

Questionnaire development: face validity and item impact testing of the Child Oral Health Impact Profile

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Abstract - Objective: The Child Oral Health Impact Profile (COHIP) was designed to assess oral-facial well-being in school-age children as reported by the child and via proxy report from a caregiver. This article describes the development of the COHIP using a multi-staged impact approach recommended by Guyatt et al. (Quality of life and pharmacoeconomics in clinical trials. Philadelphia, PA: Lippincott-Raven; 1996. p. 41). Methods: There were multiple phases to the development of the questionnaire: (i) initial pool of items developed from the literature and expert review; (ii) face validity of items; (iii) impact evaluation of the initial item pool; (iv) development of positive items and face validity of new items; (v) impact evaluation of the revised questionnaire and (vi) factor analysis and final revision of the questionnaire. Factor analysis was completed on the final questionnaire using data from the impact evaluation in order to evaluate whether the COHIP measured independent conceptual domains. Results: Factor analysis identified five domains: oral health, functional well-being, social/emotional well-being, school environment and selfimage. Readability was calculated using the Flesch-Kinkaid readability score that was finalized at a 3.5 grade reading level. Finally, two response sets, and a revised format (e.g., including pictures, increasing font size, and shading every other item) were implemented to decrease respondent fatigue and increase accuracy of participant responses. Conclusions: The final questionnaire consisted of 34 items and five conceptually distinct subscales: oral health, functional well-being, social/emotional well-being, school environment and self-image. Subsequent papers present the validity and reliability of the COHIP.

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As early as 1948, the WHO promoted the idea that 'health is more than the absence of disease' (1), and more recently the WHO Quality of Life Group further acknowledged that subjective aspects of health are dependent on 'an individual's' perception of their position in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns' (2). Multiple measures of oral health-related quality of life (OHRQoL) (3–6) have been developed and standardized for use in adult

populations in recent years. The measures have been consistent with the WHO orientation in that oral health has been conceptualized broadly as a construct that also included general well-being, and the ability to eat, speak, and socialize with confidence (7). While oral signs and symptoms are a necessary part of the conceptualization of oral health, they are not sufficient.

Recently, efforts have been made to develop a measure of OHRQoL that would be appropriate for use with children (8–11). Such measures required

attention to developmental issues such as abstract thinking and readability (12-15), as well as to goals set by the WHO definition of health. In addition, recent thinking in the QoL literature has indicated that both positive and negative perceptions of health and health outcomes should be measured (16, 17). Several current measures of adult OHRQoL measures have now included positive aspects of health (4–6), recognizing the importance of oral health to positive well-being and not solely to the negative impacts. The authors of the widelyused Child Health Questionnaire (18) have emphasized that the underlying conceptual framework of children's health-related QoL must include abilities as well as disabilities to provide a valid measure of well-being.

We sought to develop a valid and reliable instrument that could distinguish among a broad range of children with different clinical conditions and between children with the same clinical condition of different levels of severity. We developed our questionnaire for children aged 8-15 and their caregivers. There is much debate about developmental issues related to childhood and adolescence in terms of answering questions about health and well-being. By including such a broad age range we were trying to create an instrument that would be accessible to as many children as possible. We also believed that development phases would determine whether children in this age range could respond to the questions appropriately. Finally, we sought to develop a measure that was comprehensible and inclusive yet short and capable of selfadministration. Our intention was to produce a measure that could be used in clinical practice and research.

Questionnaire development incorporated a multistage process: literature review, item generation, face and content validity testing, item-impact analyses, and consideration of theoretical issues used to nominate items for inclusion and elimination.

These processes in questionnaire development were grounded in the methodological framework for assessing health indices proposed by Christie, Guyatt and others (13, 19, 20). According to this framework, a discriminative instrument should be able to distinguish among people who differ in their QoL as it relates to their underlying disease or condition. Therefore, a discriminative instrument should not contain questions to which all respondents with the disease would respond in a like manner (e.g., items to which virtually all or none of the respondents answer similarly should be deleted). Idiosyncratic items on which people with a low functional status perform well or on which people with a high functional status perform poorly should be excluded. Any items that are strongly influenced by factors other than the disease of interest should also be excluded. A discriminative instrument should also have high internal consistency (i.e., the items are related to each other and measure the same thing). One should measure the frequency with which an item was endorsed and the participants' numerical rating of how 'important' it was when it occurred (item relevance). Evaluative scales should retain items that occur relatively frequently as well as those that are subject to change as a result of treatment. Given our long-range goal to utilize the Child Oral Health Impact Profile (COHIP) in clinical studies, all of the preceding requirements guided our decision-making in item retention and reduction.

