

## REVIEW ARTICLE

# Outcomes of periodontal therapy: Strengthening the relevance of research to patients. A co-created review

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## 1 | INTRODUCTION

### 1.1 | Why is it important to measure treatment outcomes?

Periodontitis is a chronic multifactorial inflammatory disease associated with dysbiotic plaque biofilms and characterized by progressive destruction of the tooth-supporting apparatus.<sup>1</sup> It is a public health problem considering its high global prevalence, effect on life quality, economic impacts, association with social disparities, and yet high potential for successful management.<sup>2-4</sup> In contrast, health is not simply an absence of disease as was first defined by the World Health Organisation (WHO) more than 70 years ago.<sup>5</sup> The same is true for oral health as recently stated by the Federation Dentaire Internationale (Figure 1). The definition encompasses not only traditional disease/condition status but also integrates psychosocial and physiological functioning into the definition.<sup>6</sup>

Because of their high prevalence and societal impacts, there is an important global need to identify best options for managing periodontal diseases and to do this requires high quality research incorporating these concepts of health and disease. Whereas overall treatment phases for periodontal health are well recognised, there remains considerable uncertainty in the evidence to select best options within these phases.<sup>7</sup> Key to reducing this uncertainty is research which compares different options employing outcome measures that are important to people with lived experience (PWLE) of the conditions as well as to clinicians and others such as policy-makers.<sup>8</sup> We use the term PWLE here to incorporate not only patients but others affected by the condition such as a carer for a

patient with periodontitis who may be integral to the management of the condition. Therefore, PWLE bring their own expertise and perspective, which is important to capture in measuring treatment outcomes and this provides substantial opportunities for innovation in research. Furthermore, inclusion of outcome measures that are relevant to PWLE may improve health literacy and help with adherence to care, which are important contributors to achieving long-term periodontal health.<sup>9</sup> This will be discussed in more detail below with a consideration of the “expert patient”.

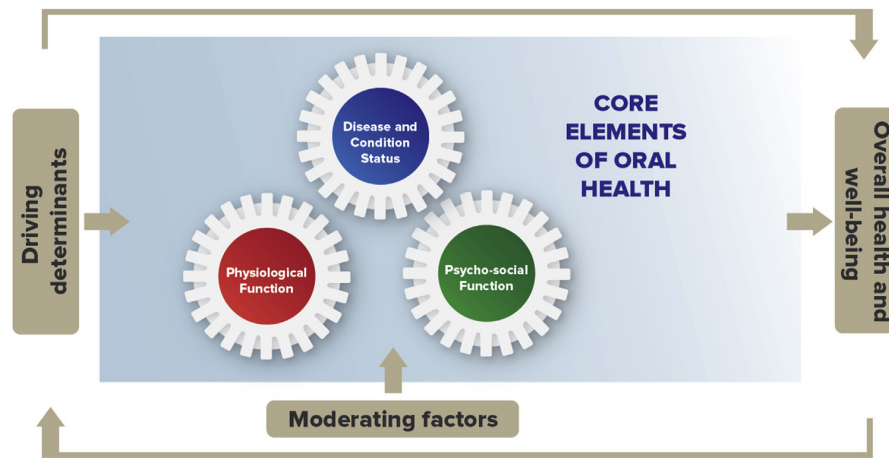
### 1.2 | What do we mean by treatment outcomes for periodontal diseases?

Treatment outcomes should measure meaningful benefits and harms of interventions and are key to evaluating comparisons between interventions. We use “meaningful” to convey outcomes that capture changes that are important in the short-term to PWLE as well as those that have longer-term significance on the course of the condition and therefore ongoing management. This is particularly important for periodontitis as it is a long-term, chronic condition. Following initial treatment to achieve health, long-term maintenance therapy (supportive periodontal care) is important for relapse prevention.<sup>7,10</sup>

A wide variety of outcome measures have been employed in periodontal research.<sup>11</sup> For instance, surrogate outcomes can be chosen to measure the disease process and these may be sensitive enough to test for differences between therapies. Surrogate outcomes can include clinical measures such as probing depth and

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**FIGURE 1** The Federation Dentaire Internationale (FDI) “Definition of Oral Health Framework” summarises three core elements of oral health (disease and condition status, physiological function, and psychosocial function), driving determinants, moderating factors, and overall health and well-being. (From Reference<sup>6</sup> with permission.)

clinical attachment level, radiographic outcomes such as bone level and laboratory measures, for example, microbiological and inflammatory markers. They have a long track record of use in periodontal research, which makes them attractive to employ. However, a defining characteristic of surrogate outcomes is that they may not be associated with tangible benefits to PWLE.<sup>12</sup> In contrast, tooth survival is a very tangible benefit and therefore usually considered a definitive outcome of periodontal therapy.<sup>11,13</sup> The reality is more nuanced as teeth may be lost for reasons other than for periodontal health and might not therefore directly reflect the outcome of periodontal treatment. Patient-reported outcomes (PRO) such as quality of life (QoL) would seem to offer greater relevance to PWLE than many clinical measures. PRO are increasingly used as key outcomes and have been shown to be able to discriminate between phases of treatment.<sup>14</sup> However, their use to evaluate and compare periodontal treatments greatly lags behind clinical measures resulting in very incomplete evidence to inform on treatment choices.<sup>10,12</sup> In part, this might be because PRO are viewed as subjective measures despite their validation as sensitive outcomes to detect change (see below).

## 2 | PROs—WHAT ARE THEY AND WHY ARE THEY IMPORTANT?

A PRO is any health status information gathered directly from the patient about a health condition or therapy, without interpretation by another person.<sup>15</sup> Examples of PROs include QoL, health-related quality of life (HR-QoL) and oral health-related quality of life (OHR-QoL).

QoL is defined by the WHO as, “an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns”.<sup>16</sup> QoL incorporates numerous elements such as health, socializing, relationships, and material comforts. One of

these aspects, health, encompasses those aspects of QoL that have been shown to affect physical or mental health<sup>17,18</sup> and is termed HR-QoL.

