Patient reported outcome and experience measures of oral disease in oral medicine

R. Ní Ríordáin*[1] and P. Wiriyakijja[1,2]

In brief

- Updates the reader regarding the worldwide emphasis on the incorporation of patient reported outcome measures (PROMs) and patient reported experience measures (PREMs) in healthcare.
- Highlights the current instruments commonly used in the oral medicine literature.
- Emphasises the importance of the robust development of PREMs and PROMs.
- Outlines suggested plans for future research in both PROMs and PREMs in oral medicine.

A recent meeting of health ministers from over 40 countries worldwide deemed that time and money should be spent on outcome and experience measures that would allow us to determine whether our health systems deliver outcomes that truly matter to patients. This meeting, along with recent national programmes to promote the use of outcome measures in evaluating medical and surgical interventions, highlighted the important role that patient reported outcome measures (PROMs) and patient reported experience measures (PREMs) have in healthcare. Oral medicine as a speciality has promoted the use of PROMs to some extent in the recent past with the use of generic and oral health specific measures in the literature and the delivery of plenary lectures at international scientific meetings. We could find no publications regarding the use of PREMs in oral medicine. This article highlights the commonly used PROM tools in the oral mucosal disease and salivary gland literature and makes recommendations for the evaluation of the development properties of currently used instruments and the establishment of core outcome sets in the commonly managed conditions in an oral medicine setting. It is also hoped that by looking at the types of PREM tools available we can determine a suitable instrument for the evaluation of patient experience in oral medicine practice.

Introduction

In early 2017, following a meeting in Paris, health ministers from the Organisation for Economic Cooperation and Development (OECD) in addition to representatives from Argentina, Colombia, Costa Rica, Kazakhstan, Lithuania, Peru and South Africa declared that we need to devote time and money to tools that will allow us to determine whether our health systems deliver outcomes that truly matter to patients. This statement represents a shift from the historical dependence in medicine and dentistry on mortality rates and clinician reported outcomes, which provide a one-dimensional perspective on the care provided. The consensus from this meeting to determine the 'Next Generation of Health Reforms' was that we need to invest in 'cross-country comparative measures of patients' own experience of medical care and healthcare outcomes' therefore emphasising the need for robust patient reported experience measures (PREMs) and patient reported outcomes measures (PROMs) in clinical practice.[1] Coulter *et al.* defined a PREM as a measure of a patient's perception of their personal experience of the healthcare they have received, focusing on the aspects of the care that matter specifically to the patients.[2] While a PROM is a tool that allows patients to self-assess their own health ensuring no external influences on the report of this assessment.[3,4] It can provide 'an insight into the way patients perceive their health and the impact that treatments or adjustments to lifestyle have on their quality of life'.[3,5]

Recording and acting upon aspects of healthcare that matter most to patients is laudable, and it would appear soon to be compulsory, but two key practical questions remain:

1. What is the patient perception of the use of PROMs and PREMs?
2. Is it practical in a clinical setting?

A number of acceptability and feasibility studies have been carried out to explore the logistics of the incorporation of these tools into clinical practice.[6–8] In a series of qualitative interviews with patients regarding the use of PROMs in colorectal cancer clinics, patients highlighted that PROM use can sometimes bring to the fore issues they may have overlooked as being of significance with regard to the impact of the disease on their lives. The patients were also undeterred by the time taken to complete PROMs and it was agreed by both patients and clinicians interviewed that PROMs used in clinical practice could

[1]UCL Eastman Dental Institute, London, UK; [2]Department of Oral Medicine, Chulalongkorn University, Bangkok, Thailand
*Correspondence to: Dr Rícheal Ní Ríordáin
Email: richeal.niriordain@gmail.com

Refereed Paper.
Accepted 25 August 2017
Published online 3 November 2017
DOI: 10.1038/sj.bdj.2017.889

facilitate the provision of critical psychological and emotional support needed by patients with chronic illness.[7]

