Scientific Research Report

Developing a Standard Set of Patient-centred Outcomes for Adult Oral Health — An International, Cross-disciplinary Consensus



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Objective: To develop a minimum Adult Oral Health Standard Set (AOHSS) for use in clinical practice, research, advocacy and population health.

Materials and methods: An international oral health working group (OHWG) was established, of patient advocates, researchers, clinicians and public health experts to develop an AOHSS. PubMed was searched for oral health clinical and patient-reported measures and case-mix variables related to caries and periodontal disease. The selected patient-reported outcome measures focused on general oral health, and oral health-related quality of life tools. A consensus was reached via Delphi with parallel consultation of subject matter

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Quality of life

content experts. Finally, comments and input were elicited from oral health stakeholders globally, including patients/consumers.

Results: The literature search yielded 1,453 results. After inclusion/exclusion criteria, 959 abstracts generated potential outcomes and case-mix variables. Delphi rounds resulted in a consensus-based selection of 80 individual items capturing 31 outcome and case-mix concepts. Global reviews generated 347 responses from 87 countries, and the patient/consumer validation survey elicited 129 responses. This AOHSS includes 25 items directed towards patients (including demographics, the impact of their oral health on oral function, a record of pain and oral hygiene practices, and financial implications of care) and items for clinicians to complete, including medical history, a record of caries and periodontal disease activity, and types of dental treatment delivered.

Conclusion: In conclusion, utilising a robust methodology, a standardised core set of oral health outcome measures for adults, with a particular emphasis on caries and periodontal disease, was developed.

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Introduction

Oral diseases directly impact the lives of individuals by causing considerable pain and suffering, altering food choices, affecting speech, self-esteem, quality of life, and participation in everyday activities^{1,2}. Measuring the impact of oral diseases has traditionally been based upon the biomedical model that provides only limited insight into the impact of oral disease on people's lives³. The emerging patient-centred care model⁴ necessitates a focus on oral health rather than oral disease. Although measures of oral health and oral health-related quality of life have been developed, they have not been shown to be useful in all of the important domains of clinical practice, health services research, epidemiology and advocacy. This is reflected in recent definitions of oral health that now include physical, psychological, emotional and social domains, which are core to overall health and wellbeing⁵⁻⁷. From the patient-centred care perspective, oral healthcare providers should thus consider not only disease processes, but also the environmental, social and personal factors, overall quality of life and participation in all major life areas, including making decisions about and control over their health and the use of health services⁸. This approach is reflected in the FDI World Dental Federation (FDI) definition of oral health⁶ (Figure 1), and provides a theoretical framework for shared decision-making in clinical practice, as well as for health services research, epidemiology and advocacy.

The ability to measure oral health outcomes from both the clinician and patient/consumer perspective in a simple reproducible manner is fundamental to the principle of valuebased oral healthcare. This takes into account the achievement of health outcomes that matter to patients and the healthcare costs incurred in achieving those 9-11, and is a central premise of the International Consortium for Health Outcomes Measurement (ICHOM). Defining a minimum standard or core set of health outcome measures that are meaningful to both patients and clinicians is a necessary first step towards assessment of the value of care provided. Accordingly, ICHOM has thus far developed 27 core outcome standard sets for a range of human diseases and conditions. Each standard set developed by ICHOM has the following components: (i) patient-centred outcomes; (ii) case-mix variables (which are factors that will affect the patient-centred outcomes that are not influenced by the management of the condition and are used to allow the construction of riskadjustment models); (iii) validated instruments that can be

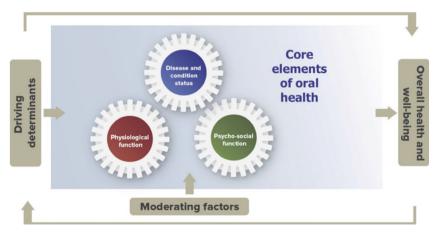


Fig. 1-FDI oral health framework.

used for the outcomes and case-mix variables; (iv) clinicianor patient-reported data sources; (v) specific time-points for data collection. Based on case studies of the implementation of these standard sets in clinical care, the benefits included fewer delays in clinical practice, greater efficiency in administrative processes and consultations with a greater focus on what mattered most to the patients. Patients reported that they were more engaged in their own care, it 'gives us more of a role that makes the appointment more tailored to what is important to us'; while clinicians reported that the routine use of these standard sets resulted in the consultations being 'far more focussed' with a better structure to their patient inter-actions¹².

The key objective of the research reported here is the development of a minimum Adult Oral Health Standard Set (AOHSS) of outcome measures, produced through a collaboration between the FDI and ICHOM, for use in routine clinical practice, research, advocacy and population health. Reflecting their predominance in routine clinical practice, caries and periodontal disease are the principal focus among clinical conditions for this standard set.

Methods

An international Oral Health Working Group (OHWG) of 22 members comprised of patient advocates, researchers, clinicians, policymakers and public health experts, representing 10 countries, was established to ensure diversity in subject matter expertise, sex and geographic location (Table 1,

OHWG membership). This membership unified the discipline-specific expertise of FDI with the strong methodological expertise of ICHOM.

The study included the following phases.