OHR-QoL can be viewed as a subset of HR-QoL; however, over the years, has been used interchangeably in the literature with the terms, “QoL”, “oral health status”, and “HR-QoL”<sup>19</sup> and there is a lack of consensus as to a definition. OHR-QoL only began to be accepted as a phenomenon in the 1970s and 1980s<sup>20,21</sup> as prior to this, it was not believed or accepted that oral conditions could have an impact on QoL in general.<sup>22</sup> The term broadly describes the status or outcomes of oral condition(s) and/or interventions for these, on everyday activities and in order to obtain a quantitative measure, researchers have developed over 15 tools to measure OHR-QoL.

QoL and OHR-QoL are areas which have received much attention in the last two decades, particularly in periodontal research. They are key aspects of clinical research, to determine and acknowledge how a variety of elements including oral health status and treatments, can have a profound effect on daily functioning of patients. It is important for patients and their families to understand possible risks or harms of a proposed treatment, and for clinicians to understand the impacts that a disease or condition can have on the patient’s ability to carry out routine daily activities. Additionally, QoL research can assist health-care providers and policy-makers to direct and focus resources and services to areas of greatest impact and need. Currently, the relationship between OHR-QoL, HR-QoL, and QoL is unclear (e.g., does a negative OHR-QoL also translate to a negative overall QoL?) and further research is required.

## 3 | PATIENT-REPORTED OUTCOME MEASURES

A patient-reported outcome measure (PROM) is a tool that is used to collect information for a PRO, regarding health, disease, and treatments.

PROMs are usually administered in the form of a questionnaire (paper or electronic); however, information may also be gathered from interviews, by telephone, or through diaries. PROMs may be gathered at a single time-point or longitudinally to capture changes over time.

The inclusion of PROMs in the clinical setting have been strongly advocated by experts in the medical and dental field<sup>23–25</sup>; however, there is still a lack of evidence to confirm that inclusion of these measures actually translates to better outcomes for patients.<sup>26,27</sup> There is strong evidence, however, that inclusion of PROM improves communication between the clinician and patients, and overall patient satisfaction.<sup>28</sup> Some additional benefits to including PROMs would be to detect previously unrecognized complications associated with a disease or treatment ideally leading to a potential change in the management of patients.

PROMs can be classified as either generic or disease/ condition specific. A generic PROM captures information on a range of medical or dental conditions, whereas condition specific PROM focusses on features of a specific condition, and the impacts on chosen outcomes. The latter, focusses on a particular group of patients or conditions, and for periodontitis, may include common symptoms such as tooth mobility or bleeding of the gums, as reasons for a negative impact. Commonly, impacts that are attributed to the condition in focus, are included in the overall “score” calculated for a particular tool. An example of a generic PROM is the EQ-5D questionnaire<sup>29,30</sup> and the Oral Impacts on Daily Performance (OIDP) questionnaire,<sup>31</sup> which is an example of a PROM which can be used as both a generic and condition-specific tool.

PROMs principally measure a patient's view of their health status at a certain time, and should be distinguished from a patient reported experience measure (PREM) (Figure 2), which aims to capture a patient's view of their experience while receiving care.<sup>32</sup> PREMs are also usually delivered in the form of a questionnaire and try to focus on the impact of the “process” of obtaining care on the patient experiences (e.g., aspects of communication or timeliness of treatment). An example of a PREM is the Consultation and Relation Empathy (CARE) questionnaire,<sup>33</sup> which is composed of 10 questions designed to measure empathy between a clinician and patient and has been frequently used by general medical practitioners. Although PROMs are quite prominent in dental and periodontal research, there is much less evidence of use of validated PREMs, with most studies using visual analogue scales or questions devised by the research team.<sup>34</sup>

A number of PROMs have been utilised in periodontal research, with the most commonly used being the Oral Health Impact Profile short version (OHIP-14), the geriatric oral assessment index (GOHAI), OIDP questionnaire, and the UK OHR-QoL Measure.<sup>35</sup> Currently, there is no consensus as to which is the preferred tool for periodontal clinical research and choice appears to be related to familiarity with a particular PROM in the research team. Reassuringly, most common PROMs used in dentistry have demonstrated adequate reliability and validity.<sup>24</sup> Key gaps in our understanding of the use of PROM in outcomes research include; what are the appropriate time-points for administering these PROM and are the tools sufficiently sensitive to detect a change (i.e., responsive)? There is also

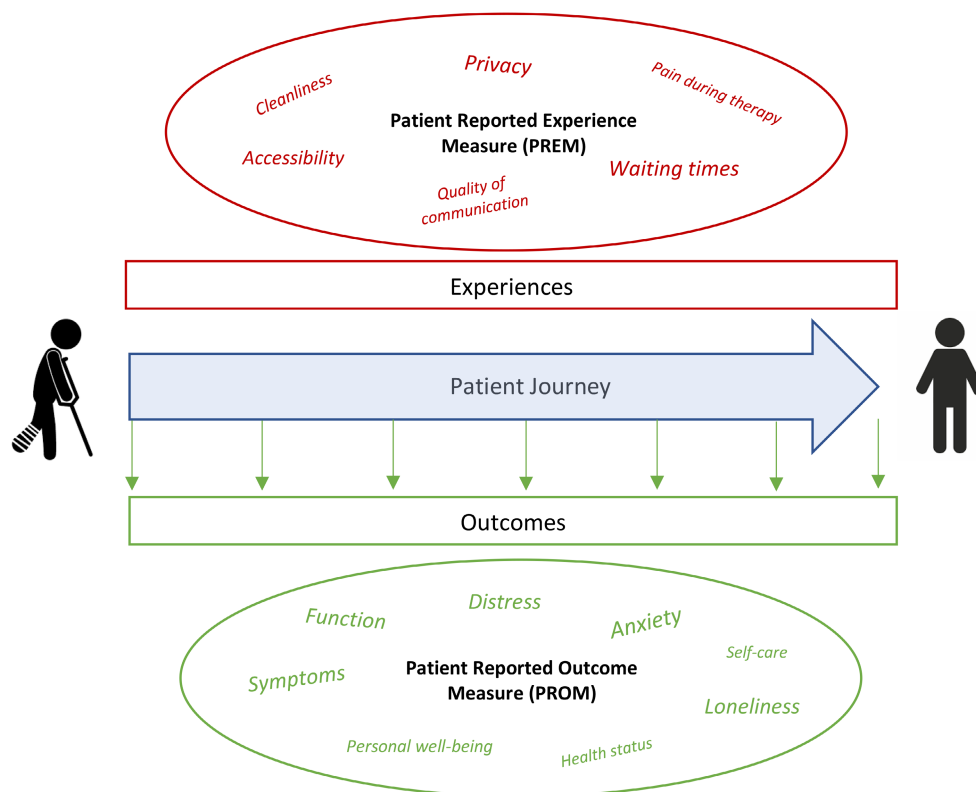


FIGURE 2 Examples of patient-reported outcome measures and patient-reported experience measures

