A patient-centered approach to developing a quality-of-life questionnaire for chronic oral mucosal diseases

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Objective. The objective of this study was to develop a self-completion questionnaire measuring quality of life in patients with chronic oral mucosal diseases.

Study design. The stages of development involved the use of both clinical expert input, via a modified Delphi technique, and patient input, via qualitative interviews, in the generation of items. Item reduction was carried out using a judgment method.

Results. Expert input was derived from 5 professors or consultants in oral medicine. Qualitative interviews were conducted with 24 patients during the item-generation phase of development. An initial item pool of 28 items was generated from the clinician and patient input. Importance ratings ranged from 4.0 to 0.44. Items with importance ratings below 1 were reviewed and considered for exclusion. Three items were subsequently excluded and 1 item added resulting in a final 26-item instrument.

Conclusions. This is the first discipline-specific quality-of-life measure developed in the field of oral medicine. (Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2011;111:578-586)

Conditions affecting the oral mucosa, commonly managed in an oral medicine clinical setting, are often chronic in nature or recurrent, painful disorders. Both the clinical manifestations and the treatment options available in the management of these longstanding diseases can affect the quality of life (QoL) of patients. Self-esteem, self-expression, communication, and increased facial esthetic value are thought to be the ways in which the oral cavity contributes to the QoL of an individual. Studies have demonstrated that oral diseases have a broad impact on everyday life with physical, economic, social, and psychological consequences. Hegarty et al. highlighted the need to establish the effect of oral mucosal diseases on QoL, with a predominance of generic and oral health–specific quality-of-life measures currently being used to a limited extent in oral medicine practice.

An outcome measure in health care has been defined as “a change in current or future health status that can be attributed to the antecedent intervention.” Patient-reported outcomes commonly include psychosocial changes, such as changes in health status, ability to function, and satisfaction with the care provided. The increase in the use of patient-reported outcome measures, including quality-of-life measures, in recent times reflects the move in health care away from simply prolonging life toward improving the overall lives of patients. Although a number of QoL instruments have been developed for the general population, they are unlikely to detect small, clinically important changes, resulting in the development of disease-specific instruments. Disease-specific questionnaires allow the inclusion of aspects of health considered by patients or clinicians to be of greatest importance. They are more sensitive to change and more likely to accurately predict clinical changes when compared with generic scales. The fault commonly associated with disease-specific questionnaires is that they do not allow comparison across diseases. This is where discipline-specific questionnaires may be of more benefit. These questionnaires are currently available in the field of dermatology: Dermatology Life Quality Index (DLQI), Dermatology Quality of Life Scales, Dermatology Specific Quality of Life Instrument, and Skindex 29. These discipline-specific instruments can assess specific effects of a number of skin conditions and are readily accepted by patients as they see the relevance of the questions to their condition.
The widespread use of these dermatology-specific QoL questionnaires with for example DLQI having been used with 33 different skin conditions in 32 different countries and translated into 55 languages. Although a dearth of QoL measures have been developed and reported on in the literature, no discipline-specific measure in the field of oral medicine has been developed to date.

Streiner and Norman recommend the used of both a generic and a specific questionnaire when measuring QoL in research. Disease-specific questionnaires in the field of dentistry are limited; however, the option exists to use oral health–related quality-of-life (OHRQoL) measures in addition to generic QoL measures.

Ni Riordain et al. reported that Oral Health Impact Profile (OHIP) was the most common OHRQoL instrument being used in the field of oral medicine. Although OHIP is a valid and reliable measure, it is not without its flaws. Locker and Allen and Allen and Locker highlighted concerns relating to OHIP-14, namely its lack of suitability for use in some population groups, its significant floor effects, and its poor responsiveness. The items for OHIP were generated following interviews in a patient cohort drawn from private dental practice, primary care clinics, and prosthetic clinics in a dental hospital. The conditions explored in this project include the following: recurrent aphthous stomatitis, oral lichen planus, the more common vesiculobullous conditions (mucous membrane pemphigoid and pemphigus vulgaris), and orofacial granulomatosis. Because of the focus of this study on patients with chronic oral mucosal conditions and the common management of these diseases in the secondary referral setting of an oral medicine unit, it is unlikely that patients with these diseases would have been interviewed in the development of OHIP. The development of an oral medicine–specific measure for patients with chronic oral mucosal conditions would, therefore, present researchers and clinicians with a specific QoL questionnaire for use in conjunction with a generic QoL instrument as recommended by Streiner and Norman.

