

PT15

Development of the Eating Drivers Diary (EDDY), a Novel Patient-Reported Outcome Measure for Use in Clinical Trials of Medications for Weight Management

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Background

- Obesity and overweight are chronic metabolic conditions that negatively impact health as well as physical, emotional, and social functioning.¹
- Both food intake and weight management can be influenced by a variety of internal feelings or drivers of eating, such as hunger, satiety, and cravings that may be modified with treatment.²⁻⁴
- Patient-reported outcome (PRO) measures, which capture patient views, feelings, and experiences, are vital for assessing treatment effect from the patient perspective—particularly for concepts known only to the individual, such as physical sensations and emotions.
- Although several PRO measures have been used in clinical research to assess drivers of eating, each has limitations in its ability to inform regulatory decision-making and support labeling claims in the United States (US).

Objectives

- The aim of this study was to develop a novel PRO measure, the Eating Drivers Diary (EDDY), to systematically evaluate internal drivers of eating in clinical trials of new medications for weight management.
 - This measure was developed with the rigor required by the US Food and Drug Administration (FDA)^{5,6} and designed to be capable of detecting a change among individuals receiving effective medications for weight reduction.

Methods

- Concepts for potential inclusion in the EDDY were identified through a literature review, consultation with 3 experts in the field of obesity (2 clinicians and 1 patient advocate), and concept elicitation interviews conducted with 16 adults with overweight or obesity.
- An initial item pool was drafted to address drivers of eating that concept elicitation interview participants identified as important to modify with weight management medication, with each item referencing a 24-hour recall period.
- The item pool was then evaluated and refined across 3 iterative rounds of cognitive debriefing interviews, conducted with a total of 24 adults with overweight or obesity.

Results

Participant Characteristics

- The majority of the participants for concept elicitation (n = 16) and cognitive debriefing interviews (n = 24) were female (n = 9 [56.3%] and n = 14 [58.3%], respectively) and White (n = 9 [56.3%] and n = 10 [41.7%], respectively) (Table 1).
- The mean ages of participants in the concept elicitation and cognitive debriefing interviews were 42.6 (range, 23-67) years and 43.5 (range, 22-66) years, respectively, and each sample was selected to ensure representation across the categories of overweight and obesity based on body mass index (BMI).

Concept Identification

- Concepts identified in the literature by obesity experts and by interview participants as important drivers of eating included hunger/appetite, feeling full/satisfied, cravings, psychological triggers, preoccupation with food, and control of eating.
- During concept elicitation interviews, all 16 participants reported or endorsed hunger, control of eating, and psychological or emotional triggers (e.g., stress, sadness) as factors influencing their ability to lose or maintain their weight (Figure 1).
 - Although a preoccupation with food was identified as an important concept in the literature and by all 3 obesity experts, it was deemed relevant by only 3 of the 16 concept elicitation participants.
- The concepts identified as most important to address with treatment included cravings (n = 10), fullness/satisfaction (n = 7), hunger (n = 6), control of eating (n = 5), and appetite (n = 2) (Table 2). Increased energy was also reported (n = 3) as a desired impact of weight loss due to pharmacological treatment.

Item Selection and Refinement

- The initial item pool addressed internal drivers of eating that were commonly identified during concept elicitation and had the potential to be modified with medication.
 - Psychological or emotional triggers were not addressed in the item pool because these triggers may be emotionally determined, and the potential for weight management medication to influence them is limited.
 - In addition, the direction of change that would represent a treatment benefit was uncertain for psychological or emotional triggers; for instance, sadness or stress reportedly caused some interview participants to eat or eat more, whereas it caused others to eat less.
- Multiple items, using different question wordings and response scales, were tested in relation to each concept.
 - Appetite was deemed largely redundant with hunger and a less specific concept; the concept of satiety (not satisfaction) was most clearly and consistently understood in items addressing fullness.
- The instruction wording and recall period of the EDDY were supported in all 3 rounds of cognitive debriefing interviews; participants found the instructions easy to understand, and they easily and consistently interpreted the “past 24 hours” recall period for EDDY items.
- The final version of the EDDY includes 6 items: 2 items evaluating hunger, 2 items evaluating fullness, 1 item evaluating cravings, and 1 item evaluating control of eating (Table 3).

