A New Comprehensive Oral Health Literacy Scale: Development and Psychometric Evaluation

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Abstract

Background: It has been widely accepted that oral health status is related to oral health literacy. The need to measure oral health literacy has led to the development of measurement instruments. This study aimed to develop a comprehensive instrument for adults and to examine its reliability and validity in China.

Methods: A three-step design process was used. First, a literature review and expert panel discussion were used to draw up a 37-item pool covering oral health knowledge, belief, practice, skill and functional oral health literacy. The Delphi method was used to delete and modify questions in the item pool. The draft instrument was evaluated by nine experts and the consensus among them was calculated using the content validity index. The scale was then used to conduct a psychometric study among 370 participants from community health centers in Beijing. Construct validity, discriminant validity and concurrent validity were examined. The Cronbach's alpha coefficient, and test–retest methods were used to assess reliability.

Results: The final scale included 30 items in four dimensions. The item–level content validity index was 0.90. Exploratory factor analysis extracted four fixed factors, and the Kaiser–Meyer–Olkin and Bartlett's tests came to 0.752, with the model explaining 35.21% of the total variance. The four dimensions were associated with oral health knowledge, perceptions of oral health issues, oral health practice and skills, and functional oral health literacy. The mean score of the lowest 27% was significantly lower than the highest 27% (p < 0.01), suggesting adequate discriminant validity. The associations between comprehensive oral health literacy scores and educational level, income and self-reported literacy level were significant (P < 0.001), showing adequate overall concurrent validity. Internal consistency and test–retest reliability were acceptable, with a Cronbach's alpha of 0.72 and a total test–retest reliability coefficient of 0.979.

Conclusions: Initial testing of the comprehensive oral health literacy instrument suggested that it is a valid and reliable instrument to evaluate individuals' oral health literacy, with four dimensions for evaluating knowledge, belief, skill and functional oral health literacy.

1 Introduction

1.1 What is health literacy?

In 1998, the WHO defined health literacy (HL) as “cognitive and social skills that determine an individual’s motivation and ability to acquire, understand, apply information and promote and maintain health through these skills”. In 2005, Zarcadoolas et al distinguished between fundamental, science, civic and cultural literacy. In 2012, Helitzer argued that other HL dimensions should be assessed, because knowledge and attitudes about a health issue affect ability and desire to participate in personal care. HL is therefore a multidimensional concept and the concept has evolved considerably over time. Good HL needs (1) reading, writing, and calculation skills; (2) basic knowledge about health promotion and disease
prevention; (3) health awareness and scientific belief about health issues; (4) ability to implement healthy practice in a way that promotes health; and (5) ability to apply scientific methods, deal with health problems, and avoid disease risk factors.\textsuperscript{3,4}

1.2 What is oral health literacy?

Oral health literacy (OHL) is an important branch of health literacy and an important influence on oral health.\textsuperscript{5} It was first defined in the US Department of Health and Human Services policy, \textit{Healthy People 2010}, as the “degree to which individuals have the capacity to obtain, process and understand basic oral health information and services needed to make appropriate health decisions”.\textsuperscript{6} This is consistent with the definition of HL.\textsuperscript{7} Naghibi argued that OHL is a general term that encompasses reading, writing, numeracy, speaking, listening, and proper decision-making skills.\textsuperscript{8} The Institute of Medicine (IOM) stated that oral health knowledge, oral health practice and self-efficacy are important components of the OHL framework. Self-efficacy is belief in personal ability to organize and execute the actions required to manage prospective situations, and suggested that good OHL required basic reading, writing, calculation and appropriate decision-making skills, knowledge about oral health, correct beliefs about health issues, and ability to use healthy practice appropriately, and deal with health problems. Like HL, OHL is therefore a multidimensional and evolving concept. It includes many of the same aspects as HL.\textsuperscript{9}