Phase 1: Selection of measures for AOHSS

According to the WHO, caries and periodontal diseases are considered the most important global oral health burdens¹³. The AOHSS focussed therefore on caries and periodontal disease in adults. A literature search was undertaken in PubMed to identify relevant oral health outcomes and case-mix variables published in the previous 10 years. Case-mix variables are used in value-based health to provide a contextual picture of a patient cohort.

The search terms and inclusion/exclusion criteria are presented in Table 2. Duplicate articles were excluded. Two reviewers, who had been calibrated to ensure consistency, reviewed all remaining titles and abstracts independently. After reviewing the first 50 abstracts, a Cohen's kappa coefficient was calculated to determine inter-rater agreement on the application of the inclusion and exclusion criteria. This iterative process was repeated until a kappa of > 0.7 was achieved; the remaining abstracts were then distributed between the two reviewers to determine inclusion and subsequent data extraction. Supplemental literature, including public health surveys and clinical guidelines, were also reviewed.

Patient-Reported Outcome Measurement (PROM) instruments, including the Oral Health Impact Profile-14 (OHIP-14)^{14,15}, Oral Impacts on Dental Performance (OIDP)^{16,17},

Table 1 - OHWG					
Initials	Country	Affiliation	Dental speciality		
RNR	(1) Ireland	(1) University College Cork	Oral Medicine		
	(2) UK	(2) University College London			
MG	USA	University at Buffalo, School of Dental Medicine	Oral Medicine		
SSAA	UAE	Dubai Health Authority	Dental Public Health		
KA	USA	American Dental Association			
JB	USA	Harvard School of Dental Medicine	Oral Health Policy and Epidemiology		
DC	Australia	Dental Health Services Victoria	Public Oral Health Service Provider		
JJC	USA	University of California Los Angeles	Paediatric Dentistry		
JEG	UK	Kings College London	Dental Public Health		
JG	Australia	Patient Advocate			
SH	Australia	Dental Health Services Victoria	Value-based Oral Healthcare		
RK	Australia	Patient Advocate			
EK	USA	University of California San Francisco	Preventive & Restorative Dentistry		
AK	UK	Public Health Wales	Dental Public Health		
RKC	Brazil	Federal University of Rio Grande do Sul	Epidemiology		
SL	(1) Netherlands	(1) Radboud University Medical Centre	Quality Improvement, Health Economics		
	(2) Germany	(2) Heidelberg University Hospital	Preventive & Restorative Dentistry		
SNM	USA	International Consortium for Health Outcome Measurement			
RN	USA	New York University	Epidemiology and Health Promotion		
TS	Switzerland	FDI World Dental Federation			
MWS	Australia	Hospital Contribution Fund			
WMT	New Zealand	University of Otago	Dental epidemiology and public health		
GT	UK	University College London	Dental Public Health		
MV	USA	Health Policy Institute - American Dental Association			
RGW	UK	University College London	Dental Public Health		
SW	USA	International Consortium for Health Outcome Measurement			
DMW	UK	Bart's and The London School of Medicine and Dentistry, Queen Mary, University of London	Global Oral Health		

Table 2 – Search terms, inclusion/exclusion criteria and search results

PubMed Search Terms

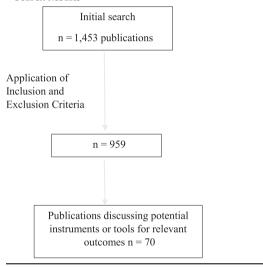
(caries OR carious OR cavity OR decay OR demineralisation OR prophylaxis OR prevention OR restoration) (periodontal disease OR periodontitis OR gingivitis OR prophylaxis OR prevention OR scaling OR root planing OR curettage OR surgical flap) AND ("Quality of Life" [Mesh] OR "Quality Indicators, Health Care" [Mesh] OR "Patient Outcome Assessment" [Mesh] "Treatment Outcome" [Mesh])

Inclusion criteria

Adult population (> 18 years) with dental caries or periodontal disease, English language abstracts from 2006 onwards of studies including systematic reviews and meta analyses, randomised controlled trials, observational studies, case series and guidelines

Exclusion criteria

Studies focusing on other dental diseases, paediatric populations, study protocols, case reports, microbiological outcomes, non-English language and irretrievable material PubMed Search Results



General Oral Health Assessment Index (GOHAI)¹⁸ and OHQoL-UK¹⁹, were reviewed by the OHWG with respect to their coverage of patient-reported outcomes, psychometric properties, content, validity and reliability, availability of language translations, and applicability of copyright/licensing fees.

A patient advisory group was organised in the USA to record response frequency of previously identified domain concepts, as well as take notes on newly raised concepts in real time. This patient insight was gathered via a focus group held in a non-clinical setting in Boston Massachusetts, USA. Eight patients, with fluency in English and who had undergone dental treatment in the last year, participated in the focus group moderated by an experienced qualitative researcher with no expertise in oral health (Figure 2, Patient advisory group demographics).

Phase 2: ICHOM consensus-driven modified Delphi technique to develop the AOHSS

A structured, consensus-driven modified Delphi technique 20,21 was used that included a combination of

videoconferences and surveys to select the AOHSS measures and case-mix variables (Figure 3). Five face-to-face meetings took place in London (twice), San Francisco and Geneva (twice), and eight videoconferences were held (January –November 2017), five of which were followed by surveys to inform decisions.

