient-reported outcomes (PROs) are critical for understanding the experience of people with MS:

### Fatigue



### Physical Function



Two Patient-Reported Outcomes Measurement Information System® (PROMIS®) measures were created specifically for measuring fatigue and physical function in people with MS:

- **PROMIS Short Form v1.0 - Fatigue-Multiple Sclerosis 8a (PROMIS FatigueMS 8a)**
- **PROMISnq Short Form v2.0 - Physical Function-Multiple Sclerosis 15a (PROMISnq PFMS 15a)**

## 2.1 Uses for PROMIS MS Measures

The PROMIS MS measures can be used many ways including:

- Monitoring an individual patient (e.g., tracking fatigue after starting a new treatment)
- Comparing small groups (i.e., subgroups of 50-75 people)
- Comparing large groups (i.e., subgroups larger than 50-75 people)

## 2.2 Fatigue Measure Details

|                                    |  |
|------------------------------------|--|
| <b>Measure name (abbreviation)</b> | PROMIS Short Form v1.0 - Fatigue-Multiple Sclerosis 8a (PROMIS FatigueMS 8a)   |
| <b>Measure content</b>             | <ul style="list-style-type: none"> <li>Assesses a range of self-reported symptoms, from mild subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that likely decreases one's ability to execute daily activities and function normally in family or social roles.</li> <li>Includes the experience of fatigue (frequency, duration, and intensity) and the impact of fatigue on physical, mental, and social activities.</li> </ul> |
| <b>Recall period</b>               | Past 7 days  |
| <b>Target respondent</b>           | Adults (18+) with multiple sclerosis   |
| <b>Method of administration</b>    | Self-report  |
| <b>Number of items</b>             | 8  |
| <b>Score</b>                       | Fatigue T-score  |
| <b>Preview measure</b>             | <a href="https://www.healthmeasures.net/index.php?option=com_instruments&amp;view=measure&amp;id=8203&amp;Itemid=992">https://www.healthmeasures.net/index.php?option=com_instruments&amp;view=measure&amp;id=8203&amp;Itemid=992</a>  |

## 2.3 Physical Function Measure Details

|                                    |  |
|------------------------------------|--|
| <b>Measure name (abbreviation)</b> | PROMISnq Short Form v2.0 - Physical Function-Multiple Sclerosis 15a (PROMISnq PFMS 15a)  |
| <b>Measure content</b>             | <ul style="list-style-type: none"> <li>Measures self-reported capability rather than actual performance of physical activities.</li> <li>Includes the functioning of one's upper extremities (dexterity), lower extremities (walking or mobility), and central regions (neck, back), as well as instrumental activities of daily living, such as running errands.</li> </ul> |
| <b>Recall period</b>               | Current function (no specified recall period)  |
| <b>Target respondent</b>           | Adults (18+) with multiple sclerosis   |
| <b>Method of administration</b>    | Self-report  |
| <b>Number of items</b>             | 15   |
| <b>Score</b>                       | Physical Function T-score  |
| <b>Preview measure</b>             | <a href="https://www.healthmeasures.net/index.php?option=com_instruments&amp;view=measure&amp;id=9918&amp;Itemid=992">https://www.healthmeasures.net/index.php?option=com_instruments&amp;view=measure&amp;id=9918&amp;Itemid=992</a>  |

## 3.0 Why Use PROMIS?

Patient-Reported Outcomes Measurement Information System (PROMIS) measures can be used to monitor the outcomes of MS for both informing individual patient care and research. The family of PROMIS measures assess physical, mental, and social health. PROMIS measures offer several advantages:

### **Comprehensive Measurement**

- Appropriate for use across patient conditions, including MS, and for patients with multiple comorbidities.
- Can precisely measure patient outcomes and symptoms across the full range of severity.
- Can precisely capture change (improvement or deterioration) in symptoms and outcomes.
- Measures are scored on a common metric and can be compared to the general population.
- Scores from all measures (e.g., computer adaptive tests, short forms of varying lengths) can be directly compared.

### **Easy for Patients to Complete**

- Measures are brief:
  - PROMIS FatigueMS has 8 items.
  - PROMISnq PFMS has 15 items.
- Measures are available in multiple languages.

### **Flexible and Efficient for Office Staff**

- Measures are easy for office staff to provide to patients before and during office visits.
- Measures are integrated into and can be viewed in multiple electronic health records and assessment platforms.

## 4.0 Access Paper and Digital PROMIS MS Measures

The requirements for access and permissions for the PROMIS MS measures vary by four factors:

1. Will you administer measures on paper or in a digital platform?
2. Are you a commercial<sup>1</sup> or non-commercial<sup>2</sup> user?
3. Are you using measures in research<sup>3</sup> or for another purpose (e.g., registries, routine outcome assessment, patient care, quality measurement)?
4. Are you using measures in languages other than English?

**The answers to these questions determine what you need to do next.**

### 4.1 Paper Administration

The PROMIS MS measures in **English** are available to download in respondent-ready PDF format at [Search & View Measures](#) on [HealthMeasures.net](#). These measures may be used in **paper administration** without permission or fees if the text is not changed. This is true for commercial and non-commercial users and applies to research and other uses.



The PROMIS FatigueMS 8a and PROMISnq Physical Function 15a are available in **more than 50 languages**. They are available for paper administration in other languages via a distribution fee<sup>4</sup>. This fee covers the distribution of the measure, preparation of a license agreement, and the certification of the translation. Information on what translations are currently available can be found at [HealthMeasures.net](#) under [Available Translations](#). Contact [translations@HealthMeasures.net](mailto:translations@HealthMeasures.net) to request a translated measure or to learn more.

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<sup>1</sup> A commercial user is any company, organization, or other incorporated limited liability entity which does not fit the definition of a Tax-exempt Organization under the regulations of the United States' Internal Revenue Service or which otherwise operates under the rubric of financial profit.

<sup>2</sup> A non-commercial user is any institution, organization, or other incorporated entity which is defined as a Tax-exempt Organization under the regulations of the United States' Internal Revenue Service; for users outside the United States, all not-for-profit entities including national health services and their affiliate providers and academic institutions.