The purpose of this report was to provide a review of the protocol and procedures used in the development of the COHIP. The process consisted of six phases: (i) development of the initial pool of items; (ii) initial face validity; (iii) initial item impact; (iv) revision of items, face validity of the revised instrument; (v) item impact of the revised instrument; and (vi) factor analysis to identify conceptual domains. The reliability and validity testing phase is presented in a separate report in this issue. Two questionnaires were developed to assess children's OHRQoL: one for children and one for caregivers.

Materials and methods

Phase 1: Initial item pool

The initial item pool consisted of 54 items that were developed by Jokovic et al. (8) representing five theoretical domains: oral symptoms, functional limitations, emotional well-being, peer interaction and school. The pool was generated based on the expertise of Jokovic et al., and their review of the existing literature on OHRQoL and HRQL instruments (8). After this initial pool was generated, four sites were identified to recruit volunteers to assess face validity and item impact in order to revise, eliminate, or add items to the scale. These sites were the Pediatric and Orthodontic clinics at the University of Medicine and Dentistry in Newark, NJ, the Pediatric and Orthodontic clinics at

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New York University School of Dentistry, the Center for Reconstructive Surgery at New York University Medical Center in NYC, and McGill University Hospital and the pediatric and orthodontic clinics at McGill University, Montreal, Canada. The procedures for recruiting volunteers and administering the questionnaires were standardized across sites and were consistent across all phases of the face validity and item impact assessment. These procedures are described in the following section. Results for each phase of scale development then follow.

Protocol common to four phases of data collection (face validity 1; item impact 1; face validity 2; item impact 2)

Prior to subject recruitment, efforts were undertaken to sensitize and inform the community at the research sites regarding the project. These efforts were important so that the staff, administrators and patients at the dental clinics were both supportive and knowledgeable as to the purpose of the project. Investigators from the sites attended the initial training session to standardize the protocol, discuss theoretical issues, and review the existing instruments with the research staff. Sample videotapes illustrating the interview process were used to train the research staff. Individuals who administered the questionnaires viewed the videotapes and were encouraged to ask questions about the interview process and content of the questionnaires. The investigators at each site observed the interviewers during interview practice sessions. Interviewers repeated practice sessions under supervision until trainers were satisfied that interviewers with the administration and recording of the questionnaires. Training and standardization took place prior to each stage of participant recruitment. Meetings with the directors and staff at the project sites as well as debriefings regarding the findings were accomplished throughout the questionnaire development period.

The target sample in each of the following phases included convenience samples of male and female children. Inclusion criteria were: (i) being between the ages of 8 and 15; (ii) seeking pediatric dental, orthodontic treatment, or craniofacial care at the four locations. Individuals scheduled for appointments were identified, whenever possible, in advance as being in the correct age range for the study. Children were excluded if they were enrolled in a special class for mental disabilities, had a mental disorder or mental retardation, or did not read English or Spanish, if recruited in the USA, or English or French if recruited in Canada. Children with craniofacial anomalies who were scheduled for surgery within a 2-week period were excluded. Children in the orthodontic clinics who had previously been banded with orthodontic braces or appliances were also excluded.

During each phase, research staff approached individuals to request participation in the project. Caregivers and children were given information sheets that described the study and consent and assent were secured, in accordance with IRB regulations at the various sites. During phases 2, 3, 4, and 5 of questionnaire development detailed in this report, data were collected from children and their parents/caregivers using face-to-face interviews at the Pediatric and Orthodontic clinics at the University of Medicine and Dentistry in Newark, NJ, the Pediatric and Orthodontic clinics at New York University School of Dentistry, the Center for Reconstructive Surgery at New York University Medical Center in NYC, and McGill University Hospital and the pediatric and orthodontic clinics at McGill University, Montreal, Canada. Participants received a monetary incentive for their time and effort.

All research materials were translated by experienced translators into French and Spanish, thereby ensuring potential participation in the study by the majority of language groups at the three locations in North America. Careful attention was given to the readability and clarity of the items. Because of nuances in language, the inclusion of alternate words to enhance linguistic clarity was deemed important by the researchers. Linguistic equivalence across the various language versions was achieved by forward and backward translation procedure and avoidance of jargon, idioms and metaphors (21). As the research materials changed over the course of the study, translations were an ongoing process throughout phases 2 through 5.

For younger children, cue cards were used as an adjunct to the questionnaire administration during the initial stages. The cue cards consisted of colored circles with numbers in ascending order to illustrate the hierarchy of response categories being elicited (e.g., never to always). Further, the Flesch-Kinkaid readability scores (22) were calculated to determine grade level of the questionnaire before validity and reliability testing commenced.

Figure 1 presents an illustration of number of items developed, added, and deleted for the final questionnaire of 34 items.



Fig. 1. Phases in the development of the COHIP. OH, oral health; tr expect, treatment expectations; hlth expect, health expectations.