As a speciality, oral medicine has certainly begun to promote the use of PREMs and PROMs in clinical practice and research in the last number of years via our national and international oral medicine organisations and their associated periodic scientific meetings. A plenary session was dedicated to PREMs, PROMs and clinician reported outcome measures (CROMs) specific to oral medicine at the British Society of Oral Medicine (BSOM) Annual Scientific Meeting in Liverpool in 2012. This session included examples of the positive effect of PREMs used in clinical practice in Liverpool, along with information regarding PROM usage in the oral medicine literature. Soon afterwards an Oral Medicine Practice Group was established for the 2014 Sixth World Workshop in Oral Medicine (WWOM VI); a group tasked with aims including exploring PROMs used in oral mucosal disease, providing direction for future PROMs in oral medicine clinical practice and research, and conducting a multi-centre cross-sectional study using oral medicine specific PROMs and CROMs in patients with oral lichen planus.[9,10] Focusing on immune-mediated disease, the 2016 European Association of Oral Medicine (EAOM) 13th Biennial Congress highlighted the importance of outcome measures in the management of patients with vesiculobullous diseases, again in a plenary session.[10] In addition to the promotion of PROM and PREM use at oral medicine scientific meetings the National Health Service (NHS) *Commissioning guide for oral surgery and oral medicine*, published in 2015, recommended the use of outcome and experience measures in regular clinical practice.[11] So although we have not extensively devoted time and money to PROM and PREM instruments in oral medicine, as recommended by the health ministries, we have certainly acknowledged the importance of determining healthcare outcomes that truly matter to our patients. The aims of this article are to summarise the literature regarding PREM use and PROM use in oral medicine, focusing on mucosal disease and salivary gland disease.

PROMs in oral medicine

Black reported that the integration of PROMs into clinical practice could transform healthcare, emphasising potential improvements in clinical decision-making and service enhancements with the routine use of PROMs.[12] For PROMs to be transformative in the delivery of patient care they must have included the patient in determining its content and have undergone a robust development process. Patient input in the generation of PROM items is surprisingly uncommon with only 10% of tools recently reviewed incorporating patient opinion on which outcomes should

Table 1 Summary of commonly used PROMs in oral mucosal diseases

PROM	Items (N)	Rating scale	Dimensions evaluated	Psychometric/validation evidence in population of oral medicine setting (country, no. of patients)	References
Oral symptom-specific					
NRS	1	0-10	pain	OLP (US, 33)	Chainani-Wu *et al.*, 2008[17]
VAS	1	0-100 mm or 0–10 cm	pain	OLP (US, 33)	Chainani-Wu *et al.*, 2008[17]
Psychosocial-specific					
BDI	21	4-point scale	depression	No evidence	–
HADS	14	4-point scale	anxiety, depression	No evidence	–
STAI	40	4-point scale	anxiety	No evidence	–
QoL-specific					
COMDQ	26	5-point scale	QoL specific to COMD	OLP (China, 72; Ireland, 109; UK, 100), RAS (China, 84; Ireland, 12; UK, 42), PV or MMP (China, 36; Ireland, 6; UK, 58) OFG (China; 8; Ireland, 7)	Ní Ríordáin and McCreary, 2011[36] Ní Ríordáin *et al.*, 2011[35] Ní Ríordáin and McCreary, 2012[37] Li and He, 2013[38] Ní Ríordáin *et al.*, 2016[39]
OHIP-14	14	5-point scale	OH-QoL	OLP (UK, 48), RAS (Turkey, 28)	Hegarty *et al.*, 2002[65] McGrath *et al.*, 2003[34] Mumcu *et al.*, 2006[66] Mumcu *et al.*, 2007[67]
OHIP-49	49	5-point scale	OH-QoL	No evidence	_
OHQOL-UK	16	5-point scale	OH-QoL	OLP (UK, 48), RAS (Turkey, 24)	Hegarty *et al.*, 2002[65] McGrath *et al.*, 2003[34] Mumcu *et al.*, 2006[66]
OIDP	8	6-point scale	OH-QoL	No evidence	_
SF-36	36	2- to 6-point scale	general QoL	RAS (Turkey, 24)	Mumcu *et al.*, 2006[66]
SF-12	12	2- to 6-point scale	general QoL	No evidence	_

Official journal of the British Dental Association.

be measured.[13] PROM development involves demonstrating evidence of psychometric properties including validity (ability of a PROM to measure the predetermined underlying concept), reliability (ability of a PROM to consistently generate reproducible scores), and responsiveness (ability of a PROM to detect a change in the concept being measured over time) in the appropriate patient population.[14] Table 1 summarises the PROMs commonly used in oral mucosal disease while Table 2 provides an overview of the PROMs commonly used in salivary gland disease. Both tables highlight the evidence for validity and reliability in oral medicine specific patient populations.

