

Title:

Validity and reliability of the Chronic Oral Mucosal Diseases Questionnaire in a UK population

Running title:

Testing a quality of life questionnaire

Key words:

Quality of life, Chronic oral mucosal diseases, Oral medicine, Validity and Reliability

Authors:

Richeal Ni Riordain, University Hospital Limerick, Ireland

[richeal.niriordain@gmail.com](mailto:richeal.niriordain@gmail.com)

Tim Hodgson, UCLH NHS Foundation Trust Eastman Dental Hospital UCL Eastman Dental Institute, Oral Medicine Unit, London, United Kingdom

Stephen Porter, University College London, UCL Eastman Dental Institute London, UK; NIHR University College London Hospitals, Biomedical Research Centre, London, United Kingdom

Stefano Fedele, University College London, UCL Eastman Dental Institute London, UK; NIHR University College London Hospitals, Biomedical Research Centre, London, United Kingdom

## Abstract

**Objective:** To investigate the validity and reliability of a the Chronic Oral Mucosal Diseases Questionnaire in a UK population

**Methods:** Two hundred patients with chronic oral mucosal disease (oral lichen planus, recurrent aphthous stomatitis, mucous membrane pemphigoid, pemphigus vulgaris) were enrolled in this study from the Oral Medicine Department of University College London Hospitals Trust (UCLHT) Eastman Dental Hospital. Individuals were interviewed using Oral Health Impact Profile (OHIP-14), Visual Analogue Scale (VAS), and Chronic Oral Mucosal Diseases Questionnaire (COMDQ) and the construct validity and internal reliability were examined.

**Results:** Of the 200 study participants, 100 respondents had oral lichen planus, 42 had recurrent aphthous stomatitis and 58 had vesiculobullous conditions (mucous membrane pemphigoid or pemphigus vulgaris). With regard to construct validity, a moderate to good degree of convergent validity was found between OHIP-14 and VAS and most subscales and the total COMDQ score except the patient support subscale of COMDQ (0.21-0.37).

**Conclusion:** COMDQ is a valid and reliable patient-reported outcome measure for patients with chronic oral mucosal diseases in a UK population. It can be considered a valuable instrument in both clinical practice and in oral medicine research.

## Introduction

Chronic oral mucosal diseases are typically immune mediated disorders affecting the soft tissue of the mouth, which are managed in an oral medicine setting. Due to the recurrent, painful nature and longevity of these conditions they can result in considerable morbidity for patients including physical, social and psychological consequences (1). Not only can the oral manifestations of these diseases impact on the daily lives of patients but the medications use in the management of these conditions can also impinge on the day-to-day activities of patients, as highlighted in a qualitative study by Ni Riordain and McCreary (2). Also of concern for patients is that some of these conditions may predispose to the development of life-threatening diseases (3, 4).

Since the 1990s the utility of outcomes measures in the medical field, both in clinical practice and in research, has grown considerably (5). Of particular importance more recently is the use of patient reported outcome measures (PROMs), which the National Health Service (NHS) in the UK describes as 'putting patients, and their families and carers, at the heart of deciding which goals are most valuable for individuals with a range of health conditions.' (6). These measures were introduced into the NHS in April 2009, initially to assess the impact of 4 surgical interventions on the quality of life of patients, with plans to incorporate PROMs into the evaluation of the management of chronic diseases such as asthma and diabetes proposed (7). Quality of Life (QoL) is acknowledged as more than merely the absence of disease or infirmity, it encompasses a person's ability to lead a productive and enjoyable life, embedded in the culture and value systems to which they are accustomed (8).

When considering the QoL of the oral cavity specifically we focus on oral health related quality of life (OHRQoL), defined by Locker et al. (9) as 'the extent to which oral disorders affect functioning and psychosocial well-being'. The oral cavity contributes to QoL by enhancing self-worth, expressiveness, communication and increased facial aesthetic value (10).

Quality of life instruments have been employed to a limited extent in oral medicine practice and research. As highlighted in the recent World Workshop in Oral Medicine review of the use of patient-reported outcome measures in oral mucosal disease there is a lack of homogeneity with regard to the instruments used, often times with ad hoc questionnaires employed to record the impact of these on patients (11). Chronic Oral Mucosal Diseases Questionnaire (COMDQ) was recently developed in an Irish population and has proven to be both a valid and reliable oral medicine-specific QoL instrument on psychometric testing (12). Culture is thought to be fundamental to the expression of beliefs and the behaviour of people, therefore, the cross-cultural sensitivity of QoL instruments must be explored in new patient populations (13). The importance of using valid and reliable instruments with proven psychometric properties was recently emphasised as a future direction for improved patient care in oral medicine (11). As COMDQ was developed and tested in an Irish population, the aims of this study were to explore the psychometric properties of COMDQ, namely validity and reliability, in an English speaking UK population.