<sup>3</sup> Research includes randomized controlled trials, cohort studies, case control studies, and cross-sectional studies.

<sup>4</sup> Distribution fees can be waived in some cases, such as for individual use by students or unfunded academic investigators.



## 4.2 Digital Administration in English

To use a PROMIS MS measure in English in a digital administration platform, start by identifying the status of the measure in the platform. There are three possibilities:



| Scenario   | Description  | What to do next  |
|--|--|--|
| <p>A) The PROMIS MS measure is <b>licensed</b> for use in a digital administration platform.</p> | <ul style="list-style-type: none"> <li>PROMIS measures have been licensed for use in many digital administration platforms.</li> <li>Often they are in a patient-reported outcome measure (PROM) library (e.g., REDCap Shared Library, Epic PROMIS CAT application).</li> <li>These platforms use the <a href="#">Assessment Center API</a> or have completed the HealthMeasures Electronic Administration Permissions (HEAP) process for the measure you want to use.</li> <li>A partial list of <a href="#">digital administration platforms</a> that have licensed PROMIS measures is on the HealthMeasures website.</li> </ul> | <ul style="list-style-type: none"> <li>Check with your digital administration platform vendor to ensure you are using licensed measures. Sometimes this is obvious, but sometimes it can be unclear.               <ul style="list-style-type: none"> <li>If the PROMIS measure you want is licensed for use in a digital administration platform, you can use the measure without additional permissions or licenses from HealthMeasures.</li> <li>If the PROMIS measure isn't licensed, see scenario B.</li> </ul> </li> </ul> |
| <p>B) The PROMIS measure is in a digital administration platform <b>without</b> a license.*</p>  | <ul style="list-style-type: none"> <li>The PROMIS measure was added without using the Assessment Center API or completing the HealthMeasures Electronic Administration Permissions process.</li> <li>The measure may not be valid. It may not be accurate or be scored correctly.</li> <li>Use of the unlicensed measure violates the Terms &amp; Conditions of Use.</li> </ul>  | <ul style="list-style-type: none"> <li>You or the digital administration platform vendor need a license to use the measure.</li> <li>Contact <a href="mailto:help@healthmeasures.net">help@healthmeasures.net</a> to license the measure or contact the digital administration platform vendor to request they add the PROMIS measure.<sup>5</sup></li> </ul>  |
| <p>C) The PROMIS measure is <b>not</b> in a digital administration platform.</p>                 | <ul style="list-style-type: none"> <li>The PROMIS measure you want to use is not included in a digital administration platform.</li> </ul>   | <ul style="list-style-type: none"> <li>Contact <a href="mailto:help@healthmeasures.net">help@healthmeasures.net</a> to license the measure or contact the digital administration platform vendor to request they add the desired PROMIS measure.<sup>5</sup></li> </ul>  |

<sup>5</sup> Measures can be added to digital administration platforms through either 1) licensing the Assessment Center API or 2) completing the HealthMeasures Electronic Administration Permissions process. See section 4.5 to learn more about these options.

**\*Note!** The REDCap Shared Library includes many PROMIS measures. Only some of these are licensed.

- Licensed PROMIS measures have “auto-scoring” or “adaptive instrument” next to their name (see image). They are displayed, administered, and scored correctly. Use them!

| Title   |
|---|
| ▶ PROMIS SF v1.0 - Fatigue-Multiple Sclerosis 8a [Auto-scoring] |

- PROMIS measures without this label are unlicensed and should not be used. They may not be accurately displayed, administered, or scored.

### 4.3 Digital Administration of a Translation

- If you would like to use a translation of a PROMIS MS measure, first identify if the desired translation exists. Information on what translations are currently available can be found at HealthMeasures.net under [Available Translations](#).
- Next, identify if the desired translation is integrated into your digital administration platform.
  - If the translated PROMIS MS measure is available in a digital administration platform, please confirm with the digital administration platform or other license holder that their license covers your use case.
  - If a translated PROMIS MS measure is not licensed for use in a digital administration platform, contact [help@healthmeasures](mailto:help@healthmeasures) to license the measure or contact the digital administration platform vendor and request the translation is added. A translation can be added in two ways:
    1. License the Assessment Center API and license the desired measure in the API Translations Database.<sup>6</sup>
    2. Add the measure manually. Complete the HealthMeasures Electronic Administration Permissions (HEAP) process.<sup>7</sup>
- If the desired translation does not exist, you will need to work with the HealthMeasures team that coordinates all translations. New translations require a letter of permission, use of a specific translation methodology, and quality and harmonization review. There are fees for these services.
- Contact [translations@HealthMeasures.net](mailto:translations@HealthMeasures.net) to request a translated measure or to learn more.



<sup>6</sup> Spanish measures are included in the Assessment Center API. Consequently, the API Translations Database is not needed for Spanish measures.

<sup>7</sup> For single, time-limited research studies conducted by non-commercial users, the HealthMeasures Electronic Administration Permissions process is not required. However, it is recommended to ensure your implementation of the measure retains validity.

## 4.4 Epic PROMIS CAT Application

The Epic PROMIS CAT Application can be used for registries, routine outcome assessment, patient care, quality measurement, and more.

### Overview

- Epic, an electronic health record used by many healthcare organizations, provides access to PROMIS measures through the PROMIS CAT Application. Measures are frequently used within Epic to inform individual patient care and as part of performance measures assessing care quality.
- The PROMIS CAT Application is natively embedded into Epic and available through Epic's Showroom.
- It includes automated response pattern scoring (preferred), score labels, and clinical severity levels.
- Patients can access measures via MyChart and the MyChart smartphone app.
- Clinic staff can use Hyperspace to access a measure to be completed by a patient without requiring MyChart login.
- Epic provides end-to-end workflows for the deployment, collection, review, and analysis of patient-reported outcome measures.
- Measures can be assigned to patients ad hoc or in a planned, automated manner.
- Clinicians can review an individual's responses over time in the patient's chart.
- Scores can be trended in a synopsis view along with other clinical data.
- Individual responses can be viewed.
- Red-flag questionnaire responses, such as a positive response to suicidal ideation, can be set up to trigger real-time notifications to appropriate resources like a crisis intervention team. MyChart can also provide real-time guidance such as instructing patients to call 911 if responses necessitate immediate medical attention.
- Measure scores can be aggregated across patients in conjunction with clinical information, providing a rich database for analysis.
- The PROMIS CAT Application is licensed by Epic.
- Contact your local Epic MyChart Technical Services (TS) point-person to learn if your organization uses the PROMIS CAT application and to request access to the PROMIS MS measures.

