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Quality of life in coeliac disease: the qualitative development of a new patient-reported outcome measure

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Aims and Background

The purpose of this study was to develop a new disease-specific patient-reported outcome measure (PROM), based on qualitative interview data, investigating the health-related quality of life of people living with coeliac disease. There are two existing disease-specific PROMs that assess quality of life in people with coeliac disease, the Celiac Disease Questionnaire (CDQ)¹ and the Coeliac Disease Quality of Life Survey (CD-QOL)². However, there are limitations in the development of both measures, including the derivation of items.

Coeliac Disease

- Coeliac disease is a chronic autoimmune disease in which an immune response is triggered by the consumption of gluten (wheat, barley, rye), resulting in intestinal damage.
- The estimated prevalence of coeliac disease is approximately 1%.
- Classic symptoms experienced prior to diagnosis include diarrhoea, abdominal discomfort, fatigue and weight loss.
- The condition is typically diagnosed by serological testing followed by duodenal biopsy.
- Treatment is a life-long gluten-free diet.

Methods

In-depth, semi-structured interviews were conducted with adults with coeliac disease between June and October 2012.

Recruitment

- Interview participants were recruited through Coeliac UK, a charity for people living with coeliac disease in the UK, and snowball sampling.
- Participants were recruited from three geographical areas within England. These areas were selected to ensure that members from both rural and urban areas, and more and less socially deprived areas were included in the study.
- Variation was sought across demographic and disease characteristics, particularly gender, age, and duration since diagnosis.

Data Collection and Analysis

- Interviews explored the impact of coeliac disease on the participant's quality of life. They were conducted at the participant's home, workplace, or at the University of Oxford and ranged between 50 minutes and two and a half hours in duration.
- Interview data was audio-recorded with the participant's consent, transcribed verbatim, and analysed thematically in NVivo 9.
- Candidate items were drafted for each theme identified.

Results

Participants

Twenty-three adults with coeliac disease were interviewed. A summary of participant characteristics can be found in Table 1.

Table 1: Summary of interview participants (total, n=23)

Participant Characteristic	Summary
Age Range (years):	29 – 90
Gender (n):	Female (15), Male (8)
Marital Status (n):	Single (1), Married (17), Widowed (3), Divorced (2)
Ethnic Origin (n):	White British (19), White Irish (3), Asian/Asian British (1)
Occupational Status (n):	Full-time work (4), Part-time work (6), Unemployed (1), Retired (12)
Time since diagnosis (years):	<1 – 40

Themes

Participants described a range of ways in which their quality of life was affected by their coeliac disease. These experiences were grouped into the following six themes: gluten-free diet, emotional health, impact on activities, symptoms, relationships, and financial issues. Sub-themes identified in relation to each theme are shown in Table 2. Of particular note, participants described various practical and social difficulties with following a gluten-free diet, for example, negotiating situations which required obtaining suitable food while away from the home. A second notable area was the impact of the condition on the participants' emotional health. Participants had various concerns and worries, such as accidentally consuming gluten and becoming unwell, and developing associated conditions.

Candidate items were drafted for each theme identified, resulting in a total of sixty-three candidate items for a new PROM exploring quality of life in coeliac disease. A selection of candidate items for each theme are presented in Table 2.

Conclusions

This research has identified the wide variety of ways in which coeliac disease impacts on the quality of life of people living with the condition. Existing disease-specific PROMs omit or poorly cover several of the quality of life issues identified, for example, the CD-QOL has no symptom items, and the CDQ has few items about the difficulties faced following a gluten-free diet.

Consequently, the content validity of these measures is limited. Candidate items for a new disease-specific PROM which proposes to address these limitations have been drafted. These items will undergo expert review, cognitive testing, and item reduction prior to an examination of the psychometric properties of this new measure.

Table 2: Analytic themes, sub-themes and selected candidate items (total number of candidate items, n=63)

Theme	Sub-themes	Number of Items	Selected Candidate Items (During the past 4 weeks, how often...)
Gluten-free Diet	<ul style="list-style-type: none"> • Food shopping • Food choice • Acceptability of gluten-free food • Cross-contamination • Risk • Eating outside of the home 	16	<ul style="list-style-type: none"> ... were you annoyed or frustrated by trying to find suitable food? ... were you disappointed with the taste or texture of gluten-free alternatives? ... did you feel uncomfortable about other people having to cater for your diet? ... did you find it difficult to explain your dietary needs to others?
Emotional Health	<ul style="list-style-type: none"> • Concerns and worries • Feelings • Isolation and exclusion • Unwanted visibility 	15	<ul style="list-style-type: none"> ... were you feeling down and / or in low spirits? ... did you feel isolated because of your coeliac disease? ... were you concerned about developing a health condition related to your coeliac disease?
Impact on Activities	<ul style="list-style-type: none"> • Work • Holidays • Other social activities • Travelling • Planning ahead • Time • Avoiding social activities 	12	<ul style="list-style-type: none"> ... were your work activities affected? ... were your holiday or leisure activities affected? ... did you have difficulty finding something to eat whilst travelling? ... did you avoid social activities?
Symptoms	<ul style="list-style-type: none"> • Gastrointestinal • Energy • Pain • Concentration • Weight 	9	<ul style="list-style-type: none"> ... were you affected by diarrhoea and/or loose bowel movements? ... were you troubled by nausea and/or vomiting? ... were you affected by tiredness or lack of energy? ... was your concentration or ability to think clearly affected?
Relationships	<ul style="list-style-type: none"> • Support • Trust • Lack of understanding 	7	<ul style="list-style-type: none"> ... were you affected by the lack of support of friends or family members? ... did you feel guilty about the impact of your condition on friends or family members? ... were you annoyed by others lack of understanding about your condition and/or dietary needs (e.g. dismissing it as a lifestyle choice)?
Financial Issues		4	<ul style="list-style-type: none"> ... were you annoyed or frustrated about the cost of gluten-free food? ... did you feel guilty about other people buying gluten-free foods for you?