

The Patient Reported Outcome Measurement Information System (PROMIS®) Sexual Function-Multiple Sclerosis (SexFS-MS) Users Guide

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Copyright Statement and Users' Agreement

The PROMIS® SexFS-MS uses subsets of the PROMIS Sexual Function item banks that are copyrighted by the PROMIS Health Organization. Northwestern University gives access to PROMIS Instruments subject to Terms of Use (available here: <https://www.healthmeasures.net/explore-measurement-systems/promis/obtain-administermeasures>). PROMIS SexFS-MS is also copyrighted by the University of Washington, but the instrument use is guided by the PROMIS Terms of Use. If you have questions about the use of PROMIS SexFS contact the PROMIS Health Organization at <https://www.healthmeasures.net/>. The development of PROMIS SexFS-MS was supported by grant funding by the National Multiple Sclerosis Society (Grant#PP-1803-30527).

Questions about the PROMIS SexFS-MS Instruments

If you have questions about the PROMIS SexFS-MS instruments or their use in clinical care or research, please contact the University of Washington Center on Outcomes Research in Rehabilitation (UWCORR).

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Overview of the PROMIS SexFS-MS

The Patient Reported Outcome Measurement Information System (PROMIS) sexual function (SexFS) v2.0 measures 16 domains of sexual function. There are 11 gender non-specific domains (interest in sexual activity, orgasm ability, orgasm pleasure, oral dryness, oral discomfort, satisfaction, sexual activities, therapeutic aids, bother, interfering factors, anal discomfort), 4 female-specific domains (lubrication, vaginal discomfort, clitoral discomfort, labial discomfort), and 1 male-specific domain (erectile function). While most of these domains can be scored, some domains consist of unscored individual items which can be included as stand-alone questions in a survey. The SexFS was developed using Item Response Theory, which allows for computer adaptive testing and custom short forms. SexFS was developed for use in any population and provides US population norms. Additional information about the PROMIS SexFS can be found in the user guide (search for the Measure Name “PROMIS Sex Function and Satisfaction v2.0 Profile” at <https://www.healthmeasures.net/search-view-measures>). There is also an introductory video about the PROMIS Sexual Function and Satisfaction measures that explains their development and use (https://youtu.be/CQwo_2GIaJA). Further information can be found in the following publications: (1) Weinfurt KP, Lin L, Bruner DW, et al. Development and Initial Validation of the PROMIS® Sexual Function and Satisfaction Measures Version 2.0. *J Sex Med* 2015; 12: 1961-1974; and (2) Flynn KE, Reeve BB, Lin L, et al. Construct validity of the PROMIS® sexual function and satisfaction measures in patients with cancer. *Health Qual Life Outcomes* 2013; 11: 40.

While a large sample of healthy people and people with health conditions were involved in the development of PROMIS SexFS, important MS-specific problems (e.g., genital numbness, fatigue, spasticity) were not included. Therefore, using the results of a qualitative research study that involved both people living with MS and clinicians who treat people with MS we modified the SexFS full and brief profiles to include topics most relevant to people with MS. We also included additional items so that the new SexFS-MS profiles cover aspects of sexual function most important to people with MS.

The SexFS-MS was developed with input from clinicians and sexually active individuals with MS. Development activities were completed in two phases. Phase 1 included ranking exercises completed by clinicians and individuals with MS. Phase 2 included cognitive interviews with people with MS to ensure that the SexFS

profile and relevant interfering factor items were understandable and meaningful to people with MS and to identify any potential problems with wording, interpretation of item content, or with response options.

The final SexFS-MS profile measures are composed of 1) the corresponding PROMIS Sexual Function & Satisfaction profile, and 2) Factors Interfering with Sexual Satisfaction items most relevant to people with MS. The PROMIS Sexual Function & Satisfaction profiles were included in the SexFS-MS profiles largely unmodified. The Factors Interfering with Sexual Satisfaction included in the SexFS-MS profiles were the items that study investigators and people with MS considered to be most important and relevant.

Instructions for Using the PROMIS SexFS-MS

Below you will find the full and brief male and female profiles, as well as the set of most relevant Interfering Factor items modified for people with MS. The profiles can be administered electronically (by computer or tablet) or on paper. The profiles typically require less than ten minutes to administer.

