**31.The endometriosis daily diary: qualitative research to explore the patient experience of endometriosis and inform the development of a patient- reported outcome (PRO) for endometriosis-related pain**

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Abstract

Purpose: Endometriosis is a chronic disorder of the female reproductive system characterized by debilitating symptoms, particularly endometriosis-related pain (ERP). Patient-reported outcome (PRO) measures of symptoms and impacts are required to assess disease severity in ERP clinical studies and clinical practice. A content-valid instrument was developed by modifying the Dysmenorrhea Daily Diary (DysDD) to form the Endometriosis Daily Diary (EDD), an electronic PRO administered via handheld device.

Methods: Qualitative research with US females with ERP was conducted in three stages: (1) Development of an endometriosis conceptual model based on qualitative literature and conduct of concept elicitation (CE) interviews (N = 30). (2) Cognitive debriefing (CD) interviews (N = 30) conducted across two rounds to assess relevance and understanding of the EDD, with modifications between interview rounds. (3) Pilot testing to assess usability/feasibility of administrating the EDD daily on an electronic handheld device (N = 15). Clinical experts provided guidance throughout the study.

Results: The conceptual model provided a comprehensive summary of endometriosis to inform modifications to the DysDD, forming the EDD. CD results demonstrated that EDD items were relevant for most participants. Instructions, items, response scales, and recall period were well-understood. The resulting daily diary assesses severity of cyclic and non-cyclic pelvic pain, dyspareunia, impact of ERP on functioning and daily life, symptoms associated with ERP, and bowel symptoms. Participants were able to complete the diary daily and found the device easy to use.

Conclusion: The EDD demonstrated good content validity in females experiencing ERP. The next step is to perform psychometric validation in an ERP sample.

Keywords: Content validity; Development; Endometriosis; Endometriosis-related pain (ERP); Patient-reported outcomes (PROs); Qualitative.