1.3 The role of oral health literacy and critical reasons to measure it

The WHO (2018) suggested that oral health means the absence of oral and facial pain, cancer of the mouth and throat, oral infections and oral sores, periodontal disease, dental caries, tooth loss and other diseases and disorders that limit ability to bite, chew, smile, or speak or affect psycho-social health.\textsuperscript{10} Untreated dental caries in permanent teeth becomes the most prevalent non-communicable diseases.\textsuperscript{11} Oral disease does not only affect the mouth, but can also influence people’s lives, and cause pain, discomfort, disfigurement and even death.\textsuperscript{11} Serious oral disease will ultimately lead to tooth loss and is associated with many systemic diseases, such as diabetes, cardiovascular problems and ischemic stroke.\textsuperscript{10} Oral diseases are highly preventable, but remain common in many countries.\textsuperscript{12} The Global Burden of Disease Study 2017 estimated that oral diseases affect nearly 3.5 billion people worldwide. This included 2.3 billion people with caries in their permanent teeth and more than 530 million children with caries in their primary teeth.\textsuperscript{13}

Many studies have shown that oral health status is related to OHL.\textsuperscript{14,15} Baskaradoss showed that more than a third of people with limited OHL had high periodontal risk levels, compared with about 7% of those with adequate OHL.\textsuperscript{15} The prevalence of oral problems such as dental caries, tooth extraction and periodontal disease was higher in people with lower OHL.\textsuperscript{16} A review suggested that low OHL is associated with poor oral health knowledge, which can lead to impaired self-care behavior.\textsuperscript{17} Patients with low OHL have difficulty understanding the importance of health instructions or preventive dental
procedures. Good OHL is therefore essential to improve awareness of oral disease and knowledge about methods of disease prevention and health maintenance, and to increase desirable attitude and practice. 

1.4 Available measurements of oral health literacy and aims of the study

The existing instruments to evaluate OHL use two main strategies: word recognition and reading comprehension. Those using word recognition (REALD-99, REALD-30, REALM-D and REALMD-20) were concentrated on respondents’ ability to correctly pronounce oral health-related words. Reading comprehension tests, such as the TOFHLaD and HKOHLAT-P were constructed to evaluate ability to understand and apply written information, including numerical data. The oral health knowledge test (CMOHK) aimed to assess OHL levels through measurement of conceptual oral health knowledge. Later developments included relative comprehensive oral health tools, such as OHL and OHL-AQ, which contain a valid measure of functional oral health literacy (FOHL) encompassing reading, writing, numeracy, speaking, listening and decision-making skills. These more comprehensive measurement tools enriched knowledge of OHL, but the stability of these scales and the applicable populations still requires further research.

A scoping review of existing OHL tools found that the majority are heavily biased towards FOHL. However, there is no evaluation tool that covers all the known elements of OHL, including oral health knowledge, oral health practice and self-efficacy. This study therefore attempted to develop and psychometrically evaluate a comprehensive instrument to measure OHL among adults in China. This aimed to encompass four dimensions of OHL: (1) functional oral health literacy (reading, writing, calculation skills and ability to make appropriate health decisions); (2) oral health knowledge (basic knowledge about oral health); (3) oral health beliefs (health awareness and scientific attitude towards health issues); (4) oral health practice (ability to implement healthy practice appropriately); and (5) oral health skills (applying scientific methods and having the necessary ability to deal with health problems).

2 Method

2.1 Conceptual framework

The concept of HL and the IOM OHL framework were used as the framework in the development of a comprehensive oral health literacy (COHL) instrument. Both HL and OHL are multidimensional concepts. The new instrument was therefore conceptualized as needing to capture oral health knowledge, belief, practice, skill and FOHL, the five hypothesized dimensions of COHL.

2.2 Item Generation

A thorough literature search was used to develop an item pool, drawing on PubMed, Web of Science, The Cochrane Library, CNKI and Wanfang to identify concepts, components and scales for OHL. We consulted
guidelines, health education leaflets and information sheets for patients to ensure that all elements were included.

The OHL-AQ scale\textsuperscript{8} formed the basis of the COHL scale. This is a valid and reliable instrument for the functional assessment of adults’ OHL.\textsuperscript{27} We obtained consent from the scale’s author to translate it into Chinese. Different studies have used different translation methods.\textsuperscript{27,28,29} We followed the WHO’s translation principle.\textsuperscript{30} A bilingual panel of experts, including the original translator, public health experts and experts with experience in translation and creation of the tool, reached a consensus about the translated version of OHL-AQ and eliminated any differences. The initial Chinese version was back-translated into English by an independent Chinese translator who was not familiar with the questionnaire. The back-translated English version was cross-matched with the original OHL-AQ.