Videoconferences were preceded as needed by breakout group meetings with subject matter experts on specific areas, including PROMs, clinical measures for caries and periodontal disease, case-mix, and data collection. Following initial presentation of material for decision at each videoconference (Figure 2: Calls 1-8), OHWG members voted electronically on the importance of the proposed items. The consensus process required at least an 80% response rate from the OHWG on every survey before data could be analysed. OHWG members were instructed to vote only on items for inclusion that met all of the following criteria: were important to adult patients with caries and/or periodontal disease; represented endresults of care and not the process of care; were feasible to measure accurately, and were modifiable with quality improvement efforts. Items were ranked on a 1-9 scale: where 1 represented an item deemed non-essential; and 9 an item considered essential. Items ranked 1-3 by 80% of respondents were excluded; items ranked 7-9 by 80% of respondents were included. Items ranked 4-6 were re-voted after further discussion²². If the vote was still inconclusive, a third voting round was undertaken where a simple majority determined inclusion or exclusion.

To ensure that the terminology in relation to diagnosis and disease staging used in the clinical measures of disease was consistent with current concepts, subject matter experts in the fields of cariology and periodontal disease were consulted. Outcome measures for both of these were based on input from content experts involved in generating and publishing the most recent guidelines on management and classification of the respective diseases^{23,24}.

Phase 3: Global open review to determine the appropriateness and feasibility of implementing the AOHSS

The worldwide open review comprised an online structured survey, in English, pertaining to the AOHSS draft. It was distributed among oral health professionals, educators, policymakers, researchers, industry representatives and national dental association members, building on the established networks of both ICHOM and FDI. Health professionals were encouraged to circulate the AOHSS draft within their networks, which included clinicians, policy advisors, payers, educators and researchers, to facilitate snowball sampling. Online platforms including Twitter and LinkedIn were used to share the survey links. The original English language version of the AOHSS was translated into German, French, Spanish and Arabic, and distributed worldwide to determine its acceptability, coverage of the minimum relevant concepts, and appropriateness. Health professionals were additionally asked to consider utility and feasibility. The findings from the global open review were used to inform decisions by the OHWG on outcomes and case-mix factors for inclusion in the final AOHSS, as well as the corresponding measures recommended to capture them.

A group of 8 patients shared their experiences and reflections on oral health to identify the outcomes of most importance to them.

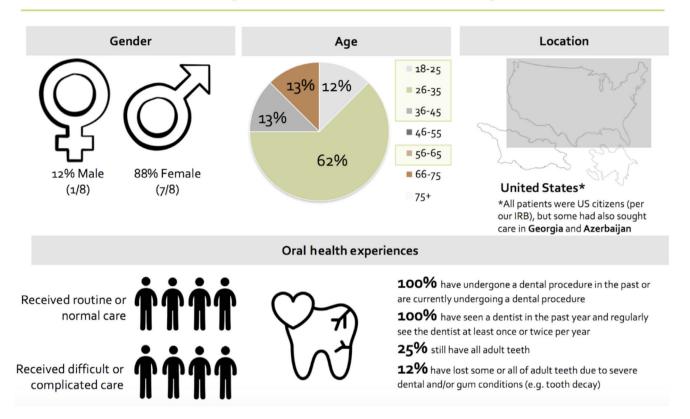


Fig. 2-Patient advisory group demographics.

Phase 4: Patient/consumer survey to determine appropriateness of AOHSS from patient/consumer perspective

To confirm the acceptability, relevance, appropriateness of the questions selected in the draft AOHSS, and to provide an initial insight into their face validity, an online survey with patients/consumers was conducted in Australia and USA. These patients/consumers, recruited via ICOHM in USA and Dental Health Services Victoria in Australia, had adequate online and English language literacy, and had undergone dental treatment in the last year. Ethics approval and exemption determination were obtained for Australia (Austin Health HREC-EC00204) and USA, respectively.

Results

Phase 1: Selection of measures for AOHSS

The literature search yielded 1,453 results, yielding 959 relevant outcome and case-mix abstracts.

Eight patients participated in a focus group moderated by an experienced qualitative researcher with no expertise in oral health (Figure 2, Patient advisory group demographics). The focus group was digitally recorded, transcribed and anonymised. The patient advisory group endorsed the concepts identified from the literature. However, they also identified the financial impact of oral healthcare on individuals as an impact to be considered for inclusion in the AOHSS.

Phase 2: Delphi voting outcome

The first modified Delphi voting survey 1 (DVS1) consisted of three voting rounds, resulting in the inclusion of the following outcome areas from the 10 outcomes identified from literature review: health-related quality of life; overall patient/ consumer satisfaction; emotional well-being; oral healthrelated quality of life (functional and psychosocial aspects); and impact of oral health on personal relationships. An agreed definition for each outcome was then established by the OHWG in advance of mapping to established PROMs. Delphi voting survey 2 (DVS2) identified the question from the established PROM that best represented the defined outcome areas identified in DVS1. Input from the patient advisory group, specifically regarding the importance of each outcome area, was then combined with OHWG findings from DVS2. During this process, impact on personal relationships was excluded and financial impact was added.