The QoL of patients with some of the conditions explored in this project has been assessed in previous studies. OHRQoL and general QoL of patients with oral lichen planus, pemphigus, and recurrent aphthous stomatitis have been reported in the current literature. However, no instrument used in these studies has been developed using direct input from oral medicine patients. The aim of this study was to develop a robust, self-completion questionnaire to measure QoL in patients with these chronic oral mucosal diseases using a patient-centered approach. This is an evaluative index, used to assess the degree of longitudinal change in patients with these conditions at review appointments.

**MATERIALS AND METHODS**

A consensus has been reached on the stages of development of QoL questionnaires.

1. **Generation and selection of an item pool**
   - review the current literature, including a review of existing questionnaires
   - consult with experts in the area
   - consult with patients

2. **Scaling of items**

3. **Item reduction**

This study was approved by the Clinical Research Ethics Committee of the Cork Teaching Hospitals.

**Clinical expert input**

The group of experts was invited purposively to incorporate varying aspects of clinical management of patients with chronic oral mucosal conditions and practitioners with a keen interest in QoL. A Modified Delphi technique was used to gather expert input. This methodology was used successfully by Cotterill et al. in the development of a QoL questionnaire for anal incontinence. E-mail–based questionnaires, with free text responses to a number of key questions, were sent these clinicians.

The goal of this process was to reach a consensus with regard to the following:

- common chronic oral mucosal conditions treated in an oral medicine setting
- areas of a patient’s life that clinicians felt could be affected by these conditions

Responses were analyzed to find areas of agreement or disagreement between clinicians and the list recirculated for clarification where consensus was not achieved.

**Patient input**

Patients, older than 18 with chronic oral mucosal conditions attending the Oral Medicine Unit of Cork University Dental School and Hospital, were invited to become involved in this study. Five focus groups were conducted with participants (n = 22) suffering from oral lichen planus, mucous membrane pemphigoid, pemphigus vulgaris, recurrent aphthous stomatitis, and orofacial granulomatosis. The diagnosis of a chronic oral mucosal condition was based on history, clinical examination, and hematological and histologic examinations, where appropriate. Six to 12 participants were
Table 1. Clinical expert input regarding the influence of chronic oral mucosal conditions on the quality of life of patients

<table>
<thead>
<tr>
<th>Influences on quality of life</th>
</tr>
</thead>
<tbody>
<tr>
<td>EI 1</td>
</tr>
<tr>
<td>● Physical pain</td>
</tr>
<tr>
<td>● Interference with eating/drinking</td>
</tr>
<tr>
<td>● Interference with speech</td>
</tr>
<tr>
<td>● Interference with work and social life</td>
</tr>
<tr>
<td>● Negative effect on mood</td>
</tr>
<tr>
<td>EI 2</td>
</tr>
<tr>
<td>● Pain</td>
</tr>
<tr>
<td>● Altered function (e.g., eating, speaking)</td>
</tr>
<tr>
<td>EI 3</td>
</tr>
<tr>
<td>● Pain</td>
</tr>
<tr>
<td>● Pain with speech</td>
</tr>
<tr>
<td>● Avoidance of social interaction</td>
</tr>
<tr>
<td>● Limited diet</td>
</tr>
<tr>
<td>● Appearance if vermillion border affected</td>
</tr>
<tr>
<td>● Acceptability of topical agents used in management</td>
</tr>
<tr>
<td>● Side effects of systemic immunosuppressant drugs</td>
</tr>
<tr>
<td>● Malignant potential</td>
</tr>
<tr>
<td>EI 4</td>
</tr>
<tr>
<td>● Nutrition difficulty</td>
</tr>
<tr>
<td>● Communication problems</td>
</tr>
<tr>
<td>● Pain</td>
</tr>
<tr>
<td>● Biological, psychological and social aspects of the conditions</td>
</tr>
<tr>
<td>EI 5</td>
</tr>
<tr>
<td>● Pain</td>
</tr>
<tr>
<td>● Problems with speech, eating, and drinking</td>
</tr>
</tbody>
</table>

enrolled in each focus group as recommended by Willms and Johnson. Unlike in quantitative research methods, power calculations are not commonplace in qualitative research. With regard to patient input for questionnaire development, Streiner and Norman proposed no more than 2 to 3 focus groups of 6 to 12 patients. In qualitative research methods, the numbers of participants are not fixed, as an iterative process is used with the data collected. Data collection is carried out in stages and the data are immediately analyzed before any further collection is undertaken. This piece-meal process continues until data saturation has been achieved.