a lack of information about the relationship between PROMs and key surrogate measures of periodontitis (e.g., periodontal probing depths, clinical attachment levels and bleeding on probing), particularly following different modalities of therapeutic intervention(s). Other uncertainties include, how PROMs might change over time or if co-morbidities (e.g., diabetes mellitus) may impact on PROMs.

### 3.1 | PROMs and improving relevance of outcomes to PWLE

Importantly, it should be recognised that even if an intervention is associated with a statistically significant change in PROM, it is difficult to know if this change is meaningful to patients.<sup>36</sup> As a result, the concept of the minimally important (clinical) difference (MID) has emerged.<sup>37–39</sup> MID is the smallest change in PROM scores that would likely be regarded as important (in regard to benefit or harm) from the patient's perspective,<sup>38</sup> and could lead to a change in management. MID is usually specific to an intervention<sup>40</sup> and is most useful when assessed together with cost-effectiveness. Additionally, MID is a key factor for sample size calculations when designing clinical trials and for use in the interpretation of results. However, only a limited number of studies have calculated the MID although it is strongly recommended.<sup>24,40,41</sup>

### 3.2 | PROMs and periodontitis

PROMs have become an important element of research to help clinicians better understand the extent to which patients are impacted by periodontitis and its treatments. Patients with periodontitis have worse OHR-QoL than healthy/stabilised patients<sup>42</sup>; however, conflicting evidence exists on whether more severe disease leads to worse OHR-QoL.<sup>43</sup>

#### 3.2.1 | Non-surgical therapy

Non-surgical therapy (NST) has been shown to improve PROMs in a number of short-term (typically up to 12 weeks) studies,<sup>14,44,45</sup> with one interesting finding from a meta-analysis<sup>46</sup> showing the greatest improvement in OHR-QoL occurred 3–4 weeks following NST, after which there was a decline at 6–12 weeks. It is still unclear whether the extent of residual disease (number of sites with PPD $\geq$ 5 mm) following NST translates to a worse OHR-QoL, with conflicting findings in the literature.<sup>43</sup>

#### 3.2.2 | Surgical therapy

The impact of surgical therapy (ST) on OHR-QoL is unclear, particularly as very few studies have explored this. Heterogeneity in research methodology has been a problem when assessing PROMs

and periodontal surgery; therefore, it is difficult to compare the outcomes of these studies. There has been wide variation in the timepoints at which PROMs were administered in relation to NST, as well as the interval between completing NST and commencing ST. It might be that a change in OHR-QoL is more noticeable between NST and ST, once the effects of NST have stabilised (e.g., a long healing period). Studies from one group<sup>47,48</sup> with a short healing time after NST (3 weeks), found no significant change in OHR-QoL between NST and ST; however, from baseline to either NST or ST, this change was statistically significant. Another study<sup>49</sup> compared NST and ST (with or without enamel matrix derivatives) at baseline and just 7 days after these interventions. Interestingly, the protocol did not include NST in any group prior to randomisation. A statistically significant improvement in OHR-QoL was observed from BL to 7 days in all groups.

#### 3.2.3 | Supportive periodontal care

Supportive periodontal care (SPC) may be seen as the *fourth step of therapy*,<sup>7</sup> and involves a bespoke maintenance programme, including monitoring and interventions as required. Evidence has shown that periodontal patients in long-term (>5 years) SPC experience both disease progression and tooth loss yet there is a remarkable lack of information on the trajectory of PROMs in long-term SPC.<sup>10</sup> Based on population studies, one might assume that tooth loss during SPC would negatively impact OHR-QoL<sup>50,51</sup>; however, a relatively small proportion of patients (9.6%) in long-term SPC (up to 20 years) might expect to lose at least one tooth during SPC. To our knowledge, no evidence exists on how disease progression or loss of multiple teeth may affect OHR-QoL in the long term, nor is there sufficient evidence to inform on the effects of frequency or different types of SPC on PROM. Clearly, research is required to inform on this as SPC is the most sustained step of therapy for periodontitis.

Expectations regarding treatment outcomes differ according to the individual and this is true for both clinicians and patients. The relative importance of each outcome will also vary among individuals. A clinician's expectation of successful periodontal treatment for example, might be resolution of disease (assessed by surrogate endpoints such as periodontal probing depth) and the ability of the patient to efficiently carry out oral hygiene practises. In contrast, a patient may have an expectation that following treatment, he/she could smile with confidence or eat any type of food without pain or sensitivity (generally measured by PROMs), and often this gap in expectation(s) is partially resolved by a frank and open discussion prior to any intervention. One study in periodontology<sup>52</sup> assessed 33 private practice patients, and evaluated expectations prior to periodontal surgery and satisfaction 3-months after treatment. The authors found that patients expressed dissatisfaction in several areas (e.g., sensitivity, mobility, and aesthetics) which were related to expectations prior to treatment. No data were given on clinical outcomes before or after the surgical interventions; thus, it

was not possible to evaluate the relationship between satisfaction and treatment outcomes. One systematic review,<sup>53</sup> which assessed expectations in relation to PROMs found that numerous studies (24 of the 60 included studies) showed improvement in PROMs when pre-treatment expectations were fulfilled; however, the authors also noted heterogeneity in methods to capture these peri-operative expectations.

In summary, PROMs have become an important and essential element in clinical research which could have far-reaching, positive impacts on patient care both in private and public dentistry. Validated PREMs on the other hand, are virtually unexplored in dentistry, yet could provide valuable insights to the patient journey which would complement information gained by PROMs. The use of patient-reported measures in periodontology is lacking in studies with long-term follow-up at all stages of therapy.