Case-mix variables specific to patient demographics, lifestyle and general health, and caries and periodontal risk factors were voted upon. Aspects of clinical care, including baseline clinical data, treatment options and outcome of

Adult oral health standard set - project workplan

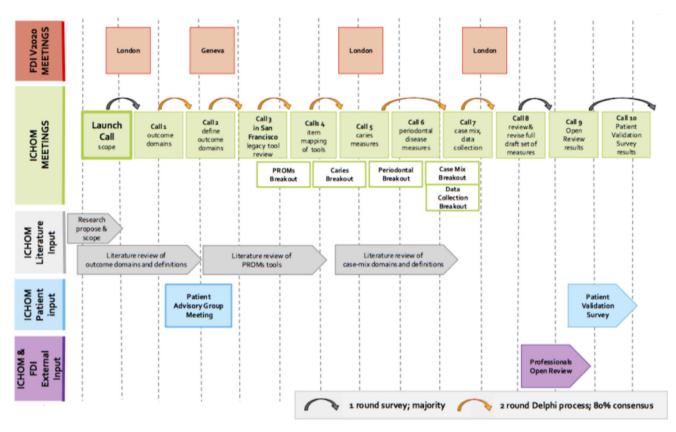


Fig. 3-Delphi process in the development of Adult Oral Health Standard Set (AOHSS).

care, were also included in the clinical measures and were included in voting surveys. Examples of case-mix variables and clinical measures that were considered but not included were occupation, living status, salivary gland hypofunction, oral health literacy and household income.

Following the OHWG and subject matter expert consultations, it was decided that the clinically reported measures for outcomes pertaining to caries and periodontal disease staging be based on existing tools aligned with the International Caries Detection and Assessment System (ICDAS)²³ and the recently internationally agreed standards for measurement of periodontal conditions²⁴.

Phase 3: Global open review to determine the appropriateness and feasibility of implementing the AOHSS

The worldwide open review generated 347 responses from participants in 87 countries (Figure 4). The respondents were from diverse sectors involved in the provision of oral health, including clinicians (67%), researchers (13%), educators (8%), along with policymakers, those involved in advocacy and industry (11%). Following a review of the draft version of the AOHSS, the responses were uniformly positive, and 93% of participants expressed an interest in receiving the final

AOHSS; 82% also indicated that they would implement the set in their day-to-day practice.

Phase 4: Patient/consumer survey to determine appropriateness of AOHSS from patient/consumer perspective

The patient/consumer surveys generated 129 responses; 69% of respondents were female and 72% were aged between 36 and 65 years. Approximately 80% of patient respondents had received routine dental care, and for the overwhelming majority this had been a positive experience; 87% of respondents wanted their dentists to routinely use the AOHSS.

Patients/consumers from USA and Australia in Phase 3 and health professionals who participated in the worldwide open in Phase 4 review expressed similar views about simplifying the question language; revising the type of questions and their response options, and clarifying the concepts captured. Health professionals were concerned about the apparent exclusion of specific population groups such as those in rural areas or those with special needs. Patients/consumers cited a high literacy requirement and the length of the questionnaire as points of concern. Some questions were also perceived to be judgemental about their circumstances.

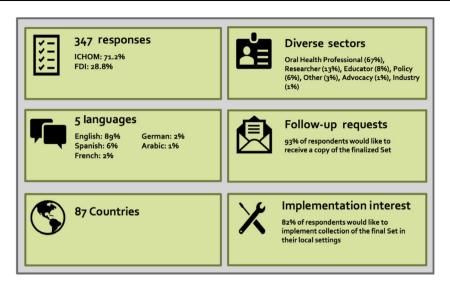


Fig. 4-Global open review.

Feedback from the worldwide open review and patient/consumer surveys was taken into consideration by the OHWG, and the AOHSS was refined accordingly. In particular, draft questions were translated into plain language.

Final version of the AOHSS

After the last OHWG voting round, agreement was reached on the final version of the AOHSS. This resulted in the inclusion of 17 outcome concepts (13 patient-reported, four clinicianreported) and 14 case-mix concepts (eight patient-reported, six clinician- or administrator-reported). The 31 conceptual outcomes included in the AOHSS ultimately comprised a total of 80 measures (25-patient reported, 55-clinician/administrative reported). These 25 items were directed towards patients (including demographics, the impact of their oral health on oral function, a record of pain and oral hygiene practices, and financial implications of care) and items for clinicians to complete, including medical history, a record of caries and periodontal disease activity, and types of dental treatment delivered. A complete overview of the measures included in the AOHSS is presented in Figure 5, with Figure 6 demonstrating the mapping of the AOHSS to the FDI oral health definition framework.

Discussion

This collaboration between FDI and ICHOM used a rigorous, consensus-driven approach involving oral health experts and patients/consumers across the globe to arrive at a harmonised list of items to be included in an AOHSS. The methodology employed in the development of this outcome set followed ICHOM protocols and focused on what matters most to patients on a daily basis. This approach has resulted in the publication of 27 ICHOM sets that have been adopted in medical institutions across the globe, which are developing systems based on the principle of value-based healthcare. They range from the implementation of the ICHOM set for

coronary artery disease in South Australia to the implementation of the cleft lip and palate ICHOM set at the Erasmus University Medical Centre in the Netherlands¹². Hence, they differ in their purpose and their methodology from, for example, the core outcome sets developed in both Core Outcome Measures in Effectiveness Trials (COMET), which focuses on standardising outcome measures for clinical trials²⁵, and Outcome Measures in Rheumatology (OMERACT), concentrating on rheumatological conditions²⁶. In terms of value-based healthcare, there is emerging debate about the relevance of defining 'value' more widely than purely monetary in the context of cost-effectiveness, and how such concepts can be applied to oral healthcare^{27,28}.

