Supplement 1 to the article: Development and Validation of the Patient Experience with Treatment and Self-Management (PETS): A Patient-Reported Measure of Treatment Burden

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Supplement 1. Drafting, Reviewing, and Pre-testing the Patient Experience with Treatment and Self-Management (PETS) Measure

Item development

Using the conceptual framework developed in the first phase of the research, two study investigators wrote a first draft of the measure. The 121 items generated were categorized into three major sections: (1) the work patients do to care for their health (35 items), (2) challenges/stressors that exacerbate felt burden (68 items), and (3) impacts of burden (18 items). The draft measure was formatted then reviewed by a stakeholder panel consisting of a primary care physician, an endocrinologist, a certified nurse practitioner, two patient advocates, a medical sociologist, and a health services researcher with expertise in patient-reported outcome measures. The panel judged each item on the importance of the issue reflected, the clarity of wording, and the appropriateness of the recall time frame. Clarity of instructions and the overall relevance of each section of questions to the concept of treatment burden were also reviewed. Revisions were made to the measure based on the feedback and included (1) changes to some response scales to better match item content, (2) re-wording of some items to clarify meaning, and (3) the addition of three screening questions for select content areas. Thirty-seven items were also dropped from the draft measure for at least one of the following reasons: deemed less important, ambiguous

content, redundant, or consolidated with other items. The remaining draft of 87 items was submitted to cognitive pre-testing with patients with multiple chronic conditions at both clinical sites (Hennepin County Medical Center [HCMC: Minneapolis, MN] and Mayo Clinic [Rochester, MN]).

Cognitive pre-testing of draft measure

Two rounds of cognitive interviews were conducted with 12 patients from Mayo Clinic and 11 patients from HCMC (11 in the first round, 12 in the second round). The Institutional Review Boards of both sites provided approval, and all patients provided written informed consent and were compensated $30. Participants' ages ranged from 39 to 80, with 74% female, and a median of 6 self-reported health conditions. All Mayo Clinic patients were Caucasian, while 82% of HCMC patients were African-American. In the first round, patients completed the draft measure before the interview. At the interview, patients were asked to rate the importance of each item to their usual care for their health conditions and to describe whether the issue was relevant to their current health situation. Items showing good frequency of endorsement (i.e., spread in rating scale responses), those rated as important (average ≥5 on a 0 to 10 importance scale) and described as relevant to current care were retained for further testing. Patients were also queried about the appropriateness of the recall time frame (past 4 weeks) and difficulty understanding any items, terms, or definitions embedded in the measure. The interviews resulted in several modifications: (1) 6 items were dropped due to low importance, frequency of endorsement, relevance, or redundancy, (2) 11 items were re-worded to clarify meaning and reduce ambiguity, (3) a "does not apply" option was added for several items, (4) the recall time frame for items addressing interactions with healthcare providers was dropped, and (5) clarifying definitions were added for a few terms (e.g., "diet plan," "self-care").

In the second round of interviews, patients repeated the same procedures as described in the first round, including completion of the revised draft measure. Feedback from these interviews led to deletion of 3 items due to low importance, frequency of endorsement, ambiguity, or redundancy with other items, and re-wording of 3 items to clarify meaning. A final draft treatment burden measure of 78 items resulted, consisting of the following fifteen content domains (and number of items within each): learning about health conditions and care (3), medications (5), difficulty with taking medications (6), medical appointments (6), monitoring health (2), exercise or physical therapy (5), diet (4), medical equipment (3), interpersonal challenges (4), medical/healthcare expenses (8), confusion/concern about medical information (6), healthcare providers (7), difficulty with healthcare services (7), role and social activity limitations (6), and physical/mental exhaustion (6). The measure was readied for an initial test of its validity.