Validation of a French language questionnaire to measure Oral Health Related Quality of Life in young children

©Shanshan Li

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ABSTRACT

Aim: To investigate the cross cultural validity of a French language version of a questionnaire that measures Oral Health related Quality of Life in young children.
Method: Data were collected from community-based and hospital dental clinic-based samples of parent-child dyads. Cross cultural validity was assessed through: i) internal consistency; ii) test-retest reliability; iii) convergent validity; iv) discriminative validity; v) cross cultural comparison and vi) responsiveness to change. Results: Indicators of internal consistency and test-retest reliability were very good. Indicators for convergent validity were good. The instrument could discriminate between the population and clinic based samples. The cross cultural comparison suggested differences between English and French speaking groups. The responsiveness evaluation was non-conclusive.
Conclusions: These results suggest this French language questionnaire has good reliability and validity, although responsiveness remains to be demonstrated.

ABRÉGÉ

Objectif: Étudier la validité inter culturel d'un questionnaire en version française mesurant la qualité de vie des enfants en lien avec leur santé buccodentaire. **Méthodologie**: Les données ont été recueillies auprès d'échantillons composés de dyades parent-enfant provenant de CLSC et d'une clinique dentaire d'un centre hospitalier. L'évaluation de la validité inter culturel s'est effectuée à partir : i) du coefficient de cohérence interne; ii) de la fiabilité test - re test; iii) de la validité concourante; iv) de la validité discriminative; v) de la comparaison inter culturelle and vi) de la sensibilité au changement. **Résultats**: Les indicateurs du coefficient de cohérence interne ainsi que de la fiabilité test - re test étaient très bien, tandis que ceux de la validité concourante étaient bien. Le questionnaire arrivait à différencier les personnes provenant de la population vs ceux provenant de la clinique dentaire. La comparaison inter culturelle semble indiquer des différences entre les groupes francophones et anglophones. L'évaluation de la sensibilité du questionnaire n'a pas été concluante. **Conclusions :** Selon les résultats, le questionnaire en version française démontre une bonne validité et faisabilité. La sensibilité reste par contre à être établie.

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CHAPTER 1 Introduction

This thesis is about validation of a French language questionnaire to measure Oral Health Related Quality of Life in young children. Children under 5 years of age can have many oral health problems, such as early childhood caries (ECC), which is defined as the occurrence of any sign of dental caries on any tooth surface during the first three years of life. Research shows that dental caries affects 18% of children aged 2-4, 52% of children aged 6-8, and 80% of adolescents younger than 17 in the United States¹⁻⁸. This disease has the highest prevalence of all chronic diseases among US children. ⁹⁻¹⁴A recent survey of a representative sample of 5-8 year old children in Quebec showed the mean caries experience of 5-year-olds to be 1.77 dmft (Index of decay, missing, filling and treatment of teeth), with 41.8% having experienced dentinal caries in permanent teeth¹⁶. Children who have ECC are more likely to have repeat episodes later in childhood compared to those who do not have ECC¹⁷⁻¹⁹. Although caries rates have dropped in the developed world over the past 30 years, this disease still remains one of the most common childhood diseases¹⁷⁻¹⁹.

Oral diseases can have adverse effects on body weight and height^{6,7,11-14,16,17,19-22}, affect a child's mental health, social health and well being, and also affect the functioning of the whole family²³⁻²⁸. Health related Quality of life (HRQoL) is used more and more widely as a health outcome measure. Defined as a multidimensional concept¹⁷, it focuses on subjectively perceived physical, psychological and social functions, as well as a sense of subjective well being rather than the traditional disease and diagnosis oriented "biomedical model". ^{11,29-31} Oral health related quality of life of measures (OHRQoL) is a subset of HRQOL, which is also a "patient based health outcome measure".

OHRQOL instruments were originally developed for the adult and geriatric populations²⁹⁻³². Recently, more and more researchers have realized the importance of addressing oral health outcomes in child populations. The impact of oral health on the social and psychological well being of children and the daily functioning of children and their families has not been thoroughly investigated^{1,32-34}. Developing instruments for children at different age groups is very complex and there are only a few instruments that measure OHRQoL in children. There are Child Perceptions questionnaires for children in age groups 6 to 7, 8 to10, and 11 to 14 years.(CPQ 6-7, CPQ8-10, CPQ11-14) and a parental caregivers perceptions questionnaire for parents of these children (age 6 to 14years) (PCPQ 6-14)^{28,35-45}.However, for children aged 0-5 years, an English language instrument to assess oral health-related quality of life has only recently been developed in the United States and subsequently been translated into French³⁸.

The goal of this study was to validate the French language version of this questionnaire, examining its cross cultural adaptation and its responsiveness to change, so that it could be used as a tool in future epidemiological studies among French speaking populations. This study may help investigators to understand OHRQoL in child populations younger than 5 years old, and subsequently help health policy making, promote oral health strategies, and improve oral health care. It may also benefit future studies in large multicenter, multicountry trials, as well as help to assess the oral health status of different cultural groups within a country.

CHAPTER 2 Literature Review

2.1 Introduction

To illustrate the need for cross cultural validation of a questionnaire that measures Oral Health related Quality of life in children younger than 5 years old, this thesis will describe the epidemiology and financial burden of oral health problems in children younger than 5 years old, clinical and patient based indicators that can measure oral health problems in these children, the theoretical background of the validation procedure and the implications of this study.

2.2 Oral health problems in young children

2.2.1 Oral health problems in the child population

Birth to age 5 is a dynamic and important period for a child's growth and development. Young children can develop many craniofacial growth and oral health problems, such as dental caries, traumatic injuries to the teeth, and anomalies of tooth formation and eruption, among which caries and traumatic injury to the teeth are the most common oral diseases in the child population. Acute problems such as pain, infection and bleeding are also prevalent. Early Childhood caries (ECC) is referred to as "extensive carious attack in infants and young children, which seems to be associated with regular exposure to sugar, often from fluid in a bottle"^{18,20}. 2.2.2 Epidemiology of oral health problems in children younger than 5 years old Most oral diseases in children are preventable. Yet oral health problems are highly prevalent around the world and unequally distributed among regions. In South East Asia, there is a high prevalence of dental caries in primary dentition. In Africa, dental caries prevalence appears to be increasing. In most developed countries, such as northern Europe, North America, Australia and New Zealand, dental caries are decreasing^{2,3,6-} ^{8,17,22,34,46,47}. This is due to the use of fluorides and oral health education and promotion programs²². In southern European countries, dental caries prevalence is still high in young children. Most caries in primary teeth are not treated^{4,9,11,14,19,21,48}.

Besides dental caries, trauma and injuries to the teeth are also very common in the child population. Among 5 year old children, 31-40% of boys and 16-30% of girls have some traumatic injuries. Traumatic incidence in the primary dentition of boys is almost twice as high as in girls. By the age of 12, 12-33% of boys and 4-19% of girls have experienced some dental trauma. Subluxation and luxation are the most common problems in primary dentition, and uncomplicated crown fractures are the most common injuries in the maxillary central incisors^{4,9,11,14,19,21,48}.

In addition to dental caries and traumatic injuries, malocclusion is also very common in young children in many countries^{2,3,6-8,17,22,34,46,47}. Research indicates that there is an increase in malocclusion or at least an increase in the demand for orthodontic treatment^{2,3,6-8,17,22,34,46,47}.

The preceding studies suggest that oral health problems are very common in young children and that there is an urgent need to find a better way to measure oral health problems in order to obtain more information about their impact on young children.

2.2.3 Financial burden of oral health problems in children younger than 5 years old

Although ECC is a preventable disease, it continues to place a large financial burden on society. In the USA, it has been estimated that the cost of restoring teeth affected by ECC per year is US\$1000 per child with an additional US\$3000-5000 for general anesthesia when required^{8,34,46}. In Canada, those costs have been estimated at \$700-1200 per child for dental treatment, plus \$200-1500 for sedation or general anesthesia per year^{8,34,46}.

2.2.4 Impacts of oral health problems on the development and daily life of children younger than 5 years old

Between birth and 5 years of age, children experience great development in primary teeth, oral function, general health, motor ability, cognitive ability, perceptual ability, language skills and social interaction. It is important for young children to have a full complement of healthy primary teeth. Dental problems such as cleft palate, disturbances in calcification, unusual numbers of teeth, oral habits, caries, and the development of malocclusions usually start during these years^{18,49,50}. If not treated, problems in primary teeth may lead to more dental problems in later life.

Research demonstrates that caries in primary teeth is correlated with caries in permanent teeth. Children with ECC are more likely to have caries when they are growing up, while children who do not have ECC in their early lives are less likely to have caries later in life^{18,49,50}.

2.2.5 Impacts of oral health problems in children younger than 5 years old on their parents and family function.

Children's dental health conditions have an enormous effect on their parents' feelings and distress. Children younger than 5 years old are unable to express their feelings through language and are dependent on their parents. Parents must also take time off from work to take the child to see the dentist and pay the bill. Children's dental problems can have a large financial impact on a family, which consequently affects the whole family's quality of life. Therefore, Oral Health related Quality of Life (OHRQoL) for young children should also include parent's distress and family function.

Over the years, very little research has investigated the impact of oral health problems on a young children's family, which is a very different but important aspect⁴⁴. Dental problems in children younger than 5 years old can affect parents emotionally and financially⁴⁵. Parents play a very important role in their children's dental health and health care. They are involved in carrying out preventive dental care, seeking professional dental services, and employing other methods to improve oral health for their young children. According to the WHO "a behavioral intervention for parents designed to improve parental efficacy and to develop key skills should lead to child behaviors that will prevent caries from an early age"⁵¹. Talekar's group measured parental perceptions of their preschool-aged children's oral health³⁸. They found that parents' perceptions of their children's oral health are strongly associated with actual disease status and perceived need.

Parents' distress and family function in relation to the overall impacts of ECC are important aspects of Oral Health related Quality of Life for young children. Therefore, it is important to explore parents' perceptions about their children's oral health^{38,50}.

2.3 Methods to measure oral health problems in children younger than 5 years old

There are two main components to assess the outcome of oral disease: clinical indicators and patient based indicators. Clinicians rely on a variety of clinical indicators, such as *deft* index, *defs* index, and *Sic* index. These primarily measure the clinician's perspective of the end-point of the disease process. Oral Health related Quality of Life is a sub part of Health related Quality of Life, which is a patient-based assessment of outcomes. OHRQoL can help us to gain more information on the impact of oral disorders on children and their families^{25,26,28,36,39,52,53}.

2.4 Clinical indicators of oral health problems in children younger than 5 years old

2.4.1 deft index

Designed for the primary dentition, the *deft* index is defined as follows: ²⁸

- *d* for decayed teeth
- e for teeth indicated for extraction
- f for filled teeth
- t for teeth

2.4.2 defs index

The *defs* index is defined as follows: *d* for decayed teeth surfaces *e* for extracted teeth surfaces *f* for filled primary teeth surfaces *s* for teeth surfaces

The *deft* index and *defs* index are ways to express the prevalence of dental caries. Compared to the *deft* index, the *defs* index is calculated based on per tooth surface. Therefore, the *defs* index is more sensitive, detailed and accurate.

2.4.3 Other indices

Other useful indices include the following:

- (1) The dmf index for use in children before the age of exfoliation
- (2) The dmf index applied only to the primary molar teeth
- (3) The df index.
- (4) Significant Caries Index (SiC Index)

The *deft* index cannot accurately reflect caries prevalence for a population, because the distribution of caries prevalence is skewed. The SiC Index is a way of expressing caries distribution in a population.

The Significant Caries Index is calculated as follows: "

1) Individuals in the population (sample) are sorted according to their DMFT values

2) One third of the population with the highest caries scores is selected

3) The mean DMFT for this subgroup is calculated. This value is the SiC Index."^{34,46}

2.5 Patient based indicators

2.5.1 HRQoL definition

Health has been defined by the World Health Organization (WHO) as "a state of complete physical, mental and social well-being and not only the absence of disease and infirmity"¹⁰. Allison defined quality of life as "a multidimensional concept that is a function of a number of variables such as stress, depression, cognitive appraisal, and coping"³¹. Health related Quality of life is concerned with people's subjective perception of their own physical, mental and social function. An individual's perceptions can be measured by using valid standardized, self-administered questionnaires^{29,31,51,54-59}.

2.5.2 HRQoL instruments for child population

In the field of HRQoL, SF-36 and WHOQOL are the most famous instruments. The SF-36 questionnaire was developed by the International Quality of life Assessment (IQOLA) ⁵⁹and the international HRQoL instrument (WHOQOL) was developed by the World Health Organization^{51,59}. For child populations, there are many HRQoL instruments, such as the Child Health Questionnaire (CHQ) and the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) among others. CHQ was developed using the same methodology as the SF-36, but specifically tailored for child populations^{35,40,60,61}. The Child Health Questionnaire (CHQ-PF50) is for school age children of about 4 or 5 years and older. The CHQ-CF87 is for adolescents. The CAOB was developed to study active quality of life, passive quality of life, distress and severity of disease in children with asthma. The Pediatric Asthma Quality of Life Questionnaire (PAQLQ) was also used to measure children's quality of life with asthma^{35,40,60,61}.

2.5.3 OHRQoL definition

Like the HRQoL, oral health related quality of life focuses on the effects of oral health problems on a person's ability to function, such as oral health states, psychological states, social interaction, and self image^{23,32,33,62-69}. Locker was the first to build a conceptual framework for measuring oral health^{63,65,66}. Since then oral-health-related quality of life (OHRQoL) has become an important health outcome measure and has been used more and more widely. Clinical indicators combined with OHRQoL can provide researchers with a comprehensive understanding of oral diseases. Similar to the HRQoL instruments, OHRQoL can be measured by a valid, standardized, self-administered questionnaire.

2.5.4 OHRQoL instruments for general population

Since Locker first published a conceptual framework for measuring oral health, many OHRQoL instruments have been developed for adult populations^{63,70-72}. The most sophisticated and commonly used instrument for measuring OHRQoL is the Oral Health Impact Profile (OHIP) ^{36,73-77}. The OHIP questionnaires are based upon a multidimensional model of oral health, comprising three theoretical divisions: Impairment, Disability, and Handicap. Each of these questionnaires has long and short forms, and the OHIP has been translated into many different languages⁷⁸⁻⁸¹.

Authors	Name of Measure
Cushing et al, 1986	Social Impacts of Dental Disease
Atchison and Dolan, 1990	Geriatric Oral Health Assessment Index
Strauss and Hunt, 1993	Dental Impact Profile
Slade and Spencer, 1994	Oral Health Impact Profile
Locker and Miller, 1994	Subjective Oral Health Status Indicators
Leao and Sheiham, 1996	Dental Impact on Daily Living
Adulyanon and Sheiham, 1997	Oral Impacts on Daily Performances
McGrath and Bedi, 2000	OH-Qol UK

Table 1 Examples of currently available oral specific health status measures

2.5.5 OHRQoL instruments for the child population

Conceptually, OHRQoL can be used for the entire age range. Because oral diseases are highly age-dependent, many differences have been found between children and adults. Tapsoba et al (2005) also pointed out that more differences may exist between younger and older adults⁸².

For children younger than 5 years, developmental characteristics are closely associated with a specific age group. Among different age groups, children's self-concepts and health cognitions are different, their emotional and behavioral characteristics are different, and language and communication skills are different^{34,46}. Different concepts and methods thus need to be employed for measuring OHRQoL in different age groups, and specific instruments need to be developed for children at each specific age. For

example, children younger than 5 are often unable to express themselves adequately through language, and are highly dependent on their parents. A questionnaire for this age group needs to be filled out by the child's parents. Children from 6-12 years can answer simple questions with a direct verbal response. For children older than 12 years, simple questionnaires can be filled out by the subjects themselves^{1,27,30}.

2.5.6 Existing OHRQoL instruments for a child population younger than 5 years old Presently there are a few instruments that can measure OHRQoL in child populations, because of the complexity of developing instruments for children of different age groups. There are Child Perceptions questionnaires for children in age groups 6 to 7, 8 to 10, and 11 to 14 years,(CPQ 6-7, CPQ8-10, CPQ11-14), a parental caregivers perceptions questionnaire for parents of these children (age 6 to 14years) (PCPQ 6-14), and the CHILD-OHIP to evaluate the oral health related quality of life index for children^{41,43-45,83}.However, for children aged 0-5 years, an English language instrument to assess oral health-related quality of life has only recently been developed by researchers at the University of North Carolina at Chapel Hill. It is the first questionnaire that can measure Oral health related Quality of life in children younger than 5 years. This questionnaire is a self administrated questionnaire filled out by the child's parents. The questionnaire has been translated into French and Portuguese.

2.5.7 Translation into French

A recent survey of a representative sample of 5-8 year old children in Quebec showed that the mean caries experience for 5-year-olds is 1.77 dmft, with 41.8% having experienced dentinal caries¹⁵. A future study should examine Oral health related Quality

of Life in children younger than 5 in Quebec, Canada, to investigate whether there is a difference between OHRQoL in French and English speaking populations in this area. The questionnaire was translated into French because most people in Quebec speak French as their first language.

2.5.8 The need to validate this French version questionnaire

Health related Quality of Life and Oral Health related Quality of Life are subjective phenomena. The development of instruments to measure Oral Health related Quality of Life must be based on a specific conceptual approach. To conduct research in a different population, either the existing instrument can be translated into the target language, or a new instrument can be developed for the target population. It is more efficient to translate the existing instrument. However, the newly developed instrument may not be the conceptual equivalent to the English one. To measure Oral Health related Quality of Life in children younger than 5 years old in Quebec, the questionnaire cannot be simply translated into French, since there are many linguistic and cultural differences between English and French. For example, there are many words in English which do not exist in French and vice versa^{37,84,85}. As well, the perception of QOL and oral health problems and their expressions are very different from culture to culture. The English speaking population and French speaking population in Quebec have different cultures and lifestyles, therefore the questionnaire needs to be translated into French and needs a systematic cross-cultural validation to ensure the validity and conceptual equivalence of this measurement.

As with other instruments, the OHRQOL is not free of error³⁷. There are two types of error that affect a measure: random error and systematic error. To provide a precise and accurate measure of the Oral Health related Quality of Life of young children in Quebec, Canada, steps were taken to ensure adequate psychometric properties of the French language version questionnaire. Two basic properties, which are reliability and validity, needed to be evaluated³⁷. There are many different types of reliability and validity. Different outcome variables, different types of questionnaires, and different study designs require the assessment of different psychometric properties. The following is an outline of psychometric properties of an instrument that applied to this study³⁷.

- Reliability
 - Internal Reliability : Internal Consistency
 - External Reliability : Test-retest reliability

• Validity

- ✤ Face validity
- Content Validity : logical, domain
- Construct Validity : Convergent validity

Discriminative validity

- Cross cultural comparison
- Responsiveness

2.6 Theory background about validation

2.6.1 Reliability

Reliability is the ratio of the variance attributable to true differences among subjects to the total variance³⁷. (Total variance = the variance due to true differences + the variance due to random errors of measurement. Errors are assumed to be independent of the measurements themselves^{37,42,86-88}.)

Reliability coefficient (γ):

 $\gamma = \frac{\text{Variance (true)}}{\text{Variance(total)}} = \frac{1 - \text{Variance(error)}}{\text{Variance(total)}} = \frac{\text{Variance(total)} - \text{Variance(error)}}{\text{Variance(total)}}$

Reliability = <u>Subject variability</u> Subject variability + Measurement error

The Reliability coefficient (γ) refers to what ratio of total variance of a measured variable is attributed to "True" variance. Usually, if the reliability coefficient is "0", then the questionnaire has no reproducibility. If the reliability coefficient is "1", the questionnaire has perfect reproducibility and no measurement error^{37,42,86-88}. The following will explain in detail about Internal Consistency and Test-retest reliability.

Internal consistency

A questionnaire consists of different items. The items in the same scale should have good internal consistency, which means the items in the same scale should measure the same concept or the same dimension of a construct, and the items should be correlated with each other³⁷. Cronbach's alpha is the preferred method to assess internal consistency. Cronbach's α (alpha) is an extension method of KR-20.

$$\alpha = \underline{n}_{n-1} \left(1 - \underline{\Sigma \, \delta_i^2}_{\delta_T^2} \right)$$

In the preceding equation, n is the number of items, δ_i^2 is the variance of the *i*th item and is the variance of the total score calculated by summing up all the items. Cronbach's α has a direct interpretation. Usually α should be above 0.70, but not higher than 0.90. If α = 1.0 or too high, it means that some items are asking the same question, and they are redundant. There are many possible explanations for a low Cronbach's α . There may be some items that are in the different scales or variance in the sample may be too high³⁷.