It is intended that the AOHSS will be used by clinicians and patients in a shared decision-making environment to co-produce care plans and track oral health outcome progress over time. From a clinical perspective, the focus of this AOHSS was on the most prevalent oral conditions, caries and periodontal disease, but the AOHSS can readily be adapted to include other oral diseases and conditions. The measurement of caries is broad, with the caries status of each tooth recorded as sound, restored, or with caries involving enamel, dentin or the pulp. This broad measurement can be considered as a foundational level of data collection with regard to dental caries. It does not preclude using other standard caries experience measures, such as the DMF (Decayed, Missing, Filled) classification, or even a more 'granular' level of information, such as the ICDAS classification^{29,30}. Similarly, with the clinical recording of periodontal disease staging, the periodontal recording per sextant as either healthy or three grades of pocketing (< 5 mm, 5-7 mm and > 7 mm) allows an overall assessment of periodontal status that is broadly in line with more detailed assessments undertaken for periodontal patients or in oral epidemiological studies of the condition³¹. From the patient perspective, the integration of PROMs is strongly linked to quality of life measures, similar to other health disciplines. Although the potential of PROMs for shifting the pattern of care provision towards addressing the concerns and priorities of the patients themselves³² is

Concept	Question	Response options	Reporting source		
Outcomes					
General oral health status	How is the health of your mouth, teeth and gums?	Very poor, Poor, Fair, Good, Very good	Patient		
Ability to eat	In the last six months, how often have you found it hard to eat because of problems with your teeth, gums or dentures?	Never, Hardly ever, Sometimes, Fairly often, Very often	Patient		
Food alteration	In the last six months, how often have you had to change what you eat or drink because of problems with your teeth, gums or dentures?	Never, Hardly ever, Sometimes, Fairly often, Very often	Patient		
Ability to speak	In the last six months, how often have you found it hard to speak clearly because of problems with your teeth, gums or dentures?	Never, Hardly ever, Sometimes, Fairly often, Very often	Patient		
Ability to sleep	In the last six months, how often have you had trouble sleeping because of problems with your teeth, gums or dentures?	Never, Hardly ever, Sometimes, Fairly often, Very often	Patient		
Productivity	In the last six months, how often have you found it hard to carry out your usual work activities or responsibilities because of problems with your teeth, gums or dentures? This includes at your job and in your home.	Never, Hardly ever, Sometimes, Fairly often, Very often	Patient		
Self- confidence	In the last six months, how often have you felt embarrassed or self-conscious because of problems with your teeth, gums or dentures?	Never, Hardly ever, Sometimes, Fairly often, Very often	Patient		
Smiling	In the last six months, how often have you felt embarrassed smiling, laughing, and showing your teeth because of problems with your teeth, gums, or dentures?	Never, Hardly ever, Sometimes, Fairly often, Very often	Patient		
Social participation	In the last six months, how often have you found it hard to interact with others because of problems with your teeth, gums or dentures?	Never, Hardly ever, Sometimes, Fairly often, Very often	Patient		
Aesthetic satisfaction	In the last six months, how often have you been happy with the way your teeth, gums or dentures look?	Never, Hardly ever, Sometimes, Fairly often, Very often	Patient		
Oral pain	In the last six months, how often have you had pain in your mouth?	Never, Hardly ever, Sometimes, Fairly often, Very often	Patient		
Dry mouth experience	In the last six months, how often has your mouth felt dry?	Never, Hardly ever, Sometimes, Fairly often, Very often	Patient		
Sensitivity experience	In the last six months, how often have your teeth been sensitive to hot or cold food or drinks?	Never, Hardly ever, Sometimes, Fairly often, Very often	Patient		
Caries staging	Record the caries status of each tooth. (encompasses a total of 32 measures – one for each individual tooth)	N/A- Missing, Sound, Restored (with no new or untreated disease) Enamel Involvement	Clinician		
		Pulp Involvement			
Periodontal disease staging	Perform a Basic Periodontal Examination (BPE) and record periodontal disease status of each sextant. (encompasses a total of 6 measures – one for each sextant)	Healthy (pristine, well maintained clinical health, periodontal stability) Pocketing < 5 mm Pocketing 5 mm to 7 mm Pocketing > 7 mm	Clinician		
Bleeding on probing	Is there bleeding upon probing?	Yes, No	Clinician		
Complications Within 30	Were there any unplanned return visits?	Yes, No	Clinician		
days of the intervention date	Did the patient experience a complication or other harm resulting from treatment or disease progression?	Yes, No	Clinician		

Fig. 5 - Adult Oral Health Standard Set (AOHSS).