Phase 2: Face validity of the initial item pool

The purposes of this phase were to: (i) assess the clarity of the wording of the items in the initial item pool; and (ii) generate new items from experts at the data collection sites and from caregivers of children with oral facial conditions. Items believed to be confusing, redundant, or concepts that were overlooked were identified.

Sample

Qualitative interviews were conducted with 10 health professionals and with 144 caregivers of children seeking dental care in pediatric, orthodontic, and craniofacial clinics in NY and NJ and Montreal, Canada. During face-to-face interviews, the participants indicated whether each of the 54 items was clear or unclear. Further, the participants were queried at the end of the interviews regarding concepts or questions that were deemed missing, irrelevant and/or confusing. These queries aimed to identify unclear or redundant items and to assess professional and respondents' reactions to questionnaire format and response usage.

Results of the qualitative interviews

Eight caregivers reported unclear ratings on at least five items (range 5-12). Eight items had unclear rating by more than two caregivers. Issues regarding 'oral hygiene' and 'confidence' were mentioned as areas related to oral health and QoL that were overlooked in the questions. Numerous items were reworded to add clarity to the item pool. For example 'ulcers' was changed to 'mouth sores'; 'pronouncing' was changed to 'speaking clearly'; and use of the word 'jaw' was eliminated. Fifteen items from the child form were dropped because of lack of clarity and relevance to the target age group (e.g., prevented from doing homework; lack of feeling; refusing to speak; drooling; child's diet had been unsatisfactory; difficulty swallowing). The latter two items were believed to be associated with eating difficulties and this concept was tapped in another item. Three new items were also created: e.g., 'clicking and popping of the jaw', 'difficulty keeping mouth clean', and 'being treated differently by teachers' were added to the item pool. The professionals generally rated similar items as inappropriate or unclear. Several caregivers and professionals also commented that oral health had positive benefits for QoL and that this aspect of oral health was missing from the questionnaire.

At the end of this stage, 42 items were retained in the item pool representing the initial theoretic domains proposed by Jokovic: oral symptoms (12 items), functional well-being (seven items), emotional well-being (nine items), peer interaction (nine items), and school (five items), Data from the qualitative interviews indicated that the positive aspects of oral health had been overlooked. Based on these comments and the theoretical importance of positive aspect of QoL, we decided to add positive items to the questionnaire which were not included in the initial item pool. We also decided to proceed with the impact reduction stage before adding positive concepts.

Phase 3: Item impact 1

The purpose of the item impact phase was to measure the prevalence and importance of items retained and revised from the initial item pool. The primary rationale was to eliminate items that the study participants perceived as relatively unimportant.

Sample

The study sample completing the item impact evaluation (IMPACT 1) included 155 children from NY/NJ and Montreal. The demographic characteristics of the study sample included: mean age 11.8 years (SD = 1.5); females = 55%; and ethnic representation: white = 48%; black = 18%; Latino = 20%, Asian = 14%. A full example of the computation of impact scores is presented in Table 1. It should be noted that due to the close proximity between NY and NJ and that participants from the two states cross state lines to seek treatment, the two sites were combined.

At this stage, the questionnaire was administered to both the child and to the caregiver. Participants responded to each item by first indicating whether or not the child had experienced the event in the past 3 months (all the time = 4, often = 3, sometimes = 2, never = 1). Participants also rated how important or relevant (e.g., feeling, symptom) the experience had been (very much = 3, quite a bit = 2, a little = 1, not at all = 0). This process yielded frequency of item endorsement (frequency) and relevance of the experience. The impact of the experience was computed as the product of frequency and relevance ratings.

Results of the item impact 1 survey

The rationale to exclude items at this stage was based on the methodology of Guyatt et al. (20) and theoretical importance of the items to our conceptual model of OHRQoL. Items were deleted in the case of extremely high or low endorsement, low impact, or potential redundancy of highly correlated items. These factors were considered in the context of the theoretical importance of an item to the original five dimensions of QoL derived from the literature. We used a conservative approach at this stage of development to retain questionable items and assess how they performed in subsequent analyses. Poor items could be deleted at a later stage but if the item was deleted at this stage it would be difficult to restore the item later. Further, we also examined whether items differed in impact scores across clinical groups and whether any oral facial treatment could possibly make a difference in the symptom or QoL issue. This process resulted in eight items being deleted because of low endorsement and/or low relevance. Table 1 presents the results of child impact scores by location and domain.

'Had any other pain in his/her mouth or jaws' was considered redundant with other retained items; 'clicking or popping in his/her mouth' was unclear and had low relevance; 'had difficulty opening or closing his/her mouth' had low endorsement; and five items had low relevance and low endorsement (Taken longer to finish a meal, Avoided eating with other children, Avoided going out with friends, Been treated differently by teachers, Avoided talking with other children). With the elimination of these items, the remaining item pool consisted of 34 items.