Assessment of symptoms

Patient reported assessment of therapeutic interventions in oral medicine is often limited to symptom severity scales.[9] For example, pain is one of the most common complaints of patients with oral mucosal diseases seeking clinical intervention. Patients may describe their mucosal pain using various terms including as 'burning sensation', 'soreness', 'itching' or 'stinging'.[15] There is currently no oral-symptom-PROM developed specifically for any oral mucosal conditions. The majority of clinical trials of oral mucosal diseases used a visual analogue scale (VAS) or numerical rating scale (NRS) for the assessment of pain intensity.[9] VAS requires patients to mark a point on a 10 cm horizontal line (labelled as 'no pain' on one end and 'worst pain possible' on the other end) that best reflects the degree of pain experienced, with VAS scores ranging from 0 to 10 cm in a continuous scale. NRS, on the other hand, is a segmented numeric version of VAS, in which patients are asked to select one of whole numbers from 0 to 10.[16] The

Table 2 Summary of commonly used PROMs in salivary gland diseases

PROM	Items (N)	Rating scale	Dimensions evaluated	Psychometric/validation evidence in population of oral medicine setting (country, no. of patients)	References
Symptom-specific					
ESSPRI	3	0-10 numerical scale	dryness, fatigue, limb pain	PSS (Argentina, Brasil, France, Germany, Greece, Italy, Japan, The Netherlands, Norway, Slovenia, Spain, Sweden, UK and USA, 395)	Seror *et al.*, 2015[68]
Liverpool Sicca Index	28	4-point scale	sicca symptoms (xerostomia, ocular dryness, vaginal dryness, sensory change)	PSS (UK, 40) Xerostomia (UK, 40)	Field *et al.*, 2003[69]
Sicca Symptoms Inventory	42	5- to 7-point scale	sicca symptoms (xerostomia, ocular dryness, vaginal dryness skin dryness)	PSS (UK, 130)	Bowman *et al.*, 2003[70]
SXI-D	5	3-point scale	xerostomia	Older adults (Australia, 882; Japan, 401; The Netherland, 50; New Zealand, 253) Xerostomia (China, 212)	Thomson *et al.*, 2011[21] van der Putten *et al.*, 2011[24] He *et al.*, 2013[71]
VAS-XQ	8	0-100 mm or 0-10 cm scale	xerostomia	Older adults (US, 18)	Pai *et al.*, 2001[72]
XI	11	5-point scale	xerostomia	Older adults (Australia, 636) Xerostomia (Spain, 41) PSS (Portugal, 30; Korea, 194) RIX (New Zealand, 57)	Thomson et *al.*, 1999[19] Thomson and Williams, 2000[20] Thomson, 2007[73] da Mata *et al.*, 2012[74] Lee *et al.*, 2016[75] Serrano *et al.*, 2016[76]
XQ by Fox *et al.*	4	yes/no	xerostomia	Xerostomia (US, 100)	Fox *et al.*, 1987[23]
Psychosocial-specific					
HADS	14	4-point scale	anxiety, depression	No evidence	–
QoL-specific					
EORTC QLQ-C30	30	4-point scale, yes/no	QoL specific to H&N cancer	H&N cancer (Norway, 126)	Bjordal and Kaasa, 1992[52] Ojo *et al.*, 2012[51]
OHIP-14	14	5-point scale	OH-QoL	No evidence	–
OIDP	8	6-point scale	OH-QoL	No evidence	–
SF-36	36	2- to 6-point scale	general QoL	No evidence	–
UWQOL	16	3- to 6-point scale	QoL specific to H&N cancer	H&N cancer (UK, 145)	Rogers *et al.*, 2002[53] Ojo *et al.*, 2012[51]
XeQoLS	15	5-point scale	QoL specific to xerostomia	RIX (US, 20)	Henson *et al.*, 2001[46]

validity of VAS and NRS have been investigated in patients with oral lichen planus (OLP) in one study and the results showed better construct validity of NRS over VAS.[17]

Patients with salivary gland diseases may present with salivary gland hypofunction and xerostomia. In fact xerostomia, the patient reported sensation of dry mouth, is reported in up to 20% of adults.[18] As highlighted by Thomson *et al.*, a single question asking a patient to rate the severity of their dry mouth would fail to divulge the collection of symptoms that present in patients with xerostomia.[19] The Xerostomia Inventory (XI) is a tool developed in the late 1990s and further refined to a shortened version (SXI-D) to determine the symptoms related to dry mouth providing a more comprehensive overview of symptomatology than a single VAS rating of oral dryness.[20,21] In an article regarding the diagnosis and management of xerostomia by Villa *et al.*, the authors found five instruments developed to assess dry mouth including the aforementioned XI.[22] These tools record the prevalence,[23] frequency[24] and severity[25] of xerostomia. There has been no comprehensive review of the psychometric properties of these instruments and therefore no comment can be made on whether these instruments have been robustly developed. In patients with Sjögren's Syndrome (SS) symptom assessment tools include the Liverpool Sicca Index and the Sicca Symptoms Inventory. These tools are not limited to oral dryness and also include assessments of ocular and vaginal dryness.[26] Most recently the European League Against Rheumatism (EULAR) SS study group recently developed a patient reported index (ESSPRI) to measure symptoms of SS.[27] The symptoms assessed in this tool include dryness, pain and fatigue.

