



The research commercialisation office of the University of Oxford, previously called **Isis Innovation**, has been renamed **Oxford University Innovation**

All documents and other materials will be updated accordingly. In the meantime the remaining content of this Isis Innovation document is still valid.

URLs beginning www.isis-innovation.com/... are automatically redirected to our new domain, www.innovation.ox.ac.uk/...

Phone numbers and email addresses for individual members of staff are unchanged

Email: enquiries@innovation.ox.ac.uk

Development of the Coeliac Disease Assessment Questionnaire (CDAQ)

Helen Crocker, Michele Peters, Crispin Jenkinson

Nuffield Department of Population Health, University of Oxford, UK



Introduction

Evaluating health-related quality of life (HRQOL) in people with coeliac disease can provide a greater understanding of the condition than can be achieved by assessing clinical factors alone. HRQOL is assessed using patient reported outcome (PRO) measures, short questionnaires that measure health from the patient's perspective. There are two existing disease-specific PROs that measure HRQOL in adults with coeliac disease, the Celiac Disease Questionnaire (CDQ) (Häuser et al., 2007) and the Coeliac Disease Quality of Life Survey (CD-QOL) (Dorn et al., 2010). However, there are limitations with both measures, in particular, with regards to the derivation and subsequent reduction of items.

The aim of this study was to develop a new PRO measure to assess HRQOL in adults with coeliac disease that meets current development guidelines, for example, those provided by the U.S. Food and Drug Administration (US FDA, 2009).

Methods

Items for the new measure, the Coeliac Disease Assessment Questionnaire (CDAQ), were developed following qualitative interviews with adults with coeliac disease, and refined through expert panels, cognitive interviews, and a translatability assessment. A draft version of the CDAQ was completed by 412 people with coeliac disease. Analysis of this data enabled the number of items to be reduced and dimensions to be generated. The key steps involved in the development of the CDAQ are shown in Figure 1 below.

Qualitative interviews

Conducted 23 qualitative interviews with people with coeliac disease.

Development of candidate items

Developed 63 candidate items following a thematic analysis of qualitative interview data.

Expert opinions

Obtained feedback from experts, including health professionals and researchers, to refine the questionnaire items.

Cognitive interviews

Conducted cognitive interviews with people with coeliac disease.

The interviews examined cognitive thought processes during questionnaire completion in order to identify sources of response error. Items were revised.

Translatability assessment

Undertook a translatability assessment to assess the cultural and linguistic translatability of the questionnaire. Items revised.

Survey

Members of Coeliac UK (n=412, response rate 52%) completed a draft 51-item version of the CDAQ.

Item reduction and scale generation

Nineteen items were removed following data analysis. A principal components analysis (with Varimax rotation) was conducted on the remaining items, identifying six meaningful dimensions, two of which were merged.

Figure 1. Methodology for the development of the Coeliac Disease Assessment Questionnaire

Results

The final version of the CDAQ contains 32 items addressing five dimensions: stigma (8 items); dietary burden (8 items); symptoms (5 items); social isolation (5 items); and worries and concerns (6 items). The questionnaire measures HRQOL over the past four weeks. Cronbach's alpha values ranged between 0.82 and 0.88 for all dimensions, indicating good internal consistency.

The dimensions, Cronbach's alpha values and example items are shown in Figure 2.



The CDAQ

Stigma

8 items, alpha = 0.88

...have you felt as though you might appear to be making a fuss about your dietary needs?

...have you received unwanted attention because of your coeliac disease or dietary needs?

Dietary burden

8 items, alpha = 0.83

...have you had difficulty finding something to eat when you were not at home?

...have you felt burdened by the time taken to find or make gluten-free food?

Symptoms

5 items, alpha = 0.82

...have you had bloating in your abdomen?

...have you had tiredness or a lack of energy that you think was caused by your coeliac disease?

During the <u>past 4 weeks</u>, how often...

Worries and concerns

6 items, alpha = 0.85

...have you been concerned about cross-contamination (gluten-free food coming into contact with food that contains gluten)?

Social isolation

5 items, alpha = 0.82

...have you avoided social activities?

...have you felt isolated from others because of your coeliac disease?

Figure 2. Coeliac Disease Assessment Questionnaire dimensions and example items

Conclusions

A new patient-reported outcome measure, the Coeliac Disease Assessment Questionnaire (CDAQ), has been developed according to current guidelines. The measure can be used in a range of settings, including clinical trials and clinical practice. For example, the questionnaire can be used in clinical trials to evaluate the effect of treatments on health-related quality of life. This will provide a broader understanding of the treatment than can be achieved by assessing clinical impact alone. Further assessment of the CDAQ's reliability and validity is currently underway.

Acknowledgements

We would like to thank interview participants for sharing their experiences of living with coeliac disease and everyone who has provided feedback on draft versions of the measure. We would also like to acknowledge Coeliac UK for assisting with the recruitment of participants. This study is part of a doctoral research programme funded by the Medical Research Council (UK).

References

Dorn et al. (2010). The development and validation of a new coeliac disease quality of life survey (CD-QOL), *Alimentary Pharmacology & Therapeutics*, 31(6), pp. 666-675. Häuser et al. (2007). Development and validation of the Celiac Disease Questionnaire (CDQ), a disease-specific health-related quality of life measure for adult patients with celiac disease, *Journal of Clinical Gastroenterology*, 41(2), pp. 157-166.

U.S. Department of Health and Human Services Food and Drug Administration. (2009). Guidance for Industry: Patient-reported outcome measures: use in medical product development to support labeling claims. Maryland: FDA.