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# Development of a Pediatric Oral Health-Related Quality-of- Life Questionnaire

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A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements of the degree of M.Sc. in Dental Science.

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## ABSTRACT

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Oral and dental health illness among children is prevalent, and associated impairments are common. However, the impact of these conditions on the lives of children has yet to be determined. The objective of this study was to carry out the initial development phase for an oral health-related quality of life instrument to assess the impact of oral and dental conditions on children aged 3-5 years. Items were generated through literature review, the use of a conceptual model, and by interviewing parents and health professionals. The most frequent and important items were retained to comprise the Pediatric Oral Health Questionnaire, evaluating five dimensions: physical, functional, emotional, and social status, and impact on the family. This preliminary questionnaire is the first to be developed for the measurement of oral health-related quality of life (QoL) in children.

# RÉSUMÉ

Les affections orales dentaires sont répandues chez les enfants, et les handicaps qui leurs sont associés sont communs. Toutefois, l'impact de ces conditions reste toujours à être déterminé. L'objectif de cette étude était d'effectuer la phase de développement initial d'un instrument d'évaluation de la qualité de vie reliée à la santé buccale qui indiquerait l'impact de la condition buccale et dentaire chez les enfants âgés de 3 à 5 ans. Les items ont été générés par une revue de la littérature, la référence à un modèle conceptuel, et par interviews auprès de parents et de professionnels. Les items les plus fréquents et les plus importants ont été retenus pour former le Questionnaire Pédiatrique de Santé Buccale, lequel évalue cinq dimensions : les états physique, fonctionnel, émotionnel et social, ainsi que l'impact sur la famille. Cette version préliminaire du questionnaire est la première à être développée pour la mesure de la qualité de vie reliée à la santé buccale chez les enfants.

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### **INTRODUCTION**

Studies over the past thirty years indicate that oral and dental disorders are seen in high prevalence among children and adults in industrialized and developing countries (Reisine, 1985; Sheiham, Maizels, & Cushing, 1982). Yet, despite the fact that periodontal diseases and caries are among the most prevalent chronic diseases in the general population and the fact that minority populations have poor dental health in epidemic proportions (Sheiham et al., 1982; Tinanoff, 1998; Tinanoff & O'Sullivan, 1997), the impact of these conditions on quality of life has received little attention as a crucial health issue (Reisine, 1985, 1988).

The prevalence of oral and dental disorders (diseases) in pre-school children varies between 17-35 %, (Coulter, Marcus, & Atchison, 1994; Moynihan & Holt, 1997; O'sullivan & Tinanoff, 1996; Tinanoff & O'Sullivan, 1995) with early childhood caries considered to be one of the most common conditions. Studies show a frequency of early childhood caries of 1-12% in developed countries, up to 70% in developing countries, and also as high as 70% within disadvantaged populations in developed countries (Harding & Camp, 1995; Milnes, 1996). As supported by recent studies in the UK, Scotland and Canada, (Jones & Worthington, 1999; Riley, Lennon, & Ellwood, 1999; Smith, 1998; Sweeny, Nugent, & Pitt, 1999) there is also a strong association between tooth decay, caries experience and social status.

Surveys of dental health in developing countries indicate that children have a declining rate of tooth decay because of water fluoridation and the use of alternative fluoride sources (Gibson & Williams, 1999; Kumar, Swango, Lininger, Leske, Green, & Haley, 1998; Obry-Musset, 1998). However, there is still a big concern about the number of pre-school children who still require invasive treatment for dental decay. As Wendt, Hallonsten, and Koch (1999) recently reported, "from 3 years of age, the prevalence of caries increases up to the age when the primary dentition exfoliates, and for some children dental caries remains a significant problem".

The early instruments used in most industrialized countries to assess the oral health of adults and children were mostly clinical indicators of the existence and prevalence of oral diseases. The focus was primarily on the disease process and its pathological manifestation. Examples of disease-based indices or clinical indicators are the DMF index (decayed, missing, filled) for caries, the Russell Index for periodontal disease, and the MTSI (malocclusion treatment severity index).

However, with the change in the definition of health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO, 1958), a new status of health had to be measured, meaning a new method needed to be devised.

To this end, a number of instruments have been developed that assess the extent to which oral and dental disorders compromise the quality of life of an individual. Highly evolved methodology concerning health status assessment and measurements are now used, and they also measure the burden poor health has placed on society. For example, these new instruments have played an essential role in oral health investigation by allowing researchers to broadly assess the oral health status of the population over the past ten years. Although subjective oral health status indicators were shown to be valid as useful tools for measuring the impact of oral and dental health on quality of life (Atchison & Dolan, 1990; Cushing, Sheiham, & Maizels, 1986; Leao & Sheiham, 1996; Locker & Miller, 1994; Slade & Spencer, 1994), as of now, these instruments have been used exclusively with adults. Thus, the potential impact of oral and dental dental disorders on the functional, emotional and social well being of children and their families has not yet been explored.

Children's health is currently conceptualized as the ability to participate fully in developmentally appropriate physical, psychological and social tasks (Cushing et al., 1986). This conceptualization calls for a multi-dimensional instrument that would measure these various domains while complementing the traditional clinical measures of oral and dental health. This would allow researchers to evaluate oral health care services for children and then identify the pediatric groups with the highest levels of oral health care needs in order to appropriately allocate resources and develop oral health care programs.

In the field of medical pediatric research, the impact of health-related quality of life is a significant research area, and a number of instruments have been developed over the last ten years to meet the increasing need for this kind of pediatric health outcome assessment. Although several of the developed instruments are generic, ((Eisen, Donald, Ware, & Brook, 1980; Fink, 1989; Landgraf, Abetz, & Ware, 1996; Lewis & Pantell, 1989; Ruth, Stein, & Jessop, 1990; Starfield, Bergner, Ensminger, Riley, Ryan, Green, et al., 1993), the majority are disease-specific. They are also mostly concept-specific, meaning that they focus on one or more health status domains (Bradlyn, Harris, Warner, Ritchey, & Zaboy, 1993; Christie, Sowden, & West, 1993; Eiser, Havermans, Craft, & Kernahan, 1995; French, Christie, & Sowden, 1994; Jenny, Kane, & Lurie, 1995; Juniper, Guyatt, & Jaeschke, 1996; Lewis-Jones & Finlay, 1995).

The lack of comprehensive multi-dimensional, age-specific instruments that capture psychological and social health is basically due to the methodological difficulties in developing pediatric measures for the "moving target" of a developing organism (French & Christie, 1996; Pal, 1996). For example, activities of daily living have a different content among different age groups, making it difficult to standardize measures of functional, emotional and social limitations among children who are not of the same age.

The scarcity of reliable and appropriate instruments has meant a lack of welldocumented research on the oral health-related quality of life in children. Thus, this project was undertaken for preliminary development of a self-administered multidimensional parental perception questionnaire of the impact of oral and dental health on the lives of children aged 3-5 years and their families. This project was conducted in parallel with Locker and colleagues at the\_University of Toronto, who are developing a multidimensional oral health outcome measure for the impact of oro-facial disorders in children aged 6-13 years.

Children ages three to five are of particular interest because they are at\_high risk for developing oral health and dental problems. Although their primary teeth have all erupted, children of this age are undergoing a transformational stage in dietary habits where improper bottle feeding habits become a significant risk factor for nursing or early childhood tooth decay. In addition, this is a time when age and cognition are not yet adequately developed for proper self oral hygiene practice.

Yet another unique characteristic of this particular age group is their underdeveloped concept of pain, and how it is expressed in the context of ongoing speech development. Vignarajah and Williams (1992) reported that small children might not yet have adequate dexterity to brush their teeth daily. as well as the ability to brush thoroughly. Furthermore, habits such as thumb sucking, sleeping with a feeding bottle, and snacking make children of this age group more susceptible to dental caries as well as other oral and dental conditions such as gingivitis, mouth sores and dental infections (dental abscesses). In addition, children with congenital anomalies such as cleft palate, non-syndromal and syndromal oligodontia and anhydrotic ectodermal dysplasia, are still too young to have their oro-facial conditions permanently resolved.

The first chapter of this discussion presents a review of the literature on various concepts of health and disease, as well as assessments of oral health. Concepts and measurements regarding the health-related qualities of children's lives and other issues of importance in the development of QoL measurement instrument are also presented. This chapter also offers the rationale behind the interest in measuring health-related QoL in children with oral and dental disorders and demonstrates that no such instrument presently exists.

The second chapter outlines the objectives of the present study and details the methodology. It describes how the instrument was developed, as well as the subjects' characteristics, ethical issues, procedures and analyses.

The third chapter reports the results of the present study. In this section, the results of the item generation, the interviewing process, item reduction, the formatting of the questionnaire, and the readability of the latest version of the questionnaire processes are described.

The final chapter discusses the results, findings and limitations of the study. After a brief conclusion, areas of future questionnaire development are proposed.

# **CHAPTER 1**

### **Literature Review**

#### **1.1 Introduction**

The development of a health-related quality of life measure requires a thorough understanding of the concepts of health, disease and quality of life.

#### 1.2 Concepts of health and disease

The concept of health and its application in dentistry have been discussed in the literature extensively and are based on various theoretical approaches and conceptual frameworks. The shift in the conceptualization of health from the medical model to the socio-environmental model involves a change in the thinking of what constitutes health and the strategies necessary to measure it. In the medical model, the oral cavity is considered an autonomous anatomical structure located within the body, and there is a tendency to isolate it from both the body and the person (Locker, 1988).

However, the socio-environmental model of health exemplified by the medical model has increasingly challenged the traditional approach by defining health as optimal functioning and social and psychological well being, as well as the absence of disease. (Lerner & Levine, 1994).

Thus, a distinction between disease and health is drawn from these two paradigms of health. This was initially articulated in the World Health Organization's definition of health. Accordingly, disease can be defined as a pathological process, which affects the biological and functional integrity of the body. The biological concept of this definition comes from the medical paradigm, which focuses on etiological and physiological parameters of clinical outcomes. However, since health can be defined as "an individual's subjective experience of his/her functional, social and psychological well being", it is therefore necessary to apply sociological and psychological tests when assessing someone's health. In fact, it is this socio-environmental paradigm that has led to the development of ways to measure perceptions. feelings and behaviors (Locker & Slade, 1993).

This distinction between health and disease leads us to an understanding and evaluation of the current definition of oral health. Yewe-Dewyer (1993) defines oral health as "a state of the mouth and associated structures where disease is contained, future disease is inhibited, the occlusion is sufficient to masticate food, and the teeth are of a socially acceptable appearance". This definition, while attempting to cross the separation between medical and socio-environmental paradigms by referring to functional and social concepts, still remains largely within the medical and biological concepts by focusing on the mouth rather than the person.

Another definition of oral health is "a comfortable and functional dentition which allows individuals to continue in their desired social role" (Dolan, 1993). While the components of this definition are comfort, function and social role, this description

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manages to place oral health within the realm of health at the level of the person, as opposed to being mouth-centered.

With this range of oral health definitions, Locker (1997) suggests that we need to focus not just on the oral cavity itself, but also on the individual and the way in which oral diseases, disorders and conditions threaten health and the quality of life. In this regard, oral diseases and disorders are no different from those diseases and disorders that affect other locations in the body.

#### **1.3 Assessment of Health**

The assessment of health can be classified into two general categories: objective and subjective measurement. The former relies almost entirely on clinical indicators of mortality and morbidity. However, where death rates are rather low, mortality rates are inadequate indicators of health because they fail to assess the burden of illness and disability imposed by disease that does not end by death. On the other hand, morbidity, although reflecting the wider range of disease, has the disadvantage of being less readily available and may vary in quality (Hunt & McEwen, 1980).

The early instruments of measurement used to survey dental health in most industrialized countries were mostly clinical indicators that assessed the physical signs and symptoms and provided objective evidence of the presence and severity of oral disease. These clinical measures focused primarily on the disease process and were professionally based, i.e., the professionals, not the patients, made the assessments. The most popular example of clinical measures is the DMFT (DMFS) Index, which refers to decayed, missing and filled teeth or surfaces (Knuston, 1940). It is considered to be one of the commonest methods of describing dental health, and has been used widely in dental health surveys since the early 1970s. This measure does have a number of limitations, however (Sheiham et al., 1987). The relevance of the DMF value to caries experience implies that both missing and filled teeth were once carious (Jackson, 1974; Murray, 1971). This, despite the fact that loss of teeth after a certain age (probably around 25 years old) is in part due to periodontal disease as well as caries. Birch (1986) criticized the DMF's failure to detect changes in the quality of teeth; for example, the transformation of a decayed tooth into a filled tooth has no effect on the DMF value.

Cushing et al. (1986) points out that the index does not identify the functional state and perceived health status of individuals. This makes the index less credible given that regular attenders may have more restorations than irregular attending patients.

Other indicators of dental health status have also been described, such as the Functional Model by Sheiham in 1987. This conceptualization of dental well-being has two indicators: one that takes into account the number of functioning teeth, (the total of filled and sound teeth), and the number of sound-equivalent teeth, (defined as a weighted average of sound, filled, and teeth with some decay), and another called the Tissue Health Index, a concept where the weights being proposed represent the correspondent amounts of sound tissue in these three categories of teeth.

Other indices used to assess periodontal health include the Periodontal Index (Russell, 1956), which has been commonly employed in epidemiological studies. However, the inability of this index to indicate a reliable estimate of treatment need has led to the development of the Community Periodontal Index of Treatment Need (CPITN) (Ainamo, Barmes, Beagrie, Cutress, Martin, & Sardoinfirri, 1982). This index measures

clinical parameters of periodontal disease such as bleeding on gingival probing, calculus and pocketing.

Clinical measures are usually designed for specific oral conditions, but a number of indices have been developed that include other essential aspects such as caries, periodontal disease, occlusion, mucosal health and patient comfort, e.g., the Oral Health Status Index (OHSI) (Marcus, Koch, & Gershen, 1980). In this index, the three components of DMFT and 15 other factors such as tempromandibular dysfunction, periodontal disease and tumors are assessed.

Koch, Gershen, and Marcus (1985) have also designed an oral health indicator for children, which includes four clinical parameters: decayed teeth, missing teeth, tooth position and occlusion. This index is designed for use as a method of direct assessment of pediatric patients in dental clinics or school programs.

Even though physical signs and symptoms are major constituents of oral health, it is not sufficient to measure signs and symptoms alone, as this gives no information of the extent to which a person's life is disrupted. In addition, clinical measures are important for describing, assessing and diagnosing oral and dental conditions. Therefore, the information yielded solely by physical signs and symptoms cannot be interpreted in terms of health, since the WHO defines it as "a state of complete physical, psychological and social well being and not merely the absence of disease" (WHO, 1958). The presence of self-described discomfort, pain or poor self-esteem as a symptom or functional barrier affects well-being and influences behavior, yet is not measured by any of the traditional clinical indicators. Thus, a major shortcoming in such clinical measures is the inability to reflect the "capacity of individuals to perform desired roles and activities" (Mechanic, 1995). This means that an appropriate assessment of oral health should include measures that look at the impact of oral and dental disorders on the patient's quality of life, as well as the extent to which these disorders disrupt normal role functioning (Locker, 1988).

#### 1.4 The Concept of Health-Related Quality of Life

Health-related quality of life is a broad concept of health that encompasses the traditional clinical meaning of the term, as well as an individual's subjective evaluation of the impact of health on well being and functioning in daily life (Stewart & Ware, 1992). This multi-dimensional view of health is receiving growing attention, echoing the definition of health proposed by the World Health Organization mentioned above. Central to this idea is the recognition that health and quality of life result from a combination of biomedical and psychosocial factors, some of which have not yet been completely elucidated.

No definition, however, has ever been universally accepted between researchers (Cook-Gotay, Korn, McCabe, Moore, & Cheson, 1992). Quality of life has been associated with a sense of well being (Padilla, Grant, & Newton, 1988; Selby & Robertson, 1987), self esteem and minimal anxiety (Lewis, 1982), happiness (Beckman & Ditlev, 1987), physical functioning (Karnofsky, Abelmann, Craver, & Berchenal, 1948) and functional capacity (Aaronson, 1989). Several other studies have found that quality of life must be defined as a multi-dimensional construct for it to reflect the

person's true situation (Campbel, Converse, & Rogers, 1976; Lewis, 1982; Spitzer, Dobson, Hall, Chesterman, Levi, Shepard, et al., 1981).

