Cognitive Review of the Patient-Reported Depression Checklist: A Patient-Reported ePRO Measure of Symptom Frequency and Functional Impact

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What is the Methodological Issue Being Addressed? The Patient-Reported Depression Checklist (PRDC) is being developed to address limitations of existing measures of depressive symptoms. Results from patient and clinician cognitive reviews focusing on the PRDC's comprehensiveness, clarity, usability, sensitivity, and perceived clinical value will be presented.

Introduction Standard approaches to measuring depression severity in clinical trials rely on clinician-rated instruments such as the MADRS, the Hamilton Depression Rating Scale (HAM-D), the CGI and the Sheehan Disability Scale (SDS). Although these widely used instruments are sensitive to change, they require clinician interpretation of patient responses and do not fully capture the patient's subjective experience of symptom frequency or the functional impact for individual symptoms. Regulatory agencies, including the FDA and EMA, increasingly emphasize the importance of patient-focused outcome measures that assess not only symptom severity but also how patients feel and function in daily life. FDA Patient-Focused Drug Development guidance specifically supports the use of patient-reported outcome measures that capture symptom burden, functional impact, and the patient experience of treatment benefit.

Methods Development of the PRDC was informed by review of depressive symptom constructs, stakeholder input, qualitative patient research, and cognitive validation. The Likert scale structured instrument uses a one-week recall period and asks patients to rate the frequency of depressive symptoms and their associated functional impact.
Patient feedback (n = 15) was collected through qualitative interviews and cognitive validation procedures evaluating relevance, comprehensiveness, clarity, interpretability, and ease of completion. Patients varied in symptom severity, age, gender, and duration of illness. Clinician feedback (n = 5) was obtained from experienced clinicians who reviewed the PRDC for content coverage, clarity, usability, respondent burden, appropriateness of response options, and potential usefulness in clinical care.

Results Patient feedback supported the relevance, acceptability, and feasibility of the PRDC. Patients generally found the instrument understandable, easy to complete, and relevant to their lived experience with depression. Cognitive validation indicated that patients understood the items, recall period, and response options. Patients also emphasized the importance of assessing not only depressive symptoms, but also the functional consequences of those symptoms, including effects on daily activities, responsibilities, relationships, and communication with others. These findings

suggest that the PRDC may capture meaningful patient-experience information that is not always elicited through standard clinician-rated assessments.
Clinician feedback supported the acceptability and potential clinical usefulness of the PRDC. Clinicians reported that the instrument had an appropriate completion time, that the one-week recall period was manageable, that the layout was easy to follow, and that the content was presented sensitively. Overall symptom coverage was rated favorably, with clinicians indicating that the PRDC covered depressive symptoms adequately to very well. All clinicians reported that the PRDC would help them better understand patients' experiences and would help patients communicate more effectively about their symptoms. Three clinicians indicated that completion of the PRDC before appointments would be helpful.
Both patients and clinicians identified opportunities for scale refinement. Suggested improvements included clarifying content related to lack of motivation or lassitude, psychomotor slowing, personal hygiene and appearance, ability to attend to responsibilities at home or with loved ones, response-option guidance, and better distinguishing between general communication difficulties and social interactions.

Conclusion Patient and clinician feedback provide preliminary support for the PRDC as an acceptable, comprehensive, and potentially clinically useful digitally administered patient-reported measure of depressive symptom frequency and related functional impact. The PRDC may complement existing clinician-rated depression instruments by capturing patient-centered information on symptom burden, functional consequences, and communication-relevant experiences. Continued validation work is warranted.

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Guidelines I have read and understand the Poster Guidelines

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