A number of demographic questions were included in the survey to determine respondents’ characteristics, including gender, age, marital status, educational attainment, monthly income, educational level, household composition, smoking status and any chronic conditions, number of false teeth, oral health self-assessment and access to oral health information.

Expert panel discussions were held to establish the initial instrument, involving seven experts in oral diseases, oral nursing, epidemiology, and community medicine. After the panel discussion, the initial instrument was formed, including demographic data and 37 items covering knowledge (six items, K1 ~ K6), belief (six items, B1 ~ B6), practice (seven items, P1 ~ P7), skills (five items, S1 ~ S7), and FOHL (13 items, F1 ~ F13).

2.3 Content Validation and Item Reduction

The Delphi method was used to modify the items further. Nine experts (three oral health specialists, three oral nursing experts, one public health expert, one health educator, and one methodologist) with different years of experience were invited to the consultation. They were given relevant information, including a brief introduction to the research and the current dimensions and items. They were asked to rate each item using a five-point Likert-type scale,\textsuperscript{31} with scores ranging from 5 (most relevant to OHL) to 1 (least relevant). They could also propose other amendments, and if they did so, were asked to provide comments or justifications. We then developed a consultation questionnaire, which was sent to the experts by e-mail, and they were asked to provide feedback within a prescribed time. The dimensions, items and some of the language used were amended following their suggestions.

2.4 Scoring criteria

The score for each question in this scale is 1 point. For single choice and questions where the respondent has to fill in the blank, 1 point is given for the correct answer, and 0 is given for wrong or unanswered questions. For multiple-choice questions (K1-5 and P7), 1 point is given for the correct answer (or correctly choosing $\geq 60\%$ of the correct options), otherwise, 0 is given.\textsuperscript{32} The total score for the questionnaire is obtained by adding the scores of all questions: 0 ~ 37 points.
2.5 Pre-survey

A small sample of the target audience (twenty participants) completed the questionnaire before recruiting the final sample, which the feedback on topics such as clarity and understanding of items will be obtained. This step: i) Verify that the instructions given are easy to follow; (ii) State how long it will take to complete the questionnaire; and (iii) allows face validity to be assessed. A reliable technique for facial validity assessment is the “think out” model, in which participants verbally describe their thought processes as they complete each item. Then a focus group interview between researchers and participants was conducted with some questions, such as 'what do you think this section is testing?', 'are you unfamiliar with any of the terms used in this question?', 'do you find this question confusing or intentionally misleading?' After two circles of these steps, we made necessary changes to terminology and wording of items. For example, we replaced ‘saprodontia’ with ‘decayed tooth’; replaced ‘gingival’ with ‘gum’ and ‘visit your dentist every six months’ with ‘visit your dentist regularly’.

2.6 Pilot study

2.6.1 Participant Recruitment

A convenience sampling strategy was used to recruit participants from 17 locations in Beijing, China (Zhongguancun, Xinjiekou and Jimenli community health service centers and 14 affiliated community service stations), between January and April 2020. The size of the sample was determined by the number of items in the scale. The sample size should be five to ten times the number of items. There were 33 items in the adjusted scale, so the sample size needed to be at least 165. This was increased by 20% to allow for invalid responses, giving a total of 200 participants required. The sample inclusion criteria were: a) 18 years old or over, b) living in Beijing; c) having normal communication ability; and d) giving written informed consent. Anyone with a cognitive impairment or mental health problems was excluded. In total, 370 participants were eventually recruited.

2.6.2 Data collection

The researchers collected the questionnaires in two ways: first, centrally during the monthly community health lecture, and second, on a one-to-one basis at the outpatient departments of the community health service centers. The members of the research group went to the target investigation site after unified training. The questionnaires were distributed to the community residents with the assistance of community medical workers. The questionnaire was filled in by the respondents themselves or by researchers during a face-to-face interview. During interviews, the investigator read the instructions and questions without offering any additional interpretation or using any inducing language. The questionnaires were collected on site, and evaluated for missing data. If necessary, the questionnaire was returned to be completed by the respondents.