Case Mix						
Age	Date of birth	MM/DD/YYYY	Patient			
Sex	What is your sex?	Male, Female, Other, Decline	Patient			
Level of education	What is the highest level of school you have completed?	Recorded via per the International Standardized Classification of Education (ISCED)	Patient			
Financial burden of care	In the last six months, have you had to put off dental care because of the cost?	Yes, No	Patient			
Oral hygiene	How often do you clean your teeth?	2 or more times per day, Once a day, A few times per week, Never	Patient			
	Do you use fluoride toothpaste every day?	Yes, No, I don't know	Patient			
	Do you need help from another person to clean your teeth?	Yes, No	Patient			
Sugar consumption	In the last six months, how often have you had sugary food and/or drinks?	Never, A few times per month, A few times per week, Once a week, Once a day, 2 to 3 times a day, 4 or more times a day	Patient			
Current tobacco use	Do you use any tobacco products?	Yes, No	Patient			
	If you do use tobacco products, how many times per day do you use them?	Number of times per day	Patient			
	If you do use tobacco products, how many years have you been using them for?	Number of years	Patient			
Current alcohol use	How often do you drink alcohol?	Never, Monthly or less, 2 to 4 times per month, 2 to 3 times per week, 4 or more times per week	Patient			
Chronic medical	Does the patient have any of the following chronic conditions?					
conditions	Cardiovascular disease	Yes, No	Clinician			
	Diabetes mellitus	Yes, No	Clinician			
	Respiratory disease	Yes, No	Clinician			
	Cancer	Yes, No	Clinician			
	Other	Yes, No	Clinician			
Other oral health	Does the patient have any of the following conditions?					
conditions	Craniofacial abnormalities	Yes, No	Clinician			
	Oral cancer	Yes, No	Clinician			
	Oral infection	Yes, No	Clinician			
	Mucosal diseases	Yes, No	Clinician			
	Other	Yes, No	Clinician			

Fig. 5b

Pregnancy status	Is the patient pregnant?	Yes, No	Clinician
Visible plaque	Is plaque visible on clinical examination?	Yes, No	Clinician
Dental appliances	Does the patient have orthodontic, prosthodontic, or other dental appliances?	Yes, No	Clinician
Treatment type	What type of treatment was delivered?	Prevention or control (i.e. fluoride varnish, oral hygiene instructions, sealants, deep scaling, etc.) Preservation (i.e. periodontal surgery, fillings, crowns, etc.)	Clinician
		Extraction	

Fig. 5c

recognised, their use in routine practice is still uncommon³³, and there are a number of challenges related to their use and interpretation³⁴. Although of importance, the following groups were excluded from the scope of this project, but warrant targeted follow-up work: children; special needs populations; older people; institutionalised persons; and those otherwise dependent on others for day-to-day oral care.

Reference periods for the most widely used subjective outcome measures for oral health and quality of life range between 6 and 12 months for adults, and national studies have used the latter as a time reference point. However, reference intervals in clinical studies are usually narrower in order to reflect the trajectory of changes in oral health after an intervention. The guideline from the National Institute for Health and Care Excellence in the UK recommends that recall intervals should be tailored to each patient depending on their need, and for adults should not be longer than 24 months³⁵. Therefore, the recommendation on data collection time-points is flexible and could mean that, at a minimum, the AOHSS should be collected during the following stages of care: baseline, described as 0 months or prior to any new treatment; treatment and recovery, described as > 30 days after each intervention; and follow-up, described as 12 months after completion of a cycle of care or at least once every 24 months for individuals not requiring any interventions (Figure 7, Time-points). The full AOHSS does not need to be collected at each time-point. Only those data points relevant to each stage in the care cycle should be collected. Furthermore, these minimum data collection time-points should not preclude more frequent data collection, such as annually, if judged to be clinically appropriate.

Following the determination of both the validity and reliability of this newly developed standard set, it is intended that the AOHSS be used in clinical, research, evaluation and community settings. Its flexibility in data collection will facilitate cross-sectional and longitudinal use within diverse global settings. Some of the selected measures have already been included in large national epidemiological surveys to document the impact of oral conditions on daily life³⁶. The applicability and adaptability of the AOHSS for the various

aforementioned settings will inevitably lead to supplemental items or tools being added to this minimum standard set. As long as the integrity of the original AOHSS is maintained and the psychometric properties of this minimum set are demonstrated, following rigorous testing in a clinical, research and population health setting, the addition of subsequent variables will allow flexible data collection whilst facilitating a basic comparison. The adaptability of the AOHSS will, however, only truly become apparent following the phase of psychometric testing. At the patient level, using the AOHSS at the beginning and end of a treatment course will facilitate assessment of preventive and treatment interventions.

Although the development process for the AOHSS has been rigorous, it is not without limitations. Although the OHWG members were recruited from across the globe, there was limited representation from Asia (with one member from UAE). The initial OHWG membership included one member from Africa, who participated in the initial planning stages of the study. Unfortunately, due to the pressure of other commitments, he was unable to participate in a sufficient number of the Delphi voting rounds to meet the criteria for inclusion in the list of authors. The patients involved in its development were also not truly representative of the diverse global population for which AOHSS is intended, and were concentrated in USA and Australia. The broad scope of the data collected and the focus restricted to minimum measures for common preventable oral conditions limits the ability to collect comprehensive disease-specific information on all oral health conditions. For its effective implementation, a clear communication strategy explaining the value of data collected will be important. Clinicians will need to use these data in their clinical practice to understand what matters to patients, and share data with patients. Regular review of data generated by this set will facilitate an assessment of which interventions are more effective in achieving outcomes important to patients.

It is hoped that the FDI-ICHOM collaboration will be viewed as a model for future quality improvement in health-care-related projects. This initiative complements other work in the field, such as the ADVOCATE project³⁷.

The AOHSS measures were selected based on the FDI definition that takes a multifaceted approach in considering oral health.