### 3.3 | What are the priorities of PWLE in relation to outcomes of periodontal treatment?

#### 3.3.1 | What do we know from the literature?

It is self-evident that what is important to PWLE of a condition might be different from the perspective of researchers or policy-makers. Furthermore, what PWLE are seeking from treatment to satisfy their needs might not be addressed by traditional research outcomes.<sup>54</sup> For instance, when PWLE and prosthodontists were asked to rate factors that determined satisfaction of intraoral prostheses, PWLE tended to rate subjective factors higher than the clinicians.<sup>55</sup> It was notable that comfort was not considered important by clinicians and occlusion was not considered important by PWLE. Similarly, several studies have demonstrated marked differences between clinicians' assessment of aesthetics in relation to gingival recession and those of PWLE.<sup>56</sup> Therefore,

designing research outcomes by either clinicians or PWLE alone is likely to result in incomplete and potentially conflicting evidence to improve health and wellbeing for those most in need. Despite this observation, the involvement of PWLE and the public more broadly in contributing to research design in periodontology is at an early stage.<sup>57</sup>

A recent study developing a core-outcomes set for clinical trials of prevention and management of periodontal disease did involve patients and was based on the COMET methodology.<sup>58</sup> Core-outcomes are the minimum recommended outcomes that should be universally included in research in order to permit greater comparison and standardisation of research. This is important as synthesis of evidence across multiple (high quality) studies has much greater potential to increase certainty of evidence for decision-making than isolated studies.<sup>59</sup>

The project followed several phases of development. First, a detailed search for existing periodontal outcomes from Cochrane Oral Health systematic reviews and protocols with collection of suggested potential missing outcomes. Second, an electronic Delphi survey to seek agreement on a long-list of outcomes and finally a consensus meeting to agree on the final core-outcomes set. PWLE were involved in each phase of the study. Interestingly, no missing outcomes were suggested by patients. The PRO and "oriented" outcomes are shown in Table 1. Of the final five core outcomes only one (QoL) was a PRO. More than previous studies, this project involved patients during the process although an important constraint was that only existing PRO were considered.

The ADVOCATE initiative (Added Value for Oral Care), funded by the European Commission's Horizon 2020 program project was established with the objective of facilitating "more patient-centred and prevention-oriented oral health care" by establishing outcomes to monitor care provided by general dental practitioners.<sup>60</sup> Six countries participated in the project: Denmark, Germany, Hungary, the United Kingdom, Ireland, and the Netherlands. The objectives were

TABLE 1 Outcomes included in each stage of core-outcome set development for periodontal trials<sup>58</sup>

Project phase	No. of outcomes included	PRO/PO
Initial literature search	37 outcomes: 23 clinical, 13 PRO, 1 economic	PRO: Analgesics required, average pain scores, changes in taste perception, patient reported behavior change, patient reported change in knowledge, patient reported health, quality of life, reliability, satisfaction with actual care provided, satisfaction with appearance, satisfaction with product, satisfaction with provider of care, self-efficacy beliefs
Additional outcomes suggested by Delphi participants	12 outcomes: 9 clinical, 3 "patient oriented"	PO: Functional occlusion, manual dexterity, patient stress
Consensus meeting	22 outcomes: 19 clinical, 3 PRO/patient-oriented	PRO: Quality of life PO: Functional occlusion, manual dexterity
Final core-outcome set	5 outcomes: 4 clinical, 1 PRO Clinical: Probing depths, quantified levels of gingivitis, quantified levels of plaque, tooth loss	PRO: Quality of life

Note: Actual indices for health measurement were not selected.

Abbreviations: PO, patient-oriented outcome; PRO, patient-reported outcome.

therefore broader than outcomes for clinical trials of periodontal therapy.<sup>61</sup> Step 1 was a detailed literature review followed by sense checking by dentists to ensure topics were measurable from available data sources, considered important, useful, and relevant and not a disease severity index. These topics were further reviewed in step 2 by 15 expert stakeholders from six European Union countries. Three patients did participate in the following Delphi survey of 46 participants. The final stage was a World Café held in Amsterdam from the network of project partners for ADVOCATE. The output was a final list of 48 topics within six clusters; (1) access to dental care, (2) symptoms and diagnosis, (3) health behaviors, (4) oral treatments, (5) oral prevention, and (6) patient perception. Several clinical and PRO related to periodontal health were included (Table 2). The involvement of patients in the project was limited and as a result is likely to have weighted the final list strongly on measures already known to dental professionals with little opportunity for identification or development of those measures more relevant to patients. In recognition of these limitations, one of the authors later commented: "In the future, co-creative review and updating (together with all relevant stakeholders) of such and similar sets of measures should be targeted at fruition of increasingly harmonized and fit-for-purpose assessments of oral health outcomes."<sup>62</sup>

Also recently published is the result of an initiative between the Federation Dentaire International (FDI) and the International Consortium for Health Outcomes Measurement (ICHOM).<sup>63</sup> The aim was to develop a minimum adult oral health standard set (AOHSS) of outcome measures which, like the ADVOCATE initiative, was for a broader use than trials alone, emphasizing adoption in use in shared decision-making, co-production of care plans with patients, and tracking progress on oral health outcomes. Although not limited to periodontal health, caries and periodontal diseases were a "principal focus" in the project to reflect their predominance in clinical practice. The working group comprised 22 participants from the Americas, Europe, Australia, and New Zealand with an emphasis on dental public health and epidemiology, including two patient representatives from Australia, although interestingly, no periodontal health specialist. Similar to COMET, the process commenced with a detailed literature search for outcomes. In parallel, existing PRO were evaluated for use. A focus group of eight patients in the United States (seven female) who had undergone dental care within the preceding 12 months was established to identify outcomes of most importance to them. The outcomes were then subjected to a combined consensus/Delphi approach to create a draft AOHSS. The draft was widely distributed and translated into German, French, Spanish,