## Materials and Methods

## Recruitment and data collection

Adult patients were recruited from the Oral Medicine department of the Eastman Dental Hospital with the following chronic oral mucosal conditions: recurrent aphthous stomatitis (RAS), oral lichen planus (OLP) and the more common vesiculobullous conditions namely mucous membrane pemphigoid (MMP) and pemphigus vulgaris (PV). Patients over the age of 18 years, who had signed the written consent, diagnosed with one of the study specific chronic oral mucosal diseases based on history, clinical examination and histological examinations where appropriate were enrolled in the study. Each participant completed Oral Health Impact Profile-14 (OHIP-14), COMDQ and Visual Analogue Scale (VAS) for pain, at review appointments within the department at a single point in time.

Oral Health Impact Profile is an instrument developed by Slade and Spencer (14) to assess the difficulties experienced by patients in the recent past regarding their oral cavity. Originally developed with 49 questions across seven domains (functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap) a shortened version was subsequently derived with 14 questions, referred to as OHIP-14 (15). A five-point response scale from 0 (never) to 4 (very often) is used to record the frequency of the oral problems encountered by patients. We calculated the unweighted OHIP-14 score, ranging from 0-56, in this study.

The Visual Analogue Scale (VAS) is a valid and reliable instrument (16) which is presented as a 10cm horizontal line, with 0 representing no pain and 10

representing the worst pain imaginable. Verbal anchors are used adjacent to point 0cm and point 10cm, namely 'None' and 'Agnoising'. To complete this PROM patients are required to indicate the intensity of their pain by placing a mark on the horizontal line.

The Chronic Oral Mucosal Diseases Questionnaire (COMDQ) is a 26-item oral medicine specific QoL instrument developed in an Irish population (17). The 26 questions are grouped into 4 domains (pain and functional limitation, medications and side effects, social and emotional and patient support) and a 5-point response scale used from 'not at all' to 'extremely' for each item leading to a cumulative score of 104. Patients were involved in all stages of the development, from item derivation via qualitative interviews to validation and reliability (12, 18, 19).

Ethical approval was sought for this study; however, as this was considered to be an evaluation of service, ethical approval was not deemed necessary.

#### Psychometric testing

Convergent validity, a type of construct validity, was assessed in this study. Construct validity determines whether an instrument can reflect theories and traits underlying the chronic oral mucosal diseases being investigated. Streiner and Norman describe convergent validity as the extent to which the PROM being tested relates to other instruments of a similar construct to which it is proposed to be related (20). Firstly, it was proposed that patients with a higher VAS score would obtain a poorer score in the COMDQ. Secondly, it

was anticipated that patients' scores for OHIP-14 would correlate with scores from COMDQ. Spearman's rho correlations were used to assess the relationship between COMDQ and VAS and COMDQ and OHIP-14. The following grading of the degree of correlation will be applied 0.2 – 0.4 is low correlation, 0.4 – 0.6 is moderate, 0.6 – 0.8 is good and 0.8 – 1.0 is high (21).

Internal consistency reliability, measured using Cronbach's alpha, is the degree to which groups of questions in an instrument designated as a subset or domain and therefore representing a single construct, coexist as a unifying set when an instrument is administered (22). Cronbach's alpha values of 0.6 to 0.69 are considered acceptable, 0.7 or higher are required before an instrument is considered adequately reliability, however, a minimum value of 0.8 is necessary for 'good' internal consistency reliability (22).

## Results

### Patient characteristics

Of the 200 study participants, 100 respondents had OLP, 42 had RAS and 58 had vesiculobullous conditions (PPM and VP). The frequencies of responses to OHIP-14 COMDQ and VAS all tended towards skewed distributions. Table 1 represents the median and inter quartile range scores for each sub-scale in OHIP-14 and the COMDQ and for VAS.

### Validity

All the Spearman's rho correlation coefficients were positive and significant at the 0.05 level as seen in Table 2. No high correlations were found amongst

the instruments used. A good degree of correlation was calculated between the COMDQ Pain and Functional and VAS, the OHIP-14 Physical Pain and the total OHIP-14 score. Again a good degree of correlation was found between COMDQ 'Social & Emotional' and OHIP 'Social Disability', OHIP 'Handicap' and the total OHIP score. A moderate to good correlation was found between COMDQ total scores and VAS, the total OHIP score and all subscale scores. Spearman's rho coefficients between 0.21 and 0.37 indicated that the 'Patient Support' domain was only weakly correlated with the other domains of COMDQ all domains of OHIP-14, and VAS scores.