*If you would like to use measures in Epic's Foundation system without a PROMIS CAT Application license, the HealthMeasures Electronic Administration Permissions (HEAP) process is required.*

## 4.5 Comparing the Assessment Center API and HealthMeasures Electronic Administration Permissions for Adding Measures to Digital Platforms

If you want to add a PROMIS measure to a digital platform you (or your digital administration platform vendor) will need to either use the Assessment Center API or the HealthMeasures Electronic Administration Permissions process. Each has unique features, advantages, disadvantages, and costs. The table below includes details on each option.

|                    | Assessment Center API  | HealthMeasures Electronic Administration Permissions (HEAP)  |
|--------------------|--|--|
| Description        | <ul style="list-style-type: none"> <li>• Software solution that provides unlimited access to 1,000+ measures in English and Spanish across all domains and age groups.</li> <li>• Encapsulated software component that is easily integrated into existing data collection software systems.</li> <li>• Does not include any display functionality and is not intended for use as a standalone application.</li> <li>• API Translations Database offers access to additional translations.</li> </ul> | <ul style="list-style-type: none"> <li>• À la carte solution for organizations that have an existing ePRO system and want to use a limited number of measures.</li> <li>• Individual measures are downloaded from HealthMeasures.net in PDF format and manually entered in ePRO platform.</li> <li>• Display, scoring, and interpretation must be managed in the ePRO system.</li> </ul> |
| Available measures | <ul style="list-style-type: none"> <li>• All PROMIS measures including computer adaptive tests (CATs), short forms, profiles, and custom measures in English and Spanish.</li> <li>• Additional translations available via the API Translations Database.</li> <li>• Other high-quality PROMs (e.g., Neuro-QoL, NIH Toolbox, TBI-QoL, SCI-QoL)</li> </ul>  | <ul style="list-style-type: none"> <li>• Only non-adaptive measures (e.g., short forms, profiles, custom measures).</li> <li>• Can be utilized for English and translations.</li> </ul>  |

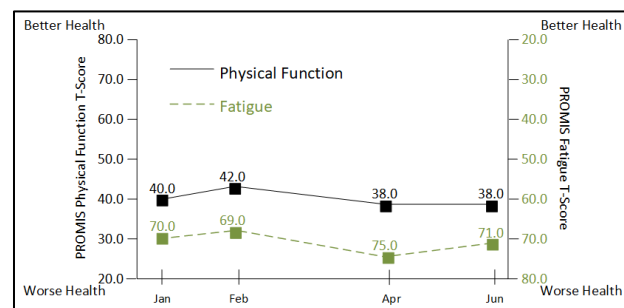
|                            | <b>Assessment Center API</b>   | <b>HealthMeasures Electronic Administration Permissions (HEAP)</b>   |
|----------------------------|--|--|
| Scoring                    | <ul style="list-style-type: none"> <li>• Automatic</li> <li>• High-precision scoring of measures (i.e., response pattern scoring)</li> </ul>   | <ul style="list-style-type: none"> <li>• Not automatic</li> <li>• Requires use of HealthMeasures Scoring Service (preferred) or raw sum to T-score conversion table. Note that conversion tables do not allow missing data and scoring is less precise.</li> </ul> |
| Validity of Administration | <ul style="list-style-type: none"> <li>• Ensures digital implementation of measures retains validity.</li> </ul>   | <ul style="list-style-type: none"> <li>• Ensures digital implementation of measures retains validity.</li> </ul>   |
| Advantages                 | <ul style="list-style-type: none"> <li>• Access to new and revised measures.</li> <li>• Scores assigned meaningful labels to aid with interpretation (e.g., mild, moderate, severe).</li> <li>• Updated semi-annually.</li> </ul>  | <ul style="list-style-type: none"> <li>• Can be cost-effective when implementing limited number of measures.</li> <li>• Can serve as a starting point to gain familiarity with measures.</li> </ul>  |
| Disadvantages              | <ul style="list-style-type: none"> <li>• Requires information technology (IT) support for installation.</li> </ul>   | <ul style="list-style-type: none"> <li>• Manual scoring and missing data may be handled differently.</li> <li>• Requires programming of measure and scoring.</li> <li>• Additional fees for translations.</li> </ul>   |
| Costs                      | <ul style="list-style-type: none"> <li>• Free sandbox access during development and testing (non-patient only).</li> <li>• Software license with flat fee for access to English and Spanish measures. Single-institution, distributor (vendor), and Translations Database licenses are available.</li> </ul> | <ul style="list-style-type: none"> <li>• Fee per measure for review.</li> </ul>  |

## 5.0 Implementation in Digital Administration Platforms



### 5.1 Guidance for Information Technology Team

1. Determine PROMIS measure(s) to administer.
  - Note that acronyms are regularly used for PROMIS measures in administration platforms.
    - SF = short form
    - MS = Multiple Sclerosis
  
2. Define contextual variables and how they will be collected.
  - Identify variables (e.g., age) needed to facilitate interpretation in clinic or enable desired analyses.
  - Identify if data can be extracted from a given digital platform (e.g., electronic health record) or if patient-report is needed.
  - Capture the date of the assessment in order to report trends or conduct analyses.
  