Despite this disparity, certain dimensions are commonly included in measures of health-related quality of life, such as physical and occupational functioning, general well being, psychological states, social interaction, somatic sensation, and role performance since all are affected by disease or treatment. Some investigators also add a financial component to quality of life measurement (Padilla, Present, Grant, Metter, Lipsett, & Heide, 1983) since one's financial situation may also have an effect on their QoL.

Contrary to generic measures that are meant to be used across a large spread of people, disease-specific measures can also include symptom dimensions that are related to a particular disease or treatment.

Various approaches have been used in attempts to define HRQoL. For example, the identification of components that contribute most to cancer patients' views of their QoL show that psychological well-being was more important to patients than physical well-being, and that symptom control was least important (Padilla & Grant, 1985). Spitzer et al. (1981) surveyed cancer sufferers and healthy people and found that both groups based their QoL on daily living activities, health, occupation, and social support. Conversely, Stewart and King (1994) focused on physical functions, cognitive functions, social functioning, perceived health, pain and discomfort, and self-esteem in their QoL measures. When Geddas (1985) asked hospitalized lung cancer patients to define QoL, they based it on happiness, health, being able to do what you want and not being a burden on others.

In 1994, the Center for Health Promotion at the University of Toronto developed a definition, which states "quality of life is the degree to which a person enjoys the important possibilities of life" (Locker, 1997). This definition proposes that quality of life has meaning only at a personal level, and it respects the autonomy of the individual by acknowledging that patients can provide information about what is in their own best interest.

A large number of instruments measuring health-related QoL also exist. One approach is through the use of generic measures, which provide a summary of HRQoL. Generic instruments are applicable in a wide variety of populations and for comparison across populations because they cover the complete spectrum of functions, disabilities and distress that are relevant to quality of life. They also have a use in economic evaluations. However, generic measures do not focus on areas of interest or may not be sensitive enough to detect differences or change, as well as having a limited ability to capture the effects of certain interventions (Guyatt et al., 1989).

An alternative approach is through the use of specific measures, which can be particular to a disease, a population of patients (e.g. the elderly), a certain function (e.g. emotional function), or to a given condition or problem (e.g. pain) that may be caused by various diseases. This narrow focus means that specific measures are potentially more responsive to small, but clinically important changes in health.

Only a few examples will be presented here for health-related quality of life approaches, both generic and disease-specific. The choice of a generic instrument is often based on how frequently it has been used in other studies or whether it has demonstrated sound psychometric properties. Because of the availability of health-related quality of life

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measures specific to oral health, the literature review will also provide some examples of oral health status-specific measures.

The Sickness Impact Profile (SIP) (Bergner, Bobbitt, Kressel, et al., 1976; Bergner, Bobbitt, Carter, et al., 1981; Gilson, Bergner, Bobbitt, Kressel, Pollard, et al., 1975) is a well-established, comprehensive multi-dimensional generic instrument essentially designed to measure outcome of care, as well as patient progress. It has been used in both clinical settings and health surveys. The SIP consists of 136 items and 12 sub-scales, and can be administered by an interviewer or self-administered. Patients are rated on a range of possible scores from 0 (dead) to 100 (normal functioning). In the development study using a sample of patients with three health conditions, hyperthyroidism, rheumatoid arthritis, and hip replacement, test-re-test reliability (r = (0.92) and internal reliability (r = 0.94) was high. It was also shown to have acceptable convergent and discriminant validity with moderate to high criterion validity. The SIP has been used to assess numerous health conditions and treatments, such as cardiac rehabilitation (Ott, Sivarajan, & Newton, 1983), total hip joint arthroplasty, and treatment of back pain (Devo, Diehl, & Rosenthal, 1986), but it has not been frequently used in studies of oral health. In two studies looking at the quality of life and functional status of oral cancer patients, SIP has been employed with good results (Langlus, Bjorvell, & Lind, 1994; Hassan & Weymuller, 1993). It has been shown to be sensitive to cancer stages, responsive to changes over time and to the type of treatment. In another study of patients presenting with periodontal diseases, tempromandibular disorder and regular check-ups, SIP was used in an attempt to assess the utility of generic measures to assess oral health status (Reisine, 1988; Reisine & Weber, 1989). The results demonstrated that SIP could

be useful in evaluating the functional status of conditions that are expected to have higher impacts, such as tempromandibular dysfunction. However, it could not effectively assess the impact of minor oral health problems. In a recent study of health-related quality of life following orthognathic surgery (Hatch, Rugh, Clark, Keeling, Tiner, & Bays, 1998), SIP was used together with the Oral Health Status Questionnaire, which was designed specifically for orthognathic surgery patients. In particular, SIP showed its usefulness as a measure of impact when used in combination with a disease or a condition -specific instrument. Employing the SIP in oral health studies would have the advantage of being a well-established instrument and placing oral health within the broader conceptual framework of health status. However, the length of the instrument and the apparent lack of sensitivity to oral-facial impacts on functional status would be its major limitations.

The SIDD measure (social impact of dental disease) (Cushing et al., 1986) is one of the first socio-dental indicators that address the failure of conventional clinical measures to include evaluation of the impacts of disease and impairment on the individual's well being. It consists of five categories of impact: eating restriction, communication restriction, pain, discomfort, and esthetic dissatisfaction. The score for each individual is constructed from responses to questions relating to those five categories. A score of 1 is given in the impact category if a positive response has been given to any of the questions in the category. The instrument was first tested in England, and the author reported good test-retest reliability, as well as showing that all the impact measures were related to some aspect of clinical dental caries status. The numbers of impacts were also correlated to two composite indicators of dental health: the Functional Teeth and Tissue Health. Results showed that people with no impacts at all, no eating, communication or aesthetic impacts had a greater number of functioning teeth, thus providing correlational validity (Sheiham, Maizels, & Maizels, 1987; Marcenes & Sheiham, 1993).

Despite the ease of application of this measure and its relevance as being one of the first oral health status instruments, it nonetheless needed further development, particularly in relation to impact weighing, so as to reflect disability and handicap (Cushing et al., 1986). This instrument is included, however, because it was one of the first successful attempts to measure oral health in the context of the impact of oral and dental diseases on the general well being and the quality of life of the individual.

The Oral Health Impact Profile (OHIP) is considered a sophisticated measure (Slade & Spencer, 1994) that complements traditional and epidemiological indices of clinical diseases. It consists of 49 items, categorized into seven conceptual dimensions: functional limitations, physical pain, psychological discomfort, physical disabilities, psychological disability, social disability, and handicap. It uses a five-point Likert scale to measure seven multi-item dimensions of impact by asking respondents how frequently they experience each item within a reference period. Response categories range from "very often" to "never", with each subscale score ranging from zero (no impact) to 40 (all impacts reported "very often"). Internal reliability has been assessed with variable results of the Cronbach alpha coefficient, ranging from moderate (0.7) to high (0.9) (Locker & Slade, 1993; Slade & Spencer, 1994; Slade, Hoskin, & Spencer, 1996). Test-retest reproducibility was evaluated in a cohort study of 122 persons aged 60 years and over, and established an intraclass correlation coefficient of 0.42-0.77, demonstrating stability.

demonstrated results of  $\delta = 0.34$  to  $\delta = 0.68$ , which shows moderately strong, statistically significant correlation.

Because of its reliability and validity, the OHIP has been used in many epidemiological studies. Compared with general dental patients, findings reveal higher scores among people who have poorer clinical oral status (Hunt, Slade, & Strauss, 1995; Locker & Slade, 1994; Slade et al., 1996), socially and economically disadvantaged groups (Hunt et al., 1995; Locker & Slade, 1994; Slade & Spencer, 1994; Slade et al., 1996), and among patients with HIV infections, (Coates, Slade, Goss, & Gorkic, 1996). In a study of older adults living independently, OHIP also showed stability in scores during a two- year follow-up (Hunt et al., 1995; Slade & Locker, 1993; Slade & Spencer, 1995). In addition to the use of OHIP in cross-sectional studies, recently it has been employed in many longitudinal studies and clinical trials on oral health. As previously reported, most of the studies that employed the OHIP looked at an adult population, the elderly in particular.

The Oral Health-Related Quality of Life measure (OHQoL) is a brief three-item instrument concerning the possible effects of oral diseases on daily activities, social interaction and avoidance of conversation because of appearance. Item responses for each are scored on a six-point scale ranging from 1 (all of the time) to 6 (none of the time); thus a higher score equals better oral health quality of life. This instrument exhibits good psychometric properties, including good internal consistency reliability with Cronbach's alpha of 0.83 and association with general life satisfaction. In studies using the OHQoL, (Kressin, Spiro, Bosse, Garcia, & Kazis, 1996) the results indicate that the instrument is sensitive to differences between samples; i.e., sicker, more socio-economically

disadvantaged samples have worse OHQoL scores and exhibit different patterns of correlation with overall health-related quality of life. Although considered an ideal instrument for population surveys due to its brevity, this same briefness is also the weakness of this measure, as it cannot assess much detail about specific impacts of oral diseases on QoL.

The Dental Impact on Daily Living (DIDL) (Leao & Sheiham, 1996) is one of the few measures that include items to assess five dimensions of quality of life, in addition to a scale, which assesses the importance respondents' attribute to the different dimensions. It consists of 36 items in five categories: comfort, appearance, pain, performance and eating restriction. The scores of items range from +1 (positive impact), 0 (impacts not totally negative), and -1 (negative impacts). This scale is used together with a questionnaire that has a number of identical scales. Each has a sliding arrow the respondent can move: the higher the arrow is placed, the higher the importance attributed to the corresponding dimension. Multiplying each dimension score by its weight (importance) and then adding them all up achieve the total score. Instrument scores range from 0 (unsatisfied) to 10 (satisfied). Reliability assessment of the questionnaire and the scale yielded good results with reliability coefficients of 0.87 and 0.78, respectively. Construct validity was established through a correlational study with clinical measures. The instrument has also been tested for responsiveness and shown to be sensitive to change with an increase in positive impacts after dental treatment. One aspect that favors this instrument is the degree of flexibility offered in terms of aggregating and disaggregating data: individual item, dimension scores or a total score. Another advantage is that the importance attributed to a dimension by a given individual is

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directly associated with his/her own impacts on that dimension, a benefit if doing comparative studies of different cultures or different ethnic backgrounds.

#### 1.5 Health-related quality of life in children

As recently as the early 1990s, health-related outcomes in children were still being predominantly defined in terms of morbidity and mortality. This, despite the fact that health measures have been used in population-based studies of children (Eisen, Donald, et al., 1980; Eisen, Ware, et al., 1997) and conceptual and methodological challenges have been identified and discussed in the literature (Landgraf, Abetz, & Ware, 1996; Starfield, 1987). The conceptual framework of health as "a state of complete physical, psychological and social well-being and not merely the absence of disease or infirmity" (WHO, 1958), and the evidence that physical and psychological components impact health, is strongly supported for adults. As a result, several measures of health-related quality of life have been developed over the past 30 years that are well tested, reliable and valid, and therefore widely used in population-based studies and clinical trials (Bergner & Rothman, 1987; McDowell & Newell, 1987; Patrick & Deyo, 1989; Ware & Sherbourne, 1992).

Subjective assessments of health status, while robust for adults, pose substantial methodological difficulties when applied to children. One of the challenges is that a child's normal development trajectory is characterized by change. They are still evolving and undergoing major changes, including interactions between biological and environmental factors, which influence the level of their dependency. A child's progression through these various stages of development makes it difficult to establish

what constitutes a "normal" or "abnormal" status. In other words, there is much less agreement on the normal roles and functions of children at each age, both within and between different social contexts, than there is for adults.

In adults, good health is often defined as the ability to be self-sufficient and economically productive (Pal, 1996). In contrast, complete self-sufficiency is not expected in children, whereas age-appropriate cognitive psychological, social, and physical developments are important considerations. Ill health may be manifested by deceleration in the rate of attainment of normal features, rather than through evidence of abnormal form or function (Pal, 1996). It becomes difficult, therefore, to determine whether failure of a child to achieve a certain area of independent function is part of the normal development process, a result of an environment that fosters development, or the loss of ability to function because of illness (Pal, 1996).

The complexity of these issues has led some to be entirely skeptical of the feasibility of measuring health status in young children (Pantell & Lewis, 1987; Rosenbaum & Saigal, 1996). Another difficulty encountered when measuring the health-related quality of life in children is the question of whose subjectivity should be sought. Parents and health professionals can differ markedly in their perspectives about children's health status (Pal, 1996). Significant areas of discord can also exist between children and their parents in reports of functioning, knowledge of what constitutes age-appropriate functioning, obtainment of accurate information and demonstration of the predictivity of health status measures (Abberley, 1992; Fletcher, Gores, Jones, Fitzpatrick, Spiegelhalter, & Cox, 1992). Furthermore, the parent's cultural, educational and social background, as well as the specific experience of the parents with their children may influence their

responses (Hack, 1999). In fact, little is known about the extent or implications of parentchild differences in perceived health status (For example, the aspects of functioning that children of different ages view as important, or aspects of adult functioning predicted by child health status measures) (Lewis & Pantell, 1989). Yet however challenging the task, there is a need for parents to act as proxy for children, especially when very young, in obtaining health status functional and quality of life measures (Hack, 1999).

Despite these difficulties, several groups have attempted to develop pediatric health status, as well as functional and quality of life measures since the late 1970s. In the medical field, health-related QoL became a significant research area ever since the American Academy of Pediatrics gave it emphasis in 1984 (Fink, 1989). Accordingly, a number of instruments have been developed to meet the growing demand for pediatric health outcome assessment. The majority of these instruments are disease-specific (Bradlyn et al., 1993; Christie et al., 1993; Eiser et al., 1995; French et al., 1994; Jenny et al., 1995; Juniper & Guyatt, 1996; Lewis-Jones & Finlay, 1995), and several are generic (Eisen et al., 1980; Fink, 1989; Landgraf et al., 1996; Lewis & Pantell, 1989; Ruth et al., 1990; Starfield et al., 1993). Generic instruments are designed to be applicable to patients with all medical conditions. The main advantage of such measures is that the burden of illness can then be compared across different medical conditions. However, because they are usually broadly comprehensive in order to cover all diseases, these instruments may fail to measure specific and important impairments associated with any one condition. On the other hand, the strength of specific instruments is that they focus on the areas of function that are most important to a particular patient population; therefore they are much more responsive to small but important changes in HRQoL (Juniper &
Guyatt, 1996). Since no oral health-specific instruments exist for use with a juvenile population, this review will deal with examples of generic measures developed in the medical field specifically for children.

The Functional Status II-R is a good example of a generic instrument that operationalizes the comprehensive concepts of health, while also tapping into the physical, psychological, and social aspects of a child's functioning. It is an intervieweradministered measure of the parent's perceptions of the impact of illness on their children's functioning (Pantell & Lewis, 1987) including a long version (43 items) and a short version (14 items), with each item (question) having two parts. Part 1 asks whether the child can perform the specified activity or exhibits a specified behavior "never or rarely", "some of the time", or "almost always". Part 2, administered after the completion of Part 1, probes those items in Part 1 that reflect poor functioning in order to determine whether a given functional or behavioral impairment was due "fully", "partially", or "not at all" to a health problem. Ruth et al. (1990) have extensively tested and revised this instrument, and their data suggest that this instrument has an acceptable internal reliability of alpha >0.8, that it distinguishes between well and ill children, and that it shows criterion validity with respect to traditional indicators of children's health, such as days of hospitalization and global evaluations by parents. Furthermore, this instrument is useful for the evaluation of disease impact across a broad range of chronic illnesses. However, although the FSII-R is comprehensive, applicable to the entire childhood age range from 0 to 16 years, and provides excellent psychometric properties, one of its problems relates to its usefulness as a self-administered instrument. This instrument was successfully modified so that it could be completed as a brief questionnaire by parents (Lewis & Pantell, 1989). The time required for administration was reduced considerably (from 30 to 10 minutes), and internal reliability was nearly comparable to the original. This suggests that the modified version can be used in clinical settings or research studies in which a 30-minutes interview is not feasible. Nevertheless, the original instrument has been much more extensively tested and validated.

A large number of projects and studies have employed the FS II-R (McCormick, McCarton, Tonascia, & Brooks-Gunn, 1993; Olson Boyle, Evans, & Zug, 1993). However, because it focuses mainly on physical functioning, some consider it to be a functional measure only, and not a true QoL measure (Bergner & Rothman, 1987).