#### Reliability

With regard to 'Patient Support' and 'Medication & Treatment' domains of COMDQ the Cronbach's alpha values of 0.61 and 0.74 indicated an internal consistency reliability of acceptable to adequate (Table 3). Cronbach's alpha values of 0.91 and 0.92, respectively, indicated very good internal consistency reliability with respect to the 'Pain & Function Limitation' and 'Social & Emotional' subscales. The overall COMDQ Cronbach's alpha value of 0.93 indicated excellent internal consistency reliability of the 26-item instrument.

#### Discussion

It has been established that patients with chronic medical and dental conditions can contribute to their own healthcare by providing key information regarding living with these longstanding diseases (23). Due to the longstanding nature of chronic oral mucosal diseases, Hegarty et al (24) and Escudier et al (25) highlighted the need to establish the effect of these



conditions on the daily lives of patients. Selecting suitable PROMs for use in clinical practice or research can present a challenge. Streiner and Norman (20) recommended using both a general and a specific PROM when evaluating the impact of a disease on the life of a patient, with SF-36 and OHIP reported as the most commonly used PROMs in the oral medicine literature (2). However, concerns were raised regarding the suitability of OHIP-14 as a QoL measure in certain patient cohorts (15, 26). COMDQ could offer a valid and reliable alternative to OHIP as a specific measure in patients with chronic oral mucosal diseases as seen in a recent study by Rajan et al (27). Patients from public and private primary dental care and hospital based prosthetic clinics were interviewed during the item generation phase of the development of OHIP (14), in contrast to COMDQ where direct quotations from qualitative interviews with patients with chronic oral mucosal diseases were used to generate the 26 items.

This study has demonstrated that the total COMDQ score has good convergent validity with both VAS and OHIP-14, with Spearman's rho correlation coefficient of 0.73 with OHIP-14 and 0.66 with VAS for pain scores, as indicated in Table 2. Although these values are considered good they are lower than the values found in an Irish population (0.82 and 0.88 respectively) (12). This variation could be further explored with qualitative interviews of patients in a UK setting regarding the instrument and the impact of chronic oral mucosal diseases on their daily lives and additional psychometric testing. COMDQ also demonstrated excellent reliability with Cronbach's alpha of 0.93, higher than values calculated in the Chinese

version of COMDQ with a value of 0.894 reported (28). Values approaching 0.95 are desirable when considering using PROMs in the individual clinical management of patients (29). When contemplating the scope of a PROM in the individual clinical management of patients with chronic diseases one can refer to the incorporation of the Dermatology Life Quality Index (DLQI) score into the eligibility criteria for the use of biologics in the management of psoriasis (30).

Skevington (13) outlined the importance of cross-cultural research in the area of QoL, highlighting the influence of changes in the provision of healthcare and the delivery of treatment on QoL. The healthcare system in Ireland is markedly different to that in the UK. In the UK the National Health Service (NHS) provides healthcare that is free at the point of delivery with a £8.05 prescription charge (31). In contrast the healthcare system in Ireland can crudely be described as two tier with fully subsidised healthcare for Health Service Executive Medical Card holders and Non-Medical Card holders entitled to free public hospital services with associated hospital charges along with subsidised prescription medications and maternity and infant care (32). Although COMDQ has been proven to be a valid and reliable measure exploration of cross-cultural elements is of critical importance due to the variations in healthcare delivery across the world.

In conclusion, this study has demonstrated that COMDQ is a valid and reliable instrument to evaluate QoL in patients with chronic oral mucosal diseases in a UK population. It can be considered a valuable PROM in both clinical

practice and in oral medicine research. Further exploration of the individual items in the questionnaire, using mixed methods research, could pinpoint the variation in correlation values between UK and Irish populations.

## References

1. MCGRATH C, BEDI R A review of the influences of oral health on the quality of life. *Int J Health Prom & Educ* 1999; 37: 116-119.
2. NI RIORDAIN R, MCCREARY C The use of quality of life measures in oral medicine: a review of the literature. *Oral Dis* 2010; 16: 419-430.
3. HEGARTY AM, MCGRATH C, HODGSON TA et al. Patient-centred outcome measures in oral medicine: are they valid and reliable? *Int J Oral Maxillofac Surg* 2002; 31: 670-4.
4. HEGARTY AM, MCGRATH C, HODGSON TA et al. Patient-centred outcome measures in oral medicine: are they valid and reliable? *International Journal of Oral and Maxillofacial Surgery* 2002; 31: 670-674.
5. WARE JE Measuring patients' views: the optimum outcome measure. *BMJ* 1993; 306: 1429-30.
6. NHS ENGLAND NHS. Patient Centred Outcome Measures. In. High quality care for all, now and for future generations. <http://www.england.nhs.uk/ourwork/pe/pcoms/>, 2015.
7. DEVLIN NJ, APPLEBY J. Getting The Most Out of PROMs  
Putting health outcomes at the heart of NHS decision-making: Vol.: Office of Health Economics, 2010.
8. WHOQOLGROUP The WHO Quality of Life Assessment (WHOQOL): development and general psychometric properties. *Soc Sci Med* 1998; 46: 1569-1585.