FDI definition of Oral Health: Oral health is multi-faceted and includes the ability to speak, smile, smell, taste, touch, chew, swallow and convey a range of emotions through facial expressions with confidence and without pain, discomfort and disease of the craniofacial complex

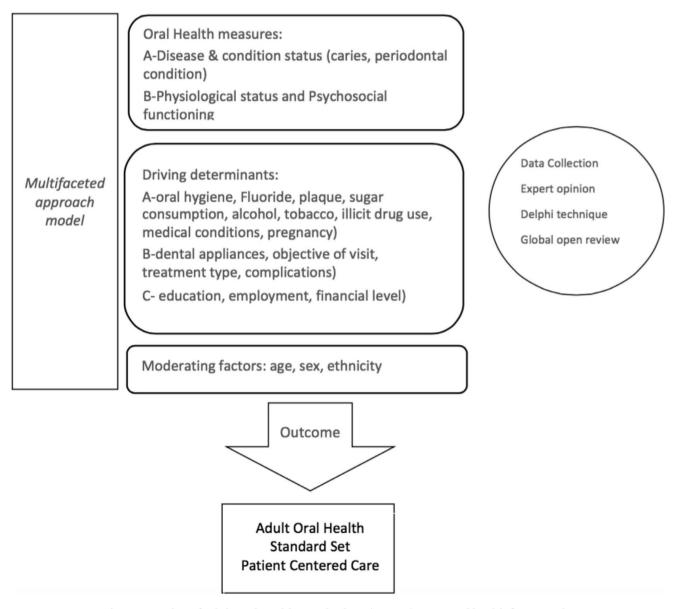


Fig. 6-Mapping of Adult Oral Health Standard Set (AOHSS) to FDI oral health framework.

In conclusion, utilising a robust methodology and a standardised core set of oral health outcome measures for adults, with a particular emphasis on caries and periodontal disease, was developed. To inform additional refinement of the AOHSS, the next step is to conduct a validation and feasibility study in diverse clinical settings. The AOHSS will ultimately empower patients to become decision-makers and co-producers in their care, and this has the potential to result in improved patient outcomes. The AOHSS could be utilised

globally and potentially facilitate international comparisons of oral health outcomes. It would also have the potential to be useful in communities with limited capacity for oral care.

Author contributions

M Glick, SN Myers, DM Williams contributed to conception, design, data analysis and interpretation, drafted the

Observation cycle is repeated indefinitely at least once every 24 months BASELINE Time: o months first visit* before delivery of an intervention cycle *either a new patient or an existing patient's first non-treatment visit since data collection started at REATMENT & RECOVERY Time: >30 days after intervention date; Eligibility: All adults (18+ years of age) FOLLOW-UP repeated for every intervention visit What's Collected: Eliqibility: All adults (18+ years of age) who Patient Reported Outcomes: general oral health, Time: 12 months post completion of care received a treatment intervention* ability to eat, food alteration, ability to speak, *excludes "oral hygiene instruction" if ability to sleep, productivity, self-confidence, Eliqibility: All adults (18+ years of age) who delivered independent of any other treatment smiling, social participation, aesthetic satisfaction, received a treatment intervention* excludes "oral hygiene instruction" if delivered oral pain, dry mouth, sensitivity independent of any other treatment type Provider Reported Outcomes: caries staging, What's Collected: periodontal disease staging, bleeding on probing Patient Reported Case Mix: age, sex, level of Provider Reported Case Mix: treatment type, What's Collected: Patient Reported Outcomes: general oral health, complications education, financial burden of care, oral hygiene, ability to eat, food alteration, ability to speak, sugar consumption, current tobacco use, current alcohol use ability to sleep, productivity, self-confidence, Provider Reported Case Mix: chronic medical smiling, social participation, aesthetic satisfaction, conditions, other oral health conditions, oral pain, dry mouth, sensitivity Provider Reported Outcomes: caries staging, pregnancy status, visible plaque, dental periodontal disease staging, bleeding on probing appliances

Fig. 7 - Time-points.

manuscript, critically revised the manuscript; R Ni Riordain, SSA AlMashhadani, J Barrow, D Cole, S Hegde, E Kalenderian, WM Thomson, G Tsakos, RG Watt contributed to data analysis and interpretation, drafted the manuscript, critically revised the manuscript; K Aravamudhan, JJ Crall, JE Gallagher, J Gibson, R Kaberry, A Karki, RK Celeste, S Listl, R Niederman, T Severin, MW Smith, M Vujicic, S Whittaker contributed to data analysis and interpretation, and critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

Conflict of interest

The authors declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

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REFERENCES

- 1. Watt R, Sheiham A. Integrating the common risk factor approach into social determinants framework. Commun Dent Oral Epidemiol 2012;40:289–96.
- Locker D, Allen F. What do measures of 'oral health-related quality of life' measure? Community Dent Oral Epidemiol 2007;35:401–11.
- Allen PF. Assessment of oral health related quality of life. Health Qual Life Outcomes 2003;1:40.
- 4. Delaney LJ. Patient-centred care as an approach to improving health care in Australia. Collegian 2018;25:119–23.
- 5. Petersen PE. The World Oral Health Report 2003: continuous improvement of oral health in the 21st century—the approach of the WHO Global Oral Health Programme. Community Dent Oral Epidemiol 2003;31(Suppl 1):3–23.
- Glick M, Williams DM, Kleinman DV, et al. A new definition for oral health developed by the FDI World Dental Federation opens the door to a universal definition of oral health. J Am Dent Assoc 2016;147:915–7.
- Peres MA, Macpherson LMD, Weyant RJ, et al. Oral diseases: a global public health challenge. Lancet 2019;394:249–60.
- 8. van Dulmen SA, Lukersmith S, Muxlow J, et al. Supporting a person-centred approach in clinical guidelines. A position paper of the Allied Health Community Guidelines International Network (G-I-N). Health Expect 2015;18:1543–58.