The Child Health and Illness Profile (CHIP) is a self-administered questionnaire that was developed primarily for individuals aged 11 to 17 (Starfield et al., 1993). It consists of 107 items in six health domains: Activity, Discomfort, Satisfaction with Health (perceived well-being), Disorders, Achievement, and Resilience. Each domain includes a different number of sub-domains; for example, the comfort domain includes acute symptoms, functional symptoms, and emotional state sub-domains. Domain scores are obtained by averaging the sub-domain scores. In the development of this instrument, acceptable standards for reliability were achieved for each domain except the disorder domain, since there was no reason to expect different illnesses to be related to each other. In a sample of 121 adolescents with diverse health status; complete health, acute and chronic illness, or emotional and behavioral problems, construct validity was examined by comparing scores for each of the sub-domains. It was determined that the scores differed in the predicted ways according to illness group, age, or gender. In a population-based study by Starfield et al. (1995), iterative testing provided more evidence of the adequacy of this instrument based on psychometric testing in eight schools in three diverse urban and rural areas. In addition to the appropriateness of this instrument to assess the health status for populations and sub-populations of adolescents, CHIP-AE can also be employed to assess changes over time or in response to health service interventions targeted at groups of adolescents (Starfield et al., 1995).

The Child Health Questionnaire (CHQ) was constructed to measure the physical and psychological well being of children five years of age and older. Three versions of the parent-completed child health questionnaire were developed with 87, 50, and 28 items respectively. Each form encompasses 14 health concepts including: Physical Functioning, Role/Social Emotional, Role/Social Behavioral, Role/Social-Physical, Bodily Pain, General Behavior, Mental Health, Self Esteem, General Health Perception, Change in Health, Parental Impact-Emotional, Parental Impact-Time, Family Activities, and Family Cohesion. A different scoring category is employed for different scales. A four-week recall period is used for all scales except for the Change in Health, Family Cohesion items and the General Health scale. The recall stem for Change in Health is compared to "last year", while General Health and Family Cohesion scales have no recall period. Higher scores signify better health related QoL, and this instrument has been shown to have good reliability with diverse populations of clinical conditions, with the internal reliability coefficient ranging from 0.75 to 0.84. Validity was also established in representative samples of both healthy and ill subjects with conditions such as epilepsy, rheumatoid arthritis, and attention deficit hyperactivity disorders (Landgraf et al., 1996). In an outcome study of epilepsy surgery (Gilliam, Wyllie, Kashden, Faught, Kotagal,

Bebin, et al., 1997), CHQ was shown to be a valid measure when comparing score results between a surgical group and an age-matched control group. The Child Health Questionnaire was translated into Canadian French, German and United Kingdom English (Landgraf, Maunsell, Speechley, Bullinger, Campbel, Abetz, et al., 1998). The item-scaling results obtained in these pilot studies supported the psychometric properties of the original American English CHQ-PF 50 and its respective translations.

#### 1.6 Issues related to Quality of Life Measures

For an assessment tool to be accepted, it must meet the requirements of being simple, relevant, and capable of rapid completion (Gough & Furnival, 1983). Nevertheless, good psychometric properties add to the usefulness of the tool. In the past, medical professionals often frowned upon self-administered questionnaires, since it was believed that the information derived from interviews is more comprehensive and complete. This attitude is changing, however, and it is now accepted that selfadministered questionnaires are the most efficient, practical and inexpensive method of obtaining patient-based information (Aaronson, 1989). The use of self- administered questionnaires also implies a certain regard for the patient (or caregiver) by recognizing that those affected by an illness are the ones most knowledgeable of their individual concerns and problems (Chubon, 1987). Still, one must always consider the respondent's ability to complete the questionnaire and acknowledge the vulnerability of selfadministered questionnaires to interpretation inconsistencies. Therefore, it is essential that the questionnaires are easy to understand, reasonably concise, and acceptable to respondents. (Aaronson, 1989; Hollen, Gralla, Kris, & Potanovich, 1993).

In order to reduce discrepancies, the time frame is critical. This means that the questions must refer to a specific time interval; i.e., "during the past week", rather than time in general. Well defined, short time frames (such as one week) are recommended to increase accuracy and to enhance memory effects (Huisman, Van Dam, Aaronson, & Hanewald, 1987; Selby & Robertson, 1987). However, clinical characteristics of a disease or illness, as well as the expected nature of its impact, should be considered when assigning a time frame.

In summary, a health related quality of life measure should meet some practical consideration such as being self rated (administered), easy to understand and have a definite time span depending on the population under study. Nonetheless, once the measure has been initially developed, psychometric properties must then be evaluated.

## **CHAPTER 2**

# **Objectives & Methods**

Ethical approval for this study was obtained from the Ethics Committee of the Institutional Review Board upon scientific approval by McGill University and the Montreal Children's Hospital Research Institute.

### 2.1 Objectives

To describe the preliminary steps in the development of a pediatric oral healthrelated quality of life questionnaire. This involved:

- 1) The development of the conceptual framework.
- 2) Item generation.
- 3) Item reduction.
- 4) Formatting of the questionnaire.

(See Figure 1).

The purpose of this instrument, the Pediatric Oral Health Questionnaire, is\_to be used in dental health services research as an evaluative tool in the assessment of the impact of pediatric oral health care programs and in clinical trials. It could also be used as a discriminative tool in population-based oral health surveys as a complement to conventional clinical indices in measuring the\_burden of pediatric oral-dental disorders in the general population, population subgroups and groups of patients.

# Figure 1

## **DIAGRAM OF STUDY PROCEDURES**



**Questionnaire Formatting** 

#### 2.2 Methods:

#### 2.2.1 Development of the conceptual framework

#### **Overview**

The use of a conceptual framework aids in the definition of which variables to include in the questionnaire, as well as the specification of the potential relationship between them. When carefully elaborated, a conceptual model serves to identify areas of relevance for data collection and to organize observations into a coherent framework. Only then can data interpretation occur within a meaningful context, and the significance of findings understood more clearly. A conceptual model can be conceived of as a diagram of proposed causal linkage among a set of concepts believed to be related to health, which renders explicit alternative routes to a same end point (Earp & Ennet, 1991). A concept is a factor that can be empirically observed and measured.

Nikias (1985) suggests that role theory could provide a framework for oral health assessment, while Reisine (1981), applied Parson's sick role theory to dental conditions and concluded that the impact of disease should be conceptualized in terms of disruption in social role performances. However, neither role theory nor sick role theory embraces the full scope of changes consequent upon oral conditions (Locker, 1988).

A conceptual framework that provides the basis for the development of a broad range of oral health-specific measures is found in a generic model of disease, with its consequences derived from the World Health Organization's International Classification of Impairments, Disabilities, and Handicaps. Locker in 1988 had described in detail this model and its application to oral health, including the following key concepts: impairment, functional limitation, pain and discomfort, disability, and handicap. As shown in Figure 2, the key concepts are linked in a linear sequence that moves from a biological to behavioral to a social level of analysis, thus providing a theoretical basis in the empirical search of the links between different dimensions of health.

The applicability of this dynamic model to dental and oral conditions has been illustrated by a reference in a paper by Smith and Sheiham (1979) concerning the oral health problems of the elderly. Impairment caused by poor and ill-fitting dentures, as well as edentulism, were largely the result of caries and periodontitis (disease). This, in turn, meant difficulty chewing (functional limitations), which restricted the ability to eat (disability). Inability to eat foods of one's choice and social discomfort because of the poor appearance of the dentition, causes embarrassment and difficulty with talking and socializing (handicap).

In the same way, dental and oral conditions in children could have a negative impact on the quality of life and could lead to various forms of physical, social and psychological deprivation.

#### The concepts

Throughout the definitions of each concept constituting the conceptual model, the distinct areas of human experience relative to disease and illness will be identified, as well as the outcomes, which need to be measured.

**Disease:** Refers to the pathological process that affects the physical and psychological make-up of human individuals, and is measured in terms of frequency in

# Figure 2

# The Conceptual Model



The conceptual model as adapted and described by Locker (1988) from WHO (1980).

the population. The two most common ways of estimating prevalence and incidence rates are based on clinical diagnoses or self-reported diagnosis. Data on the prevalence and incidence of oral disorders are always obtained from clinical examinations undertaken as part of population surveys that use traditional dental health indices to estimate the proportion of the population with common oral disorders.

**Impairment:** Refers to any anatomical loss, structural abnormality or disturbance in physical or psychological processes. Measures of impairment that give an indication of the nature and extent of anatomical loss or abnormality are common in dentistry; for example: edentulousness, the M component of the DMFT index and the periodontal disease assessment systems.

**Functional limitation:** Refers to the restrictions in the functions performed by body parts or systems. Specific to the oral cavity, this could be the ability to chew or the ability to produce intelligible speech. In dentistry, measures of functional limitations are also used; for example, the limitation of jaw movement is used to classify the severity of tempromandibular dysfunction. Similarly, indices of chewing efficiency (Carlsson, 1984) measure the functional limitation arising out of oral disorders.

Pain and Discomfort: refer to the experimental aspect of oral conditions in the form of symptoms. Physical and psychological symptoms are sometimes used as proxy measures of disease, as well as measures in their own right. Pain can be regarded as an indicator of an underlying pathological process (Patrick, 1982), or a psychological consequence of disease (Nikias, 1985). Similarly, discomfort is considered a socio-medical measure, as it is subjectively perceived and experienced even in the absence of a

recognized clinical condition. Pain is considered the most common symptom of oral and dental disorders, and the assessment of oro-facial pain and its social, work loss and psychological impact has been previously evaluated (Cushing et al., 1986; Locker & Grushka, 1987; Reisine, 1985).

**Disability:** refers to any restriction or lack of ability to perform the activities of daily living as a result of an impairment, and encompasses physical. psychological and social well-being dimensions. Activity restriction such as mobility, eating, sleeping (physical well being), limitation in social roles such as work, household management, recreation (social well being), and emotional changes such as anxiety, depression, feeling of hopelessness (psychological well being), are all affected by disease. In the context of dentistry, acute and chronic pain is most likely to have such impacts.

**Handicap:** is a disadvantage resulting from an impairment or disability that limits or prevents the fulfillment of a role that is normal for that individual. Any loss or abnormality of structure and function, or the behavioral limitations involved, can have an effect on the quality of everyday life and long-term opportunities. Some of these effects have been reported with respect to dental and oral diseases, either directly or because of their relationship to physical attractiveness. They include social acceptability and school performance of children (Shaw, Addy, & Ray, 1980), and the effect of facial clefts on marriage and family formation (Peter & Chinsky, 1974). The best indicators for handicap, disadvantage and deprivation are quality of life measures (Andrews & Withey, 1974) Having identified the conceptual framework and defined the health concepts relevant for data collection, the next step is translating those concepts into measurable entities or domains. In terms of measurement theory, this implies devising the empirical indicants that will best represent each concept and sampling the items, which will best operationalize those indicants for the particular study population.

First, we decided to adopt this conceptual framework as the basis for our questionnaire development. We have adopted the health domains that were identified by Locker and his colleagues in their parallel project, to develop an oral health questionnaire for children aged 6-13 years, as our criteria for deciding on the final questionnaire domains. They are 1) Physical pain & discomfort; 2) Functional limitations; 3) Emotional well being; 4) Social role; and 5) Impact on the family (See Appendix A). Second, a list of relevant items or issues was generated for each of the identified health domains taking into consideration the age appropriateness to the target study population.

#### 2.2.2 Item Generation

Items were generated from the following sources: 1) an extensive review of health-related quality of life measures in adult and pediatric population as well as oral health-specific instruments 2) interviews with parents of 3 to 5 years old children with oral and dental conditions; and 3) interviews with health professionals looking after those children.

#### Literature Review

Having conceptualized the framework and adopted the conceptual domains identified by Locker and colleagues in their parallel project, themes and issues relating to those domains were then selected from existing validated health-related quality of life measures for children and from oral health-specific quality of life measures (e.g. Landgraf et al., 1990; Leao & Sheiham, 1996; Slade & Spencer, 1994).

Table 1 presents the major sources from which themes and issues related\_to each domain were selected. In addition, some items that are pertinent to a certain theme were also inspired from those existing instruments.

As Kirshner and Guyatt (1985) suggested, "regardless of the route taken to generate items, a priori criteria must be set for item selection". The criteria for the selection of themes and items in our study were: (a) relevance to the target population; (b) appropriateness of the domain being measured; (c) potential for differentiating the target population; and (d) clarity of expression.

The themes/issues and the items selected from the literature generated a preliminary item pool, which formed the basis for a semi-structured interview.

#### Interviews

To generate a more comprehensive set of items and to ensure that all areas of dysfunction appropriate and relevant to the target population were included, a set of semistructured interviews were conducted with two groups of subjects felt to have direct knowledge about the problems of having oral and dental ill-health: parents of the target population of children with oral health problems, and health care professionals in this field which included paedodontists, dental assistants and hygienists. The subjects were recruited from McGill University's Faculty of Dentistry, as well as its teaching hospital, the Montreal Children's Hospital (MCH), a clinical setting where a relatively large number of the targeted child population is treated.

#### Subjects, recruitment strategies, and ethical considerations

Patients and their parents were recruited through their dentists and a dental hygienist. The researcher also contacted the head of the Dental Department at the Montreal Children's Hospital, who is also a staff member at the Faculty of Dentistry and a cosupervisor of the current research. A meeting was arranged with all the members of the dental department to explain the purpose of the study and to request access to their patients. In addition, a memo, together with ethical approval, was sent to the preoperative clinic at the MCH to request access to the patients who were booked for dental treatment under general anesthesia, as well as their parents.

#### **Inclusion Criteria:**

- 1) The parents of children:
  - a) aged 3-5 years old attending the MCH Dental Clinic.
  - b) who have current oral and dental disorders, specifically caries, pulpal and periapical infection, trauma, mouth ulcers, and gingivitis.
- 2) The parents must be able to speak, write, and read English.
- The parents who volunteer to participate must be willing to sign an informed consent.

# Table 1

## Sources of themes/items from the literature

| Instrument  | Author(s)                               |
|---|---|
| The Social Impacts of Dental Disease (SIDD).      | Cushing, Sheiham, and<br>Maizels, 1986. |
| The Oral Health Impact Profile (OHIP).            | Slade and Spencer, 1994.                |
| The General Oral Health Assessment Index (GOHAI). | Atchison and Dolan, 1990.               |
| Subjective Oral Health Status Indicators.         | Locker and Miller, 1994.                |
| The Dental Impact on Daily Living (DIDL).         | Leao and Sheiham,<br>1996.              |
| The Child Health and Illness Profile (CHIP).      | Starfield et al., 1993.                 |
| The Child Health Questionnaire (CHQ).             | Landgraf et al., 1990.                  |

#### **Exclusion Criteria:**

The parents of children with:

- 1) Co-morbid oral pathologies such as cleft palate or cleft lip.
- 2) Chronic medical condition associated with secondary causes of poor oral health.
- 3) Developmental impairments.

Children with such conditions were excluded from the study to avoid bias or confounding with variables specific for those conditions.

Several different recruitment strategies were used to adapt to the demands of the clinic and the availability of personnel. At the MCH dental clinic, the researcher checked the daily list of patients, and potential subjects based on the assigned age range were highlighted. On the day of their appointment, the researcher would inform the treating dentist or hygienist of the potentiality of his patient and the accompanying parent as candidates for the interview. The receptionists were also informed.

Depending on the availability of time and personnel, the parents of the potential subjects were approached either by the receptionist, researcher, or treating dentist or hygienist, who informed them about the study and asked if they would like to participate. If they agreed, the purpose of the project was explained, and they were asked to undergo a semi-structured interview. To facilitate participation at the MCH pre-operative clinic, the researcher contacted the receptionist weekly to get the list of patients who were booked for dental treatment under general anesthesia. The researcher then contacted the parents of age-appropriate candidates, explained the study and asked if they wished to take part. If the response was positive, an appointment was set up on the same day of the pre-

operative screening appointment. Once recruited and the inclusion criteria met, the parents were provided with an informed consent to read and sign and were invited to be interviewed.