3. Define assessment time intervals and triggers.
  - Program assessment window (e.g., 1 week before a medical visit to end of medical visit date).
  - Plan reminders (e.g., 2 days before visit).
  - Program follow-up assessments. Can be:
    - i. Triggered by an event (e.g., medical appointment) or
    - ii. Fixed calendar schedule (e.g., every 3 months).
  - Program reminder emails for multiple contacts to increase patient response rate.
  
4. Define scoring algorithms and report criteria.
  - Identify if you will use native scoring (e.g., using Assessment Center API) or manual scoring (see [Calculate Scores](#) section).
  - Determine if a report of scores is needed (e.g., using measure for individual patient care). If so:
    - i. Determine report content. Identify if need to enable reporting of scores and dates over time (trends). Determine if graph is needed and feasible (see example figure).
    - ii. Determine report location in digital platform. Make access easy.
  
5. If using electronic health record, enable assessment at the visit.
  - Apply criteria for home-based assessment for use when in the clinic setting.
  - Select hardware (e.g., tablets, kiosks, patient screens on exam room computers).



### 5.1.1 Correct Appearance of Items

PROMIS measures have requirements for how they appear to the respondent. This helps support administration that is consistent with how the measures were developed, tested, and validated.

- The PDF versions of PROMIS measures from [Search & View Measures](#) on [HealthMeasures.net](#) meet these requirements.
- PROMIS measures that are already part of digital administration platforms (e.g., REDCap Shared Library auto-scored/adaptive instrument, Epic PROMIS CAT Application) typically also meet these requirements.
- If you are integrating PROMIS measures into a digital administration platform, please contact [Help@HealthMeasures.net](mailto:Help@HealthMeasures.net) to learn more about how items should appear and how to have your implementation approved.

### 5.1.2 Report Scores

T-scores and associated Standard Errors should be reported as integers. Additional decimal places may be retained in interim computations, but the reported value should be rounded to an integer to maintain the appropriate level of significant figures.

Example:

PROMIS Fatigue T=61 (SE=2)

### 5.1.3 Create Management Reports for Clinical Care

When PROMIS MS measures are used in individual patient care, reports targeting specific teams can aid with assessment and interpretation.

1. Reports for staff:
  - List of incomplete pre-visit assessments daily for each clinic to guide in-office PROMIS assessment.
  - List of incomplete follow-up assessments to identify patients requiring reminders to complete the assessment.
2. Reports for clinical management:
  - Dashboard of completion rates (by clinic, clinician, or other meaningful groups).
  - Descriptive statistics of aggregate PROMIS measure completers vs. non-completers by assessment (e.g., pre-procedure, 7 days post-procedure).
3. Reports for clinicians:
  - Score descriptors (e.g., within normal limits, mild, moderate, severe) and trajectories for all patients and meaningful patient subgroups.

## 5.2 Guidance for Clinic Staff



When PROMIS MS measures are collected in a clinical care setting, the assessment should be integrated into routine office procedures with clear staff accountability.

### 5.2.1 Before the Office/Virtual Visit

**Integrate PROMIS measures into pre-visit procedures already in place.**

- Enable patients to complete PROMIS measures, preferably electronically, before the office/virtual visit. Maximizing complete assessments prior to the visit minimizes disruption in the office.
- Include a letter from the patient's physician with the electronic (or mail) invitation to encourage patients to complete the assessment prior to the visit.
- Provide a script to staff explaining the value of PROMIS measures to patient care decisions.

**Reliance on patients to log into the patient portal to complete an assessment is insufficient.**

- Not all patients maintain portal accounts.
- Many patients will require technical assistance (e.g., need to retrieve a lost password).
- Greatest success is achieved through multi-modal strategies to collect PROMIS measures:
  - Before the clinic visit,
  - In clinic, and
  - After clinic using reminders and phone prompts as needed.

### 5.2.2 At the Office Visit

**Enable assessment in the clinical visit—either in the waiting room or exam room—for those patients who do not complete the PROMIS measures from home.**

- Work with IT to generate a list of patients with that day's visits who did **not** complete the assessment beforehand.
- Determine which front-line staff member will ensure PROMIS measures are completed and data are available for review in the visit.
- Determine where and how patients will complete measures (e.g., kiosk in waiting room, tablet in exam room). Establish a disinfection protocol for shared devices.
- Enable easy access to PROMIS scores for the clinical team to facilitate use during the office visit, such as opening the EHR view to the results when rooming the patient.
- Repeat these procedures for each visit to monitor PROMIS score change over time.



### 5.2.3 After the Office Visit

**Implement a workflow that is independent of a clinic/virtual visit to collect PROMIS measures at routine follow-up intervals.**

- Define guidelines regarding the time interval appropriate for the post-visit assessment, as well as administration platform to be used (e.g., repeat EHR patient portal messages).
- Collaborate with IT to generate a list of patients due for a PROMIS follow-up assessment within the desired time interval.
- Consider multi-modal methods to collect the follow-up PROMIS measures, including during a post-treatment visit, through the patient portal, or via a personal phone call.
- Include a clinician message in the request so patients understand that PROMIS measures are important to their follow-up clinical care.
- Identify staff responsible for follow-up PROMIS collection.

### 5.2.4 Best Practices in Administration

- PROMIS FatigueMS 8a and PROMISnq PFMS 15a are intended to be completed by the respondent without help from anyone else.
- If respondents are unable to answer on their own, have someone else (“proxy”) report on their behalf. Respondents requiring a proxy may include people in the early stages of dementia who may not recognize the extent of their impairment, people with cognitive or communication deficits, and people with severe disease burden.
- Use the same proxy across multiple assessments. Different proxies may have different perspectives.
- If measures must be administered by an interviewer, the items and responses should be read verbatim.
- Keep respondents’ privacy in mind but have staff readily available to help with any technology issues that may arise.
- It is acceptable for staff to define a term (e.g., “uneven”), but not to define a concept where the respondent’s subjective interpretation is the goal of the question (e.g., “quality of life”).
- Respondents should be instructed to answer all items to the best of their ability. For a respondent who indicates the item asks about an activity they don’t do, instruct them to consider what that activity would be like, and imagine or predict how it would be for them. For example, for the item “Are you able to carry a laundry basket up a flight of stairs?” imagine the upper body strength, dexterity, coordination, balance, and stamina needed to carry a laundry basket up about 15 steps and evaluate to what degree they have that level of function. Respondents should always have the opportunity to skip an item, if needed, as well.
- Utilize the same method (e.g., computer, telephone, or paper) and mode (e.g., self vs. interviewer) of administration. However, this is not always possible, and PROMIS measures have produced similar scores when the method of administration varied.
- In clinical settings, give respondents the optimal time needed to capture the most relevant perspective and complete data (e.g., before/after clinician visit or in between visits). This may depend on the study aims and/or clinic workflow.