New item development

Based on the theoretical importance of the positive domains in the health-related QoL literature and the qualitative comments provided by participants, we created additional items representing this conceptual domain. These new items were generated from participant comments elicited during the interviews from the previous phases. This methodology was consistent with theoretical saturation in grounded theory (23) and methods reported by other investigators developing QoL measures (2).

Participant comments suggested that specific unexplored constructs existed. Such constructs were largely positive ones: confidence, positive expectations (satisfaction) about oral care, coping, empathy, overall health status and adjustment. Following an extensive review of child healthrelated QoL measures, 20 new items were developed. Other items related to defects of enamel appearance, dental anxiety, malocclusion and hygiene were also created. After tabulating the responses elicited from the interviews, several discussions and deliberations among the investigative team members ensued. Further, two additional response sets were considered for inclusion in the measure.

These new items, questionnaire format (e.g., shading, pictures) and response sets were pilot-tested on a small sample (n = 20) by the investigators from Montreal and NY/NJ locations. Based on the qualitative data and frequency distributions of the responses from the interviews, 3 of the 20 new items were deleted largely due to clarity and relevance. The 17 items retained for the next phase face validity testing 2 were:

Had discolored teeth or spots (white, yellow or brown) on your teeth; Been able to keep your teeth clean; Been able to eat food you want to eat; Been upset or uncomfortable with being asked questions about your teeth, mouth, or face; Get sick more

Table 1.	Child	impact	1	scores	by	location	and	domain
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29. Felt that s/he looks different 8.3 1.0 8.3 32.8 1.8 60).74
32. Felt that s/he is not good looking 8.3 1.5 12.45 23.7 2.03 48	3.15
33. Felt s/he has less friends than other children 4.2 1.0 4.2 4.6 1.75 8	3.05
35. Been worried about what other people think 8.3 1.0 8.3 33.6 1.67 56	5.31
about his/her teeth or mouth or mouth	
44. Fought or argued with other children 12.5 1.33 16.66 11.5 1.7 20	0.34
Peer interaction	
18. Avoided eating with other 4.2 0 0 4.6 1.33 6	5.13
children (at school or parties) ^b	
23 Avoided smiling or laughing with other children 125 10 125 237 15 35	5 55
27 Reen tessed bulliad or called participation that children 83 10 83 101 233 44	1.56
20 Been tracted differently or left out by other children 125 1.0 125 0.2 2.2 20	1.00 0.24
So been treated uniformation by other children 12.5 1.0 12.5 5.2 2.2 20 26 Available agains given with friends ^b 12 0 0 60 2 12).24 20
4.2 0 0 6.7 2 13).0 0 E 4
38. Avoided meeting new people 12.5 1.0 12.5 5.3 1.8 9	1.54
40. Been asked questions by others about $45.8 ext{ 1.0} ext{ 45.8 } 53.4 ext{ 1.63 } 87$	7.09
41. Avoided taking part in activities $12.5 1.0 12.5 9.9 1.625 16$	5.08
like sports, clubs, drama,	
school trips, playing a musical instrument ^o	
42. Avoided talking with other children ^b 12.5 1.33 16.66 9.9 1.5 15	5.39
School	
17. Missed school for any reason because 33.3 1.0 33.3 38.9 1.73 67	7.41
of his/her teeth or mouth	
22. Had difficulty paying attention in school 8.3 1.0 8.3 13.0 1.85 24	4.14
26. Did not want to speak/read out loud in class 20.8 1.0 20.8 20.6 1.7 35	5.02
37. Not wanted to go to school 16.7 1.5 25.05 9.2 1.87 17	7.2
39. Been treated differently by teachers ^b 16.7 1.33 22.26 3.8 2.0 7	76

^aIndicates percentage of subjects with frequency ratings from 'all the time' to 'sometimes'. ^bIndicates that the item was deleted.

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than most children; Felt happy; Felt that you were attractive (good looking); Had crooked teeth or spaces between my teeth; I have healthy teeth; When I am older, I believe (think) that I will have good teeth; I am happy with my smile; I will feel better about myself when my dental treatment is completed; Been confident in social situations; When I am older, I believe (think) that I will have good health; I am nervous (anxious) about the treatment that I need for my teeth, mouth, or face; Feel good about myself; and More sensitive to other people's feelings than other children my age.

The frequency distribution response set ('never' to 'always') was ranked highest for some of the retained items (e.g., had discolored teeth, able to keep teeth clean, able to eat food you want to eat, been confident in social situations, felt happy, been comfortable being asked questions about your teeth mouth or face, sensitivity toward others; and felt you were good looking). The response set, 'strongly agree to strongly disagree', was ranked highest for the other items (e.g., I have healthy teeth, look forward to dental treatment, when I am older, I will be a healthy person, pleased with my smile, anxious about dental care, and life will be better for me when my dental treatment is completed). Therefore, two response sets were retained.