About PROMIS SexFS Profiles

Profiles are collections of short forms and items that assess a person with respect to multiple aspects of sexual function and satisfaction. The SexFS-MS currently includes the PROMIS SexFS Brief Profiles and Full Profiles. Items were selected for inclusion in the SexFS profiles based on rankings using psychometric and pragmatic criteria.

Brief Profiles (Male, Female). The Brief Profiles—one for males, one for females—efficiently assess interest in sexual activity followed by a screener item about sexual activity. For those who have not been sexually active in the past 30 days, a fourth and final question asks about reasons for not having sexual activity. For those who have been sexually active in the past 30 days, men are asked about erectile function, while women are asked about vaginal lubrication, vaginal discomfort, and vulvar discomfort; men and women are asked about orgasm, satisfaction with sex life, and factors that might interfere with their sexual function. These are the domains that are most likely relevant for the majority of healthy people and those suffering from chronic diseases.

Full Profiles (Male, Female). The Full Profiles—one for males, one for females—include all of the domains measured in the Brief Profiles, but also add oral dryness, oral discomfort, anal discomfort, and additional questions about factors that might interfere with sexual function. For the domains that overlap between the Brief and Full Profiles, the Full Profiles use equal or greater number of items to assess each domain.

Choose the profile version (brief or full) you feel best fits the needs or requirements of your study or clinic.

How to Score the PROMIS SexFS-MS

The SexFS-MS profiles are composed of two sections: 1) the PROMIS Sexual Function & Satisfaction profile, which is scored using existing summary score to T-score conversion tables found in the PROMIS SexFS user guide, and 2) the Factors Interfering with Sexual Satisfaction items, which are unscored individual stand-alone questions. Scoring the PROMIS Sexual Function & Satisfaction profile section of the SexFS-MS profile will yield the scores shown in the table.

| SexFS Profile domain score: | Gender | Profile |
|---|--------|--------------|
| Interest in Sexual Activity | M & F | Full & Brief |
| Orgasm – Ability | M & F | Full & Brief |
| Orgasm – Pleasure | M & F | Full & Brief |
| Satisfaction with Sex Life | M & F | Full & Brief |
| Oral Discomfort with Sexual Activity | M & F | Full |
| Oral Dryness with Sexual Activity | M & F | Full |
| Anal Discomfort with Sexual Activity | M & F | Full |
| Erectile Function | M only | Full & Brief |
| Vaginal Lubrication for Sexual Activity | F only | Full & Brief |
| Vaginal Discomfort with Sexual Activity | F only | Full & Brief |
| Vulvar Discomfort with Sexual Activity – Labial | F only | Full & Brief |
| Vulvar Discomfort with Sexual Activity – Clitoral | F only | Full & Brief |

For instructions on how to code and score the PROMIS Sexual Function & Satisfaction profile, please select the *Measure-Specific Scoring Guide* for the appropriate profile at <https://www.healthmeasures.net/search-view-measures>:

- PROMIS Sexual Function and Satisfaction v2.0 Brief Profile (Female)
- PROMIS Sexual Function and Satisfaction v2.0 Brief Profile (Male)
- PROMIS Sexual Function and Satisfaction v2.0 Full Profile (Female)
- PROMIS Sexual Function and Satisfaction v2.0 Full Profile (Male)

In general, the PROMIS Sexual Function & Satisfaction profile is scored by summing the responses to the relevant profile items and then transforming the summary score to an IRT-based T-score using the conversion tables provided in the Measure-Specific Scoring Guide. **The summary score generated by adding up raw item scores is not interpretable and should not be used for any purposes; only the T-score should be used.** The Factors Interfering with Sexual Satisfaction items are not scored across items. Each item in the Factors Interfering with Sexual Satisfaction section measures an individual concept. Accordingly, the raw responses to the individual item should be taken as the score for that item. These items are included to provide further sexual function information about the patient or study participant.