## 6.0 Calculate Scores

### 6.1 Handling Missing Data

#### 6.1.1 Form-level Missing Data

Form-level missing data refers to a respondent missing an entire PROMIS assessment for a given time point. In general, form-level data may be missing due to a respondent's early withdrawal from a study, forgetting to complete an individual assessment, or the inability to evaluate an endpoint at a particular time point. Computing a score (i.e., imputation) is not recommended for either the PROMIS FatigueMS 8a or the PROMISnq PFMS 15a for that time point.

#### 6.1.2 Item-level Missing Data

Administrators may decide to allow respondents to skip individual items within a PROMIS short form. If respondents are allowed to skip items, missing data at the item level may be present. Based on missing data simulation analyses, **at least 4 items must be answered to produce a score.** Only response pattern scoring (see Response Pattern Scoring section) should be used when there is item-level missing data. If 3 or fewer items are answered, the entire form is considered missing.

### 6.2 Handling Multiple Responses on a Paper Form

- If a respondent marks two or more responses to one item and the responses are next to one another, then a data entry specialist should randomly select one of the marked responses to use. The data entry specialist should record on the form which answer was selected.
  - To randomly select one of two responses, flip a coin. If heads, select the higher response score. If tails, select the lower response score.
  - To randomly select one of three (or more) responses, use a table of random numbers with a statistician's assistance.
- If a respondent marks two or more responses to one item and the responses are NOT all next to one another, consider the response missing.

### 6.3 Score Translations

Translations of the PROMIS MS short forms use the same scoring as the English measures. Following the same instructions for response pattern scoring or using the raw summed score to T-score conversion tables.

## 6.4 Preferred Scoring Instructions – Response Pattern Scoring

### 6.4.1 Description

PROMIS MS measures are scored using item-level calibrations. This means that the most accurate way to score a PROMIS MS short form is to use the HealthMeasures Scoring Service ([https://www.assessmentcenter.net/ac\\_scoring-service](https://www.assessmentcenter.net/ac_scoring-service)), the Assessment Center API, or an administration platform that automatically calculates scores (e.g., REDCap auto-score). This method of scoring uses responses to each item for each participant. We refer to this as “response pattern scoring.” **Because response pattern scoring is more precise than the use of raw summed score/scale score look up tables, it is preferred.** Response pattern scoring is especially useful when:

- There is item-level missing data (i.e., a respondent skipped an item).
- Different groups of participants responded to different items from the same calibrated measure (e.g., item bank).

### 6.4.2 Minimum Responses

Platforms that use response pattern scoring can produce a T-score for a respondent as long as 1 item has been answered. However, to produce a **precise** score using response pattern scoring, a respondent must answer at least 4 items in a PROMIS MS short form. If fewer than 4 items have been answered, the resulting T-score may not be sufficiently precise. Depending on how the score will be used, you may want to discard the score or proceed with caution.

### 6.4.3 Response Pattern Scoring within an Administration Platform

Multiple administration platforms (e.g., REDCap Shared Library auto-scored, Epic PROMIS CAT Application) automatically use response pattern scoring with PROMIS MS measures. Use the calculated T-score and Standard Error.

### 6.4.4 Response Pattern Scoring via the HealthMeasures Scoring Service

The [HealthMeasures Scoring Service](#) is a free, web-based application that scores a de-identified .csv file of raw participant responses and returns (by email) a file with calculated T-scores and standard errors.

#### Instructions

1. Download the Input Template from the HealthMeasures Scoring Service home page.
2. Add your data (all respondents’ individual answers to questions) for one PROMIS measure to the [Input Template](#) (multiple timepoints are okay).
3. Determine how much data is missing. To produce a precise score, a respondent must answer at least 4 items in the PROMIS MS measures. If a precise score is required, remove respondents who answered less than 4 items from the input template and do not calculate their T-scores.
4. Upload your input data (saved as a .csv file) to the HealthMeasures Scoring Service. If this is your first time, register as a new user.
5. Access your email to receive an output spreadsheet with calculated scores.

### 6.4.5 Response Pattern Scoring via the Assessment Center API

The [Assessment Center API](#) is a licensed web service that uses response-pattern scoring. It is installed on your desired server. It is especially useful when:

- You want your data to remain behind your firewall.
- You administered a short form, but not all participants answered every question.
- Different groups of participants responded to different items.

#### How it Works

The API can be hosted on a statistician's computer and called as a web service from the desired statistical package for scoring.

- SAS has [Proc SOAP](#) to allow the calling of a web service, which can also be hosted within the SAS environment.
- R can use the [httr](#) library to call a web service. SPSS Modeler can call a web service via CLEF.
- STATA and other software packages have similar capabilities.

## 6.5 Manual Scoring Instructions – Convert Raw Summed Scores to T-scores with Tables

When response-pattern scoring is not available, you can calculate a T-score by summing the responses to all items in a short form and using a conversion table to find the corresponding T-score.

