Content and Convergent Validity of the Patient-Reported Depression Checklist (PRDC): A Patient-Centered ePRO Measure of Symptom Frequency and Functional Impact

Larry Alphs[1]; Elan A. Cohen[2]; Moses Njuguna[1]; Stephenie Iglesias[2]; Hila Anderson[2]; Jillian Pine[2]; Sheryl A. Roach[2]

[1]Larry Alphs Consulting, LLC; [2]CenExel Marlton, New Jersey

STUDY QUESTION

Does adding structured patient-reported symptom-frequency and functional-impact information improve clinician assessment of depression?

BACKGROUND

Major depressive disorder affects emotional, cognitive, physical, and functional well-being. Existing validated scales (PHQ-9, QIDS-SR, BDI-II) focus mostly on symptom severity and provide limited assessment of how symptoms affect daily functioning, relationships, work, and role performance.

Given the heterogeneity of depression and the potential divergence between clinician and patient perspectives, a brief patient-reported measure that captures both symptom frequency and functional impact would support treatment evaluation, shared decision-making, and outcome monitoring.

The PRDC was designed to address this gap: 30 items across 7 symptom domains, each rated for both frequency AND functional impact, plus a Patient Global Impression (PGI) of overall functional impact.

Regulators and clinicians require extensive validation of new assessment instruments to establish the value of their use in clinical trials and clinical practice. This work serves to begin that validation process.

Comparison of Patient-Reported Depression Scales

Feature	PHQ-9	QIDS-SR16	BDI-II	PRDC
Symptom coverage	9 DSM symptoms	9 DSM domains	Cognitive/ affective bias	30 items: 7 symptom domains (mood, anxiety/stress, suicide, energy/fatigue, cognition, social/relationships, and emotional regulation)
Functional impairment detail	1 item	Not explicitly expressed	Minimal	Impact rating for each symptom + overall impact
Cognitive and executive symptoms	Minimal	Partial	Some	3 items (memory, concentration, decision-making)
Positive affect measurement	None	None	Limited	Explicit reversed items
Anxiety / irritability / stress	No	No	Partial	Separate items (14, 17, 21)
Social/interpersonal domains	Only "trouble doing work"	None	Minimal	Communication, intimacy, loneliness
Adherence and behavior tracking	None	None	None	Medication adherence, substance use
Anchoring and comprehension guidance	None	None	Minimal	"Compared to when you felt at your best" with rating definitions
Scoring approach	Frequency only	Frequency only	Frequency only	Dual frequency × impact scoring
Focus on functional remission	Minimal	Minimal	Minimal	Central (impact ratings + functioning item)
Sensitivity to comorbidity/context	Low	Low	Low–moderate	High (captures anxiety, pain, stress, substance use)
Time to complete	2-5 Minutes	5-7 Minutes	5-10 Minutes	10-15 Minutes

Work supported by Larry Alphs Consulting, LLC

METHODS

- Iterative cognitive validation with 30 adults meeting DSM-5 criteria for MDD (recruited at CenExel Marlton, NJ)
- **Phase 1:** Patient (n=15) completion and review of PRDC/Clinician review PRDC (n=5)
  - Blinded convergent-validity test (PGI vs CGI)
    - Clinician completed CGI **BEFORE** reviewing patient PRDC ratings
- **Revision**: PRDC revised based on patient and clinician feedback
  - (item wording, response anchors, and coverage)
- **Phase 2:** Patient (n=15) completion and review of PRDC/Clinician review PRDC (n=5)
  - Unblinded convergent-validity test (PGI vs CGI)
    - Clinician completed CGI AFTER reviewing patient PRDC ratings
- **Statistical analysis**: Pearson's r for continuous measures; item-level within-symptom frequency-impact correlations; comparison of correlation magnitudes between Phase 1 (blind) and Phase 2 (informed) CGI conditions

DEMOGRAPHICS & CLINICAL PROFILE

	Phase 1 (n=15)	Phase 2 (n=15)	Combined (n=30)
Age, mean (SD)	52.5 (9.9)	49.9 (14.2)	51.2 (12.1)
Male, n (%)	13 (86.7)	7 (46.7)	20 (66.7)
Black or African descent, n (%)	8 (53.3)	10 (66.7)	18 (60.0)
MDD recurrent, n (%)	4 (26.7)	8 (53.3)	12 (40.0)
CGI-S (1–5), mean (SD)	3.7 (0.8)	3.5 (1.3)	3.6 (1.0)

