

# Assessing the Impact of Major Depressive Disorder (MDD) on Family Functioning: Development of the Depression and Family Functioning Scale

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## ABSTRACT

**Objective:** To assess family functioning from patients' and partners' perspectives to better understand the impact of depression on family functioning. To develop and test patient and partner versions of a new self-reported measure, the Depression and Family Functioning Scale (DFFS), for use in clinical trials.

**Method:** First, 32 in-depth interviews were conducted separately with adults with moderate-to-severe MDD and their respective partners to 1) gather qualitative data describing the impact of depression on family functioning, and 2) identify constructs relevant to measuring this impact. Next, based on the interview results and a targeted literature review conducted to supplement these results, 26 items were drafted to address each aspect of family functioning likely to be affected by depression. Questionnaire items were then tested and refined through two iterative sets of cognitive interviews with a total of 15 MDD patients and 15 partners of MDD patients to allow for enhanced comprehension of questionnaire items, as well as optimization of the recall period and response scales used in the final DFFS.

**Results:** Depression negatively affects family functioning, most notably through poorer communication, increased conflicts, decreased family interaction, and decreased intimacy. Family functioning constructs most commonly referenced in the literature review included communication, satisfaction, and cohesion. Draft DFFS items generally tested well and only minor modifications were made to the items after the second set of interviews to further facilitate comprehension and accurate responses. Both patients and partners found the final 15 DFFS items important and relevant.

**Conclusions:** Depression negatively affects family functioning in multiple ways. The DFFS is a brief scale designed to evaluate depression's impact on family functioning in patients with MDD and their partners. The DFFS has the potential to provide unique and important information facilitating more comprehensive evaluation of new treatments in clinical trial settings.

## INTRODUCTION

### Background

- Major Depressive Disorder (MDD) has a negative impact on family functioning.
- Family functioning is evaluated with high variability across studies (including different study designs and different measures of family functioning used).
- No self-reported instruments have been developed and validated with depressed patients and their partners to assess family functioning, particularly in the context of clinical trial settings.

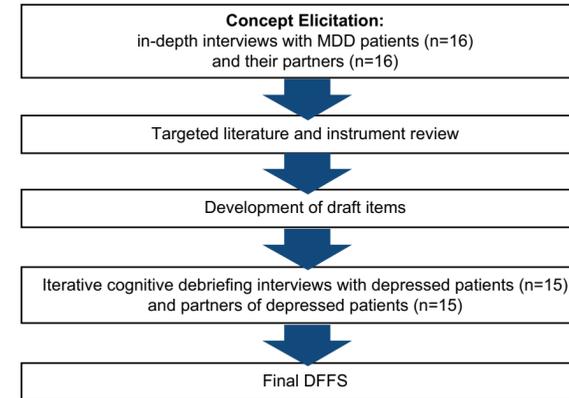
### Objectives

1. To assess family functioning from patients' and partners' perspectives to better understand the impact of depression on family functioning;
2. To develop and test patient and partner versions of a new self-reported instrument, the Depression and Family Functioning Scale (DFFS), for use in clinical trials.

## METHODS

- The DFFS was developed according to the recommendations of the Food and Drug Administration's (FDA's) guidance for new patient reported outcomes (PRO) instruments.
- The method used to develop the DFFS is represented in **Figure 1**.
- The DFFS was developed in several steps:
  - First, 32 in-depth interviews were conducted with adults with moderate-to-severe MDD and separately with their respective partners in order to:
    1. Gather qualitative data describing the impact of depression on family functioning, and
    2. Identify constructs relevant to measuring this impact.
  - Second, a targeted literature review was conducted to identify the PRO instruments targeting the domains of interest for family functioning.
  - Then, 26 items were drafted to address each aspect of family functioning likely to be affected by depression, based on the interview results and targeted literature review conducted to supplement these results.
  - Finally, these items were tested and refined through two iterative sets of cognitive interviews with 15 MDD patients and 15 partners of MDD patients to allow for enhanced comprehension of questionnaire items, as well as optimization of the recall period and response scales used in the final DFFS.

**Figure 1. The DFFS Development Process**



## RESULTS

### Participant Characteristics

- Sixteen MDD patients and their respective partners (N = 32) participated in the concept elicitation interviews. More than half (56.3%) of the MDD patients were women, and the average ages of the patients and their partners were similar: 48 and 47 years, respectively. All except one couple were married, and the average duration of cohabitation was 18 years (range: 3.5-37 years).
- Patients had been diagnosed with depression for an average of 11 years (range: 2 months to 40 years).
- At the time of screening, all patients reported use of an antidepressant within the previous year.