Assessment of psychosocial aspects of disease and quality of life

Oral mucosal diseases have been shown to have negative impacts on psychosocial status and quality of life (QoL) of patients.[28] According to a qualitative study on patients with chronic oral mucosal diseases, a majority of patients reported difficulties with daily activities due to oral symptoms as well as limitation on certain foods which can result in psychological distress and issues of social participations.[29] Assessment of psychosocial status and QoL using PROMs in patients with oral mucosal diseases should therefore not be neglected.

A number of generic psychosocial-PROMs have been used in clinical studies of oral mucosal diseases, and these instruments measure different psychosocial constructs such as anxiety, depression, stress, distress, coping with illness, psychological wellbeing, vulnerability, mood, loneliness, anger, and social support.[9,30–32] Of these constructs, anxiety and depression are generally the two most commonly assessed psychosocial constructs in the literature. Three frequently used PROMs measuring anxiety and/or depression include the Hospital Anxiety and Depression Scale (HADS), State-Trait Anxiety Inventory (STAI) and Beck Depression Inventory (BDI).[9] Both BDI and HADS were provided as examples of clinical outcomes measures of pain measurement used in research in the aforementioned NHS Commissioning Guide;[11] however, none of these PROMs have been psychometrically examined in patients with oral mucosal diseases.

QoL can be evaluated through the use of generic-QoL, oral health-related QoL (OH-QoL) PROMs and disease-specific-QoL PROMs. Two commonly used generic-QoL PROMs in oral mucosal diseases are the 36-item and 12-item Short Form Health Survey (SF-36, SF-12), both of which measure general aspects of QoL including vitality, physical functioning, bodily pain, general health perceptions, physical functioning, emotional functioning, social functioning and mental health.[9,33] OH-QoL PROMs comprise items that predominantly focus on patients' perception of QoL aspects with respect to their oral health. A number of instruments have been used in clinical studies of oral mucosal diseases including the 14-item and 49-item Oral Health Impact Profile (OHIP-14, OHIP-49), the Oral Health-related Quality Of Life-UK (OHQOL-UK) and the Oral Impacts on Daily Performance (OIDP).[9] Both generic and oral health specific QOL tools were highlighted as well validated and commonly used in the NHS Commissioning Guide, specifically referring to SF-12, SF-20 and SF-36 along with OHIP-14 and OHIP-49.[11] When reviewing the psychometric properties of these QOL instruments in oral medicine, we found that only OHIP-14 and OHQOL-UK have been examined for their psychometric properties in OLP and RAS populations.[34] At present only one discipline-specific PROM was identified in the literature. The Chronic Oral Mucosal Disease Questionnaire (COMDQ) is a recently developed oral medicine-specific PROM for the assessment of QoL in patients with chronic oral mucosal disease. The COMDQ was produced following extensive review of the current literature, input from oral medicine experts and input from patients with chronic oral mucosal diseases including OLP, recurrent aphthous stomatitis (RAS), pemphigus vulgaris (PV), mucous membrane pemphigoid (MMP) and orofacial granulomatosis (OFG) via qualitative interviews.[35] The COMDQ comprises 26 items addressing four key domains including pain and functional limitation, medications and side effects, social and emotional and patient support. The COMDQ has been shown to have the highest number of validation studies and psychometric properties tested (content validity, convergent validity, discriminant validity, internal consistency, test-retest reliability, responsiveness) in oral mucosal diseases and can be recommended for use in both clinical and research settings to assess QoL in patients with chronic oral mucosal diseases.[35–39]

Numerous studies have been published exploring psychological status and QoL in patients with salivary gland disease. These studies can broadly be categorised into three types – general xerostomia, SS and xerostomia secondary to radiotherapy. Similar tools have been employed in these studies including HADS,[40] SF-36,[41,42] OIDP[43] and OHIP-14.[44,45] A xerostomia-specific QoL tool, XeQoLS, was developed the 1990s. It is a 15-item questionnaire consisting of four domains namely physical function, psychological function, social function and pain issues measured with a 5-point Likert scale.[46] The psychometric properties have been tested and described in a patient group with radiotherapy-induced xerostomia (RIX).[47–49] In an extensive review of the methods of measuring RIX, Eisbruch *et al.*[50] also highlight the incorporation of questions relating to xerostomia in a number of head and neck cancer specific QoL instruments. The most commonly used tools[51] were EORTC module for head and neck cancer[52] and the University of Washington Quality of Life questionnaire.[53] The psychometric properties of these head and neck specific tools have been extensively reviewed using the Scientific Advisory Committee of the Medical Outcomes Trust (SAC-MOT) tool.[51]