Phase 4: Face validity 2

Sample

The second face validity testing included 50 children (22 from Montreal and 28 from NY/NJ) and 55 caregivers (29 from Montreal and 26 from NY/NJ). Several of the items retained were unchanged: Had discolored teeth or spots (white, yellow or brown) on your teeth; Been able to eat food you want to eat; Felt that you were attractive (good looking); I am nervous (anxious) about the treatment that I need for my teeth, mouth, or face; When I am older, I believe (think) that I will have good health; and When I am older, I believe (think) that I will have good teeth. Five items were considered 'important' but required rewording to improve clarity. These items were: Been confident in social situations with other people my age; Had crooked teeth or spaces between my teeth; I have good teeth; Been sensitive to or cared more about other people's feelings; and I will feel better about myself when my dental treatment is completed. Two Items were deleted: Get sick more than most children; and Felt happy. Each of the deleted items had unclear ratings by at least 10 of the children and caregivers from the two locations and the majority of the children and caregivers rated the items as 'not at all' relevant. This face validity phase started with 51 items, 34 items from the initial item impact and 17 new positive items. Two items were deleted, thus, 49 items were used in the item impact 2 survey.

Phase 5: Item impact stage 2

This phase included the testing of prevalence, relevance, and impact of 49 items retained from preceding stages (face 1, item impact 1, and face 2).

Sample

The sample for the item impact 2 study consisted of 50 children from Montreal and 128 children recruited from New York and New Jersey. In the New York/New Jersey sample, the ethnic distribution included 57% White, 16% Black, 20% Latino, and 7%Asian. The children averaged 12.1 years (SD = 1.4) and 51% (n = 65) were female. The ethnic distribution in the Montreal sample included 76% White, 9% Black, 4% Latino, 4% Asian, and 7% other. The children averaged 12.2 years (SD = 1.4) and 54% (n = 27) were female. The results from Impact 2 are presented in Table 2. The endorsement scores indicated how often the item was experienced and relevance was rated on a 4-point scale from 'very much' to 'not at all'. Impact scores were similar at the two locations and were in agreement in terms of item deletion (see below). Impact scores ranged from a low of 15.04 to a high of 271.05.

As illustrated in Table 2, nine items were deleted because of low impact scores. The items were: Had numbness (lack of feeling) in your lips or mouth; Had food sticking in roof/top of your mouth; Been treated differently or left out by other children; Had less friends than other children; Avoided meeting new people; Been asked questions by others about...; Avoided taking part in activities like sports, clubs, drama, school trips, playing a musical instrument; Fought or argued with other children. The item, Been sensitive to or cared more about other people's feelings, was viewed by the majority of the craniofacial children/caregivers as clear and relevant but was rated unclear by the children in the pediatric group and their caregivers. The item was retained for craniofacial studies only but was deleted from the COHIP questionnaire. Despite the lower impact item scores relative to the school domain, they were retained as they were believed to be theoretically relevant.