It was recognized that young children might have difficulty responding to a direct interview, so parents were asked if they would allow us to interview their children while they drew or played with dolls. We made it clear that this was not an attempt to verify the parent's answers, but merely to learn more about their child's perspectives and experiences related to their illness. Unfortunately, that was not feasible; therefore, no children were enrolled for this interviewing process. Despite this limitation however, a total of 33 participants (parents of child patients) were enrolled. Finally, as a token of appreciation, all participating children were given gift bags containing dental kits (toothbrush, toothpaste), brochures (oral hygiene instructions, dietary advice, etc), and other items such as pencils, coloring pens, and stickers.

A total of ten health professionals (paedodontists, hygienists, and dental assistants) who work with this particular age group also completed the semi- structured interview. They were approached either by direct contact at their work place or by telephone, told the purpose of the study, and asked to participate. The criteria for including a health professional in the study were: at least five years experience working with children, present contact with the target age group, fluency in reading and speaking English and willingness to participate.

#### Procedures

Parents and health professionals were each interviewed once by the researcher. A semi-structured format was used to assess the impact of oral and dental disorders on the quality of life of the children and the impact on the family. The interviews were conducted face-to-face, except in the case of two health professionals whose interviews took place by telephone. With the respondent's permission the interviews were taperecorded. The format of the interview (Appendix A) was established by integrating the chosen conceptual framework with the health domains adapted for this study. It was based on issues and items obtained from critical review of the literature and on information from oral and dental literature, as well as clinical experience with this clientele. Because investigations related to the effects of oral and dental disorders in the pediatric population are lacking, questions were assembled in the form of open-ended queries and probes. Interviewees were asked open-ended questions to allow them to describe any symptoms their children had related to the mouth or teeth and how these conditions affected their/their children's normal daily lives. If certain issues (items) were not raised in the course of the interview, the interviewer introduced them as probes when appropriate. These areas included; physical symptoms, functional limitations such as eating and sleeping, changes in mood or feelings, social interaction with family and peers, and the effects on the life as a family. The individual interview with the parents lasted approximately 30 minutes, was tape-recorded in accordance with the signed consent form and was generally well-accepted by all subjects. The interviews with health professionals were also in a semi-structured format, but contained more direct and brief questions about 1) how quality of life parameters are affected and presented in children with oral and

dental disorders, and 2) what quality of life parameters are affected from the parents' perspective. Each interview lasted approximately 15 minutes.

#### **Data Management and Analysis**

The participant lists, the informed consent forms and the audiotapes remained under the supervision of the interviewer. In most cases, a copy of the consent form was given to each participant at the end of the interview. However, due to the unavailability of a photocopy machine, some subjects were asked to leave their addresses so that a copy of the consent form could be mailed to them in an official McGill University envelope.

The tapes of the interviews with parents and health professionals were transcribed. All free format responses provided to the open questions as well as responses to specific questions were hand-tallied, and analysis carried out on the material. This resulted in the production of a list of 169 statements/phrases taken from the interview transcripts, maintaining as far as possible the interviewees' actual words. This list of expressions from the interviews was analyzed for content by identifying themes in the statements/phrases, and those which referred to a similar concept were grouped, sorted into the pre-identified domains that relate to the adopted conceptual framework. A code was then ascribed to each domain (HJ Rubin & IS Rubin, 1995). Statements and comments that are not related to any of the concepts were coded as "others".

DeVellis (1991) suggested that if the item pool generated was large, the researcher could eliminate some items based on a priori criteria. The a priori criteria used for the qualitative item analysis were: a) inappropriateness of the domains being measured, b) ambiguity of the sentiments expressed, and c) undesirable similarity. As the raw data from open-ended questions were recorded verbatim, redundancy and repetition were expected.

To meet the criteria, statements that were not appropriate for the domains being measured were excluded. Therefore, statements that were not related to the chosen domains (pages 37-38), the physical symptoms, the functional limitations, the emotional well being, the social role and the impact on the family, were excluded. Next, for phrases that refer to a same type of concept, a qualitative selection was performed. The most frequently and clearly mentioned wordings used by the interviewees were selected. Those items difficult to understand (ambiguous, complicated to read, too long and negatively worded) were excluded (Prieto, Santed, Cobo, & Alonso, 1999; Streiner & Norman, 1995). All redundant and similar items were also eliminated, not only to meet the a priori criterion, but also because it is a common qualitative practice (Parkin, Kirpalani, Rosenbaum, Fehlings, Van Nie, Willan, et al., 1997; Rubin & Rubin, 1995; Weitzner, Jacobsen, Wagner, Friedland & Cox, 1999).

The qualitative analysis of the raw interview data (169 statements) resulted in 60 unique items of the impact of oral and dental disorders that appeared to fall into the five identified domains. These sixty items were included in a preliminary questionnaire that was used for the next stage of the study, the item reduction phase (Appendix C).

#### 2.2.3 Item reduction

#### Subjects

The researcher contacted the head of the Dental Department at the Montreal Children's Hospital who informed all dentists about the second part of the project. Most of the dentists had already participated in the recruitment of subjects for the item generation part of the study. These dentists were informed of the inclusion criteria and were asked to recruit suitable subjects for the study. The inclusion criteria were the same as in the item generation part; parents of children 3-5 years old who have current oral and dental disorders and are able to read and write English.

Sample size for the item reduction process can be selected by deciding how precise one would want the estimates of the impact of an item on the population to be (Juniper, Guyatt & Jaeschke, 1996). This item reduction questionnaire was designed to obtain a reasonable estimate of the frequency and importance of each area of dysfunction in the target population. Guyatt, Bombardier, & Tugwell (1986) advocated the use of at least 50 patients, so that the width of the confidence interval for a frequency of 50% would be about 15%, and subsequently, it would rise as the sample size decreased. In our study, although sample size was limited by patient availability, we tried to recruit at least 50 patients.

#### Procedures

Two principles guided our approach to item reduction. Firstly, our primary criterion for including an item was the impact of the item on the population, that is, how often respondents labeled the item as a problem for them/their children (the frequency), and the importance they attached to it (Guyatt et al., 1986).

Secondly, in order to decrease the variability in the responses and to reduce any impact of idiosyncratic responses to individual questions, each domain to be measured requires adequate representation on the questionnaire and must include at least three to four items (Guyatt et al., 1986).

The first approach used in this study for selecting items for the final questionnaire was the item impact method that was suggested by Guyatt et al., where the frequency of each item was multiplied by it's mean importance (Guyatt et al., 1986; Juniper et al., 1996; Juniper, Guyatt, Streiner & King, 1997).

The item reduction questionnaire contained 60 items; each item was formatted as a statement within its respective domain, of which 10 items dealt primarily with physical symptoms (pain & discomfort), 13 items dealt with functional limitations, 10 items dealt with emotional well-being, and 13 items with social role. The impact on the family domain contained 14 items.

Fifty participants were included for the item reduction phase. Participants were asked to identify items that their children have experienced as a result of their oral and dental conditions. For each positively identified item, they were asked to rate the importance of that item on a five-point Likert scale (1=Does not bother my child at all, 2=A little bothersome, 3=Somewhat bothersome, 4=Very bothersome, 5=Extremely bothersome).

For those items related to the impact on the family, participants were asked to identify item that he/she (parents) has experienced as a result of their children's oral and dental conditions, and to rate the importance of that item on a five-point Likert scale (1=Not important at all, 2= A little important, 3=Somewhat important, 4=Very important, 5=Extremely important).

#### **Data Analysis**

The responses of 50 participants who completed the item reduction questionnaire were used in the analysis. Results were expressed as frequency, importance, and impact. Frequency counts were obtained for each item by summing the number of subjects who answered positively to that item. Importance ratings were obtained by calculating the mean importance score given to each item.

For each item, an "impact score" was then calculated, by multiplying the proportion of respondents identifying the item as a problem (frequency), and the mean importance attributed to that item.

The items were then ranked according to their impact score and the highest scoring items were retained for the final questionnaire, balancing between minimizing respondent burden and including sufficient number to detect meaningful differences and allow analysis within each domain. An impact score of a minimum of 0.5 was set as a cut-off point for retaining an item for the final questionnaire.

Our second approach to item reduction was the representation of each domain by at least four items (Guyatt et al., 1986). Items scoring the highest were retained and reviewed, and it was made sure that they included at least four items within each domain, if not, then the next highest scoring items related to a specific domain were added.

#### 2.2.4 Formatting the Questionnaire

Since the questionnaire content overlaps with some other established QoL instruments, the wording of some of the questions was borrowed from these measures. For content areas unique to this study population, the researcher consulted established

guidelines and principles of cognitive psychology and visual perception for designing a self-administered questionnaire (Bowling, 1997; Sudman & Bradburn, 1982; Woodward & Chambers, 1995).

#### Procedures

In writing the questions, the words that applied to the widest range of the cultural subgroups in the target population were used, as well as the most frequently mentioned word used by the respondents referring to a specific concept. Some questions were formulated for the oral health-specific characteristics of the impact on quality of life as reported by study participants. Others that overlapped in content with previously developed and valid generic and disease specific instruments for children and adults, that had proven their clarity and accuracy, were tailored to the specific purpose of the study and to the special characteristics of the respondents (Hully & Cummings, 1988). Jargon, idioms and metaphors were avoided to facilitate translation. (Juniper et al., 1996) and the questions were drafted to be coherent with impressions acquired from the literature concerning health-related QoL.

#### **Response format**

The response format used was a Likert categorical scale, chosen because of its ease of administration and interpretation and because it is considered the most commonly used response format in quality of life measures (Bowling, 1995; Jaeschke, Singer & Guyatt, 1990).

There is inconsistency in the literature over the optimum number of response choices to be provided in these instruments. Some authors suggest that a Likert scale with seven to ten response options is reasonable (Guyatt et al., 1986), while others suggest that a five to seven-point scale is adequate (Streiner &\_Norman, 1995). Since the eventual intention is to use this instrument in the assessment of the impact of oral health care programs and as an evaluative tool in clinical trials, it was decided to include seven categories to ensure and enhance the sensitivity and responsiveness to detect small changes over time (Guyatt et al., 1986; Juniper et al., 1996; Streiner & Norman, 1995). In addition, previous work suggests that seven point scales combine excellent responsiveness with ease of administration and patient understanding (Guyatt, Townsend, Berman & Keller, 1987; Jaeschke et al., 1990).

#### **Time specification**

A period of four weeks was chosen as the reference time frame for the scale. Considering the clinical characteristics of oral and dental disorders, the intuitively expected nature of their impact on a child's well being and the instrument response format, it was reasonable to assume that this interval would allow for the related impairments to occur and to be reported accurately.

#### Readability

Our aim was to construct a simple, unambiguous questionnaire that would encourage accurate responses. Donovan, Sanson-Fisher and Redman (1989) suggested using the Flesch formula to ensure the comprehensibility of a quality of life questionnaire, but did not propose any guidelines as to the optimal grade level. Traditionally however, a text requiring the completion of the 8 <sup>th</sup> grade is considered a standard reading difficulty. Thus, Office '2000' software for\_Windows '98' was used to verify the grammatical structure and the vocabulary of the questions. The grammar checker indicates, among other information, the Flesch Reading Ease (RE) score and the corresponding grade level. The Flesch RE is based on the average number of words per sentence and the average number of syllables per 100 words (Flesch, 1948). Reading ease scores range from very easy (90-100: equivalent to four years of formal schooling) to very difficult (0-30: equivalent to 15 years of schooling). The Flesch RE Grade Level is an estimate of the minimal school grade a person should have completed in order to easily read the given text.

# **CHAPTER 3**

## Results

The results of this study, the preliminary development of a questionnaire, are listed in chronological sequence, much in the same manner as the chapter covering the objectives and methods. This sequence is necessary to the understanding of the project, as each step depends on the results of the preceding one.

#### 3.1 The Conceptual Framework

The adopted Locker's model of oral health identifies the four main conceptual dimensions of impact (Appendix A): physical pain &discomfort (acute symptoms e.g. sensitivity of teeth), functional limitations (e.g. difficulty chewing), psychological or emotional well being (e.g. change of mood), and social role (e.g. interaction with family), as well as the impact on the family domain (e.g. worries in the family). It was defined in the initial criteria that those domains are to be included in the final questionnaire; therefore, it was ensured that these criteria were met.

#### 3.2 Item generation

#### 3.2.1 Literature review

The review of the literature on oral health and disease impact (Locker & Grushka, 1987; Reisine, 1985; Smith & Sheiham, 1979) and existing questionnaires dealing with oral functional status, oral symptoms, and emotional well being (Atchison & Dolan, 1990; Cushing et al., 1986; Leao & Sheiham, 1996; Slade & Spencer, 1994) provided themes and issues that were relevant to the target population and appropriate for the domains being measured. In addition, generic pediatric health questionnaires (Landgraf et al., 1990; Starfield et al., 1993) provided themes pertinent to the emotional well being and social role domains, as well as issues related to the impact on the family domain.

Table 2 presents the identified domains and the themes/items found in the literature that pertain to each individual domain. The physical pain & discomfort domain included acute oral and dental symptoms, such as pain, bad breath, and tooth sensitivity. The functional limitations domain included issues such as chewing and eating restrictions, sleeping disturbances, and speech difficulties. The emotional well being domain included issues such as change in mood or feelings because of problems related to the teeth or mouth. Themes pertaining to the social role domain were related to schooling, peer interaction, and family interaction. Issues related to the impact on the family included worry and concern of the parents, family relationships, and social relationships.

#### **Characteristics of the subjects**

A total of 34 parents of 34 children, as well as 10 dental health professionals, were interviewed using the semi-structured format of questions and probes presented in Appendix A. The socio-demographic characteristics of these subjects are listed in Table 3 and Table 4. To summarize, the mean age of participating children was 4.2 years; and the gender breakdown was 19 boys and 15 girls. Seventy percent of the participants (n=24) were recruited from the dental clinic at the Montreal Children Hospital, and the rest came from the pre-operative clinic at the same hospital.

All of the participants had previous histories of oral and dental disorders of variable severity. The range of conditions included caries (decayed teeth), gingivitis (bleeding gums), mouth sores, dental abscess (apical infection) and traumatized teeth. Dental caries and oral infections relating to abscessed teeth were the two most common conditions, 73% of children had caries, and 47% had dental abscesses. For those patients with conditions related to the teeth only, the number of affected teeth varied from one to fourteen, with an average of 5.6 affected teeth.

Participating health professionals included 7 dentists, 2 dental assistants and one hygienist, and their experience with children of all age groups varied from ten to twenty five years, with an average of 15.8 years. Most of the dentists do not treat solely children within our target age group (preschoolers), but practice general dentistry on children and adults. Nevertheless, eight of the health professionals were recruited from the MCH where child patients are the main clientele. For all dentists, at least 20% of their clientele consisted of preschoolers (3-5 years), with an average across dentists of 35%. The types

of interventions provided by these dentists were restorative, extractions, endodontics, preventive and simple orthodontic treatment. All dentists treated juvenile patients on an emergency or routine basis, either at the outpatient clinic or in the operating room under general anesthesia.

| Table 2   |  |  |
|---|--|--|
| Domains and themes/items selected from the literature |  |  |

| Domain                                | Themes/Items   |
|---------------------------------------|--|
| Physical Symptoms (Pain & Discomfort) | <ul> <li>Pain</li> <li>Bleeding gums</li> <li>Bad breath</li> <li>Sensitive teeth</li> </ul>   |
| Functional Limitations                | <ul> <li>Chewing ability</li> <li>Eating restrictions</li> <li>Sleep disturbances</li> <li>Speech difficulties</li> </ul>  |
| Emotional Well Being                  | <ul> <li>Worry and concern</li> <li>Mood changes e.g.<br/>happy/sad</li> <li>Feelings e.g.<br/>frustrated/cranky</li> </ul>  |
| Social Role                           | <ul> <li>Schooling<br/>Attendance<br/>Activities</li> <li>Peer interaction<br/>Avoidance by peers<br/>Avoid: smiling/ laughing,<br/>and<br/>eating with others.</li> <li>Family interaction<br/>Overly demanding<br/>Argumentative<br/>More difficult to manage</li> </ul> |
| Impact on the Family                  | <ul> <li>Worry and concern</li> <li>Missed work</li> <li>Family relationship</li> <li>Social relationship</li> </ul>   |

 Table 3

 Socio-demographic and clinical data of child subjects in item generation study

# (n=34)

| Characteristics              | Mean (S D) |
|------------------------------|------------|
| Age                          | 4.2 (0.7)  |
| Sex: Male                    | 19         |
| : Female                     | 15         |
| Affected teeth (number)      | 5.6(3.6)   |
| Dental History               |            |
| Caries (%)                   | 73%        |
| Bleeding Gum                 | 17%        |
| Mouth Ulcers                 | 2.9%       |
| Abscess (infection)          | 47%        |
| Trauma                       | 8.8%       |
| Others (malpositioned teeth) | 2.9%       |

# Table 4Clinical Profile of the Health Professionals in item generation study<br/>(Interviews)<br/>(n= 10)

| Characteristics                                  | Mean<br>(S D) |
|--|---------------|
| Experience with child population (yrs.)          | 15.8 (4.9)    |
| Age range of typical patients (yrs.)             | 2-22          |
| 3-5 year old patients (% of the total clientele) | 35% (14.4)    |

#### **Qualitative Data**

All free format responses to the open-ended questions, as well as specific questions of the interviews with parents and health professionals were transcribed verbatim for each interviewee, resulting in a total of 169 statements (Appendix B). Initially, these statements were grouped and categorized within the identified domains that relate to the adopted conceptual framework: physical pain & discomfort, functional limitations, emotional well being and social role (age-appropriate), as well as the impact on the family. Simple frequency counts of these raw data (Figure 3) demonstrated that the most frequently occurring items were identified as belonging to the impact on the family which included emotional distress and family relationships, followed by physical symptoms (pain and discomfort) domain. The least frequent items cited were those related to the social role domain, which included items on schooling, peer interaction and family interaction. This finding is not unexpected considering the particular character of the study population with regard to age and level of dependency and the underdeveloped distinct social roles.