TABLE 2 Core outcomes and measures from three recent consensus studies

	Periodontal	Other conditions	Broader oral health impacts	Oral symptoms	Other topics
<b>Lamont et al. 2021<sup>60</sup></b>	<ol style="list-style-type: none"> <li>1. Probing depths</li> <li>2. Quantified levels of plaque</li> <li>3. Quantified levels of gingivitis</li> <li>4. Tooth loss</li> </ol>		<ol style="list-style-type: none"> <li>1. Quality of life</li> </ol>		
<b>Ni Riordain et al. 2021<sup>65</sup></b>	<ol style="list-style-type: none"> <li>1. Basic periodontal examination <ul style="list-style-type: none"> <li>• Healthy (pristine, well maintained clinical health, periodontal stability)</li> <li>• Pocketing &lt; 5mm</li> <li>• Pocketing 5mm to 7 mm</li> <li>• Pocketing &gt; 7mm</li> </ul> </li> <li>2. Bleeding on probing</li> </ol>	<ol style="list-style-type: none"> <li>1. Caries staging</li> <li>2. Complications within 30 days of intervention</li> <li>3. Craniofacial abnormalities</li> <li>4. Oral Cancer</li> <li>5. Oral infection</li> <li>6. Mucosal diseases</li> </ol>	<ol style="list-style-type: none"> <li>1. General oral health status</li> <li>2. Ability to eat</li> <li>3. Food alteration</li> <li>4. Ability to speak</li> <li>5. Ability to sleep</li> <li>6. Productivity</li> <li>7. Self-confidence</li> <li>8. Smiling</li> <li>9. Aesthetic satisfaction</li> </ol>	<ol style="list-style-type: none"> <li>1. Oral pain</li> <li>2. Dry mouth</li> <li>3. Sensitivity</li> </ol>	<ol style="list-style-type: none"> <li>1. Oral hygiene</li> <li>2. Sugar consumption</li> <li>3. Tobacco use</li> <li>4. Alcohol use</li> <li>5. Chronic medical conditions</li> </ol>
<b>Baadoudi et al. 2017<sup>63</sup></b>	<ol style="list-style-type: none"> <li>1. Periodontal examination</li> <li>2. Bleeding gums</li> </ol>	<ol style="list-style-type: none"> <li>1. Oral mucosa and cancer screening</li> <li>2. New caries lesions</li> </ol>	<ol style="list-style-type: none"> <li>1. Oral function</li> <li>2. Appearance of teeth</li> </ol>	<ol style="list-style-type: none"> <li>1. Current symptoms</li> </ol>	<ol style="list-style-type: none"> <li>1. Access to dental care</li> <li>2. Symptoms</li> <li>3. Diagnosis</li> <li>4. Health behaviors including oral</li> <li>5. Oral treatments</li> <li>6. Oral prevention</li> <li>7. Dental anxiety</li> <li>8. Satisfaction with treatment</li> <li>9. Patient perception on dental care</li> </ol>

Note: Specific oral health measures/indices often open to clinician choice. Measures in green are patient reported.

and Arabic for feedback achieving 347 responses from 87 counties. Similarly, the online survey which was sent to patients/consumers in Australia and the United States received 129 responses, 69% female with 72% aged 36–65 years. Most had received recent dental care which had been a positive experience.

Feedback from the outreach led to simplification of language and recognition that specific population groups had been excluded such as those from rural areas and with special needs. The final list comprised 31 concepts including a total of 80 measures; 25 patients and 55 clinical/administrators reported (Figure 3). For the periodontal diseases staging outcome, the Basic Periodontal Examination (BPE) was selected as the minimum level of recording, although more detailed data collection could be substituted (Table 2). Curiously, the nominated categories for the BPE do not directly match with the recommended BPE categories or associated measuring probe. The developers recognised important issues about the limited representation of the public and professionals in Africa and Asia, and it will be interesting to follow the project as it is implemented and as additional learning and experiences contribute to its development.

As an alternative to beginning the process of identifying outcomes from the existing literature, initial engagement with PWLE can avoid constraining discussion and, therefore, focusing on the already available but limited methods. Qualitative methods include focus groups, interviews, and workshops. Often, this will begin with

a broad consideration of the topic to agree on the objectives, followed by an open discussion to identify possibly relevant items. Various strategies are then used to rank and prioritize items that participants feel are most important. For example, PWLE of periodontitis, diabetes, or with both conditions were included in a study to explore research priorities.<sup>64</sup> The composition of the groups was designed to encourage interaction and new learning from different perspectives (i.e., PWLE of two long-term conditions both of which have demanding requirements for self-management for success) and was emphasised by differing priorities between the groups. Whereas the focus was on research topics rather than outcomes, it was notable that the fourth ranked priority for those with periodontitis was side-effects of treatment; measuring and communicating their impact on patients' lives. Adverse effects are typically poorly reported in the periodontal literature but are considered important by PWLE of periodontitis. Interestingly, interviews with academic researchers who were informed of the workshop results found that they would not change their existing research priorities.

In summary, a few studies have involved PWLE of periodontal diseases, clinicians, and other professionals to identify and prioritize outcomes for periodontal health evaluation, although only one specifically for research. It is not possible to determine from these studies whether the important outcomes for patients have yet been identified, and this is therefore a major limitation for future periodontal research. However, the prioritized outcomes



FIGURE 3 Adult Oral Health Standard Set (AOHSS) outcomes wheel of final prioritized topics.<sup>61</sup> With permission International Consortium for Health Outcomes Measurement

from these studies focus on traditional measures of periodontal health such as probing depth and psychosocial measures particularly QoL.

