

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

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Abstract:

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 highlight the important role that patient reported outcome measures (PROMs) and patient reported experience measures (PREMs) have in healthcare. Oral Medicine as a specialty 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 be to 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 Co-operation 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 health care outcomes' therefore emphasising the need for robust patient reported experience measures (PREMs) and patient reported outcomes measures (PROMs) in clinical practice¹. 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 patients². While a PROM is a tool that allows patients to self-assess their own health ensuring no external influences 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 2 key practical questions are 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 patients and clinicians interviewed that PROMs used in clinical practice could facilitate the provision of critical psychological and emotional support needed by patients with chronic illness ⁷.

As a specialty, 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 organizations 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

afterward an Oral Medicine Practice Group was established for the 2014 6th World Workshop in Oral Medicine (WWOM VI), a group tasked with aims including exploring PROM 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 acknowledge 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, emphasizing potential improvements in clinical decision-

making and service enhancements with the routine use of PROMs ¹². For PROMs to be of transformative in the delivery patient care they must have included the patient in determining its content and 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 be measured ¹³. PROM development includes 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 analog scale (VAS) or numerical rating scale (NRS) for the

assessment of pain intensity⁹. VAS requires patients to mark a point on a 10-cm horizontal line, labeled 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 10cm in a continuous scale. NRS, on the other hand, is a segmented numeric version of VAS, with patients are asked to select one of whole numbers from 0 to 10¹⁶. The 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 VAS¹⁷.

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 adults¹⁸. 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 xerostomia¹⁹. 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 5 instruments developed to assess dry mouth including the aforementioned XI²². These tools record prevalence²³, frequency²⁴ and severity²⁵ of xerostomia. There has been no comprehensive review of the psychometric properties of these instruments 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 include assessments of ocular and vaginal dryness also 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 can result in psychological distress and issues on 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 well-being, 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 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 can find 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 PROMs 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 4 key domains including pain and functional limitation, medications and side effects, social and emotional and patient support. The COMDQ has been shown to have 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 setting 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 3 types – general xerostomia, SS and xerostomia secondary to radiotherapy. Similar tools have been employed 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 4 domains namely physical function, psychological function, social function and pain issues measured with a 5-point likert scale⁴⁶. 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 by 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 tools⁵¹ 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 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 3 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 the 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 3 aforementioned categories ⁵⁹. Looking at

outpatient experience, as it is most align 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 with a recent publication outlining the development of a tool evaluating the experience of paediatric patients with diabetes ⁶¹. The NHS Commissioning Guide outlines 7 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.

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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
<i>Oral symptom-specific</i>					
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
<i>Psychosocial-specific</i>					
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	-
<i>QoL-specific</i>					
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)	Ni Riordain and McCreary, 2011 ³⁶ Ni Riordain et al, 2011 ³⁵ Ni Riordain and McCreary, 2012 ³⁷
OHIP-14	14	5-point scale	OH-QoL	OLP (UK, 48), RAS (Turkey, 28)	Li and He, 2013 ³⁸ Ni Riordain et al, 2016 ³⁹ 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	-

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
<i>Symptom-specific</i>					
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
<i>Psychosocial-specific</i>					
HADS	14	4-point scale	anxiety, depression	No evidence	-
<i>QoL-specific</i>					
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 e al, 2012 ⁵¹
XeQoLS	15	5-point scale	QoL specific to xerostomia	RIX (US, 20)	Henson et al, 2001 ⁴⁶