Next, a qualitative analysis was performed on the raw data from the interviews, from which the 169 statements were gathered. Since the selection of items for the next stage of our study was based upon a priori criteria, it was made sure that those criteria were met. Therefore, identical and similar statements were eliminated, and items (statements) not appropriate for the domains being measured were excluded. The remaining interview statements then underwent a qualitative selection as suggested in the literature (Miles, 1994; Rubin & Rubin, 1995; Streiner & Norman, 1995). For those



## Frequency Counts of the Different Domains (Interview Data)



- PS: Physical Symptoms (Pain & Discomfort)
- FL: Functional limitations
- EW: Emotional Well being
- SR: Social Role
- IF: Impact on Family
- Oth: Others
statements representing the same concept or theme, the most frequently and clearly mentioned wordings used by the interviewees were selected. Statements that were difficult to understand (ambiguous, complicated to read, too long and negatively worded, grammatically incorrect) were excluded, and statements that were clear and directly to the point were retained. We attempted to keep the same words and phrases used by the interviewees in the final product.

This process resulted in sixty unique statements of the impact of oral and dental disorders that appeared to fall into the identified domains (physical pain & discomfort; functional limitation; emotional well-being; social role; and the impact on the family). These 60 issues were incorporated into a preliminary questionnaire (Appendix C), which was used for the next stage of the study, the item reduction phase.

Overall, the interviewing process for item generation revealed health perceptions unique to children with respect to oral-dental disorders that were not covered in instruments developed for adults. Some of these items are related to their age-specific social role and specific interaction with peers; e.g., the item asking about the likelihood of a child being teased by other children because of problems with the teeth or mouth. Other items relate to the impact on the family and the parents particularly, since one can expect that children of the targeted age group are almost, if not totally dependent on their parents. Therefore, emotional distress and worry about current dental status and future dentition was a concern more for the parents than for the children.

#### 3.3 Item reduction

#### Characteristics of the subjects

A total of 50 parents of 50 children completed the item reduction questionnaire and provided complete data sets. The sociodemographic characteristics of children are listed in Table 5. In summary, there were 29 girls and 21 boys, with a mean age of 4.3 years (SD = 0.8 years). All of the participant

had previous histories and current oral and dental conditions of variable severity. Most children (76%) had caries (decayed teeth), represented as either simple cavity or extensive multiple cavities. The second most common condition was root canal infection; fifty six percent of the children had abscessed teeth. Thirty\_two percent had trauma to the teeth, resulting in discolored non-vital teeth, especially the anteriors. Eight children (16%) had other conditions, such as congenitally malpositioned, discolored, or missing teeth.

#### Item reduction results (Frequency and importance)

The analysis of the item reduction questionnaire is shown in Table 6. The table presents the number and proportion of children who experienced each item, the mean importance score for each positively identified item (importance), and the overall impact of the item (proportion x importance).

Initially, items with the highest impact scores of 0.5 or greater were selected and presented in Table 7. Next, as we had already conceptualized the framework and predefined the domains that would be included in the final questionnaire, these selected 26

### Table 5

# Socio-demographic and clinical data of child subjects in item reduction study (n=50)

| Characteristics                                      | Mean (S D) |  |  |  |
|--|------------|--|--|--|
| Age  | 4.3 (0.8)  |  |  |  |
| Sex: Male  | 21         |  |  |  |
| : Female   | 29         |  |  |  |
| Affected teeth (number)                              | 5.8 (4.1)  |  |  |  |
| Dental History                                       |            |  |  |  |
| Caries (%)   | 76%        |  |  |  |
| Bleeding Gum   | 24%        |  |  |  |
| Abscess (infection)                                  | 56%        |  |  |  |
| Trauma   | 32%        |  |  |  |
| Others (malpositioned,<br>discolored, missing teeth) | 16%        |  |  |  |

highest scoring items were reviewed and grouped to ensure that they described the five identified domains (Juniper et al., 1996).

However, when the highest scoring items were reassessed, only two items relating to emotional well being and three relating to social role remained. Therefore, since each domain should be represented by at least four items (as specified in the initial criteria for item reduction), the next two highest scoring emotional well being items and the next highest social role item from the item reduction questionnaire were also included (Table 8).

This procedure resulted in 29 items related to five domains. Most of these items (11 items) were related to the impact on the family domain. The physical symptom domain contained 4 items, the functional limitation domain contained 6 items, 4 items were selected for emotional well being, and 4 for the social role domain.

#### 3.4 The Preliminary Questionnaire

As a result of the item reduction process, the draft version of the questionnaire consisted of the 29 items with the highest frequency-importance scores representing the four impact domains on the children's quality of life and the impact on the family domain.

Each item was formulated as a question. Questions concerning the children share the same heading phrase "How often has your child", and ended with "because of problems with his/her teeth or mouth"

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# Table 6Frequency and Importance Results

| Item                                      | Frequency | Proportion | Importance | Impact* |
|---|-----------|------------|------------|---------|
| Pain                                      | 30        | .60        | 2          | 1.20    |
| Bleeding gums                             | 14        | .28        | 0.74       | 0.21    |
| Bad breath                                | 28        | .56        | 1.72       | 0.96    |
| Sensitive teeth                           | 16        | .32        | 1.29       | 0.41    |
| Mouth ulcers                              | 8         | .16        | 0.76       | 0.12    |
| Sore mouth                                | 12        | .24        | 0.92       | 0.22    |
| Swelling/abscess                          | 14        | .28        | 1.04       | 0.29    |
| Teeth grinding                            | 23        | .46        | 1.58       | 0.73    |
| Teeth breaking apart                      | 20        | .40        | 1.20       | 0.48    |
| Teeth discoloration                       | 26        | .52        | 1.68       | 0.87    |
| Trouble biting/chewing                    | 18        | .36        | 1.36       | 0.49    |
| Difficult to eat any food                 | 20        | .40        | 1.26       | 0.50    |
| Toothache with hot/cold                   | 26        | .52        | 1.64       | 0.85    |
| Refused to eat                            | 22        | .44        | 1.50       | 0.66    |
| Unable to eat what would like to          | 20        | .40        | 1.35       | 0.54    |
| Food gets stuck in between<br>the teeth   | 30        | .60        | 1.92       | 1.15    |
| Bad/unsatisfactory diet                   | 18        | .36        | 1.14       | 0.41    |
| Takes longer to finish a meal             | 31        | .62        | 2.14       | 1.33    |
| Unable to brush                           | 17        | .34        | 1.02       | 0.35    |
| Unable to sleep at night                  | 7         | .14        | 0.40       | 0.06    |
| Interrupted sleep                         | 18        | .36        | 1.08       | 0.39    |
| Difficulty pronouncing certain words      | 16        | .32        | 1.00       | 0.32    |
| Difficulty speaking clearly               | 15        | .30        | 0.84       | 0.25    |
| Feels frustrated                          | 14        | .28        | 1.00       | 0.28    |
| Acts shy                                  | 26        | .52        | 1.49       | 0.76    |
| Worries that his/her teeth look different | 10        | .20        | 0.71       | 0.15    |
| Be cranky                                 | 17        | .34        | 0.88       | 0.30    |
| Is withdrawn                              | 9         | .18        | 0.45       | 0.08    |
| Is upset                                  | 20        | .40        | 1.14       | 0.46    |
| Is angry                                  | 12        | .24        | 0.78       | 0.19    |
| Feels insecure                            | 12        | .24        | 0.76       | 0.18    |
| Feels like crying                         | 15        | .30        | 0.86       | 0.26    |
| Feels embarrassed                         | 21        | .42        | 1.12       | 0.47    |
| Worries about being treated differently   | 21        | .42        | 1.27       | 0.53    |

(continued)

| Feels unhappy  | 9  | .18 | 0.47 | 0.08 |
|--|----|-----|------|------|
| Be demanding, wants more attention                                     | 24 | .48 | 1.68 | 0.80 |
| Argues a lot   | 24 | .48 | 1.40 | 0.67 |
| Trouble getting along with brother or sister                           | 15 | .30 | 0.8  | 0.24 |
| Be more difficult to manage  | 18 | .36 | 1.17 | 0.40 |
| Fights more with brother or sister                                     | 23 | .46 | 1.29 | 0.59 |
| Missed kindergarten  | 13 | .26 | 0.67 | 0.18 |
| Can't participate in some activities/hobbies                           | 15 | .30 | 0.84 | 0.25 |
| Teased by other kids   | 13 | .26 | 0.80 | 0.21 |
| Rejected by other kids   | 13 | .26 | 0.71 | 0.19 |
| Could not play with friends  | 8  | .16 | 0.43 | 0.07 |
| Avoid smiling/laughing   | 11 | .22 | 0.84 | 0.18 |
| Parents been worried   | 35 | .70 | 2.46 | 1.7  |
| Parents had concern about<br>the look of the child's teeth             | 38 | .76 | 2.88 | 2.2  |
| Parents been concerned<br>about the child's pain                       | 40 | .80 | 2.91 | 2.3  |
| Extra time and effort from<br>parents to attend<br>appointment         | 35 | .70 | 2.85 | 1.99 |
| Frustration in the family  | 17 | .34 | 1.24 | 0.24 |
| Tension or conflict in the family                                      | 14 | .28 | 1.00 | 0.28 |
| Parents been<br>stressed/bothered                                      | 26 | .53 | 1.79 | 0.95 |
| Needed to make arrangement<br>or change plans                          | 21 | .42 | 1.47 | 0.62 |
| Parents been nervous about<br>child having treatment at a<br>young age | 34 | .68 | 2.45 | 1.67 |
| Parents had to change preparation of food                              | 18 | .36 | 1.29 | 0.46 |
| Parents missed work  | 21 | .42 | 1.28 | 0.54 |
| Limited time for parent's personal needs                               | 25 | .50 | 1.40 | 0.69 |
| Parents been concerned of<br>their child's experience at<br>young age  | 38 | .76 | 2.59 | 1.97 |
| Parents had difficulty convincing the child to brush                   | 27 | .54 | 1.73 | 0.94 |

\*Impact = Proportion x Importance



# Table 7The 26 Highest Impact Scores

| Item                               | Frequency | Proportion | Importance                            | Impact* |
|------------------------------------|-----------|------------|---------------------------------------|---------|
| Parents been concerned and         |           |            |                                       |         |
| worried about the child's pain     | 40        | .80        | 2.91                                  | 2.30    |
| Parents had concerns about the     |           |            |                                       |         |
| look of the child's teeth.         | 38        | .76        | 2.88                                  | 2.20    |
| Extra time and effort from parents |           |            |                                       |         |
| to attend dental appointments.     | 35        | .70        | 2.85                                  | 1.99    |
| Parents been concerned of their    |           |            | · · · · · · · · · · · · · · · · · · · |         |
| child's experience at young age.   | 38        | .76        | 2.59                                  | 1.97    |
| Parents been worried.              | 35        | .70        | 2.46                                  | 1.70    |
| Parents been nervous about child   |           |            |                                       |         |
| having treatment at a young age.   | 34        | .68        | 2.45                                  | 1.67    |
| Takes longer time to finish a      | 31        | .62        | 2.14                                  | 1.33    |
| meal.                              |           |            |                                       |         |
| Pain.                              | 30        | .60        | 2.00                                  | 1.20    |
| Food gets stuck in between the     |           |            |                                       |         |
| teeth.                             | 30        | .60        | 1.92                                  | 1.15    |
| Bad breath.                        | 28        | .56        | 1.72                                  | 0.96    |
| Parents been stressed/bothered     | 26        | .53        | 1.79                                  | 0.95    |
| Parents had difficulty convincing  |           |            |                                       |         |
| the child to brush.                | 27        | .54        | 1.73                                  | 0.94    |
| Teeth discoloration                | 26        | .52        | 1.68                                  | 0.87    |
| Toothache or sensitivity when      | 26        | .52        | 1.64                                  | 0.85    |
| eating or drinking                 |           |            |                                       |         |
| hot/cold/sweets.                   |           |            |                                       |         |
| Be demanding/wants more            |           |            |                                       |         |
| attention.                         | 24        | .48        | 1.68                                  | 0.80    |
| Acts shy.                          | 26        | .52        | 1.49                                  | 0.76    |
| Teeth grinding.                    | 23        | .46        | 1.58                                  | 0.73    |
| Parents had limited amount of      |           |            |                                       |         |
| time for personal needs.           | 25        | .50        | 1.40                                  | 0.69    |
| Argues a lot.                      | 24        | .48        | 1.40                                  | 0.67    |
| Refused to eat.                    | 22        | .44        | 1.50                                  | 0.66    |
| Parents needed to make             |           |            |                                       |         |
| arrangement or change plans at     |           |            |                                       |         |
| the last minute.                   | 21        | .42        | 1.47                                  | 0.62    |
| Fights more with brother(s) or     |           |            |                                       |         |
| sister(s).                         | 23        | .46        | 1.29                                  | 0.59    |
| Parents missed work.               | 21        | .42        | 1.28                                  | 0.54    |
| Unable to eat what he/she would    |           |            |                                       |         |
| like to eat.                       | 20        | .40        | 1.35                                  | 0.54    |
| Worries that he/she is being       |           |            |                                       |         |
| treated differently by other kids. | 21        | .42        | 1.27                                  | 0.53    |
| Difficult or uncomfortable to eat  |           |            |                                       |         |
| any food.                          | 20        | .40        | 1.26                                  | 0.50    |

\*Impact = Proportion x Importance

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| Item                         | Frequency | Proportion | Importance | Impact |
|------------------------------|-----------|------------|------------|--------|
| Feels embarrassed.           | 21        | .40        | 1.12       | 0.47   |
| Is upset or bothered.        | 20        | .40        | 1.14       | 0.46   |
| Be more difficult to manage. | 18        | .36        | 1.17       | 0.40   |
|                              |           |            |            |        |

 Table 8

 Additional Items (item reduction study)

Each individual question was accompanied by a 7-point Likert scale (see page 51): 1=All of the time, 2=Most of the time, 3=A good bit of the time, 4=Some of the time, 5=A little of the time, 6=Hardly any of the time, 7=None of the time.

The reference time frame chosen for the scale was a period of four weeks and was given as a heading instruction throughout the questionnaire in the form of "During the last 4 weeks". This time interval was chosen after taking the following into consideration: the clinical characteristics of oral and dental disorders; the predicted nature of the impact of these disorders on a child's well being; and the instrument response format. It was felt that this time interval would allow the associated impairments to occur and to be reported accurately.

The final draft (version) of the questionnaire has 29 items in five domains. The first domain reflects the physical pain and discomfort that children experience with their oral and dental symptoms. The second domain consists of items dealing with functional limitation, predominantly eating and chewing restrictions. The third domain consists of emotional well being items and how childrens' moods and feelings change with oral and dental problems. The fourth domain deals with social role (age appropriate), and this mainly includes questions concerning family interaction. The final domain was titled "impact on the family", and this includes questions concerning emotional distress of the parents because of problems with their children's teeth or mouth, in addition to the effect of these problems on familial and social relationships.