Test-retest Reliability refers to the ability of a questionnaire to reproduce measures. If you give a test to a person or a group of people more than once, they should get about the same score each time, assuming their situation did not change during this time period³⁷. Test-retest reliability is defined as the ratio of the score variance that is attributable to the true differences between subjects, assuming that subjects' oral health status did not change over time"³⁷. It is difficult to determine the amount of time required between the two tests. The time period should be long enough that participants cannot remember what they answered the first time they completed the questionnaire but short enough that their oral health situation has not changed. The time period often ranges from two weeks to a couple months^{31,37,76,89-92}.

2.6.2 Validity

Validity refers to whether the instrument adequately measures the characteristic being studied³⁷. Validation is a process of hypotheses testing and proving that the instrument

measures what it is supposed to measure. There are 3 types of validity applicable to our study: face validity, content validity and construct validity³⁷.

Face validity refers to whether the questionnaire appears to be assessing the desired $concept^{37}$.

Content validity involves checking the comprehensibility of the questionnaire, the response format, whether the scale has covered enough material and whether it appears to be assessing the desired quality³⁷. Face validity and content validity are determined during the data collection phase.

Construct validity is the most abstract and complex type of validity³⁷. It relates to the theory of the measurement, and the variability of interest. If a questionnaire measures a specific construct or concept, then this questionnaire was built based on the theoretical model, and construct validity needs to be examined. "Construct" is something that is more "psychological" or "conceptual". It cannot be observed or measured directly. Therefore, a 'mini-theory' is built to explain the relationships among various behaviors or attitudes³⁷. For example, in this study, the construct is the perception of Oral Health related Quality of Life. In this theoretical model, Oral Health related Quality of Life has two dimensions: Child Impact Section and Family Impact Section. In each section, there are various behaviors and attitudes that can provide information about OHRQoL of young children. Construct validity is a process of hypotheses testing. For this study, it can be further distinguished according to convergent validity and discriminate validity.

Convergent validity is concerned with "how closely the new scale is related to other variables and other measures of the same construct to which it should be related"³⁷. If there is another measure that assesses the same or related construct of your instrument, and you compare your instrument to the other measure, there should be a certain level of correlation, or the relation should result in the expected direction. The correlation may be positive or negative³⁷.

Discriminative validity is also called extreme groups. If, in two groups of people, one group has a higher level of the given construct than the other group, then it follows that if the instrument is given to both groups, there should be a difference between the groups³⁷. A powerful way to examine convergent and discriminate validity at the same time is the multitrait-multimethod matrix, or MTMM^{24,28,31,37,37,41-43,45,82,92}.

2.6.3 Cross cultural comparison

Summary of Herdman and colleagues' (1998) definitions for six types of equivalence Bowden and his colleagues conducted a systematic review of the process of translation and adaptation of health related quality of life measures spanning countries and continents, including Africa, Asia, Eastern Europe, the Middle East and South America⁹³. A model has been generated to examine equivalence between source and target language versions of HRQoL instruments. This model defined six types of equivalence, which also apply to Oral Health related Quality of Life measure^{93,94}.

Table 2 Summary of the Herdman et al. (1998) definitions for each type of equivalence^{93,94}

Equivalence	Definition
Conceptual	Achieved when the questionnaire has the same relationship to the
	underlying concept in both cultures, primarily in terms of the domains
	included and the emphasis placed on different domains.
Item	"Item equivalence exists when items estimate the same parameters on
	the latent trait being measured and when they are equally relevant and
	acceptable in both cultures" (P.325)
Semantic	The transfer of meaning across languages, achieving a "similar effect"
	on respondents who speak different languages.
Operational	"The possibility of using a similar questionnaire format, instructions,
	mode of administration and measurement methods" (P.329)
Measurement	The psychometric properties of the adapted version of the HRQoL
	measures are equivalent.
Functional	" The extent to which an instrument does what it is supposed to do
	equally well in two or more cultures" (P.331). This is demonstrated by
	being able to state how the "underlying trait" is defined or
	conceptualized, how well the instrument design reflects that underlying
	trait, and how the results compare across cultures. This is assessed by
	examining the degree to which the other five types of equivalence
	summarized above have been achieved.

Guidelines to preserve equivalence in cross-cultural adaptation of HRQOL measures

Guillemin and his colleagues proposed set of guidelines to translate the questionnaire

and to ensure the semantic, idiomatic, experiential, and conceptual equivalence of scale

items^{5,37,75,77,84,85,93-95,95-103}.

Table 3 Guillemin *et al.* Guidelines for cross culture validation⁹⁵:

1. Translation Produce several translations Use qualified translators

2. Back-translation Produce as many back-translations as translations Use appropriate back-translators

3. Committee review Constitute committee to compare source and final versions Membership of the committee should be multidisciplinary Use structured techniques to resolve discrepancies Modify instructions or format, modify/reject inappropriate items, generate new items Ensure that the translation is fully comprehensible Verify cross-cultural equivalence of source and final versions

4. Pre-testing Check for equivalence in source and final versions using a pre-test technique Either use a probe technique Or submit the source and final versions to bilingual lay people Immigrants: choose the language of administration or use a dual-format measure

5. Weighting of scores Consider adapting the weights of scores to the cultural context.

Examine cross cultural validity after translation

Emil Berkanovic *et al.* pointed out that different perceptions, values and attitudes toward health measures, and the circumstances under which the questionnaire has been filled out will result in different responses⁹⁹. Schim Kutlay and colleagues examined cross cultural validity of the Turkish version of the Rheumatoid Arthritis Quality of Life Scale through analyses of differential item functioning (DIF) between the original and adapted versions. The modern psychometric approach to this would be an examination of DIF by culture or the fit of a Rasch model⁹⁷. Nilsson *et al.* also used the Rasch model to examine cross cultural validity. Segu *et al.* studied the psychometric properties of Oral Health Impact Profile for temporomandibular disorders^{75,84,93-95,98-101}. By factorial structure analysis of the questionnaire, the cross-cultural consistency between the two versions of the OHIP was ensured. Allison and his colleagues conducted a Cross-cultural study of the OHIP to compare item weights generated by a sample of English- speaking Canadians and French-speaking Canadians. They used Thurstone's paired-comparison technique to generate weights, based on the judgments of convenience samples of subjects drawn from each of the three cultural settings⁹⁶.

Cross cultural adaptation VS. Cross cultural comparison

Guillemin *et al.* indicated that cross cultural adaptation is clearly different from crosscultural comparison: the two processes are based on totally different research hypotheses⁹⁵. To measure a similar phenomena or perception in different cultures you need to make cross cultural adaptations to produce an equivalent instrument. To compare or identify differences in a phenomena or perceptions between different cultures, it's necessary to engage in cross cultural comparison. Cross-cultural adaptation of an instrument is a prerequisite. Once the measurement tool has been deemed equivalent in both cultures, cross cultural comparison can be done to investigate cross cultural differences^{104,105}."

2.6.4 Responsiveness

Definition of Responsiveness

The psychometric properties mentioned above are properties that are measured at a specific point in time, which is cross-sectional. Besides reliability, validity and cross cultural validity, another important property of the questionnaire is responsiveness, or longitudinal validity. Responsiveness refers to the instrument's ability to measure change over time and to detect minimally important clinical changes. Responsiveness of a measure to change is a complex definition^{37,68,73,74,106-110}. Liang *et al.* distinguished between the terms "sensitivity to change" and "responsiveness"^{104,105}. "Sensitivity" refers to the usefulness of the instrument designed to measure any change over time, even though the change may not be clinically meaningful or relevant. "Responsiveness" is defined as "the ability of an instrument to measure a meaningful or important change in a clinical state"; such a change must be clinically meaningful¹¹¹⁻¹¹⁶. Currently not all HRQoL and OHRQoL measures have been examined for their responsiveness.

Potential determinants of Responsiveness

Researchers have summarized some potential determinants of sensitivity or responsiveness of HRQoL, which are also applicable to the detection of OHRQoL change¹¹⁷⁻¹²¹.
Table 4 Some Potential Determinants of Sensitivity or Responsiveness

Questionnaires and their administration
Wording of questions or responses
Scaling
Timing of administration
Single change question vs. computation with 2 questions
Respondent does or does not see prior responses
Statistical or methodological issues
Missing data
Statistical tests to detect responsiveness
Sample size to detect responsiveness
Patient/responder issues
Responder: Patient, healthy norm, caregiver, health care provider
Gender
Socioeconomic status
Severity of illness
Duration of illness
Health beliefs/expectations
Setting
Investigator: gender, usual provider or not
Informed consent
Payment to participate
Clinical trial vs. observational study
Intervention/natural history change
Has no real effect on HRQOL
No change in natural history

Minimal Clinically Important Difference

Jaeschke *et al.* defined Minimal Clinically Important Difference (MCID) as "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management¹¹¹."

Effect size

Effect size is a way to quantify the magnitude of the change. It represents change in a group or a difference in change between two groups¹²²⁻¹²⁴. Effect size is a standardized,

unit-less measure. Cohen (1977) described an effect size of 0.20 as small, 0.50 as moderate and 0.80 as large.

Methods to assess Responsiveness

To assess the responsiveness of an instrument, a longitudinal study design is required. Locker *et al.* describe four methods to measure change in oral health outcomes 75,109 . 1) Compare the distribution or means of health status variables before and after intervention; 2) compare raw change in scores, which is calculated by subtracting post intervention scores from pre intervention scores; 3) global transition judgment and; 4) global transition scales". They also suggested that the relative responsiveness of different health status measures can be assessed by effect sizes, by comparing the amount of change after interventions. Three methods for assessing responsiveness have been suggested in the field of HRQoL research^{104,105,117-121}. : 1) to examine scale score changes "before" and "after" an intervention of known efficacy (Liang et al^{104,105}.); 2) To assess an instrument's responsiveness by correlating between score changes in functional scale with score changes in physiologic measure (Meenan et al^{116} .) and; 3) to calculate the sensitivity and specificity of scales, which means developing ROC curves for each scale (Devo et al^{100,107,113,115}.). The area under the ROC curve is "the probability of correctly identifying the improved patient from randomly selected pairs of improved and unimproved patients", which indicates improvement or deterioration^{37,68,73,74,106-111}

Summary & Study Rationale

Although preventable, most oral diseases are still very common among children younger than 5 years old, potentially affecting child growth, mental health, social health and well being, and the functioning of the whole family. With the expansion of interest in quality of life outcomes, recent research has focused on oral health-related quality of life in children. Currently there are valid questionnaires available for children aged 6 to 7, 8 to10, and 11 to 14 years. In addition, parental/caregiver questionnaires for parents of these children (age 6 to 14 years) are available. However, for children aged 0-5 years, an instrument to assess oral health-related quality of life has only recently been developed in English. This study translated the questionnaire into French for use in future studies. Several psychometric properties need to be examined to ensure the conceptual equivalence of the French language questionnaire before it can be used in studies in Quebec. Thus, it was important to assess reliability, validity, cross cultural comparison and responsiveness.

Aim

The aim of our study is to evaluate the cross cultural validity of this French language version of an English OHRQoL questionnaire so that it can be used in the future as a tool to measure oral health outcomes in children younger than 5 years old in a French speaking population.

Research Question and Hypotheses

Hypothesis I: Face validity Hypothesis II: Content validity Hypothesis III: Internal consistency Hypothesis IV: Test-retest reliability Hypothesis V: Convergent validity Hypothesis VI: Discriminative validity Hypothesis VII: Cross cultural comparison Hypothesis VIII: Responsiveness

The principal research question to be addressed is "Is the translated French language questionnaire equivalent to the English questionnaire?" This question will be addressed through various hypotheses:

Hypothesis I: On the face of it, the instrument should appear to be assessing the desired qualities. This is to examine face validity of the questionnaire.

Hypothesis II: The instrument should sample all the relevant or important contents or domains about Oral Health related Quality of Life for children younger than 5 years old. This is to examine content validity of the questionnaire. Hypothesis I & II are part of the translation process. The original English language scale had good face and content validity. Our translation process was designed to maintain these properties. The subsequent hypotheses are to test the validity of the translated questionnaire.

Hypothesis III: The question responses from the same domain should be strongly associated with each other. This is to examine internal consistency of the questionnaire.

Hypothesis IV: If you give a test to a person more than once, assuming his oral health situation does not change, he should get about the same score each time. This is to examine test-retest reliability of the questionnaire.

Hypothesis V: Compared to parents who reported their children have more oral health problems, parents who reported that their children have less oral health problems should report "Good" more frequently in the question "Overall, how do you rate your children's oral health?". This is to examine convergent validity of the questionnaire.

Hypothesis VI: The instrument should be able to discriminate between children in the community with no expressed need for dental care and those in a dental clinic with an expressed need for dental care. This is to examine discriminate validity of the questionnaire.

Hypothesis VII: For subjects recruited in the same settings, there should be a good degree of consensus of responses between the French speaking population and the

English speaking population. This is to examine cross-cultural equivalency of the questionnaire.

Hypothesis VIII: In testing the responsiveness to change of the instrument, in a sample of children undergoing dental treatment, reports of improvement, no change or deterioration in oral health should be associated with appropriate scores change in the instrument. This is to examine responsiveness to change of the questionnaire.

Study Design, Methodology and Statistical Approach

6.1. Questionnaire

Originally developed by researchers at the University of North Carolina at Chapel Hill, the questionnaire was translated into French by researchers at McGill University. It consists of 13 questions and has two main parts: part one is the child impact section and the other is the family impact section. In the child impact section, there are four domains: child symptom, child function, child psychology, self-image and social interaction. The questionnaire begins with problems with oral health and how these problems affect the well-being and everyday lives of children and their families. A box is provided for participants to choose the responses that best describe the child or the parents' own experiences. If a question does not apply, participants are asked to choose "Never". In the child symptom domain, they are asked "Has your child had pain in the teeth, mouth or jaws?" According to the questionnaire as shown in Appendix, Questions 2-5 related to child function domain, Questions 6 and 7 are in the child psychology domain, Questions 8 and 9 refer to the self-image and social interaction domain. In the family impact section, there are two domains: parental distress and family function. Questions 10-12 relate to the parental distress domain and question 13 refers to the family function domain.

Table 5 OHRQoL Questionnaire for children younger than 5 years old

Problems with the teeth, mouth or jaws and their treatment can affect the well-being and everyday lives of children and their families. For each of the following questions please mark the box for the response that best describes your child's experiences or your own. Consider the child's whole life from birth until now when answering each question. If a question does not apply, mark "Never".

		Never	Hardly ever	Occasionally	Often	Very often	Don't know
1	Has your child had pain in the teeth, mouth or jaws?	Π ,			Π,	□₅	Π,
	Because of dental problems or dental treatments has your child ever						-
2	Had difficulty drinking hot or cold beverages?	Π,			Ω,	□₅	
3	Had difficulty eating some foods?						Ū,
4	Had difficulty pronouncing any words?	D ,		□₃		□.	
5	Missed preschool or daycare?					□₅	
6	Had trouble sleeping?					□₅	
7	Been irritable or frustrated?						D,
8	Avoided smiling or laughing when around other children?			□3		□₅	
9	Avoided talking with other children?						Π,
	Because of your child's dental problems or dental treatments have you or another family member ever			-			
10	Been upset?					□,	
11	Felt guilty?					□.	
12	Taken time off from work?						
13	Has your child ever had dental problems or dental treatments that had a financial impact on your family ?					D₅	

The questionnaire is scored using a simple Likert frequency type of scale, ranging from 1-5. We generated "1" score to "Never", "2" to "Hardly ever", "3" to "Occasionally", "4" to "Often", "5" to "Very often". Consequently, a higher score indicates that the problem is impacting on a specific aspect of life more severely, whereas a lower score indicates that the problem is not causing much trouble at all in a specific domain. Score "6" was given to "Don't know". Additive score were generated for different domains and sections, which is represented by ADD scores. ADD total score is an overall additive score of the whole scale by adding up the response score for the 13 questionnaire items.

The questionnaire was translated into French using forward and backward translation. In a pilot study, 10 participants, chosen from the target population, completed the French version of the questionnaire. Qualitative methods were used to get feedback about the questionnaire's comprehensibility, content and response format. Minor revisions were made to ensure face validity and content validity of this questionnaire. Thus, Hypotheses I& II were tested during the pilot study. The following will describe in detail the study design, methodology and the statistical approach addressing each psychometric property. All data analyses have been done using SAS program (SAS7.0).

6.2. Study design, methodology and statistical approach address hypothesis III (internal consistency of the questionnaire)

Data used in this work were collected from a prospective, cohort study of 412 parents who had a 6 month old child recruited to a randomized controlled trial (RCT) of an early childhood caries prevention program. Caregivers with a child of 6 months, and who were attending the vaccination clinics of the study 11 Centres Locales des Services Communitaires (CLSCs) and had lived with that child for 50% or more of the time were asked to participate. They were excluded if they were unable to understand the consent form and self-complete questionnaires for linguistic reasons. Questionnaire data were collected only from the experimental group in the RCT. All participants were asked to complete the French language versions of the "Dental-related quality of life questionnaire" when their child was 12, 18 and 24 months old. Socio demographic data concerning the children and their parents were also collected. Missing data and "Don't know" responses were imputed by the median based on the distribution of each item.

Internal consistency is estimated by a statistic known as Cronbach's alpha and by examining correlations between the child and family impact sections of the questionnaire. The 13 items should all measure the same construct, which is oral health related quality of life and should thus be correlated with each other. Cross sectional data analyses were performed in the 12, 18 and 24 month old groups. Acceptable levels of Cronbach's alpha are between $0.8-1.0^{125,125,126,126}$.

6.3. Study design, methodology and statistical approach address hypothesis IV (Test-retest reliability of the questionnaire)

Two weeks after initial administration of questionnaire to 412 participants who had a 12 month old child, a subgroup of 100 participants were chosen to complete the same OHRQoL questionnaire a second time and these data were used to examine test-retest reliability. The time interval between the first and second completions of the questionnaire was two weeks, because this is a time period during which the oral health

status should not change, and they are not able to remember their answers from the first questionnaire completion.

With the exception of the OHRQoL questionnaire, there are two more questions. Participants were asked whether their child's oral health condition has changed from the time of completion of the baseline questionnaire to the second one. If they answer "Yes", they will be asked the kind of problems the child experienced. The responses are "teething", "toothache", "filling", "other types of treatment" and "others".

Intraclass Correlation Coefficient (model 3) is the preferred method of test-retest reliability in our study. The intraclass correlation coefficient is defined as the ratio of the variance in subject score to the total variance in score. The variance in subject score is the variance attributable to characteristics of the subjects. Total variance in score includes variance attributable both to between subject differences and to differences within subjects over multiple repetitions of the test. Therefore the intraclass correlation coefficient can measure not only the concordance of the two datasets, but also can tell us the extent of repetition of the test, this questionnaire can give us the same results in the same individuals if their situation did not change.

ICC model 3 uses a repeated measures analysis of variance design. In this model, the tested raters are considered the only raters of interest, which are 412 subjects in our study. Shrout and Fleiss suggest that model 3 is good for testing intrarater reliability. ANOVA analysis was used to calculate ICC for the 12 months dataset. ICC was calculated according to the following formula:

ICC
$$(3,\kappa) = \underline{BMS - EMS}$$
.
BMS

BMS = between-subjects mean square from the output of variance analysis EMS = within-groups, error mean square from the output of variance analysis κ = the number of ratings for each subject

ICC ranges between 0.00 and 1.00, 0 representing no agreement at all, 1.00 representing perfect reliability. ICC greater than 0.75 indicates good reliability. ICC below 0.75 indicates poor to moderate reliability.

6.4. Study design, methodology and statistical approach address hypothesis V (Convergent validity of the questionnaire)

In order to examine convergent validity, an extra question, "Overall, how would you rate your children's oral health status?" was added at the end of questionnaire. The responses are: "very good" "good" "fair" "poor" "very poor". A Likert scale was generated with "1" score given to "very good", "2" to "good", "3" to "fair", "4" to "poor" and "5" to "very poor". Convergent validity is a process of hypothesis testing. Convergent validity was evaluated based on correlations between questionnaire scores and subjective health measure and the result of the dental examinations. A parent who reported impacts "occasionally or more often" on the questionnaire would rate the dental health of his or her child fair or poor and the child would have clinically determined dental caries that were not treated. Because the trial is ongoing, there are no clinical data about children's dental caries. In this thesis, relationships between questionnaire scores with the rating of child's dental health were examined. The underlying hypothesis is that parents who rate their child's dental health as "good" should have a lower questionnaire score, which means good oral health related quality of life, compared to those who rate their child's dental health "poor". In future, correlations between OHRQoL scores with clinically determined dental caries will be examined to further test convergent validity of this questionnaire.