PREMs in oral medicine

As there is a dearth of literature regarding the use of PREMs in oral medicine we need to begin by looking at PREMs in general, their application and what is considered important to record when implementing these tools in clinical practice. Manary *et al.* highlight the prominent role of PREMs in research and the determination of healthcare policy, stating that

Official journal of the British Dental Association.

when these tools are designed and administered appropriately they can prove to be robust indicators of the quality of healthcare being provided.[54] Although PREMs are more commonplace, the lack of consensus regarding a universal definition of the components or underlying concept of the 'patient experience' leads to numerous diverse PREM tools being available for use.[55] In addition to the diversity of the tools available there remain three fundamental points of concern regarding the merits of PREMs:[54]

1. Feedback from patients is thought by some to lack credibility as it must be remembered that patients are not medically trained
2. PREMs may be confounded by elements not associated with the quality of the healthcare provided but rather an evaluation by the patient of their current health status independent of the care received
3. Patients may evaluate their healthcare experience based on the fulfilment of predetermined expectations of treatment interventions.

In spite of these concerns and controversies the incorporation of PREMs into clinical practice is being promoted at national level. The National Health Service (NHS) Friends and Family Test has been incorporated in clinical practice in the UK in recent years. It consists of a single question, 'How likely are you to recommend our ward/department to friends and family if they needed similar care or treatment?', with a 6-point response scale (Extremely likely, Likely, Neither likely nor unlikely, Unlikely, Extremely unlikely, Don't know).[56] When appropriately developed, PREMs allow the inclusion of the patient voice in a simple, quantifiable and reproducible way.[2] Coulter *et al.* highlight the importance of not only recording a rating of the patient experience of care but also determining the details of the patients' experience to allow us to shape any resultant quality improvement.[2] In recording these evaluations of patient experience we must also commit to act on the findings.[57]

The PREM tools currently recording these patient interactions can be broadly categorised into inpatient experience measures, primary care experience measures and outpatient experience measures.[58] Extensive work has been carried out by the Picker Institute regarding PREMs, including outlining the key domains required for each of the three aforementioned categories.[59] Looking at outpatient experience, as it is most aligned to oral medicine practice in the UK, the key domains for priority attention included 'dealing with issues for which patients presented themselves, doctors, cleanliness, other professionals, information about discharge, information about treatment'.[60] PREMs are not limited to the clinical setting in which they are administered; for example, a recent publication outlined the development of a tool evaluating the experience of paediatric patients with diabetes.[61] The NHS Commissioning Guide outlines seven questions suitable for use with oral surgery and oral medicine patients, which include provision of information regarding treatment, the provision of information regarding the merits of an intervention, the provision of information regarding adverse effects of medications prescribed, and the provision of post-operative instruction avoiding jargon, along with appropriate management of pain and anxiety intraoperatively.[11]

Conclusion

Although oral medicine as a speciality has somewhat embraced the use of PROMs, as evidenced in the literature discussed in this article, we have achieved little with regard to ensuring the tools we use are robust and fit for purpose. Evaluation of the development process and psychometric properties of instruments commonly used in oral medicine could be conducted using checklists such as SAC-MOT[62] or the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN).[63] This would allow us to be confident that the scores generated from PROMs are valid, reliable and responsive to change. Further work is also needed to achieve a consensus on the PROMs that should be used consistently in research or in clinical practice. This process of determining a consensus on outcome measures used in research and clinical practice could facilitate meta-analysis of data from clinical trials leading to more robust evidence for the management of oral disease in an oral medicine setting.[64] Taylor *et al.* has undertaken this consensus process in determining a Core Outcome Set (COS) in recurrent aphthous stomatitis (RAS) which could help direct the speciality in applying this methodology to other common conditions in oral medicine.[10] Considerable work is needed when evaluating the patient experience in oral medicine with recommendation for the use of the Picker Institute outpatient experience tool as a starting point for future PREM research.