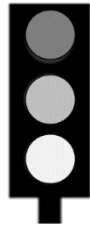
1. To use the scoring tables in this guide, calculate a summed score. Each question has five response options ranging in value from one to five. To find the total raw summed score for a short form with all questions answered, sum the values of the responses to each question.
  - For example, for the PROMIS FatigueMS 8a, the lowest possible raw summed score is 8; the highest possible raw summed score is 40.
  - **All questions must be answered in order to produce a valid T-score using the scoring tables.** If a participant has skipped a question, use the HealthMeasures Scoring Service or Assessment Center API to generate a final T-score.
2. Locate the applicable raw sum to T-score conversion table below. Find your total raw summed score in the first column. Use the second column to translate the total raw summed score into a T-score for each participant.
  - The T-score rescales the raw summed score into a standardized score (a T-score) with a mean of 50 and a standard deviation (SD) of 10. Therefore, a person with a T-score of 40 is one SD below the mean.

**Example:** For the adult PROMIS FatigueMS 8a short form, a raw summed score of 20 converts to a T-score of 54.1 with a standard error (SE) of 2.0. Thus, the 95% confidence interval around the observed score ranges from 50.2 to 58.0 (T-score  $\pm$  (1.96\*SE) or 54.1  $\pm$  (1.96\*2.0)).

| <b>PROMIS Adult Short Form v1.0 -<br/>Fatigue–Multiple Sclerosis 8a</b> |                |            |
|---|----------------|------------|
| <i>Short Form Conversion Table</i>                                      |                |            |
| <b>Raw Summed<br/>Score</b>   | <b>T-Score</b> | <b>SE*</b> |
| 8   | 34.1           | 5.0        |
| 9   | 39.3           | 3.1        |
| 10  | 41.8           | 2.6        |
| 11  | 43.6           | 2.3        |
| 12  | 45.1           | 2.1        |
| 13  | 46.4           | 2.1        |
| 14  | 47.6           | 2.0        |
| 15  | 48.7           | 2.0        |
| 16  | 49.8           | 2.0        |
| 17  | 50.9           | 2.0        |
| 18  | 52.0           | 2.0        |
| 19  | 53.0           | 2.0        |
| 20  | 54.1           | 2.0        |
| 21  | 55.1           | 2.0        |
| 22  | 56.2           | 2.0        |
| 23  | 57.3           | 2.0        |
| 24  | 58.3           | 2.0        |
| 25  | 59.3           | 2.0        |
| 26  | 60.4           | 2.0        |
| 27  | 61.5           | 2.0        |
| 28  | 62.5           | 2.0        |
| 29  | 63.6           | 2.0        |
| 30  | 64.7           | 2.0        |
| 31  | 65.8           | 2.0        |
| 32  | 66.9           | 2.0        |
| 33  | 68.1           | 2.0        |
| 34  | 69.3           | 2.0        |
| 35  | 70.5           | 2.1        |
| 36  | 71.9           | 2.1        |
| 37  | 73.4           | 2.3        |
| 38  | 75.1           | 2.5        |
| 39  | 77.5           | 3.0        |
| 40  | 80.9           | 3.9        |
| SE = Standard Error on T-score metric                                   |                |            |

| <b>PROMIS<sub>nq</sub> Adult Short Form v2.0 -<br/>           Physical Function–Multiple Sclerosis 15a</b><br><i>Short Form Conversion Table</i> |                |            |                         |                |            |
|--|----------------|------------|-------------------------|----------------|------------|
| <b>Raw Summed Score</b>  | <b>T-Score</b> | <b>SE*</b> | <b>Raw Summed Score</b> | <b>T-Score</b> | <b>SE*</b> |
| 15   | 14.7           | 2.6        | 46                      | 37.7           | 1.4        |
| 16   | 16.8           | 2.5        | 47                      | 38.2           | 1.4        |
| 17   | 18.6           | 2.4        | 48                      | 38.6           | 1.4        |
| 18   | 19.9           | 2.2        | 49                      | 39.1           | 1.4        |
| 19   | 21.1           | 2.1        | 50                      | 39.6           | 1.4        |
| 20   | 22.2           | 2.0        | 51                      | 40.0           | 1.4        |
| 21   | 23.2           | 2.0        | 52                      | 40.5           | 1.4        |
| 22   | 24.0           | 1.9        | 53                      | 41.0           | 1.4        |
| 23   | 24.9           | 1.9        | 54                      | 41.4           | 1.4        |
| 24   | 25.7           | 1.8        | 55                      | 41.9           | 1.4        |
| 25   | 26.4           | 1.8        | 56                      | 42.4           | 1.5        |
| 26   | 27.1           | 1.8        | 57                      | 42.9           | 1.5        |
| 27   | 27.8           | 1.8        | 58                      | 43.5           | 1.5        |
| 28   | 28.5           | 1.7        | 59                      | 44.0           | 1.5        |
| 29   | 29.1           | 1.7        | 60                      | 44.5           | 1.5        |
| 30   | 29.7           | 1.7        | 61                      | 45.1           | 1.6        |
| 31   | 30.3           | 1.6        | 62                      | 45.7           | 1.6        |
| 32   | 30.9           | 1.6        | 63                      | 46.3           | 1.6        |
| 33   | 31.4           | 1.6        | 64                      | 47.0           | 1.7        |
| 34   | 32.0           | 1.5        | 65                      | 47.6           | 1.7        |
| 35   | 32.5           | 1.5        | 66                      | 48.3           | 1.7        |
| 36   | 33.0           | 1.5        | 67                      | 49.1           | 1.8        |
| 37   | 33.5           | 1.5        | 68                      | 49.9           | 1.9        |
| 38   | 34.0           | 1.5        | 69                      | 50.8           | 2.0        |
| 39   | 34.5           | 1.5        | 70                      | 51.8           | 2.1        |
| 40   | 35.0           | 1.4        | 71                      | 53.0           | 2.4        |
| 41   | 35.4           | 1.4        | 72                      | 54.3           | 2.6        |
| 42   | 35.9           | 1.4        | 73                      | 56.1           | 3.1        |
| 43   | 36.4           | 1.4        | 74                      | 58.1           | 3.4        |
| 44   | 36.8           | 1.4        | 75                      | 63.6           | 5.4        |
| 45   | 37.3           | 1.4        |                         |                |            |

\*SE = Standard Error on T-score metric



## 7.0 Interpret Scores

### 7.1 T-score

The PROMIS MS measures use T-scores. A T-score is a standardized score, like z-scores and IQ scores. All standardized scores have a “middle” score; it is zero for z-scores, 100 for IQ scores, and 50 for T-scores. This middle score is the mean of a large group of people. This group is known as the **reference population**. T-scores have a standard deviation (SD) of 10. Consequently, if a respondent produces a score of 60, that is one SD higher than the mean.