2.7 Statistical analysis
The database was built using Epidata3.0 software, and data were analyzed using SPSS 21.0. Continuous variables are shown as mean and standard deviation (SD), and categorical variables as numbers and frequency. The psychometric properties of the new scale were measured using validity and reliability.

### 2.7.1 Content validity

Content validity is the degree to which the items of an instrument fully reflect the construct. The content validity in this study was assessed using the content validity index (CVI) in the final round of Delphi. The CVI was quantified as the proportion of experts who agreed that the item was either very or quite relevant. Items for which the CVI exceeded 0.8 were considered sufficiently relevant to OHL, and consensus among the judges indicated high content validity.

### 2.7.2 Construct validity

Exploratory factor analysis was used to examine the construct validity of the scale. If the Kaiser–Meyer–Olkin (KMO) value was < 0.6, and Bartlett’s test of sphericity was not significant (P > 0.05), the sample data were considered unsuitable for factor analysis. Principal component factor analysis was used to determine the common factors. Five common factors were extracted using the maximum variance rotation method, and the output was the rotation solution. If the item–factor loadings were < 0.40, this item was deleted.

### 2.7.3 Discriminant validity

Discriminant validity is the ability to distinguish two or more distinct groups. Every participant was given a total score for the questionnaire, then two independent sample t-tests were used to compare the highest- and lowest-scoring 27% of the samples (PH and PL) to test the discriminative efficiency of the scale. If p < 0.05, the scale was considered to have discriminant validity.

### 2.7.4 Concurrent validity

Concurrent validity assesses the ability of the instrument to distinguish between groups that it should, theoretically, be able to distinguish. Concurrent validity was measured by examining the association of COHL scores with the general characteristics of the participants. We hypothesized that people with poor COHL were likely to be older, less educated, with lower income and poorer self-assessment of their oral health.

### 2.7.5 Internal consistency reliability

The internal consistency was judged using Cronbach’s alpha coefficient and split-half reliability. It was considered unacceptable if the Cronbach’s alpha coefficient was lower than 0.60.

### 2.7.6 Test–retest reliability

The test–retest analysis asked 30 individuals to complete the scale again after 15 days. These participants came to the community health service center again after an interval of two weeks. The test–
retest reliability was acceptable when the correlation coefficient was higher than 0.75.  

3 Results

A total of 370 people participated in testing the scale (see Table 1 for the general characteristics of the sample), of whom 64% were women. The mean age was 46 ± 18 years, with a range of 18 to 86 years. The level of educational attainment was higher than we expected, and more than half of the sample had university degrees or above. Most of the remainder attended junior college. The mean monthly income was more than $6,000. Only a fifth of participants rated their oral health as good, and over 60% rated it as average. Nearly 71% had a chronic disease, often hypertension, and 55.9% said that they had obtained their oral health knowledge from medical workers.
Table 1
General characteristics of the study participants