The preliminary questionnaire that was developed and is now prepared to undergo further testing is presented in Appendix D. It has a total of 29 questions and seven response options. Therefore, the sum of the scores gives a total score ranging from 29 (if all items are scored "1") to 203 (if all items are scored "7"). Higher scores signify a better oral health-related quality of life.

#### 3.5 Readability

The Flesch-Kincaid score and the Flesch Reading Ease Grade Level were calculated to determine if the questionnaire is at or below the 8<sup>th</sup> grade level and if the Flesch RE for the entire questionnaire is within a standard value of 80 (Flesch 1948). The grade level for the entire questionnaire was calculated to be 6.6, i.e., approximately six years of formal schooling.

### **CHAPTER 4**

### Discussion

#### 4.1 Introduction

Oral and dental health illnesses among children are prevalent, and associated impairments are common. However, due to the fact that proper measurement tools have not been heretofore available, the impact of these conditions on the quality of life of children and the impact on the families have yet to be ascertained. Although the oral health quality of life measures developed to date have been shown to be valid and useful tools, the current conceptualization of children's health as the ability to participate fully in developmentally appropriate physical, psychological and social tasks calls for an instrument capable of tapping into these domains while at the same time being ageappropriate. Thus, developing a proper tool that met these needs was the primary motivation for this project.

This research project attempted to develop an oral health quality of life questionnaire for children ages 3-5 years.

Our approach to item generation which utilized a variety of sources including input from parents of children seeking treatment and their health professionals was comprehensive and ensured that we captured all items found to be important to the children and their families. Furthermore, involvement of fifty participants in the item reduction process enhances the content of the final questionnaire by including only items with the highest frequency/importance scores from the respondents' perspectives.

The discussion of this project is divided into sections that respect the design of the study and facilitate its interpretation.

#### 4.2 The conceptual framework

The adoption of the conceptual model and the proposed health domains by the research team of the parallel project at the University of Toronto (Locker, et al.) was a noteworthy contribution to the choice of dimensions for this study questionnaire.

#### 4.3 The literature review

The review of the literature revealed the fact that measures of oral health-\_related quality of life for children are not available and accordingly, investigations on the impact of oral and dental health on the quality of life of children do not exist.

The existing validated oral health quality of life instruments provide a wide range of information and concepts, some pertinent only to adults, but some issues can be generalized to a child population. On the other hand, generic pediatric health instruments provide quite broad concepts of health that might not be significant to oral health. However, establishing a priori criteria for the selection of themes/items from the literature guided our search and our decision to what would constitute the initial item pool.

#### 4.4 The interview content and process

The interviewing process to generate items and identify components of the oral health questionnaire could have been greatly influenced by the questions included in the semi-structured interviews. One could inquire about areas of physical and emotional dysfunction, inconvenience and limitations by direct questioning. However, respondents might spontaneously recall only a small proportion of dysfunction and inadvertently omit important information. We included, therefore, an introductory open-ended question as well as a comprehensive series of probes covering all possible areas of dysfunction related to oral and dental disorders. The use of such a format, devised with a comprehensive series of probes, has been recommended for item selection by Guyatt and his colleagues (1986) when developing an evaluative instrument of quality of life. It is also recognized as being the best strategy presently available. The use of a standard openended question at the beginning of the interview also helps because it allows the respondents to tell in their own words how these illnesses affect their lives as well as those of their childrens'. This guards against the possibility of the interviewers directing the process according to their particular point of view, rather than the participant's. The more specific questions with regard to quality of life parameters were not simply asked in a question-answer fashion, but rather the subjects were actively involved in the process of interviewing and were invited to share concerns and areas from their own children's experience not yet mentioned. Subsequent analysis of the data demonstrated that subjects were not limited by the questions or probes. In fact, this open-ended style enabled us to garner a wealth of useful information.

A small sample (n=44) participated in this part of the study. Forty-four subjects were interviewed. These included parents of children with a range of oral and dental conditions (n=34), and health professionals (paedodontists, dental assistants, and one hygienist; n=10). The interview data were monitored continuously after 2-3 consecutive interviews, and new items were analyzed. Depending on the level of variability of information, the sampling was to be ceased or to be continued. Therefore, the interviews were discontinued once the information obtained was repetitive and not contributory to the comprehensiveness of the item pool.

Although we attempted to conduct interviews with more parents than health professionals, the sample of 34 parents was still too small to include the broad range of oro-facial conditions such as congenital anomalies, cleft palate, oligodontia, and ectodermal dysplasia. However, the inclusion of parents of children with more severe conditions could have reduced the importance of the effects of moderate and minor, but more common, oral and dental conditions and would have introduced areas of impact that are specific for a particular condition (and which can not be generalized to other situations). Moreover, the included patients were representatives of our target population with oral and dental disorders, in general, rather than a sub-population with major orofacial disorders.

Several factors influenced subjects' responses. One factor was whether the patient had been recruited from the outpatient dental clinic or the pre-operative clinic. Another was if the child was receiving treatment and if so, the approach of that treatment. For example, parents of children who had already started receiving treatment on an outpatient clinic basis may offer more limited responses than parents of children who had been on a waiting list for a minimum of six months to have treatment under general anesthesia. As well, factors possibly influencing responses from health professionals were the type of patient they treated and the treatment performed. For most health professionals, it was difficult to generalize amongst all dental patients who come for treatment, for example, emergency, routine follow-up or general anesthesia list. One could also expect that health professionals could be influenced by their different disciplines. Some clinicians had a more limited view of the problem but, in general, no areas of potential discord could be identified.

Another factor that could have influenced subjects' responses was the site of the interviews. In the beginning, different locations such as a dental office or a common room were used. However, parents may feel more willing to disclose personal information in a quiet environment. Therefore, this was subsequently adjusted so that the interviews could take place in a quiet environment, free from interruptions and distractions.

Despite the limitations of the interviewing process, the information obtained from the interviews, along with the concepts and health domains from the review of literature, provided the core content of the item reduction questionnaire that was utilized for the next stage of the project.

#### 4.5 Qualitative data

The statements that were transcribed from interviews with parents and health professionals were grouped and categorized within the identified domains; physical pain & discomfort, functional limitations, emotional well being, social role, and the impact on the family. As was seen in Figure 2 (page 60), items relating to the impact on the family which included emotional distress, concern, and worries in the family were the most frequently occurring items, followed by items related to physical symptoms. The least frequently cited items were related to the social role domain. This finding could be explained by considering the character of the study population with regard to age and level of dependency and the underdeveloped distinct social role. In addition, since oral and dental disorders are symptom-dominated conditions, physical symptoms were also frequently cited.

The overall interviewing process revealed health perceptions unique to children with oral and dental disorders that were not described in instruments developed for adults. One item was related to the social role, specifically the interaction with peers and the likelihood of a child being teased by other children because of problems with the teeth or mouth. Other items related to the impact on the family, specifically the emotional distress and worry about dental status, pain, appearance of the teeth, treatment at a young age, and future dentition. Since children of the targeted age group are almost, if not totally, dependent on the parents, one may presume that distress and worries about dental problems were a concern more for the parents than for the children.

#### 4.6 Item reduction

After having fifty participants complete the item reduction questionnaire, the impact scores were examined. These could have varied from 0 to 5. However, as seen in Table 6, the scores obtained from our item reduction analysis ranged from 0.06 to 2.30.

Since the highest impact ratings were found in the family domain, this suggests that the greatest impact arising from these conditions is in the emotional impact on the family. It may be that, with a different population, other domains would be rated as more important. However, in this sample, worry about the child's condition was rated to be of greater importance than other factors, such as physical symptoms or functional limitations. It is possible that, since the parents are those who completed the questionnaire, their personal view of the condition might have been more strongly rated than their child's. Finally, it may also be possible that the oral conditions found in this study population do not have a great impact, particularly since this study sample was recruited from individuals who were in a therapeutic environment.

Another approach to item reduction used in this study was the representation of each dimension to be measured by at least the three or four items with the highest impact scores. The two reasons for doing so are to decrease the variability in response found even in stable patients, and to minimize the impact of idiosyncratic responses to individual questions (Guyatt et al., 1986). When the retained highest scoring items were reviewed, they represented the five identified domains. However, the emotional well being domain included only two items, and the social role domain included three items, therefore, two items were added to the emotional well being domain and one item was added to the social role domain, thus ensuring adequate representations of all domains in the final questionnaire.

#### 4.7 Construction of the questionnaire

Health related quality of life instruments acknowledge a broad definition of health (Schipper, Clinch, & Olweny 1996). In addition, these instruments are patient-derived, and explicitly acknowledge issues of importance to the patient themselves (Rsenbaum. Cadman, & Kirpalani 1990; Rosenbaum & Saigal 1996), as compared with physiologic or functional measures, which may be entirely health care provider-derived.

In our study, only items with the highest frequency-importance ranking from the parent's perspective were retained to comprise the content of the developed instrument. For this reason, the instrument contains the phrase "How often do you think your child/you...", rather than "How much does your child/you...".

It was noted that subjects expressed a limited range of responses to interview questions. For example, when interviewees expressed that the child had difficulty chewing, a probe question of how often and when this occurred was asked in an attempt to get more detailed information. The responses were generally limited to "all of the time", "every time he/she eats", "sometimes, when eating hard food", "never", or "not at all".

The choice of a 7-point Likert scale gives a respondent a wide gradation of responses to choose from. Suggestions for the optimal number of response options are variable (Guyatt et al, 1986; Streiner & Norman, 1995). However, one of the main purposes of this instrument is that it is to be used as an evaluative tool in the assessment of the impact of oral health care programs and in clinical trials to measure change over time. It is therefore crucial to ensure item responsiveness. Thus, the choice of a 7-point Likert scale will likely ensure that a relatively fine gradation of change can be detected.

Considering the clinical characteristics of oro-dental disorders, the intuitively expected nature of their impact on a child's well being, and the instrument response format, the period of 4 weeks was chosen for the time frame. This interval would allow for related impairments to occur and to be reported accurately. The results of this preliminary development do not allow us to know whether this reference period is optimal. However, when the instrument is tested in a future study, this can be assessed.

Furthermore, readability of the questionnaire was kept to a fairly easy standard, so that it would be suitable for those in the general population who have completed a minimum of six years of formal schooling. This is another aspect of the testing of the final questionnaire that will be carried out in a future study.

#### 4.8 Limitations of Study

One limitation of this project was in the sample selection. Our aim was to develop the questionnaire in English. Therefore, the interviews were conducted in English, and the item reduction questionnaire was written in English. The composition of a sample of only English-speaking subjects restricted our population for both the interview and the item reduction processes. Although we recognize that cultural differences are significant, this was necessary for completion of this preliminary work. Once the questionnaire is fully validated, it can be translated and cross-culturally adapted and tested for use with other populations (Guillemin, Bombardier, & Beaton, 1993).

During the interviewing process, the sample consisted of parents of children representing the targeted population and of health professionals. The parents were recruited from the outpatient dental clinic and the pre-operative clinic. This heterogeneous sample favored the gathering of a wide range of items. However, during the item reduction process, the entire sample was recruited only from the outpatient dental clinic. Considering the nature and severity of oral and dental disorders in children attending the pre-operative clinic and the status of treatment (all were on a waiting list), the composition of the sample probably influenced the responses to items in the item reduction questionnaire.

Additional concern includes the recruitment of participants (parents) from a single dental center (Montreal Children's Hospital Dental Center). Although we attempted to sample patients with different severities of oral conditions, as well as including patients of various ethnic and cultural backgrounds, a selection bias is still possible.

#### 4.9 Future Studies

In this report, we described the preliminary development of a quality of life instrument. In future studies, the psychometric properties of the instrument with regard to reliability, reproducibility, responsiveness, and construct validity will be tested.

#### 4.10 Conclusion

In the course of this research project, we developed a preliminary disease and agespecific instrument to measure the impact of oral and dental disorders on the quality of life of children (3-5 years) and the impact on their families. This questionnaire was constructed following the guidelines suggested in the theory of measurement, as well as the methods used in the development of the comparable generic and disease-specific quality of life instruments in the medical field. The instrument described is a preliminary attempt to assess specific concerns of young children with oral and dental conditions and their families, and is based on issues identified from the viewpoint of children, their parents and health care providers. It is simple, explicit, consists of easily understandable items and instructions, and a readability range that is easy to understand. The latest version of the questionnaire consists of twenty-nine questions; measuring four dimensions of impact on the children's quality of life and the impact on the family.

For this Master's thesis, the initial development of a pediatric oral health related quality of life instrument has been carried out. Our approach to item selection, which utilized a variety of sources, including input from parents of children with variable oral and dental conditions, ensured that we captured all the important items. Item reduction using impact scores and the involvement of another fifty patients further enhanced the content validity of our questionnaire. The questionnaire was formatted according to the established guidelines for designing a self-administered questionnaire. However, the next phase should involve field-testing in a much larger sample. Furthermore, internal consistency reliability, test-retest reproducibility, various aspects of validity, and responsiveness should be examined before qualifying the instrument for clinical or research use.

In summary, this Pediatric Oral Health Questionnaire for children (3-5 years) is the first attempt to develop an oral health specific quality of life instrument for children using a systematic approach. It has a number of potential uses as a tool in the assessment of the impact of pediatric oral health care programs and in clinical trials. It also has a use in population-based oral health surveys to complement the conventional clinical indices in measuring the burden of pediatric oral and dental disorders in the general population, population subgroups, and groups of patients with specific conditions.

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## **APPENDIX** A

## PROPOSED CONCEPTUAL DOMAINS

# SEMI-STRUCTURED QUALITY OF LIFE INTERVIEWS

Format

Informed Consent
Impact of Oral Health on the Quality of Life

PROPOSED COCEPTUAL DOMAINS

Physical Symptoms (Pain & Discomfort)

**Functional Limitations** 

Emotional Well being

Social Role

Impact on the Family

### Interview Format

#### Interviews with parents

Hello, M/Mrs.\_\_\_\_\_

Thank you for allowing us to take some of your time to participate in our survey. Let me start by explaining what we will be doing. I am part of a research team: we are aiming to develop a questionnaire to measure the effect of oral and dental problems on the quality of life of young children and the effect on the family. In order to do this, we must first identify what it is that affects your child's quality of life, and for this your opinion is important to us. In this phase, we are interviewing parents of children who have oral and dental disorders, and if possible, we will be also interviewing children. The interview lasts about 30-45 minutes. After meeting a sufficient number of parents and children, we will look at items that are most frequently mentioned in the interviews and these are the items that will be used to create the oral health quality of life questionnaire.

Do you have any questions?

Before we go any further. If you are willing to participate, I would like you to read this informed consent, a brief explanation of the project is included, if you agree about all this conditions, we will sign out the consent form.

The interview starts with a general question:

1- How is your child's general health?

2- What would you say about your child's dental health?

3- What made you think you needed to bring your child to see the dentist? (an open ended question)

Probes:

Does your child have pain, toothache, sensitive teeth, broken tooth?

Does your child have decay in his/her teeth?

Have you noticed his/her gums bleed when brushing?

Does your child have any soreness or infections related to his/her teeth and/or mouth?

4- Because of the problem your child has with his/her teeth or mouth, how is this affecting or limiting his/her normal daily activities?

Probes:

-Eating patterns, chewing ability, any restriction in eating such as hard food

-Sleeping patterns, disturbed sleep, bad night's sleep, wake-up at night, inability to get to sleep.

-Speech been unclear, difficulty pronouncing certain words

5- Does the problem with your child's teeth cause any change in his/her emotions. feelings?

Probes:

Is your child concerned about having problems with his/her teeth or mouth?

Any changes in his/her mood such as being happy, sad etc...

Any changes in his/her feelings: being frustrated, cranky etc..

6- How would you describe your child's social behavior?

Probes:

-Relationship with peers

-Socializing with friends. peers. family such as avoid smiling, laughing, eating with others.

-Schooling, kindergarten, attendance, activities

-Family interaction, such as being demanding, difficult to manage, etc..

7- Has the problem with your child's teeth or mouth affected your life as a family?

Probes:

-Caused tension. conflict. arguments, disagreement

-Worry and concern.

-Missed work.

-Interruption of family daily activities.

8- Is there anything that has been affected in your child's quality of life and the family as a result of oral and dental problems that we have not mentioned?