The following is a summary of the components included in each of the SexFS-MS profiles:

SexFS-MS Full Profile - Female:

The SexFS-MS Full Female Profile includes these sections:

- PROMIS Sexual Function & Satisfaction full profile (11 separately scored domains): items #1 - 26
- Factors Interfering with Sexual Satisfaction items (18 individual unscored items): items #27 – 44
- Reasons decided not to have sexual activity in the past 30 days (1 item): item #45

Follow the instructions for the PROMIS Sexual Function and Satisfaction v2.0 Full Profile (Female) in the *Measure-Specific Scoring Guide* (available at <https://www.healthmeasures.net/search-view-measures>) in order to code and score items #1 - 26 for the 11 scored domains included in this profile.

SexFS-MS Full Profile - Male:

The SexFS-MS Full Male Profile includes these sections:

- PROMIS Sexual Function & Satisfaction full profile (8 separately scored domains): items #1 - 20
- Factors Interfering with Sexual Satisfaction items (19 individual unscored items): items #21 – 38
- Reasons decided note to have sexual activity in the past 30 days (1 item): item #39

Follow the instructions for the PROMIS Sexual Function and Satisfaction v2.0 Full Profile (Male) in the *Measure-Specific Scoring Guide* (available at <https://www.healthmeasures.net/search-view-measures>) in order to score items #1 – 20 for the 8 scored domains included in this profile.

SexFS-MS Brief Profile - Female:

- The SexFS-MS Brief Female Profile includes these sections: PROMIS Sexual Function & Satisfaction brief profile (8 separately scored domains): items #1 - 14
- Factors Interfering with Sexual Satisfaction items (10 individual unscored items): items #15 – 24
- Reasons decided note to have sexual activity in the past 30 days (1 item): item #25

Follow the instructions for the PROMIS Sexual Function and Satisfaction v2.0 Brief Profile (Female) in the *Measure-Specific Scoring Guide* (available at <https://www.healthmeasures.net/search-view-measures>) in order to code and score items #1 – 14 for the 8 scored domains included in this profile.

SexFS-MS Brief Profile - Male:

The SexFS-MS Brief Male Profile includes these sections:

- PROMIS Sexual Function & Satisfaction brief profile (5 separately scored domains): items #1 - 10
- Factors Interfering with Sexual Satisfaction items (10 individual unscored items): items #11 – 20
- Reasons decided note to have sexual activity in the past 30 days (1 item): item #21

Follow the instructions for the PROMIS Sexual Function and Satisfaction v2.0 Brief Profile (Male) in the *Measure-Specific Scoring Guide* (available at <https://www.healthmeasures.net/search-view-measures>) in order to code and score items #1 – 10 for the 5 scored domains included in this profile.

Interpreting PROMIS SexFS-MS Scores

With the exception of the Orgasm domain, all domain scores are expressed as T scores (mean = 50, standard deviation = 10). At present, a T score of 50 corresponds to the mean response among sexually active US adults in the normative sample used for the development of SexFS version 2.0 (N=2281 men; N=1686 women). A higher T-score represents a higher level of the domain being measured. For example, a respondent that receives a T-score of 60 in the Satisfaction with Sex Life domain has reported a level of sexual satisfaction that is approximately 1 standard deviation higher than the mean of sexually active US adults who participated in development. Please refer to the SexFS user guide for more information about interpreting T-scores (<https://www.healthmeasures.net/search-view-measures>). included in this profile.

Referencing the PROMIS SexFS-MS

Additional information about the development and testing of the PROMIS SexFS-MS can be found in the published manuscript: Amtmann D, Bamer AM, Salem R, McMullen K, Beier M, Flynn KE, Foley FW, Weinfurt KP, Wilkie D, Alschuler KN (2022, *in press*) Extension and evaluation of the PROMIS Sexual Function and Satisfaction measures for use in adults living with multiple sclerosis. *Journal of Sexual Medicine*.

Please reference this manuscript when publishing results utilizing the PROMIS SexFS-MS.

PROMIS® SexFS-MS
Participant Forms

PROMIS® SexFS-MS Brief Profile – Female
(Participant Version)

PROMIS[®] SexFS-MS Brief Profile – Male
(Participant Version)

PROMIS[®] SexFS-MS Full Profile – Female
(Participant Version)

PROMIS[®] SexFS-MS Full Profile – Male
(Participant Version)

PROMIS[®] SexFS-MS Factors Interfering with
Sexual Satisfaction – Item Pool
(Participant Version)