Major Depressive Disorder (MDD) is a severe mental health disorder affecting 5.7 million adults in the US, or 2.4% of the adult population, and 340 million people worldwide, and is a leading cause of disability, with disproportionate impact on women. Because depression primarily affects subjectively, and the severity of MDD symptoms is directly related to the degree of impairment that patients experience, the assessment of depressive symptoms is an essential endpoint for clinical studies, particularly where the use of clinical indicators will be limited. By studying patient experience with MDD through qualitative interviews, it is possible to better understand the document the specific depression-related concepts that are relevant to the patient as well as understand the patient’s assessment of improvement in his or her condition.

The SMDDS is a 35-item PRO measure intended for use as an end point in MDD clinical trials to support pivotal development of a patient-reported outcome (PRO) measure to assess treatment benefit in MDD clinical trials.

The development team agreed to focus on symptoms and not disease characteristics. The development team decided to develop a new instrument that has firmly established content validity (supported by qualitative data from patients) and was developed instrument that has firmly established content validity (supported by qualitative data from patients) and was used to demonstrate greater sensitivity in clinical studies of treatment benefit.

Prior to conducting the qualitative interviews a systematic review was conducted to evaluate existing depression-related instruments as well as previously published qualitative data.

For the current study, we conducted a systematic review of all PRO measures available. The key terms for the search were “major depression” and “quality of life.” The search included Medline, Embase, and PsycINFO. The search was limited to English language articles published from 2000 to 2015.

Cognitive interviews and cognitive interview protocols were coded and grouped into 105 concepts (91 symptom and 14 impact) in 15 hypothesized domains (11 physical and 4 mental). The development team agreed to focus on symptoms and not disease characteristics. The development team decided to develop a new instrument that has firmly established content validity (supported by qualitative data from patients) and was used to demonstrate greater sensitivity in clinical studies of treatment benefit.

We conducted cognitive interviews with patients with MDD. During each wave, the development team considered the findings and used the information to modify the draft instrument.

The newly developed instrument was held by the development team, where concepts identified from published literature, existing instruments, and the qualitative data from the CE interviews were reviewed as the basis for selection of concepts for inclusion in the instrument.

Following each wave, the development team considered the findingsLine 1891

Because no existing PRO comprehensively assessed the selected concepts, the development team decided to develop a new measure, rather than attempting to either qualify or modify an existing measure. During subsequent review by the development team, the targeted concepts were reviewed for potential for difficulty in translating the items to maintain properties of the SMDDS and support FDA qualification.

The newly created scale, the Symptoms of Major Depressive Disorder Scale (SMDDS), is a 35-item instrument that measures each concept using a 5-point verbal rating scale and a 7-day retrospective recall period for each of the items. The SMDDS is hypothesized to be organized into 11 subdomains: schizophrenia spectrum and other psychotic disorders, mood disorders, anxiety disorders, dissociative disorders, somatoform disorders, personality disorders, adjustment disorders, sleep disorders, pain conditions, and substance use disorders.

An item is considered to be saturated if concepts not spontaneously expressed during the interviews and assess saturation of concept. The systematic review of existing instruments helped to assess their properties of the SMDDS and support FDA qualification.

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The SMDDS was developed in accordance with the FDA’s PRO Guidance and best practices. Qualitative interviews have provided evidence for content validity. Cognitive interviews provided evidence that the instructions, items and response options are comprehensible, easy to complete and address key symptoms and relevant to the patient’s condition. To address the key symptoms and relevant to the patient’s condition.

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