|                                      | n (%) or mean ± SD | %     |
|--------------------------------------|--------------------|-------|
| Age (range: 18–86 years)             | 46 ± 18            | /     |
| Gender                               |                    |       |
| Male                                 | 133                | 35.9  |
| Female                               | 237                | 64.1  |
| educational attainment               |                    |       |
| Less than primary school             | 6                  | 1.6   |
| Junior high school                   | 16                 | 4.3   |
| Senior high school or technical secondary school | 37 | 10.0 |
| junior college                       | 79                 | 21.4  |
| College/university diploma or higher | 232                | 62.7  |
| monthly income (RMB yuan)            |                    |       |
| < 2000                               | 18                 | 4.9   |
| < 4000                               | 37                 | 10.0  |
| < 6000                               | 84                 | 22.7  |
| < 8000                               | 80                 | 21.6  |
| < 10000                              | 43                 | 11.6  |
| ≥ 10000                              | 108                | 29.2  |
| living with                          |                    |       |
| live alone                           | 69                 | 18.5  |
| Spouse                               | 228                | 61.7  |
| Children                             | 40                 | 10.9  |
| other caregivers                     | 33                 | 8.9   |
| Smoking                              |                    |       |
| Yes                                  | 35                 | 9.5   |
| No                                   | 335                | 90.5  |
| Chronic diseases                     |                    |       |
| Condition                              | n (%) or mean ± SD | %  |
|----------------------------------------|--------------------|----|
| No                                     | 108                | 29.2 |
| hypertension                           | 66                 | 17.8 |
| hyperlipidemia                         | 45                 | 12.2 |
| Diabetes                               | 29                 | 7.8  |
| cardiovascular and cerebrovascular diseases | 33              | 8.9  |
| Number of false teeth                  |                    |      |
| None                                   | 220                | 59.5 |
| 1–5                                    | 69                 | 18.6 |
| 6–12                                   | 29                 | 7.8  |
| 13–20                                  | 18                 | 4.9  |
| ≥ 20                                   | 34                 | 9.2  |
| Oral condition self-assessment         |                    |      |
| Good                                   | 78                 | 21.1 |
| General                                | 233                | 63.0 |
| Bad                                    | 54                 | 14.6 |
| Unknown                                | 5                  | 1.3  |
| Access to oral health information      |                    |      |
| medical workers                        | 207                | 55.9 |
| Broadcast                              | 130                | 35.1 |
| Newspapers or books                   | 87                 | 23.5 |
| mobile phone or network                | 165                | 44.6 |
| friends and relatives                  | 103                | 27.8 |
| Lecture                                | 57                 | 15.4 |
| Other                                  | 6                  | 1.6  |

### 3.1 Content Validity
In the first Delphi round, there was no change in dimensions. However, there were 33 items with I-CVI values of > 0.8, so items K6 (What is the most important preventive measure for root caries?), P1 (How many times do you brush your teeth every day?), P2 (How do you place your toothbrush?) and S5 (How should you protect dentures in daily life?) were deleted, leaving 33 items. In the second round, the CVI was above 0.80 for each item, and the average CVI for all items was 0.90. There was therefore no change in dimensions and items. However, the wording of two items was improved following feedback. After two rounds, the opinions of the experts tended to be consistent, indicating that the filtering of dimensions and items was complete. Therefore, the scale included demographic data and 33 items covering knowledge (five items), belief (six items), practice (five items), skill (four items) and FOHL (10 items).

3.2 Construct validity

The KMO coefficient was 0.752, and the Bartlett’s test of sphericity was significant at the advanced level ($\chi^2 = 2236.0; p < 0.001$). The sample size was suitable and sufficient for factor analysis. As shown in Table 2, the principal component factor analysis with varimax rotation yielded a four-factor solution. F3 (What should you do if some bleeding occurs after brushing or flossing?), F4 (What should you do if you have pain in your mouth?) and F10 (Should you swallow mouthwash?) were removed. The four sub-dimensions were considered to explain 35.21% of the total variance.
| Item | Question                                                                 | Factor1 | Factor2 | Factor3 | Factor4 |
|------|--------------------------------------------------------------------------|---------|---------|---------|---------|
| **Functional Oral Health literacy**                                                                                       |         |         |         |         |
| F8   | If you take the first capsule at 14:00, when should you take the next one?       | 0.657   | 0.031   | -0.067  | -0.049  |
| F9   | If your symptoms are gone by the 4th day of taking the medication, should you stop taking the medication? | 0.626   | -0.010  | 0.134   | -0.069  |
| F11  | If you use it at 12 am, when can you eat or drink?                        | 0.608   | -0.008  | -0.076  | 0.018   |
| F12  | If your tooth was extracted at 8 am, when should you take the gauze out of your mouth? | 0.537   | 0.003   | -0.008  | -0.036  |
| F2   | How many teeth do each person have and when do they grow?                | 0.522   | 0.229   | 0.150   | 0.068   |
| F13  | If your tooth was extracted at 8 am, can you eat hot food at 2 PM?       | 0.519   | 0.041   | 0.036   | -0.061  |
| F6   | What is the meaning of “I exonerate my dentist from unintentional complications of treatment” in your opinion? | 0.455   | 0.223   | 0.008   | 0.086   |
| F1   | What kind of toothpaste can you use to prevent tooth decay?             | 0.424   | 0.194   | 0.212   | 0.236   |
| F5   | Which of the following is the best way to remove stain and calculus from teeth? | 0.419   | 0.240   | 0.130   | 0.294   |
| F7   | What is the meaning of “I have a history of allergy to some drugs” in your opinion? | 0.413   | -0.040  | -0.065  | 0.163   |
| **Oral Health knowledge**                                                                                                  |         |         |         |         |
| K3   | Which of the following are detrimental factors to oral health?          | 0.087   | 0.738   | -0.094  | 0.061   |
| K5   | Which of the following are the symptoms and manifestations of periodontal disease? | 0.079   | 0.684   | 0.079   | -0.050  |
| K1   | Which of the following are signs of poor oral health?                   | 0.267   | 0.675   | -0.140  | 0.084   |
| K2   | Which of the following behaviors are good for oral health?             | 0.258   | 0.652   | -0.023  | 0.089   |
| P7   | If you have any of the following situations, would you go to the hospital for treatment? | -0.083  | 0.598   | 0.222   | 0.071   |