Table 2. Results from child	item impact 2 testing	ıg by location and domain
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	Canada (n = 50)		NY/NJ (r	ı = 128)	
Y.	%	М	• .	%	М	. .
Item	Endorse	Relevance	Impact	Endorse	Relevance	Impact
Oral symptoms						
1. Had pain in your teeth/toothache	54.8	1.5	82.2	53.2	1.82	96.82
4. Been breathing through your mouth or snoring	64.5	1.4	90.3	58.2	1.53	89.05
50. Had discolored teeth or spots (white,	93.6	2	187.2	92.4	1.8	166.32
yellow or brown) on your teeth	70 (1.05		20.2	0.10	0 0 F
58. Had crooked teeth or spaces between my teeth	/2.6	1.95	141.57	39.Z	2.13	83.5
5. Had numbress (lack of feeling) in your lips or mouth	9.7	1.55	15.04	13.9	1.75	24.33
6. Had sores or sore spots (ulcer, abscess)	35.5	1.76	62.48	30.4	1.51	45.90
in or around your mouth	00.0	1 50	120.02	()	1.07	100 14
8. Had blad breath	02.3 E1 (1.38	130.03	62 40-4	1.97	122.14
9. Had bleeding gums	51.6 77.4	1.75	90.3	49.4	2.02	99.79 104 70
10. Had food sticking in or between your teeth	//.4	1.66	128.48	73.4 25.4	1./	124.78
12. Had food sticking in root/top of your mouth	55.9 E1 (1.70	07.00	33.4 42	1.45	51.55
12. Had pain or sensitivity in your teeth with	51.6	1.8	92.00	43	1.73	74.39
not or cold things	FO	1 5	75	(0)	1 (00.7
Functional wall being	50	1.5	75	62	1.0	99.2
15. Had trouble biting off or showing foods such	25 5	1 5	E2 2E	24.2	1 05	62.07
15. Had trouble biting off or chewing foods such	33.3	1.5	55.25	34.2	1.85	63.27
as apple carrot or firm meat	2E E	1 5	E2 2E	27.0	2.22	(1.04
19. Had difficulty eating foods you would like to eat	35.5	1.5	55.25	27.9	2.22	61.94
51. Been able to keep your teeth clean	88.7	1.76	156.11	96.2	2.56	246.27
24. Had trouble sleeping	25.8	1./1	44.1Z	20.3	2.18	44.25
28. Flad difficulty saying certain words	48.4 92 F	1.78	00.15	25.5	1.91	40.52
52. Been able to eat food you want to eat	82.5 25.2	1.94	160.05	96.Z	2.33	224.15
31. Have people had difficulty understanding	33.3	2	70.6	31.7	2.07	65.62
24 Used differenties because a second starthy along	(1 5	1 (4	105 70	E1 0	2 20	102 E0
54. Had difficulty keeping your teeth clean	64.5	1.64	105.78	51.9	2.38	123.52
Emotional well-being	10 1	1 54	75 50	44.2	0.11	02.47
16. been unnappy or sad	48.4	1.36	75.50	44.5	2.11	93.47
20. Felt worried of anxious	41.9	1.5	54.47	37.7	1.96	73.89
21. Feit sny or withdrawn	30.7	1.66	50.96	30.4	1.93	58.67
25. Got angry	45.2	1.68	75.94	32.9	2.1	69.09
35. Been worried about what other people think	27.4	2	54.8	38	2.03	//.14
about your teeth, mouth, or face	20 7	1.00	74.20	22.0	1 -	40.25
56. Been upset or uncomfortable with	38.7	1.92	74.30	32.9	1.5	49.35
being asked questions						
about your teetn, mouth, or face						
E4 Been en Gilent in again situations	02.0	1 76	147((02 7	2 5	224.25
54. Been confident in social situations	83.9	1.76	147.00	95.7	2.5	234.23
22 Assided emilies on least in a with other shildren	20.7	1 75	E2 72	22.0	2.26	74.25
23. Avoided smiling or laugning with other children	30.7	1.75	55.75	32.9	2.26	74.33
27. Been teased, builded of called names by other children 20. Been tracted differentiation of left such that the shift and b	33.9 DE 9	1.09	37.29	20.0	2.56	00.10
30. Been treated differently or left out by other children	23.8	1.85	47.21	13.9	2 57	27.8
33. Had less friends than other children 2^{9} Associated meeting mean hab	24.Z	1.72	41.62	8.9	2.57	22.87
38. Avoided meeting new people	19.4 E1.(1.55	30.07	0.9 12	Z.I 1 771	18.69
40. Deen asked questions by others about	51.0 11.2	1.35	09.00 17.74	45	1./1	16 20
41. Avoided taking part in activities	11.5	1.37	17.74	0.9	1.65	16.29
nke spons, clubs, drama,						
44. Equals a musical instrument	22 (1.0	42.04	11 /	0.11	24 OF
44. Fought or argued with other children	22.0	1.9	42.94	11.4	2.11	24.05
20. Felt that you were attractive (good looking)	02.3 25 5	1.00	102.20	0∠ 25.2	∠.U9 1.97	129.00
27. Felt that you look different	30.5 27 1	1.01	04.20 71.00	20.0	1.0/	47.31 60.21
52. Felt that you were not good looking	37.1 41.0	1.7Z 1.04	71.23	32.9 16 9	1.00	00.21
other people's feelings ^c	41.9	1.04	77.09	40.0	2.20	100.70
other people's reelings						
17 Missed school for any resson because of	22.2	266	95 (F	24.2	0.1	71 00
17. Wissed school for any reason because of	32.2	∠.00	03.63	34.2	∠.1	/1.82
22 Had difficulty paying attention in school	29	1.62	16 98	15.2	2	30.4
22. The uniculty paying allention in school	<u>_</u>)	1.04	TU.90	10.4	4	50.4

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Table 2. Continued

	Canada (1	n = 50)		NY/NJ (n	= 128)	
Item	% Endorse ^a	M Relevance	Impact	% Endorse ¹	M Relevance	Impact
26. Did not want to speak/read out loud in class	21	2.11	44.31	10.1	1.57	15.86
37. Not wanted to go to school	22.6	1.77	40.00	12.7	2.5	31.75
Health/treatment expectations						
60. I have healthy teeth	96.8	2.56	247.81	95	2.58	245.1
63. When I am older, I believe (think) that I will have good teeth	93.6	2.4	224.64	98.7	2.59	255.63
68. When I am older, I believe (think) that I will have good health	93.6	2.63	246.17	97.5	2.78	271.05
64. I am happy with my smile	96.8	2.22	214.89	92.4	2.47	228.23
65. I will feel better about myself when my dental treatment is completed	82.3	2.5	205.75	97.5	2.56	249.6
66. I am nervous (anxious) about the treatment that I need for my teeth, mouth, or face	93.6	1.95	182.52	73.4	2.33	171.02

^aIndicates percentage of subjects with frequency ratings from 'all the time' to 'sometimes'.