1. OECD Health Ministers. The next generation of health reforms: Ministerial statement. Published April 20th 2017.
2. Coulter A, Fitzpatrick R, Cornwell J. The point of care. Measures of patients' experience in hospital: purpose, methods and uses. *Ideas that change healthcare*. London: The King's Fund; 2009.
3. Devlin N J, Appleby J. Getting the most out of PROMs. Putting health outcomes at the heart of NHS decision-making. London: The King's Fund, 2010.
4. Basch E, Torda P, Adams K. Standards for patient-reported outcome-based performance measures. *JAMA* 2013; **310:** 139–140.
5. Department of Public Health and PROM Group University of Oxford. Patient Reported Outcomes Measurement Group Info 2017.
6. Kotronoulas G, O'Brien F, Simpson M F, Maguire R. Feasibility and acceptability of the use of patient-reported outcome measures in the delivery of nurse-led, supportive care to women with cervical cancer. *Clin Nurse Spec* 2017; **31:** E1-E10.
7. Kotronoulas G, Papadopoulou C, MacNicol L, Simpson M, Maguire R. Feasibility and acceptability of the use of patient-reported outcome measures (PROMs) in the delivery of nurse-led supportive care to people with colorectal cancer. *Eur J Oncol Nurs* 2017; **29:** 115–124.
8. Kotronoulas G C, Papadopoulou C N, Papapetrou A, Patiraki E. Psychometric evaluation and feasibility of the Greek Pittsburgh Sleep Quality Index (GR-PSQI) in patients with cancer receiving chemotherapy. *Support Care Cancer* 2011; **19:** 1831–1840.
9. 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. e111.
10. The Biennial Congress of the European Association of Oral Medicine, 15–17 September 2016, Torino, Italy. *Oral Dis* 2016; **22 (Suppl 2):** 5–51.
11. NHS England Chief Dental Officer Team. Guide for commissioning oral surgery and oral medicine. NHS England, 2015.
12. Black N. Patient reported outcome measures could help transform healthcare. *BMJ* 2013; **346:** f167.
13. Wiering B, de Boer D, Delnoij D. Patient involvement in the development of patient-reported outcome measures: a scoping review. *Health Expect* 2017; **20:** 11–23.
14. Mokkink L B, Terwee C B, Patrick D L *et al.* The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol* 2010; **63:** 737–745.
15. Abdalla-Aslan R, Benoliel R, Sharav Y, Czerninski R. Characterization of pain originating from oral mucosal lesions. *Oral Surg Oral Med Oral Pathol Oral Radiol* 2016; **121:** 255–261.
16. Hawker G A, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analogue Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). *Arthritis Care Res (Hoboken)* 2011; **63 (Suppl 11):** S240–252.
17. Chainani-Wu N, Silverman S, Jr., Reingold A, Bostrom A, Lozada-Nur F, Weintraub J. Validation of instruments to measure the symptoms and signs of oral lichen planus. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2008; **105:** 51–58.
18. Mavragani C P, Moutsopoulos H M. Sjogren syndrome. *CMAJ* 2014; 186: E579–586.
19. Thomson W M, Chalmers J M, Spencer A J, Williams S M. The xerostomia inventory: a multi-item approach to measuring dry mouth. *Community Dent Health* 1999; **16:** 12–17.
20. Thomson W M, Williams S M. Further testing of the xerostomia inventory. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2000; **89:** 46–50.
21. Thomson W M, van der Putten G J, de Baat C *et al.* Shortening the xerostomia inventory. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2011; **112:** 322–327.
22. Villa A, Connell C L, Abati S. Diagnosis and management of xerostomia and hyposalivation. *Ther Clin Risk Manag* 2015; **11:** 45–51.