*Item number:30*
3.3 Discriminant validity

Table 3 shows the discriminant validity of the scale. Each of the factors and total COHL all had a statistically significant difference between the mean scores of the highest (PH) and lowest (PL) 27% of respondents (p < 0.05).
Table 3
Discriminant validity of the scale

| Range of scores | Mean ± SD | Scores of PH | Scores of PL | t     | P    |
|-----------------|----------|--------------|--------------|-------|------|
| Knowledge       | 0–5      | 3.4 ± 1.3    | 1.0 ± 1.4    | 12.8  | < 0.001 |
| Belief          | 0–6      | 5.7 ± 0.5    | 4.5 ± 1.3    | 8.6   | < 0.05  |
| Skill           | 0–9      | 5.4 ± 1.8    | 2.0 ± 1.4    | 15.1  | < 0.05  |
| FOHL            | 0–10     | 8.2 ± 1.5    | 3.5 ± 2.1    | 18.2  | < 0.05  |
| Total           | 0–30     | 22.6 ± 1.7   | 11.0 ± 2.8   | 35.1  | < 0.05  |

3.4 Concurrent validity

Table 4 shows that the overall performance of the scale indicated good concurrent validity. There was a significant correlation between the scores and age, educational attainment, income and self-reported oral health, which confirmed our hypotheses that these factors are related to COHL of adults.
Table 4
Comparison of sample characteristics associated with scores (n = 370)

|                          | Mean (SD) | P-value |
|--------------------------|-----------|---------|
| Age (years)              |           |         |
| 18–44                    | 18.5 ± 5.0| < 0.001 |
| 45–64                    | 16.1 ± 5.2|         |
| 65–80                    | 14.5 ± 4.7|         |
| educational attainment   |           |         |
| Less than primary school | 11.2 ± 4.5| < 0.001 |
| Junior high school       | 10.7 ± 4.1|         |
| Senior high school or technical secondary school | 14.2 ± 5.1 |         |
| junior college           | 16.5 ± 4.8|         |
| College/university diploma or higher | 18.4 ± 4.0 |         |
| monthly income (RMB yuan)|           |         |
| < 2000                   | 14.0 ± 5.9| 0.003   |
| < 4000                   | 16.0 ± 5.1|         |
| < 6000                   | 16.6 ± 5.2|         |
| < 8000                   | 16.7 ± 4.5|         |
| < 10000                  | 17.8 ± 4.5|         |
| ≥ 10000                  | 18.4 ± 3.9|         |
| Oral condition self-assessment |     |         |
| good                     | 18.2 ± 5.0| 0.023   |
| general                  | 17.0 ± 4.7|         |
| bad                      | 15.9 ± 4.5|         |

3.5 Internal consistency reliability

The Cronbach’s alpha coefficient for the entire scale was 0.777, and the results of each factor are shown in Table 5. This suggested that the scale was reliable and had good internal consistency.