Purposive sampling was used and focus groups were mixed with regard to gender, age, chronic oral mucosal condition, time since diagnosis, and severity (Table 1). The grading of severity was derived from a type of clinical rating of the condition within the preceding 6 months. The clinician determined how well controlled the patient’s condition was, based on the medications required to alleviate symptoms, as follows:

- Mild = Exacerbations managed well with topical agents
- Moderate = Systemic agents needed during periods of exacerbation
- Severe = Systemic agents needed long-term for management of the condition.

Two participants were unwilling to attend the focus groups, expressing anxiety owing to the physical manifestations of their conditions, and requested individual interviews. Telephone interview were subsequently carried out with these participants.

To adhere to the principal of reflexivity, specifically positional reflexivity as outlined by Malterud, it was decided that an experienced independent facilitator, who was unaware of the issues regarding oral mucosal disease, would convene all focus groups. These interviews were held in a nonclinical setting and timetabling was flexible to facilitate diverse participation.

A topic guide (Fig. 1) was developed to facilitate standardization across all interviews conducted and to provide a framework in which the researcher could conduct these interviews. The guide consisted of a list of topics of interest, developed as follows:

- by using issues raised in past QoL instruments and the literature
- with informal discussions with patients
- with clinical expert input

This topic guide was then piloted on a cohort of patients with the study-specific chronic oral mucosal conditions in the forum of a focus group. Although the topic guide was used, discussions were allowed to be flexible according to the experience of each participant. The focus groups and telephone interviews were digitally recorded and field notes were also taken. To maintain the iterative process, the interview schedule consisted of 2 interviews followed by analysis of the data and subsequent review and refining of the topic guide. This process continued until data saturation was achieved. The recordings were transcribed and participants were anonymized with each subject being assigned a participant number.

Item generation

Transcripts were imported into NVivo qualitative data analysis software (Version 8, 2008; QSR International Pty Ltd., Cambridge, MA, USA) and a thematic analysis was undertaken. The transcripts were analyzed and coded on a line-by-line basis independently by 2 researchers. Miles and Huberman define codes as “tags or labels, for assigning units of meaning to the descriptive or inferential information compiled during a study.” Detailed definitions of each code were produced in a code book. Revision of the codes was continual, combining some codes together while separating and differentiating others. The master list of codes was then reviewed and classified into potential themes. The coded extracts for each theme were read and reread to ensure suitability.

Items were then selected from the themes found in the analysis of the transcripts. Items included fulfilled
the following criteria: (1) relevant to Locker’s model of oral health,\textsuperscript{25} (2) applicable to all possible respondents, and (3) unambiguous.

**Item reduction**

An item reduction by judgment method was used in this study, as outlined by Stevens et al.\textsuperscript{26} Participants completing the initial draft of a questionnaire were asked to rate the “importance” of items in the instrument. Patients were requested to rate questionnaire items on a 5-point scale, ranging from extremely important\textsuperscript{4} to of no importance (0).\textsuperscript{27} This took place in the forum of a focus group where patients completed the newly developed question-

**Topic guide**

- Have you made many changes in your life since your initial diagnosis?

- **Diagnostic delay**
  - seen by multiple practitioners
  - varying advice given
  - multiple medications/treatments given
  - fear due to diagnostic delay
  - sufficient information given / know enough now about condition

- **Chronic nature of conditions**
  - no cure
  - no idea of duration of conditions
  - fear of the possibility of it worsening = increased anxiety

- **Need for regular medications**
  - types of medication
  - means of administration
  - inconvenience of treatment regimens
  - side effects
  - cost of attending practitioner and cost of medication
  - is this their first preference for treatment (if not what is).
  - what influences their choice of treatment money, time, access etc.