9. LOCKER D, CLARKE M, PAYNE B Self-perceived oral health status, psychological well-being, and life satisfaction in an older adult population. *J Dent Res* 2000; 79: 970-5.
10. KUSHNIR D, ZUSMAN SP, ROBINSON PG Validation of a Hebrew version of the Oral Health Impact Profile 14. *J Public Health Dent* 2004; 64: 71-5.
11. NI RIORDAIN R, SHIRLAW P, ALAJBEG I et al. World Workshop on Oral Medicine VI: Patient-reported outcome measures and oral mucosal disease: current status and future direction. *Oral Surg Oral Med Oral Pathol Oral Radiol* 2015; 120: 152-160 e11.
12. NI RIORDAIN R, MCCREARY C Validity and reliability of a newly developed quality of life questionnaire for patients with chronic oral mucosal diseases. *J Oral Pathol Med* 2011; 40: 604-9.
13. SKEVINGTON SM Advancing cross-cultural research on quality of life: observations drawn from the WHOQOL development. *World Health Organisation Quality of Life Assessment. Qual Life Res* 2002; 11: 135-44.
14. SLADE GD, SPENCER AJ Development and evaluation of the Oral Health Impact Profile. *Community Dent Health* 1994; 11: 3-11.
15. LOCKER D, ALLEN PF Developing short-form measures of oral health-related quality of life. *J Public Health Dent* 2002; 62: 13-20.
16. BIJUR PE, SILVER W, GALLAGHER EJ Reliability of the visual analog scale for measurement of acute pain. *Acad Emerg Med* 2001; 8: 1153-7.

17. NI RIORDAIN R, MEANEY S, MCCREARY C A patient-centered approach to developing a quality-of-life questionnaire for chronic oral mucosal diseases. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2011; 111: 578-586 e2.
18. NI RIORDAIN R, MCCREARY C Further reliability and responsiveness of the Chronic Oral Mucosal Diseases Questionnaire. *Oral Dis* 2012; 18: 60-6.
19. NI RIORDAIN R, MEANEY S, MCCREARY C Impact of chronic oral mucosal disease on daily life: preliminary observations from a qualitative study. *Oral Dis* 2010; 17: 265-269.
20. STREINER DL, NORMAN GR. *Health Measurement Scales A practical guide to their development and Use*. Oxford University Press: Oxford, 2006.
21. ANASTASI A, URBINA S. *Psychological testing*. Prentice Hall International: Upper Saddle River, NJ, 1997.
22. GRAVETTER FJ, FORZANO L-AB. *Research methods for the behavioural sciences*. Wadsworth: Belmont, CA, 2008.
23. DOH. *The Expert Patient - A New Approach to Chronic Disease Management for the 21st Century* In: HEALTH DO ed. HMSO: London, 2001.
24. HEGARTY AM, HODGSON TA, LEWSEY JD et al. Fluticasone propionate spray and betamethasone sodium phosphate mouthrinse: a randomized crossover study for the treatment of symptomatic oral lichen planus. *J Am Acad Dermatol* 2002; 47: 271-9.

25. ESCUDIER M, AHMED N, SHIRLAW P et al. A scoring system for mucosal disease severity with special reference to oral lichen planus. Br J Dermatol 2007; 157: 765-70.
26. ALLEN F, LOCKER D A modified short version of the oral health impact profile for assessing health-related quality of life in edentulous adults. Int J Prosthodont 2002; 15: 446-50.
27. RAJAN B, AHMED J, SHENOY N et al. Assessment of quality of life in patients with chronic oral mucosal diseases: a questionnaire-based study. Perm J 2014; 18: e123-7.
28. LI M, HE SL Reliability and validity of the Chinese version of the chronic oral mucosal diseases questionnaire. J Oral Pathol Med 2013; 42: 194-9.
29. BLAND JM, ALTMAN DG Statistical Notes - Cronbach's alpha. Br Med J 1997; 314: 572.
30. NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE. Psoriasis: The assessment and management of psoriasis: Vol. <http://www.nice.org.uk/guidance/cg153/chapter/1-recommendations#systemic-therapy>, 2012; No. NICE guideline [CG153].
31. NHS CHOICES NHS. NHS England Health Costs. In., 2014.
32. CITIZENS INFORMATION CIB. Entitlement to health services. In., 2014.