### 3.4 | What are the recommended approaches to determining priorities for outcomes for PWLE from treatment?

As the reader will have seen from the discussion above, there is no single gold standard for determining the treatment outcome priorities of PWLE. A well-recognised approach for determining overall research prioritization are the Priority Setting Partnerships (PSP) of the James Lind Alliance, which aim to identify and rank the top 10 unanswered questions or evidence uncertainties for patients, carers and clinicians<sup>65</sup> and has been conducted for oral health.<sup>66</sup> Key aspects of the PSP are engagement of patients, carers and clinicians to design the process, identify gaps and uncertainties and finally to set top 10 priorities to be addressed. There is no attempt to limit prioritization by existing knowledge or research but instead to identify topics judged most important to the project. In terms of development of sets of health outcomes, those approaches which are most widely regarded such as COMET for research measures and ICHOM for health-care evaluation follow similar methods. Variations in methodology tend to reflect resource availability particularly the involvement of participants who do not speak English and may therefore lead to a lack of diversity. However, components common to both and which appear to be most important include:

1. Establishment of a research design group representing clinical experts, methodologists, public health and policy and PWLE, carers, and/or members of the public.
2. Scoping of topic.
3. Literature search for existing outcomes.
4. Screening for eligibility and identification of potentially missing outcomes.
5. Delphi survey to allow anonymous iterative agreement on long list of outcomes.
6. Wider stakeholder engagement on proposed outcomes.
7. Consensus-type meeting to rank and prioritize final agreed outcomes.

### 3.5 | What is the diversity and inclusivity of PWLE as periodontal research participants?

An important element of certainty of evidence is its generalisability outside of the study sample. In the context of this paper, different groups of PWLE may have very different needs, priorities, and expectations from treatment. The coronavirus disease 2019 (COVID-19) pandemic has highlighted the effect of inequalities on disease outcomes and therefore shone a light on the importance

of inclusivity in clinical research. What is clear is that clinical trials typically perform badly from this perspective with underrepresentation of many groups including ethnic minorities, older people, and those with multiple comorbidities.<sup>67,68</sup> Thinking specifically about periodontal health, the example described earlier shows that there are substantial differences in research priorities for PWLE of periodontitis alone and those with both periodontitis and diabetes.<sup>69</sup>

A variety of strategies have been recommended to address this issue although with limited assessment in oral health. These include; broadening eligibility criteria, facilitating access to study centers, reducing the burden of participation, community engagement by physical or digital means, and targeted recruitment.<sup>70</sup> Engagement with clinicians working in the community can also achieve improved diversity.<sup>68,71</sup> As part of a 5-year study to investigate antimicrobial mouthwash-use to reduce tooth loss in community-dwelling older people in Vancouver, Canada, two recruitment strategies were tested.<sup>67</sup> First, a traditional “indirect” approach through newspaper advertisements and posters. Secondly a “direct” approach based around community meetings facilitated by a cultural liaison member of each community center. The meetings included a lecture, general discussion, and request for recruits with materials translated into the key linguistic groups. Sixty percent of the community centers initially approached expressed interest with meetings run eventually at 9 (7%) centers. Fifty-four percent of those attending the meetings were recruited which is remarkably high. A further 192 participants (48% of the total) were recruited from newspapers for whom 88% had English as a first language in marked contrast to the direct approach whereby 8% had English as first language. Importantly, recruitment costs were more than double (\$CAN 23.1 vs. 10.9) for the direct approach.

In summary, with recognition that experience of health and disease differs across societies comes an understanding of the importance of diversity within clinical research of periodontal health and its relevance to PWLE. There has been little systematic assessment of this diversity, but since the experience across many health areas is underrepresentation of non-majority groups it is reasonable to believe the same is true for periodontal research. Considering and planning for diversity at all stages of research design should help to improve the representativeness of trial results to the people and communities most affected by periodontal diseases.

### 3.6 | The expert patient

An expert patient is defined as a person who has the knowledge skills and confidence to manage their health and wellbeing in partnership with clinicians. It recognises the direct lived experience of the individual.<sup>72</sup> Other terms that may be used are “activated” or “health literate” patients.

The concept of the expert patient and associated terms has risen in importance due to the extensive evidence showing the link between having the expertise in managing health conditions and both patient outcomes and service utilisation.



The last 20 years of the 20th century saw a fundamental shift in the public's attitudes toward how their care is provided and the relationship between the public and the clinician. A number of core models began to emerge which have been further developed over the last 40 years through a range of key policies but also driven by concepts such as the rights of the consumer, PWLE empowerment, the expert PWLE, shifting the balance of power as well as pressure from the area of disability rights.

A key model in the 1990s was the Wagner model of chronic care<sup>73</sup> which at its essence set out the need to ensure clinical teams are trained in approaches that support PWLE autonomy and decision-making and the need to support PWLEs to have confidence, knowledge, and skills to manage their health and wellbeing (Figure 4).

The key shift for the NHS in England was the publication of the white paper *Saving Lives Our Healthier Nation*<sup>74</sup> which set out the concept of the "expert PWLE". The concept recognises that people with long-term health conditions are often in the best position to know how to manage their condition. There is increasing evidence from research studies and from PWLE associations<sup>75</sup> that people have improved health and reduced incapacity if they are in control of managing their health and wellbeing with good support from the health service. This is not about being expert in the clinical aspects but in how to live with that condition on a day-to-day basis, take on changes in lifestyle and manage the emotional and physical impact and limitations the health condition may create. Clearly, this represents a fundamental shift in the role of the health care professional (Table 3).

Alongside this, there is an increasing body of evidence that shows that services based on a health literacy and person-centered methodology, are the foundation for improving outcomes and managing the demand associated with the increasing prevalence of multiple long-term conditions in the population. There is no reason to expect that management of periodontitis would be any different in view of its long-term nature, interaction with other long-term conditions and reliance on self-management for successful outcomes. However, a whole systems transformation is needed to achieve the cultural and behavioral changes needed to improve health literacy. It also requires a local understanding of the needs and assets within communities, that can support people to stay well and reduce reliance on clinical services for issues that are driven by social factors. It is these emerging new models of care that will shape the future of health services and the role of self-care in the decades to come.

To enable this way of working, clinicians need to be trained and people with lived experience need the support to develop the confidence, knowledge, and skills to be a pro-active manager of their health. Therefore, a further key need to inform and support health literacy is a research-base with outcomes that are relevant and meaningful to PWLE.