If so, what?

Thank you for allowing me to interview you. I think you provided me with valuable information; I will listen to the audiotape again, would it be possible to contact you if I have any question?

9- Would you allow me to interview your child? I just need to know what is the effect of having dental problems on his/her life from his/her perspective. If you allow me, I will use dolls and drawings to help me get the information I need.

Thank you again for your participation and cooperation.

#### Interview with health professionals

#### General Questions

- 1- Can I ask you what kind of dental work do you provide your clientele?
- 2- What age group do you see most commonly?
- 3- When children come to see you, what is the usual procedures you follow?

Specific Questions

4- Could you tell me, what makes the parents bring their children to see you? Probes:

-Referrals-Pediatrician, other dentist.

-Medical health problems.

-Routine check-ups.

-Dental or oral complaints: pain, trauma, missing teeth, mal-posed teeth, gingival bleeding, infections, etc...

5- Suppose that a mother came to you with a child, what would she say about the child's oral and dental problem in her own words?

6- Do you usually ask children themselves what they feel?

If yes, can you tell me what words or expressions they use to describe their problem?

Specific areas (Probes):

How do you think having oral and dental disorders affect the quality of life of children and their families?

Probes:

- -Pain and discomfort
- -Changes in eating patterns.
- -Sleeping disturbances.
- -Mood changes.
- -Behavioral disturbances
- -Esthetic complaints.
- -Relationship with others (family&friends).
- -Schooling and general attitude.
- -Family social relationship
- -Family concern, stress, worry

# **INFORMED CONSENT**

Development of an oral health measurement instrument for children aged 3-5 years

### Purpose of the study

The purpose of the study is to develop a questionnaire, which will measure the effect of oral health and disease on all aspects of life of children aged 3-5 years old.

## Procedure

If you agree that your child can participate in this study, the following procedures will take place:

1-On the day of your visit to the Dental Clinic or to the pre-operative consultation, you will be interviewed briefly for 10-15 min. about the oral and dental status of your child to determine which items are important to you and to your child.

The interview will be recorded with audiotape.

2-Your child might be asked to be interviewed. The interviewer will talk with your child and possibly ask him/her to draw pictures or act out a scene with dolls.

3-Once the preliminary questionnaire has been developed, you will be asked to participate in the pilot studies.

Your participation will involve answering a questionnaire and discussing the questions with an interviewer.

### **Risks and Discomfort**

No risk from interviewing or completing the questionnaire is foreseen. The interviewing and the questionnaire response will take place in a comfortable environment at the Montreal Children's Hospital. These sessions will coincide with your child's dental appointments.

The interview will be recorded on an audiocassette, and the information, as well as your name, will be kept confidential.

## Sequence of appointments

Appointment 1: 10-15 min. Interview.
Appointment 2: Fill out questionnaire and discuss the questions.
Appointment 3: 10-15 min. Fill out questionnaire.
Appointment 4: 20-25 min. Fill out questionnaire.

## **Benefits**

Your participation in this study may indirectly benefit others by helping to determine the impact of oral health on the lives of young children and on their families.

## <u>Alternatives</u>

Your participation in the study is voluntary, and you have the right to withdraw at any time during the study without prejudice or penalty.

## **Confidentiality**

Your participation in this study is entirely confidential: No names will appear on the files; only code numbers. The list of names corresponding to the numbers, the consent forms and the audiotape of the interview will be locked in a file cabinet. These same precautions will be followed when submitting the results of the study to scientific journals or during other types of communication.

## Scientific publication

The results of this study may be published in scientific journals or presented at clinical and scientific meetings.

## New information

If, during the study, new information is found that may influence your decision to continue in the study, you will be informed.

# **Further information**

If you have questions at any time during the study, please contact Dr. Etidal Basri at 398-7203 ext. 7223 or Dr. S. Schwartz at 934-4479.

# **APPENDIX B**

# QUALITATIVE DATA

Interviews

QUALITATIVE DATA (Statements as recoded verbatim) Interviews Montreal Children hospital, Dental Clinic & Pre-operative Clinic

| 1. Gum bleeding   | PS |
|---|----|
| 2. A lot of pain  | PS |
| 3. Refused to brush Brushing hurts                        | PS |
| 4. Bleeding when brushing                                 | PS |
| 5. Sensitive teeth even when washing the face             | PS |
| 6. Pain, teeth hurts                                      | PS |
| 7. Too much pain  | PS |
| 8. Black spots  | PS |
| 9. Infection and swelling                                 | PS |
| 10. Teeth in the front are breaking apart, chipping a way | PS |
| 11.Teeth are breaking in halves                           | PS |
| 12.Grind teeth while a sleep                              | PS |
| 13.Grinding her teeth                                     | PS |
| 14. Mother noticed cavities, holes                        | PS |
| 15.Bleeding gum   | PS |
| 16.Bad breath   | PS |
| 17.Noticed cavities                                       | PS |
| 18.Noticed brown spots                                    | PS |
| 19.Brown spots  | PS |
| 20.Brown teeth  | PS |
| 21.Bad breath   | PS |
| 22.Black teeth  | PS |
| 23.Mouth ulcers   | PS |
| 24.Bad breath   | PS |
| 25.Had fever from teeth infection                         | PS |
| 26. Tooth decay mostly in the front teeth                 | PS |
| 27.Tooth broke off  | PS |
| 28.It hurts   | PS |
| 29.Abnormal front tooth                                   | PS |
| 30.Enamel was not hard enough                             | PS |
|   |    |

| 31 Had a lot of nain   | nc           |
|--|--------------|
| 32 Have cavities   |              |
| 33 Mother noticed the teeth are blackening                   |              |
| 34 Child complain of pain                                    |              |
| 35 Brushing is a problem because the teeth are sensitive     |              |
| 36 Child can't touch the teeth                               | - 15<br>- PS |
| 37 Child says his mouth is sore                              | PS           |
| 38 Bleeding gum  | PS           |
| 39 Had an abscess  | PS           |
| 40 Painful teeth   | PS           |
| 41 Refused to eat  | FI           |
| 4? Can't eat what he/she wants                               | FI           |
| 43 Eat restricted food e $\alpha$ can't eat meat             | FI           |
| 44 Cries when eating e.g. when eating hot & cold food        | FI           |
| 45 Changed preparation of food                               | FI           |
| 46.Can't eat certain food                                    | FI           |
| 47. Tries to eat some kind of food but can't                 | FI           |
| 48 Chewing is difficult                                      | FI           |
| 49.Refused to eat  | FI           |
| 50.Just drink milk, refused to eat                           | FL           |
| 51. Eat only soft food                                       | FL           |
| 52. It hurts when eating especially sweet food               | FL           |
| 53. More difficult to eat hard food                          | FL           |
| 54.Can't bite hard food needs to cut it                      | FL.          |
| 55.Can't bite hard food, needs to cut it in pieces.          | FL           |
| 56. Prevented from eating what she likes                     | FL           |
| 57.Food got stuck in the cavities like meat or chicken       | FL           |
| 58.Can't sleep when teeth hurt her                           | FL           |
| 59.Doesn't eat   | FL           |
| 60.Pain when eating sweets or even drinking juice            | FL           |
| 61.Child is being prevented from eating certain food that he |              |
| likes such as sweets   | FL           |
| 62.Child gets far less sweet than other children             | FL           |
| 63.Child sometimes make faces when eating certain food       | FL           |
| 64.Child had hard time pronouncing certain words and letters | FL           |
| 65.Child feels pain when he eats apples or drink cold        | FL           |
| 66.Pronunciation is worse when she had cavities              | FL           |
| 67. Mother tries not to give child hard food                 | FL           |
| -  |              |

.

| 68.Child can't chew on both sides                                | FL |
|--|----|
| 69.Very bad eating   | FL |
| 70.Can't eat what he likes to eat                                | FL |
| 71.Child can't eat everything, prefer drinking                   | FL |
| 72. Child have some difficulty with certain words                | FL |
| 73. Feels frustrated because inability to eat as normal or brush |    |
| as supposed to.  | EW |
| 74. Child is concerned about dental problem                      | EW |
| 75.Shy, hides her teeth when smiling                             | EW |
| 76. Wining about dental problems                                 | EW |
| 77.Shy   | EW |
| 78. Cranky most of the time when teeth hurt                      | EW |
| 79.Feels withdrawn, play alone                                   | EW |
| 80.Get upset   | EW |
| 81.Get defensive that nothing is wrong with her teeth            | EW |
| 82. Child is concerned about appearance                          | EW |
| 83. Child is concerned about black teeth                         | EW |
| 84.More angry, irritable child                                   | EW |
| 85.Frustrated child  | EW |
| 86.Feels insecure  | EW |
| 87.Get quiet when people tell her about her teeth                | EW |
| 88.Child is crying a lot   | EW |
| 89.Feels upset because he can't eat on both sides                | EW |
| 90.Child is cranky and frustrated                                | EW |
| 91.Cranky and frustrated but not sure because of the teeth       | EW |
| 92.Child recognize that he have dental problem                   | EW |
| 93.Child is very conscious about her front tooth being black     | EW |
| 94.Child is much happier after the front tooth was fixed         | EW |
| 95.Child felt embarrassed  | EW |
| 96.Child worry about the look of his teeth (Why mine are not     |    |
| the same as other kids?).  | EW |
| 97.Missed school to come for dental appointment                  | SR |
| 98.Can't do some activities like swimming because of the cold    | SR |
| water sensitivity.   | SR |
| 99.Missed school to come for appointments                        | SR |
| 100. Other children ask about dental problems                    | SR |
| 101. Children bug her about black teeth                          | SR |
| 102. Missed school to go the dentist                             | SR |
| 103. Prevented from playing with others                          | SR |
| 104. Can't go to play  | SR |

| 105  | Rejected by neers  | SR |
|------|--|----|
| 105. | Avoid smiling try to cover the teeth with hands            | SR |
| 100. | Never smile- didn't like to smile                          | SR |
| 107. | Become demanding, wants more attention                     | SR |
| 109. | Not happy event when the child brush cries                 | SR |
| 110. | Child argue a lot  | SR |
| 111. | Fight with brother more                                    | SR |
| 112. | Big fight at home to let child brush                       | SR |
| 113. | Child wants attention all the time                         | SR |
| 114. | Mother needs to cut the food into small pieces so the      |    |
|      | child could eat it especially hard food.                   | IF |
| 115. | Mother feels dental problem is a big issue because of      |    |
|      | the difficulty to let the child brush.                     | IF |
| 116. | Time is wasted from parents to come for appointments       | IF |
| 117. | Change preparation of food for the family                  | IF |
| 118. | Worry and concern about appearance of the child's teeth    | IF |
| 119. | Avoid conversation with others.                            | IF |
| 120. | Worry when the child have pain (mother)                    | IF |
| 121. | Taking long time to bring him for dental treatment         | IF |
| 122. | Mother missed work to bring the child to fix his/her teeth | IF |
| 123. | Worried about the teeth later on                           | IF |
| 124. | Worry if his/her grown-up teeth are going to be O.K.       | IF |
| 125. | Mother is concerned about the teeth because of the         |    |
|      | difficulty of having treatment.                            | IF |
| 126. | Hard time to brush the teeth                               | IF |
| 127. | Parent are worried about the dental problem                | IF |
| 128. | Difficulty, time consuming to bring the child for          |    |
|      | appointments.  | IF |
| 129. | Difficulty of the transport to bring the child             | IF |
| 130. | Mother is worried because she wants her to have good       |    |
|      | teeth  | IF |
| 131. | Worry about appearance (mother)                            | IF |
| 132. | Time consuming to bring child for dental appointments      | IF |
| 133. | Frustration in the family                                  | IF |
| 134. | Change preparation of food, cut off all hard food          | IF |
| 135. | Miss work to bring the child for appointments              | IF |
| 136. | Mother is concerned about the child dental problems        | IF |
| 137. | Mother is worried  | IF |
| 138. | Conflict in the family about dental problems               | IF |
| 139. | Worry in the family a lot                                  | IF |

| 140. | Concern in the family  | IF |
|------|--|----|
| 141. | Parents are worried that dental problem could affect                           |    |
|      | all his life.  | IF |
| 142. | Missed work to bring the child to fix his teeth                                | IF |
| 143. | Stressful for the parent that the child can't eat certain                      |    |
|      | food such as crunchy food.   | IF |
| 144. | Parent miss work to bring the child for appointments                           | IF |
| 145. | Parent worry about the child's dental problem                                  | IF |
| 146. | Stressful to make the child brush  | IF |
| 147. | Parent are nervous that the child might lose more teeth                        | IF |
| 148. | Parent is stressed about the child being in pain and the                       |    |
|      | fear of the possibility of infection later on.                                 | IF |
| 149. | Mother is worried because she does not know why the                            |    |
|      | child had all this dental problems.  | IF |
| 150. | Mother is concerned about brushing   | IF |
| 151. | Mother is really bothered by the child having dental                           |    |
|      | problems.  | IF |
| 152. | Mother is concerned about the child's teeth                                    | IF |
| 153. | Mother is very much concerned that having cavities                             | •• |
| 100. | now would affect permanent teeth   | IF |
| 154  | Mother is concerned about the look of the child's teeth                        | IF |
| 155  | Parent discuss the child's dental problems and make                            |    |
| 155. | sure the child brush well  | ſF |
| 156  | Mother is worried that the child have cavities at so                           |    |
| 150. | voung age  | IF |
| 157  | Parents need to make arrangements to bring the child                           | 11 |
| 157. | for dental appointments and not miss work                                      | IF |
| 158  | Eather is worried because he doesn't want the child to                         | 11 |
| 150. | suffer from pain   | IF |
| 150  | Bed time is difficult because of brushing                                      | IF |
| 160  | Parents blame each other that the child has many dental                        | 11 |
| 100. | Problems   | IF |
| 161  | Time consuming for the parent to bring the child for                           | 11 |
| 101. | dental visits  | IE |
| 162  | Mother had to change preparation of food because child                         | 11 |
| 102. | would had to change preparation of toou because child                          | IC |
| 162  | Vall i gai flatu 1000<br>Mother is worried what will harmon to the teeth leter |    |
| 103. | Mother is worried about the appearance of the new testh                        | 11 |
| 104. | (might some out all creaked?)  | IE |
|      | (might come out an crookeu?)   | 11 |
|      |  |    |

| 165. | Mother is worried and concerned about the pain and the   |     |
|------|--|-----|
|      | look of the child's teeth.                               | IF  |
| 166. | Mother is concerned that the child has to go through all |     |
|      | these dental problems in such young age                  | IF  |
| 167. | Poor dental health                                       | Oth |
| 168. | Very poor dental health                                  | Oth |
| 169. | Put the finger on the tooth that hurts                   | Oth |

<u>N.B</u>

PS-----Physical Symptoms (Pain & Discomfort)

FL-----Functional Limitations

EW-----Emotional Well-being

SR-----Social Role

IF-----Impact on Family

Oth----Others

# **APPENDIX C**

The 60 ITEM QUESTONNAIRE

Item Reduction Phase

# The Effects of Oral and Dental Problems on the Child's Quality of Life

<u>Please read</u> carefully. <u>indicate</u> how bothersome each of the statements is to your child's quality of life.