6.5 Study design, methodology and statistical approach address hypothesis VI (Discriminate validity of the questionnaire)

The OHRQoL questionnaire should be able to discriminate between children in the community with no immediate need for dental care and those in a dental clinic with an expressed need for dental care. Therefore, participants chosen from the community should have a lower score than participants chosen from a dental clinic, which means children with no expressed need for dental care, have a higher level of oral health related quality of life. Data were collected when the children from the community based population were 12, 18 and 24 months old. Because oral health problems in young children are highly age dependent, therefore, we built a multiple linear regression model: ADD total score = $\alpha + \beta$ *Clinic + γ *Age + δ *Language + ϵ * Gender The variable "clinic" is a binary variable, with "0" representing the population based sample and "1" representing the clinic based sample. We examined the variable "clinic" in the multiple linear regressions, both to see if the variable "clinic" variable is significant when adjusted for "age", "gender", and "language spoken". If β is significant,

then there is a significant difference of OHRQoL between the population and clinic based samples.

6.6. Study design, methodology and statistical approach address hypothesis VII (Cross cultural comparison)

In 87% of the participating CLSCs, the vast majority of subjects have French as their first language and in the remaining CLSCs, there is a mixture of English and French spoken. This program was available in both languages. If participants preferred to answer in English, they were given an English version of the questionnaire.

The translation process followed guidelines to ensure the conceptual equivalence of the questionnaire. First, two translators who were native speakers of French forward translated the original US English questionnaire into French. Translators may have experience in questionnaire translation but were not necessarily familiar with this OHRQoL questionnaire. Each translator produced one French language version of this questionnaire. Conceptual equivalence was emphasized rather than literal equivalence. The backward-translation was given to two translators who were native English speakers, and they translated the questionnaire back into English. The backward-translation should be conceptually equivalent with the original American version. Following the forward and backward translation, a pilot study was conducted in the target population, and minor modifications were made upon qualitative feedback to make sure the questionnaire was easily to complete and understood correctly.

In the 12, 18 and 24month old group, we compared the question responses within the same age group between the English speaking population and that of the French speaking population. We also examined internal consistency between the English speaking and French speaking population in these three age groups. Because most participants answer "Never", the distribution of responses is not normal. Therefore, the Wilcoxon two sample test was used to compare total score and sub scores for each subscale between the English and French speaking population. Chi square was used to compare responses for each question of the French and English population. Internal consistency was examined by Cronbach's alpha. We also compared Cronbach's alpha of US study data with those from our study. For the 12 month group, we also built a multi variables model to compare OHRQoL in different language spoken populations controlled for sociodemgraphic variables, such as income, education, gender etc.

6.7. Study design, methodology and statistical approach address hypothesis VIII (responsiveness to change of the questionnaire)

The responsiveness to change of this French version questionnaire was assessed by comparing scores before and after treatment in a clinic based sample. This sample was sought because of the need to demonstrate the instrument's ability to detect changes. The sample sought comprised of children seeking treatment for a dental problem. The assumption is: Following treatment, the problems would have been diminished. This study was geared toward pedodontic cases, and so all of our subjects for the responsiveness test were 5 years old or less, both boys and girls, and of many different ethnic backgrounds. The subjects and their parents or legal guardians were approached

while attending the Montreal Children's Hospital Dental Clinic for treatment of a "dental problem". "Dental problem" was defined in various ways, including any condition requiring a filling, pulpotomy or pulpectomy, tooth extraction, or pharmacological intervention. These patients were identified by the administrative staff of the clinic, and their accompanying parent or guardian was approached prior to treatment. They were asked to fill out some personal contact information, and then to fill out the 13 items OHRQoL questionnaire. After the initial interview the patient underwent treatment, and after a period of 2-4 weeks, the same questionnaire was sent by mail to the home of the patient, where the parent or guardian was able to fill it out at their leisure. However, included in this mailing was an additional sheet of paper which asked the parent to globally asses whether their child's condition had improved, stayed the same, or deteriorated since their treatment 2-4 weeks ago.

Change scores for the scale and subscales were calculated by subtracting post-treatment scores from pretreatment scores. Consequently, negative change scores indicate an improvement in OHRQoL, while positive scores indicate deterioration. Because the distribution of responses were not normal, Wilcoxon Signed rank sum test and Kruskal-Wallis test were used to examine the significance of the within-subject change of those who changed and those who reported stability. The Kruskal-Wallis test is a nonparametric method of one way analysis of variance. It was used to examine the association between score change and the global transition judgments collected post treatment. Changed scores should be in the same direction as dental health assessment. This study was based on a small sample size with only 68 subjects. More subjects need to be recruited in this study.

Results

7.1. Descriptive analyses

7.1.1 Descriptive analysis of 12 months old group

Table 6 shows the descriptive statistical analysis for the socioeconomic information of a 12 months sample. Table 7 indicates that gender distribution was almost equal in the 12, 18 and 24 month old groups. Table 8 describes the distribution of responses to the OHRQoL questionnaire in the 12 month old group. About 11% of responses were missing one or more questions on the 13-item questionnaire. The "Don't know" and missing responses can be found in the methodology section of this manuscript.

In the 12 month old group, the items related to "pain" (46.31%), "sleeping" (25.32%) and "frustrated" (36.83%) were reported most frequently on the child impact section of the questionnaire. The distribution of responses to each question was skewed because most participants responded "never" (Table 8).

Variable	Categories	N	%
level of education - child's mother ^a	Did not graduate from high school	34	8.6
	Graduated from high school	107	26.9
	College/Cegep	143	36.0
	University	113	28.5
relationship of caregiver to child	Biological mother	391	98.2
	biological father	7	1.8
child's age at recruitment	4 months	80	20.1
	5 months	102	25.6
	6 months	145	36.4
	7 months	71	17.8
recruitment method	vaccination clinic	197	49.5
	Organised appointment	99	24.9
	Other	102	25.6
child's family yearly income	less than \$14.000	23	5.8
	\$15,000 - \$29,000	61	15.3
	\$30,000 - \$49,000	123	30.9
	\$50,000 or more	171	42.9
	I don't know	20	5.0
older brothers or sisters	Yes	209	52.5
	No	189	47.5
Siblings have had fillings ^b	Yes	57	27.5
	No	150	72.5
Siblings have had tooth extracted ^c	Yes	9	4.5
	No	190	95.5
Last time mother saw dentist ^d	less than 12 months ago	244	61.5
	Between 1 and 2 years ago	94	23.8
	2 -5 years ago	41	10.3
	more than 5 years ago	18	4.5
lives in area with fluoridated water supply	Yes	28	7.1
	No	369	92.9
Child's Weight	Mean weight (Kg)	7.7 ±	1.0

 Table 6-Descriptive analysis for socioeconomic information of the 12 month sample

 (Total N=398)

^a Missing N=1 ^b Missing N=191 ^c Missing N=199 ^d Missing N=1

Variable	Categories	12 months 18 months		24 months			
		N	%	N	%	N	%
Gender	Boy	192	48.2	174	46.9	185	47.56
	Girl	206	51.8	197	53.1	204	52.44

Table 7-Gender distribution of 12, 18 and 24 month group

Table 8-Distribution of responses to the OHRQoL questionnaire in the 12 months old group^e_____

Impacts	Never	Hardly ever	occasionally	Often	Very often
Pain	187 (49.1)	18 (4.7)	92 (24.2)	59 (15.5)	25 (6.6)
Drinking	366 (94.1)	15 (3.9)	6 (1.5)	1 (0.3)	1 (0.3)
Eating	333 (84.3)	21 (5.3)	32 (8.1)	6 (1.5)	3 (0.8)
Pronouncing	372 (96.6)	9 (2.3)	2 (0.5)	0	2 (0.5)
Absence School	382 (98.5)	3 (0.8)	3 (0.8)	0	0
Sleeping	260 (66.5)	32 (8.2)	72 (18.4)	16 (4.1)	11 (2.8)
Frustrated	201 (51.4)	46 (11.8)	106 (27.1)	24 (6.1)	14 (3.6)
Smiling	367 (93.6)	17 (4.3)	8 (2.0)	0	0
Talking	384 (98.0)	6 (1.5)	2 (0.5)	0	0
Upset	340 (86.7)	22 (5.6)	25 (6.4)	4 (1.0)	1 (0.3)
Guilty	378 (95.9)	10 (2.5)	6 (1.5)	0	0
Work	382 (97.5)	4 (1.0)	6 (1.5)	0	0
Financial	391 (99.2)	2 (0.5)	0	1 (0.3)	0

^e Total number=398 about 11% of parents responded "Don't know" to one or more questions on the 13item questionnaire.

Impacts	No of items	ADD range	ADD Mean	ADD Sd
Child symptoms	1	1-5	2.2	1.4
Child function	4	4-20	4.5	1.2
Child psychology	2	2-10	3.6	2.0
Self image and social interaction	2	2-10	2.1	0.5
Parental distress	2	2-10	2.3	0.8
Family function	2	2-10	2.1	0.4
Total	13	13-65	16.7	4.5

Table 9-Descriptive analysis of additive scores for each domain in the 12 month old group

Additive score (ADD score) for each domain was calculated.

7.1.2 Descriptive analysis of the 18 month old group

Table 10 The distribution of responses to the OHRQoL questionnaire in the 18 month

old group.

Impacts	Never	hardly ever	Occasionally	Often	Very often
Pain	204 (56.7)	26 (7.2)	77 (21.4)	37 (10.3)	16 (4.4)
Drinking	344 (94.8)	13 (3.6)	5 (1.4)	1 (0.3)	0
Eating	314 (86.0)	13 (3.6)	23 (6.3)	13 (3.6)	2 (0.6)
Pronouncing	349 (97.2)	7 (1.9)	2 (0.6)	1 (0.3)	0
Absence School	349 (96.9)	3 (0.8)	6 (1.7)	2 (0.6)	0
Sleeping	269 (74.1)	32 (8.8)	43 (11.9)	16 (4.4)	3 (0.8)
Frustrated	241 (66.6)	28 (7.7)	61 (16.9)	29 (8.0)	3 (0.8)
Smiling	343 (94.8)	14 (3.9)	5 (1.4)	0	0
Talking	346 (96.1)	13 (3.6)	1 (0.3)	0	0
Upset	330 (90.2)	13 (3.6)	18 (4.9)	3 (0.8)	2 (0.6)
Guilty	349 (95.6)	11 (3.0)	2 (0.6)	1 (0.3)	2 (0.6)
Work	352 (96.7)	5 (1.4)	3 (0.8)	1 (0.3)	3 (0.8)
Financial	357 (98.4)	2 (0.6)	3 (0.8)	0	1 (0.3)

Table 10-The distribution of responses to the OHRQoL questionnaire in the 18 month old group^f

The distribution of responses to each question was highly skewed because most participants responded "never" (Table 10). In the 18 month old group, items related to "pain" (36.1%), "sleeping" (17.1%), "frustrated" (25.7%) and "had difficulty eating" (10.4%) were reported most frequently on the child impact section of the questionnaire. In the family impact section, "feeling upset" (6.3%) was reported most frequently.

^f Total number=371 about 9.7% of parents responded "Don't know" to one or more questions on the 13item questionnaire.

Impacts	No of	ADD	ADD Mean	ADD Sd
Child symptoms	1	1-5	2.0	1.3
Child function	4	4-20	4.5	1.2
Child psychology	2	2-10	3.2	1.8
Self image and social interaction	2	2-10	2.1	0.5
Parental distress	2	2-10	2.3	0.9
Family function	2	2-10	2.1	0.6
Total	13	13-65	16.0	4.7

Table 11-Descriptive analysis of additive scores for each domain for the 18 month old group

7.1.3 Descriptive analysis of the 24 month old group

Table 12 describes the distribution of responses to the OHRQoL questionnaire in the 24 month old group. The distribution of responses to each question was highly skewed because most participants responded "never" (Table 12). In the 24 month old group, the items related to "pain" (13.7%), "sleeping" (7.5%) and "frustrated" (11.4%) were reported most frequently on the child impact section of the questionnaire. In the family impact section, the question about "feeling upset" (2.8%) was reported most frequently. The Additive score (ADD score) for each domain was calculated.

Impacts	Never	Hardly ever	Occasionally	Often	Very often
Pain	310 (81.6)	18 (4.7)	31 (8.2)	19 (5.0)	2 (0.5)
Drinking	379 (97.4)	6 (1.5)	3 (0.8)	1 (0.3)	0
Eating	366 (94.1)	7 (1.8)	12 (3.1)	3 (0.8)	1 (0.3)
Pronouncing	372 (96.9)	5 (1.3)	5 (1.3)	1 (0.3)	1 (0.3)
Absence School	386 (99.7)	1 (0.3)	0	0	0
Sleeping	346 (89.6)	11 (2.9)	20 (5.2)	8 (2.1)	1 (0.3)
Frustrated	331 (85.8)	11 (2.9)	29 (7.5)	11 (2.9)	4 (1.1)
Smiling	377 (97.2)	7 (1.8)	2 (0.5)	1 (0.3)	1 (0.3)
Talking	383 (98.7)	4 (1.0)	1 (0.3)	0	0
Upset	368 (94.6)	8 (2.1)	8 (2.1)	2 (0.5)	1 (0.3)
Guilty	385 (99.2)	2 (0.5)	0	1 (0.3)	0
Work	383 (99.0)	3 (0.8)	1 (0.3)	0	0
Financial	382 (99.2)	2 (0.5)	1 (0.3)	0	0

Table 12-Distribution of responses to the OHRQoL questionnaire in 24 month old group^g

Table 13-Descriptive analysis of additive scores for each domain for 24 month old group

Impacts	No of	ADD	ADD	ADD
	items	Range	Mean_	Sd
Child symptoms	1	1-5	1.4	0.9
Child function	4	4-20	4.2	0.8
Child psychology	2	2-10	2.5	1.4
Self image and social interaction	2	2-10	2.1	0.4
Parental distress	2	2-10	2.1	0.5
Family function	2	2-10	2.0	0.2
Total	13	13-65	14.3	3.1

^g Total number= 389. About 5.4% of parents responded "Don't know" to one or more questions on the 13item questionnaire.



Mean score of 9 items in child impact section in 12, 18, 24 months groups



Mean score of 4 items in family impact section in 12, 18, 24 months groups





Bars show Means

7.2 Reliability

7.2.1 Internal Consistency

Table 14-Cronbach's alpha for each section and the whole scale of 12, 18 and 24 month groups

	12 months old	18 months old	24 months old
Child Impact sections	0.73	0.79	0.77
Family Impact sections	0.51	0.79	0.54
Whole Scale	0.77	0.82	0.78

Cronbach's alpha for internal consistency of items on the child and family impacts sections were 0.73 and 0.51 for the 12 month group, 0.79 and 0.79 for the 18 month group and 0.77 and 0.54 for the 24 month group respectively. Cronbach' alpha for the whole scale for different age groups were 0.77, 0.82 and 0.78 respectively. Cronbach's alpha greater than 0.7 indicates good internal consistency. For the 12 month and 24 month age group, there was a reduced internal consistency in the family impact section. The correlation between child and family impact sections for three age groups were all statistically significant. This indicated that the scale has strong links with the latent variable.

month old groups			
	12 months old	18 months old	24 months old
The correlation between	Pearson $\gamma = 0.54$	Pearson $\gamma = 0.49$	Pearson $\gamma = 0.45$
the child and family	P<0.0001	P<0.0001	P<0.0001
impact sections			

Table 15-Pearson correlation between child and family impact section for 12, 18 and 24 month old groups

Item scale correlations are the correlation of the individual item with the scale total omitting that item in order to check the homogeneity of the scale. Item scale correlations should be roughly equal for all items in a given scale. Table 16 shows that in this questionnaire, item scale correlation is 0.21-0.71, 0.20-0.73, and 0.11-0.78 for different age groups, supports the contention that this questionnaire has good internal consistency.

	12	12 months old 18 months		nths old	d 24 months old	
	γ	P value	γ	P value	γ	P value
Pain	0.57	<0.0001	0.64	<0.0001	0.67	<0.0001
Drinking	0.34	<0.0001	0.47	<0.0001	0.24	<0.0001
Eating	0.54	<0.0001	0.66	<0.0001	0.54	<0.0001
Pronouncing	0.31	<0.0001	0.20	0.0001	0.28	<0.0001
Absence	0.21	<0.0001	0.34	<0.0001	0.18	0.0004
Sleeping	0.68	<0.0001	0.67	<0.0001	0.71	<0.0001
Frustrated	0.71	<0.0001	0.73	<0.0001	0.78	<0.0001
Smiling	0.38	<0.0001	0.42	<0.0001	0.44	<0.0001
Talking	0.22	<0.0001	0.43	<0.0001	0.29	<0.0001
Upset	0.52	<0.0001	0.66	<0.0001	0.52	<0.0001
Guilty	0.38	<0.0001	0.45	<0.0001	0.30	<0.0001
Work	0.32	<0.0001	0.45	<0.0001	0.32	<0.0001
Finance	0.25	<0.0001	0.25	<0.0001	0.11	0.03

Table 16-Item scale correlations for 12, 18 and 24 month old groups

7.2.2 Test retest reliability

The Intraclass correlation coefficient was 0.95 for test-retest reliability. This questionnaire has good test-retest reliability. In the retest questionnaire, participants were asked whether their health status had changed since the last time they completed the questionnaire. If the answer was positive, a question about "what was the treatment received?" was asked. 52% of participants in the 12 month retest group (53 participants) reported that their oral health status had changed. Among them, 42 (84%) participants reported because of "teething". Other reasons were "fillings" (4 participants), "broken tooth" (2 participants), "toothache" (1 participant) and "other types of treatment" (1 participant). There were 49 (48%) participants reporting no change. Records for 25 participants were missing.

	Initial test	Retest
	Mean ± Std Dev	Mean ± Std Dev
Pain	2.2 ± 1.36	2.10 ± 1.21
Drinking	1.08 ± 0.39	1.10 ± 0.41
Eating	1.28 ± 0.74	1.24 ± 0.68
Pronouncing	1.05 ± 0.34	1.05 ± 0.26
Absence School	1.02 ± 0.19	1.07 ± 0.43
Sleeping	1.67 ± 1.07	1.65 ± 0.94
Frustrated	1.96 ± 1.16	1.82 ± 1.04
Smiling	1.08 ± 0.34	1.13 ± 0.59
Talking	1.02 ± 0.18	1.08 ± 0.37
Upset	1.22 ± 0.62	1.34 ± 0.69
Guilty	1.05 ± 0.28	1.04 ± 0.25
Work	1.04 ± 0.26	1.05 ± 0.36
Financial	1.01 ± 0.16	1.00 ± 0.09
Whole scale	16.73 ± 4.52	16.55 ± 4.37

Table17-Mean Score and Std Dev of 13 items in Initial test and Retest of OHRQoL of children in 12 month old group

	Initial test	Retest	Test-retest reliability
	Mean ± Std Dev	Mean ± Std Dev	ICC
Child impact section	12.41 ± 3.94	12.11 ± 3.68	0.93
Child symptoms	2.2 ± 1.36	2.10 ± 1.21	0.63
Child function	4.45 ±1.17	4.39 ± 1.03	0.54
Child psychology	3.64 ± 2.01	3.49 ± 1.86	0.78
Self image and social interaction	2.11 ±0.47	2.16 ± 0.64	0.26
Family impact section	4.32 ± 0.96	4.46 ± 0.91	0.51
Parental distress	2.28 ± 0.77	2.39 ± 0.80	0.42
Family function	2.05 ± 0.36	2.07 ± 0.40	0.13
Whole scale	16.73 ± 4.53	16.55 ± 4.37	0.95

Table18-Test retest reliability of OHRQoL questionnaire

Intraclass correlation coefficient (model 3) =0.95

Intraclass correlation coefficient (model 3) was 0.95 for the whole scale, 0.93 for the child impact section and 0.51 for the family impact section. For different domains, ICC ranged from 0.13-0.78. Overall, ICC was good and this questionnaire has good test-retest reliability.

7.3 Validity

7.3.1 Convergent validity

Table 19-Distribution of responses to the global rating of the Oral Health question in the
12, 18 and 24 month groups

	Very poor	Poor	Acceptable	Good	Very good	Don't know	N
12 months	1 (0.3)	0	8 (2.1)	90 (23.4)	285 (74.2)	14	398
18 months	1 (0.3)	0	8 (2.2)	88 (24.2)	266 (73.3)	8	371
24 months	2 (0.5)	1 (0.3)	12 (3.1)	81 (21.2)	287 (74.9)	6	389

Due to the skewed distribution of responses to the questionnaire, Spearman's Correlation was used to examine the association of ADD scores for different domains and the global rating of Oral Health.