9. Porter ME, Teisberg EO. How physicians can change the future of health care. JAMA 2007;297:1103–11.

- Porter M, Teisberg E. Redefining Health Care: Creating Value-Based Competition on Results. Boston, MA: Harvard Business School Press; 2006.
- 11. Porter ME. Value-based health care delivery. Ann Surg 2008:248:503–9.
- International Consortium for Health Outcomes Measurement
 I. ICHOM Case Studies. Vol 2019. https://www.ichom.org/implementation/#case-studies2019
- WHO. What is the Burden of Oral Disease?, 2020. World Health Organization; 2020 https://www.who.int/oral_health/ disease_burden/global/en/.
- 14. Slade GD, Spencer AJ. Development and evaluation of the oral health impact profile. Community Dent Health 1994;11:3–11.
- Slade G. Derivation and validation of a short-form oral health impact profile. Community Dent Oral Epidemiol 1997;25:284– 90
- Adulyanon SSA. Oral impacts on daily performances editor.
 In: Salde G, editor. Measuring Oral Health and Quality of Life.
 Chapel Hill: University of North Carolina; 1997. p. 151–60.
- Tsakos G, Marcenes W, Sheiham A. Evaluation of a modified version of the index of Oral Impacts on Daily Performances (OIDP) in elderly populations in two European countries. Gerodontology 2001;18:121–30.
- 18. Atchison KA, Dolan TA. Development of the geriatric oral health assessment index. J Dent Educ 1990;54:680–7.
- McGrath C, Bedi R. An evaluation of a new measure of oral health related quality of life—OHQoL-UK(W). Community Dent Health 2001;18:138–43.
- Geist MR. Using the Delphi method to engage stakeholders: a comparison of two studies. Eval Program Plann 2010;33:147–54.
- 21. Goodman CM. The Delphi technique: a critique. J Adv Nurs 1987;12:729–34.
- 22. Boulkedid R, Abdoul H, Loustau M, et al. Using and reporting the Delphi method for selecting healthcare quality indicators: a systematic review. PLoS One 2011;6:e20476.
- Martignon S, Pitts NB, Goffin G, et al. CariesCare practice guide: consensus on evidence into practice. Br Dent J 2019;227:353–62.
- 24. Chapple ILC, Mealey BL, Van Dyke TE, et al. Periodontal health and gingival diseases and conditions on an intact and a reduced periodontium: Consensus report of workgroup 1 of the 2017 World Workshop on the Classification of Periodontal

- and Peri-Implant Diseases and Conditions. J Periodontol 2018;89(Suppl 1):S74–84.
- Core Outcome Measures in Effectiveness Trials. COMET Initiative. Vol 2019. http://www.comet-initiative.org; COMET
- Outcome Measures in Rheumatology O. OMERACT (Outcome Measures in Rheumatology, 2019; 2019. 2019 https://omeract. org.
- Expert Panel on effective ways of investing in Health E. Defining value in "value-based healthcare". Vol. 2019. https://op.europa.eu/en/publication-detail/-/publication/beaebce1-ac29-11e9-9d01-01aa75ed71a1/language-en/format-PDF/source-search2019.
- 28. Listl S. Value-based oral health care: moving forward with dental patient-reported outcomes. Journal of Evidence Based Dental Practice 2019;19:255–9.
- Fisher J, Glick M, Committee FDIWDFS. A new model for caries classification and management: the FDI World Dental Federation caries matrix. J Am Dent Assoc 2012;143:546–51.
- Ismail AI, Sohn W, Tellez M, et al. The International Caries Detection and Assessment System (ICDAS): an integrated system for measuring dental caries. Community Dent Oral Epidemiol 2007;35:170–8.
- 31. British Society of Periodontology. The Good Practitioner's Guide to Periodontology. The Good Practitioner's Guide to Periodontology: BSP British Society of Periodontology; 2016.
- **32.** Dawson J, Doll H, Fitzpatrick R, et al. The routine use of patient reported outcome measures in healthcare settings. BMJ 2010;340:c186.
- **33.** Rosen EB, Donoff RB, Riedy CAUS. Dental school deans' views on the value of patient-reported outcome measures in dentistry. J Dent Educ 2016;80:721–5.
- **34.** Tsakos G, Allen PF, Steele JG, et al. Interpreting oral health-related quality of life data. Community Dent Oral Epidemiol 2012;40:193–200.
- **35.** National Institute for Health and Clinical Excellence N. Clinical Guideline (CG19): Dental checks: intervals between oral health reviews. 2004.
- Information Centre for Health and Social Care Office for National Statistics. Social Survey Division. Adult Dental Health Survey, 2009 [data collection]. UK Data Services; 2012. doi: 10.5255/UKDA-SN-6884-2.
- Baadoudi F, Trescher A, Duijster D, et al. A consensus-based set of measures for oral health care. J Dent Res 2017: 22034517702331.