### 7.2 Standard Error

The PROMIS MS measures also produce a standard error (SE) associated with a given respondent’s T-score. The Standard Error is a statistical measure of variance or precision; it represents the “margin of error” for the T-score.

An SE can be used to estimate precision by calculating confidence intervals around a T-score. A 95% confidence interval means there is a 95% probability that the true T-score is within this range. The formula for a 95% confidence interval is  $T\text{-score} \pm (1.96 * SE)$ .

### 7.3 Direction of Scores (Higher Scores = More)

A higher PROMIS T-score represents MORE of the concept being measured.



- For negatively worded concepts like Fatigue, higher scores represent *worse* health.
  - A T-score of 60 is one SD worse (more fatigue) than average.
  - A T-score of 40 is one SD better than average.

More Fatigue



Less Fatigue



- For positively worded concepts like Physical Function, higher scores represent *better* health.
  - A T-score of 60 is one SD better (more physical function) than average.
  - A T-score of 40 is one SD worse than average.

More Physical Function



Less Physical Function



## 7.4 Score Range

For both the PROMIS FatigueMS 8a and PROMISnq PFMS 15a, the T-score range is generally 20 – 80.

## 7.5 Reference Population

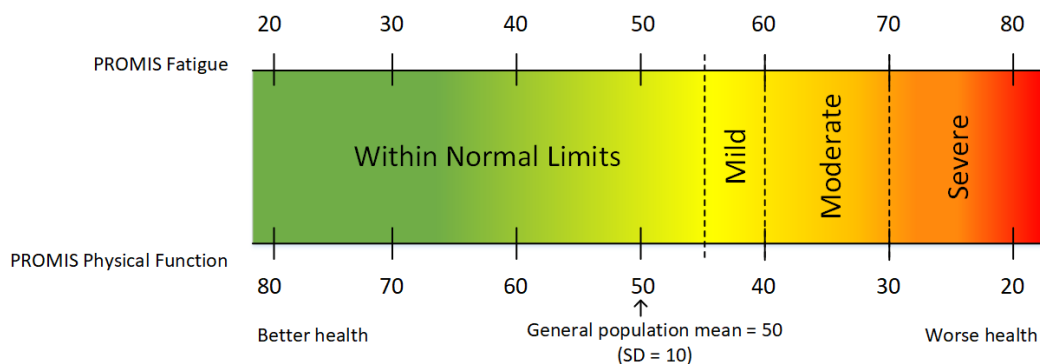
A PROMIS score of 50 is the mean score for a specific, relevant group of people (e.g., the general population). That group is the **reference population**. For both the PROMIS FatigueMS 8a and PROMISnq PFMS 15a, the reference population is the general population.

## 7.6 Reliability

Reliability is the degree to which a measure is free of error. For item response theory-based scaled scores like PROMIS, reliability =  $1 - SE^2$  using SEs on the theta metric (i.e., the T-score SE divided by 10). IRT-based reliability varies across the measurement continuum. That is, a measure may have much higher reliability for some score ranges (e.g., near the mean) compared to other score ranges (e.g., extreme ends of the continuum such as +/- 2 SDs from the mean).

## 7.7 Score Cut Points

PROMIS MS measure scores can be divided into the categories of Within Normal Limits, Mild, Moderate, and Severe. Below in the figure and table are general guidelines for interpreting scores.



| Measure                        | Within Normal Limits | Mild    | Moderate | Severe |
|--------------------------------|----------------------|---------|----------|--------|
| PROMIS FatigueMS 8a            | ≤55                  | 56 – 60 | 61 – 70  | ≥71    |
| PROMISnq Physical Function 15a | ≥45                  | 40 – 44 | 30 – 39  | ≤29    |

Cut points may be refined over time as additional research with the PROMIS MS measures is published.

## 7.8 Comparing Scores

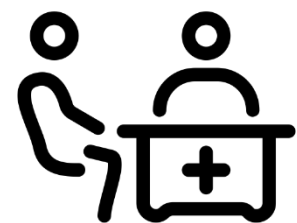
- The PROMIS FatigueMS 8a short form includes items from the PROMIS Fatigue Item Bank v1.0. This means that scores from the PROMIS FatigueMS 8a are comparable with other measures derived from the same item bank. This includes other PROMIS Fatigue short forms and computer adaptive tests.
- The PROMISnq PFMS 15a short form includes items from the PROMIS Physical Function Item Bank v2.0 plus two items from the Neuro-QoL Mobility Item Bank. The Neuro-QoL items were psychometrically linked so that the PROMISnq PFMS 15a's score is on the PROMIS Physical Function metric. Consequently, the PROMISnq PFMS 15a's score can be compared to other short forms and computer adaptive tests derived from the PROMIS Physical Function item bank v2.0. It can also be compared with earlier versions of PROMIS Physical Function measures (i.e., v1.0, v1.1, v1.2).

## 7.9 Change Scores

- A change in scores over time indicates improvement or decline in symptoms or function.
- There is no one single value that reflects meaningful change for all PROMIS measures, for all respondents, and for all purposes. Selecting a value requires using your judgement.
- In general, defining a change of 3 to 6 T-score points on a PROMIS measure as important is reasonable when evaluating within-group change or making between-group comparisons, (Terwee et al., 2021).
- When evaluating change in scores for an individual patient, a change of 5 to 8 T-score points is reasonable. Evidence from Kamudoni et al (2021, 2022) suggests it is possible that individual changes as low as 3 to 4 T-score points on the PROMIS FatigueMS 8a and PROMISnq PFMS 15a may be meaningful.