^bDenotes item deleted solely due to item impact.

^cItem deleted from the general COHIP questionnaire.

Phase 6: factor analyses

Factor analysis was performed as a last step in questionnaire development. The rationale for such analyses was to ascertain the underlying structure of the domains that had been theoretically constructed. Additionally, we examined correlations and factor loadings for the clinical samples to create the most parsimonious questionnaire by removing redundancy. Table 3 presents the factor loadings for a five-factor unconstrained solution using promax rotation performed with Mplus (24).

The factor loadings are the correlation coefficients between the variables and factors. The loadings are analogous to Pearson's correlation coefficient r and the squared factor loading is the percent of variance in that variable (item) explained by the factor (domain). Factor loadings greater than or equal to 0.30 are considered the minimal level that can be of interest (explaining approximately 10% of the item/variables total variance accounted for by the domain/factor). Loadings of 0.40 are considered more important (explaining approximately 16% of the variance) (25). We chose the 0.40 threshold as determining that an item loaded sufficiently on a subscale and thus loadings equal to or greater than 0.40 are highlighted. The eigenvalues, sum of the squared loadings for a given factor represents the amount of variance accounted for by a factor (domain), are presented in Table 3. Once the empirical structure of the scale was examined, final decisions regarding the composition of the subscales were made. The factor analysis was conducted using data from 26 items. Health expectancies and treatment expectations (four items) were excluded due to the nature of the cross-sectional study and Oral health symptoms (10 items) were excluded *a priori* as too heterogeneous and likely to influence the loadings of other items).

Sample

A total of 419 children made up the convenience sample used for the factor analysis. It was composed of children seeking pediatric dental, orthodontic, or craniofacial care at university-based dental clinics and a hospital center in New Jersey, New York, Montreal. For the whole sample the ethnic distribution included 44% White, 21% Black, 25% Latino, 5% Asian, and 5% other. 50.5% of the children were female. The average age was 11.8 (SD = 1.5). The characteristics were similar for the respective sites with the exception of ethnicity: NY included 37% White, 22% Black, 33% Latino, 4% Asian, and 4% other; NJ included 36% White, 34% Black, 28% Latino, 0% Asian, and 2% other; Montreal included 69% White, 11% Black, 1% Latino, 11% Asian, and 8% other.

Results of the factor analyses

The results of the exploratory factor analysis (EFA) were generally consistent with the expected underlying structure of the COHIP. The functional wellbeing items loaded on various factors. As expected, the functional well-being items did not evenly load due to the heterogeneity of the items in that

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Table 3.	