Table 1. Participant Characteristics

	Concept elicitation interviews (n = 16)	Cognitive debriefing interviews (n = 24)
Age, mean (range), years	42.6 (23-67)	43.5 (22-66)
Gender, n (%)		
Female	9 (56.3)	14 (58.3)
Male	6 (37.5)	10 (41.7)
Gender fluid	1 (6.3)	0 (0.0)
Race or ethnicity, n (%) ^a		
White	9 (56.3)	10 (41.7)
Black	4 (25.0)	8 (33.3)
Hispanic/Latin American	1 (6.3)	5 (20.8)
Asian American	1 (6.3)	1 (4.2)
Native Hawaiian/Pacific Islander	1 (6.3)	0 (0.0)
Native American	1 (6.3)	0 (0.0)
BMI category, n (%)		
27.0-34.9 kg/m ²	5 (31.3)	7 (29.2)
35.0-39.9 kg/m ²	6 (37.5)	7 (29.2)
≥ 40.0 kg/m ²	5 (31.3)	10 (41.7)
Type 2 diabetes	1 (6.3)	12 (50.0)

All data based on participant self-report.
^a Participants were able to select multiple response options for this category; as such, n > 16.

Table 2. Desired Changes With Medication: Concept Importance Ratings

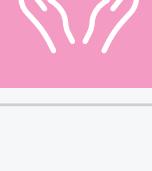
Concept	Mean rating (range, 0-10 ^a)	Number of times rated 10: “Extremely important” (Total n = 16)
Feel more in control of eating	8.9 (4-10)	8
Help you eat less	8.9 (5-10)	7
Experience fewer cravings	8.8 (6-10)	7
React less to emotional triggers	8.2 (4-10)	8
Feel more full/satisfied after meals	8.1 (2-10)	3
Less hunger	7.5 (2-10)	4
Choose healthier foods	7.3 (0-10)	5
Think about food less often	7.1 (0-10)	4

^a 0 = not at all important to 10 = extremely important.

Table 3. Final EDDY Concepts

Concept	Response scale
Item 1: Average hunger	11-point numeric rating scale (0, Not hungry at all, to 10, Extremely hungry)
Item 2: Peak hunger	
Item 3: Amount of food required to feel full	5-point verbal rating scales tailored to the concept of measurement
Item 4: Fullness duration	
Item 5: Cravings	
Item 6: Feeling of control over eating	

Figure 1. Concepts Identified as Drivers of Eating

Concept and number of participants (n)	Representative quote
 HUNGER n = 16	“Usually, my stomach just feels so empty or I feel a pinching, nauseous feeling.”
 CONTROL OF EATING n = 16	“To me, it [to be able to control your eating] would mean being able to stick to 3 meals a day and with the proper portion size, and not go back for more.”
 PSYCHOLOGICAL/ EMOTIONAL TRIGGERS n = 16	“Typically, if I’m feeling anxious about something, I would eat less. Or not eat at all.”
 CRAVINGS n = 15	“It means it’s something that I have a taste for. And you can’t take not having this taste and now you have to go and eat it.”
 APPETITE n = 15	“I’ve never really thought about this...So, I guess hunger would be more physical, whereas appetite is just even if I’m full, sometimes I might be able to eat a lot more. So, I would say I have a bigger appetite even if I’m not hungry.”
 FEELING FULL/ SATISFIED n = 11	“It just feels like I’m good, I’m not thinking about food. I’m not hungry, I’m not really worrying about food.”
 BOREDOM n = 9	“I try not to, but there are times when I might eat out of boredom, and that’s probably why I have the weight problem.”
 PREOCCUPATION WITH FOOD n = 3	“I would think that like for me focusing on food too much probably negatively impacts me...”

Discussion

- The final version of the EDDY was found to be easy to understand and answer. The measure was determined to be comprehensive, including each of the internal drivers of eating that are salient to individuals with overweight or obesity and influence weight management.
- The EDDY was developed in accordance with FDA guidance^{5,6} and is anticipated to be administered as a daily diary for 7 consecutive days.
- Individual EDDY item scores will support key endpoints in future weight management clinical trials, making it possible to determine the extent to which each of the internal drivers of eating are modified with medication.

Conclusions

- Results of this qualitative study demonstrate that the EDDY captures important impediments to weight management from the patient perspective.
- These findings provide strong support for the content validity of the 6-item EDDY; rigorous psychometric evaluations are planned using data from clinical trials.
- The EDDY can contribute to the comprehensive evaluation of new weight management therapies and allow for clearer and more informative communications regarding potential treatment benefits.