· · · · · · · · · · · · · · · · · · ·	12 mont	hs	18 months		24 months	
	γ	P ^h	γ	Р	γ	Р
Child symptoms	0.01	0.77	-0.12	0.02	-0.02	0.75
Child function	-0.03	0.58	-0.09	0.10	-0.04	0.43
Child psychology	-0.02	0.77	-0.10	0.06	-0.03	0.54
Self image and social interaction	0.04	0.43	-0.11	0.04	-0.08	0.11
Parental distress	0.01	0.86	-0.20	0.00	-0.05	0.32
Family function	-0.06	0.25	-0.13	0.01	-0.03	0.50
Whole scale	-0.002	0.96	-0.14	0.01	-0.01	0.78

Table 20-Spearman's correlation of ADD score between the OHRQoL score and the global rating of Oral Health in the 12, 18 and 24 month groups

In the 18 and 24 months old group, Spearman's correlation coefficients were all negative, which indicated that there was a negative relationship between ADD scores and the global ratings of oral health. Because correlation coefficients were very low and most parents responded "very good", the "poor", and "very poor" and "fair" responses were combined and "good" and "very good" were combined in order to examine discriminative validity. Mean ADD total scores for three age groups were compared between "poor" and "good". Parents who rated their child as having "very poor" or

^h P value

"poor" oral health, compared with parents who rated "good" "very good", had higher

OHRQoL impact scores suggesting good convergent validity.

<u>good</u> in 12,	good in 12, 18 and 24 month group					
		Poor, Very Poor, Fair	Good	Very Good		
12 months	Frequency	9	90	285		
	Mean \pm std	18.4 ± 6.6	16.6 ± 4.3	16.7 ± 4.4		
18 months	Frequency	9	88	266		
	Mean \pm std	23.8 ± 9.1	16.4 ± 4.6	15.7 ± 4.4		
24 months	Frequency	14	81	287		
	Mean ± std	15.0 ± 4.6	14.3 ± 2.9	14.2 ± 3.1		

Table 21-Mean ADD total score comparison between response "poor", "good", "very good" in 12, 18 and 24 month group

7.3.2 Discriminative validity

Table 22 describes the distribution of responses in the clinic-based sample. Table 12 and Table 13 shows the descriptive analysis for the 24 month old group (page 50), which are the data chosen from general population to compare with those of the clinic-based sample. In the 24 month group, very few of participants answered "very often" (around 0.3-1.1%). In the clinic-based sample, there are around 1.0-5.9% participants answered "very often". For items "Absence School", "Talking" and "Work", in the 24 month group, there is no participant answered "often" or "very often". But in the clinic-based sample, 1% participants answered "often" or "very often" to the question "Absence school", 3.9% to "talking" and 5% to "work". For these two different samples, none of participants answered "often" or "very often" to the "Finance" question. In the 24 month group, 99.2% participants answered "Never". In the clinic-based sample, 82.2% participants answered "Never". To test the discriminative validity of this questionnaire, further analyses were done to compare score between population based and clinic-based sample, adjusting for child's age, language spoken and child's gender.

To perform this comparison while controlling for age, language and gender, a full model with all independent variables was fitted. The corresponding regression equation was:

ADD total score = $\alpha + \beta$ *Clinic + γ *Age + δ *Language + ϵ * Gender

Simple linear regression models were built for each variable in the full model.

Impacts	Never	Hardly ever	Occasionally	Often	Very often
Pain	59 (58.4)	15 (14.9)	11 (10.9)	4 (3.9)	6 (5.9)
Drinking	79 (78.2)	10 (9.9)	5 (5.0)	4 (3.9)	2 (1.9)
Eating	77 (76.2)	5 (4.9)	7 (6.9)	5 (4.9)	4 (3.9)
Pronouncing	80 (79.2)	9 (8.9)	3 (2.9)	5 (4.9)	1 (1.0)
Absence School	81 (80.2)	11 (10.9)	4 (3.9)	1 (1.0)	0
Sleeping	80 (79.2)	9 (8.9)	5 (4.9)	1 (1.0)	3 (2.9)
Frustrated	74 (73.3)	6 (5.9)	11 (10.9)	3 (2.9)	3 (2.9)
Smiling	87 (86.1)	6 (5.9)	5 (4.9)	1 (1.0)	1 (1.0)
Talking	87 (86.1)	7 (6.9)	0	3 (3.9)	0
Upset	71 (70.3)	11 (10.9)	14 (13.9)	2 (1.9)	3 (2.9)
Guilty	71 (70.3)	7 (6.9)	12 (11.9)	5 (4.9)	4 (3.9)
Work	77 (76.2)	6 (5.9)	12 (11.9)	2 (2.0)	3 (3.0)
Financial	83 (82.2)	9 (8.9)	7 (6.9)	0	0

 Table 22-Distribution of responses to the OHRQoL questionnaire in the clinic-based sampleⁱ

Table 23- ADD Mean domain scores for the clinic and population groups

Impacts	No of item	ADD Population Clini Range group (N=6 n <u>(N=398)</u>		Clinic group (N=68)
			Mean± Sd	Mean± Sd
Child symptoms	1	1-5	1.4±0.9	1.6±1.1
Child function	4	4-20	4.2±0.8	5.6±2.3
Child psychology	2	2-10	2.5±1.4	2.8±1.5
Self image and social interaction	2	2-10	2.1±0.4	2.4±1.0
Parental distress	2	2-10	2.1±0.5	3.5±2.1
Family function	2	2-10	2.0±0.2	2.6±1.1
Total	13	13-65	14.3±3.1	

 Table 24-Simple linear regression models for each variable

Variable	Parameter estimate	P value	R^2	
Clinic	3.61	< 0.0001	0.12	
Gender	-0.22	0.55	0.001	
Language	1.50	0.01	0.02	
Age	0.08	< 0.0001	0.07	_

Variable "clinic", which means "Whether the children are from clinic or population based sample", and variable "Age" were the most significant predictors of Oral Health related Quality of life in the simple linear regression models with a highly significant p value of <0.0001 for each of them. These two variables explained 12.21% and 7.29% of the total variance of the dependent variable ADD total score, in simple regression. The R square value of the other two variables was much lower.

The overall F value of 18.43 was highly significant at $\alpha = 0.05$ level with a p value of < 0.0001, which indicates that the model explained a significant portion of the variance of ADD total score. The R square value of 0.15 indicates that 14.61% of the variance of ADD total score was explained by the model. Therefore, the full model was:

ADD total score = 17.61 + 6.97*Clinic - 0.08*Age- 1.53*Language + 0.05* Gender

The variable "clinic" is the most significant variable in the full model with a p value < 0.0001. This indicates that the variable "clinic" is an important predictor of the ADD total score. OHRQoL was different between the population sample and clinic-based sample, when controlled for age, language and gender. This suggests that the questionnaire has good discriminative validity.

Variable	Parameter estimates	P value
Intercept	17.61	<0.0001
Clinic	6.97	<0.0001
Age	- 0.08	0.01
Language	- 1.53	0.01
Gender	0.05	0.88

Table 25-Full variables in the Multiple Linear Regression model

7.4 Cross- cultural comparison

Table 26 shows the distribution of parents' language spoken among 12, 18, and 24 month old groups. Most of them speak French; only 19-25 people speak English in the different age groups. Mean scores were calculated in order to compare between different language spoken groups. (Table 27) Because of the skewed distribution, and unequal sample size in the two languages, Wilcoxon two sample tests were used to compare mean score between the English and French speaking population. (Table 28, 29, 30)

Table 26-Distribution of language spoken in 12, 18 and 24 month group

	12 months	18 months	24 months	
French	373	352	367	
English	25	19	22	

Table 27-Descriptive analysis of total score of English and French speaking population among 12, 18 and 24 month groups

	12 months		18 months		24 months	
	Mean score	Std Dev	Mean score	Std Dev	Mean score	Std Dev
French	16.84	4.45	16.06	4.76	14.32	3.15
English	15.12	_5.43	15.11	4.05	13.5	1.06
	French	English	Wicoxon	P value		
-----------------------------------	----------------	----------------	---------	----------		
	N=373	N=25	two			
	Mean±Std	Mean±Std	sample			
			test			
Child symptoms	2.3 ± 1.4	1.3 ± 1.0	3178.0	0.0005 *		
Child function	4.5 ± 1.2	4.3 ± 1.3	4560.0	0.2		
Child psychology	3.7 ± 2.0	2.8 ± 2.0	3490.0	0.004 *		
Self image and social interaction	2.1 ±0.4	2.2 ± 0.8	5078.0	0.7		
Parental distress	2.3 ± 0.8	2.3 ± 0.8	4917.5	0.8		
Family function	2.0 ± 0.3	2.2 ± 1.0	5054.0	0.7		
Whole scale	16.8 ± 4.5	15.1 ± 5.4	1392.0	0.0009 *		

Table 28-Comparisons of ADD score for each domain of English and French speaking population in the 12 month old group

Table 29-Comparisons of ADD score for each domain of English and French speaking population in the 18 month old group

	French	English	Wicoxon	Р
	N=352	N=19	two	value
	Mean±Std	Mean±Std	sample	
			test	
Child symptoms	1.9 ± 1.3	1.5 ± 1.1	2892.5	0.1
Child function	4.5 ± 1.2	4.5 ± 1.1	3695.0	0.6
Child psychology	3.2 ± 1.8	2.4 ± 1.1	2741.5	0.05 *
Self image and social interaction	2.1 ± 0.5	2.1 ± 0.2	3494.5	0.8
Parental distress	2.3 ± 0.9	2.3 ± 0.8	3554.5	0.9
Family function	2.1 ± 0.6	2.4 ± 1.1	3771.5	0.1
Whole scale	16.1 ± 4.8	15.1 ± 4.1	1322.5	0.02 *
Whole scale	16.1 ± 4.8	15.1 ± 4.1	1322.5	0.02 *