3.6 Test–retest reliability
The total test–retest reliability coefficient after 2 weeks was 0.979, and ranged from 0.832 to 0.941 for individual factors; the consistency between the two measurements was statistically significant (p < 0.05) (Table 5). The scale therefore showed excellent test–retest reliability.

| No. of items | Cronbach's α (n = 370) | Test-retest reliability (n = 30) |
|--------------|-------------------------|---------------------------------|
| Oral Health knowledge | 5 | 0.727 | 0.894(P<0.05) |
| Oral Health belief | 6 | 0.512 | 0.832(P<0.05) |
| Oral Health skill | 9 | 0.623 | 0.929(P<0.05) |
| Functional Oral Health literacy | 10 | 0.737 | 0.941(P<0.05) |
| Total: COHL | 30 | 0.777 | 0.979(P<0.05) |

4 Discussion

The aim of this research was to develop a COHL instrument for adults and assess its reliability and validity in a Chinese population. The new scale was based on the theoretical framework for OHL created by the IOM, integrating oral health knowledge, oral health practice, and self-efficacy. It combined these three elements with FOHL, covering a broader range of OHL skills. Items in the tool included essential oral health knowledge, views on oral health care and how to maintain good oral health. Other items covered real-life situations that might be encountered in clinical settings. The format of the test items was diverse to allow an assessment of reading, listening, understanding, numeracy, application, and analytical skills. The scale was therefore considered to be a comprehensive assessment tool for OHL.

Integrating oral health and primary care practice is crucial for improving health. Healthcare providers are responsible for prevention of oral disease, and increasing OHL level among all population groups is critical in addressing national oral health. One of the most effective strategies is patient education, which requires positive patient interactions and effective communication. However, it is also necessary to provide ongoing training in communication skills to healthcare providers, to ensure that individuals with any level of health literacy can adequately understand the information provided.

During the development of the COHL instrument, a three-step design process was used, covering item generation, content validation and psychometric evaluation. A mixed-methods approach was used for item generation, to make the items more comprehensive and accurate. We reviewed the existing OHL questionnaires, related guidelines and health education leaflets, considering them against the OHL concept and the IOM theoretical framework for OHL. Next, we translated the OHL-AQ scale using WHO principles. During expert panel discussions, the item-pool was screened and confirmed, to give an initial
instrument containing 37 items. Literature searches are widely used in the development of instruments.\textsuperscript{7,23,26} Methods such as focus groups and semi-structured interviews have also been used.\textsuperscript{46,47} Expert panel discussions are efficient because experts have experience in the field and can contribute effectively to the process.\textsuperscript{48} The techniques used in this study may therefore be a good model for an effective way to develop an item pool.

The content validity was assessed by the Delphi method using the item-level CVI to reflect the adequacy of item sampling.\textsuperscript{49} The instrument was sent to nine experts with experience in oral health to calculate the index. The Delphi technique is a systematic way of determining the consensus among experts and answering questions that are not subject to experimental and epidemiological methods.\textsuperscript{50} It is the most commonly used and convincing approach for measuring content validity.\textsuperscript{51} In this study, after two rounds, four items were removed because the CVI was less than 0.8.\textsuperscript{38} These questions were also considered either too basic or too hard to understand. The average CVI for the remaining 33 items on the scale was 0.90. The overall content validity for the scale was therefore considered acceptable and the remaining 33 questions were considered to be relevant and to cover all topics.

Finally, the item pool was tested for construct validity, discriminant validity, concurrent validity, internal consistency and test–retest reliability. Exploratory factor analysis was used to identify and confirm the construct validity.\textsuperscript{41} Principal component factor analysis with varimax rotation and a scree plot gave a five-factor solution in line with our original conception. However, the result of rotation did not match the model. The panel of experts therefore recommended merging the skill and practice elements, giving four dimensions. The factor analysis results (Table 2) showed that a four-factor model was a good fit. However, the factor loads of items F3, F4 and F10 were all less than 0.40, suggesting that they should be deleted.\textsuperscript{31} From the item content perspective, F3 and F4 were about decision-making, and were very similar to P7, so deleting them did not affect the comprehensiveness of the scale. The correct response rate for F10 was above 99%. Stucky and colleagues\textsuperscript{23} also removed questions about sugar and smoking because both items were answered correctly by 99.5% of the sample. It was therefore considered reasonable to omit F10. Item P7 carried a lower factor loading at the practice level than at the knowledge level, which did not conform to the predicted model. However, the item was considered essential and significant, so it was retained on the advice of the experts. The basic model was therefore considered valid and able to measure OHL across four different levels, with 10 items for FOHL (Factor 1), five for oral health knowledge (Factor 2), nine for oral health skill (Factor 3) and six for oral health beliefs (Factor 4).