| l<br>Does not bother<br>my child at all | 2<br>Alittle<br>bothersome | 3<br>Somewhat<br>bothersome | e   | be | 4<br>Very<br>othersome |   | Extreme<br>botherse | 5<br>ely<br>ome |
|---|----------------------------|-----------------------------|-----|----|------------------------|---|---------------------|-----------------|
| <u>Please circle</u>                    | the number that best a     | pplies.                     |     |    |                        |   |                     |                 |
| 1. Pain fr                              | om teeth or mouth          |                             | 1   | 2  | 3                      | 4 | 5                   |                 |
| Has yo                                  | our child ever experier    | nced this?                  | Yes |    | No                     |   |                     |                 |
| 2. Bleedi                               | ng gums                    |                             | 1   | 2  | 3                      | 4 | 5                   |                 |
| Has yo                                  | our child ever experier    | ced this?                   | Yes |    | No                     |   |                     |                 |
| 3. Bad br                               | reath                      |                             | 1   | 2  | 3                      | 4 | 5                   |                 |
| Has yo                                  | our child ever experien    | ced this?                   | Yes |    | No                     |   |                     |                 |
| 4. Sensiti                              | ve teeth                   |                             | 1   | 2  | 3                      | 4 | 5                   |                 |
| Has yo                                  | our child ever experien    | ced this?                   | Yes |    | No                     |   |                     |                 |
| 5. Mouth                                | ulcers                     |                             | 1   | 2  | 3                      | 4 | 5                   |                 |
| Has yo                                  | our child ever experien    | ced this?                   | Yes |    | No                     |   |                     |                 |
| 6. Sore m                               | outh                       |                             | 1   | 2  | 3                      | 4 | 5                   |                 |
| Has yo                                  | our child ever experien    | ced this?                   | Yes |    | No                     |   |                     |                 |
| 7. Swellin                              | ng and/or abscess          |                             | 1   | 2  | 3                      | 4 | 5                   |                 |
| Has yo                                  | ur child ever experien     | ced this?                   | Yes |    | No                     |   |                     |                 |

| 8. Grinding the teeth while sleeping  | 1   | 2 3 | 4 | 5 |
|---|-----|-----|---|---|
| Has your child ever experienced this?   | Yes | No  |   |   |
| 9. Teeth are breaking apart   | 1   | 2 3 | 4 | 5 |
| Has your child ever experienced this?   | Yes | No  |   |   |
| 10. Discoloration of the teeth  | 1   | 2 3 | 4 | 5 |
| Has your child ever experienced this?   | Yes | No  |   |   |
| <ol> <li>Trouble biting off or chewing food<br/>such as apple or firm meat</li> </ol>       | 1   | 2 3 | 4 | 5 |
| Has your child ever experienced this?   | Yes | No  |   |   |
| 12. Uncomfortable or difficult to eat any food  | 1 2 | 2 3 | 4 | 5 |
| Has your child ever experienced this?   | Yes | No  |   |   |
| <ol> <li>Toothache or sensitivity when eating<br/>or drinking hot/cold or sweets</li> </ol> | 1 2 | 2 3 | 4 | 5 |
| Has your child ever experienced this?   | Yes | No  |   |   |
| 14. Refused to eat  | 1 2 | 2 3 | 4 | 5 |
| Has your child ever experienced this?   | Yes | No  |   |   |
| 15. Could not eat what he/she would like<br>to eat  | 1 2 | 2 3 | 4 | 5 |
| Has your child ever experienced this?   | Yes | No  |   |   |
| <b>16.</b> Food gets stuck/caught in between the teeth                                      | 1 2 | 3   | 4 | 5 |
| Has your child ever experienced this?   | Yes | No  |   |   |
| 17. Bad/unsatisfactory diet   | 1 2 | 3   | 4 | 5 |
| Has your child ever experienced this?   | Yes | No  |   |   |

| 18. | Took longer to finish a meal                 | 1   | 2 | 3  | 4 | 5 |
|-----|--|-----|---|----|---|---|
|     | Has your child ever experienced this?        | Yes |   | No |   |   |
| 19. | Unable to brush because brushing hurts       | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?        | Yes |   | No |   |   |
| 20. | Unable to sleep at night                     | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?        | Yes |   | No |   |   |
| 21. | Interrupted sleep                            | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?        | Yes |   | No |   |   |
| 22. | Difficulty pronouncing certain words         | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?        | Yes |   | No |   |   |
| 23. | Difficulty speaking clearly                  | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?        | Yes |   | No |   |   |
| 24. | Feels frustrated                             | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?        | Yes |   | No |   |   |
| 25. | Acts shy                                     | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?        | Yes |   | No |   |   |
| 26. | Worries that his/her teeth look<br>different | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?        | Yes |   | No |   |   |
| 27. | Be cranky                                    | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?        | Yes |   | No |   |   |
| 28. | Is withdrawn/plays alone                     | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?        | Yes |   | No |   |   |

| 29. | Is upset or bothered   | 1   | 2 | 3  | 4 | 5 |
|-----|--|-----|---|----|---|---|
|     | Has your child ever experienced this?                          | Yes |   | No |   |   |
| 30. | Is angry, irritable  | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?                          | Yes |   | No |   |   |
| 31. | Feels insecure   | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?                          | Yes |   | No |   |   |
| 32. | Feels like crying  | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?                          | Yes |   | No |   |   |
| 33. | Feels embarrassed  | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?                          | Yes |   | No |   |   |
| 34. | Worries that he/she is being treated differently by other kids | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?                          | Yes |   | No |   |   |
| 35. | Feels unhappy  | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?                          | Yes |   | No |   |   |
| 36. | Be demanding, wants more attention                             | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?                          | Yes |   | No |   |   |
| 37. | Argues a lot   | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?                          | Yes |   | No |   |   |
| 38. | Has trouble getting along with brother(s) or sister(s)         | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?                          | Yes |   | No |   |   |
| 39. | Be more difficult to manage                                    | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?                          | Yes |   | No |   |   |

| 40  | . Fights more with brother(s) or sister(s)       | 1   | 2 | 3  | 4 | 5 |
|-----|--|-----|---|----|---|---|
|     | Has your child ever experienced this?            | Yes |   | No |   |   |
| 41  | . Misses school/kindergarten                     | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?            | Yes |   | No |   |   |
| 42  | . Can't participate in some activities / hobbies | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?            | Yes |   | No |   |   |
| 43  | . Teased by other kids                           | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?            | Yes |   | No |   |   |
| 44. | . Rejected by other kids                         | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?            | Yes |   | No |   |   |
| 45. | . Could not play with friends                    | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?            | Yes |   | No |   |   |
| 46. | Avoids smiling or laughing with other kids       | 1   | 2 | 3  | 4 | 5 |
|     | Has your child ever experienced this?            | Yes |   | No |   |   |
|     |  |     |   |    |   |   |

# **Effects on The Family**

**<u>Please read</u>** carefully, and <u>indicate</u> how important each of the statements is to your quality of life because of problems your child has with their teeth or mouth.

| l<br>Not important<br>at all         | 2<br>Alittle<br>important      | 3<br>somewhat<br>important |     | V<br>imŗ | 4<br>ery<br>portant |   | 5<br>Extremely<br>important |
|--------------------------------------|--------------------------------|----------------------------|-----|----------|---------------------|---|-----------------------------|
| <u>Please circle</u> t               | he number that                 | best applies.              |     |          |                     |   |                             |
| 47. Been worr                        | ied                            |                            | 1   | 2        | 3                   | 4 | 5                           |
| Have you e                           | ever experience                | d this?                    | Yes |          | No                  |   |                             |
| <b>48.</b> Had conce child's tee     | erns about the w               | ay your                    | 1   | 2        | 3                   | 4 | 5                           |
| Have you e                           | ever experienced               | l this?                    | Yes |          | No                  |   |                             |
| <b>49.</b> Been conc<br>child`s pair | erned and worr                 | ed about your              | 1   | 2        | 3                   | 4 | 5                           |
| Have you e                           | ever experienced               | l this?                    | Yes |          | No                  |   |                             |
| <b>50.</b> Took extra dental app     | a time and effort<br>ointments | to come for                | 1   | 2        | 3                   | 4 | 5                           |
| Have you e                           | ever experienced               | l this?                    | Yes |          | No                  |   |                             |
| <b>51.</b> Frustration               | in the family                  |                            | 1   | 2        | 3                   | 4 | 5                           |
| Have you e                           | ever experienced               | l this?                    | Yes |          | No                  |   |                             |
| <b>52.</b> Tension or                | conflict in the f              | amily                      | 1   | 2        | 3                   | 4 | 5                           |
| Have you e                           | ver experienced                | this?                      | Yes |          | No                  |   |                             |
| <b>53.</b> Been stress               | sed/bothered                   |                            | 1   | 2        | 3                   | 4 | 5                           |
| Have you e                           | ver experienced                | this?                      | Yes |          | No                  |   |                             |

| 54. Needed to make arrangements or change plans at the last minute                 | 1   | 2 | 3  | 4 | 5 |
|--|-----|---|----|---|---|
| Have you ever experienced this?  | Yes |   | No |   |   |
| <b>55.</b> Been nervous about the child having treatment at a young age            | 1   | 2 | 3  | 4 | 5 |
| Have you ever experienced this?  | Yes |   | No |   |   |
| <b>56.</b> Had to change preparation of food for the family                        | 1   | 2 | 3  | 4 | 5 |
| Have you ever experienced this?  | Yes |   | No |   |   |
| <b>57.</b> Missed work   | 1   | 2 | 3  | 4 | 5 |
| Have you ever experienced this?  | Yes |   | No |   |   |
| <b>58.</b> Limited the amount of time you had for your personal needs              | 1   | 2 | 3  | 4 | 5 |
| Have you ever experienced this?  | Yes |   | No |   |   |
| <b>59.</b> Concerned that the child has to experience this problems at a young age | 1   | 2 | 3  | 4 | 5 |
| Have you ever experienced this?  | Yes |   | No |   |   |
| <b>60.</b> Difficulty to convince the child to brush his/her teeth                 | 1   | 2 | 3  | 4 | 5 |
| Have you ever experienced this?  | Yes |   | No |   |   |
|  |     |   |    |   |   |

# **APPENDIX D**

# THE PRELIMINARY QUESTIONNAIRE

#### Please answer the questions by marking the appropriate box 🗵

#### During the last (4 weeks):

- 1. How often has your child had pain because of problems with his/her teeth or mouth?
  - □ All of the time
  - Most of the time
  - $\Box$  A good bit of the time
  - □ Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - □ None of the time
- 2. How often has your child had bad breath because of problems with his/her teeth or mouth?
  - □ All of the time
  - $\Box$  Most of the time
  - A good bit of the time
  - Some of the time
  - A little of the time
  - □ Hardly any of the time
  - □ None of the time
- 3. How often has your child had discoloration of his/her teeth?
  - $\Box$  All of the time
  - Most of the time
  - □ A good bit of the time
  - $\Box$  Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - $\Box$  None of the time
- 4. How often has your child grind his/her teeth while sleeping?
  - □ All of the time
  - Most of the time
  - A good bit of the time
  - $\Box$  Some of the time
  - $\Box$  A little of the time
  - □ Hardly any of the time
  - $\Box$  None of the time

- 5. How often has it taken your child longer to finish a meal than other people because of problems with his/her teeth or mouth?
  - All of the time
  - Most of the time
  - A good bit of the time
  - □ Some of the time
  - **A** little of the time
  - □ Hardly any of the time
  - □ None of the time
- 6. How often has your child had food catching/getting stuck in between his/her teeth?
  - $\Box$  All of the time
  - Most of the time
  - $\Box$  A good bit of the time
  - □ Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - None of the time
- 7. How often has your child had sensitive teeth or toothache when eating or drinking hot / cold liquids or sweets?
  - All of the time
  - $\Box$  Most of the time
  - □ A good bit of the time
  - □ Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - □ None of the time
- 8. How often has your child refused to eat because of problems with his/her teeth or mouth?
  - $\Box$  All of the time
  - □ Most of the time
  - □ A good bit of the time
  - □ Some of the time
  - **a** A little of the time
  - □ Hardly any of the time
  - $\Box$  None of the time

- 9. How often has your child been prevented from eating foods he/she would like to eat because of problems with his/her teeth or mouth?
  - □ All of the time
  - $\Box$  Most of the time
  - $\Box$  A good bit of the time
  - □ Some of the time
  - $\Box$  A little of the time
  - □ Hardly any of the time
  - □ None of the time
- 10. How often has your child found it uncomfortable to eat any food?
  - $\Box$  All of the time
  - $\Box$  Most of the time
  - $\Box$  A good bit of the time
  - □ Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - $\Box$  None of the time
- 11. How often do you think your child has acted shy because of problems with his/her teeth or mouth?
  - $\Box$  All of the time
  - $\Box$  Most of the time
  - □ A good bit of the time
  - □ Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - $\Box$  None of the time
- 12. How often do you think your child has worried that he/she is being treated differently by other kids because of problems with his/ her teeth or mouth?
  - $\Box$  All of the time
  - □ Most of the time
  - □ A good bit of the time
  - □ Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - □ None of the time

- 13. How often do you think your child has been embarrassed because of problems with his/her teeth or mouth?
  - $\Box$  All of the time
  - $\square$  Most of the time
  - □ A good bit of the time
  - □ Some of the time
  - $\Box$  A little of the time
  - □ Hardly any of the time
  - None of the time
- 14. How often do you think your child has acted upset or bothered because of problems with his/her teeth or mouth?
  - $\Box$  All of the time
  - $\Box$  Most of the time
  - $\Box$  A good bit of the time
  - □ Some of the time
  - $\Box$  A little of the time
  - □ Hardly any of the time
  - □ None of the time
- 15. How often do you think your child has been demanding or needed more attention because of problems with his/her teeth or mouth?
  - $\Box$  All of the time
  - $\Box$  Most of the time
  - □ A good bit of the time
  - $\Box$  Some of the time
  - $\Box$  A little of the time
  - □ Hardly any of the time
  - $\Box$  None of the time
- 16. How often do you think your child argued a lot because of problems with his/her teeth or mouth?
  - $\Box$  All of the time
  - $\square$  Most of the time
  - □ A good bit of the time
  - Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - $\Box$  None of the time

- 17. How often do you think your child had trouble getting along with brother(s) or sister(s) because of problems with his/her teeth or mouth?
  - $\Box$  All of the time
  - $\Box$  Most of the time
  - $\Box$  A good bit of the time
  - □ Some of the time
  - $\Box$  A little of the time
  - □ Hardly any of the time
  - □ None of the time
- 18. How often do you think your child has been more difficult to manage because of problems with his/her teeth or mouth?
  - $\Box$  All of the time
  - □ Most of the time
  - $\Box$  A good bit of the time
  - □ Some of the time
  - $\Box$  A little of the time
  - □ Hardly any of the time
  - $\Box$  None of the time
- 19. How often have you been worried about your child's pain?
  - $\Box$  All of the time
  - □ Most of the time
  - $\Box$  A good bit of the time
  - $\square$  Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - $\Box$  None of the time
- 20. How often have you had concerns about the look of your child's teeth?
  - $\Box$  All of the time
  - $\Box \quad Most of the time$
  - $\Box$  A good bit of the time
  - $\Box$  Some of the time
  - $\Box$  A little of the time
  - □ Hardly any of the time
  - $\Box$  None of the time

- 21. How often have the problems with your child's teeth or mouth caused you to spend extra time and effort?
  - All of the time
  - □ Most of the time
  - A good bit of the time
  - **G** Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - □ None of the time
- 22. How often have you been concerned that your child has to experience these problems with his/her teeth or mouth at a young age?
  - $\Box$  All of the time
  - □ Most of the time
  - □ A good bit of the time
  - □ Some of the time
  - □ A little of the time
  - $\Box$  Hardly any of the time
  - $\Box$  None of the time
- 23. How often have you worried because of the problems with your child's teeth or mouth?
  - $\Box$  All of the time
  - $\square$  Most of the time
  - $\Box$  A good bit of the time
  - □ Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - □ None of the time
- 24. How often have you been nervous about your child having treatment at a young age?
  - □ All of the time
  - □ Most of the time
  - A good bit of the time
  - □ Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - □ None of the time

- 25. How often have you been stressed/bothered because of problems with you child's teeth or mouth?
  - $\Box$  All of the time
  - □ Most of the time
  - $\Box$  A good bit of the time
  - □ Some of the time
  - A little of the time
  - □ Hardly any of the time
  - □ None of the time

26. How often have you had difficulty convincing your child to brush?

- $\Box$  All of the time
- □ Most of the time
- $\Box$  A good bit of the time
- □ Some of the time
- □ A little of the time
- □ Hardly any of the time
- □ None of the time
- 27. How often have the problems with your child's teeth or mouth limited the amount of time you had for your own personal needs?
  - □ All of the time
  - Most of the time
  - □ A good bit of the time
  - □ Some of the time
  - $\Box$  A little of the time
  - □ Hardly any of the time
  - $\Box$  None of the time
- 28. How often have the problems with your child's teeth or mouth caused you to cancel or change plans (personal or work) at the last minute?
  - $\Box$  All of the time
  - Most of the time
  - □ A good bit of the time
  - $\Box$  Some of the time
  - $\Box$  A little of the time
  - □ Hardly any of the time
  - $\Box$  None of the time

- 29. How often have you missed work because of the problems with your child's teeth or mouth?
  - □ All of the time
  - □ Most of the time
  - □ A good bit of the time
  - $\Box$  Some of the time
  - □ A little of the time
  - □ Hardly any of the time
  - □ None of the time