A person's ability to manage their health (to be an expert patient) is encompassed within a number of key concepts. These are

- Health literacy: The ability of an individual to obtain and translate knowledge and information in order to maintain and improve

health in a way that is appropriate to the individual and system contexts'.<sup>76</sup>

- Self-efficacy refers to an individual's belief in his or her capacity to execute behaviors necessary to produce specific performance attainments. Self-efficacy reflects confidence in the ability to exert control over one's own motivation, behavior, and social environment.<sup>77</sup>
- Patient activation: Activation is a measure of a person's skills, confidence, and knowledge to manage their own health.<sup>78</sup>

The prevalence of low health literacy (i.e., a level that has a negative impact on a person's health) was highlighted in the 2011 European health literacy survey of eight European Member States: Austria, Bulgaria, Germany (North Rhine-Westphalia), Greece, Ireland, the Netherlands, Poland, and Spain and more recently in a 2019–2021 survey. Although the prevalence of low health literacy varied considerably across Member States, when taken together, the health literacy of 47.6% of the adult population was below the recommended levels of sufficient and excellent (levels were defined as inadequate, problematic, sufficient, and excellent) In all, 12.4% of the adult population had the lowest level of health literacy and would thus be expected to experience severe difficulties.<sup>79</sup>

There are a number of interventions that can significantly improve people's levels of health literacy such as health coaching, self-management education, and also the way clinicians interact with PWLEs. Many clinicians involved in periodontal health care will realise that they are already delivering some of these aspects. These approaches in England are now collectively known as personalized care,<sup>80</sup> where care focuses on what matters to the person (Figure 5) rather than purely "what's the matter with you" and comprise;

- Personalized care and support planning,
- Shared decision-making
- Self-management education
- Health coaching 1-1 and group
- Peer support
- Social prescribing including access to community resources such as housing and employment support, debt advice, and group-based activities

The "Realising the Value" programme reports showed that these interventions are effective across all health and care settings and are important as they support the person in becoming "expert" in their condition and enable effective partnership working and collaboration.

Personalized care and support planning and shared decision-making (Figure 6) all involve advanced communication skills and understanding of motivation and behavior. They are designed so that people feel fully involved in making decisions about their care and fully understand the range of treatment options including doing nothing and lifestyle modification. The associated risks and benefits of the different options and how they may apply to their own

# Wagner Chronic Care Model

FIGURE 4 The Wager chronic care model<sup>73</sup>

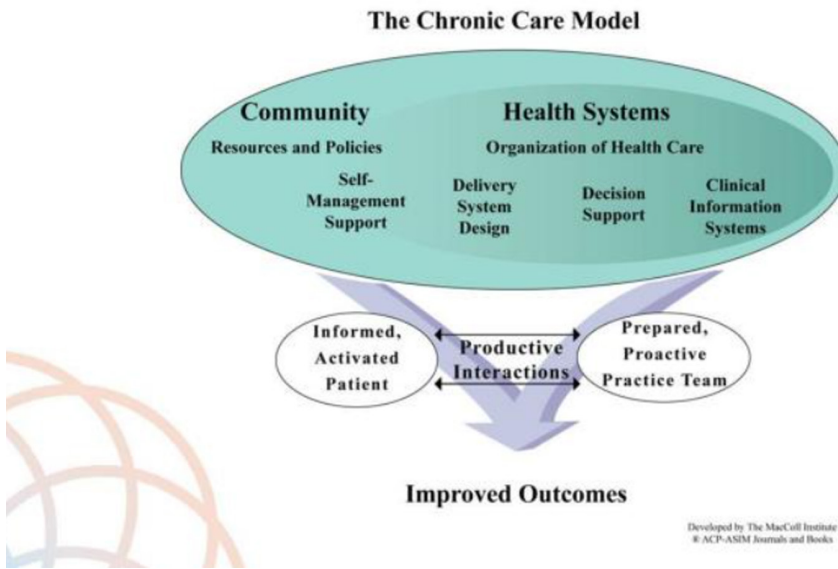


TABLE 3 Comparison of traditional versus collaborative models of health-care consultations

Traditional versus collaborative health-care professional consultations	
<ul style="list-style-type: none"> <li>Information and skills are taught based on clinician agenda</li> <li>There is a belief that knowledge creates behavior change</li> <li>The person believes it is the clinician's role to improve health</li> <li>Goals are set by the clinician and success is measured by them</li> <li>Decisions are made by the clinician</li> </ul>	<ul style="list-style-type: none"> <li>Both share their agendas and collaboratively decide what information and skills are taught</li> <li>There is a belief that one's confidence in the ability to change, together with skills and knowledge creates behavior change</li> <li>The person believes that they have an active role to play in changing their own behaviors and improve their own health</li> <li>They are supported by the clinician in defining their own goals and success is measured by their ability to attain those goals</li> <li>Decisions are made as a PWLE-clinician partnership</li> </ul>

## Why focus a focus on personalised care?

Nearly 40% of people weren't as involved as they wanted to be in decisions

59% felt they didn't have enough support to manage their condition

GP survey 28: 'were you as involved as you wanted to be in decisions?' 'Yes, definitely= 60.5% (2018=60.9%)

GP survey 38: 'have you had enough support to help you manage your conditions?' 'Yes, definitely= 41.8% (2018=43.2%)

FIGURE 5 The 2019 survey data from National Health Service (NHS) England supporting a need for personalized care<sup>80,81</sup>

Information from the NHS England GP Patient Survey dated 2019

GP: General medical practitioner.

circumstances are also explored again identifying a critical need place for relevant and meaningful outcomes.

In addition to the interventions which make up the personalized care approach there are key skills and tools that can be used by people engaging in health care. These tools are simple to present in a variety of formats such as leaflets or by digital delivery.

The following have been evaluated and shown to be effective:

1. Ask three questions (Figure 7)- three simple questions that people often want the answers to-<sup>82</sup>
  - a. What are my choices?
  - b. What is good and bad about each choice?