	French	English	Wicoxon	Р
	N=367	N=22	two	value
	Mean \pm Std	Mean \pm Std	sample	
			test	
Child symptoms	1.4 ± 0.9	1.1 ± 0.2	3688.5	0.1
Child function	4.2 ± 0.8	4.1 ± 0.4	4109.5	0.5
~~~~				
Child psychology	$2.5 \pm 1.4$	$2.2 \pm 0.6$	4010.0	0.4
Selfimage and social interaction	$21 \pm 0.4$	$21 \pm 0.4$	1252 5	07
Sen image and social interaction	$2.1 \pm 0.4$	$2.1 \pm 0.4$	4333.3	0.7
Parental distress	$2.1 \pm 0.5$	$2.0 \pm 0$	4081.0	0.3
Family function	$2.0 \pm 0.2$	$2.1 \pm 0.4$	4430.0	0.2
-				
Whole scale	$14.3 \pm 3.2$	$13.5 \pm 1.1$	2938.0	0.5

Table 30-Comparisons of ADD score for each domain of English and French speaking population in the 24 month old group

In the 12 month old group, in child symptoms, child psychology, and the whole scale, there was a significant difference between the French speaking population and English speaking population. In the 18 month old group, the French speaking population and English speaking population had a significant difference in the child psychology, and the whole scale. In the 24 month old group, there was no significant different between the two groups.

A Chi square test was used to examine whether there was a difference between the French and English speaking population in frequency of responses to each question. In the 12 month old group, responses to questions about "pain", "talking" and "rate" were significantly different between the French and English speaking population. In the 18 month group, the French and English speaking populations were significantly different in their responses to the questions "pronounce", "work", "finance" and "rate". In the 24 month group, there was a difference in responses to the question "finance".

	12 months		18 months		24 months	
	Chi- Square	P value	Chi- Square	P value	Chi- Square	P value
Pain	15.1	0.0046 *	4.3	0.4	3.6	0.5
Drinking	1.6	0.8	0.5	0.9	0.6	0.9
Eating	2.2	0.7	2.1	0.7	1.5	0.8
Pronounce	7.2	0.1	16.6	0.0008 *	2.4	0.7
Absence	0.4	0.8	0.6	0.9	0.1	0.8
Sleeping	6.6	0.2	3.4	0.5	2.1	0.7
Frustrated	8.9	0.1	5.1	0.3	1.5	0.8
Smiling	0.5	0.8	1.1	0.6	1.2	0.9
Talking	6.9	0.0316 *	0.2	0.9	2.9	0.2
Upset	0.9	0.9	0.5	0.9	1.2	0.9
Guilty	1.4	0.5	4.2	0.4	0.2	0.9
Work	1.4	0.5	10.3	0.0362 *	0.2	0.9
Finance	15.1	0.0005 *	8.5	0.0362 *	16.8	0.0002 *
Rate	30.0	<0.0001 *	33.1	<0.0001 *	1.9	0.7

Table 31-Comparison of frequency of problems between English and French speaking groups at 12, 18 and 24 months.^j

^j Chi-Square

Internal consistency of the French language questionnaire and English language questionnaire in our study was examined by Cronbach's alpha. Internal consistency was also compared with the original American study.

#### Internal consistency comparison across French and English speaking groups

	American study	12 months		18 months		24 months	
	·	French	English	French	English	French	English
N	274	373	25	352	19	367	22
Child impact section	0.91	0.73	0.82	0.79	0.71	0.77	0.48
Family impact section	0.95	0.42*	0.89	0.80	0.63	0.56	0
Whole scale	0.89	0.76	0.89	0.82	0.81	0.79	0.34

Table 32-Cronbach's alpha of each section and the whole scale for English and French
speaking population in 12, 18 and 24 month group and the American sample

Table 32 shows that in the French language questionnaire, there was a reduced internal consistency in the Family impact section. Cronbach's alpha was 0.73 and 0.76 for the child impact section and the whole scale. Descriptive analysis of each response in Table 33 shows that standardized deviation for the "upset" item was 0.63, while standardized deviation for the "finance" item was 0.073, and most replied to "finance" items as "never". In the family section, the standardized deviation ranged from 0.07 to 0.63, which was a big difference, which made Cronbach's alpha low. If we deleted the item "upset", Cronbach's alpha was 0.35. If we deleted the item "finance", Cronbach's alpha was 0.44.

The correlation between the response to the "upset" question and the total was 0.37, and the "finance" correlation with total was 0.183, which was very low (Table 33). Standardized deviation for the "finance" item was 0.073. Most replied to the "finance" items as "never". In our pilot study, a lot of parents reported that this question was not applicable. This suggests that the "finance" question was not relevant in the Quebec study. This is because in Quebec, Canada, dental care is free for this age group.

Table 33-Descriptive analysis of Cronbach's alpha for the 12 month group Cronbach's Ν Mean  $\pm$  Std Dev Correlation alpha with Total  $1.23\pm0.63$ 0.42 373 0.37 Upset  $1.05 \pm 0.27$ Guilty 0.35 Work  $1.04 \pm 0.25$ 0.32 Finance  $1.01 \pm 0.07$ 0.18

Table 34-Cronbach's alpha for the 12 month group when deleted variable "Upset"					
	Cronbach's	N	Mean ± Std	Correlation	_
	alpha		Dev	with Total	
Guilty	0.35	373	$1.05 \pm 0.27$	0.26	
Work			$1.04 \pm 0.25$	0.22	
Finance			$1.01 \pm 0.07$	0.25	

Table 35-Cronbach's alpha for the 12 month group when deleted variable "Finance"

	Cronbach's	N	Mean ± Std	Correlation
	alpha		Dev	with Total
Upset	0.44	373	$1.23 \pm 0.63$	0.38
Guilty			$1.05 \pm 0.27$	0.33
Work			$1.04 \pm 0.25$	0.31

In the 18 month age group, Cronbach's alpha ranged from 0.63-0.82, which indicates this French language questionnaire had good internal consistency. In the 24 month group, Cronbach's alpha was low in the English language version questionnaire. This was due to the small sample size and the low standardized deviation of the English speaking group in the 24 month group (N=22). Compared to the English speaking population, 367 parents answered the French language questionnaire, and variability was higher. Variance also plays a vital role in Cronbach's Alpha calculation. Without variance there will be no result. Table 36 shows that everybody scored 1.0 in response to the questions

"Drinking", "Eating", "Absence", "Upset", "Guilty" and "Work". Because there was no variance, Cronbach's Alpha, which is based on the covariance matrix, cannot be as such

computed.

Table 30-Descriptive alla	Tysis of 15 hellis	s loi ule 24 mont	n group		_
	French		English		
	N=367		N=22		
	Mean	Std Dev	Mean	Std Dev	•
Pain	1.39	0.89	1.05	0.21	
Drinking	1.04	0.27	1.0	0	
Eating	1.12	0.50	1.0	0	
Pronouncing	1.05	0.35	1.09	0.43	
Absence	1.01	0.05	1.0	0	
Sleeping	1.21	0.66	1.05	0.21	
Frustrated	1.31	0.82	1.14	0.47	
Smiling	1.05	0.32	1.05	0.21	
Talking	1.01	0.14	1.05	0.21	
Upset	1.09	0.44	1.0	0	
Guilty	1.01	0.17	1.0	0	
Work	1.01	0.14	1.0	0	
Finance	1.00	0.07	1.1	0.43	

Table 36-Descriptive analysis of 13 items for the 24 month group

Table 5 /-Combare language spoken and medine of value-0.04	Table 37-Compare	language spoken ar	1d income ^k (	(P value=0.04)
------------------------------------------------------------	------------------	--------------------	--------------------------	----------------

	less than \$14.000	\$15,000 - \$29,000	\$30,000 - \$49,000	\$50,000 or more	I don't know
French	18	54	117	157	16
English	4	7	6	8	0

^k Chi-Square

Table 37 shows that, between English and French speaking populations, there were significant differences in family income. We built simple regressions to examine the association of potential confounding variables with ADD total score, which is OHRQoL.

			2	
variables Param	eter Standard	P value	$\mathbf{R}^2$	
estima	te Error			
Language -1.80	0.91	0.04	0.0097	
Gender -0.91	0.45	0.04	0.0103	
Education -0.39	0.25	0.11	0.0065	
Income* 0.007	0.24	0.97	0.0000	
Siblings -0.22	0.46	0.64	0.0006	
Moth dent -0.41	0.27	0.13	0.006	
Weight -0.15	0.20	0.48	0.0013	
Fluor water -0.006	0.01	0.58	0.0008	

Table 38-Simple regression with Sociodemagraphic variables for cross cultural comparison

Variables "income" did not contribute to the model at all with

 $R^2 = 0.0000$  (Table 37). We built a full model as follows and ran forward and backward

selection. Both selection procedures gave the same results (Table 39).

ADD total= Language + Gender + Child age + Education + Income + Siblings + Moth dent + Weight + Fluor water

Final model:

OHRQoL = 24.26 - 1.88* Language - 1.06* Gender - 0.39* Education - 0.43* Moth dent - 0.27* Weight

Tuble 39 Tillar maniphe regression moder for eross cultural comparison							
variables	Parameter Estimate	Standard Error	F value	P value			
Intercept	24.26	2.3	109.93	< 0.0001			
Language	-1.88	0.9	3.97	0.0470*			
Gender	-1.06	0.5	5.02	0.0256			
Education	-0.39	0.2	2.52	0.1130			
Moth dent	-0.43	0.3	2.50	0.1148			
Weight	-0.27	0.2	1.72	0.1903			

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Table 30_Hinal mi	litinie rearection	model for a	race cultural	comparison
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### 7.5 Responsiveness

The sample size for examining responsiveness of the questionnaire was 101 participants in total. Among the 101 participants, 68 answered the questionnaire post treatment (67.32%) and 33 patients could not be located after treatment (32.68%) (Those patients were excluded). Mean age of the 68 subjects was  $54.65 \pm 13.3$  months, which ranged from 0.25 to 72 months old (Median=58 months). Table 42 shows that 28 (41.18%) subjects reported "no change" after treatment, 35 (51.47%) subjects reported "getting better" after treatment, while 5 (7.35%) subjects reported "getting worse".

Variables	Category	N	%
Relationship	Mother	50	73.5
	Father	17	25.0
	Other	1	1.5
Gender	Boy	41	60.3
	Girl	27	39.7
Language spoken at home	French	16	23.5
	English	29	42.6
	Both	3	4.4
	Other	20	29.4
Language of questionnaire	French	23	33.8
	English	45	66.2
Treatment	Filling	58	86.3
	Root canal therapy/ pulpectomy/pulpotomy	3	4.4
	Tooth extraction	3	4.4
	Other	4	5.9
Whether or not the patient had	Painkiller( Tylenol)	1	1.5
another dental treatment after the one included in the study	Antibiotic (Penicillin V, Amoxicillin, Clindamycin)	1	1.5
•	Filling	10	14.7
	No post treatment	56	82.4
Condition change	No change	28	41.2
	Better	35	51.5
	Worse	5	7.4

Table 40-Sociodemographic information from the responsiveness sample (n=68)

	Before treatment		After trea	ıtment	
	Mean ± Std	Median	Mean ± Std	Median	
Child Symptoms	1.6 ± 1.1	1.0	1.7 ± 1.1	1.0	
Child Function	5.3 ± 2.1	4.0	$5.6 \pm 2.3$	4.0	
Child Psychology	$2.8 \pm 1.7$	2.0	2.8 ± 1.5	2.0	
Self-image and social interaction	$2.4 \pm 1.1$	2.0	$2.4 \pm 1.0$	2.0	
Parental distress	$3.2 \pm 2.0$	2.0	$3.5 \pm 2.1$	2.0	
Family function	$2.5 \pm 1.1$	2.0	2.6 ± 1.1	2.0	
Whole scale	$17.8 \pm 5.9$	16.0	$18.5 \pm 6.9$	15.0	

Table 41-Mean, Std Dev and Median of responses of OHRQoL questionnaire before and after treatment in 68 subjects

Table 41 shows that subjects had a higher score in different domains and sections after treatment. A Wilcoxon Signed rank sum test was used to compare the medians of score differences between pre and post treatment groups.

Table 42 shows that there is no significant difference in mean score after treatment. However, the differences of mean scores of pre-treatment and post treatment in two groups, "better" and "worse" were in the right direction. In the "getting better" group, after treatment, the mean score became lower, which means higher Oral Health related Quality of Life, While in the "getting worse" group, the mean score was higher in the post treatment score, which means lower OHRQoL.

	Mean (Std Dev) of total score in pre-treatment group ^B	Mean( Std Dev) of total score in post treatment group $\gamma$	Mean difference ^α	P value for signed rank test
Pooled data	$17.81 \pm 5.87$	$18.52 \pm 6.87$	$0.71 \pm 5.89$	0.53
(n=68)	16.0*	15.0*	0*	9
Better	18.74 ± 5.54	$18.0 \pm 5.02$	-0.74 ± 5.22	0.38
(n=35)	18.0*	$16.0^*$	0*	
Stable	16.07 ± 4.35	17.36 ± 5.36	$1.29 \pm 4.43$	0.21
(n=28)	14.5*	15.0*	0*	
Worse	21.0 ± 12.1	28.6 ± 15.63	7.6 ± 11.76	0.25
(n=5)	14.0*	23.0*	9.0*	

Table 42-Comparison of total score before and after treatment for the whole sample. Subjects reported "Better", "Stable" and "Worse".

 $\alpha$ : Mean difference = Mean of total score differences between pre and post treatment `group

 $\beta$ : pre-treatment group = the group recruited at the beginning of the study

 $\gamma$ : Post treatment group = the group we have followed up in out study, which had already got their treatment

*: Median

Kruskal-Wallis test and ANOVA test were used to compare median and mean scores of

three groups (stable, better, worse group) for pre-treatment dataset, post treatment

dataset, and Change scores. Table 42 and 43 show that before treatment, the three groups

"Better", "Stable" and "Worse" were not significantly different. But after treatment, the

three groups were different. There is a significant difference in the change scores.

<b>-</b>	Better (n=35) mean	Stable (n=28) mean	Worse (n=5) mean	Kruskal- Wallis test Chi-Square	DF	Analysis of Variance (p value)	p value
Pre-treatment	18.7	16.1	21.0	4.9	2	0.09	0.09
Post treatment	18.0	17.4	28.6	3.4	2	0.002 *	0.18
Change scores	-0.7	1.3	7.6	3.4	2	0.008 *	0.18

Table 43-Comparison of mean pre- & post-treatment scores in subjects reporting their health improved, remained the same or deteriorated.

# **CHAPTER 8**

#### Discussion

### **8.1 Introduction**

The aim of this study was to demonstrate that the French language questionnaire is equivalent to the English version, so that it can be used in the future as a tool to measure Oral Health related Quality of Life in young children in a French speaking population. To achieve this goal, internal consistency, test-retest reliability, convergent validity, discriminative validity, cross cultural comparison and responsiveness were examined. By all these measures, the questionnaire was shown to have good internal consistency, test-retest reliability, convergent validity, discriminative validity and responsiveness. For the cross cultural comparison, there was some similarity of responses between the French and English speaking population. There was a low internal consistency in the Family Impact Section in this French questionnaire.

# **8.2 Results interpretation**

#### Socioeconomic information

For the community based sample, children were chosen when they were 12 months old and followed up until they were 24 months old. The sample we chose was a convenience sample of the target population. However, samples chosen across the eleven CLSCs, and a hospital based sample has a good variation in the level of education of the child's mother, recruitment method, child's family yearly income, and the last time the mother saw a dentist. Most of the participants spoke French; only 25 participants spoke English in the 12 months age group, 19 participants in the 18 months age group and 22 participants in the 24 months age group. (Table 6) Each of the groups (French and English speaking) had different sample sizes, along with the fact that these were convenience samples, there are some limitations of generalizability to the remaining population.

# Floor/Ceiling Effects

From Table 8 to Table 13, most participants responded "never" to 13 items. The distribution of responses to each question was highly skewed. This is a floor/ceiling effect. In the US study, most parents also responded "never" or "very little" impact to this questionnaire. The sample chosen from the general population was followed up from 12 to 24 months. We recruited them from a community based population and there was no immediate need for dental care. In the clinic-based sample, which we used for testing responsiveness, the distributions were skewed but some people reported "often" and "very often" (Table 37).

Graph 1 and 2 show mean scores of items in the child impact section and family impact section as we followed the children from 12 months to 24 months. The questions about "Pain", "Sleeping" and "Frustrated" have the highest percentage of participants answered "often" or "very often" in the child impact section. The problems diminished when the children got older. Graph 2 shows that the question about "feeling upset" had

the highest percentage of participants answered "often" or "very often" in the family impact section. There was a decline in the mean score as the children grew older.

#### Non response

In the 13 item questionnaire, approximately 5% of participants answered "Don't know" to one or more of the questions. In the global dental health rating question, there were 14 participants who answered "don't know" in the 12 month group, 8 participants in the 18 month group and 6 participants in the 24 month group. It would be interesting to do a qualitative interview with those parents who answered "don't know" about their child's overall oral health rating. It was not clear whether it is because they did not understand the question or because they do not have anyone to compare their child with.

#### Internal consistency

For the child impact section, Cronbach's alphas were 0.73, 0.79 and 0.77 for the 12, 18 and 24 months group (Table 14). This indicates good internal consistency of child impact section of this French language questionnaire. In the family impact section, Cronbach's alphas were 0.51, 0.79 and 0.54 respectively, which suggest a reduced internal consistency in this section. Cronbach's alphas were 0.77, 0.82 and 0.78 respectively for the whole scale. Pearson correlations were all significant and positive (Table 15). This indicates good Internal Consistency of the whole scale of this French language questionnaire. Cronbach's alpha for the family impact section varied so much with the age groups because it is depends on the study sample we chosen. With different study samples, Cronbach's alpha value will be different.

### Item scale correlations

As Table 16 indicates, almost all scale items have a significant relationship with each other. All scale items have a positive relationship with each other, and several have values above r = 0.50. Thus, the French language questionnaire has high item-scale reliability.

#### Test-retest reliability

Table 18 indicates that the ICC for the whole scale was 0.95, which suggests this questionnaire has good test-retest reliability. For different domains, the ICC ranged from 0.42 to 0.93, except for the self image & social interaction domain and family function domain, which were 0.26 and 0.13 respectively. ICC was low for these two domains, maybe because participants did not agree, or because the variability among subjects' scores was not large enough to demonstrate reliability. The standard deviation for the self image and social interaction domain was 0.64, and for the family function domain was 0.40, which were the lowest among the whole questionnaire. The sample was homogeneous in these two domains, with most ratings "Never" or "Hardly ever" (Table 17). Therefore ICC was low for these two domains.

### Convergent validity

Table 20 shows that in the 18 and 24 month old group, even though Spearman's correlations were non significant, correlation coefficients were all in the same direction, which were all negative. Therefore, people who score higher have lower Oral Health

related Quality of Life, and poorer oral health. Although correlation coefficients were low and non significant, Table 21 provided evidence for good convergent validity. For the 12 month old group, Spearman's correlation coefficient was positive for child symptoms, self image and social interaction and Parental distress domains. Table 21 shows that in the 12 months group mean scores for "good" and "very good" were 16.6 and 16.7 respectively. This might suggest some parents in the 12 months group may have different standards to evaluate the overall oral health of their child or they did not answer the questionnaire consistently, for example: a participant answered most of the 13 items questions "never", but in the oral health ranking questions, he rated his child's oral health as "poor".

### Discriminative validity

Discriminative validity was examined by administering the questionnaire to different populations with known differences in oral health status. One is a population based sample with no expressed need of dental care. The other is a clinic based sample with an expressed need for dental care, which has only 68 subjects and a mean age of 54.6 months. The two groups we compare has significant differences in age, therefore a multilinear regression model was built to compare OHRQoL of the clinic based sample with the population based sample and adjusted for age. In Table 24, the variable "Clinic" was highly significant with R² equal to 0.12. This indicates good discriminative validity. In the future, it would be beneficial and more accurate if we could have more subjects in the clinic based sample and have a similar mean age for the two populations.

### Sample size for cross cultural comparison

In the cross cultural comparison, most of the participants speak French. There were 373 participants who spoke French in the 12 months group, 352 in the 18 months group and 367 in the 24 months group. Only 25, 19 and 22 participants in each age group spoke English. In the cross cultural comparison study, the French speaking population and English speaking population had unequal sample sizes. Some statistics tests were significant, however this may be due to the difference in variability. It would be more accurate if we had a similar sample of the English speakers and French speakers in our study. This is one of the limitations of our study.

### Cronbach's alpha

There are two types of Cronbach's alpha: Raw standardized Cronbach's alpha and standardized Cronbach's alpha. Standardized Cornbach's alpha is based on covariance. Raw Cronbach's alpha is based on an item correlation matrix. Raw Cronbach's alpha is indicated for our study. For 12 months, there was reduced internal consistency in the family impact section, with Cronbach's alpha at 0.42. Cronbach's alpha calculation takes variance into account. Table 32 shows that standardized deviation in the family impact section in the 12 month group ranged from 0.07-0.63, which was a big change that makes Cronbach's alpha low. In the 24 months group, the standardized deviations for the family impact section were all 0 (Table 35). That was why Cronbach's alpha is 0 (Table 31).

### Cross cultural comparison: the "Finance" question

In response to the question "Have your child's dental problem or treatment cause a financial impact on your family?", most parents reported "Never". The standardized

deviation was very low in this question (Table 32). The same results were found in the pilot study. In Quebec, Canada, dental care is free for this age group. Therefore the "Finance" question was not applicable in Quebec. We would suggest deleting this question.

#### Cross cultural comparison: controlling for sociodemagraphic data

Table 40 shows that the variable "language" was an important variable in order to predict OHRQoL. There was a very small sample size for the English speaking population (n=25); it is borderline significant (P value= 0.047). When controlled for gender, education, mother's consulting to a dentist and child' weight, the English speaking population had a lower OHRQoL compared with the French speaking population.

#### Responsiveness

In the study to test responsiveness, the sample size was only 68 subjects. There were more boys (60.3%) than girls (39.7%). 66.3% people answered in English, 33.8% participants answered in French. 23.5% of participants speak French at home, and 42.6% speak English at home. 29.4% participants speak other languages at home. Table 43 shows that the Mean total score increased from 21.0 to 28.6 after treatment among those people who reported that their oral health were "Getting worse". The mean total score decreased from 18.7 to 18.0 after treatment in the "Getting Better" group. In the "Stable" group, the mean total score changed from 16.1 to 17.4 after treatment. Because of the skewed distribution, Wilcoxon Signed rank sum tests were used to compare the median of the score difference before treatment and after treatment for "Better", "Stable" and