- **Regular reviews needed**
  - reviews needed not only in hospital but also with general dentist and hygienist
  - access / travel arrangements for regular reviews in hospital (only 2 Oral Medicine centres in Rep of Irl therefore some must travel)
  - plan year around appointments (+ +cost) annual leave used for dental treatment
  - cost (self, government, parents)

- **Risk of change – malignant transformation possible in oral lichen planus (OLP)**

- **Unpredictable nature**
  - unsure when flare-up will occur
  - severity of flare-up
  - no specific trigger

Fig. 1. Topic guide used for qualitative interviews.
-lack of control over the condition
-access when flare up occurs – with severe flare when change of medication required (can be inconvenient such as holidays. Would it influence where you take holidays etc?)

- Activities of daily life
- Eating / Chewing
- Drinking
- Care with type of food and temperature of food and drink
- Speaking

-Social interactions
  - Work
  - School
  - Friends/family

- Appearance
  - bleeding
  - crusting
  - swelling

- Concern about involvement of sites outside the mouth or underlying / associated medical conditions.
  Impact on other health outcomes – particularly related to medications used (side effects can lead to other serious medical conditions)

- Daily routine when it’s not flared up?
  Constant care needed or just when flare-up?
  Fear that something in their daily routine will trigger flare up?
  Would their daily routine be different than just the general brushing and flossing?

- What about the future?
  What do they envisage in the future with regards to care and treatment and other physical, social and psychological factors?

Fig. 1. (Continued).

naire and rated each individual item on the aforementioned 5-point scale. According to Streiner and Norman,11 participants should be interviewed until no new problems are uncovered. In most cases, this occurs in from 8 to 15 interviews. Ten patients were involved in these focus groups.

A “double interview technique” was used in the focus groups, where participants were asked to think aloud when completing the questionnaire and were then verbally probed regarding their answers.11 The “importance ratings” of each individual item were summed: frequency (the proportion of patients experiencing a particular item) × importance (the mean importance attached to that item) = importance rating, leading to a potential range of 4.0 to 0. Items with importance ratings below 1 (frequency of < 0.5 × importance of 2) were reviewed and considered for exclusion.

RESULTS

Clinical expert input

Five professors or consultants in oral medicine were enrolled in this part of the study. The goals were to determine a consensus with regard to common chronic oral mucosal conditions and the impact of these conditions on the lives of patients.

The common oral mucosal conditions treated in an oral medicine setting were

- oral lichen planus
- recurrent aphthous stomatitis
- mucous membrane pemphigoid
pemphigus vulgaris
orofacial granulomatosis (OFG)

The areas of a patient’s life that clinicians felt could be affected by these conditions (Table I) can be summarized as follows:

- pain
- limitation of function
- medications and side effects
- social limitations

Patient input

Qualitative interviews were conducted with 24 patients during the item-generation phase of development. Table II represents the characteristics of the study participants. The findings from these qualitative interviews, presented as 4 key themes in relation to patients’ experiences of their chronic oral mucosal condition, were presented in an earlier article.28

These themes were

- biopsychosocial issues
- treatment limitations and side effects
- unpredictability of the conditions and the potential for malignant transformation
- issues for the health care professionals

Item generation and scaling

An initial item pool of 28 items was generated from both clinician and patient input. These items were grouped into domains based on intuition, informed by clinical judgment.29 A 5-point Likert scale was used for responses to the items generated (Appendix 1).

Item reduction

Importance ratings ranged from 4.0 to 0.44 (Table III). Three items were subsequently removed, as they fell below the importance-rating threshold of 1. The items removed were “How much does your oral condition interfere with speech or conversation?” “How much does your oral condition cause you to be embarrassed?” and “How much does your oral condition limit your future plans?” One item was then added as a result of patient feedback, regarding the impact of these conditions on denture usage. The final version of the questionnaire therefore consisted of 26 items.

**DISCUSSION**

The development of only one QoL instrument using input from oral medicine patients has been reported in the literature, the Behcet’s specific measure developed by Gilworth et al.30 As highlighted by the authors, the use of in-depth qualitative interviews with patients enables the development of instruments with very high content validity and responsiveness. The role of the patient in the development of this new QoL measure has been central to ensure maximal relevance of the items generated to the population being tested. This new instrument will allow accurate evaluation of QoL.
in patients while also facilitating comparison across the conditions being studied.