## What is being shared?

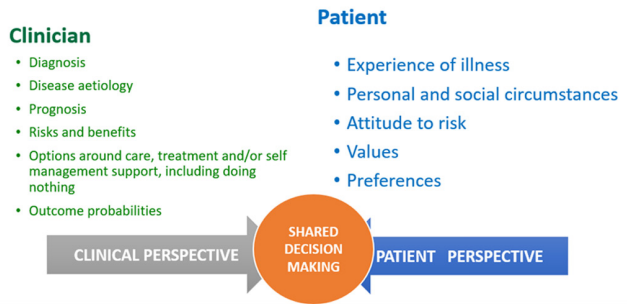


FIGURE 6 The components of shared decision-making<sup>91</sup>



FIGURE 7 Three questions for people with lived experience (PWLE) to ask during health consultations<sup>82</sup>

- c. How do I get support to help me make a decision that is right for me?
2. Decision support tools- Decision support tools (also called patient decision aids) are a set of questions and answers to help people living with a health condition make informed choices about their treatments. They are used together with a health-care professional to support a conversation, taking into account the context of people's lives, and not assuming that there is a single "best" option for everyone. They often set out the advantages and disadvantages of options including a summary of evidence. They can be sent to people prior to a treatment consultation to help the person prepare for the meeting and to think through their options. Whilst these are more common in areas such as musculoskeletal conditions we do not see them in periodontology. There is guidance on the development of decision support tools.<sup>83</sup>

As can be clearly seen in these examples of tools to support the autonomy and decision-making of PWLE, relevant and meaningful outcomes data (both benefits and harms) are the foundations of the information on which they are based.

For practitioners involved in the treatment of periodontitis taking into account a person's level of health literacy, their capability to follow a course of treatment and the motivation to do so are key in achieving the best outcomes for the person. Engagement is likely to be enhanced by communicating expected benefits and risks/harms that are meaningful to PWLE. Experience and evidence show that when people are actively engaged in choices about treatments there is a higher degree of treatment concordance leading to improved outcomes.<sup>84</sup> This in turn leads to an improved experience of care as measured through PRO.<sup>85</sup>

### 3.7 | Strengths and limitations of this review

A key strength of this review is the co-creation of the paper bringing together expertise in periodontal health (I.N., N.L.), lived experience of periodontitis (N.A.) and expertise in patient empowerment (J.P.). We believe this is unique within periodontology. Co-creation meant a level hierarchy supporting all co-authors to contribute and comment equally although led by one author (I.N.). The chief limitation is that we did not base the paper on a series of systematic reviews for each topic. Therefore, it is possible that a biased selection of studies was chosen to support our views.

### 3.8 | What key issues remain in our knowledge about the relevance of periodontal treatment outcomes to PWLE—future directions?

In a provocative paper in this journal in 2012, the authors asked the question, Is periodontal research good for patients?<sup>86</sup> They identified that there was a focus on the methodological quality of trials and went on to question whether the results of many trials would have any meaningful value to patient health even if they reported statistically significant benefits. They concluded that "It would seem logical that randomized clinical trials should include variables rated as important by patients as valid outcome measures". The call for progress in routinely incorporating such outcomes in periodontal outcome research has also been clearly made by others.<sup>9,87</sup>

As we have seen, only a few studies have so far explored stakeholders' views on relevance and prioritization of periodontal treatment outcomes and only one specifically for the purpose of research.<sup>58</sup> They have each employed comprehensive methods to screen the literature for potentially relevant measures and to involve stakeholders including selected PWLE. Their endeavour allows us to learn from their experiences and to identify gaps, opportunities, and recommendations for the future.

- Issue 1. Most studies are based on a review of existing outcomes. Although this is logical for clinical outcomes because of the decades of their use in periodontal research, it constrains the understanding of relevance and prioritization to PWLE since there has been very little development in this field. What is needed is the identification of outcomes potentially important to PWLE followed by their development and validation as outcome measures. The James Lind Alliance PSP methodology would appear to be a suitable approach to achieve this.<sup>65</sup>
- Issue 2. The diversity of PWLE who are involved in studies to develop and prioritize periodontal treatment outcomes is low. This is particularly evident in relation to an existing focus on English-speaking participants from high-income countries. Inclusivity does not happen by chance but requires careful planning.<sup>88</sup> Aspects that should be considered will include different ages, genders and sexual orientations, races and ethnic backgrounds, physical abilities, and faiths since different people may have different needs and priorities.<sup>89</sup> Some of these groups are commonly termed “hard-to-reach,” but the reality is that instead they are “seldom-heard,” meaning that researchers do not (or not know how) to seek their input.<sup>90</sup> We have a responsibility to include them. The guidance in the cited papers will help to understand how this can be achieved successfully but will require resource and co-production with people who have the skills and experience of such involvement.
- Issue 3. The use and development of PROM in periodontology remains limited. There is a need for high quality prospective trials with a sufficiently large sample size to account for both PREMs and PROMs. These trials ideally would investigate in further detail how PROs are affected by disease severity, a variety of treatment regimes, and long-term SPC. Additionally, determining optimum time-periods for administering both PREMs and PROMs is important in order to better understand and appreciate the patient journey. The minimally important difference should be estimated where possible, and consideration of a variety of complementary PROMs could be included to have a broader picture of HR-QoL overall.
- Issue 4. Implementation. Determining and validating PWLE relevant outcomes might turn out to be the easier phase of development. What is likely to be more difficult is to achieve implementation and widespread adoption in research. This will be crucial in developing a broad research base with studies investigating and comparing many therapeutic approaches in different settings. We need evidence that can be incorporated into systematic reviews and therefore have the potential to contribute to guidelines and policy. One consideration might be to ensure that agreed outcomes are incorporated into SNOMED CT. SNOMED is an international coding system for health measures in electronic records with global reach. It is likely to be increasingly

influential for both health-care and research data collection as electronic records gain dominance over other methods of data recording. SNOMED already includes a number of clinical periodontal outcomes. Alignment between consensus-derived outcomes and such a system could increase the availability and communication of these outcomes. Furthermore, the potential for large observational community/population outcome studies could be substantial.

We hope that putting PWLE at the front and center of periodontal outcomes will act as a stimulus to the periodontal health research community to consider how to accelerate these developments. Not only is there important work to be done to determine and agree on such outcomes, but also crucially, in how to implement and adopt their use widely to gain common currency. Periodontal research has achieved spectacular success in its breadth and innovation of studies. The routine incorporation of outcomes demonstrated to be relevant to the day-to-day decision-making of PWLE could be transformative in increasing the impact of the research and therefore improving health and wellbeing.

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#### CONFLICT OF INTEREST

None declared.

#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are openly available in UCL Research Publication Service at <https://www.ucl.ac.uk/isd/how-to/research-publications-service-rps>.

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