"Worse" groups. Although these were not significant, the score changed in the right direction. This suggested that this questionnaire has good responsiveness. We intend to recruit more participants in a future study, and effect size will be calculated for the questionnaire variable. We also need to examine the longitudinal construct validity of these scores changes.

#### Convergent validity and Construct validity

In the RCT study, subjects were going to have a clinical examination at the end of study. Therefore, at the end of RCT, we have the opportunity to examine the convergent validity of the questionnaire by correlations. Compared to parents who reported their children have more oral health problems, parents who reported that their children have less oral health problems should have better clinical indicators, such as child's weight, *dmfs* etc. In other word, ADD total score should associate with clinical indicators.

#### 8.3 Comparison with original US questionnaire

In the original US study, 295 parents of 5-year-old children were chosen from 5 high income and 3 low income counties in North Carolina. It was a convenience sample.

In the child impact section, the items related to "Pain", "Frustrated", "Sleeping" and "Eating" were reported most frequently in out study. In the US study, "Pain", "Irritation", "Difficulty eating and smiling" and "missing preschool" were reported most frequently in the child impact section. In the family impact section, items about "Upset" and "Guilty" were reported most frequently. Item "Financial" was reported the least frequently in our study. In the US study, "Taking time off from work", "Guilty" and "Financial impacts" were reported most frequently in the family impact section.

In the US study, the correlation between child and family impact sections was statistically significant (Pearson  $\gamma = 0.36$ , P <0.001). In our study, we found the same results. (Pearson  $\gamma$  is 0.54, 0.49 and 0.45 for 12, 18 and 24 month's group (P value < 0.0001). This suggested that the French version questionnaire also had strong links with OHRQoL, which was the latent variable.

Cronbach's alpha for the child impact section and family impact section were 0.7 and 0.5-0.7 respectively, and 0.7-0.8 for the scale in our study. In the US study, they were 0.91 and 0.95 for child and family impacts section respectively, and 0.89 for the whole scale. Compared to the English language questionnaire, there was a reduced internal consistency in the Family impact section. We suggest deleting the "Finance" question in the French language questionnaire because it is not applicable in Quebec.

#### **8.4 Comparison with other literatures**

In most of literatures, Cronbach's alpha was used to examine internal consistency. For test-retest reliability, some researcher's use Intraclass correlation coefficient, while others use correlation coefficient. S. Tubert-jeannin et al. validated an oral health quality of life index (GOHAI) in France, even though it has already been validated in Canadian French. For test-retest reliability, they use weighted kappa coefficients and Pearson's correlation coefficient⁸⁹. We prefer intraclass correlation coefficient, because correlation

does not reflect agreement and weighted Kappa is not very helpful for continuous data. ICC reflects both degree of correspondence and agreement.

For convergent validity, correlation coefficient was the preferred method. Hein Raat et al. evaluated convergent validity by correlating CHQ scale scores with the VAS rating of the child's current health^{42,89}.

For discriminant validity, t test and ANOVA were often used. Jokovic A. *et al.* validated a Child Perceptions Questionnaire (CPQ11-14) and they compared scores overall and domain scores for the three clinical groups, Pedodontic, Orthodontic and Oro-facial using Kruskal-Wallis test^{28,41}. S. Tubert-jeannin et al. evaluated discriminant validity by correlating the participants' responses with the objectively assessed dental status⁸⁹. Hein Raat et al. examined discriminative validity between a subgroup with no parent reported chronic conditions and subgroups with asthma^{42,89}. Cohen's effect sizes were also calculated⁴².

For construct validity, factor analysis and person's correlation were commonly used. For construct validity, Jokovic A. *et al.* determined the associations between questionnaire scores and the two global indicators^{28,41,43}. M Wong et al. validated a Chinese version of the oral health impact profile (OHIP)⁷⁷. Construct validity of the translated Chinese version questionnaire was supported by the corresponding score changes as the subject's perceived oral health status changed. Robert K McKinley et al. examined construct validity by the correlation matrix and examining factor structure⁹¹. Factor analysis can identify the concepts structure and helpful to reduce variables and group variables⁹¹.

For responsiveness, change scores were visually inspected. Effect size, minimal clinically important difference and ROC curve were also calculated. Asa Lundgren-Nilsson et al. using Rasch analysis to test cross-cultural validity of functional independence measure items in stroke¹⁰¹. Differential Item Functioning was examined by countries. S. Kutlay also use Rasch analysis to adapted and validated the Turkish version of the Rheumatoid Arthritis Quality of Life Scale⁹⁷.

#### **8.5 Limitation**

Most responses in our questionnaire were "Never" or "Hardly ever". There is a ceiling/ floor effect, particularly a floor effect. This affected the reliability and validity of this questionnaire.

In our study, the sample sizes between the English speaking population and French speaking population were unequal. This may take variance into account.

Another limitation of this study is the sample size for responsiveness study. A higher sample size would provide more information and evidence of good responsiveness of this questionnaire, such as effect size, minimal clinical important difference, correlation with clinical examinations, and develop ROC curve.

Because the data used in our study is chosen from a randomized clinical trial, participants will have a clinical examination at the end of the clinical trial. Clinical examination information is not available. In future, when all data have been collected, convergent validity will be further examined by correlations with OHRQoL level and clinical indicators. Construct validity will be further examined by factor analysis. Compared to parents who reported their children have more oral health problems, parents who reported that their children have less oral health problems should have better clinical indicators at the end of the study.

There are some limitations of generalizbility of this study to the remaining population, because samples for this study were convenience samples.

#### 8.6 Implications of this study

The questionnaire that measure Oral Health related Quality of Life in children younger than 5 years old is new. Ours was the first research group to translate this questionnaire into French and it is the first time research on OHRQoL in children younger than 5 years old has been done in Quebec, Canada. Validation of the French language OHRQoL questionnaire provides a research tool that should help researchers gain a greater understanding of the consequences and impacts of oral diseases in young children, parent's perceptions and feelings about their child's oral health, and the differences in Oral Health related Quality of Life in young children between French and English speaking populations in Quebec, Canada. Clinicians and scientists can use a validated French language questionnaire to supplement information about the quality of dental care and help improve communication between young children, parents and the professional dental services team. Validation of the French language OHRQoL questionnaire provides the opportunity to assess Oral Health related Quality of Life in children younger than 5 years old in a French speaking population, and can assist oral health policy and decision making, improve preventive dental care and dental services for children, provide information for validation of similar health instruments, and also suggest means of measuring health outcomes in other language populations.

## **CHAPTER 9**

# Conclusion

### Reliability

### Internal Consistency

For the whole scale and child impact section, there was good internal consistency in the questionnaire. But there was reduced internal consistency in the family impact section. The correlation between child and family impact sections for the three age groups were all statistically significant. This indicates that the scale has strong links with the latent variable. Item scale correlations were roughly equal for all 13 items in the questionnaire. The question responses from the same domain have strong association with each other, which suggested this questionnaire has good internal consistency.

### Test retest reliability

Intraclass correlation coefficient (model 3) was 0.95 for the whole scale, 0.93 for the child impact section and 0.51 for the family impact section. This questionnaire has good test-retest reliability. If we give a test to a person more than once, assuming his or her oral health situation does not change, the results are reproducible.

### Validity

## **Convergent** validity

In three age groups, Parents who reported their child's dental health "fair" or "poor" had higher scores than parents who reported "good". Compared to parents who reported their children have more oral health problems, parents who reported that their children have less oral health problems had lower ADD score for the whole scale, and reported "good" more frequently in the question "Overall, How do you rate your children's oral health?" This indicates this questionnaire have good convergent validity.

### Discriminative validity

The questionnaire can discriminate between children in the community with no expressed need for dental care and those children in a dental clinic with an expressed need for dental care. The variable "clinic" was the most significant variable in the full model with p value < 0.0001. This indicates this questionnaire have good discriminative validity.

### **Cross- cultural validity**

There was some degree of consensus of responses between French speaking population and English speaking population. But the French language questionnaire needs some minor revision to make it cross-culture validated and more adaptable to Quebec, Canada.

# Responsiveness

Children reports of improvement, no change or deterioration in oral health were associated with appropriate change scores in the instrument. Because of the small sample size, they were non significant. This indicates this questionnaire may have good responsiveness, but is not conclusive. New participants are still being recruited in this study. In future, we will examine further responsiveness.

# APPENDIX

This study was approved by The McGill University Faculty of Medicine Institutional Review Board. Written consent was obtained from all participants.

### **Reference** List

- 1. McGrath, C., Broder, H. & Wilson-Genderson, M. Assessing the impact of oral health on the life quality of children: implications for research and practice. *Community dentistry and oral epidemiology* **32**, 81-85 (2004).
- 2. Kerosuo, H., Ngassapa, D., Kerosuo, E. & Ranta, K. Caries experience in the primary dentition of nursery school children in Dar es Salaam, Tanzania. *Caries research* 22, 50-54 (1988).
- 3. Holm, A. K. Caries in the preschool child international trends. *Journal of dentistry* 18, 291-295 (1990).
- 4. Kaste Coronal caries in the primary and permanent dentition of children and adolescents 1-17 years of age: United States, 1988-1991. *Journal of dental research* **75**, 631-641 (1996).
- 5. Kleinman, A., Eisenberg, L. & Good, B. Culture, Illness, and Care. Annals of *internal medicine* 88, 251 (1978).
- 6. Olojugba, O. O. & Lennon, M. A. Dental caries experience in 5- and 12-year-old school children in Ondo State, Nigeria in 1977 and 1983. *Community dental health* **4**, 129-135 (1987).
- Songpaisan, Y. & Davies, G. N. Dental caries experience in the Chiangmai/Lamphun provinces of Thailand. *Community dentistry and oral* epidemiology 17, 131-135 (1989).
- 8. Brian A.Burt & Stephen A.Eklund Dentistry, Dental Practice, and the Community. (2005).
- 9. Wathen WF International implications of "oral health in America: a report of the Surgeon General". *Quintessence international* **31**, 697 (2000).
- Buck, D. & Newton, J. T. Non-clinical outcome measures in dentistry: publishing trends 1988-98. *Community dentistry and oral epidemiology* 29, 2-8 (2001).

- 11. Oral health in America: a report of the Surgeon General. *Journal of the California Dental Association* **28**, 685-695 (2000).
- 12. VARGAS, C. M., CRALL, J. J. & SCHNEIDER, D. A. Sociodemographic Distribution of Pediatric Dental Caries: NHANES III, 1988-1994. *The Journal of the American Dental Association* **129**, 1229-1238 (1998).
- 13. Support the framework for action on oral health in America: a report of the Surgeon General. *American journal of public health* **91**, 520c (2001).
- 14. Kleinman DV The future of the dental profession: perspectives from Oral Health in America: a report of the Surgeon General. *The Journal of the American College of Dentists* **69**, 6-10 (2002).
- Brodeur, J. M., Payette, M. & Bedos, C. Association des variables socioeconomiques avec la prevalence de la carie dentaire chez les ecoliers quebecois de deuxieme et sixieme annee en 1989-1990. *Canadian journal of public health* 89, 274 (1998).
- Li, Y. & Wang, W. Predicting Caries in Permanent Teeth from Caries in Primary Teeth: An Eight-year Cohort Study. *Journal of dental research* 81, 561-566 (2002).
- 17. Duperon, D. F. Early childhood caries: a continuing dilemma. *Journal of the California Dental Association* 23, 15 (1995).
- 18. Acs, G., Lodolini, G., Kaminsky, S. & Cisneros, G. Effect of nursing caries on body weight in a pediatric population. *Pediatric dentistry* 14, 302-305 (1992).
- 19. Tinanoff Introduction to the Early Childhood Caries Conference: initial description and current understanding. *Community dentistry and oral epidemiology* **26**, 5-7 (1998).
- 20. Burke A synopsis of the adult dental health survey: oral health in the United Kingdom 1998. *Dental update* 27, 184-186 (2000).
- 21. Petersen Dental caries and oral health behaviour situation of children, mothers and schoolteachers in Wuhan, People's Republic of China. *International dental journal* **48**, 210-216 (1998).
- 22. McNulty, J. A. & Fos, P. J. The study of caries prevalence in children in a developing country. *ASDC J Dent Child* **56**, 129-136.
- 23. John, M. T. et al. Dimensions of Oral-health-related Quality of Life. Journal of dental research 83, 956-960 (2004).

- 24. Brennan, D. & Spencer, A. Dimensions of oral health related quality of life measured by EQ-5D+ and OHIP-14. *Health and quality of life outcomes* **2**, 35 (2004).
- 25. Wilson, I. B. & Cleary, P. D. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. *JAMA* 273, 59-65 (1995).
- 26. Gift, H. C., Atchison, K. A. & Drury, T. F. Perceptions of the natural dentition in the context of multiple variables. *Journal of dental research* 77, 1529-1538 (1998).
- 27. de Oliveira, C. M. & Sheiham, A. The relationship between normative orthodontic treatment need and oral health-related quality of life. *Community dentistry and oral epidemiology* **31**, 426-436 (2003).
- 28. Jokovic, A. *et al.* Validity and Reliability of a Questionnaire for Measuring Child Oral-health-related Quality of Life. *Journal of dental research* **81**, 459-463 (2002).
- 29. Inglehart M & Bagramian R Oral health related quality of life: an introduction. Chicago IL: Quintessence, (2002).
- 30. C Eiser & R Morse Quality-of-life measures in chronic diseases of childhood. Health Technology Assessment (Winchester, England) 5, 1-157 (2001).
- 31. Allison, P. J., Locker, D. & Feine, J. S. Quality of life: A dynamic construct. *Social science & medicine* **45**, 221-230 (1997).
- 32. Gift, H. C., Atchison, K. A. & Dayton, C. M. Conceptualizing oral health and oral health-related quality of life. *Social science & medicine* 44, 601-608 (1997).
- KRESSIN, N., SPIRO, A., BOSSÉ, R., GARCIA, R. & KAZIS, L. Assessing oral health-related quality of life: findings from the normative aging study. *Medical care* 34, 416-427 (1996).
- 34. Richard R.Welbury Paediatric Dentistry. Oxford Medical Publications, (2005).
- 35. Rydstrom, I., Dalheim-Englund, A. C., Holritz-Rasmussen, B., Moller, C. & Sandman, P. O. Asthma quality of life for Swedish children. *Journal of Clinical Nursing* 14, 739-749 (2005).
- 36. Gherunpong, Tsakos G & Sheiham A Developing and evaluating an oral healthrelated quality of life index for children; the CHILD-OIDP. *Community dental health* **21**, 161-169 (2004).
- 37. David L.Streiner & Geoffrey R.Norman Health Measurement Scales; A Practical Guide to Their Development and Use. Oxford Medical Publications, (1995).

- 38. TALEKAR, B. S., ROZIER, R. G., Slade, G. D. & ENNETT, S. T. Parental perceptions of their preschool-aged children's oral health. *The Journal of the American Dental Association* **136**, 364-372 (2005).
- 39. Pal DK Quality of life assessment in children: a review of conceptual and methodological issues in multidimensional health status measures. *Journal of Epidemiology & Community Health* **50**, 391-396 (1996).
- 40. Koscik RL et al. Quality of life of children with cystic fibrosis. The Journal of pediatrics 147, S64-S68 (2005).
- 41. Jokovic A, Locker D, Tompson B & Guyatt G Questionnaire for measuring oral health-related quality of life in eight- to ten-year-old children. *Pediatric dentistry* **26**, 512-518 (2004).
- 42. Raat, H., Botterweck, A. M., Landgraf, J. M., Hoogeveen, W. C. & Essink-Bot, M. L. Reliability and validity of the short form of the child health questionnaire for parents (CHQ-PF28) in large random school based and general population samples. *Journal of epidemiology and community health* **59**, 75-82 (2005).
- 43. Jokovic, A., Locker, D. & Guyatt, G. Short forms of the Child Perceptions Questionnaire for 11-14-year-old children (CPQ11-14): Development and initial evaluation. *Health and quality of life outcomes* **4**, 4 (2006).
- 44. Theunissen, N. C. M. *et al.* The proxy problem: child report versus parent report in health-related quality of life research. *Quality of life research* **7**, 387-397 (1998).
- 45. Foster Page, L. A., Thomson, W. M., Jokovic, A. & Locker, D. Validation of the Child Perceptions Questionnaire (CPQ11-14). *Journal of dental research* 84, 649-652 (2005).
- 46. Stephen H. & Y.Wei. *Pediatric dentistry : total patient care*. Lea & Febiger, Philadelphia (1988).
- Manji, F. The prevalence of dental caries in children of African and Asian origin in Nairobi, Kenya. *Odonto-Stomatologie Tropicale = Tropical Dental Journal* 6, 27-33 (1983).
- 48. Peng Oral health status and oral health behaviour of 12-year-old urban schoolchildren in the People's Republic of China. *Community dental health* **14**, 238-244 (1997).
- 49. Sheiham Impact of dental treatment on the incidence of dental caries in children and adults. *Community dentistry and oral epidemiology* **25**, 104-112 (1997).
- 50. McGrath C & Bedi R A review of the influences of oral health on the quality of life. *Internation journal of Health Education* **37**, 116-119 (1999).

- 51. Study protocol for the World Health Organization project to develop a Quality of Life assessment instrument (WHOQOL). *Quality of life research* **2**, 153-159 (1993).
- 52. Pantell Measuring the impact of medical care on children. *Journal of chronic diseases* **40**, 99S-115S (1987).
- 53. Leao, A. & Sheiham, A. Relation between clinical dental status and subjective impacts on daily living. *Journal of dental research* 74, 1408-1413 (1995).
- 54. Patrick DL & Erickson P Health status and health policy- quality of life in health care evaluation and resource allocation. New York: Oxford University Press, (1993).
- 55. Strauss RP & Hunt RJ Understanding the value of teeth to older adults: influences on the quality of life. *The Journal of the American Dental Association* **124**, 105-110 (1993).
- 56. Axelsson G & Helgadottir S Comparison of oral health data from selfadministered questionnaire and clinical examination. *Community dentistry and oral epidemiology* 23, 365-368 (1995).
- 57. Guyatt, G. H., Feeny, D. H. & Patrick, D. L. Measuring Health-related Quality of Life. *Annals of internal medicine* **118**, 622-629 (1993).
- 58. Guyatt, G. H., Kirshner, B. & Jaeschke, R. Measuring health status: What are the necessary measurement properties? *Journal of clinical epidemiology* **45**, 1341-1345 (1992).
- 59. John, E. & Gandek, B. Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) Project. *Journal of clinical epidemiology* **51**, 903-912 (1998).
- 60. Yang, B.-H., Chen, Y.-C., Chiang, B.-L. & Chang, Y.-C. Effects of nursing instruction on asthma knowledge and quality of life in schoolchildren with asthma. *Journal of Nursing Research* 13, 174-183 (2005).
- 61. Alberts, K. A., Jaerveus J & Zyto K Nail versus screw fixation of femoral neck fractures. A 2-year radiological and clinical prospective study. *Annales chirurgiae et gynaecologiae* **78**, 298-303 (1989).
- 62. P Finbarr Allen review assessment of oral health related quality of life. *Health* and quality of life outcomes I, (2003).
- 63. Locker D & Miller Y Evaluation of subjective oral health status indicators. Journal of public health dentistry 54, 167-176 (1994).

- 64. Slade GD *et al.* Conference summary: assessing oral health outcomes-measuring health status and quality of life. *Community dental health* **15**, 3-7 (1998).
- 65. Locker D Health outcomes of oral disorders. *International journal of epidemiology* 24, S85-S89 (1995).
- 66. Locker D Measuring oral health: a conceptual framework. *Community dental health* **5**, 3-18 (1988).
- 67. Slade GD *Measuring oral health related quality of life*. Chapel Hill: University of North Carolina, Dental Ecology, (1997).
- 68. Dolan TA, Peek CW, Stuck AE & Beck JC Three-year changes in global oral health rating by elderly dentate adults. *Community dentistry and oral epidemiology* **26**, 62-69 (1998).
- 69. John, M. T. *et al.* Demographic factors, denture status and oral health-related quality of life. *Community dentistry and oral epidemiology* **32**, 125-132 (2004).
- 70. Slade GD & Spencer AJ Development and evaluation of the Oral Health Impact Profile. *Community dental health* **11**, 3-11 (1994).
- 71. Leao A & Sheiham A The development of a socio-dental measure of dental impacts on daily living. *Community dental health* **13**, 22-26 (1996).
- 72. Atchison KA & Dolan TA Development of the Geriatric Oral Health Assessment Index. *Journal of dental education* **54**, 680-687 (1990).
- 73. Allen, P. F., McMillan, A. S. & Locker, D. An assessment of sensitivity to change of the Oral Health Impact Profile in a clinical trial. *Community dentistry and oral epidemiology* **29**, 175-182 (2001).
- 74. Slade GD Assessing change in quality of life using the Oral Health Impact Profile. *Community dentistry and oral epidemiology* **26**, 52-61 (1998).
- 75. Locker, D., Matear, D., Stephens, M., Lawrence, H. & Payne, B. Comparison of the GOHAI and OHIP-14 as measures of the oral health-related quality of life of the elderly. *Community dentistry and oral epidemiology* **29**, 373-381 (2001).
- 76. John, M. T., Patrick, D. L. & Slade, G. D. The German version of the Oral Health Impact Profile translation and psychometric properties. *European journal of oral sciences* **110**, 425-433 (2002).