As anticipated, the revised scale had good discriminant and concurrent validity. It can therefore help clinicians to distinguish between patients with higher and lower health literacy.\textsuperscript{31} Like other studies,\textsuperscript{45,52,53} we found that older and less educated patients tended to have poorer health literacy, and the COHL score had a significant correlation with income and self-reported oral health. These results confirmed our hypotheses that these factors are related to oral health literacy among adults.
The COHL scale displayed high internal consistency and good test–retest reliability in our study. The Cronbach's $\alpha$ for the entire questionnaire was 0.78, which is an acceptable value according to Nunnally and comparable to other study. However, the Cronbach's for belief element was 0.51. Deleting items in the belief construct increased Cronbach's $\alpha$, but the items were eventually retained after expert panel discussion, because they were considered important for the overall concept, and lower Cronbach's $\alpha$ values have been considered acceptable in other studies. A high test–retest reliability (0.97) indicates that the questions are understandable and the responses reproducible. The cross-sectional nature of the data means that computation of test-retest reproducibility was an added advantage.

Our results therefore suggest that the new scale is a comprehensive instrument to measure OHL among adults, with acceptable reliability and validity.

**Limitation**

The study results should be considered in the light of some limitations. We used a convenience sample and some bias may have been introduced because participants were recruited predominantly from areas with larger numbers of research institutes and universities. Our sample therefore had relatively high levels of educational attainment. Further psychological assessment is needed to verify the instrument's universality in a more representative sample. Future studies should also consider sample heterogeneity to improve scale validity. Educational level is not always a good predictor of literacy, but it does play a role. We plan to assess dental health literacy among a population with more diverse educational attainment in a future study. We also did not categorize COHL scores by OHL ability, so further research is needed to establish new cut-offs for COHL scores.

**5 Conclusion**

This study developed a new COHL instrument with acceptable psychometric properties. The new scale is comprehensive, and we believe that it is a valid and reliable instrument for the assessment of adults’ OHL.

**Abbreviations**

HL: Health literacy; OHL: Oral health literacy; IOM: Institute of Medicine; REALD: Rapid Estimate of Adult literacy in Dentistry; REALMD: Rapid Estimate of Adult Literacy in Medicine; TOFHLID: Test of Functional Health Literacy in Dentistry; HKOHLAT-P: Hong Kong OHL Assessment Task for Paediatric Dentistry; CMOHK : Comprehensive Measure of Oral Health Knowledge; OHLI: oral health literacy instrument; OHL-AQ: Oral Health Literacy-Adult Questionnaire; FOHL: Functional oral health literacy; COHL: Comprehensive oral health literacy; CVI: Content validity index; KMO: Kaiser–Meyer–Olkin.

**Declarations**
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Author contributions

(1) Yue Sun and Jing Sun were responsible for the conceptualization, design of the project and item pool generation. Aixiao Cheng and Junhong Zhou made contributions to the item pool generation. Yue Sun, Yan Zhao, Aixiao Cheng and Junhong Zhou were responsible for the data collection. Yue Sun and Jing Sun made substantial contributions to the various analytical approaches and interpretations of data. (2) Yue Sun drafted the main manuscript and prepared table 1-5. Jing Sun made major contributions to the revising of the manuscript. (3) All authors reviewed the manuscript.

Ethics declarations

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The research was approved by the Institutional Ethics Review Board of Peking University Health Science Center (IRB00001052-19149). Written informed consent was obtained from all participants.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Availability of data and materials

The data used to generate and support the findings of this study are available from the corresponding author upon request.

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