	Factor loading	gs ^a for item on fiv	e domains		
Questionnaire item	Self-esteem	Psycho-social	School	Speak	Self-image
Functional well-being Had trouble biting off or chewing foods such as apple, carrot or firm meat	0.114	-0.008	0.408	0.113	0.072
Had difficulty eating foods he/she would like to because of his/her teeth, mouth, or face Been able to keen his/her teeth clean ^b	0.244	-0.141 0.019	0.486 0.012	0.195 0.041	0.078 0.119
Had trouble sleeping because of his/her teeth, mouth, or face	-0.108	0.067	0.571	-0.106	-0.008
Had difficulty saying certain words because of his/her teeth, mouth or face	-0.151	0.175	0.202	0.468	-0.083
Been able to eat food he/she wants to eat because of his/her teeth, mouth, or face Had people have difficulty understanding what he/she was saying.	0.411 0.148	-0.052 -0.015	0.069 0.022	0.016 0.79	0.113 0.006
Had difficulty keeping his/her teeth clean Psychological well-heing	0.372	-0.045	0.329	0.101	-0.046
Been unhappy or sad	0.15	0.73	0.099	-0.162	-0.024
Felt worried or anxious because of his/her teeth, mouth, or face	0.057	0.581	0.267	-0.064	0.035
Avoided smiling or laughing with other children because of his/her teeth, mouth or face Falt that ha/she was not coord looking because of his/her teeth, mouth or face ^b	-0.041	0.579 0.66	0.017	0.06 -0.082	-0.222 -0.138
Felt that he/she looks different because of his/her mouth teeth, or face	-0.009	0.586	0.077	0.082	-0.081
Been worried about what other people think about his/her teeth, mouth, or face He/she is harry with his/her smile ^b	0.066 0.118	0.752 0.184	-0.086 -0.033	-0.018	-0.038 -0.816
Social well-being					
Felt shy or withdrawn because of his/her teeth, mouth, or face Been teased. bullied or called names by other children because of his/her teeth. mouth or face	0.371 - 0.089	0.695 0.714	-0.106 0.002	0.13 - 0.003	0.171 0.025
Been upset or uncomfortable with being asked questions about his/her teeth, mouth, or face	0.022	0.67	0.041	0.052	0.079
School				1	
Missed school for any reason because of his/her teeth, mouth or face Had difficulty naving attention in school because of his/her teeth, mouth, or face	-0.036 -0.051	-0.065 0.309	0.526	-0.05 -0.066	-0.062 0.06
Not wanted to speak/read out loud in class because of his/her teeth, mouth or face	-0.046	0.275	0.402	0.068	-0.09
Not wanted to go to school because of his/her teeth, mouth, or face	0.019	0.468	0.333	-0.167	0.103
Seir-image Been confident because of his/her teeth, mouth, or face	0.400	0.097	-0.144	-0.061	-0.084
Felt that he/she was attractive (good looking) because of his/her teeth, mouth, or face	0.482	-0.043	0.049	-0.096	-0.175
He/she has good teeth	0.587	0.092	-0.052	0.064	-0.225
He/she feels good about him/nerseif	0.213	0.177	U.104	0.003	-0.409
Eigenvalues	8.354	2.367	1.810	1.289	1.160
^a Data presented (except eigenvalues in last row) are factor loadings. Eigenvalues presented were con of variance accounted for by a factor (domain). ^b Denotes deleted item.	nputed using th	e sample correlatio	on matrix ar	ıd represent	the amount

Development of the COHIP

domain. The psychological and social items (Psycho-social factor) loaded strongly (>0.50 – range: 0.58–0.75) together with the exception of item 42 'is happy with his smile'. The items on the school subscale (School factor) loaded together with the exception of item 36 'Not wanted to go to school' which loaded both on the School and Social or Psychological subscales. Finally the items on the self-esteem subscale (Self-esteem factor) loaded together with the exception of item 43 'feels good about self'.

The final decisions regarding the composition and structure of the COHIP were based on examination of the EFA, the correlations between items, and the discriminatory power of individual items in the clinical groups. Thus four additional items were dropped prior to the reliability and validity phase presented in the next paper. The dropped items were: Item 32 (PSY) Felt that you were not good looking because of your teeth, mouth or face; item 42 (PSY) I am happy with my smile; Lastly items 17 (FWB) Been able to keep your teeth clean and Item 29 (FWB) Been able to eat food you want to eat because of your teeth, mouth or face were deleted because they did not perform logically and were thought to have multiple interpretations. Furthermore, due to the consistent loading of the social and psychological questions on the same factor, the decision was made to combine these two subscales. The health expectancies questions (items 40 and 41) were also combined with the self-image subscale and treatment expectancies were retained for epidemiological studies only. Thus, the final questionnaire consisted of 34 items: 10 oral health items, 22 items from the factor analysis, and two health expectancy items. The two treatment expectations items were not included as they apply only to clinical trials.

Readability

The Flesch-Kinkaid method (22) produced a score of 3.5, indicating that the COHIP is suitable for children in grades 3 and higher. Responses regarding format and font were elicited from the participants. The use of pictures and shading every other item were indicated to decrease test-taker fatigue and improve the accuracy of recording the participant response to the items.

Discussion

The findings revealed that a multi-staged and iterative approach in questionnaire development

was essential. These findings were consistent with other measures that describe questionnaire construction (8, 16, 26). Using both qualitative and quantitative processes were relevant in selecting, rephrasing, and deleting items based on the grounded theory employed. The results from pretesting items indicated that clarity, relevance, and redundancy were pertinent, and required much attention in particular when attempting to use questions across diagnostic groups and backgrounds. Additionally, using qualitative information from the study sample enabled us to ascertain the full range of experiences and feelings despite investigators' skills in health services research and clinical treatment of the target population. It was noteworthy that impact scores among the positive items emphasized the importance of such concepts for the target clinical groups in this study. Further, the item impact scores may underestimate the socio-emotional and school-related questions given the exclusion criteria (e.g. omission of children enrolled in special classes and those with reading problems).

Nuances associated with language and readability must be taken into account when working with varying ethnicities and individuals from diverse backgrounds and oral health conditions. Recently, issues associated with health literacy and the comprehension and effective communication of dental health information and surveys have been underscored (27). The factor analysis provided information supporting our underlying model across patient groups and further testing using confirmatory factor analyses may be important. Validity testing of the COHIP follows in the next reports.

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