Although a methodological consensus has been established for the development of patient-reported outcome measures, developmental variations exist in the literature. Patient involvement in the generation of items is considered crucial, as they are only people who can truly report on the subjective elements of the conditions being studied. In an article by Chassany et al., the authors reported that clinicians underestimated both the pain and impact of QoL of conditions on patients. The number of patients involved in the qualitative interviews (n = 24) is in keeping with the aforementioned recommendations by Streiner and Norman and in line with a number of other studies in the literature detailing the development of a new questionnaire. Hunt and McKenna conducted qualitative interviews with 30 patients with depression in the development of The Quality of Life in Depression Scale, Price et al. interviewed 14 patients with vaginal symptoms in the development of The International Consultation on Incontinence Vaginal Symptoms Questionnaire, and Poole et al. interviewed 27 patients during the development of A Quality-of-Life Measure for Neuropathic Pain.

The heterogeneity of the sample used in this study is due to the type of sampling strategy used. The goal with regard to purposive sampling with maximum variation in qualitative research, as used in this study, is to achieve an element of commonality with a maximum degree of variation. The chronicity of the mucosal diseases is the commonality and the variation is achieved by mixing the groups with regard to age, gender, severity of the conditions, and time since diagnosis. Although the term severity of the condition is used in this study, it would be more appropriate to label this as the degree of symptom control. We explored using previous scoring systems, for example those used by Hegarty et al., Thongprason et al., and Carbonne et al.; however, because of the variation in the clinical manifestations of the conditions in this study it was not possible to use a single scoring system.

A number of QoL questionnaires developed have bypassed patient involvement, limiting the initial stage to a literature review and input from health care professionals. In a recent questionnaire developed by Stevens et al., no patient input was sought in the initial generation of items with great emphasis placed on introducing a variety of health care professionals for the expert input. The authors conducted a focus group with 2 nurses, 2 dieticians, 1 radiation oncologist, and 1 head and neck surgeon to generate items for a questionnaire on QoL for patients with head and neck cancer with enteral feeding tubes. To ensure a patient-centered approach to the development of this outcome measure, particular emphasis was placed on the results of the qualitative interview with patients for the generation of items. The current literature and the expert input were principally used in the derivation of the topic guide for the qualitative interviews.

Again, variation exists in methodology with regard to item reduction. Item reduction can be carried out by judgment or by statistical methods, such as use of the Rasch theory or factor analysis. In an article by Juniper et al., a comparison was made between item reduction by judgment and item reduction by factor analysis. The authors found that 2 very different instruments were derived from the same item pool when using the different approaches to item reduction. Item reduction by judgment was used in this study to maintain the patient-centered approach to the development of this questionnaire. Factor analysis can be carried out at a later stage to determine the number of factors underlying the set of items so that procedures, such as computing Cronbach’s alpha, can be performed correctly.

Evaluation of this outcome measure is currently taking place to test for construct validity; this assesses the ability of the questionnaire to reflect theories and traits underlying these chronic oral mucosal diseases. The

### Table III. Item importance rating

<table>
<thead>
<tr>
<th>Item</th>
<th>Frequency</th>
<th>Importance</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain and functional limitation 1</td>
<td>0.9</td>
<td>3.8</td>
<td>3.42</td>
</tr>
<tr>
<td>Pain and functional limitation 2</td>
<td>0.8</td>
<td>2.9</td>
<td>2.32</td>
</tr>
<tr>
<td>Pain and functional limitation 3</td>
<td>0.9</td>
<td>3.2</td>
<td>2.88</td>
</tr>
<tr>
<td>Pain and functional limitation 4</td>
<td>0.9</td>
<td>3.4</td>
<td>3.33</td>
</tr>
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<td>Pain and functional limitation 5</td>
<td>0.9</td>
<td>4.0</td>
<td>3.60</td>
</tr>
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<td>Pain and functional limitation 7</td>
<td>0.4</td>
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<td>Pain and functional limitation 8</td>
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<td>3.1</td>
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</tr>
<tr>
<td>Pain and functional limitation 9</td>
<td>0.5</td>
<td>3.1</td>
<td>1.55</td>
</tr>
<tr>
<td>Medication and treatment 1</td>
<td>0.7</td>
<td>2.6</td>
<td>1.82</td>
</tr>
<tr>
<td>Medication and treatment 2</td>
<td>1.0</td>
<td>4.0</td>
<td>4.00</td>
</tr>
<tr>
<td>Medication and treatment 3</td>
<td>0.9</td>
<td>2.9</td>
<td>2.61</td>
</tr>
<tr>
<td>Medication and treatment 4</td>
<td>0.9</td>
<td>2.9</td>
<td>2.61</td>
</tr>
<tr>
<td>Medication and treatment 5</td>
<td>0.6</td>
<td>2.5</td>
<td>1.50</td>
</tr>
<tr>
<td>Medication and treatment 6</td>
<td>1.0</td>
<td>4.0</td>
<td>4.00</td>
</tr>
<tr>
<td>Social and emotional 1</td>
<td>0.4</td>
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</tr>
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<td>Social and emotional 3</td>
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<td>Patient support 1</td>
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<td>Patient support 2</td>
<td>1.0</td>
<td>3.2</td>
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<tr>
<td>Patient support 4</td>
<td>0.7</td>
<td>1.5</td>
<td>1.05</td>
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</table>
reliability is being examined in the form of internal consistency and test–retest reliability, and the responsiveness of the new instrument to change in a patient’s condition is also being investigated. It is hoped that this QoL measure will be used at outpatient appointments to allow a greater focus to the limited time available at these appointments. Often times these outpatient visits focus on symptomatic exacerbations of these conditions to the exclusion of other aspects of a patient’s health. This QoL instrument could supply valuable information regarding the patients’ perspectives on the diseases in question and hence allow clinicians to modify the treatment provided following this in-depth evaluation. The role of this outcome measure will not be limited to an evaluative one; as highlighted by Streiner and Norman,11 outcome measures developed as evaluative indexes have subsequently been validated as both predictive and discriminative indexes.