### Concept Elicitation

- Both patients and their partners reported that depression negatively affected many areas of family functioning.
- The most impacted domains of family functioning were:
  - General family impacts (including poor communication, increased conflict, decreased social interaction, and decreased intimacy)
  - The partner's work, free time and mood
  - The time spent together as a couple
  - The shared activities and responsibilities
  - The quality of the relationship
- The assessment of the magnitude of MDD impact on different areas of family functioning was not always consistent between patients and their partners. This finding emphasized the importance of separately measuring both patients' and partners' perspectives of depression's impact on family functioning with two different versions of the same instrument.
- Successful treatment of depression led to a positive impact on various aspects of family functioning and the patient/partner relationship and this was consistently noted for both patients and partners. Patients reported that they felt 'normal' or happy again, less irritable and less anxious, with improvement in self-esteem, social interest, communication, and ability to resume normal routines. Some treatment-related side effects could negatively impact family functioning (such as, decreased libido or sexual functioning, sleep problems).

### Targeted Literature and Instrument Review

- More than 25 PRO instruments related to family functioning were identified but none of them evaluated all the domains of family functioning identified as the most impacted from both the patients' and the partners' perspectives.
- Although some of the instruments had been used in clinical studies with depressed patients, none were developed in a population of depressed patients and their partners, and none were validated in these populations; nor did it appear that any had been used in clinical trials assessing pharmaceutical compounds for depression. Finally, none of the PRO instruments were developed and psychometrically evaluated in a manner consistent with the FDA's PRO guidance.

### Item Development

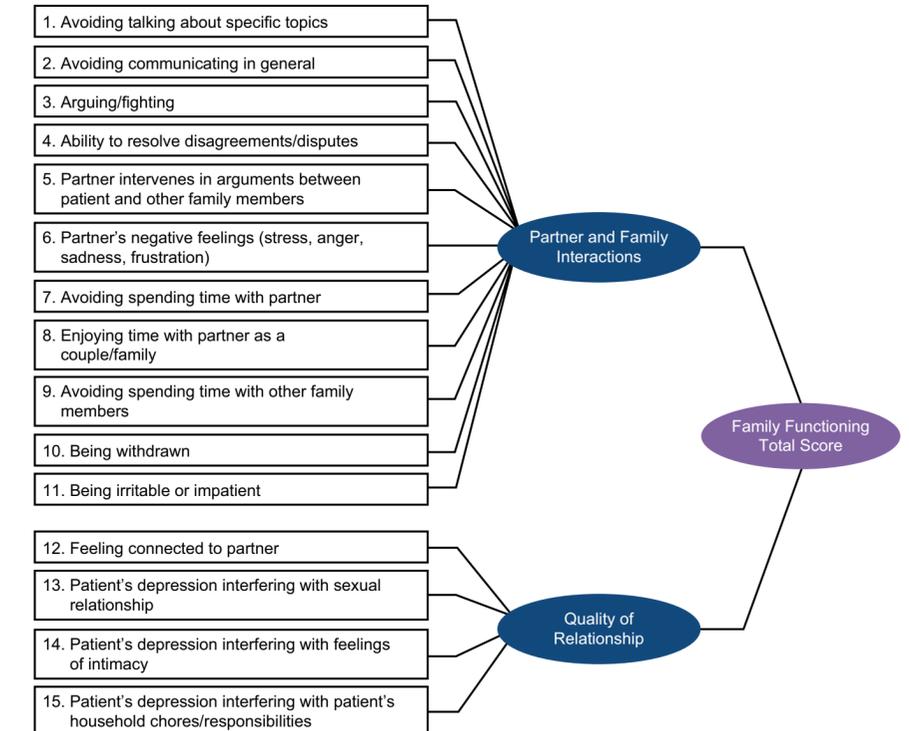
- The data collected through the first two steps (the 32 concept elicitation interviews and the literature and instrument review) were used to generate the initial items of the DFFS.

- The initial patient and partner versions of the DFFS each contained 26 items, with a 5-point ordinal response scale in both versions, and all items asked about the same concepts. The recall period was 4 weeks.

### Cognitive Debriefing Interviews

- The DFFS was cognitively tested in a total of 15 MDD patients and 15 partners of MDD patients including 5 couples plus 10 patients and 10 partners who were not members of a couple participated in two iterative rounds of cognitive interviews.
- After two rounds of cognitive testing, the initial 26-item set was reduced to a final set of 15 items assessing two higher-level concepts—partner and family interactions, and quality of relationship.
- Both patients and partners indicated that the DFFS items comprehensively covered the important areas of family functioning associated with depression and that the 5-point ordinal response scale and the length of the recall period were appropriate.
- A preliminary conceptual framework was developed (**Figure 2**).

**Figure 2. Depression and Family Functioning Scale (DFFS) Preliminary Conceptual Framework**



The psychometric properties of the DFFS will be evaluated in the next phase of development.

## CONCLUSIONS

- The DFFS is the first scale designed to evaluate the impact of depression on family functioning from both patients' and partners' perspectives.
- The DFFS has the potential to provide unique and important information facilitating more comprehensive evaluation of new treatments in clinical trial settings.

This poster has been supported by H. Lundbeck A/S

Presented at the International Society for Pharmacoeconomics and Outcome Research (ISPOR) 16<sup>th</sup> Annual International Meeting, May 21-25, 2011, Baltimore, MD, USA