PHASE 1 vs PHASE 2 — VALIDITY ANALYSIS

	Phase 1 (CGI blind)	Phase 2 (CGI informed)
Patients	15	15
Descriptive statistics — mean (SD)		
Total Frequency (0-5 scale)	57.9 (27.3)	72.2 (33.3)
Total Impact (0-6 scale)	49.6 (28.7)	67.0 (52.4)
PGI (0-6 scale)	1.7 (1.7)	2.7 (2.1)
CGI Severity, 1–5	3.7 (0.8)	3.5 (1.3)
Internal consistency — Pearson r		
Total Frequency × Total Impact	0.81 ***	0.96 ***
PGI × Total Frequency	0.73 **	0.79 ***
PGI × Total Impact	0.81 ***	0.87 ***
Convergent validity — Pearson r		
CGI Severity × PGI	0.56 *	0.73 **
CGI Severity × Total Frequency	0.42	0.85 ***
CGI Severity × Total Impact	0.40	0.76 ***
CGI Functional × PGI	0.18	0.77 ***

*Pearson correlation coefficients (r). *p<.05, **p<.01, ***p<.001, ns = not significant*

***p<.05 **p<.01 ***p<.001*

RESULTS AT A GLANCE

Content coverage & acceptability (from patient reviews)

- 81% rated coverage as "Very well" or "Quite well"
- 0% reported missing important symptom areas
- 0% found completing the checklist uncomfortable
- 76% would use it to prepare for clinical appointments

Scoring behavior (n=30)

- Total Frequency range: 18–137 Total Impact range: 5–178
- Scale discriminates mild from severely ill patients
- All 30 items endorsed by ≥1 patient reviewer
- No item exceeded the 20–30% revision threshold

KEY FINDINGS

➢ Item-level frequency × impact: supports the dual-scoring rationale

Within each of the 30 symptom items, frequency and impact ratings correlate strongly with PGI in both phases (r = 0.73–0.87), indicating that both dimensions carry information yet are not redundant.

Phase 1: median item-level r = 0.70 | 23 / 30 items reach p<.05
Phase 2: median item-level r = 0.86 | 29 / 31 items reach p<.05

Strongest Phase 2 items: Overeating r = 0.96 · Substances r = 0.94 · Worthlessness r = 0.93 · Motivation r = 0.92 · Interests r = 0.92 · Social r = 0.92

➢ PRDC captures high-burden symptoms missed by standard scales

Several PRDC items were rated as high patient burden (mean impact ≥ 2.5 on 0–6) are not directly assessed by PHQ-9, QIDS-SR16, or BDI-II:

Stress/overwhelmed · Anxiety · Motivation/drive · Physical pain · Loneliness · Communication

The PRDC's broader symptom set surfaces functionally meaningful burden that standard depression scales overlook.

➢ Clinician severity judgment converges with patient scores

In Phase 1 with blind clinician CGI, CGI Severity × Total Impact = 0.40 (ns). In Phase 2 with informed CGI, this rises to 0.76 (p<.001). Clinicians and patients are seeing the same clinical picture — but the alignment emerges only when the clinician has access to PRDC data.

➢ Clinician judgment of functional impairment significantly improved when informed by PRDC

Phase I: CGI Functional × PGI r = 0.18 (ns)
Phase 2: CGI Functional × PGI r = 0.77 (p<.001)

INTERPRETATION: The clinician's independent examination on the CGI does not fully capture the patient's own functional experience. The PRDC helps inform the clinical picture.

CONCLUSIONS

Content validity — supported.
Patients endorse the domains, find the instrument tolerable, and would use it to prepare for care.

Structural validity — supported.
Item-level and scale-level Freq × Impact correlations justify the dual-scoring design.

Convergent validity — supported and informative.
Patient scores align with independent clinician severity judgment (Phase 1); alignment strengthens further when the clinician reviews the PRDC (Phase 2). The Phase-1 → Phase-2 shift indicates that the PRDC delivers unique functional information.

Implications for use.
The PRDC is ready for further psychometric evaluation. It is a candidate ePRO measure for clinical trials and treatment monitoring where symptom heterogeneity and functional impact are both of interest.

Continued validation to meet regulatory (FDA/EMA) guidance is warranted.