- 77. Wong, M. C. M., Lo, E. C. M. & McMillan, A. S. Validation of a Chinese version of the Oral Health Impact Profile (OHIP). *Community dentistry and oral epidemiology* **30**, 423-430 (2002).

- Heydecke, G., Tedesco, L. A., Kowalski, C. & Inglehart, M. R. Complete dentures and oral health-related quality of life - do coping styles matter? *Community dentistry and oral epidemiology* 32, 297-306 (2004).
- 79. McGrath, C. & Bedi, R. The importance of oral health to older people's quality of life. *Gerodontology* **16**, 59-63 (1999).
- 80. Sheiham, A. *et al.* Prevalence of impacts of dental and oral disorders and their effects on eating among older people; a national survey in Great Britain. *Community dentistry and oral epidemiology* **29**, 195-203 (2001).
- 81. McGrath, C. & Bedi, R. Can dentures improve the quality of life of those who have experienced considerable tooth loss? *Journal of dentistry* **29**, 243-246 (2001).
- Tapsoba, H., Deschamps, J. P. & Marie-Hélène Leclercq Factor analytic study of two questionnaires measuring oral health-related quality of life among children and adults in New Zealand, Germany and Poland. *Quality of life research* 9, 559-569 (2000).
- 83. Rong, W. S., Bian, J. Y., Wang, W. J. & De Wang, J. Effectiveness of an oral health education and caries prevention program in kindergartens in China. *Community dentistry and oral epidemiology* **31**, 412-416 (2003).
- 84. Allison P, Locker D, Jokovic A & Slade G A cross-cultural study of oral health values. *Journal of dental research* **78**, 643-649 (1999).
- Bullinger, M. et al. Translating Health Status Questionnaires and Evaluating Their Quality: The IQOLA Project Approach. Journal of clinical epidemiology 51, 913-923 (1998).
- 86. Bartko JJ & Carpenter, W. T. J. on the methods and theory of reliability. *J Nerv Ment Dis* **163**, (1976).
- 87. Fleiss, J. L. Inter-examiner reliability in caries trials. *Journal of dental research* **58**, 604-609 (1979).
- Fleiss, J. L. Reliability of discrete measurements in caries trials. *Caries research* 13, 23-31 (1979).
- 89. Tubert-Jeannin, S., Riordan, P. J., Morel-Papernot, A., Porcheray, S. & Saby-Collet, S. Validation of an oral health quality of life index (GOHAI) in France. *Community dentistry and oral epidemiology* **31**, 275-284 (2003).
- Cunningham, S. J., Garratt, A. M. & Hunt, N. P. Development of a conditionspecific quality of life measure for patients with dentofacial deformity: II. Validity and responsiveness testing. *Community dentistry and oral epidemiology* 30, 81-90 (2002).
- 91. McKinley, R. K., Manku-Scott, T., Hastings, A. M., French, D. P. & Baker, R. Reliability and validity of a new measure of patient satisfaction with out of hours primary medical care in the united kingdom: development of a patient questionnaire. *BMJ* **314**, 193 (1997).
- 92. Robinson, P. G., Gibson, B., Khan, F. A. & Birnbaum, W. Validity of two oral health-related quality of life measures. *Community dentistry and oral epidemiology* **31**, 90-99 (2003).
- 93. Bowden, A. & Fox-Rushby, J. A. A systematic and critical review of the process of translation and adaptation of generic health-related quality of life measures in Africa, Asia, Eastern Europe, the Middle East, South America. *Social science & medicine* 57, 1289-1306 (2003).
- 94. Herdman, M., Fox-Rushby, J. & Badia, X. A Model of Equivalence in the Cultural Adaptation of HRQoL Instruments: The Universalist Approach. *Quality* of life research 7, 323-335 (1998).
- 95. Guillemin, F., Bombardier, C. & Beaton, D. Cross-cultural adaptation of healthrelated quality of life measures: Literature review and proposed guidelines. *Journal of clinical epidemiology* **46**, 1417-1432 (1993).
- 96. Allen PF & Locker D Do item weights matter? An assessment using the oral health impact profile. *Community dental health* **14**, 133-138 (1997).
- 97. Sehim Kutlay, A. A. K. D. G. A. T. Adaptation and validation of the Turkish version of the Rheumatoid Arthritis Quality of Life Scale. *Rheumatology international* **23**, 21-26 (2003).
- Wagner, A. K. *et al.* Cross-Cultural Comparisons of the Content of SF-36 Translations across 10 Countries: Results from the IQOLA Project. *Journal of clinical epidemiology* 51, 925-932 (1998).
- 99. Berkanovic, E. The Effect of Inadequate Language Translation on Hispanics' Responses to Health Surveys. *American journal of public health* **70**, 1273 (1980).
- 100. Deyo, R. A. Pitfalls in Measuring the Health Status of Mexican Americans: Comparative Validity of the English and Spanish Sickness Impact Profile. American journal of public health 74(6), 569. 1984. Ref Type: Abstract
- Lundgren-Nilsson, +. et al. CROSS-CULTURAL VALIDITY OF FUNCTIONAL INDEPENDENCE MEASURE ITEMS IN STROKE: A STUDY USING RASCH ANALYSIS. Journal of rehabilitation medicine 37, 23-31 (2005).

- 102. Patrick, D. L., Sittampalam, Y., Somerville, S. M., Carter, W. B. & Bergner, M. A Cross-Cultural Comparison of Health Status Values. *American journal of public health* 75, 1402 (1985).
- 103. Hunt, S. M. *et al.* Cross-cultural adaptation of health measures. *Health policy* **19**, 33-44 (1991).
- 104. Liang MH, Larson MG, Cullen KE & Schwartz JA Comparative measurement efficiency and sensitivity of five health status instruments for arthritis research. *Arthritis & Rheumatism* 28, 542-547 (1985).
- 105. Liang MH Longitudinal construct validity: establishment of clinical meaning in patient evaluative instruments. *Medical care* **38**, II84-II90 (2000).
- 106. Locker D Issues in measuring change in self-perceived oral health status. Community dentistry and oral epidemiology 26, 41-47 (1998).
- Deyo RA, Diehr P & Patrick DL Reproducibility and responsiveness of health status measures. Statistics and strategies for evaluation. *Controlled clinical trials* 12, 142S-158S (1991).
- C.Jenkinson, V.Peto & A.Coulter Measuring change over time: a comparison of results from a global single item of health status and the multi-dimensional SF-36 health status survey questionnaire in patients presenting with menorrhagia. *Quality of life research* 3, 317-321 (1994).
- Locker, D., Jokovic, A. & Clarke, M. Assessing the responsiveness of measures of oral health-related quality of life. *Community dentistry and oral epidemiology* 32, 10-18 (2004).
- 110. Juniper, E. F., Guyatt, G. H., Willan, A. & Griffith, L. E. Determining a minimal important change in a disease-specific quality of life questionnaire. *Journal of clinical epidemiology* **47**, 81-87 (1994).
- 111. Jaeschke, R., Singer, J. & Guyatt, G. H. Measurement of health status : Ascertaining the minimal clinically important difference. *Controlled clinical trials* 10, 407-415 (1989).
- 112. Fitzpatrick R, Ziebland S, Jenkinson C, Mowat A & Mowat A A comparison of the sensitivity to change of several health status instruments in rheumatoid arthritis. *The Journal of rheumatology* **20**, 429-436 (1993).
- Deyo, R. A. & Centor, R. M. Assessing the responsiveness of functional scales to clinical change: An analogy to diagnostic test performance. *Journal of chronic diseases* 39, 897-906 (1986).

- 114. Norman, G. R., Stratford, P. & Regehr, G. Methodological problems in the retrospective computation of responsiveness to change: The lesson of Cronbach. *Journal of clinical epidemiology* **50**, 869-879 (1997).
- 115. Deyo RA & Inui TS Toward clinical applications of health status measures: sensitivity of scales to clinically important changes. *Health services research* **19**, 275-289 (1984).
- 116. Meenan RF et al. Outcome assessment in clinical trials. Evidence for the sensitivity of a health status measure. Arthritis & Rheumatism 27, 1344-1352 (1984).
- 117. Hanley JA Receiver operating characteristic (ROC) methodology: the state of the art. *Critical Reviews in Diagnostic Imaging* **29**, 307-335 (1989).
- Hajian-Tilaki, K. O. & Hanley, J. A. Comparison of Three Methods for Estimating the Standard Error of the Area under the Curve in ROC Analysis of Quantitative Data. *Academic Radiology* 9, 1278-1285 (2002).
- 119. Tugwell P *et al.* The MACTAR Patient Preference Disability Questionnaire--an individualized functional priority approach for assessing improvement in physical disability in clinical trials in rheumatoid arthritis. *The Journal of rheumatology* **14**, 446-451 (1987).
- Stucki, G., Liang, M. H., Fossel, A. H. & Katz, J. N. Relative responsiveness of condition-specific and generic health status measures in degenerative lumbar spinal stenosis. *Journal of clinical epidemiology* 48, 1369-1378 (1995).
- 121. Epstein RS Responsiveness in quality-of-life assessment: nomenclature, determinants, and clinical applications. *Medical care* **38**, II91-II94 (2000).
- Guyatt, G., Walter, S. & Norman, G. Measuring change over time: Assessing the usefulness of evaluative instruments. *Journal of chronic diseases* 40, 171-178 (1987).
- 123. Hanley, J. A. & McNeil, B. J. The meaning and use of the area under a receiver operating characteristic (ROC) curve. *Radiology* 143, 29-36 (1982).
- 124. Husted, J. A., Cook, R. J., Farewell, V. T. & Gladman, D. D. Methods for assessing responsiveness: a critical review and recommendations. *Journal of clinical epidemiology* **53**, 459-468 (2000).
- 125. Bland, J. M. & Altman, D. G. Statistics notes: Cronbach's alpha. *BMJ* **314**, 572 (1997).
- 126. Fleiss, J. L. & Shrout, P. E. The Effects of Measurement Errors On Some Multivariate Procedures. *American journal of public health* 67, 1188 (1977).



Faculty of Medicine

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#### CERTIFICATION OF ETHICAL ACCEPTABILITY FOR RESEARCH INVOLVING HUMAN SUBJECTS

The Faculty of Medicine Institutional Review Board consisting of:

LAWRENCE HUTCHISON, MD

PATRICIA DOBKIN, PHD

ROBERT L. MUNRO, BCL

LUCILLE PANET-RAYMOND, BA

ARTHUR CANDIB, MED

CATHERINE GARDNER, BSC

ROBERTA PALMOUR, PHD

MARGARET SWAINE, BA

has examined the research project A12-M120-02A entitled "A Clinical Trial of the Effectiveness of a Dental Caries Prevention Program for Young Children"

to

as proposed by:

Paul Allison Applicant <u>CIHR</u> Granting Agency, if any

and consider the experimental procedures to be acceptable on ethical grounds for research involving human subjects.

January 6, 2003 Date

Chair, IRB

Dean of Faculty

Institutional Review Board Assurance Number: M-1458

#### A clinical trial of the effectiveness of a dental caries prevention program for young children Dr Paul Allison, McGill University

#### Consent form

#### Purpose of the study

Dental caries is a transmissable and infectious disease. It is the most common disease in young children. However, the dental public health program currently running in Quebec is applied by CLSC dental hygienists at school and applies to 5 year old children only. Furthermore, dentists in private practice rarely accept to see very young children. So there is currently no program or service aimed at preventing dental decay in children under 5 years of age.

This study aims to see if we can prevent dental decay by teaching parents about the subject when their children are still very young. We have designed an education program to be delivered by dental hygienists at CLSCs and we want to do this study to see whether it works. Does it really help parents prevent dental decay in their young children? In order to test whether the program works, we need to perform a study in which there are two groups. One group consists of parents or other guardians with their young child who will receive the new program and the other group consists of parents and young children who will receive simple written information once only.

#### **Expected procedures**

If you agree to participate in this study, this is what will happen:

#### 1. Randomisation

This is a procedure that allocates participants evenly into two different groups by chance. This process is done by somebody else in an office elsewhere and is something we have no control over. With it, you (and your child) have a 50% chance of being allocated to either group (the one with the new program or the one with simple written information). The hygienist will phone this randomization office elsewhere and be told which of the 2 groups you will be in. She will then tell you. It is totally out of her control and she cannot let you choose to change to the other group.

#### 2. Assignment to one of the two groups

If you are assigned to group A, you will receive the new educative program concerning child dental health. This will be given to you at the CLSC by the hygienist who has been specially trained for this program.

First of all we will collect some data from you and have you complete some questions concerning dental decay. Then the program will start. You will attend a total of 4 education sessions: one every six months during the next 18 months. The first one is today, as your child is approximately 6 months old. The next two visits correspond to the time of vaccination clinics for you child, at approximately 12 and at 18 months of age. The last session will take place when

your child will be two years old. The dental hygienist will call you before your next sessions to remind you of your following visit.

Each visit will last about 15 minutes. Prevention issues, such as diet and dental hygiene, will be discussed at each of the sessions. Information will concern potential causes of dental decay in children your child's age at the time of the visit. Educative material (place mat, brochures, etc) will be given to you. The hygienist will demonstrate brushing your child's mouth at the second (12 months old) and fourth visits (24 months old).

Finally, you will have to return with your child in 2 years time (2 months after the last education visit, when your child is approximately 30 months old) so that a dental hygienist can look in your child's mouth to see if there is any decay. In addition we will have you complete some questionnaires. This is done to see the results of the new program.

If you are assigned to group B, first of all we will collect some data from you and have you complete some questions concerning dental decay. Then you will be given a simple written summary of all the material that is discussed in the new program. This will be given to you today and then you will be free to go. We will not need to see you again for two years. Then we will contact you and ask you to come back to the CLSC so that a dental hygienist can look in your child's mouth to see if there is any decay. In addition we will have you complete some questionnaires. This is done to see how your child's teeth are doing.

#### 3. For both groups: Filling out questionnaires and baby weighing

Regardless of whether you are in group A or group B, the study will involve filling out a few short questionnaires. The questionnaires ask about information to help us reach you in the future, about your familial situation and about your knowledge and behaviours regarding dental prevention. We will also note your baby's weight. These procedures will be done twice: once at the beginning of the study, when your participation has been confirmed and, again, at the end of the study, in 2 years, when your child will be 30 months old. The questionnaires are not used to evaluate you; rather, they are use to test whether the new program is any different from the simple written information.

#### 4. Evaluation of child's dental condition at the end of the study

At your last visit, your child will be 30 months old. All the children in both groups A and B will then be seen again at the CLSC. At that time, a dental exam of your child will take place. It will be done by different hygienists than those who did the education for group A. The examination takes place with the child on the parent's and the hygienist's knees. Each of the teeth surfaces are observed with a dental mirror. This examination is the only one your child will get during the study, regardless of the group you are appointed to.

#### **Benefits**

Both groups will receive more than what parents in your situation would normally receive. If you are in group A, you will receive more detailed information and closer attention than if you are in group B.

#### Risks

There are no risks involved in this study.

#### Alternatives

The only other source of information similar to that provided during the study is a dentist specialising in paediatric dentistry.

#### Confidentiality

If you participate in the study, you allow us to gather information concerning you and your child. This will be collected during the first and last visits of the project. At the beginning of the study, you and your child will be given a code number to ensure that all information concerning you and your child will be kept anonymous throughout the project and afterwards. The investigators in this research project intend to use the results to write scientific papers or to present them at conferences. However, all data is kept and reported in an anonymous form. Your and your child's name will never be used. The questionnaires that you fill out will be securely kept by the researchers while they analyse the results and will later be destroyed.

#### Information

You may obtain information about this project from the dental hygienist at the CLSC at any time during the course of the study. She can also show you, in advance, some of the educative material if you wish. You may also contact the study's site coordinator, Dr Jacques Veronneau, at 819-693-3996 or the main investigator, Dr Paul Allison, at 514-398-7203 ext. 00045.

#### Your rights as a volunteer

Your participation is completely voluntary. You are at liberty to refuse to participate in this study and if you do, it will have no effect on the care you receive at this CLSC. Also, during the course of the study, you are entirely free to withdraw and stop your participation at any time without any consequences for you or for your child. If you prefer, you can take more time to think about participating.

By signing this consent form, I agree and confirm that:

- 1. The study and this form have been explained to be by _____, who has responded satisfactorily to my questions.
- 2. My participation is voluntary. My refusal to participate will not lead to any loss of services.
- 3. I have a 50% chance of being allocated to the new program or not and I understand the implications of each situation in terms of timing and procedures.
- 4. A copy of the present form will be given to me and another one will be kept in a file created for the study.

5. I will sometimes be contacted, as a reminder, by _____, the dental hygienist responsible for the intervention.

Participant's signature Date Full name, in block letters

Witness' signature

Date

Full name, in block letters

VISIT CHECKLIST (completed by hygienist)

	Dyad identification	n numbe	r:
<ol> <li>Recruitment visit (intervention 1)</li> <li>Signed consent</li> <li>Bandomization allocation</li> </ol>	Yes	<b>No</b> □	intervention C control
<ul> <li>Dyad personal identification information</li> <li>Dyad study identification information</li> <li>Socio demographic data</li> </ul>			
<ul> <li>Caries-related knowledge questionnaire</li> <li>Weight taken</li> <li>Pamphlet given</li> <li>Next appointment organised (intervention group)</li> </ul>	□ □ up only)		☐ (to be done later)
Hygienist's name Hygienist's signature Date (dd)/ (mm)/ (yyyy)			
<ul> <li>2. Second visit (intervention 2)</li></ul>	Yes		(to be done later)
Hygienist's name Hygienist's signature Date (dd)/ (mm)/ (yyyy)			

3. Third visit (intervention 3)			
	Yes	No	
Dyad attended			
Pamphlet given			
Next appointment organised			(to be done later)
Hygienist's name			
Hygienist's signature			
Date (dd)/ (mm)/ (yyyy)			
4. Fourth visit (intervention 4)	Vac	No	
Dvad attended			
Pamphlet given			
<ul> <li>Next appointment organised (for evaluation)</li> </ul>			🔲 (to be done later)
Hygienist's name			
Hygienist's signature			
Date (dd)/ (mm)/ (yyyy)			
5. Outcomes evaluation			
	Yes	No	
Dyad attended			
Socio demographic data			
Caries-related knowledge questionnaire			
Clinical caries data			
Weight taken			
Hygienist's name			
Hygienist's signature			
Date (dd)/ (mm)/ (yyyy)			

### DYAD PERSONAL IDENTIFICATION INFORMATION (completed by hygienist)

Name of CLSC	CLSC identification nu	CLSC identification number		
Name of caregiver	(first name)	(family name)		
Caregiver lives with child 50% of time or more	□ ₁ Yes □ ₂ No ( <b>exclude</b> )			
Relationship of caregiver to child	☐ 1 Biological mother ☐ 2 Biological father ☐ 3 Step-parent ☐ 4 Other (specify)			
Name of child:(fin	st name)	(family name)		
Child date of birth: (dd)/ (mm)/	(уууу)			
Child age at recruitment months				
Gender of child: ☐₁ Male ☐₂ Female				
Address where child lives 50% or more of his/he	er time:			
·	<u> </u>			
Contact phone numbers for caregiver:	Home ()	<u></u>		
	work ()			
Name of an alternative caregiver	(first name)	(family name)		
Relationship of alternative caregiver to child:				
Contact phone numbers of alternative caregive	r: Home () Work ()			
Name of person recruiting dyad	(first name)	(family name)		
Date of recruitment(dd)/(mm)/	(уууу)			

### DYAD STUDY IDENTIFICATION INFORMATION (completed by hygienist)

1. Dyad identification (allocated by randomisation centre) :		
	2. CLSC identification number :	]
3. De	ental hygienist identification number :	]
4. Randomization allocation:	□ ₁ Test □ ₂ Control	4
5. Relationship of caregiver to child:	<ul> <li>☐, Biological mother</li> <li>_2 Biological father</li> <li>_3 Step-parent</li> <li>_4 Grandparent</li> <li>_5 Other (specify)</li> </ul>	5
6. Child age at recruitment	months	6
7. Gender of child:	☐₁ Male ☐₂ Female	7
8. How was the child recruited?	<ul> <li>☐₁ Vaccination clinic</li> <li>☐₂ Organised appointment</li> <li>☐₃ Other (specify)</li> </ul>	8

SOCIO DEMOGRAPHIC AND OTHER BASELINE DATA (completed by hygienist)

	Dyad Identification number :
9. At what level did the child's mother finish her	education?
☐, Did not graduate fro ☐₂ Graduated from hig ☐₃ College/Cegep ☐₄ University ☐₅ I don't know	n high school h school 9
10. The <u>yearly income</u> of the <u>child's family</u> (i.e. in child stays 50% or more of the time) is approx	cluding the income of both parents where the ximately
Less than \$15,000 2 \$15,000 - \$29,999 3 \$30,000 - \$49,999 4 \$50,000 or more 6 I don't know	10
11. Does the child have older brothers or sisters	?
□, Yes □₂ No	11
12. (if yes to question 11) Have <u>any</u> of the	m ever had any fillings?
☐₁ Yes ☐₂ No	12
13. (if yes to question 11) Have <u>any</u> of the <u>decay</u> ?	m ever had a tooth extracted because of <u>dental</u>
☐, Yes ☐₂ No	13
14. When was the last time the <u>child's mother</u> or	onsulted a dentist for her own dental care?
Less than 12 mont Between 1 and 2 yı 3 2-5 years ago A More than 5 years Not known	ns ago ears ago ago
15. Child's weight kg	15
16. Dyad lives in area with fluoridated water sup fluoridated areas)	pply? (check home address against list of

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THE EFFECTIVENESS OF A DENTAL CARIES PREVENTION PROGRAM FOR YOUNG CHILDREN

**BASELINE** QUESTIONNAIRES





Faculty of Dentistry McGill University

Dyad Identification number :	
17. When <u>feeding your child</u> do you ever put the spoon you are using in <u>both your child's and your mouth</u> (e.g. lick the spoon clean before using it again to feed the child)?	17
18. If your child's pacifier falls out of its mouth, <u>do you ever clean it by sucking it yourself</u> before replacing it in their mouth? ☐, Yes □, No	18
19. Do you ever <u>clean your child's teeth</u> using something (e.g. a toothbrush) that you have used to clean your <u>own teeth</u> ? Yes □_₂ No	19
20. Yesterday, did the child's mother use chewing gum containing xylitol?	20
