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CONTENT VALIDITY OF A PATIENT BLADDER DIARY AMONG PATIENTS WITH INCONTINENCE DUE TO IDIOPATHIC OVERACTIVE BLADDER (IOAB)

Hypothesis / aims of study

The aim of this study is to test the content validity of a Patient Bladder Diary (PBD) for use in clinical trials of new therapy for urinary incontinence (UI) due to IOAB.

Study design, materials and methods

In the first phase of research, we conducted in-depth, individual interviews among patients with UI due to IOAB to elicit symptoms of the condition and gather feedback on the initial PBD content. Patients completed the PBD and rated the relevance and understandability of concepts, words and pictures used. The PBD was revised based on this patient input. In a second phase, the revised PBD was evaluated for patients' understanding of the content of the revised items, for the ease of completing the diary on a daily basis and for expressed willingness to complete the diary as required during the course of a clinical trial.

Results

19 patients were interviewed. Of the 10 in Phase 1, 8 (80%) were females and the
mean age was 56. Of the 9 patients in Phase 2, 5 (55%) were female and the mean age was 59. In Phase 1, the most common spontaneously-reported symptoms were: accident, leakage, or trickle (n=10); urge to urinate (n=6); and frequent urination (n=6). In the cognitive debriefing portion, most subjects found the PBD to be relevant, understandable, and
comprehensive. Majority of the patients did not suggest additional questions, and said they would complete the required information including a 24-hour urine collection. Specific recommendations included removing the term "void", (unfamiliar/technical) and
clarifying the instructions. The PBD was revised according to patient recommendations, and a separate instruction manual was created. In Phase 2, patients confirmed that (1) the revised PBD addressed their condition and (2) the items and new instruction manual were relevant and understandable. The majority of subjects did not suggest adding questions to the diary and did say they would be able to complete the required information including the urine collection.

Interpretation of results

The most common symptoms reported by the patients were represented
in the PBD. This qualitative research led to refinement of the PBD for use among subjects with UI due to IOAB, and cognitive debriefing showed that the final PBD has strong content validity and is acceptable to patients similar to a clinical trial population.

Concluding message

The revised PBD is comprehensive and is deemed appropriate for use in a clinical trial setting by incontinent IOAB patients.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Copernicus Group**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**