## 7.10 Discussing PROMIS MS Measure Scores with an Individual Patient

- Reviewing scores can inform where to start a clinical interview.
  - E.g., “It looks like your fatigue is significant these days. Tell me about that.”
- An interview can aid in interpreting PROMIS scores for baseline status and change over time.
- Integrate PROMIS scores in the context of other clinical factors.
  - Many other factors can influence fatigue and physical function scores. Consider a patient's unique history and how this is contributing.



## 8.0 Publishing PROMIS Data

A Publication Checklist should be used when writing about PROMIS measures in publications and presentations. Checklist categories include measure details, administration, scoring, and reporting. The checklist is available on HealthMeasures.net at [Publication Checklist](#) as well as in Hanmer et al., 2020.



### 8.1 Reporting Scores

T-scores and associated Standard Errors should be reported as integers. Additional decimal places may be retained in interim computations, but the reported value should be rounded to an integer to maintain the appropriate level of significant figures.

## 9.0 PROMIS MS Measure Development

### 9.1 Development of PROMISnq PFMS 15a

The measure was developed using a multi-step mixed methods approach that included:

1. Literature review.
2. Concept elicitation interviews with individuals with MS to understand functional limitations.
3. Mapped concepts to items in the PROMIS Physical Function item bank.
4. Clinicians reviewed and reduced candidate item pool based on relevance.
5. Measure experts and a patient partner further reduced candidate item pool based on qualitative and quantitative data and content coverage.
6. Cognitive interviews were conducted with new sample of people with MS to evaluate relevance, comprehensiveness, and comprehensibility of the draft measure.
7. The measure was tested via a survey of people with MS in the UK and the US. Testing evaluated unidimensionality, floor and ceiling effects, test-retest reliability, construct validity via known groups validity, convergent validity, sensitivity to change/responsiveness, and estimation of minimal important difference thresholds.
8. Measure experts made final item selection based on all data with an aim to cover the full continuum of physical function, have minimal overlap between items, and retain content validity.

#### 9.1.1 Source of Items

- 12 items from PROMIS Physical Function Item Bank v2.0
- 2 items from Neuro-QoL Mobility Item Bank
- 1 new item

The measure is named “PROMISnq” to reflect the inclusion of PROMIS and Neuro-QoL items.

#### 9.1.2 Item Content

- Carrying a laundry basket upstairs
- Balance while standing
- Getting up from the floor
- Holding a plate of food
- Dressing oneself
- Running errands and shopping
- Pushing open a heavy door
- Exercising hard
- Walking with a heavy backpack
- Hiking for miles on uneven surfaces or hills
- Climbing stairs
- Moderate housework
- Vigorous activities
- Walking on uneven surfaces
- Standing from a low, seated position

### 9.1.3 Score

- PROMIS and Neuro-QoL item banks were psychometrically linked using an item response theory fixed parameter approach.
- Measure produces one Physical Function T-score on the PROMIS metric.

### 9.1.4 Primary Reference for Measure

Kamudoni P, Amtmann D, Johns J, Cook KF, Salem R, Salek S, Raab J, Middleton R, Repovic P, Alschuler KN, von Geldern G, Wundes A, Barrett A, Olayinka-Amao O, Henke C. The validity, responsiveness, and score interpretation of the PROMIS<sub>nf</sub> Physical Function - Multiple Sclerosis 15a short form in multiple sclerosis. *Mult Scler Relat Disord*. 2022 Jun;62:103753. doi: 10.1016/j.msard.2022.103753. Epub 2022 Mar 21. PMID: 35598408.

## 9.2 Development of PROMIS FatigueMS 8a

The PROMIS FatigueMS 8a was developed using a multi-step mixed methods approach that included:

1. Experts (i.e., clinicians and measurement scientists) reviewed the PROMIS Fatigue item bank and reduced the candidate item pool based on item wording, response options, and duplicative content.
2. Clinicians reviewed and rank ordered items based on relevance to MS further reducing the candidate item pool.
3. Patients reviewed and rank ordered items based on relevance to their experience with MS.
4. Final items were selected based on rankings by people with MS and clinicians, item performance, and representativeness of the full content of the PROMIS Fatigue item bank.
5. Cognitive interviews were conducted with new sample of people with MS to evaluate appropriateness, comprehensiveness, and comprehensibility of the draft measure.
6. The measure was tested via a) a survey of people with MS in the UK (Kamudoni et al 2021) and b) the Fatigue Development Study (Cook et al 2012). Testing evaluated floor and ceiling effects, inter-item consistency, test-retest reliability, convergent validity, construct validity via known groups validity, sensitivity to change, and estimation of within-person meaningful change thresholds.

### 9.2.1 Source of Items

- 8 items from PROMIS Fatigue Item Bank v1.0

### 9.2.2 Item Content

- Feeling too tired to think clearly
- Feeling too tired to enjoy life
- Getting tired easily
- Feeling tired without cause
- Trouble finishing things because of fatigue
- Having to push oneself to get things done because of fatigue
- Fatigue interfering with social activities
- Fatigue interfering with physical functioning

### 9.2.3 Score

- Measure produces one Fatigue T-score

### 9.2.4 Primary Reference for Measure

Kamudoni P, Johns J, Cook KF, Salem R, Salek S, Raab J, Middleton R, Henke C, Repovic P, Alschuler K, von Geldern G, Wundes A, Amtmann D. Standardizing fatigue measurement in multiple sclerosis: the validity, responsiveness and score interpretation of the PROMIS SF v1.0 - Fatigue (MS) 8a. *Mult Scler Relat Disord*. 2021 Sep;54:103117. doi: 10.1016/j.msard.2021.103117. Epub 2021 Jun 29. PMID: 34256350.

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Franklin PD, Bond CP, Rothrock NE, Cella D. Strategies for effective implementation of patient-reported outcome measures in arthroplasty practice. *J Bone Joint Surg Am*. 2021 Jun. doi: 10.2106/JBJS.20.02072. [PMID: 34143757](https://pubmed.ncbi.nlm.nih.gov/34143757/).

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