23. Fox P C, Busch K A, Baum B J. Subjective reports of xerostomia and objective measures of salivary gland performance. *J Am Dent Assoc* 1987; **115:** 581–584.
24. van der Putten G J, Brand H S, Schols JM, de Baat C. The diagnostic suitability of a xerostomia questionnaire and the association between xerostomia, hyposalivation and medication use in a group of nursing home residents. *Clin Oral Investig* 2011; **15:** 185–192.
25. Pai S, Ghezzi E M, Ship J A. Development of a Visual Analogue Scale questionnaire for subjective assessment of salivary dysfunction. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2001; **91:** 311–316.
26. Bowman S J. Patient-reported outcomes including fatigue in primary Sjogren's syndrome. *Rheum Dis Clin North Am* 2008; **34:** 949–962, ix.
27. Seror R, Ravaud P, Mariette X *et al.* EULAR Sjogren's Syndrome Patient Reported Index (ESSPRI): Development of a consensus patient index for primary Sjogren's syndrome. *Ann Rheum Dis* 2011; **70:** 968–972.
28. Tabolli S, Bergamo F, Alessandroni L, Di Pietro C, Sampogna F, Abeni D. Quality of life and psychological problems of patients with oral mucosal disease in dermatological practice. *Dermatology* 2009; **218:** 314–320.
29. Ni Riordain R, Meaney S, McCreary C. Impact of chronic oral mucosal disease on daily life: preliminary observations from a qualitative study. *Oral diseases* 2011; **17:** 265–269.
30. Pippi R, Patini R, Ghiciuc C M *et al.* Diurnal trajectories of salivary cortisol, salivary alpha-amylase and psychological profiles in oral lichen planus patients. *J Biol Regul Homeost Agents* 2014; **28:** 147–154.
31. Mehdipour M, Taghavi Zenouz A, Farnam A *et al.* The relationship between anger expression and its indices and oral lichen planus. *Chonnam Med J* 2016; **52:** 112–116.
32. Rana M, Kanatas A, Herzberg P Y, Gellrich N C, Rana M. Relevance of psychosocial factors to quality of life in oral cancer and oral lichen planus: a prospective comparative study. *Br J Oral Maxillofac Surg* 2015; **53:** 621–626.
33. McHorney C A, Ware J E, Jr., Raczek A E. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Med Care* 1993; **31:** 247–263.
34. McGrath C, Hegarty A M, Hodgson T A, Porter S R. Patient-centred outcome measures for oral mucosal disease are sensitive to treatment. *Int J Oral Maxillofac Surg* 2003; **32:** 334–336.
35. Ni Riordain R, Meaney S, McCreary C. A patient-centreed 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. e572.
36. 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:** 604–609.
37. Ni Riordain R, McCreary C. Further reliability and responsiveness of the Chronic Oral Mucosal Diseases Questionnaire. *Oral Dis* 2012; **18:** 60–66.
38. Li M, He S L. Reliability and validity of the Chinese version of the chronic oral mucosal diseases questionnaire. *J Oral Pathol Med* 2013; **42:** 194–199.
39. Ni Riordain R, Hodgson T, Porter S, Fedele S. Validity and reliability of the Chronic Oral Mucosal Diseases Questionnaire in a UK population. *J Oral Pathol Med* 2016; **45:** 613–616.
40. Milin M, Cornec D, Chastaing M *et al.* Sicca symptoms are associated with similar fatigue, anxiety, depression, and quality-of-life impairments in patients with and without primary Sjogren's syndrome. *Joint Bone Spine* 2016; **83:** 681–685.
41. Sutcliffe N, Stoll T, Pyke S, Isenberg D A. Functional disability and end organ damage in patients with systemic lupus erythematosus (SLE), SLE and Sjogren's syndrome (SS), and primary SS. *J Rheumatol* 1998; **25:** 63–68.
42. Strombeck B, Ekdahl C, Manthorpe R, Wikstrom I, Jacobsson L. Health-related quality of life in primary Sjogren's syndrome, rheumatoid arthritis and fibromyalgia compared to normal population data using SF-36. *Scand J Rheumatol* 2000; **29:** 20–28.
43. Baker S R, Pankhurst C L, Robinson P G. Testing relationships between clinical and non-clinical variables in xerostomia: a structural equation model of oral health-related quality of life. *Qual Life Res* 2007; **16:** 297–308.
44. Meijer J M, Meiners P M, Huddleston Slater J J *et al.* Health-related quality of life, employment and disability in patients with Sjogren's syndrome. *Rheumatology (Oxford)* 2009; **48:** 1077–1082.
45. Thomson W M, Lawrence H P, Broadbent J M, Poulton R. The impact of xerostomia on oral-health-related quality of life among younger adults. *Health Qual Life Outcomes* 2006; **4:** 86.
46. Henson B S, Inglehart M R, Eisbruch A, Ship J A. Preserved salivary output and xerostomia-related quality of life in head and neck cancer patients receiving parotid-sparing radiotherapy. *Oral Oncol* 2001; **37:** 84–93.
47. Ship J A, Eisbruch A, D'Hondt E, Jones R E. Parotid sparing study in head and neck cancer patients receiving bilateral radiation therapy: one-year results. *J Dent Res* 1997; **76:** 807–813.
48. Jones R E, Takeuchi T, Eisbruch A, D'Hondt E, Hazuka M, Ship J A. Ipsilateral parotid sparing study in head and neck cancer patients who receive radiation therapy: results after 1 year. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 1996; **81:** 642–648.