In conclusion, this is the first discipline-specific QoL measure developed in the field of oral medicine. A patient-centered approach to development was adopted because of the critical role of patients in determining the impact of conditions on their daily lives.

REFERENCES

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## Appendix 1. Chronic Oral Mucosal Diseases Quality of Life Questionnaire

### Pain and functional limitation

1. How much do certain types of food/drink cause you discomfort (spicy food, acidic food)?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

2. How much does your oral condition cause you to limit the types of food/drinks you consume?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

3. How much do certain food textures cause you discomfort (rough food, crusty food)?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

4. How much does your oral condition cause you to limit the textures of the food you consume?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

5. How much does the temperature of certain foods/drinks cause you discomfort?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

6. How much does your oral condition cause you to limit the temperature of the foods/drinks you consume?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

7. How much does your oral condition lead to discomfort when carrying out your daily oral hygiene routine (brushing, flossing, mouthwash usage)?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

8. How much does your oral condition cause you to limit your daily oral hygiene routine (brushing, flossing, mouthwash usage)?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

9. How much does your oral condition lead to discomfort when wearing a denture (false teeth)?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

### Medication and treatment (including mouthwashes, gels, creams, ointments, injections, tablets, infusions)

1. How much do you feel you need medication to help you with activities of daily life (talking, eating, etc.)?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

2. How satisfied are you with the medication being used to treat your oral condition?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

### Social and emotional

1. How much does your oral condition get you down?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

2. How much does your oral condition cause you anxiety?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

3. How much does your oral condition cause you stress?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

4. How much does the unpredictability of your oral condition bother you?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

5. How much does your oral condition cause you to worry about the future (spread of the condition, possible cancer risk)?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

6. How much does your oral condition make you pessimistic about the future?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

7. How much does your oral condition disrupt social activities in your life (social gatherings, eating out parties)?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4

### Patient support

1. How satisfactory do you consider the information available to you regarding your oral condition?
   - Not at all 0
   - Slightly 1
   - Moderately 2
   - Considerably 3
   - Extremely 4
Appendix 1. Continued

| 2. How satisfied are you with the level of support and understanding shown to you by family regarding this oral condition? | Not at all 4  
|                                                                 | Slightly 3  
|                                                                 | Moderately 2  
|                                                                 | Considerably 1  
|                                                                 | Extremely 0  

| 3. How satisfied are you with the level of support and understanding shown to you by friends/work colleagues regarding your oral condition? | Not at all 4  
|                                                                 | Slightly 3  
|                                                                 | Moderately 2  
|                                                                 | Considerably 1  
|                                                                 | Extremely 0  

| 4. How isolated do you feel as a result of this oral condition? | Not at all 0  
|                                                               | Slightly 1  
|                                                               | Moderately 2  
|                                                               | Considerably 3  
|                                                               | Extremely 4  