$\square_1$ Yes $\square_2$ No $\square_3$ I don't know (if she chewed gum or if the gum contained xylitol)	
21. Does your child have any teeth yet?	21
$[ ]_1$ Yes $[ ]_2$ NO (go to question 24) $[ ]_3$ I don't know (go to question 24)	
22. Yesterday, how often were your child's teeth cleaned?	22
$\Box_1$ Not at all (go to question 24) $\Box_2$ Once $\Box_3$ Twice or more $\Box_4$ I don't know (go to question 24)	
23. Yesterday, when cleaning your child's teeth, how much toothpaste was put on the brush?	
☐, Teeth were not cleaned ☐₂ A pea-size amount ☐₃ The toothpaste covered the brush bristles ☐₄ Teeth were brushed without toothpaste ☐₅ I don't know	23
24. Yesterday, did your child have a mid-morning snack?	
$\square_1$ Yes $\square_2$ No (go to question 26) $\square_3$ I don't know (go to question 26)	24
25. If <u>your child</u> did have a <u>mid-morning snack,</u> what was it? (mark any eaten)	
<ul> <li>Cookies</li> <li>Fresh fruit or vegetable</li> <li>Milk</li> <li>Fruit-juice</li> <li>Soft drink (e.g. Coca Cola)</li> <li>Natural yoghurt</li> <li>Fruit-flavored yoghurt</li> <li>Cheese of any sort</li> <li>Other(specify)</li> </ul>	25

				ļ
26.	Yesterday, did <u>your</u>	<u>child</u> have a <u>mid-afternoon sna</u>	ack?	
	□, Yes	<b>□</b> ₂ NO (go to question 28)		26
	27. If your child did h	nave a <u>mid-afternoon snack,</u> w	hat was it? (mark any eaten)	
			Cookies	
			☐, Fruit-juice ☐, Soft drink (e.g. Coca Cola)	27
			☐ Natural yoghurt	
			$\square_{\bullet}$ Cheese of any sort	
			Other(specify)	
28.	Last night before go	ping to bed, was your child		
		Breast-fe	d (go to question 30)	
		⊡₂ Bottle-teo	d (go to question 29) ing (go to question 30)	28
		☐, I don't kn	IOW (go to question 30)	
	29. If your child was	s bottle-fed last night before go	ing to bed, what was in the bottle?	
	₁ Milk	Ū Ū		
		additive (e.g. chocolate)		
				29
	Fruit juice a     Green fruit juice a	and water cify)		
30	. Last night, did you	r child go to sleep with a bottle	in his/her bed	
		[l₂ NO (go to question 32)	l don't know (go to question 32)	30
	31 If your child did	fall to sleep with a bottle in his	Iner bed, what was in the bottle?	
	∭₂ Milk with an	n additive (e.g. chocolate)		
	☐ Fruit juice			31
	s Fruit juice a	and water cify)		
		••••;;; <u></u>		

32. Has your child bee	n taken to see a	dentist yet?		
∐₁ Yes	₂ No	□]₃ I don't know		32
33. How many times in medicine (e.g. tem	his/her life has pra, antibiotics)?	your child taken	<ul> <li>Never</li> <li>2 Once</li> <li>3 Two or three times</li> <li>4 More often</li> </ul>	33
34. How many times in	his/her life has	your child been <u>prescrib</u>	ed a medication by a physician?	
			<ul> <li>☐₁ Never</li> <li>☐₂ Once</li> <li>☐₃ Two or three times</li> <li>☐₄ More often</li> </ul>	34

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35. What causes tooth decay?			
□, Sugar alone		acteria 🔲 Bacteria alone 🔲, I don't know	35
36. Can bacteria go fi	rom a mother's mo	outh to her baby's mouth?	
[]₁ Yes	□₂ No	□]₃ I don't know	36
37. Could a mother c	hewing gum conta	ining <u>xylitol</u> prevent tooth decay in her baby?	
, Yes	□_₂ No	□]₃ I don't know	37
38. What can be use	d to prevent tooth	decay? (one response only)	
☐, Vitamins	□₂ Antibiotics	□,₃ Fluoride □,₄ I don't know	38
39. When should we	start to clean our o	child's teeth? ☐, As soon as the first tooth appears ☐₂ When the child is 1 year old ☐₃ When the child is 3 years old ☐, I don't know	39
40. Can cookies cau	se tooth decay?		
[], Yes	□]₂ No	☐₃ I don't know	40
41. Can orange juice cause tooth decay?			
, Yes	□]₂ No	□]₃ I don't know	41
42. Can cheese cau	se tooth decay?		
∐₁ Yes	D₂ No	□]₃ I don't know	42
43. Can <u>natural</u> yoghurt cause tooth decay?			
□, Yes	₂ No	□]₃ I don't know	43
44. Can chocolate milk cause tooth decay?			
C, Yes	□ ₂ No	□]₃ I don't know	44
45. Can an apple ca	use tooth decay?		
, Yes	[]]₂ No	☐₃ I don't know	45

# INTERVENTION FIRST VISIT DATA (completed by hygienist)

Dyad identification (allocated by randomisation	on centre):
CLSC identification	on number :
Dental hygienist identification	on number :
46. Date (dd)/ (mm)/ (yyyy)	ļ
47. Child age months	47
48. Dyad presented for intervention □, Yes □₂ No	48
49. Dyad stayed for whole intervention, Yes No	, 49
50. Caregiver present today	50
51. Time for educational intervention only (not recruitment)	minutes 51

## INTERVENTION SECOND VISIT DATA (completed by hygienist)

Dyad identification (allocated by randomisation centre) :	
CLSC identification number :	
Dental hygienist identification number :	
52. Date (dd)/ (mm)/ (yyyy)	
53. Time since previous intervention months	53
54. Child age months	54
55. Dyad presented for intervention □, Yes □₂ No	55
56. Dyad stayed for whole intervention □, Yes □₂ No	56
57. Caregiver present today ☐ Biological mother ☐ Biological father ☐ Step-parent	
⊡₄ Grandparent □₅ Other (specify)	57
58. Caregiver present today , Same as person at first intervention D ₂ Different to person at first intervention	58
59. Caregiver present today $\square_1$ A caregiver (i.e. lives with child 50% or more of the time) $\square_2$ Non-caregiver (i.e. lives with child less than 50% of the time)	59
60. Was the education intervention the same time as the vaccination visit? $\Box_1$ Yes $\Box_2$ No	60
61. Time for educational intervention minutes	61
62. Time when participants arrived and when they departed Total CLSC time minutes	62
63. Time it took for them to get	
A) from home to CLSC: minutes Total travel time min	63
64. What was the transport mode (check the appropriate item(s): 1 Walk, Bus Taxi, Metro Gar, Other	64

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## INTERVENTION THIRD VISIT DATA (completed by hygienist)

Dyad identification (allocated by randomisation centre) :	
CLSC identification number :	
Dental hygienist identification number :	
65. Date (dd)/ (mm)/ (yyyy)	
66. Time since previous intervention months	66
67. Child age months	67
68. Dyad presented for intervention1 Yes2 No	68
69. Dyad stayed for whole intervention □, Yes □₂ No	69
70. Caregiver present today ☐₁ Biological mother ☐₂ Biological father ☐₃ Step-parent ☐₄ Grandparent	
Other (specify)	70
$\square_2 \text{ Different to person at first intervention}$	71
72. Caregiver present today $\square_1$ A caregiver (i.e. lives with child 50% or more of the time) $\square_2$ Non-caregiver (i.e. lives with child less than 50% of the time)	72
73. Was the education intervention the same time as the vaccination visit? $\Box_1$ Yes $\Box_2$ No	73
74. Time for educational intervention minutes	74
75. Time when participants arrived and when they departed Total CLSC time minutes	75
76. Time it took for them to get	1
A) from home to CLSC: minutes Total travel time min	76
77. What was the transport mode (check the appropriate item(s): 1 Walk, Bus 2 Taxi, Metro 3 Car, Other	π

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# INTERVENTION FOURTH VISIT DATA (completed by hygienist)

Dyad identification (allocated by randomisation centre) :	
CLSC identification number :	
Dental hygienist identification number :	
78. Date (dd)/ (mm)/ (yyyy)	
79. Time since previous intervention months	79
80. Child age months	80
81. Dyad presented for intervention Yes No	81
82. Dyad stayed for whole intervention, Yes? No	82
83. Caregiver present today a Biological mother biological father biological father c Biological fathe	83
84. Caregiver present today $\Box_1$ , Same as person at first intervention $\Box_2$ Different to person at first intervention	84
85. Caregiver present today $\square_1$ A caregiver (i.e. lives with child 50% or more of the time) $\square_2$ Non-caregiver (i.e. lives with child less than 50% of the time)	85
86. Time for educational intervention minutes	86
87. Time when participants arrived and when they departed	
Total CLSC time minutes	87
88. Time it took for them to get	
A) from home to CLSC: minutes Total travel time min	88
89. What was the transport mode (check the appropriate item(s): ¹ Walk ² Taxi ³ Car ⁴ Bus ⁵ Metro ⁶ Other	89

 90. What is the estimated distance if traveled by car: ______ km
 90_____

 91. If you had to pay for parking, what was the cost ______ (dollars and cents)
 91_____

 92. If you had to take a taxi, what was the cost ______ (dollars and cents)
 92_____

## **OUTCOMES EVALUATION ATTENDANCE INFORMATION (completed by hygienist)**

Dyad identification	(allocated by randomisation centre) :	
	CLSC identification number :	
D	ental hygienist identification number :	
93. Date (dd)/ (mm)/	(уууу)	ł
94. Child age months		94
95. Dyad presented for evaluation	□₁ Yes □₂ No	95
96. If no, why?	<ul> <li>☐₁ Refused</li> <li>☐₂ Unable to organise appointment</li> <li>☐₃ Unable to contact</li> <li>☐₄ Other (specify)</li> </ul>	96
97. Caregiver present today	<ul> <li>☐₁ Biological mother</li> <li>☐₂ Biological father</li> <li>☐₃ Step-parent</li> <li>☐₄ Grandparent</li> <li>☐₅ Other (specify)</li> </ul>	97
98. Caregiver present today, San	ne as person at first intervention (recruitment) erent to person at first intervention (recruitment)	96
99. Caregiver present today □, A ca □₂ Nor	aregiver (i.e. lives with child 50% or more of the time) n-caregiver (i.e. lives with child less than 50% of the time)	99
		1

SOCIO DEMOGRAPHIC AND OTHER OUTCOME DATA (completed by hygienist)

Dyad Identification number :	]
100. At what level did the child's mother finish her education?	
<ul> <li>Did not graduate from high school</li> <li>2 Graduated from high school</li> <li>3 College/Cegep</li> <li>4 University</li> <li>5 I don't know</li> </ul>	100
101. The <u>yearly income</u> of the <u>child's family</u> (i.e. including the income of both parents where the child stays 50% or more of the time) is approximately	
, Less than \$15,000 ₂ \$15,000 - \$29,999 ₃ \$30,000 - \$49,999 ₄ \$50,000 or more ₅ I don't know	101
102. Does the child have older brothers or sisters?	
$\square_1$ Yes $\square_2$ No	102
103. (if yes to question 102) Have any of them ever had any fillings?	
□, Yes □₂ No	103
104. (if yes to question 102) Have any of them ever had a tooth extracted because of dental decay?	
105. When was the last time the <u>child's mother</u> consulted a dentist?	104
Less than 12 months ago 2 Between 1 and 2 years ago 3 2-5 years ago More than 5 years ago 5 Not known	105
106. Child's weight kg	106
107. Dyad lives in area with fluoridated water supply? (check home address against list of fluoridated	
$\square_1 \text{ Yes } \square_2 \text{ No}$	107

THE EFFECTIVENESS OF A DENTAL CARIES PREVENTION PROGRAM FOR YOUNG CHILDREN

# **OUTCOME** QUESTIONNAIRES





Faculty of Dentistry McGill University

Dyad Identification number :	
108. When <u>feeding your child</u> do you ever put the spoon you are using in <u>both your child's and your</u> <u>mouth</u> (e.g. lick the spoon clean before using it again to feed the child)?	108
[_], Yes [_]₂ No 109. If your child's pacifier falls out of its mouth, <u>do you ever clean it by sucking it yourself</u> before	
replacing it in their mouth? □, Yes □₂ No	109
110. Do you ever <u>clean your child's teeth</u> using something (e.g. a toothbrush) that you have used <u>to</u> <u>clean your own teeth</u> ? ☐, Yes ☐₂ No	110
111. Yesterday, did the child's mother use chewing gum containing xylitol?	
$\square_1$ Yes $\square_2$ No $\square_3$ I don't know (if she chewed gum or if the gum contained xylitol)	111
112. Yesterday, how often were <u>your child's teeth</u> cleaned? ☐, Not at all (go to question 114) ☐ 2 Once ☐ 3 Twice or more ☐ 4 I don't know (go to question 114)	112
113. Yesterday, when cleaning your child's teeth, how much toothpaste was put on the brush?	
☐ Teeth were not cleaned ☐ A pea-size amount ☐ The toothpaste covered the brush bristles ☐ Teeth were brushed without toothpaste ☐ I don't know	113
114. Yesterday, did your child have a mid-morning snack?	
A Yes D₂ No (go to question 116) J don't know (go to question 116)	114
115. If your child did have a mid-morning snack, what was it? (mark any eaten)	
<pre>, Cookies? Fresh fruit or vegetable3 Milk, Fruit-juice</pre>	115

116. <b>Yesterday</b> , did <u>your child</u> have a <u>mid-afternoon snack</u> ?					
□, Yes			116		
117. If <u>your child</u> die	i have a <u>mid-afternoon snack,</u> wha	t was it? (mark any eaten)			
		<ul> <li>☐, Cookies</li> <li>☐₂ Fresh fruit or vegetable</li> <li>G Milk</li> <li>G Fruit-juice</li> <li>G Soft drink (e.g. Coca Cola)</li> <li>G Natural yoghurt</li> <li>G Fruit-flavored yoghurt</li> <li>G Cheese of any sort</li> <li>G Other(specify)</li> </ul>	117		
118. Last night bei	fore going to bed, was your child				
		Breast-fed (go to question 120) Bottle-fed (go to question 119) Fed nothing (go to question 120) I don't know (go to question 120)	118		
119. If your child w	as bottle-fed last night before going	g to bed, what was in the bottle?			
, Milk , Milk with , Water , Fruit juice , Fruit juice , Other (sp	an additive (e.g. chocolate) e e and water pecify)		119		
120. Last night, di	id your child go to sleep with a bott	le in his/her bed			
☐, Yes	☐₂ No (go to question 122)	☐₃ I don't know (go to question 122)	120		
121. If your child d	id fall to sleep with a bottle in his/h	er bed, what was in the bottle?			
☐, Milk ☐₂ Milk with ☐₃ Water ☐₄ Fruit juic ☐₅ Fruit juic ☐₅ Other (sp	an additive (e.g. chocolate) e e and water pecify)		121		

122. Has your child been ever been to see a dentist?

□₂ No

□ I don't know

123. Was the child in the group who came to the CLSC and received education concerning dental health over the course of 4 visits to the CLSC or in the group who received information once at the beginning only?

122_

123_

124 ____

Received dental education four times Received information once only

124. If the child was in the group who received dental education over 4 visits, how many of these education sessions did you attend?



125.	What causes tool	h decay?			
	Sugar alone	₂ Sugar with	bacteria 🔲 🗍	Bacteria alone □ I don't know	125
126.	Can bacteria go f	rom a mother's r	nouth to her bab	y's mouth?	
	Yes	² NO		N	126
127.	Could a mother c	hewing gum con	taining <u>xylitol</u> pre	event tooth decay in her baby?	
	□, Yes	□]₂ No		w	127
128.	What can be use	d to prevent toot	h decay? (one re	esponse only)	
	Utamins	₂ Antibiotics	S Fluoride	☐, I don't know	128
129.	When should we	start to clean ou	r child's teeth?	As soon as the first tooth appears ₂ When the child is 1 year old ₃ When the child is 3 years old	129
130.	Can cookies cau	se tooth decay?			
	, Yes	₂ No		w	130
131.	Can orange juice	e cause tooth dec	cay?		
	□, Yes	□_₂ No		w	131
132.	Can cheese cau	se tooth decay?			
	□, Yes	□_₂ No	₃ I don't kno	W	132
133.	Can <u>natural</u> yogl	hurt cause tooth	decay?		
	, Yes	₂ No	□]₃ I don't kno	W	133
134.	Can chocolate n	nilk cause tooth o	lecay?		
	□, Yes	□_2 NO		W	134
135.	Can an apple ca	use tooth decay	?		
	□, Yes	□_₂ No	□]₃ I don't kno	W	135
					1

Problems with the teeth, mouth or jaws and their treatment can affect the well-being and everyday lives of children and their families. For each of the following questions please mark the box for the response that best describe your child's experiences or your own. Consider the child's whole life from birth until now when answering each question. If a question does not apply, mark "Never".

		Never	Hardly ever	Occasionally	Often	Very often	Don't know	
136	Has your child had <b>pain</b> in the teeth, mouth or jaws?				Π,	<b>□</b> ₅	Π,	136
	Because of dental problems or dental treatments has your child ever							
137	had difficulty drinking hot or cold beverages?			□,	Π,	□₅		137_
138	had difficulty eating some foods?			Π,	Π,		Π,	138_
139	had difficulty pronouncing any words?	Π,		□,	Π.			139_
140	missed preschool or daycare?			<b>D</b> ³	Π,			140_
141	had trouble sleeping?	Π,			Π.	□,		141_
142	been irritable or frustrated?	Π,		Π,	Π.	۵	Π,	142
143	avoided smiling or laughing when around other children?			□,	Π,		□,	143_
144	avoided talking with other children?			Π,	Π,	□,		144_
	Because of your child's dental problems or dental treatments have you or another family member ever			-				
145	been upset?	Π,			Π.	,		145_
146	felt guilty?	Π,			Π.	□,		146_
147	taken time off from work?	Π,			Π.	□,		147_
148	Has your child ever had dental problems or dental treatments that had a financial impact on your family?	Π,		□,	Π.	<b>D</b> 5		148_

149.	In the last 6 months has your child seen a accident (e.g. fell over and broke a tooth)?	dentist di ?	ue to dental pain/tootha	ache other than for teething or an	149
		D, Yes	s □₂ No	□ ₃ I don't know	
	150. If yes, how long	g did the	visit (including travel	time) to the dentist take?	
		[ [ [	]₁ less than 30 min ]₂ 30 to 60 min ]₃ 1 to 2 hours	☐, 3 to 4 hours □₅ longer	150
151.	In the last 6 months has your child seen a or an accident (e.g. fell over and broke a t	tooth)?	doctor due to dental pa	in/toothache other than for teething	151
		Ll₁ Yes	s Ll₂ No	Ll₃ I don't know	
	152. If yes, how long	g did the	visit (including travel	time)to the medical doctor take?	152
		[ [ [	□₁ less than 30 min □₂ 30 to 60 min □₃ 1 to 2 hours	☐, 3 to 4 hours ☐₅ longer	
153	Has your child ever had a filling other than	n for an a	ccident (e.g. fell over a	nd broke a tooth)?	153
			s 🗖 No	□ ₃ I don't know	
	154 If yes, how lon	a did the	visit (including trave	I time) to the dentist take?	
	<b>,</b> ,	5     	$\square$ less than 30 min $\square$ 30 to 60 min $\square$ 1 to 2 hours	□₄ 3 to 4 hours □₅ longer	154
155.	Has your child ever had a tooth extracted	to treat c	<u>lental pain/toothache</u> o	ther than for teething or an accident	
	(e.g. fell over and broke a tooth)?	🗖 , Ye	s □₂ No	□₃ I don't know	155
	156. If yes, how lon	ng did the	e visit (including trave	I time) to the dentist take?	
			□₁ less than 30 min □₂ 30 to 60 min □₃ 1 to 2 hours	□, 3 to 4 hours □₅ longer	156
157	Has your child <u>ever had a general and</u> than for teething or an accident (e.g. 1	esthetic ( fell over a □, Ye	( <u>been put to sleep) to</u> and broke a tooth)? es □₂ No	treat dental pain/toothache other	157
	158. If yes, how lor	ng did the	e <u>visit</u> (including trave $\square_1$ less than 30 min $\square_2$ 30 to 60 min $\square_3$ 1 to 2 hours	el time) to the hospital/clinic take? □, 3 to 4 hours □, longer	158

159.	During the past year, how many times has your	r child been ill?				
		]₁ Never ]₂ Once ]₃ Two or three times	□, Four or five times □₅ more often	159		
160. During the past year, how many times has your child been prescribed a medication by a physician?						
		]₁ Never ]₂ Once ]₃ Two or three times	☐, Four or five times ☐₅ more often	160		

### CLINICAL CARIES OUTCOMES DATA

(to be completed by the hygienist)

Tooth	Mesial	Occlusal	Distal	Lingual	Buccal
55	161	162	163	164	165
54	166	167	168	169	170
53	171	N/A	172	173	174
52	175	N/A	176	177	178
51	179	N/A	180	181	182
61	183	N/A	184	185	186
62	187	N/A	188	189	190
63	191	N/A	192	193	194
64	195	196	197	196	199
65	200	201	202	203	204
75	205	206	207	208	209
74	210	211	212	213	214
73	215	N/A	216	217	218
72	219	N/A	220	221	222
71	223	N/A	224	225	226
81	221	N/A	228	229	230
82	231	N/A	232	233	234
83	235	N/A	236	237	238
84	239	240	241	242	243
85	244	245	246	247	248

Dyad Identification number :

Code: 0 = healthy

1 = D1 (initial – colour change but no substance loss) caries

2 = D2 (substance loss) enamel caries

3 = D3 dentinal caries

4 = D4 pulpal caries



Numéro d'identification de la dyade :

No. d'identification de l'hygiéniste dentaire :

Date :								
	j	j	m	m	а	а	а	а

#### **QUESTIONNAIRE IMPACT**

Les problèmes reliés aux dents, à la bouche ou à la mâchoire ainsi que leur traitement peuvent avoir un effet sur le bien-être et la vie quotidienne des enfants et leur famille. Pour chacune des questions suivantes, s.v.p. indiquez la case qui décrit le mieux l'expérience de votre enfant ou la vôtre selon le cas. Si une question ne s'applique pas, indiquez « Jamais ».

15	Depuis la dernière est-il arrivé quelque de dents, pousse d etc.)?	fois où vous avez rempli ce que e chose aux dents de votre enfa e dents, bris de dents, traitemer		Non Oui	
16	Si oui, qu'est-il	□1 Maux de dents	□₄ Obturatio	on (ploi	mbage)
		□ ₂ Pousse de dents	□₅ Autres ty	vpes de	e traitements dentaires
		$\square_3$ Bris de dents		pécifiez	z)

		Jamais	Presque jamais	Å I'occasion	Souvent	Très souvent	Ne sais pas
17	<u>Au cours de la semaine dernière</u> , votre enfant a-t-il eu de la <b>douleur</b> aux dents, à la bouche ou à la mâchoire?	Π,		□,	۵.	Π,	Π.
	À cause de problèmes dentaires ou de traitements dentaires, votre enfant a-t-il, <u>au cours de la semaine dernière</u> ,						
18	eu de la difficulté à boire des boissons chaudes ou froides?	Π,		□,	۵,		Π,
19	eu de la difficulté à manger des aliments?	Π,		Π,	Π.		
20	eu de la difficulté à prononcer des mots?						
21	eu à manquer la maternelle ou la garderie?	Π,			Π.		
22	eu de la difficulté à dormir?	Π,			Π.		Π,
23	été irritable ou frustré?			□,			Π,
24	évité de sourire ou de rire en présence d'autres enfants?	Π,			Π.		
25	évité de parler avec d'autres enfants?				Π.	□,	

Continuez à l'endos...
		Jamais	Presque jamais	À l'occasion	Souvent	Très souvent	Ne sais pas
26	À cause des problèmes dentaires ou des traitements dentaires de votre enfant, est-ce que vous ou un autre membre de votre famille avez, au cours de la semaine dernière						
	été perturbé et/ou bouleversé?	Π,			Π.	□,	۵.
27	ressenti de la culpabilité?				Π.		
28	eu à s'absenter du travail?	Π,		Π,	Π,	□₅	
29	Votre enfant a-t-il eu des problèmes dentaires ou reçu des traitements dentaires <u>au cours de la semaine dernière</u> qui ont eu <b>un impact financier sur votre famille</b> ?	Π,		□,	Π,	□,	

		Très mauvaise	Mauvaise	Acceptable	Bonne	Très bonne	Ne sais pas
30	Comment évalueriez-vous la santé buccodentaire actuelle de votre enfant?			Π,	Π,	□,	Π,

Nous vous remercions d'avoir pris le temps de remplir ce questionnaire. Veuillez s.v.p.

nous le retourner en utilisant l'enveloppe-réponse pré timbrée.

## **Preliminary Questions**

1. Name of subject
2. Name of patient
3. Address
Phone #
Phone #2
E-mail
4. How do you prefer to be contacted in 1-4 weeks?
$\Box$ by phone $\Box$ at the clinic $\Box$ by mail
5. What is your relationship to the child?
$\Box$ father $\Box$ mother $\Box$ grandparent $\Box$ other
6. What is the child's birthdate? = months
7. Is the child a boy or a girl? $\Box$ boy $\Box$ girl
8. What langauge do you speak most often at home?
□ English □ French □ both □ other
9. In what langauge are you taking the questionnaire?  □ English □ French
10. Over the past 4 months, has your child had any signs symptoms or problems
associated with his/her mouth? $\Box$ yes $\Box$ no
11. Is your child receiving any treatment for that problem today? $\Box$ yes $\Box$ no
12. If your child is receiving treatment, what form is that treatment taking?
<ul> <li>☐ filling</li> <li>☐ root canal therapy/pulpectomy/pulpotomy</li> <li>☐ tooth extraction</li> <li>☐ medication - □ painkiller (Tylenol)         <ul> <li>□ antibiotic (Penicillin V, Amoxicillin, Clindamycin)</li> <li>□ Antiviral (Benadryl, Zovirax)</li> </ul> </li> </ul>

## **Follow-up Questions**

- **1.** Are you the same person who filled out the questionnaire originally?  $\Box$  yes  $\Box$  no
- 2. What is your relationship to the child?
- $\Box$  father  $\Box$  mother  $\Box$  grandparent  $\Box$  other
- 3. How has your child's condition changed since before dental treatment?

 $\Box$  no change  $\Box$  got better  $\Box$  got worse

4. Beyond the treatment performed on your child the day you first completed this

questionnaire, has your child received any other medical or dental treatment since?

🗆 yes 🛛 no

5. If yes, what form did that treatment take?

- □ filling
- □ root canal therapy/pulpectomy/pulpotomy
- $\Box$  tooth extraction
- □ medication □ painkiller (Tylenol)

antibiotic (Penicillin V, Amoxicillin, Clindamycin)
 Antiviral (Benadryl, Zovirax)

□ other_

🗆 I don't know