49. Eisbruch A, Ten Haken R K, Kim H M, Marsh L H, Ship J A. Dose, volume, and function relationships in parotid salivary glands following conformal and intensity-modulated irradiation of head and neck cancer. *Int J Radiat Oncol Biol Phys* 1999; **45:** 577–587.
50. Eisbruch A, Rhodus N, Rosenthal D *et al.* How should we measure and report radiotherapy-induced xerostomia? *Semin Radiat Oncol* 2003; **13:** 226–234.
51. Ojo B, Genden E M, Teng M S, Milbury K, Misiukiewicz K J, Badr H. A systematic review of head and neck cancer quality of life assessment instruments. *Oral Oncol* 2012; **48:** 923–937.
52. Bjordal K, Kaasa S. Psychometric validation of the EORTC Core Quality of Life Questionnaire, 30-item version and a diagnosis-specific module for head and neck cancer patients. *Acta Oncol* 1992; **31:** 311–321.
53. Rogers S N, Gwanne S, Lowe D, Humphris G, Yueh B, Weymuller E A Jr. The addition of mood and anxiety domains to the University of Washington quality of life scale. *Head Neck* 2002; **24:** 521–529.
54. Manary M P, Boulding W, Staelin R, Glickman S W. The patient experience and health outcomes. *N Engl J Med* 2013; **368:** 201–203.
55. LaVela S L. Evaluation and measurement of patient experience. *Patient Experience Journal* 2014; **1:** 28–36.
56. Cain J. The NHS Friends and Family Test. Publication Guidance. UK: Department of Health, 2013.
57. Coulter A, Locock L, Ziebland S, Calabrese J. Collecting data on patient experience is not enough: they must be used to improve care. *BMJ* 2014; 348: g2225.
58. Jenkinson C, Coulter A, Bruster S. The Picker Patient Experience Questionnaire: development and validation using data from in-patient surveys in five countries. *Int J Qual Health Care* 2002; **14:** 353–358.
59. Europe P I. Discussion Paper 1. *Core domains for measuring inpatients' experience of care*. Picker Institute, 2009.
60. Picker Insitute Europe. Discussion Paper 2. *Key domains of the experience of hospital outpatients*. Picker Institute, 2010.
61. Christie D. Developing the national paediatric diabetes audit patient reported experience measure. *Diab Care Child Young People* 2012; **1:** 47–48
62. Aaronson N, Alonso J, Burnam A *et al.* Assessing health status and quality-of-life instruments: attributes and review criteria. *Qual Life Res* 2002; **11:** 193–205.
63. Mokkink L B, Prinsen C A, Bouter L M, Vet H C, Terwee C B. The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) and how to select an outcome measurement instrument. *Braz J Phys Ther* 2016; **20:** 105–113.
64. Williamson P, Clarke M. The COMET (Core Outcome Measures in Effectiveness Trials) Initiative: Its role in improving Cochrane Reviews. *Cochrane Database Syst Rev* 2012; **5:** ED000041.
65. Hegarty A, McGrath C, Hodgson T, Porter S. Patient-centred outcome measures in oral medicine: are they valid and reliable? *Int J Oral Maxillofac Surg* 2002; **31:** 670–674.
66. Mumcu G, Inanc N, Ergun T *et al.* Oral health related quality of life is affected by disease activity in Behcet's disease. *Oral Diseases* 2006; **12:** 145–151.
67. Mumcu G, Hayran O, Ozalp D *et al.* The assessment of oral health-related quality of life by factor analysis in patients with Behcet's disease and recurrent aphthous stomatitis. *J Oral Pathol Med* 2007; **36:** 147–152.
68. Seror R, Theander E, Brun J G *et al.* EULAR Sjögren's Task Force. Validation of EULAR primary Sjögren's syndrome disease activity (ESSDAI) and patient indexes (ESSPRI). *Ann Rheum Dis* 2015; **74:** 859–866.
69. Field E A, Rostron J L, Longman L P, Bowman S J, Lowe D, Rogers S N. The development and initial validation of the Liverpool sicca index to assess symptoms and dysfunction in patients with primary Sjögren's syndrome. *J Oral Pathol Med* 2003; **32:** 154–162.
70. Bowman S J, Booth D A, Platts R G, Field A, Rostron J; UK Sjögren's Interest Group. Validation of the Sicca Symptoms Inventory for clinical studies of Sjögren's syndrome. *J Rheumatol* 2003; **30:** 1259–1266.
71. He S L, Wang J H, Li M. Validation of the Chinese version of the Summated Xerostomia Inventory (SXI). *Qual Life Res* 2013; **22:** 2843–2847.
72. Pai S, Ghezzi E M, Ship J A. Development of a Visual Analogue Scale questionnaire for subjective assessment of salivary dysfunction. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2001; **91:** 311–316.
73. Thomson W M. Measuring change in dry-mouth symptoms over time using the Xerostomia Inventory. *Gerodontology* 2007; **24:** 30–35.
74. da Mata AD, da Silva Marques D N, Freitas F M *et al.* Translation, validation, and construct reliability of a Portuguese version of the Xerostomia Inventory. *Oral Dis* 2012; **18:** 293–298.
75. Lee J, Koh J H, Kwok S K, Park S H. Translation and Validation of a Korean Version of the Xerostomia Inventory in Patients with Primary Sjögren's Syndrome. *J Korean Med Sci* 2016; **31:** 724–728.
76. Serrano C, Fariña M P, Pérez C, Fernández M, Forman K, Carrasco M. Translation and validation of a Spanish version of the xerostomia inventory. *Gerodontology* 2016; **33:** 506–512.

Official journal of the British Dental Association.